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Commissioner for Patents
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PCT/FR2004/001189
-filed May 14, 2004

Re: Application of Fabien POULARD
FLUID PRODUCT DISPENSER
Assignee: VALOIS S.A.S
Our Ref: Q91404

Dear Sir:

The following documents are submitted herewith in connection with the above application for the purpose of entering the National stage under 35 U.S.C. §371 and in accordance with the Patent Cooperation Treaty:

- ☒ a copy of the executed Declaration and Power of Attorney.
- ☒ an English translation of the International Application.
- ☒ thirteen (13) sheets of drawings (Figs. 1-21).
- ☒ Article 34 Amendment.
- ☒ a copy of the executed Assignment and PTO 1595 form.
- ☒ an Information Disclosure Statement and a copy of the ISR.
- ☒ a PTO/SB/08 A & B (modified) listing the ISR references and copy of each references cited in the ISR.
- ☒ a Preliminary Amendment.

In addition to the documents submitted herewith, it is assumed that copies of the International Application, the International Search Report and cited references, the International Preliminary Examination Report, and any Articles 19 and 34 amendments as required by §371(c) will be supplied directly by the International Bureau, but if further copies are needed, the undersigned will undertake to provide them upon request.

It is expressly requested that the national stage of processing be commenced immediately in accordance with 35 U.S.C. § 371(f).



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Attorney Docket No. Q91404
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The Government filing fee, after entry of the Article 34 Amendment, is calculated as follows:

Total claims	<u>20</u>	-	<u>20</u>	=		x	\$50.00	=	<u>\$0.00</u>
Independent claims	<u>1</u>	-	<u>3</u>	=		x	\$200.00	=	<u>\$0.00</u>
Base Fee									<u>\$300.00</u>
Search Fee*									<u>\$400.00</u>
Examination Fee*									<u>\$200.00</u>
TOTAL FILING FEE									<u>\$900.00</u>
Recordation of Assignment									<u>\$ 40.00</u>
<u>TOTAL FEE</u>									<u>\$940.00</u>

* The international search fee for all claims was not paid to the USPTO, as the ISA, but the ISR is being submitted herewith.

Checks for the statutory filing fee of \$900.00 and Assignment recordation fee of \$40.00 are attached. The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this transmittal letter is attached.

Priority is claimed from:

<u>Country</u>	<u>Application No</u>	<u>Filing Date</u>
France	03/05858	May 15, 2003

Respectfully submitted,


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A FLUID DISPENSER

The present invention relates to a fluid dispenser, and more particularly to such a dispenser including a dose indicator device for indicating to the user the number of doses that have been dispensed or that remain to be dispensed from the reservoir of said fluid dispenser.

Dose indicator devices are well known, and can include either counters, displaying a number corresponding to the number of doses that have been dispensed or that remain to be dispensed, or indicators, informing the user by means of symbols, color codes, or similar numbers, about the number of doses that have been dispensed or that remain to be dispensed. In particular, in fluid dispensers containing pharmaceuticals, it is important for the dose indicator device to function in reliable manner, and in particular for it to count the dispensing of a dose each time the fluid is dispensed, regardless of whether the dose is complete or incomplete, e.g. because of accidental actuation or actuation that is interrupted before the end of the actuation cycle. It is generally preferable for the dispensing of an incomplete dose to be counted as a complete dose rather than for it not to be counted at all, since failure to count could present a high risk to the user, informing the user of a reservoir content that is greater than the reality. In dispensers of pharmaceuticals, it is thus generally desirable to avoid any risk of under-counting, in particular by triggering counting just before the active substance is expelled. Another important point with dose indicator devices for dispensers of pharmaceuticals is that once actuation has taken place and a dose has been dispensed, while the dispenser is returning to its rest position, any further actuation that is performed before the end of the return stroke of the dispenser, and that would cause a complete or incomplete dose to be dispensed, should also be counted by the indicator

device, likewise to avoid any risk of under-counting. In most fluid dispensers, once a dose has been dispensed, the next dose is loaded into the chamber of the dispenser member (pump or valve) while the dispenser is returning
5 to its rest position. In order to avoid any risk of under-counting during the return stroke of the dispenser, it is desirable for the fluid dispenser to be blocked as soon as the return stroke has allowed the chamber to be filled, and until the indicator device is once again able
10 to count the actuation of the dispenser.

An object of the present invention is to provide a fluid dispenser which satisfies one or more of the above-mentioned requirements.

In particular, an object of the present invention is
15 to provide a fluid dispenser including a dose indicator device that prevents any risk of under-counting, i.e. that guarantees that the indicator device is actuated each time fluid is dispensed by the fluid dispenser.

When the actuation of the dispenser does not cause
20 any fluid to be dispensed, another object of the present invention is to provide such a dispenser that prevents dose dispensing from being counted, and thus prevents the dose indicator device from being actuated.

Another object of the present invention is to
25 provide such a fluid dispenser that is simple and inexpensive to manufacture and to assemble, and that is reliable in use.

The present invention thus provides a fluid dispenser comprising a body, a fluid reservoir, a
30 dispenser member, such as a pump or a valve, mounted on said reservoir, and a dose indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, the dispenser being characterized in that said
35 dose indicator device includes a first safety system for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation

stroke, even if the dispenser does not perform the complete actuation stroke.

Preferably, said dose indicator device includes a second safety system which, during the return stroke of the dispenser after dispensing a dose, prevents the pharmaceutical from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

Advantageously, said reservoir is axially displaceable relative to said body, said body including at least one stationary gear, said dose indicator device including a counter element that is displaceable axially and in rotation relative to said body, said counter element co-operating, while the dispenser is being actuated, firstly with said at least one stationary gear of said body, and secondly with said reservoir.

In a first embodiment of the invention, said body includes a stationary gear co-operating with a first gear of said counter element, said counter element including a second gear co-operating with an actuator gear of an actuator member of the dispenser, the teeth of said second gear and/or of said actuator gear being made so that axial displacement of the actuator member causes said counter element to be displaced axially and in rotation, the stationary gear preventing said counter element from turning until said counter element no longer co-operates with said stationary gear, after a predetermined axial displacement of said counter element corresponding to said predetermined incomplete actuation stroke of the dispenser.

The stationary gear advantageously includes abutment means preventing said counter element from turning once

said counter element has turned at least in part, an additional axial displacement of said counter element being necessary to enable it to continue to turn and/or to return the indicator device to its rest position.

5 These abutments position the second gear of the counter element in such a manner that the dispenser is blocked on its return prior to the chamber being filled and until its rest position.

Advantageously, said abutment means comprise an
10 axial projection.

Advantageously, said stationary gear and/or said counter element include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once
15 again, while the counter element is returning to its rest position after a preceding actuation, and until the dispenser has completed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

Advantageously, said blocking means comprise axial
20 projections provided on the body and on the counter element respectively, each of said projections having an axial end-profile that is plane, said projections facing each other, at least in part, until the counter element
25 has turned sufficiently to offset said projections, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

Advantageously, the teeth of the second gear of the counter element include an intermediate step, the
30 actuator member co-operating with said step while the dispenser is being actuated, and co-operating with the end wall of said second gear while returning to the rest position, after being actuated, the displacement between the intermediate step and the end wall being obtained by
35 said counter element turning.

Advantageously, once the predetermined incomplete return stroke has been performed, the actuator member is

positioned facing the following tooth of the second gear of the counter element, enabling the dispenser and the dose indicator device to be actuated once again.

In a second embodiment of the present invention,
5 said body includes a first stationary gear and a second stationary gear, said counter element including a first gear for co-operating with said first stationary gear and a second gear for co-operating with said second
10 stationary gear, said counter element being put axially into contact with the actuator member of the dispenser by means of a return spring and being turnable relative to said actuator member, the teeth of said second gear and of said second stationary gear being oblique, at least in part, so that an axial displacement of the actuator
15 member initially causes said counter element to be displaced axially over a predetermined incomplete actuation stroke until the oblique portion of said second gear of the counter element co-operates with said oblique portion of said second stationary gear, causing the
20 counter element to be turned over a first portion of a turn cycle, the teeth of said first gear and of said first stationary gear being oblique, at least in part, so that when the counter element returns to its rest position, it is caused to turn so as to terminate its
25 turn cycle, which corresponds to one actuation of the dispenser being counted.

Advantageously, said first and second stationary gears of the body and/or said first and second gears of the counter element are offset relative to each other, so
30 that whenever the counter element is displaceable in rotation, returning said counter element to its rest position without terminating the actuation stroke of the dispenser causes the counter element to turn over its complete turn cycle, guaranteeing that one actuation of
35 the dispenser is counted after said predetermined incomplete actuation stroke.

Advantageously, said second stationary gear of the body and/or said second gear of the counter element include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element is returning to its rest position following a preceding actuation, and until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

Advantageously, said blocking means have an axial end-profile that is plane, at least in part, and that is formed on the teeth of said second stationary gear of the body and on the teeth of said second gear of the counter element, said plane profiles of said teeth facing each other, at least in part, until the counter element has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

Advantageously, said actuator member of the dispenser is secured to said reservoir and is displaced axially therewith.

In a third embodiment of the present invention, said body includes a first stationary gear and a second stationary gear, said counter element comprising a first gear for co-operating with said first stationary gear, a second gear for co-operating with said second stationary gear, and a third gear for co-operating with an actuator gear secured to an actuator member of the dispenser, the teeth of said third gear and/or of said actuator gear being made so that axial displacement of the actuator member causes said counter element to be displaced axially and in rotation, the first stationary gear preventing said counter element from turning until said counter element no longer co-operates with said stationary gear, after a predetermined axial displacement of said counter element corresponding to said

predetermined incomplete actuation stroke of the dispenser.

Advantageously, said second stationary gear of the body and/or said second gear of the counter element
5 include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element is returning to its rest position following a preceding actuation, until said dispenser has
10 performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

Advantageously, said blocking means have an axial end-profile that is plane and that is formed on the teeth of said second stationary gear and on the teeth of said
15 second gear, said teeth facing each other, at least in part, until the counter element has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

Advantageously, said actuator gear includes abutment means limiting the extent to which the counter element can turn, until the actuator member has performed said
20 predetermined incomplete return stroke.

Advantageously, said abutment means comprise an
25 axial projection formed on said actuator gear.

Advantageously, said actuator member of the dispenser is secured to said reservoir and is displaced axially therewith.

Other characteristics and advantages of the present
30 invention appear more clearly from the following detailed description of three embodiments thereof, given by way of non-limiting example, and with reference to the accompanying drawings, and in which:

Figures 1 to 8 are diagrams of a fluid dispenser
35 constituting a first embodiment of the present invention, showing the successive positions of the dispenser during an actuation cycle;

• Figures 9 to 12 are diagrams of a dispenser constituting a second embodiment of the present invention, also showing various positions of the dispenser during the actuation cycle; and

5 • Figures 13 to 21 are diagrams of a fluid dispenser constituting a third embodiment of the present invention, showing various positions of the dispenser during the actuation cycle.

10 The descriptions of the three embodiments below relate to actuation cycles of the dispenser, and to the various functional features of the indicator device that make it possible to guarantee operational and counting reliability of said indicator device. The drawings to which the present description refers are therefore highly
15 simplified diagrams which do not show the fluid dispenser in detail, but only in very diagrammatic manner relating to the various portions that can be moved relative to one another, for explaining the actuation cycle of said dispenser and of said indicator device. Thus, for
20 example, the dispenser member, e.g. a pump or a valve, is not shown in the drawings. In addition, the dispenser head including the dispenser orifice is also not shown, since these elements are not directly involved in the present invention.

25 It should be observed that the present invention applies more particularly to "Metered Dose Inhaler" (MDI) devices which comprise a metering valve mounted on a reservoir containing the fluid and a propellant gas, the displacement of the reservoir relative to the valve
30 member causing a dose of fluid to be dispensed by means of said propellant gas. The present invention is not limited to that particular application, but said application represents the preferred application of the present invention.

35 With reference to Figures 1 to 8, a first embodiment of the present invention is described. In this first embodiment, the dispenser includes a reservoir 2 that is

axially displaceable in a body 1, which is considered below as being the stationary portion of the dispenser. The axial displacement of the reservoir 2 relative to the body 1 actuates the dispenser member and thus causes a
5 dose of fluid to be dispensed from said reservoir. In this first embodiment, the dispenser includes an actuator member 30 on which the user exerts an axial actuation force so as to actuate the dispenser and thus displace said reservoir 2 relative to the body 1. The dispenser
10 further includes a dose indicator device for counting or indicating the dispensing of one fluid dose each time the dispenser is actuated. Thus, by means of the indicator device, the user can tell how many doses have been dispensed from said reservoir 2, or how many doses remain
15 inside said reservoir 2. This information must be very accurate, in particular when the fluid is a pharmaceutical, and any risk of under-counting must be eliminated. In the event of under-counting, i.e. in the event of the indicator device failing to count one or
20 more occasions on which a dose of fluid is dispensed in full or in part, the user can end up with a dispenser that indicates that one or two doses remain in the reservoir, whereas in reality, the reservoir is empty. In the event of an asthma attack, the user can thus end
25 up with a dispenser that is no longer functional, and that does not enable the user to take the medicine.

The present invention makes it possible to avoid any risk of under-counting. To do this, the dose indicator device includes at least one safety system, and
30 preferably two. The first safety system guarantees that the dose indicator device is actuated, and thus that the dispensing of a dose of fluid is counted, as soon as the dispenser, on being actuated, has traveled along a predetermined incomplete stroke. The second safety
35 system is for preventing a dose from being expelled during the return stroke of the dispenser, while the dose indicator device is not ready to count the next dose.

The dosage chamber of the dispenser is generally filled while the dispenser is returning to its rest position, after a preceding actuation. If the return stroke is not complete, but the device is actuated once again before it has returned to its rest position, it is possible for some fluid to be dispensed. However, if the dose indicator device has not returned to, or close to, its rest position, this dispensing of fluid cannot be counted. Under-counting would thus occur. In order to avoid this, the second safety system blocks any new actuation, or at least any new dispensing of fluid. Blocking is performed until the return stroke is sufficient for the dose indicator device to be actuated once again, and for it to be able to count the next dose.

In short, the present invention provides one or two safety systems that avoid any risk of the indicator device under-counting.

Initially, the first safety system is described below with reference to Figures 1 to 4.

With reference to these figures, it should be observed that the stationary body 1 includes a stationary gear 110, and that the indicator device comprises a counter element 20 for co-operating firstly with said stationary gear 110 of the body 1, and secondly with the actuator member 30 and/or the reservoir 2. More particularly, the counter element 20 is displaceable both axially and in rotation relative to the body 1. The counter element 20 includes a first gear 210 for co-operating with said stationary gear 110 of the body, and a second gear 230 for co-operating with an actuator gear 300 secured to the actuator member 30.

Figures 1 to 4 show the first half of an actuation cycle of the dispenser, i.e. the displacement of the dispenser from the rest position (shown in Figure 1) to the actuated position (shown in Figure 4). Thus, when the user presses on the actuator member 30 so as to displace said actuator member axially downwards in Figure

1, the oblique profile of the teeth of the actuator gear 300 and of the second gear 230 of the counter element urge the counter element 20 to be displaced axially downwards, and also in rotation because of the oblique profile of the above-mentioned gears. However, while the first gear 210 of the counter element 20 is co-operating with the stationary gear 110 of the body 1, the counter element 20 is prevented from turning at all. Consequently, at the start of the actuation stroke of the dispenser, and thus of the actuator member 30, the counter element 20 can be displaced only axially together with the actuator member 30, without being able to turn. When the system reaches the position shown in Figure 2, the axial displacement of the counter element 20 has also caused the reservoir 2 to be displaced axially over a first fraction of the actuation stroke. In the position shown in Figure 2, the first gear 210 of the counter element 20 reaches a position in which it no longer co-operates with the stationary gear 110 of the body 1. As a result, the counter element, which is urged to turn by the force exerted on the actuator member 30, can turn relative to the body 1. As soon as the counter element starts to turn a little, the dose indicator device is actuated and the counting of one dose of fluid is initiated. This incomplete axial displacement stroke of the counter element 20 corresponds to said predetermined incomplete actuation stroke of the dispenser, and more particularly of the reservoir 2. In this type of dispenser, the dose of fluid is not necessarily expelled at the end of the actuation stroke, but starting from a predetermined incomplete stroke, which is itself a function of the displacement of the valve member, or a function of the displacement of the piston in a pump. By making the co-operation of the first gear 210 of the counter element with the stationary gear 110 of the body 1 correspond with said predetermined incomplete actuation stroke of the dispenser, it is ensured that, as soon as

there is any possibility of the fluid being dispensed from the reservoir 2, then the indicator device counts one dose as being dispensed.

5 Figure 3 shows that the stationary gear 110 of the body 1 includes abutment means 115, preferably formed by an axial projection co-operating with the first gear 210 of the counter element 20, and which abutment means cause the counter element to be axially displaced once again, by a very small but non-zero amount, so as to enable
10 sufficient meshing of the actuator gear 300 in the first step, defined by the abutment 235 on the second gear 230. Thus, the chamber of the dispenser cannot be filled unless the abutment 235 has been passed over. Once it has been passed over, the actuator gear 300 is positioned
15 at the second step or the end wall of the second gear 230 of the counter element 20, before the dispenser chamber is filled, so as to prevent the pharmaceutical from being expelled, as shown in Figure 6.

Continuing the actuation stroke brings the reservoir
20 2 into the position shown in Figure 4, in which the complete actuation stroke has been performed, and the entire dose has been expelled from the reservoir. However, it should be observed that even if the user ceases to exert force on the actuator member 30 before
25 the end of the complete actuation stroke, the indicator device counts the dispensing of one dose as soon as the incomplete actuation stroke has been performed, so that any under-counting is prevented thereby.

With reference to Figures 5 to 8, the second stage
30 of the actuation cycle of the dispenser is described below, namely the return from the dispensing position to the rest position (shown in Figure 8). With reference to Figure 5, it should be observed that when the user releases the pressure on the actuator member 30, the
35 return spring (not shown) of the dispenser returns the reservoir 2 to its rest position by displacing the reservoir 2 axially relative to the body 1 in the

direction opposite to the direction of the above-described actuation displacement. The displacement of the reservoir 2 causes the counter element 20 to be axially displaced, so that the first gear 210 comes to co-operate once again with the stationary gear 110 of the body 1, but this time via the oblique portions, thereby causing said counter element to turn, so as to terminate the counting cycle of the indicator device. While the counter element is turning relative to the body 1 during the return stroke, it should be observed that the actuator member 30 comes to co-operate with the end wall of the second gear 230 of the counter element 20, whereas during the actuation stage, the actuator gear 300 co-operates with the first step, defined by the abutment 235, formed on said second gear 230 of the counter element 20.

Figure 6 is a diagram showing an attempt to perform a new actuation before the dispenser has completed its return stroke. It should be observed that the body 1 includes axial projections 120 that co-operate with axial projections 220 formed on the counter element 20. In a variant, the axial projections 120, 220 can be replaced by gears of corresponding shape. Preferably, the axial end-profiles of said projections 120 and 220 are formed by planes, and the axial projections 120 and 220 are disposed facing each other, at least in part, so that if the return stroke of the dispenser is insufficient, it is impossible to expel a new dose of fluid, as shown in Figure 6. In order to be able to actuate the dispenser once again, it is necessary for the counter element 20 to turn sufficiently about its axis of rotation, for said projections 120 and 220 to be offset relative to each other, thereby enabling a new actuation. The offset is achieved by freeing the actuator member 30 from the end wall of the second gear 230 of the counter element 20, so as to position it facing the first step, defined by the abutment 235 of the following tooth. The new actuation

can be permitted before the dispenser has completed its return stroke, as soon as the indicator device is once again capable of counting a new actuation of the dispenser. The present invention makes it possible to
5 fulfill this requirement, as shown in Figure 7, in which the return stroke is not complete, but the actuator member 30 of the dispenser, and in particular the actuator gear 300, is in a position in which it can co-operate with the next tooth of the second gear 230 of the
10 counter element, so that a new actuation at this moment causes the counter element to turn through the end of its preceding cycle, thereby causing said axial projections 120 and 220 to be offset, and thus enabling the dispenser and the dose indicator device to be actuated once again.
15 The aim is to prevent expulsion when the chamber is full, so long as the counter is not ready to count another dose.

In Figure 8, the device is returned to its initial rest position and a new actuation cycle can be performed.

20 Figures 9 to 12 show a second embodiment of the invention. The second embodiment differs from the first embodiment as follows: Firstly, the body 1 includes two stationary gears 110 and 120, and the counter element 20 includes two gears 210, 220, each co-operating with one
25 of the stationary gears of the body. The actuator member 30 is secured to the reservoir 2, and the counter element 20 is axially displaceable with said actuator member 30. It can be turned relative to said actuator member 30. In fact, in the second embodiment, there is not really an
30 actuator member, but the user generally displaces the reservoir 2 itself, relative to the body 1, so as to perform the actuation. The second stationary gear 120 of the body 1 and the second gear 220 of the counter element include respective portions 121 and 221 that are oblique,
35 at least in part, and said portions co-operate with each other while the dispenser is being actuated. The oblique portions urge the counter element 20 to turn, and thus

initiate a counting cycle of the dose indicator device. As shown in Figures 9 and 10, while the dispenser is being actuated, the counter element is firstly displaced axially without turning, by being secured to the actuator member 30 and the reservoir 2. Once the dispenser has performed the predetermined incomplete actuation stroke, the oblique portions 220, 221 of the second gears 120, 220 co-operate so as to cause the actuator member to turn, as shown in Figure 10.

It should be observed that if, in the position shown in Figure 10, the user stops actuating the dispenser, the system returns to its rest position by means of a return spring 50, and the counting cycle is completed since the first gear 210 of the counter element 20 comes to co-operate with the teeth of the first stationary gear 110 so as to urge the counter element 20 to turn even more, in order to bring it to the end of its counting cycle. The first safety system is thus provided in that the actuation of the dose indicator device is ensured as soon as the dispenser has performed its predetermined incomplete actuation stroke, from which at least some fluid can be dispensed (a full dose or an incomplete dose).

Figure 11 shows the actuated position in which the complete actuation stroke has been performed, and Figure 12 shows the second safety means, provided by means of the second stationary gear 120, and the second gear 220 of the counter element 20. The two gears also include respective plane portions, each having a plane axial end-profile, so that when the return stroke of the dispenser is not sufficient, as can be seen in Figure 12, a new actuation of the system brings the counter element 20 into axial abutment with the second stationary gear 120 via their plane end-portions, thereby preventing any pharmaceutical from being expelled, by preventing the dispenser from being actuated. It is only once a predetermined incomplete return stroke has been performed

that the oblique portions of the second gears 120 and 220 are facing each other, so as to enable the dispenser and the dose indicator device to be actuated once again.

5 Figures 13 to 21 show a third embodiment of the present invention. The third embodiment differs from the second embodiment in that the counter element 20 is not axially secured to the actuator member 30 and to the reservoir. The actuator member 30 and the reservoir 2 include an actuator gear 300 that co-operates with a
10 third gear 230 provided on the counter element 20. In the third embodiment, turning of the counter element 20 during the actuation stroke of the dispenser is thus no longer caused by the second stationary gear 120, but by means of the third gear 230 and the actuator gear 300.
15 The third embodiment is thus a combination of the first and second embodiments described above. At the start of actuation, when in the situation in Figure 13, the co-operation between the first stationary gear 110 and the first gear 210 of the counter element 20, prevents the
20 counter element 20 from turning, and thus causes said counter element to be axially displaced. When in the position shown in Figure 14, the above-mentioned first gears no longer co-operate, and the oblique profiles of the teeth of the actuator gear 300 and of the third gear
25 230 of the counter element 20, cause the counter element 20 to turn. This takes place after said incomplete actuation stroke of the dispenser, after which a complete or incomplete dose of fluid can be dispensed. Figure 15 shows that if the axial actuation force is eliminated at
30 this moment, the return spring 50 causes the counter element to turn through its complete counting cycle, thereby preventing any risk of under-counting.

 Figure 16 shows the final actuated position in which the complete actuation stroke has been performed. At
35 this moment, when the user releases the actuation force on the actuator member 30, the system rises under the effect of the return spring 50, and the co-operation

between the first gears 210 and 110 of the counter element 20 and the body 1, respectively, causes the counter element to continue to turn. This continued turning is blocked in the actuator gear 300 by abutment means 305. With reference to Figure 18, if in this position the user presses once again on the actuator member 30, it should be observed that actuation of the dispenser and of the counter device is prevented as a result of the second gear 220 of the counter element, and the second stationary gear 120 of the body 1, facing each other at their plane axial end-profiles. Figure 19 shows an attempt to perform an actuation while the second safety system is operational. For the dispenser and the dose indicator device to be actuated once again, it is necessary to perform a predetermined incomplete return stroke, which is shown in Figure 20. If from this position the user actuates again, the counter element 20 would turn, thereby enabling the dispenser and the indicator device to be actuated once again.

Finally, Figure 21 shows the position in which such an attempt to perform an additional actuation is made, after said incomplete return stroke has been completed.

Naturally the detailed description of the three embodiments given above is not limiting, and other embodiments can be envisaged without going beyond the ambit of the present invention, as defined by the accompanying claims.

CLAIMS

1. A fluid dispenser comprising a body (1), a fluid reservoir (2), a dispenser member, such as a pump or a valve, mounted on said reservoir (2), and a dose
5 indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, the dispenser being characterized in that said dose indicator device includes
10 a first safety system for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform the complete actuation stroke.
2. A dispenser according to claim 1, in which said dose
15 indicator device includes a second safety system which, during the return stroke of the dispenser after dispensing a dose, prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose
20 indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.
- 25 3. A dispenser according to claim 1 or claim 2, in which said reservoir (2) is axially displaceable relative to said body (1), said body (1) including at least one stationary gear (110, 120), said dose indicator device
30 including a counter element (20) that is displaceable axially and in rotation relative to said body (1), said counter element (20) co-operating, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 120) of said body, and secondly with said
35 reservoir (2).

4. A dispenser according to claim 3, in which said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20), said counter element (20) including a second gear (230) co-
5 operating with an actuator gear (300) of an actuator member (30) of the dispenser, the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in
10 rotation, the stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said
15 predetermined incomplete actuation stroke of the dispenser.

5. A dispenser according to claim 4, in which the stationary gear (110) includes abutment means (115)
20 preventing said counter element (20) from turning once said counter element (20) has turned at least in part, an additional axial displacement of said counter element (20) being necessary to enable it to continue to turn and/or to return the indicator device to its rest
25 position.

6. A dispenser according to claim 5, in which said abutment means (115) comprise an axial projection.

30 7. A dispenser according to any one of claims 3 to 6, in which said stationary gear (110) and/or said counter element (20) include(s) blocking means (120, 220) preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being
35 expelled once again, while the counter element (20) is returning to its rest position after a preceding actuation, and until the dispenser has completed a

predetermined incomplete return stroke, after which the indicator device can count the next dose.

8. A dispenser according to claim 7, in which said
5 blocking means comprise axial projections (120, 220)
provided on the body (1) and on the counter element (20)
respectively, each of said projections (120, 220) having
an axial end-profile that is plane, said projections
10 (120, 220) facing each other, at least in part, until the
counter element has turned sufficiently to offset said
projections (120, 220), with that sufficient turn
corresponding to said predetermined incomplete return
stroke of the dispenser.
- 15 9. A dispenser according to claim 8, in which the teeth
of the second gear (230) of the counter element (20)
include an intermediate step (235), the actuator member
(30) co-operating with said step (235) while the
dispenser is being actuated, and co-operating with the
20 end wall of said second gear (230) while returning to the
rest position, after being actuated, the displacement
between the intermediate step (235) and the end wall
being obtained by said counter element (20) turning.
- 25 10. A dispenser according to claim 8 or claim 9, in
which, once the predetermined incomplete return stroke
has been performed, the actuator member (30) is
positioned facing the following tooth of the second gear
(230) of the counter element (20), enabling the dispenser
30 and the dose indicator device to be actuated once again.
11. A dispenser according to claim 3, in which said body
(1) includes a first stationary gear (110) and a second
stationary gear (120), said counter element (20)
35 including a first gear (210) for co-operating with said
first stationary gear (110) and a second gear (220) for
co-operating with said second stationary gear (120), said

counter element (20) being put axially into contact with the actuator member (30) of the dispenser by means of a return spring (50) and being turnable relative to said actuator member (30), the teeth of said second gear (220) and of said second stationary gear (120) being oblique, at least in part, so that an axial displacement of the actuator member (30) initially causes said counter element (20) to be displaced axially over a predetermined incomplete actuation stroke until the oblique portion (221) of said second gear (220) of the counter element (20) co-operates with said oblique portion (121) of said second stationary gear (120), causing the counter element (20) to be turned over a first portion of a turn cycle, the teeth of said first gear (210) and of said first stationary gear (110) being oblique, at least in part, so that when the counter element (20) returns to its rest position, it is caused to turn so as to terminate its turn cycle, which corresponds to one actuation of the dispenser being counted.

12. A dispenser according to claim 11, in which said first and second stationary gears (110, 120) of the body (1) and/or said first and second gears (210, 220) of the counter element (20) are offset relative to each other, so that whenever the counter element (20) is displaceable in rotation, returning said counter element to its rest position without terminating the actuation stroke of the dispenser causes the counter element (20) to turn over its complete turn cycle, guaranteeing that one actuation of the dispenser is counted after said predetermined incomplete actuation stroke.

13. A dispenser according to claim 11 or claim 12, in which said second stationary gear (120) of the body (1) and/or said second gear (220) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing

pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, and until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

14. A dispenser according to claim 13, in which said blocking means have an axial end-profile that is plane, at least in part, and that is formed on the teeth of said second stationary gear (120) of the body (1) and on the teeth of said second gear (220) of the counter element (20), said plane profiles of said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

15. A dispenser according to any one of claims 11 to 14, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

16. A dispenser according to claim 3, in which said body (1) includes a first stationary gear (110) and a second stationary gear (120), said counter element (20) comprising a first gear (210) for co-operating with said first stationary gear (110), a second gear (220) for co-operating with said second stationary gear (120), and a third gear (230) for co-operating with an actuator gear (300) secured to an actuator member (30) of the dispenser, the teeth of said third gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member (30) causes said counter element (20) to be displaced axially and in rotation, the first stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary

gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

5
17. A dispenser according to claim 16, in which said second stationary gear (120) of the body (1) and/or said second gear (220) of the counter element (20) include(s) blocking means preventing the dispenser from being
10 actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, until said dispenser has performed a predetermined incomplete return stroke, after
15 which the indicator device can count the next dose.

18. A dispenser according to claim 17, in which said blocking means have an axial end-profile that is plane and that is formed on the teeth of said second stationary
20 gear (120) and on the teeth of said second gear (220), said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete
25 return stroke of the dispenser.

19. A dispenser according to claim 17 or claim 18, in which said actuator gear (300) includes abutment means (305) limiting the extent to which the counter element
30 (20) can turn, until the actuator member (30) has performed said predetermined incomplete return stroke.

20. A dispenser according to claim 19, in which said abutment means (305) comprise an axial projection formed
35 on said actuator gear (300).

21. A dispenser according to any one of claims 16 to 20, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

A B S T R A C T

A FLUID DISPENSER

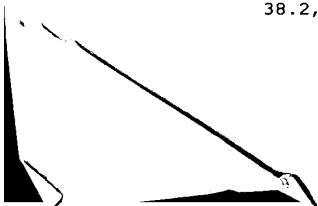
5 A fluid dispenser comprising a body (1), a fluid
reservoir (2), a dispenser member, such as a pump or a
valve, mounted on said reservoir (2), and a dose
indicator device for indicating the number of doses of
10 fluid that have been dispensed or that remain to be
dispensed from said reservoir, the dispenser being
characterized in that said dose indicator device includes
a first safety system for actuating the dose indicator
device once the dispenser has performed a predetermined
incomplete actuation stroke, even if the dispenser does
15 not perform the complete actuation stroke.

20

25

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35 Translation of the title and the abstract as they were when originally filed by the
Applicant. No account has been taken of any changes that may have been made
subsequently by the PCT Authorities acting ex officio, e.g. under PCT Rules 37.2,
38.2, and/or 48.3.



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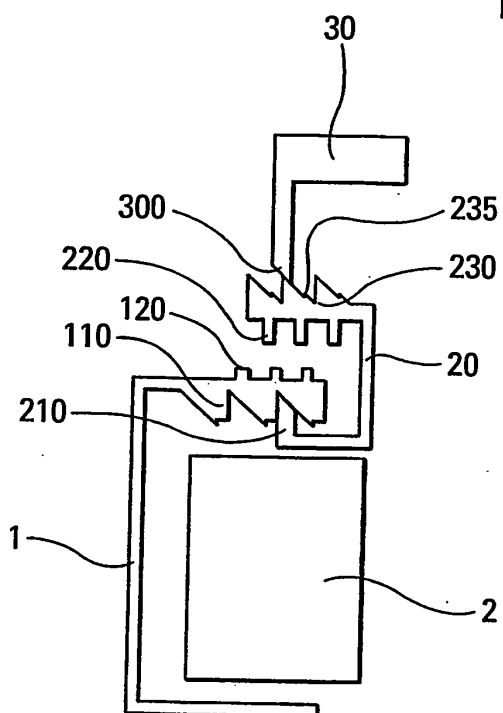


Fig. 1

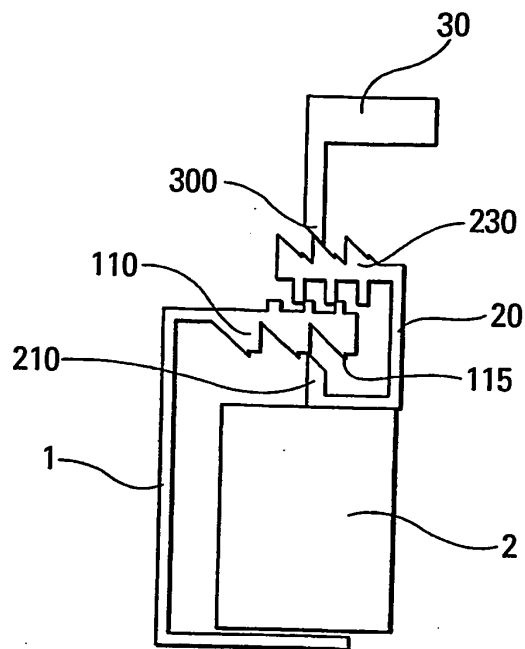


Fig. 2

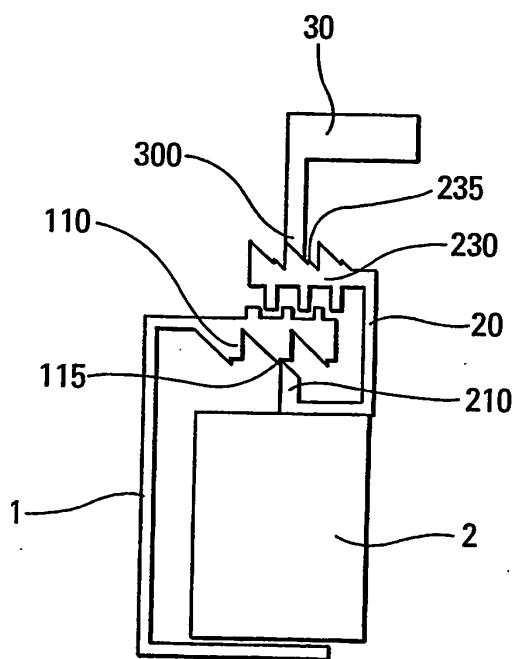


Fig. 3

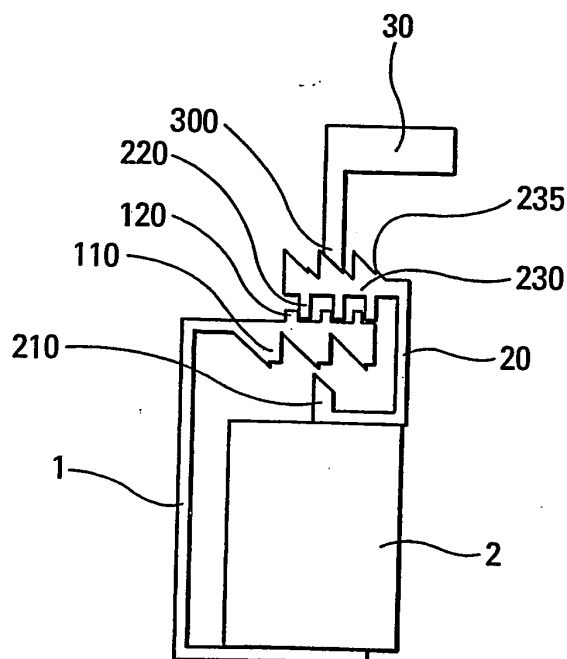


Fig. 4

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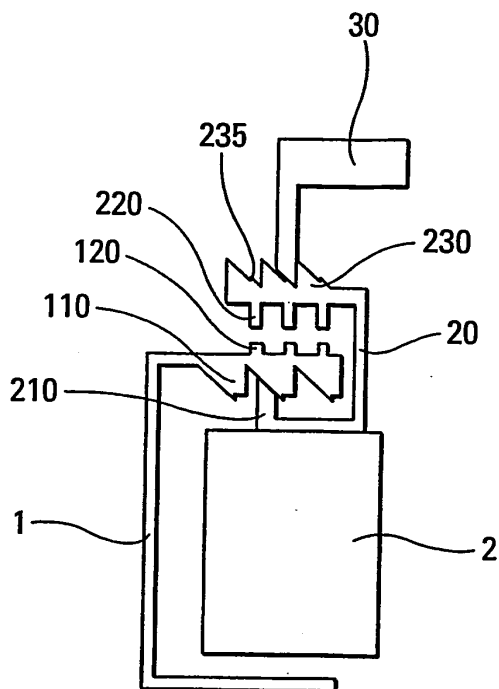


Fig. 5

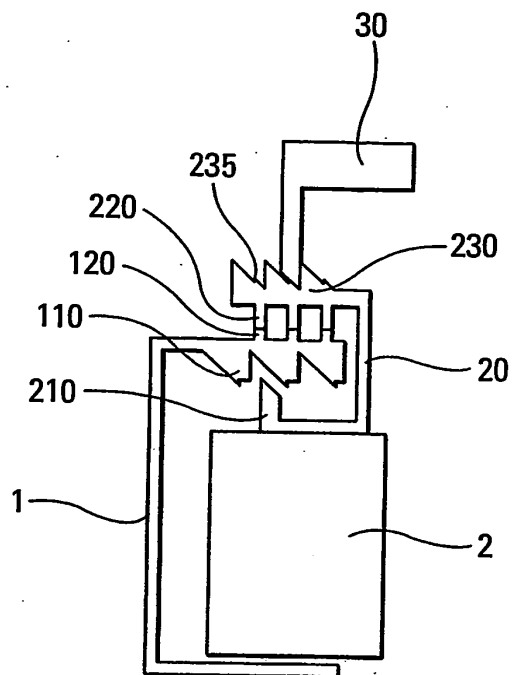


Fig. 6

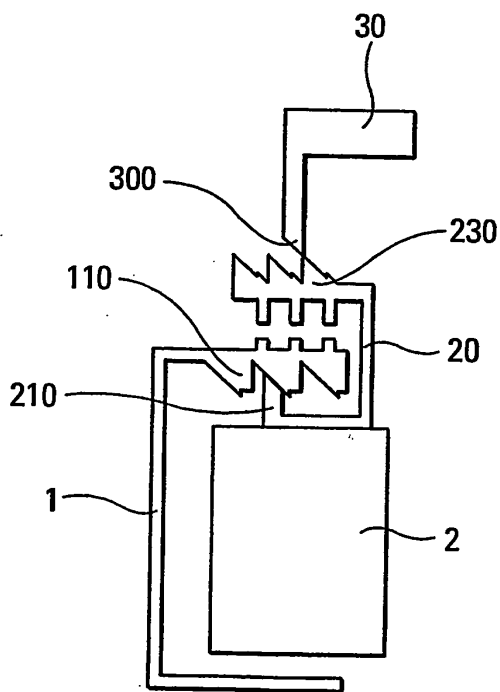


Fig. 7

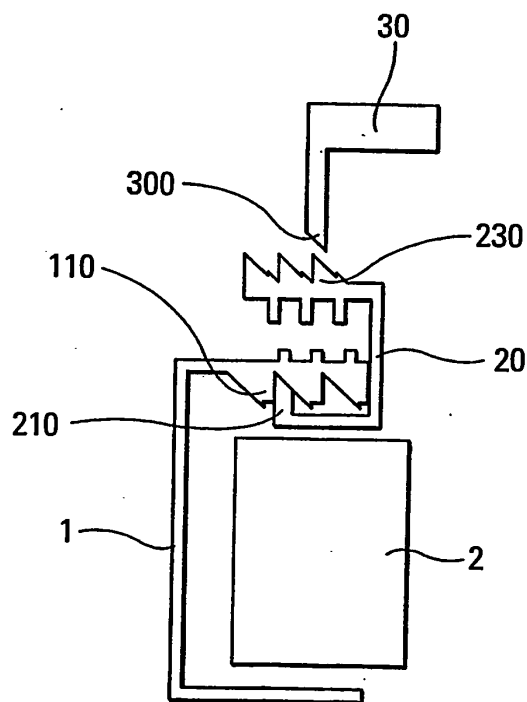


Fig. 8

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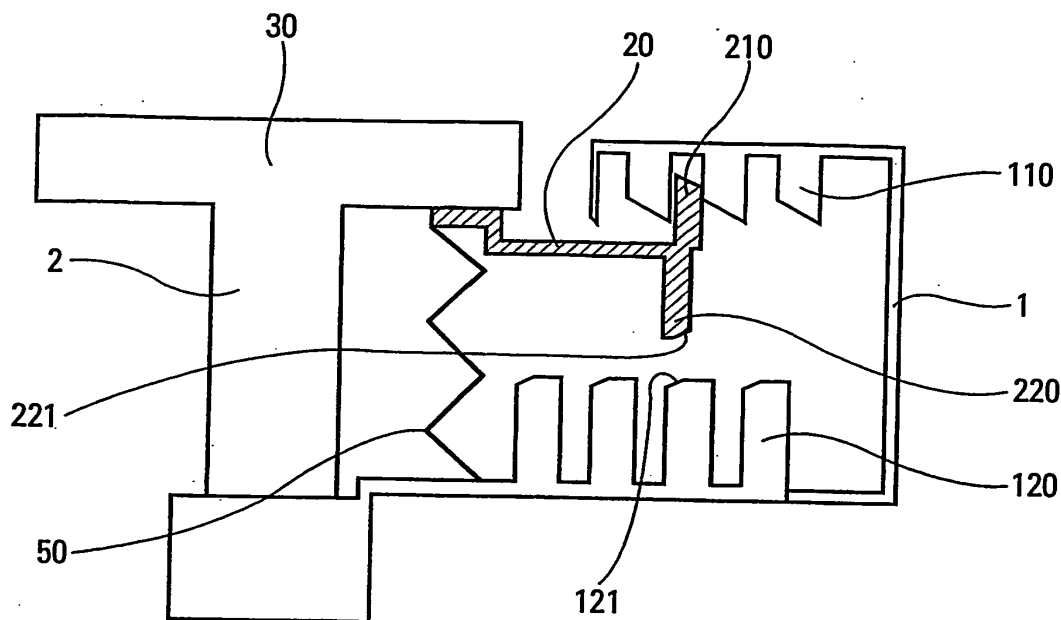


Fig. 9

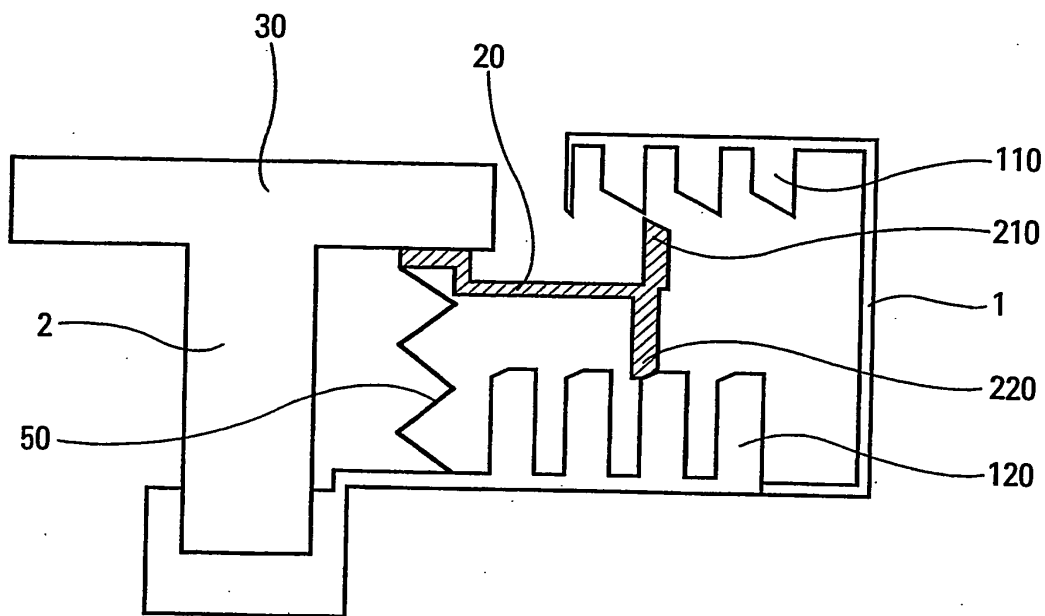


Fig. 10

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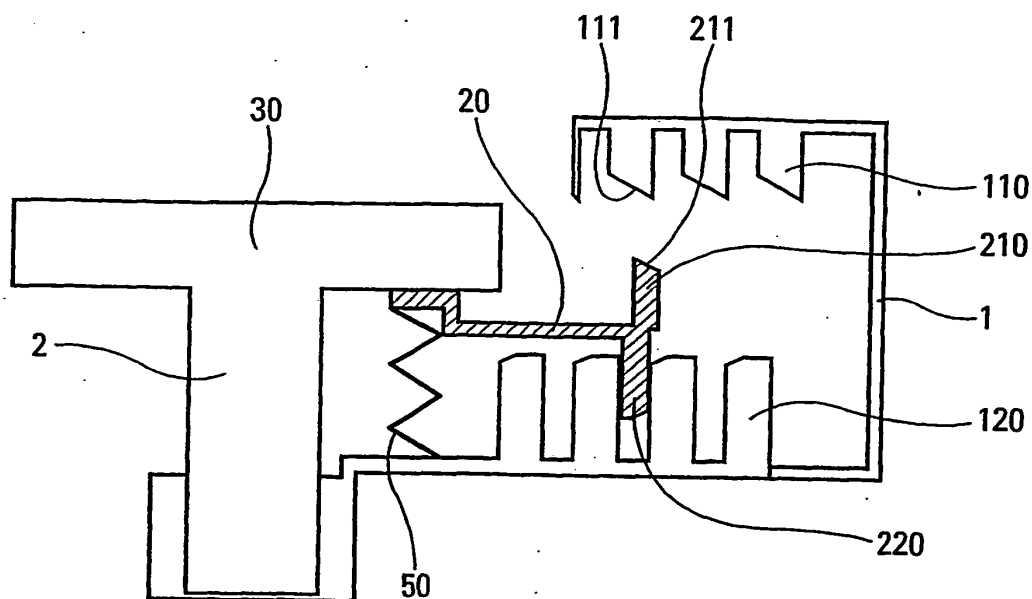


Fig. 11

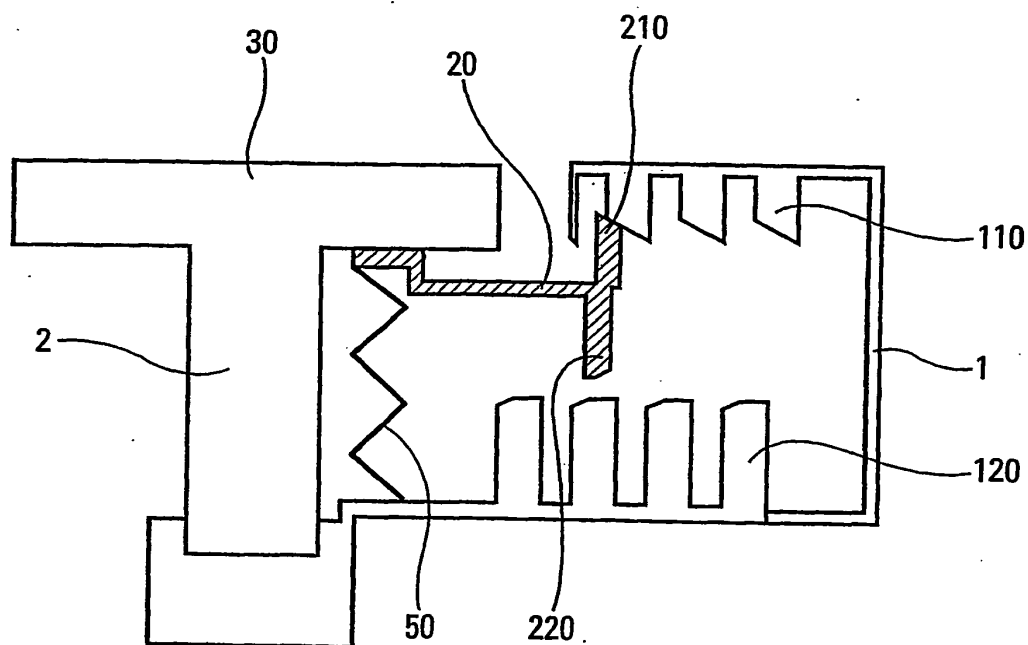


Fig. 12

SUBSTITUTE SHEET (RULE 26)

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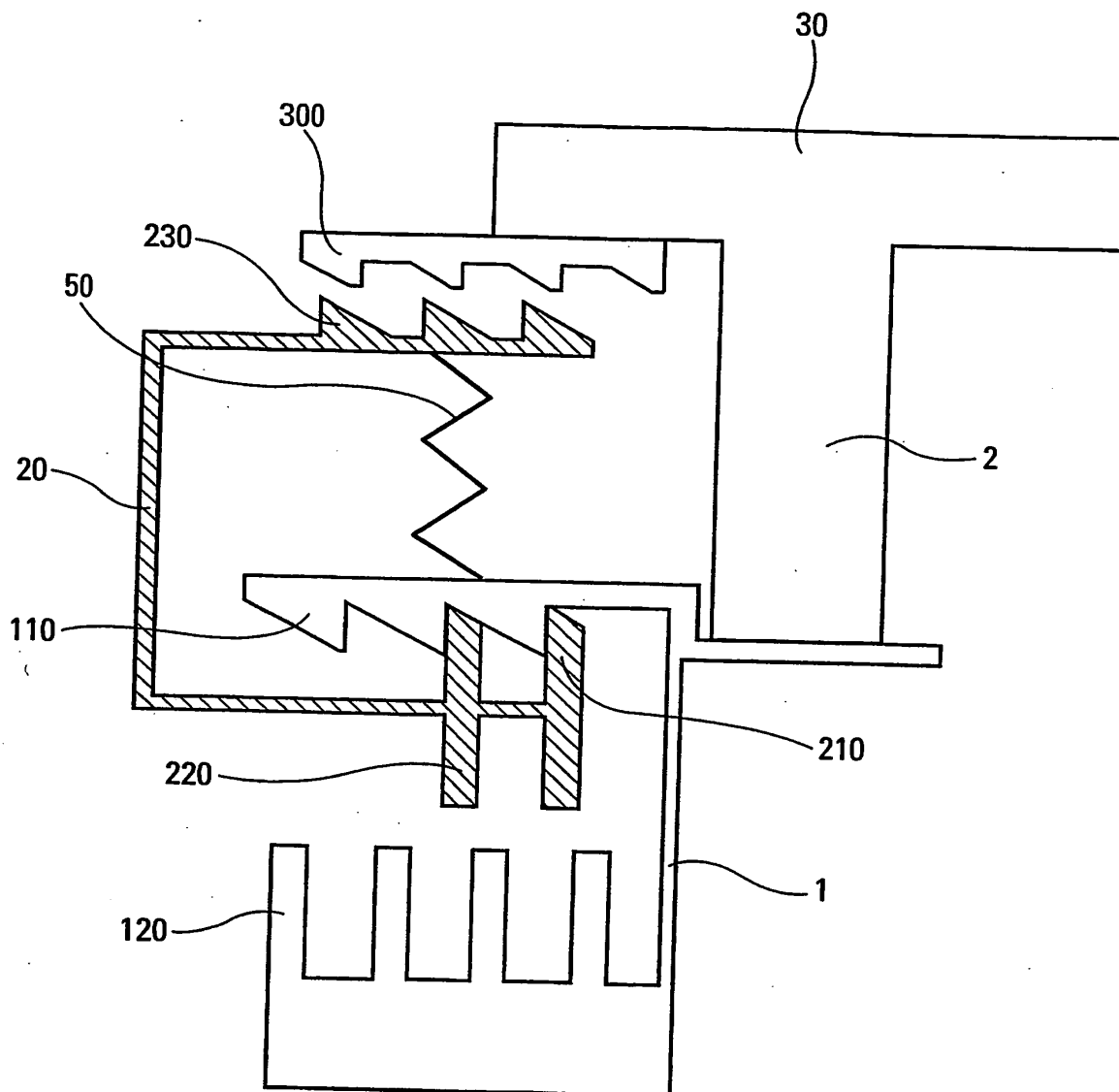


Fig. 13

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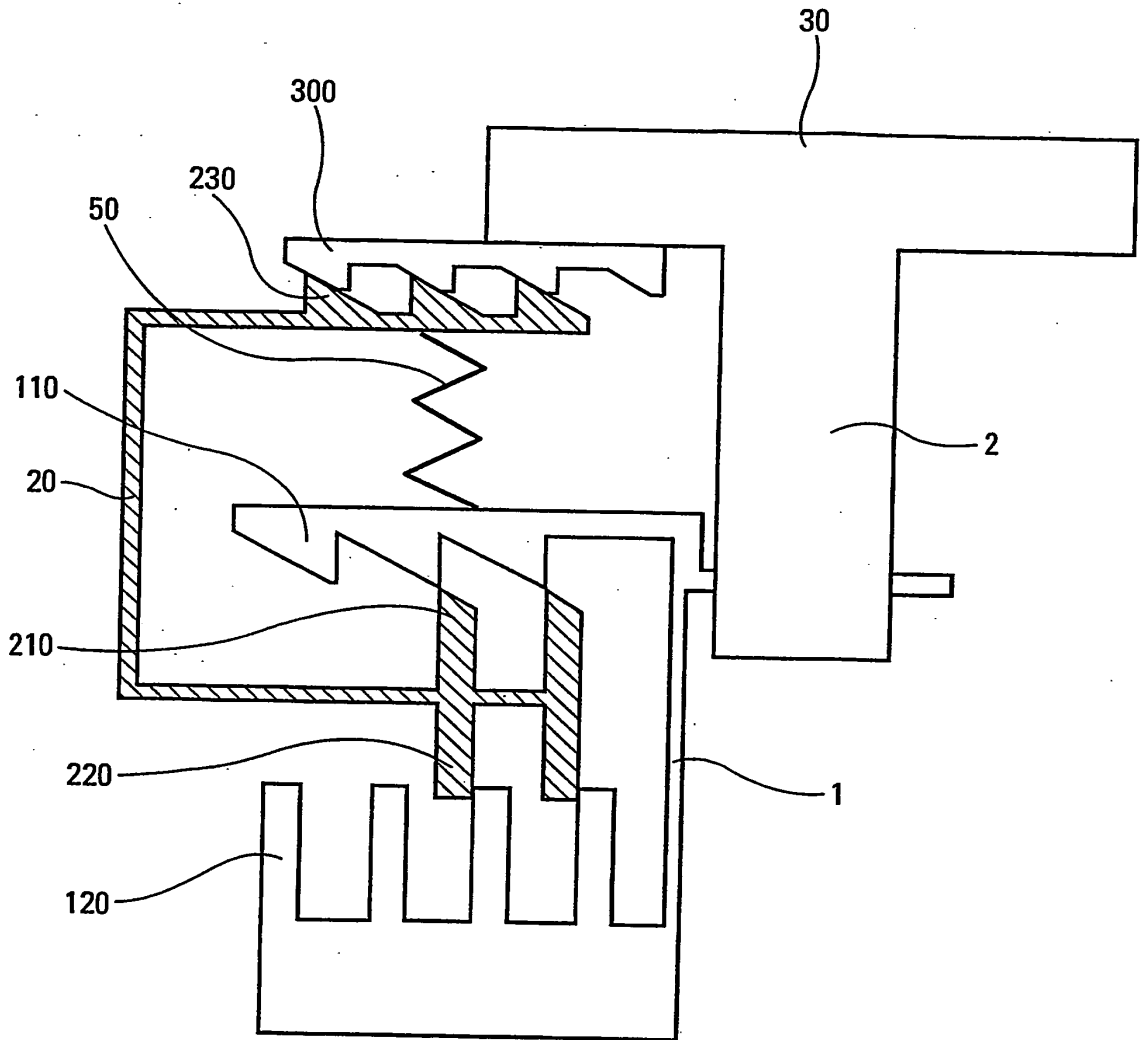


Fig. 14

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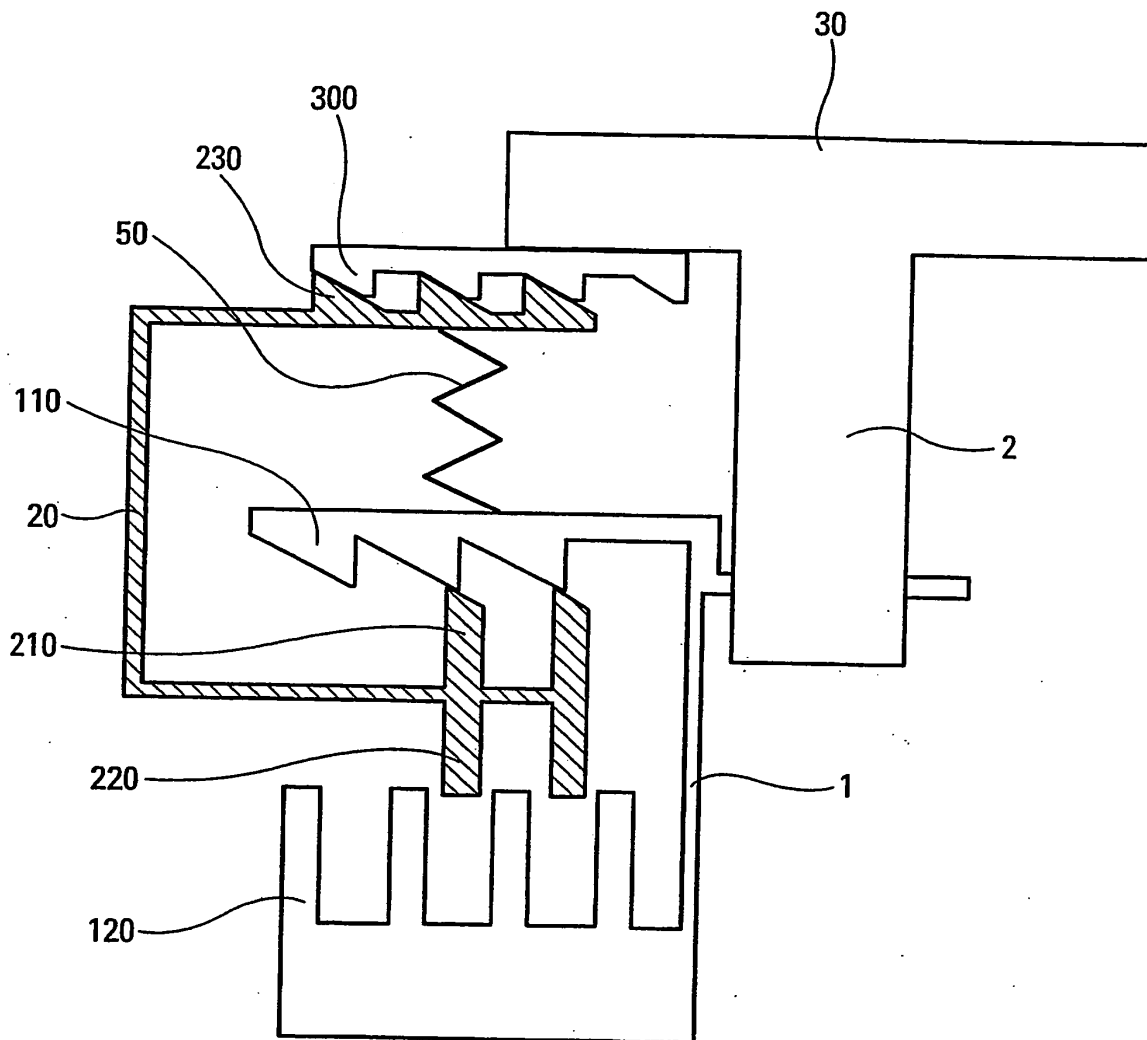


Fig. 15

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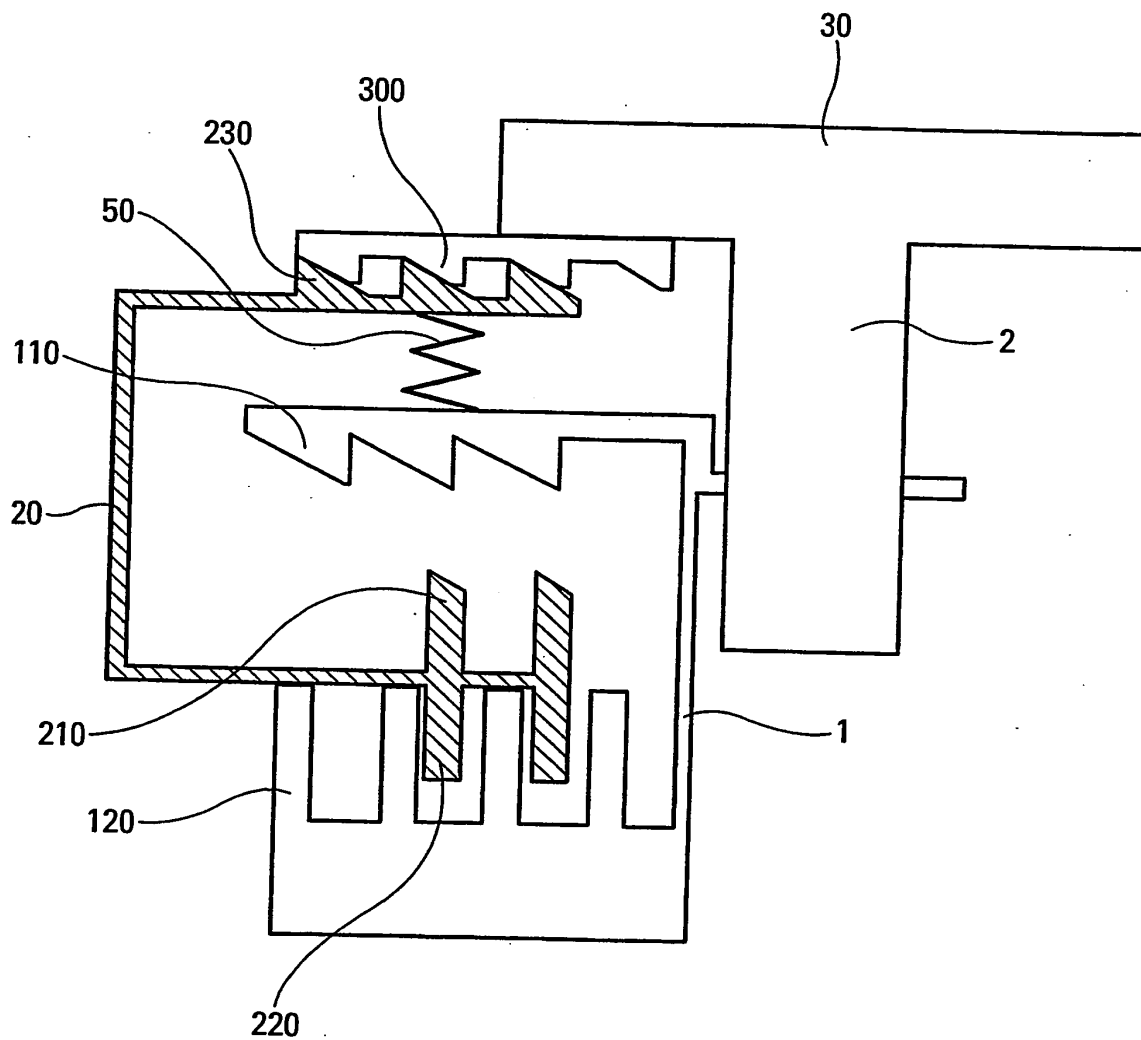


Fig. 16

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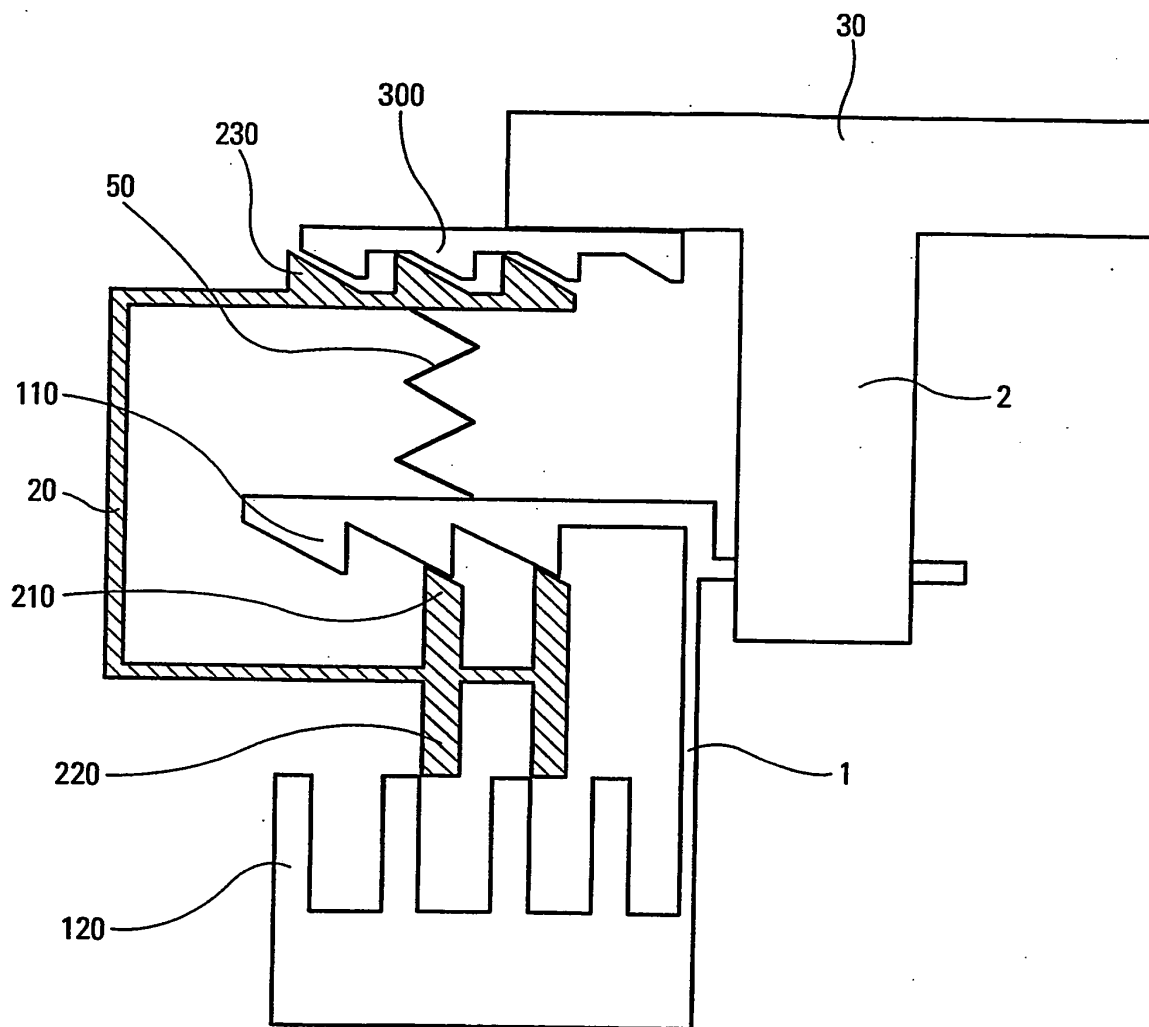


Fig. 17

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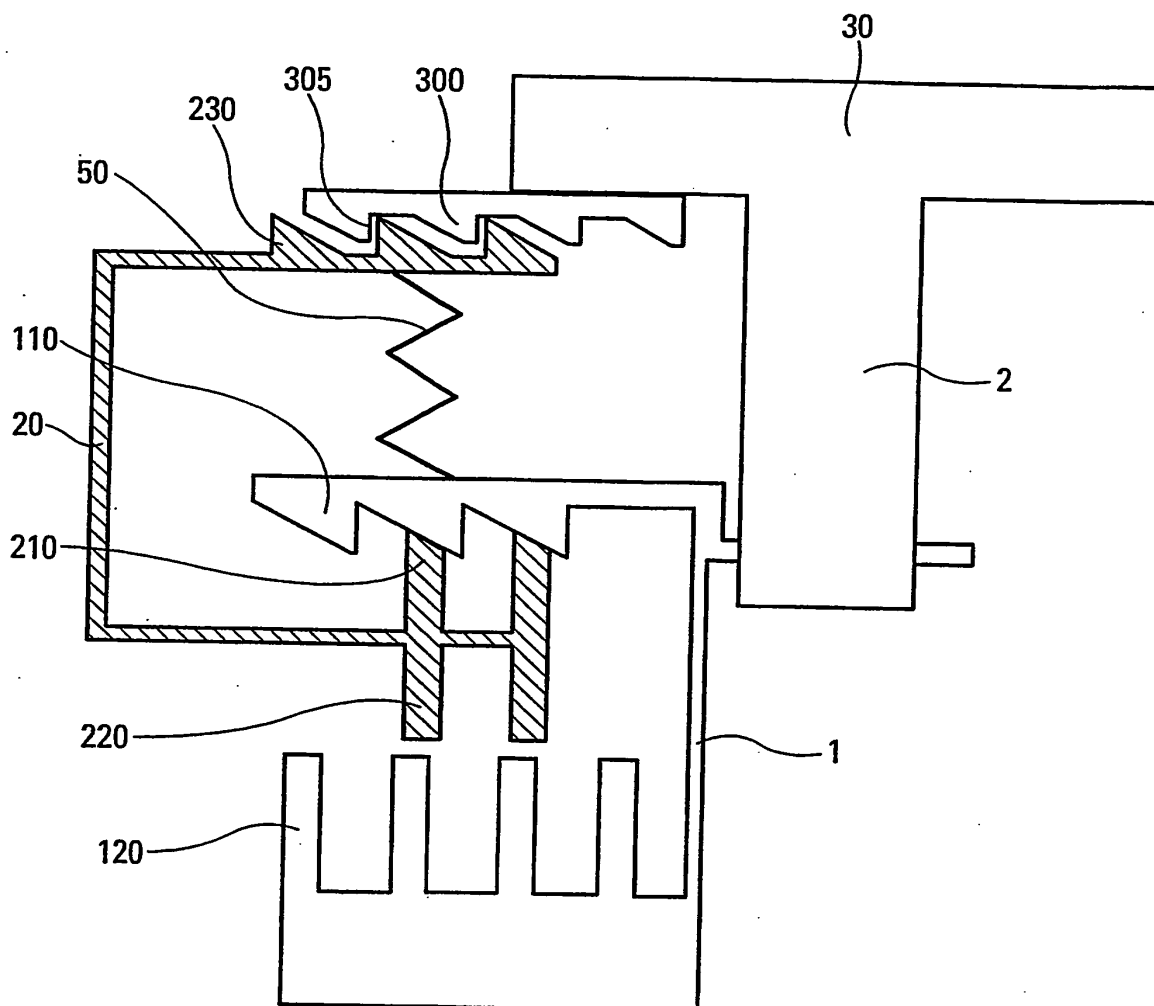


Fig. 18

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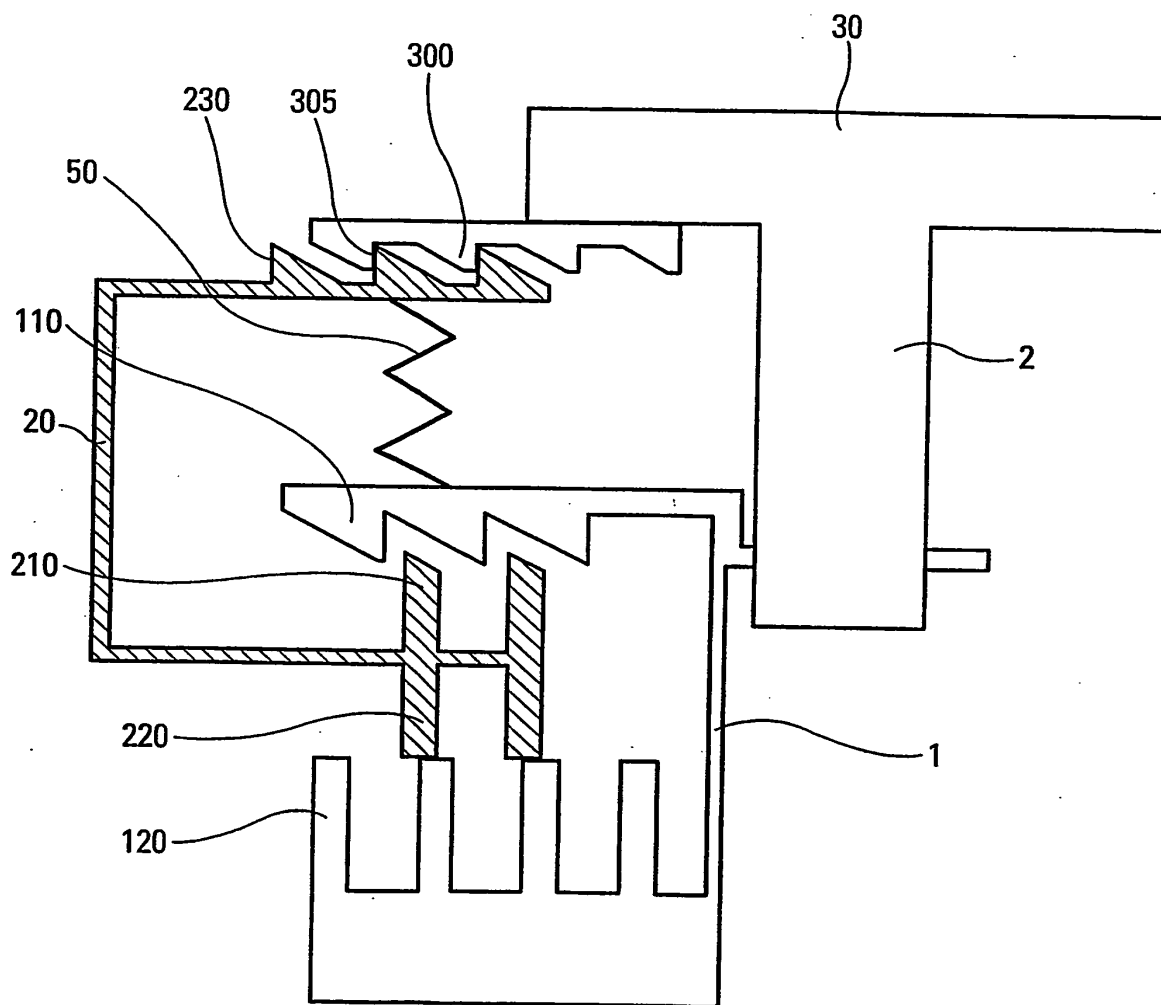


Fig. 19



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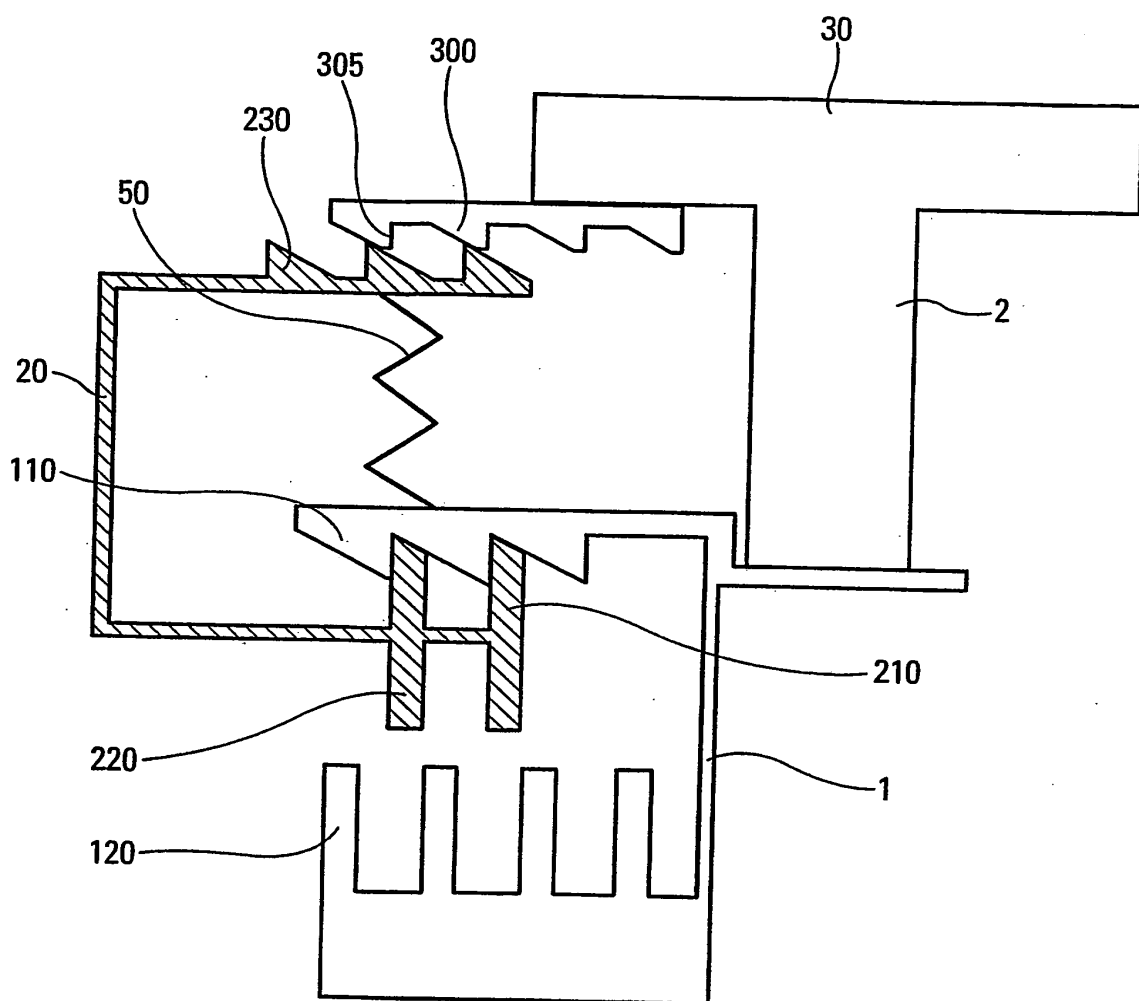


Fig. 21

Declaration and Power of Attorney for Patent Application

Déclaration et pouvoirs pour demande de brevet

French Language Declaration

En tant que l'inventeur nommé ci-après, je déclare par le présent acte que :

Mon domicile, mon adresse postale et ma nationalité sont ceux figurant ci-dessous à côté de mon nom

Je crois être le premier inventeur original et unique (si un seul nom est mentionné ci-dessous), ou l'un des premiers co-inventeurs originaux (si plusieurs noms sont mentionnés ci-dessous) de l'objet revendiqué, pour lequel une demande de brevet a été déposée concernant l'invention intitulée

et dont la description est fournie ci-joint à moins que la case suivante n'ait été cochée :

- ☐ a été déposée le
sous le numéro de demande des Etats-Unis ou le numéro
de demande international PCT
_____ (n° de confirmation _____) et
modifiée le
_____ (le cas échéant).

Je déclare par le présent acte avoir passé en revue et compris le contenu de la description ci-dessus, revendications comprises, telles que modifiées par toute modification dont il aura été fait référence ci-dessus.

Je reconnais devoir divulguer toute information pertinente à la I acknowledge the duty to disclose information which is material to brevetabilité, comme défini dans le Titre 37, § 1.56 du Codepatentability as defined in Title 37, Code of Federal Regulations, fédéral des réglementations. § 1.56.

As a below named inventor, I hereby declare that:

My residence, mailing address and citizenship are as stated next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

FLUID PRODUCT DISPENSER

the specification of which is attached hereto unless the following box is checked:

- ☒ was filed on May 14, 2004
as United States Application Number or PCT
International Application Number
PCT / FR04 / 01189 (Conf. No.)
and was amended on
_____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

French Language Declaration

Je revendique par le présent acte avoir la priorité étrangère, en vertu du Titre 35, § 119(a)-(d) ou § 365(b) du Code des Etats-Unis, sur toute demande étrangère de brevet ou certificat d'inventeur ou, en vertu du Titre 35, § 365(a) du même Code, sur toute demande internationale PCT désignant au moins un pays autre que les Etats-Unis et figurant ci-dessous et, en cochant la case, j'ai aussi indiqué ci-dessous toute demande étrangère de brevet, tout certificat d'inventeur ou toute demande internationale PCT ayant une date de dépôt précédant celle de la demande à propos de laquelle une priorité est revendiquée.

Prior foreign application(s)
Demande(s) de brevet antérieure(s)

FR-03/05858

(Number)
(Numéro)

FRANCE

(Country)
(Pays)

(Number)
(Numéro)

(Country)
(Pays)

Je revendique par le présent acte tout bénéfice, en vertu du Titre 35, § 119(e) du Code des Etats-Unis, de toute demande de brevet provisoire effectuée aux Etats-Unis et figurant ci-dessous.

(Application No.)
(N° de demande)

(Filing Date)
(Date de dépôt)

(Application No.)
(N° de demande)

(Filing Date)
(Date de dépôt)

Je revendique par le présent acte tout bénéfice, en vertu du Titre 35, § 120 du Code des Etats-Unis, de toute demande de brevet effectuée aux Etats-Unis, ou en vertu du Titre 35, § 365(c) du même Code, de toute demande internationale PCT désignant les Etats-Unis et figurant ci-dessous et, dans la mesure où l'objet de chacune des revendications de cette demande de brevet n'est pas divulgué dans la demande antérieure américaine ou internationale PCT, en vertu des dispositions du premier paragraphe du Titre 35, § 112 du Code des Etats-Unis, je reconnais devoir divulguer toute information pertinente à la brevetabilité, comme défini dans le Titre 37, § 1.56 du Code fédéral des réglementations, dont j'ai pu disposer entre la date de dépôt de la demande antérieure et la date de dépôt de la demande nationale ou internationale PCT de la présente demande :

(Application No.)
(N° de demande)

(Filing Date)
(Date de dépôt)

(Application No.)
(N° de demande)

(Filing Date)
(Date de dépôt)

Je déclare par le présent acte que toute déclaration ci-incluse est, à ma connaissance, véridique et que toute déclaration formulée à partir de renseignements ou de suppositions est tenue pour véridique; et de plus, que toutes ces déclarations ont été formulées en sachant que toute fausse déclaration volontaire ou son équivalent est passible d'une amende ou d'une incarcération, ou des deux, en vertu de la Section 1001 du Titre 18 du Code des Etats-Unis, et que de telles déclarations volontairement fausses risquent de compromettre la validité de la demande de brevet ou du brevet délivré à partir de celle-ci.

I hereby claim foreign priority under Title 35, United States Code, § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT International application which designated at least one country other than the United States, listed below, and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

Priority Claimed
Droit de priorité revendiqué
Yes/Oui No/Non

15 MAY 2003

(Day/Month/Year Filed)
(Jour/Mois/Année de dépôt)

☒ ☐

☐ ☐

(Day/Month/Year Filed)
(Jour/Mois/Année de dépôt)

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s), or § 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

(Status: patented, pending, abandoned)
(Statut : breveté, en cours d'examen, abandonné)

(Status: patented, pending, abandoned)
(Statut : breveté, en cours d'examen, abandonné)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

French Language Declaration

POUVOIRS : je désigne par les présentes tous avocats de SUGHRUE MION, PLLC énumérés sous le Numéro de Client USPTO figurant ci-après comme mes avocats pour poursuivre la présente procédure et traiter avec l'Office des brevets et des marques (*Patent and Trademark Office*) toute affaire en liaison avec celle-ci, reconnaissant formellement que les avocats spécifiques énumérés sous ce Numéro de Client peuvent être modifiés à tout moment, à la discrétion exclusive de Sughrue Mion, PLLC, et demande que toute correspondance relative à la demande soit adressée à l'adresse mentionnée sous le même Numéro USPTO.

POWER OF ATTORNEY: I hereby appoint all attorneys of SUGHRUE MION, PLLC who are listed under the USPTO Customer Number shown below as my attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, recognizing that the specific attorneys listed under that Customer Number may be changed from time to time at the sole discretion of Sughrue Mion, PLLC, and request that all correspondence about the application be addressed to the address filed under the same USPTO Customer Number.

23373

23373

PATENT TRADEMARK OFFICE

Adresser tout appel téléphonique à : (*nom et numéro de téléphone*)

SUGHRUE MION, PLLC
+1 (202) 293-7060

Direct Telephone Calls to: (*name and telephone number*)

SUGHRUE MION, PLLC
+1 (202) 293-7060

Nom complet de l'unique ou premier inventeur <i>Fabien POULARD</i>	Full name of sole or first inventor
Signature de l'inventeur Date October 20, 2005	Inventor's signature Date
Domicile Résidence Le Régency, 12 rue Crosne F-76000 Rouen, France	Residence
Nationalité Française	Citizenship French
Adresse postale Idem adresse domicile	Mailing Address
Nom complet du deuxième co-inventeur, le cas échéant	Full name of second joint inventor, if any
Signature du deuxième inventeur Date	Second inventor's signature Date
Domicile	Residence
Nationalité	Citizenship
Adresse postale	Mailing Address

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

11/21/2005 HKAYPAGH 00000061 10556432

01 FC:1631	300.00 OP
02 FC:1642	400.00 OP
03 FC:1633	200.00 OP

PTO-1556
(5/87)

*U.S. Government Printing Office: 2002 — 489-257/99033

10/556432
JC06 Rec'd PCT/PTO 09 NOV 2005

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: National Stage of PCT/FR2004/001189

Confirmation No.: Unknown

Group Art Unit: Unknown

Filed: November 9, 2005

Examiner: Unknown

For: FLUID PRODUCT DISPENSER

PRELIMINARY AMENDMENT

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Prior to examination, please amend the above-identified application as follows on the accompanying pages.

TABLE OF CONTENTS

AMENDMENTS TO THE SPECIFICATION	2
AMENDMENTS TO THE CLAIMS	3
REMARKS	11

Preliminary Amendment
National Stage of PCT/FR2004/001189

AMENDMENTS TO THE SPECIFICATION

Please replace the present title with the following amended title:

FLUID PRODUCT DISPENSER

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1. (original): A fluid dispenser comprising a body (1), a fluid reservoir (2), a dispenser member, such as a pump or a valve, mounted on said reservoir (2), and a dose indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, the dispenser being characterized in that said dose indicator device includes a first safety system for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform the complete actuation stroke, said reservoir (2) being axially displaceable relative to said body (1), said body (1) including at least one stationary gear (110, 120), said dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to said body (1), said counter element (20) co-operating, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 120) of said body, and secondly with said reservoir (2).

2. (original): A dispenser according to claim 1, in which said dose indicator device includes a second safety system which, during the return stroke of the dispenser after dispensing a dose, prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being

actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

3. (currently amended): A dispenser according to claim 1 ~~or claim 2~~, in which said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20), said counter element (20) including a second gear (230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser, the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation, the stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

4. (original): A dispenser according to claim 3, in which the stationary gear (110) includes abutment means (115) preventing said counter element (20) from turning once said counter element (20) has turned at least in part, an additional axial displacement of said counter element (20) being necessary to enable it to continue to turn and/or to return the indicator device to its rest position.

5. (original): A dispenser according to claim 4, in which said abutment means (115) comprise an axial projection.

6. (currently amended): A dispenser according to claim 1 ~~any preceding claim~~, in which said stationary gear (110) and/or said counter element (20) include(s) blocking means (120, 220) preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position after a preceding actuation, and until the dispenser has completed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

7. (original): A dispenser according to claim 6, in which said blocking means comprise axial projections (120, 220) provided on the body (1) and on the counter element (20) respectively, each of said projections (120, 220) having an axial end-profile that is plane, said projections (120, 220) facing each other, at least in part, until the counter element has turned sufficiently to offset said projections (120, 220), with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

8. (original): A dispenser according to claim 7, in which the teeth of the second gear (230) of the counter element (20) include an intermediate step (235), the actuator member (30) co-operating with said step (235) while the dispenser is being actuated, and co-operating with the end wall of

said second gear (230) while returning to the rest position, after being actuated, the displacement between the intermediate step (235) and the end wall being obtained by said counter element (20) turning.

9. (currently amended): A dispenser according to claim 7 ~~or claim 8~~, in which, once the predetermined incomplete return stroke has been performed, the actuator member (30) is positioned facing the following tooth of the second gear (230) of the counter element (20), enabling the dispenser and the dose indicator device to be actuated once again.

10. (currently amended): A dispenser according to claim 1 ~~any preceding claim~~, in which said body (1) includes a first stationary gear (110) and a second stationary gear (120), said counter element (20) including a first gear (210) for co-operating with said first stationary gear (110) and a second gear (220) for co-operating with said second stationary gear (120), said counter element (20) being put axially into contact with the actuator member (30) of the dispenser by means of a return spring (50) and being turnable relative to said actuator member (30), the teeth of said second gear (220) and of said second stationary gear (120) being oblique, at least in part, so that an axial displacement of the actuator member (30) initially causes said counter element (20) to be displaced axially over a predetermined incomplete actuation stroke until the oblique portion (221) of said second gear (220) of the counter element (20) co-operates with said oblique portion (121) of said second stationary gear (120), causing the counter element (20) to be turned over a first portion of a turn cycle, the teeth of said first gear (210) and of said first stationary gear (110)

being oblique, at least in part, so that when the counter element (20) returns to its rest position, it is caused to turn so as to terminate its turn cycle, which corresponds to one actuation of the dispenser being counted.

11. (original): A dispenser according to claim 10, in which said first and second stationary gears (110, 120) of the body (1) and/or said first and second gears (210, 220) of the counter element (20) are offset relative to each other, so that whenever the counter element (20) is displaceable in rotation, returning said counter element to its rest position without terminating the actuation stroke of the dispenser causes the counter element (20) to turn over its complete turn cycle, guaranteeing that one actuation of the dispenser is counted after said predetermined incomplete actuation stroke.

12. (currently amended): A dispenser according to claim 10 ~~or claim 11~~, in which said second stationary gear (120) of the body (1) and/or said second gear (220) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, and until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

13. (original): A dispenser according to claim 12, in which said blocking means have an axial

end-profile that is plane, at least in part, and that is formed on the teeth of said second stationary gear (120) of the body (1) and on the teeth of said second gear (220) of the counter element (20), said plane profiles of said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

14. (currently amended): A dispenser according to claim 10~~any one of claims 10 to 13~~, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

15. (currently amended): A dispenser according to claim 1~~any preceding claim~~, in which said body (1) includes a first stationary gear (110) and a second stationary gear (120), said counter element (20) comprising a first gear (210) for co-operating with said first stationary gear (110), a second gear (220) for co-operating with said second stationary gear (120), and a third gear (230) for co-operating with an actuator gear (300) secured to an actuator member (30) of the dispenser, the teeth of said third gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member (30) causes said counter element (20) to be displaced axially and in rotation, the first stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

16. (original): A dispenser according to claim 15, in which said second stationary gear (120) of the body (1) and/or said second gear (220) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

17. (original): A dispenser according to claim 16, in which said blocking means have an axial end-profile that is plane and that is formed on the teeth of said second stationary gear (120) and on the teeth of said second gear (220), said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

18. (currently amended): A dispenser according to claim 16 ~~or claim 17~~, in which said actuator gear (300) includes abutment means (305) limiting the extent to which the counter element (20) can turn, until the actuator member (30) has performed said predetermined incomplete return stroke.

19. (original): A dispenser according to claim 18, in which said abutment means (305) comprise an axial projection formed on said actuator gear (300).

Preliminary Amendment
National Stage of PCT/FR2004/001189

20. (currently amended): A dispenser according to claim 15~~any one of claims 15 to 19~~, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

Preliminary Amendment
National Stage of PCT/FR2004/001189

REMARKS

Entry and consideration of this Amendment are respectfully requested.

Respectfully submitted,



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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: November 9, 2005

10/556432

JCOG Rec'd PCT/PTO 09 NOV 2005
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: National Stage of PCT/FR2004/001189

Confirmation No.: Unknown

Group Art Unit: Unknown

Filed: November 9, 2005

Examiner: Unknown

For: FLUID PRODUCT DISPENSER

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after

10/556432

JCCS Rec'd PCT/PTO 09 NOV 2005

INFORMATION DISCLOSURE STATEMENT
Appln. No.: National Stage of PCT/FR2004/001189
Attorney Docket No. Q91404

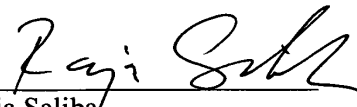
filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant encloses herewith a copy of a Communication from a foreign patent office in a counterpart application citing such documents (International Search Report for PCT/JP2004/001189 dated November 24, 2004), together with an English-language version (if not already included) of at least that portion of the Communication indicating the degree of relevance found by the foreign patent office.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

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23373

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Substitute for Form 1449 A & B/PTO		Complete if Known	
		National Stage of	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	PCT/FR2004/001189
		Confirmation Number	Unknown
		Filing Date	November 9, 2005
		First Named Inventor	Fabien POULARD
		Art Unit	Unknown
		Examiner Name	
Sheet	1	of	1
		Attorney Docket Number	Q91404

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		
		US 2002/0195102	A1	12/26/2002	PAUL KENNETH RAND, ET AL
		US 6,446,627	B1	09/10/2002	NICHOLAS JOHN BOWMAN, ET AL
		US			
		US			
		US			
		US			
		US			
		US			
		US			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			
		DE	100 61 723	A1	07/11/2002	ROSEMARIE ECKERT	
		EP	0 480 488	A1	04/15/1992	ELETTRO PLASTICA S.p.A.	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.

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19 BUNDESREPUBLIK
DEUTSCHLAND



DEUTSCHES
PATENT- UND
MARKENAMT

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Antrag auf Nichtnennung

56 Entgegenhaltungen:

DE	33 02 160 A1
DE	298 14 647 U1
GB	13 17 315
US	58 29 434

Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

Prüfungsantrag gem. § 44 PatG ist gestellt

- 54 Zählwerk zum Zählen dosierter Abgaben flüssiger, pastöser oder fester Produkte sowie Einrichtung zum dosierten Abgeben solcher Produkte
- 57 Zählwerk zum Zählen dosierter Abgaben flüssiger, pastöser oder fester Produkte, insbesondere Medikamente, aus einem Vorratsbehälter, umfassend:
- einen ersten Zählring und einen zweiten Zählring, die koaxial zur Längsachse des Zählwerks angeordnet und relativ zueinander drehbar und miteinander koppelbar sind,
 - eine Schaltvorrichtung zum Bewegen des ersten Zählrings bei Betätigung eines zur Abgabe des Produkts zu betätigenden Betätigungsmittels, und
 - eine Kopplungsvorrichtung zur Kopplung des ersten Zählrings mit dem zweiten Zählring zum gemeinsamen Bewegen beider Zählringe,
- dadurch gekennzeichnet, dass die Schaltvorrichtung ein Führungselement und ein Schaltelement umfasst, die beide koaxial zur Längsachse angeordnet sind, wobei das Schaltelement bezüglich des Führungselements axial bewegbar ist und einen Abschnitt aufweist, der bei einer Betätigung des Betätigungselements entlang einer am Führungselement vorgesehenen Kurvenfläche derart geführt wird, dass ein am Schaltelement vorgesehener Schaltenocken in Eingriff mit einer am ersten Zählring vorgesehene Nockenaufnahme gebracht und anschließend eine Drehbewegung eingeleitet wird, durch die der erste Zählring um ein Winkelinkrement gedreht wird.

DE 100 61 723 A 1

Beschreibung

[0001] Die Erfindung betrifft ein Zählwerk zum Zählen dosierter Abgaben flüssiger, pastöser oder fester Produkte, insbesondere Medikamente, aus einem Vorratsbehälter, umfassend:

- einen ersten Zählring und einen zweiten Zählring, die koaxial zur Längsachse des Zählwerks angeordnet und relativ zueinander drehbar und miteinander kopplbar sind,
- eine Schaltvorrichtung zum Bewegen des ersten Zählrings bei Betätigung eines zur Abgabe des Produkts zu betätigenden Betätigungsmittels, und
- eine Kopplungsvorrichtung zur Kopplung des ersten Zählrings mit dem zweiten Zählring zum gemeinsamen Bewegen beider Zählringe.

[0002] Solche Zählwerke kommen beispielsweise bei Abgabeeinrichtungen für Tabletten oder bei Aerosolspendern zum Einsatz. Sie dienen im Falle des Tablettenpenders beispielsweise dazu, die jeweilige von einem Patienten pro Tag zu nehmende Menge an Tabletten sicher erfassen zu können. Zu diesem Zweck wird jede Betätigung des Abgabemechanismus der Abgabeeinrichtung, die zur Abgabe einer Tablette führt, gezählt und mittels der beiden Zählringe tagesspezifisch angezeigt. Der Patient kann so genau erkennen, wie viele Tabletten er bereits an einem Tag genommen hat und ob noch weitere zu nehmen sind.

[0003] Darüber hinaus können solche Zählwerke auch zur Erfassung der Gesamtmenge an abgegebenen Tabletten oder ähnlichen Gegenständen verwendet werden, so dass erkannt werden kann, wie viele Produkte einer Gesamtmenge X bereits entnommen sind. Entsprechend umgekehrt kann das Zählwerk auch zum Erfassen der vorhandenen Restmenge verwendet werden.

[0004] Die gleichen Erfassungsmöglichkeiten bieten sich auch im Falle eines Aerosolspenders und auch hier können je nach Ausführung des Zählwerks Tages-, Gesamt- oder Restmengen erfasst werden.

[0005] Neben der Abgabe von Medikamenten kann ein solches Zählwerk natürlich auch zur Abgabe beliebiger anderer flüssiger, pastöser oder fester Produkte dienen. Bekannte Zählwerke sind zum einen sehr kompliziert aus einer Vielzahl von Einzelelementen aufgebaut. So sind beispielsweise Zählwerke bekannt, die zum Bewegen eines Zählrings um ein Winkelinkrement bei einer einzelnen Betätigung einen Kniehebelmechanismus umfassend eine Vielzahl komplex geformter und miteinander zusammenwirkender Teile umfassen. Daneben sind auch Zählwerke bekannt, die mehrere miteinander zusammenwirkende Scheibeneinheiten sowie verschiedene Übertragungsmittel zur Übertragung der Drehbewegung von einer Scheibeneinheit auf die andere umfassen. Jede der bekannten Zählwerkausgestaltungen ist äußerst komplex aufgebaut, was die Gefahr von Fehlfunktionen mit sich bringt. Diese Fehlfunktion kann jedoch zu schwerwiegenden Folgeschäden führe, insbesondere wenn das Zählwerk zum Zählen von Medikamentenabgaben dient.

[0006] Der Erfindung liegt damit das Problem zugrunde, ein Zählwerk anzugeben, das ein funktionssicheres Erfassen einer Produktabgabe zulässt.

[0007] Zur Lösung dieses Problems ist bei einem Zählwerk der eingangs genannten Art erfindungsgemäß vorgesehen, dass die Schaltvorrichtung ein Führungselement und ein Schaltelement umfasst, die beide koaxial zur Längsachse angeordnet sind, wobei das Schaltelement bezüglich des Führungselements axial bewegbar ist und einen Ab-

schnitt aufweist, der bei einer Betätigung des Betätigungselements entlang einer am Führungselement vorgesehenen Kurvenfläche derart geführt wird, dass ein am Schaltelement vorgesehenen Schaltnocken in Eingriff mit einer am ersten Zählring vorgesehenen Nockenaufnahme gebracht und anschließend eine Drehbewegung eingeleitet wird, durch die der erste Zählring um ein Winkelinkrement gedreht wird.

[0008] Das erfindungsgemäße Zählwerk zeichnet sich durch einen äußerst funktionssicheren Mechanismus zur Führung des Schaltelements aus. Bei diesem Mechanismus ist am feststehenden Führungselement wenigstens eine Kurvenfläche als Führungsfläche für einen am Schaltelement vorgesehenen, entlang der Kurvenfläche gleitenden Abschnitt vorgesehen. Wird nun über ein Betätigungselement eine Abgabeeinrichtung, die das erfindungsgemäße Zählwerk umfasst, betätigt, so wird hierbei das Schaltelement koaxial bewegt, wobei der Abschnitt an der Führungsfläche anliegt. Dies ist nun so geführt, dass zum einen ein am Schaltelement vorgesehener Schaltnocken in Eingriff mit einer am ersten Zählring vorgesehenen Nockenaufnahme gebracht wird, zum anderen ist aufgrund der gewählten Kurvenform gewährleistet, dass bei einer weiteren Bewegung des Betätigungselements und damit des Schaltelements eine Drehbewegung aufgrund der Kurvenform eingeleitet wird, die bedingt durch den Nockeneingriff dazu führt, dass der erste Zählring um ein von der Länge des Bewegungsweges des Betätigungselements und damit des Hubs des Schaltelements abhängiges Winkelinkrement gedreht wird. Es ist hier also ein äußerst funktionssicher arbeitender Zwangsführungsmechanismus realisiert, der eine Betätigung und damit eine Produktabgabe zwingend erfasst.

[0009] Die Kurvenfläche ist zweckmäßigerweise an der Stirnkante einer Ausnehmung der Wand des im Wesentlichen ringförmigen Führungselements vorgesehen, wobei der Abschnitt in die Ausführung eingreift. Die Kurvenfläche kann erfindungsgemäß derart geformt sein, dass zu Beginn der Bewegung des Schaltelements eine axiale Bewegung, anschließend eine kombinierte axiale und radiale Bewegung und am Ende die Hubbewegung vorzugsweise eine axiale Bewegung erfolgt. Dies hat den Vorteil, dass die eigentliche der Betätigungserfassung dienende Drehbewegung erst nach einer axialen Bewegung und damit nach einem hinreichend weiten Eindringen des Betätigungselements erfolgt, so dass nicht jede sich beispielsweise aus Unachtsamkeit ergebende leichte Betätigung des Betätigungselements zu einer Zählung führt. Hier zeigt sich ein besonderer Vorteil der Erfindung, als es natürlich problemlos möglich ist, durch entsprechende Variierung der Kurvenform einen beliebigen Bewegungsablauf zu realisieren, insbesondere betreffend die Einleitung der Drehung, die durch entsprechende Steigung der Kurvenfläche beliebig variiert werden kann. So ist es beispielsweise möglich, zu Beginn der eingeleiteten Drehbewegung eine relativ geringe Drehung bezogen auf den Hub vorzusehen, und erst später die starke Drehbewegung durch entsprechend geänderte Kurvenform zu realisieren, die dann in der endgültigen Zählung resultiert. Das Führungselement kann erfindungsgemäß im Wesentlichen ringförmig und das Schaltelement im Wesentlichen hohlzylindrisch und im Inneren des Führungselements angeordnet sein. Aus Sicherheitsgründen und zur weitergehenden Verbesserung des funktionssicheren Systems hat es sich als zweckmäßig erwiesen, wenn zwei vorzugsweise einander gegenüberliegende Abschnitte am Schaltelement und zwei vorzugsweise einander gegenüberliegende Kurvenflächen am Führungselement vorgesehen sind. Gemäß dieser Erfindungsausgestaltung wird das Schaltelement also an zwei Punkten geführt, so dass ein Verkippen bei einer druckbedingten Belastung des Schaltelements – das letztlich auch

bei nur einem Abschnitt und einer Kurvenfläche bedingt durch die Führung des Schaltelements im Inneren des ringförmigen und letztlich ebenfalls hohlzylindrischen Führungselements ausgeschlossen ist – noch unwahrscheinlicher ist.

[0010] Besonders vorteilhaft ist es, wenn das Schaltelement gegen eine Rückstellkraft bewegbar ist, die dazu führt, dass es nach Lösen des betätigungsbedingten Drucks wieder in die Ausgangsstellung zurückgeführt wird. Dabei ist es denkbar, dass die Rückstellkraft – die erfindungsgemäß von einer Feder erzeugt werden kann – lediglich dazu führt, dass das Schaltelement nach Lösen des Betätigungsdrucks einfach nach oben gedrückt wird. In einem solchen Fall ist es zweckmäßig, wenn eine weitere Kurvenfläche vorgesehen ist, an die das Schaltelement mit dem (jeweiligen) Abschnitt gedrückt wird und entlang dieser Kurvenfläche wieder zurück in die Ausgangsstellung geführt wird. In diesem Fall wäre also eine zweite Zwangsführung unter Verwendung einer Kurvenfläche vorgesehen.

[0011] Besonders zweckmäßig ist es jedoch, wenn die die Rückstellkraft erzeugende Feder während der Drehbewegung tordiert wird, so dass das Schaltelement nach Lösen des Eingriffs des Schaltnockens in der Nockenaufnahme und damit nach Lösen des Betätigungsdrucks bei gleichzeitiger Rückdrehung in die Ausgangsstellung rückführt. Bei dieser Erfindungsausgestaltung wird also durch die von der Kurvenfläche bedingte Zwangsdrehung die erfindungsgemäß als Spiralfeder ausgebildete Feder, die mit einem Ende an einer Grundplatte und mit ihrem anderen Ende an dem Schaltelement gelagert ist, tordiert, so dass eine torsionsbedingte Rückstellkraft erzeugt wird. Diese Rückstellkraft zusammen mit der durch Kompression der Feder eingebrachte Rückstellkraft führen nun dazu, dass bei einer Entspannung das Schaltelement zwangsläufig wieder in die Ausgangsstellung zurückgeführt wird.

[0012] In Weiterbildung des Erfindungsgedankens kann vorgesehen sein, dass die Verzahnung des ersten Zählrings, die mit dem Schaltnocken, der zweckmäßigerweise in Verlängerung des Abschnitts angeformt ist, zusammenwirkt, an der dem Schaltnocken zugewandten Seite eine Schrägfläche aufweist. Diese Schrägfläche bewirkt, dass, wenn der Schaltnocken bei Betätigung des Betätigungsmittels axial bewegt wird und in die Verzahnung eintaucht, zunächst an der Schrägfläche anschlägt, was dazu führt, dass bei einer weiteren axialen Bewegung des Schaltnockens eine erste Drehbewegung eingeleitet wird. Anschließend wird diese Drehbewegung kurvenflächenbedingt fortgesetzt.

[0013] Wie ausgeführt ist das Schaltelement sicher in dem ringförmigen und ebenfalls hohlzylindrischen Führungselement geführt. Hierzu ist ein oder mehrere Führungsabschnitte vorgesehen, an denen das Schaltelement anliegt, und entlang welcher es gleitet. Um insbesondere im Falle einer Verwendung des Zählwerks zusammen mit einem Aerosolbehälter eine sichere Luftnachsaugung zu erzielen, ist es zweckmäßig, wenn wenigstens ein Bereich vorgesehen ist, in dem das Schaltelement zum Führungselement beabstandet ist. Hierdurch kann problemlos ein Luftkanal realisiert werden.

[0014] Um zu verhindern, dass ein Zählring zurückdreht und mithin das Zählergebnis nicht mehr stimmt, was versehentlich passieren kann oder aber bei gezielter Manipulation, kann erfindungsgemäß vorgesehen sein, dass am Führungselement mindestens zwei Sperrklinken vorhanden sind, von denen je eine mit einer Verzahnung des ersten und des zweiten Zählrings derart zusammenwirken, dass ein Drehen in der zur Zählrichtung entgegengesetzten Richtung gesperrt wird. Die als Federarme ausgebildeten Sperrklinken verfügen über entsprechende Schrägflächen, an der eine

Zahnflanke der Verzahnung angreift und bei einer Zahndrehung die Sperrklinke anhebt, die anschließend hinter der Verzahnung verrastet. Dabei ist es zweckmäßig, wenn jeweils zwei derart zueinander versetzt angeordnete Sperrklinken vorgesehen sind, dass sie bei unterschiedlichen Drehwinkeln bei der Drehung des jeweiligen Zählrings in die Verzahnung eingreifen. Diese als Primär- und Sekundärsperrklinken benennbaren Sperrklinken ermöglichen es, dass zum einen eine Produktabgabe, die bereits erfolgt ist, wenn das Betätigungselement nicht gänzlich durchgedrückt wurde, erfasst wird, da in diesem Fall die erste Sperrklinke bereits eingreift, wenn beispielsweise die Drehbewegung lediglich zu 90% erfolgte. Bei einer Drehbewegung 90% ist aber die Produktabgabe bereits erfolgt, wenngleich der gesamte Hub noch nicht durchfahren ist. Wird nun das Betätigungselement entlastet, so wird gleichwohl einerseits die Zählung registriert, zum anderen ist aber auch eine Sperrung des Zählrings durch die früher eingreifende Sperrklinke gegeben. Im Falle einer vollständigen Durchdrückung des Betätigungselements greifen beide Sperrklinken. Ein weiterer Vorteil ist, dass hierdurch eine Manipulation verhindert wird, da für ein manipulationsbedingtes Zurückdrehen eines Zählrings beide Sperrklinken ausgerastet werden müssten, was – insbesondere da die Sperrklinken in einem nachfolgend noch beschriebenen Gehäuse noch gekapselt sind – fast unmöglich ist.

[0015] Nach einer besonders zweckmäßigen Weiterbildung des Erfindungsgedankens kann vorgesehen sein, dass am Führungselement Führungsflächen für den ersten und den zweiten Zählring sowie mindestens zwei Rastelemente vorgesehen sind, von denen eines einen Rastabschnitt des zweiten Zählrings und das andere einen Rastabschnitt der ersten Zählring an der dem Führungselement gegenüberliegenden Seite führenden Grundplatte hintergreift, so dass die Zählringe, das Führungselement, das Schaltelement, das Federelement und die Grundplatte eine handhabbare Einheit bilden. Das eigentliche Kernstück des Zählwerks umfasst lediglich diese sechs Elemente, die alle mittels der Rastelemente, die an entsprechenden Rastabschnitten der endseitigen Teile, nämlich des zweiten Zählrings und der Grundplatte verrasten, zusammengehalten werden. Sie bilden also quasi eine unlösbare handhabbare Einheit. Diese Einheit kann beispielsweise problemlos in ein Winkelstück eingesetzt werden, welches dann auf einen Aerosolbehälter aufgesetzt wird.

[0016] Die Kopplungsvorrichtung kann erfindungsgemäß wenigstens einen an einer Grundplatte vorgesehenen ersten Vorsprung und eine am ersten Zählring vorgesehene Rastklinke mit einem zweiten Vorsprung umfassen, wobei der erste Vorsprung mit dem zweiten Vorsprung bei entsprechender Drehstellung des ersten Zählrings derart zusammenwirkt, dass die Rastklinke angehoben und in Eingriff mit einer am zweiten Zählring vorgesehenen Verzahnung kommt. Durch entsprechende Positionierung des ersten Vorsprungs ist es also möglich, nach einer beliebigen Anzahl an Betätigungen eine Kopplung mit dem zweiten Zählring zu realisieren und diesen um ein Winkelinkrement weiter zu drehen. So ist es beispielsweise möglich, im Falle eines Tagesmengenzählers den Vorsprung so anzuordnen, dass insgesamt drei Einzeldosen pro Tag zu entnehmen sind und bei Entnahme der dritten Dosis die Zählringe gekoppelt und gemeinsam gedreht werden. Der zweite Zählring zeigt dabei die Anzahl der jeweiligen Einzeldosis an, der erste Zählring gibt beispielsweise den Wochentag oder den Montagstag an. Der zweite Zählring wird dann auf den nächsten Tag gestellt, der erste Zählring zeigt beispielsweise wieder eine Eins, so dass der Patient weiß, dass er am folgenden Tag noch keine Dosis entnommen hat, jedoch für den jetzigen

Tag alle vorgeschriebenen Dosen eingenommen wurden. Durch entsprechende Anzahl an Zähnen am zweiten Zählring sowie entsprechende Positionierung der gegebenenfalls mehreren Vorsprünge an der Grundplatte ist es problemlos möglich, beliebige Tagesdosen und damit Kopplungszeitpunkte einzustellen.

[0017] Weiterhin kann am Führungselement ein Anschlag vorgesehen sein, an dem ein am zweiten Zählring vorgesehener Vorsprung bei Erreichen einer Enddrehstellung anschlägt. Im Falle eines Restmengen Zählers verhindert der am Vorsprung anliegende Anschlag, dass der zweite Zählring, an dem beispielsweise die Zahlen 31, 29, 28, . . . 3, 2, 1 aufgebracht sind, trotz Betätigung des Betätigungselements noch mal weitergedreht wird, wenn ausgehend von einer Maximalmenge von 300 die letzte Dosis entnommen wurde. Wäre hier kein Sperrmittel vorgesehen, so würde der zweite Zählring von 1 wieder auf die Zahl 31 weitergedreht, was zu Irritationen seitens des Benutzers führen würde. Um entsprechendes auch bei dem ersten Zählring zu verhindern, ist vorgesehen, dass am zweiten Zählring ein Abdeckabschnitt zum bereichsweisen Abdecken des ersten Zählrings vorgesehen ist, der beim Bewegen in die Endstellung des zweiten Zählrings in eine Sichtstellung gedreht wird. Dieser Abdeckabschnitt wird dann in ein Sichtfenster gedreht, wenn die letzte Dosis entnommen wurde und die beiden Zählringe "000" anzeigen. Der zweite Zählring kann aufgrund der Sperrung nicht weitergedreht werden, anders jedoch der erste Zählring, der bei einer weiteren Betätigung wieder auf "9" springen würde. Damit diese "9" nicht sichtbar ist, ist der zweckmäßige Abdeckabschnitt vorgesehen, der auch bei einer weiteren Betätigung unbewegbar im Sichtfenster verbleibt. Die Restmenge kann dennoch entnommen werden, ohne dass jedoch eine Zählanzeige erfolgt.

[0018] Zur Kapselung der Zählringe, des Führungselements, des Schaltelements etc. ist zweckmäßigerweise eine im Wesentlichen hohlzylindrisches Gehäuse vorgesehen, dass wenigstens einen Fensterabschnitt aufweist, durch den die an der Außenfläche der Zählringe, die bevorzugt aus Kunststoff bestehen und zweckmäßigerweise durch Laserbeschriftung markiert sind, angebrachten Markierungen sichtbar sind. Zur Verbesserung der Erkennbarkeit ist es zweckmäßig, wenn in dem Fensterabschnitt ein optisches Vergrößerungselement in Form einer Lupe angeordnet ist. Das Gehäuse selbst besteht ebenfalls aus Kunststoff, wobei hier ein durchsichtiger Kunststoff verwendet werden kann, an dem das optische Vergrößerungselement integral angeformt sein kann.

[0019] Um die Zählringe insbesondere bei einem Tagesmengen Zähler, bei dem mittels des ersten Zählrings die jeweilige Tagesdosis, und mittels des zweiten Zählrings der jeweilige Wochen- oder Monatstag angezeigt wird, die Zählringe einstellen zu können, sind zweckmäßigerweise an dem Gehäuse wenigstens zwei Durchbrechungen vorgesehen, durch die in jeweils eine Verzahnung am ersten beziehungsweise am zweite Zählring zu Stellzwecken eingegriffen werden kann. Dem Benutzer ist es also problemlos unter Verwendung eines kleinen Werkzeugs oder dergleichen möglich, die Zählringe entsprechend einzustellen. Dabei können jedem Zählring jeweils zwei am Umfang des Gehäuses beabstandet zueinander angeordnete Durchbrechungen zugeordnet sein, die eine Handhabung durch Rechtshänder Linkshänder mühelos ermöglichen.

[0020] Um das Gehäuse fest mit seinem "Innenleben" zu verbinden sind zweckmäßigerweise an wenigstens einer Stirnseite des Gehäuses Rastelemente zum Hintergreifen eines Rastabschnitts an der Grundplatte vorgesehen. An der gegenüberliegenden Stirnseite des Gehäuses ist zweckmäßigerweise eine das Betätigungselement gegenlagernde

Schulter ausgebildet. Das Schaltelement selbst liegt direkt an dem bei einer Betätigung axial verschiebbaren Betätigungselement an, so dass eine unmittelbare Bewegungskopplung realisiert ist.

[0021] Das Betätigungselement kann erfindungsgemäß eine Taste sein, die als Teil des Zählwerks fest gekoppelt ist. Eine solche Taste ist beispielsweise bei einem Tabletten-spender oder dergleichen zweckmäßig. Alternativ kann das Betätigungselement auch ein Aerosolbehälter sein, der entweder fest mit dem Zählwerk gekoppelt ist, das heißt das Zählwerk ist fest auf diesen aufgesetzt. Alternativ besteht auch die Möglichkeit einer lösbaren Kopplung Aerosolbehälter-Zählwerk.

[0022] Je nach Ausgestaltung, ob es sich also um einen Tabletten- oder dergleichen Spender oder einen Aerosol-spender handelt, kann ein an der Grundplatte angeformter oder befestigter Deckel, der einen Vorratsbehälter abdeckt, oder eine an der Grundplatte angeformte oder befestigte Spraydüse vorgesehen sein. Schließlich hat es sich als zweckmäßig erwiesen, wenn ein Sicherungsmechanismus zum Verhindern einer unbeabsichtigten oder unbefugten Betätigung vorgesehen ist. Dieser Sicherungsmechanismus, der beispielsweise zur Betätigung des Betätigungselements zunächst ein leichtes Verdrehen desselben voraussetzt, dient insbesondere als Kindersicherung.

[0023] Neben dem Zählwerk betrifft die Erfindung ferner eine Einrichtung zum dosierten Abgeben flüssiger, pastöser oder fester Produkte, insbesondere von Medikamenten. Diese Einrichtung zeichnet sich durch einen das abzugebende Produkt beinhaltenden Vorratsbehälter sowie ein erfindungsgemäßes Zählwerk der eingangs beschriebenen Art aus.

[0024] Dabei kann das Zählwerk auf den Vorratsbehälter lösbar aufsetzbar sein, so dass sich eine Nachfüllmöglichkeit ergibt. Dies ist insbesondere bei Tabletten Spendern, aber auch bei anderen Abgabeeinrichtungen für flüssige oder pastöse Produkte zweckmäßig. Auch bei einem Aerosol-spender lässt sich auf diese Weise eine problemlose Mehrfachverwendung realisieren, da lediglich der Aerosolbehälter ausgetauscht werden muss.

[0025] Schließlich kann nach einer zweckmäßigen Weiterbildung des Erfindungsgedankens vorgesehen sein, dass ein gegebenenfalls gewinkeltes Mundstück vorgesehen ist, in das das Zählwerk lösbar oder unlösbar integriert ist, und in das die Aerosolflasche lösbar einsetzbar ist. In dieses gewinkelte Mundstück, in dem beispielsweise die Spraydüse fest integriert sein kann, wird beispielsweise das Zählwerk samt Aerosolflasche lösbar eingesetzt. Das Mundstück kann wiederverwendet werden, während die Aerosolflasche nach Entleerung ausgetauscht wird. Das Zählwerk selbst kann gegebenenfalls ebenfalls wiederverwendet werden.

[0026] Weitere Vorteile, Merkmale und Einzelheiten der Erfindung ergeben sich aus den im Folgenden beschriebenen Ausführungsbeispielen sowie anhand der Zeichnungen. Dabei zeigen:

[0027] Fig. 1 eine Ansicht einer erfindungsgemäßen Abgabeeinrichtung einer ersten Ausführungsform,

[0028] Fig. 2 eine Sprengdarstellung der Einrichtung aus Fig. 1,

[0029] Fig. 3 eine zweite Ausführungsform einer erfindungsgemäßen Abgabeeinrichtung,

[0030] Fig. 4 eine Sprengdarstellung der Einrichtung aus Fig. 3,

[0031] Fig. 5 eine Perspektivansicht eines Führungselements,

[0032] Fig. 6 eine Perspektivansicht eines Schaltelements,

[0033] Fig. 7 eine Perspektivansicht einer Feder,

[0034] Fig. 8 und 9 Perspektivansichten der Ober- und

Unterseiten des ersten Zählrings,

[0035] Fig. 10 eine Perspektivansicht des zweiten Zählrings,

[0036] Fig. 11 eine Perspektivansicht der Grundplatte,

[0037] Fig. 12 und 13 zwei perspektivische Ansichten des Gehäuses und

[0038] Fig. 14, 15 perspektivische Ansichten der Spraydüse.

[0039] Fig. 1 zeigt eine erfindungsgemäße Einrichtung 1 zum dosierten Abgeben eines Produktes, im gezeigten Beispiel beispielsweise von Tabletten. Die Einrichtung besteht aus einem Zählwerk 2, das auf einem Vorratsbehälter 3 aufgesetzt ist. Zum Abgeben einer Tablette aus dem Vorratsbehälter 3 ist ein Betätigungselement in Form einer Taste 4 nach unten zu drücken, wodurch ein Abgabemechanismus betätigt wird, über den eine Tablette ausgegeben wird. Mittels des Zählwerks wird diese Tablettenabgabe erfasst und angezeigt, wozu die in einer Fensteröffnung 5 an einem Gehäuse 6 sichtbaren Zahlen 7 dienen. Beim gezeigten Ausführungsbeispiel handelt es sich um einen Tagesmengen-Zähler, der über die Ziffern "01" den jeweiligen Monatstag, hier den Ersten des Monats angibt, die Ziffer "4" gibt an, dass an diesem Tag die vierte Tablettendosis entnommen wurde. Auf die Einzelelemente wird nachfolgend bezüglich Fig. 2 näher eingegangen.

[0040] In Fig. 2 ist eine Sprengdarstellung sämtlicher Elemente der Einrichtung 1 aus Fig. 1 gezeigt. Die Einrichtung 1 besteht aus der Taste 4, an der endseitig ein Betätigungsstößel 8 angeordnet ist, der mit einem im Vorratsbehälter 3 integrierten Ausgabemechanismus zusammenwirkt. Die Taste 4 ist in dem Gehäuse 6 integriert und dort unverlierbar gehalten.

[0041] Das Zählwerk 2 umfasst ferner einen ersten Zählring 9 sowie einen zweiten Zählring 10, die zum Anzeigen der relevanten Zahleninformationen betreffend die Abgabe dienen. Im gezeigten Ausführungsbeispiel betreffend den Tageszähler zeigt der erste Zählring 9 die entnommene Tagesmenge, hier die Zahl "4", der zweite Zählring 10 gibt den jeweiligen Monatstag an, bezogen auf Fig. 1 die Zahlenfolge "01". Die beiden Zählringe 9, 10 sind aus Kunststoff gefertigt und an ihren Außenseiten mit den entsprechenden Zahlenfolgen beschriftet, was durch Laserdrucken besonders einfach und ansehnlich möglich ist. Der Zählring 10 trägt die Ziffernfolgen "01, 02, 03, ..., 29, 30, 31", der Zählring 9 trägt je nach Produktspezifikation die Zahlen "0, 1, 2, ..., x", abhängig davon, wie die Tagesdosis verordnungsseitig bemessen ist. "x" kann z. B. "9" sein.

[0042] Mit jeder Betätigung der Taste 4, die zur Ausgabe eines Produktes führt, wird der Zählring 9 um ein Winkelinkrement weiterbewegt, so dass die nächstfolgende Zahl in dem Fenster 5 sichtbar ist. Mit der Entnahme der letzten Tagesdosis werden beide Zählringe 9, 10 über einen geeigneten Koppelmechanismus miteinander gekoppelt und gemeinsam um ein Winkelinkrement weitergedreht. Der erste Zählring würde dann "0", der zweite Zählring im gezeigten Beispiel "02" zeigen, also den zweiten Tag des Monats, an dem noch keine Tablette entnommen wurde. Auf den Koppelmechanismus wird nachfolgend noch eingegangen.

[0043] Ferner umfasst das Zählwerk ein Führungselement 11, das ringförmig und hohlzylindrisch ausgebildet ist und in dem ein Schaltelement 12 axial verschiebbar und radial drehbar aufgenommen ist. Weiterhin ist eine Feder 13, hier eine Spiralfeder vorgesehen, die mit einem Ende an dem Schaltelement 12 und mit dem anderen an einer Grundplatte 14 gelagert ist und eine Rückstellkraft erzeugt, gegen die das Schaltelement bewegt wird.

[0044] Über dieses Schaltelement, das mit seiner in Fig. 2 rechten Stirnkante direkt an der gegenüberliegenden Boden-

fläche der Taste 4 aufliegt, erfolgt die Drehbewegung des ersten Zählrings 9. Beim Betätigen der Taste 4 wird das Schaltelement 12 in dem feststehenden Führungselement 11 axial verschoben, bis am Schaltelement 12 vorgesehene Schalnocken in Eingriff mit einer entsprechenden Nocken-aufnahme in Form einer Verzahnung des ersten Zählrings 9 stehen, wonach eine Drehbewegung des Schaltelements eingeleitet wird, die zur kopplungsbedingten Drehung des ersten Zählrings und damit zur Bewegung des Zählrings um ein Winkelinkrement führt. Während der Bewegung des Stellelements 12 wird die Feder 13 gespannt, nach Lösen des Tastendrucks entspannt sich die Feder 13 und führt das Schaltelement 12 wieder in die Ausgangsstellung zurück. Hierauf wird nachfolgend im Detail noch eingegangen.

[0045] Ferner ist ein Deckel 15 vorgesehen, der zum Abdecken des Vorratsbehälters 3 dient, und an dem die Grundplatte 14 befestigbar ist, gegebenenfalls kann die Grundplatte mit diesem Deckel 15 auch einstückig sein.

[0046] Fig. 3 zeigt eine zweite erfindungsgemäße Ausführungsform einer Einrichtung 16 zum Abgeben von Aerosoldosen. Diese Einrichtung 16 entspricht - siehe Fig. 4 - vom Aufbau ihres Zählwerks 17 her in soweit dem Zählwerk 2, es fehlt hier lediglich die Taste 4. Als Betätigungselement dient hier der Aerosolbehälter 18 selbst, der mit einer Spraydüse 19 im zusammengesetzten Zustand gekoppelt ist, über die das Aerosol abgegeben wird.

[0047] Das Funktionsprinzip der Zählereinrichtung 17 ist das gleiche wie der Zählereinrichtung 2, jedoch dient die in Fig. 3 gezeigte Zählereinrichtung 17 als Restmengen-Zähler, der stets angibt, wie viele Aerosolabgaben noch möglich sind. Dies ist für denjenigen, der das Aerosol aus medizinischen Gründen benötigt, sehr wichtig zu wissen, damit er rechtzeitig für Ersatz sorgen kann. Im gezeigten Beispiel geben die in dem Fenster 5 gezeigten Zahlen 7 des ersten und zweiten Zählrings 9, 10 die Zahlenfolge "131" wieder, das heißt, ausgehend beispielsweise von einer Ausgangszahl von "300" sind noch 131 Aerosolabgaben möglich. Bei diesem Beispiel trägt der zweite Zählring die Zahlenfolgen "30, 29, 28, ..., 02, 01, 00", der erste Zählring trägt die Zahlenfolge "0, 1, 2, ..., 8, 9". Wie auch bei der vorher beschriebenen Ausführungsform kann die Zahlenfolge des ersten Zählrings um seinen Umfang mehrfach aufgebracht sein.

[0048] Da die Funktionsweise des Zählwerks 17 der des Zählwerks 2 entspricht und die im Wesentlichen gleichartig ausgebildeten Elemente zum Einsatz kommen, werden nachfolgend die Elemente des Zählwerks 2 beschrieben, sofern Unterschiede zur Ausführungsform des Zählwerks 17 gegeben sind, werden diese explizit erwähnt.

[0049] Das zentrale Element des Zählwerks 2 ist das Führungselement 11. Das Führungselement 11 ist ringförmig und hohlzylindrisch ausgebildet und weist an seiner Innenseite Führungsabschnitte 20 auf, an denen das in Fig. 6 gezeigte Schaltelement mit seiner Außenseite 21 anliegt und geführt wird. Die am Führungselement 11 vorgesehenen Freimachungen 22 dienen als Nachsaugkanäle für Luft im Falle der Verwendung des Zählwerks bei einem Aerosolbehälter.

[0050] In der Wandung 23 des Führungselements 11 sind gegenüberliegend zwei Ausnehmungen 24 vorgesehen, wobei an einer Ausnehmungskante 25 eine Kurvenfläche 26 ausgebildet ist, die zur Zwangsführung des beim Abgeben einer Dosis bezüglich des feststehenden Führungselements 11 bewegten Schaltelements 21 dient. Am Schaltelement 12 sind nach außen vorspringend zwei Abschnitte 27 vorgesehen, die die Ausnehmung 26 von innen nach außen durchsetzen. Wird nun das Schaltelement 12 durch Druck auf die Taste 4 axial verschoben, so gleiten die Abschnitte 27 an der jeweiligen Kurvenfläche 26 entlang. Die Kurvenfläche 26

verfügt insgesamt über drei unterscheidbare Abschnitte 26a, 26b, 26c. Der Abschnitt 26a, der im Prinzip parallel zur Längsachse des Zählwerks läuft, bewirkt, dass das Schaltelement 12 beim Bewegen eine rein axiale Bewegung durchführt. Erst wenn der Abschnitt 27 in den Kurvenflächenabschnitt 26b läuft wird bei fortschreitender axialen Verschiebung gleichzeitig eine Drehung des Schaltelements 21 um die Längsachse eingeleitet. Diese Drehung bezogen auf den Hub des Schaltelements 21 hängt von der Form der Kurve ab und kann beliebig eingestellt werden. In Abschnitt 26c ist die Drehbewegung weitestgehend beendet, der Abschnitt 26c lässt wiederum im Wesentlichen nur noch eine axiale Bewegung zu, die den Resthub auffängt.

[0051] Während der axialen Bewegung des Schaltelements 21 im Bereich 26a werden die an den Abschnitten 27 angeformten Schaltnocken 28 in jeweils eine mittels einer Innenverzahnung 29 ausgebildete Nockenaufnahme 30 am ersten Zählring 19 eingeführt. Hierdurch entsteht eine Bewegungskopplung derart, dass auf den Zählring 9 die Drehbewegung des Schaltelements 21 übertragen wird. Die Stirnkanten der einzelnen Zähne der Verzahnung 29 sind mit Schrägflächen 31 versehen. Beim Einführen trifft die Schaltnocke 28 zunächst auf eine Schrägfläche 31, was dazu führt, dass der Zählring 9 bereits leicht angedreht wird, wonach dann die eigentliche kurvengesteuerte Drehbewegung einsetzt. Zum Ende der Drehbewegung, wenn also die Taste 4 weitgehend durchgedrückt und die Tablette entnommen ist, wurde der Stellring 9 um ein Winkelinkrement weiterbewegt, so dass die nächstfolgende Zahl im Fenster sichtbar ist.

[0052] Wie beschrieben wird das Schaltelement 21 gegen die Kraft der Feder 13 bewegt. Die Feder 13 – siehe Fig. 7 – weist an jedem Ende einen Haltezapfen 32 auf, wobei ein Haltezapfen in einer Zapfenaufnahme 33 an den Schaltelement 21 befestigt ist, der andere Zapfen 32 ist an einer Zapfenaufnahme 34 der Grundplatte 14 gehalten. Die Grundplatte 14 selbst steht fest. Wird nun das Schaltelement 21 bewegt, so wird die Feder 13 zum einen komprimiert, zum anderen wird sie bei Einleitung der kurvengesteuerten Drehbewegung auch tordiert, so dass in zwei Richtungen wirkende Rückstellkräfte erzeugt werden. Wird nun nach Beendigung der Dosisabgabe die Taste 4 entlastet, so entspannt sich die Feder 13. Die aufgrund der axialen Komprimierung einsetzende Relaxation führt dazu, dass das Schaltelement 21 axial verschoben wird, die torsionsbedingte Relaxation führt dazu, dass das Schaltelement gleichzeitig um die kurvengesteuerte Drehbewegung zurückgedreht wird und in die Ausgangsstellung gebracht wird. Unterstützt wird die Rückbewegung auch durch die Kurvenfläche 35, die ebenfalls an der Stirnwand der Ausnehmung 24 ausgebildet ist.

[0053] Am Führungselement 11 sind ferner Führungsflächen 36, 37 vorgesehen, wobei an der Führungsfläche 36 der erste Zählring mit seiner inneren Hinterschneidungsfläche 38 aufliegt, auf der Führungsfläche 37 liegt der zweite Zählring mit seiner Führungsfläche 39 auf. Die Zählringe sowie die Führungsflächen sind derart ausgebildet beziehungsweise angeordnet, dass der umlaufende Abschnitt 40 des ersten Zählrings 9, an dessen Außenfläche die Beschriftung aufgebracht ist, den etwas hinterschnittenen Abschnitt 41 des zweiten Zählrings 10 übergreift, so dass die mit den jeweiligen Beschriftungen versehenen Außenflächen 42 des ersten Zählrings und 43 des zweiten Zählrings im Wesentlichen bündig aneinander anschließen. An dem ersten Zählring 10 ist ferner ein Abdeckabschnitt 44 vorgesehen, der zum Abdecken der Beschriftung auf dem ersten Zählring 9 dient, wenn im Falle eines Restmengen-zählers die Gesamtdosismenge vollständig entnommen ist.

[0054] Obenstehend wurde beschrieben, wie der erste Zählring bei einer Betätigung des jeweiligen Betätigungs-

elements um ein Winkelinkrement gedreht wird. Es ist jedoch auch erforderlich, bestimmte Zeitpunkte beziehungsweise nach bestimmten Entnahmemengen den zweiten Zählring ebenfalls um ein Winkelinkrement weiter zu drehen. Hierzu ist ein Kopplungsmechanismus vorgesehen, der nachfolgend beschrieben wird.

[0055] Dieser Kopplungsmechanismus umfasst zum einen eine an dem ersten Zählring vorgesehene Rastklinke 45, die nach Art eines Federarms beweglich ist. Die Rastklinke 45 verfügt über einen ersten Vorsprung 46 und eine Rastnase 47. Der erste Vorsprung 46 erstreckt sich nach unten in Richtung der Grundplatte 14. An der Grundplatte 14 ist, siehe Fig. 11, an dem gezeigten Beispiel ein weiterer Vorsprung 48 ausgebildet, der an einer bestimmten Position angeordnet ist, und der, wenn der erste Zählring 9 eine entsprechende Drehstellung aufweist, bei der nächstfolgenden Drehung mit dem Vorsprung 46 zusammenwirkt. Der Vorsprung 46 läuft mit seiner Schrägfläche 49 auf den weiteren Vorsprung 48 auf, was dazu führt, dass die Rastklinke 45 angehoben wird. Bei diesem Anheben greift die Rastnase 47 in die Stirnverzahnung 50 des zweiten Zählrings 10, wobei auch die Verzahnung 50 entsprechende Schrägflächen 51 aufweist. Wird nun der erste Ring 9 weitergedreht, so wird gleichzeitig auch infolge der Bewegungskopplung der zweite Ring 10 mitbewegt. Sobald der Vorsprung 46 über dem Vorsprung 48 gewandert ist, rastet er dahinter wieder in die Ausgangsstellung zurück, wodurch die Bewegungskopplung gelöst wird. Der zweite Ring wurde zusammen mit dem ersten also um ein Winkelinkrement weiterbewegt, bei jeder weiteren Bewegung des ersten Rings wird der zweite Ring nicht mitbewegt. Es versteht sich von selbst, dass am Umfang der Grundplatte 14 mehrere Vorsprünge 48 verteilt sein können, je nachdem, wie beziehungsweise wann der zweite Ring mit zu bewegen ist.

[0056] Um dafür zu sorgen, dass die Zählringe 9, 10 auch in den jeweiligen Stellungen verbleiben, sind am Führungselement 11 federarmartige Sperrklinken 52 und 53 vorgesehen, die im Falle der Sperrklinken 52 mit der Innenverzahnung 29 und im Falle der Sperrklinken 53 mit der Stirnverzahnung 51 zusammenwirken. Über Rastnasen 54, 55 greifen die Sperrklinken 52, 53, in die jeweilige Verzahnung ein und arretieren so den jeweiligen Zählring in seiner Position. Dabei sind die Sperrklinken 52 bzw. 53 jeweils paarweise angeordnet, wobei die eine Sperrklinke 52 zeitlich etwas vor der anderen Sperrklinke 52 greift. Entsprechendes gilt für die Sperrklinken 53. Hierdurch wird sichergestellt, dass eine Betätigung, die zur Abgabe einer Tablette oder dergleichen geführt wird, bei der jedoch der Hub noch nicht vollständig durchlaufen wurde, trotzdem gezählt wird, da dann bereits die erste voreilende Sperrklinke gegriffen hat, die zweite jedoch noch nicht. Wenn jetzt der Hub beendet und die Taste entlastet wird, bleibt die Zählung erhalten, wenngleich lediglich eine Sperrklinke gegriffen hat.

[0057] Fig. 5 zeigt ferner eine Anschlag 55 am Führungselement 11, an dem ein am zweiten Zählring 10 vorgesehener Vorsprung 55a anschlägt, wenn der zweite Zählring seine Enddrehstellung erreicht hat, wenn also die Zahlenfolge "00" im Sichtfenster erscheint, wobei diese Endstellungsbegrenzung nur bei einem Rest- oder Gesamtmengen-zähler erforderlich ist. Bei einem normalen Tagesmengen-zähler fehlt entweder der Anschlag 55 oder der Vorsprung 55a.

[0058] Weiterhin sind am Führungselement 11 mehrere Rastelemente 56 vorgesehen, mittels denen das Führungselement 11 an der Grundplatte 14, dort an einer entsprechenden, dem Ringraum 57 begrenzenden Randschulter 58, verastet, so dass sich eine nur schwer lösbare Einheit bildet.

[0059] An der gegenüberliegende Seite des Führungsele-

ments 11 sind weitere Rastelemente 59 vorgesehen, die hinter der ringförmigen Öffnung 60 des zweiten Zählrings 10 begrenzenden Schulter 61 verrasten. Diese Verrastung des Führungselements 11 an der Grundplatte sowie dem zweiten Zählring 10 führt dazu, dass die Elemente zweiter Zählring, Führungselement, Schaltelement, Feder, erster Zählring, Grundplatte eine schwer lösbare, vormontierbare Einheit bilden.

[0060] Wie die Fig. 8 und 9 zeigen, besitzt der erste Zählring 9 eine um ca. 270° umlaufende Außenverzahnung 62. Der zweite Zählring 10 besitzt, siehe Fig. 10, an der die Stirnverzahnung 50 aufweisenden Stirnkante gegenüberliegende Stirnkante eine weitere Verzahnung 63. Die Verzahnungen 62, 63 dienen dazu, die Position des jeweiligen Zählrings einstellen zu können, was insbesondere bei Tagesmengenzählern erforderlich ist, da zu Beginn der Entnahme der jeweilige Tag und gegebenenfalls auch der erste Zählring auf "1" gestellt werden muss.

[0061] Die Fig. 12 und 13 zeigen schließlich das Gehäuse 6 im Detail. Dieses Gehäuse 6, das – siehe die Fig. 1 und 3 – das Zählwerk fast vollständig kapselt, besitzt neben der Fensterausnehmung 5 weitere Durchbrechungen 64, durch welche – siehe die Fig. 1 und 3 – die Verzahnungen 62, 63 erreichbar und mittels eines Werkzeugs greifbar sind. Auf diese Weise kann die Einstellung problemlos erfolgen. Das Gehäuse 6 selbst weist an seiner einen Stirnkante mehrere Rastelemente 65 auf, mittels denen das Gehäuse an der Grundplatte 14, diese umgreifend, verrastet wird. An der gegenüberliegenden Stirnseite ist eine hinterschnittene Schulter 66 ausgebildet, an der die Taste 4 mit der dort vorgesehenen Schulter 67 gegengelagert ist. Insgesamt ergibt sich so ein quasi unlösbares, vollständig gekapseltes Zählwerk, das auf einfache Weise auf einen Vorratsbehälter – sei es ein Tablettenbehälter oder ein Aerosolbehälter – aufgesetzt werden kann.

[0062] Im Falle der Verwendung des Zählwerks mit einem Aerosolbehälter ist schließlich – siehe die Fig. 14 und 15 – eine Spraydüse 68 vorgesehen, die eine Aufnahme 69 für die Sprühhülse 70 des Aerosolbehälters 18 hat. Davon abgehend ist die eigentliche Düse 71 vorgesehen, aus welcher das Aerosol ausgestoßen wird. Die Düse 71 ragt in eine Randausnehmung 72 des Gehäuses hinein, so dass das Aerosol aus dem Gehäuse im Bereich dieser Randausnehmung 72 ausgestoßen wird.

[0063] Abschließend ist festzuhalten, dass sämtliche Elemente des Zählwerks aus Kunststoff gefertigt sind. Die zentralen Elemente bilden das Führungs- und das Schaltelement, die zweckmäßigerweise aus einem qualitativ sehr hochwertigen Kunststoff, z. B. POM gefertigt sind. Das Zählwerk ist insgesamt aufgrund der Zwangskurvenführung äußerst sicher bei gleichzeitiger Einfachheit der Elemente und geringer Elementenzahl. Die Montage ist ebenfalls einfach möglich, da es sich um ein einfaches Stecksystem handelt. Lediglich die Feder ist zweckmäßigerweise aus Metall, es kann aber auch hier eine Kunststofffeder eingesetzt werden. Beim Gehäuse besteht die Möglichkeit, in der Fensteröffnung eine Lupe zu integrieren, sei es als separates Element, wenn das Gehäuse beispielsweise aus einem undurchsichtigen weißen Kunststoff gefertigt ist, alternativ kann sie auch einstückig mit dem Gehäuse sein, wenn dieses aus einem durchsichtigen Kunststoff, z. B. PMMA gefertigt ist.

[0064] Das gesamte Zählwerk ist aufgrund der geringen Teilezahl sehr preiswert herstell- und montierbar und kann universell eingesetzt werden. Der Verwendungszweck ist nicht auf die Abgabe von Medikamenten beschränkt. Gleichmaßen kann das Zählwerk bei jedweden Spendersystem zum Einsatz kommen, wo die exakte Zählung abgegebener Dosen erforderlich ist. Das Zählwerk selbst kann sehr klein

gehalten werden, so dass es mit fast allen handelsüblichen Spraysystemen ohne wesentliche Veränderung eingesetzt werden kann. Insbesondere sind keine Veränderungen der üblichen Behältnisse insbesondere seitens des Aerosolbehälters erforderlich. Es ist noch darauf hinzuweisen, dass das System auch in Verbindung mit einem Winkelstück bei der Verwendung eines Inhalators eingesetzt werden kann. In diesem Fall kann die Spraydüse im Winkelstück integriert sein und lediglich der Aerosolbehälter mitsamt dem auf den Aerosolbehälter aufgeschnappten Zählwerk in das Winkelstück eingesetzt werden.

Patentansprüche

1. Zählwerk zum Zählen dosierter Abgaben flüssiger, pastöser oder fester Produkte, insbesondere Medikamente, aus einem Vorratsbehälter, umfassend: einen ersten Zählring und einen zweiten Zählring, die koaxial zur Längsachse des Zählwerks angeordnet und relativ zueinander drehbar und miteinander koppelbar sind, eine Schaltvorrichtung zum Bewegen des ersten Zählrings bei Betätigung eines zur Abgabe des Produkts zu betätigenden Betätigungsmittels, und eine Kopplungsvorrichtung zur Kopplung des ersten Zählrings mit dem zweiten Zählring zum gemeinsamen Bewegen beider Zählringe, **dadurch gekennzeichnet**, dass die Schaltvorrichtung ein Führungselement und ein Schaltelement umfasst, die beide koaxial zur Längsachse angeordnet sind, wobei das Schaltelement bezüglich des Führungselements axial bewegbar ist und einen Abschnitt aufweist, der bei einer Betätigung des Betätigungselements entlang einer am Führungselement vorgesehenen Kurvenfläche derart geführt wird, dass ein am Schaltelement vorgesehenes Schaltnocken in Eingriff mit einer am ersten Zählring vorgesehene Nockenaufnahme gebracht und anschließend eine Drehbewegung eingeleitet wird, durch die der erste Zählring um ein Winkelinkrement gedreht wird.
2. Zählwerk nach Anspruch 1, dadurch gekennzeichnet, dass die Kurvenfläche an der Stirnkante einer Ausnehmung der Wand des im Wesentlichen ringförmigen Führungselements vorgesehen ist, in die der Abschnitt eingreift.
3. Zählwerk nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Kurvenfläche derart geformt ist, dass zu Beginn der Bewegung des Schaltelements eine axiale Bewegung, anschließend eine kombinierte axiale und radiale Bewegung und am Ende der Hubbewegung vorzugsweise eine axiale Bewegung erfolgt.
4. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass das Führungselement im Wesentlichen ringförmig und das Schaltelement im Wesentlichen hohlzylindrisch und im Inneren des Führungselements angeordnet ist.
5. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass zwei vorzugsweise einander gegenüberliegende Abschnitte am Schaltelement und zwei vorzugsweise einander gegenüber liegenden Kurvenflächen am Führungselement vorgesehen sind.
6. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass das Schaltelement gegen eine Rückstellkraft bewegbar ist.
7. Zählwerk nach Anspruch 6, dadurch gekennzeichnet, dass die Rückstellkraft eine Feder ist, die während der Drehbewegung tordiert wird und das Schaltelement

nach Lösen des Eingriffs des Schaltnockens in der Nockenaufnahme bei gleichzeitiger Rückdrehung in die Ausgangsstellung rückführt.

8. Zählwerk nach Anspruch 7, dadurch gekennzeichnet, dass die Feder eine Spiralfeder ist, die mit einem Ende an einer Grundplatte und mit ihrem anderen Ende an dem Schaltelement gelagert ist.

9. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass der Schaltnocken in Verlängerung des Abschnitts angeformt ist.

10. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass die Verzahnung des ersten Zählrings, die mit dem Schaltnocken zusammenwirkt, an der dem Schaltnocken zugewandten Seite eine Schrägfläche aufweist.

11. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass am Führungselement ein oder mehrere Führungsabschnitte vorgesehen sind, an denen das Schaltelement anliegt, wobei wenigstens ein Bereich vorgesehen ist, in dem das Schaltelement beabstandet zum Führungselement ist.

12. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass am Führungselement mindestens zwei Sperrklinken vorgesehen sind, von denen je eine mit einer Verzahnung des ersten und des zweiten Zählrings derart zusammenwirken, dass ein Drehen in der zur Zählrichtung entgegengesetzten Richtung gesperrt wird.

13. Zählwerk nach Anspruch 12, dadurch gekennzeichnet, dass jeweils zwei derart versetzt zueinander angeordnete Sperrklinken vorgesehen sind, dass sie bei unterschiedlichen Drehwinkeln bei der Drehung des jeweiligen Zählrings in die Verzahnung eingreifen.

14. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass am Führungselement Führungsflächen für den ersten und den zweiten Zählring sowie mindestens zwei Rastelemente vorgesehen sind, von denen eines einen Rastabschnitt des zweiten Zählrings und das andere einen Rastabschnitt der ersten Zählring an der dem Führungselement gegenüberliegenden Seite führenden Grundplatte hintergreift, so dass die Zählringe, das Führungselement, das Schaltelement, das Federelement und die Grundplatte eine handhabbare Einheit bilden.

15. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass die Kopplungsvorrichtung wenigstens einen an einer Grundplatte vorgesehenen ersten Vorsprung und wenigstens eine am ersten Zählring vorgesehene Rastklinke mit einem zweiten Vorsprung umfasst, wobei der erste Vorsprung mit dem zweiten Vorsprung bei entsprechender Drehstellung des ersten Zählrings derart zusammenwirkt, dass die Rastklinke angehoben und in Eingriff mit einer am zweiten Zählring vorgesehenen Verzahnung kommt.

16. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass am Führungselement ein Anschlag vorgesehen ist, an dem ein am zweiten Zählring vorgesehener Vorsprung bei Erreichen einer Enddrehstellung anschlägt.

17. Zählwerk nach Anspruch 16, dadurch gekennzeichnet, dass am zweiten Zählring ein Abdeckabschnitt zum bereichsweisen Abdecken des ersten Zählrings vorgesehen ist, der beim Bewegen in die Enddrehstellung des zweiten Zählrings in eine Sichtstellung gedreht wird.

18. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass ein im Wesentlichen hölzylindrisches Gehäuse vorgesehen ist, das wenig-

stens einen Fensterabschnitt aufweist, durch den die an den Außenflächen der Zählringe angebrachten Markierungen sichtbar sind.

19. Zählwerk nach Anspruch 18, dadurch gekennzeichnet, dass in dem Fensterabschnitt ein optisches Vergrößerungselement angeordnet ist.

20. Zählwerk nach Anspruch 18 oder 19, dadurch gekennzeichnet, dass an dem Gehäuse wenigstens zwei Durchbrechungen vorgesehen sind, durch die in jeweils eine Verzahnung am ersten bzw. am zweiten Zählring zu Stellzwecken eingegriffen werden kann.

21. Zählwerk nach Anspruch 20, dadurch gekennzeichnet, dass jedem Zählring jeweils zwei am Umfang des Gehäuses beabstandet zueinander angeordnete Durchbrechungen zugeordnet sind.

22. Zählwerk nach einem der Ansprüche 18 bis 21, dadurch gekennzeichnet, dass an wenigstens einer Stirnseite des Gehäuses Rastelemente zum Hintergreifen eines Rastabschnitts der Grundplatte vorgesehen sind.

23. Zählwerk nach Anspruch 22, dadurch gekennzeichnet, dass an der gegenüberliegenden Stirnseite des Gehäuses eine das Betätigungselement gegenlagernde Schulter vorgesehen ist.

24. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass das Schaltelement direkt an dem bei einer Betätigung axial verschiebbaren Betätigungselement anliegt.

25. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass das Betätigungselement eine Taste ist, die als Teil des Zählwerks fest gekoppelt ist, oder dass das Betätigungselement ein Aerosolbehälter ist, der mit dem Zählwerk koppelbar ist.

26. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass ein an der Grundplatte angeformter oder befestigter Deckel, der einen Vorratsbehälter abdeckt, oder eine an der Grundplatte angeformte oder befestigte Spraydüse vorgesehen ist.

27. Zählwerk nach einem der vorangehenden Ansprüche, dadurch gekennzeichnet, dass ein Sicherungsmechanismus zum Verhindern einer unbeabsichtigten oder unbefugten Betätigung vorgesehen ist.

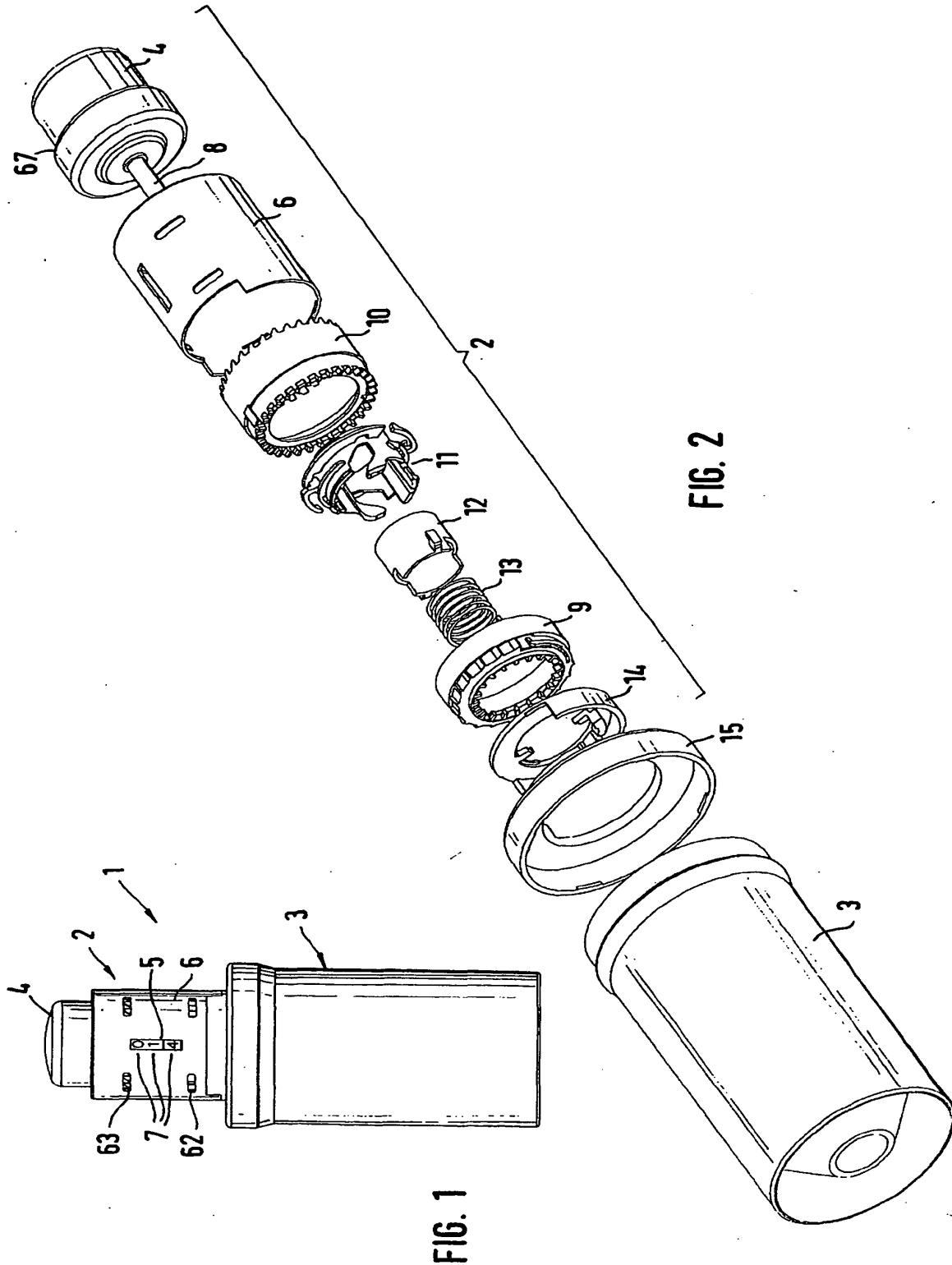
28. Einrichtung zum dosierten Abgeben flüssiger, pastöser oder fester Produkte, insbesondere von Medikamenten, umfassend einen das abzugebende Produkt beinhaltenden Vorratsbehälter sowie ein Zählwerk nach einem der Ansprüche 1 bis 27.

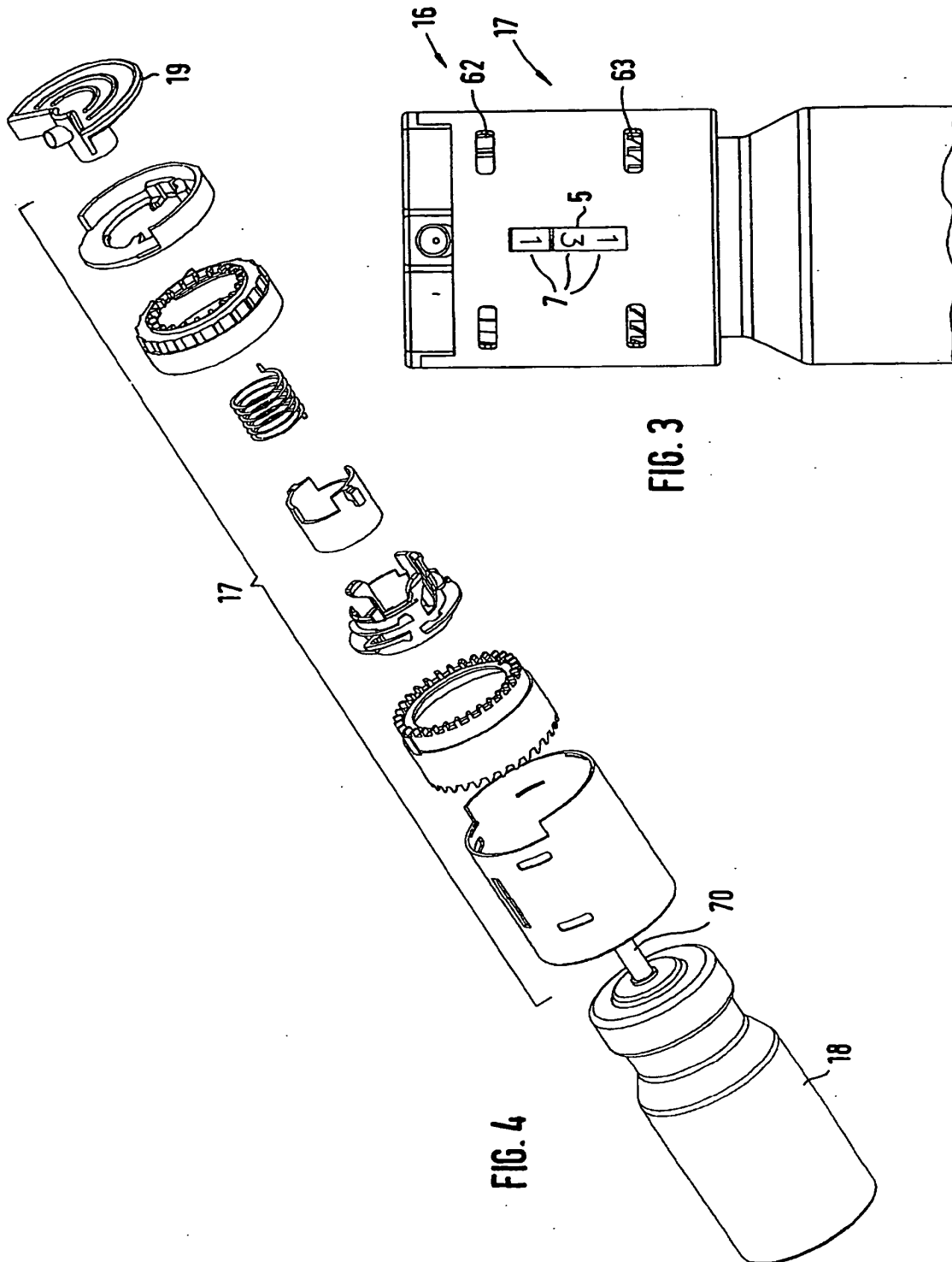
29. Einrichtung nach Anspruch 28, dadurch gekennzeichnet, dass das Zählwerk auf den Vorratsbehälter lösbar aufsetzbar oder an diesen unlösbar integriert ist.

30. Einrichtung nach Anspruch 28 oder 29, dadurch gekennzeichnet, dass der Vorratsbehälter eine Aerosolflasche oder ein topfartiger Behälter ist.

31. Einrichtung nach Anspruch 30, dadurch gekennzeichnet, dass ein gegebenenfalls gewinkelte Mundstück vorgesehen ist, in das das Zählwerk lösbar oder unlösbar integriert ist, und in das die Aerosolflasche lösbar einsetzbar ist.

Hierzu 7 Seite(n) Zeichnungen





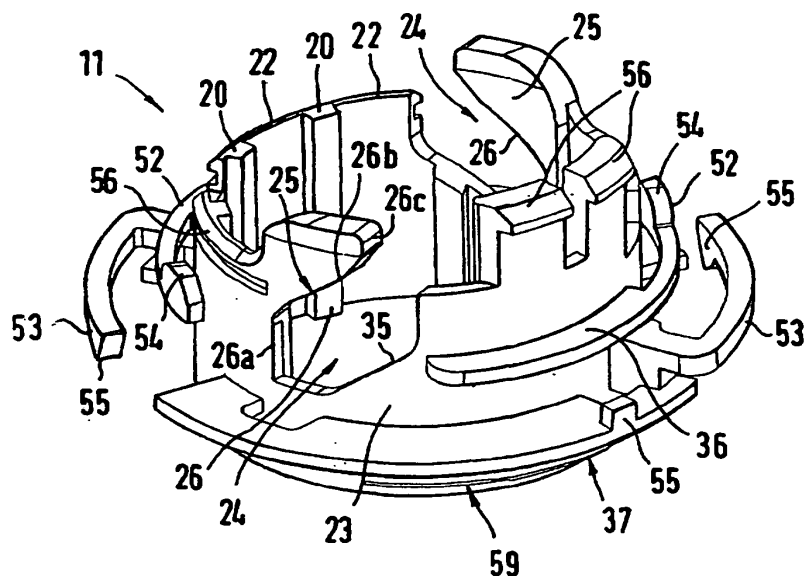


FIG. 5

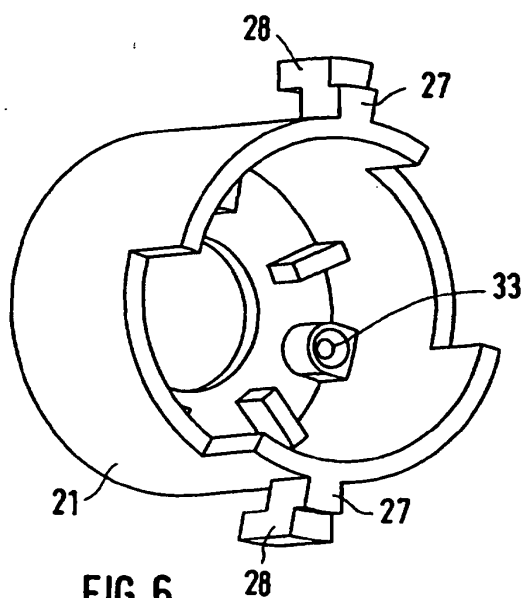


FIG. 6

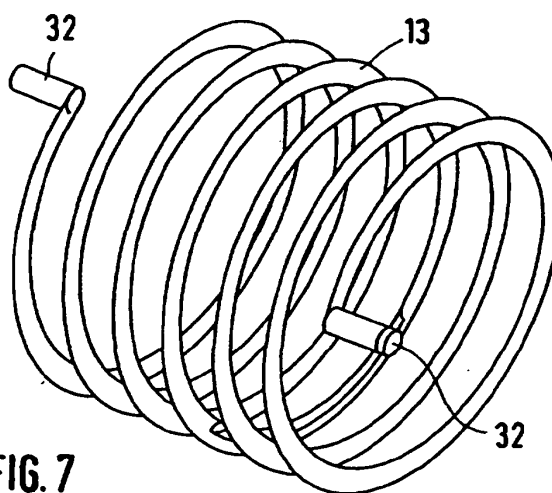
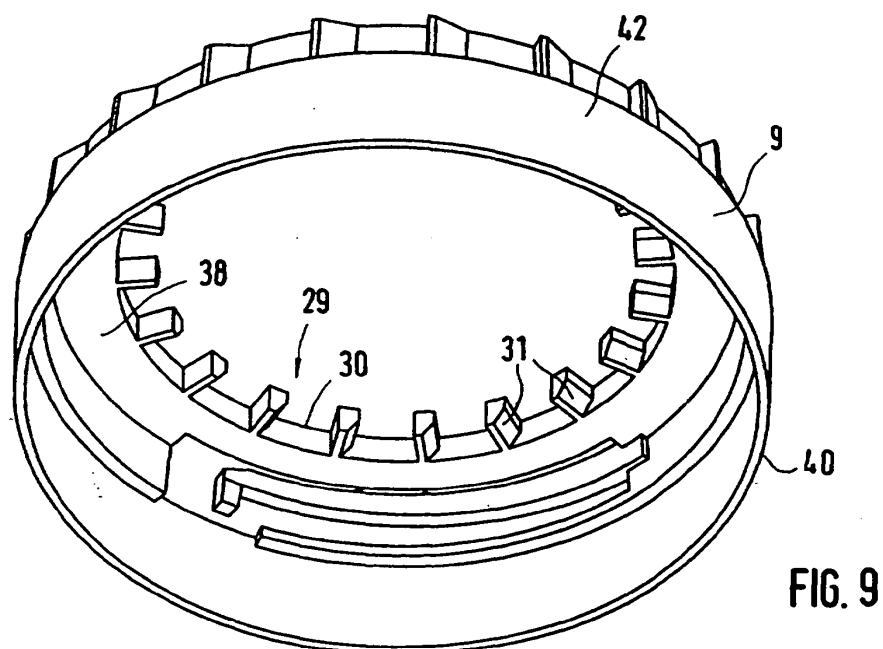
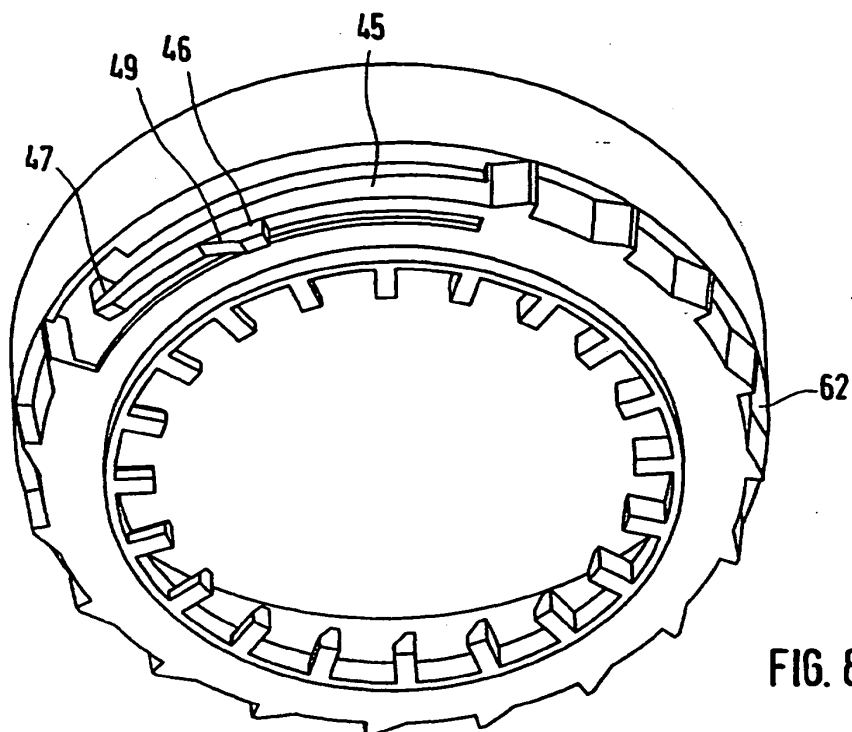
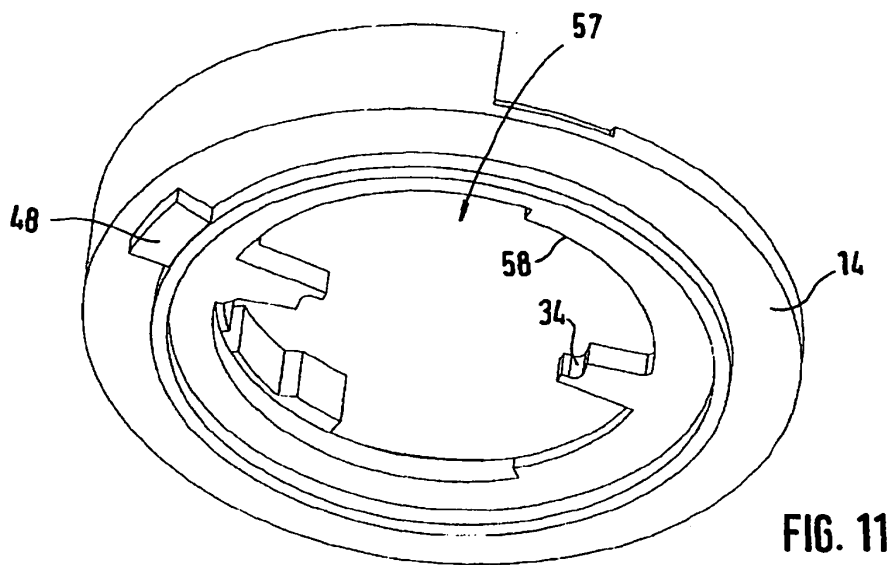
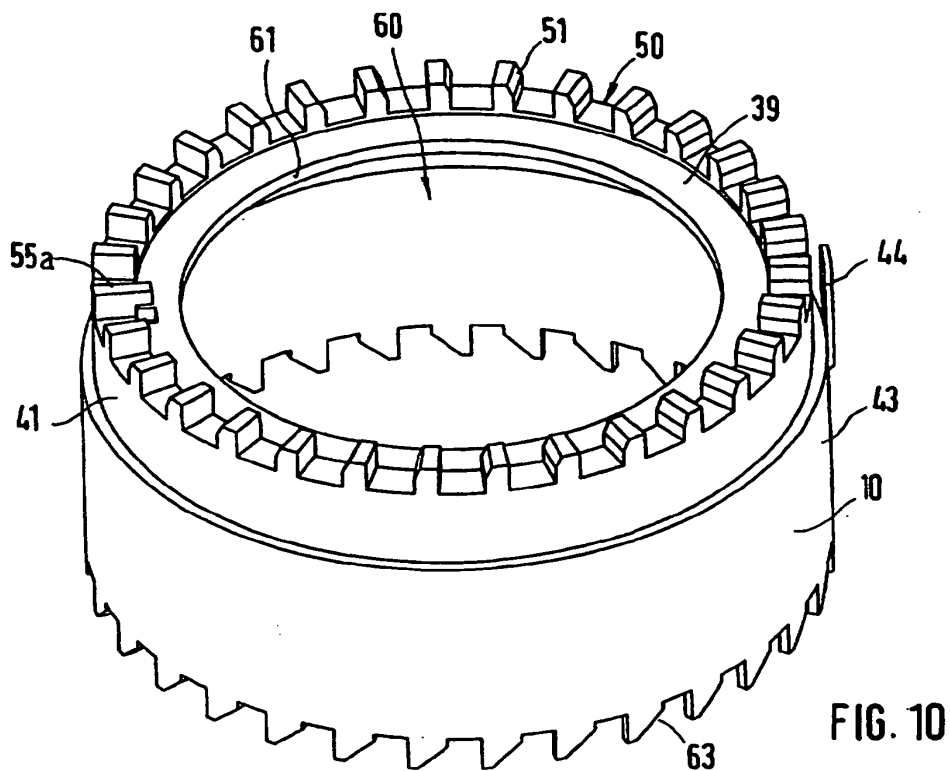
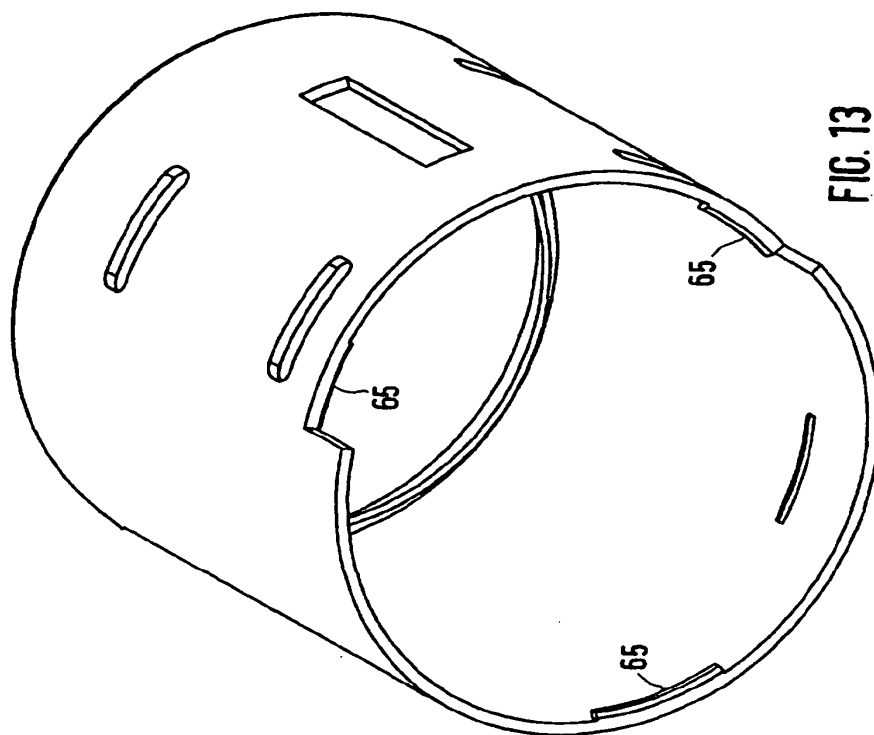
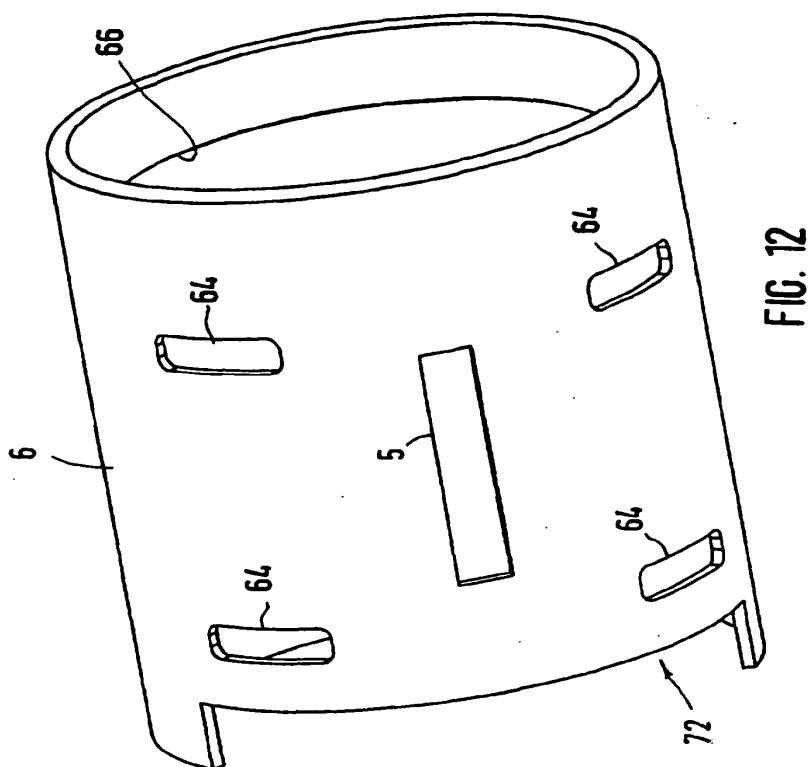


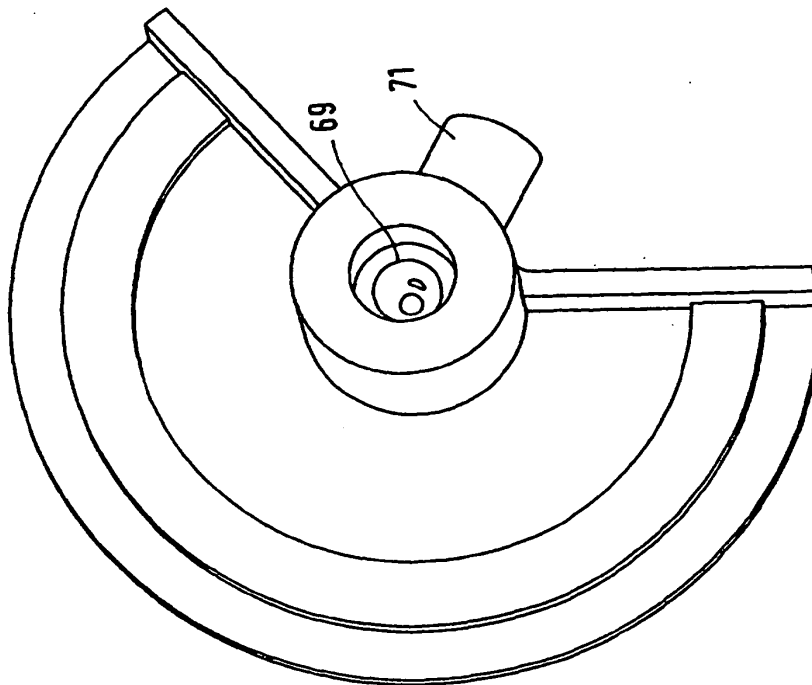
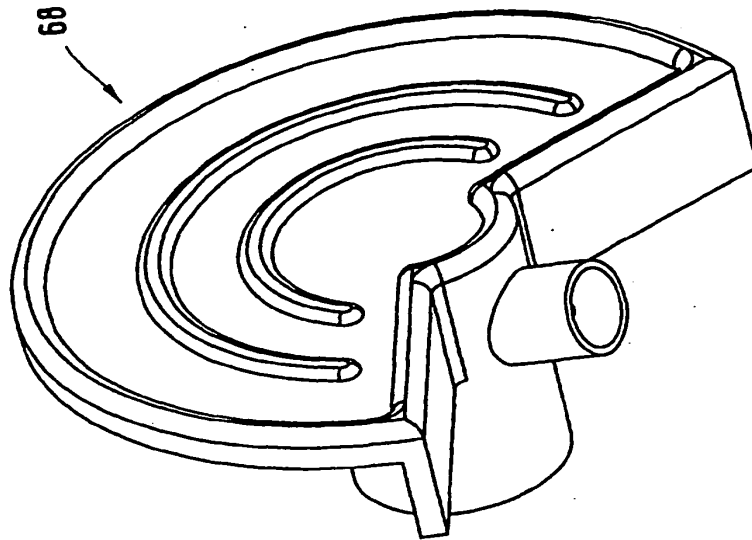
FIG. 7



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(54) **Dose counting device for a distributor of doses of fluid products, especially for pharmaceutical use.**

(57) The device comprises a distributor provided with an operating member (8) for a counting means of doses of fluid associated with a mouth (31) of a container (1), a ring nut (4) for fastening the distributor means (2) onto the mouth (31) and elastic means (16) suitable for transforming the translatory motion of said operating member (8) with respect to the ring nut (4) in a rotatory and axially reciprocating motion of a rotating and axially translatable element (9) to cause the appearance of a different numerical index provided on the rotating element (9) at an observation position (19) obtained in the operating member (8).

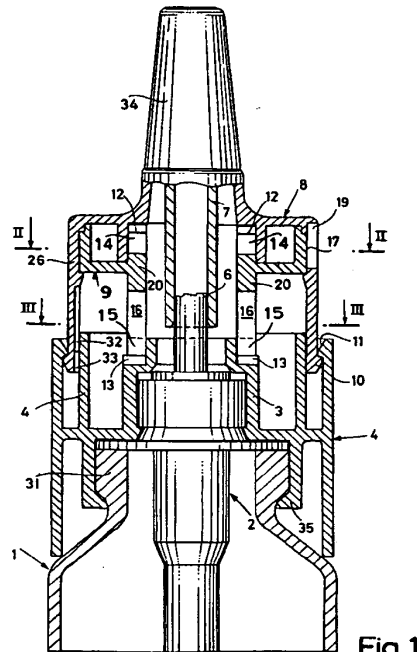


Fig.1

EP 0 480 488 A1

Rank Xerox (UK) Business Services

BNSDOCID: <EP_0480488A1_1_>

The present invention relates to a dose counting device for a distributor of doses of fluid products, especially for pharmaceutical use.

Such dose counting devices find particular application in the field of nasal distributors.

The latter essentially comprise a bottle open at its upper end and tapered for the introduction of a member for the distribution of the product contained inside it. The member for the distribution of the product has a terminal spout at its upper end from which the distributed product is introduced in a truncated-cone element, called «nasal», shaped so as to be able to be inserted in the nasal cavities and thus allow the product to be injected into the nostrils.

A ring nut screwed or fastened to the bottle accomplishes the connection between the bottle, the distribution member and the nasal.

In such distributors the distribution of the product is operated by successive strokes on the nasal so as to cause it to slide with respect to the coupling ring nut and to correspondingly activate the distribution member.

Every stroke imparted to the nasal causes the distribution of a given dose of product. Since the product contained in the nasal distributors consists mainly of substances to be administered in a controlled dose, it is particularly important to have available a dose counting device suitable for visualizing the total number of doses distributed.

The object of the present invention is to accomplish a dose counting device that is easy and safe to use as the distributor of doses of liquid products, especially but not exclusively for nasal distributors, with the possibility of indicating with a progressive numerical index the number of doses distributed over time.

According to the present invention such object is attained with a dose counting device for a dose distributor of fluid products, especially for pharmaceutical use, said distributor comprising a container of liquid product provided with a mouth, means for the distribution of doses of fluid from said container through said mouth, a ring nut for fastening said distributor means onto said mouth of the container, a translatable operating member for the operation of said distribution means, characterized in that it comprises elastic means suitable for transforming the translatory motion of said operating member with respect to the ring nut in a rotatory and axially reciprocating motion of a rotating and axially translatable element provided with progressive numerical indices which can be positioned in succession with every dose distributed in a pre-set observation position, said elastic means comprising a succession of small flexible circumferentially distanced legs having an upper part suitable for reacting with a first set of one-directional

teeth of the operating member, a lower part suitable for reacting with a second set of one-directional teeth of the ring nut and an intermediate part fastened to the rotating element, so that when said first set of one-directional teeth approaches said second set of one-directional teeth under the action of said operating member, the upper part of said small legs disengages from the corresponding tooth of the first set of teeth to be inserted in an immediately adjacent tooth and thus drives in rotation and axial forward movement said intermediate part of the small leg and when said first set of teeth is moved away from said second set of teeth when the action of said operating member ceases the lower part of said small legs disengages from the corresponding tooth of the second set of teeth to be inserted in an immediately adjacent tooth and thus drives in rotation and axial backward movement said intermediate part (20) of the small leg (16).

In particular the ring nut is provided with radial ridges suitable for their engagement in slots of the operating member in order to guide the latter's translation with respect to it.

The same dose counter, used in the case in question in the pharmaceutical field, can also find application in cosmetics when fluid products are to be distributed.

There is also the possibility of applying it to a distributor of pills with a controlled dosing.

Given the reduced dimensions wherein it is necessary to silk-screen the numerical indices there is lastly the possibility of using suitable colour hues for them giving an auxiliary and immediately understandable piece of information.

The features of the present invention shall be made more evident by an embodiment illustrated as a non-limiting example in the enclosed drawings, wherein:

Fig. 1 shows an axial sectional view of a dose counting device according to the present invention;

Fig. 2 is a transversal cross-sectional view taken along the line II-II of Fig. 1;

Fig. 3 is a transversal cross-sectional view taken along the line III-III of Fig. 1;

Fig. 4 illustrates with a full line a small flexible leg and the two sets of teeth in the starting position and in a dotted line the same small leg and the corresponding sets of teeth during the course of the operation of the operating member for the distribution of a dose of product;

Fig. 5 illustrates the same small leg of fig. 4 after the return of the operating member to the starting position;

Fig. 6 shows the upper part of the nasal, seen from the right hand side with respect to Fig. 1.

With reference to Figs 1 to 3 and 6, the device

comprises a container 1 of a fluid product, not shown, in the form of a bottle with its upper mouth open 31 to allow the introduction inside it of a distribution valve 2 for the fluid contained in it. Such valve 2, already described in the Italian patent application No. 22133 B/87 filed on 30 July 1987 in the name of the same applicant, is associated with the container 1 through a flange 3 forming part of a ring nut 4 fastened to the container 1 by means of an annular protrusion 35 of the same and terminates at the upper end with an axially slidable distribution spout 6 inserted and blocked in a guide channel 7 for the fluid, which forms part of and passes right through an axially translatable nasal 8, constituting the operating member of the valve 2.

The latter is an internally hollow cylinder 26 terminating at its lower end with an annular edge 10 turned outward, connected to a corresponding annular edge 11 of the ring nut 4 so as to prevent the separation of the nasal 8 from the ring nut 4 and provided with axial slots 32 in which there are slidably inserted radial ridges 33 of the ring nut 4 for the axial translation of the nasal 8 with respect to it. At its upper end and in its middle portion the nasal 8 extends in a protrusion 34 shaped in the form of a nose so that it can be inserted into the nostrils for the introduction of the fluid product to be distributed.

Inside both the nasal 8 and the ring nut 4 there are accomplished internal sets of saw-tooth shaped teeth 12, 13 in engagement with corresponding upper parts 14 and lower parts 15 of a circumferential succession of small elastically flexible legs 16 whose intermediate part 20 is integral with a rotating element 9 with progressive numerical indices 17. With reference to Fig. 6, such indices 17 during the rotation of the rotating element 9 are positioned in succession in an observation position constituted by a window 19 obtained in the annular part 26 of the nasal 8, indicating the number of strokes that have been imparted to the nasal 8 up to that time. The rotating element 9 is also provided with a radial locator 9A suitable for coming to a stop against a corresponding locator 8A protruding radially from the nasal 8 to prevent the rotation of the rotating element 9 after a given number of strokes has been imparted to the nasal 8 and thus a pre-set maximum number of doses distributed highlighted, as explained above, by the progressive numerical indices 17 in the window 19.

It should also be noted that in the specific case the ring nut 4 is fastened onto the container 1, but it is also possible for the ring nut 4 to be screwed down onto the container 1 itself.

The operation of the dose counting device according to the present invention is as follows.

At each operation of the distributor the nasal 8

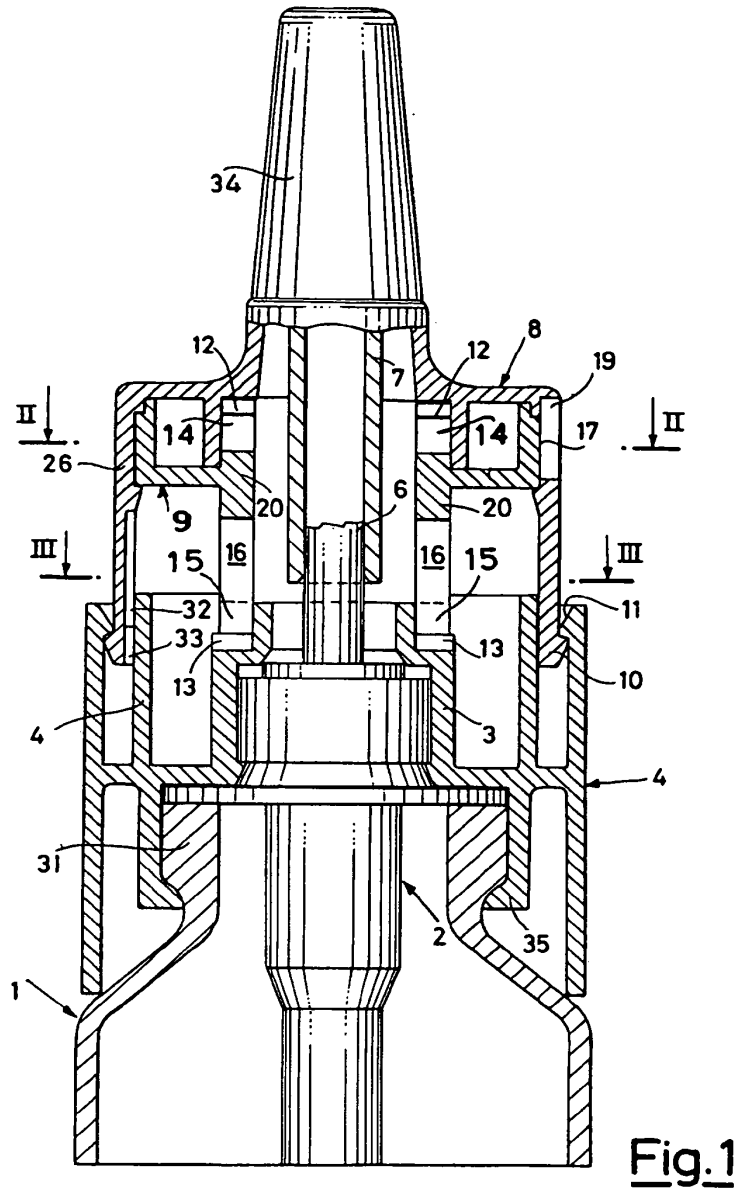
is moved in an axial translation with respect to the ring nut 4 by the axial depression of the same and thanks to the engagement of the radial ridges 33 of the ring nut 4 in the slots 32 of the nasal 8. More accurately, with reference to Fig. 4, initially the small generic leg 16 of the succession of the small circumferentially distanced legs is with its upper part 14 engaged with a tooth 21 of the internal set of teeth 12 of the nasal 8. The same small leg 16 is now with one of its lower parts 15 engaged with a tooth 22 of the internal set of teeth 13 of the ring nut 4, while its middle portion 20 is integral with the rotating element 9. Pressing on the nasal 8, while the same nasal operates through the slidable spout 6 the valve 2 for the distribution of a dose of product, the small leg 16 is elastically urged by the approach of the set of teeth 12 towards the set of teeth 13 in the configuration illustrated by a dotted line in the same Figure 4. During this urging its upper part 14 leaves the tooth 21 to position itself in a tooth 24 adjacent to it. With reference to Fig. 5, when the pressure on the nasal 8 is released, the latter translates in a direction opposite to the ring nut 4, the set of teeth 12 moves away from the set of teeth 13 and the lower part 15 of the small leg 16 leaves the tooth 22 to position itself in the tooth adjacent to it. The displacement of the upper part 14 in the notch 24 and of the lower part 15 in the notch 25 is equivalent to the forward movement of the small leg 16 through one position. During this forward movement the intermediate part 20 of the small leg 16 takes with it the rotating element 9 in a unitary rotation. The numerical index 17 attached to the rotating element 9 shall be rotated through one position and behind the window 19 there shall appear the immediately successive numerical index 17, updating the information related to the number of strokes imparted to the nasal 8 and thus to the number of doses distributed. At the end of a given maximum number of strokes imparted to the nasal 8 and thus of a given maximum number of doses of product distributed, the radial locator 9A protruding from the rotating element 9 comes to a stop against the radial locator 8A protruding from the nasal 8. The rotation of the rotating element 9 is blocked and behind the window 19 there appears the progressive numerical index 17 corresponding to the maximum allowed number of doses distributed. Even after the blocking of the rotation of the rotating element 9 it is still possible to press against the nasal 8 in order to use up completely the product contained in the container.

Claims

1. Dose counting device for a distributor of doses of fluid products, especially for pharmaceutical

- use, said distributor comprising a container (1) of liquid product provided with a mouth (31), means (2) for the distribution of doses of fluid from said container (1) through said mouth (31), a ring nut (4) for fastening said distributor means (2) onto said mouth (31) of the container (1), a translatable operating member (8) for the operation of said distribution means (2), characterized in that it comprises elastic means (16) suitable for transforming the translatory motion of said operating member (8) with respect to the ring nut (4) in a rotatory and axially reciprocating motion of a rotating and axially translatable element (9) provided with progressive numerical indices (17) which can be positioned in succession with every dose distributed in a pre-set observation position (19), said elastic means comprising a succession of small flexible circumferentially distanced legs (16) having an upper part (14) suitable for reacting with a first set of one-directional teeth (12) of the operating member (8), a lower part (15) suitable for reacting with a second set of one-directional teeth (13) of the ring nut (4) and an intermediate part (20) fastened to the rotating element (9), so that when said first set of one-directional teeth (12) approaches said second set of one-directional teeth (13) under the action of said operating member (8), the upper part (14) of said small legs (16) disengages from the corresponding tooth (21) of the first set of teeth (12) to be inserted in an immediately adjacent tooth (24) and thus drives in rotation and axial forward movement said intermediate part (20) of the small leg (16) and when said first set of teeth (12) is moved away from said second set of teeth (13) when the action of said operating member (8) ceases the lower part (15) of said small legs (16) disengages from the corresponding tooth (22) of the second set of teeth (13) to be inserted in an immediately adjacent tooth (25) and thus drives in rotation and axial backward movement said intermediate part (20) of the small leg (16).
2. Device according to claim 1, characterised in that said ring nut (4) is provided with radial ridges (33) suitable for their engagement in longitudinal slots (32) of the operating member (8) in order to guide the latter's translation with respect to it.
3. Device according to claim 1, characterised in that said operating member (8) has a top portion (12) in the shape of a nose.
4. Device according to claim 1, characterised in

that said rotating element (9) is provided with a radial locator (9A) suitable for coming to a stop against a corresponding radial locator (8A) of the operating member (8) to prevent the rotation of the rotating element (9), but allowing its axial translation, after a given number of strokes has been imparted to the operating member (8) and thus after a given maximum number of doses distributed.



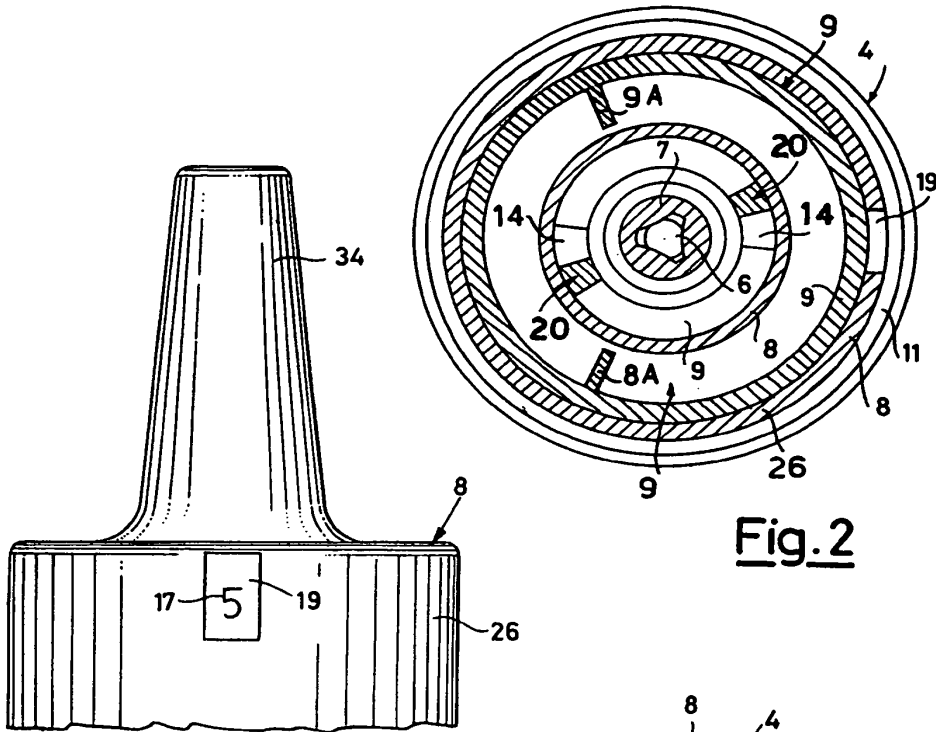


Fig. 6

Fig. 2

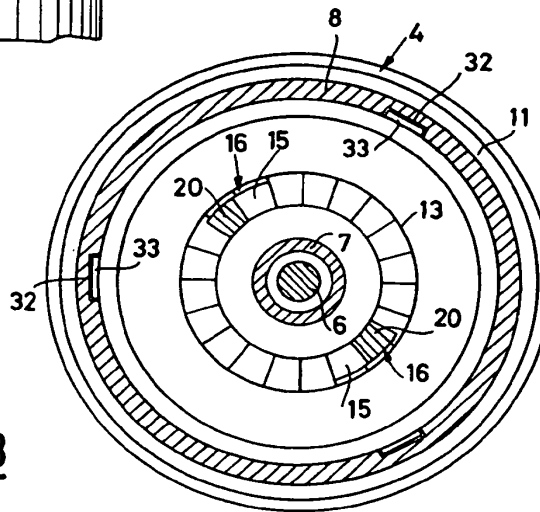
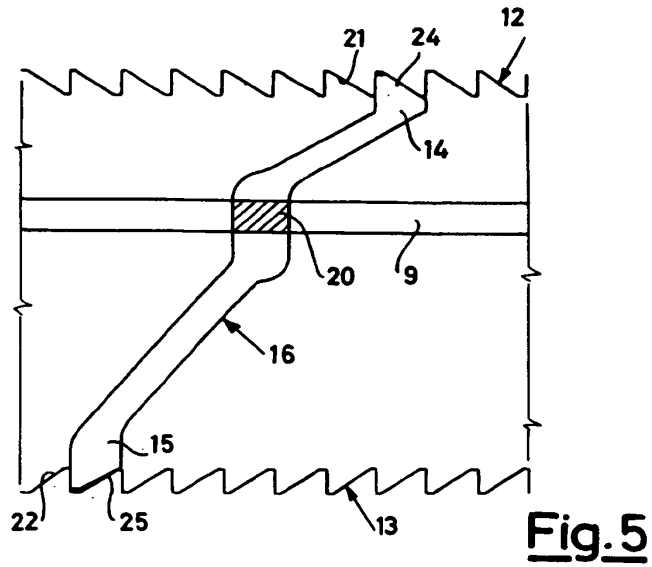
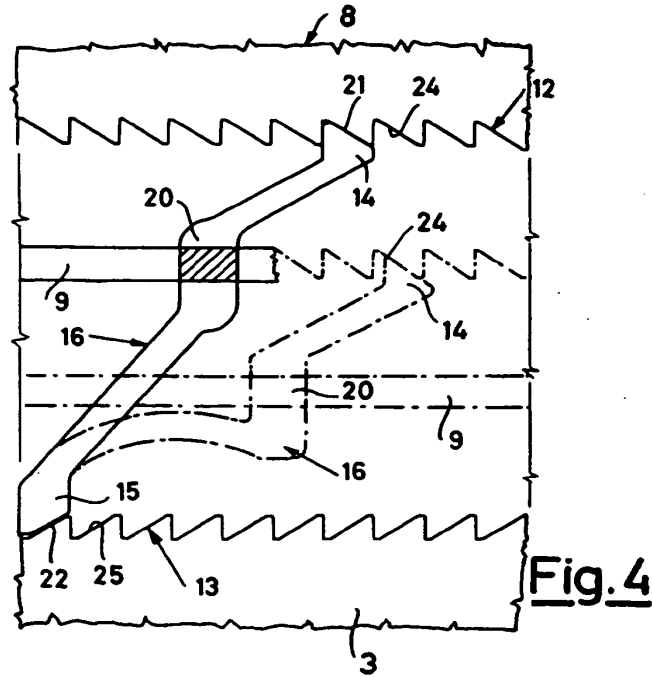


Fig. 3





European Patent
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EUROPEAN SEARCH REPORT

Application Number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 91201759.7
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	<u>GB - A - 1 317 315</u> (ENGL. NUMB.) * Totality; especially fig. 1-36; page 2, lines 6-113 *	1,4	A 61 M 15/00 A 61 M 15/08 G 06 M 1/04 B 67 D 5/08
A	<u>FR - A - 2 450 640</u> (PFEIFFER ZERST.) * Fig. 1,2 *	1,2	
D,A	<u>EP - A - 0 301 615</u> (ELETTRIO PL.) * Fig. 1; column 3, line 6 - column 4, line 5 *	1	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A 61 M B 67 D G 06 M
The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
VIENNA		22-01-1992	LUDWIG
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EPO FORM 1503 (01.92) (P4001)

PCT/FR 2004/001189

28 MAI 2004



REÇU 30 AOUT 2004

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REQUÊTE EN DÉLIVRANCE page 1/2



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ou demande de certificat d'utilité initiale		N°	Date
Transformation d'une demande de brevet européen		☐	Date
Demande de brevet initiale		N°	Date
3 TITRE DE L'INVENTION (200 caractères ou espaces maximum) DISTRIBUTEUR DE PRODUIT FLUIDE.			
4 DÉCLARATION DE PRIORITÉ OU REQUÊTE DU BÉNÉFICE DE LA DATE DE DÉPÔT D'UNE DEMANDE ANTÉRIEURE FRANÇAISE		Pays ou organisation Date N° Pays ou organisation Date N° Pays ou organisation Date N° ☐ S'il y a d'autres priorités, cochez la case et utilisez l'imprimé «Suite»	
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BR2

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	Code postal et ville	[7 5 10 11 16] PARIS	
	Pays	FRANCE	
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N° de télécopie (facultatif)		01 45 25 43 70	
Adresse électronique (facultatif)		capri@caprisas.fr	
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Les demandeurs et les inventeurs sont les mêmes personnes		☐ Oui ☒ Non : Dans ce cas remplir le formulaire de Désignation d'inventeur(s)	
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La présente invention concerne un distributeur de produit fluide, et plus particulièrement un tel distributeur comportant un dispositif d'indication de doses pour indiquer à l'utilisateur le nombre de doses distribuées ou restant à distribuer à partir du réservoir dudit distributeur de produit fluide.

5 Les dispositifs d'indication de doses sont bien connus, et peuvent comporter soit des compteurs, affichant un chiffre correspondant au nombre de doses distribuées ou restant à distribuer, soit des indicateurs, informant l'utilisateur par des symboles, codes couleurs, chiffres similaire sur le nombre de doses distribuées ou restant à distribuer. En particulier dans les distributeurs de
10 produit fluide contenant des produits pharmaceutiques, il est important que le dispositif d'indication de doses fonctionne de manière fiable, et notamment qu'il compte la distribution d'une dose à chaque fois que du produit est distribuée, que la dose soit complète ou partielle, par exemple en raison d'un actionnement défaillant ou interrompu avant la fin du cycle d'actionnement. En effet, il est
15 généralement préférable de compter la distribution d'une dose incomplète, plutôt que de ne pas la compter, ce qui peut présenter un risque important vis-à-vis de l'utilisateur en lui indiquant un contenu du réservoir supérieur à la réalité. Dans les distributeurs de produit pharmaceutique, on souhaite donc généralement éviter tout risque de sous-comptage, notamment en permettant le comptage juste
20 avant l'expulsion de produit actif. Un autre point important avec les dispositifs d'indication de doses de distributeur de produits pharmaceutiques, est qu'après un actionnement et une distribution d'une dose, lorsque le distributeur revient dans sa position de repos, tout nouvel actionnement réalisé avant la fin de la course de retour du distributeur et qui occasionnerait la distribution d'une dose
25 complète ou partielle, devrait également être compté par le dispositif d'indication, pour à nouveau éviter tout risque de sous-comptage. Dans la plupart des distributeurs de produit fluide, après distribution d'une dose, la prochaine dose est chargée dans la chambre de l'organe de distribution (pompe ou valve) lors de la course de retour du distributeur vers sa position de repos.
30 Pour éviter tout risque de sous-comptage lors de la course de retour du distributeur, il est souhaitable que le distributeur de produit fluide soit bloqué à

partir du moment où la course de retour a permis le remplissage de la chambre et jusqu'à ce que le dispositif d'indication soit de nouveau apte à compter l'actionnement du distributeur.

5 La présente invention a pour but de fournir un distributeur de produit fluide qui remplit la ou les exigences susmentionnées.

En particulier, la présente invention a pour but de fournir un distributeur de produit fluide comportant un dispositif d'indication de doses, qui évite tout risque de sous-comptage, c'est-à-dire qui garantisse l'actionnement du dispositif d'indication à chaque fois que du produit fluide est distribué par le distributeur de produit fluide.

10 La présente invention a également pour but de fournir un tel distributeur, qui évite de compter la distribution d'une dose, et donc d'actionner le dispositif d'indication de doses lorsque l'actionnement du distributeur n'implique aucune distribution de produit fluide.

15 La présente invention a encore pour but de fournir un tel distributeur de produit fluide qui soit simple et peu coûteux à fabriquer et assembler, et fiable d'utilisation.

La présente invention a donc pour objet un distributeur de produit fluide, comportant un corps, un réservoir de produit fluide, un organe de distribution, tel qu'une pompe ou une valve, monté sur ledit réservoir, et un dispositif d'indication de doses pour indiquer le nombre de doses de produit distribuées ou restant à distribuer à partir dudit réservoir, caractérisé en ce que ledit dispositif d'indication de doses comporte un premier système de sécurité destiné à actionner le dispositif d'indication de doses à partir d'une course d'actionnement partielle prédéterminée du distributeur, même si la course d'actionnement totale n'est pas réalisée par le distributeur.

20 De préférence, ledit dispositif d'indication de doses comporte un second système de sécurité qui, lors de la course retour du distributeur, après distribution d'une dose, empêche la prochaine expulsion de produit pharmaceutique jusqu'à ce que ledit distributeur a accompli une course de retour partielle prédéterminée, ledit distributeur et ledit dispositif d'indication de doses pouvant à nouveau être

actionnés à partir de cette course de retour partielle prédéterminée, même si la course de retour totale n'est pas réalisée par le distributeur et que celui-ci est actionné à nouveau avant de revenir à sa position de repos.

5 Avantageusement, ledit réservoir est déplaçable axialement par rapport audit corps, ledit corps comportant au moins un engrenage fixe, ledit dispositif d'indication de doses comportant un élément de comptage déplaçable axialement et en rotation par rapport audit corps, ledit élément de comptage coopérant d'une part avec ledit au moins un engrenage fixe dudit corps et d'autre part avec ledit réservoir lorsque le distributeur est actionné.

10 Selon un premier mode de réalisation de l'invention, ledit corps comporte un engrenage fixe coopérant avec un premier engrenage dudit élément de comptage, ledit élément de comptage comportant un second engrenage coopérant avec un engrenage d'actionnement d'un organe d'actionnement du distributeur, les dents dudit second engrenage et/ou dudit engrenage
15 d'actionnement étant réalisées de telle sorte qu'un déplacement axial de l'organe d'actionnement sollicite ledit élément de comptage à se déplacer axialement et en rotation, l'engrenage fixe empêchant une rotation dudit élément de comptage jusqu'à ce que ledit élément de comptage ne coopère plus avec ledit engrenage fixe, après un déplacement axial prédéterminé dudit élément de comptage
20 correspondant à ladite course d'actionnement partielle prédéterminée du distributeur.

 Avantageusement, l'engrenage fixe comporte des moyens de butée bloquant en rotation ledit élément de comptage après au moins une rotation partielle dudit élément de comptage, un déplacement axial supplémentaire dudit
25 élément de comptage étant nécessaire pour permettre la poursuite de sa rotation et/ou le retour du dispositif d'indication vers sa position de repos. Ces butées positionnent le second engrenage de l'élément de comptage de tel sorte que le distributeur soit bloqué à son retour avant le remplissage de la chambre et jusqu'à sa position de repos.

30 Avantageusement, lesdits moyens de butée comportent une projection axiale.

Avantageusement, ledit engrenage fixe et/ou ledit élément de comptage comporte(nt) des moyens de blocage empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique, lorsque l'élément de comptage revient vers sa position de repos après un actionnement précédent, jusqu'à ce que le distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la
5 prochaine dose.

Avantageusement, lesdits moyens de blocage comportent des projections axiales prévues respectivement sur le corps et sur l'élément de comptage, lesdites
10 projections comportent chacune un profil d'extrémité axiale plan, lesdites projections étant au moins partiellement face à face jusqu'à ce que l'élément de comptage a accompli une rotation suffisante pour décaler lesdites projections correspondant à ladite course de retour partielle prédéterminée du distributeur.

Avantageusement, les dents du second engrenage de l'élément de comptage comportant un palier intermédiaire, l'organe d'actionnement coopérant avec ledit palier lors de l'actionnement du distributeur, et coopérant avec le fond dudit second engrenage lors du retour vers la position de repos, après actionnement, le déplacement entre le palier intermédiaire et le fond étant
15 obtenu par rotation dudit élément de comptage.

Avantageusement, lorsque la course de retour partielle prédéterminée a été réalisée, l'organe d'actionnement est placé face à la dent suivante du second engrenage de l'élément de comptage, permettant un nouvel actionnement du distributeur et du dispositif d'indication de doses.
20

Selon un second mode de réalisation de la présente invention, ledit corps comporte un premier engrenage fixe et un second engrenage fixe, ledit élément de comptage comportant un premier engrenage destiné à coopérer avec ledit premier engrenage fixe, et un second engrenage destiné à coopérer avec ledit second engrenage fixe, ledit élément de comptage étant axialement mis en contact avec l'organe d'actionnement du distributeur par l'intermédiaire d'un
25 ressort de rappel et étant déplaçable en rotation par rapport audit organe d'actionnement, les dents dudit second engrenage et second engrenage fixe étant
30

au moins partiellement obliques de telle sorte qu'un déplacement axial de l'organe d'actionnement sollicite d'abord ledit élément de comptage à se déplacer axialement sur une course d'actionnement partielle prédéterminée, jusqu'à ce que la partie oblique dudit second engrenage de l'élément de comptage coopère avec ladite partie oblique dudit second engrenage fixe, sollicitant l'élément de comptage à se déplacer en rotation sur une première partie de cycle de rotation, les dents desdits premier engrenage et premier engrenage fixe étant au moins partiellement obliques de telle sorte que lorsque l'élément de comptage revient vers sa position de repos, il est sollicité en rotation pour terminer son cycle de rotation correspondant au comptage d'un actionnement du distributeur.

Avantageusement, lesdits premier et second engrenages fixes du corps et/ou lesdits premier et second engrenages de l'élément de comptage sont décalés l'un par rapport à l'autre de telle sorte que dès que l'élément de comptage est déplaçable en rotation, un retour de celui-ci vers sa position de repos sans terminer la course d'actionnement du distributeur entraîne la rotation de l'élément de comptage sur son cycle complet de rotation, garantissant le comptage d'un actionnement du distributeur après ladite course d'actionnement partielle prédéterminée.

Avantageusement, ledit second engrenage fixe du corps et/ou ledit second engrenage de l'élément de comptage comporte(nt) des moyens de blocage empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique lorsque l'élément de comptage revient vers sa position de repos après un actionnement précédent jusqu'à ce que ledit distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

Avantageusement, lesdits moyens de blocage comportent un profil d'extrémité axial au moins partiellement plan formé sur les dents dudit second engrenage fixe du corps et dudit second engrenage de l'élément de comptage, lesdits profils plan desdites dents étant au moins partiellement face à face jusqu'à ce que l'élément de comptage a accompli une rotation suffisante pour décaler

lesdites dents, correspondant à ladite course de retour partielle prédéterminée du distributeur.

Avantageusement, ledit organe d'actionnement du distributeur est solidaire dudit réservoir et se déplace axialement avec lui.

5 Selon un troisième mode de réalisation de la présente invention, ledit corps comporte un premier engrenage fixe et un second engrenage fixe, ledit élément de comptage comportant un premier engrenage destiné à coopérer avec ledit premier engrenage fixe, un second engrenage destiné à coopérer avec ledit second engrenage fixe, et un troisième engrenage destiné à coopérer avec un engrenage d'actionnement, solidaire d'un organe d'actionnement du distributeur, les dents dudit troisième engrenage et/ou dudit engrenage d'actionnement étant réalisées de tel sorte qu'un déplacement axial de l'organe d'actionnement sollicite ledit élément de comptage à se déplacer axialement et en rotation, le premier engrenage fixe empêchant une rotation dudit élément de comptage jusqu'à ce que ledit élément de comptage ne coopère plus avec ledit premier engrenage fixe, après un déplacement axial prédéterminé dudit élément de comptage correspondant à ladite course d'actionnement partielle prédéterminée du distributeur.

15 Avantageusement, ledit second engrenage fixe du corps et/ou ledit second engrenage de l'élément de comptage comporte(nt) des moyens de blocage empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique lorsque l'élément de comptage revient vers sa position de repos après un actionnement précédent jusqu'à ce que ledit distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

25 Avantageusement, lesdits moyens de blocage comportent un profil d'extrémité axial plan formé sur les dents dudit second engrenage fixe et dudit second engrenage, lesdites dents étant au moins partiellement face à face jusqu'à ce que l'élément de comptage a accompli une rotation suffisante pour décaler lesdites dents, correspondant à ladite course de retour partielle prédéterminée du distributeur.

Avantageusement, ledit engrenage d'actionnement comporte des moyens de butée limitant la rotation de l'élément de comptage jusqu'à ce que l'organe d'actionnement a réalisé ladite course de retour partielle prédéterminée.

5 Avantageusement, lesdits moyens de butée comportent une projection axiale formée sur ledit engrenage d'actionnement.

Avantageusement, ledit organe d'actionnement du distributeur est solidaire dudit réservoir et se déplace axialement avec lui.

10 D'autres caractéristiques et avantages de la présente invention apparaîtront plus clairement au cours de la description détaillée suivante de trois modes de réalisation de celle-ci, faite en référence aux dessins joints, donnés à titre d'exemples non limitatifs, et sur lesquels

15 - les figures 1 à 8 sont des représentations schématiques d'un distributeur de produit fluide selon un premier mode de réalisation de la présente invention, montrant les positions successives lors d'un cycle d'actionnement du distributeur ;

- les figures 9 à 12 sont des représentations schématiques d'un distributeur selon un second mode de réalisation de la présente invention, montrant également diverses positions dans le cycle d'actionnement du distributeur ; et

20 - les figures 13 à 21 sont des représentations schématiques d'un distributeur de produit fluide selon un troisième mode de réalisation de la présente invention, montrant différentes positions dans le cycle d'actionnement du distributeur.

25 Les descriptions des trois modes de réalisation qui vont être faites ci-après concernent les cycles d'actionnement du distributeur et les différentes spécificités fonctionnelles du dispositif d'indication permettant de garantir la fiabilité de fonctionnement et de comptage dudit dispositif d'indication. Les dessins auxquels la présente description fera référence sont donc des schémas très simplifiés, qui ne représentent pas le distributeur de produit fluide en détail, mais seulement de manière très schématisée par les différentes parties déplaçables les
30 une par rapport aux autres, pour permettre l'explication du cycle d'actionnement dudit distributeur et dudit dispositif d'indication. Ainsi par exemple, l'organe de

distribution, par exemple une pompe ou une valve, n'est pas représentée sur les dessins. De même, la tête de distribution comportant l'orifice de distribution n'est pas non plus représentée, ces éléments n'intervenant pas directement dans la présente invention.

5 Il est à noter que la présente invention s'applique plus particulièrement aux dispositifs dits MDI (METERED DOSE INHALER), qui comportent une valve doseuse montée sur un réservoir contenant du produit fluide et un gaz propulseur, le déplacement du réservoir par rapport à la soupape de la valve engendrant la distribution d'une dose de produit au moyen dudit gaz propulseur.
10 La présente invention n'est pas limitée à cette application particulière, mais celle-ci représente l'application préférée de la présente invention.

En référence aux figures 1 à 8, nous allons décrire un premier mode de réalisation de la présente invention. Selon ce premier mode de réalisation, le distributeur comporte un réservoir 2 déplaçable axialement dans un corps 1, qui
15 sera ci-après considéré comme la partie fixe du distributeur. Le déplacement axial du réservoir 2 par rapport au corps 1 actionne l'organe de distribution et donc réalise la distribution d'une dose de produit hors dudit réservoir. Selon ce premier mode de réalisation, le distributeur comporte un organe d'actionnement 30 sur lequel l'utilisateur exerce une force d'actionnement axial pour réaliser
20 l'actionnement du distributeur et donc pour déplacer ledit réservoir 2 par rapport au corps 1. Le distributeur comporte en outre un dispositif d'indication de doses destinées à compter ou à indiquer à chaque actionnement du distributeur la distribution d'une dose de produit fluide. L'utilisateur peut donc grâce à ce dispositif d'indication savoir combien de doses ont été distribuées hors dudit
25 réservoir 2, ou combien de doses restent à l'intérieur dudit réservoir 2. Cette information doit être très précise, en particulier lorsque le produit fluide est un produit pharmaceutique et tout risque de sous-comptage doit être éliminé. En effet, dans l'hypothèse d'un sous-comptage, c'est-à-dire lorsque le dispositif d'indication ne compte pas une ou plusieurs distribution(s) partielle(s) ou
30 complète(s) de dose de produit, l'utilisateur peut se retrouver avec un distributeur lui indiquant qu'il reste une ou deux dose(s) dans le réservoir, alors qu'en réalité

le réservoir est vide. En cas de crise, l'utilisateur peut donc se retrouver avec un distributeur ne fonctionnant plus et ne lui permettant pas de prendre son médicament.

La présente invention permet d'éviter tout risque de sous-comptage. Pour ce faire, le dispositif d'indication de doses comporte au moins un système de sécurité, et de préférence deux. Le premier système de sécurité est destiné à garantir l'actionnement du dispositif d'indication de doses, et donc le comptage de la distribution d'une dose de produit, à partir du moment où, lors de l'actionnement du distributeur, une course partielle prédéterminée a été parcourue. Le second système de sécurité est destiné à empêcher, pendant la course de retour du distributeur, l'expulsion de dose tant que le dispositif d'indication de doses n'est pas prêt à compter la prochaine dose. En effet, la chambre de dosage du distributeur se remplit généralement lors de la phase retour du distributeur vers sa position de repos, après un actionnement précédent. Si cette course de retour n'est pas complète mais que le dispositif est actionné à nouveau avant qu'il ne revienne vers sa position de repos, il serait possible que du produit soit distribué. Or, si le dispositif d'indication de doses n'est pas revenu dans sa position de repos ou proche de celle-ci, il ne pourra pas compter cette distribution de produit. Il se produirait alors un sous-comptage. Pour éviter ceci, le second système de sécurité bloque tout nouvel actionnement, ou pour le moins toute distribution de produit. Ce blocage sera réalisé jusqu'à ce que la course de retour soit suffisante pour que le dispositif d'indication de dose puisse être de nouveau actionné et qu'il compte la prochaine dose.

En résumé, la présente invention fournit un ou deux système(s) de sécurité qui évite(nt) tout risque de sous-comptage du dispositif d'indication-

Nous allons ci-après d'abord décrire le premier système de sécurité, en référence aux figures 1 à 4.

En se référant à ces figures, on constate que le corps fixe 1 comporte un engrenage fixe 110 et que le dispositif d'indication comporte un élément de comptage 20 destiné à coopérer d'une part avec ledit engrenage fixe 110 du corps 1, et d'autre part avec l'organe d'actionnement 30 et/ou le réservoir 2. Plus

particulièrement, l'élément de comptage 20 est déplaçable axialement par rapport au corps 1 ainsi qu'en rotation par rapport à celui-ci. L'élément de comptage 20 comporte un premier engrenage 210 destiné à coopérer avec ledit engrenage fixe 110 du corps et un second engrenage 230 destiné à coopérer avec un engrenage d'actionnement 300 solidaire de l'organe d'actionnement 30.

En se référant aux figures 1 et 4, il est représenté la première moitié d'un cycle d'actionnement du distributeur, c'est-à-dire le déplacement du distributeur de la position de repos (représenté sur la figure 1) vers la position d'actionnement (représenté sur la figure 4). Ainsi, lorsque l'utilisateur appuie sur l'organe d'actionnement 30 pour déplacer celui-ci axialement vers le bas sur la figure 1, le profil oblique des dents de l'engrenage d'actionnement 300 et du second engrenage 230 de l'élément de comptage sollicite l'élément de comptage 20 en déplacement axial vers le bas et aussi en rotation en raison du profil oblique des engrenages susmentionnés. Or, tant que le premier engrenage 210 de l'élément de comptage 20 coopère avec l'engrenage fixe 110 du corps 1, toute rotation de l'élément de comptage 20 est empêchée. Par conséquent, au début de la course d'actionnement du distributeur, et donc de l'organe d'actionnement 30, l'élément de comptage 20 est uniquement déplacé axialement ensemble avec l'organe d'actionnement 30, sans pouvoir tourner. Lorsque le système arrive dans la position représentée sur la figure 2, le déplacement axial de l'élément de comptage 20 a également provoqué le déplacement axial du réservoir 2 sur une première partie de course d'actionnement. Dans la position de la figure 2, le premier engrenage 210 de l'élément de comptage 20 arrive dans une position où il ne coopère plus avec l'engrenage fixe 110 du corps 1. De cette manière, l'élément de comptage, qui est sollicité en rotation par la force exercée sur l'organe d'actionnement 30, peut tourner par rapport au corps 1. A partir du moment où l'élément de comptage va un peu tourner, le dispositif d'indication de doses est actionné et le comptage d'une dose de produit est initié. Cette course partielle de déplacement axiale de l'élément de comptage 20 correspond à ladite course d'actionnement partielle prédéterminée du distributeur, plus particulièrement du réservoir 2. En effet, dans ce type de distributeur, la dose de

produit n'est pas nécessairement expulsée en toute fin de course d'actionnement, mais à partir d'une course partielle prédéterminée, qui est fonction du déplacement de la soupape dans une valve, ou du déplacement du piston dans une pompe. En faisant correspondre la coopération du premier engrenage 210 de l'élément de comptage avec l'engrenage fixe 110 du corps 1 avec ladite course d'actionnement partielle prédéterminée du distributeur, on assure dès que du produit fluide risque d'être distribué hors du réservoir 2, le dispositif d'indication compte cette distribution.

La figure 3 montre que l'engrenage fixe 110 du corps 1 comporte des moyens de butée 115, de préférence formés par une projection axiale coopérant avec le premier engrenage 210 de l'élément de comptage 20, et qui impose un nouveau déplacement axial de l'élément de comptage, très faible mais non nul, pour permettre un engrènement suffisant de l'engrenage d'actionnement 300 dans le premier palier, marqué par la butée 235 sur le second engrenage 230. Ainsi la chambre du distributeur ne pourra pas être rempli si la butée 215 n'est pas dépassée. Si elle est passée l'engrenage d'actionnement 300 se positionnera dans le second palier ou fond du second engrenage 230 de l'élément de comptage 20 avant remplissage de la chambre du distributeur pour bloquer l'expulsion de produit pharmaceutique comme il représenté sur la figure 6.

Une poursuite de la course d'actionnement amène le réservoir 2 dans la position représentée sur la figure 4, dans laquelle la course d'actionnement totale a été réalisée, et la totalité de la dose a été expulsée hors du réservoir. Toutefois, on constate que même si la force exercée par l'utilisateur cesse sur l'organe d'actionnement 30 avant la fin de la course d'actionnement totale, à partir du moment où la course d'actionnement partielle a été réalisée, le dispositif d'indication a compté la distribution de la dose, de sorte que tout sous-comptage est évité à ce niveau là.

En référence aux figures 5 à 8, on va décrire la seconde phase du cycle d'actionnement du distributeur, à savoir le retour de la position de distribution vers la position de repos (représenté sur la figure 8). En se référant à la figure 5, on constate que lorsque l'utilisateur lâche sa pression sur l'organe

d'actionnement 30, le ressort de rappel (non représenté) du distributeur amène le réservoir 2 vers sa position de repos en déplaçant axialement le réservoir 2 par rapport au corps 1 dans le sens inverse à celui du déplacement d'actionnement décrit précédemment. Le déplacement du réservoir 2 provoque un déplacement axial de l'élément de comptage 20 de sorte que le premier engrenage 210 vient à nouveau coopérer avec l'engrenage fixe 110 du corps 1, mais cette fois au niveau des parties obliques, ce qui implique une rotation dudit élément de comptage, pour terminer le cycle de comptage du dispositif d'indication. Lorsque l'élément de comptage tourne par rapport au corps 1 lors de la course de retour, on constate que l'organe d'actionnement 30 vient coopérer avec le fond du second engrenage 230 de l'élément de comptage 20, alors que pendant la phase d'actionnement, l'engrenage d'actionnement 300 coopérerait avec le premier palier, marqué par la butée 235, réalisée sur ledit second engrenage 230 de l'élément de comptage 20.

La figure 6 représente schématiquement une tentative de nouvel actionnement avant la fin de la course de retour du distributeur. On constate que le corps 1 comporte des projections axiales 120 qui coopèrent avec des projections axiales 220 réalisées sur l'élément de comptage 20. En variante, ces projections axiales 120, 220 peuvent être remplacée par des engrenages ayant une forme correspondante. De préférence, les profils d'extrémités axiales desdites projections 120 et 220 sont réalisées par des plans et ces projections axiales 120 et 220 sont au moins partiellement disposées face à face, de sorte que si la course de retour du distributeur est insuffisante, il est impossible d'expulser une nouvelle dose de produit, comme cela est représenté sur la figure 6. Pour pouvoir à nouveau actionner le distributeur, il faut que l'élément de comptage 20 tourne suffisamment autour de son axe de rotation pour que lesdites projections 120 et 220 soient décalées l'une par rapport à l'autre, et ainsi permettre un nouvel actionnement. Ce décalage sera réalisé en libérant l'organe d'actionnement 30 du fond du second engrenage 230 de l'élément de comptage 20 pour le positionner en face du premier palier, marqué par la butée 235, de la dent suivante. Ce nouvel actionnement peut être permis avant la fin de la course

de retour totale du distributeur après que le dispositif d'indication soit de nouveau apte à compter un nouvel actionnement du distributeur. La présente invention permet de remplir cette exigence, comme le montre la figure 7 dans laquelle la course de retour n'est pas complète, mais l'organe d'actionnement 30 du distributeur et notamment l'engrenage d'actionnement 300 est dans une position où il peut coopérer avec la prochaine dent du second engrenage 230 de l'élément de comptage, de sorte qu'un nouvel actionnement à ce moment là provoque la rotation de l'élément de comptage sur la fin de son cycle précédent, ce qui amène le décalage desdites projections axiales 120 et 220, et autorisent donc un nouvel actionnement du distributeur et du dispositif d'indication de doses. Le but est de bloquer l'expulsion quand la chambre est remplie tant que le compteur n'est pas prêt à compter une prochaine dose.

Dans la figure 8, le dispositif est revenu vers sa position de repos initiale et un nouveau cycle d'actionnement peut être réalisé.

Les figures 9 à 12 représentent un deuxième mode de réalisation de l'invention. Ce deuxième mode de réalisation diffère du premier mode de réalisation par les points suivants. D'une part, le corps 1 comporte deux engrenages fixes 110 et 120 et l'élément de comptage 20 comporte deux engrenages 210, 220, chacun coopérant avec un des engrenages fixes du corps. L'organe d'actionnement 30 est solidaire du réservoir 2 et l'élément de comptage 20 est déplaçable axialement avec ledit organe d'actionnement 30. Il peut se déplacer en rotation par rapport audit organe d'actionnement 30. En fait, dans ce second mode de réalisation, il n'y a pas véritablement d'organe d'actionnement, mais l'utilisateur déplace généralement le réservoir 2 lui-même par rapport au corps 1 pour réaliser l'actionnement. Le second engrenage fixe 120 du corps 1 et le second engrenage 220 de l'élément de comptage comportent au moins partiellement une partie oblique respectivement 121 et 221, qui coopèrent l'une avec l'autre lors de l'actionnement du distributeur. Ces parties obliques sollicitent l'élément de comptage 20 à se déplacer en rotation, et donc à initier un cycle de comptage du dispositif d'indication de doses. Comme représenté sur les figures 9 et 10, lors de l'actionnement du distributeur, l'élément de comptage est

d'abord déplacé axialement sans tourner en étant solidaire de l'organe d'actionnement 30 et du réservoir 2. Lorsque le distributeur a réalisé la course d'actionnement partielle prédéterminée, les parties obliques 220, 221 des seconds engrenages 120, 220 coopèrent pour faire tourner l'organe d'actionnement comme représenté sur la figure 10.

On constate que si dans la position représentée sur la figure 10, l'utilisateur arrête d'actionner le distributeur, le système revient vers sa position de repos grâce à un ressort de rappel 50 et le cycle de comptage se complète puisque le premier engrenage 210 de l'élément de comptage 20 vient coopérer avec les dents du premier engrenage fixe 110 pour solliciter encore d'avantage l'élément de comptage 20 en rotation pour l'amener à la fin de son cycle de comptage. Le premier système de sécurité est donc réalisé en ce que l'actionnement du dispositif d'indication de doses est assuré à partir du moment où le distributeur a réalisé sa course d'actionnement partielle prédéterminé à partir de laquelle une dose de produit (complète ou partielle) peut être distribuée.

La figure 11 montre la position d'actionnement dans laquelle la course d'actionnement totale a été réalisée, et la figure 12 illustre le second système de sécurité, réalisé aux moyens du second engrenage fixe 120 et du second engrenage 220 de l'élément de comptage 20. En effet, ces deux engrenages comportent également respectivement une partie plane, ayant un profil d'extrémité axiale plan, de sorte que lorsque la course de retour du distributeur n'est pas suffisante, comme visible sur la figure 12, un nouvel actionnement du système provoque une butée axiale entre l'élément de comptage 20 et le second engrenage fixe 220 par l'intermédiaire de leur partie d'extrémité plane, ce qui empêche l'expulsion de produit pharmaceutique en bloquant l'actionnement du distributeur. Ce n'est qu'à partir du moment où une course de retour partielle prédéterminée est réalisée, que les parties obliques des seconds engrenages 120 et 220 sont face à face pour permettre un nouvel actionnement et du distributeur et du dispositif d'indication de doses.

Les figures 13 à 21 montrent un troisième mode de réalisation de la présente invention. Ce troisième mode de réalisation diffère du second mode de

réalisation en ce que l'élément de comptage 20 n'est pas solidaire axialement de l'organe d'actionnement 30 et du réservoir. L'organe d'actionnement 30 et le réservoir 2 comportent un engrenage d'actionnement 300 qui coopère avec une troisième engrenage 230 réalisé sur l'élément de comptage 20. Dans ce troisième mode de réalisation, la rotation de l'élément de comptage 20 lors de la course d'actionnement du distributeur n'est donc plus provoquée par le second engrenage fixe 120, mais aux moyens du troisième engrenage 230 et de l'engrenage d'actionnement 300. En faite, ce troisième mode de réalisation combine les premiers et seconds modes de réalisation décrits précédemment. En début d'actionnement, lorsqu'on est dans la situation de la figure 13, la coopération entre le premier engrenage fixe 110 et le premier engrenage 210 de l'élément de comptage 20 empêche une rotation de l'élément de comptage 20 et donc provoque un déplacement axial de celui-ci. Lorsqu'on arrive dans la position représentée sur la figure 14, les premiers engrenages susmentionnés ne coopèrent plus et les profils obliques des dents de l'engrenage d'actionnement 300 et du troisième engrenage 230 de l'élément de comptage 20 provoque une rotation de l'élément de comptage 20. Ceci est réalisé à partir de ladite course d'actionnement partielle du distributeur à partir de laquelle une dose complète ou partielle de produit peut être distribuée. La figure 15 montre que si la force d'actionnement axial est supprimée à partir de ce moment là, le dispositif de comptage, grâce au ressort de rappel 50 amènera l'élément de comptage à tourner sur son cycle complet de comptage, évitant ainsi tout risque de sous-comptage.

La figure 16 montre la position d'actionnement finale dans laquelle la course d'actionnement totale a été réalisée. A ce moment là, lorsque l'utilisateur relâche la force d'actionnement sur l'organe d'actionnement 30, le système remonte sous l'effet du ressort de rappel 50 et la coopération entre les premiers engrenages 210 et 110 respectivement de l'élément de comptage 20 et du corps 1 provoque la poursuite de la rotation de l'élément de comptage. Cette poursuite de la rotation est bloquée dans l'engrenage d'actionnement 300 par des moyens de butée 305. En référence à la figure 18, si l'utilisateur appuie à nouveau sur

l'organe d'actionnement 30 dans cette position, on constate que l'actionnement du distributeur et du dispositif de comptage est bloqués par le fait que le deuxième engrenage 220 de l'élément de comptage et le deuxième engrenage fixe 120 du corps 1 sont face à face, au niveau de leur profil d'extrémité axiale plan. La figure 19 illustre une tentative d'actionnement alors que le second système de sécurité est opérationnel. Pour permettre un nouvel actionnement du distributeur et du dispositif d'indication de doses, il faut qu'une course de retour partielle prédéterminée soit réalisée, qui est représentée sur la figure 20. En effet, à partir de cette position, si l'utilisateur actionne à nouveau, il provoquera une rotation de l'élément de comptage 20 qui permettra un nouvel actionnement du distributeur et du dispositif d'indication.

Enfin, la figure 21 montre la position dans laquelle une telle tentative d'actionnement supplémentaire est réalisée après que ladite course de retour partielle est été complétée.

Il est entendu que la description détaillée des trois modes de réalisation, donnée ci-dessus, n'est pas limitative, et que d'autres variantes de réalisation sont envisageables sans sortir du cadre de la présente invention, telle que définie par les revendications annexées.

Revendications

1.- Distributeur de produit fluide, comportant un corps (1), un réservoir de produit fluide (2), un organe de distribution, tel qu'une pompe ou une valve, monté sur ledit réservoir (2), et un dispositif d'indication de doses pour indiquer le nombre de doses de produit distribuées ou restant à distribuer à partir dudit réservoir, caractérisé en ce que ledit dispositif d'indication de doses comporte un premier système de sécurité destiné à actionner le dispositif d'indication de doses à partir d'une course d'actionnement partielle prédéterminée du distributeur, même si la course d'actionnement totale n'est pas réalisée par le distributeur.

2.- Distributeur selon la revendication 1, dans lequel ledit dispositif d'indication de doses comporte un second système de sécurité qui, lors de la course de retour du distributeur, après distribution d'une dose, empêche la prochaine expulsion de produit jusqu'à ce que ledit distributeur a accompli une course de retour partielle prédéterminée, ledit distributeur et ledit dispositif d'indication de doses pouvant à nouveau être actionnés à partir de cette course de retour partielle prédéterminée, même si la course de retour totale n'est pas réalisée par le distributeur et que celui-ci est actionné à nouveau avant de revenir à sa position de repos.

3.- Distributeur selon la revendication 1 ou 2, dans lequel ledit réservoir (2) est déplaçable axialement par rapport audit corps (1), ledit corps (1) comportant au moins un engrenage fixe (110, 120), ledit dispositif d'indication de doses comportant un élément de comptage (20) déplaçable axialement et en rotation par rapport audit corps (1), ledit élément de comptage (20) coopérant d'une part avec ledit au moins un engrenage fixe (110, 120) dudit corps et d'autre part avec ledit réservoir (2) lorsque le distributeur est actionné.

4.- Distributeur selon la revendication 3, dans lequel ledit corps (1) comporte un engrenage fixe (110) coopérant avec un premier engrenage (210) dudit élément de comptage (20), ledit élément de comptage (20)

comportant un second engrenage (230) coopérant avec un engrenage d'actionnement (300) d'un organe d'actionnement (30) du distributeur, les dents dudit second engrenage (230) et/ou dudit engrenage d'actionnement (300) étant réalisées de telle sorte qu'un déplacement axial de l'organe d'actionnement sollicite ledit élément de comptage (20) à se déplacer axialement et en rotation, l'engrenage fixe (110) empêchant une rotation dudit élément de comptage (20) jusqu'à ce que ledit élément de comptage (20) ne coopère plus avec ledit engrenage fixe (110), après un déplacement axial prédéterminé dudit élément de comptage (20) correspondant à ladite course d'actionnement partielle prédéterminée du distributeur.

5.- Distributeur selon la revendication 4, dans lequel l'engrenage fixe (110) comporte des moyens de butée (115) bloquant en rotation ledit élément de comptage (20) après au moins une rotation partielle dudit élément de comptage (20), un déplacement axial supplémentaire dudit élément de comptage (20) étant nécessaire pour permettre la poursuite de sa rotation et/ou le retour du dispositif d'indication vers sa position de repos.

6.- Distributeur selon la revendication 5, dans lequel lesdits moyens de butée (115) comportent une projection axiale.

7.- Distributeur selon l'une quelconque des revendications 3 à 6, dans lequel ledit engrenage fixe (110) et/ou ledit élément de comptage (20) comporte(nt) des moyens de blocage (120, 220) empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique, lorsque l'élément de comptage (20) revient vers sa position de repos après un actionnement précédent, jusqu'à ce que le distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

8.- Distributeur selon la revendication 7, dans lequel lesdits moyens de blocage comportent des projections axiales (120, 220) prévues respectivement sur le corps (1) et sur l'élément de comptage (20), lesdites projections (120, 220) comportant chacune un profil d'extrémité axiale

plan, lesdites projections (120, 220) étant au moins partiellement face à face jusqu'à ce que l'élément de comptage (20) a accompli une rotation suffisante pour décaler lesdites projections (120, 220) correspondant à ladite course de retour partielle prédéterminée du distributeur.

5 9.- Distributeur selon la revendication 8, dans lequel les dents du second engrenage (230) de l'élément de comptage (20) comportent un palier intermédiaire (235), l'organe d'actionnement (30) coopérant avec ledit palier (235) lors de l'actionnement du distributeur, et coopérant avec
10 le fond dudit second engrenage (230) lors du retour vers la position de repos, après actionnement, le déplacement entre le palier intermédiaire (235) et le fond étant obtenu par rotation dudit élément de comptage (20).

10.- Distributeur selon la revendication 8 ou 9, dans lequel, lorsque la course de retour partielle prédéterminée a été réalisée, l'organe d'actionnement (30) est placé face à la dent suivante du second engrenage
15 (230) de l'élément de comptage (20), permettant un nouvel actionnement du distributeur et du dispositif d'indication de doses.

11.- Distributeur selon la revendication 3, dans lequel ledit corps (1) comporte un premier engrenage fixe (110) et un second engrenage fixe (120), ledit élément de comptage (20) comportant un premier engrenage
20 (210) destiné à coopérer avec ledit premier engrenage fixe (110), et un second engrenage (220) destiné à coopérer avec ledit second engrenage fixe (120), ledit élément de comptage (20) étant axialement mis en contact avec l'organe d'actionnement (30) du distributeur par l'intermédiaire d'un ressort de rappel (50) et étant déplaçable en rotation par rapport audit
25 organe d'actionnement (30), les dents dudit second engrenage (220) et second engrenage fixe (120) étant au moins partiellement obliques de telle sorte qu'un déplacement axial de l'organe d'actionnement (30) sollicite d'abord ledit élément de comptage (20) à se déplacer axialement sur une course d'actionnement partielle prédéterminée, jusqu'à ce que la partie
30 oblique (221) dudit second engrenage (220) de l'élément de comptage (20) coopère avec ladite partie oblique (121) dudit second engrenage fixe (120),

sollicitant l'élément de comptage (20) à se déplacer en rotation sur une première partie de cycle de rotation, les dents desdits premier engrenage (210) et premier engrenage fixe (110) étant au moins partiellement obliques de telle sorte que lorsque l'élément de comptage (20) revient vers sa position de repos, il est sollicité en rotation pour terminer son cycle de rotation correspondant au comptage d'un actionnement du distributeur.

12.- Distributeur selon la revendication 11, dans lequel lesdits premier et second engrenages fixes (110, 120) du corps (1) et/ou lesdits premier et second engrenages (210, 220) de l'élément de comptage (20) sont décalés l'un par rapport à l'autre de telle sorte que dès que l'élément de comptage (20) est déplaçable en rotation, un retour de celui-ci vers sa position de repos sans terminer la course d'actionnement du distributeur entraîne la rotation de l'élément de comptage (20) sur son cycle complet de rotation, garantissant le comptage d'un actionnement du distributeur après ladite course d'actionnement partielle prédéterminée.

13.- Distributeur selon l'une quelconque des revendications 11 ou 12, dans lequel ledit second engrenage fixe (120) du corps (1) et/ou ledit second engrenage (220) de l'élément de comptage (20) comporte(nt) des moyens de blocage empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique, lorsque l'élément de comptage (20) revient vers sa position de repos après un actionnement précédent jusqu'à ce que ledit distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

14.- Distributeur selon la revendication 13, dans lequel lesdits moyens de blocage comportent un profil d'extrémité axial au moins partiellement plan formé sur les dents dudit second engrenage fixe (120) du corps (1) et dudit second engrenage (220) de l'élément de comptage (20), lesdits profils plan desdites dents étant au moins partiellement face à face jusqu'à ce que l'élément de comptage (20) a accompli une rotation suffisante pour décaler

lesdites dents, correspondant à ladite course de retour partielle prédéterminée du distributeur.

15.- Distributeur selon l'une quelconque des revendications 11 à 14, dans lequel ledit organe d'actionnement (30) du distributeur est solidaire dudit réservoir (2) et se déplace axialement avec lui.

16.- Distributeur selon la revendication 3, dans lequel ledit corps (1) comporte un premier engrenage fixe (110) et un second engrenage fixe (120), ledit élément de comptage (20) comportant un premier engrenage (210) destiné à coopérer avec ledit premier engrenage fixe (110), un second engrenage (220) destiné à coopérer avec ledit second engrenage fixe (120), et un troisième engrenage (230) destiné à coopérer avec un engrenage d'actionnement (300), solidaire d'un organe d'actionnement (30) du distributeur, les dents dudit troisième engrenage (230) et/ou dudit engrenage d'actionnement (300) étant réalisées de tel sorte qu'un déplacement axial de l'organe d'actionnement (30) sollicite ledit élément de comptage (20) à se déplacer axialement et en rotation, le premier engrenage fixe (110) empêchant une rotation dudit élément de comptage (20) jusqu'à ce que ledit élément de comptage (20) ne coopère plus avec ledit premier engrenage fixe (110), après un déplacement axial prédéterminé dudit élément de comptage (20) correspondant à ladite course d'actionnement partielle prédéterminée du distributeur.

17.- Distributeur selon la revendication 16, dans lequel ledit second engrenage fixe (120) du corps (1) et/ou ledit second engrenage (220) de l'élément de comptage (20) comporte(nt) des moyens de blocage empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique, lorsque l'élément de comptage (20) revient vers sa position de repos après un actionnement précédent jusqu'à ce que ledit distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

18.- Distributeur selon la revendication 17, dans lequel lesdits moyens de blocage comportent un profil d'extrémité axial plan formé sur les dents dudit second engrenage fixe (120) et dudit second engrenage (220), lesdites dents étant au moins partiellement face à face jusqu'à ce que l'élément de comptage (20) a accompli une rotation suffisante pour décaler lesdites dents, correspondant à ladite course de retour partielle prédéterminée du distributeur.

19.- Distributeur selon la revendication 17 ou 18, dans lequel ledit engrenage d'actionnement (300) comporte des moyens de butée (305) limitant la rotation de l'élément de comptage (20) jusqu'à ce que l'organe d'actionnement (30) a réalisé ladite course de retour partielle prédéterminée.

20.- Distributeur selon la revendication 19, dans lequel lesdits moyens de butée (305) comportent une projection axiale formée sur ledit engrenage d'actionnement (300).

21.- Distributeur selon l'une quelconque des revendications 16 à 20, dans lequel ledit organe d'actionnement (30) du distributeur est solidaire dudit réservoir (2) et se déplace axialement avec lui.

* * *

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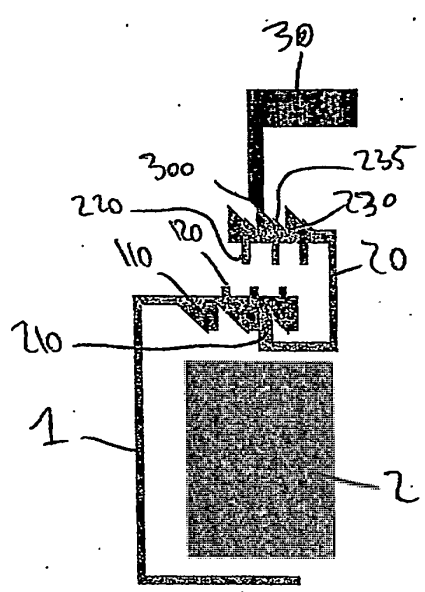


Fig. 1

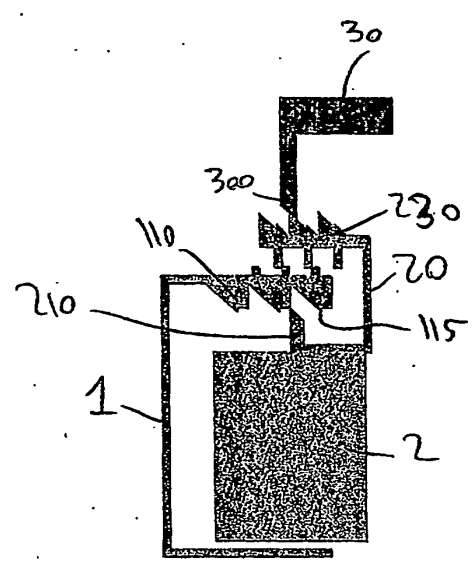


Fig. 2

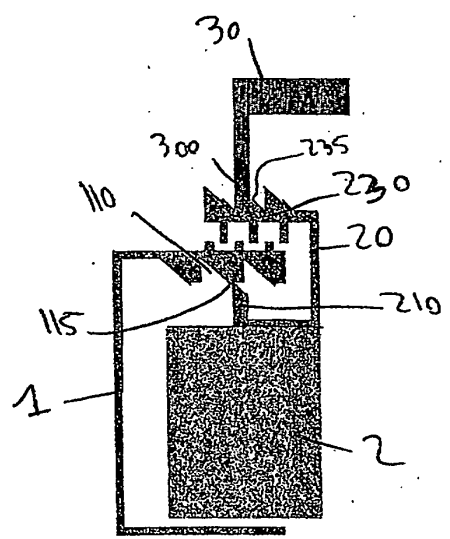


Fig. 3

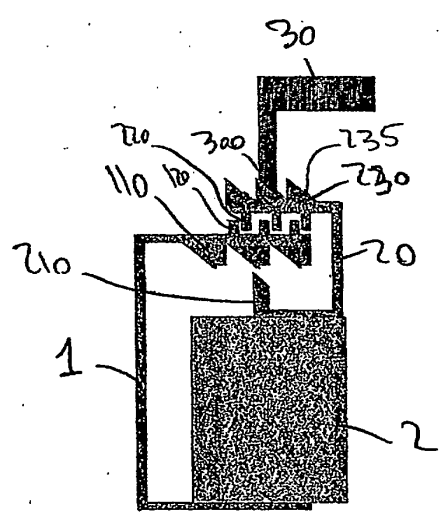


Fig. 4

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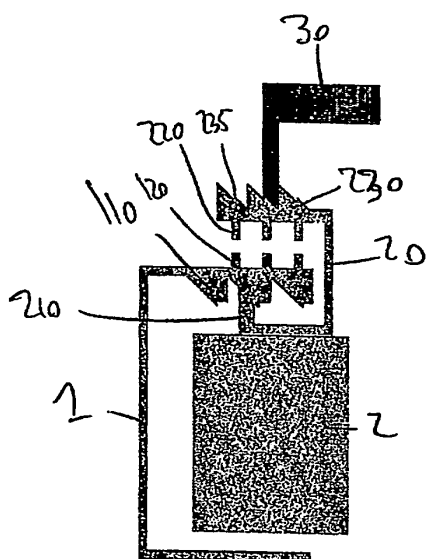


Fig. 5

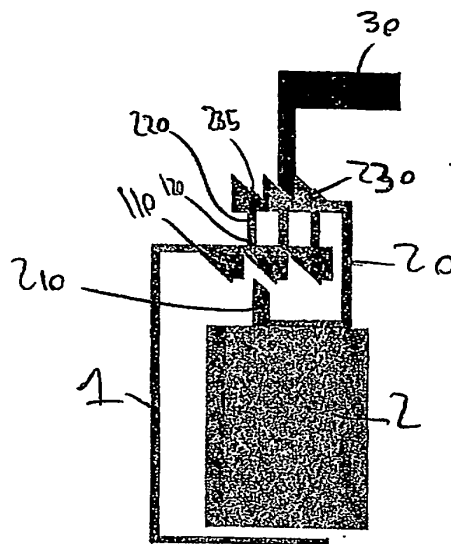


Fig. 6

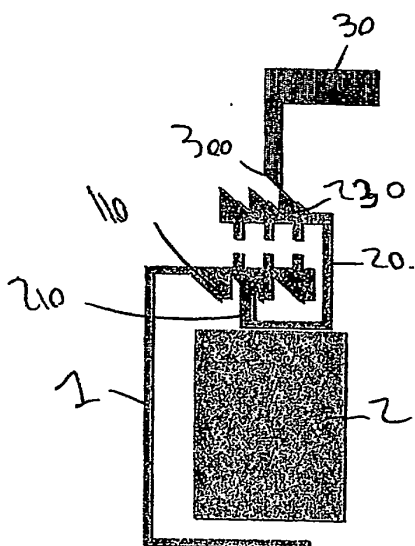


Fig. 7

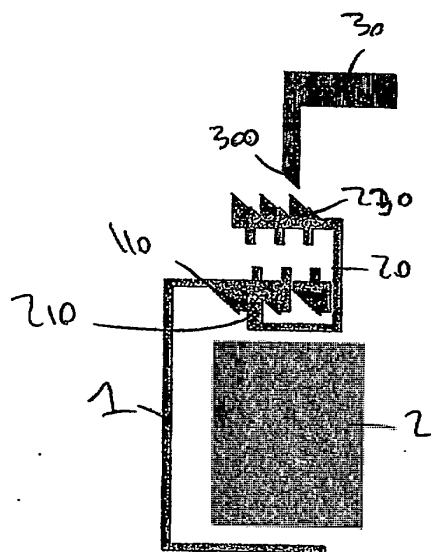


Fig. 8

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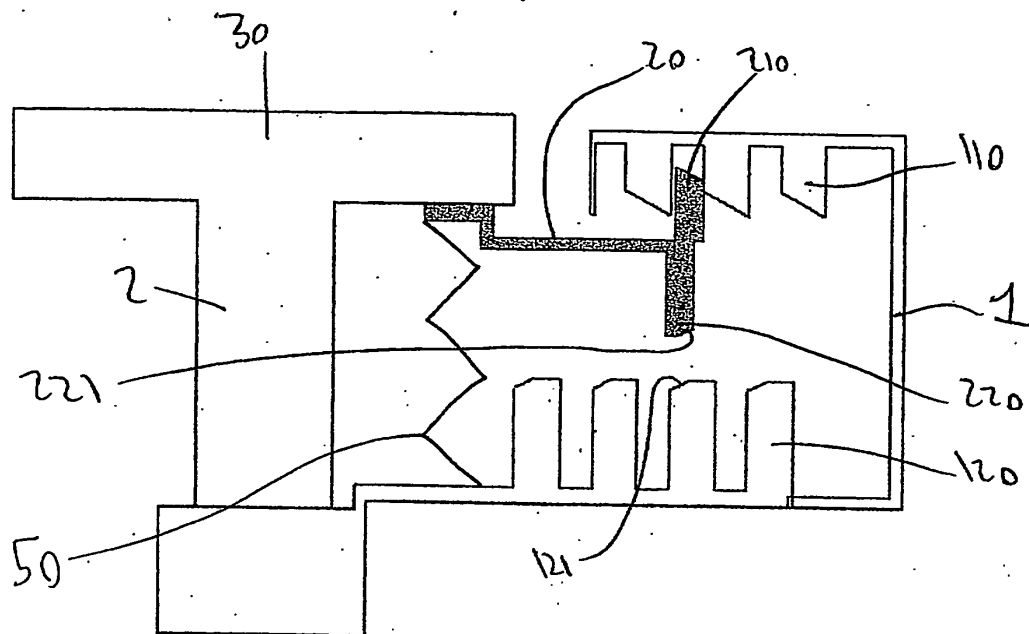


Fig. 9

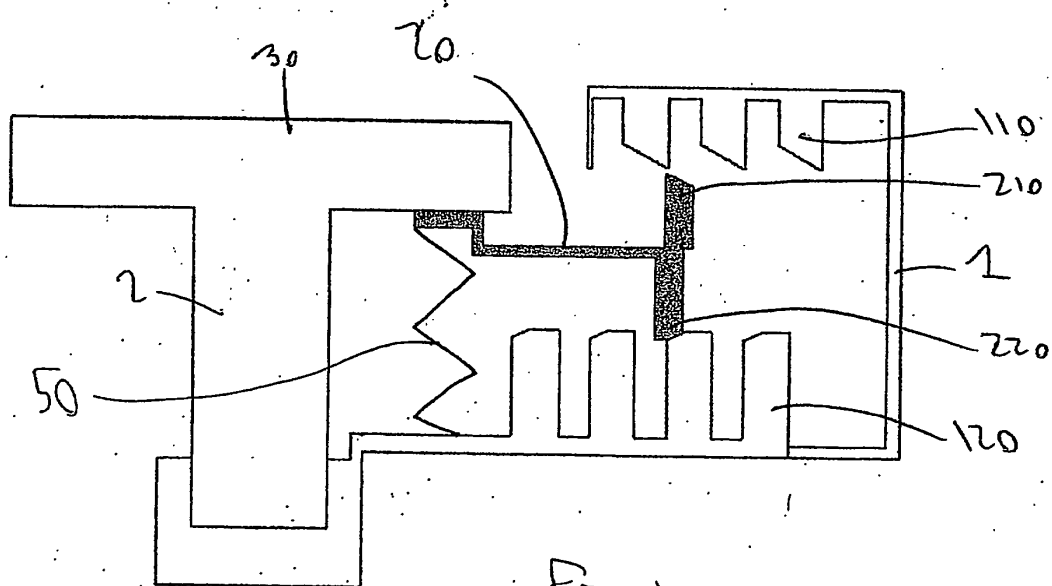
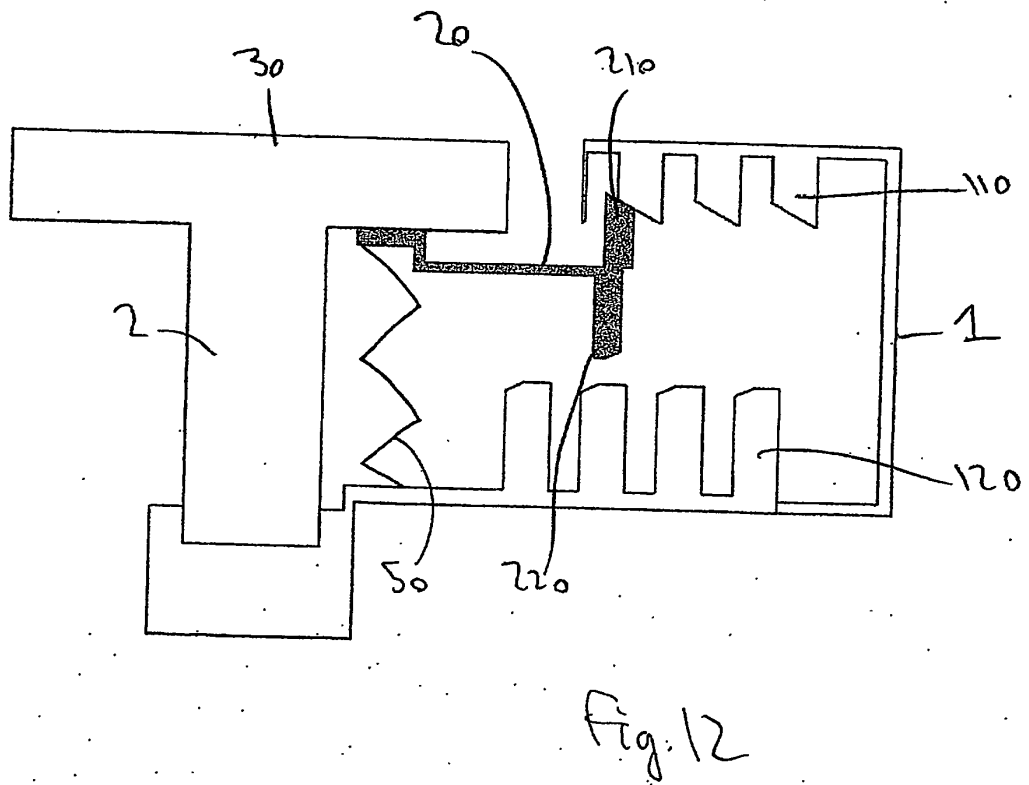
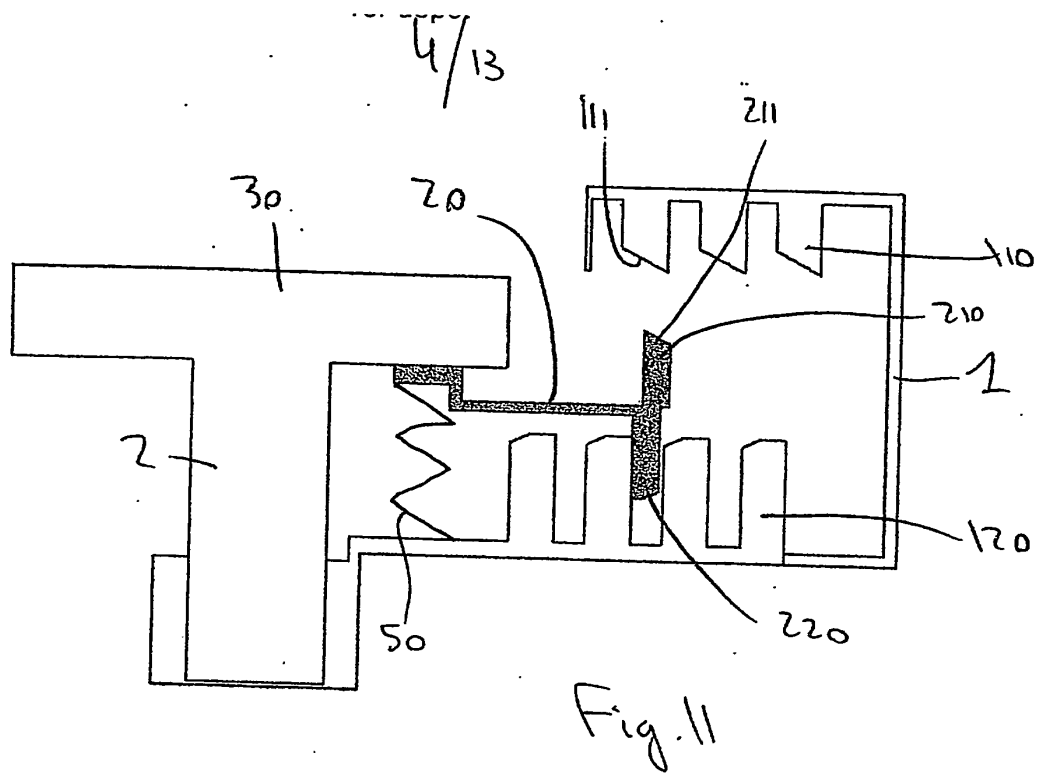


Fig. 10



This diagram shows a cross-sectional view of a mechanical assembly. A base component (1) features a series of vertical rectangular protrusions (20) on its top surface. A second component (2) is positioned above the base, with a horizontal section (30) and a vertical section (300). A third component (50) is located between the base and the second component, featuring a series of vertical rectangular protrusions (230) on its top surface. A fourth component (20) is positioned between the base and the third component, featuring a series of vertical rectangular protrusions (210) on its top surface. A fifth component (220) is positioned between the base and the fourth component, featuring a series of vertical rectangular protrusions (220) on its top surface. The components are shown in cross-section with hatching indicating different materials or sections.

Fig. 13

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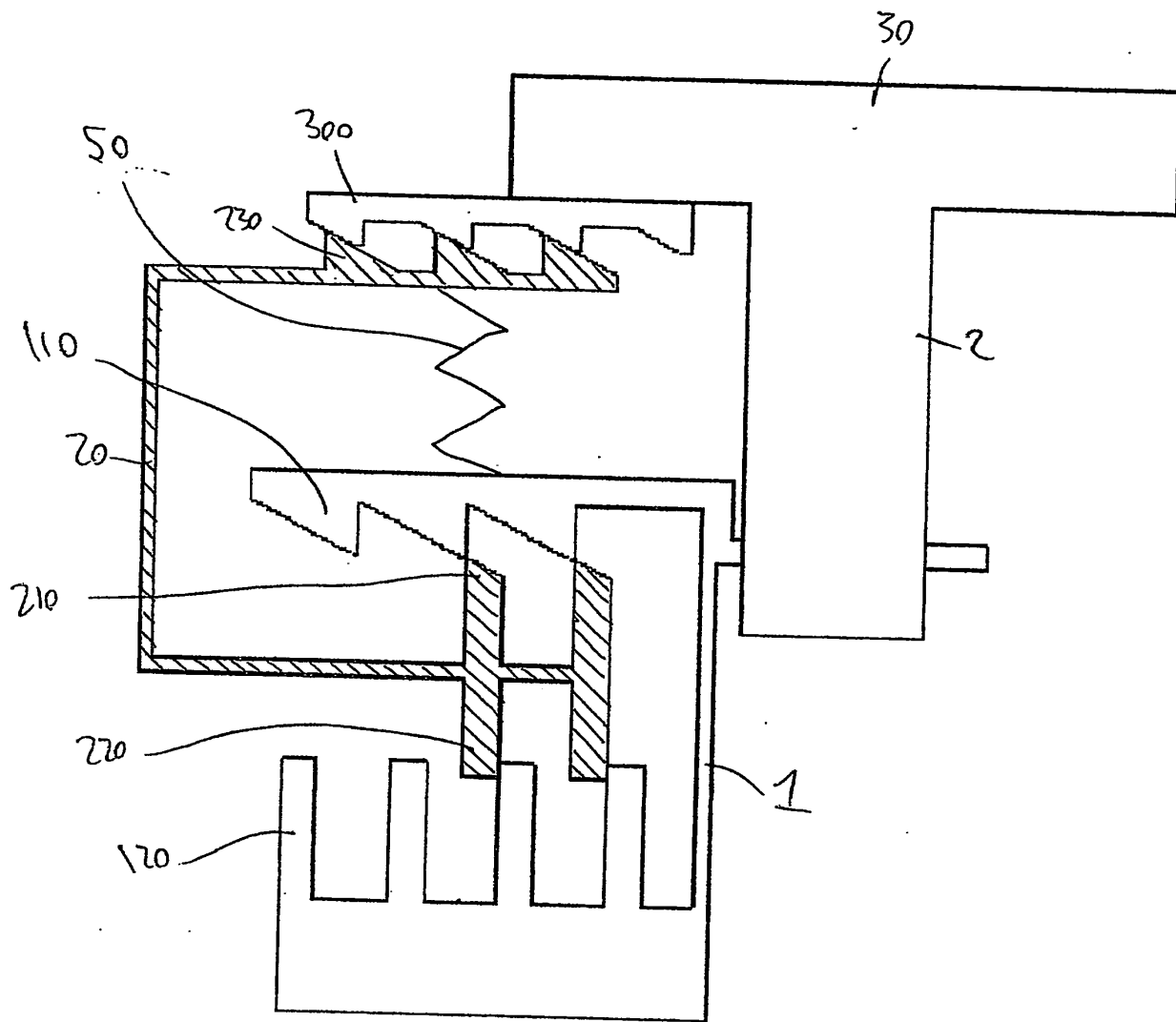


Fig. 14

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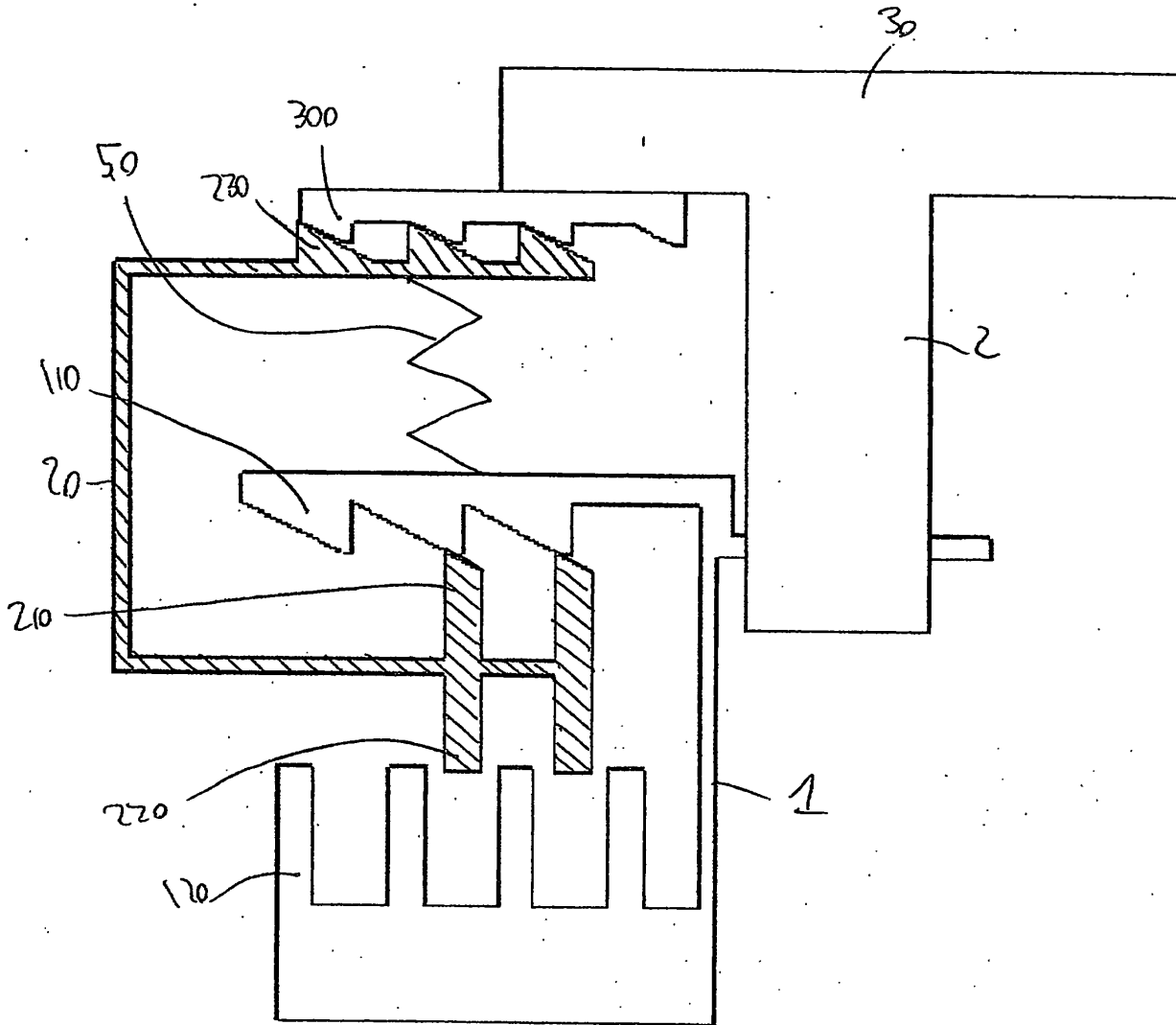


Fig. 15

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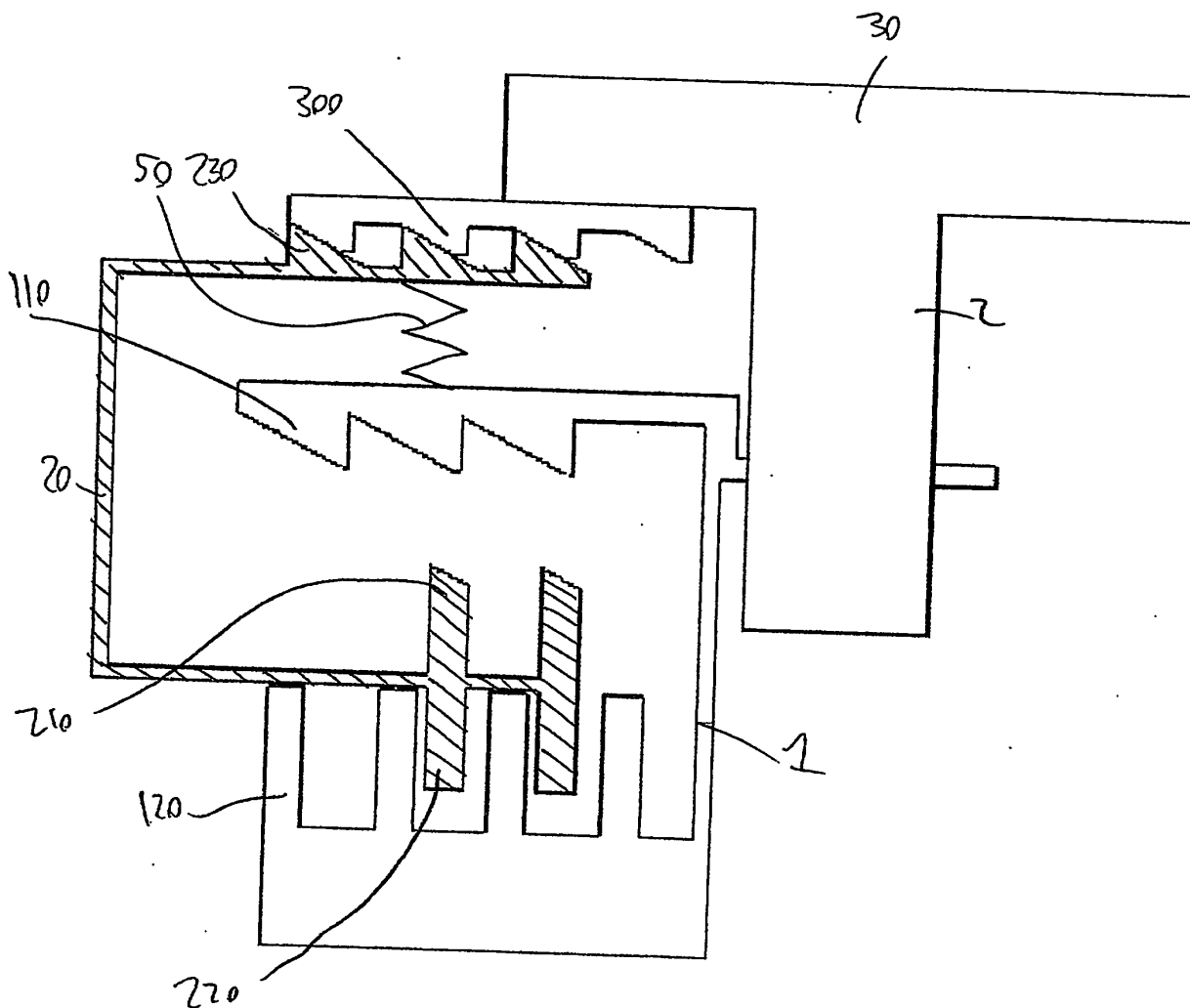


Fig. 16

[illegible]

Fig. 17

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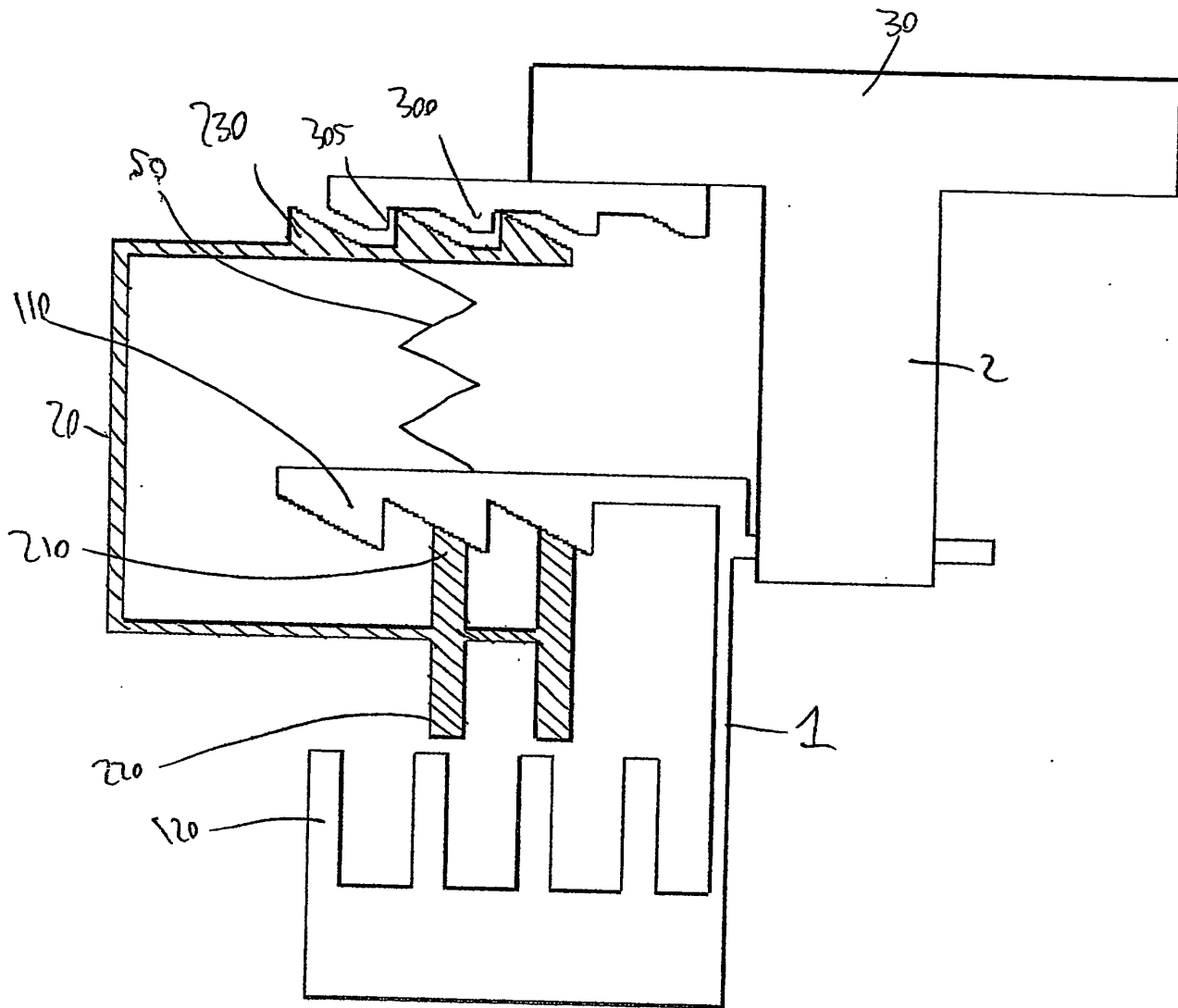


Fig. 18

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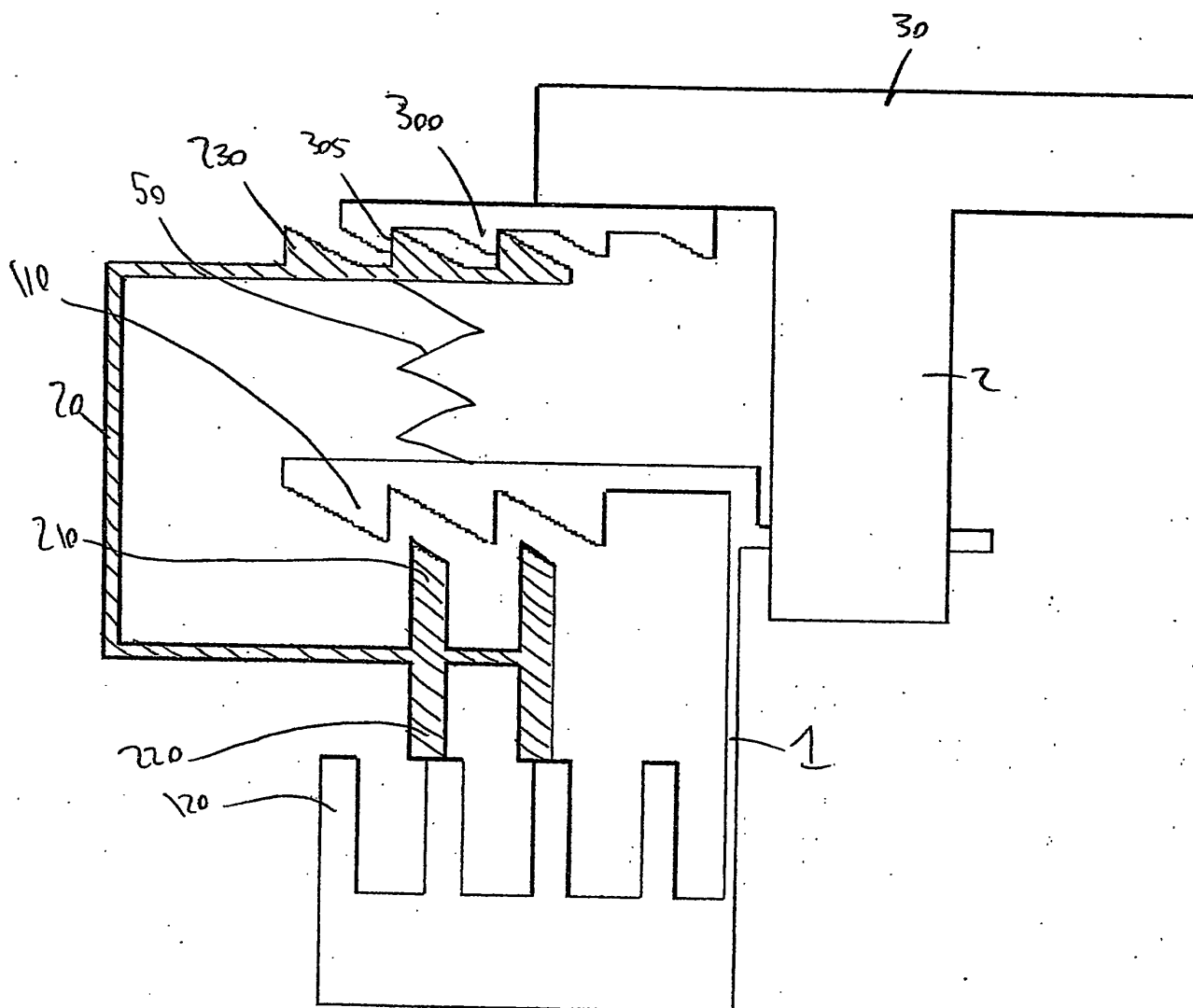


Fig. 19

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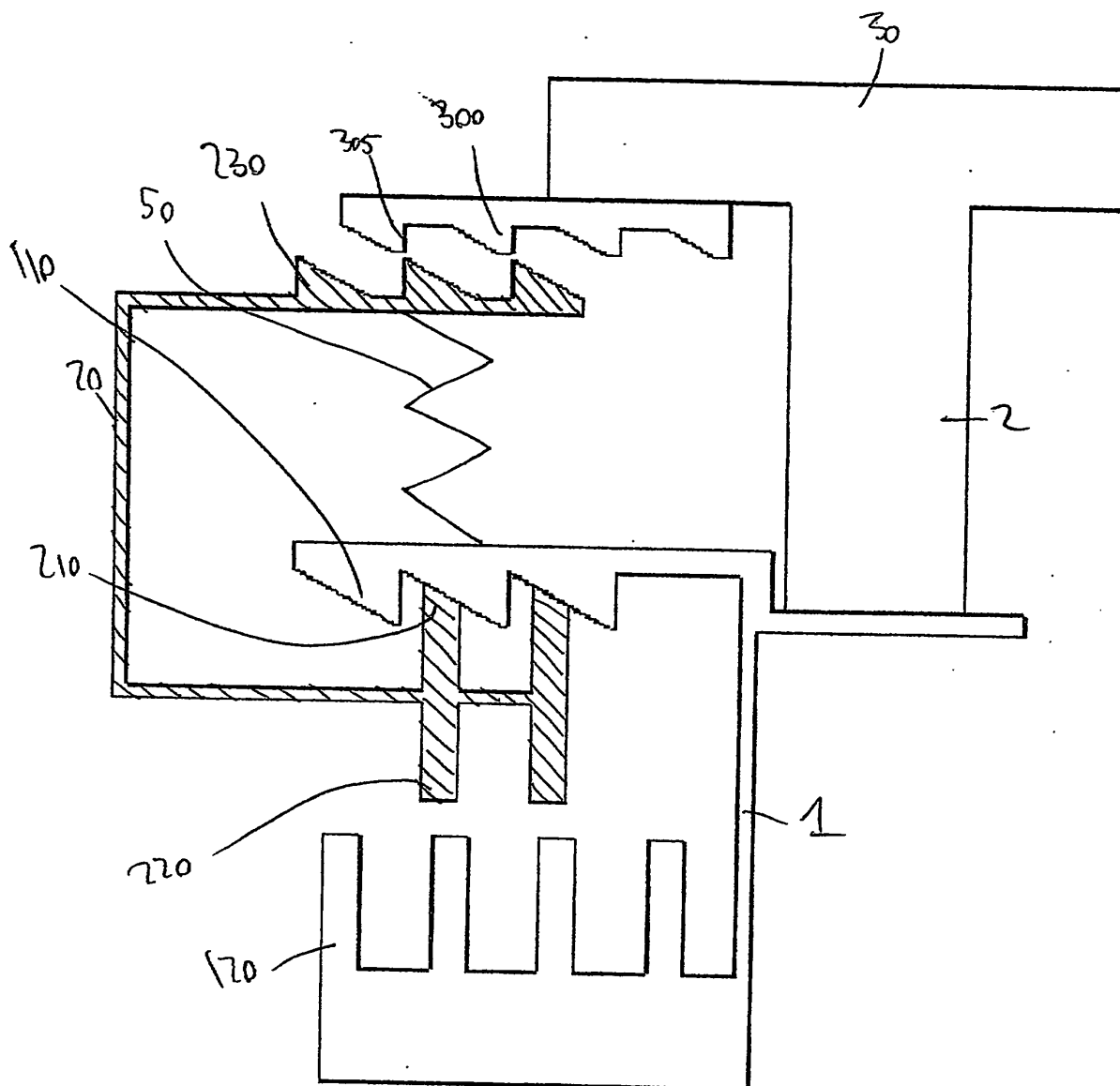


Fig. 20

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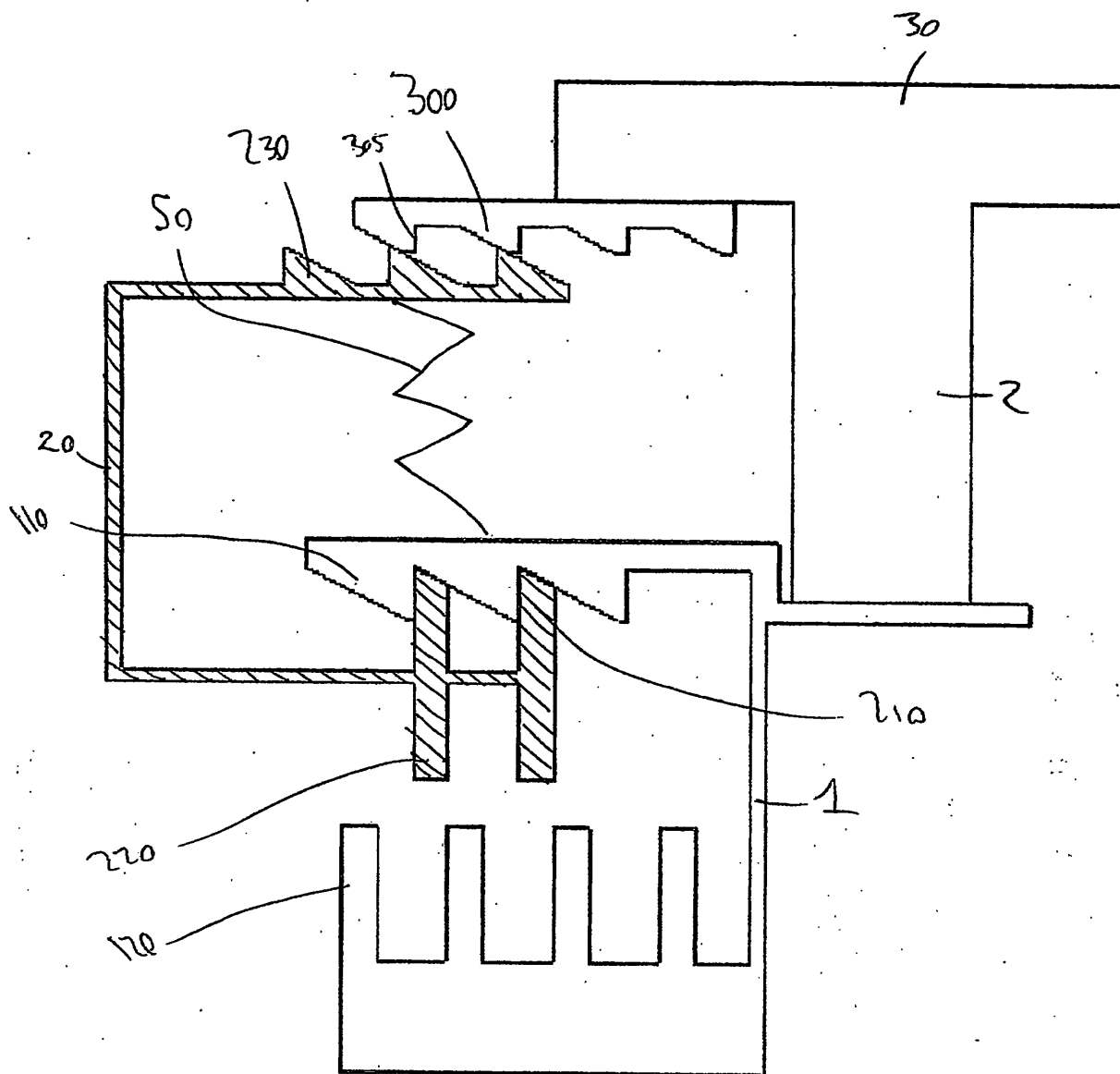


Fig. 21



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DÉSIGNATION D'INVENTEUR(S) Page N° 1../1..

(À fournir dans le cas où les demandeurs et les inventeurs ne sont pas les mêmes personnes)



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DISTRIBUTEUR DE PRODUIT FLUIDE.		
LE(S) DEMANDEUR(S) :		
La demanderesse, la société par actions simplifiée dite VALOIS SAS		
représentée par : CAPRI 94, avenue Mozart 75016 PARIS		
DESIGNE(NT) EN TANT QU'INVENTEUR(S) :		
1	Nom	POULARD
	Prénoms	Fabien
Adresse	Rue	Résidence Le Régency 12, rue de Crosne
	Code postal et ville	7 6 0 0 0 ROUEN
Société d'appartenance (<i>facultatif</i>)		
2	Nom	
	Prénoms	
Adresse	Rue	
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Société d'appartenance (<i>facultatif</i>)		
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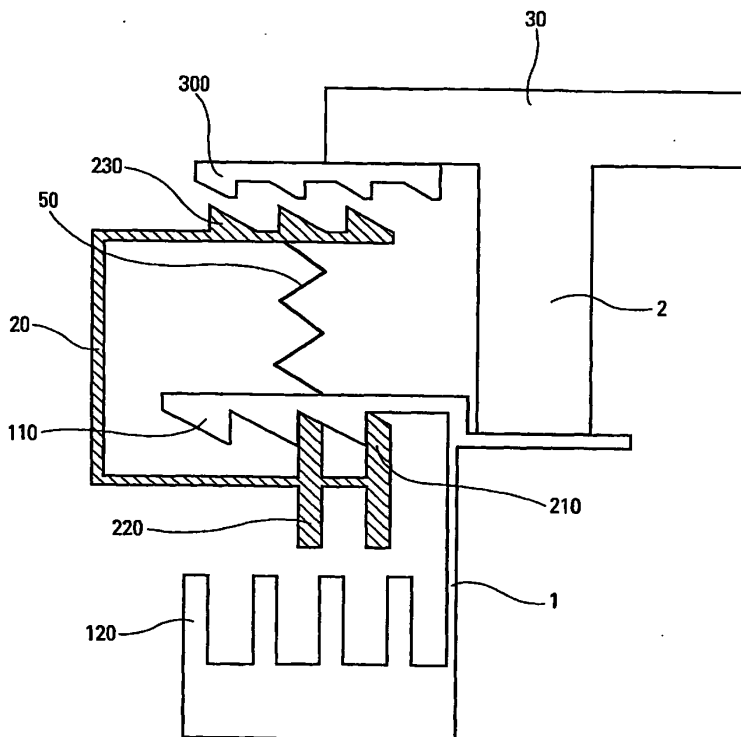
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- (74) Mandataire : **CAPRI**; 33 rue de Naples, F-75008 Paris (FR).
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[Suite sur la page suivante]

(54) Title: FLUID PRODUCT DISPENSER

(54) Titre : DISTRIBUTEUR DE PRODUIT FLUIDE



(57) Abstract: A fluid product dispenser, comprising a body (1), a fluid product reservoir (2), a dispensing element such as a pump or a valve which is mounted on said reservoir (2), and a dose-indicating device which indicates the number of doses of the dispensed product or which remain to be dispensed from said reservoir, characterized in that said dose-indicating device comprises a first safety system used to activate the dose-indicating device from a partial predetermined course of actuation of the dispenser even if the total course of activation is not carried out by the dispenser.

(57) Abrégé : Distributeur de produit fluide, comportant un corps (1), un réservoir de produit fluide (2), un organe de distribution, tel qu'une pompe ou une valve, monté sur ledit réservoir (2), et un dispositif d'indication de doses pour indiquer le nombre de doses de produit distribuées ou restant à distribuer à partir dudit réservoir, caractérisé en ce que ledit dispositif d'indication de doses comporte un premier système de sécurité destiné à

actionner le dispositif d'indication de doses à partir

[Suite sur la page suivante]

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d'une course d'actionnement partielle prédéterminée du distributeur, même si la course d'actionnement totale n'est pas réalisée par le distributeur.

Distributeur de produit fluide

La présente invention concerne un distributeur de produit fluide, et plus particulièrement un tel distributeur comportant un dispositif d'indication de doses pour indiquer à l'utilisateur le nombre de doses distribuées ou restant à distribuer à partir du réservoir dudit distributeur de produit fluide.

Les dispositifs d'indication de doses sont bien connus, et peuvent comporter soit des compteurs, affichant un chiffre correspondant au nombre de doses distribuées ou restant à distribuer, soit des indicateurs, informant l'utilisateur par des symboles, codes couleurs, chiffres similaire sur le nombre de doses distribuées ou restant à distribuer. En particulier dans les distributeurs de produit fluide contenant des produits pharmaceutiques, il est important que le dispositif d'indication de doses fonctionne de manière fiable, et notamment qu'il compte la distribution d'une dose à chaque fois que du produit est distribuée, que la dose soit complète ou partielle, par exemple en raison d'un actionnement défaillant ou interrompu avant la fin du cycle d'actionnement. En effet, il est généralement préférable de compter la distribution d'une dose incomplète, plutôt que de ne pas la compter, ce qui peut présenter un risque important vis-à-vis de l'utilisateur en lui indiquant un contenu du réservoir supérieur à la réalité. Dans les distributeurs de produit pharmaceutique, on souhaite donc généralement éviter tout risque de sous-comptage, notamment en permettant le comptage juste avant l'expulsion de produit actif. Un autre point important avec les dispositifs d'indication de doses de distributeur de produits pharmaceutiques, est qu'après un actionnement et une distribution d'une dose, lorsque le distributeur revient dans sa position de repos, tout nouvel actionnement réalisé avant la fin de la course de retour du distributeur et qui occasionnerait la distribution d'une dose complète ou partielle, devrait également être compté par le dispositif d'indication, pour à nouveau éviter tout risque de sous-comptage. Dans la plupart des distributeurs de produit fluide, après distribution d'une dose, la prochaine dose est chargée dans la chambre de l'organe de distribution (pompe ou valve) lors de la course de retour du distributeur vers sa position de repos.

Pour éviter tout risque de sous-comptage lors de la course de retour du distributeur, il est souhaitable que le distributeur de produit fluide soit bloqué à partir du moment où la course de retour a permis le remplissage de la chambre et jusqu'à ce que le dispositif d'indication soit de nouveau apte à compter
5 l'actionnement du distributeur.

La présente invention a pour but de fournir un distributeur de produit fluide qui remplit la ou les exigences susmentionnées.

En particulier, la présente invention a pour but de fournir un distributeur de produit fluide comportant un dispositif d'indication de doses, qui évite tout
10 risque de sous-comptage, c'est-à-dire qui garantisse l'actionnement du dispositif d'indication à chaque fois que du produit fluide est distribué par le distributeur de produit fluide.

La présente invention a également pour but de fournir un tel distributeur, qui évite de compter la distribution d'une dose, et donc d'actionner le dispositif
15 d'indication de doses lorsque l'actionnement du distributeur n'implique aucune distribution de produit fluide.

La présente invention a encore pour but de fournir un tel distributeur de produit fluide qui soit simple et peu coûteux à fabriquer et assembler, et fiable d'utilisation.

La présente invention a donc pour objet un distributeur de produit fluide, comportant un corps, un réservoir de produit fluide, un organe de distribution, tel qu'une pompe ou une valve, monté sur ledit réservoir, et un dispositif
20 d'indication de doses pour indiquer le nombre de doses de produit distribuées ou restant à distribuer à partir dudit réservoir, caractérisé en ce que ledit dispositif d'indication de doses comporte un premier système de sécurité destiné à
25 actionner le dispositif d'indication de doses à partir d'une course d'actionnement partielle prédéterminée du distributeur, même si la course d'actionnement totale n'est pas réalisée par le distributeur.

De préférence, ledit dispositif d'indication de doses comporte un second
30 système de sécurité qui, lors de la course retour du distributeur, après distribution d'une dose, empêche la prochaine expulsion de produit pharmaceutique jusqu'à

ce que ledit distributeur a accompli une course de retour partielle prédéterminée, ledit distributeur et ledit dispositif d'indication de doses pouvant à nouveau être actionnés à partir de cette course de retour partielle prédéterminée, même si la course de retour totale n'est pas réalisée par le distributeur et que celui-ci est actionné à nouveau avant de revenir à sa position de repos.

Avantageusement, ledit réservoir est déplaçable axialement par rapport audit corps, ledit corps comportant au moins un engrenage fixe, ledit dispositif d'indication de doses comportant un élément de comptage déplaçable axialement et en rotation par rapport audit corps, ledit élément de comptage coopérant d'une part avec ledit au moins un engrenage fixe dudit corps et d'autre part avec ledit réservoir lorsque le distributeur est actionné.

Selon un premier mode de réalisation de l'invention, ledit corps comporte un engrenage fixe coopérant avec un premier engrenage dudit élément de comptage, ledit élément de comptage comportant un second engrenage coopérant avec un engrenage d'actionnement d'un organe d'actionnement du distributeur, les dents dudit second engrenage et/ou dudit engrenage d'actionnement étant réalisées de telle sorte qu'un déplacement axial de l'organe d'actionnement sollicite ledit élément de comptage à se déplacer axialement et en rotation, l'engrenage fixe empêchant une rotation dudit élément de comptage jusqu'à ce que ledit élément de comptage ne coopère plus avec ledit engrenage fixe, après un déplacement axial prédéterminé dudit élément de comptage correspondant à ladite course d'actionnement partielle prédéterminée du distributeur.

Avantageusement, l'engrenage fixe comporte des moyens de butée bloquant en rotation ledit élément de comptage après au moins une rotation partielle dudit élément de comptage, un déplacement axial supplémentaire dudit élément de comptage étant nécessaire pour permettre la poursuite de sa rotation et/ou le retour du dispositif d'indication vers sa position de repos. Ces butées positionnent le second engrenage de l'élément de comptage de tel sorte que le distributeur soit bloqué à son retour avant le remplissage de la chambre et jusqu'à sa position de repos.

Avantageusement, lesdits moyens de butée comportent une projection axiale.

Avantageusement, ledit engrenage fixe et/ou ledit élément de comptage comporte(nt) des moyens de blocage empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique, lorsque
5 l'élément de comptage revient vers sa position de repos après un actionnement précédent, jusqu'à ce que le distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

Avantageusement, lesdits moyens de blocage comportent des projections axiales prévues respectivement sur le corps et sur l'élément de comptage, lesdites projections comportent chacune un profil d'extrémité axiale plan, lesdites projections étant au moins partiellement face à face jusqu'à ce que l'élément de comptage a accompli une rotation suffisante pour décaler lesdites projections
10 correspondant à ladite course de retour partielle prédéterminée du distributeur.

Avantageusement, les dents du second engrenage de l'élément de comptage comportant un palier intermédiaire, l'organe d'actionnement coopérant avec ledit palier lors de l'actionnement du distributeur, et coopérant avec le fond dudit second engrenage lors du retour vers la position de repos,
15 après actionnement, le déplacement entre le palier intermédiaire et le fond étant obtenu par rotation dudit élément de comptage.

Avantageusement, lorsque la course de retour partielle prédéterminée a été réalisée, l'organe d'actionnement est placé face à la dent suivante du second engrenage de l'élément de comptage, permettant un nouvel actionnement du distributeur et du dispositif d'indication de doses.
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Selon un second mode de réalisation de la présente invention, ledit corps comporte un premier engrenage fixe et un second engrenage fixe, ledit élément de comptage comportant un premier engrenage destiné à coopérer avec ledit premier engrenage fixe, et un second engrenage destiné à coopérer avec ledit
25 second engrenage fixe, ledit élément de comptage étant axialement mis en contact avec l'organe d'actionnement du distributeur par l'intermédiaire d'un
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ressort de rappel et étant déplaçable en rotation par rapport audit organe d'actionnement, les dents dudit second engrenage et second engrenage fixe étant au moins partiellement obliques de telle sorte qu'un déplacement axial de l'organe d'actionnement sollicite d'abord ledit élément de comptage à se déplacer axialement sur une course d'actionnement partielle prédéterminée, jusqu'à ce que la partie oblique dudit second engrenage de l'élément de comptage coopère avec ladite partie oblique dudit second engrenage fixe, sollicitant l'élément de comptage à se déplacer en rotation sur une première partie de cycle de rotation, les dents desdits premier engrenage et premier engrenage fixe étant au moins partiellement obliques de telle sorte que lorsque l'élément de comptage revient vers sa position de repos, il est sollicité en rotation pour terminer son cycle de rotation correspondant au comptage d'un actionnement du distributeur.

Avantageusement, lesdits premier et second engrenages fixes du corps et/ou lesdits premier et second engrenages de l'élément de comptage sont décalés l'un par rapport à l'autre de telle sorte que dès que l'élément de comptage est déplaçable en rotation, un retour de celui-ci vers sa position de repos sans terminer la course d'actionnement du distributeur entraîne la rotation de l'élément de comptage sur son cycle complet de rotation, garantissant le comptage d'un actionnement du distributeur après ladite course d'actionnement partielle prédéterminée.

Avantageusement, ledit second engrenage fixe du corps et/ou ledit second engrenage de l'élément de comptage comporte(nt) des moyens de blocage empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique lorsque l'élément de comptage revient vers sa position de repos après un actionnement précédent jusqu'à ce que ledit distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

Avantageusement, lesdits moyens de blocage comportent un profil d'extrémité axial au moins partiellement plan formé sur les dents dudit second engrenage fixe du corps et dudit second engrenage de l'élément de comptage,

lesdits profils plan desdites dents étant au moins partiellement face à face jusqu'à ce que l'élément de comptage a accompli une rotation suffisante pour décaler lesdites dents, correspondant à ladite course de retour partielle prédéterminée du distributeur.

5 Avantageusement, ledit organe d'actionnement du distributeur est solidaire dudit réservoir et se déplace axialement avec lui.

 Selon un troisième mode de réalisation de la présente invention, ledit corps comporte un premier engrenage fixe et un second engrenage fixe, ledit élément de comptage comportant un premier engrenage destiné à coopérer avec
10 ledit premier engrenage fixe, un second engrenage destiné à coopérer avec ledit second engrenage fixe, et un troisième engrenage destiné à coopérer avec un engrenage d'actionnement, solidaire d'un organe d'actionnement du distributeur, les dents dudit troisième engrenage et/ou dudit engrenage d'actionnement étant réalisées de tel sorte qu'un déplacement axial de l'organe d'actionnement
15 sollicite ledit élément de comptage à se déplacer axialement et en rotation, le premier engrenage fixe empêchant une rotation dudit élément de comptage jusqu'à ce que ledit élément de comptage ne coopère plus avec ledit premier engrenage fixe, après un déplacement axial prédéterminé dudit élément de comptage correspondant à ladite course d'actionnement partielle prédéterminée
20 du distributeur.

 Avantageusement, ledit second engrenage fixe du corps et/ou ledit second engrenage de l'élément de comptage comporte(nt) des moyens de blocage empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique lorsque l'élément de comptage revient
25 vers sa position de repos après un actionnement précédent jusqu'à ce que ledit distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

 Avantageusement, lesdits moyens de blocage comportent un profil d'extrémité axial plan formé sur les dents dudit second engrenage fixe et dudit
30 second engrenage, lesdites dents étant au moins partiellement face à face jusqu'à ce que l'élément de comptage a accompli une rotation suffisante pour décaler

lesdites dents, correspondant à ladite course de retour partielle prédéterminée du distributeur.

Avantageusement, ledit engrenage d'actionnement comporte des moyens de butée limitant la rotation de l'élément de comptage jusqu'à ce que l'organe d'actionnement a réalisé ladite course de retour partielle prédéterminée.

Avantageusement, lesdits moyens de butée comportent une projection axiale formée sur ledit engrenage d'actionnement.

Avantageusement, ledit organe d'actionnement du distributeur est solidaire dudit réservoir et se déplace axialement avec lui.

D'autres caractéristiques et avantages de la présente invention apparaîtront plus clairement au cours de la description détaillée suivante de trois modes de réalisation de celle-ci, faite en référence aux dessins joints, donnés à titre d'exemples non limitatifs, et sur lesquels

- les figures 1 à 8 sont des représentations schématiques d'un distributeur de produit fluide selon un premier mode de réalisation de la présente invention, montrant les positions successives lors d'un cycle d'actionnement du distributeur ;

- les figures 9 à 12 sont des représentations schématiques d'un distributeur selon un second mode de réalisation de la présente invention, montrant également diverses positions dans le cycle d'actionnement du distributeur ; et

- les figures 13 à 21 sont des représentations schématiques d'un distributeur de produit fluide selon un troisième mode de réalisation de la présente invention, montrant différentes positions dans le cycle d'actionnement du distributeur.

Les descriptions des trois modes de réalisation qui vont être faites ci-après concernent les cycles d'actionnement du distributeur et les différentes spécificités fonctionnelles du dispositif d'indication permettant de garantir la fiabilité de fonctionnement et de comptage dudit dispositif d'indication. Les dessins auxquels la présente description fera référence sont donc des schémas très simplifiés, qui ne représentent pas le distributeur de produit fluide en détail, mais seulement de manière très schématisée par les différentes parties déplaçables les

une par rapport aux autres, pour permettre l'explication du cycle d'actionnement dudit distributeur et dudit dispositif d'indication. Ainsi par exemple, l'organe de distribution, par exemple une pompe ou une valve, n'est pas représentée sur les dessins. De même, la tête de distribution comportant l'orifice de distribution n'est pas non plus représentée, ces éléments n'intervenant pas directement dans la présente invention.

Il est à noter que la présente invention s'applique plus particulièrement aux dispositifs dits MDI (METERED DOSE INHALER), qui comportent une valve doseuse montée sur un réservoir contenant du produit fluide et un gaz propulseur, le déplacement du réservoir par rapport à la soupape de la valve engendrant la distribution d'une dose de produit au moyen dudit gaz propulseur. La présente invention n'est pas limitée à cette application particulière, mais celle-ci représente l'application préférée de la présente invention.

En référence aux figures 1 à 8, nous allons décrire un premier mode de réalisation de la présente invention. Selon ce premier mode de réalisation, le distributeur comporte un réservoir 2 déplaçable axialement dans un corps 1, qui sera ci-après considéré comme la partie fixe du distributeur. Le déplacement axial du réservoir 2 par rapport au corps 1 actionne l'organe de distribution et donc réalise la distribution d'une dose de produit hors dudit réservoir. Selon ce premier mode de réalisation, le distributeur comporte un organe d'actionnement 30 sur lequel l'utilisateur exerce une force d'actionnement axial pour réaliser l'actionnement du distributeur et donc pour déplacer ledit réservoir 2 par rapport au corps 1. Le distributeur comporte en outre un dispositif d'indication de doses destinées à compter ou à indiquer à chaque actionnement du distributeur la distribution d'une dose de produit fluide. L'utilisateur peut donc grâce à ce dispositif d'indication savoir combien de doses ont été distribuées hors dudit réservoir 2, ou combien de doses restent à l'intérieur dudit réservoir 2. Cette information doit être très précise, en particulier lorsque le produit fluide est un produit pharmaceutique et tout risque de sous-comptage doit être éliminé. En effet, dans l'hypothèse d'un sous-comptage, c'est-à-dire lorsque le dispositif d'indication ne compte pas une ou plusieurs distribution(s) partielle(s) ou

complète(s) de dose de produit, l'utilisateur peut se retrouver avec un distributeur lui indiquant qu'il reste une ou deux dose(s) dans le réservoir, alors qu'en réalité le réservoir est vide. En cas de crise, l'utilisateur peut donc se retrouver avec un distributeur ne fonctionnant plus et ne lui permettant pas de prendre son médicament.

La présente invention permet d'éviter tout risque de sous-comptage. Pour ce faire, le dispositif d'indication de doses comporte au moins un système de sécurité, et de préférence deux. Le premier système de sécurité est destiné à garantir l'actionnement du dispositif d'indication de doses, et donc le comptage de la distribution d'une dose de produit, à partir du moment où, lors de l'actionnement du distributeur, une course partielle prédéterminée a été parcourue. Le second système de sécurité est destiné à empêcher, pendant la course de retour du distributeur, l'expulsion de dose tant que le dispositif d'indication de doses n'est pas prêt à compter la prochaine dose. En effet, la chambre de dosage du distributeur se remplit généralement lors de la phase retour du distributeur vers sa position de repos, après un actionnement précédent. Si cette course de retour n'est pas complète mais que le dispositif est actionné à nouveau avant qu'il ne revienne vers sa position de repos, il serait possible que du produit soit distribué. Or, si le dispositif d'indication de doses n'est pas revenu dans sa position de repos ou proche de celle-ci, il ne pourra pas compter cette distribution de produit. Il se produirait alors un sous-comptage. Pour éviter ceci, le second système de sécurité bloque tout nouvel actionnement, ou pour le moins toute distribution de produit. Ce blocage sera réalisé jusqu'à ce que la course de retour soit suffisante pour que le dispositif d'indication de dose puisse être de nouveau actionné et qu'il compte la prochaine dose.

En résumé, la présente invention fournit un ou deux système(s) de sécurité qui évite(nt) tout risque de sous-comptage du dispositif d'indication.

Nous allons ci-après d'abord décrire le premier système de sécurité, en référence aux figures 1 à 4.

En se référant à ces figures, on constate que le corps fixe 1 comporte un engrenage fixe 110 et que le dispositif d'indication comporte un élément de

comptage 20 destiné à coopérer d'une part avec ledit engrenage fixe 110 du corps 1, et d'autre part avec l'organe d'actionnement 30 et/ou le réservoir 2. Plus particulièrement, l'élément de comptage 20 est déplaçable axialement par rapport au corps 1 ainsi qu'en rotation par rapport à celui-ci. L'élément de comptage 20 comporte un premier engrenage 210 destiné à coopérer avec ledit engrenage fixe 110 du corps et un second engrenage 230 destiné à coopérer avec un engrenage d'actionnement 300 solidaire de l'organe d'actionnement 30.

En se référant aux figures 1 et 4, il est représenté la première moitié d'un cycle d'actionnement du distributeur, c'est-à-dire le déplacement du distributeur de la position de repos (représenté sur la figure 1) vers la position d'actionnement (représenté sur la figure 4). Ainsi, lorsque l'utilisateur appuie sur l'organe d'actionnement 30 pour déplacer celui-ci axialement vers le bas sur la figure 1, le profil oblique des dents de l'engrenage d'actionnement 300 et du second engrenage 230 de l'élément de comptage sollicite l'élément de comptage 20 en déplacement axial vers le bas et aussi en rotation en raison du profil oblique des engrenages susmentionnés. Or, tant que le premier engrenage 210 de l'élément de comptage 20 coopère avec l'engrenage fixe 110 du corps 1, toute rotation de l'élément de comptage 20 est empêchée. Par conséquent, au début de la course d'actionnement du distributeur, et donc de l'organe d'actionnement 30, l'élément de comptage 20 est uniquement déplacé axialement ensemble avec l'organe d'actionnement 30, sans pouvoir tourner. Lorsque le système arrive dans la position représentée sur la figure 2, le déplacement axial de l'élément de comptage 20 a également provoqué le déplacement axial du réservoir 2 sur une première partie de course d'actionnement. Dans la position de la figure 2, le premier engrenage 210 de l'élément de comptage 20 arrive dans une position où il ne coopère plus avec l'engrenage fixe 110 du corps 1. De cette manière, l'élément de comptage, qui est sollicité en rotation par la force exercée sur l'organe d'actionnement 30, peut tourner par rapport au corps 1. A partir du moment où l'élément de comptage va un peu tourner, le dispositif d'indication de doses est actionné et le comptage d'une dose de produit est initié. Cette course partielle de déplacement axiale de l'élément de comptage 20 correspond à ladite

course d'actionnement partielle prédéterminée du distributeur, plus particulièrement du réservoir 2. En effet, dans ce type de distributeur, la dose de produit n'est pas nécessairement expulsée en toute fin de course d'actionnement, mais à partir d'une course partielle prédéterminée, qui est fonction du déplacement de la soupape dans une valve, ou du déplacement du piston dans une pompe. En faisant correspondre la coopération du premier engrenage 210 de l'élément de comptage avec l'engrenage fixe 110 du corps 1 avec ladite course d'actionnement partielle prédéterminée du distributeur, on assure dès que du produit fluide risque d'être distribué hors du réservoir 2, le dispositif d'indication compte cette distribution.

La figure 3 montre que l'engrenage fixe 110 du corps 1 comporte des moyens de butée 115, de préférence formés par une projection axiale coopérant avec le premier engrenage 210 de l'élément de comptage 20, et qui impose un nouveau déplacement axial de l'élément de comptage, très faible mais non nul, pour permettre un engrenement suffisant de l'engrenage d'actionnement 300 dans le premier palier, marqué par la butée 235 sur le second engrenage 230. Ainsi la chambre du distributeur ne pourra pas être rempli si la butée 215 n'est pas dépassée. Si elle est passée l'engrenage d'actionnement 300 se positionnera dans le second palier ou fond du second engrenage 230 de l'élément de comptage 20 avant remplissage de la chambre du distributeur pour bloquer l'expulsion de produit pharmaceutique comme il représenté sur la figure 6.

Une poursuite de la course d'actionnement amène le réservoir 2 dans la position représentée sur la figure 4, dans laquelle la course d'actionnement totale a été réalisée, et la totalité de la dose a été expulsée hors du réservoir. Toutefois, on constate que même si la force exercée par l'utilisateur cesse sur l'organe d'actionnement 30 avant la fin de la course d'actionnement totale, à partir du moment où la course d'actionnement partielle a été réalisée, le dispositif d'indication a compté la distribution de la dose, de sorte que tout sous-comptage est évité à ce niveau là.

En référence aux figures 5 à 8, on va décrire la seconde phase du cycle d'actionnement du distributeur, à savoir le retour de la position de distribution

vers la position de repos (représenté sur la figure 8). En se référant à la figure 5, on constate que lorsque l'utilisateur lâche sa pression sur l'organe d'actionnement 30, le ressort de rappel (non représenté) du distributeur amène le réservoir 2 vers sa position de repos en déplaçant axialement le réservoir 2 par rapport au corps 1 dans le sens inverse à celui du déplacement d'actionnement décrit précédemment. Le déplacement du réservoir 2 provoque un déplacement axial de l'élément de comptage 20 de sorte que le premier engrenage 210 vient à nouveau coopérer avec l'engrenage fixe 110 du corps 1, mais cette fois au niveau des parties obliques, ce qui implique une rotation dudit élément de comptage, pour terminer le cycle de comptage du dispositif d'indication. Lorsque l'élément de comptage tourne par rapport au corps 1 lors de la course de retour, on constate que l'organe d'actionnement 30 vient coopérer avec le fond du second engrenage 230 de l'élément de comptage 20, alors que pendant la phase d'actionnement, l'engrenage d'actionnement 300 coopérait avec le premier palier, marqué par la butée 235, réalisée sur ledit second engrenage 230 de l'élément de comptage 20.

La figure 6 représente schématiquement une tentative de nouvel actionnement avant la fin de la course de retour du distributeur. On constate que le corps 1 comporte des projections axiales 120 qui coopèrent avec des projections axiales 220 réalisées sur l'élément de comptage 20. En variante, ces projections axiales 120, 220 peuvent être remplacée par des engrenages ayant une forme correspondante. De préférence, les profils d'extrémités axiales desdites projections 120 et 220 sont réalisées par des plans et ces projections axiales 120 et 220 sont au moins partiellement disposées face à face, de sorte que si la course de retour du distributeur est insuffisante, il est impossible d'expulser une nouvelle dose de produit, comme cela est représenté sur la figure 6. Pour pouvoir à nouveau actionner le distributeur, il faut que l'élément de comptage 20 tourne suffisamment autour de son axe de rotation pour que lesdites projections 120 et 220 soient décalées l'une par rapport à l'autre, et ainsi permettre un nouvel actionnement. Ce décalage sera réalisé en libérant l'organe d'actionnement 30 du fond du second engrenage 230 de l'élément de comptage

20 pour le positionner en face du premier palier, marqué par la butée 235, de la dent suivante. Ce nouvel actionnement peut être permis avant la fin de la course de retour totale du distributeur après que le dispositif d'indication soit de nouveau apte à compter un nouvel actionnement du distributeur. La présente invention permet de remplir cette exigence, comme le montre la figure 7 dans laquelle la course de retour n'est pas complète, mais l'organe d'actionnement 30 du distributeur et notamment l'engrenage d'actionnement 300 est dans une position où il peut coopérer avec la prochaine dent du second engrenage 230 de l'élément de comptage, de sorte qu'un nouvel actionnement à ce moment là provoque la rotation de l'élément de comptage sur la fin de son cycle précédent, ce qui amène le décalage desdites projections axiales 120 et 220, et autorisent donc un nouvel actionnement du distributeur et du dispositif d'indication de doses. Le but est de bloquer l'expulsion quand la chambre est remplie tant que le compteur n'est pas prêt à compter une prochaine dose.

Dans la figure 8, le dispositif est revenu vers sa position de repos initiale et un nouveau cycle d'actionnement peut être réalisé.

Les figures 9 à 12 représentent un deuxième mode de réalisation de l'invention. Ce deuxième mode de réalisation diffère du premier mode de réalisation par les points suivants. D'une part, le corps 1 comporte deux engrenages fixes 110 et 120 et l'élément de comptage 20 comporte deux engrenages 210, 220, chacun coopérant avec un des engrenages fixes du corps. L'organe d'actionnement 30 est solidaire du réservoir 2 et l'élément de comptage 20 est déplaçable axialement avec ledit organe d'actionnement 30. Il peut se déplacer en rotation par rapport audit organe d'actionnement 30. En fait, dans ce second mode de réalisation, il n'y a pas véritablement d'organe d'actionnement, mais l'utilisateur déplace généralement le réservoir 2 lui-même par rapport au corps 1 pour réaliser l'actionnement. Le second engrenage fixe 120 du corps 1 et le second engrenage 220 de l'élément de comptage comportent au moins partiellement une partie oblique respectivement 121 et 221, qui coopèrent l'une avec l'autre lors de l'actionnement du distributeur. Ces parties obliques sollicitent l'élément de comptage 20 à se déplacer en rotation, et donc à initier un

cycle de comptage du dispositif d'indication de doses. Comme représenté sur les figures 9 et 10, lors de l'actionnement du distributeur, l'élément de comptage est d'abord déplacé axialement sans tourner en étant solidaire de l'organe d'actionnement 30 et du réservoir 2. Lorsque le distributeur a réalisé la course d'actionnement partielle prédéterminée, les parties obliques 220, 221 des seconds engrenages 120, 220 coopèrent pour faire tourner l'organe d'actionnement comme représenté sur la figure 10.

On constate que si dans la position représentée sur la figure 10, l'utilisateur arrête d'actionner le distributeur, le système revient vers sa position de repos grâce à un ressort de rappel 50 et le cycle de comptage se complète puisque le premier engrenage 210 de l'élément de comptage 20 vient coopérer avec les dents du premier engrenage fixe 110 pour solliciter encore d'avantage l'élément de comptage 20 en rotation pour l'amener à la fin de son cycle de comptage. Le premier système de sécurité est donc réalisé en ce que l'actionnement du dispositif d'indication de doses est assuré à partir du moment où le distributeur a réalisé sa course d'actionnement partielle prédéterminé à partir de laquelle une dose de produit (complète ou partielle) peut être distribuée.

La figure 11 montre la position d'actionnement dans laquelle la course d'actionnement totale a été réalisée, et la figure 12 illustre le second système de sécurité, réalisé aux moyens du second engrenage fixe 120 et du second engrenage 220 de l'élément de comptage 20. En effet, ces deux engrenages comportent également respectivement une partie plane, ayant un profil d'extrémité axiale plan, de sorte que lorsque la course de retour du distributeur n'est pas suffisante, comme visible sur la figure 12, un nouvel actionnement du système provoque une butée axiale entre l'élément de comptage 20 et le second engrenage fixe 220 par l'intermédiaire de leur partie d'extrémité plane, ce qui empêche l'expulsion de produit pharmaceutique en bloquant l'actionnement du distributeur. Ce n'est qu'à partir du moment où une course de retour partielle prédéterminée est réalisée, que les parties obliques des seconds engrenages 120 et 220 sont face à face pour permettre un nouvel actionnement et du distributeur et du dispositif d'indication de doses.

Les figures 13 à 21 montrent un troisième mode de réalisation de la présente invention. Ce troisième mode de réalisation diffère du second mode de réalisation en ce que l'élément de comptage 20 n'est pas solidaire axialement de l'organe d'actionnement 30 et du réservoir. L'organe d'actionnement 30 et le réservoir 2 comportent un engrenage d'actionnement 300 qui coopère avec une troisième engrenage 230 réalisé sur l'élément de comptage 20. Dans ce troisième mode de réalisation, la rotation de l'élément de comptage 20 lors de la course d'actionnement du distributeur n'est donc plus provoquée par le second engrenage fixe 120, mais aux moyens du troisième engrenage 230 et de l'engrenage d'actionnement 300. En faite, ce troisième mode de réalisation combine les premiers et seconds modes de réalisation décrits précédemment. En début d'actionnement, lorsqu'on est dans la situation de la figure 13, la coopération entre le premier engrenage fixe 110 et le premier engrenage 210 de l'élément de comptage 20 empêche une rotation de l'élément de comptage 20 et donc provoque un déplacement axial de celui-ci. Lorsqu'on arrive dans la position représentée sur la figure 14, les premiers engrenages susmentionnés ne coopèrent plus et les profils obliques des dents de l'engrenage d'actionnement 300 et du troisième engrenage 230 de l'élément de comptage 20 provoque une rotation de l'élément de comptage 20. Ceci est réalisé à partir de ladite course d'actionnement partielle du distributeur à partir de laquelle une dose complète ou partielle de produit peut être distribuée. La figure 15 montre que si la force d'actionnement axial est supprimée à partir de ce moment là, le dispositif de comptage, grâce au ressort de rappel 50 amènera l'élément de comptage à tourner sur son cycle complet de comptage, évitant ainsi tout risque de sous-comptage.

La figure 16 montre la position d'actionnement finale dans laquelle la course d'actionnement totale a été réalisée. A ce moment là, lorsque l'utilisateur relâche la force d'actionnement sur l'organe d'actionnement 30, le système remonte sous l'effet du ressort de rappel 50 et la coopération entre les premiers engrenages 210 et 110 respectivement de l'élément de comptage 20 et du corps 1 provoque la poursuite de la rotation de l'élément de comptage. Cette poursuite

de la rotation est bloquée dans l'engrenage d'actionnement 300 par des moyens de butée 305. En référence à la figure 18, si l'utilisateur appuie à nouveau sur l'organe d'actionnement 30 dans cette position, on constate que l'actionnement du distributeur et du dispositif de comptage est bloqués par le fait que le deuxième engrenage 220 de l'élément de comptage et le deuxième engrenage fixe 120 du corps 1 sont face à face, au niveau de leur profil d'extrémité axiale plan. La figure 19 illustre une tentative d'actionnement alors que le second système de sécurité est opérationnel. Pour permettre un nouvel actionnement du distributeur et du dispositif d'indication de doses, il faut qu'une course de retour partielle prédéterminée soit réalisée, qui est représentée sur la figure 20. En effet, à partir de cette position, si l'utilisateur actionne à nouveau, il provoquera une rotation de l'élément de comptage 20 qui permettra un nouvel actionnement du distributeur et du dispositif d'indication.

Enfin, la figure 21 montre la position dans laquelle une telle tentative d'actionnement supplémentaire est réalisée après que ladite course de retour partielle est été complétée.

Il est entendu que la description détaillée des trois modes de réalisation, donnée ci-dessus, n'est pas limitative, et que d'autres variantes de réalisation sont envisageables sans sortir du cadre de la présente invention, tel que défini par les revendications annexées.

Revendications

1.- Distributeur de produit fluide, comportant un corps (1), un réservoir de produit fluide (2), un organe de distribution, tel qu'une pompe ou une valve, monté sur ledit réservoir (2), et un dispositif d'indication de doses pour indiquer le nombre de doses de produit distribuées ou restant à distribuer à partir dudit réservoir, caractérisé en ce que ledit dispositif d'indication de doses comporte un premier système de sécurité destiné à actionner le dispositif d'indication de doses à partir d'une course d'actionnement partielle prédéterminée du distributeur, même si la course d'actionnement totale n'est pas réalisée par le distributeur.

2.- Distributeur selon la revendication 1, dans lequel ledit dispositif d'indication de doses comporte un second système de sécurité qui, lors de la course de retour du distributeur, après distribution d'une dose, empêche la prochaine expulsion de produit jusqu'à ce que ledit distributeur a accompli une course de retour partielle prédéterminée, ledit distributeur et ledit dispositif d'indication de doses pouvant à nouveau être actionnés à partir de cette course de retour partielle prédéterminée, même si la course de retour totale n'est pas réalisée par le distributeur et que celui-ci est actionné à nouveau avant de revenir à sa position de repos.

3.- Distributeur selon la revendication 1 ou 2, dans lequel ledit réservoir (2) est déplaçable axialement par rapport audit corps (1), ledit corps (1) comportant au moins un engrenage fixe (110, 120), ledit dispositif d'indication de doses comportant un élément de comptage (20) déplaçable axialement et en rotation par rapport audit corps (1), ledit élément de comptage (20) coopérant d'une part avec ledit au moins un engrenage fixe (110, 120) dudit corps et d'autre part avec ledit réservoir (2) lorsque le distributeur est actionné.

4.- Distributeur selon la revendication 3, dans lequel ledit corps (1) comporte un engrenage fixe (110) coopérant avec un premier engrenage (210) dudit élément de comptage (20), ledit élément de comptage (20) comportant un second engrenage (230) coopérant avec un engrenage

d'actionnement (300) d'un organe d'actionnement (30) du distributeur, les dents dudit second engrenage (230) et/ou dudit engrenage d'actionnement (300) étant réalisées de telle sorte qu'un déplacement axial de l'organe d'actionnement sollicite ledit élément de comptage (20) à se déplacer axialement et en rotation, l'engrenage fixe (110) empêchant une rotation dudit élément de comptage (20) jusqu'à ce que ledit élément de comptage (20) ne coopère plus avec ledit engrenage fixe (110), après un déplacement axial prédéterminé dudit élément de comptage (20) correspondant à ladite course d'actionnement partielle prédéterminée du distributeur.

5.- Distributeur selon la revendication 4, dans lequel l'engrenage fixe (110) comporte des moyens de butée (115) bloquant en rotation ledit élément de comptage (20) après au moins une rotation partielle dudit élément de comptage (20), un déplacement axial supplémentaire dudit élément de comptage (20) étant nécessaire pour permettre la poursuite de sa rotation et/ou le retour du dispositif d'indication vers sa position de repos.

6.- Distributeur selon la revendication 5, dans lequel lesdits moyens de butée (115) comportent une projection axiale.

7.- Distributeur selon l'une quelconque des revendications 3 à 6, dans lequel ledit engrenage fixe (110) et/ou ledit élément de comptage (20) comporte(nt) des moyens de blocage (120, 220) empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique, lorsque l'élément de comptage (20) revient vers sa position de repos après un actionnement précédent, jusqu'à ce que le distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

8.- Distributeur selon la revendication 7, dans lequel lesdits moyens de blocage comportent des projections axiales (120, 220) prévues respectivement sur le corps (1) et sur l'élément de comptage (20), lesdites projections (120, 220) comportant chacune un profil d'extrémité axiale plan, lesdites projections (120, 220) étant au moins partiellement face à face

jusqu'à ce que l'élément de comptage (20) a accompli une rotation suffisante pour décaler lesdites projections (120, 220) correspondant à ladite course de retour partielle prédéterminée du distributeur.

5 9.- Distributeur selon la revendication 8, dans lequel les dents du second engrenage (230) de l'élément de comptage (20) comportent un palier intermédiaire (235), l'organe d'actionnement (30) coopérant avec ledit palier (235) lors de l'actionnement du distributeur, et coopérant avec le fond dudit second engrenage (230) lors du retour vers la position de repos, après actionnement, le déplacement entre le palier intermédiaire
10 (235) et le fond étant obtenu par rotation dudit élément de comptage (20).

10.- Distributeur selon la revendication 8 ou 9, dans lequel, lorsque la course de retour partielle prédéterminée a été réalisée, l'organe d'actionnement (30) est placé face à la dent suivante du second engrenage (230) de l'élément de comptage (20), permettant un nouvel actionnement
15 du distributeur et du dispositif d'indication de doses.

11.- Distributeur selon la revendication 3, dans lequel ledit corps (1) comporte un premier engrenage fixe (110) et un second engrenage fixe (120), ledit élément de comptage (20) comportant un premier engrenage (210) destiné à coopérer avec ledit premier engrenage fixe (110), et un
20 second engrenage (220) destiné à coopérer avec ledit second engrenage fixe (120), ledit élément de comptage (20) étant axialement mis en contact avec l'organe d'actionnement (30) du distributeur par l'intermédiaire d'un ressort de rappel (50) et étant déplaçable en rotation par rapport audit organe d'actionnement (30), les dents dudit second engrenage (220) et
25 second engrenage fixe (120) étant au moins partiellement obliques de telle sorte qu'un déplacement axial de l'organe d'actionnement (30) sollicite d'abord ledit élément de comptage (20) à se déplacer axialement sur une course d'actionnement partielle prédéterminée, jusqu'à ce que la partie oblique (221) dudit second engrenage (220) de l'élément de comptage (20)
30 coopère avec ladite partie oblique (121) dudit second engrenage fixe (120), sollicitant l'élément de comptage (20) à se déplacer en rotation sur une

première partie de cycle de rotation, les dents desdits premier engrenage (210) et premier engrenage fixe (110) étant au moins partiellement obliques de telle sorte que lorsque l'élément de comptage (20) revient vers sa position de repos, il est sollicité en rotation pour terminer son cycle de rotation correspondant au comptage d'un actionnement du distributeur.

12.- Distributeur selon la revendication 11, dans lequel lesdits premier et second engrenages fixes (110, 120) du corps (1) et/ou lesdits premier et second engrenages (210, 220) de l'élément de comptage (20) sont décalés l'un par rapport à l'autre de telle sorte que dès que l'élément de comptage (20) est déplaçable en rotation, un retour de celui-ci vers sa position de repos sans terminer la course d'actionnement du distributeur entraîne la rotation de l'élément de comptage (20) sur son cycle complet de rotation, garantissant le comptage d'un actionnement du distributeur après ladite course d'actionnement partielle prédéterminée.

13.- Distributeur selon l'une quelconque des revendications 11 ou 12, dans lequel ledit second engrenage fixe (120) du corps (1) et/ou ledit second engrenage (220) de l'élément de comptage (20) comporte(nt) des moyens de blocage empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique, lorsque l'élément de comptage (20) revient vers sa position de repos après un actionnement précédent jusqu'à ce que ledit distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

14.- Distributeur selon la revendication 13, dans lequel lesdits moyens de blocage comportent un profil d'extrémité axial au moins partiellement plan formé sur les dents dudit second engrenage fixe (120) du corps (1) et dudit second engrenage (220) de l'élément de comptage (20), lesdits profils plan desdites dents étant au moins partiellement face à face jusqu'à ce que l'élément de comptage (20) a accompli une rotation suffisante pour décaler lesdites dents, correspondant à ladite course de retour partielle prédéterminée du distributeur.

15.- Distributeur selon l'une quelconque des revendications 11 à 14, dans lequel ledit organe d'actionnement (30) du distributeur est solidaire dudit réservoir (2) et se déplace axialement avec lui.

5 16.- Distributeur selon la revendication 3, dans lequel ledit corps (1) comporte un premier engrenage fixe (110) et un second engrenage fixe (120), ledit élément de comptage (20) comportant un premier engrenage (210) destiné à coopérer avec ledit premier engrenage fixe (110), un second engrenage (220) destiné à coopérer avec ledit second engrenage fixe (120), et un troisième engrenage (230) destiné à coopérer avec un engrenage
10 d'actionnement (300), solidaire d'un organe d'actionnement (30) du distributeur, les dents dudit troisième engrenage (230) et/ou dudit engrenage d'actionnement (300) étant réalisées de tel sorte qu'un déplacement axial de l'organe d'actionnement (30) sollicite ledit élément de comptage (20) à se déplacer axialement et en rotation, le premier engrenage
15 fixe (110) empêchant une rotation dudit élément de comptage (20) jusqu'à ce que ledit élément de comptage (20) ne coopère plus avec ledit premier engrenage fixe (110), après un déplacement axial prédéterminé dudit élément de comptage (20) correspondant à ladite course d'actionnement partielle prédéterminée du distributeur.

20 17.- Distributeur selon la revendication 16, dans lequel ledit second engrenage fixe (120) du corps (1) et/ou ledit second engrenage (220) de l'élément de comptage (20) comporte(nt) des moyens de blocage empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique, lorsque l'élément de comptage (20)
25 revient vers sa position de repos après un actionnement précédent jusqu'à ce que ledit distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

30 18.- Distributeur selon la revendication 17, dans lequel lesdits moyens de blocage comportent un profil d'extrémité axial plan formé sur les dents dudit second engrenage fixe (120) et dudit second engrenage (220), lesdites

dents étant au moins partiellement face à face jusqu'à ce que l'élément de comptage (20) a accompli une rotation suffisante pour décaler lesdites dents, correspondant à ladite course de retour partielle prédéterminée du distributeur.

5 19.- Distributeur selon la revendication 17 ou 18, dans lequel ledit engrenage d'actionnement (300) comporte des moyens de butée (305) limitant la rotation de l'élément de comptage (20) jusqu'à ce que l'organe d'actionnement (30) a réalisé ladite course de retour partielle prédéterminée.

10 20.- Distributeur selon la revendication 19, dans lequel lesdits moyens de butée (305) comportent une projection axiale formée sur ledit engrenage d'actionnement (300).

15 21.- Distributeur selon l'une quelconque des revendications 16 à 20, dans lequel ledit organe d'actionnement (30) du distributeur est solidaire dudit réservoir (2) et se déplace axialement avec lui.

* * *

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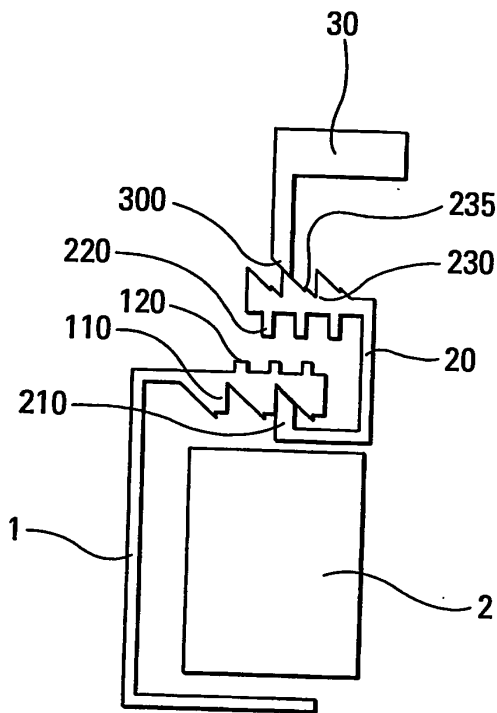


Fig. 1

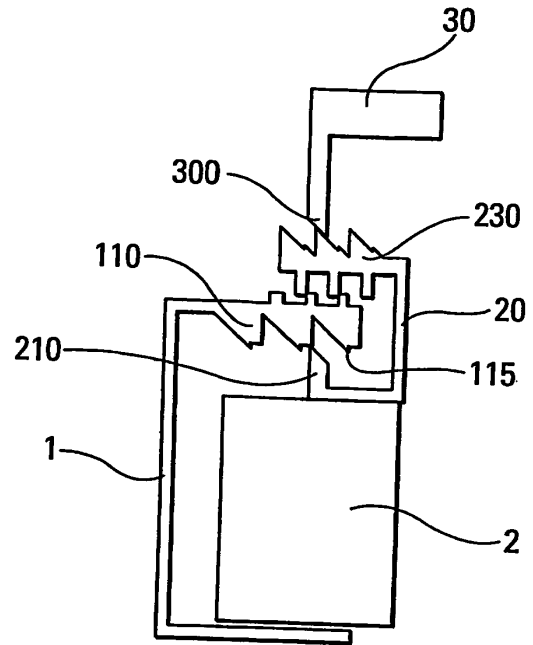


Fig. 2

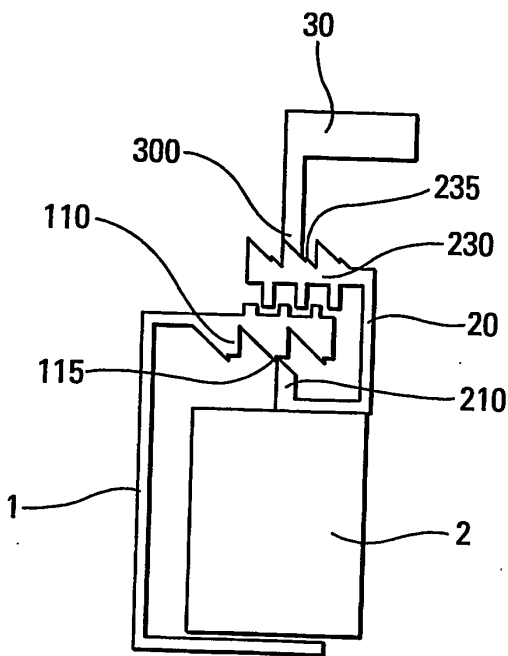


Fig. 3

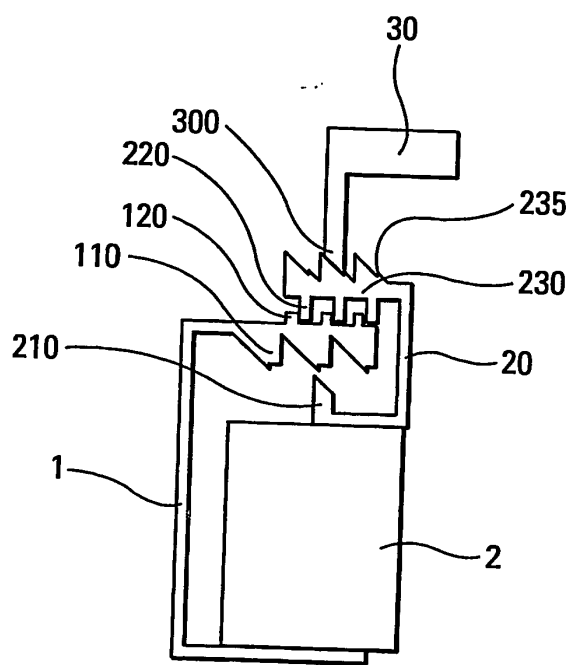


Fig. 4

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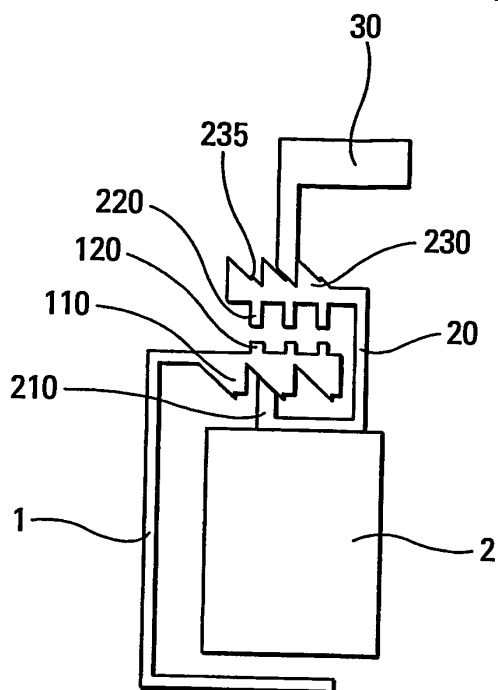


Fig. 5

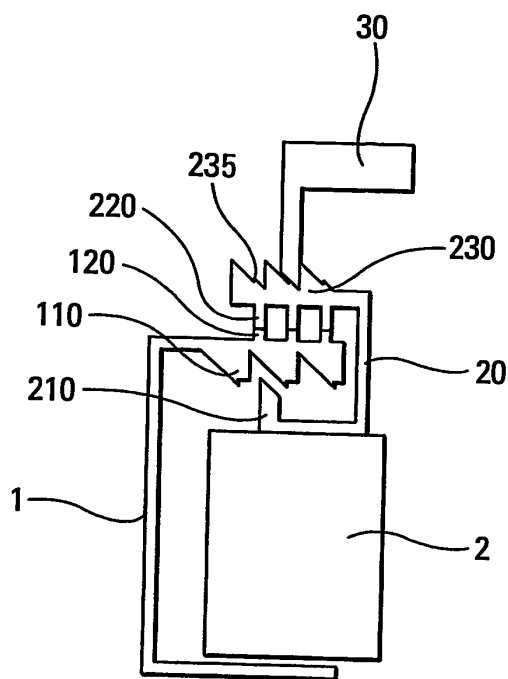


Fig. 6

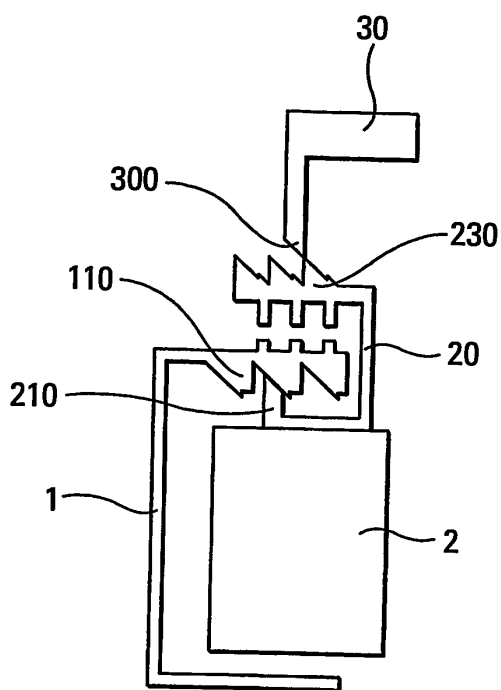


Fig. 7

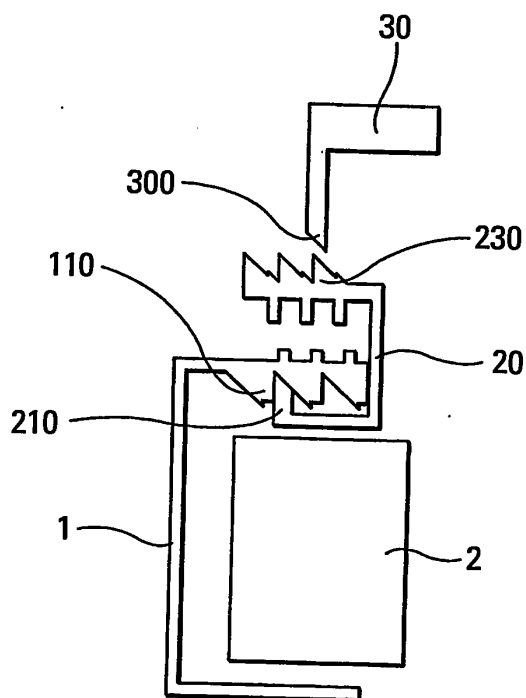


Fig. 8

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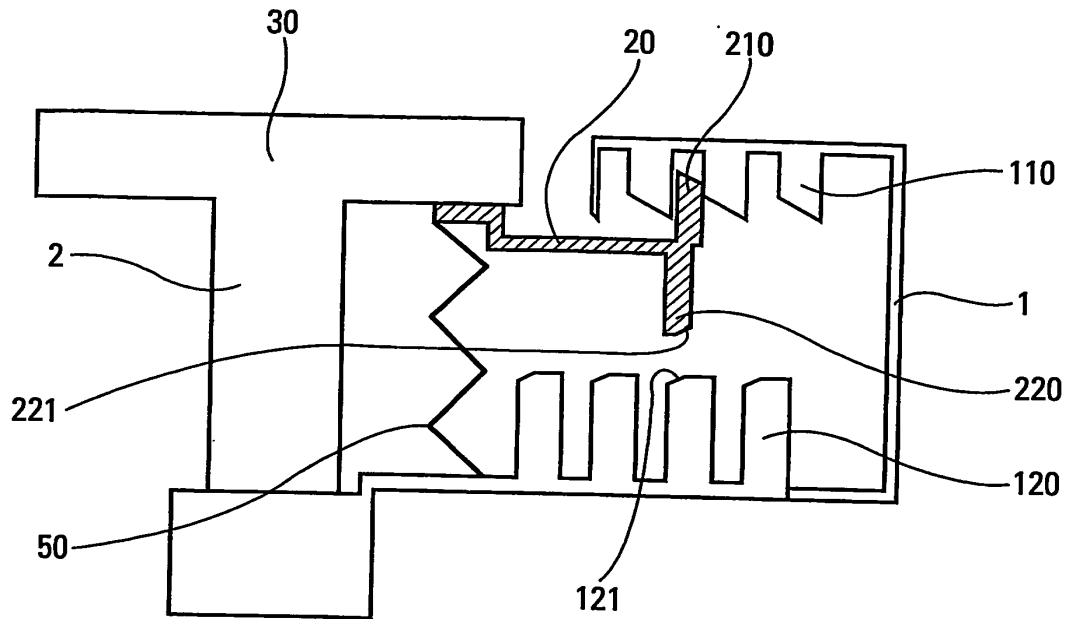


Fig. 9

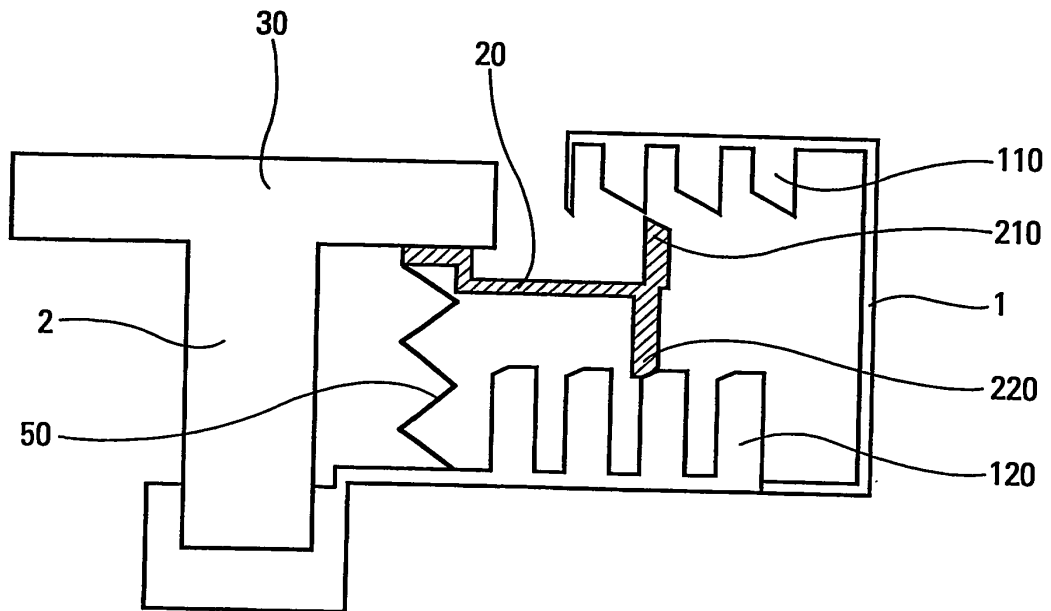


Fig. 10

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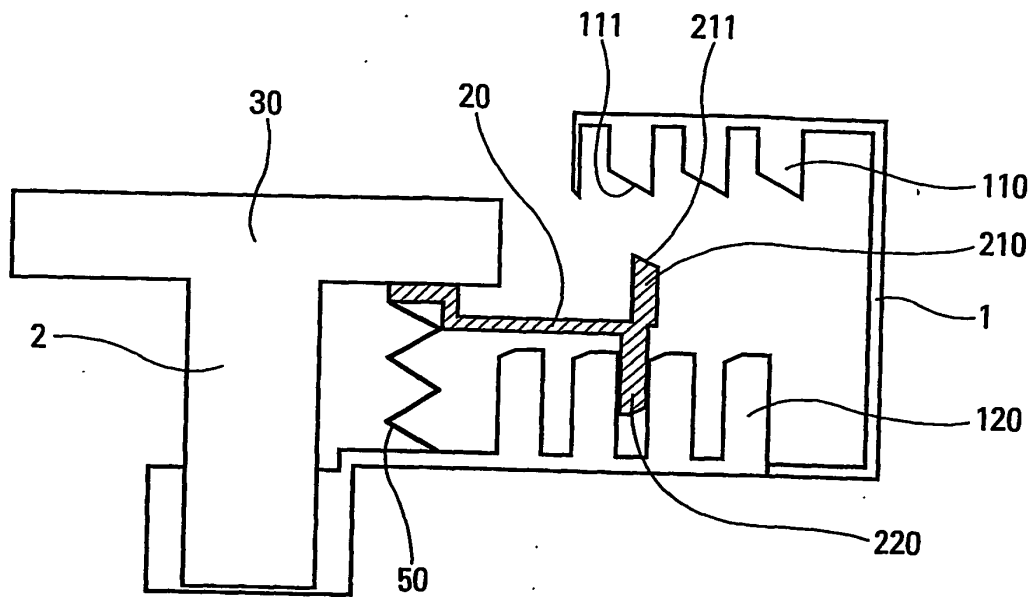


Fig. 11

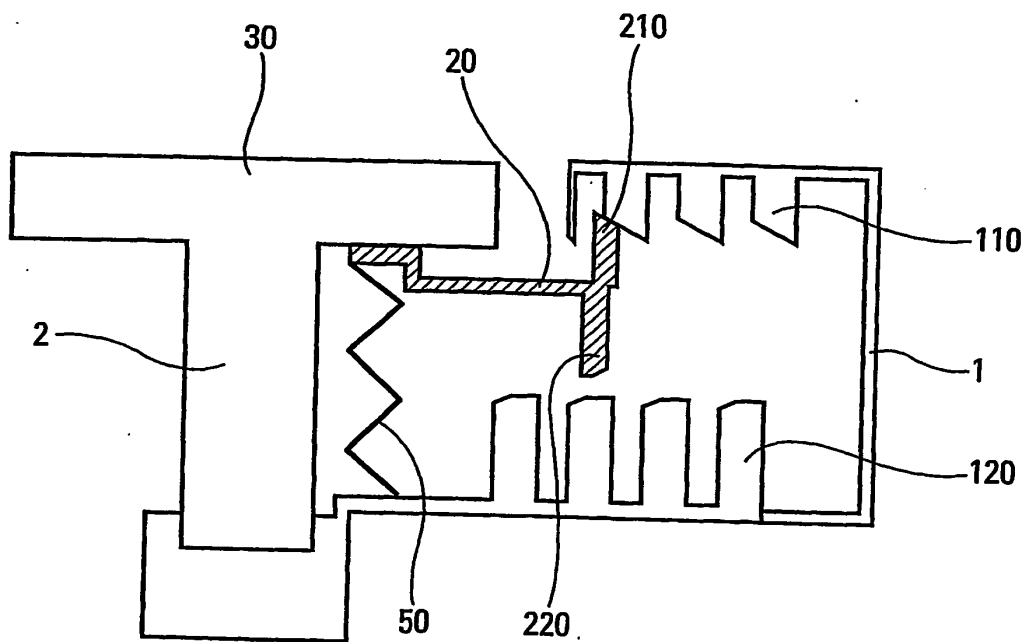


Fig. 12

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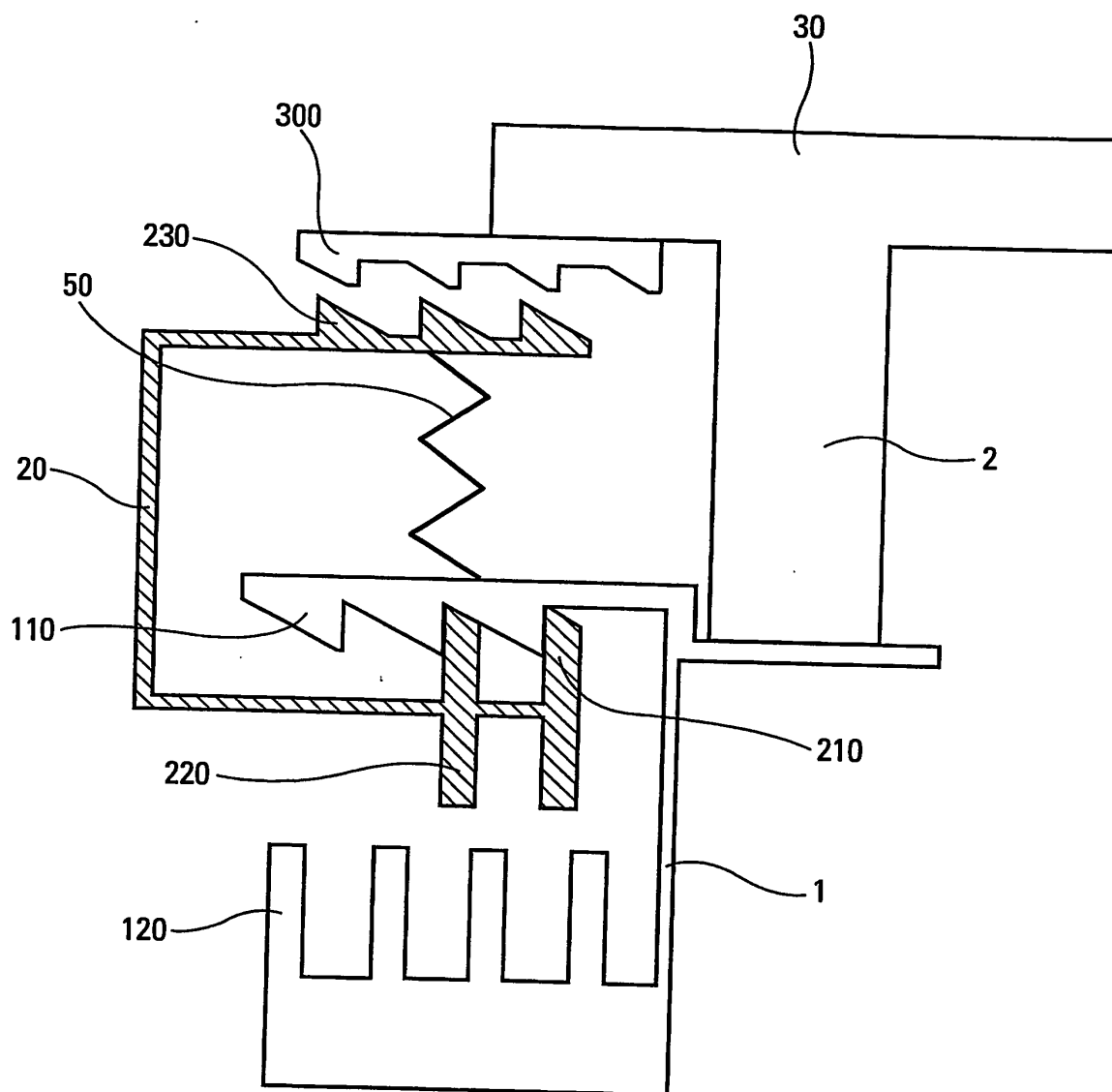


Fig. 13

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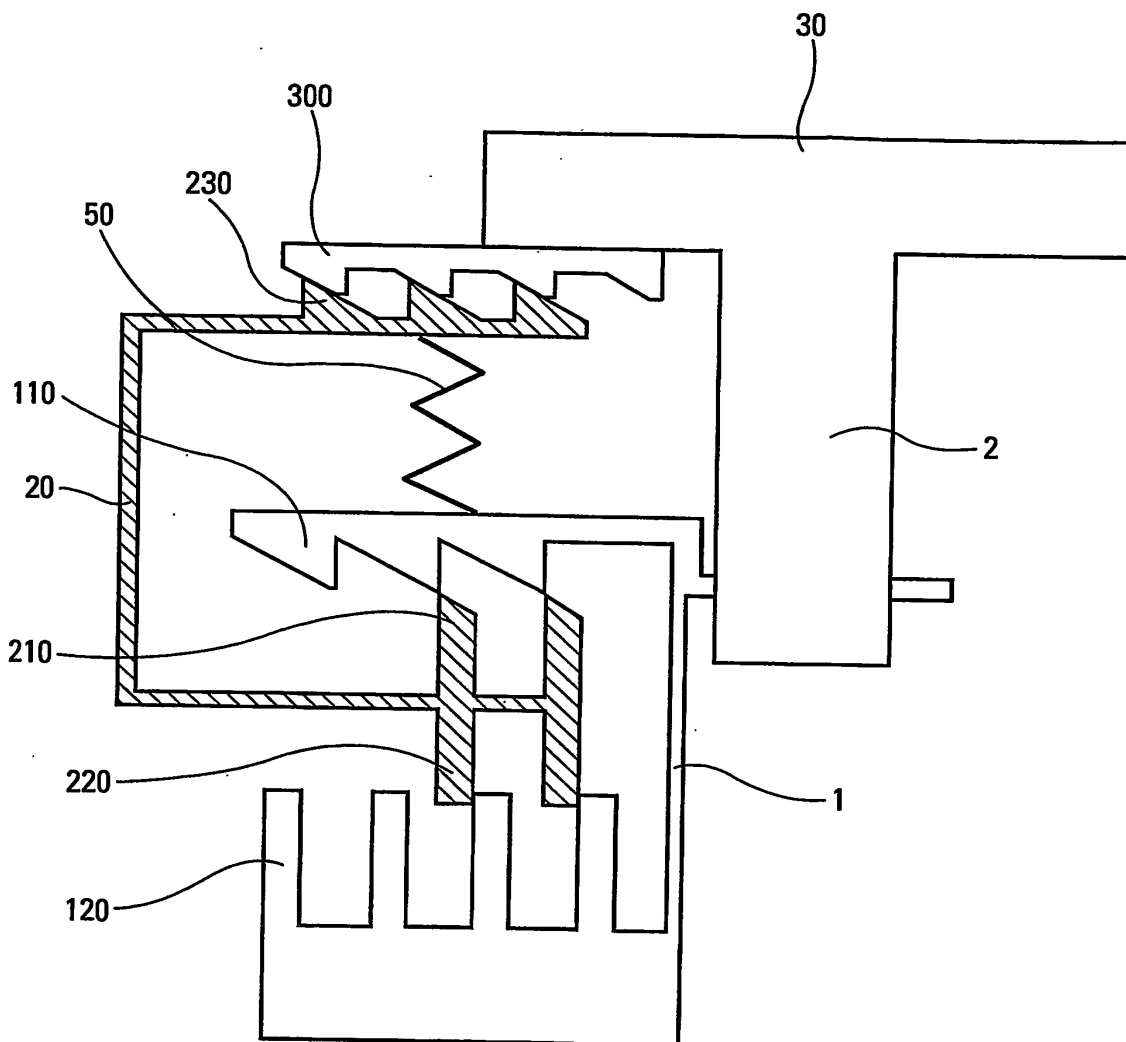


Fig. 14

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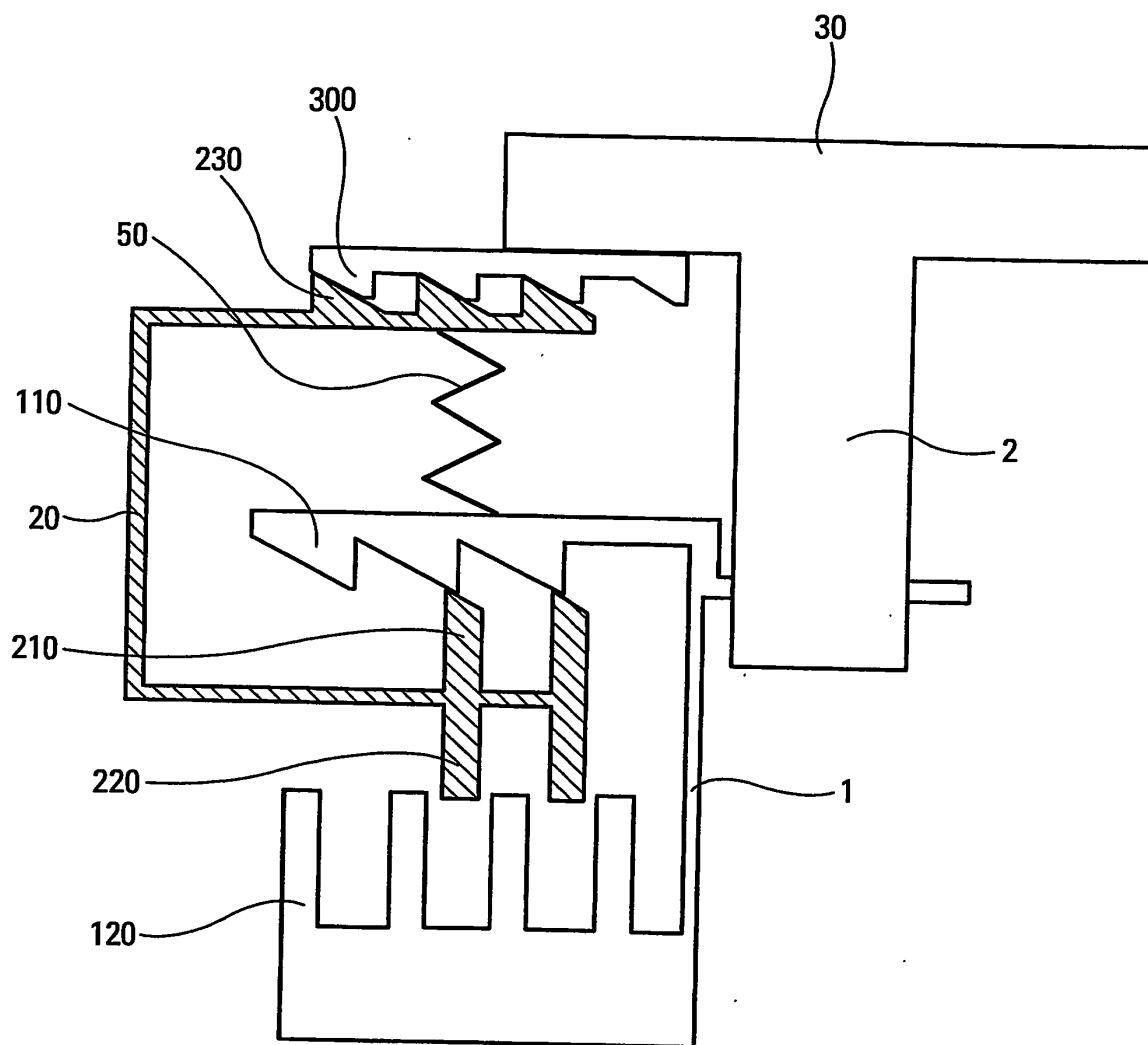


Fig. 15

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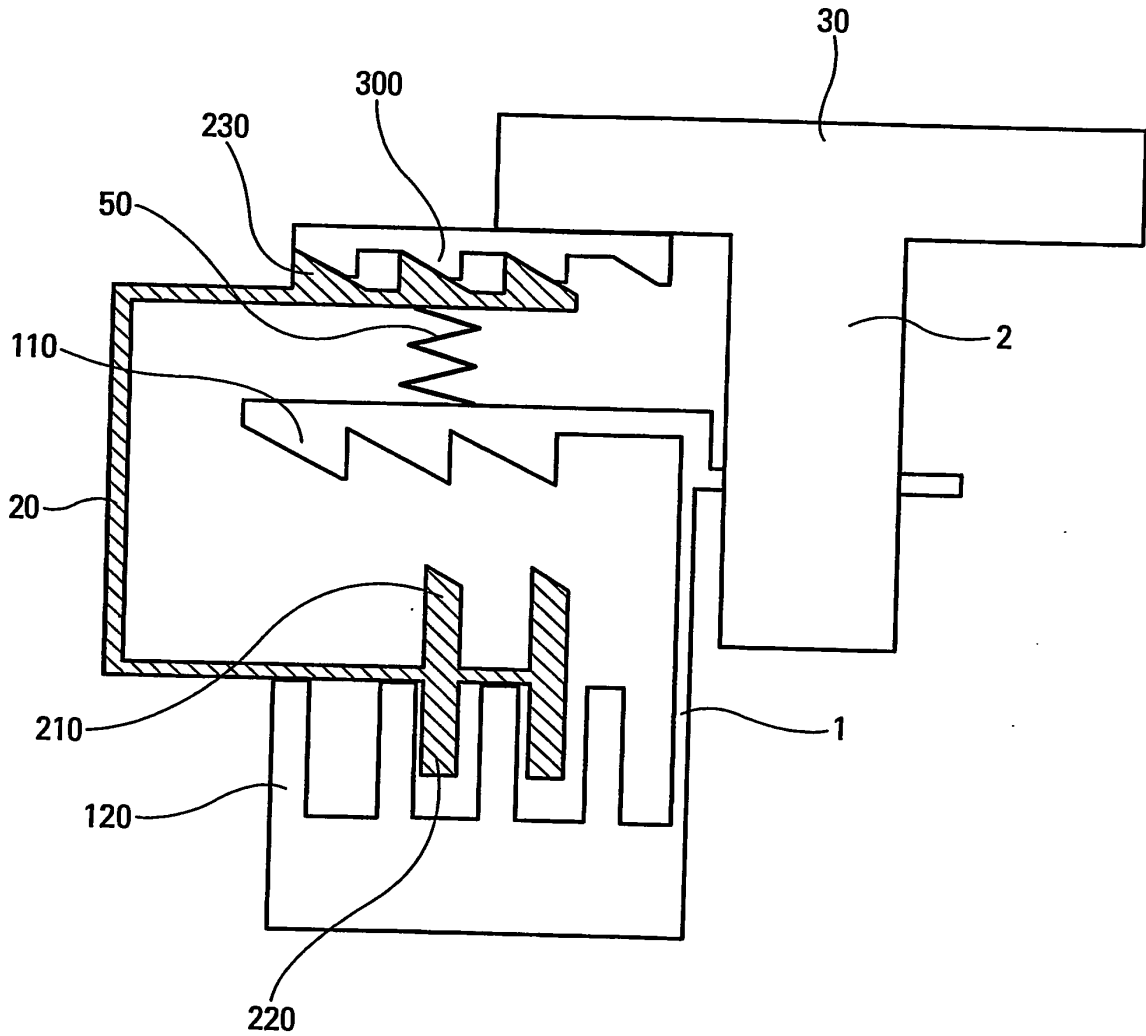


Fig. 16

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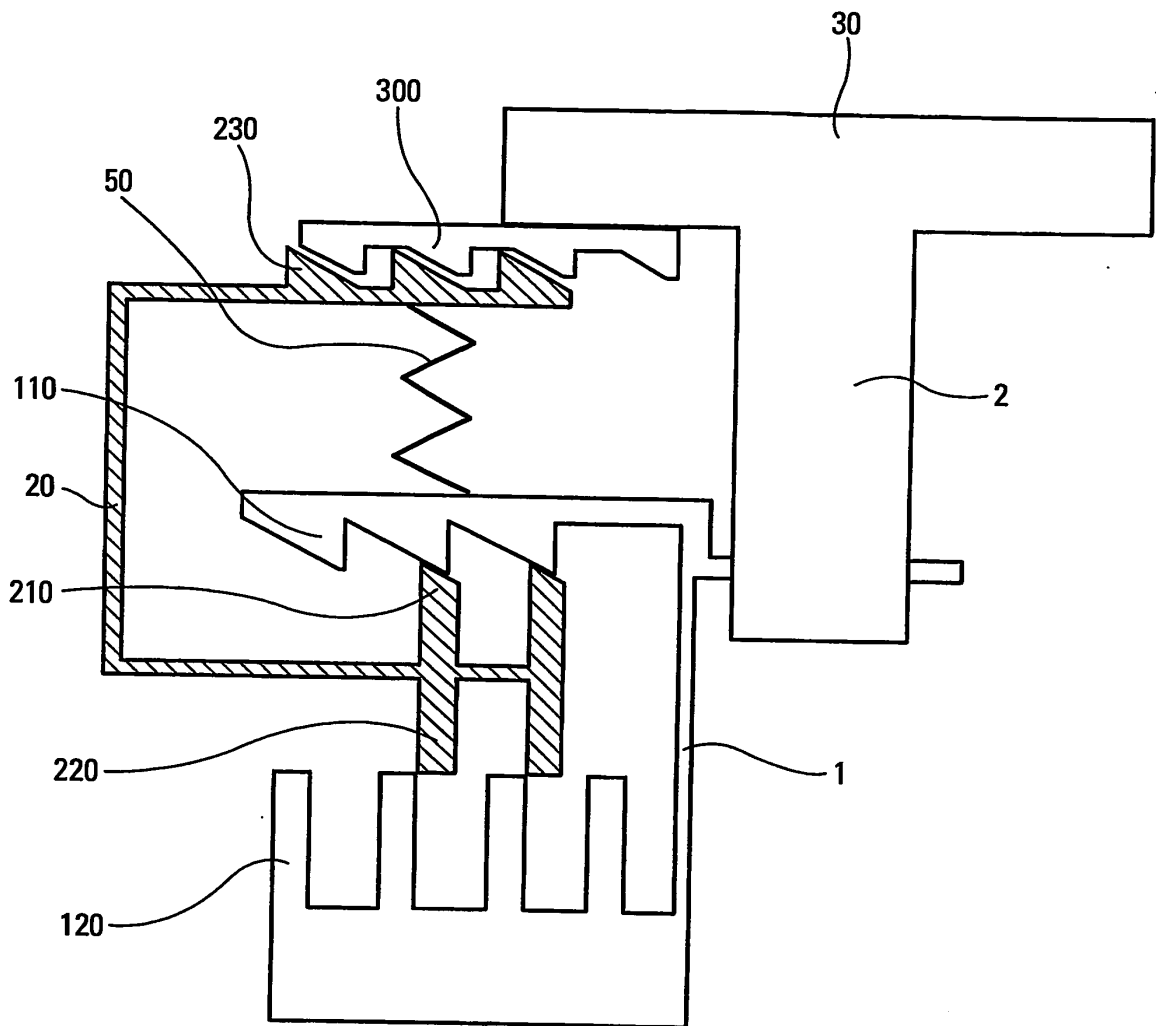


Fig. 17

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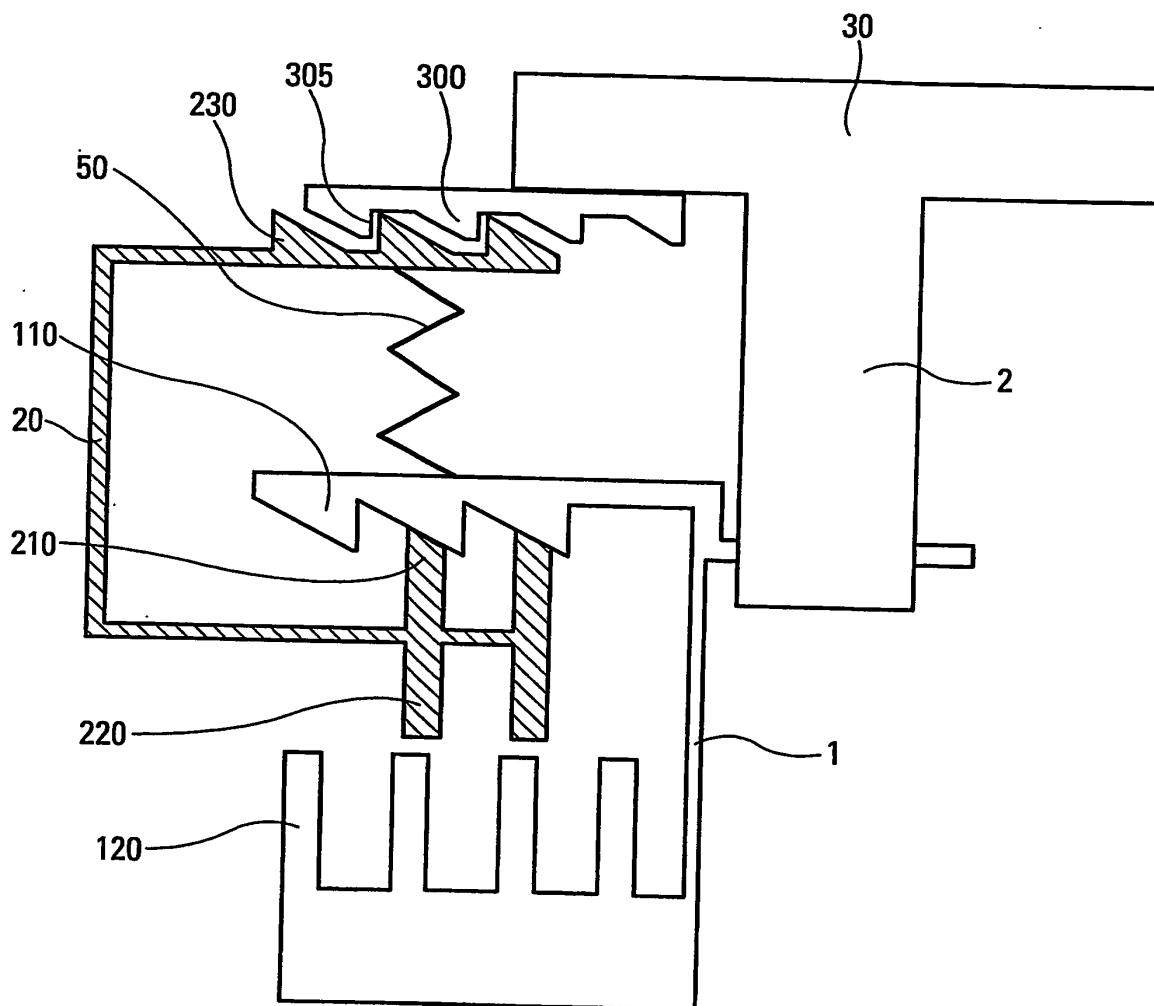


Fig. 18

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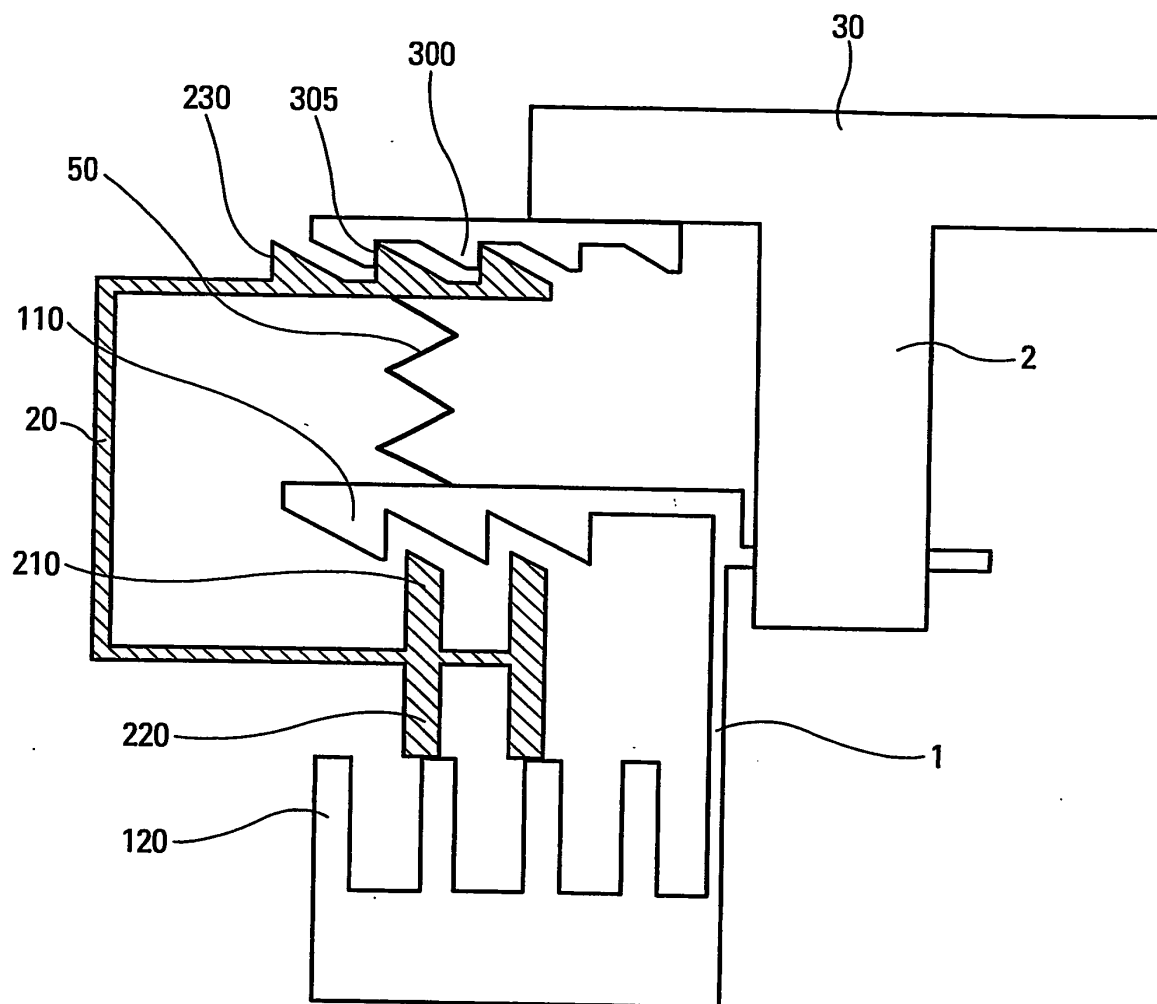


Fig. 19

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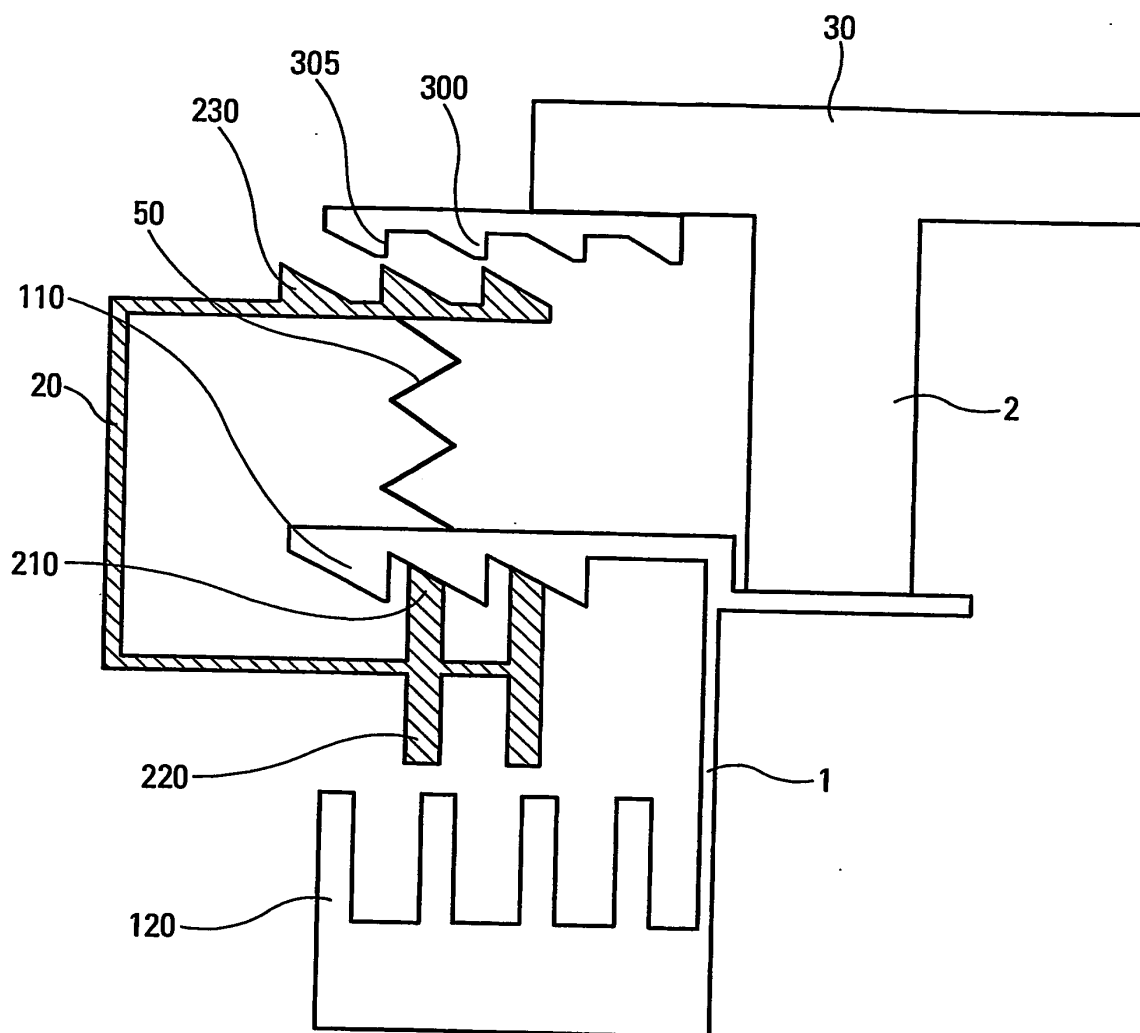


Fig. 20

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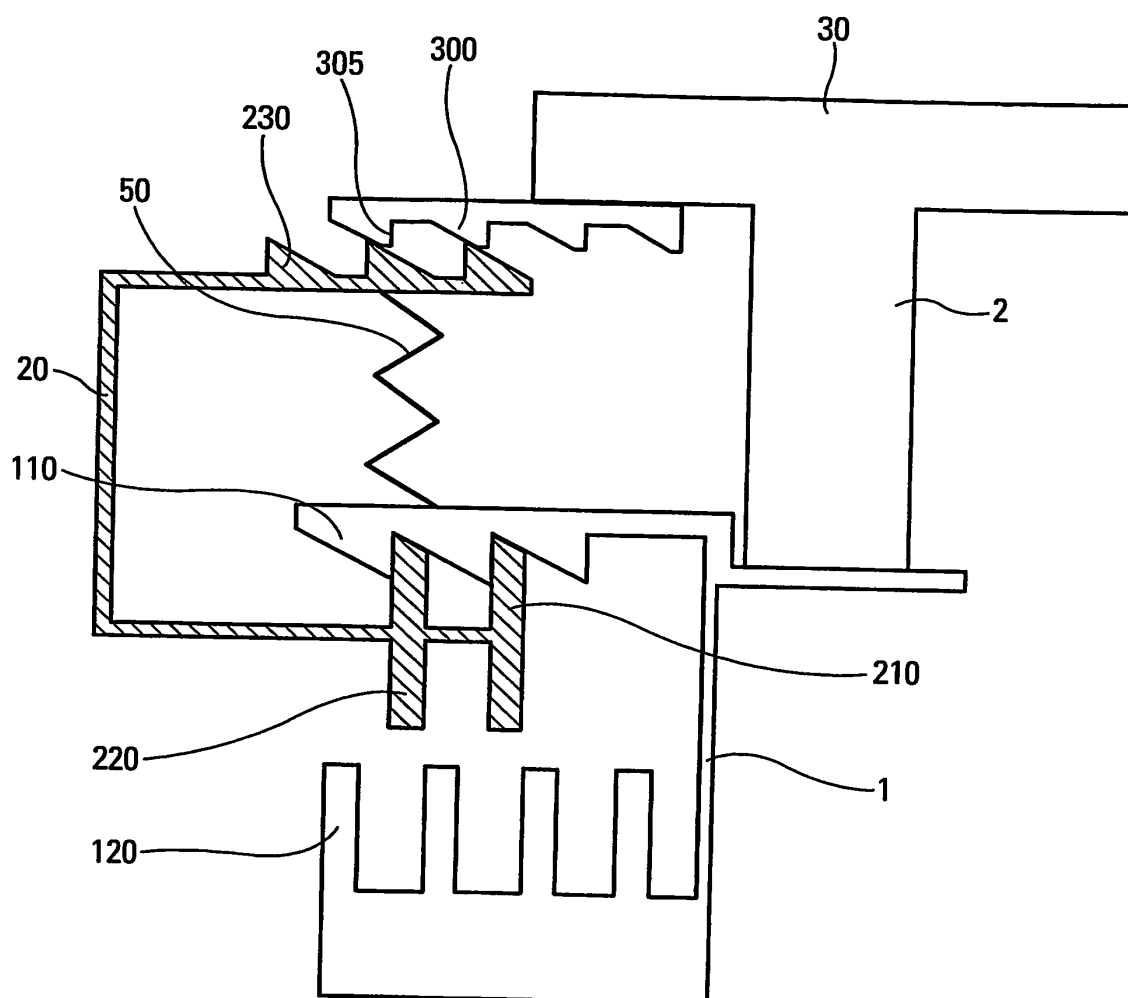


Fig. 21

(12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION
EN MATIÈRE DE BREVETS (PCT)

(19) Organisation Mondiale de la Propriété
Intellectuelle
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25 novembre 2004 (25.11.2004)

PCT

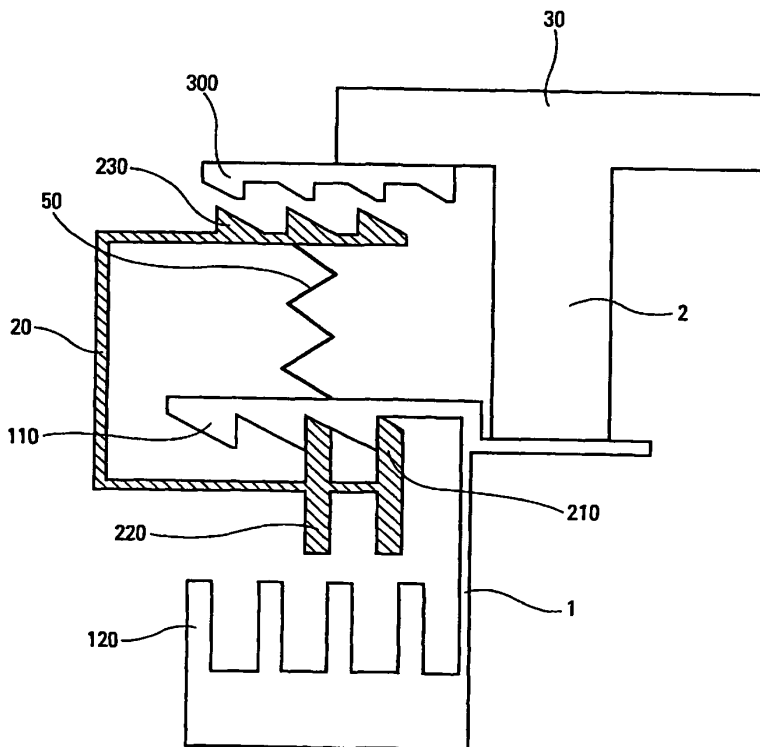
(10) Numéro de publication internationale
WO 2004/101042 A3

- (51) Classification internationale des brevets⁷ : **A61M 15/00**
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- (74) Mandataire : **CAPRI**; 33 rue de Naples, F-75008 Paris (FR).
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[Suite sur la page suivante]

(54) Title: FLUID PRODUCT DISPENSER

(54) Titre : DISTRIBUTEUR DE PRODUIT FLUIDE



(57) Abstract: A fluid product dispenser, comprising a body (1), a fluid product reservoir (2), a dispensing element such as a pump or a valve which is mounted on said reservoir (2), and a dose-indicating device which indicates the number of doses of the dispensed product or which remain to be dispensed from said reservoir, characterized in that said dose-indicating device comprises a first safety system used to activate the dose-indicating device from a partial predetermined course of actuation of the dispenser even if the total course of activation is not carried out by the dispenser.

(57) Abrégé : Distributeur de produit fluide, comportant un corps (1), un réservoir de produit fluide (2), un organe de distribution, tel qu'une pompe ou une valve, monté sur ledit réservoir (2), et un dispositif d'indication de doses pour indiquer le nombre de doses de produit distribuées ou restant à distribuer à partir dudit réservoir, caractérisé en ce que ledit dispositif d'indication de doses comporte un premier système de sécurité destiné à actionner le dispositif d'indication de doses à partir d'une course d'actionnement partielle

prédéterminée du distributeur, même si la course d'actionnement totale n'est pas réalisée par

[Suite sur la page suivante]

WO 2004/101042 A3



AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

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En ce qui concerne les codes à deux lettres et autres abréviations, se référer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

le distributeur.

INTERNATIONAL SEARCH REPORT

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PCT/FR2004/001189

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/00

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 2002/195102 A1 (GODFREY JAMES WILLIAM ET AL) 26 December 2002 (2002-12-26) paragraphs '0019!', '0042!', '0043!', '0046!', '0049!', '0050!; figures 1-4	1, 3 2
X	US 6 446 627 B1 (PANAYI COSTANINOS ET AL) 10 September 2002 (2002-09-10) column 9, lines 26-36; figures 1-3,5	1
X	DE 100 61 723 A (ECKERT ROSEMARIE) 11 July 2002 (2002-07-11) paragraph '0056!; figures 3-15	1
A	EP 0 480 488 A (ELETTRIO PLASTICA SPA) 15 April 1992 (1992-04-15) the whole document	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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- *8* document member of the same patent family

Date of the actual completion of the international search

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Date of mailing of the international search report

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Balz, O

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002195102 A1	26-12-2002	US 2003209239 A1	13-11-2003
		AU 741218 B2	29-11-2001
		AU 8213898 A	30-12-1998
		BR 9809983 A	01-08-2000
		CA 2293487 A1	17-12-1998
		EP 0988078 A1	29-03-2000
		JP 3487867 B2	19-01-2004
		JP 2000513634 T	17-10-2000
		US 6474331 B1	05-11-2002
		AP 1126 A	05-12-2002
		AT 274952 T	15-09-2004
		AT 251481 T	15-10-2003
		AT 215389 T	15-04-2002
		AU 741693 B2	06-12-2001
		AU 8213798 A	30-12-1998
		AU 742913 B2	17-01-2002
		AU 8436498 A	30-12-1998
		BR 9809554 A	20-06-2000
		BR 9809980 A	01-08-2000
		CA 2293484 A1	17-12-1998
		CA 2293488 A1	17-12-1998
		CN 1265601 T	06-09-2000
		DE 69804609 D1	08-05-2002
		DE 69804609 T2	12-09-2002
		DE 69818819 D1	13-11-2003
		DE 69818819 T2	12-08-2004
		DE 69826039 D1	07-10-2004
		DK 988077 T3	12-01-2004
		DK 986412 T3	22-07-2002
		EA 1396 B1	26-02-2001
		EG 21520 A	28-11-2001
		WO 9856444 A1	17-12-1998
		WO 9856445 A1	17-12-1998
		WO 9856446 A1	17-12-1998
		EP 1163922 A2	19-12-2001
		EP 1475116 A2	10-11-2004
		EP 0988077 A1	29-03-2000
		EP 0986412 A1	22-03-2000
		ES 2207841 T3	01-06-2004
		ES 2175737 T3	16-11-2002
		HK 1023956 A1	27-09-2002
		HR 980304 A1	30-04-1999
		HU 0003328 A2	28-02-2001
		ID 24128 A	06-07-2000
		JP 3487865 B2	19-01-2004
		JP 2000513632 T	17-10-2000
		JP 3487866 B2	19-01-2004
		JP 2000513633 T	17-10-2000
		MA 24562 A1	31-12-1998
		NO 996085 A	09-02-2000
US 6446627 B1	10-09-2002	GB 2320489 A	24-06-1998
		AT 268619 T	15-06-2004
		AU 5329298 A	17-07-1998
		DE 69729485 D1	15-07-2004
		EP 0966309 A2	29-12-1999
		WO 9828033 A2	02-07-1998
		PT 966309 T	30-09-2004

Form PCT/ISA/210 (patent family annex) (January 2004)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/FR2004/001189

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
DE 10061723	A	11-07-2002	DE 10061723 A1	11-07-2002
EP 0480488	A	15-04-1992	IT 1243820 B	28-06-1994
			AT 113486 T	15-11-1994
			AU 646873 B2	10-03-1994
			AU 8025891 A	16-04-1992
			BR 9103035 A	16-06-1992
			CA 2046806 A1	10-04-1992
			DE 69104950 D1	08-12-1994
			DE 69104950 T2	09-03-1995
			EP 0480488 A1	15-04-1992
			ES 2066336 T3	01-03-1995
			JP 3211894 B2	25-09-2001
			JP 5228213 A	07-09-1993
			US 5174473 A	29-12-1992

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RAPPORT DE RECHERCHE INTERNATIONALE

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PCT/FR2004/001189

A. CLASSEMENT DE L'OBJET DE LA DEMANDE
CIB 7 A61M15/00

Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB

B. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE

Documentation minimale consultée (système de classification suivi des symboles de classement)
CIB 7 A61M

Documentation consultée autre que la documentation minimale dans la mesure où ces documents relèvent des domaines sur lesquels a porté la recherche

Base de données électronique consultée au cours de la recherche internationale (nom de la base de données, et si réalisable, termes de recherche utilisés)
EPO-Internal

C. DOCUMENTS CONSIDERES COMME PERTINENTS

Catégorie *	Identification des documents cités, avec, le cas échéant, l'indication des passages pertinents	no. des revendications visées
X	US 2002/195102 A1 (GODFREY JAMES WILLIAM ET AL) 26 décembre 2002 (2002-12-26)	1, 3
A	alinéas '0019!', '0042!', '0043!', '0046!', '0049!', '0050!; figures 1-4	2
X	US 6 446 627 B1 (PANAYI COSTANINOS ET AL) 10 septembre 2002 (2002-09-10)	1
	colonne 9, ligne 26-36; figures 1-3,5	
X	DE 100 61 723 A (ECKERT ROSEMARIE) 11 juillet 2002 (2002-07-11)	1
	alinéa '0056!; figures 3-15	
A	EP 0 480 488 A (ELETTRIO PLASTICA SPA) 15 avril 1992 (1992-04-15)	1
	le document en entier	

☐ Voir la suite du cadre C pour la fin de la liste des documents

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- *Y* document particulièrement pertinent; l'invention revendiquée ne peut être considérée comme impliquant une activité inventive lorsque le document est associé à un ou plusieurs autres documents de même nature, cette combinaison étant évidente pour une personne du métier
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Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
US 2002195102 A1	26-12-2002	US 2003209239 A1	13-11-2003
		AU 741218 B2	29-11-2001
		AU 8213898 A	30-12-1998
		BR 9809983 A	01-08-2000
		CA 2293487 A1	17-12-1998
		EP 0988078 A1	29-03-2000
		JP 3487867 B2	19-01-2004
		JP 2000513634 T	17-10-2000
		US 6474331 B1	05-11-2002
		AP 1126 A	05-12-2002
		AT 274952 T	15-09-2004
		AT 251481 T	15-10-2003
		AT 215389 T	15-04-2002
		AU 741693 B2	06-12-2001
		AU 8213798 A	30-12-1998
		AU 742913 B2	17-01-2002
		AU 8436498 A	30-12-1998
		BR 9809554 A	20-06-2000
		BR 9809980 A	01-08-2000
		CA 2293484 A1	17-12-1998
		CA 2293488 A1	17-12-1998
		CN 1265601 T	06-09-2000
		DE 69804609 D1	08-05-2002
		DE 69804609 T2	12-09-2002
		DE 69818819 D1	13-11-2003
		DE 69818819 T2	12-08-2004
		DE 69826039 D1	07-10-2004
		DK 988077 T3	12-01-2004
		DK 986412 T3	22-07-2002
		EA 1396 B1	26-02-2001
		EG 21520 A	28-11-2001
		WO 9856444 A1	17-12-1998
		WO 9856445 A1	17-12-1998
		WO 9856446 A1	17-12-1998
		EP 1163922 A2	19-12-2001
		EP 1475116 A2	10-11-2004
		EP 0988077 A1	29-03-2000
		EP 0986412 A1	22-03-2000
		ES 2207841 T3	01-06-2004
		ES 2175737 T3	16-11-2002
		HK 1023956 A1	27-09-2002
		HR 980304 A1	30-04-1999
		HU 0003328 A2	28-02-2001
		ID 24128 A	06-07-2000
		JP 3487865 B2	19-01-2004
		JP 2000513632 T	17-10-2000
		JP 3487866 B2	19-01-2004
		JP 2000513633 T	17-10-2000
		MA 24562 A1	31-12-1998
		NO 996085 A	09-02-2000
US 6446627 B1	10-09-2002	GB 2320489 A	24-06-1998
		AT 268619 T	15-06-2004
		AU 5329298 A	17-07-1998
		DE 69729485 D1	15-07-2004
		EP 0966309 A2	29-12-1999
		WO 9828033 A2	02-07-1998
		PT 966309 T	30-09-2004

Formulaire PCT/SA/210 (annexe familles de brevets) (Janvier 2004)

RAPPORT DE RECHERCHE INTERNATIONALE

Renseignements relatifs aux membres de familles de brevets

Demande internationale No

PCT/FR2004/001189

Document brevet cité au rapport de recherche		Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
DE 10061723	A	11-07-2002	DE 10061723 A1	11-07-2002
EP 0480488	A	15-04-1992	IT 1243820 B	28-06-1994
			AT 113486 T	15-11-1994
			AU 646873 B2	10-03-1994
			AU 8025891 A	16-04-1992
			BR 9103035 A	16-06-1992
			CA 2046806 A1	10-04-1992
			DE 69104950 D1	08-12-1994
			DE 69104950 T2	09-03-1995
			EP 0480488 A1	15-04-1992
			ES 2066336 T3	01-03-1995
			JP 3211894 B2	25-09-2001
			JP 5228213 A	07-09-1993
			US 5174473 A	29-12-1992

Formulaire PCT/ISA/210 (annexe familles de brevets) (Janvier 2004)

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Article 34 Amendment

CLAIMS

1. A fluid dispenser comprising a body (1), a fluid reservoir (2), a dispenser member, such as a pump or a valve, mounted on said reservoir (2), and a dose
5 indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, the dispenser being characterized in that said dose indicator device includes
10 a first safety system for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform the complete actuation stroke, said reservoir (2) being axially displaceable relative to said body (1),
15 said body (1) including at least one stationary gear (110, 120), said dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to said body (1), said counter element (20) co-operating, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 120)
20 of said body, and secondly with said reservoir (2).

2. A dispenser according to claim 1, in which said dose indicator device includes a second safety system which, during the return stroke of the dispenser after
25 dispensing a dose, prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke
30 has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

3. A dispenser according to claim 1 or claim 2, in which
35 said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20), said counter element (20) including a second gear

CORRECTED SHEET

This translation of an amended page covers the amendments made in the original. However, the page breaks match the translation, so that this page is also a replacement page that fits in with the remainder of the translation.

(230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser, the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation, the stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

4. A dispenser according to claim 3, in which the stationary gear (110) includes abutment means (115) preventing said counter element (20) from turning once said counter element (20) has turned at least in part, an additional axial displacement of said counter element (20) being necessary to enable it to continue to turn and/or to return the indicator device to its rest position.

5. A dispenser according to claim 4, in which said abutment means (115) comprise an axial projection.

6. A dispenser according to any preceding claim, in which said stationary gear (110) and/or said counter element (20) include(s) blocking means (120, 220) preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position after a preceding actuation, and until the dispenser has completed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

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7. A dispenser according to claim 6, in which said blocking means comprise axial projections (120, 220) provided on the body (1) and on the counter element (20) respectively, each of said projections (120, 220) having
5 an axial end-profile that is plane, said projections (120, 220) facing each other, at least in part, until the counter element has turned sufficiently to offset said projections (120, 220), with that sufficient turn
10 corresponding to said predetermined incomplete return stroke of the dispenser.

8. A dispenser according to claim 7, in which the teeth of the second gear (230) of the counter element (20) include an intermediate step (235), the actuator member
15 (30) co-operating with said step (235) while the dispenser is being actuated, and co-operating with the end wall of said second gear (230) while returning to the rest position, after being actuated, the displacement between the intermediate step (235) and the end wall
20 being obtained by said counter element (20) turning.

9. A dispenser according to claim 7 or claim 8, in which, once the predetermined incomplete return stroke has been performed, the actuator member (30) is positioned facing
25 the following tooth of the second gear (230) of the counter element (20), enabling the dispenser and the dose indicator device to be actuated once again.

10. A dispenser according to any preceding claim, in
30 which said body (1) includes a first stationary gear (110) and a second stationary gear (120), said counter element (20) including a first gear (210) for co-operating with said first stationary gear (110) and a second gear (220) for co-operating with said second
35 stationary gear (120), said counter element (20) being put axially into contact with the actuator member (30) of the dispenser by means of a return spring (50) and being

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turnable relative to said actuator member (30), the teeth of said second gear (220) and of said second stationary gear (120) being oblique, at least in part, so that an axial displacement of the actuator member (30) initially causes said counter element (20) to be displaced axially over a predetermined incomplete actuation stroke until the oblique portion (221) of said second gear (220) of the counter element (20) co-operates with said oblique portion (121) of said second stationary gear (120), causing the counter element (20) to be turned over a first portion of a turn cycle, the teeth of said first gear (210) and of said first stationary gear (110) being oblique, at least in part, so that when the counter element (20) returns to its rest position, it is caused to turn so as to terminate its turn cycle, which corresponds to one actuation of the dispenser being counted.

11. A dispenser according to claim 10, in which said first and second stationary gears (110, 120) of the body (1) and/or said first and second gears (210, 220) of the counter element (20) are offset relative to each other, so that whenever the counter element (20) is displaceable in rotation, returning said counter element to its rest position without terminating the actuation stroke of the dispenser causes the counter element (20) to turn over its complete turn cycle, guaranteeing that one actuation of the dispenser is counted after said predetermined incomplete actuation stroke.

12. A dispenser according to claim 10 or claim 11, in which said second stationary gear (120) of the body (1) and/or said second gear (220) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position

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3M Company Exhibit 1004

3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp., v. AptarFrance S.A.S.

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following a preceding actuation, and until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

5 13. A dispenser according to claim 12, in which said blocking means have an axial end-profile that is plane, at least in part, and that is formed on the teeth of said second stationary gear (120) of the body (1) and on the teeth of said second gear (220) of the counter element
10 (20), said plane profiles of said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

15 14. A dispenser according to any one of claims 10 to 13, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

20 15. A dispenser according to any preceding claim, in which said body (1) includes a first stationary gear (110) and a second stationary gear (120), said counter element (20) comprising a first gear (210) for co-
25 operating with said first stationary gear (110), a second gear (220) for co-operating with said second stationary gear (120), and a third gear (230) for co-operating with an actuator gear (300) secured to an actuator member (30) of the dispenser, the teeth of said third gear (230)
30 and/or of said actuator gear (300) being made so that axial displacement of the actuator member (30) causes said counter element (20) to be displaced axially and in rotation, the first stationary gear (110) preventing said counter element (20) from turning until said counter
35 element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said

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This translation of an amended page covers the amendments made in the original. However, the page breaks match the translation, so that this page is also a replacement page that fits in with the remainder of the translation.

3M Company Exhibit 1004

3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp., v. AptarFrance S.A.S.

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predetermined incomplete actuation stroke of the dispenser.

- 5 16. A dispenser according to claim 15, in which said second stationary gear (120) of the body (1) and/or said second gear (220) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.
- 10 17. A dispenser according to claim 16, in which said blocking means have an axial end-profile that is plane and that is formed on the teeth of said second stationary gear (120) and on the teeth of said second gear (220), said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.
- 15 18. A dispenser according to claim 16 or claim 17, in which said actuator gear (300) includes abutment means (305) limiting the extent to which the counter element (20) can turn, until the actuator member (30) has performed said predetermined incomplete return stroke.
- 20 19. A dispenser according to claim 18, in which said abutment means (305) comprise an axial projection formed on said actuator gear (300).
- 25 20. A dispenser according to any one of claims 15 to 19, in which said actuator member (30) of the dispenser is
- 30
- 35

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3M Company Exhibit 1004

3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp., v. AptarFrance S.A.S.

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secured to said reservoir (2) and is displaced axially therewith.

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TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS

PCT

WIPO

PCT
REC'D

25 AUG 2005

RAPPORT PRÉLIMINAIRE INTERNATIONAL SUR LA BREVETABILITÉ

(chapitre II du Traité de coopération en matière de brevets)

(article 36 et règle 70 du PCT)

Référence du dossier du déposant ou du mandataire	POUR SUITE À DONNER		voir formulaire PCT/PEA/416
Demande internationale No. PCT/FR2004/001189	Date du dépôt international (jour/mois/année) 14.05.2004	Date de priorité (jour/mois/année) 15.05.2003	
Classification internationale des brevets (CIB) ou à la fois classification nationale et CIB A61M15/00			
Déposant VALOIS SAS et al.			
1. Le présent rapport est le rapport d'examen préliminaire international, établi par l'administration chargée de l'examen préliminaire international en vertu de l'article 35 et transmis au déposant conformément à l'article 36. 2. Ce RAPPORT comprend 5 feuilles, y compris la présente feuille de couverture. 3. Ce rapport est accompagné d'ANNEXES, qui comprennent : a. ☒ un total de (envoyées au déposant et au Bureau international) 6 feuilles, définies comme suit : ☒ les feuilles de la description, des revendications ou des dessins qui ont été modifiées et qui servent de base au présent rapport ou des feuilles contenant des rectifications autorisées par la présente administration (voir la règle 70.16 et l'instruction administrative 607). ☐ des feuilles qui remplacent des feuilles précédentes, mais dont la présente administration considère qu'elles contiennent une modification qui va au-delà de l'exposé de l'invention qui figure dans la demande internationale telle qu'elle a été déposée, comme il est indiqué au point 4 du cadre n° I et dans le cadre supplémentaire. b. ☐ (envoyées au Bureau international seulement) un total de (préciser le type et le nombre de support(s) électronique(s)) , qui contiennent un listage de la ou des séquences ou un ou des tableaux y relatifs, déposés sous forme déchiffrable par ordinateur seulement, comme il est indiqué dans le cadre supplémentaire relatif au listage de la ou des séquences (voir l'instruction administrative 802).			
4. Le présent rapport contient des indications et les pages correspondantes relatives aux points suivants : ☒ Cadre n° I Base de l'opinion ☐ Cadre n° II Priorité ☐ Cadre n° III Absence de formulation d'opinion quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle ☐ Cadre n° IV Absence d'unité de l'invention ☒ Cadre n° V Déclaration motivée selon l'article 35(2) quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle; citations et explications à l'appui de cette déclaration ☐ Cadre n° VI Certains documents cités ☐ Cadre n° VII Irrégularités dans la demande internationale ☐ Cadre n° VIII Observations relatives à la demande internationale			
Date de présentation de la demande d'examen préliminaire internationale 08.12.2004	Date d'achèvement du présent rapport 24.08.2005		
Nom et adresse postale de l'administration chargée de l'examen préliminaire international  Office européen des brevets D-80298 Munich Tél. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Fonctionnaire autorisé Balz, O N° de téléphone +49 89 2399-7218 		

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**RAPPORT PRÉLIMINAIRE INTERNATIONAL
SUR LA BREVETABILITÉ**

Demande internationale n°
PCT/FR2004/001189

Cadre n° V Déclaration motivée selon l'article 35.2) quant à la nouveauté, l'activité inventive et la possibilité d'application industrielle; citations et explications à l'appui de cette déclaration

1. Déclaration			
Nouveauté	Oui:	Revendications	2,4-20
	Non:	Revendications	1
Activité inventive	Oui:	Revendications	2,4-20
	Non:	Revendications	1
Possibilité d'application industrielle	Oui:	Revendications	1-20
	Non:	Revendications	

2. Citations et explications (règle 70.7) :

voir feuille séparée

**RAPPORT PRÉLIMINAIRE INTERNATIONAL
SUR LA BREVETABILITÉ
(FEUILLE SÉPARÉE)**

Demande internationale n°

PCT/FR2004/001189

Concernant le point V.

- 1 Il est fait référence aux documents suivants dans la présente notification:
D1 : US 2002/195102 A1 (GODFREY JAMES WILLIAM ET AL) 26 décembre 2002 (2002-12-26)
D2 : US 6 446 627 B1 (PANAYI COSTANINOS ET AL) 10 septembre 2002 (2002-09-10)
D3 : DE 100 61 723 A (ECKERT ROSEMARIE) 11 juillet 2002 (2002-07-11)

2. La présente demande ne remplit pas les conditions énoncées dans l'Article 33(1) PCT, l'objet de la revendication 1 n'étant pas conforme au critère de nouveauté défini par l'Article 33(2) PCT.

Le document D1 décrit (les références entre parenthèses s'appliquant à ce document):

un distributeur de produit fluide, comportant un corps (1), un réservoir de produit fluide (2), un organe de distribution, tel qu'une pompe ou une valve (4), monté sur ledit réservoir (2), et un dispositif d'indication de doses (13) pour indiquer le nombre de doses de produit distribuées ou restant à distribuer à partir dudit réservoir, ledit dispositif d'indication de doses comporte un premier système de sécurité destiné à actionner le dispositif d'indication de doses à partir d'une course d'actionnement partielle prédéterminée du distributeur, même si la course d'actionnement totale n'est pas réalisée par le distributeur, ledit réservoir étant déplaçable axialement par rapport audit corps, ledit corps comportant au moins un engrenage fixe (17), ledit dispositif d'indication de doses comportant un élément de comptage (13) déplaçable axialement et en rotation par rapport audit corps, ledit élément de comptage coopérant d'une part avec ledit au moins un engrenage fixe dudit corps et d'autre part avec ledit réservoir lorsque le distributeur est actionné (voir alinéa 49).

Le dispositif d'indication ne nécessite pas une actionnement totale du distributeur, car à partir du moment où le crochet (18a) engage le roue d'engrenage (19), le crochet ne peut plus bouger, même si le distributeur est encore actionné.

**RAPPORT PRÉLIMINAIRE INTERNATIONAL
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Donc le distributeur selon la revendication 1 n'est pas nouveau.

3. La combinaison des caractéristiques des autres revendications dépendantes 2, 4-20 n'est pas comprise dans l'état de la technique et n'en découle pas de manière évidente.
4. Contrairement à ce qu'exige la règle 5.1 a) ii) PCT, la description n'indique pas l'état de la technique antérieure pertinent exposé dans le documents D1 et ne cite pas ce document.

Revendications

1.- Distributeur de produit fluide, comportant un corps (1), un réservoir de produit fluide (2), un organe de distribution, tel qu'une pompe ou une valve, monté sur ledit réservoir (2), et un dispositif d'indication de doses pour indiquer le nombre de doses de produit distribuées ou restant à distribuer à partir dudit réservoir, caractérisé en ce que ledit dispositif d'indication de doses comporte un premier système de sécurité destiné à actionner le dispositif d'indication de doses à partir d'une course d'actionnement partielle prédéterminée du distributeur, même si la course d'actionnement totale n'est pas réalisée par le distributeur, ledit réservoir (2) étant déplaçable axialement par rapport audit corps (1), ledit corps (1) comportant au moins un engrenage fixe (110, 120), ledit dispositif d'indication de doses comportant un élément de comptage (20) déplaçable axialement et en rotation par rapport audit corps (1), ledit élément de comptage (20) coopérant d'une part avec ledit au moins un engrenage fixe (110, 120) dudit corps et d'autre part avec ledit réservoir (2) lorsque le distributeur est actionné.

2.- Distributeur selon la revendication 1, dans lequel ledit dispositif d'indication de doses comporte un second système de sécurité qui, lors de la course de retour du distributeur, après distribution d'une dose, empêche la prochaine expulsion de produit jusqu'à ce que ledit distributeur a accompli une course de retour partielle prédéterminée, ledit distributeur et ledit dispositif d'indication de doses pouvant à nouveau être actionnés à partir de cette course de retour partielle prédéterminée, même si la course de retour totale n'est pas réalisée par le distributeur et que celui-ci est actionné à nouveau avant de revenir à sa position de repos.

3.- Distributeur selon la revendication 1 ou 2, dans lequel ledit corps (1) comporte un engrenage fixe (110) coopérant avec un premier engrenage (210) dudit élément de comptage (20), ledit élément de comptage (20) comportant un second engrenage (230) coopérant avec un engrenage

d'actionnement (300) d'un organe d'actionnement (30) du distributeur, les dents dudit second engrenage (230) et/ou dudit engrenage d'actionnement (300) étant réalisées de telle sorte qu'un déplacement axial de l'organe d'actionnement sollicite ledit élément de comptage (20) à se déplacer axialement et en rotation, l'engrenage fixe (110) empêchant une rotation dudit élément de comptage (20) jusqu'à ce que ledit élément de comptage (20) ne coopère plus avec ledit engrenage fixe (110), après un déplacement axial prédéterminé dudit élément de comptage (20) correspondant à ladite course d'actionnement partielle prédéterminée du distributeur.

4.- Distributeur selon la revendication 3, dans lequel l'engrenage fixe (110) comporte des moyens de butée (115) bloquant en rotation ledit élément de comptage (20) après au moins une rotation partielle dudit élément de comptage (20), un déplacement axial supplémentaire dudit élément de comptage (20) étant nécessaire pour permettre la poursuite de sa rotation et/ou le retour du dispositif d'indication vers sa position de repos.

5.- Distributeur selon la revendication 4, dans lequel lesdits moyens de butée (115) comportent une projection axiale.

6.- Distributeur selon l'une quelconque des revendications précédentes, dans lequel ledit engrenage fixe (110) et/ou ledit élément de comptage (20) comporte(nt) des moyens de blocage (120, 220) empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique, lorsque l'élément de comptage (20) revient vers sa position de repos après un actionnement précédent, jusqu'à ce que le distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

7.- Distributeur selon la revendication 6, dans lequel lesdits moyens de blocage comportent des projections axiales (120, 220) prévues respectivement sur le corps (1) et sur l'élément de comptage (20), lesdites projections (120, 220) comportant chacune un profil d'extrémité axiale plan, lesdites projections (120, 220) étant au moins partiellement face à face

jusqu'à ce que l'élément de comptage (20) a accompli une rotation suffisante pour décaler lesdites projections (120, 220) correspondant à ladite course de retour partielle prédéterminée du distributeur.

8.- Distributeur selon la revendication 7, dans lequel les dents du second engrenage (230) de l'élément de comptage (20) comportent un ~~palier intermédiaire (235), l'organe d'actionnement (30) coopérant avec~~ ledit palier (235) lors de l'actionnement du distributeur, et coopérant avec le fond dudit second engrenage (230) lors du retour vers la position de repos, après actionnement, le déplacement entre le palier intermédiaire (235) et le fond étant obtenu par rotation dudit élément de comptage (20).

9.- Distributeur selon la revendication 7 ou 8, dans lequel, lorsque la ~~course de retour partielle prédéterminée a été réalisée, l'organe d'actionnement (30) est placé face à la dent suivante du second engrenage~~ (230) de l'élément de comptage (20), permettant un nouvel actionnement du distributeur et du dispositif d'indication de doses.

10.- Distributeur selon l'une quelconque des revendications précédentes, dans lequel ledit corps (1) comporte un premier engrenage fixe (110) et un second engrenage fixe (120), ledit élément de comptage (20) comportant un premier engrenage (210) destiné à coopérer avec ledit premier engrenage fixe (110), et un second engrenage (220) destiné à coopérer avec ledit second engrenage fixe (120), ledit élément de comptage (20) ~~étant axialement mis en contact avec l'organe d'actionnement (30) du~~ distributeur par l'intermédiaire d'un ressort de rappel (50) et étant déplaçable en rotation par rapport audit organe d'actionnement (30), les dents dudit second engrenage (220) et second engrenage fixe (120) étant au moins partiellement obliques de telle sorte qu'un déplacement axial de l'organe d'actionnement (30) sollicite d'abord ledit élément de comptage (20) à se déplacer axialement sur une course d'actionnement partielle prédéterminée, jusqu'à ce que la partie oblique (221) dudit second engrenage (220) de l'élément de comptage (20) coopère avec ladite partie oblique (121) dudit second engrenage fixe (120), sollicitant l'élément de

comptage (20) à se déplacer en rotation sur une première partie de cycle de rotation, les dents desdits premier engrenage (210) et premier engrenage fixe (110) étant au moins partiellement obliques de telle sorte que lorsque l'élément de comptage (20) revient vers sa position de repos, il est sollicité en rotation pour terminer son cycle de rotation correspondant au comptage d'un actionnement du distributeur.

11.- Distributeur selon la revendication 10, dans lequel lesdits premier et second engrenages fixes (110, 120) du corps (1) et/ou lesdits premier et second engrenages (210, 220) de l'élément de comptage (20) sont décalés l'un par rapport à l'autre de telle sorte que dès que l'élément de comptage (20) est déplaçable en rotation, un retour de celui-ci vers sa position de repos sans terminer la course d'actionnement du distributeur entraîne la rotation de l'élément de comptage (20) sur son cycle complet de rotation, garantissant le comptage d'un actionnement du distributeur après ladite course d'actionnement partielle prédéterminée.

12.- Distributeur selon l'une quelconque des revendications 10 ou 11, dans lequel ledit second engrenage fixe (120) du corps (1) et/ou ledit second engrenage (220) de l'élément de comptage (20) comporte(nt) des moyens de blocage empêchant un nouvel actionnement du distributeur, et donc une nouvelle expulsion de produit pharmaceutique, lorsque l'élément de comptage (20) revient vers sa position de repos après un actionnement précédent jusqu'à ce que ledit distributeur réalise une course de retour partielle prédéterminée à partir de laquelle le dispositif d'indication peut compter la prochaine dose.

13.- Distributeur selon la revendication 12, dans lequel lesdits moyens de blocage comportent un profil d'extrémité axial au moins partiellement plan formé sur les dents dudit second engrenage fixe (120) du corps (1) et dudit second engrenage (220) de l'élément de comptage (20), lesdits profils plan desdites dents étant au moins partiellement face à face jusqu'à ce que l'élément de comptage (20) a accompli une rotation suffisante pour décaler

lesdites dents, correspondant à ladite course de retour partielle ~~prédéterminée du distributeur.~~

~~14.- Distributeur selon l'une quelconque des revendications 10 à 13,~~
dans lequel ledit organe d'actionnement (30) du distributeur est solidaire
dudit réservoir (2) et se déplace axialement avec lui.

~~15.- Distributeur selon l'une quelconque des revendications~~
~~précédentes, dans lequel ledit corps (1) comporte un premier engrenage fixe~~
~~(110) et un second engrenage fixe (120), ledit élément de comptage (20)~~
~~comportant un premier engrenage (210) destiné à coopérer avec ledit~~
~~premier engrenage fixe (110), un second engrenage (220) destiné à coopérer~~
~~avec ledit second engrenage fixe (120), et un troisième engrenage (230)~~
~~destiné à coopérer avec un engrenage d'actionnement (300), solidaire d'un~~
~~organe d'actionnement (30) du distributeur, les dents dudit troisième~~
~~engrenage (230) et/ou dudit engrenage d'actionnement (300) étant réalisées~~
~~de tel sorte qu'un déplacement axial de l'organe d'actionnement (30)~~
~~sollicite ledit élément de comptage (20) à se déplacer axialement et en~~
~~rotation, le premier engrenage fixe (110) empêchant une rotation dudit~~
~~élément de comptage (20) jusqu'à ce que ledit élément de comptage (20) ne~~
~~coopère plus avec ledit premier engrenage fixe (110), après un déplacement~~
~~axial prédéterminé dudit élément de comptage (20) correspondant à ladite~~
~~course d'actionnement partielle prédéterminée du distributeur.~~

16.- Distributeur selon la revendication 15, dans lequel ledit second
engrenage fixe (120) du corps (1) et/ou ledit second engrenage (220) de
l'élément de comptage (20) comporte(nt) des moyens de blocage
empêchant un nouvel actionnement du distributeur, et donc une nouvelle
expulsion de produit pharmaceutique, lorsque l'élément de comptage (20)
revient vers sa position de repos après un actionnement précédent jusqu'à
ce que ledit distributeur réalise une course de retour partielle prédéterminée
à partir de laquelle le dispositif d'indication peut compter la prochaine
dose.

17.- Distributeur selon la revendication 16, dans lequel lesdits moyens de blocage comportent un profil d'extrémité axial plan formé sur les dents dudit second engrenage fixe (120) et dudit second engrenage (220), lesdites dents étant au moins partiellement face à face jusqu'à ce que l'élément de comptage (20) a accompli une rotation suffisante pour décaler lesdites dents, correspondant à ladite course de retour partielle prédéterminée du distributeur.

18.- Distributeur selon la revendication 16 ou 17, dans lequel ledit engrenage d'actionnement (300) comporte des moyens de butée (305) limitant la rotation de l'élément de comptage (20) jusqu'à ce que l'organe d'actionnement (30) a réalisé ladite course de retour partielle prédéterminée.

19.- Distributeur selon la revendication 18, dans lequel lesdits moyens de butée (305) comportent une projection axiale formée sur ledit engrenage d'actionnement (300).

20.- Distributeur selon l'une quelconque des revendications 15 à 19, dans lequel ledit organe d'actionnement (30) du distributeur est solidaire dudit réservoir (2) et se déplace axialement avec lui.

* * *

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PATENT APPLICATION FEE DETERMINATION RECORD
Effective December 8, 2004

Application or Docket Number

25 NOV 2006

10/556432

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
U.S. NATIONAL STAGE FEES		
BASIC FEE	SMALL ENT. = \$ 150	LARGE ENT. = \$ 300
EXAMINATION FEE	Satisfies POT Article 88(1) (4) = \$ 50 / \$ 100	All other situations = \$ 100 / \$ 200
SEARCH FEE	U.S. is ISA = \$ 50 / \$ 100 ALL other countries = \$ 200 / \$ 400	All other situations = \$ 250 / \$ 500
FEE FOR EXTRA SPEC. PGS.	minus 100 =	/ 50 =
TOTAL CHARGEABLE CLAIMS	20 minus 20 =	=
INDEPENDENT CLAIMS	1 minus 3 =	=
MULTIPLE DEPENDENT CLAIM PRESENT ☐		

SMALL ENTITY TYPE ☐ OR

OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	
EXAM. FEE	
SEARCH FEE	
X \$ 125 =	
X \$ 25 =	
X \$ 100 =	
+ \$ 180 =	
TOTAL	

RATE	FEE
BASIC FEE	300
EXAM. FEE	200
SEARCH FEE	400
X \$ 250 =	
X \$ 50 =	
X \$ 200 =	
+ \$ 380 =	
TOTAL	900

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

	(Column 1)	(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	* 20	Minus ** 20	=
Independent	* 1	Minus *** 3	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

SMALL ENTITY OR

OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE
X \$ 25 =	
X \$ 100 =	
+ \$ 180 =	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X \$ 50 =	
X \$ 200 =	
+ \$ 380 =	
TOTAL ADDIT. FEE	

	(Column 1)	(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus **	=
Independent	*	Minus ***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

RATE	ADDITIONAL FEE
X \$ 25 =	
X \$ 100 =	
+ \$ 180 =	
TOTAL ADDIT. FEE	

RATE	ADDITIONAL FEE
X \$ 50 =	
X \$ 200 =	
+ \$ 380 =	
TOTAL ADDIT. FEE	

- * If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
 - ** If the "Highest Number Previously Paid For" in THIS SPACE is less than "20", enter "20".
 - *** If the "Highest Number Previously Paid For" in THIS SPACE is less than "3", enter "3".
- The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-578 (Rev. 02/2006)

Patent and Trademark Office - U.S. DEPARTMENT OF COMMERCE

Rec'd PCT/PTO 27 JUN 2005 10/556432

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference VALS 907 B PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/FR2004/001189	International filing date (day/month/year) 14.05.2004	Priority date (day/month/year) 15.05.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant VALOIS SAS		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☒ (sent to the applicant and to the International Bureau) a total of <u>6</u> sheets, as follows: ☒ sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).																	
4. This report contains indications relating to the following items: <table border="0"> <tr> <td>☒ Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td>☐ Box No. II</td> <td>Priority</td> </tr> <tr> <td>☐ Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>☐ Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td>☒ Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td>☐ Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td>☐ Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td>☐ Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		☒ Box No. I	Basis of the report	☐ Box No. II	Priority	☐ Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	☐ Box No. IV	Lack of unity of invention	☒ Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	☐ Box No. VI	Certain documents cited	☐ Box No. VII	Certain defects in the international application	☐ Box No. VIII	Certain observations on the international application
☒ Box No. I	Basis of the report																
☐ Box No. II	Priority																
☐ Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																
☐ Box No. IV	Lack of unity of invention																
☒ Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																
☐ Box No. VI	Certain documents cited																
☐ Box No. VII	Certain defects in the international application																
☐ Box No. VIII	Certain observations on the international application																

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

Form PCT/IPEA/409 (cover sheet) (January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/001189

Box No. I	Basis of the report
1.	With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item. ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of: ☐ international search (Rule 12.3 and 23.1(b)) ☐ publication of the international application (Rule 12.4) ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2.	With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report): ☐ the international application as originally filed/furnished ☒ the description: pages <u>1-16</u> _____ as originally filed/furnished pages* _____ received by this Authority on _____ pages* _____ received by this Authority on _____ ☒ the claims: nos. _____ as originally filed/furnished nos.* _____ as amended (together with any statement) under Article 19 nos.* <u>1-20</u> _____ received by this Authority on <u>28.02.2005 with telefax</u> nos.* _____ received by this Authority on _____ ☒ the drawings: sheets <u>1/13-13/13</u> _____ as originally filed/furnished sheets* _____ received by this Authority on _____ sheets* _____ received by this Authority on _____ ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3.	☐ The amendments have resulted in the cancellation of: ☐ the description, pages _____ ☐ the claims, nos. _____ ☐ the drawings, sheets/figs _____ ☐ the sequence listing (specify): _____ ☐ any table(s) related to sequence listing (specify): _____
4.	☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)). ☐ the description, pages _____ ☐ the claims, nos. _____ ☐ the drawings, sheets/figs _____ ☐ the sequence listing (specify): _____ ☐ any table(s) related to sequence listing (specify): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

Form PCT/ISPEA/409 (Box No. I) (January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/001189

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	<u>2, 4-20</u>	YES
	Claims	<u>1</u>	NO
Inventive step (IS)	Claims	<u>2, 4-20</u>	YES
	Claims	<u>1</u>	NO
Industrial applicability (IA)	Claims	<u>1-20</u>	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
1. In the present report, reference is made to the following documents: D1: US 2002/195102 A1 (GODFREY JAMES WILLIAM ET AL) 26 December 2002 (2002-12-26) D2: US 6 446 627 B1 (PANAYI COSTANINOS ET AL) 10 September 2002 (2002-09-10) D3: DE 100 61 723 A (ECKERT ROSEMARIE) 11 July 2002 (2002-07-11) 2. The present application fails to meet the requirements of PCT Article 33(1), since the subject matter of claim 1 does not comply with the criterion of novelty as defined by PCT Article 33(2). D1 describes (the references between parentheses apply to said document): A fluid dispenser comprising a body (1), a fluid container (2), a dispensing member, such as a pump or a valve (4), mounted on said container (2) and a metered amount indicating device (13) for indicating the number of metered amounts of fluid dispensed or remaining to be dispensed from said container; said metered amount indicating device			

Form PCT/IPEA/409 (Box No. V) (January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/001189

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
	comprises a first safety system for actuating the metered amount indicating device on completion of a predetermined partial actuation stroke of the dispenser, even if the total actuation stroke is not achieved by the dispenser; said container is axially movable relative to said body; said body comprises at least one stationary gear assembly (17); said metered amount indicating device comprises a counting element (13) that is axially and rotationally movable relative to said body; when the dispenser is actuated, said counting element engages, on the one hand, said at least one stationary gear assembly of said body and, on the other hand, said container (see paragraph 49). The indicating device does not require the dispenser to be fully actuated, since, from the moment the hook (18a) engages the gear wheel (19), the hook can no longer move, even if the dispenser is actuated further. The dispenser according to claim 1 is therefore not novel. 3. The combination of features of the other dependent claims 2 and 4 to 20 is not found in the prior art and cannot be derived in an obvious manner therefrom. 4. Contrary to the requirement of PCT Rule 5.1(a)(ii), the relevant prior art disclosed in D1 has not been indicated in the description, nor has said document been cited.

Form PCT/IPEA/409 (Box No. V) (January 2004)



IFW

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: Unknown

Confirmation No.: Unknown

Examiner: Unknown

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

**SUBMISSION OF INTERNATIONAL PRELIMINARY
EXAMINATION REPORT (IPER)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

For the Examiner's convenience, enclosed herewith is a copy of the English translation of the International Preliminary Examination Report (IPER). It is noted that the three references cited in the International Search Report were previously submitted to the U.S. Patent and Trademark Office with an Information Disclosure Statement on November 9, 2005, and are therefore not enclosed herewith.

Respectfully submitted,

Raja N. Saliba
Registration No. 43,078

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: August 24, 2006

Expéditeur : le BUREAU INTERNATIONAL

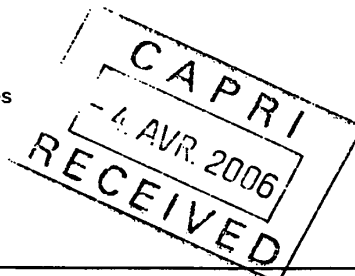
PCT

NOTIFICATION DE TRANSMISSION DE COPIES
DE LA TRADUCTION DU RAPPORT D'EXAMEN
PRELIMINAIRE INTERNATIONAL
SUR LA BREVETABILITE (CHAPITRE I OU CHAPITRE II
DU TRAITE DE COOPERATION EN MATIERE DE BREVETS)

(règles 44bis.3.c) et 72.2 du PCT)

Destinataire :

CAPRI
33 rue de Naples
F-75008 Paris
FRANCE



Date d'expédition (jour/mois/année) 30 mars 2006 (30.03.2006)	
Référence du dossier du déposant ou du mandataire VALS 907 B PCT	NOTIFICATION IMPORTANTE
Demande internationale n° PCT/FR2004/001189	Date du dépôt international (jour/mois/année) 14 mai 2004 (14.05.2004)
Déposant VALOIS SAS etc	

1. Transmission de la traduction au déposant.

- ☐ Le Bureau international transmet ci-joint copie de la traduction en langue anglaise du rapport préliminaire international sur la brevetabilité (chapitre I).
- ☒ Le Bureau international transmet ci-joint copie de la traduction en langue anglaise du rapport préliminaire international sur la brevetabilité (chapitre II).

2. Transmission d'une copie de la traduction aux offices désignés ou élus.

Le Bureau international notifie au déposant qu'une copie de cette traduction a été transmise aux offices désignés ou élus suivants qui exigent la traduction en question:

KR

Les offices désignés ou élus suivants ayant renoncé à l'exigence selon laquelle la transmission doit être effectuée à cette date recevront une copie de cette traduction du Bureau international seulement à leur demande:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Rappel concernant la traduction dans la ou l'une des langues officielles de l'office ou des offices élus.

Il est rappelé au déposant que, lorsqu'une traduction de la demande internationale doit être remise à un office élu, cette traduction doit comporter la traduction de toute annexe du rapport préliminaire international sur la brevetabilité (chapitre II).

Il appartient au déposant d'établir la traduction en question et de la remettre directement à chaque office élu intéressé dans le délai applicable (règle 74.1). Voir le volume II du *Guide du déposant du PCT* pour de plus amples renseignements.

Bureau international de l'OMPI 34, chemin des Colombettes 1211 Genève 20, Suisse	Fonctionnaire autorisé Athina Nickitas-Etienne
n° de télécopieur+41 22 740 14 35	n° de télécopieur+41 22 338 89 95

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference VALS 907 B PCT		FOR FURTHER ACTION	See Form PCT/IPEA/416																								
International application No. PCT/FR2004/001189	International filing date (day/month/year) 14.05.2004	Priority date (day/month/year) 15.05.2003																									
International Patent Classification (IPC) or national classification and IPC																											
Applicant VALOIS SAS																											
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☐	Box No. II	Priority																									
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Date of submission of the demand		Date of completion of this report																									
Name and mailing address of the IPEA/EP		Authorized officer																									
Facsimile No.		Telephone No.																									

Form PCT/IPEA/409 (cover sheet) (January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/001189

Box No. 1	Basis of the report
1.	With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item. ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of: ☐ international search (Rule 12.3 and 23.1(b)) ☐ publication of the international application (Rule 12.4) ☐ international preliminary examination (Rule 55.2 and/or 55.3) 2. With regard to the elements of the international application, this report is based on <i>(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 1-4 are referred to in this report as "originally filed" and are not annexed to this report)</i>: ☐ the international application as originally filed/furnished ☒ the description: pages <u>1-16</u> _____ as originally filed/furnished pages* _____ received by this Authority on _____ pages* _____ received by this Authority on _____ ☒ the claims: nos. _____ as originally filed/furnished nos.* _____ as amended (together with any statement) under Article 19 nos.* <u>1-20</u> _____ received by this Authority on <u>28.02.2005 with</u> nos.* _____ received by this Authority on <u>telefax</u> ☒ the drawings: sheets <u>1/13-13/13</u> _____ as originally filed/furnished sheets* _____ received by this Authority on _____ sheets* _____ received by this Authority on _____ ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing. 3. ☐ The amendments have resulted in the cancellation of: ☐ the description, pages _____ ☐ the claims, nos. _____ ☐ the drawings, sheets/figs _____ ☐ the sequence listing (specify): _____ ☐ any table(s) related to sequence listing (specify): _____ 4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)). ☐ the description, pages _____ ☐ the claims, nos. _____ ☐ the drawings, sheets/figs _____ ☐ the sequence listing (specify): _____ ☐ any table(s) related to sequence listing (specify): _____ * If item 4 applies, some or all of those sheets may be marked "superseded."

Form PCT/1PEA/409 (Box No. 1) (January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/FR2004/001189

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
1. Statement	
Novelty (N)	Claims <u>2, 4-20</u> YES Claims <u>1</u> NO
Inventive step (IS)	Claims <u>2, 4-20</u> YES Claims <u>1</u> NO
Industrial applicability (IA)	Claims <u>1-20</u> YES Claims _____ NO
2. Citations and explanations (Rule 70.7)	
1.	In the present report, reference is made to the following documents: D1: US 2002/195102 A1 (GODFREY JAMES WILLIAM ET AL) 26 December 2002 (2002-12-26) D2: US 6 446 627 B1 (PANAYI COSTANINOS ET AL) 10 September 2002 (2002-09-10) D3: DE 100 61 723 A (ECKERT ROSEMARIE) 11 July 2002 (2002-07-11)
2.	The present application fails to meet the requirements of PCT Article 33(1), since the subject matter of claim 1 does not comply with the criterion of novelty as defined by PCT Article 33(2). D1 describes (the references between parentheses apply to said document): A fluid dispenser comprising a body (1), a fluid container (2), a dispensing member, such as a pump or a valve (4), mounted on said container (2) and a metered amount indicating device (13) for indicating the number of metered amounts of fluid dispensed or remaining to be dispensed from said container; said metered amount indicating device

Form PCT/IPEA/409 (Box No. V) (January 2004)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/FR2004/001189

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

comprises a first safety system for actuating the metered amount indicating device on completion of a predetermined partial actuation stroke of the dispenser, even if the total actuation stroke is not achieved by the dispenser; said container is axially movable relative to said body; said body comprises at least one stationary gear assembly (17); said metered amount indicating device comprises a counting element (13) that is axially and rotationally movable relative to said body; when the dispenser is actuated, said counting element engages, on the one hand, said at least one stationary gear assembly of said body and, on the other hand, said container (see paragraph 49).

The indicating device does not require the dispenser to be fully actuated, since, from the moment the hook (18a) engages the gear wheel (19), the hook can no longer move, even if the dispenser is actuated further.

The dispenser according to claim 1 is therefore not novel.

3. The combination of features of the other dependent claims 2 and 4 to 20 is not found in the prior art and cannot be derived in an obvious manner therefrom.
4. Contrary to the requirement of PCT Rule 5.1(a)(ii), the relevant prior art disclosed in D1 has not been indicated in the description, nor has said document been cited.

DO/EO WORK SHEET — DATE 25 NOV 2006

✓ US APPLICATION: 10/556432 WIPO No: 04/101042 Pub. Date: 25 NOV 04
App. Not Pub. — RO101 — Priority Doc. 1 — Basic fee — Entity: L — S —
Int. Application No. FR04/01189 Language: Eng, Jpx, Dex, Cnx, Krx, Frx, Esx, Rux
✓ Specification Pages 16 Claim Pages 6 Drawings 13 Abs. Pages 1 Seq. Pages —
✓ Translation of Application 11/09/05 Trans. of Foreign Text in drawings Yes — No —
✓ Search Report: EP, JP, SE, AU, US, CN, ES, RU, AT, KR: Search Report Ref. —
✓ I.P.E. Report/409: 11/09/05 EP, JP, SE, AU, US, CN, ES, RU, AT, KR. Other —
✓ Annexes to IPER Report: 11/09/05 Translation of the Annexes Yes — No —
✓ Specification Pages — Claims 1/20 Drawings — Annexes entered Yes — No —
Reason annexes were not entered: —
ISA/237 Report: — EP, JP, SE, AU, US, CN, ES, RU, AT, KR: Other —
Art. 19 Amd't: EP JP SE AU US CN ES RU AT KR: Translated — Entered —
✓ Preliminary Amendment: (1) 11/09/05 (2) — (3) — Entered Yes — No —
Reason why the Preliminary Amendment/Art. 19 Amd't was not entered: —
Substitute Specification: — Mark Up Copy: —
✓ I.D.S Date: (1) 11/09/05 (3), Declaration/Oath Date: 11/09/05
✓ Power of Attorney: 11/09/05 Change of Power of Attorney: —
Change of Address Date: — Application Data Sheet: —
✓ Assignment Date: 11/09/05 DNA Diskette Date: — Seq. Listing Date: —
✓ 35 U.S.C. 371 Receipt of Request (PTO-1390): 11/09/05
✓ Date of acceptable Oath/Declaration Received: 11/09/05
✓ Date of completion of requirements under 35 U.S.C. 371: 11/09/05
✓ Date of completion of all Requirements: 11/09/05
✓ Date of completion of notice of Acceptance DO/EO 903: 11/25/06
Date of completion of Notification of Missing Requirements DO/EO 905: —
Date of completion of Defective Response DO/EO 916: —
Date of completion of DO/EO 922 (Sequence Listing & Diskette): —
Date of completion of DO/EO 923: —
Date of completion of Notice of Abandonment DO/EO 909: —

Remarks: —
—
—

PATENT APPLICATION FEE DETERMINATION RECORD

Effective December 8, 2004

25 NOV 2006

Application or Docket Number

10/556432

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
U.S. NATIONAL STAGE FEES		
BASIC FEE	SMALL ENT. = \$ 150	LARGE ENT. = \$ 800
EXAMINATION FEE	Satisfies PCT Article 83(1)-(4) = \$ 50 / \$ 100	All other situations = \$ 100 / \$ 200
SEARCH FEE	U.S. ISA = \$ 50 / \$ 100 ALL other countries = \$ 200 / \$ 400	All other situations = \$ 250 / \$ 500
FEE FOR EXTRA SPEC. PGS.	minus 100 =	/ 50 =
TOTAL CHARGEABLE CLAIMS	20 minus 20 =	-
INDEPENDENT CLAIMS	1 minus 3 =	-
MULTIPLE DEPENDENT CLAIM PRESENT ☐		

* If the difference in column 1 is less than zero, enter "0" in column 2

CLAIMS AS AMENDED - PART II

	(Column 1)	(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**
Independent	*	Minus	***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

	(Column 1)	(Column 2)	(Column 3)
	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA
Total	*	Minus	**
Independent	*	Minus	***
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM ☐			

SMALL ENTITY TYPE ☐

OR

OTHER THAN SMALL ENTITY

RATE	FEE
BASIC FEE	
EXAM. FEE	
SEARCH FEE	
X \$ 125 =	
X \$ 25 =	
X \$ 100 =	
+ \$ 180 =	
TOTAL	

OR

OR

OR

OR

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OR

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OR

OR

OR

RATE	FEE
BASIC FEE	300
EXAM. FEE	300
SEARCH FEE	400
X \$ 250 =	
X \$ 50 =	
X \$ 200 =	
+ \$ 360 =	
TOTAL	900

SMALL ENTITY TYPE ☐

OR

OTHER THAN SMALL ENTITY

RATE	ADDITIONAL FEE
X \$ 25 =	
X \$ 100 =	
+ \$ 180 =	
TOTAL ADDIT. FEE	

OR

OR

OR

OR

OR

OR

OR

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OR

OR

OR

OR

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OR

OR

OR

OR

OR

OR

OR

OR

RATE	ADDITIONAL FEE
X \$ 50 =	
X \$ 200 =	
+ \$ 360 =	
TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than "20", enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than "3", enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

FORM PTO-876 (Rev. 02/2005)

Patent and Trademark Office - U.S. DEPARTMENT OF COMMERCE

3M Company Exhibit 1004

3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp., v. AptarFrance S.A.S.

Page 200 of 1348

**MULTIPLE DEPENDENT CLAIM
FEE CALCULATION SHEET**
(FOR USE WITH FORM PTO-875)

SERIAL NO.

10/556432

FILING DATE

25 NOV 2006

APPLICANT(S)

CLAIMS

	AS FILED		AFTER 1 st AMENDMENT		AFTER 1 st AMENDMENT	
	IND.	DEP.	IND.	DEP.	IND.	DEP.
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TOTAL IND.	1		1			
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U.S. DEPARTMENT OF COMMERCE



UNITED STATES PATENT AND TRADEMARK OFFICE

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P.O. Box 1450
Alexandria, Virginia 22313-1450
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U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/556,432	Fabien Poulard	Q91404

23373
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

INTERNATIONAL APPLICATION NO.	
PCT/FR04/01189	
I.A. FILING DATE	PRIORITY DATE
05/14/2004	05/15/2003

CONFIRMATION NO. 3524
371 ACCEPTANCE LETTER



Date Mailed: 11/28/2006

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

<u>11/09/2005</u>	<u>11/09/2005</u>
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Copy of the International Application filed on 11/09/2005
- English Translation of the IA filed on 11/09/2005
- Copy of the International Search Report filed on 11/09/2005
- Copy of IPE Report filed on 11/09/2005
- Preliminary Amendments filed on 11/09/2005
- Information Disclosure Statements filed on 11/09/2005
- Oath or Declaration filed on 11/09/2005
- Request for Immediate Examination filed on 11/09/2005
- U.S. Basic National Fees filed on 11/09/2005
- Assignment filed on 11/09/2005
- Priority Documents filed on 11/09/2005

- Power of Attorney filed on 11/09/2005

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

WINSTON M ALVARADO
Telephone: (703) 308-9140 EXT 206

PART 3 - OFFICE COPY

FORM PCT/DO/EO/903 (371 Acceptance Notice)



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
10/556,432	11/09/2005	3754	900	Q91404	13	20	1

CONFIRMATION NO. 3524

23373
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC20037

FILING RECEIPT

Date Mailed: 11/28/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Fabien Poulard, Rouen, FRANCE;

Assignment For Published Patent Application

VALOIS S.A.S., LE NEUBOURG, FRANCE

Power of Attorney: The patent practitioners associated with Customer Number 23373

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/FR04/01189 05/14/2004

Foreign Applications

FRANCE 03/05858 05/15/2003

If Required, Foreign Filing License Granted: 11/25/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/556,432**

Projected Publication Date: 03/08/2007

Non-Publication Request: No

Early Publication Request: No

Title

Fluid product dispenser

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the

subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



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APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
10/556,432	11/09/2005	Fabien Poulard	Q91404

CONFIRMATION NO. 3524

23373
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC20037

Title: Fluid product dispenser

Publication No. US-2007-0051745-A1

Publication Date: 03/08/2007

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publicly available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently <http://www.uspto.gov/patft/>.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently <http://pair.uspto.gov/>. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 703-305-3028.

Pre-Grant Publication Division, 703-605-4283



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 07/22/2008 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER CHOI, HYE A JUNG	
			ART UNIT 3754	PAPER NUMBER
			MAIL DATE 07/22/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/556,432	POULARD, FABIEN	
	Examiner	Art Unit	
	HYEA J. CHOI	3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 24 August 2006.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-20 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 09 November 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>09 November 2005</u> .	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ 5) ☐ Notice of Informal Patent Application 6) ☐ Other: _____.

DETAILED ACTION

1. This application has been treated as being obviously informal. Note, it is impractical to give a complete action on the merits because of the insufficiencies noted below. A reasonable search has been made in so far as the invention could be understood from the disclosure.

Information Disclosure Statement

2. The information disclosure statement filed on 11/09/05 has been received and considered. The search report from PCT/FR2004/001189 has also been received and considered.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the details as described in the specification. Note, the drawings only show a container, a body, and an actuator, and fail to specifically show how such elements are connected/mounted to one another in order for them to operate. Applicant is warned about the insertion of new matter under rule 37 CFR 1.53(b). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be

removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to under 37 CFR 1.83(b) because they are incomplete. 37 CFR 1.83(b) reads as follows:

When the invention consists of an improvement on an old machine the drawing must when possible exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings

for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pump or valve of claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “120” has been used to designate both an axial projection (page 13 of specification, line 20) and a stationary gear (page 14, line 23). Also, reference character “220” has been used to designate both an axial projection (page 13, line 21) and a gear (page 14, line 24). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

7. Drawings submitted after the filing date may not be used to overcome any insufficiency of the specification due to lack of an enabling disclosure or otherwise inadequate disclosure therein, or to supplement the original disclosure thereof for the purpose of interpretation of the scope of any claim.

Claim Objections

8. Claim 13 and 17 are objected to because of the following informalities. It appears that the word "plane" in these claims should be replaced with the word --planar--. For the purpose of prosecuting this case, the examiner has assumed that the word --planar--was intended. Appropriate correction is required.

9. Claims 1, 10-13, and 15-17 refer to part 120 as a stationary gear.

Claim 6 refers to part 120 as blocking means.

Claim 7 refers to part 120 as an axial projection.

Please indicate which part has been correctly labeled.

10. Claims 10-13 and 15-17 refer to part 220 as a second gear.

Claim 6 refers to part 220 as blocking means.

Claim 7 refers to part 220 as an axial projection.

Please indicate which part has been correctly labeled.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide an adequate description of the invention that would enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The disclosure (specification and drawings) is a vague description of desired function without specific means to implement. Note, it is not clear from the disclosure

as to how the dispenser/counter functions/operates. While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details as to enable those persons skilled in the art to make and utilize the invention. Specific operative embodiments or examples of the invention must be set forth.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. The following noted informalities are merely exemplary thereof:

16. Claim 8 recites the limitations "the second gear" and "the actuator member". There is lack of antecedent basis for these limitations in the claim.

17. Claims 9-10 and 14 recite the limitation "the actuator member". There is lack of antecedent basis for this limitation in the claims.

18. In light of the informalities, the claims have been examined as could best be understood by the examiner. The examiner's failure to apply prior art to any of the claims should not be construed as allowable subject matter.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

20. Claim 1 is rejected under 35 U.S.C. 102(e) as being rejected by U.S. Publication 2002/0195102 to Rand et al. (Rand)

Rand discloses a fluid dispenser as shown in Fig. 1, 2a, and 3, comprising a body 1, a fluid reservoir 2, a dispenser member, such as a pump or a valve 4, mounted on the reservoir 2, a dose indicator 13 that includes a first safety system for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke. The reservoir 2 is axially displaceable relative to the body 1. The body 1 includes at least one stationary gear 17. The dose indicator device includes a counter element 13 that is displaceable axially and in rotation relative to the body. The counter element co-operates firstly with at least one stationary gear and secondly with the reservoir.

The indicating device does not require the dispenser to be fully actuated, since, from the moment the hook 18a engages the gear wheel 19, the hook can no longer move, even if the dispenser is actuated further.

Conclusion

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Blacker et al. shows a dispenser that keeps track of the dosages dispensed/remaining.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HYE A. CHOI whose telephone number is (571)270-5061. The examiner can normally be reached on Monday through Friday; 7:30 A.M. to 5:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. J. C./
Examiner, Art Unit 3754

/Kevin P. Shaver/
Supervisory Patent Examiner, Art Unit 3754

Notice of References Cited	Application/Control No. 10/556,432	Applicant(s)/Patent Under Reexamination POULARD, FABIEN	
	Examiner HYEA J. CHOI	Art Unit 3754	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,142,339	11-2000	Blacker et al.	222/23
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
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FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
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	Q					
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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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BIB DATA SHEET

CONFIRMATION NO. 3524

SERIAL NUMBER 10/556,432	FILING or 371(c) DATE 11/09/2005 RULE	CLASS 222	GROUP ART UNIT 3754	ATTORNEY DOCKET NO. Q91404	
APPLICANTS Fabien Poulard, Rouen, FRANCE; ** CONTINUING DATA ***** This application is a 371 of PCT/FR04/01189 05/14/2004 ** FOREIGN APPLICATIONS ***** FRANCE 03/05858 05/15/2003 ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 11/25/2006					
Foreign Priority claimed ☒ Yes ☐ No 35 USC 119(a-d) conditions met ☒ Yes ☐ No Verified and Acknowledged <u>/HYEA JUNG CHOI/</u> Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY FRANCE	SHEETS DRAWINGS 13	TOTAL CLAIMS 20	INDEPENDENT CLAIMS 1
ADDRESS SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 UNITED STATES					
TITLE Fluid product dispenser					
FILING FEE RECEIVED 900	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:		☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit		

EAST Search History

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	477	222/162.ccls.	US-PGPUB; USPAT; FPRS; EPO; JPO; IBM_TDB	OR	ON	2008/07/16 08:15
S1	14	(fabien near poulard). in.	US-PGPUB; USPAT; FPRS; EPO; JPO; IBM_TDB	OR	ON	2008/07/15 16:31
S2	1	"2002195102"	US-PGPUB; USPAT; FPRS; EPO; JPO; IBM_TDB	OR	ON	2008/07/15 16:42
S3	27	(godfrey near william).in.	US-PGPUB; USPAT; FPRS; EPO; JPO; IBM_TDB	OR	ON	2008/07/15 16:43
S4	122	(godfrey near james). in.	US-PGPUB; USPAT; FPRS; EPO; JPO; IBM_TDB	OR	ON	2008/07/15 16:45
S5	1	"6446627".pn.	US-PGPUB; USPAT; FPRS; EPO; JPO; IBM_TDB	OR	ON	2008/07/15 16:47
S6	3	"10061723"	US-PGPUB; USPAT; FPRS; EPO; JPO; IBM_TDB	OR	ON	2008/07/15 16:49
S7	2	"0480488"	US-PGPUB; USPAT; FPRS; EPO; JPO; IBM_TDB	OR	ON	2008/07/15 16:55
S8	262	222/36.ccls.	US-PGPUB; USPAT; FPRS; EPO; JPO; IBM_TDB	OR	ON	2008/07/15 18:01
S9	230	222/38.ccls.	US-PGPUB; USPAT; FPRS; EPO; JPO; IBM_TDB	OR	ON	2008/07/15 18:23

7/ 16/ 2008 8:57:20 AM

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Search Notes 	Application/Control No. 10556432	Applicant(s)/Patent Under Reexamination POULARD, FABIEN
	Examiner HYEA J CHOI	Art Unit 3754

SEARCHED			
Class	Subclass	Date	Examiner
222	36, 38, and 162	July 2008	Hyea Jung Choi

SEARCH NOTES			
Search Notes		Date	Examiner
Got search in class 222 from Kevin Shaver.		July 2008	Hyea Jung Choi
See attached EAST history.			

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

<i>Index of Claims</i> 	Application/Control No. 10556432	Applicant(s)/Patent Under Reexamination POULARD, FABIEN
	Examiner HYE A J CHOI	Art Unit 3754

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47										
CLAIM		DATE								
Final	Original	07/16/2008								
	1	✓								
	2	✓								
	3	✓								
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	19	✓								
	20	✓								

Substitute for Form 1449 A & B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10556432 PCT/FR2004/001189
		Confirmation Number	Unknown
		Filing Date	November 9, 2005
		First Named Inventor	Fabien POULARD
		Art Unit	Unknown
		Examiner Name	
Sheet	1	of	1
		Attorney Docket Number	Q91404

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		
/H.C./		US 2002/0195102	A1	12/26/2002	PAUL KENNETH RAND, ET AL
/H.C./		US 6,446,627	B1	09/10/2002	NICHOLAS JOHN BOWMAN, ET AL
		US			
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		US			
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FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			
/H.C./		DE	100 61 723	A1	07/11/2002	ROSEMARIE ECKERT	
/H.C./		EP	0 480 488	A1	04/15/1992	ELETTRO PLASTICA S.p.A.	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶

Examiner Signature	/Hyea Choi/	Date Considered	07/15/2008

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Hyea Jung CHOI

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

AMENDMENT UNDER 37 C.F.R. § 1.111

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated July 22, 2008, please amend the above-identified application as follows on the accompanying pages.

TABLE OF CONTENTS

AMENDMENTS TO THE SPECIFICATION	2
AMENDMENTS TO THE CLAIMS	8
AMENDMENTS TO THE DRAWINGS	15
REMARKS	16

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph no. 32 with the following amended paragraph:

The descriptions of the three embodiments below relate to actuation cycles of the dispenser, and to the various functional features of the indicator device that make it possible to guarantee operational and counting reliability of said indicator device. The drawings to which the present description refers are therefore highly simplified diagrams which do not show the fluid dispenser in detail, but only in very diagrammatic manner relating to the various portions that can be moved relative to one another, for explaining the actuation cycle of said dispenser and of said indicator device. Thus, for example, the dispenser member, e.g. a pump or a valve, is ~~not shown in the drawings~~ only shown in Figure 1. In addition, the dispenser head including the dispenser orifice is also not shown, since these elements are not directly involved in the present invention.

Please replace the paragraph no. 34 with the following amended paragraph:

With reference to FIGS. 1 to 8, a first embodiment of the present invention is described. In this first embodiment, the dispenser includes a reservoir 2 that is axially displaceable in a body 1, which is considered below as being the stationary portion of the dispenser. The axial displacement of the reservoir 2 relative to the body 1 actuates the dispenser member 3 (shown in FIG. 1) and thus causes a dose of fluid to be dispensed from said reservoir. In this first embodiment, the dispenser includes an actuator member 30 on which the user exerts an axial actuation force so as to actuate the dispenser and thus displace said reservoir 2 relative to the body 1. The dispenser further includes a dose indicator device for counting or indicating the dispensing of one fluid dose each time the dispenser is actuated. Thus, by means of the indicator

device, the user can tell how many doses have been dispensed from said reservoir 2, or how many doses remain inside said reservoir 2. This information must be very accurate, in particular when the fluid is a pharmaceutical, and any risk of under-counting must be eliminated. In the event of under-counting, i.e. in the event of the indicator device failing to count one or more occasions on which a dose of fluid is dispensed in full or in part, the user can end up with a dispenser that indicates that one or two doses remain in the reservoir, whereas in reality, the reservoir is empty. In the event of an asthma attack, the user can thus end up with a dispenser that is no longer functional, and that does not enable the user to take the medicine.

Please replace the paragraph no. 43 with the following amended paragraph:

FIG. 6 is a diagram showing an attempt to perform a new actuation before the dispenser has completed its return stroke. It should be observed that the body 1 includes axial projections 120 that co-operate with axial projections 220 formed on the counter element 20. In a variant, the axial projections 120, 220 can be replaced by gears 122, 222 of corresponding shape. Preferably, the axial end-profiles of said projections 120 and 220 are formed by planes, and the axial projections 120 and 220 are disposed facing each other, at least in part, so that if the return stroke of the dispenser is insufficient, it is impossible to expel a new dose of fluid, as shown in FIG. 6. In order to be able to actuate the dispenser once again, it is necessary for the counter element 20 to turn sufficiently about its axis of rotation, for said projections 120 and 220 to be offset relative to each other, thereby enabling a new actuation. The offset is achieved by freeing the actuator member 30 from the end wall of the second gear 230 of the counter element 20, so as to position it facing the first step, defined by the abutment 235 of the following tooth. The new actuation can be permitted before the dispenser has completed its return stroke, as soon as the indicator device

is once again capable of counting a new actuation of the dispenser. The present invention makes it possible to fulfill this requirement, as shown in FIG. 7, in which the return stroke is not complete, but the actuator member 30 of the dispenser, and in particular the actuator gear 300, is in a position in which it can co-operate with the next tooth of the second gear 230 of the counter element, so that a new actuation at this moment causes the counter element to turn through the end of its preceding cycle, thereby causing said axial projections 120 and 220 to be offset, and thus enabling the dispenser and the dose indicator device to be actuated once again. The aim is to prevent expulsion when the chamber is full, so long as the counter is not ready to count another dose.

Please replace the paragraph no. 45 with the following amended paragraph:

FIGS. 9 to 12 show a second embodiment of the invention. The second embodiment differs from the first embodiment as follows: Firstly, the body 1 includes two stationary gears 110 and ~~120~~122, and the counter element 20 includes two gears 210, ~~220~~222, each co-operating with one of the stationary gears of the body. The stationary gear 122 and the gear 222 are used in this embodiment in place of the axial projections 120 and 220. The actuator member 30 is secured to the reservoir 2, and the counter element 20 is axially displaceable with said actuator member 30. It can be turned relative to said actuator member 30. In fact, in the second embodiment, there is not really an actuator member, but the user generally displaces the reservoir 2 itself, relative to the body 1, so as to perform the actuation. The second stationary gear ~~120~~122 of the body 1 and the second gear ~~220~~222 of the counter element include respective portions 121 and 221 that are oblique, at least in part, and said portions co-operate with each other while the dispenser is being actuated. The oblique portions urge the counter element 20 to turn, and thus initiate a counting cycle of the dose indicator device. As shown in FIGS. 9 and 10, while the

dispenser is being actuated, the counter element is firstly displaced axially without turning, by being secured to the actuator member 30 and the reservoir 2. Once the dispenser has performed the predetermined incomplete actuation stroke, the oblique portions ~~220~~121, 221 of the second gears ~~120~~122, ~~220~~222 co-operate so as to cause the actuator member to turn, as shown in FIG. 10.

Please replace the paragraph no. 47 with the following amended paragraph:

FIG. 11 shows the actuated position in which the complete actuation stroke has been performed, and FIG. 12 shows the second safety means, provided by means of the second stationary gear ~~120~~122, and the second gear ~~220~~222 of the counter element 20. The two gears also include respective plane portions, each having a plane axial end-profile, so that when the return stroke of the dispenser is not sufficient, as can be seen in FIG. 12, a new actuation of the system brings the counter element 20 into axial abutment with the second stationary gear ~~120~~122 via their plane end-portions, thereby preventing any pharmaceutical from being expelled, by preventing the dispenser from being actuated. It is only once a predetermined incomplete return stroke has been performed that the oblique portions of the second gears ~~120~~122 and ~~220~~222 are facing each other, so as to enable the dispenser and the dose indicator device to be actuated once again.

Please replace the paragraph no. 48 with the following amended paragraph:

FIGS. 13 to 21 show a third embodiment of the present invention. The third embodiment differs from the second embodiment in that the counter element 20 is not axially secured to the actuator member 30 and to the reservoir. The actuator member 30 and the reservoir 2 include an

actuator gear 300 that co-operates with a third gear 230 provided on the counter element 20. In the third embodiment, turning of the counter element 20 during the actuation stroke of the dispenser is thus no longer caused by the second stationary gear ~~120~~122, but by means of the third gear 230 and the actuator gear 300. The third embodiment is thus a combination of the first and second embodiments described above. At the start of actuation, when in the situation in FIG. 13, the co-operation between the first stationary gear 110 and the first gear 210 of the counter element 20, prevents the counter element 20 from turning, and thus causes said counter element to be axially displaced. When in the position shown in FIG. 14, the above-mentioned first gears no longer co-operate, and the oblique profiles of the teeth of the actuator gear 300 and of the third gear 230 of the counter element 20, cause the counter element 20 to turn. This takes place after said incomplete actuation stroke of the dispenser, after which a complete or incomplete dose of fluid can be dispensed. FIG. 15 shows that if the axial actuation force is eliminated at this moment, the return spring 50 causes the counter element to turn through its complete counting cycle, thereby preventing any risk of under-counting.

Please replace the paragraph no. 49 with the following amended paragraph:

FIG. 16 shows the final actuated position in which the complete actuation stroke has been performed. At this moment, when the user releases the actuation force on the actuator member 30, the system rises under the effect of the return spring 50, and the co-operation between the first gears 210 and 110 of the counter element 20 and the body 1, respectively, causes the counter element to continue to turn. This continued turning is blocked in the actuator gear 300 by abutment means 305. With reference to FIG. 18, if in this position the user presses once again on the actuator member 30, it should be observed that actuation of the dispenser and of the counter

device is prevented as a result of the second gear ~~220~~222 of the counter element, and the second stationary gear ~~120~~122 of the body 1, facing each other at their plane axial end-profiles. FIG. 19 shows an attempt to perform an actuation while the second safety system is operational. For the dispenser and the dose indicator device to be actuated once again, it is necessary to perform a predetermined incomplete return stroke, which is shown in FIG. 20. If from this position the user actuates again, the counter element 20 would turn, thereby enabling the dispenser and the indicator device to be actuated once again.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1. (currently amended): A fluid dispenser comprising a body (1), a fluid reservoir (2), a dispenser member, ~~such as a pump or a valve~~, mounted on said reservoir (2), and a dose indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, the dispenser being characterized in that said dose indicator device includes a first safety system ~~for actuating~~ that actuates the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform the complete actuation stroke, said reservoir (2) being axially displaceable relative to said body (1), said body (1) including at least one stationary gear (110, ~~120~~122), said dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to said body (1), said counter element (20) co-operating, while the dispenser is being actuated, firstly with said at least one stationary gear (110, ~~120~~122) of said body, and secondly with said reservoir (2).

2. (original): A dispenser according to claim 1, in which said dose indicator device includes a second safety system which, during the return stroke of the dispenser after dispensing a dose, prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been

performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

3. (previously presented): A dispenser according to claim 1, in which said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20), said counter element (20) including a second gear (230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser, the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation, the stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

4. (original): A dispenser according to claim 3, in which the stationary gear (110) includes abutment means (115) preventing said counter element (20) from turning once said counter element (20) has turned at least in part, an additional axial displacement of said counter element (20) being necessary to enable it to continue to turn and/or to return the indicator device to its rest position.

5. (original): A dispenser according to claim 4, in which said abutment means (115) comprise an axial projection.

6. (currently amended): A dispenser according to claim 1, in which said stationary gear

(110) and/or said counter element (20) include(s) blocking means ~~(120, 220)~~ preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position after a preceding actuation, and until the dispenser has completed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

7. (currently amended): A dispenser according to claim 6, in which said blocking means comprise axial projections (120, 220) provided on the body (1) and on the counter element (20) respectively, each of said projections (120, 220) having an axial end-profile that is ~~plane~~planar, said projections (120, 220) facing each other, at least in part, until the counter element has turned sufficiently to offset said projections (120, 220), with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

8. (currently amended): A dispenser according to claim ~~7~~3, in which the teeth of the second gear (230) of the counter element (20) include an intermediate step (235), the actuator member (30) co-operating with said step (235) while the dispenser is being actuated, and co-operating with the end wall of said second gear (230) while returning to the rest position, after being actuated, the displacement between the intermediate step (235) and the end wall being obtained by said counter element (20) turning.

9. (currently amended): A dispenser according to claim ~~7~~3, in which, once the predetermined incomplete return stroke has been performed, the actuator member (30) is positioned facing the following tooth of the second gear (230) of the counter element (20),

enabling the dispenser and the dose indicator device to be actuated once again.

10. (currently amended): A dispenser according to claim 1, in which said body (1) includes a first stationary gear (110) and a second stationary gear (~~120~~122), said counter element (20) including a first gear (210) for co-operating with said first stationary gear (110) and a second gear (~~220~~222) for co-operating with said second stationary gear (~~120~~122), said counter element (20) being put axially into contact with ~~the~~an actuator member (30) of the dispenser by means of a return spring (50) and being turnable relative to said actuator member (30), the teeth of said second gear (~~220~~222) and of said second stationary gear (~~120~~122) being oblique, at least in part, so that an axial displacement of the actuator member (30) initially causes said counter element (20) to be displaced axially over a predetermined incomplete actuation stroke until the oblique portion (221) of said second gear (~~220~~222) of the counter element (20) co-operates with said oblique portion (121) of said second stationary gear (~~120~~122), causing the counter element (20) to be turned over a first portion of a turn cycle, the teeth of said first gear (210) and of said first stationary gear (110) being oblique, at least in part, so that when the counter element (20) returns to its rest position, it is caused to turn so as to terminate its turn cycle, which corresponds to one actuation of the dispenser being counted.

11. (currently amended): A dispenser according to claim 10, in which said first and second stationary gears (110, ~~120~~122) of the body (1) and/or said first and second gears (210, ~~220~~222) of the counter element (20) are offset relative to each other, so that whenever the counter element (20) is displaceable in rotation, returning said counter element to its rest position without terminating the actuation stroke of the dispenser causes the counter element (20) to turn

over its complete turn cycle, guaranteeing that one actuation of the dispenser is counted after said predetermined incomplete actuation stroke.

12. (currently amended): A dispenser according to claim 10, in which said second stationary gear (~~120~~122) of the body (1) and/or said second gear (~~220~~222) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, and until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

13. (currently amended): A dispenser according to claim 12, in which said blocking means have an axial end-profile that is ~~plane~~planar, at least in part, and that is formed on the teeth of said second stationary gear (~~120~~122) of the body (1) and on the teeth of said second gear (~~220~~222) of the counter element (20), said ~~plane~~planar profiles of said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

14. (previously presented): A dispenser according to claim 10, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

15. (currently amended): A dispenser according to claim 1, in which said body (1)

includes a first stationary gear (110) and a second stationary gear (~~120~~122), said counter element (20) comprising a first gear (210) for co-operating with said first stationary gear (110), a second gear (~~220~~222) for co-operating with said second stationary gear (~~120~~122), and a third gear (230) for co-operating with an actuator gear (300) secured to an actuator member (30) of the dispenser, the teeth of said third gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member (30) causes said counter element (20) to be displaced axially and in rotation, the first stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

16. (currently amended): A dispenser according to claim 15, in which said second stationary gear (~~120~~122) of the body (1) and/or said second gear (~~220~~222) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

17. (currently amended): A dispenser according to claim 16, in which said blocking means have an axial end-profile that is ~~plane~~planar and that is formed on the teeth of said second stationary gear (~~120~~122) and on the teeth of said second gear (~~220~~222), said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to

offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

18. (previously presented): A dispenser according to claim 16, in which said actuator gear (300) includes abutment means (305) limiting the extent to which the counter element (20) can turn, until the actuator member (30) has performed said predetermined incomplete return stroke.

19. (original): A dispenser according to claim 18, in which said abutment means (305) comprise an axial projection formed on said actuator gear (300).

20. (previously presented): A dispenser according to claim 15, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

21. (new): A dispenser according to claim 1, wherein the dispenser member is a pump or a valve.

AMENDMENTS TO THE DRAWINGS

Figure 1 is amended to show the dispenser member. Figures 9-21 are amended to change reference numerals 120 and 220 to 122 and 222, respectively.

Attachment: Replacement Sheets 1-13.

1/13

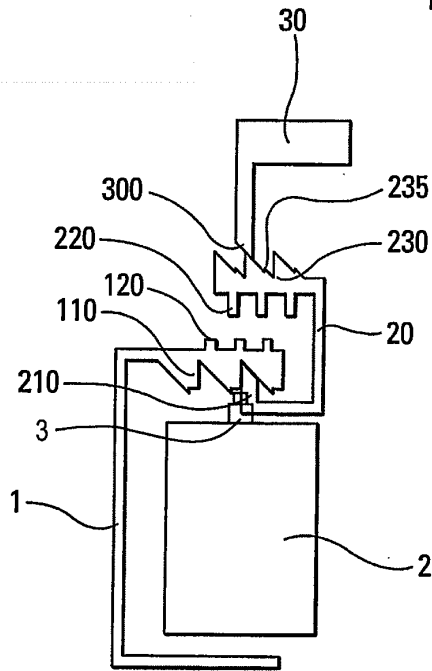


Fig. 1

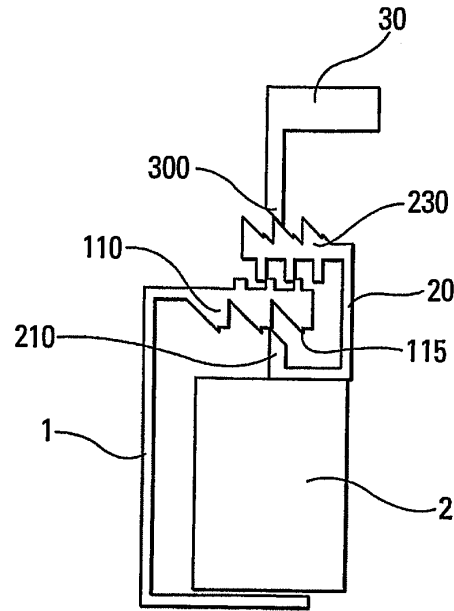


Fig. 2

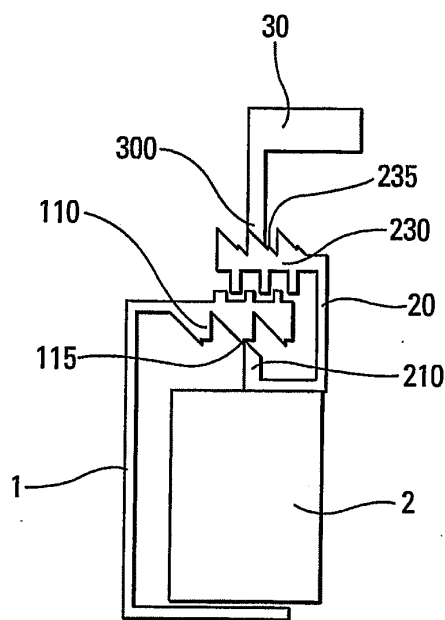


Fig. 3

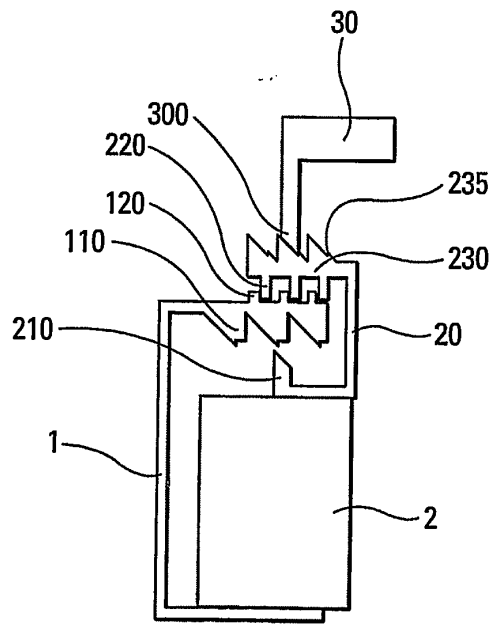


Fig. 4

2/13

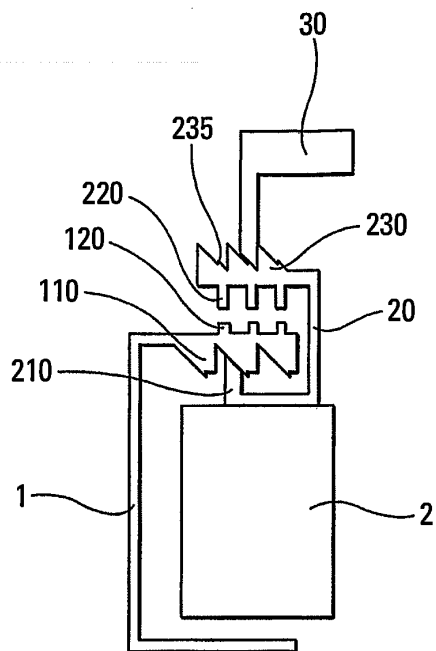


Fig. 5

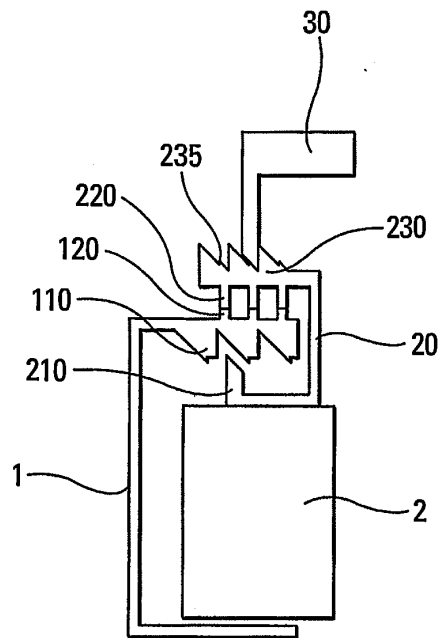


Fig. 6

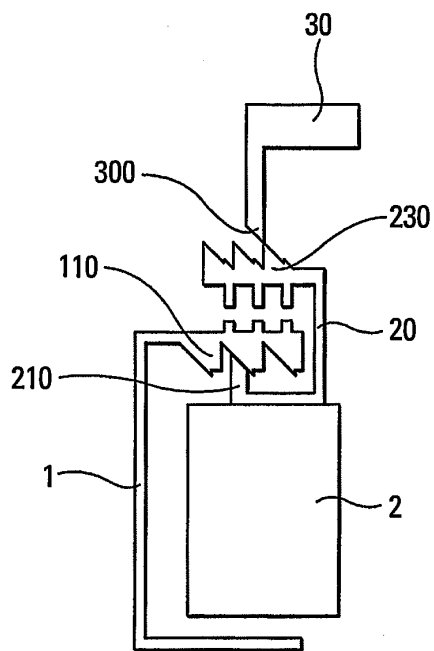


Fig. 7

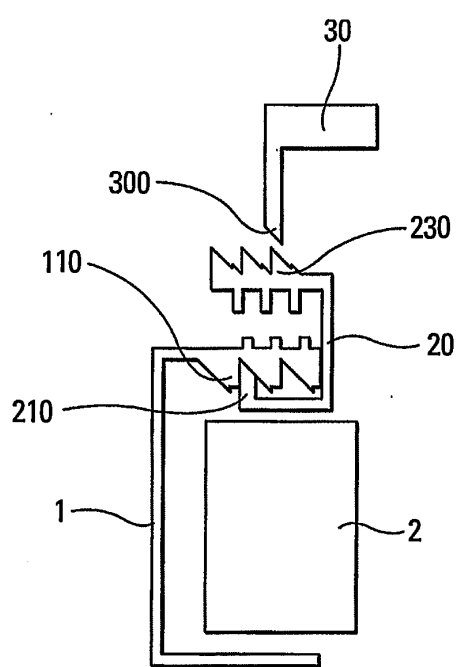


Fig. 8

3/13

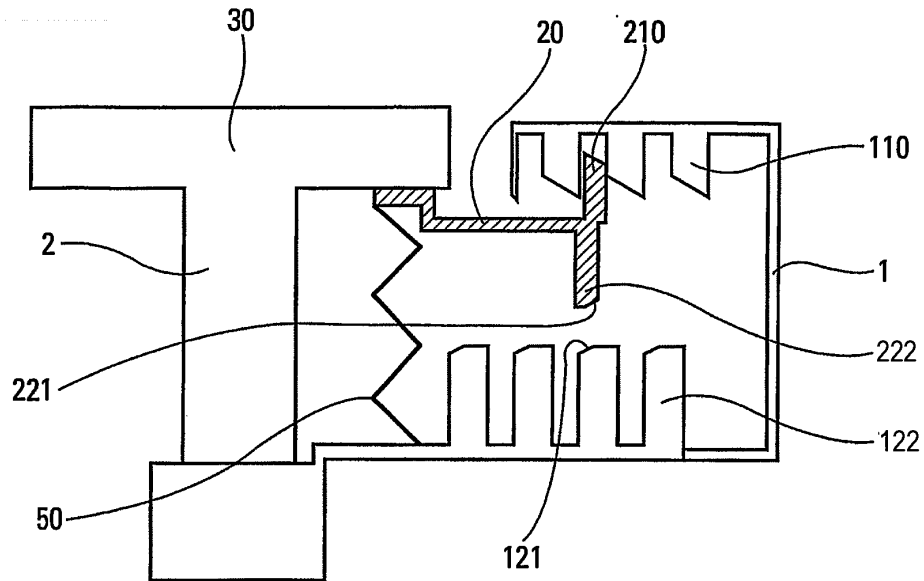


Fig. 9

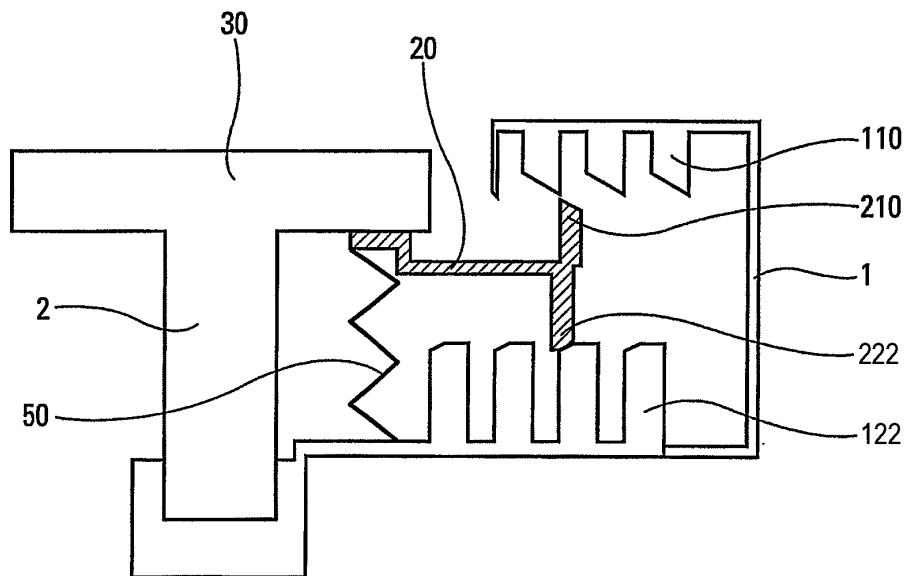


Fig. 10

4/13

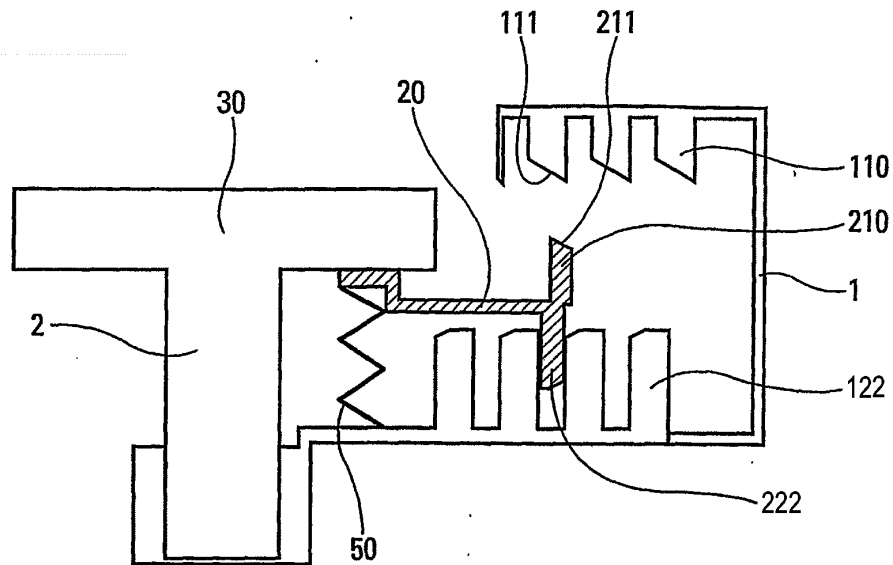


Fig. 11

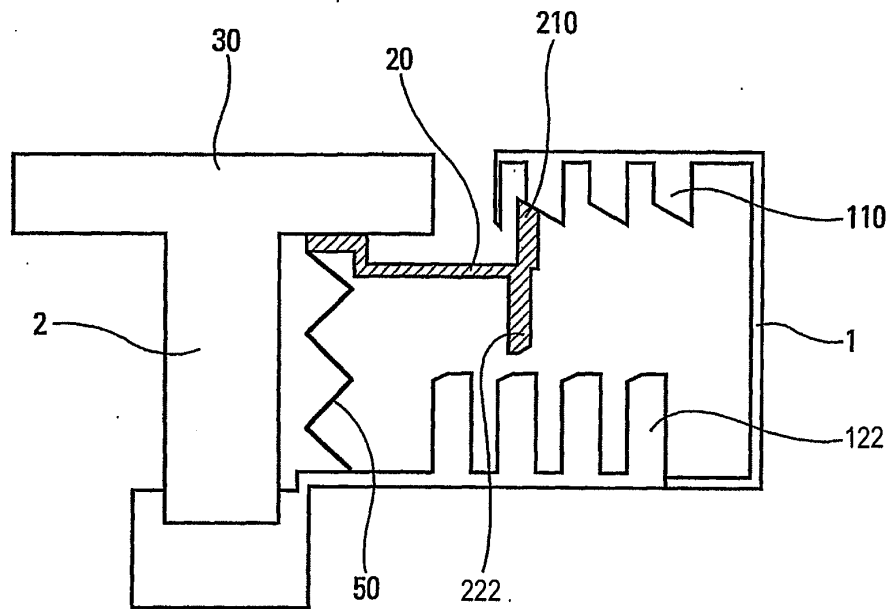


Fig. 12

5/13

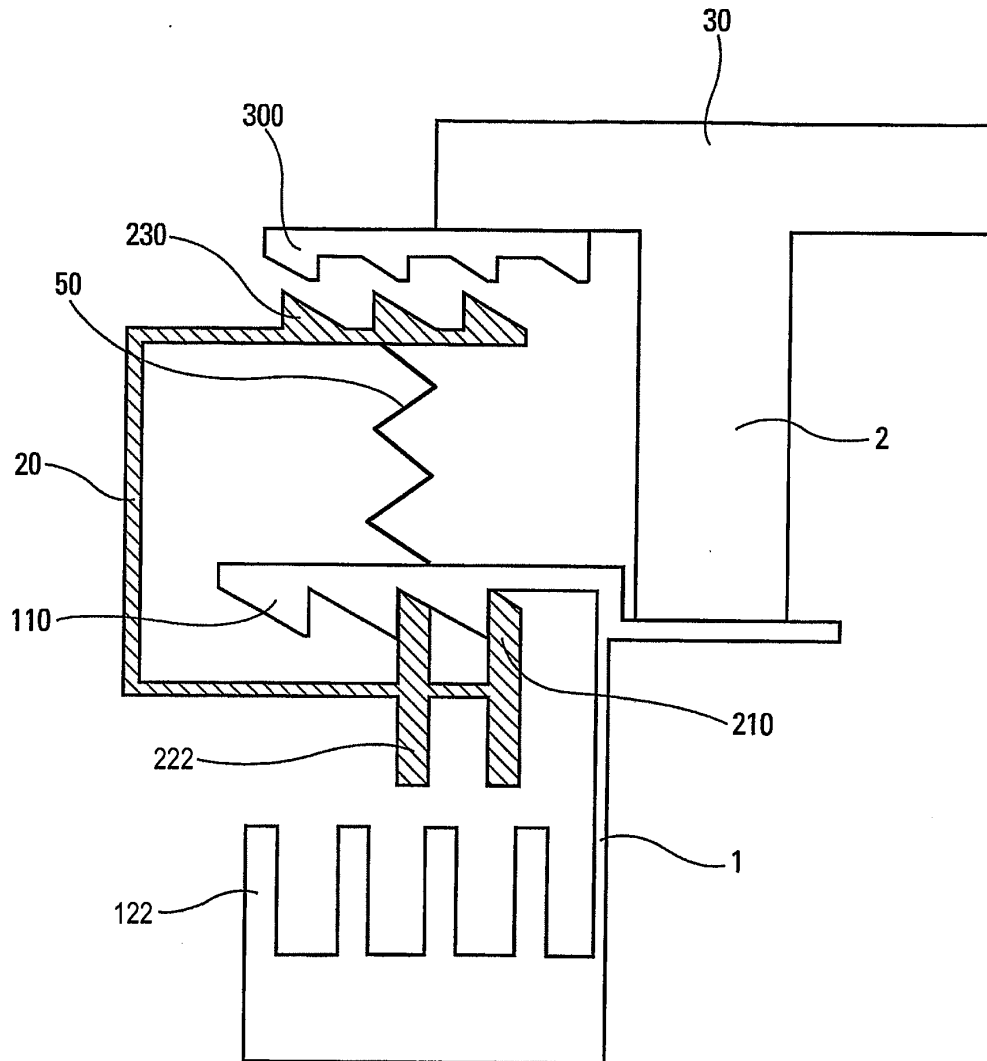


Fig. 13

6/13

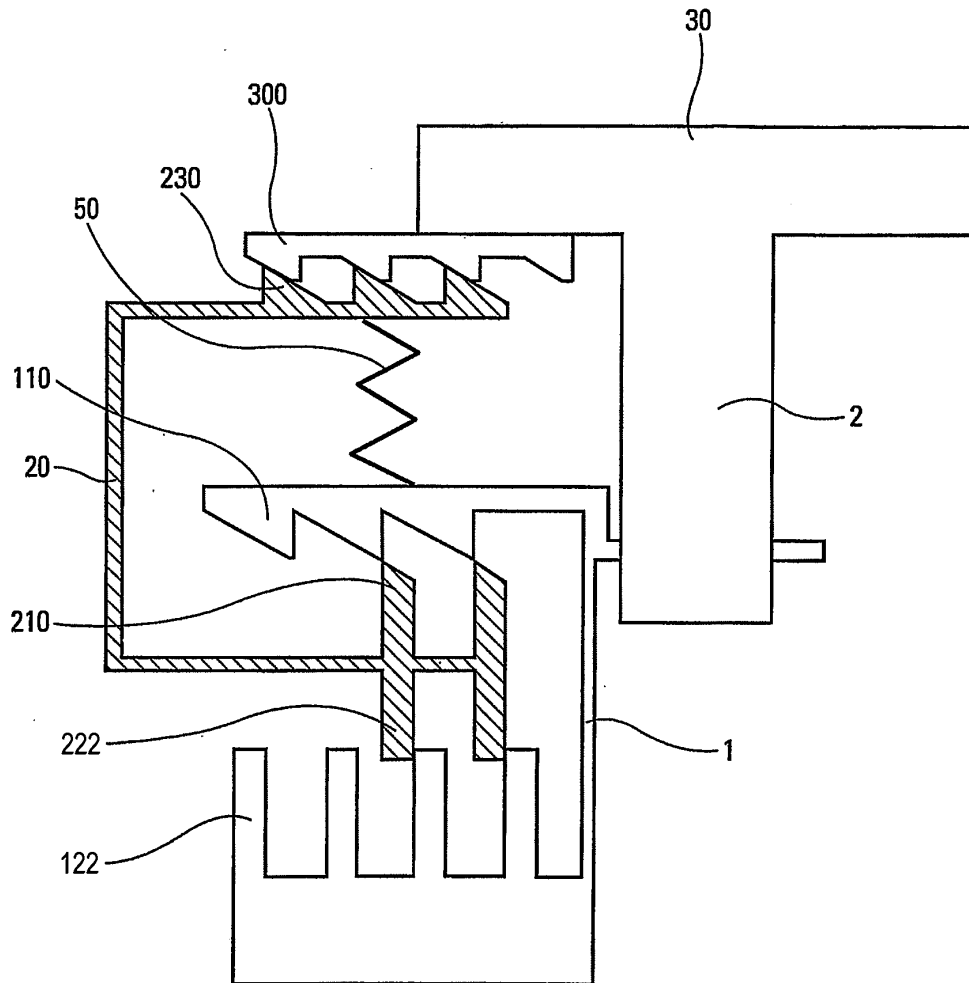


Fig. 14

7/13

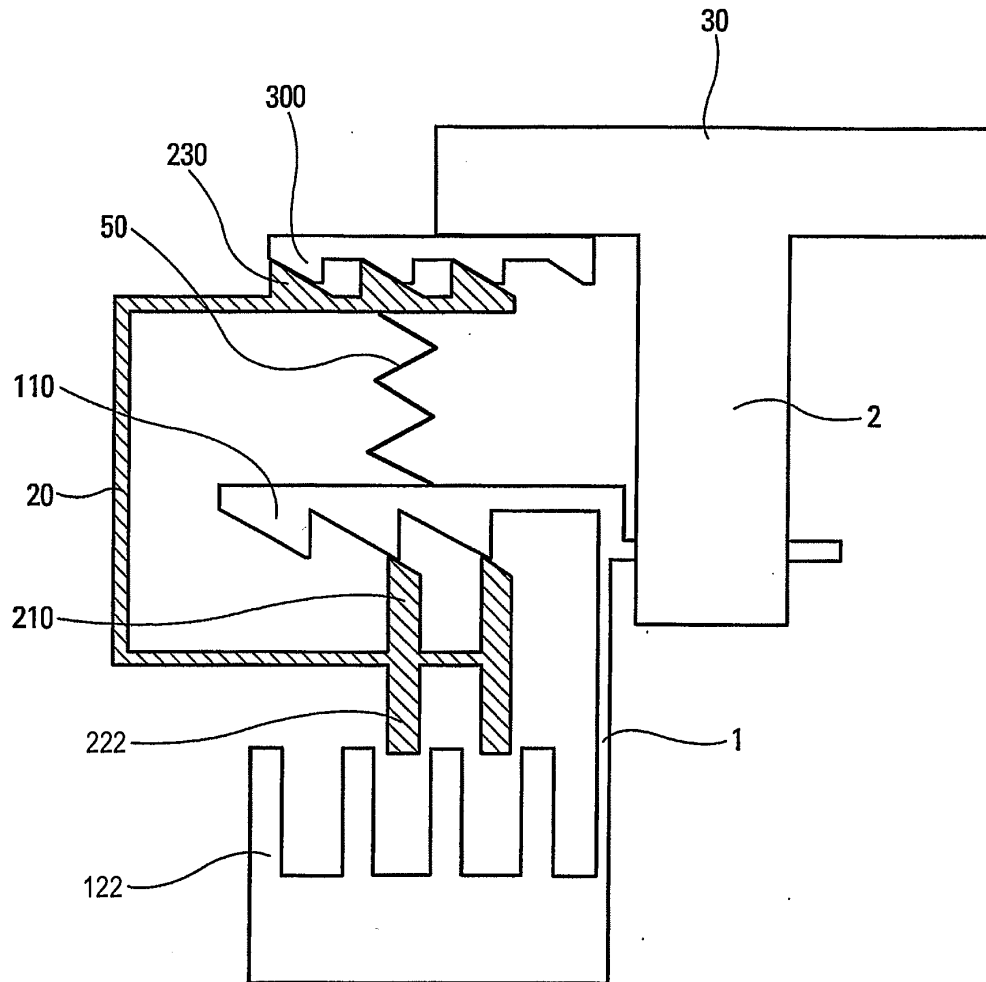


Fig. 15

8/13

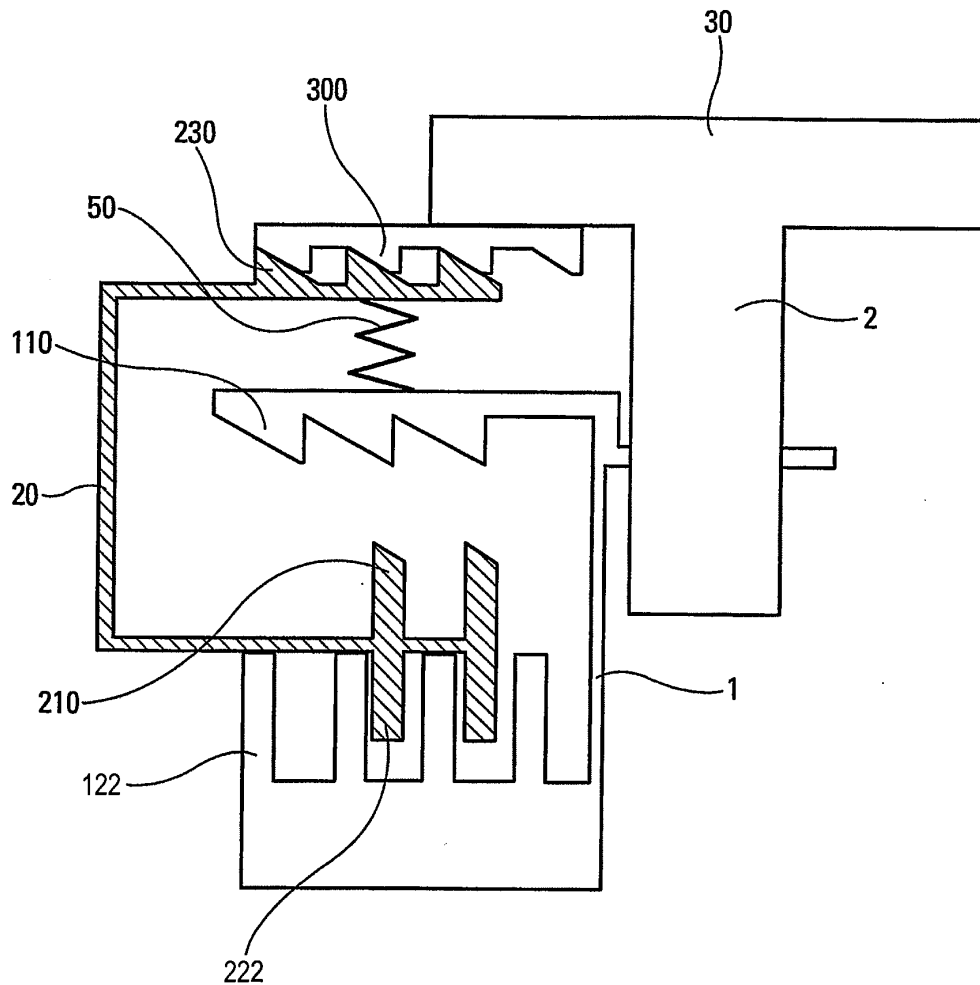


Fig. 16

9/13

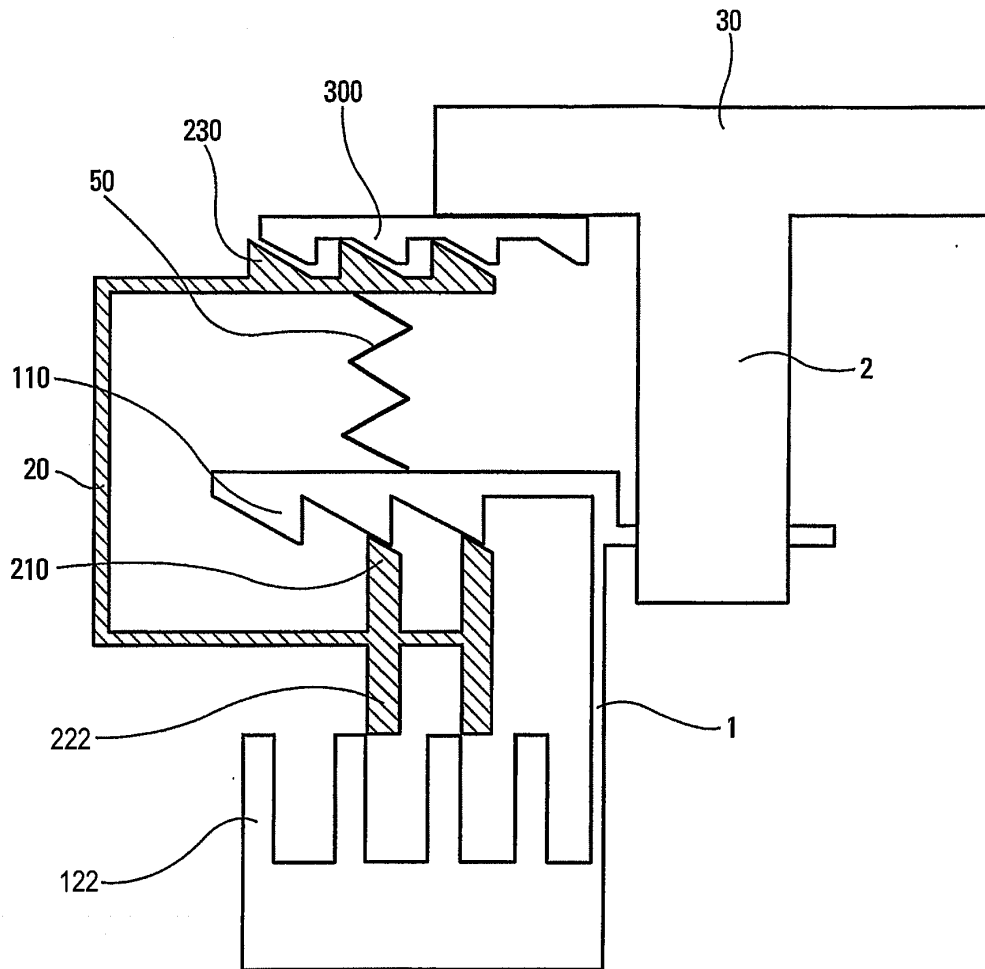


Fig. 17

10/13

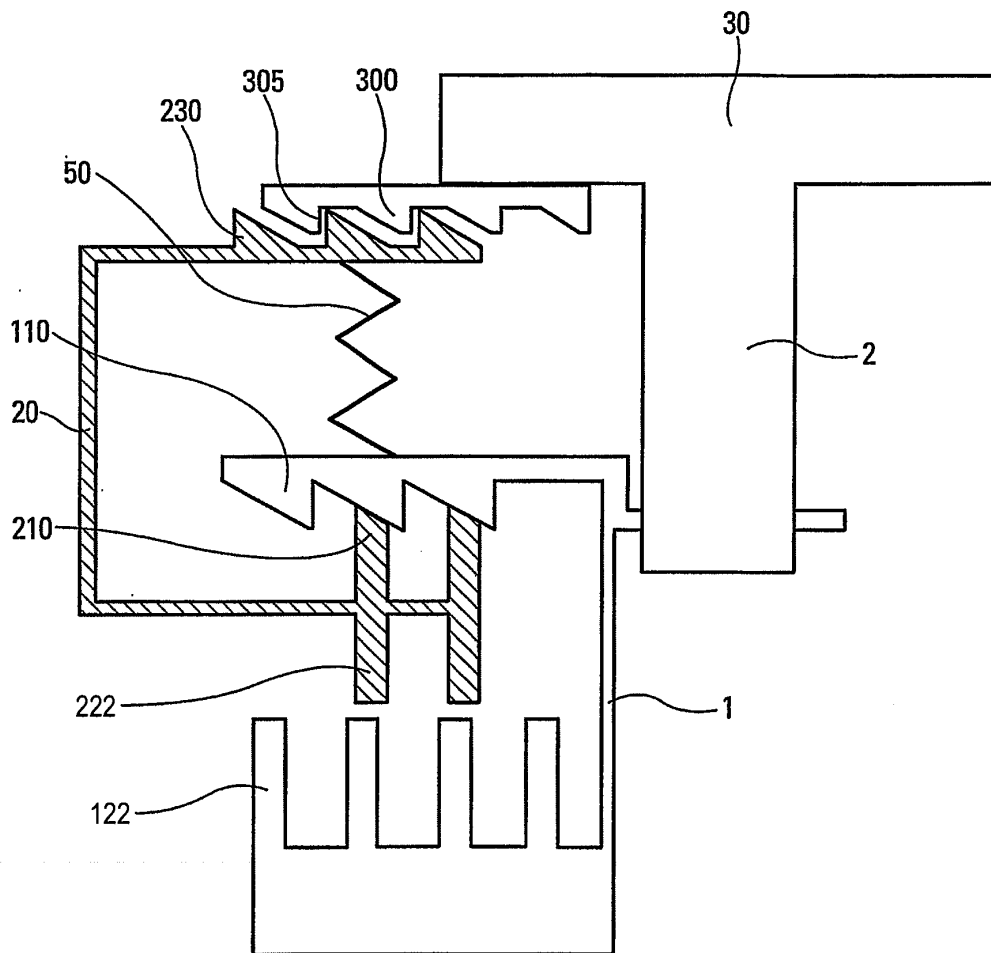


Fig. 18

11/13

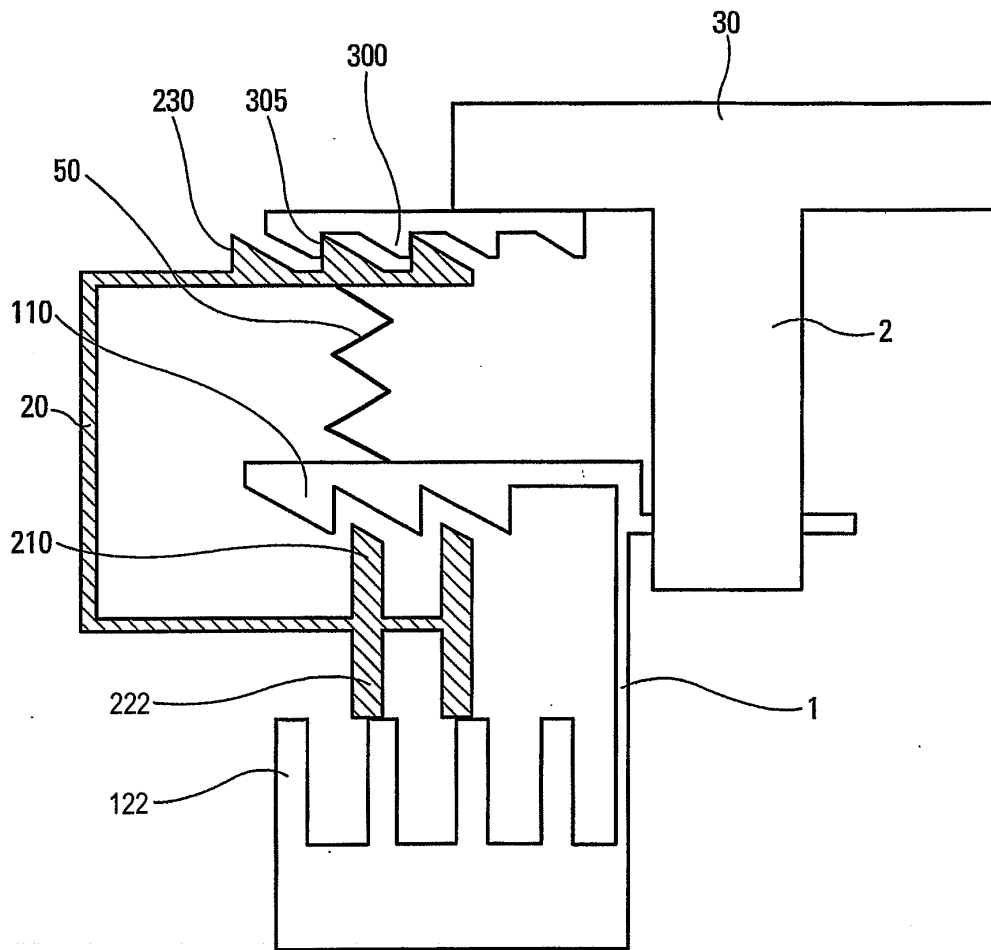


Fig. 19

12/13

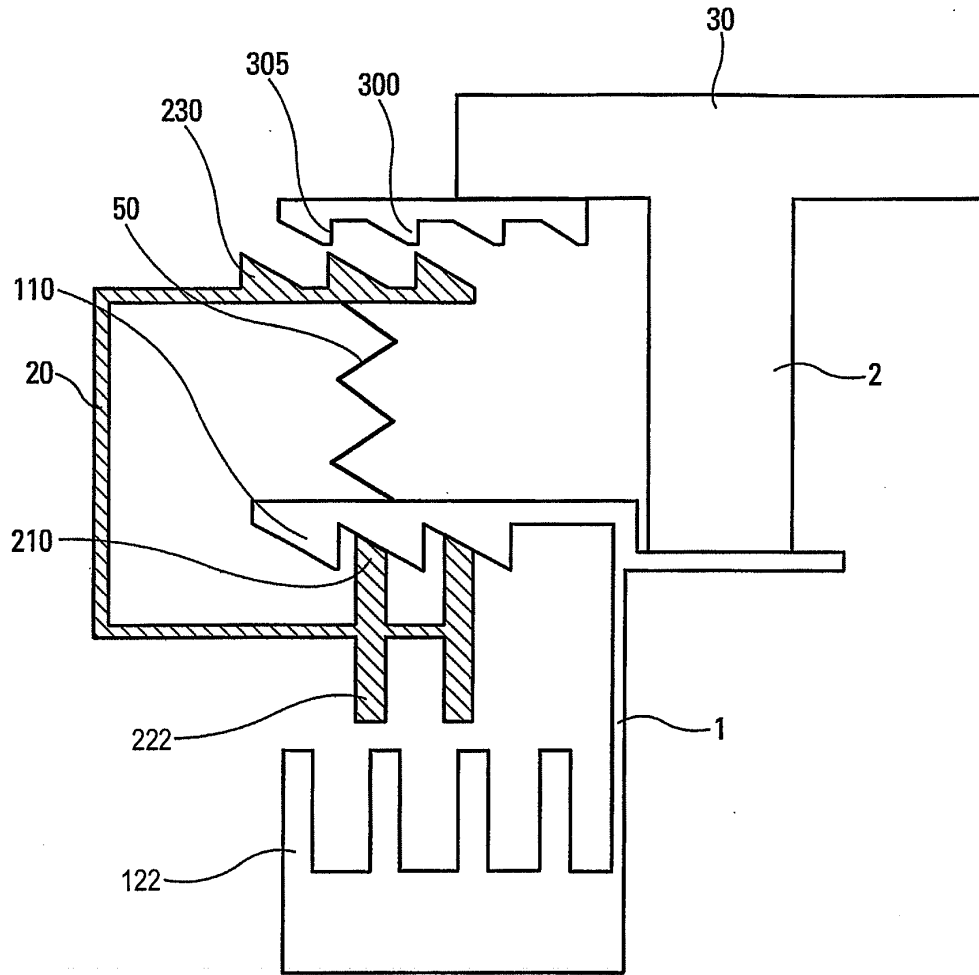


Fig. 20

13/13

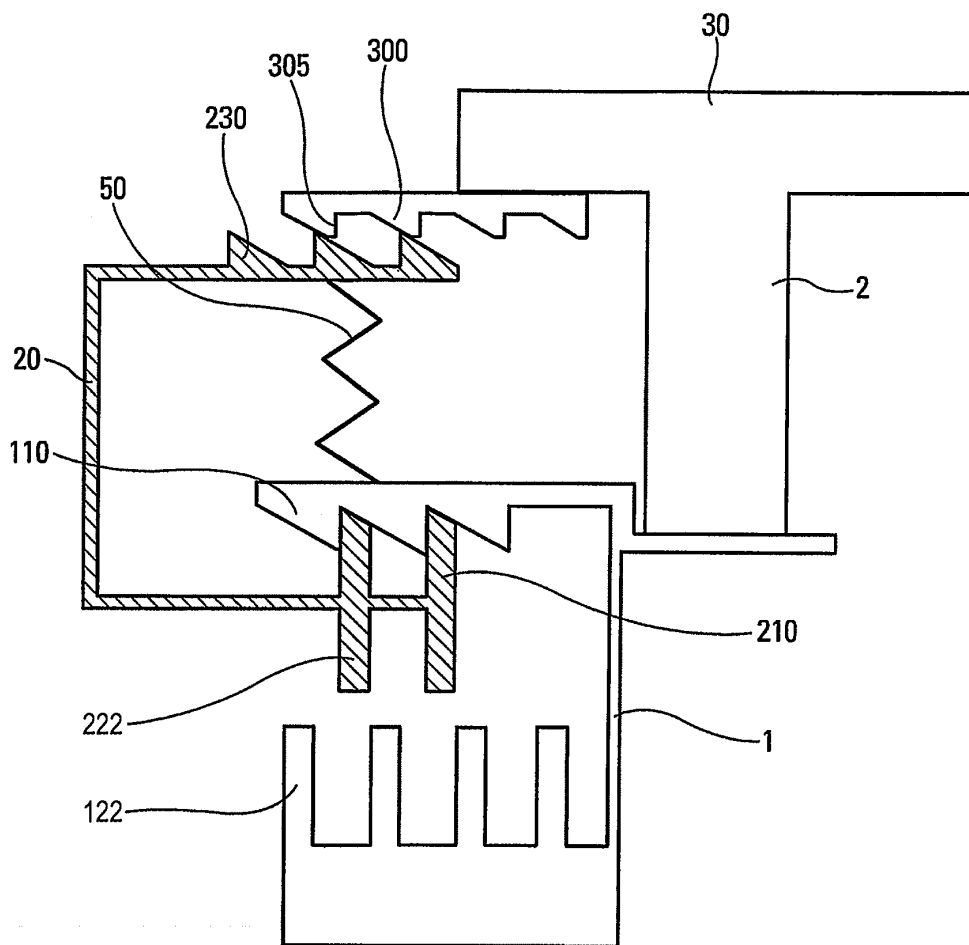


Fig. 21

REMARKS

Summary Of The Office Action & Formalities

Status of Claims

Claims 1-21 are all the claims pending in the application. By this Amendment, Applicant is amending claims 1, 6-13, and 15-17 and adding new claim 21. No new matter is introduced.

Claim to Foreign Priority

Applicant thanks the Examiner for acknowledging the claim to foreign priority and for confirming that the certified copy of the priority document was received.

Information Disclosure Statement

Applicant also thanks the Examiner for initialing the references listed on form PTO/SB/08 submitted with the Information Disclosure Statement filed on November 9, 2005.

Drawings

The Examiner objects to the drawings for the following reasons:

The drawings are objected to under 37 CFR 1.83(a)
because they allegedly fail to show the details as described in the specification. Note, the drawings only show a container, a body, and an actuator, and fail to specifically show how such elements are connected/mounted to one another in order for them to operate.

Office Action at pages 2-3.

Applicant respectfully submits that the amended drawing sheets show all of the features that are essential to the understanding of how the claimed invention functions. Section 1.83(a) states: "The drawing in a nonprovisional application must show every feature of the invention *specified in the claims*. However, conventional features *disclosed in the description and claims*, where their detailed illustration is not essential for a proper understanding of the invention,

should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation.” 37 C.F.R. § 1.83(a) (emphasis added).

The connections between the various elements of the invention, however, are not disclosed in the specification or the claims. As a result, these elements do not need to be included in the drawings.

Nor are the connecting means essential to the understanding of the invention. The elements of the claimed invention can be connected to each other using various techniques that would be apparent to one of ordinary skill in the art having read Applicant’s disclosure. Therefore, it is not essential to show the specific connections between the various elements in detail because a person having ordinary skill would understand how the claimed invention functions based on the drawings. To the contrary, showing these connections in detail would complicate the drawings and make it more difficult for one of ordinary skill to understand the actuation cycle of the dispenser and counter. To improve one’s ability to understand the claimed invention, the figures are “simplified diagrams . . . for explaining the actuation cycle of said dispenser and of said indicator device.” (Current app., ¶ 32.) As such, Applicant submits that the drawings show all elements that are essential to understand how the invention works and respectfully requests that the Examiner withdraw this objection to the drawings.

The drawings are objected to under 37 CFR 1.83(b)
because they are incomplete.

Office Action at page 3.

Applicant respectfully submits that it is not readily apparent how the drawings are incomplete. (See Examiner’s Note, MPEP 608.02(d).) Applicant further submits that Figures 1-21 show all of the features of the claimed invention sufficient for one skilled in the art to

understand how the claimed invention functions. Without a more detailed explanation of why the drawings are incomplete, Applicant requests that the Examiner withdraw this objection to the drawings.

The drawings are objected to under 37 CFR 1.83(a).

The drawings must show every feature of the invention specified in the claims. Therefore, the pump or valve of claim 1 must be shown or the feature(s) canceled from the claim(s).

Office Action at page 4.

The new Figure 1 is amended to depict the dispenser member. As such, Applicant respectfully requests that the Examiner withdraw this objection to the drawings.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “120” has been used to designate both an axial projection (page 13 of specification, line 20) and a stationary gear (page 14, line 23). Also, reference character “220” has been used to designate both an axial projection (page 13, line 21) and a gear (page 14, line 24).

Office Action at page 5.

Applicant is amending the drawings and corresponding portions of the specification, as noted above, to change the reference numerals corresponding to the stationary gear (formerly 120, now 122) and the gear (formerly 220, now 222). As such, Applicant respectfully requests that the Examiner withdraw this objection to the drawings.

Claim Objections

The claims are objected to by the Examiner for the following reasons:

Claims 13 and 17 are objected to because “plane” is used where the Examiner alleges “planar” is proper.

Office Action at page 6.

Applicant is amending claims 13 and 17 to recite “planar.” Claim 7 is also being amended to recite “planar.” As such, Applicant respectfully requests that the Examiner withdraw this objection to the claims.

Claims 1, 10-13, and 15-17 refer to part 120 as a stationary gear. Claim 6 refers to part 120 as blocking means. Claim 7 refers to part 120 as an axial projection.

Office Action at page 6.

Applicant is amending claims 1, 10-13, and 15-17 so that reference numeral 122 corresponds with a stationary gear. Reference numeral 120 has been deleted from claim 6. As such, reference numeral 120 only corresponds with an axial projection in claim 7. Applicant respectfully requests that the Examiner withdraw this objection to the claims.

Claims 10-13 and 15-17 refer to part 220 as a second gear. Claim 6 refers to part 220 as blocking means. Claim 7 refers to part 220 as an axial projection.

Office Action at page 6.

Applicant has amended claims 10-13, and 15-17 so that reference numeral 222 corresponds with a second gear. Reference numeral 220 has been deleted from claim 6. As such, reference numeral 220 only corresponds with an axial projection in claim 7. Applicant respectfully requests that the Examiner withdraw this objection to the claims.

Claim Rejections - § 112, First Paragraph

The Examiner rejected claims 1-20 under 35 U.S.C. § 112, *first paragraph*, as allegedly failing to enable one skilled in the art to make and/or use the invention. In rejecting claims 1-20, the Examiner states:

The disclosure (specification and drawings) is a vague description of desired function without specific means to implement. Note, it is not clear from the disclosure as to how the dispenser/counter functions/operates. While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details as to enable those persons skilled in the art to make and utilize the invention. Specific operative embodiments or examples of the invention must be set forth.

Office Action at pages 6-7.

The test for enablement is whether one skilled in the art could make and use the claimed invention without undue experimentation. See *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Thus, “[a] patent need not teach, and preferably omits, what is well known in the art.” MPEP § 2164.01 (citing *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986)). It is not necessary to “enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim to that effect.” MPEP § 2164 (citing *CFMT, Inc. v. Yildup Int’l Corp.*, 349 F.3d 1333 (Fed. Cir. 2003)). As such, “[d]etailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.” MPEP § 2164. In fact, “[i]n examining a patent application, the PTO is required to assume that the specification complies with the enablement provision of Section 112 unless it has ‘acceptable evidence or reasoning’ to suggest otherwise. . . . The PTO thus must provide reasons supported by the record as a whole why the specification is not enabling. . . . Then and only then does the burden shift to the applicant to show that one of ordinary skill in the art could have practiced the claimed invention without undue experimentation. . . .” *Gould v. Mossinghoff*, 229 USPQ 1, 13-14 (D.D.C.

1985) (citations omitted), *aff'd* in part, vacated in part on other grounds, and remanded sub nom.

Gould v. Quigg, 3 USPQ2d 1302 (Fed. Cir. 1987); *see also* MPEP 2164.04.

Applicant respectfully submits that the Examiner has not overcome the presumption that the disclosure is enabling. The Examiner has only indicated that the “disclosure is a vague description of the desired function without specific means to implement” and that “specific operative embodiments or examples of the invention must be set forth.”

To the contrary, one skilled in the art would be able to make and use the claimed invention because it is described in detail in the specification by reference to three exemplary embodiments. (*See generally*, 1st embodiment, ¶¶ 37-44; 2nd embodiment, ¶¶ 45-47; and 3rd embodiment, ¶¶ 48-50.) Additionally, for each embodiment, a figure depicts each step of the dispensing cycle of the dispenser. (*See generally*, 1st embodiment, FIGS. 1-8; 2nd embodiment, FIGS. 9-12; 3rd embodiment, FIGS. 13-21.) In view of these embodiments, a person having ordinary skill in the art would be able to examine the specification and drawings and make and use the claimed invention. For example, claim 1 recites that “said reservoir [is] axially displaceable relative to said body.” Given the art of fluid dispensers, one having ordinary skill would be able to make and use a reservoir that is axially displaceable relative to said body without undue experimentation. Further, as argued above in response to the drawing objections, all elements that are essential to the understanding of the invention are disclosed. As such, Applicant respectfully requests that the disclosure is enabling and that the Examiner withdraw the rejections to claims 1-20.

Claim Rejections - § 112, Second Paragraph

Claims 1-20 are rejected under 35 U.S.C. 112, *second paragraph*, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In rejecting claims 1-20, the Examiner stated:

The claims [1-20] are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. The following noted informalities are merely exemplary thereof:

Claim 8 recites the limitations “the second gear” and “the actuator member”. There is lack of antecedent basis for these limitations in the claim.

Claims 9-10 and 14 recite the limitation “the actuator member”. There is lack of antecedent basis for this limitation in the claims.

Office Action at page 7.

Applicant is amending claims 8, 9 and 10 to correct the antecedent basis for the second gear and the actuator member. Since claim 14 depends from claim 10, claim 14 also now has a proper antecedent basis. Applicant has reviewed the remainder of the claims and was unable to identify any additional antecedent basis problems. Since the Examiner only provided examples of antecedent basis problems, it is unclear how the remainder of the claims “fail[] to conform with current U.S. practice.”

Furthermore, Applicant would like to note that functional language is clearly permissible in apparatus claims. “There is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper.”

MPEP § 2173.05 (citations omitted). Without a more detailed description of the rejections of the

remaining claims, Applicant respectfully requests that the Examiner withdraw this rejection of the claims.

Art Rejections

Claim 1 is rejected under 35 U.S.C. § 102(e) as being anticipated by Rand et al. (U.S. Pub. No. 2002/0195102). In rejecting claim 1 in view of Rand, the grounds of rejection state:

Rand discloses a fluid dispenser as shown in Fig. 1, 2a, and 3, comprising a body 1, a fluid reservoir 2, a dispenser member, such as a pump or a valve 4, mounted on the reservoir 2, a dose indicator 13 that includes a first safety system for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke. The reservoir 2 is axially displaceable relative to the body 1. The body 1 includes at least one stationary gear 17. The dose indicator device includes a counter element 13 that is displaceable axially and in rotation relative to the body. The counter element co-operates firstly with at least one stationary gear and secondly with the reservoir.

The indicating device does not require the dispenser to be fully actuated, since, from the moment the hook 18a engages the gear wheel 19, the hook can no longer move, even if the dispenser is actuated further.

Office Action at page 8. Applicant respectfully traverses.

Regarding claim 1, Applicant submits that Rand fails to disclose at least “a first safety system for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform the complete actuation stroke.” Rand, on the other hand, indicates that the counter is not actuated unless the valve stem and container are fully depressed returned. (See Rand, ¶¶ 49-50.) For example, Rand states that the star wheel, which is connected to a counter mechanism, is moved “an incremental anti-clockwise rotation of a half tooth pitch” upon depressing the aerosol container. (See Rand, ¶ 49). The star wheel is then moved another “incremental anti-clockwise rotation of a half tooth pitch”

upon release. (*See* Rand, ¶ 50.) As such, “[e]ach time the aerosol dispenser is actuated the star wheel is made to rotate through two incremental anti-clockwise movements.” (Rand, ¶ 51; *see also* FIGS. 4A-B, showing star wheel during actuation of container; FIGS 4C-D, showing star wheel during release of container.) Referring to Figures 4A-4D of Rand, elements 18a and 18b, which are moved during the actuation and release of the container, move the star wheel. As can be seen in Figure 4D, there is no safety device to prevent element 18a from being partially depressed and released before contacting the star wheel. Thus, a partial actuation of the container, where element 18a does not contact the star wheel, will not result in the partial actuation being counted.

By comparison, claim 1 recites “a first safety system to actuate the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke.” Thus, the counter is actuated even if the actuation stroke is not complete. This forms the claimed security, as an incomplete actuation stroke could provide a partial dose dispensing. In such a case, the counter counts the dose, although incomplete, as it would otherwise to prevent the risk of overdosage by the user. As noted in the specification, it is preferable to count an incomplete dose than not to count it. (Current app., ¶ 2.) Furthermore, the operation of the safety system is supported in detail in both the specification and drawings. (*See* current app., ¶¶ 37-41; FIGS. 1-4.)

In view of the above, Applicant respectfully submits that Rand does not anticipate claim 1. Regarding claims 2-20, these claims depend from independent claim 1. As such Applicant submits that these claims are allowable at least by virtue of their dependency from claim 1. Furthermore, the Examiner has not addressed each element of claims 2-19 and therefore has not established a *prima facie* case of anticipation.

New Claims

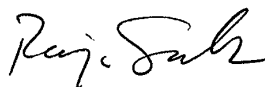
New claim 21 depends from independent claim 1. Since claim 21 depends from independent claim 1, this claim is allowable at least by virtue of its dependency from claim 1.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: October 22, 2008

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Hyea Jung CHOI

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

EXCESS CLAIM FEE PAYMENT LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

An Amendment Under 37 C.F.R. § 1.111 is attached hereto for concurrent filing in the above-identified application. The resulting excess claim fee has been calculated as shown below:

	After Amendment		Highest No. Previously Paid For						
All Claims	21	-	20	=	1	X	\$52.00	=	\$52.00
					TOTAL			=	\$52.00

The USPTO is directed and authorized to charge the statutory fee of \$52.00 and all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: October 22, 2008

Electronic Patent Application Fee Transmittal				
Application Number:		10556432		
Filing Date:		09-Nov-2005		
Title of Invention:		Fluid product dispenser		
First Named Inventor/Applicant Name:		Fabien Poulard		
Filer:		Jennifer Hayes/EASTLYN BLAIR		
Attorney Docket Number:		Q91404		
Filed as Large Entity				
U.S. National Stage under 35 USC 371 Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1615	1	52	52
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				52

Electronic Acknowledgement Receipt	
EFS ID:	4160145
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	Fluid product dispenser
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Jennifer Hayes/EASTLYN BLAIR
Filer Authorized By:	Jennifer Hayes
Attorney Docket Number:	Q91404
Receipt Date:	22-OCT-2008
Filing Date:	09-NOV-2005
Time Stamp:	18:04:52
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 52
RAM confirmation Number	3268
Deposit Account	194880
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Q91404_Amd111andExcessClaimFee.pdf	1353925 ebf9cb5fd47a628050b8a355051f485423a934f	yes	39
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Amendment/Req. Reconsideration-After Non-Final Reject		1	1	
	Specification		2	7	
	Claims		8	14	
	Drawings-only black and white line drawings		15	28	
	Applicant Arguments/Remarks Made in an Amendment		29	38	
	Miscellaneous Incoming Letter		39	39	
Warnings:					
Information:					
2	Fee Worksheet (PTO-06)	fee-info.pdf	30062 2a652483e98dff2cf2786fbe166152dde5c51d50	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1383987		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.					
New Applications Under 35 U.S.C. 111					
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.					
National Stage of an International Application under 35 U.S.C. 371					
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.					
New International Application Filed with the USPTO as a Receiving Office					
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 10/556,432		Filing Date 11/09/2005		☐ To be Mailed									
APPLICATION AS FILED – PART I																		
(Column 1)			(Column 2)			SMALL ENTITY ☐		OR		OTHER THAN SMALL ENTITY								
FOR		NUMBER FILED		NUMBER EXTRA		RATE (\$)		FEE (\$)		RATE (\$)		FEE (\$)						
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))		N/A		N/A		N/A				N/A								
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))		N/A		N/A		N/A				N/A								
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))		N/A		N/A		N/A				N/A								
TOTAL CLAIMS (37 CFR 1.16(i))		minus 20 =		*		X \$ =				X \$ =								
INDEPENDENT CLAIMS (37 CFR 1.16(h))		minus 3 =		*		X \$ =				X \$ =								
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))		If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).																
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))																		
* If the difference in column 1 is less than zero, enter "0" in column 2.						TOTAL				TOTAL								
APPLICATION AS AMENDED – PART II																		
(Column 1)			(Column 2)			(Column 3)			SMALL ENTITY		OR		OTHER THAN SMALL ENTITY					
AMENDMENT	10/22/2008		CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NUMBER PREVIOUSLY PAID FOR		PRESENT EXTRA		RATE (\$)		ADDITIONAL FEE (\$)		RATE (\$)		ADDITIONAL FEE (\$)			
	Total (37 CFR 1.16(i))		* 21		Minus ** 20		= 1		X \$ =				OR X \$52=		52			
	Independent (37 CFR 1.16(h))		* 1		Minus *** 3		= 0		X \$ =				OR X \$220=		0			
	☐ Application Size Fee (37 CFR 1.16(s))																	
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))																	
											TOTAL ADD'L FEE				OR TOTAL ADD'L FEE		52	
AMENDMENT	Total (37 CFR 1.16(i))		*		Minus **		=		X \$ =				OR X \$ =					
	Independent (37 CFR 1.16(h))		*		Minus ***		=		X \$ =				OR X \$ =					
	☐ Application Size Fee (37 CFR 1.16(s))																	
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))																	
											TOTAL ADD'L FEE				OR TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.											Legal Instrument Examiner: /SHARAIN MORELAND/							

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 01/21/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER	
			NGO, LIEN M	
			ART UNIT	PAPER NUMBER
			3754	
			MAIL DATE	DELIVERY MODE
			01/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/556,432	POULARD, FABIEN	
	Examiner	Art Unit	
	LIEN TM NGO	3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 22 October 2008.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-21 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) ☐ Notice of Informal Patent Application 6) ☐ Other: _____.

DETAILED ACTION

1. This application has been treated as being obviously informal. Note, it is impractical to give a complete action on the merits because of the insufficiencies noted below. A reasonable search has been made in so far as the invention could be understood from the disclosure.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the details and connections of components of the invention as described in the specification. Note, the drawings of figs. 1-21 only show a simplified diagrams of a reservoir, a body, an actuator, a counter element, and fail to specially show such elements are connected/mounted to one another in order to one having an ordinary skill to understand how the system of the invention can work, for example, what is connection between the container, body, actuator and counter elements so that the reservoir can be stored in the body and axially displaceable to the body; the counter element can indicate the number of doses dispensed or remained and can be displaceable and rotatable; the dose indicator device can be actuated once the dispenser has performed a predetermined incomplete actuation stroke; why just a oblique tooth of the actuator and the counter element can be considered a gear; how the gear of the body is stationary but the gear of the actuator is axial displaceable and the gears of the counter element are axially and rotatably displaceable; why and how the abutments of the actuator gear and the station gear as shown in the drawing can perform as disclosed in page 12, lines 4-28, etc. Any structural detail that is essential

for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to under 37 CFR 1.83(b) because they are incomplete. Figs. 1-21 in the present application show only simplified diagrams without clearly providing the structural shapes and connections of one element to one another in order to one having an ordinary skill to understand the claimed invention functions, working and improvement as disclosed in the specification. 37 CFR 1.83(b) reads as follows:

When the invention consists of an improvement on an old machine the drawing must when possible exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to under 37 CFR 1.71, as being so incomprehensible as to preclude a reasonable search of the prior art by the examiner. For example, the following items are not understood: what are connections between the container, body, actuator and counter elements so that the reservoir can be stored in the body and axially displaceable to the body; the counter element can indicate the number of doses

dispensed or remained and can be displaceable and rotatable; the dose indicator device can be actuated once the dispenser has performed a predetermined incomplete actuation stroke; why just a oblique tooth of the actuator and the counter element can be considered a gear; how the gear of the body is stationary but the gear of the actuator is axial displaceable and the gears of the counter element are axially and rotatably displaceable; why and how the abutments of the actuator gear and the station gear as shown in the drawing can perform as disclosed in page 12, lines 4-28; what is actual structural shapes and connections of one element to one another in order to one having an ordinary skill to understand the invention functions, working and improvement, etc.

Applicant is required to submit an amendment which clarifies the disclosure so that the examiner may make a proper comparison of the invention with the prior art.

Applicant should be careful not to introduce any new matter into the disclosure (i.e., matter which is not supported by the disclosure as originally filed).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide an adequate description of the invention that would enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. The disclosure (specification and drawings) is a vague description of desired function without specific means to implement. Note, it is not clear from the disclosure as to how the claimed invention functions/operates. While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details as to enable those persons skilled in the art to make and utilize the invention. Specific operative embodiments or examples of the invention must be set forth.

7. In view of the insufficiencies of the drawings and specification, and 35 U.S.C. 112 issue, comment as to the allowability of the claims can not be made at this time.

Response to Arguments

8. Applicant's arguments filed 10/22/08 have been fully considered but they are not persuasive as pointed out in the objections and rejections above.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LIEN TM NGO whose telephone number is 571-272-4545. The examiner can normally be reached on Monday through Friday from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, KEVIN SHAVER can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LIEN TM NGO/
Primary Examiner, Art Unit 3754

January 15, 2009

Application/Control Number: 10/556,432
Art Unit: 3754

Page 8

AMENDMENT UNDER 37 C.F.R. § 1.116
EXPEDITED PROCEDURE
GROUP 3754
PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

RESPONSE UNDER 37 C.F.R. § 1.116

MAIL STOP AF

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated January 21, 2009, please amend the above-identified application as follows on the accompanying pages.

TABLE OF CONTENTS

REMARKS.....	2

REMARKS

Status of the Application & Formalities

Claim Status

Claims 1-21 are all the claims pending in the application.

Request for Interview

Applicant's representative telephoned the Examiner to schedule an interview to discuss this application and the current grounds of rejection. The Examiner is kindly requested to contact the undersigned to schedule an interview at his earliest convenience.

Drawings

The Examiner objects to the drawings for the following reasons:

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the details and connections of components of the invention as described in the specification. Note, the drawings of figs. 1-21 only show a simplified diagrams of a reservoir, a body, an actuator, a counter element, and fail to specially show such elements are connected/mounted to one another in order to one having an ordinary skill to understand how the system of the invention can work, for example, what is connection between the container, body, actuator and counter elements so that the reservoir can be stored in the body and axially displaceable to the body; the counter element can indicate the number of doses dispensed or remained and can be displaceable and rotatable; the dose indicator device can be actuated once the dispenser has performed a predetermined incomplete actuation stroke; why just a oblique tooth of the actuator and the counter element can be considered a gear; how the gear of the body is stationary but the gear of the actuator is axial displaceable and the gears of the counter element are axially and rotatably displaceable; why and how the abutments of the actuator gear and the station gear as shown in the drawing can perform as disclosed in page 12, lines 4-28, etc. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

Office Action at pages 2-3.

Applicant respectfully submits that the amended drawing sheets show all of the features that are essential to the understanding of how the claimed invention functions. Section 1.83(a) states: “The drawing in a nonprovisional application must show every feature of the invention specified in the claims. However, conventional features *disclosed in the description and claims*, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of a graphical drawing symbol or a labeled representation.” 37 C.F.R. § 1.83(a) (emphasis added).

The connections between the various elements of the invention, however, are not disclosed in the specification or the claims. As a result, these elements do not need to be included in the drawings.

Nor are the connecting means essential to the understanding of the invention. The elements of the claimed invention can be connected to each other using various techniques that would be apparent to one of ordinary skill in the art having read Applicant’s disclosure. Therefore, it is not essential to show the specific connections between the various elements in detail because a person having ordinary skill would understand how the claimed invention functions based on the drawings. To the contrary, showing these connections in detail would complicate the drawings and make it more difficult for one of ordinary skill to understand the actuation cycle of the dispenser and counter. To improve one’s ability to understand the claimed invention, the figures are “simplified diagrams . . . for explaining the actuation cycle of said dispenser and of said indicator device.” (Current app., ¶ 32.)

As such, Applicant submits that the drawings show all elements that are essential to understand how the invention works and respectfully requests that the Examiner withdraw this objection to the drawings.

The Examiner further objects to the drawings because:

The drawings are objected to under 37 CFR 1.83(b) because they are incomplete. Figs. 1-21 in the present application show only simplified diagrams without clearly providing the structural shapes and connections of one element to one another in order to one having an ordinary skill to understand the claimed invention functions, working and improvement as disclosed in the specification.

Office Action at page 3.

Applicant reiterates that the connections between the elements are not essential to provide one with ordinary skill in the art with an understanding of how to make and use the claimed invention. Applicant further submits that Figures 1-21 show all of the features of the claimed invention sufficient for one skilled in the art to understand how the claimed invention functions.

Objections to the Specification

The Examiner objected to the specification for the following reasons:

The disclosure is objected to under 37 CFR 1.71, as being so incomprehensible as to preclude a reasonable search of the prior art by the examiner. For example, the following items are not understood: what are connections between the container, body, actuator and counter elements so that the reservoir can be stored in the body and axially displaceable to the body; the counter element can indicate the number of doses dispensed or remained and can be displaceable and rotatable; the dose indicator device can be actuated once the dispenser has performed a predetermined incomplete actuation stroke; why just a oblique tooth of the actuator and the counter element can be considered a gear; how the gear of the body is stationary but the gear of the actuator is axial displaceable and the gears of the counter element are axially and rotatably displaceable; why and how the abutments of the actuator gear and the station gear as shown in the drawing can perform as disclosed in page 12, lines 4-28; what is actual structural shapes and connections of one element to one another in order to one having an ordinary skill to understand the invention functions, working and improvement, etc.

Office Action at pages 4-5.

Again Applicant submits that disclosure of the specific connections are not necessary to understand how the claimed invention functions. Further, one skilled in the art would be able to understand the invention of the current application because the specification describes the invention in detail by reference to three exemplary embodiments. (*See generally*, 1st embodiment, ¶¶ 37-44; 2nd embodiment, ¶¶ 45-47; and 3rd embodiment, ¶¶ 48-50.) Additionally, for each embodiment, a figure depicts each step of the dispensing cycle of the dispenser. (*See generally*, 1st embodiment, FIGS. 1-8; 2nd embodiment, FIGS. 9-12; 3rd embodiment, FIGS. 13-21.) In view of these embodiments, a person having ordinary skill in the art would be able to examine the specification and drawings and understand the invention of the current application.

Claim Rejections - § 112

The Examiner rejected claims 1-20 under 35 U.S.C. § 112, *first paragraph*, as allegedly failing to enable one skilled in the art to make and/or use the invention. In rejecting claims 1-20, the Examiner states:

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide an adequate description of the invention that would enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The disclosure (specification and drawings) is a vague description of desired function without specific means to implement. Note, it is not clear from the disclosure as to how the claimed invention functions/operates. While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details as to enable those persons skilled in the art to make and utilize the invention. Specific operative embodiments or examples of the invention must be set forth.

In view of the insufficiencies of the drawings and specification, and 35 U.S.C. 112 issue, comment as to the allowability of the claims can not be made at this time.

Office Action at pages 5-6.

The test for enablement is whether one skilled in the art could make and use the claimed invention without undue experimentation. See *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Thus, “[a] patent need not teach, and preferably omits, what is well known in the art.” MPEP § 2164.01 (citing *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986)). It is not necessary to “enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim to that effect.” MPEP § 2164 (citing *CFMT, Inc. v. Yildup Int’l Corp.*, 349 F.3d 1333 (Fed. Cir. 2003)). As such, “[d]etailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.” MPEP § 2164. In fact, “[i]n examining a patent application, the PTO is required to assume that the specification complies with the enablement provision of Section 112 unless it has ‘acceptable evidence or reasoning’ to suggest otherwise. . . . The PTO thus must provide reasons supported by the record as a whole why the specification is not enabling. . . . Then and only then does the burden shift to the applicant to show that one of ordinary skill in the art could have practiced the claimed invention without undue experimentation. . . .” *Gould v. Mossinghoff*, 229 USPQ 1, 13-14 (D.D.C. 1985) (citations omitted), *aff’d in part, vacated in part on other grounds, and remanded sub nom. Gould v. Quigg*, 3 USPQ2d 1302 (Fed. Cir. 1987); *see also* MPEP 2164.04.

Applicant respectfully submits that the Examiner has not overcome the presumption that the disclosure is enabling. The Examiner has only indicated that the “disclosure is a vague description of the desired function without specific means to implement” and that “specific operative embodiments or examples of the invention must be set forth.”

To the contrary, one skilled in the art would be able to make and use the claimed invention because it is described in detail in the specification by reference to three exemplary embodiments. (*See generally*, 1st embodiment, ¶¶ 37-44; 2nd embodiment, ¶¶ 45-47; and 3rd embodiment, ¶¶ 48-50.) Additionally, for each embodiment, a figure depicts each step of the dispensing cycle of the dispenser. (*See generally*, 1st embodiment, FIGS. 1-8; 2nd embodiment, FIGS. 9-12; 3rd embodiment, FIGS. 13-21.) In view of these embodiments, a person having ordinary skill in the art would be able to examine the specification and drawings and make and use the claimed invention. For example, claim 1 recites that “said reservoir [is] axially displaceable relative to said body.” Given the art of fluid dispensers, one having ordinary skill would be able to make and use a reservoir that is axially displaceable relative to said body without undue experimentation. Further, as argued above in response to the drawing objections, all elements that are essential to the understanding of the invention are disclosed. As such, Applicant respectfully requests that the disclosure is enabling and that the Examiner withdraw the rejections to claims 1-21.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

RESPONSE UNDER 37 C.F.R. § 1.116
Application No.: 10/556,432

Attorney Docket No.: Q91404

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Raja N. Saliba
Registration No. 43,078

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: April 21, 2009

Electronic Acknowledgement Receipt	
EFS ID:	5194598
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	Fluid product dispenser
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Jennifer Hayes/Nicholas Lane
Filer Authorized By:	Jennifer Hayes
Attorney Docket Number:	Q91404
Receipt Date:	21-APR-2009
Filing Date:	09-NOV-2005
Time Stamp:	21:46:04
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment		no			
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Q91404_116Response.pdf	337745 f6b61d8d42da164ff7e5661c29b8f3e68e1e c9bd	yes	8

	Multipart Description/PDF files in .zip description		
	Document Description	Start	End
	Amendment After Final	1	1
	Applicant Arguments/Remarks Made in an Amendment	2	8
Warnings:			
Information:			
Total Files Size (in bytes):		337745	
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524

23373	7590	04/30/2009
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037		

EXAMINER	
NGO, LIEN M	

ART UNIT	PAPER NUMBER
3754	

MAIL DATE	DELIVERY MODE
04/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 05/01/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER	
			NGO, LIEN M	
			ART UNIT	PAPER NUMBER
			3754	
			MAIL DATE	DELIVERY MODE
			05/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/556,432	POULARD, FABIEN	
	Examiner	Art Unit	
	LIEN TM NGO	3754	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 April 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 1-21.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
- Examiner remains the objections of the drawings and the specification; and the 112 rejections in the final office action dated 1/21/09.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/LIEN TM NGO/
Primary Examiner, Art Unit 3754

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the interview conducted on

April 28, 2009:

REMARKS

An Examiner's Interview Summary Record (PTO-413) was attached with the Advisory Action dated May 1, 2009.

During the interview, the following was discussed:

1. Brief description of exhibits or demonstration: None
2. Identification of claims discussed: None
3. Identification of art discussed: None
4. Identification of principal proposed amendments: None
5. Brief Identification of principal arguments: The written description and the figures adequately enable one of ordinary skill in the art to make and use the claimed invention.

STATEMENT OF SUBSTANCE OF INTERVIEW
U.S. Application No.: 10/556,432

Attorney Docket No.: Q91404

6. Indication of other pertinent matters discussed: None

7. Results of Interview: The Examiner did not agree that the disclosure of the present application in the specification and the drawing would enable to one skilled in the art to understand the claimed inventions.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

It is believed that no petition or fee is required. However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



Raja N. Saliba
Registration No. 43,078

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: May 8, 2009

Electronic Acknowledgement Receipt	
EFS ID:	5300229
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	Fluid product dispenser
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Jennifer Hayes/Eastlyn Blair
Filer Authorized By:	Jennifer Hayes
Attorney Docket Number:	Q91404
Receipt Date:	08-MAY-2009
Filing Date:	09-NOV-2005
Time Stamp:	12:05:11
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no				
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant summary of interview with examiner	Q91404_StatementofSubofInte rview.pdf	60129 f4cc63fdb56c0f89f35d4327b698d0d17108d9e6	no	2
Warnings:					
Information:					

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

NOTICE OF APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant hereby appeals to the Board of Patent Appeals and Interferences from the final Office Action dated January 21, 2009.

The USPTO is directed and authorized to charge the statutory fee of \$540.00 and all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880.

Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Raja N. Saliba
Registration No. 43,078

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: May 20, 2009

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

PETITION FOR EXTENSION OF TIME UNDER 37 C.F.R. § 1.136

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.136, Applicant hereby petitions for an extension of time of one month, extending the time for responding to the Final Office Action dated January 21, 2009 to May 21, 2009.

The USPTO is directed and authorized to charge the statutory fee of \$130.00 and all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Raja N. Saliba
Registration No. 43,078

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: May 20, 2009

Electronic Patent Application Fee Transmittal				
Application Number:		10556432		
Filing Date:		09-Nov-2005		
Title of Invention:		Fluid product dispenser		
First Named Inventor/Applicant Name:		Fabien Poulard		
Filer:		Jennifer Hayes/Eastlyn Blair		
Attorney Docket Number:		Q91404		
Filed as Large Entity				
U.S. National Stage under 35 USC 371 Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Notice of appeal	1401	1	540	540
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 1 month with \$0 paid	1251	1	130	130
Miscellaneous:				
Total in USD (\$)				670

Electronic Acknowledgement Receipt	
EFS ID:	5367395
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	Fluid product dispenser
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Jennifer Hayes/Eastlyn Blair
Filer Authorized By:	Jennifer Hayes
Attorney Docket Number:	Q91404
Receipt Date:	20-MAY-2009
Filing Date:	09-NOV-2005
Time Stamp:	13:11:48
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$ 670
RAM confirmation Number	7758
Deposit Account	194880
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Q91404_NoticeofAppealandEO T.pdf	58357	yes	2
			7673e7d8a8f55d23494e241395982f861b992b82		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Notice of Appeal Filed		1	1	
	Extension of Time		2	2	
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	31667	no	2
			89c9d8bea827b64cac04c3e14b806f852f1670ea		
Warnings:					
Information:					
Total Files Size (in bytes):			90024		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



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United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 11/16/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER	
			NGO, LIEN M	
			ART UNIT	PAPER NUMBER
			3754	
			NOTIFICATION DATE	DELIVERY MODE
			11/16/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@SUGHRUE.COM
PPROCESSING@SUGHRUE.COM

Notice of Abandonment	Application No.	Applicant(s)	
	10/556,432	POULARD, FABIEN	
	Examiner	Art Unit	
	LIEN TM NGO	3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on 21 January 2009.
 - (a) ☒ A reply was received on 20 May 2009 (with a Certificate of Mailing or Transmission dated 20 May 2009), which is after the expiration of the period for reply (including a total extension of time of 2 month(s)) which expired on 7/20/09.
 - (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
(A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
 - (c) ☐ A reply was received on _____ but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
 - (d) ☐ No reply has been received.
2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
 - (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
 - (b) ☐ The submitted fee of \$_____ is insufficient. A balance of \$_____ is due.
The issue fee required by 37 CFR 1.18 is \$_____. The publication fee, if required by 37 CFR 1.18(d), is \$_____.
 - (c) ☐ The issue fee and publication fee, if applicable, has not been received.
3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
 - (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
 - (b) ☐ No corrected drawings have been received.
4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.
5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.
6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.
7. ☐ The reason(s) below:

/LIEN TM NGO/
Primary Examiner, Art Unit 3754

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

**PETITION FOR WITHDRAWAL OF HOLDING OF ABANDONMENT UNDER
37 C.F.R. § 1.181**

MAIL STOP PETITION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Notice of Abandonment mailed November 16, 2009, and in accordance with the requirements of 37 C.F.R. § 1.181, Applicant hereby petitions for withdrawal of the holding of abandonment.

As stated in the MPEP, “[o]nce Applicant timely files a notice of appeal in compliance with 37 CFR 41.31, the time period for reply set forth in the last Office action is tolled and is no longer relevant for the time period for filing an appeal brief.” (MPEP § 1205.01, 3rd paragraph.) Further, “37 CFR 41.37(a) provides 2 months from the date of the notice of appeal for the appellant to file an appeal brief.” (MPEP § 1205.01, 1st paragraph.) The 2-month period for submitting an Appeal brief is extendable under 37 CFR 1.136(a) for up to 5 months. (MPEP § 1205.01, paragraphs 4 and 5.)

PETITION FOR WITHDRAWAL OF HOLDING OF ABANDONMENT

U.S. Application No.: 10/556,432

Attorney Docket No.: Q91404

A timeline below lists the relevant dates and actions relating to the pendency of the present application:

January 21, 2009 - Final Office Action is mailed;

April 21, 2009 - Applicant submits a Response;

April 30, 2009 - Advisory Action is mailed;

May 20, 2009 - Applicant files Notice of Appeal, and Petition for Extension of Time of 1-month;

November 16, 2009 - Examiner erroneously issues Notice of Abandonment for "failure to timely file a proper reply."

In the present application, the filing of the Notice of Appeal, along with the Petition for Extension of Time tolled the time period for reply set forth in the final Office Action dated January 21, 2009. Further, the original time period for filing the Appeal Brief was 2 months from the filing of the notice of appeal (July 20, 2009) which is extendable by another five months (December 20, 2009). Accordingly, as the Notice of Abandonment was issued prior to the last extendable time period, the Notice of Abandonment was issued in error.

The holding of abandonment is believed to have been issued by the Patent Office in error and no fee is believed to be required with the filing of this Petition. Withdrawal of the holding of abandonment is hereby requested.

SUGHRUE MION, PLLC
Telephone: (650) 625-8100
Facsimile: (650) 625-8110

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: November 19, 2009

Respectfully submitted,



Raja N. Saliba
Registration No. 43,078

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the interview conducted on

November 18, 2009:

REMARKS

Applicant's representative, Raja Saliba, contacted the Examiner to discuss the erroneous issuance of the Notice of Abandonment dated November 16, 2009.

During the interview, the following was discussed:

1. Brief description of exhibits or demonstration: None.
2. Identification of claims discussed: None.
3. Identification of art discussed: None.
4. Identification of principal proposed amendments: None.
5. Brief Identification of principal arguments: The Examiner issued the Notice of

Abandonment for "failure to properly file a timely reply" in error.

STATEMENT OF SUBSTANCE OF INTERVIEW
U.S. App. No.: 10/556,432

Attorney Docket: Q91404

6. Indication of other pertinent matters discussed: None.

7. Results of Interview: The Examiner agreed that the Notice of Abandonment was issued in error and that the present application is still pending. The Examiner indicated that no action needed to be taken, and stated that only the Appeal Brief with the appropriate extension of time needed to be filed.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

It is believed that no petition or fee is required. However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: November 19, 2009

Raja N. Saliba
Registration No. 43,078

Electronic Patent Application Fee Transmittal				
Application Number:		10556432		
Filing Date:		09-Nov-2005		
Title of Invention:		Fluid product dispenser		
First Named Inventor/Applicant Name:		Fabien Poulard		
Filer:		Jennifer Hayes/Eastlyn Blair		
Attorney Docket Number:		Q91404		
Filed as Large Entity				
U.S. National Stage under 35 USC 371 Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Filing a brief in support of an appeal	1402	1	540	540
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 4 months with \$0 paid	1254	1	1730	1730
Miscellaneous:				
Total in USD (\$)				2270

Electronic Acknowledgement Receipt	
EFS ID:	6490737
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	Fluid product dispenser
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Jennifer Hayes/Eastlyn Blair
Filer Authorized By:	Jennifer Hayes
Attorney Docket Number:	Q91404
Receipt Date:	19-NOV-2009
Filing Date:	09-NOV-2005
Time Stamp:	17:55:14
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Deposit Account
Payment was successfully received in RAM	\$2270
RAM confirmation Number	4617
Deposit Account	194880
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		Q91404_AppealBrief.PDF	1466632	yes	46
			6384b6914efa7c57fe8d1f851fd774cae780a371		
	Multipart Description/PDF files in .zip description				
	Document Description		Start	End	
	Appeal Brief Filed		1	45	
	Extension of Time		46	46	
Warnings:					
Information:					
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PATENT APPLICATION

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. § 41.37, Appellant submits the following:

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is VALOIS SAS (assignee), of France, by virtue of an assignment executed by Fabien POULARD (inventor), of France, on October 20, 2005.

The assignment was previously submitted and was recorded on October 20, 2005, at Reel 017925, Frame 0909.

II. RELATED APPEALS AND INTERFERENCES

To the knowledge and belief of Appellant, the Assignee, and the Appellant's legal representative, there are no other appeals or interferences before the Board of Appeals and Interferences that will directly affect or be affected by the Board's decision in the instant Appeal.

III. STATUS OF CLAIMS

Claims 1-21 are all the claims pending in the present application and all are rejected.

Claims 1-21 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate description of the invention that would enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-21 are being appealed.

On November 16, 2009, the Examiner erroneously issued a Notice of Abandonment for the present Application. The Notice of Appeal was filed on May 20, 2009, such that the initial due date for the Appeal Brief was July 20, 2009, and the Applicant is permitted up to five months extension under 37 C.F.R. § 1.136(a). Applicant's representative, Mr. Raja Saliba, telephoned the Examiner on November 17, 2009, advising the Examiner of this fact and requesting withdrawal of the Notice of Abandonment. On November 18, 2009, the Examiner again spoke with Mr. Saliba and confirmed that the Notice of Abandonment was erroneously mailed and that if the Applicant files the Appeal Brief and appropriate Petitions for Extension of Time, the Application will remain active.

IV. STATUS OF AMENDMENTS

A Final Rejection was mailed on January 21, 2009. Appellant submitted a Response under 37 C.F.R. § 1.116 on April 21, 2009, which requested reconsideration of the Final Rejection, but did not amend any claims. Thus, no Amendments have been submitted after the Final Rejection. In the Advisory Action dated May 1, 2009, the Examiner maintained the rejections of the Final Rejection mailed January 21, 2009.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Claim 1 is the only independent claim. The claimed subject matter will be explained with reference to three exemplary and non-limiting embodiments disclosed in the specification of the current application.

The subject matter of claim 1 concerns a fluid dispenser comprising a body 1, a fluid reservoir 2, a dispenser member 3, and a dose indicator (*see e.g.* counter element 20) for indicating the number of doses that have been dispensed or remain to be dispensed. (*See e.g.*, original specification, 1st Embodiment: page 8, line 36 to page 9, line 15; FIGS 1-8; 2nd Embodiment: page 14, lines 21-25; FIGS. 9-12; 3rd Embodiment: page 16, lines 1-16; FIGS. 13-21; *see also* amendments to specification and drawings filed October 22, 2008.) Claim 1 recites that the dose indicator device includes a first safety system that actuates the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform the complete actuation stroke. (*See e.g.*, original specification, 1st embodiment: page 10, lines 18-19, “[i]nitially the first safety system is described below with reference to Figures 1-4;” *see also* page 10, line 20 to page 12, line 28, describing FIGS. 1-4 in detail; 2nd embodiment: page 15, lines 18-23, “[t]he first safety system is thus provided [above];” *see also* page 14, line 20 to page 15, line 17 describing the first safety system; 3rd Embodiment: page 16, lines 16-28, “[t]his takes place after said incomplete actuation stroke of the dispenser . . . ;” *see also* page 16, lines 4-32.) Claim 1 also provides that the reservoir 2 is axially displaceable relative to the body 1. (*See e.g.*, original specification, 1st embodiment: page 8, line 35 to page 9, line 5; 2nd embodiment: page 14, lines 28-42; 3rd embodiment: FIGS 13-21,

showing the reservoir 2 being axially displaced relative to the body 1.) The body 1 includes at least one stationary gear 110 (and reference numeral 122 for 2nd and 3rd embodiments). (*See e.g.*, original specification, 1st embodiment: page 10, lines 20-25; 2nd embodiment: page 14, lines 22-23; 3rd embodiment: page 16, lines 11-21; *see also* amendment to the specification filed October 22, 2008.) The dose indicator device includes a counter element 20 that is displaceable axially and in rotation relative to the body 1. (*See e.g.*, original specification, 1st embodiment: page 10, lines 25-31; 2nd embodiment: page 14, lines 23-27; 3rd embodiment: page 16, lines 16-26.) The counter element 20 co-operates, while the dispenser is being actuated, firstly with the at least one stationary gear 110 (or 122) of the body, and secondly with the reservoir 2. (*See e.g.*, original specification, 1st embodiment: page 10, lines 22-25; 2nd embodiment: page 14, lines 25-27, 32-36; 3rd embodiment: page 16, lines 16-21, 21-26.)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues on appeal are summarized as follows:

1. Whether claims 1-21 are properly rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate description of the invention that would enable one skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed subject matter.

VII. ARGUMENT

1. Whether claims 1-21 are properly rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate description of the invention that would enable one skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed subject matter.

As an initial matter, the Examiner has not identified any specific claim language that is not enabled, nor has the Examiner even identified which claims are not sufficiently enabled. Accordingly, as discussed in more detail below, Applicant submits that the Examiner has not overcome the presumption that the claims are enabled.

Furthermore, the disclosure of the current application enables one of ordinary skill in the art to make and use the claimed subject matter after conducting a complete and thorough review of the disclosure of the original application. Accordingly, the Examiner's rejection of claims 1-21 as allegedly not being enabled is improper.

A. The Examiner's Rejection

The Examiner rejected claims 1-21¹ under 35 U.S.C. § 112, *first paragraph*, as allegedly failing to enable one skilled in the art to make and/or use the invention. In rejecting claims 1-21, the Examiner states:

Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to provide an adequate description of the invention that would enable one skilled in the art to which it

¹ In the Office Action dated January 21, 2009, the Examiner indicated that claims 1-20 are rejected. (*See* Office Action dated 1/21/2009, page 5.) However, claims 1-21 are pending in the application and the Office Action Summary indicates that claims 1-21 are rejected. As such, Applicants are treating claim 21, which depends from independent claim 1, as being rejected under 35 U.S.C. § 112, first paragraph, in the absence of any additional reasoning provided by the Examiner.

pertains, or with which it is most nearly connected, to make and/or use the invention. The disclosure (specification and drawings) is a vague description of desired function without specific means to implement. Note, it is not clear from the disclosure as to how the claimed invention functions/operates. While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details as to enable those persons skilled in the art to make and utilize the invention. Specific operative embodiments or examples of the invention must be set forth.

In view of the insufficiencies of the drawings and specification, and 35 U.S.C. 112 issue, comment as to the allowability of the claims can not be made at this time.

(Final Office Action dated January 21, 2009 at pages 5-6.) (emphasis added)

Additionally, while the objections to the drawings and specification are not on appeal, the Examiner's objections to the drawings and specification provide some insight into the Examiner's lack of understanding of the claimed subject matter. With respect to the drawings, the Examiner states:

The drawings are objected to under 37 CFR 1.83(a) because they fail to show the details and connections of components of the invention as described in the specification. Note, the drawings of figs. 1-21 only show a simplified diagrams of a reservoir, a body, an actuator, a counter element, and fail to specially show such elements are connected/mounted to one another in order to one having an ordinary skill to understand how the system of the invention can work, for example, what is connection between the container, body, actuator and counter elements so that the reservoir can be stored in the body and axially displaceable in the body; the counter element can indicate the number of doses dispensed or remained and can be displaceable and rotatable; the dose indicator device can be actuated once the dispenser has performed a predetermined incomplete actuation stroke; why just a oblique tooth of the actuator and the counter element can be considered a gear; how the gear of the body is stationary but the gear of the actuator is axial displaceable and the

gears of the counter element are axially and rotatably displaceable; why and how the abutments of the actuator gear and the station gear as shown in the drawing can perform as disclosed in page 12, lines 4-28, etc. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

Applicants submit that every element that is essential to understanding the claimed subject matter is disclosed in the original specification and that a thorough and complete reading of the specification would enable one of ordinary skill in the art to make and use the claimed subject matter.

B. The Test for Enablement

The test for enablement is whether one skilled in the art could make and use the claimed invention without undue experimentation. See *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (emphasis added). Thus, “[a] patent need not teach, and preferably omits, what is well known in the art.” MPEP § 2164.01 (citing *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986)) (emphasis added). It is not necessary to “enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim to that effect.” MPEP § 2164 (citing *CFMT, Inc. v. Yildup Int’l Corp.*, 349 F.3d 1333 (Fed. Cir. 2003)). As such, “[d]etailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.” MPEP § 2164 (emphasis added). In fact,

[i]n examining a patent application, the PTO is required to assume that the specification complies with the enablement provision

of Section 112 unless it has ‘acceptable evidence or reasoning’ to suggest otherwise. . . . The PTO thus must provide reasons supported by the record as a whole why the specification is not enabling. . . . Then and only then does the burden shift to the applicant to show that one of ordinary skill in the art could have practiced the claimed invention without undue experimentation. . . .”

Gould v. Mossinghoff, 229 USPQ 1, 13-14 (D.D.C. 1985) (citations omitted), *aff’d* in part, vacated in part on other grounds, and remanded sub nom. *Gould v. Quigg*, 3 USPQ2d 1302 (Fed. Cir. 1987) (emphasis added); *see also* MPEP 2164.04.

C. The Examiner has Not Overcome the Presumption that the Disclosure is Enabling and Has not Shifted the Burden to the Applicant

The Examiner has not cited any specific claim language that is not enabled. Nor has the Examiner provided any specific reasoning as to why the claim language is not enabled. Rather, regarding the claim language, the Examiner only states in general and conclusory terms that:

The disclosure (specification and drawings) is a vague description of desired function without specific means to implement. Note, it is not clear from the disclosure as to how the claimed invention functions/operates.

(Final Office Action dated January 21, 2009, at pages 5-6.)

To the contrary, Applicants submit that the disclosure of the current application provides great detail to the structure and function of the claimed subject matter. For example, the specification provides three exemplary embodiments, with multiple figures corresponding to each embodiment, that show the actuation cycle of the dispenser member for each embodiment.

D. The Examiner is Improperly Applying a Heightened Standard of Enablement

Applicant respectfully submits that the Examiner is requiring that a perfected embodiment be disclosed, rather than applying the enablement test which examines whether one of ordinary skill could make and use the claimed invention without undue experimentation. The elements that the Examiner alleges are necessary to understand the claimed subject matter, e.g., the connections between the recited elements, would be able to be produced by one of ordinary skill in the art without undue experimentation in view of the disclosure of the current application and the state of the art.

In order to appreciate the fact that the claims are fully enabled, a proper understanding of the disclosure is required. To aid the Board in understanding the subject matter of the current application, Applicant is providing below a step-by-step description of the actuation of an embodiment of the dispenser and dose indicator as disclosed in the current application.

In fact, Applicant believes that the Examiner's rejection under 35 U.S.C. § 112, paragraph 1, is predicated on her lack of understanding the technology to which the disclosure pertains. (*See e.g.*, Office Action dated January 21, 2009 at pages 5-6, "it is not clear from the disclosure as to how the claimed invention functions/operates.") However, as explained in the following sections, one skilled in the art would readily comprehend the disclosure and particularly understand "how the claimed invention functions/operates."

E. Disclosure of the Current Application

A first embodiment is described in detail from page 8, line 36 to page 14, line 19 of the specification of the present application.

In this embodiment, “the dispenser includes a reservoir 2 that is axially displaceable in a body 1, which is considered as being the stationary portion of the dispenser.” (Original specification, page 8, line 36, to page 9, line 2.) “The axial displacement of the reservoir 2 relative to the body 1 actuates the dispenser member and thus causes a dose of fluid to be dispensed from said reservoir.” (Original specification, page 9, lines 3-5.)

Further this embodiment includes “an actuator member 30 on which the user exerts an axial actuation force so as to actuate the dispenser and thus displace said reservoir 2 relative to the body 1.” (Original specification, page 9, lines 5-9; *see also* FIG. 1 of the current application, reproduced below.) Additionally, “the stationary body 1 includes a stationary gear 110.” (Original specification, page 10, lines 21-22.) The “counter element 20 is displaceable both axially and in rotation relative to the body 1.” (Original specification, page 10, lines 25-27.)

Figures 1-8, shown on the following page in sequence for a side-by-side comparison, depict the actuation of this embodiment. Furthermore, each figure will be discussed in greater detail individually on the following pages, and enlarged views of each figure are included in an attached appendix. The figures are color-coded to assist the Board in distinguishing the elements of this embodiment. A courtesy color copy of the Appeal Brief is being hand delivered to the Examiner. Further, courtesy color copies will be delivered to the Board, if necessary.

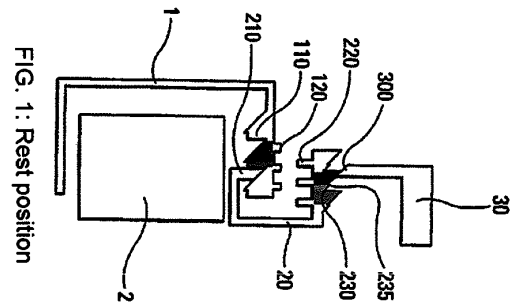


FIG. 1: Rest position

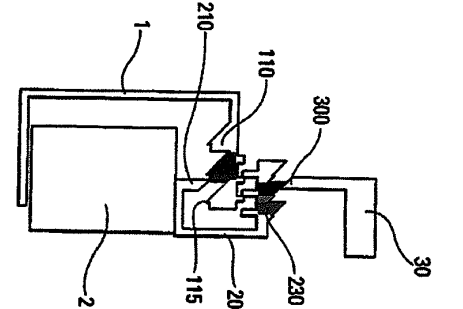


FIG. 2: initial axial displacement of counter element 20

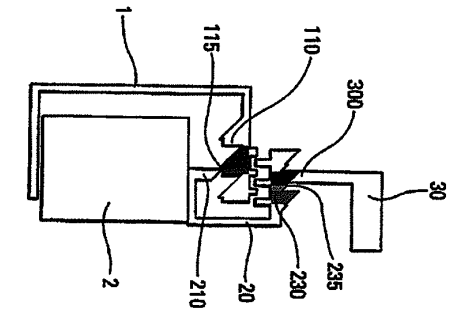


FIG. 3: initial rotation of the counter element 20

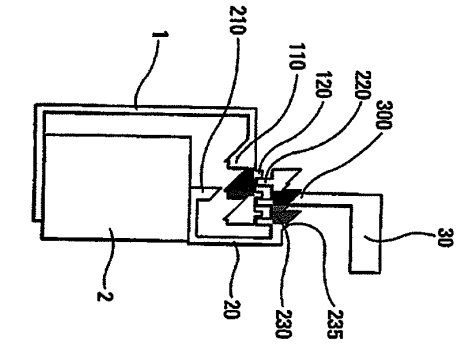


FIG. 4: completion of axial displacement of counter element 20 and incremental rotation of counter element 20

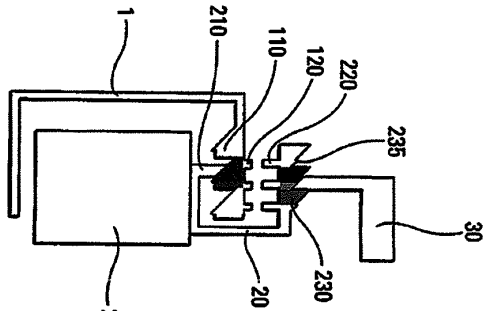


FIG. 5: partial upward release of actuator 30 and incremental rotation of counter element 20

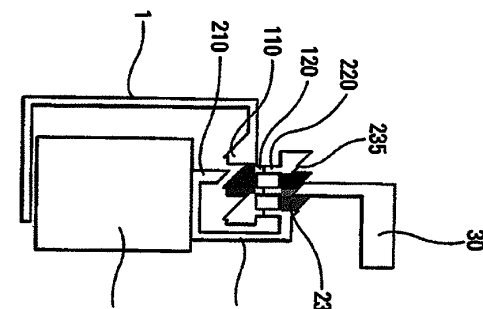


FIG. 6: prevention of actuation prior to complete release of actuator 30

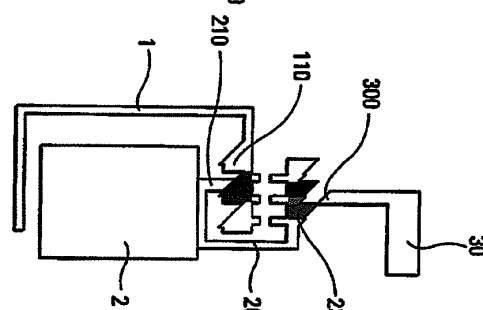


FIG. 7: continued release of actuator 30

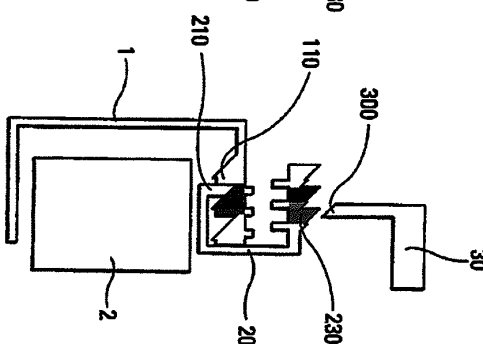


FIG. 8: completion of release of actuator 30, completion of rotation of counter element 20

This embodiment is described in the specification below with respect to Figures 1-8 of the application.

Steps 1 and 2: see FIG. 1

- 1) Starting from a rest position, actuation begins by depressing the actuator 30 in the axial direction (downward in Fig. 1). (Original specification, page 10, line 35 to page 11, line 5.) The oblique portion of the tooth of the actuator gear 300 contacts the oblique portion of the first tooth (purple) of the second gear 230, which urges the counter element 20 downward and applies a force on the counter element 20 to the left. (Original specification, page 11, lines 1-5.)
- 2) While the oblique portions of the actuator gear 300 and the first tooth (purple) of the second gear 230 apply a force to the left on the counter element 20, the end wall (blue) of the stationary gear 110 prevents the counter element 20 from rotating to the left and only allows the counter element 20 to be displaced downward in an axial direction. (Original specification, page 11, lines 5-8.)

Step 3: see FIG. 2

- 3) The counter element 20 is displaced downward by the actuator 30 until the first gear 210 of the counter element 20 passes the end wall (blue) of the stationary gear in the axial direction. As the counter element 20 is displaced downward, the bottom of the counter element 20 contacts the reservoir 2 and displaces the reservoir 2 downward, thereby actuating the dispenser. (Original specification, page 11, lines 9-16.)

Steps 4 and 5: see FIG. 3

- 4) The counter element 20 is then urged to rotate to the left by the engagement of the oblique portions of the tooth of the actuator gear 300 and the first tooth (purple) of the second gear 230, thereby initiating the counting of one dose of fluid. (Original specification, page 11, lines 16-28.) Accordingly, the counter element 20 rotates before the complete actuation of the dispenser member, thereby ensuring that a count is registered if there is any possibility that fluid was dispensed. (Original specification, page 11, line 33 to page 12, line 3.)
- 5) The first gear 210 of the counter element 20 rotates until it contacts the abutment means 115 (tip of the red section extending past the end wall (blue section) in the axial direction) which again prevents the rotation of the counter element 20, and causes the vertical displacement of the counter element 20. (Original specification, page 12, lines 4-11.)

Step 6: see FIG. 4

- 6) Once the first gear 210 of the counter element 20 is displaced past the abutment means 115 (red) in the axial direction, the engagement of the oblique portions of the actuator gear 300 and the first tooth (purple) of the second gear 230 rotate the counter element 20 until the actuator gear 300 meshes with the first abutment 235 (orange) on the second gear 230. (Original specification, page 12, lines 7-11.) This prevents the counter element 20 from rotating again.

Steps 7 & 8: see FIG. 5

- 7) When the actuator 30 is released, a spring (not shown in the drawings) displaces the reservoir 2 axially upward towards the rest position. (Original specification, page 12, line 32 to page 13, line 2.) The displacement of the reservoir 2 causes the counter 20 to be displaced axially upward until the oblique portion of the first gear 210 engages the oblique portion of the second tooth (red) of the stationary gear 110. (Original specification, page 13, lines 4-8.) At this point, the abutment 235 prevents rotation of the counter element 20, and the engagement of the first gear 210 and the stationary gear 110 prevents axial displacement of the counter element 20. Accordingly, the actuator 30 moves axially relative to the counter element 20 when the actuator 30 is further released, and the actuator gear 300 passes over the abutment 235 (orange). At this point, the chamber of the dispenser can be filled. (Original specification, page 12, lines 12-18.)
- 8) The engagement of the oblique portion of the first gear 210 with the oblique portion of second tooth (red) of the stationary gear 110 causes the counter element 20 to rotate until the actuator gear 300 contacts an end wall of the second tooth (green) of the second gear 230. (Original specification, page 13, lines 4-16.)

Step 9: see FIG. 6

- 9) If one were to attempt to actuate the dispenser at this point, before completing the return stroke, the axial projections 120 of the counter element 20 (shown in red on following page) would engage the axial projections 220 of the body 1 (shown in red on the

following page), thereby preventing actuation of the dispenser member. (Original specification, page 13, lines 17-29.)

Step 10: see FIG. 7

10) With the end wall of the second tooth (green) of the second gear 230 preventing rotation of the counter element 20, and with the first gear 210 and the second tooth (red) of the stationary gear 110 preventing axial displacement of the counter element 20, the actuator 30 will move in the axial direction relative to the end wall of the second tooth (green) of the second gear 230 when the actuator 30 is further released, and the actuator gear 300 will pass over the end wall of the second tooth (green) of the second gear 230. (Original specification, page 13, lines 29-37.)

In the position shown in Figure 6 (step 9 described above), a new action of the dispenser is not possible because of an insufficient return stroke.

Figure 7 (step 10 described above), however, shows a position before the completion of a return stroke where it is possible to have a new actuation of the dispenser despite the uncompleted return stroke of the first actuation.

In Figure 7 (step 10) the new actuation is possible because the actuator gear 300 has passed over the end wall of the second tooth (green) of the second gear 230. Thus, the engagement of the first gear 210 with the second tooth (red) of the stationary gear 110

further rotates counter element 20, and a new actuation stroke would make the actuator gear 300 cooperate with the oblique portion of the second tooth (green) of the second gear 230.

Step 11: see FIG. 8

- 11) Once the actuator gear 300 passes over the end wall of the second tooth (green) of the second gear 230, the oblique portions of the first gear 210 and the oblique portions of the second tooth (red) of the stationary gear 110, cause the counter element 20 to complete the rotation cycle. (See FIG. 8 on page 18, original specification, page 14, lines 18-19.)

F. Comparison of Claims with Disclosure

Independent claim 1 recites:

A fluid dispenser comprising a body (1), a fluid reservoir (2), a dispenser member mounted on said reservoir (2), and a dose indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, the dispenser being characterized in that said dose indicator device includes a first safety system that actuates the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform the complete actuation stroke, said reservoir (2) being axially displaceable relative to said body (1), said body (1) including at least one stationary gear (110, 122), said dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to said body (1), said counter element (20) co-operating, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2).

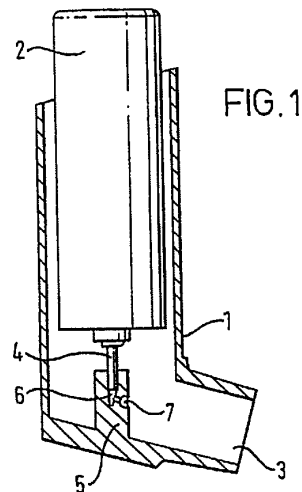
The language of independent claim 1 will be compared with first exemplary embodiment described above. It should be noted that the claims should not be limited to this embodiment,

and that the comparison is only being done to show that the claimed subject matter is adequately enabled.

1. "... a body (1), a fluid reservoir (2), a dispenser member mounted on said reservoir (2), ... said reservoir (2) being axially displaceable relative to said body (1), said body (1) including at least one stationary gear (110, 122), said dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to said body (1)...."

The specification of the original application discloses that "the dispenser includes a reservoir 2 that is axially displaceable in a body 1, which is considered as being the stationary portion of the dispenser." (Original specification, page 8, line 36, to page 9, line 2.) "The axial displacement of the reservoir 2 relative to the body 1 actuates the dispenser member and thus causes a dose of fluid to be dispensed from said reservoir." (Original specification, page 9, lines 3-5.)

In view of the specification of the current application and the state of the art, one having ordinary skill in the art would know how to make and use a reservoir that is axially displaceable relative to a body to actuate a dispenser member on the reservoir without undue experimentation. (*See for example* U.S. Pub. No. 2002/0195102, FIG. 1 (reproduced right), cited in current application in Information Disclosure Statement filed on November 9, 2005, showing a reservoir 2 that is axially displaceable within a body 1 to actuate a dispenser member 4.)



Additionally, one having ordinary skill in the art would know how to make and use a stationary gear 110 that is stationary with the body 1 and a counter element 20 that it is axially displaceable and rotatable relative to the body 1 without any undue experimentation. The details of known structural elements for the “connections” between the reservoir 2, the body 1, the actuator 3, and the counter element 20 were intentionally omitted because they are not required to understanding the claimed subject matter. (*See for example*, MPEP 2164.01; original specification, page 8, lines 13-24, “[t]he drawings to which the present description refers are highly simplified diagrams which do not show the fluid dispenser in detail, but only in very diagrammatic manner relating to the various portions that can be moved relative to one another, for explaining the actuation cycle of said dispenser and of said indicator device.”)

In fact, the inclusion of these features would unnecessarily complicate the disclosure, making it more difficult for one of ordinary skill in the art to understand the claimed subject matter. Thus, what the disclosure intentionally focuses on is the inventive aspects of providing a dispensing mechanism with a counter element with a safety system.

2. “. . . the dispenser being characterized in that said dose indicator device includes a first safety system that actuates the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform the complete actuation stroke”

Steps 4 and 5 of the actuation cycle, described above on page 20, describe the first safety system that actuates the dose indicator after an incomplete actuation stroke. As described in step 5, after the first gear 210 disengages the stationary gear 110, which is at a position of an incomplete actuation stroke, the counter element 20 is rotated by the oblique surfaces of the

actuator gear 30 engaging the oblique surface of the second gear 230. As such, the counter element 20 is actuated during a predetermined incomplete actuation stroke.

3. "... said counter element (20) co-operating, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2).

Step 2 of the actuation cycle, described above on page 16, discloses that the counter element 20 firstly co-operates with the stationary gear 110, at the time that the counter element 20 is in the rest position, to prevent the counter element 20 from rotating.

Step 4 of the actuation cycle, described above on page 19, discloses that after the counter element 20 has been displaced in a downward axial direction, the bottom of the counter element 20 contacts the reservoir 2 to displace the reservoir. Accordingly, the counter element 20 firstly contacts the stationary gear and secondly contacts the reservoir.

In view of the above, independent claim 1 is fully disclosed and enabled by the original specification.

4. Dependent Claims

All of the dependent claims are fully described and enabled by the disclosure of the original application, as described above. As previously noted, the Examiner has not specifically identified any claim language or claims that are not enabled. Accordingly, Applicants are only providing analysis with respect to independent claim 1. Nevertheless, claims 2-21 are fully enabled by the disclosure of the current application.

5. Objections to Drawings and Specification

The objections to the drawings and specification are not on appeal. However, to the extent that the Examiner's comments may relate to the claim language, Applicants are responding to the Examiner's comments. The features that the Examiner alleges are not understood in view of the disclosure are listed below with Applicant's response to each allegation directly below:

Examiner: "what is connection between the container, body, actuator and counter elements so that the reservoir can be stored in the body and axially displaceable in the body."

Response: None of the claims recite any specific connections between the container, body, actuator and counter element. Furthermore, in view of the disclosure of the current application and the state of the art, one of ordinary skill in the art would not have to engage in undue experimentation to produce a reservoir that is axially displaceable inside of a body.

Examiner: "the counter element can indicate the number of doses dispensed or remained and can be displaceable and rotatable."

Response: It is not beyond the skill of one of ordinary skill in the art to produce a rotatable counter element to count the number of doses that are dispensed or remain to be dispensed or to make the counter element displaceable in an axial direction.

Examiner: "the dose indicator device can be actuated once the dispenser has performed a predetermined incomplete actuation stroke;"

Response: The dose indicator device is actuated after a predetermined actuation stroke, as described above in detail with regard to steps 1-4 of the actuation device at pages 16-20.

Examiner: “why just a oblique tooth of the actuator and the counter element can be considered a gear”

Response: Whether or not the oblique tooth of the actuator gear 300 or the oblique tooth of the first gear 210 of the counter element can be considered a “gear” is irrelevant to the understanding of the subject matter of the invention. One of ordinary skill in the art would be able to make the oblique tooth of the actuator gear 300 and the oblique tooth of the first gear 210 based on the drawings and written description. It is irrelevant whether these elements are identified as a gear, a widget or any other name.

Examiner: “how the gear of the body is stationary but the gear of the actuator is axial displaceable and the gears of the counter element are axially and rotatably displaceable;”

Response: The stationary gear 110 is defined as being stationary to the body 1. It is not beyond the skill of one of ordinary skill to make and use a gear that engages the fixed gear and is rotatable to the stationary gear and displaceable along an axial direction. Again, such features would not require undue experimentation.

Examiner: “why and how the abutments of the actuator gear and the station gear as shown in the drawing can perform as disclosed in page 12, lines 4-28.”

Response: The function of the abutments are described above in detail with regard to steps 5 and 6 of the actuation device at pages 20-23.

In view of the above, Applicant submits that one of ordinary skill in the art would have been able to make and use the claimed subject matter.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37
U.S. Application No. 10/556,432

Attorney Docket No.: Q91404

Conclusion

The USPTO is directed and authorized to charge the statutory fee (37 C.F.R. §41.37(a) and 1.17(c)) and all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: November 19, 2009

Raja N. Saliba
Registration No. 43,078

CLAIMS APPENDIX

CLAIMS 1-21 ON APPEAL:

1. (previously presented): A fluid dispenser comprising a body (1), a fluid reservoir (2), a dispenser member mounted on said reservoir (2), and a dose indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, the dispenser being characterized in that said dose indicator device includes a first safety system that actuates the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform the complete actuation stroke, said reservoir (2) being axially displaceable relative to said body (1), said body (1) including at least one stationary gear (110, 122), said dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to said body (1), said counter element (20) co-operating, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2).

2. (original): A dispenser according to claim 1, in which said dose indicator device includes a second safety system which, during the return stroke of the dispenser after dispensing a dose, prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been

performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

3. (previously presented): A dispenser according to claim 1, in which said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20), said counter element (20) including a second gear (230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser, the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation, the stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

4. (original): A dispenser according to claim 3, in which the stationary gear (110) includes abutment means (115) preventing said counter element (20) from turning once said counter element (20) has turned at least in part, an additional axial displacement of said counter element (20) being necessary to enable it to continue to turn and/or to return the indicator device to its rest position.

5. (original): A dispenser according to claim 4, in which said abutment means (115) comprise an axial projection.

6. (previously presented): A dispenser according to claim 1, in which said stationary gear (110) and/or said counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position after a preceding actuation, and until the dispenser has completed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

7. (previously presented): A dispenser according to claim 6, in which said blocking means comprise axial projections (120, 220) provided on the body (1) and on the counter element (20) respectively, each of said projections (120, 220) having an axial end-profile that is planar, said projections (120, 220) facing each other, at least in part, until the counter element has turned sufficiently to offset said projections (120, 220), with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

8. (previously presented): A dispenser according to claim 3, in which the teeth of the second gear (230) of the counter element (20) include an intermediate step (235), the actuator member (30) co-operating with said step (235) while the dispenser is being actuated, and co-operating with the end wall of said second gear (230) while returning to the rest position, after being actuated, the displacement between the intermediate step (235) and the end wall being obtained by said counter element (20) turning.

9. (previously presented): A dispenser according to claim 3, in which, once the predetermined incomplete return stroke has been performed, the actuator member (30) is positioned facing the following tooth of the second gear (230) of the counter element (20), enabling the dispenser and the dose indicator device to be actuated once again.

10. (previously presented): A dispenser according to claim 1, in which said body (1) includes a first stationary gear (110) and a second stationary gear (122), said counter element (20) including a first gear (210) for co-operating with said first stationary gear (110) and a second gear (222) for co-operating with said second stationary gear (122), said counter element (20) being put axially into contact with an actuator member (30) of the dispenser by means of a return spring (50) and being turnable relative to said actuator member (30), the teeth of said second gear (222) and of said second stationary gear (122) being oblique, at least in part, so that an axial displacement of the actuator member (30) initially causes said counter element (20) to be displaced axially over a predetermined incomplete actuation stroke until the oblique portion (221) of said second gear (222) of the counter element (20) co-operates with said oblique portion (121) of said second stationary gear (122), causing the counter element (20) to be turned over a first portion of a turn cycle, the teeth of said first gear (210) and of said first stationary gear (110) being oblique, at least in part, so that when the counter element (20) returns to its rest position, it is caused to turn so as to terminate its turn cycle, which corresponds to one actuation of the dispenser being counted.

11. (previously presented): A dispenser according to claim 10, in which said first and second stationary gears (110, 122) of the body (1) and/or said first and second gears (210, 222) of the counter element (20) are offset relative to each other, so that whenever the counter element (20) is displaceable in rotation, returning said counter element to its rest position without terminating the actuation stroke of the dispenser causes the counter element (20) to turn over its complete turn cycle, guaranteeing that one actuation of the dispenser is counted after said predetermined incomplete actuation stroke.

12. (previously presented): A dispenser according to claim 10, in which said second stationary gear (122) of the body (1) and/or said second gear (222) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, and until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

13. (previously presented): A dispenser according to claim 12, in which said blocking means have an axial end-profile that is planar, at least in part, and that is formed on the teeth of said second stationary gear (122) of the body (1) and on the teeth of said second gear (222) of the counter element (20), said planar profiles of said teeth facing each other, at least in part, until the

counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

14. (previously presented): A dispenser according to claim 10, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

15. (previously presented): A dispenser according to claim 1, in which said body (1) includes a first stationary gear (110) and a second stationary gear (122), said counter element (20) comprising a first gear (210) for co-operating with said first stationary gear (110), a second gear (222) for co-operating with said second stationary gear (122), and a third gear (230) for co-operating with an actuator gear (300) secured to an actuator member (30) of the dispenser, the teeth of said third gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member (30) causes said counter element (20) to be displaced axially and in rotation, the first stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

16. (previously presented): A dispenser according to claim 15, in which said second stationary gear (122) of the body (1) and/or said second gear (222) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus

preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

17. (previously presented): A dispenser according to claim 16, in which said blocking means have an axial end-profile that is planar and that is formed on the teeth of said second stationary gear (122) and on the teeth of said second gear (222), said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

18. (previously presented): A dispenser according to claim 16, in which said actuator gear (300) includes abutment means (305) limiting the extent to which the counter element (20) can turn, until the actuator member (30) has performed said predetermined incomplete return stroke.

19. (original): A dispenser according to claim 18, in which said abutment means (305) comprise an axial projection formed on said actuator gear (300).

20. (previously presented): A dispenser according to claim 15, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

21. (previously presented): A dispenser according to claim 1, wherein the dispenser member is a pump or a valve.

DRAWINGS APPENDIX

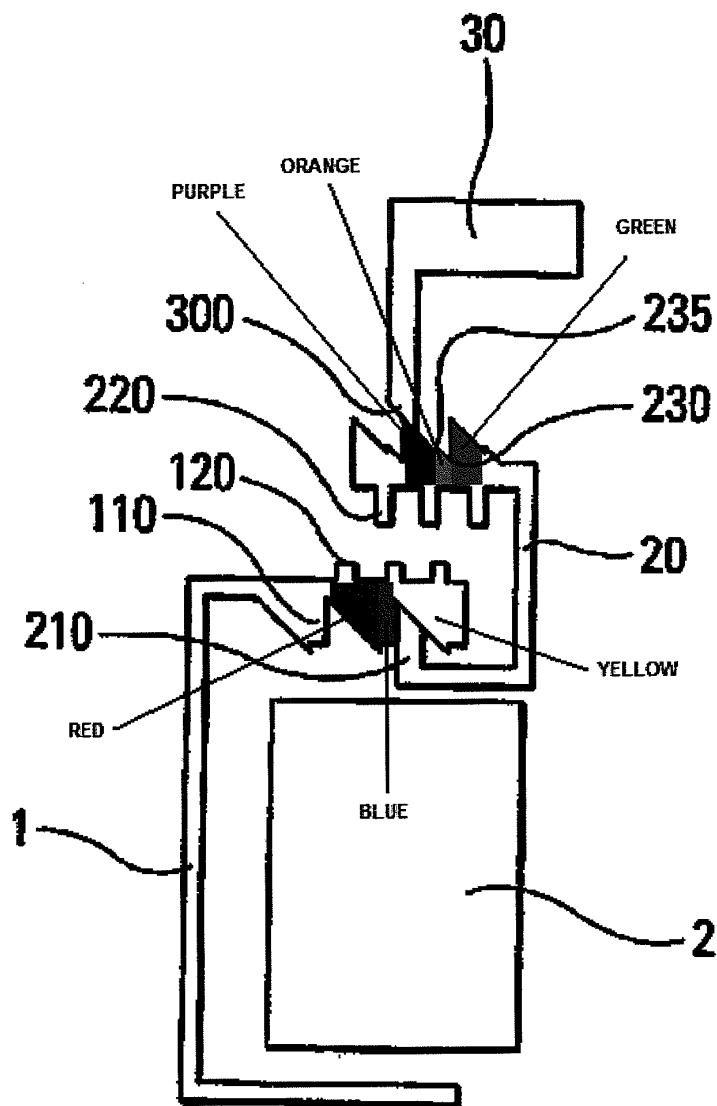


Fig. 1

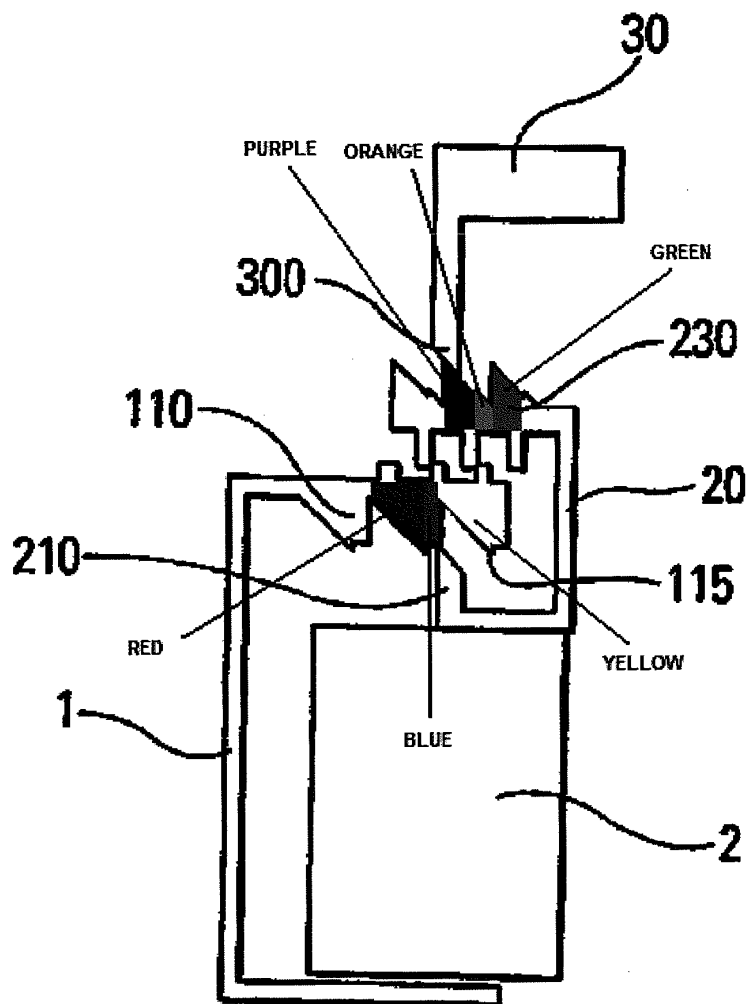


Fig. 2

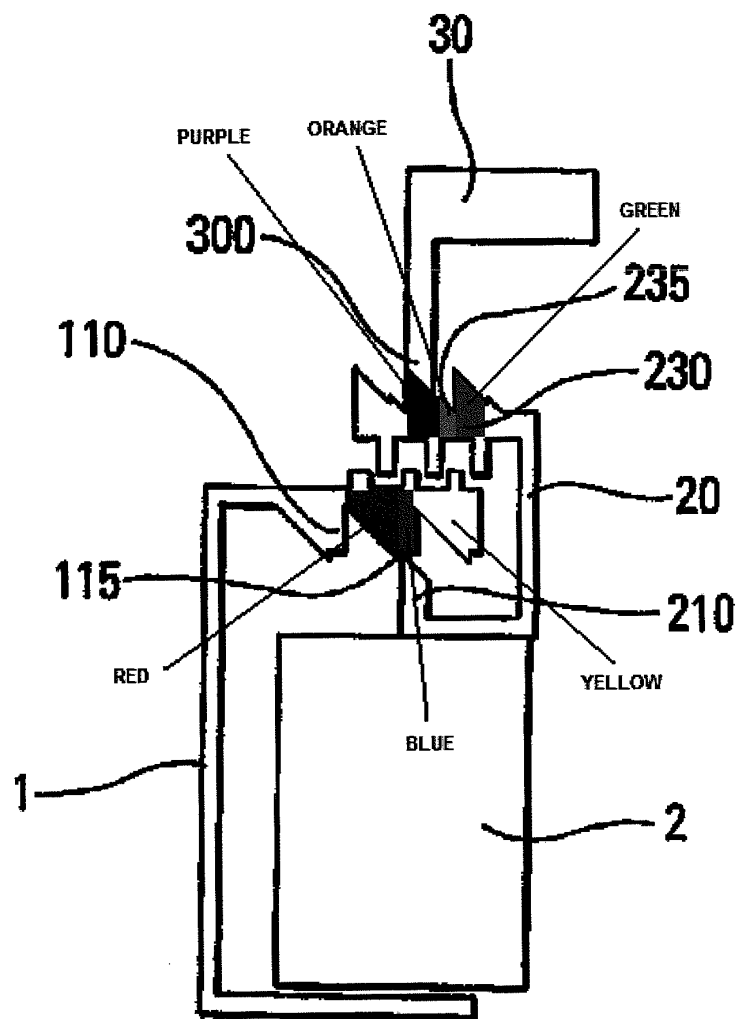


Fig. 3

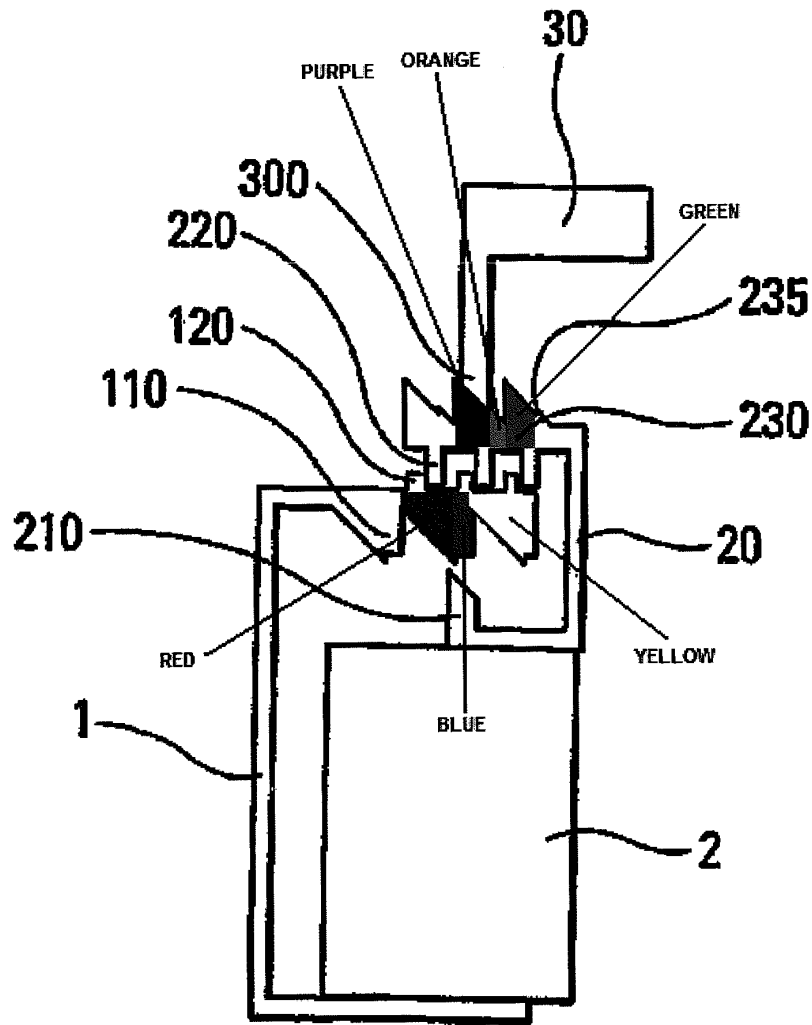


Fig. 4

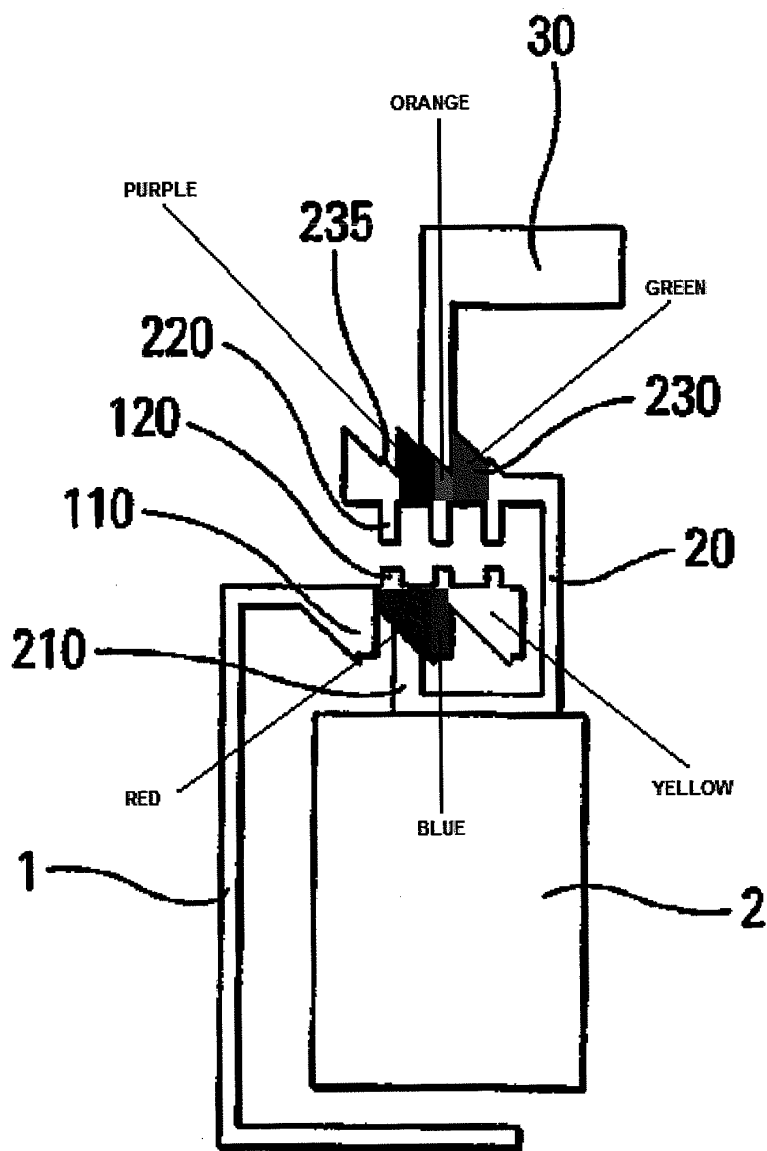


Fig. 5

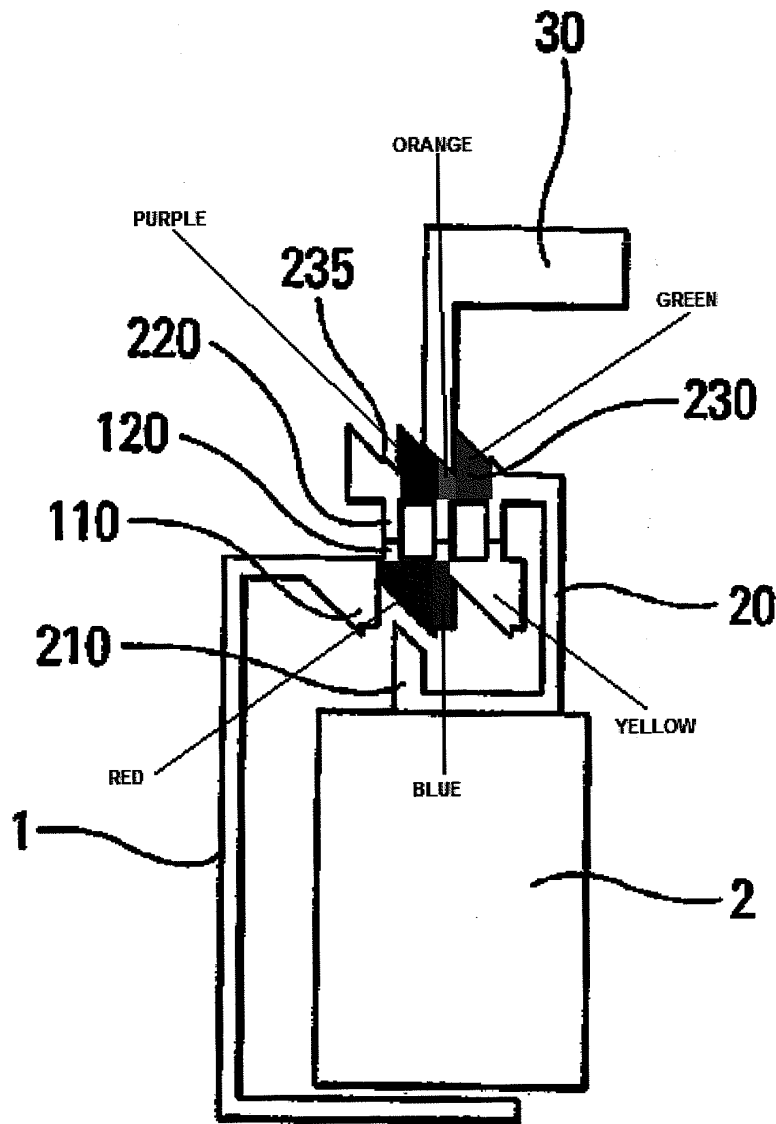


Fig. 6

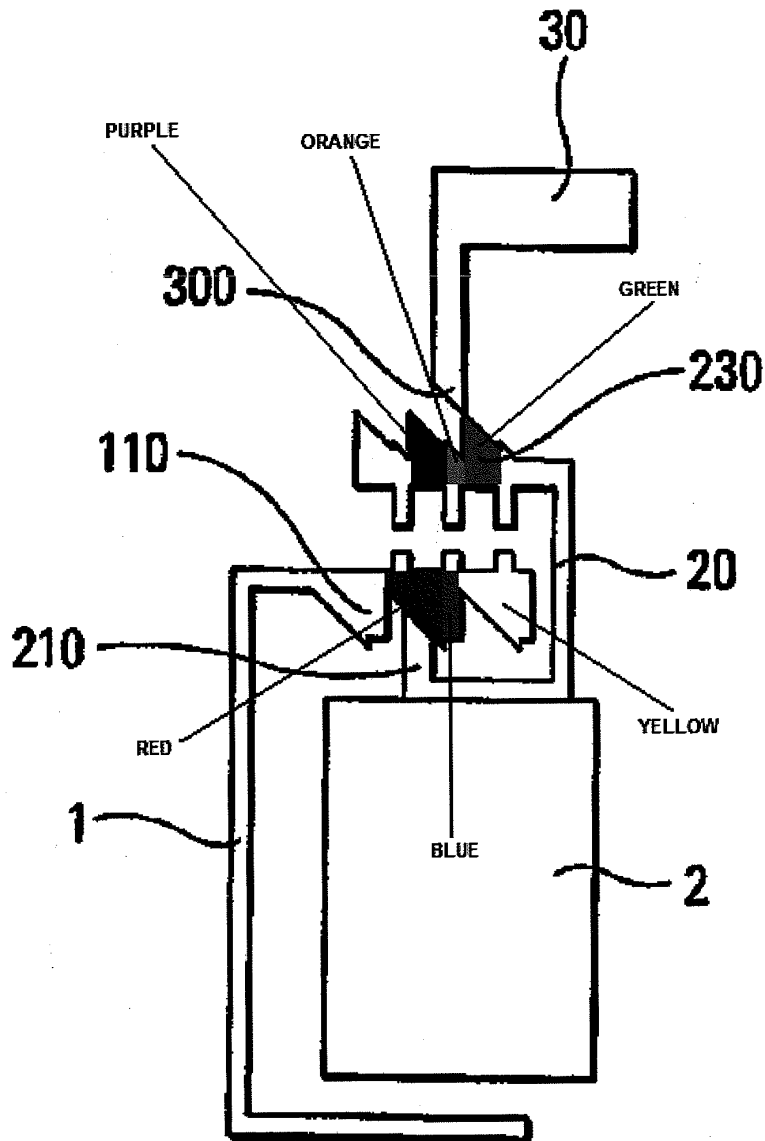


Fig. 7

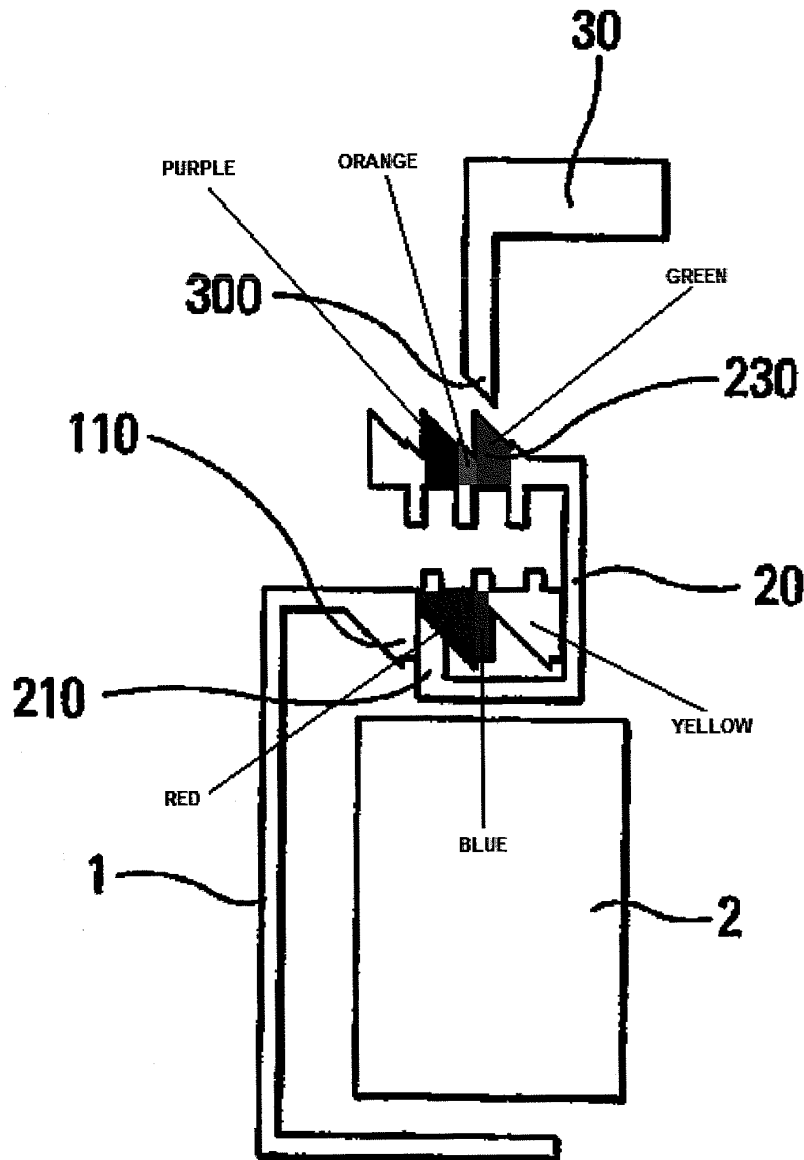


Fig. 8

EVIDENCE APPENDIX:

Pursuant to 37 C.F.R. § 41.37(c)(1)(ix), submitted herewith are copies of any evidence submitted pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132 or any other evidence entered by the Examiner and relied upon by Appellant in the appeal.

None.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37
U.S. Application No. 10/556,432

Attorney Docket No.: Q91404

RELATED PROCEEDINGS APPENDIX

None.

PATENT APPLICATION

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

SUBMISSION OF APPEAL BRIEF

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an Appeal Brief. The USPTO is directed and authorized to charge the statutory fee of \$540.00 and all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Raja N. Saliba
Registration No. 43,078

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: November 19, 2009

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

PETITION FOR EXTENSION OF TIME UNDER 37 C.F.R. § 1.136

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.136, Applicant hereby petitions for an extension of time of four month(s), extending the time for filing an Appeal Brief from the Notice of Appeal filed on May 20, 2009, to November 20, 2009.

The USPTO is directed and authorized to charge the statutory fee of \$1730.00 and all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880.

Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Raja N. Saliba
Registration No. 43,078

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: November 19, 2009



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON DC 20037

COPY MAILED

FEB 17 2010

In re Application of	:	
Fabien Poulard	:	
Application No. 10/556,432	:	DECISION ON PETITION
Filed: November 9, 2005	:	
Attorney Docket No. Q91404	:	

This is a decision on the petition, filed November 19, 2009, under 37 CFR 1.181(a) to Withdraw Holding of Abandonment.

The petition under 37 CFR 1.181(a) is **GRANTED**.

The application was held abandoned for failure to timely reply to the final rejection mailed January 21, 2009. A Notice of Appeal was filed on May 20, 2009. A Notice of Abandonment was mailed on November 16, 2009.

The petitioner states that, "In the present application, the filing of the Notice of Appeal, along with the Petition for Extension of Time tolled the time period for reply set forth in the final Office Action date January 21, 2009. Further, the original time period for filing the Appeal Brief was 2 months from the filing of the notice of appeal (July 20, 2009) which is extendable by another five months (December 20, 2009). Accordingly, as the Notice of Abandonment was issued prior to the last extendable time period, the Notice of Abandonment was issued in error."

A review of the Office records show receipt of an Appeal Brief along with an extension of time for four months on November 19, 2009, which would make the response timely.

In view of the above, the holding of abandonment is hereby withdrawn and the application restored to pending status.

Telephone inquiries concerning this decision should be directed to the undersigned at (571) 272-3208.

This matter is being referred to Technology Center AU 3754 for appropriate action by the Examiner in the normal course of business on the reply received November 19 2009.

/KOC/
Karen Creasy
Petitions Examiner
Office of Petitions



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 06/04/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER NGO, LIEN M	
			ART UNIT 3754	PAPER NUMBER
			NOTIFICATION DATE 06/04/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/556,432	POULARD, FABIEN	
	Examiner	Art Unit	
	LIEN TM NGO	3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 19 November 2009.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-21 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on 22 October 2008 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892) 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) ☐ Notice of Informal Patent Application 6) ☐ Other: _____.

DETAILED ACTION

1. In view of the Appeal Brief filed on 11/19/09, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Kevin P. Shaver/

Supervisory Patent Examiner, Art Unit 3754

1. This application has been treated as being obviously informal. Note, it is impractical to give a complete action on the merits because of the insufficiencies noted below. A reasonable search has been made in so far as the invention could be understood from the disclosure.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed 10/22/08 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.21 (a) (6) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of a pump or valve 3 located on top of the reservoir 2 as shown in fig. 1.

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the details of structure and connections of components of the invention as described in the specification as improvement of the prior art to make the invention work and function. Note, the drawings of figs. 1-21 only show a simplified diagrams of a reservoir, a body, an actuator member, a counter element, and fail to specially show such elements are structurally connected/mounted to one another in order to one having an ordinary skill to understand how the system of the invention can perform the functions and work as disclosed in the original specification, for example, what are actual structures of the body, reservoir, dispenser member, dose indicator device, actuator member, station gear(s), counter element gear(s), actuator gear(s) and how are connections between the elements so that the body gear is stationary, the reservoir can

be stored in the body and axially displaceable to the body, the counter element can indicate the number of doses dispensed or remained and can be axially displaceable and rotatable, why just a oblique tooth of the actuator and the counter element can be considered a gear, why the gear of the body is stationary but the gear of the actuator is axial displaceable and the gears of the counter element are axially and rotatably displaceable. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to under 37 CFR 1.83(b) because they are incomplete. 37 CFR 1.83(b) reads as follows:

When the invention consists of an improvement on an old machine the drawing must when possible exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith.

The specification of the application, pages 1 and 2, discloses the invention, which is a fluid dispenser comprising a dose indicator as an improvement on a prior art. Figs. 1-21 in the present application show only simplified diagrams without clearly providing the structural shapes and connections between one element to one another in order to one having an ordinary skill to understand the claimed invention functions, working and improvement as disclosed in the specification. The drawing does not exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and

appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the dispenser member mounted on the reservoir or a pump or a valve in claims 1 and 21, the counter element is in rotation relative to the body in claim 1, and the counter element is turnable relative to the actuator member, the counter element co-operating, while the dispenser being actuated, first with at least one station gear of the body and secondly with the reservoir in claims 10 and 15, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The amendment filed 10/22/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "a pump or a valve is only shown in Figure 1" in the replacement of paragraph no.32, "the dispenser member 3 (shown in Fig. 1)" in the replacement of paragraph no. 34. Amendment of Fig. 1 introduces new matter because the original disclosure does not support the showing of a pump or valve 3 located on top of the reservoir 2.

Applicant is required to cancel the new matter in the reply to this Office Action.

7. The disclosure is objected to under 37 CFR 1.71, as being so incomprehensible as to preclude a reasonable search of the prior art by the examiner. For example, the following items are not understood: what are structural connections between the

container, body, actuator and counter elements so that the reservoir can be stored in the body and axially displaceable to the body, the counter element can indicate the number of doses dispensed or remained and can be axially displaceable and rotatable; why just a oblique tooth of the actuator and the counter element can be considered a gear; why the gear of the body can be stationary but the gear of the actuator is axial displaceable and the gears of the counter element are axially and rotatably displaceable; what are actual structural shapes and connections of one element to one another in order to one having an ordinary skill to understand the invention functions, working and improvement, etc. as disclosed in the specification.

Applicant is required to submit an amendment which clarifies the disclosure so that the examiner may make a proper comparison of the invention with the prior art.

Applicant should be careful not to introduce any new matter into the disclosure (i.e., matter which is not supported by the disclosure as originally filed).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In regard to claim 1-9, the claims recite the elements and their functions related one to another without actual structures and connections between them. The specification of the present application does not disclose in full, clear, concise of the actual structures of a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element and structural connections between them in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or perform the first safety system in claim 1, so that the counter element is displaceable axially and in rotation relative to the body, the body gear is stationary, the reservoir is axially displaced relative to the body even if the dispenser does not perform a complete actuator stroke and the counter element co-operating, while the dispenser is being actuated, firstly with the at least one stationary gear and secondly with the reservoir; and the second safety system as in claim 2 during the return stroke; and also claimed subject matter in claims 3-9.

In regard to claims 10-14, the specification of the present application does not disclose in full, clear, concise of the actual structures of a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element and structural connections between them in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or perform the claimed subject matter of claims 10-14, which examiner believe they are claimed directly from the embodiment of figs. 9-12 in the application. Moreover, the specification does not support the claimed subject

matter of claim 10-14 as disclosed in figs. 9-12, which enables for the counter element co-operating, while the dispenser is being actuated, firstly with the at least one stationary gear and secondly with the reservoir, as claimed in claim 1. In regard to claims 15-20, the specification of the present application does not disclose in full, clear, concise of the actual structures of a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element and structural connections between them in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or perform the claimed subject mater of claims 15-20, which examiner believe they are claimed directly from the embodiment of figs. 13-21. Moreover, the specification does not support the claimed subject matter of claim 15-20 as disclosed in figs. 13-21, which enables for the counter element co-operating, while the dispenser is being actuated, firstly with the at least one stationary gear and secondly with the reservoir, as claimed in claim 1.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-21 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the claims comprising many elements but do not include structures or shapes of elements and

structural connections between the elements, such omission amounting to a gap between the necessary structural connections.

12. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because it is not clear what are required for structures or shapes of the elements in the claims, such as a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element, etc., and structural connections between them to understand the claimed subject matter which applicant regards as the invention.

Also it is indefinite what are included for "a first safety system" in claim 1, and "a second safety system" in claim 2.

13. In view of the insufficiencies of the drawings and specification, and 35 U.S.C. 112 issue, comment as to the allowability of the claims can not be made at this time.

Response to Arguments

14. Applicant's arguments with respect to claims 1-21 have been considered but are moot in view of the new ground(s) of rejection.

15. Applicant's responses in pages 24-25 of the Argument in the Appeal Brief, filed 11/19/09, fail to comply with 37 CFR 1.111(b) because they amount to a general allegation of the missing of structures and connections of the invention's elements in drawing and specification, which are within level of ordinary skill in the art rather than to

point out or provide evidences for they are within the level of ordinary skill in the art would have been able to make and use the claimed subject matter.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LIEN TM NGO whose telephone number is 571-272-4545. The examiner can normally be reached on Monday through Friday from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, KEVIN SHAVER can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LIEN TM NGO/
Primary Examiner, Art Unit 3754

May 26, 2010

Notice of References Cited	Application/Control No. 10/556,432		Applicant(s)/Patent Under Reexamination POULARD, FABIEN	
	Examiner LIEN TM NGO		Art Unit 3754	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,164,494	12-2000	Marelli, Andrea	222/38
*	B	US-4,817,822	04-1989	Rand et al.	222/38
*	C	US-4,565,302	01-1986	Pfeiffer et al.	222/38
*	D	US-7,650,883	01-2010	Scarrott et al.	128/200.23
*	E	US-5,611,444	03-1997	Garby et al.	215/230
*	F	US-5,988,496	11-1999	Bruna, Pascal	235/91R
*	G	US-6,234,148	05-2001	Hartke et al.	123/447
*	H	US-6,752,153	06-2004	Eckert, Joseph	128/205.23
*	I	US-7,191,918	03-2007	Ouyang et al.	222/36
*	J	US-6,234,168	05-2001	Bruna, Pascal	128/203.12
*	K	US-6,446,627	09-2002	Bowman et al.	128/200.23
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

AMENDMENT UNDER 37 C.F.R. § 1.111

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated June 4, 2010, please amend the above-identified application as follows on the accompanying pages.

TABLE OF CONTENTS

AMENDMENTS TO THE SPECIFICATION.....	2
AMENDMENTS TO THE CLAIMS	4
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REMARKS

Claims 1-23 are all the claims pending in the application. Applicant amends claims 1 and 2 and adds claims 22 and 23 by way of this Amendment. Support for these changes is provided in the originally filed disclosure and thus, no new matter is added.

Applicant submits concurrently herewith (1) Appendix A, which includes a greyscale version of the color-coded drawings filed with the Appeal Brief of November 19, 2009, and (2) a Declaration under 37 C.F.R. § 1.132, which includes Attachments A, B, and C. Additionally, **color versions** of Appendix A and Declaration Attachment C are being separately submitted to Examiner Ngo by e-mail.

Applicant respectfully requests the Examiner to reconsider and withdraw the objections and rejections in view of the following remarks.

I. Drawings

A. New Matter Objection

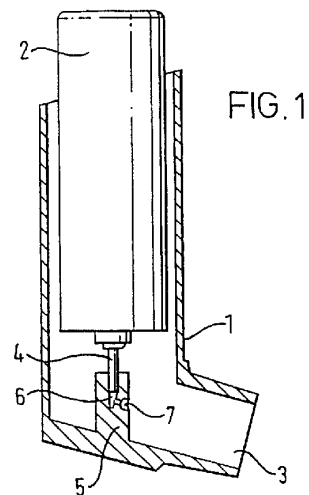
At **paragraph no. 2**, of the Office Action, the drawings are “disapproved” for allegedly containing new matter under 37 C.F.R. § 1.21 (a)(6). Specifically, the Examiner asserts that the “original disclosure does not support the showing of a pump or valve 3 located on the top of the reservoir 2 as shown in fig. 1.”

Applicant respectfully disagrees with this analysis because the original disclosure includes a description of a dispenser member mounted on a reservoir.

The originally filed claim 1 recited “A fluid dispenser comprising...a dispenser member, such as a pump or valve, mounted on said reservoir”.

Thus, a dispenser member mounted on a reservoir was described *explicitly* in the originally filed disclosure and thus supported by the original disclosure. The claims as filed in the original specification are part of the disclosure and therefore, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). See MPEP 2163.06(III).

The originally filed disclosure also described a dispenser member, dispenser head, and dispenser orifice, as being related to the invention (specification at paragraph no. 32), and that the “axial displacement of the reservoir 2 relative to the body 1 actuates the dispenser member and thus causes a dose of fluid to be dispensed from said reservoir” (specification at paragraph no. 34). The *particular location on the top of the reservoir* is well understood by those of ordinary skill in the art, as evidenced by numerous patents and patent applications published by the U.S. Patent and Trademark Office, which consistently show the location of the dispenser member on the top of the reservoir. (*See for example*, U.S. Pub. No. 2002/0195102, FIG. 1 (reproduced to the right), cited by the Examiner in the Office Action dated July 22, 2008 and cited by Applicant in the Information Disclosure Statement filed on November 9, 2005, showing a dispenser member 4 mounted on a top of a reservoir 2).



In view of the foregoing, amended Fig. 1 is fully supported by the originally filed disclosure and does not introduce new matter.

B. Drawing Objections under 37 C.F.R. § 1.83(a)

The Examiner objects to the drawings in **paragraph number 3** under 37 C.F.R. § 1.83(a) allegedly “because they fail to show the details of structure and connections of components of the invention as described in the specification as improvement of the prior art to make the invention work and function.” The Examiner asserts that the drawings fail to meet the requirements of 1.83(a) because they show simplified diagrams of the elements without showing how they are structurally connected and mounted together.

Applicant respectfully submits that the drawings show all of the features that are essential to the understanding of how the claimed invention functions. Section 1.83(a) states: “The drawing in a non provisional application must show every feature of the invention *specified in the claims*. However, conventional features *disclosed in the description and claims*, where their detailed illustration is not essential for a proper understanding of the invention, should be illustrated in the drawing in the form of graphical drawing symbol or labeled representation.”

The Examiner states that the drawings “only show [a] simplified diagrams of a reservoir, a body, an actuator member, a counter element...what are actual structures of the body, reservoir, dispenser member, dose indicator device, actuator member, station gear(s), counter element gear(s) and how are connections between the elements so that the body gear is stationary...”.

It appears that the Examiner is approaching Applicant’s disclosure in a vacuum, without any consideration of the person of ordinary skill in the art. Applicant reduced the complexity of the drawings by purposefully providing diagrammatic drawings to illustrate the body, gears, reservoir, actuator member, etc., in order to facilitate understanding of the invention.

One of ordinary skill in the art already knows the structure of a conventional reservoir, dispenser member, body and a gear, and how they exist in a conventional dispenser environment. The drawings focus on the particular novel relationship between the stationary and rotating gears and how they interact with each other in the dispensing system.

Moreover, the use of simplified drawings does not render the drawings insufficient for the requirements of 1.83(a). As noted in the Declaration filed concurrently herewith, one of ordinary skill in the art would understand how the improved portion of the present invention is connected with the old portion and structure. *See*, Declaration at paragraph no. 7 and associated Attachments A and B.

Also, in **paragraph number 5**, the Examiner argues that the drawings do not show all the claimed features of the invention as required under 37 C.F.R. § 1.83(a). Applicant directs the Examiner's attention to the color-coded drawings originally filed in the Appeal Brief filed on November 19, 2009 (at page 15). A greyscale version of the colored drawings is provided herewith in Appendix A, and an additional copy of the colored version is being separately submitted to the Examiner to aid the Examiner's understanding of the invention.

The Examiner asserts that the following elements are not shown:

i. The dispenser member mounted on the reservoir

As discussed above, FIG. 1 was previously amended to include the dispenser member mounted on the reservoir. Therefore, this objection should be withdrawn accordingly.

ii. The counter element turnable relative to the actuator

The counter element 20 and the actuator 30 are shown. The written description describes how the counter element is rotatable relative to the actuator. (Original specification, page 11, lines 1-8.) The rotating movement is illustrated step by step in FIGS. 1-8 (see also Appendix A), wherein the counter 20 is initially displaced axially when the actuator gear 300 contacts the oblique portion of the first tooth of the second gear 230 (FIG. 1). As the gear 300 and gear 230 engage, the axial movement translates to an initial *rotational movement* for the counter element 20. The gear 210 is displaced further so as to move past the tooth of the stationary gear 110 of the body until a complete incremental rotation is achieved relative to the actuator.

iii. The counter element co-operating, while the dispenser being actuated, first with at least one station gear of the body and secondly with the reservoir

The counter element 20, the stationary gear 110 of the body 1 and the reservoir 2 are all shown in the drawings. The cooperative relationship of the counter element with the stationary gear 110 of the body 1 and the reservoir 2 is shown in a step-by-step view in FIGS. 1-8 (see attached). The first gear 210 of the counter element 20 cooperates with the stationary gear 110 of the body 1, as it is permitted to incrementally rotate one tooth of the stationary gear 110. *See* Appeal Brief filed November 19, 2009, at pages 15-20.

C. Objections under 37 C.F.R. § 1.83(b)

In **paragraph number 4**, the Examiner argues that the drawings are incomplete because they fail to show the improved portion disconnected from the old portion, or the old structure to show the connection with the invention.

However, Applicant's drawings specifically focus on the improved portion, and show the improved portion in the fluid dispenser. The drawings adequately show a body 1 and a reservoir 2, and how they connect with the invention.

A set of pictures (i.e., computer aided design drawings) are provided in Attachment C of the Declaration, which show the invention in its environment. This rejection should be withdrawn, in light of the fact that one of ordinary skill in the art would clearly understand the present invention and how it relates to a dispenser body and reservoir (*See*, Declaration at paragraph numbers 6 and 7).

II. Specification

A. Objection under 35 U.S.C. § 132(a)

In **paragraph number 6**, the Examiner objects to the specification under 35 U.S.C. § 132(a) because the amendments filed on October 22, 2008, which were made in accordance with the drawing amendments, allegedly introduce new matter. In particular, the Examiner asserts that the original disclosure does not support "a pump or a valve is only shown in Figure 1" and "the dispenser member 3 (shown in FIG. 1)".

Applicant amends the specification to conform to the language of the claims as filed in the original disclosure. The claims as filed in the original specification are part of the disclosure and therefore, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985). See MPEP 2163.06(III).

The Examiner also remarks that the amendment of Fig. 1 introduces new matter. The changes to FIG. 1 are supported by the originally filed specification for the reasons noted above.

B. Objection under 37 C.F.R. § 1.71

In **paragraph number 7**, the Examiner objects to the specification under 37 C.F.R. § 1.71, “as being so incomprehensible so as to preclude a reasonable search of the prior art by the examiner.” The Examiner then lists various features which she does not understand:

i. “What are structural connections ...”

The Examiner does not understand how the reservoir can be stored in the body and axially displaceable to the body or how the counter element can indicate the number of doses dispensed or remained, and how it can be axially displaceable and rotatable.

As is well understood by those of ordinary skill in the art, the reservoir is stored in the body in such a manner that it may be axially displaced therein when pressed down. (See Section I.A. above, citing U.S. Pub. No. 2002/0195102, which is cited by the Examiner in the Office Action dated July 22, 2008 and cited by Applicant in the Information Disclosure Statement filed on November 9, 2005, showing a reservoir 2 stored in a body 1). See also, Declaration filed concurrently herewith at paragraph 8 and Attachment A, which provides examples of the art).

Counter elements are known in the art of dispensers to enable a user to know how many doses have been dispensed or how many doses remain. See, Declaration at paragraph 8 filed concurrently herewith. For the present invention, the specification explains that the movement of the actuator 30 causes the counter element 20 to be axially displaced with respect to the stationary gear 110 of the body 1. Through the step-by-step movement illustrated in FIGS. 1-8

and the written description provided at pages 11-14 of the specification, the counter element advances through the rotation cycle. Since indicia is provided on the counter element as known in the art, the indicia counts up or down as the counter element rotates.

The counter element is axially displaceable and rotatable in the manner fully described on pages 11-14 and FIGS. 1-8 (*see also*, grayscale-coded drawings in Appendix A and color-coded drawings from Appeal Brief filed November 19, 2009). The counter element is axially displaced due to the movement of the actuator presses against the second gear 230 of the counter element 20, and it is rotated due to the oblique surfaces of the gears engaging and then disengaging with each other to allow the biased counter element 20 to rotate incrementally tooth by tooth.

ii. “Why just an oblique tooth of the actuator and the counter element can be considered a gear”

An oblique tooth of the actuator and the counter element is not a gear *per se*, but rather representative of one of many teeth that make up a gear. Toothed gears are known in the art, and toothed gears are used as ratchet mechanisms in the art of dispensers. As mentioned above, for the sake of simplicity, the drawings are provided in diagrammatic form to ease understanding of the structural cooperation of the various gears with each other and how they engage in the step-by-step movement illustrated in FIGS. 1-8.

Representation of a gear in this manner is well understood by those of ordinary skill in the art (*see*, Declaration at paragraph numbers 5 and 6, and Attachments B and C). For instance, *see* Attachment B at EP 0480 488 (also previously cited in IDS filed November 9, 2005), which shows diagrammatic drawings (FIGS. 4 and 5) to illustrate teeth. *See also*, Attachment B at EP 0 949 584, which shows a diagrammatic view of annular teeth (FIG. 5).

In view of the foregoing, one of ordinary skill in the art would understand the diagrammatic representation of the gears in the pending application, and would correspond such diagrammatic drawings to gears as shown in the computer renderings of the invention provided in Attachment C of the Declaration.

iii. “Why the gear of the body can be stationary but the gear of the actuator is axially displaceable and the gears of the counter element are axially and rotatably displaceable”

In the originally filed specification, the body 1 is described as being stationary (paragraph bridging pages 8-9), and thus, the gear 110 of the body is stationary. This does not preclude the ability for the actuator to be axially displaceable. “The dispenser includes an actuator member 30 on which the user exerts an actual actuation force so as to actuate the dispenser and thus displace said reservoir 2 relative to the body 1.” (Page 9, lines 6-9.)

“[T]he counter element 20 is displaceable both axially and in rotation relative to the body 1...when the user presses on the actuator member 30 so as to displace said actuator member axially downwards in Figure 1, the oblique profile of the teeth of the actuator gear 300 and of the second gear 230 of the counter element urge the counter element 20 to be displaced axially downwards, and also in rotation because of the oblique profile of the above-mentioned gears.” (Specification page 10, line 35 to page 11, line 5.) The stationary gear 110 cooperates with the first gear 210 to prevent rotation of the first gear 210 until the counter element (first gear 210) is pressed past a certain point at which the first gear 210 is no longer engaged with the stationary gear 110, and is able to rotate. (See, Specification at page 11, lines 5-22.)

iv. “What are actual structural shapes and connections of one element to one another in order to one having an ordinary skill to understand the invention functions, working and improved ...”

One of ordinary skill in the art is familiar with how dispensers function. A person of such skill is knowledgeable so as to know that the actuator causes the reservoir to move axially in the stationary body. In view of the foregoing, the novel features of the invention, i.e., the manner of engagement and the timing of such engagement between the teeth of the various gears is clearly explained by the drawings and written description. A person of ordinary skill in the art would easily comprehend structural shapes and connections of one element to another to understand the invention.

III. Claims

A. Rejections under 35 U.S.C. § 112, first paragraph

In **paragraph number 9**, claims 1-21 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. In particular, the Examiner states that claims 1-21 recite elements and functions without reciting structures and connections between the elements. The Examiner also states that the specification does not disclose the structure.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. (MPEP 2164.01 and 2164.01(a)). In order to determine whether a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue,” the Examiner must consider the *Wands* factors, which are provided

in MPEP 2164.01(a). Among these factors, includes the nature of the invention, the state of the prior art, the level of one of ordinary skill, the amount of direction provided by the inventor, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The Examiner, however, does not apply any of the *Wands* factors for making a determination of enablement, and thus, does not apply the correct standard for establishing a prima facie case of lack of enablement.

For example, in considering the state of the prior art, the specification discloses that dose indicator devices are well known, including counters that display the number of doses (specification at page 1, lines 8-15). The specification also discloses that once a dose has been dispensed, the next dose is loaded into the chamber of the dispenser member (pump or valve) (specification at page 2, lines 2-4). Still further, the specification states that the present invention applies particularly well to “Metered Dose Inhaler” (MDI) devices which comprise a metering valve mounted on a reservoir containing the fluid and a propellant gas, the displacement of the reservoir relative to the valve member causing a dose of fluid to be dispensed by means of said propellant gas” (specification at page 8, lines 25-34).

Accordingly, one skilled in the art would readily understand an MDI or similar device and its structural configurations, including a dispenser member to dispense the pharmaceutical, a body to hold the reservoir therein, a counter to count dispensed doses, and how a counter could be actuated upon the dispensing of a dose.

MPEP 2164.01 states:

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with **information known in the art without undue experimentation**. A patent need not teach, and **preferably omits**, what is known in the art. (emphasis added)

As noted above, metered dose inhalers, dispenser members, dose indicator devices and actuation of a dispenser are well known in the art, and one of ordinary skill would understand the structure and connection of a body, reservoir, actuator, counter and dispenser member. Thus, such specific structural connections need not be disclosed in the specification.

In view of the context of the explanation provided by the specification that previous fluid dispensers included dose indicator devices, counters, reservoirs, dispenser members, etc., (specification at pages 1-2 and 8), one skilled in the art would readily understand how to make and use the present invention in a fluid dispenser without any undue experimentation.

The language of independent claim 1 will be compared with the first exemplary embodiment of the invention. It should be noted that the claims should not be limited to this embodiment, and that the comparison is only being done to show that the claimed subject matter is adequately enabled.

*i. “... a body (1), a fluid reservoir (2), a dispenser member **mounted on said reservoir (2)**, ... said reservoir (2) being **axially displaceable** relative to said body (1), said body (1) including at least one stationary gear (110, 122), said dose indicator device including a counter element (20) that is **displaceable axially and in rotation relative to said body (1)**”*

The specification of the original application discloses that “the dispenser includes a reservoir 2 that is axially displaceable in a body 1, which is considered as being the stationary portion of the dispenser.” (Original specification, page 8, line 36, to page 9, line 2.) “The axial displacement of the reservoir 2 relative to the body 1 actuates the dispenser member and thus causes a dose of fluid to be dispensed from said reservoir.” (Original specification, page 9, lines 3-5.)

In view of the specification of the current application and the state of the art, one having ordinary skill in the art would know how to make and use a reservoir that is axially displaceable relative to a body to actuate a dispenser member on the reservoir without undue experimentation. (See, Declaration at paragraph number 9 and Attachment A.)

Additionally, one having ordinary skill in the art would know how to make and use a stationary gear 110 that is stationary with the body 1 and a counter element 20 that it is axially displaceable and rotatable relative to the body 1 without any undue experimentation. The details of known structural elements for the “connections” between the reservoir 2, the body 1, the actuator 3, and the counter element 20 were intentionally omitted because they are not required to understand the claimed subject matter. (See for example, MPEP 2164.01; original specification, page 8, lines 13-24, “[t]he drawings to which the present description refers are highly simplified diagrams which do not show the fluid dispenser in detail, but only in very

diagrammatic manner relating to the various portions that can be moved relative to one another, for explaining the actuation cycle of said dispenser and of said indicator device.”)

In fact, the inclusion of these features would unnecessarily complicate the disclosure, making it more difficult for one of ordinary skill in the art to understand the claimed subject matter. Thus, what the disclosure intentionally focuses on is the inventive aspects of providing a dispensing mechanism with a counter element with a safety system.

ii. “... said dose indicator device includes a first safety system that actuates the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform the complete actuation stroke... .”

Steps 4 and 5 of the actuation cycle, described above on page 20, describe the first safety system that actuates the dose indicator after an incomplete actuation stroke. As described in step 5, after the first gear 210 disengages the stationary gear 110, which is at a position of an incomplete actuation stroke, the counter element 20 is rotated by the oblique surfaces of the actuator gear 30 engaging the oblique surface of the second gear 230. As such, the counter element 20 is actuated during a predetermined incomplete actuation stroke.

iii. “... said counter element (20) co-operating, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2).”

Step 2 of the actuation cycle, described above on page 16, discloses that the counter element 20 firstly co-operates with the stationary gear 110, at the time that the counter element 20 is in the rest position, to prevent the counter element 20 from rotating.

Step 4 of the actuation cycle, described above on page 19, discloses that after the counter element 20 has been displaced in a downward axial direction, the bottom of the counter element 20 contacts the reservoir 2 to displace the reservoir. Accordingly, the counter element 20 firstly contacts the stationary gear and secondly contacts the reservoir.

In view of the above, independent claim 1 is fully disclosed and enabled by the original specification.

iv. Dependent Claims

All of the dependent claims are fully described and enabled by the disclosure of the original application, for similar reasons to those described above.

For at least the foregoing reasons, the connections between the elements is clear, and any aspects of the connections between the elements which is not explicitly stated would have been understood by one of ordinary skill in this field of art which pertains to fluid dispensers having counting mechanisms.

B. Rejections under 35 U.S.C. § 112, second paragraph

i. Allegedly incomplete

In **paragraph number 11** of the Office Action, claims 1-21 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential structural cooperative relationships of elements.

As stated in MPEP 2172.01, a claim can be rejected as incomplete if it omits essential elements, steps or necessary structural cooperative relationships of elements, such omission amounting to a gap between the elements, steps or necessary structural connections.

It is not essential to a patentable invention that there be interdependency between the elements of the claimed device or that all of the elements operate concurrently toward the desired result. The claims require only a reasonable degree of particularity and distinction, when analyzed with respect to the specification, the prior art and the claim interpretation given by one of ordinary skill in the art at the time of the invention.

ii. Allegedly indefinite

In **paragraph number 12** of the Office Action, claims 1-21 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

The Examiner asserts that it is not clear what are required for structures or shapes of the elements in the claims, such as a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element, etc. and structural connections between them to understand the claimed subject matter.

However, as discussed above in Section III. A., one of ordinary skill in the art would have already been apprised of how a conventional body, reservoir, dispenser member and indicator device could be shaped and structured. Additional detail is not necessary for an understanding of the claims. Thus, Applicant respectfully requests the Examiner to withdraw this rejection.

The Examiner also indicates that the claims are indefinite because of the recitation of “a first safety system” and “a second safety system”. Applicant amends claims 1 and 2 to remove any ambiguities.

IV. New Claims

Applicant adds claims 22 and 23 to further define the invention. These claims are fully supported by the specification at page 10, lines 20-31, and page 11 line 22 - page 12, line 3; originally filed claim 1; and FIGS. 1-8.

V. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Ellen R. Smith/

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: December 6, 2010

Ellen R. Smith
Registration No. 43,042

APPENDIX

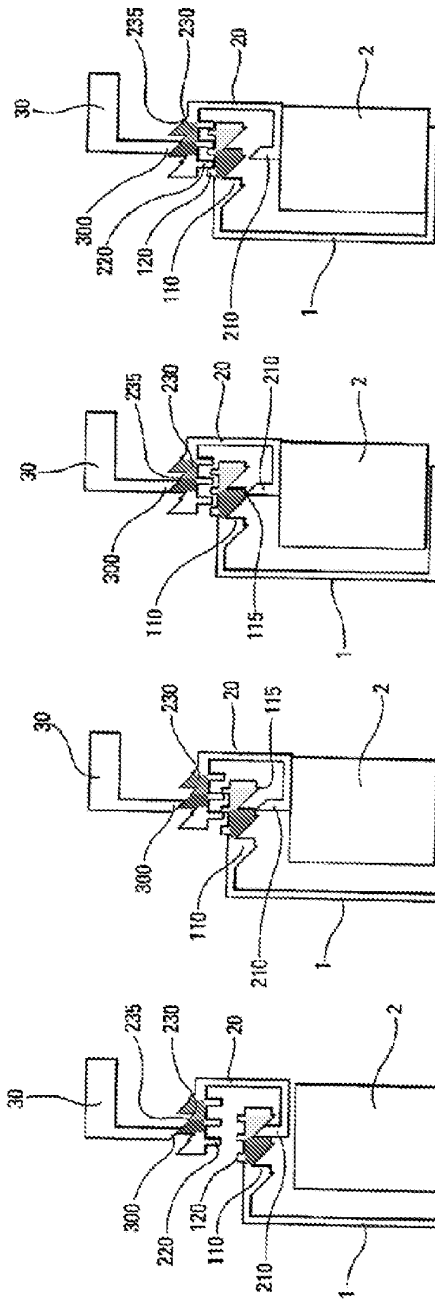


FIG. 1: Rest position

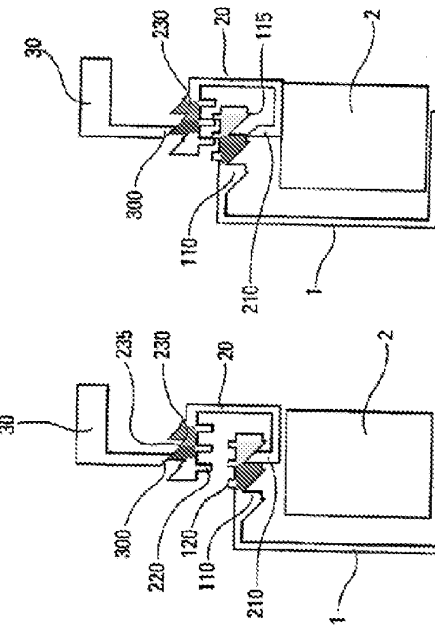


FIG. 2: initial axial displacement of counter element 20

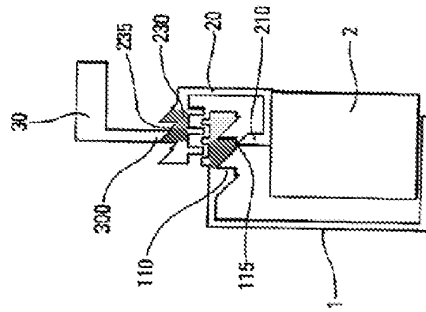


FIG. 3: initial rotation of the counter element 20

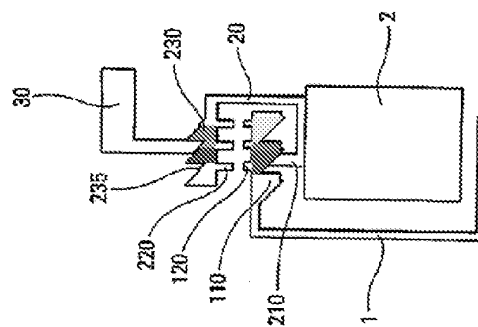


FIG. 4: completion of axial displacement of counter element 20 and incremental rotation of counter element 20

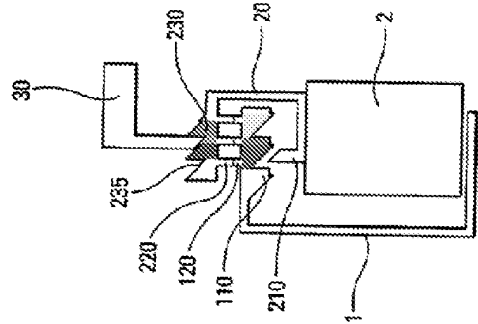


FIG. 5: partial upward release of actuator 30 and incremental rotation of counter element 20

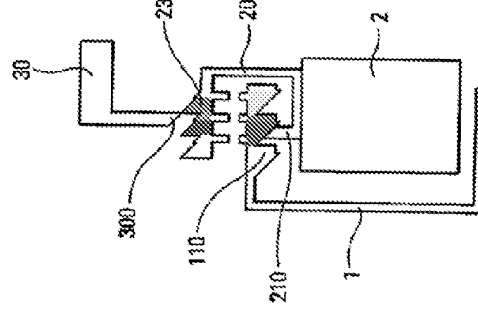


FIG. 6: prevention of actuation prior to complete release of actuator 30

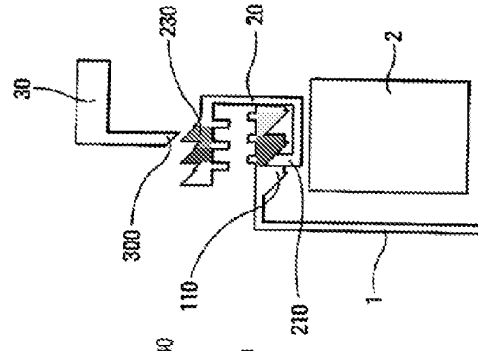


FIG. 7: continued release of actuator 30

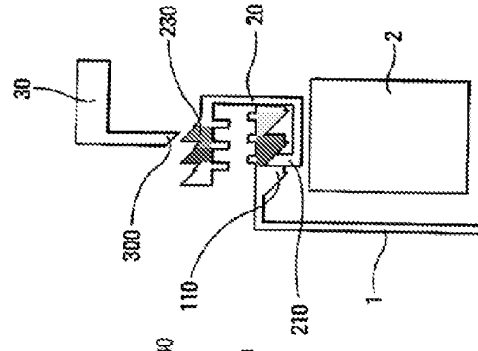


FIG. 8: completion of release of actuator 30, completion of rotation of counter element 20

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

EXCESS CLAIM FEE PAYMENT LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

An Amendment Under 37 C.F.R. § 1.111 is attached hereto for concurrent filing in the above-identified application. The resulting excess claim fee has been calculated as shown below:

	After Amendment		Highest No. Previously Paid For					
All Claims	23	-	21	=	2	X	\$52.00	= \$104.00
Independent	3	-	3	=		X	\$220.00	= \$.00
TOTAL								= \$104.00

The statutory fee of \$104.00 is being remitted. The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Ellen R. Smith/

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

Ellen R. Smith
Registration No. 43,042

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: December 6, 2010

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

FY 2009

(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)

Docket Number

Q91404

Confirmation Number

3524

Application Number 10/556,432

Filing Date November 9, 2005

For FLUID PRODUCT DISPENSER

Art Unit 3754

Examiner Name Lien M. Ngo

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	<u>Fee</u>	<u>Small Entity Fee</u>	
☐ One month (37 CFR 1.17(a)(1))	\$130.00	\$65.00	
☐ Two month (37 CFR 1.17(a)(2))	\$490.00	\$245.00	
☒ Three month (37 CFR 1.17(a)(3))	\$1110.00	\$555.00	\$1,110.00
☐ Four month (37 CFR 1.17(a)(4))	\$1730.00	\$865.00	
☐ Five month (37 CFR 1.17(a)(5))	\$2350.00	\$1175.00	
☐ Previous Payment Amount	Date Submitted		
☐ Applicant claims small entity status. See 37 CFR 1.27			
☐ A check in the amount of the fee is enclosed.			
☒ Payment by credit card.			
☐ The Director has already been authorized to charge fees in this application to a Deposit Account.			
☒ The Director is hereby authorized to charge any fees, except for the Issue Fee and the Publication Fee , or credit any overpayment, to Deposit Account Number 19-4880.			

I am the ☐ applicant/inventor
☐ assignee of record of the entire interest. See 37 CFR 3.71.
 Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96).
☒ attorney or agent of record. Registration Number 43,042
☐ attorney or agent under 37 CFR 1.34.
☐ Registration number if acting under 37 CFR 1.34 _____

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

/Ellen R. Smith/

Signature

Ellen R. Smith

Typed or printed name

December 6, 2010

Date

(202) 293-7060

Telephone Number

Note: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☒ Total of 1 form is submitted.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98**

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, except for the following: U.S. patents and/or U.S. patent publications; and co-pending non-provisional U.S. applications filed after June 30, 2003.

The present Information Disclosure Statement is being filed (without a Statement Under 37 C.F.R. § 1.97(e)) after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore the fee of **\$180.00** under 37 C.F.R. § 1.17(p) is being remitted.

INFORMATION DISCLOSURE STATEMENT
U.S. Appln. No.: 10/556,432

Attorney Docket No.: Q91404

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, for foreign reference WO 00/09187 Applicant is submitting the US corresponding patent US 6,752,153, and for foreign reference WO 00/21593 Applicant is submitting the US corresponding patents US 6,679,251 and US 6,481,438.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Ellen R. Smith/

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Registration No. 43,042

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Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: December 6, 2010

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	10/556,432
	Confirmation Number	3524
	Filing Date	November 9, 2005
	First Named Inventor	Fabien POULARD
	Art Unit	3754
	Examiner Name	Lien M. Ngo
	Attorney Docket Number	Q91404

U.S. PATENTS						
Examiner Initials*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	5349945	A	1994-09-27	WASS et al.	
	2.	5718355	A	1998-02-17	GARBY et al.	
	3.	5904139	A	1999-05-18	HAUSER	
	4.	6161724	A	2000-12-19	BLACKER et al.	
	5.	6155251	A	2000-12-05	HAUSER	
	6.	6328037	B1	2001-12-11	SCARROTT et al.	
	7.	6752153	B1	2004-06-22	ECKERT	
	8.	6679251	B1	2004-01-20	GALLEM et al.	
	9.	6481438	B1	2002-11-19	GALLEM et al.	

U.S. PATENT APPLICATION PUBLICATIONS						
Examiner Initials*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
	10.	93/24167	WO	A1	1993-12-09	Norton Healthcare Limited		
	11.	98/52634	WO	A1	1998-11-26	PA Consulting Services Limited		
	12.	98/56444	WO	A1	1998-12-17	Glaxo Group Limited		
	13.	00/09187	WO	A1	2000-02-24	Joseph Wicherath GmbH & Co Kg		Abstract and US '153
	14.	00/21593	WO	A1	2000-04-20	Pari GmbH Spezialisten fur Eff		Abstract and Hauser US '251 and US '438
	15.	00/59806	WO	A1	2000-10-12	Bespak PLC		
	16.	01/28887	WO	A1	2001-04-26	Glaxo Group Limited		
	17.	01/37909	WO	A1	2001-05-31	Ernst Horlins Ingenjorbyra AB		
	18.	0 254 391	EP	A1	1988-01-27	Glaxo Group Limited		
	19.	0 949 584	EP	A2	1999-10-13	Bason, Neil Peter		
	20.	1 010 438	EP	A1	2000-06-21	Bespak PLC		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. 2 Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). 3 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 4 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 5 Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	10/556,432
	Confirmation Number	3524
	Filing Date	November 9, 2005
	First Named Inventor	Fabien POULARD
	Art Unit	3754
	Examiner Name	Lien M. Ngo
	Attorney Docket Number	Q91404

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
	21.	1 163 922	EP	A2	2001-12-19	Glaxo Group Limited		
	22.	1 065 477	EP	A2	2001-01-03	Microspray Delta S.p.A.		

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	T ⁵

EXAMINER SIGNATURE			
Examiner Signature		Date Considered	

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1 See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. 2 Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). 3 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 4 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 5 Applicant is to place a check mark here if English language translation is attached.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number	10/556,432
Confirmation Number	3524
Filing Date	November 9, 2005
First Named Inventor	Fabien POULARD
Art Unit	3754
Examiner Name	Lien M. Ngo
Attorney Docket Number	Q91404

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☐ That each item of information contained in the Information Disclosure Statement filed concurrently herewith was first cited in any communication from a foreign patent office in a counterpart foreign application, and that the communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of said Information Disclosure Statement. See 37 CFR 1.704(d).

- ☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☒ The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.
- ☐ None

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Ellen R. Smith/	Date (YYYY-MM-DD)	2010-12-06
Name/Print	Ellen R. Smith	Registration Number	43,042

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. 2 Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). 3 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 4 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 5 Applicant is to place a check mark here if English language translation is attached.



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 15/00		A1	(11) International Publication Number: WO 93/24167
			(43) International Publication Date: 9 December 1993 (09.12.93)
(21) International Application Number: PCT/GB93/01064 (22) International Filing Date: 24 May 1993 (24.05.93) (30) Priority data: 9211436.2 29 May 1992 (29.05.92) GB (71) Applicant (for all designated States except US): NORTON HEALTHCARE LIMITED [GB/GB]; Gemini House, Flex Meadow, Harlow, Essex CM19 5TS (GB). (72) Inventor; and (75) Inventor/Applicant (for US only): HOLROYD, Michael, John [GB/GB]; 1 The Green, Thriplow, Royston, Hertfordshire SG8 7QX (GB). (74) Agent: BEN-NATHAN, Laurence, Albert; Urquhart-Dykes & Lord, 91 Wimpole Street, London W1M 8AH (GB).			(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report.
(54) Title: DOSE INDICATING DEVICE			
(57) Abstract A medicament dispensing device comprises a housing (400) for receiving a medicament delivery system (25), e.g., an aerosol can, actuable to deliver discrete doses of medicament. An actuation device has a spring loaded sleeve (420) for engaging the aerosol can at its base end, when the actuation device is released on inhalation at a mouthpiece (405) of the housing. A dose counter comprises a rotary dose indicating ring (101) surrounding the sleeve (420) to be indexed incrementally by a resilient indexing member provided on the sleeve, on each actuation of the aerosol can (25) to discharge a dose of medicament.			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
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CZ	Czech Republic	MC	Monaco	TG	Togo
DE	Germany	MD	Madagascar	UA	Ukraine
DK	Denmark	ML	Mali	US	United States of America
ES	Spain	MN	Mongolia	VN	Viet Nam
FI	Finland				

DOSE INDICATING DEVICE

This invention relates to a dose indicating device for a dispensing device suitable for dispensing discrete amounts of fluid or particulate material entrained in an air stream.

Metered dose inhalers are well known in medicine for treatment, or alleviation of the effects of respiratory complaints, for example asthma. Breath-actuated devices are also known.

Aerosol dispensers provided with dose counting devices are also known. Some of these devices require substantial modification of the body part or housing of the dispenser to accommodate the counters or require additional containing structures. EP-0,197,113 provides a counter device which is mounted on top of the dispenser housing. US-4,817,822 utilizes a linear or rotary scale accommodated in a separate compartment outside to the dispenser housing. EP-0,258,238 utilizes a vertically disposed numbered wheel which projects upwardly of the dose metering device.

EP-0,269,496 describes a push button actuator for mounting on the neck of an aerosol dispenser, having a stroke counter comprising a counting ring with axially facing teeth which are engaged by an axially inclined flexible blade on the push button for actuating the aerosol valve.

GB-1,317,315; GB-1,290,484 and WO 92/09324 relate to counters for basic dispensers having an open ended housing in which aerosol cans are slidably mounted such that when the cans are manually depressed, a dose of medicament is released from the aerosol and inhaled through a mouthpiece at the opposite end of the housing. However, the counters are located beneath the cans and must be engaged by the lower, valve ends of the cans to cause the counters to index on each manual depression of the cans. Such arrangements have the disadvantages that modification of the housing geometry is

required at the critical area of the housing lower end where atomization takes place, the counter is accessible to a patient and could lead to misuse and its disposition could result in the inhalation of foreign matter if breakage of parts of the counter mechanism takes place.

Therefore, although several dose counting devices have been proposed the prior art devices are subject to many technical disadvantages.

It is an object of this invention to provide an improved dispensing device having actuating means, which may be breath actuated, capable of actuating a pressurized aerosol container or a dry powder drug delivery system, and a dose indicating means operated in association with the actuating means, the indicating means being relatively simple and convenient in structure and capable of being readily accommodated within the dispenser housing without substantial modification thereof as well as reducing the risks of incorrect actuation by a patient and of inhalation of small components which could become separated from the mechanism.

The invention provides a dispensing device for use with a medicament delivery system which can be actuated to deliver discrete doses of medicament, the dispensing device comprising a housing for receiving the medicament delivery system, the housing having an inhalation nozzle and a dose indicating device comprising an annular or arcuate dose indicating element rotatably mounted in the housing with a section of the indicating element being visible from outside the housing, and an indexing member movable on discharge of a dose of medicament to index the indicating element incrementally, characterized in that actuating means are provided in the housing for acting on an end of a medicament delivery system remote from said nozzle, to cause dispensing of doses of medicament; in that the indicating element is located in the housing around a part associated with the actuating means and in that the indexing member is carried by said part for movement in one axial direction through the indicating element on actuation of the medicament delivery system and in the

opposite axial direction for resetting the actuating means, with the indicating element being incrementally indexed on each movement of the indexing member in said one direction only.

Said actuating means are preferably breath-actuated on inhalation through the nozzle.

The indicating element may have internal teeth which are engaged by an indexing member which is resiliently mounted on the aforesaid part so that it can move inwardly of the teeth when it moves in said opposite direction, being the teeth and the engagement portion of said indexing member inclined with respect to the axis of rotation of the indicating element.

Preferably there may be provided means for restraining said actuating means, and means to release said restraining means. The release means are preferably breath actuated.

The actuation means may comprise means for applying a preload capable of actuating said drug delivery system.

The restraining means may comprise means for applying a resisting pneumatic force capable of preventing actuation of the actuation means. The pneumatic resisting means may be provided by a gas, e.g. air, which is either held at a positive pressure greater than atmospheric or a negative pressure below atmospheric prior to release. The release means will act to return the pressure to atmospheric or prior equilibrium, thus allowing the full force of the preload to act.

The means for applying a resisting pneumatic force may comprise an expandable gas tight chamber, the release means including valve means which can be opened to release a negative pressure prevailing in said low pressure chamber.

Although this device has been described in particular relation to a system using air, it will be realised that in a closed system any suitable gas could be used.

A device according to the invention is particularly suited for use with pressurized inhalation aerosols having valves which can be actuated to dispense a dose of medicament. However in other embodiments, a device according to the

invention can be used with a dry powder drug delivery system disposed within said housing, in which a dose of powdered medicament is dispensed by said system into an air flow in said housing created by inhalation at an outlet nozzle associated with the housing.

In some arrangements according to the invention for use with an aerosol dispensing container or a dry powder delivery system, the housing may include a slidable inner sleeve for enclosing the top portion of the main body of the aerosol container or the dry powder delivery system with the depending member being associated with the inner sleeve, with the indexing member being carried on the sleeve. This inner sleeve is preferably arranged to form one end of a gas tight piston cylinder, bellows or diaphragm, such that movement of the inner sleeve will result in an increase in the enclosed volume within the piston cylinder, bellows or diaphragm producing a vacuum or low pressure volume to form the resisting force capable of preventing the actuation of the drug delivery system.

A preferred breath-actuating release means comprises a movable vane mechanism. A valve seal is preferably attached to said vane, such that on inhalation the vane moves from its rest position closing said inlet means to its actuating position, thus moving the valve seal out of contact with the valve port, causing the opening of the valve to release the aforesaid resisting force. The vane mechanism is preferably dynamically balanced, and may be biased towards its closed position, e.g., by a spring.

Air inlets into the housing may take the form of slots in an upper end wall of said housing.

The medicament may be a drug per se or in any form of carrier, e.g., including a powder or a gaseous carrier.

Preferably the actuating means act on the aforesaid inner sleeve, and are reset by causing the inner sleeve member to move in said opposite direction.

Preferably a cover for an outlet nozzle of the housing is movably mounted on the housing, and a cam formation on the

cover cooperates with the lower end of at least one depending member associated with the inner sleeve such that, when the cover is closed, the depending member moves the inner sleeve to reset the actuating means.

An embodiment of the invention will now be described by way of example and with reference to the accompanying drawings, in which:-

Figure 1 is a diagrammatic sectional view through a metered dose inhaler having a dose indicating mechanism in accordance with the present invention;

Figures 2A, 2B and 2C are sectional details of the inhaler showing the diaphragm in the pre-actuated, cocked, and actuated states, respectively;

Figure 3 is a diagrammatic perspective view of the dose counting mechanism of Figure 1; and

Figure 4 is a diagrammatic perspective detail of parts of the mechanism of Figure 3.

Referring to Figure 1, an inhalation device consists of a main body 400 which is generally cylindrical in cross section, with a mouthpiece section 405 at one end and an end cap section 407 housing air inlets 419 at the other end. A known type of aerosol dispensing container 25 of generally cylindrical shape is housed within the main body of the device. The aerosol dispensing container has a stem 40 which contains an aerosol dispensing valve (not shown). The bore 15 of a pedestal 16 in the housing, is such that it forms an airtight seal on the stem 40 of the aerosol dispensing container 25. A shoulder 45 limits and locates the position of the stem 40, which in turn locates the aerosol dispensing container 25 in position in the main body 400. A passage 50 extends from the bore 15, continuing from the shoulder 45 to interconnect with a dispensing nozzle 55.

The opposite end of the dispensing container is contained within a sleeve 420 of slightly smaller cross section to the main body 400. The longitudinal axis of both the sleeve 420 and main body 400 is generally coaxial. The sleeve is slidable within the inner wall of the main body to allow free

passage of air in the main body past the sleeve. The sleeve 420 may be held in place by connection with a diaphragm 440 held in connection with the top of the main body 400, as will now be described. Thus, the sleeve 420 effectively hangs from the top of the main body.

One end of an e.g., moulded flexible diaphragm 440 (as indicated in Figure 2C) comprising a rigid disc-like section 441, a flexible generally cylindrical wall section 445 and a stiffer annular connector flange 447. The sleeve 420 has a cooperating annular connection flange 450. An annular U-section clip 470 snaps over the flanges 447 and 450 to hold them together in an air-tight manner. A further lip 418 on the clip provides a snug fit for one end of a compression spring 460. The compression spring is thus located and free to act on the sleeve. The other end of the compression spring is located by an annular flange of a predominantly cylindrical flanged insert 480 housed in the top section of the main body 400. This insert includes a groove 485 into which the disc-like section 441 of the flexible diaphragm 440 is snap-fitted.

The shape of the top surface 422 of the closed end of the sleeve to conform to the internal shape of the diaphragm such that in the rest (preactuated) position of the inhaler (Figure 2A) the two surfaces are in close proximity, and the enclosed space between them very small.

The cylindrical insert 480 is retained in place by the end cap 407 comprising the upper part of the main body 400 of the device. This forms a chamber 590 between the air inlet slots 419 and the rigid part 441 of the diaphragm. The chamber is provided with one or more air pathways 580 such that air may pass from the air inlet slots 419 to the mouthpiece 405. The rigid disc-like section 441 of the diaphragm also includes a small valve port 495 which is normally covered by a diaphragm valve seal 540 housed in a vane 550 pivotally connected to the insert 480.

The vane 550 in its rest position divides the chamber 590 between the air inlets 419 and the air pathways 580 that link to the mouthpiece such that it may move from its rest position

by means of a pressure drop between the air inlets and the mouthpiece. On movement of the vane to the actuated position (Figure 2C) the valve seal 540 is moved sufficiently to open the valve port 495. The vane 550 may be biased closed by a light spring flexure, a weight or a magnet not shown.

As shown in Figure 1, the lower end of the main body has a moulded section 500 beneath the mouthpiece 405 to which a dust cap is pivotally connected. A cam 520 is integrally formed on each side of a dust cap 510, one on each side of the moulded section 500. An annular yoke member 425 is secured to the lower end of the sleeve 420 and has a pair of downwardly depending legs 530, the lower ends of which act on the cams 520 such that when the dust cap is in the closed position the inner sleeve is forced by the cam follower to its uppermost position.

When the dust cap is rotated to its open position the cam profile is such that the cam follower is free to move downwards by an amount sufficient to allow actuation of the device.

In its rest position (Figure 2A) the dust cap 510 is closed, the legs 530 of the yoke member restrain the inner sleeve 420 in its uppermost position such that the enclosed space trapped between the diaphragm 440 and the top surface 422 of the inner sleeve is at a minimum and the spring 460 is compressed. The valve port 495 is closed by the valve seal 540 and the sleeve 420 is clear of the top of the aerosol can 25 which is thus unloaded.

The dust cap is opened rotating the integral cam 520 allowing the cam follower 530 to drop by an initial amount of downward movement. The inner sleeve is forced downwards under the action of the spring 460. As the inner sleeve moves downwards the enclosed volume between the diaphragm 440 and inner sleeve is increased. Since the valve port 495 is closed this creates a low pressure volume or near vacuum in the space 600 then defined between the upper surface 422 of the sleeve 420 and the diaphragm 440. The effect of the pressure differential between the enclosed volume 600 and atmospheric

pressure is such that the inner sleeve tends to resist the action of the spring 460. As the inner sleeve moves downwards it contacts the aerosol can 25 and begins compression of the aerosol valve (not shown).

Downward movement of the inner sleeve 420 will continue until there is a balance of forces between the compressive force in the spring 460 and resisting forces created by the pressure differential and compression of the aerosol valve. This represents the cocked position shown in Figure 2B. The geometry of the device is arranged such that this balance occurs before the aerosol valve has been sufficiently compressed to actuate it.

A typical aerosol requires about 20N force to actuate. The spring 460 should accordingly provide a greater force, preferably 10% to 50% greater.

It may also be possible to arrange for the balance of forces to take place before the inner sleeve has contacted the aerosol can, such that the spring force is balanced by the resisting force produced on the inner sleeve by virtue of the pressure differential.

On inhalation by the patient through the mouthpiece 405, a small pressure differential is created across the vane 550 which is pivoted towards one end. The pressure differential causes the vane to move from the rest position to the actuated position. The vane and design of the air passageway 580 in the chamber 590 are such that in the actuated position air can flow freely from the air inlets 419 to the patient.

The movement of the vane 550 causes the valve seal 540 to be moved out of a sealing position with the valve port 495. Opening the valve port allows air into the space defined between the diaphragm 440 and inner sleeve 420 such that the enclosed space reaches atmospheric pressure. This causes an imbalance of forces acting on the sleeve 420 and the container 25. The sleeve and the container are thus forced downwards (Figure 2C) by the spring 460 resulting in the release of a measured dose of medicament through the dispensing nozzle 55 and into the mouthpiece at the same time as the patient

breathes in. Thus the patient inhales air with a metered dose of medicament.

After the inhalation of the dose by the patient, the dust cap 510 is returned to its closed position. This rotates the cam 520 and causes the legs 530 of the yoke 425 to be forced upwards. This in turn acts on the inner sleeve 420 moving it upwards to compress the spring 460 and to close the space between the diaphragm 440 and the inner sleeve top surface 422. This forces air out of that space, which escapes through the valve port 495 lifting the valve seal 540. Since the valve seal is only lightly biased to its closed position it presents little resistance to air flow out of the enclosed space. The aerosol can is free to return to the rest position under the action of its own aerosol valve spring.

In use the patient loads the aerosol dispensing container into the main body. The aerosol container may be loaded by forming the main body 400 in two separable parts 350, 360, which are joined by a threaded coupling. When the upper part 350 of the main body 400 has been unscrewed, the aerosol can be inserted. The upper part 350 can then be replaced locating the inner sleeve 420 over the top end of the can, and the device is ready for use. As described previously, the device could be manufactured as a sealed unit.

The construction and operation of the inhalation device is also described in WO 92/09323, to which reference should be made for further details.

The inhalation device is provided with a dose indicating mechanism in accordance with the present invention. The upper part 407 of the main body 400 of the inhaler is formed with a viewing window 100 through which numbers or other dose indication markings provided on a rotary ring 101, can be viewed. The ring 101 is located in annular recess defined in the upper body part 407.

The ring 101 is formed at its upper end with a set of internal, axially inclined ratchet teeth 103.

The ring 101 is rotationally indexed, in the direction of the arrow in Figure 3, by a predetermined amount, each time a

dose is dispensed from the aerosol container 25. This is achieved by providing an indexing member 109 on the sleeve 420 to cooperate with the internal teeth 103 on the ring 101. The member 109 is made of a strip of a suitable resilient material, e.g., spring steel, and has a flat base portion 108 secured to the outer wall of the sleeve 420. The free edge of the strip is bent outwardly and shaped to form the indexing member 109 which is also inclined with respect to the axis of the ring 101. A rectangular portion 107 is cut out of the flexible arm portion connecting the indexing member 109 to the base portion 108 so the connection is made by upper and lower limbs 105, 106. This construction produces a resilient support structure for the indexing member 109 which is torsionally relatively rigid but is relatively flexible along its length. In this way the indexing member can readily flex radially inwardly of the ring 101 during each return stroke, as described below.

The teeth 103 and the indexing face 110 of the member 109 are similarly inclined to the axis of the body part 400. When the sleeve 420 is moved downwardly sufficiently to dispense a dose from the aerosol container 25, the indexing member 109 moves to its lower position as shown in Figure 4, thereby causing the indicating ring 101 to index by a predetermined increment to change the dose number displayed in the window 100.

In practice, with the indexing member 109 at its uppermost position, there is a small amount of play between the member 109 and the tooth 103 with which it is engaged. This play is taken up over an initial movement of the sleeve 420 as the breath actuating means is set on opening the cover 510, as described above. This accounts for an initial stroke of about 1 mm of the movement of the indexing member 109.

When the device is triggered by inhalation at the mouthpiece 405 to dispense a dose of medicament, the indexing member 109 completes its stroke of about 4.5 mm. At the end of its stroke the indexing member 109, which has a height of about 8 mm, remains still engaged with the teeth 103, as

indicated in Figure 4. On the return stroke, the indexing member 109 first engages the next inclined tooth 103, and then resiliently rides over that tooth to engage in the gap behind that tooth, ready for the next indexing operation. The indexing member at the beginning of its stroke is engaged with the teeth 103, which have a depth of about 2 mm, over a distance of about 1.5 mm.

As the yoke 425 is lifted to reset the device, by closing the mouthpiece cover 510, the indexing member 109 flexes radially inwardly of the ratchet teeth 103 on the ring 101 until, in its upper position, it engages in the next notch defined between the teeth 103 ready for a subsequent indexing operation.

It will be appreciated that the dose indicating mechanism is only actuated when the inner sleeve 420 moves downwards sufficiently to cause a dose to be dispensed from the aerosol 25. Therefore merely opening the mouthpiece cover 510 to reach the cocked position (Figure 2B) will not cause the dose indicating mechanism to be indexed.

Moreover a gap 600' is formed in the set of teeth 103 so that after the maximum number of doses have been dispensed from the aerosol can 25 the indicating ring 101 is no longer indexed by the indexing member 109. At this point an "empty" indication could be shown in the window 100.

The device may also be provided with a means such that it will not operate below a certain predetermined air flow rate, e.g., 10 to 30 litres per minute. In one embodiment the vane 550 will be biased by a spring such that the predetermined minimum air flow is necessary for it to move to its actuated position and enable the valve seal to open.

The main body of a dispensing device is preferably manufactured from a plastic such as polypropylene, acetal or moulded polystyrene. It may however be manufactured from metal or other suitable material.

CLAIMS

1. A dispensing device for use with a medicament delivery system (25) which can be actuated to deliver discrete doses of medicament, the dispensing device comprising a housing (400) for receiving the medicament delivery system (25), the housing having an inhalation nozzle (405) and a dose indicating device comprising an annular or arcuate dose indicating element (101) rotatably mounted in the housing (400) with a section of the indicating element being visible from outside the housing, and an indexing member (109) movable on discharge of a dose of medicament to index the indicating element (101) incrementally, characterized in that actuating means (420,440,460,550) are provided in the housing for acting on an end of a medicament delivery system (25) remote from said nozzle (405), to cause dispensing of doses of medicament; in that the indicating element (101) is located in the housing around a part (420) associated with the actuating means and in that the indexing member (109) is carried by said part (420) for movement in one axial direction through the indicating element (101) on actuation of the medicament delivery system and in the opposite axial direction for resetting the actuating means, with the indicating element being incrementally indexed on each movement of the indexing member (109) in said one direction only.

2. A dispensing device according to Claim 1 wherein said actuating means (420,440,460,550) are breath-actuated, on inhalation at said nozzle (405).

3. A dispensing device according to Claim 1 wherein the indicating element (101) has internal teeth (103) which are engaged by the indexing member (109), the teeth (103) and the engagement portion of the indexing member (109) being inclined with respect to the axis of rotation of the indicating member (101), and the indexing member (109) being resiliently mounted

so that it can move inwardly of the teeth (103) when moved in said opposite axial direction.

4. A dispensing device according to Claim 3 wherein a predetermined number of teeth (103) are provided so that said indexing member (109) disengages therefrom after a corresponding number of indexing operations of said indicating element (101) which then gives an empty indication on said section thereof visible from outside the housing.

5. A dispensing device according to Claim 3 wherein said indexing member (109) is carried by a connecting portion (105,106) which is attached to said part (420) and is resiliently biased towards said teeth (103).

6. A dispensing device according to Claim 5 wherein said connecting portion is made of a resilient material so as to bias the indexing member towards said teeth (103).

7. A dispensing device according to Claim 5 wherein said connecting portion comprises two spaced apart resilient, connecting limbs (105,106).

8. A dispensing device according to Claim 1 wherein said actuating means comprise a loading member (420) for engaging said end of the medicament delivery system (25), said indexing member (109) being carried by said loading member, means (460) to load said loading member (420) to actuate said medicament delivery system, means (440) to restrain said loading means (46), and means (550) to release said restraining means (440).

9. A dispensing device according to Claim 8 wherein said restraining means (440) comprise means for applying a resisting pneumatic force capable of preventing said loading means (460) from actuating the medicament delivery system (25).

10. A dispensing device according to Claim 1 wherein a cover (510) for said nozzle (405) of the housing is movably mounted on the housing, and a cam formation (520) on the cover (510) cooperates with the lower end of a depending member (530) associated with said part of the actuating means such that, when the cover is closed, the depending member moves said part to reset the actuating means and thereby to move said indexing member (109) in said axial direction.

11. A dispensing device according to Claim 1 in combination with a drug delivery system in the form of an aerosol dispensing container (25) having a valve capable of being actuated to release a metered amount of the pressurized aerosol contents.

12. A dispensing device according to Claim 1 in combination with a dry powder drug delivery system disposed within said housing and adapted to dispense, when actuated, a dose of powdered medicament into an air flow in said housing created by inhalation at said nozzle (405).

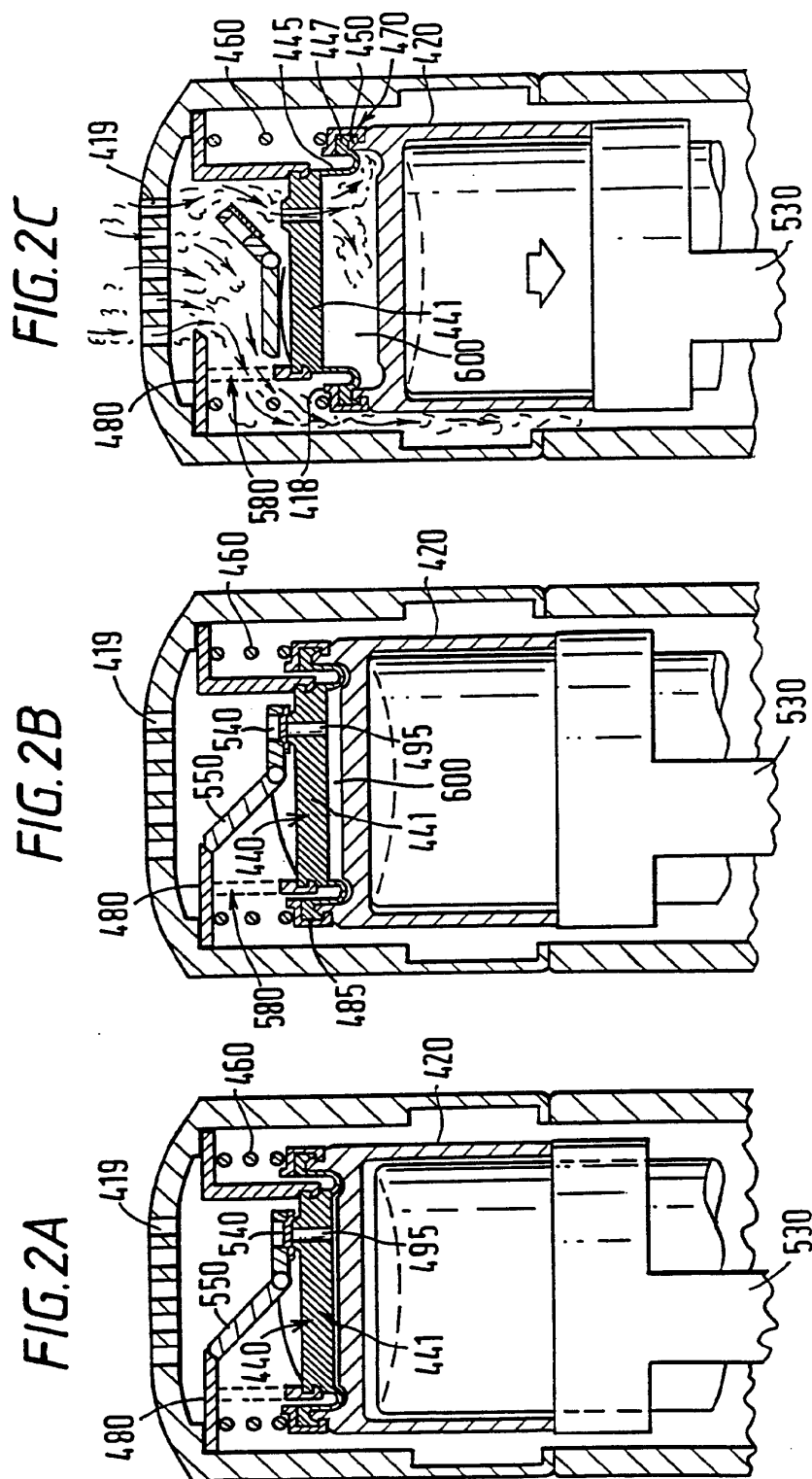
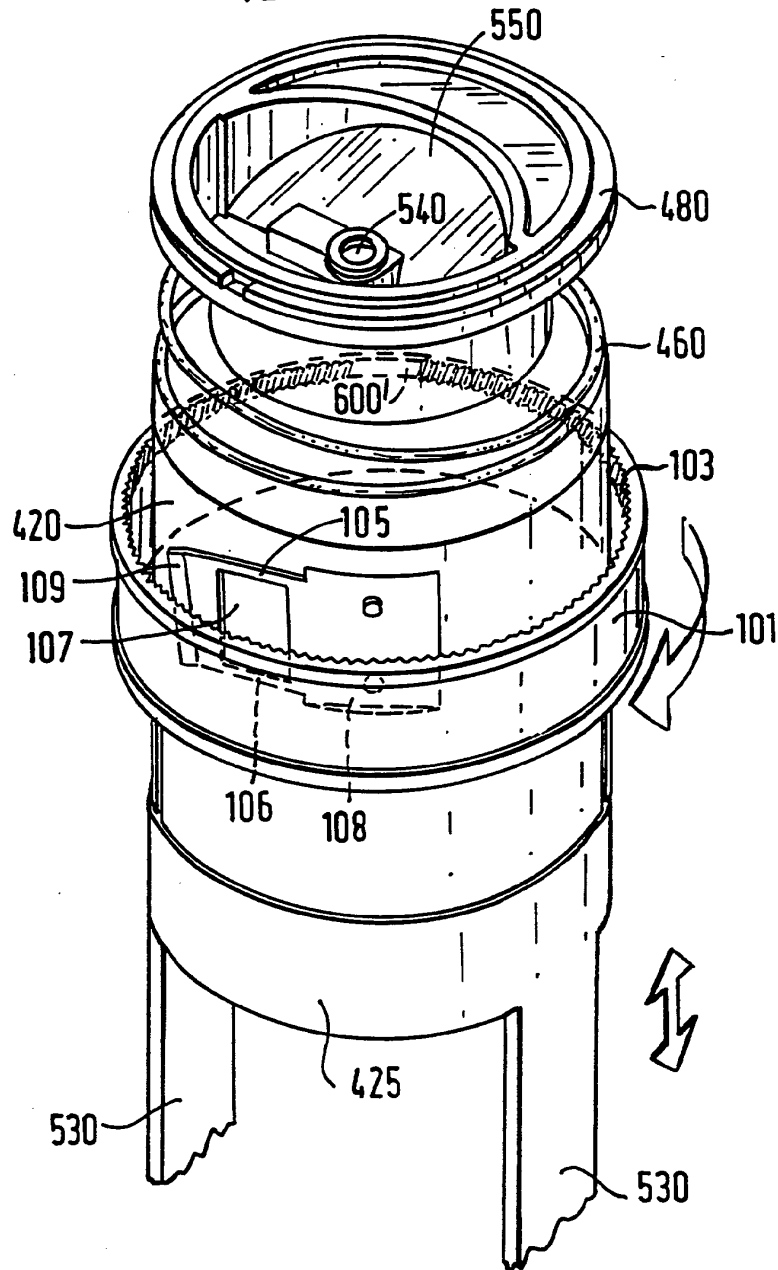
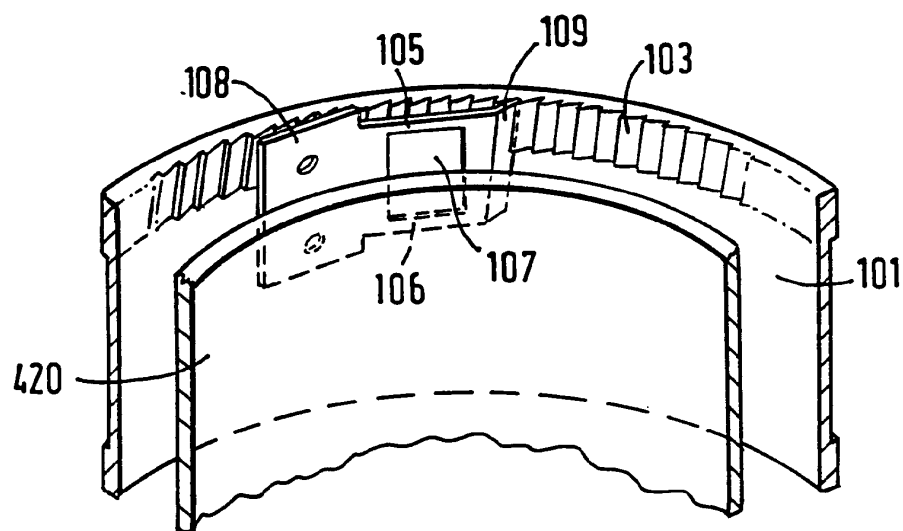


FIG. 3



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FIG. 4



INTERNATIONAL SEARCH REPORT

PCT/GB 93/01064

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61M15/00		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
Int.Cl. 5	A61M ; G06M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	GB,A,1 317 315 (ENDLISH NUMBERING MACHINES LTD) 16 May 1973 cited in the application see page 2, line 6 - page 3, line 11 see figures 1-3	1, 3, 11
P,A	WO,A,9 209 324 (MINNESOTA MINING AND MANUFACTURING COMPANY) 11 June 1992 cited in the application see page 9, line 23 - page 10, line 3 see page 13, line 12 - page 14, line 35 see figures 5,6,9	1, 2, 4, 10, 11
¹⁰ Special categories of cited documents : ¹⁰ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search 18 AUGUST 1993		Date of Mailing of this International Search Report 24. 08. 93
International Searching Authority EUROPEAN PATENT OFFICE		Signature of Authorized Officer SCHOENLEBEN J.

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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
P,A	WO,A,9 209 323 (NORTON HEALTHCARE LTD.) 11 June 1992 cited in the application see page 9, line 27 - page 13, line 29 see figures 3-5	1,2,8-11
A	EP,A,0 269 496 (VALOIS) 1 June 1988 cited in the application see figures 6,7	3
A	WO,A,8 605 991 (AKTIEBOLGET DRACO) 23 October 1986 see page 2, line 10 - line 17	12

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**ANNEX TO THE INTERNATIONAL SEARCH REPORT
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GB 9301064
SA 74380

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
GB-A-1317315	16-05-73	None		
WO-A-9209324	11-06-92	AU-A-	9060491	25-06-92
WO-A-9209323	11-06-92	AU-A-	9034091	25-06-92
		CA-A-	2091367	02-06-92
		CN-A-	1062091	24-06-92
EP-A-0269496	01-06-88	FR-A-	2606506	13-05-88
		DE-A-	3774539	19-12-91
WO-A-8605991	23-10-86	SE-B-	448277	09-02-87
		AU-B-	587460	17-08-89
		AU-A-	5771686	05-11-86
		CA-A-	1250503	28-02-89
		EP-A, B	0258238	09-03-88
		JP-T-	62502451	24-09-87
		SE-A-	8501806	13-10-86
		US-A-	4668218	26-05-87

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 15/00	A1	(11) International Publication Number: WO 98/52634 (43) International Publication Date: 26 November 1998 (26.11.98)									
(21) International Application Number: PCT/GB98/01501 (22) International Filing Date: 22 May 1998 (22.05.98) (30) Priority Data: <table border="0"> <tr> <td>9710634.8</td> <td>23 May 1997 (23.05.97)</td> <td>GB</td> </tr> <tr> <td>9720594.2</td> <td>30 September 1997 (30.09.97)</td> <td>GB</td> </tr> <tr> <td>9800862.6</td> <td>15 January 1998 (15.01.98)</td> <td>GB</td> </tr> </table> (71) Applicant (for all designated States except US): PA CONSULTING SERVICES LIMITED [GB/GB]; 123 Buckingham Palace Road, London SW1W 9SR (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): MACMICHAEL, Donald, Bruce, Atherton [GB/GB]; 104 Bedford Road, Hitchin, Hertfordshire SG5 2UE (GB). HEARNE, David, John [GB/GB]; 27 Church Road, Harlington, Bedfordshire LU5 6LE (GB). (74) Agent: KEITH W. NASH & CO.; 90-92 Regent Street, Cambridge CB2 1DP (GB).		9710634.8	23 May 1997 (23.05.97)	GB	9720594.2	30 September 1997 (30.09.97)	GB	9800862.6	15 January 1998 (15.01.98)	GB	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
9710634.8	23 May 1997 (23.05.97)	GB									
9720594.2	30 September 1997 (30.09.97)	GB									
9800862.6	15 January 1998 (15.01.98)	GB									
(54) Title: INHALER MECHANISM (57) Abstract A dosing device comprising a dispensing means (24, 26, 12) for dispensing a dose material, and a dose actuation mechanism, in which the dose actuation mechanism (42) comprises a readily deflectable member (40), and a cascade of at least two pivoted elements (46, 48), movement of one causing movement of the other, wherein the deflectable member (40) is movable by the user, and its movement is transferred to the first of the cascade of pivoted elements, so as to actuate the dispensing means. A first biasing means (56) communicates with one pivoted element (48) so that as movement is transferred between the pivoted elements (46, 48), energy stored in the first biasing means (50) is released to increase the force associated with the movement. A dose actuating mechanism for use in a dosing inhaler is also provided.											

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BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
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CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
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CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
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CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

Title: Inhaler Mechanism**Field of Invention**

This invention concerns a dosing device and in particular relates to dosing devices for drug delivery such as injectors and inhalers, and a mechanism for use in such devices.

Background to the Invention

In treatment for asthma and other respiratory problems, a patient may take medication into his lungs by inhaling either an aerosol mist or a cloud of fine particles from an inhaler. Conventional asthma inhalers fall into two categories: 'dry powder inhalers' and 'metered dose inhalers' (MDI's).

Breath operated MDI's are known. For example US patent 3565070 describes an 'inhalation actuable aerosol dispenser' and in addition WO 92/09232 and European patent 0147028 disclose further examples of breath operated MDI's.

An MDI consists of a small canister containing medication with a metering valve and a valve stem. The MDI delivers a metered dose to the patient when the valve stem is pressed. The fundamental problem in the design of breath operated MDI's is that a large force (of the order of 30 N) is required to depress the valve stem and actuate an MDI. However only a very small force is available from the patient's breath. This problem is partly overcome in the prior art by manually compressing a large spring to a sufficient force to actuate the device. The spring is compressed by the patient, either by a positive 'cocking' process or automatically when the patient opens the mouthpiece cover. The spring is then released by a trigger operated by the patient's breath. The operation of the trigger is however difficult to engineer reliably and cheaply

since releasing a spring with a stored force of 30N using a low force from the patient's breath is a difficult technical challenge.

WO 92/09323 describes a pneumatic system for holding the stored force. This requires a number of components which must be carefully manufactured to maintain a satisfactory vacuum seal during operation. European patent 0147028 describes a mechanical trigger design which requires extremely tight manufacturing tolerances and which to some extent depends on consistent levels of friction for repeatable operation.

The present invention seeks to provide an inhaler with a dose actuation mechanism which provides a very substantial amplification of the force being available from a patient's breath, whilst not being vulnerable to changes in the coefficient of friction between moving parts.

Summary of the Invention

According to the present invention, there is provided a dosing device comprising a dispensing means for dispensing a dose material, and a dose actuation mechanism, in which the dose actuation mechanism comprises a readily deflectable member, and a series of at least two movable elements which transmit and magnify movement of the first element in the series to the last element in the series by a cascade effect, wherein the deflectable member is movable by airflow, and its movement is transferred to the first element of the said series so as to actuate the dispensing means.

Preferably the moveable elements are pivoted and arranged sequentially to inter-communicate, movement of a first pivoted element by the deflectable member effecting movement of at least another pivoted element so as to actuate the dispensing means.

The deflectable member is preferably movable in response to inhalation by a patient. Thus in use only inhalation by the patient is required to activate the dose actuation mechanism and thus cause the measured dose to be dispensed.

The use of a cascade of moveable pivoted elements provides a form of amplification of the originating force created by the intake of breath, and whilst any number of such elements may be employed in the cascade, in general two such elements are sufficient.

As a preferred feature of the invention, this amplification may be achieved by a first biasing means which communicates with one moveable element so that as movement is transferred between the moveable elements, energy stored in the first biasing means is released to increase the force associated with the movement. This ensures that a small initial force exerted on the deflectable member is increased in magnitude as it cascades through the moveable elements. In such a way, a small initial force is magnified to allow actuation of the dispensing means.

Preferably one moveable element remote from the deflectable member is attached to, or acts on, the dispensing means so as to restrain actuation thereof until the said moveable element is deflected as a result of a cascade action. In this way the movement of the deflectable member and the pivoted elements can be used to release stored energy to provide sufficient force to dispense a dose from the dispensing means. In particular the dispensing means may be associated with a second biasing means, in which energy is stored in compression, which stored energy is released on movement of a pivoted element.

The invention also lies in a dose actuating mechanism for use in a dosing device, comprising a deflectable member and a cascade of at least two moveable elements, movement of the deflectable member being transferred to and between the moveable elements, in such a manner as to trigger the release

of stored energy sufficient to release a dose.

Preferably the dosing device is also provided with a lid including at least one cam surface, wherein movement of the lid results in the pivoted elements being restored to positions of unstable equilibrium ready to cause actuation of the dispensing means when the cascade is triggered.

The pivoted elements are preferably movable into a first position of unstable equilibrium, which movement is translated into stored energy, in the second biasing means, and when triggered, move into a second position of equilibrium, during which movement the stored energy is released from the second biasing means to dispense a dose from the dispensing means.

Preferably the moveable pivoted elements each comprise over-centre mechanisms. Thus where the over-centre mechanisms are arranged sequentially, movement of a first over-centre mechanism in the cascade, triggered by movement of the deflectable member, results in subsequent movement of the next, and in turn, any subsequent over-centre mechanisms, the last of which allows for actuation of the dispensing means.

Particularly preferred is the use of a first and a second over-centre mechanism as the moveable elements, the first over-centre mechanism communicating with first biasing means and the second over-centre mechanism communicating, via the dispensing means, with a second biasing means.

The use of two over-centre mechanisms in this way provides a force cascade which eventually results in actuation of the dispensing means. Thus an initial small force produced by movement of air due to inhalation, moves the deflectable member, which movement causes a first over-centre mechanism to shift over-centre, to produce an increased intermediate force because of the action of the first biasing means, this intermediate force in turn causes a second over-centre

mechanism to shift over-centre to release a larger stored force, typically 30N, from a second biasing means, so as to operate the inhaler. The use of over-centre mechanisms allows for a very substantial force amplification whilst reducing the effect of changes in the co-efficient of friction between moving parts.

The dose actuation mechanism of the present invention is applicable to various inhalers where breath actuation is desirable and where the drug is delivered by the release of stored energy in a spring. For example there is a family of devices known as pump jets in which the drug is delivered under pressure through a nozzle by the action of a mechanical pump, typically a piston pump. These have been used in the past for nasal drug delivery and for perfumes where the droplet size is not as critical as for inhaled drugs but they are now being developed to the point where very small droplets can be produced, suitable for inhalation. The mechanical pump may be driven by a powerful spring which is released by the patient's inhalation. The present invention is suitable for this type of inhaler either used in the mouth or for nasal drug delivery.

There are also some types of dry powder inhaler (DPI) in which the release of the drug particles is assisted by air movement caused by a piston driven by the release of a compressed spring or the drug particles are mechanically released by the direct action of a triggered spring. Again there is a need for a trigger mechanism capable of being reliably triggered by a small force, and thus the present invention is also applicable for these inhalers.

The present invention is also applicable in other fields where force amplification is valuable, for example other drug delivery and medical devices where stored energy is released by a manually operated trigger. Examples of this are needle-free injection systems (both with liquid drug and powder) in which the drug is accelerated towards the patient's skin

through the release of stored energy, auto-injectors in which a conventional syringe and needle are actuated by the release of stored energy and nasal or topical sprays in which the dosing pump is spring actuated.

The invention will now be described by way of example, and with reference to the accompanying drawings in which:

Figure 1 is a section through a base of a breath operated meter dose inhaler according to the preset invention illustrating a first chamber and a second chamber;

Figure 2 is a partial sectional view on the line II-II of Figure 1 showing the second chamber of the inhaler before a dose has been supplied;

Figure 3 is a partial sectional view on the line III-III of Figure 1 showing the first chamber of the inhaler before a dose has been supplied, line I-I is the section along which Figure 1 is taken;

Figure 4 is a partial sectional view on the line II-II of Figure 1 after a dose has been supplied;

Figure 5 is a partial sectional view on the line III-III of Figure 1 after a dose has been supplied;

Figure 6 is a sectional view, to an enlarged scale, on the line II-II of Figure 1 illustrating the interaction of linkage components in the second chamber when delivering a dose;

Figures 7 and 8 are a partial sectional view on the line VII-VII of Figure 1 illustrating the positioning of a cam feature during operation of the inhaler;

Figures 9 and 10 are a sectional view, to an enlarged scale, on the line VII-VII of Figure 1 showing an alternative cam feature;

Figures 11 and 12 show alternative arrangements of the link mechanism and their interaction when delivering a dose;

Figure 13 shows a series of views illustrating a dose counter mechanism used with the meter dose inhaler; and

Figure 14 is a schematic illustration showing individual components of the metered dose inhaler prior to assembly.

Referring to Figures 1, 2 and 3, a preferred embodiment of a breath operated metered dose inhaler (MDI) in accordance with the present invention comprises a hollow outer body 10, typically made of plastics material, which includes a protruding portion 12 with a central aperture 14. The protruding portion 12 and aperture 14 form a mouthpiece from which a dose may be inhaled on operation of the MDI. A mouthpiece cover 16 is pivotally attached to the outer body 10 and in Figure 1 the mouthpiece cover 16 is shown pivoted away from the body 10 to allow access to the mouthpiece.

Internally the body 10 is provided with a supporting platform 18 bearing boss 20. A biasing means 22, such as a spring, is positioned at one end to an inner base wall of body 10 with the other end of the spring 22 engaging with a canister 24 which contains the dosing medium. The canister 24 is held between the spring 22 and the boss 20 provided on the supporting platform 18. The canister 24 is provided with a stem 26 which connects with a passage 28 within boss 20 providing a nozzle 30 through which the dose is emitted.

Two adjacent chambers 32, 34 as shown in Figure 1 are defined within the outer body 10 by the supporting platform 18 and part of the inner wall of the lower part of outer body 10. Chamber 34 as shown in Figure 3 provides an actuation chamber with two apertures, an inlet aperture 36 and an outlet aperture 38, so as to provide an air passage through the first chamber 34 over vane 40. An actuation mechanism 42 is contained in the second chamber 32 shown in Figure 2 and comprises a shaft 44 which is rotatable and attached to vane 40, over-centre links 46, 48 and a biasing means 50. The shaft 44 is attached to the over-centre link 48 by a push rod 52 with over-centre link 46 being attached at one end to a neck of the canister 24 via a push rod 54 and yoke 56.

In Figures 2 and 3, the MDI is shown with the mouthpiece cover 16 opened and is ready for operating to provide a dose. Over-

centre link 46 is held in place by the pressure of the spring 22 acting on canister 24, and thus on push rod 54. The second over-centre link 48 is held in place by the action of the small 7 spring 50. The vane 40 is shown in Figure 3 and not in Figure 2 because typically the vane is mounted in a separate compartment to that containing the over-centre links 46, 48, the shaft 44 and push rod 52.

In use, a patient places his mouth over mouthpiece 12, 14 and inhales. This creates a flow of air through the chambers 32, 34, air entering from inlet aperture 36 and passing via aperture 38 into aperture 14 and thus the patient's mouth. The resulting flow of air over the vane 40 causes the vane to rotate as shown in Figure 5 and so apply a compressive force to the push rod 52. Providing the air flow has reached a pre-determined level which is sufficient to overcome the effect of spring 50, the second over-centre link 48 moves over-centre as shown in Figure 4. Thus the effect of the small spring 50 is to drive linkage 48 against linkage 46. The relative sizes of the springs 22 and 50 and the geometry of both the actuating chambers 32, 34 and the general internal body of the device, are selected to ensure that linkage 46 is driven over-centre by the action of linkage 48.

Figures 4 and 5 show the breath operated MDI after a dose has been released, with corresponding reference numerals to those used in Figure 1, 2 and 3 having been used for the common features. Figures 4 and 5 show how movement of the vane 40 results in over-centre movement of linkage 48 and subsequently linkage 46. The springs 22 and 50 are seen in their extended unbiased positions, where less energy is stored.

A detailed view of how the mechanism 42 works is given in Figure 6. Figure 6a) shows the actuation mechanism before inhalation. As inhalation occurs, a relatively small force, for example of the order of 0.25 N, in rod 52 is sufficient to displace link 48 to the right, even though a larger force, for

example 3.5 N, may be stored in spring 50. In Figure 6b), link 48 now has moved to the right and is pressing against link 46. The force of spring 50, which may have reduced to perhaps 2.5N because the spring has expanded, is sufficient to displace link 46 to the right, although link 46 is supporting a much greater force of perhaps 30N through pushrod 54. In this way the can 24 is released when the mechanism 42 collapses into the final position shown in Figure 6c).

As linkage 46 is driven over-centre, the restraining force on the canister 24 due to the force exerted by the push rod 54 is removed and the spring 22 is free to urge the canister 24 downwards against boss 20, causing a dose to be released through stem 26.

It can be seen that over-centre link 46 exerts a force on the neck of the canister 24 so storing compressive energy in the spring 22, and similarly over-centre link 48 stores compressive energy in spring 50. On inhalation, the vane 40 is deflected by a small force from the patient inhaling, and the vane 40 moves linkage 48 releasing the stored energy in spring 50.

This results in a force cascade, the lesser force of inhalation causing an increased intermediate force at the link 48. This intermediate force is sufficient to deflect link 46, as seen in Figure 6. As link 46 is deflected, rod 54 moves away from the neck of container 24, releasing the stored compressive energy in spring 22 and so providing a further increase in the force. Thus a force of the order of 30N is achieved, which is sufficient to dispense a dose from the stem 26.

After use, the patient closes the mouthpiece cover 16 and thereby replaces the linkages to their original position. The replacement is achieved by reset link 100 as shown in Figures 7 and 8. At one end of the link there is a slot 102 which engages with one drive pin 104 at the pivot of the mouthpiece cover. At the other end of the reset link 100 there are two

pins 106, 108 which are positioned underneath the linkages of the over-centre mechanism 46, 48. A drive pin 110 on the opposite side of the mouthpiece cover seen in Figure 3 and Figure 5 acts against yoke 56 to lift the canister and compress spring 22.

Figure 7 shows the mechanism after the device has been actuated. The over-centre mechanism is dropped and the reset link 100 is in the lower position. The user then closes the mouthpiece cover.

As the mouthpiece cover closes, the two drive pins 104, 110 in the mouthpiece cover take effect. Drive pin 110 engages with yoke 56 and lifts the canister 24 upwards, compressing spring 22. Drive pin 104 is engaged in reset link 100 and lifts this link upwards. The two pins 106, 108 on the reset link then press on features in the over-centre mechanism linkage and return the linkage to an upright position. Figure 8 shows the linkage 340 and the reset link 100 in this position.

The position of the two drive pins 104, 110 in the mouthpiece cover is arranged such that the action of pin 110 is to lift the canister 24 first, before pin 104 takes effect and reset link 100 starts to move the over-centre linkage, thus avoiding an over-stressed condition for the linkages.

When the mouthpiece cover is opened, the process is largely reversed. However the size of slot 102 in the reset link 100 is larger than the diameter of pin 104, thus causing the reset link 100 to remain in position and retain the over-centre link 46 in an upright position until can 24 is lowered in place, then holding the mechanism 42 in position as shown in Figure 8.

An alternative arrangement for resetting the inhaler mechanism is illustrated in Figures 9 and 10. In this case, after use, the patient closes the mouthpiece cover 16, and cam feature 60

inside the cover 16, compresses springs 22 and 50 and also returns the linkages 46 and 48 and the vane 40 to the rest, or cocked position, of Figure 2. Cam feature 62 only acts to compress spring 22 at the same time. Figures 9 and 10 illustrate the cam profiles for cam 60. Cams 60 and 62 are positioned on opposite sides of the cover 16. Cam feature 60 is provided on an internal wall of the mouthpiece cover 16, with cam feature 62 being provided in the corresponding position on the opposite inner wall of the cover 16. The cam features 60, 62 are designed such that during storage the smaller plastics components of the actuation mechanism 42 are not held under stress.

The cam 60 is positioned within the outer body 10, adjacent to the actuation mechanism 42. The lower part of the cam 60 has toothed portions 64, 66 and 68 which engage against pegs 70, 72 and 74 which extend to the side of the linkage mechanisms 46 and 48. In Figure 9, the linkage mechanisms are shown dotted for clarity and this Figure shows the post-triggered condition, i.e. after delivery of a dose.

When the mouthpiece cover 16 is closed as shown in Figure 10, the cam 60, which is directly attached to the cover 16, rotates clockwise and returns the over-centre mechanisms, or links, 46 and 48, to their starting position as required for operation of the inhaler to produce a dose. At the same time a lobe 76 provided on the cam 60 engages on a yoke 78 to lift the canister 24 and so compress the spring 22. The corresponding cam 62 provided within the mouthpiece cover 16 has a lobe identical with lobe 76, but does not have any toothed portions. By setting dimensions correctly, toothed portion 68 and lobe 76 hold the stored force from springs 50 and 22 respectively. By this means, there will be no stress on the linkages 46 and 48 during storage with the mouthpiece cover 16 closed.

The action of closing the cover 16 restores compressed energy within the biasing means so that the breath operated MDI is

once again in the pre-triggering position and is capable of providing a single dose on inhalation. Thus the action of closing the cover 16 ensures the breath operated MDI is primed, priming being achieved by the interaction of the cam surfaces with the pegs and the yoke.

In the present invention, two over-centre mechanisms are used to store and release energy in the springs 22 and 50. The use of at least two over-centre mechanisms which can cascade together ensures that a very small force, as provided by a patient inhaling, can release an intermediate force stored in an intermediate spring 50 and that the intermediate force can then be used to release a larger stored force, typically 30N, which then operates the inhaler. The use of two over-centre mechanisms ensures that the inhaling force does not need to be great and that tight manufacturing tolerances are not required. The two over-centre mechanical linkages can be constructed from a very small number of parts with moulded-in flexible hinges. Thus a breath operated MDI can be provided with a trigger mechanism which does not require precise dimensions for manufacture and which is cost effective.

Figure 11 shows an alternative arrangement of the link mechanism with an additional flexing piece 201 between links 52 and 48. This allows the linkage to be driven with a higher mechanical advantage as follows. Figure 11a) shows the mechanism in the primed position. When the user inhales, the vane pivots around shaft 44 and link 52 presses to the right against link 48. When over-centre mechanism 48 collapses to the right, link 201 allows link 48 to accelerate away from link 52 as Figure 11b). Link 48 then strikes link 46 causing the device to operate as in Figure 11c).

The additional link 201 means that the travel required from arm 202 on shaft 44 is less than the travel required from the mechanism shown in Figure 6. This means that arm 202 is shorter and hence the mechanical advantage available to drive

the trigger mechanism is greater.

Figure 12 shows a different alternative arrangement. In this case there is no spring 50. Instead, there is a link 203 bridging the top of mechanisms 48 and 46 and having a hinged connection to push rod 54. The effect of this is that links 48 and 46 are both held in compression by the compressive force transmitted by push rod 54 as shown in Figure 12a) with the mechanism primed before triggering. In this position, by way of example, the compressive force in push rod 54 may be 30N. If link 203 is constructed with a 10:1 lever ratio, then the compressive forces in links 48 and 46 would be approximately 27N and 2.7N respectively. This means that link 48 can be collapsed by the use of a very low force such as 0.2 or 0.3 N in push rod 52, as described previously. Figures 12b) and 12c) shows the device during operation.

The benefit of this arrangement is that spring 50 is eliminated which not only saves the cost of that component but also reduces the amount of space required by the mechanism.

Figure 13 illustrates operation of a dose counter used with the inhaler and as shown in Figure 14. The count indication is given by two wheels 112, 114. Each wheel comprises a toothed disc portion and a smooth disc, the smooth disc of wheel 112 bearing digits 00 to 20 and wheel 114 bearing digits 0 to 9. When the wheels are viewed together through window 116, the display can show any number from 000 to 209. Typically the display is used as an indication of doses remaining for the patient, ie the display starts at, for example, 200 and counts down to 000.

Wheel 114 is driven round by the action of flexible lever 118 acting on the ratchet teeth moulded on the wheel 114. Reverse movement is prevented by the action of sprung pawl 120 acting against the same ratchet teeth.

Lever 118 contains a pin feature 122 which engages with yoke 56. When the inhaler device is actuated and reset, the can 24 moves first downwards, then upwards. This action causes lever 118 to move, which drives round wheel 114 thereby causing the counter indication to change by one unit. The design ensures that a count is only made when a dose is taken by the user. In the event of the mouthpiece cover 16 being opened and closed without a dose being taken, the can 24 will not have dropped and therefore the counter will not have been actuated.

The smooth disc of wheel 114 has a single protruding feature 124 which is designed to engage in teeth moulded into wheel 112. Once per revolution, this feature will cause wheel 112 to index its position by a single count. Thus, for example wheel 114 may change from 0 to 9, wheel 112 may change from 17 to 16 and the display would change from 170 to 169.

Sprung lever 126 is provided to engage in tooth features 128 in wheel 112 to provide a 'detent' action, retaining the wheel in its correct orientation at all times except when engaged with and driven by the wheel 114.

All the features of the counter are moulded in a single component from plastics material, thus providing a construction which is very simple and low cost.

Figure 14 shows how a breath operated MDI in accordance with the invention could be manufactured with the actuation mechanism being composed of few separate components. Figure 12 is an exploded view of a typical breath operated MDI, comprising an outer body 150, biasing means 22, canister 24, a yoke 78 with protruding leg 152, a mouthpiece element 154, biasing means 50, an actuating section 158, a lower cap element 160 and mouthpiece cover 16. The actuating section 158 is moulded in one piece to include both linkages 46 and 48, push rod 52, shaft 44 and vane 40. The making of multiple parts of the actuation mechanism by moulding in plastics material as a

one piece actuating section 158 simplifies assembly of the breath operated MDI and reduces costs. Drive pin feature 104 is provided on an internal wall of the mouthpiece cover 16, with drive pin 110 being provided in the corresponding position on the opposite inner wall of the cover 16.

It will be apparent to a skilled person that the same effect could be achieved by counters of different physical construction including, for example, concentric indicating wheels or cylindrical indicating wheels which might provide different user benefits in terms of the size of the display digits, the size of the counter package and the number of components.

It will also be apparent to a skilled person in the art that the actuation mechanism 42 as described above may be positioned in various places within the outer body 10, for example above the canister 24, inside the biasing means 22, or alongside the canister 24. The actuation mechanism may also release the main spring 22 by the use of push rods, levers or other links as is readily apparent. The vane 40 could also be independently positioned elsewhere and linked to the two over-centre links by means other than push rod 52. The upper end of linkage 46 could be supported by a flexing arm similar to the arm linked to the upper end of linkage 48 and in such a case the connection to canister 24 could be by push rod or other mechanical link.

Claims

1. A dosing device comprising a dispensing means for dispensing a dose material, and a dose actuation mechanism, in which the dose actuation mechanism comprises a readily deflectable member, and a series of at least two movable elements which transmit and magnify movement of the first element in the series to the last element in the series by a cascade effect, wherein the deflectable member is movable by airflow, and its movement is transferred to the first element of the said series so as to actuate the dispensing means.
2. A dosing device according to claim 1, wherein the moveable elements are pivoted.
3. A dosing device according to claim 1, wherein the moveable elements are arranged to inter-communicate sequentially, so as to actuate the dispensing means.
4. A dosing device according to claim 1, or 2 or 3, wherein the deflectable member is movable in response to inhalation by a patient.
5. A dosing device according to any of the preceding claims, wherein a first biasing means communicates with one moveable element so that as movement is transferred between the moveable elements, energy stored in the first biasing means is released to increase the force associated with the movement.
6. A dosing device according to any of the preceding claims, wherein one moveable element remote from the deflectable member is attached to, or acts on, the dispensing means so as to restrain actuation thereof until the said moveable element is deflected as a result of a cascade action.

7. A dosing device according to any of the preceding claims, wherein the dispensing means is associated with a second biasing means, in which energy is stored in compression, which stored energy is released on movement of a moveable element.

8. A dosing device according to any of the preceding claims, further comprising a lid including at least one cam surface, wherein movement of the lid results in the moveable elements being restored to positions of unstable equilibrium ready to cause actuation of the dispensing means when the cascade is triggered.

9. A dosing device according to any of the preceding claims, wherein the moveable elements are movable into a first position of unstable equilibrium, which movement is translated into stored energy, in the second biasing means, and when triggered, move into a second position of equilibrium, during which movement the stored energy is released from the second biasing means to dispense a dose from the dispensing means.

10. A dosing device according to any preceding claims, wherein the moveable elements each comprise over-centre mechanisms.

11. A dosing device according to any preceding claims, wherein the moveable elements are a first and a second over-centre mechanism, the first over-centre mechanism communicating with first biasing means and the second over-centre mechanism communicating, via the dispensing means, with a second biasing means.

12. A dose actuating mechanism for use in a dosing inhaler, comprising a deflectable member and a cascade of at least two moveable elements, movement of the deflectable member being transferred to and between the moveable elements, in such a manner as to trigger the release of stored energy sufficient to release a dose.

13. A dose actuating mechanism according to claim 12, wherein each moveable element is pivoted and comprises an over-centre mechanism.

14. A dose actuating mechanism according to claim 12 or claim 13, wherein first biasing means and second biasing means communicate with the over-centre mechanisms.

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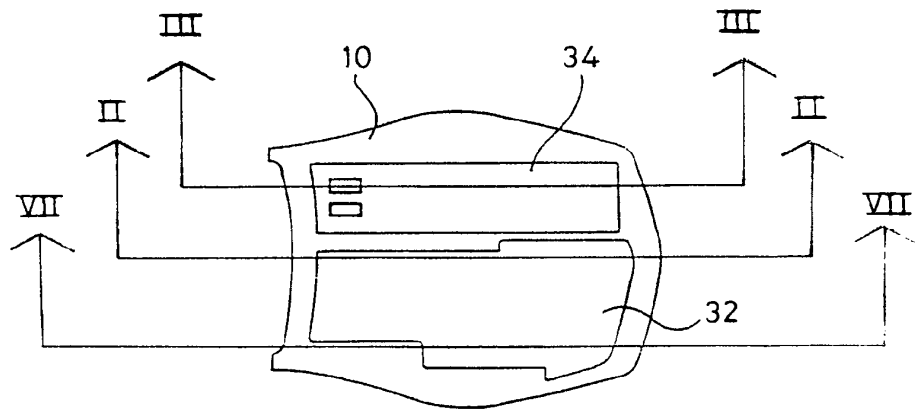


Fig. 1

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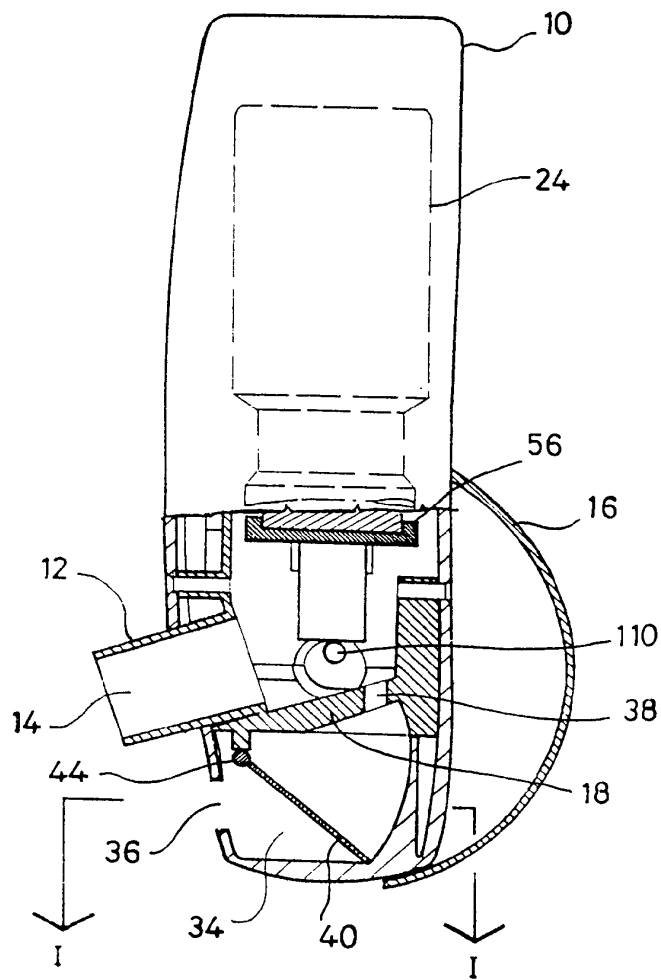


Fig. 3

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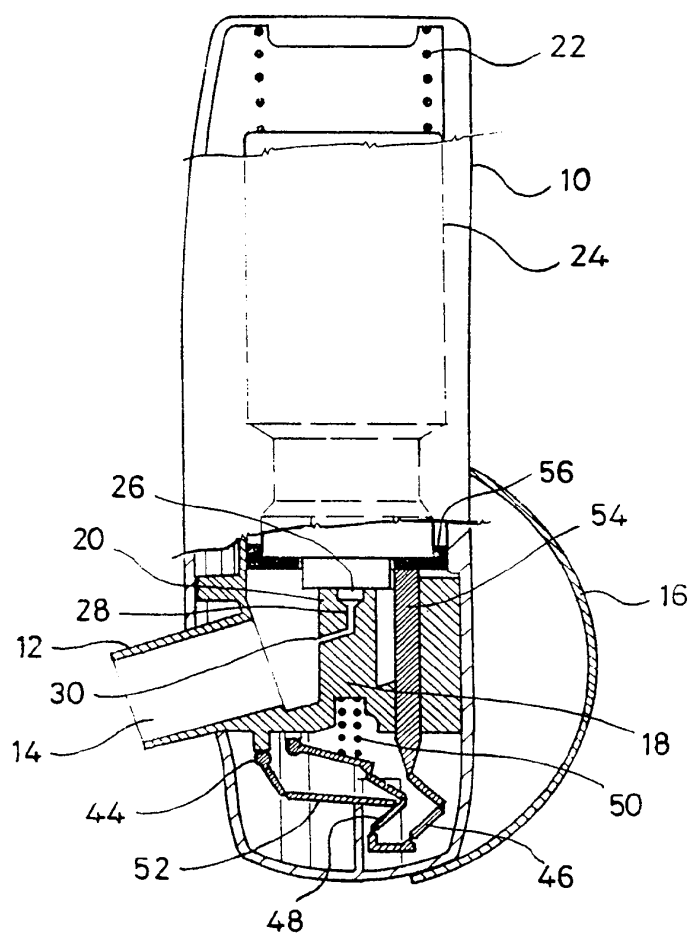


Fig. 4

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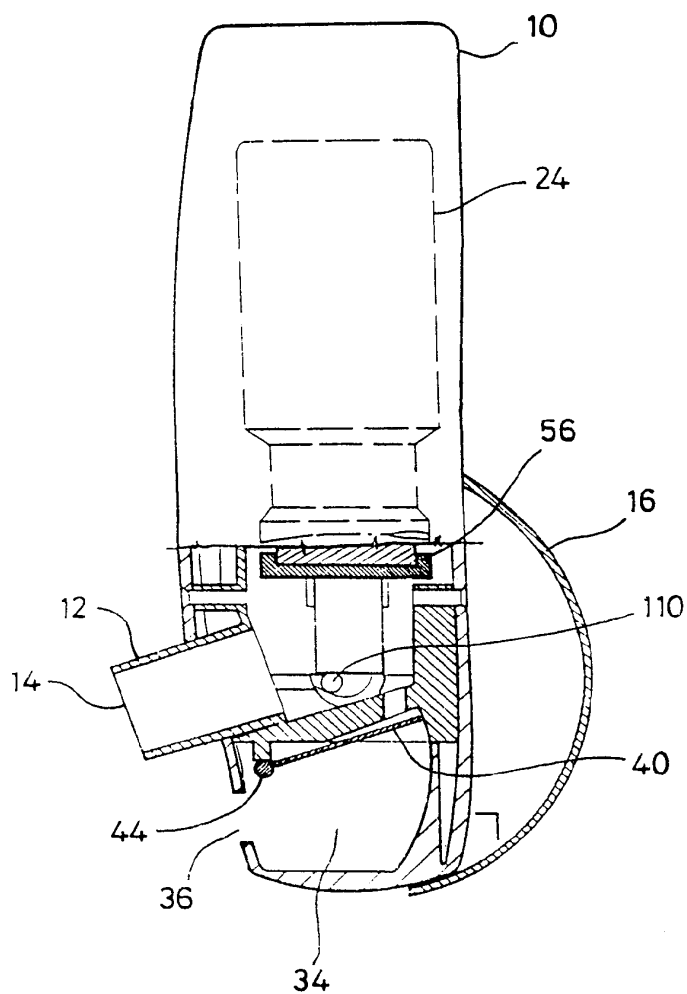


Fig. 5

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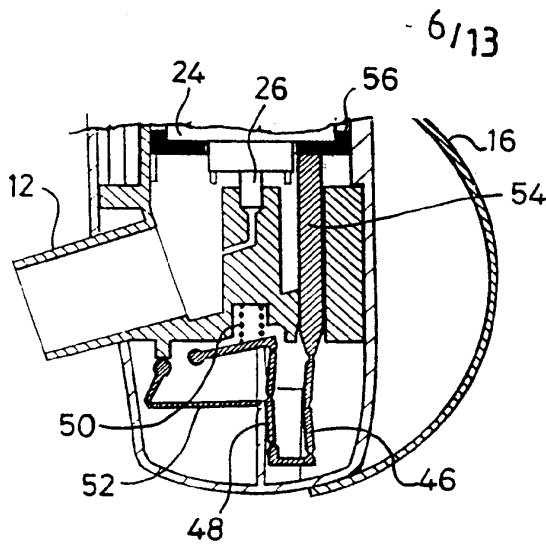


Fig. 6a

Fig. 6b

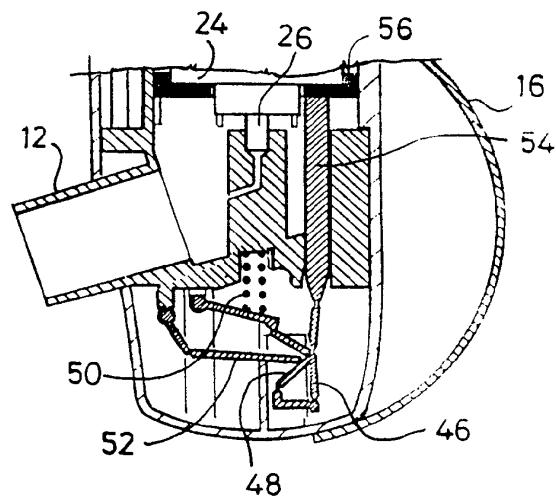
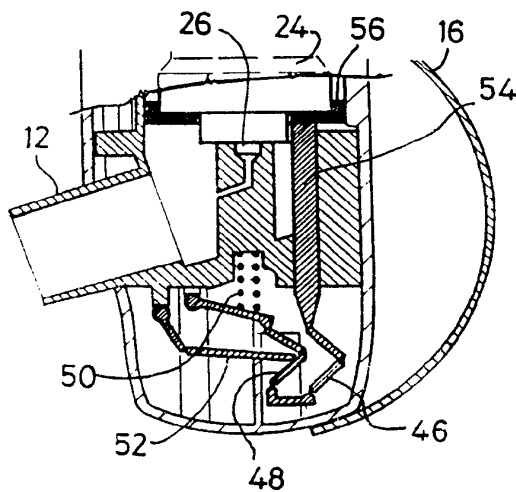


Fig. 6c



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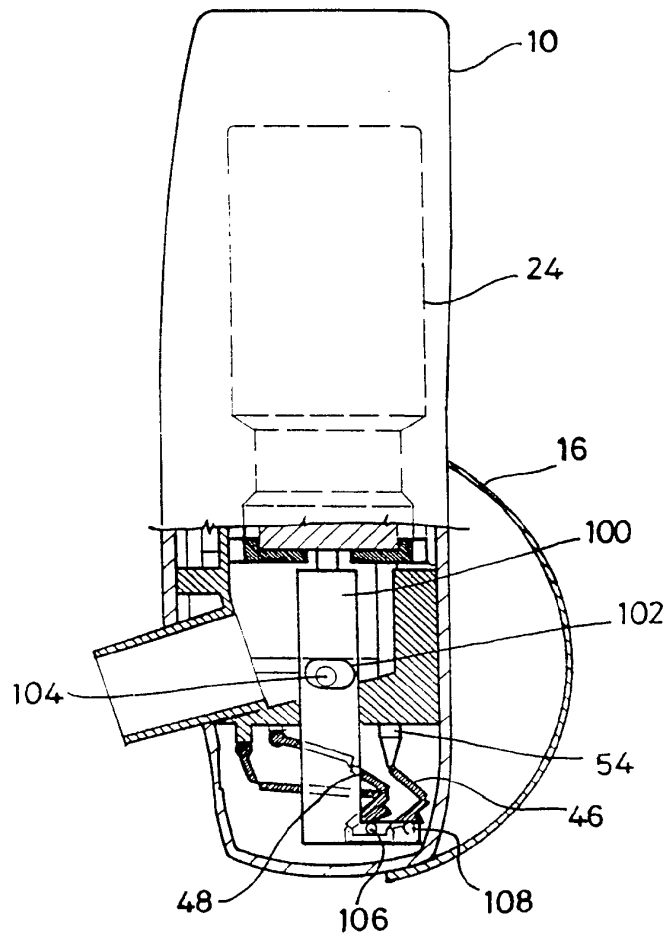


Fig. 7

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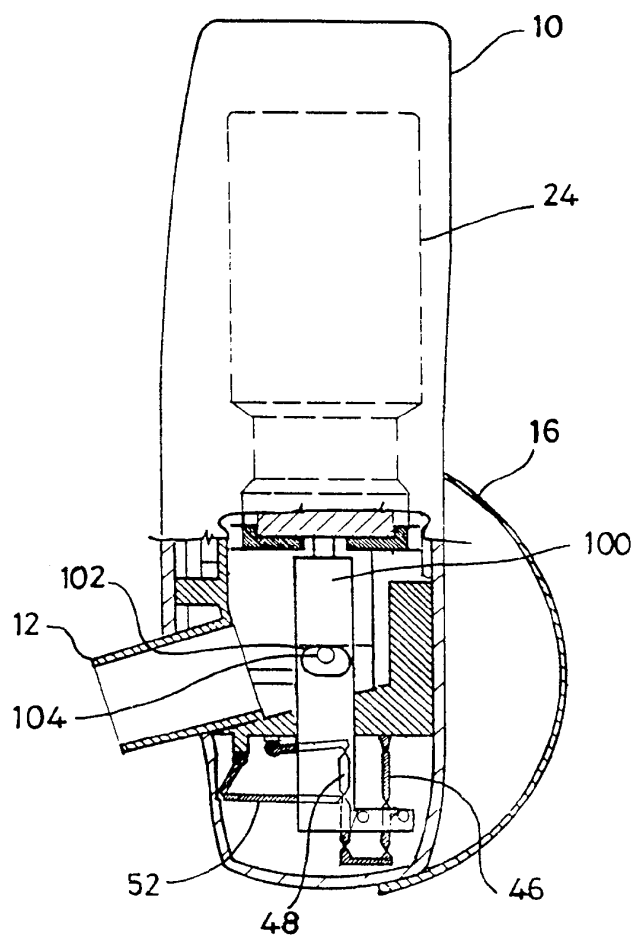


Fig. 8

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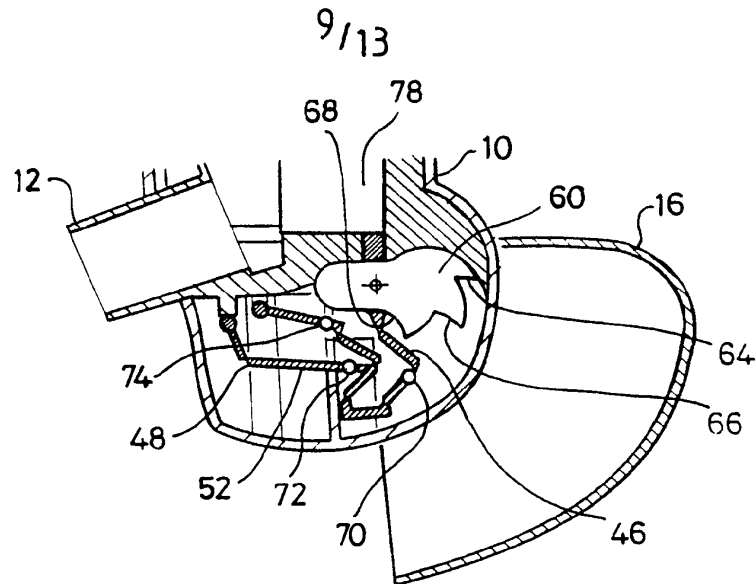


Fig. 9

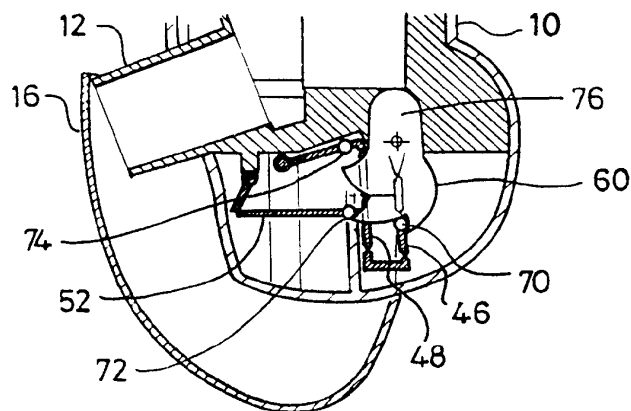


Fig. 10

SUBSTITUTE SHEET (rule 26)

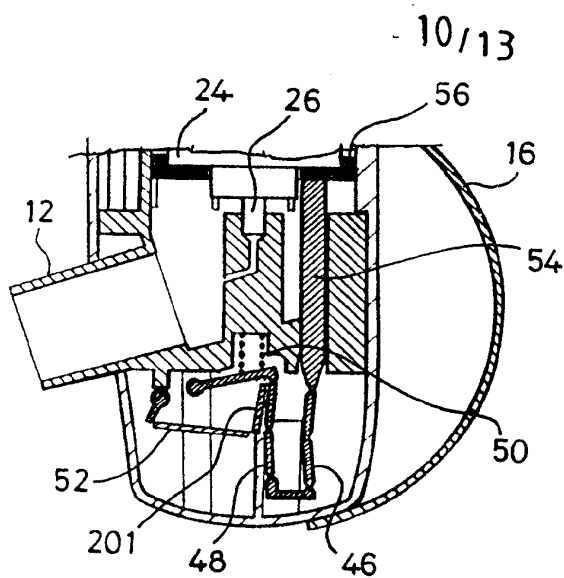


Fig. 11a

Fig. 11b

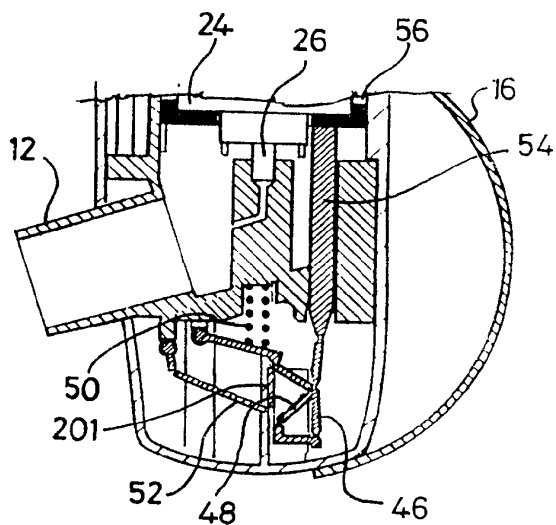
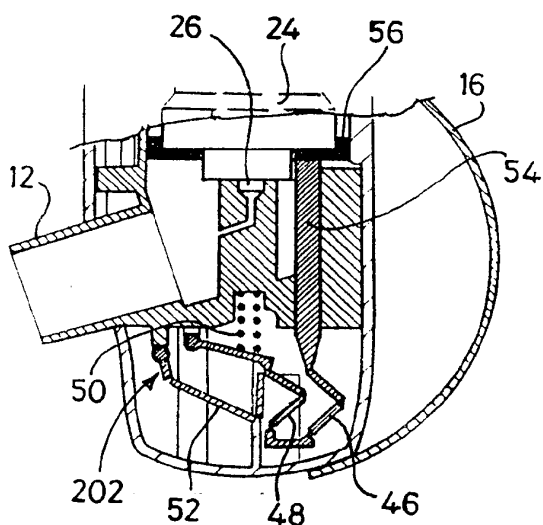


Fig. 11c



SUBSTITUTE SHEET (rule 26)

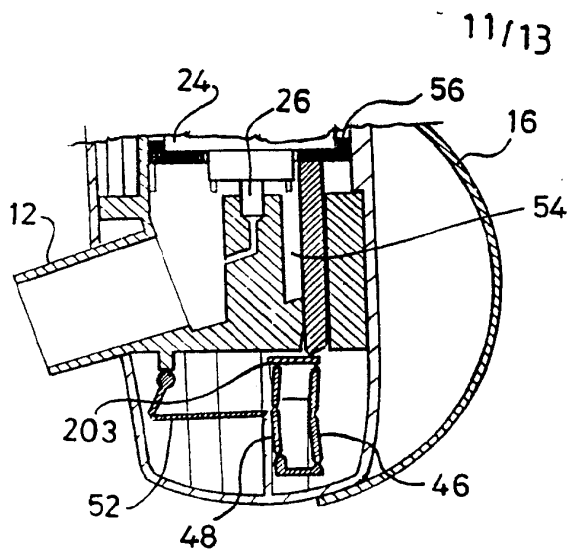


Fig. 12a

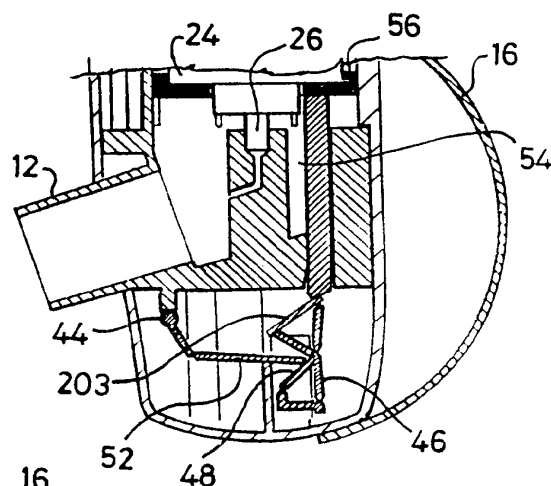


Fig. 12b

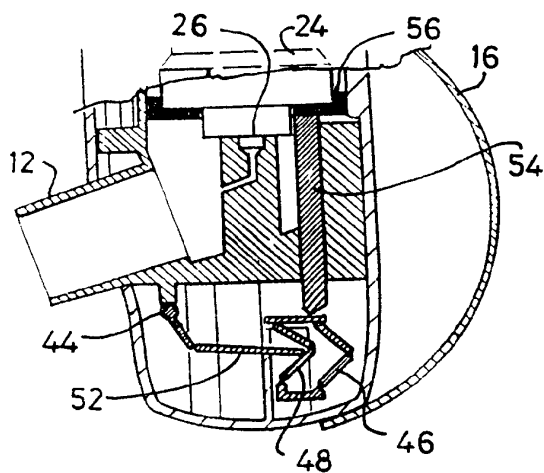


Fig. 12c

SUBSTITUTE SHEET (rule 26)

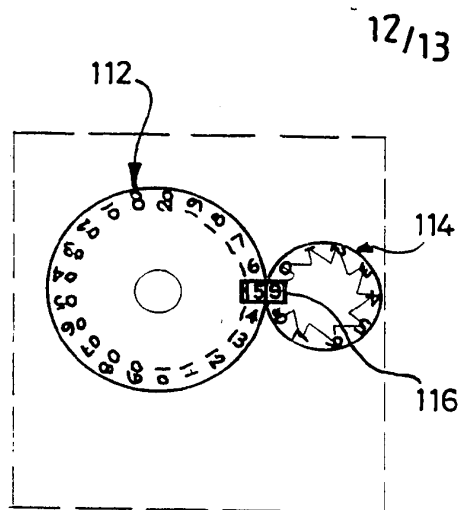


Fig. 13a

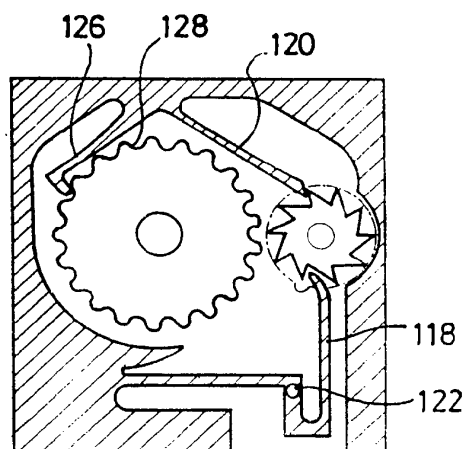


Fig. 13b

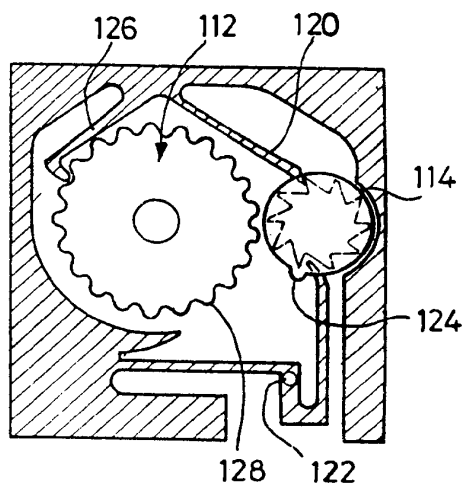
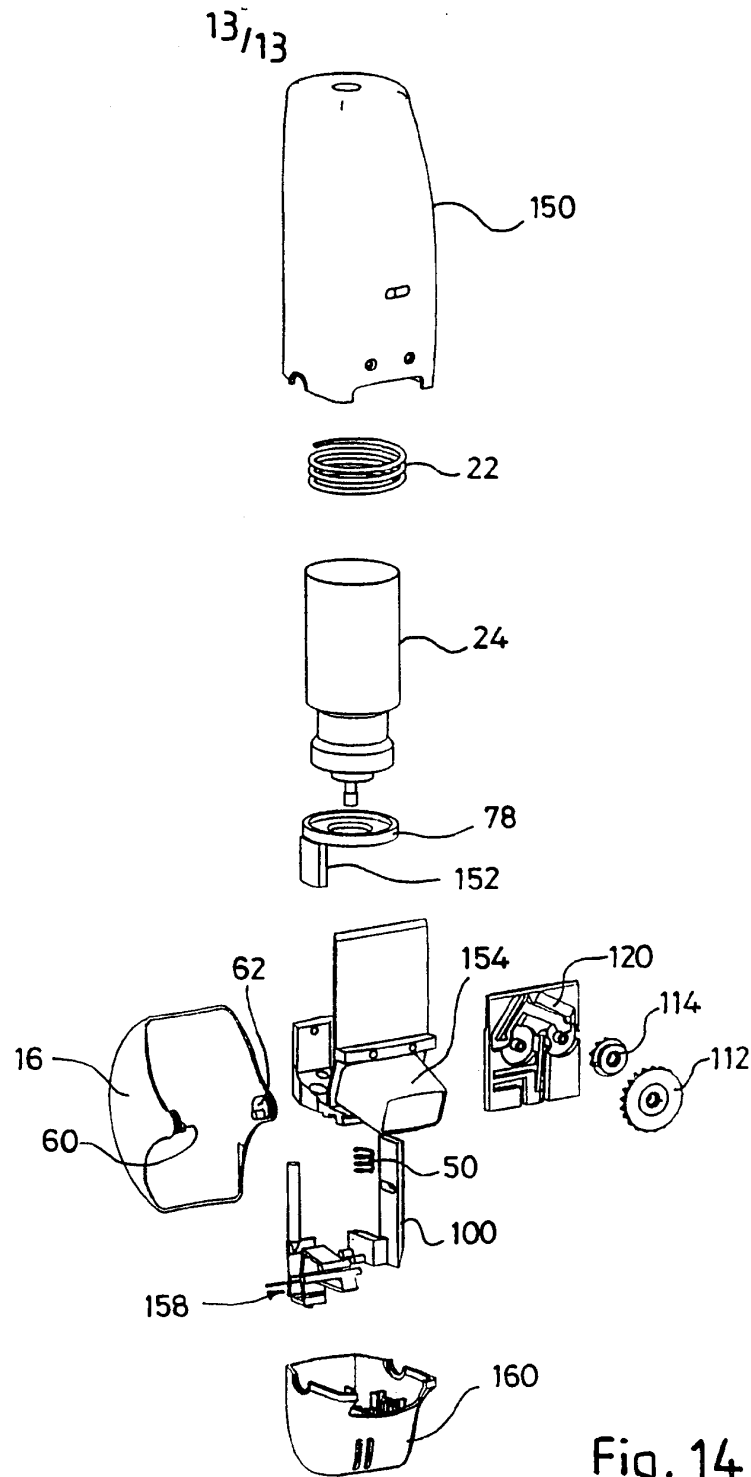


Fig. 13c

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SUBSTITUTE SHEET (rule 26)

INTERNATIONAL SEARCH REPORT

In national Application No
PCT/GB 98/01501

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 546 932 A (GALLI ROSARIA) 20 August 1996 see column 8, line 10 - line 32; figures 7-11	1,4-7,12
A	US 5 060 643 A (RICH MICHAEL ET AL) 29 October 1991 see figures 2,4	1,10,13

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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Date of the actual completion of the international search

4 September 1998

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Villeneuve, J-M

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 98/01501

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5546932 A	20-08-1996	IT 1257321 B IT 1257471 B DE 69319107 D EP 0632734 A WO 9318812 A JP 7505075 T	15-01-1996 25-01-1996 16-07-1998 11-01-1995 30-09-1993 08-06-1995
US 5060643 A	29-10-1991	NONE	

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 15/00	A1	(11) International Publication Number: WO 98/56444 (43) International Publication Date: 17 December 1998 (17.12.98)						
(21) International Application Number: PCT/EP98/03377 (22) International Filing Date: 8 June 1998 (08.06.98) (30) Priority Data: <table border="0"> <tr> <td>9711889.7</td> <td>10 June 1997 (10.06.97)</td> <td>GB</td> </tr> <tr> <td>9721875.4</td> <td>16 October 1997 (16.10.97)</td> <td>GB</td> </tr> </table> (71) Applicant (for all designated States except US): GLAXO GROUP LIMITED [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): RAND, Paul, Kenneth [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts SG12 0DP (GB). BRAND, Peter, John [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts SG12 0DP (GB). GODFREY, James, William [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts SG12 0DP (GB). BONNEY, Stanley, George [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts SG12 0DP (GB). (74) Agent: PIKE, Christopher, G.; Glaxo Wellcome plc, Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).		9711889.7	10 June 1997 (10.06.97)	GB	9721875.4	16 October 1997 (16.10.97)	GB	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
9711889.7	10 June 1997 (10.06.97)	GB						
9721875.4	16 October 1997 (16.10.97)	GB						
(54) Title: DISPENSER WITH DOSES' COUNTER (57) Abstract There is provided a dispenser suitable for dispensing medicament, particularly medicament for use in the treatment of respiratory disorders. The dispenser comprises a housing (1) having a support (5); a container (2), locatable within said housing (1), having an outlet member, wherein said container (2) is movable relative to the housing (1) to enable dispensing therefrom and said outlet member is connectable with said support (5) to prevent relative movement therebetween; and a dose indicator (13, 43), locatable within said housing (1). The container (2) and dose indicator (13, 43) are reversibly removable from the housing (1) as a single unit.								

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DISPENSER WITH DOSES' COUNTER

5 The present invention relates to a dispenser having an actuation indicator for indicating the number of actuations thereof. In particular, the invention relates to metered dose inhalers by means of which medicaments contained in an aerosol container may be administered to a patient.

10 It is well known to treat patients with medicaments contained in an aerosol, for example, in bronchodilator therapy. It is also known to use for such therapy, medicaments which are contained in an aerosol and are administered to a patient by means of an inhalation device comprising a tubular housing or sleeve in which the aerosol container is located and an outlet tube leading out of the tubular housing. The aerosol containers used in such inhalation devices are
15 designed to deliver a predetermined dose of medicament upon each actuation by means of an outlet valve member at one end which can be opened either by depressing the valve member while the container is held stationary or by depressing the container while the valve member is held stationary. In the use of such devices, the aerosol container is placed in the tubular housing with the
20 outlet valve member of the container communicating via a support with the outlet tube, for example a nozzle or mouthpiece. When used for dispensing medicaments, for example in bronchodilation therapy, the housing is then held by the patient in a more or less upright condition and the mouthpiece or nozzle of the inhalation device is placed in the mouth or nose of the patient. The
25 aerosol container is pressed towards the support to dispense a dose of medicament from the container which is then inhaled by the patient.

A disadvantage arising from use of such known devices is that the patient cannot determine the amount of medicament in the container at any given time.
30 In an extreme case this could mean that the patient, possibly suffering from severe bronchospasm and needing a dose of medicament, will find that the container will not dispense a dose because its contents have already been exhausted.

US Patent No. 4817822 describes an aerosol dispenser of the type described above having a dose indicating device which, in a first embodiment is removably attached to the end of the protruding portion of the aerosol container. The operating mechanism of the dose counter is located within a housing which
5 extends from the end of the aerosol container along the external surface of the tubular housing. It is important with inhalation devices containing medicament that the contents of the aerosol container are clearly marked to ensure that the patient knows exactly what medication is contained. One disadvantage associated with this positioning of the dose indicating device is that the device
10 obscures at least a part of the aerosol container and housing which creates labelling difficulties.

A further disadvantage of the device described is that if the dose indicating device is removably attached to the aerosol container, it is possible that the
15 dose indicating device may become separated from its aerosol container with the result that the aerosol dispenser could be used without the dose indicating device, or the actuating mechanism of the indicating device could be tampered with leading to a false reading when the indicating device is re-attached to the dispenser. With patients having several different inhalers, it could even result in
20 the indicating device being re-attached to the wrong dispenser.

In a second embodiment described in US4817822 the operating mechanism of the dose indicating device is located within a compartment in the housing and is actuated by means of an actuator member attached to the aerosol container. In
25 this embodiment, once the aerosol container is fitted into the housing it cannot be removed. This makes cleaning of the housing very difficult. Even if the container were removable, the operating mechanism of the dose indicating device would be vulnerable to damage when washing with water, soap, disinfectant or antiseptic solutions. This is important because sprays of many
30 aerosol formulations leave residues which can entrap dust and dirt particles. Some provide a media for the growth of undesired micro-organisms. If the growth of these micro-organisms is unchecked, they can serve as a source of infection for the patient and will often introduce pathogens into the patient's respiratory tract.

35

WO96/16686 describes an aerosol dispenser wherein the operating mechanism of the dose indicating device is electronic and wherein the actuating member comprises a microswitch set into the wall of the housing. The electronic counting mechanism and microswitch are contained within a hermetically sealed enclosure. However, electronic assemblies of this type are relatively expensive compared to equivalent mechanical mechanisms, typically costing five or six times as much to produce depending on quantities manufactured. Such expense must ultimately be borne by the customer and may be prohibitive.

US5482030 describes an aerosol dispenser having a mechanical dose indicator device located in and connected to the housing in the vicinity of the outlet tube of the aerosol container when fitted. Its mechanical construction makes it difficult to seal against moisture ingress and so this dispenser again is difficult to wash without damaging the operating mechanism of the dose indicating device.

Many different pharmaceutical products are sold in the form of aerosol containers as discussed above, requiring different sized container bodies and/or valves according to the required specifications. It is therefore normal for there to be dimensional variations between different aerosol containers. Even between the same products there can be dimensional variations due to manufacturing tolerances. One problem which is common to all of the dose indicating devices discussed above is that the indicator mechanism, which is actuated by means of a switch which detects relative movement between the container body and housing, lacks any means of compensating for dimensional variations between different aerosol containers. Hence, the indicators described must be dimensioned according to the product with which they are to be used, and so will not be interchangeable with other products. Furthermore, in order for the dose indicators to work properly, the dimensions of the indicator, aerosol container and housing must be accurate.

It is an object to provide a dispenser having an actuation indicator which overcomes at least some of the above described disadvantages. It is a further object to provide such a dispenser which from the point of view of the patient closely resembles currently marketed dispensers in both external appearance and operation.

According to one aspect of the present invention there is provided a dispenser for dispensing medicament comprising a housing having a support; a container, locatable within said housing, having an outlet member, wherein said container
5 is movable relative to the housing to enable dispensing therefrom and said outlet member is connectable with said support to prevent relative movement therebetween; and an actuation indicator, locatable within said housing, wherein the container and dose indicator are reversably removable from the housing as a single unit.

10 Suitably, the actuation indicator is engagable with the container in the vicinity of the outlet member. More preferably, the actuation indicator is engagable with the outlet member.

15 Suitably, the actuation indicator is provided with a grip member which is engagable with a neck portion of the container. Preferably, the neck portion is adjacent to or on the outlet member.

Suitably, the container is an aerosol container.

20 Suitably, the housing is provided with an outlet, more preferably in the form of a mouthpiece. Preferably, the dispenser comprises a passage through which dispensed doses may pass from the container to the outlet.

25 Suitably, the container provides measured doses.

Suitably, the actuation indicator indicates the number of doses dispensed from or remaining in the container.

30 Suitably, the actuation indicator comprises an indexing mechanism actuated by a predetermined movement of the aerosol container relative to the housing.

Preferably, the indexing mechanism comprises a lost motion coupling to allow and compensate for excess movement ('overtravel') of the aerosol container
35 relative to the housing.

By use of a lost motion coupling it is possible to create an actuation indicator of one size which can accomodate valves and actuators made within a wide range of manufacturing tolerances and can even fit a range of dispensers made to different dimensions.

Suitably, the indexing mechanism indexes the actuation indicator by means of a predetermined rotary movement of a first member driven by movement relative to a second member during actuation of the aerosol dispenser.

Suitably, the second member remains stationary relative to the housing during actuation of the aerosol dispenser.

Suitably, the first member comprises a pinion carried by a shaft through the lost motion coupling and the second member comprises a rack. Alternatively, the first member comprises a yoke and the second member comprises a post engaged by the yoke through the lost motion coupling.

Preferably, the lost motion coupling comprises a friction drive mechanism.

Suitably, the dispenser is a breath operated inhaler which is actuatable in response to the inward breath of a user.

According to a particularly preferred aspect of the present invention there is provided an aerosol dispenser comprising a housing in which a container is removably located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the container and having a passage through which the contents of the container may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being moveable relative to the outlet and housing to dispense its contents in measured doses, and a dose indicating device having a dose indicator for indicating the number of doses dispensed from or remaining in the container, characterised in that the dose indicating device is tightly connected to the container in the vicinity of the outlet member, such that the container and dose indicating device may be removed from the housing as a single unit.

According to a further aspect of the present invention there is provided an actuation indicating device for use with a dispenser comprising a housing and a container, locatable within said housing, having an outlet member, the actuation
5 indicating device comprising attachment means to enable attachment to the container.

Suitably, the attachment means comprises a grip member which firmly engages a neck portion formed around the container. More preferably, the neck portion is
10 located at the connection between the container and outlet member.

According to a particularly preferred aspect of the present invention the actuation indicating device has an actuation indicator for indicating the number of doses dispensed from or remaining in the container, wherein the actuation
15 indicating device comprises attachment means to enable tight connection to the container in the vicinity of the outlet member.

By fixing the actuation indicating device to the container in the vicinity of the outlet member may be possible to make use of the physical dimensions of the crimped ferrule of standard containers to provide a tight snap fit between the
20 dose indicating device and aerosol container for easy assembly yet which once assembled cannot be easily separated. This ensures that the actuation indicator presents accurate information concerning the container with which it is assembled.

25 In a preferred aspect, the dispenser is a metered dose inhaler comprising a housing in which the container is removably located, an outlet leading from the housing, a support in the housing arranged to receive the outlet member of the container and having a passage through which the contents of the container
30 may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being moveable relative to the outlet and housing to dispense its contents in measured doses, and a window through which the dose indicator may be viewed.

5 The location of the dose indicator in the vicinity of the outlet member of the container in a metered dose inhaler provides the advantage that visually and operationally the device may appear very similar to current marketed metered dose inhalers without dose indicating devices such that when switched to the metered dose inhaler according to the invention, patients perceive little change over their conventional dispensers, so creating minimal impact upon patients and their use of the device.

10 A dispenser according to the invention will now be described with reference to the accompanying drawings in which:

Fig. 1 is a section through a standard inhalation device comprising an aerosol dispenser;

15 Fig. 2 is a section through the dose indicating device as fitted to an aerosol dispenser in an inhalation device;

Fig 2a is a sectional view of an aspect of a dose indicating device herein;

20 Fig. 3 is a perspective view of a counting mechanism used in the dose indicating device of Fig. 2;

Fig. 4 shows the sequence of operation of the counter mechanism of Fig. 3;

25 Fig. 5 shows a lateral and a longitudinal section through a second embodiment of the dose indicating device as fitted into the housing of an inhalation device;

Fig. 6 shows an exploded view of a dose indicating device according to a third embodiment of the invention;

30 Fig. 7 shows another exploded view of the dose indicating device of figure 6 together with an aerosol container and housing;

35 Fig. 8 shows a schematic section through an inhalation device comprising the dose indicating device of figure 6 in a rest position; and

Fig. 9 shows a schematic section through the inhalation device of figure 8 in an actuated position.

5 The standard metered dose inhaler shown in Fig 1 comprises a tubular housing 1 in which an aerosol container 2 can be located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. An outlet 3 leads laterally from the closed end of the housing 1. In the embodiment illustrated, the outlet 3 is in the form of a mouthpiece intended for insertion into the mouth of the patient but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

15 The aerosol container 2 has an outlet valve stem 4 at one end. This valve member can be depressed to release a measured dose from the aerosol container or, alternatively, the valve stem 4 can be fixed and the main body of the container can be moved relative to the valve member to release the dose.

20 As shown clearly in Fig 1, the aerosol container 2 is located in the housing 1 so that one end protrudes from its open top. Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1. A support 5 is provided at the lower end of the housing 1 and has a passage 6 in which the valve stem 4 of the aerosol container 2 can be located and supported. A second passage 7 is provided in the support 5 and is directed towards the interior of the outlet 3.

25 Thus, when the parts are in the positions shown in Fig 1, the protruding portion of the aerosol container 2 can be depressed to move the container relative to the valve stem 4 to open the valve and a dose of medicament contained in the aerosol will be discharged through the passage 7 and into the outlet 3 from which it can be inhaled by a patient. One dose will be released from the aerosol container each time it is fully depressed.

30

Fig 2 shows the lower part of a device similar to that of Fig 1 but incorporating a dose indicating device according to the invention. The dose indicating device comprises a body 8 firmly attached to the aerosol container by means of tubular portion 9 formed with grips 10. Tubular portion 9 tightly engages the periphery

35

of valve ferrule 11 while a grip in the form of lip 10 engages around neck 12 of valve ferrule 11 which is formed during assembly when valve ferrule 11 is crimped onto aerosol container 2. Thus the tubular portion 9 and lip 10 form a tight connection to the aerosol container which once assembled by pushing the tubular portion 9 over the valve ferrule 11 cannot easily be disassembled.

Below tubular portion 9, body 8 forms a cradle 22 for mounting counter mechanism 13 and drive pinion 14. Drive pinion 14 is friction mounted on counter mechanism drive shaft 15. Drive pinion 14 is formed with a number of teeth or pegs 21 which can engage with a number of recesses or grooves formed on post 17 in the form of a rack moulded inside housing 1 and extending from the base of the housing 1 parallel to valve stem 4.

Whilst in the embodiment shown in Fig 2 the post 17 forms a moulded part of the housing other variations can be envisaged in which the post 17 forms a part of the dose indicating device itself. For example, Fig 2a shows a simplified representation of a dose indicating device in which the head of post 17 is receivable within a recess provided in the body 8 of the device. Teeth formed on the post 17 engage corresponding teeth on drive pinion 14. Spring 28 acts such as to urge the post from the recess. The protruding lip 24 of the post 17, however, abuts stop 26, thereby retaining at least a portion of the post 17 within the recess.

As shown in Figs 3 and 4, drive shaft 15 is connected to driver yoke 16 of counter mechanism 13. Driver yoke 16 has two switching latches 18a and 18b spaced either side of star wheel 19 such that driver yoke 16 may tilt about the axis of drive shaft 15 between a first position shown in Fig 4b in which switching latch 18a engages one side of star wheel 19, and a second position shown in Fig 4d in which switching latch 18b engages the other side of star wheel 19. Star wheel 19 is connected through a mechanism, similar to that described with reference to reference numerals 2 to 8 in Figs 1 to 3 of European Patent No. 0280104, to three digit wheels 33, which have numbers printed on their circumferential faces as described below. When located in the housing 1, counter mechanism 13 is small enough to be located to the sides of and behind

support 5 so as not to interfere with the aerosol flume as it emerges from passage 7.

5 The aerosol container 2 may be supplied to the patient with the dose indicating device ready assembled thereto. Alternatively, the housing 1 may be supplied to the patient with the dose indicating device located in the position shown in Fig 2 and the aerosol container 2 supplied separately. In this case, the patient is instructed to insert the aerosol container 2 into the housing 1 with the valve stem first. Upon first insertion of the container into the housing, the tubular portion 9
10 and lip 10 of the dose indicating device ride over the periphery of valve ferrule 11 of the aerosol container 2 until lip 10 snaps around neck 12. Thereafter, the dose indicating device is attached to the aerosol container 2.

15 Other means of attachment of the dose indicator to the container are envisaged including adhesive attachment; use of welded shrink sleeves; heat forming; crimping; ultra-sonic welding; and by the presence of an o-ring elastomer on the container which is fixedly piercable by barbs on the attachment member of the dose indicator. In one aspect, permanent means of attachment are preferred.

20 To actuate the device, the protruding portion of the aerosol container is depressed as described above with reference to Fig. 1. As the aerosol container carrying the dose indicating mechanism moves within housing 1, drive pinion 14 starts to turn, through its engagement with post 17, causing rotation of drive shaft 15 and driver yoke 16. As driver yoke 16 tilts with rotation of drive shaft 15 switching latch 18a moves into engagement with star wheel 19 (Fig 4a)
25 causing an incremental anti-clockwise rotation of a half tooth pitch of the star wheel until the switching latch 18a can move no further in this direction, the switching latch being positioned between two adjacent teeth of the star wheel (Fig 4b). At this point, drive shaft 15 cannot rotate any further and any further
30 movement of the aerosol container into housing 1 results in drive pinion 14 continuing to rotate through its engagement with post 17 by virtue of the friction coupling between pinion 14 and drive shaft 15.

35 When the valve stem 4 has reached its fully depressed position and a metered dose of medicament has been discharged from the aerosol container, the

aerosol container is allowed to return to its original position. As the aerosol container and dose indicating mechanism return to their original position, drive pinion 14 starts to rotate in the opposite direction together with drive shaft 15 and driver yoke 16. Thus, driver yoke 16 tilts such that switching latch 18a moves out of engagement with star wheel 19 while switching latch 18b moves into engagement therewith (Fig 4c), causing further incremental anti-clockwise rotation of a half tooth pitch of the star wheel until switching latch 18b can move no further in this direction (Fig 4d). Again, drive shaft 15 cannot rotate any further at this point and any further movement of the aerosol container out of housing 1 results in drive pinion 14 continuing to rotate through its engagement with post 17 by virtue of the friction coupling between pinion 14 and drive shaft 15. In this way it can be seen that the friction coupling acts as a lost motion coupling which allows the dose indicating device to be used with aerosol containers having valves with different lengths of travel of valve stem during actuation.

Each time the aerosol dispenser is actuated the star wheel is made to rotate through two incremental anti-clockwise movements as described above. These movements are translated through the counter mechanism into appropriate movements of the digit wheels 33, one number on each of the printed circumferential faces of the digit wheels being clearly visible through the widow 20 at the back of the housing 1 (as shown in Fig 2), to indicate that a further dose of medicament has been dispensed. By having three digit wheels 33 it is possible for the dose counter to be used to count hundreds of doses. Clearly if fewer than one hundred doses are to be contained within the dispenser, the dose counter could comprise fewer digit wheels. Alternatively, if a thousand or more doses are to be contained, then one or more additional digit wheels could be added as appropriate.

To remove the aerosol container 2 from the housing for cleaning, the aerosol container 2 may be withdrawn from the housing 1 in the usual manner. As the container is withdrawn, the friction coupling between drive pinion 14 and drive shaft 15 allows such further movement as is required for the drive pinion to come out of engagement with the post 17 without causing any further indexing of the counter mechanism. Once removed, the housing 1 may be cleaned as

described without fear of interfering with or damaging the dose indicating device, which remains firmly connected to the aerosol container 2.

5 When the housing 1 is clean, the aerosol container 2 with dose indicating device may be re-inserted into the housing 1. During insertion, drive pinion 14 will engage post 17 and start to rotate until the aerosol container reaches its normal rest position with the valve stem 4 located in support 5. As the drive pinion 14 rotates, the friction coupling will act as a lost motion mechanism as described above, allowing for any travel of the aerosol container as between first
10 engagement of drive pinion 14 and post 17, and location of valve stem 14 in support 5. In this way, the friction coupling automatically accommodates and compensates for different lengths of valve stems protruding from the ferrule.

15 Fig 5 shows an alternative lost motion coupling mechanism which may be used in an aerosol dispenser according to the invention. In this embodiment, instead of a pinion, driver yoke 16 is formed with two resilient arms 30 between which post 17 is grippingly engaged (Fig 5a). Post 17 is formed with ribs on its surface (not shown) which provide a rough surface finish to create the level of friction required between arms 30 and post 17 such that arms 30 will grip post 17 until
20 the load applied overcomes the friction.

Upon actuation of the device, as the aerosol container and dose indicating mechanism move, the friction engagement between arms 30 and post 17 cause driver yoke 16 to tilt about the axis of shaft 15 (not shown in Fig 5), so moving
25 switching latch 18a into engagement with star wheel 19 as discussed in relation to the first embodiment. As switching latch 18a reaches its limit of travel, driver yoke 16 can move no further, and any further movement of the aerosol container into housing 1 results in arms 30 slipping down post 17 by virtue of the friction coupling. Upon return to its original position, driver yoke 16 tilts in the other
30 direction until switching latch 18b moves into engagement with star wheel 19 and can move no further. Any further movement of the aerosol container out of housing 1 results in arms 30 slipping up post 17.

35 Figures 6 to 9 show an inhalation device fitted with an electro-mechanical dose indicating device according to the invention. As with the mechanical

embodiments discussed above, the dose indicating device comprises a body 40 firmly attached to the aerosol container by means of tubular portion 41 formed with grips (not shown). Tubular portion 41 tightly engages the periphery of valve ferrule 11 while a grip in the form of a lip engages around neck 12 of valve ferrule 11. Thus the tubular portion 41 and lip form a tight connection to the aerosol container which once assembled by pushing the tubular portion 41 over the valve ferrule 11 cannot easily be disassembled.

Below tubular portion 41, body 40 forms a cradle for mounting counter mechanism 43, and defines a chamber for accommodating switch slide 44. Switch slide 44 is a cylindrical washer made of silicone rubber and having a bore of such a diameter that, with the can and dose indicating device mounted within the actuator housing, it provides a friction fit on pin 45, which is moulded in the housing and protrudes through a hole in body 40. The friction fit of switch slide 44 on pin 45 ensures the switch slide will not move along the pin unless pushed. Two contact members 46, 47, both of which comprise a switch contact and a circuit board contact, and one of which further comprises a battery contact, are mounted such that the battery and circuit board contacts are in constant contact with a first terminal of the battery 48 and printed circuit board (PCB) 49 respectively. The switch contacts do not contact each other but are positioned either side of pin 45, and define the upper limit of movement of the switch slide 44 within its chamber. Thus, when switch slide 44 is in its upper position as shown in figure 9, it makes contact with both switch contacts, so closing the circuit between them due to the electrical conductivity of the silicone rubber of the switch slide. Although in the embodiment described the switch slide is made of silicone rubber, it will be appreciated that it could alternatively be made of a non-conductive rubber having an insert at its upper face made of metal or some other conductive material.

In addition to its connections with contact members 46, 47, PCB 49 also has connections to the other terminal of the battery and to a three digit liquid crystal display (LCD) 50 in a conventional manner. The PCB comprises an application specific integrated circuit (ASIC), which provides the logic by which the dose indicator can be checked, programmed and made operational, as discussed in more detail below. to keep a record of how many times the switch contact circuit

is closed and drives the LCD to display the number of doses remaining in the aerosol container. The ASIC is thus designed and programmed accordingly in a known manner.

5 Instead of a digital display, the LCD could alternatively be formatted to display an analogue indication. When the aerosol container is mounted in the actuator housing, LCD 50 is visible through window 20. In the embodiment depicted in figure 7, the LCD and window are located at the back of the housing, but they could equally be located at the front or some other part of the housing.

10

The Counter mechanism 43 is small enough to be located to the sides of and behind the stem block (support 5) moulded in housing so as not to interfere with the aerosol flume as it emerges.

15

To actuate the device, the protruding portion of the aerosol container when fitted into the actuator housing is depressed as described above. As the aerosol container carrying the dose indicating mechanism moves within the housing from its rest position (shown in figure 8), the chamber accommodating switch slide 44 moves down until the upper face of switch slide 44, which is mounted

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on pin 45, meets switch contacts 46, 47 and the switch circuit is closed. This causes the ASIC to decrement the number displayed by the LCD 50. As the aerosol container continues to move, a metered dose of medicament is discharged from the valve, while switch slide 44 is pushed down along pin 45 by virtue of the friction fit of the switch slide on the pin until the valve stem reaches

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its limit of travel and the aerosol container moves no further (figure 9). In this way, it can be seen that the friction fit of the switch slide 44 on pin 45 allows for over-travel of the valve stem after the switch circuit has been closed, so acting as a lost motion coupling. The aerosol container is then allowed to return to its original position within the housing, and as it returns, the chamber

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accommodating switch slide 44 moves up breaking the switch circuit as switch contacts 46, 47 move away from switch slide 44. Body 40 then meets the lower face of switch slide 44 and draws the switch slide up along pin 45 until the valve stem returns to its rest position (figure 8).

Because the dose indicating device is designed to be suitable for use in connection with different sized aerosol containers containing different numbers of doses to be delivered, the ASIC is designed to be factory set in accordance with the size of aerosol container with which the dose indicating device is assembled. After assembly of the dose indicating device and first connection of the battery, the ASIC enters a self-test mode. After this, the programming mode may be entered by activating the switch, allowing it to be programmed to count down from the appropriate number of doses (e.g. 200, 120, 80 or 60). This may be done automatically on a packing line. After programming has taken place, the ASIC enters the counting mode, where the LCD decrements upon closing of the switch contact circuit. When the count of zero is reached, the ASIC is designed to prevent the count from decrementing any further in a known manner. In order to prevent spurious readings due to the effects of switch 'bounce', the ASIC may be designed to decrement only after the switch circuit has been closed for a predetermined length of time in a known manner. In the event of the aerosol container getting jammed in the actuated position after operation, or the switch circuit jamming closed due to mechanical damage or contamination, the ASIC may be designed to blank the LCD to alert the user that there is a problem.

As with the other embodiments of the invention described above, the aerosol container may be withdrawn from the actuator housing in the usual manner. As the container is withdrawn, body 40 draws the switch slide up along pin 45 until it clears the pin altogether. Once removed, the housing may be cleaned without interfering with or damaging the dose indicating device, which remains firmly connected to the aerosol container.

During re-insertion of the aerosol container, which can only occur when the body of the dose indicating device is correctly orientated with respect to the housing by virtue of their respective shapes, switch slide 44 engages and is pushed up by pin 45 until the upper face meets the switch contacts. Further insertion of the aerosol container results in switch slide 44 being pushed down along pin 45 until the valve stem is seated back within support 5.

It will be appreciated that by programming of the ASIC, one design of dose indicating device could be used in conjunction with a range of aerosol containers

of various capacities. By virtue of the switch mechanism, the same design of dose indicating device can also be used in conjunction with a range of different valves having different lengths of valve stem and different stem travel specifications.

5

Whilst the present invention has been described in detail in respect of a metered dose inhaler actuable manually by the patient it will be appreciated that other actuation mechanisms can be substituted. In particular, the use of a breath operated inhaler in which the actuation is assisted, and is responsive to,

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The dispenser of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders. Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or nedocromil; anti-infectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti-inflammatories, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro- α -[[[6-[2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

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Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclometasone dipropionate and salts or sovents thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

- 5 Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

10

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

- 15 The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more
- 20 of the following claims:

CLAIMS:

1. A dispenser for dispensing medicament comprising
5 a housing having a support;

a container, locatable within said housing, having an outlet member, wherein
said container is movable relative to the housing to enable dispensing therefrom
and said outlet member is connectable with said support to prevent relative
10 movement therebetween; and

an actuation indicator, locatable within said housing,

wherein the container and actuation indicator are reversably removable from the
15 housing as a single unit.
2. A dispenser according to claim 1 wherein the actuation indicator is
engagable with the container in the vicinity of said outlet member.
- 20 3. A dispenser according to claim 2 wherein the actuation indicator is
engagable with the outlet member.
4. A dispenser according to any of claims 1 to 3, wherein the actuation
indicator is provided with a grip member which is engagable with a neck portion
25 of the container.
5. A dispenser according to claim 4, wherein the neck portion is adjacent
to or on the outlet member.
- 30 6. A dispenser according to any of claims 1 to 5 wherein the container is
an aerosol container.
7. A dispenser according to any of claims 1 to 6 wherein the housing is
provided with an outlet, preferably in the form of a mouthpiece.
35

8. A dispenser according to claim 7 comprising a passage through which dispensed doses may pass from the container to said outlet.

5 9. A dispenser according to any of claims 1 to 8 wherein said container provides measured doses.

10 10. A dispenser according to any of claims 1 to 9 wherein said actuation indicator indicates the number of doses dispensed from or remaining in the container.

11 11. A dispenser according to any of claims 1 to 10, wherein the actuation indicator comprises an indexing mechanism actuated by a predetermined movement of the container relative to the housing.

15 12. A dispenser according to claim 11, wherein the indexing mechanism comprises a lost motion coupling to allow and compensate for excess movement of the container relative to the housing.

20 13. A dispenser according to either of claims 11 or 12, wherein the indexing mechanism indexes the actuation indicator by means of a predetermined rotary movement of a first member driven by movement relative to a second member during actuation of the dispenser.

25 14. A dispenser according to claim 13, wherein the second member remains stationary relative to the housing during actuation of the dispenser.

30 15. A dispenser according to claim 13 or 14, wherein the first member comprises a pinion carried by a shaft through the lost motion coupling and the second member comprises a rack.

16. A dispenser according to claim 13 or 14, wherein the first member comprises a yoke for engagement with the second member through the lost motion coupling.

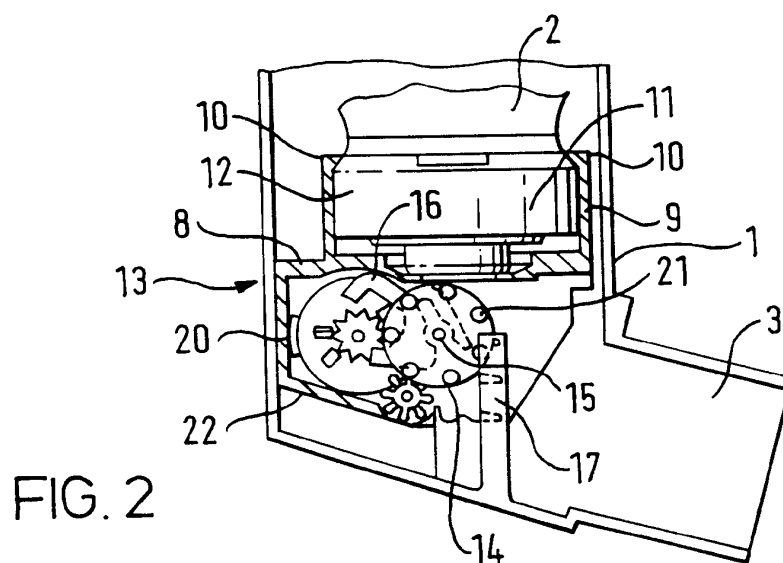
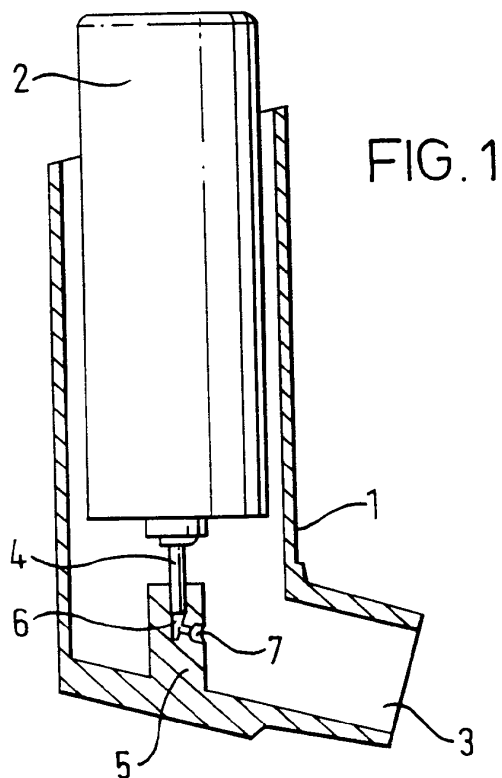
17. A dispenser according to any of claims 12 to 16, wherein the lost motion coupling comprises a friction drive mechanism.
18. A dispenser according to any of claims 1 to 17, actuable in response to the inward breath of a user.
19. An aerosol dispenser according to claim 1 comprising a housing in which a container is removably located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the container and having a passage through which the contents of the container may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being moveable relative to the outlet member and housing to dispense its contents in measured doses, and a dose indicating device having a dose indicator for indicating the number of doses dispensed from or remaining in the container, characterised in that the dose indicating device is tightly connected to the container in the vicinity of the outlet member, such that the container and dose indicating device may be removed from the housing as a single unit.
20. An actuation indicating device for use with a dispenser comprising a housing and a container, locatable within said housing, having an outlet member, the actuation indicating device comprising attachment means to enable attachment to the container.
21. An actuation indicating device according to claim 20, wherein the attachment means comprises a grip member which firmly engages a neck portion formed around the container.
22. An actuation indicating device according to claim 21, wherein the neck portion is located at the connection between the container and outlet member.
23. An actuation indicating device according to claim 20, wherein the actuation indicating device has an actuation indicator for indicating the number of doses dispensed from or remaining in the container, wherein the actuation

indicating device comprises attachment means to enable tight connection to the container in the vicinity of the outlet member.

24. Electromechanical dose indicating device according to any of claims
5 20 to 23.

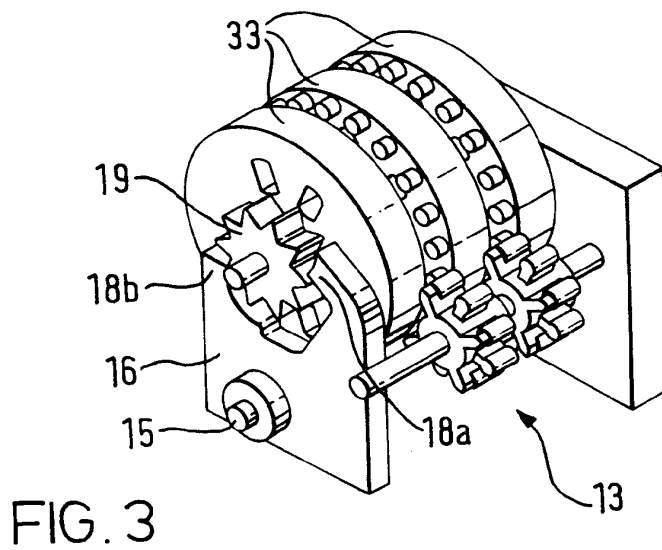
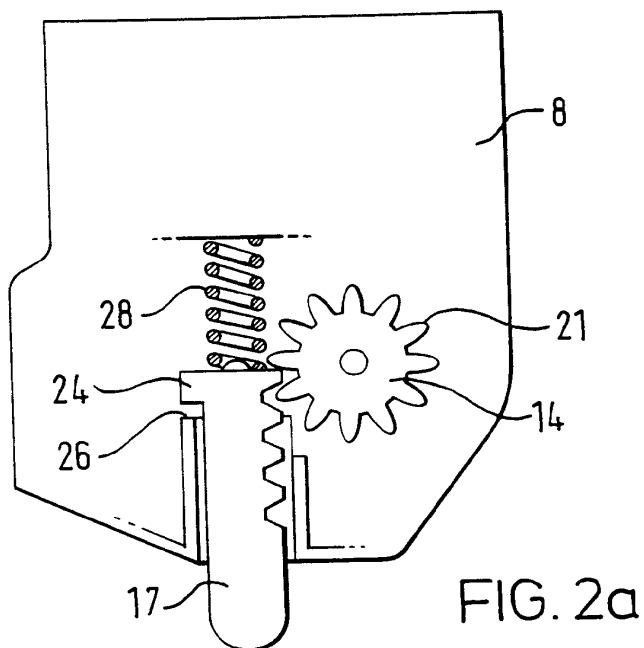
25. Use of a dispenser according to any of claims 1 to 18 for dispensing
medicament.

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SUBSTITUTE SHEET (rule 26)

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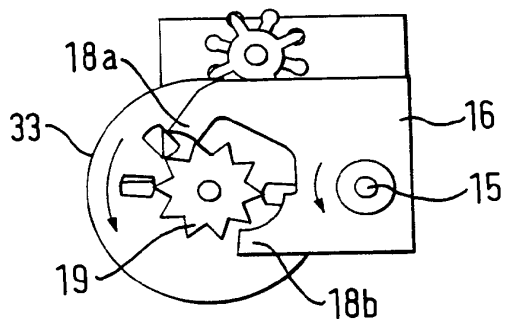


FIG. 4a

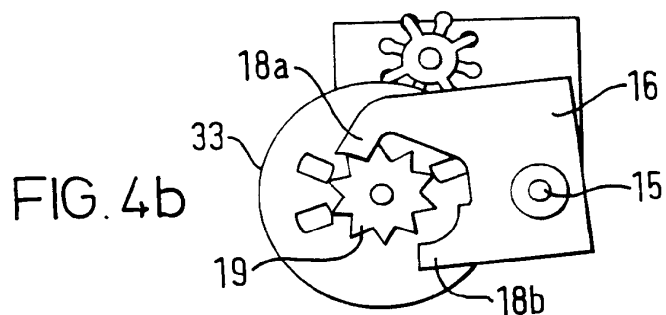


FIG. 4b

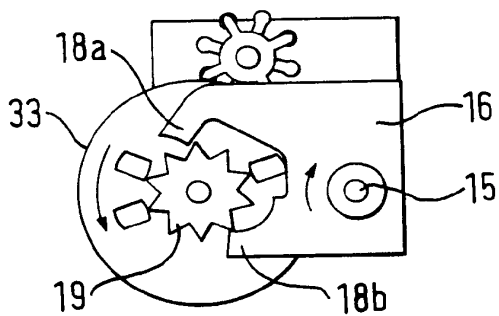


FIG. 4c

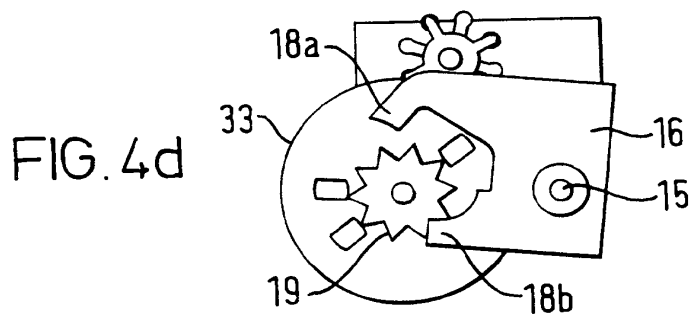


FIG. 4d

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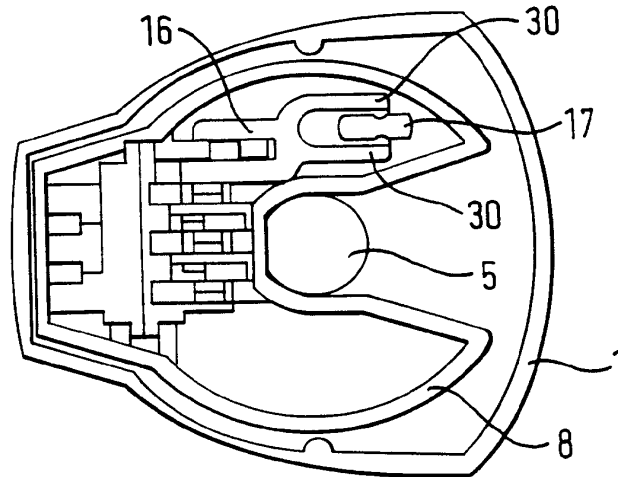


FIG. 5a

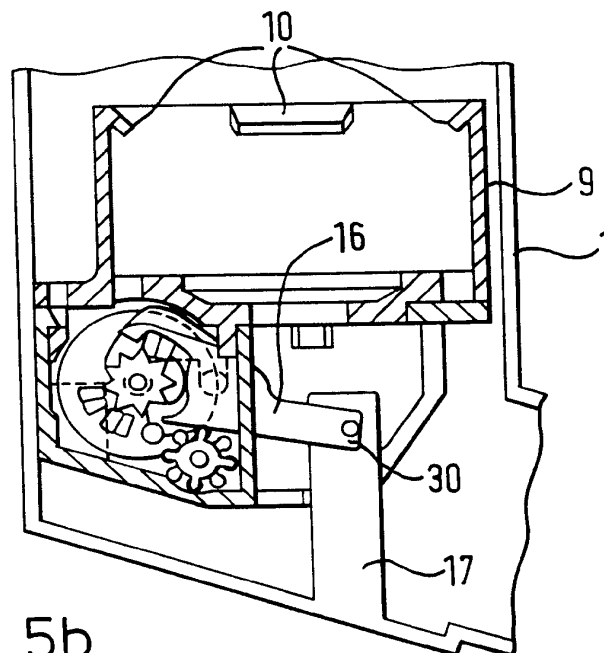
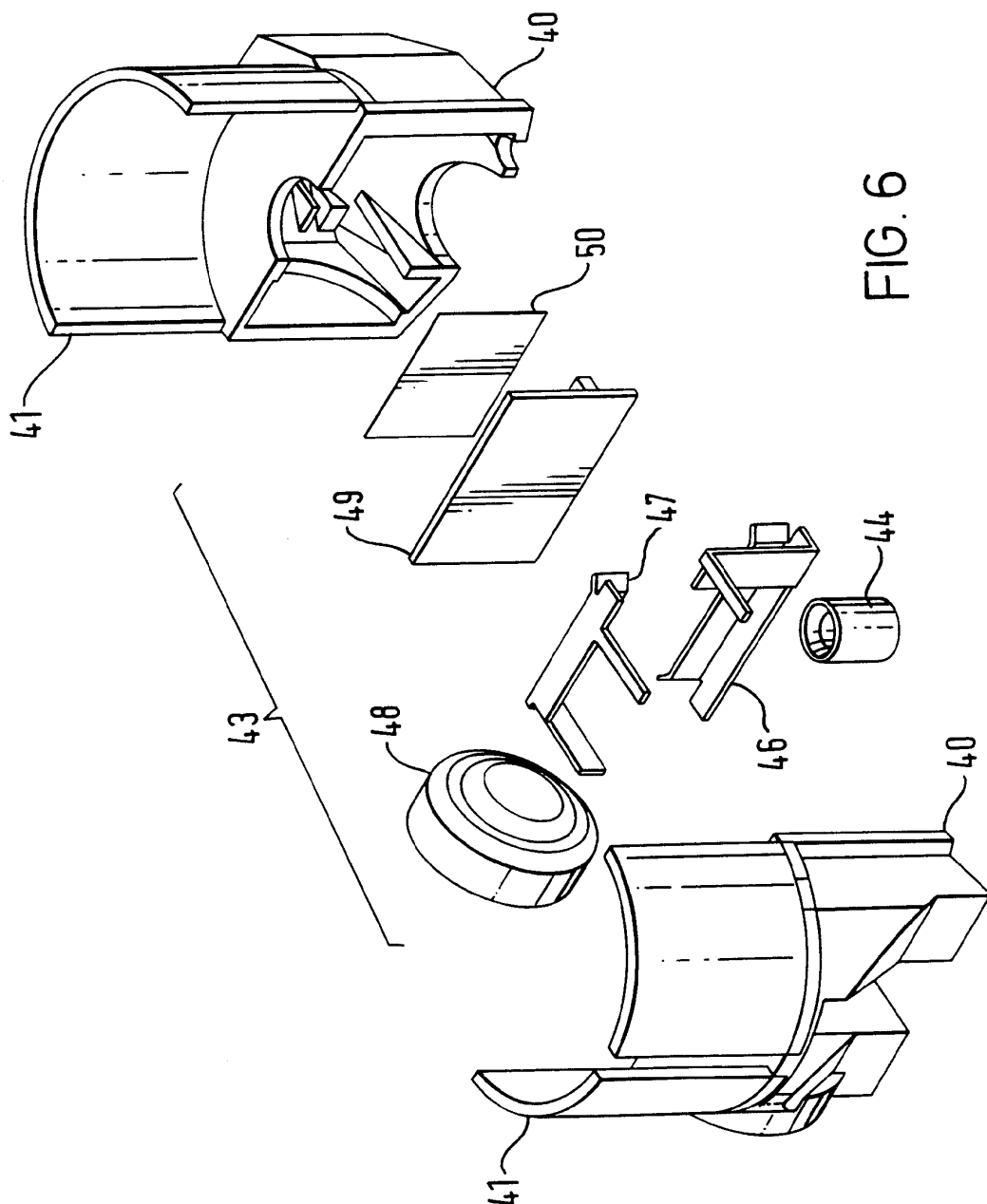


FIG. 5b

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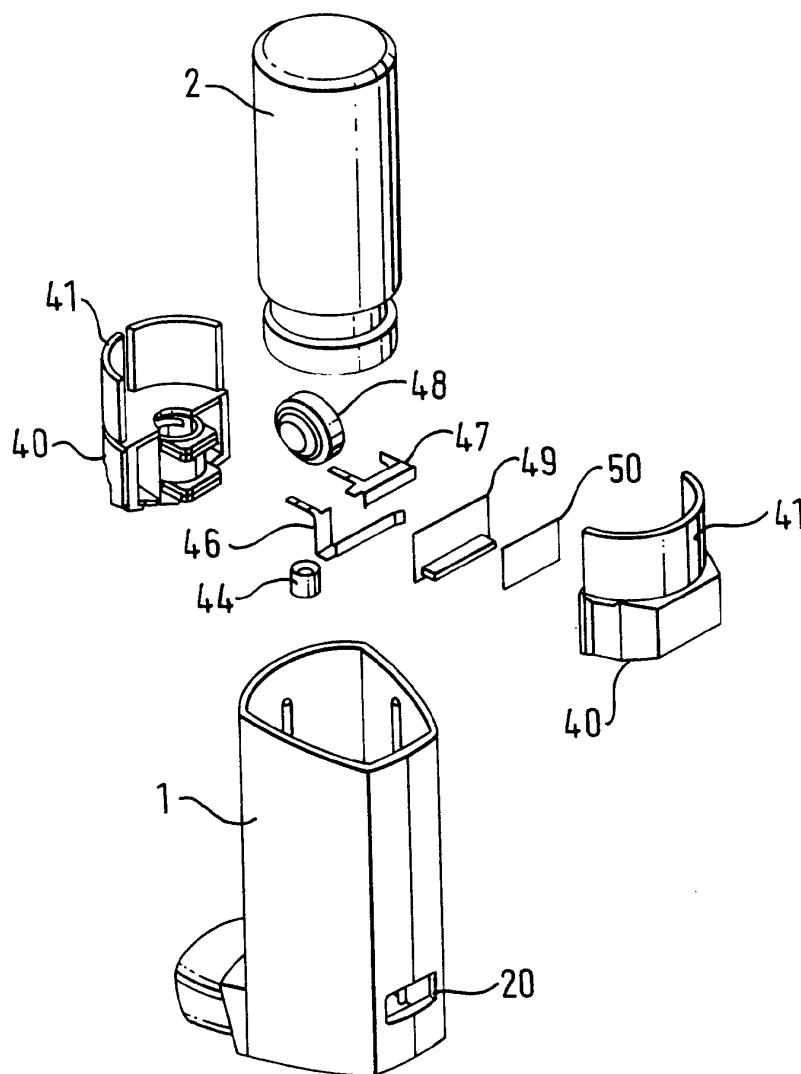


FIG. 7

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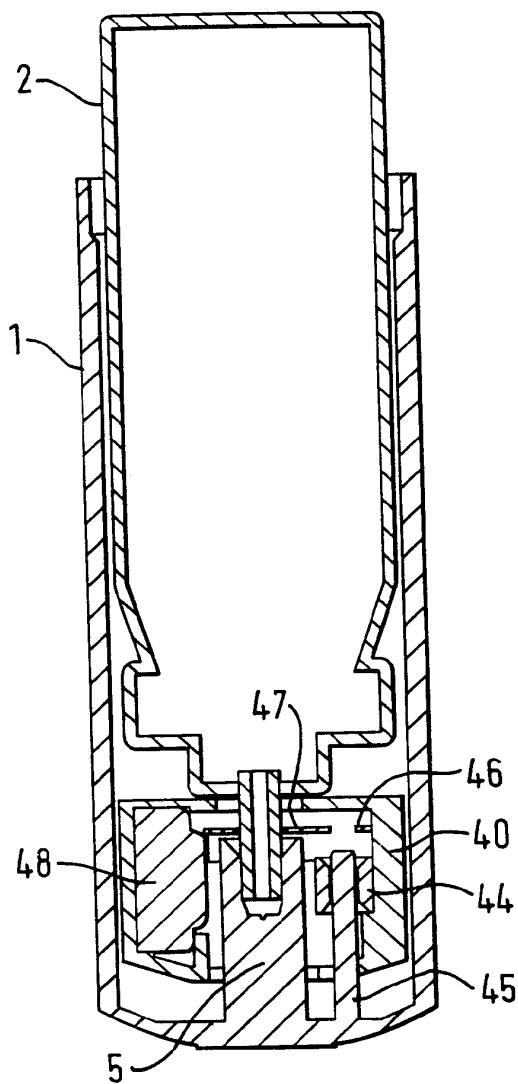


FIG. 8

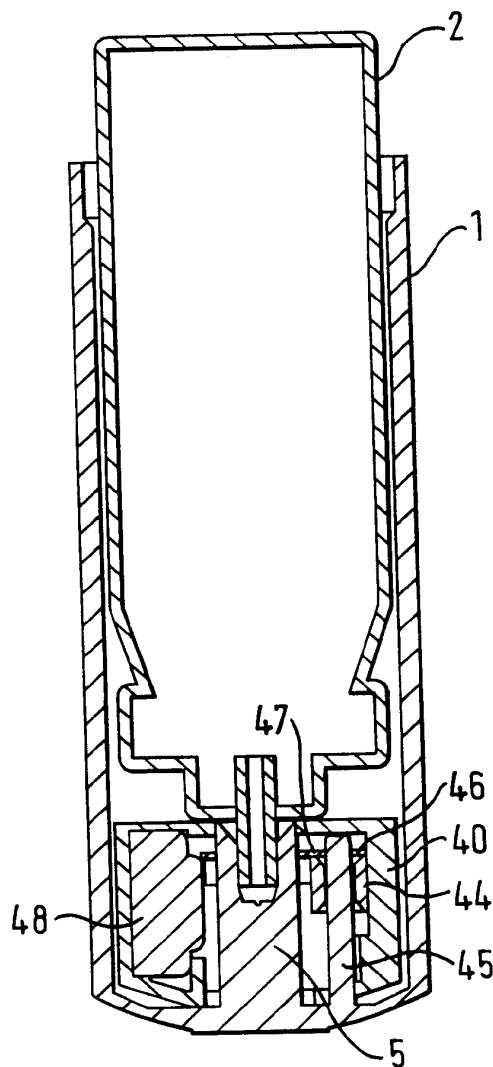


FIG. 9

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 98/03377

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 622 163 A (JEWETT ET AL) 22 April 1997 see column 4, line 4 - column 5, line 64; figures 1-3 & WO 96 16686 A (IEP GROUP INC) 6 June 1996 cited in the application ----	20,21,24 1,6-10, 19,25
X A	DE 86 02 238 U (JOSEF WISCHERATH GMBH & CO) 10 April 1986 see page 3, line 8 - page 5, line 27; figures 1-3 ----- -/--	20-22 1-9,11, 19,23,25

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

21 October 1998

Date of mailing of the international search report

30/10/1998

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page 1 of 2

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 98/03377

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 92 17231 A (INNOMED INC) 15 October 1992 see page 4, line 9 - page 6, line 4 see page 8, line 17 - page 10, line 3; figures 1-5 -----	1,2, 6-11,19, 25

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 98/03377

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5622163 A	22-04-1997	US 5544647 A	13-08-1996
		AU 7174596 A	29-05-1997
		CA 2190204 A	23-05-1997
		EP 0775499 A	28-05-1997
		JP 9168593 A	30-06-1997
		NO 964943 A	23-05-1997
		NZ 299619 A	24-11-1997
		AU 687290 B	19-02-1998
		AU 4236096 A	19-06-1996
		CA 2181789 A	06-06-1996
		EP 0746366 A	11-12-1996
		JP 9508845 T	09-09-1997
		NO 963134 A	28-08-1996
		NZ 297246 A	22-09-1997
		WO 9616686 A	06-06-1996
		ZA 9510129 A	06-06-1996
DE 8602238 U	10-04-1986	NONE	
WO 9217231 A	15-10-1992	NONE	

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 INTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE
 INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT)



(51) Internationale Patentklassifikation ⁷ : A61M 15/00, G06M 1/08, 1/14	A1	(11) Internationale Veröffentlichungsnummer: WO 00/09187 (43) Internationales Veröffentlichungsdatum: 24. Februar 2000 (24.02.00)
(21) Internationales Aktenzeichen: PCT/EP99/05939 (22) Internationales Anmeldedatum: 13. August 1999 (13.08.99) (30) Prioritätsdaten: 298 14 647.9 14. August 1998 (14.08.98) DE (71) Anmelder (für alle Bestimmungsstaaten ausser US): JOSEPH WISCHERATH GMBH & CO. KG [DE/DE]; Donatusstrasse 102, D-50259 Pulheim (DE). (72) Erfinder; und (75) Erfinder/Anmelder (nur für US): ECKERT, Joseph [DE/DE]; Suhlesstrasse 69, D-97638 Mellrichstadt (DE). (74) Anwalt: GRÜNECKER, KINKELDEY, STOCKMAIR & SCHWANHÄUSSER; Maximilianstrasse 58, D-80538 München (DE).	(81) Bestimmungsstaaten: DE, JP, US, europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Veröffentlicht <i>Mit internationalem Recherchenbericht.</i>	

(54) Title: INHALATOR COMPRISING A DOSAGE COUNTING DEVICE

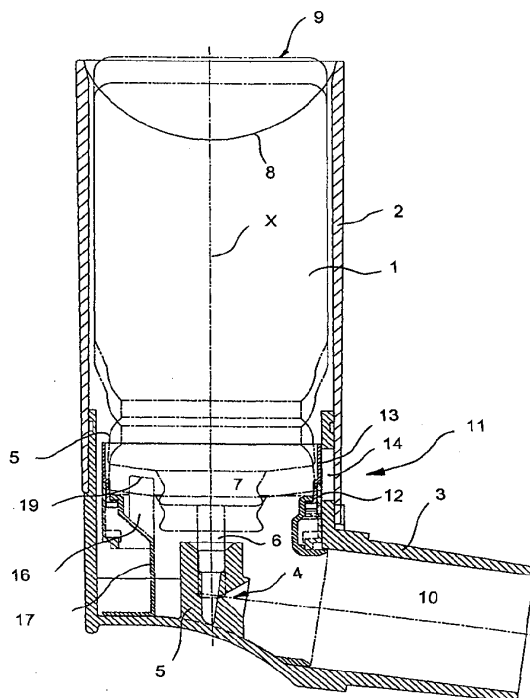
(54) Bezeichnung: INHALATOR MIT EINER DOSIERZÄHLEINRICHTUNG

(57) Abstract

The invention relates to an inhalator for discharging an aerosol comprising a dosage counting device (11). The dosage counting device comprises a first (12) and a second (13) counting ring and has a coupling device (24, 25, 26, 27) located between the counting rings.

(57) Zusammenfassung

Die Erfindung betrifft einen Inhalator zur Abgabe eines Aerosols mit einer Dosierzähleinrichtung (11), die einen ersten (12) und einen zweiten (13) Zählring aufweist und mit einer Koppelungsvorrichtung (24, 25, 26, 27) zwischen den Zählringen.



LEDIGLICH ZUR INFORMATION

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EE	Estland						

Inhalator mit einer Dosierzähleinrichtung

Die Erfindung betrifft einen Inhalator zur Abgabe eines Aerosols mit einer Dosierzähleinrichtung, einem Gehäuseteil und einem relativ zu dem Gehäuseteil entlang seiner Längsachse verschiebbar angeordneten Aerosol-Abgabebehälter.

Ein derartiger Inhalator ist aus EP-A1-0 254 391 bekannt. Bei diesem herkömmlichen Inhalator ist ein Aerosol-Abgabebehälter verschiebbar in einen rohrförmigen Abschnitt eines Gehäuseteils eingesetzt. Der Abgabebehälter umfaßt ein aus einem Kopfbereich des Abgabebehälters herausgeführtes Sprührohr, das in abdichtender Weise in einen Sprühsockelabschnitt eingesetzt ist, der einstückig mit dem Gehäuse ausgebildet ist. Zur Abgabe einer festgelegten Dosis eines in dem Abgabebehälter bevorrateten Mediums wird auf einen Bodenabschnitt des Abgabebehälters eine Druckkraft ausgeübt und der Behälter kurzzeitig in das Gehäuse hineingedrängt. Über das in den Sprühsockel eingesetzte Sprührohr wird kurzzeitig ein Ventilmechanismus geöffnet und eine vorbestimmte Menge des in dem Abgabebehälter bevorrateten Mediums aus dem Sprühkopf abgesprüht. In einem Seitenbereich des Gehäuses ist ein drehbewegbar gelagertes Anzeigerad vorgesehen, das bei jedem Abgabehub des Inhalators über ein Untersetzungsgetriebe um einen geringen Drehbetrag weitergedreht wird. Das Anzeigerad ist mit mehreren Füllstandsangaben versehen, die bei sukzessiver Drehung des Anzeigerades über einen Fensterabschnitt ablesbar sind. Wenn der Abgabebehälter nahezu vollständig entleert ist, wird in dem Fenster ein entsprechendes Symbol sichtbar und dem Benutzer damit signalisiert, daß der Abgabebehälter im wesentlichen vollständig entleert ist. Durch eine werkseitig vorgenommene Überfüllung des Abgabebehälters um ca. 10 bis 15 % ist gewährleistet, daß bei Erreichen dieser End-Markierung noch eine ausreichende Wirkstoffmenge in dem Abgabebehälter bevorratet ist.

Diese werkseitig vorgenommene Überfüllung des Abgabebehälters führt insbesondere bei der Abfüllung von vergleichsweise teuren Wirkstoffen zu einer Verteuerung des Inhalators. Auch unter Umweltverträglichkeitsaspekten erscheint eine Überfüllung des Abgabebehälters im bislang üblichen Umfang als problematisch.

Der Erfindung liegt daher die Aufgabe zugrunde, einen Inhalator zur Abgabe eines Aerosols zu schaffen, welcher sich durch eine hohe Funktions-Zuverlässigkeit und eine

hinsichtlich Ablesbarkeit und Anzeigegenauigkeit verbesserte Dosiermengen Zähleinrichtung auszeichnet.

Diese Aufgabe wird erfindungsgemäß durch einen Inhalator mit den im Schutzanspruch 1 angegebenen Merkmalen gelöst.

Dadurch wird es auf vorteilhafte Weise möglich, einen unter fertigungstechnischen Gesichtspunkten günstig herstellbaren Inhalator zu schaffen, bei welchem bedarfsweise jeder einzelne Dosierhub gezählt und angezeigt wird. Neben der damit erreichten zuverlässigen Überwachung der Restfüllmenge eines in dem Inhalator bevorrateten Wirkmediums wird es ferner möglich, die rezeptgemäße Einnahme eines Dosieraerosols besser im Auge zu behalten. Die erfindungsgemäß ausgebildete Dosierzähleinrichtung erlaubt beispielsweise eine von 0 bis ca. 200 aufsteigende Zählung der einzelnen Dosierungen. Alternativ dazu ist es auch möglich, die Zifferanordnung auf den beiden Zählringen derart vorzunehmen, daß eine von der maximalen Hubzahl abwärts laufende Dosierzählung erfolgt. Die Zählung kann beispielsweise von der Zahl 200 abwärts laufend erfolgen, wobei beispielsweise dann, wenn die Resthubzahl ≤ 50 ist, in der Anzeigeeinrichtung eine Farbmarkierung, beispielsweise in Form eines Signalbalkens, sichtbar wird, der dem entsprechenden Benutzer rechtzeitig die Nachbeschaffung eines entsprechenden Inhalators signalisiert.

Die mittels der erfindungsgemäßen Dosierzähleinrichtung erreichte Verbesserung der Anzeigegenauigkeit erlaubt es, die aus Sicherheitsgründen vorgenommene Überfüllung des Abgabebehälters und damit die ggf. in dem Abgabebehälter verbleibende Wirkstoffrestmenge zu verringern.

Eine im Hinblick auf eine besonders zuverlässige Weiterschaltung des ersten Zählrings vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß der Schaltfinger von der Rotationsachse beabstandet und zu dieser geneigt angeordnet ist. Dadurch wird es auf kinematisch günstige Weise möglich, den Schaltfinger mit zählringseitig vorgesehenen Stellelementen in Eingriff zu bringen und den Schaltfinger anschließend um eine im wesentlichen quer zur Längsrichtung des Schaltfingers verlaufende Kippachse zu kippen. Der Anstellwinkel des Schaltfingers relativ zu einer durch den Zählring definier-

ten Radialebene liegt vorzugsweise im Bereich von 30 bis 60°. Hierbei ergeben sich bei günstigen Kräfteverhältnissen hinreichend große Transportwege des Schaltfingers.

Gemäß einer bevorzugten Ausführungsform der Erfindung ist der Schaltfinger aus einer Ausgangsstellung in eine zu dieser Ausgangsstellung geneigte Endstellung auslenkbar, wobei ein Eingriffsabschnitt des Schaltfingers bereits in der Ausgangsstellung desselben federnd nachgiebig in eine Eingriffsstellung mit dem ersten Zählring gedrängt ist. Dadurch wird auf zuverlässige Weise gewährleistet, daß jeder einzelne Abgabehub des Inhalators durch die Dosierzähleinrichtung erfaßt wird.

Eine im Hinblick auf eine besonders günstige Umsetzung der Abgabehubbewegung des Abgabebehälters des Inhalators in eine zum Betrieb der Dosierzähleinrichtung erforderliche Weiterschaltbewegung vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß ein Armteil vorgesehen ist, das mit dem Schaltfinger gekoppelt ist, wobei das Armteil und der Schaltfinger einen Kniegelenkmechanismus bilden. Dadurch wird bei weiterhin vorteilhaften Kräfteverhältnissen ein vergleichsweise großer Schaltfinger-Transportweg gewährleistet, wodurch es möglich wird, die auf dem ersten Zählring vorgesehenen Ziffern derart weit voneinander beabstandet anzuordnen, daß stets nur eine einzige Ziffer des Zählrings in einem Fensterabschnitt sichtbar ist.

Die zur Zurückstellung des Schaltfingers erforderlichen Rückstellkräfte können auf vorteilhafte Weise durch elastische Verformung des Schaltfingers oder der mit dem Schaltfinger gekoppelten Betätigungselemente aufgebracht werden. Der Schaltfinger besteht in vorteilhafter Weise aus einem Kunststoffmaterial, vorzugsweise einem thermoplastisch umformbaren Kunststoffmaterial.

Eine im Hinblick auf eine zuverlässige Betätigung des Schaltfingers vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß das Armteil und der Schaltfinger über einen Betätigungsabschnitt miteinander verbunden sind. Der Betätigungsabschnitt bildet in vorteilhafter Weise eine einem Schulterabschnitt des Abgabebehälters des Inhalators zugewandte Anlagefläche, die beim Absenken des Abgabebehälters im Rahmen eines Dosierhubs aus einer Ausgangsstellung ausgelenkt, insbesondere im wesentlichen in Axialrichtung des Abgabebehälters, verschoben wird.

Das Armteil und der Schaltfinger sind gemäß einer bevorzugten Ausführungsform der Erfindung einstückig ausgebildet. Vorteilhafterweise ist bei dieser Ausführungsform der Betätigungsabschnitt in einem Verbindungsbereich zwischen Armteil und Schaltfinger vorgesehen. Die Bewegbarkeit von Armteil und Schaltfinger zueinander resultiert im wesentlichen aus der Elastizität des Werkstoffes im Bereich der entsprechenden Übergangsstellen. Die Geometrie dieser Übergangsabschnitte ist derart gewählt, daß zumindest im Rahmen der vorgesehenen Anzahl an Dosierhüben keine erhebliche Materialermüdung oder Querschnittsschwächung in den entsprechenden Verbindungsabschnitten auftritt.

Eine im Hinblick auf eine besonders hohe Funktionszuverlässigkeit der Dosierzähleinrichtung vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß zumindest der erste Zählring, vorzugsweise auch der zweite Zählring, und in besonders vorteilhafter Weise auch der Schaltfinger aus POM gefertigt sind. Die restlichen Komponenten des Inhalators können aus vergleichsweise preiswerten Kunststoffen, wie beispielsweise Polystyrol oder Polyethylen oder sonstigen, vorzugsweise thermoplastisch umformbaren Kunststoffen gebildet sein.

Eine im Hinblick auf eine besonders kompakte und funktionszuverlässige Ausführungsform der Erfindung vorteilhafte Ausgestaltung der Dosierzähleinrichtung ist dadurch gegeben, daß der Schaltfinger, der Betätigungsabschnitt und das Armteil sich im wesentlichen bogenförmig um die Rotationsachse des ersten Zählrings erstrecken. Der Radius dieses Bogens entspricht in vorteilhafter Weise im wesentlichen dem halben Durchmesser der an dem Abgabebehälter ausgebildeten Schulter. Dadurch wird es auf vorteilhafte Weise möglich, die Zählring-Weiterschaltvorrichtung unmittelbar im Bereich des Abgabeventils des Inhalators anzuordnen. Dadurch wird es auf weiterhin vorteilhafte Weise möglich, einen zur Führung des Abgabebehälters des Inhalators vorgesehenen Gehäuseabschnitt durch ein separat ausgebildetes und auf ein Mundstück des Inhalators aufgestecktes Rohrelement auszubilden.

Eine im Hinblick auf eine zuverlässige Zählung der einzelnen Dosierhübe vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß eine Rücklaufsperrvorrichtung vorgesehen ist, die eine Rastklinke aufweist, die spätestens beim Weitertransport des ersten Zählrings um einen Zählschritt in einen entsprechenden zählringseitig ausgebilde-

ten Eingriffsabschnitt eingreift. Alternativ dazu oder auch in Kombination mit einer derartigen Rastklinke ist es möglich, eine Drehung des ersten Zählrings entgegen der Zählring-Weiterschalttrichtung auch durch einen reibschlüssig sperrenden Mechanismus zu verhindern. Die Zählring-Weiterschaltvorrichtung und in vorteilhafter Weise auch die Rücklaufsperrvorrichtung sind gemäß eines besonderen Aspekts der vorliegenden Erfindung derart ausgebildet, daß diese jeden Abgabe- bzw. Dosierhub zählt.

In vorteilhafter Weise ist der Weiterschaltmechanismus derart ausgebildet, daß der erste Zählring auch dann betätigt bzw. weitergedreht wird, wenn ein Abgabehub nur unvollständig ausgeführt wurde. Eine im Hinblick auf eine besonders leichtgängige Ausgestaltung der Rücklaufsperrvorrichtung vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß mehrere Rastklinken vorgesehen sind, die mit entsprechenden am ersten Zählring ausgebildeten Eingriffsabschnitten in Eingriff bringbar sind, wobei die einzelnen Rastklinken derart versetzt ausgebildet sind, daß diese Rastklinken sich jeweils in unterschiedlichen Eingriffszuständen befinden.

Die Länge des Armteils und die Länge des Schaltfingers sowie die Position des Armteils und des Schaltfingers sind in vorteilhafter Weise derart abgestimmt, daß bei einer Verlagerung des Betätigungselementes um eine vorgegebene Wegstrecke der Eingriffsabschnitt des Schaltfingers sich in Umfangsrichtung des ersten Zählrings um eine Wegstrecke verlagert, deren Länge im wesentlichen der Schrittlänge einer umfangsseitig an dem ersten Zählring vorgesehenen Skalierung entspricht. Dadurch wird es auf vorteilhafte Weise möglich, die zur Anzeige jedes einzelnen Zählschrittes erforderliche Nummernkombination eindeutig zur Anzeige zu bringen.

Eine im Hinblick auf eine besonders zuverlässige Zählung und Anzeige der einzelnen Dosierhübe vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß die Skalierung des ersten Zählringes die Ziffern 0, 1, 2... bis 9 trägt, wobei diese Ziffern in gleicher Umfangsteilung am Umfang des ersten Zählrings ausgebildet sind. Diese Ziffern können beispielsweise durch ein Siebdruckverfahren auf den Zählring aufgebracht werden. Gemäß einer besonders bevorzugten Ausführungsform der Erfindung wird die Skalierung jedoch über ein Laser-Beschriftungsverfahren unmittelbar in das Kunststoffmaterial des Zählrings eingebrannt.

Auch die Skalierung des zweiten Zählrings trägt in vorteilhafter Weise die Ziffern 0, 1, 2... bis 9. Die Beschriftung des zweiten Zählrings kann in der gleichen Weise erfolgen wie dies bezüglich des ersten Zählring vorangehend beschrieben wurde.

Eine im Hinblick auf die Zählung einer vergleichsweise großen Hubzahl vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß die Skalierung des zweiten Zählrings die Zahlen 0, 1, 2... bis 20 trägt. Dadurch wird es auf vorteilhafte Weise möglich, mit lediglich zwei Zählringen insgesamt 200 Dosierhübe zu zählen. Insbesondere bei dieser Ausführungsform ist an dem ersten Zählring die Ziffernfolge 0, 1, 2... bis 9 mehrfach, insbesondere 2- oder 3fach, abfolgend angeordnet. Dadurch wird der erforderliche Weiterschalttransportweg des ersten Zählrings erheblich verkürzt.

Die Koppelungsvorrichtung zur Koppelung des zweiten Zählrings mit dem ersten Zählring zur schrittweisen Drehung des zweiten Zählrings gemeinsam mit dem ersten Zählring umfaßt in vorteilhafter Weise eine an dem ersten Zählring ausgebildete, elastisch auslenkbare und mit einem Eingriffsabschnitt des zweiten Zählrings unmittelbar in Eingriff bringbare Zunge. Diese Zunge wird gemäß einer bevorzugten Ausführungsform der Erfindung durch eine relativ zum ersten Zählring stationär angeordnete Anlaufnase ausgelenkt, welche die elastisch auslenkbare Zunge mit dem zweiten Zählring über ein Winkelintervall in Eingriff hält, das exakt dem Weiterschalt-Schrittwinkel des zweiten Zählrings entspricht. Zur Realisierung entsprechender Übersetzungsverhältnisse können bedarfsweise mehrere derartige Anlaufnasen an einem relativ zum ersten Zählring stationär angeordneten Bauteil des Inhalators ausgebildet sein. Gegebenenfalls ist es auch möglich, mehrere elastisch auslenkbare und mit dem zweiten Zählring unmittelbar in Eingriff bringbare Zungenelemente an dem ersten Zählring auszubilden.

Eine im Hinblick auf eine besonders zuverlässige Betriebsweise dieser Koppelungsvorrichtung vorteilhafte Ausführungsform des Inhalators ist dadurch gegeben, daß der zweite Zählring einen Lagerungsabschnitt aufweist, der in den ersten Zählring drehbar eingesetzt oder auf den ersten Zählring aufgesetzt ist. Durch Ausbildung entsprechender Umfangsnuten und Eingriffsabschnitte zwischen den beiden Zählringen ist es möglich, die beiden Zählringe zueinander drehbar zu lagern und ein axiales Auseinanderziehen der beiden Zählringe zu verhindern. Die Position des ersten Zählrings relativ zu der An-

laufnase kann auf vorteilhafte Weise durch eine an dem ersten Zählring ausgebildete Umfangsnut eingehalten werden.

Die Drehung des zweiten Zählringes entgegen der Weiterschalttrichtung wird in vorteilhafter Weise durch eine weitere Rücklaufsperrvorrichtung verhindert.

Weitere Einzelheiten und Merkmale der Erfindung ergeben sich aus der nachfolgenden Beschreibung eines bevorzugten Ausführungsbeispiels in Verbindung mit der Zeichnung. Es zeigen:

Fig. 1 eine Längsschnittansicht durch einen Inhalator mit Mundstück und verschiebbar angeordnetem Abgabebehälter,

Figuren 2a, 2b und 2c eine Schemadarstellung zur Erläuterung der Transportmechanik der bei dem Inhalator gem. Fig. 1 vorgesehenen Zählring-Weiterschaltvorrichtung,

Figuren 3a und 3b Schemadarstellungen zur näheren Beschreibung einer bevorzugten Geometrie eines Schaltfingers, eines Betätigungsabschnittes und eines Armteiles,

Figuren 4a, 4b und 4c Axialschnittansichten durch den ersten und den zweiten Zählring zur Erläuterung der Funktionsweise der zur unmittelbaren Koppelung der ersten und zweiten Zählringe vorgesehenen Koppelungseinrichtung,

Fig. 5 eine Längsschnittansicht durch ein Blendenteil mit integral ausgebildetem Schaltfinger sowie integral ausgebildeter Rücklaufsperrvorrichtung,

Fig. 6 eine Radialschnittansicht entlang der Linie A-A in Fig. 5 zur Erläuterung des Aufbaus der Rücklaufsperrvorrichtung und

Fig. 7 eine vereinfachte Seitenansicht des Inhalators gemäß Fig. 1 mit einem im wesentlichen rechteckig ausgebildeten und entlang der Längsachse des Inhalators ausgerichtet verlaufenden Ablesefenster.

Der in Fig. 1 vereinfacht dargestellte Inhalator zur Abgabe eines Aerosols umfaßt einen entlang seiner Axialrichtung verschiebbar gelagerten Abgabebehälter 1, und einen zur Lagerung des Abgabebehälters 1 vorgesehenen Führungsschaft 2, der passend auf einen entsprechend ausgebildeten Verbindungsabschnitt eines Winkelstückes 3 aufgesetzt ist.

In dem Winkelstück 3 ist eine Sprühdüseneinrichtung 4 angeordnet, die in einem einstückig mit dem Winkelstück 3 ausgebildeten Zapfenabschnitt 5 ausgebildet ist. In diesen Zapfenabschnitt 5 ist ein Abgaberohr 6 des Abgabebehälters 1 in abdichtender Weise eingesetzt. Das Abgaberohr 6 ist in einem Kopfbereich 7 des Abgabebehälters 1 in axialer Richtung nachgiebig aufgenommen und durch eine Federeinrichtung (nicht sichtbar) derart vorgespannt, daß der Abgabebehälter 1 über das Abgaberohr 6 von dem Zapfenabschnitt 5 hinweggedrängt wird.

Im oberen Bereich des Führungsschaftes 2 ist eine Ausmuldung 8 vorgesehen, aus welcher ein Bodenbereich 9 des Abgabebehälters 1 hervorragt. Durch Aufbringen einer Druckkraft auf diesen Bodenbereich 9 kann der Abgabebehälter 1 zu dem Zapfenabschnitt 5 hin verschoben werden, wie dies durch Strichpunktlinien vereinfacht angedeutet ist. Sobald das Abgaberohr 6 an einer entsprechend in dem Zapfenabschnitt 5 ausgebildeten Anlagefläche ansteht, wird das Abgaberohr 6 in den Abgabebehälter 1 hineingedrängt und wirkt dabei mit einem Ventilmechanismus zusammen, über welchen eine vorbestimmte Menge eines in dem Abgabebehälters 1 bevorrateten Mediums aus diesem entströmen und über das Abgaberohr 6 zur Sprühdüseneinrichtung 4 und von dort aus in einen in dem Winkelstück 3 gebildeten Ansaugbereich 10 vordringen kann. Diese nachfolgend als Abgabehub bezeichnete Eintauchbewegung des Abgabebehälters 1 wird durch eine Dosierzähleinrichtung 11 gezählt.

Die Dosierzähleinrichtung 11 umfaßt hierzu einen ersten Zählring 12 und einen zweiten Zählring 13. Der erste Zählring 12 und der zweite Zählring 13 sind zueinander drehbar angeordnet. Der zweite Zählring 13 weist einen Dreh-Lagerungsabschnitt auf, der in einen entsprechenden Öffnungsbereich des ersten Zählrings 12 eingesetzt ist.

Der erste Zählring 12 und der zweite Zählring 13 sind coaxial zur Längsachse X des Abgabebehälters 1 angeordnet. Die beiden Zählringe 12, 13 sind in einem rohrförmigen Abschnitt des Winkelstückes 3 drehbewegbar angeordnet. An den Außenumfangsflächen der beiden Zählringe 12, 13 sind in nachfolgend noch näher erläuteter Weise Ziffern vorgesehen, die über eine Fensteröffnung 14, die in dem Winkelstück 3 ausgebildet ist, ablesbar sind.

Bei der in Fig. 1 dargestellten Ausführungsform des Inhalators befindet sich der zweite Zählring in etwa auf Höhe einer an dem Aufnahmebehälter 1 ausgebildeten Schulter 15. Der zweite Zählring 13 ist hinsichtlich seines Innendurchmessers derart dimensioniert, daß die Schulter 15 des Abgabebehälters 1 über eine der Abgabehublänge entsprechende Wegstrecke in den zweiten Führungsring 13 hinein eindringen kann.

In einem zwischen den beiden Zählringen 12, 13 und dem Kopfbereich 7 des Abgabebehälters verbleibenden Ringraum ist eine Zählring-Weiterschaltvorrichtung 16 vorgesehen, welche den coaxial zum Abgabebehälter 1 angeordneten Zählring 12 bei jedem Abgabehub um einen vorbestimmten Drehwinkel weiterdreht.

Die Zählring-Weiterschaltvorrichtung 16 ist bei der hier dargestellten Ausführungsform einstückig mit einem Blendenteil 17 ausgebildet, das in dem Winkelstück 3 eingesetzt ist. Das Blendenteil 17 bildet einen sich im wesentlichen ringförmig um die Längsachse X erstreckenden Lagerungsabschnitt, an welchem der zweite Zählring 13 gelagert ist.

An dem Blendenteil 17 ist einstückig mit diesem je eine Rücklaufsperrvorrichtung zum Sperren einer Drehbewegung der Zählringe 12, 13 in Gegenrichtung vorgesehen.

Das Blendenteil 17 ist ferner mit einer Anlaufnase versehen, die Teil einer im folgenden, ausführlich beschriebenen Koppelungsvorrichtung zur direkten Koppelung der beiden Zählringe 12, 13 bildet.

Die Zählring-Weiterschaltvorrichtung ist innerhalb der beiden Zählringe 12, 13 derart angeordnet, daß ein Betätigungsabschnitt 19 derselben mit der an dem Abgabebehälter 1 ausgebildeten Schulter in Berührungskontakt bringbar ist.

Die Funktionsweise der Zählring-Weiterschaltvorrichtung wird durch die Figuren 2a, 2b und 2c verdeutlicht. Die in den Figuren 2a, 2b und 2c dargestellte Zählring-Weiterschaltvorrichtung 16 umfaßt ein nachfolgend als Schaltfinger 20 bezeichnetes Getriebeglied, das bei der hier dargestellten Ausführungsform über den Betätigungsabschnitt 19 mit einem Armteil 21 gekoppelt ist. Bei der hier dargestellten Ausführungsform sind der Schaltfinger 20, der Betätigungsabschnitt 19 und das Armteil 21 einstückig miteinander ausgebildet und aufgrund der Eigenelastizität des hierbei verwendeten Kunststoffmaterials bewegbar miteinander gekoppelt.

Das Armteil 21 weist ein dem Betätigungsabschnitt 19 abgewandtes, stationäres Ende auf, über welches sich der gesamte durch Armteil 21, Betätigungsabschnitt 19 und Schaltfinger 20 gebildete Gelenkmechanismus in Umfangsrichtung des ersten Zählrings 12 abstützt.

Bei der hier gezeigten Anordnung bilden das Armteil 21 und der Schaltfinger 20 einen Kniehebel-Gelenkmechanismus. Durch allmähliches Niederdrücken des Betätigungsabschnittes entlang der hier angedeutet dargestellten Längsachse X des Abgabebehälters 1 werden das Armteil 21 und der Schaltfinger 20 allmählich in die in Fig. 2 dargestellte Endlage geschwenkt. Bezogen auf eine zu der Achse X senkrechte Projektionsfläche ergibt sich zwischen der Projektion der Position des bewegbaren Endes des Armteils 21 gegenüber der Projektion der Position dieses Endes in der Endstellung ein Versatz. Entsprechend diesem Versatz wird der Betätigungsabschnitt in Umfangsrichtung des ersten Zählrings verlagert. Auch der Schaltfinger 20 wird beim Niederdrücken des Betätigungsabschnittes geschwenkt, so daß sich dabei insgesamt eine Verlängerung der Projektion des Schaltfingers 20 in die zur genannten Längsachse X senkrechte Projektionsfläche ergibt. Nachdem der Schaltfinger 20 mit seinem dem ersten Zählring 12 abgewandten Endabschnitt ebenfalls mit dem Betätigungsabschnitt gekoppelt ist, ergibt sich eine Addition der durch Schwenken des Armteils und des Schaltfingers 20 erreichten Versatzstrecken. Zur Übertragung der entsprechenden in Umfangsrichtung des ersten Zählrings wirksamen Bewegungskomponente auf den ersten Zählring ist der Schaltfinger 20 mit einem Eingriffsabschnitt 22 versehen, der mit zählringseitig ausgebildeten Stellelementen in Eingriff bringbar ist. Durch entsprechende Verlagerung des Eingriffsabschnittes 22 des Schaltfingers 20 in Umfangsrichtung des ersten Zählrings 12 wird aufgrund des Eingriffs mit den Stellelementen 23 der erste Zählring 12 in Umfangsrichtung um eine vor-

bestimmte Wegstrecke weitertransportiert. Diese vorbestimmte Wegstrecke entspricht im wesentlichen dem Abstand zwischen zwei benachbarten Stellelementen 23. Nachdem der Betätigungsabschnitt 19 durch die an dem Abgabebehälter 1 ausgebildete Schulter in eine untere Endlage verlagert ist, federt beim Zurückfahren des Abgabebehälters 1 in dem Führungsschaft 2 auch der Betätigungsabschnitt 19 aufgrund der Eigenelastizität des Armteils 21 wieder in seine Ausgangsstellung zurück. Bei dieser Rückzugsbewegung überspringt der Schaltfinger 20 bzw. dessen Eingriffsabschnitt das beim nächsten Zählhub mit diesem in Eingriff tretende Stellelement 23 und federt unmittelbar hinter diesem Stellelement 23 wieder in eine Eingriffsstellung. Bei erneutem Niederdrücken des Betätigungsabschnittes 19 schiebt der Eingriffsabschnitt 22 des Schaltfingers das an dem ersten Zählring ausgebildete Stellelement 23 wieder um ein Transportintervall in Umfangsrichtung weiter. Hierbei tritt die nächstfolgende, an der Umfangsfläche des ersten Zählrings 12 vorgesehene Ziffer in die Fensteröffnung 14.

Bei den Darstellungen gemäß Fig. 2a, Fig. 2b und Fig. 2c ist die zur Weberschaltung des ersten Zählrings vorgesehene Zählring-Weberschaltvorrichtung in Form einer Abwicklung dargestellt.

Bei der in Fig. 1 dargestellten Ausführungsform erstreckt sich wie in Fig. 3b dargestellt der durch das Armteil 21, dem Betätigungsabschnitt 19 und den Schaltfinger 20 gebildete Gelenkmechanismus der Zählring-Weberschaltvorrichtung im wesentlichen bogenförmig um die Längsachse X des Abgabebehälters 1 (in Fig. 3b nicht dargestellt). Durch Niederdrücken des in Fig. 3b dargestellten Betätigungsabschnittes 19 wird ein Versatz des Eingriffsabschnittes 22 des Schaltfingers 21 in Umfangsrichtung erreicht. Durch den Versatz des Eingriffsabschnittes 22 des Schaltfingers 20 in Umfangsrichtung kann der erste Zählring 12 um einen Weberschaltwinkel α weitergedreht werden. Für den Fall, daß am Außenumfang des ersten Zählrings 12 drei Ziffern-Folgen der Ziffern 0 bis 9 vorgesehen sind, beträgt der Weberschaltwinkel α ca. 12° . Bei einem derartigen Drehwinkel ergibt sich bereits bei einem dem Durchmesser des Abgabebehälters 1 entsprechenden Durchmesser des ersten Zählrings 12 ein hinreichend großer Abstand zwischen den benachbarten Ziffern, wodurch eine gute Ablesbarkeit der einzelnen Ziffern in der Fensteröffnung 14 gewährleistet ist. Entsprechend der Anzahl der am Umfang des ersten Zählrings 12 abgebildeten Ziffernfolgen wird das Übersetzungsverhältnis zwischen dem ersten Zählring 12 und dem zweiten Zählring 13 bestimmt. Das erforderliche

Übersetzungsverhältnis zwischen den beiden Zählringen kann in vorteilhafter Weise durch die nachfolgend in Verbindung mit den Figuren 4a, 4b und 4c beschriebene Koppelungsvorrichtung erreicht werden.

Die in den Figuren 4a, 4b und 4c in unterschiedlichen Koppelungszuständen dargestellte Koppelungsvorrichtung umfaßt ein einstückig mit dem ersten Zählring 12 ausgebildetes Zungenelement 24, das sich bei der Darstellung gemäß Fig. 4a in einer Neutralstellung befindet. An dem Zungenelement 24 ist ein Mitnehmerabschnitt 25 ausgebildet. Dieser Mitnehmerabschnitt 25 ist mit Eingriffsvorsprüngen 26, die einstückig mit dem zweiten Zählring 13 ausgebildet sind, in Eingriff bringbar. Hierzu ist eine am Blendenteil 17 ausgebildete Anlaufnase 27 vorgesehen, die das Zungenelement in eine Kopplungsposition drängt, in welcher der am Ende des Zungenelementes 24 ausgebildete Mitnehmerabschnitt 25 mit dem unmittelbar benachbarten Eingriffsvorsprung 26 des zweiten Zählrings 13 in Eingriff tritt. Sobald ein entsprechender Eingriffszustand hergestellt ist, wird der zweite Zählring 13 gemeinsam mit dem ersten Zählring 12 solange weitergedreht, bis das Zungenelement 24 von der Anlaufnase 27 abfällt und damit der Eingriffszustand zwischen dem Mitnehmerabschnitt 25 und dem entsprechenden Eingriffsvorsprung 26 aufgehoben ist. Sobald dieser Eingriffszustand aufgehoben ist, kann der erste Zählring 12 über eine vorbestimmte Wegstrecke, unabhängig von dem zweiten Zählring 13, weitergedreht werden.

In Fig. 4b ist das Zungenelement 24 durch die in dieser Darstellung nicht sichtbare Anlaufnase 27 in die genannte Koppelungsstellung gedrängt. Die Länge der hier durch den Buchstaben b angegebenen Koppelungsstrecke ist durch die Geometrie der Anlaufnase 27 bestimmt.

In Fig. 4c ist das Zungenelement 24 bereits in seine Ausgangsstellung zurückgefedert und der Eingriff zwischen dem Mitnehmerabschnitt 25 und dem entsprechenden Eingriffsvorsprung 26 des zweiten Zählrings 13 aufgehoben.

Das bei der hier dargestellten Ausführungsform vorgesehene Zungenelement 24 ist einstückig mit dem ersten Zählring 12 als im wesentlichen flachblattfederartiges Bauteil ausgebildet. Im Hinblick auf die erforderlichen mechanischen Eigenschaften des Zungenelementes sowie im Hinblick auf eine besonders hohe Maßhaltigkeit des ersten

Zählrings 12 ist dieser vorzugsweise aus POM-Kunststoffmaterial gebildet. Bei der hier dargestellten Ausführungsform sind an der Außenumfangsfläche des zweiten Zählrings 13 die Zahlen 1 bis 20 angeordnet. Durch die beiden Zählringe 12, 13 können in dieser Ausführungsform 200 Dosierungen einzeln gezählt werden. Mit zwei Zählringen ist eine Zählung bis 999 möglich. Unter Verwendung eines dritten Zählrings sind 9.999 Zählungen möglich. Die Koppelungsvorrichtung zur Koppelung eines dritten Zählrings mit dem zweiten Zählring entspricht in ihrem Aufbau in vorteilhafter Weise der zwischen dem ersten Zählring 12 und dem zweiten Zählring 13 vorgesehenen Koppelungsvorrichtung.

Zur Verhinderung einer Drehbewegung des zweiten Zählrings 13 relativ zu dem ersten Zählring 12 entgegen der durch die Koppelungsvorrichtung 24, 25, 26 sowie die Anlaufnase 27 bestimmten Transportrichtung ist für die Zählringe 12 und 13 eine Rücklaufsperrvorrichtung 29 vorgesehen, die mit entsprechenden Rastabschnitten in Eingriff bringbar ist. Bei der hier dargestellten Ausführungsform werden diese Rastabschnitte der Rücklaufsperrvorrichtung auf einfache Weise durch die Eingriffsvorsprünge 23 und 26 gebildet.

In Fig. 5 sind das bei dem Inhalator gemäß Fig.1 vorgesehene Blendenteil 17 und der darauf aufgesetzte erste Zählring 12 vergrößert dargestellt. Bei der gezeigten Ausführungsform umfaßt die zur Verhinderung einer Drehbewegung des ersten Zählrings 12 entgegen der Zählringweiterrichtung vorgesehene Rücklaufsperrvorrichtung 28 ein einstückig mit dem Blendenteil 17 ausgebildetes Federelement 29, das mit Rastvorsprüngen 30, die am Innenumfang des ersten Zählrings 12 ausgebildet und der Zählringrotationsachse X zugewandt sind, in Eingriff bringbar ist. Die bei dieser Ausführungsform verwirklichte spezielle Geometrie des einstückig mit dem Blendenteil 17 ausgebildeten Federelementes geht aus der in Fig.6 vereinfacht dargestellten Radialschnittansicht entlang der Linie A-A hervor.

Wie aus der Darstellung gemäß Fig.5 weiter ersichtlich, weist das zur direkten Weiterdrehung des zweiten Zählrings 13 (nicht dargestellt) vorgesehene Zungenelement 24 einen flach rechteckförmigen Querschnitt auf und ragt von einer Innenumfangswandung des ersten Zählrings 12 in einen zwischen dem ersten Zählring 12 und dem Blendenteil 17 gebildeten Ringraum hinein. Dieser Ringraum ist in seinem oberen Bereich von einem Anlaufabschnitt 31 begrenzt, welcher den hier nicht dargestellten

zweiten Zählring 13 in axialer Richtung lagert. Das hier gezeigte Blendenteil 17 bildet ferner einen zweiten Anlaufabschnitt 32, durch welchen der erste Zählring 12 in axialer Richtung gelagert ist. Im Hinblick darauf, daß sich die ersten und zweiten Zählringe 12, 13 gegeneinander in axialer Richtung aufgrund der in Fig. 1 gezeigten Schulterstruktur abstützen, sind durch die genannten ersten und zweiten Anlaufabschnitte 31 und 32 die beiden Zählringe 12, 13 insgesamt in axialer Richtung gelagert.

Lediglich in Strichpunktlinien ist in der Schnittansicht gemäß Fig. 5 auch die zur Auslenkung des am Endabschnitt des Zungenelementes 24 vorgesehenen Mitnehmerabschnittes 25 vorgesehene Anlaufnase 27 gezeigt. Die einstückig mit dem Blendenteil 17 ausgebildete Zählringweitschaltvorrichtung 16, insbesondere deren Armteil 21, ist ebenfalls in Strichpunktlinien angedeutet dargestellt.

Die Ausbildung der angesprochenen Filigranstrukturen an einem in einem Hauptgehäuseabschnitt des Inhalators einsetzbaren Blendenteil erweist sich unter fertigungstechnischen Gesichtspunkten als vorteilhaft. Grundsätzlich ist es jedoch auch möglich, auf das Blendenteil 17 zu verzichten und die zur Sperrung der Rücklaufdrehbewegung des ersten Zählrings 12 vorgesehene Rücklaufsperrvorrichtung 28, die Zählringweitschaltvorrichtung und die entsprechenden Lagerungsabschnitte zur Lagerung der ersten und zweiten Zählringe 12, 13 unmittelbar, d.h. einstückig mit dem Winkelstück 3 auszubilden.

Die in der Schnittansicht gemäß Fig. 6 erkennbare Teilung der an dem ersten Zählring 12 vorgesehenen Rastvorsprünge 30 ist derart festgelegt, daß die durch das Federelement 23 gebildete Rücklaufsperrvorrichtung den ersten Zählring 12 nach jedem Zählschritt erneut verrastet. Durch entsprechende Verkleinerung der Rastvorsprünge 30 und Verkleinerung der Abstände zwischen den abfolgenden Rastvorsprüngen ist es möglich, das Rastintervall der Rücklaufsperrvorrichtung zu verkleinern und damit eine Drehbewegung des ersten Zählrings auch dann zu verhindern, wenn dieser erste Zählring 12 nicht um einen vollständigen Zählschritt weitergedreht ist. Durch entsprechende Auslegung der Geometrie des Federelementes 29 kann der durch die Rücklaufsperrvorrichtung 28 erzeugte Drehwiderstand auf einem vergleichsweise geringen Wert gehalten werden.

In Fig.7 ist eine Seitenansicht (Seitenansicht von rechts) des in Fig.1 dargestellten Inhalators gezeigt. In der auf seiten des Ansaugbereiches 10 angeordneten Fensteröffnung 14 ist hier die Nummernangabe „200“ ablesbar. Diese Nummernangabe wird gebildet durch die über den ersten Zählring 12 in die Fensteröffnung 14 geschobene Ziffer „0“ und die über den zweiten Zählring 13 in die Fensteröffnung geschobene Zahl „20“. Im Falle einer beispielsweise abwärts laufenden Zählung wird bei der nächsten Betätigung des Inhalators sowohl der erste Zählring 12 als auch der zweite Zählring 13 um ein Winkelintervall (α) um die Längsachse X des Inhalators weitergedreht. Hierbei gelangt über den ersten Zählring 12 die Ziffer „9“ und über den zweiten Zählring 13 die Zahl „19“ in die Fensteröffnung 14. Damit wird in der Fensteröffnung 14 die Zahl „199“ angezeigt. Bei der nächsten Betätigung des Inhalators wird nur der erste Zählring 12 weitergedreht und die Ziffer „8“ gelangt in die Fensteröffnung 14. In der Fensteröffnung 14 wird nunmehr die Zahl „198“ angezeigt. Im Rahmen der nachfolgenden Dosierhübe wird zunächst nur der erste Zählring 12 jeweils um einen Zählschritt weitergedreht, bis die Ziffer „1“ in die Fensteröffnung 14 eintritt und in der Fensteröffnung 14 die Zahl „191“ angezeigt wird. Bei der nächstfolgenden Betätigung des Inhalators wird über den in den Fig.4a bis 4c gezeigten Koppelungsmechanismus der erste Zählring 12 unmittelbar mit dem zweiten Zählring gekoppelt und der erste Zählring 12 gemeinsam mit dem zweiten Zählring 13 um einen Zählschritt weitergedreht. Hierbei gelangt die umfangsseitig an dem ersten Zählring vorgesehene Ziffer 0 und die umfangsseitig an dem zweiten Zählring 13 vorgesehene Zahl „19“ in die Fensteröffnung 14. In der Fensteröffnung 14 wird nunmehr die Zahl „190“ angezeigt. Sobald die Zahl „19“ vollständig in die Fensteröffnung 14 gelangt ist, tritt der zur direkten Koppelung der ersten und zweiten Zählringe 12,13 vorgesehene Koppelungsmechanismus wieder in eine Freigabestellung und der erste Zählring 12 wird im Rahmen der nächsten Dosierhübe unabhängig von dem zweiten Zählring 13 gedreht, bis erneut die an dem ersten Zählring 12 vorgesehene Ziffer „1“ in die Fensteröffnung 14 gelangt.

Um eine im wesentlichen gleiche Teilung der Ziffernfolgen an dem ersten Zählring 12 und dem zweiten Zählring 13 zu erreichen, ist die Ziffernfolge 0 bis 9 zweifach abfolgend am Außenumfang des ersten Zählrings 12 ausgebildet. Bei einer, bezogen auf die Umfangsrichtung der Zählringe schmalere Ausgestaltung der Fensteröffnung 14 können an dem zweiten Zählring 13 beispielsweise die Zahlen 0 bis 40 ausgebildet

werden. Bei entsprechender Abstimmung des Übersetzungsverhältnisses zwischen dem ersten und dem zweiten Zählring 12, 13, beispielsweise durch Vervielfachung der zum Weitertransport des zweiten Zählrings vorgesehenen Anzahl an Anlaufnasen 27 können mit lediglich zwei Zählringen Hubzahlen von 0 bis 400 aufsteigend oder bedarfsweise auch abfallend gezählt werden.

Die Erfindung ist nicht auf das vorgehend beschriebene Ausführungsbeispiel beschränkt. Beispielsweise ist es auch möglich, auf das bei dem vorangehend beschriebenen bevorzugten Ausführungsbeispiel des Inhalators vorgesehene Blendenteil 17 zu verzichten und die entsprechenden Funktionsteile integral mit dem Gehäuse des Inhalators auszubilden. Bedarfsweise können durch den beschriebenen Inhalator auch aerosolfreie Wirkstoffe abgegeben werden. Zur Bereitstellung eines noch größeren Zählbereiches ist es möglich, einen dritten Zählring vorzusehen, der über einen entsprechenden Koppelungsmechanismus mit dem zweiten Zählring koppelbar ist.

Schutzansprüche:

1. Inhalator zur Abgabe eines Aerosols, mit:

- einer Dosierzähleinrichtung (11),
- einer Gehäuseeinrichtung (2, 3), und
- einem relativ zu der Gehäuseeinrichtung (2, 3) entlang seiner Längsachse verschiebbar angeordneten Aerosol-Abgabebehälter (1),

gekennzeichnet durch

- einen ersten Zählring (12), der coaxial zur Längsachse (X) des Aerosol-Abgabebehälters (1) angeordnet ist und um diese Längsachse (X) drehbar ist,
- einen zweiten Zählring (13), der coaxial zu dem ersten Zählring (12) angeordnet und mit diesem direkt koppelbar und relativ zu diesem drehbar ist,
- einer Zählringweitschaltvorrichtung (16) zur Drehung des ersten Zählringes (12) bei Betätigung des Inhalators, und
- einer Koppelungsvorrichtung (24, 25, 26, 27) zur Koppelung des zweiten Zählringes (13) mit dem ersten Zählring (12), zur schrittweisen Drehung des zweiten Zählringes (13) gemeinsam mit dem ersten Zählring (12),
- wobei die Zählringweitschaltvorrichtung (16) einen Betätigungsabschnitt (19) und einen mit diesem gekoppelten Schaltfinger (20) aufweist, der zur Drehung des zugehörigen Zählringes (12) mit Stellelementen (23) desselben in Eingriff bringbar ist.

2. Inhalator nach Anspruch 1, **dadurch gekennzeichnet**, daß der Schaltfinger (20) von der Rotationsachse (X) beabstandet und zu dieser geneigt angeordnet ist.

3. Inhalator nach Anspruch 1 oder 2 **dadurch gekennzeichnet**, daß der Schaltfinger (20) aus einer Ausgangsstellung in eine zu dieser Ausgangsstellung geneigte Endstellung auslenkbar ist, und in der Ausgangsstellung ein Eingriffsabschnitt des Schaltfingers (20) federnd nachgiebig in eine Eingriffsstellung mit dem ersten Zählring (12) gedrängt ist.

4. Inhalator nach mindestens einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet**, daß ein Armteil (21) vorgesehen ist das mit dem Schaltfinger (20) gekoppelt

ist, und daß das Armteil (21) und der Schaltfinger (20) einen Kniegelenkmechanismus bilden.

5. Inhalator nach mindestens einem der Ansprüche 1 bis 4, **dadurch gekennzeichnet**, daß das Armteil (21) elastisch nachgiebig ausgebildet ist und an einem stationären Teil (17) insbesondere einem mit der Gehäuseeinrichtung (2, 3) gekoppelten Teil abgestützt ist.

6. Inhalator nach mindestens einem der Ansprüche 1 bis 5, **dadurch gekennzeichnet**, daß das Armteil (21) und der Schaltfinger (20) über den Betätigungsabschnitt (17) miteinander verbunden sind.

7. Inhalator nach mindestens einem der Ansprüche 1 bis 6, **dadurch gekennzeichnet**, daß das Armteil (21) und der Schaltfinger (20) einstückig ausgebildet sind.

8. Inhalator nach mindestens einem der Ansprüche 1 bis 7, **dadurch gekennzeichnet**, daß das Armteil (21) und der Schaltfinger (20) aus einem Kunststoffmaterial insbesondere POM ausgebildet sind.

9. Inhalator nach mindestens einem der Ansprüche 1 bis 8, **dadurch gekennzeichnet**, daß der Betätigungsabschnitt (19) in eine zur Rotationsachse des ersten Zählringes (12) im wesentlichen parallele Richtung geführt ist, und daß das Armteil (21) ein Federelement bildet das den Schaltfinger (20) in seine Ausgangsstellung drängt.

10. Inhalator nach mindestens einem der Ansprüche 1 bis 9, **dadurch gekennzeichnet**, daß der Betätigungsabschnitt (19) eine Anlagefläche bildet die mit einer Schulter (19) des Aerosol-Abgabebehälters (1) in Anlage bringbar ist.

11. Inhalator nach mindestens einem der Ansprüche 1 bis 10, **dadurch gekennzeichnet**, daß der Schaltfinger (20), der Betätigungsabschnitt (19) und das Armteil (21) sich im wesentlichen bogenförmig um die Rotationsachse (X) des ersten Zählringes (12) erstrecken.

12. Inhalator nach mindestens einem der Ansprüche 1 bis 11, **dadurch gekennzeichnet**, daß eine Rücklaufsperrvorrichtung (28) vorgesehen ist, zum Verhindern einer Drehbewegung des ersten Zählrings (12) entgegen der Zählrichtung.

13. Inhalator nach Anspruch 12, **dadurch gekennzeichnet**, daß die Rücklaufsperrvorrichtung (28) eine Rastklinke aufweist.

14. Inhalator nach mindestens einem der Ansprüche 1 bis 13, **dadurch gekennzeichnet**, daß die Länge des Armteiles (21) und die Länge des Schaltfingers (20) sowie die Position des Armteiles (21) und des Schaltfingers (2a) derart abgestimmt sind, daß bei einer Verlagerung des Betätigungselementes (19) um eine vorgegebene Wegstrecke der Eingriffsabschnitt (22) des Schaltfingers (20) sich in Umfangsrichtung des ersten Zählrings (12) um eine Wegstrecke verlagert deren Länge im wesentlichen der Schrittlänge einer umfangsseitig an dem ersten Zählring (12) vorgesehenen Skalierung entspricht.

15. Inhalator nach mindestens einem der Ansprüche 1 bis 14, **dadurch gekennzeichnet**, daß die Skalierung des ersten Zählrings (12) die Ziffern 0, 1, 2... bis 9 trägt.

16. Inhalator nach mindestens einem der Ansprüche 1 bis 15, **dadurch gekennzeichnet**, daß die Skalierung des zweiten Zählrings (13) die Ziffern 0, 1, 2,... bis 9 trägt.

17. Inhalator nach mindestens einem der Ansprüche 1 bis 15, **dadurch gekennzeichnet**, daß die Skalierung des zweiten Zählrings (13) die Zahlen 0, 1, 2,...9, 10, 11,... 19 und 20 trägt.

18. Inhalator nach Anspruch 15, **dadurch gekennzeichnet**, daß die Ziffernfolge 0, 1...9 am Umfang des ersten Zählrings (12) mehrfach; insbesondere dreimal abfolgend vorgesehen ist.

19. Inhalator nach mindestens einem der Ansprüche 1 bis 18, **dadurch gekennzeichnet**, daß der zweite Zählring (13) einen Lagerungsabschnitt aufweist, der in den ersten Zählring (12) drehbar eingesetzt oder auf diesen aufgesetzt ist.

20. Inhalator nach mindestens einem der Ansprüche 1 bis 19, **dadurch gekennzeichnet**, daß die Koppelungsvorrichtung (24, 25, 26, 27) ein Mitnehmerelement aufweist das mit dem ersten Zählring (12) gekoppelt ist.

21. Inhalator nach Anspruch 20, **dadurch gekennzeichnet**, daß das Mitnehmerelement durch ein elastisch nachgiebiges Zungenelement (24) gebildet ist, das einstückig mit dem ersten Zählring (12) ausgebildet ist.

22. Inhalator nach Anspruch 20 oder 21, **dadurch gekennzeichnet**, daß der zweite Zählring (13) einen Verzahnungsabschnitt aufweist der mit dem Zungenelement (24) in Eingriff bringbar ist.

23. Inhalator nach einem der Ansprüche 20 bis 22, **dadurch gekennzeichnet**, daß die Koppelungsvorrichtung eine stationäre Anlauf-Nase (27) aufweist, zum Auslenken des Zungenelements (24) derart, daß dieses über eine, einem Zählschritt entsprechende Umfangslänge mit dem zweiten Zählring (13) in Eingriff tritt und den zweiten Zählring (13) um diese Umfangslänge weiterdreht.

24. Inhalator nach Anspruch 23, **dadurch gekennzeichnet**, daß drei in Umfangsrichtung gleichmäßig beabstandete stationäre Anlauf-Nasen (27) vorgesehen sind derart, daß der zweite Zählring (13) bei einem vollständigen Umlauf den zweiten Zählring (13) um drei Zählschritte weiterdreht.

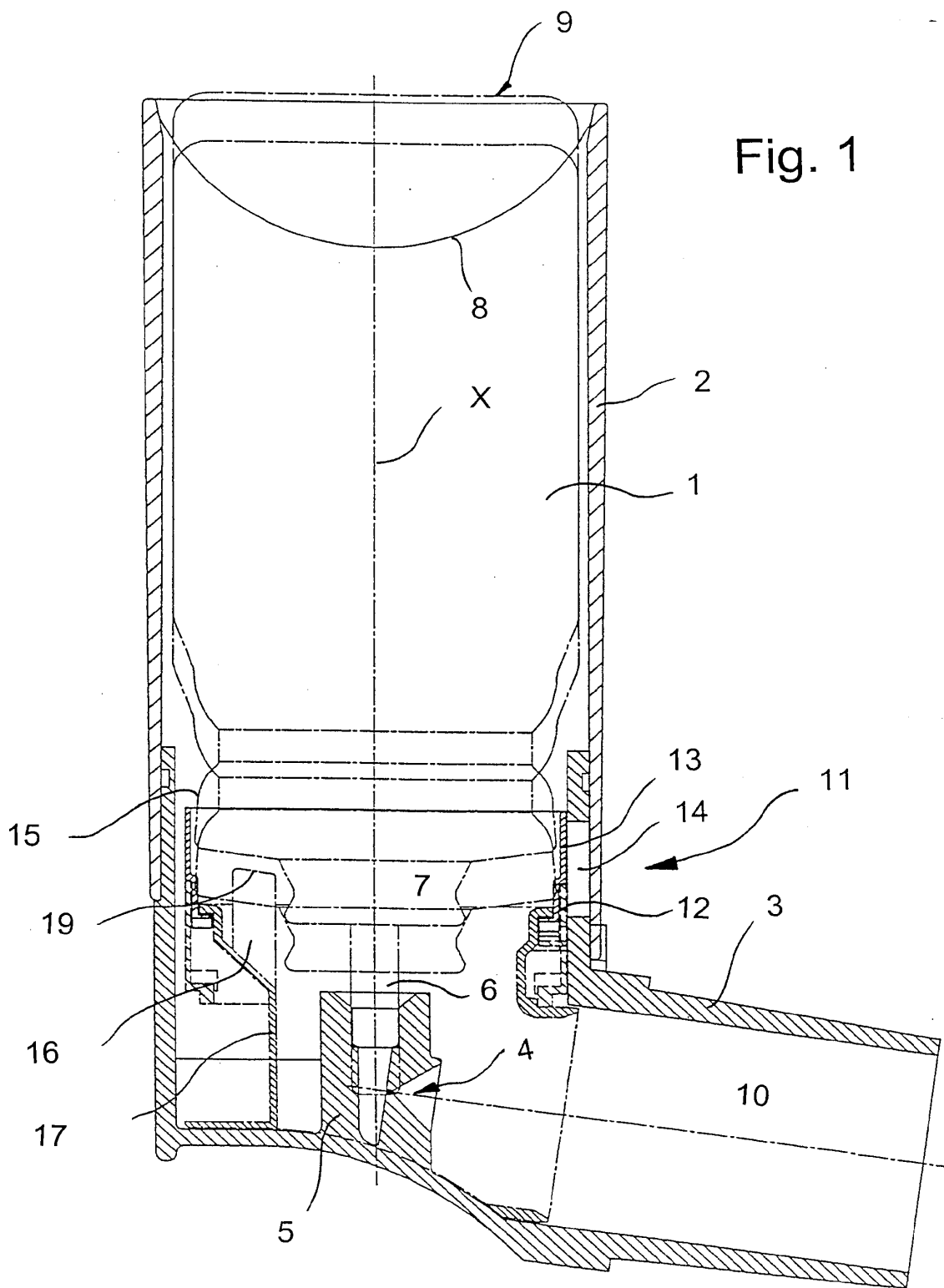


Fig. 2a

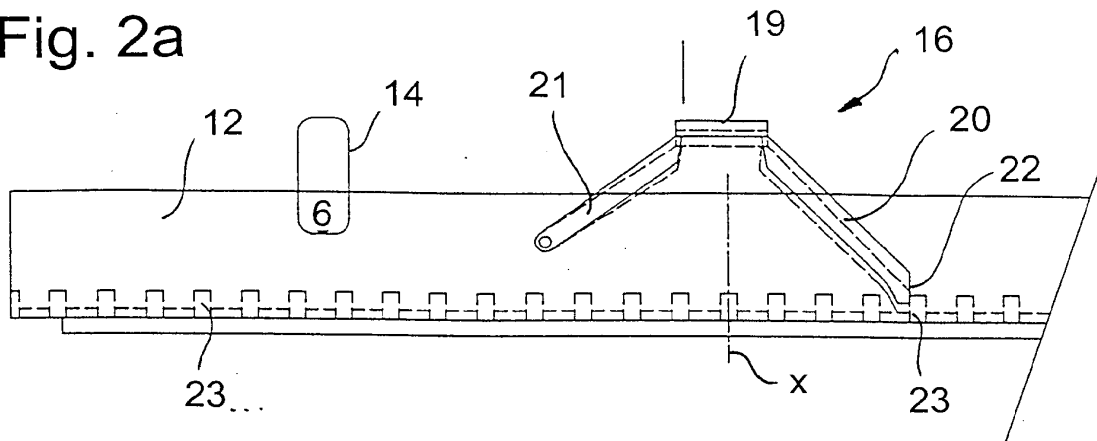


Fig. 2b

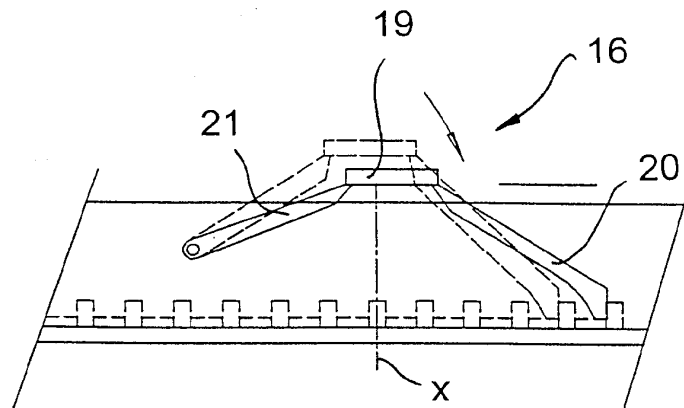


Fig. 2c

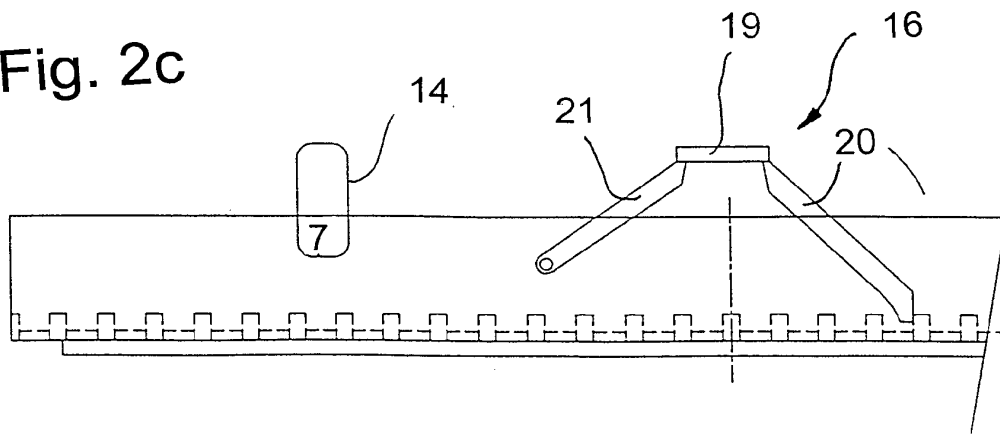


Fig. 3a

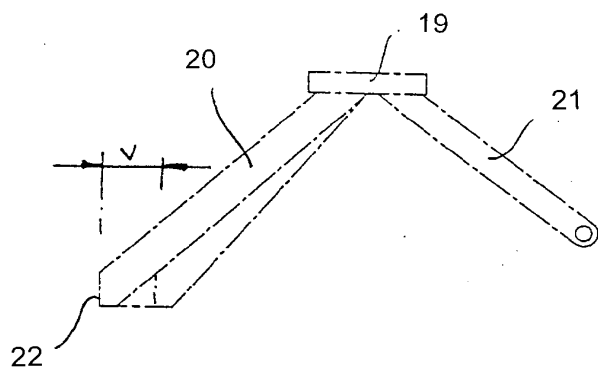
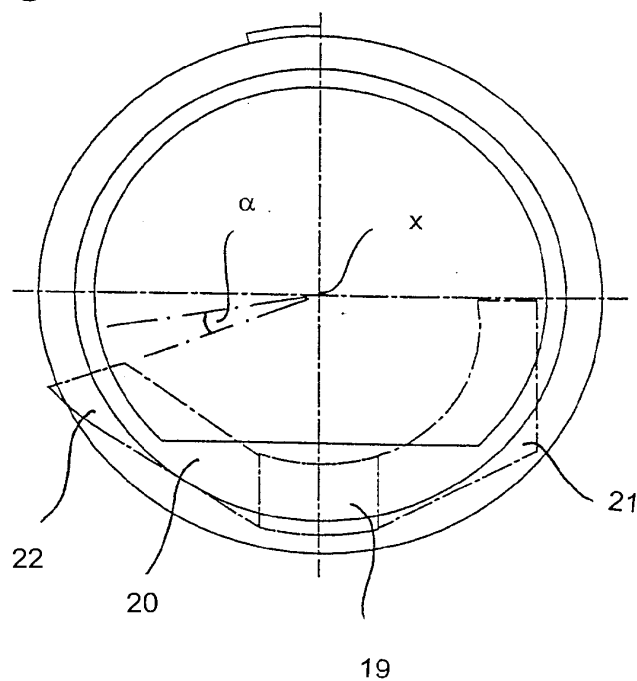


Fig. 3b



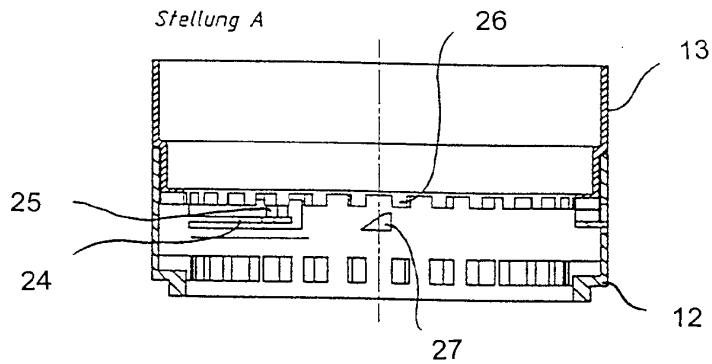


Fig. 4a

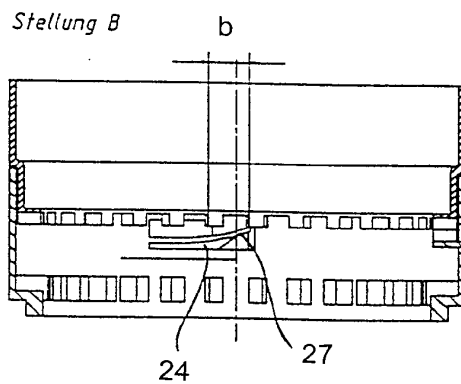


Fig. 4b

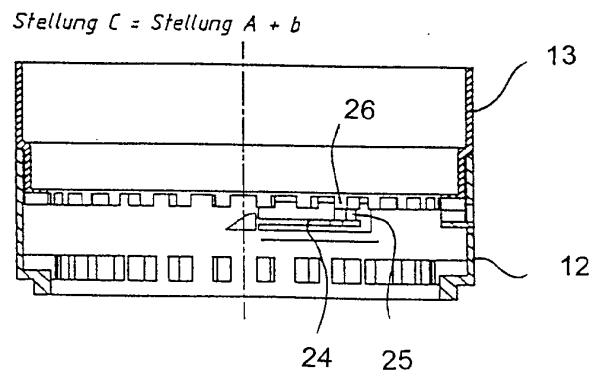


Fig. 4c

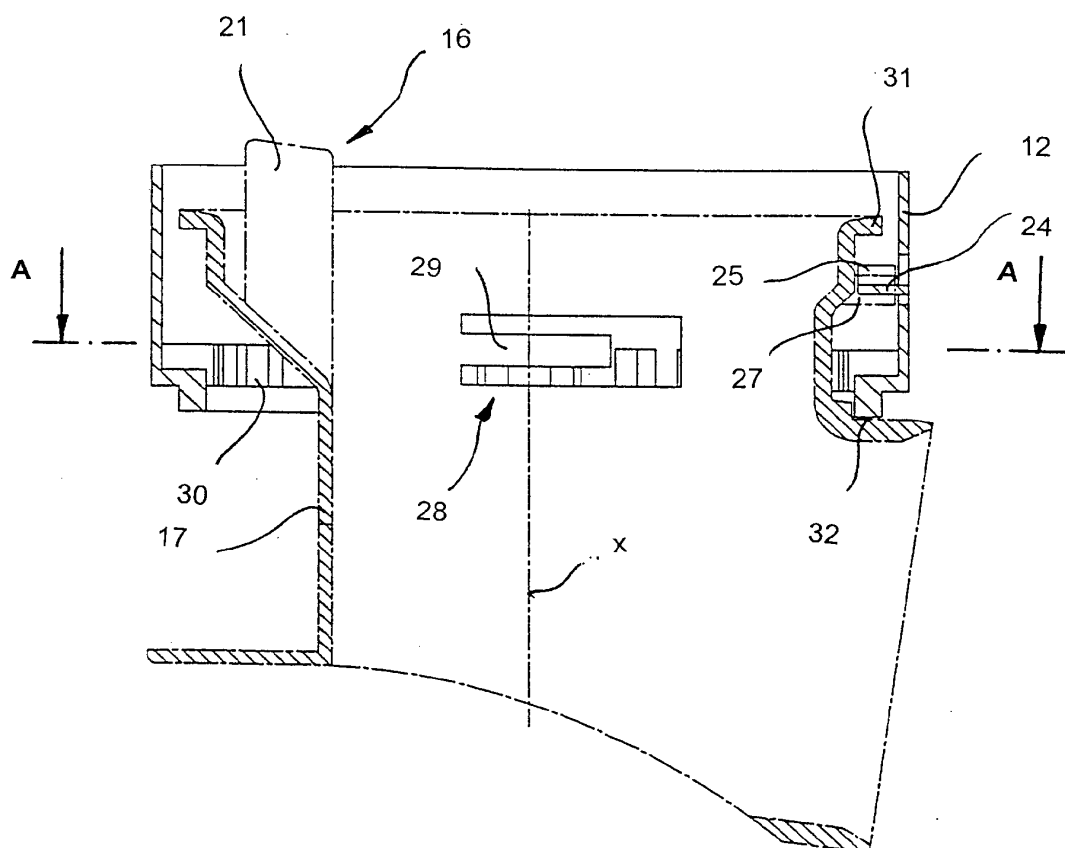


Fig. 5

A-A

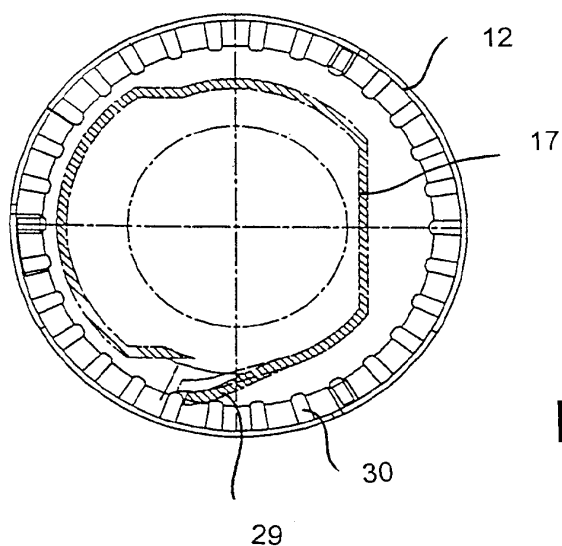


Fig. 6

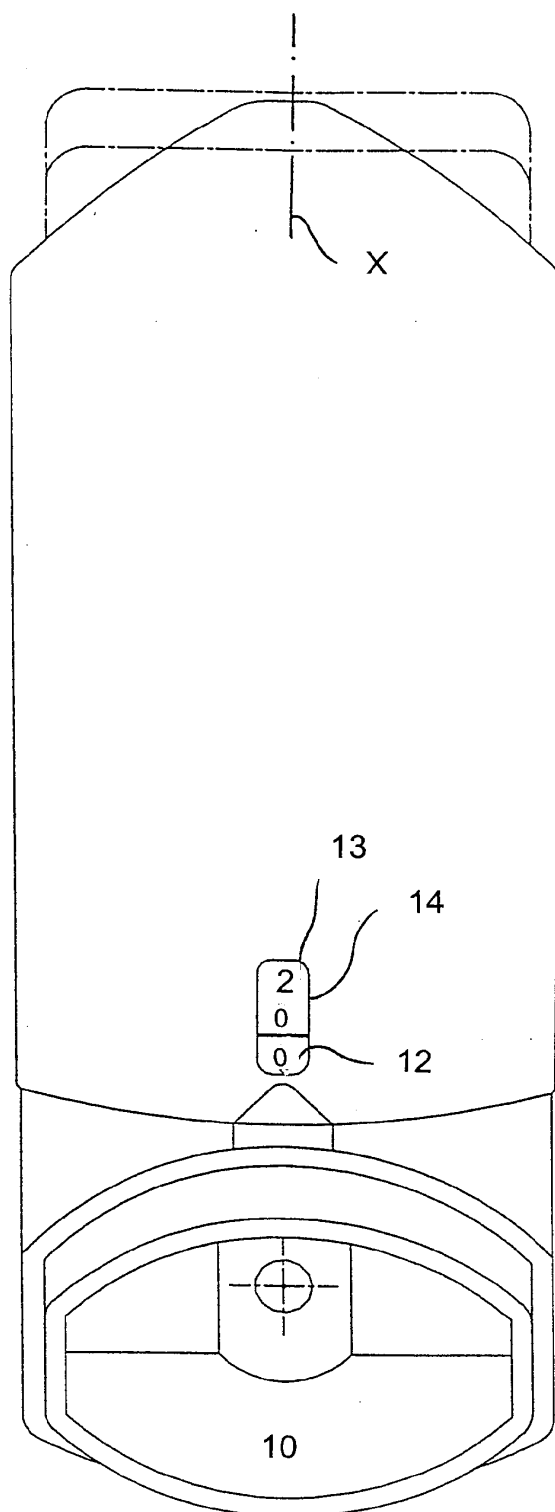


Fig. 7

INTERNATIONAL SEARCH REPORT

International Application No
PC/EP 99/05939

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M15/00 G06M1/08 G06M1/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M G06M B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 022 212 A (VANTOREX LTD) 31 July 1970 (1970-07-31) page 3, line 37 -page 4, line 24 figures 1,2	1, 15, 16, 20
Y		2-7, 9, 12-14, 17-19
Y	EP 0 480 488 A (ELETTRIO PLASTICA SPA) 15 April 1992 (1992-04-15) column 4, line 4 - line 33 figures 4,5 --- -/--	2-7, 9, 14

☒ Further documents are listed in the continuation of box C.

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Date of the actual completion of the international search

24 November 1999

Date of mailing of the international search report

01/12/1999

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Lakkis, A

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 99/05939

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 94 14492 A (AMBROSIO THOMAS J ;MANTHENA SRINIVAS (US); SCHERING CORP (US); WIL) 7 July 1994 (1994-07-07) page 30, line 5 -page 31, line 5 page 49, line 26 - line 30 page 50, line 13 - line 25 page 65, line 35 -page 66, line 14 figures 3,4,67,71,75,105	12,13, 17-19
A	----	2,3,5,11
A	WO 96 29278 A (SENETICS INC) 26 September 1996 (1996-09-26) ----	
E	EP 0 949 584 A (BASON NEIL PETER) 13 October 1999 (1999-10-13) paragraphs '0018!-'0021! figures 2,3 -----	1,15-17, 19-22

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page 2 of 2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PC, EP 99/05939

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2022212 A	31-07-1970	AU 6168869 A GB 1290484 A ZA 6906865 A	08-04-1971 27-09-1972 27-05-1971
EP 0480488 A	15-04-1992	IT 1243820 B AT 113486 T AU 646873 B AU 8025891 A CA 2046806 A DE 69104950 D DE 69104950 T ES 2066336 T JP 5228213 A US 5174473 A	28-06-1994 15-11-1994 10-03-1994 16-04-1992 10-04-1992 08-12-1994 09-03-1995 01-03-1995 07-09-1993 29-12-1992
WO 9414492 A	07-07-1994	AT 177323 T AU 683036 B AU 5748794 A CA 2152088 A CN 1091321 A CZ 9501535 A DE 69323897 D DE 69323897 T EP 0674533 A ES 2128550 T FI 952976 A GR 3030035 T HU 73522 A, B IL 108061 A JP 2924924 B JP 8500756 T NO 952429 A NZ 259241 A PL 309401 A SG 52237 A SK 80695 A US 5829434 A US 5687710 A US 5740792 A ZA 9309472 A	15-03-1999 30-10-1997 19-07-1994 07-07-1994 31-08-1994 15-05-1996 15-04-1999 04-11-1999 04-10-1995 16-05-1999 16-06-1995 30-07-1999 28-08-1996 10-06-1997 26-07-1999 30-01-1996 18-08-1995 20-12-1996 02-10-1995 28-09-1998 07-02-1996 03-11-1998 18-11-1997 21-04-1998 19-06-1995
WO 9629278 A	26-09-1996	US 5421482 A AU 7732794 A EP 0720568 A WO 9508484 A AU 688794 B BR 9407608 A CA 2172537 A CN 1133584 A JP 9502951 T US 5611444 A US 5718355 A US 5799651 A	06-06-1995 10-04-1995 10-07-1996 30-03-1995 19-03-1998 14-01-1997 30-03-1995 16-10-1996 25-03-1997 18-03-1997 17-02-1998 01-09-1998
EP 0949584 A	13-10-1999	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PC./EP 99/05939

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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	FR 2 022 212 A (VANTOREX LTD) 31. Juli 1970 (1970-07-31) Seite 3, Zeile 37 -Seite 4, Zeile 24 Abbildungen 1,2	1,15,16, 20
Y	---	2-7,9, 12-14, 17-19
Y	EP 0 480 488 A (ELETTRIO PLASTICA SPA) 15. April 1992 (1992-04-15) Spalte 4, Zeile 4 - Zeile 33 Abbildungen 4,5 --- -/--	2-7,9,14

☒ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

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24. November 1999

Absenddatum des internationalen Recherchenberichts

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Name und Postanschrift der internationalen Recherchenbehörde
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Bevollmächtigter Bediensteter

Lakkis, A

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PC 1, EP 99/05939

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN		
Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	WO 94 14492 A (AMBROSIO THOMAS J ;MANTHENA SRINIVAS (US); SCHERING CORP (US); WIL) 7. Juli 1994 (1994-07-07) Seite 30, Zeile 5 -Seite 31, Zeile 5 Seite 49, Zeile 26 - Zeile 30 Seite 50, Zeile 13 - Zeile 25 Seite 65, Zeile 35 -Seite 66, Zeile 14 Abbildungen 3,4,67,71,75,105	12,13, 17-19
A	----	2,3,5,11
A	WO 96 29278 A (SENETICS INC) 26. September 1996 (1996-09-26) ----	
E	EP 0 949 584 A (BASON NEIL PETER) 13. Oktober 1999 (1999-10-13) Absätze '0018!-'0021! Abbildungen 2,3 -----	1,15-17, 19-22

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Seite 2 von 2

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichung, die zur selben Patentfamilie gehören

Internationales Aktenzeichen

PC 17 EP 99/05939

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
FR 2022212 A	31-07-1970	AU 6168869 A	08-04-1971
		GB 1290484 A	27-09-1972
		ZA 6906865 A	27-05-1971
EP 0480488 A	15-04-1992	IT 1243820 B	28-06-1994
		AT 113486 T	15-11-1994
		AU 646873 B	10-03-1994
		AU 8025891 A	16-04-1992
		CA 2046806 A	10-04-1992
		DE 69104950 D	08-12-1994
		DE 69104950 T	09-03-1995
		ES 2066336 T	01-03-1995
		JP 5228213 A	07-09-1993
		US 5174473 A	29-12-1992
WO 9414492 A	07-07-1994	AT 177323 T	15-03-1999
		AU 683036 B	30-10-1997
		AU 5748794 A	19-07-1994
		CA 2152088 A	07-07-1994
		CN 1091321 A	31-08-1994
		CZ 9501535 A	15-05-1996
		DE 69323897 D	15-04-1999
		DE 69323897 T	04-11-1999
		EP 0674533 A	04-10-1995
		ES 2128550 T	16-05-1999
		FI 952976 A	16-06-1995
		GR 3030035 T	30-07-1999
		HU 73522 A,B	28-08-1996
		IL 108061 A	10-06-1997
		JP 2924924 B	26-07-1999
		JP 8500756 T	30-01-1996
		NO 952429 A	18-08-1995
		NZ 259241 A	20-12-1996
		PL 309401 A	02-10-1995
		SG 52237 A	28-09-1998
		SK 80695 A	07-02-1996
		US 5829434 A	03-11-1998
		US 5687710 A	18-11-1997
		US 5740792 A	21-04-1998
		ZA 9309472 A	19-06-1995
WO 9629278 A	26-09-1996	US 5421482 A	06-06-1995
		AU 7732794 A	10-04-1995
		EP 0720568 A	10-07-1996
		WO 9508484 A	30-03-1995
		AU 688794 B	19-03-1998
		BR 9407608 A	14-01-1997
		CA 2172537 A	30-03-1995
		CN 1133584 A	16-10-1996
		JP 9502951 T	25-03-1997
		US 5611444 A	18-03-1997
		US 5718355 A	17-02-1998
		US 5799651 A	01-09-1998
EP 0949584 A	13-10-1999	KEINE	

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 INTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE
 INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT)



(51) Internationale Patentklassifikation ⁷ : A61M 15/00	A1	(11) Internationale Veröffentlichungsnummer: WO 00/21593 (43) Internationales Veröffentlichungsdatum: 20. April 2000 (20.04.00)
(21) Internationales Aktenzeichen: PCT/EP99/06205 (22) Internationales Anmeldedatum: 24. August 1999 (24.08.99) (30) Prioritätsdaten: 198 46 382.0 8. Oktober 1998 (08.10.98) DE (71) Anmelder (für alle Bestimmungsstaaten ausser US): PARI GMBH SPEZIALISTEN FÜR EFFEKTIVE INHALATION [DE/DE]; Moosstrasse 9, D-82319 Starnberg (DE). (72) Erfinder; und (75) Erfinder/Anmelder (nur für US): GALLEM, Thomas [DE/DE]; Plinganserstrasse 26, D-81369 München (DE). STAPLETON, Kevin [US/US]; Apartment 3, 6 Beals Street, Brookline, MA 02446-3011 (US). KNOCH, Martin [DE/DE]; Am Vogelbichl 5, D-82335 Berg (DE). (74) Anwälte: FÜCHSLE, Klaus usw.; Hoffmann . Eitle, Arabelstrasse 4, D-81925 München (DE).		
(81) Bestimmungsstaaten: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO Patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), eurasisches Patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Veröffentlicht Mit internationalem Recherchenbericht.		
(54) Title: ACTUATING DEVICE FOR METERS AND METERING AEROSOL DISPENSING DEVICE WITH AN ACTUATING DEVICE FOR METERS (54) Bezeichnung: BETÄTIGUNGSVORRICHTUNG FÜR ZÄHLWERKE UND DOSIERAEROSOLABGABEVORRICHTUNG MIT EINER BETÄTIGUNGSEINRICHTUNG FÜR ZÄHLWERKE (57) Abstract A metering aerosol dispensing device comprising an aerosol container (23); a nozzle (31, 32) that is arranged in a nozzle body (30), whereby the aerosol is dispensed via said nozzle when the aerosol container (23) is pushed against the body (30) of the nozzle once the metering aerosol dispensing device is actuated; a meter (1, 2, 4) that counts the number of times that the metering aerosol dispensing device is actuated; and an actuating device (10) that enables the meter (1, 2, 3, 4) to move forward when the metering aerosol dispensing device is actuated. The invention is characterized in that the actuating device (10) is designed and arranged in the metering aerosol dispensing device in such a way that the body (30) of the nozzle is accommodated in the interior of the actuating device (10) and the nozzle (31) is released in order to produce aerosol in an unrestricted manner. (57) Zusammenfassung Dosieraerosolabgabevorrichtung mit einem Aerosolbehälter (23), einer in einem Düsenkörper (30) angeordneten Düse (31, 32), über die ein Aerosol abgegeben wird, wenn der Aerosolbehälter (23) gegenüber dem Düsenkörper (30) bei einer Betätigung der Dosieraerosolabgabevorrichtung verschoben wird, einem Zählwerk (1, 2, 3, 4) zur Zählung der Betätigungen der Dosieraerosolabgabevorrichtung und einer Betätigungsverrichtung (10) zur Weiterschaltung des Zählwerks (1, 2, 3, 4) bei einer Betätigung der Dosieraerosolabgabevorrichtung, dadurch gekennzeichnet, daß die Betätigungsverrichtung (10) so ausgestaltet und in der Dosieraerosolabgabevorrichtung angeordnet ist, dass der Düsenkörper (30) im Innern der Betätigungsverrichtung (10) aufgenommen und die Düse (31) zur unbeeinflussten Aerosolerzeugung freigegeben ist.		

LEDIGLICH ZUR INFORMATION

Codes zur Identifizierung von PCT-Vertragsstaaten auf den Kopfbögen der Schriften, die internationale Anmeldungen gemäss dem PCT veröffentlichen.

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BESCHREIBUNG

Betätigungsvorrichtung für Zählwerke und
Dosieraerosolabgabevorrichtung mit einer
Betätigungseinrichtung für Zählwerke

Die vorliegende Erfindung betrifft
Dosieraerosolabgabevorrichtungen, und insbesondere eine
Betätigungsvorrichtung für Zählwerke zur einfachen Verwendung
in Dosieraerosolabgabevorrichtungen.

Verschiedene Dosieraerosolabgabevorrichtungen für
Inhalationszwecke sind bekannt, die beispielsweise zur
Behandlung von Atemwegserkrankungen eine dosisgenaue
Medikamentenmenge in Form eines Sprühnebels oder Aerosols
abgeben. Hierbei kommt es insbesondere auf die zuverlässige
Dosierung des abgegebenen Medikaments an, damit ein gezielter
Therapieeffekt beim Patienten hervorgerufen wird. Derartige
Dosieraerosolvorrichtungen sind beispielsweise die allgemein
bekannten MDI (metered dose inhalers), die in der Regel ein
Gehäuse, einen Behälter zur Aufnahme eines flüssigen oder
pulverförmigen Medikaments, eine geeignet ausgebildete Düse
zum Zerstäuben und Verteilen des Medikaments und ein

Mundstück aufweisen, über das das erzeugte medikamentenhaltige Aerosol eingeatmet wird. Die Betätigung der Dosieraerosolvorrichtungen erfolgt beispielsweise bei Treibgasaerosolen derart, daß der Medikamentenbehälter gegenüber der in dem Gehäuse angeordneten Düse geradlinig verschoben wird, wodurch eine definierte Menge des Zerstäubungsguts freigesetzt wird. Eine Dosieraerosolvorrichtung dieser Art ist beispielsweise in EP 0 254 391 beschrieben.

Dosieraerosolabgabevorrichtungen sind in der Regel für Mehrfachdosierungen ausgelegt. Dabei ist es wünschenswert, dem Benutzer die Anzahl der abgegebenen Dosen, in anderen Worten der abgegebenen Sprühstöße, bzw. die noch zur Verfügung stehenden Sprühstöße anzuzeigen, um sicher zustellen, daß der Patient frühzeitig darauf hingewiesen wird, daß das Medikament verbraucht ist. Auf diese Weise wird vermieden, daß ein Patient, beispielsweise zur Vorbeugung eines akuten Asthmaanfalls, eine bereits nahezu leere Dosieraerosolabgabevorrichtung mit sich führt.

Aus diesem Grund sind Dosiervernebler bzw. Dosierinhalatoren mit unterschiedlichen Zählwerken ausgestattet worden. EP 0 254 391 beschreibt zum Beispiel einen Inhalator mit einem flachen Zählwerk, das auf der dem Patienten zugewandten Seite eines Aerosolspenders ausgebildet ist. Aus EP 0 505 321 ist ein wiederverwendbarer Inhalator mit rücksetzbarem Zähler bekannt, der beim Erreichen der ersten Relativposition von Vorratskammer und Dosierstift inkrementiert wird. Das in GB 1 317 315 offenbarte Zählwerk weist eine Vielzahl von ringförmigen Elementen auf, die mechanisch zusammenwirken, um an einem Anzeiger die noch zur Verfügung stehenden Dosierungen anzuzeigen. Weitere Medikamentenspender mit

mechanischem Zählwerk sind beispielsweise in WO 86/02275 und WO 93/24167 offenbart.

Die bekannten Lösungen für Dosierungsvorrichtungen weisen jedoch entweder einen komplexen, unhandlichen Aufbau auf oder erfordern, daß eine bereits vorhandene Dosisaerosolabgabevorrichtung in erheblichem Umfang modifiziert werden muß. Eine derartige Modifikation einer bereits vorhandenen Dosieraerosolabgabevorrichtung ist jedoch insofern von Nachteil, da diese dann erneut einem amtlichen Genehmigungsverfahren und den damit einhergehenden Versuchen für die medizinische Anwendbarkeit unterworfen werden muß. Dies ist jedoch in der Regel ein langwieriger und kostspieliger Prozess und daher unerwünscht.

Ausgehend vom Stand der Technik ist es daher die Aufgabe der vorliegenden Erfindung, für eine Dosieraerosolvorrichtung eine Betätigungsvorrichtung für Zählwerke mit kleinen Abmessungen zu schaffen, die mit unterschiedlichen Dosieraerosolabgabevorrichtungen zur Dosiszählung verwendet werden kann, ohne daß wesentliche Modifikationen an den Dosieraerosolvorrichtungen durchgeführt werden müssen. Die Aufgabe wird erfindungsgemäß gelöst durch eine Dosieraerosolabgabevorrichtung mit einem Aerosolbehälter, einer in einem Düsenkörper angeordneten Düse, über die ein Aerosol abgegeben wird, wenn der Aerosolbehälter gegenüber dem Düsenkörper bei einer Betätigung der Dosieraerosolabgabevorrichtung verschoben wird, einem Zählwerk zur Zählung der Betätigungen der Dosieraerosolabgabevorrichtung und einer Betätigungsvorrichtung zur Weiterschaltung des Zählwerks bei einer Betätigung der Dosieraerosolabgabevorrichtung, wobei die Betätigungsvorrichtung so ausgestaltet und in der

Dosieraerosolabgabevorrichtung angeordnet ist, dass der Düsenkörper im Innern der Betätigungsvorrichtung aufgenommen und die Düse zur unbeeinflussten Aerosolerzeugung freigegeben ist.

Vorteilhaft besteht die Betätigungsvorrichtung aus zwei gegeneinander verschiebbaren Hülsen, die im Inneren den Düsenkörper der Dosieraerosolabgabevorrichtung aufnehmen.

Die beiden Hülsen der Betätigungsvorrichtung sind vorteilhaft durch Federelemente miteinander verbunden, die die Hülsen der Betätigungsvorrichtung in eine Ausgangsposition zurück bewegen.

Die Federelemente sind vorteilhaft in Form von flachen, gebogenen Federelementen realisiert, die an den Außenseiten der Hülsen befestigt oder einstückig angeformt sind.

Um eine Verkantung der Hülsen zu vermeiden, sind an den Hülsen der Betätigungsvorrichtung Führungselemente vorgesehen sind, die eine geradlinige Verschiebung der beiden Hülsen gegeneinander gewährleisten. Alternativ können die Federelemente derart ausgestaltet werden, dass sie eine geradlinige Verschiebung der beiden Hülsen gegeneinander gewährleisten.

Für die Weiterschaltung des Zählwerks umfasst die Betätigungsvorrichtung einen Betätigungsarm umfasst, der auf das Zählwerk einwirkt.

Um ein möglichst kleines Zählwerk zu realisieren, besteht das Zählwerk aus mehreren parallel angeordneten Scheibeneinheiten wobei eine erste Scheibeneinheit eine Außenverzahnung

aufweist, die mit der Betätigungsvorrichtung, insbesondere mit dem Betätigungsarm zusammenwirkt.

Um aus Zählwerk und Betätigungsvorrichtung eine Einheit zu machen, weist die Betätigungsvorrichtung eine Öffnung auf, in der ein Lagerbolzen des Zählwerks zur Halterung des Zählwerks an der Betätigungsvorrichtung befestigbar ist.

Damit die Aerosolerzeugung und -ausbreitung nicht beeinflusst wird, weist die Betätigungseinrichtung, insbesondere das Unterteil eine Aussparung oder eine Öffnung auf, durch die die Düse freigegeben ist.

Weitere Merkmale und Vorteile der vorliegenden Erfindung ergeben sich aus der folgenden Beschreibung eines bevorzugten Ausführungsbeispiels, das im Zusammenhang mit den beigefügten Abbildungen erläutert wird, in denen zeigt:

- Fig. 1 eine Explosionsdarstellung eines Zählwerks, das mit einer erfindungsgemäßen Betätigungsvorrichtung für eine Dosieraerosolabgabevorrichtung zusammenwirkt;
- Fig. 2 eine Explosionsdarstellung des in Fig. 1 gezeigten Zählwerks, betrachtet aus der zu Fig. 1 anderen Blickrichtung;
- Fig. 3 eine schematische Querschnittsansicht einer Ausgangs- bzw. Ruheposition der zweiten und dritten Scheibeneinheiten zur Erläuterung des Zusammenwirkens von zweiter und dritter Scheibeneinheit;

- Fig. 4 eine schematische Querschnittsansicht analog zu Fig.3, die die zweite und dritte Scheibeneinheit in einer Position zeigt, in der die zweite Scheibeneinheit durch die dritte Scheibeneinheit veranlaßt wird, mit der vierten Scheibeneinheit zusammenzuwirken;
- Fig. 5 eine separate Ansicht der in Fig. 1 und 2 dargestellten Betätigungsvorrichtung;
- Fig. 6 die Anordnung der erfindungsgemäßen Betätigungseinrichtung für Zählwerke in einer Dosieraerosolabgabevorrichtung; und
- Fig. 7 eine vergrößerte Darstellung der Anordnung der Betätigungseinrichtung an der Düse einer Dosieraerosolabgabevorrichtung.

Zur Einleitung und für ein besseres Verständnis der Erfindung wird im folgenden zunächst ein Zählwerk für Dosieraerosolabgabevorrichtungen unter Bezugnahme auf Fig. 1 und 2 beschrieben. Fig. 1 und 2 zeigen jeweils aus zwei unterschiedlichen Blickrichtungen betrachtete Explosionsdarstellungen des Zählwerks.

Das Zählwerk weist im wesentlichen vier Scheibeneinheiten 1, 2, 3 und 4 auf, die parallel zueinander angeordnet sind. Die Mittelpunkte der Scheibeneinheiten 1, 2, 3 und 4 liegen auf einer zu den Scheibeneinheiten senkrecht stehenden Achse und sind, wie nachstehend noch genauer erläutert wird, über einen Lagerbolzen 8 mit einer Betätigungsvorrichtung 10 eines Dosieraerosolerzeugers (nicht dargestellt) verbunden. Die erste, zweite und vierte Scheibeneinheit 1, 2 und 4 sind

bezogen auf die Betätigungsvorrichtung 10 drehbar angeordnet. Die dritte Scheibeneinheit 3 nimmt eine feste Position bezogen auf die Betätigungsvorrichtung 10 und damit auch auf die übrigen Scheibeneinheiten ein.

Die erste Scheibeneinheit 1 besitzt ein Mittel zur Aufnahme einer Kraft, die eine Drehung der ersten Scheibeneinheit hervorruft; dabei handelt es sich um eine Außenverzahnung 1a, in die ein an der Betätigungsvorrichtung 10 angebrachter Betätigungsarm 5 eingreift (siehe Fig. 1 und 2). Die erste Scheibeneinheit 1 weist einen kleineren Radius als die zweite Scheibeneinheit 2 auf und ist mit dieser fest verbunden. Durch diese feste Verbindung wird die Übertragung der Drehbewegung von der ersten Scheibeneinheit 1 auf die zweite Scheibeneinheit 2 realisiert. Es können aber auch andere Mittel zur Übertragung der Drehbewegung und zur Aufnahme der eine Drehbewegung hervorufenden Kraft an den beiden Scheibeneinheiten vorgesehen sein.

Um die Drehbewegung an eine vierte Scheibeneinheit 4 zu übertragen, ist als Übertragungsmittel am Außenumfang der zweiten Scheibeneinheit 2 ein keilförmiger Nocken 6 angebracht, der über ein Federelement 6a mit der zweiten Scheibeneinheit 2 verbunden ist und der im folgenden als Federnocken bezeichnet wird. Das Federelement 6a bildet im wesentlichen die Außenkontur der zweiten Scheibeneinheit 2 nach, besitzt aber ein frei schwingendes Ende. An dem frei schwingendem Ende ist der keilförmige Federnocken 6 derart angebracht, daß er in der Ruhestellung über die Außenkontur der zweiten Scheibeneinheit 2 in radialer Richtung übersteht. Die Geometrie des Federnocken ist so gewählt, daß der Nocken bzw. die Nase bei einer Auslenkung in radialer Richtung in

die Innenverzahnung 13 der vierten Scheibeneinheit 4 eingreift.

Dazu ist der keilförmige Federnocken 6 so angeordnet, daß die scharfe und die stumpfe Kante senkrecht zur Ebene der zweiten Scheibeneinheit 2 orientiert sind. Der Federnocken 6 weist ferner eine Breite auf, die größer ist als die Dicke der zweiten Scheibeneinheit 2, so daß sich der Federnocken 6 parallel zur Achse der Scheibeneinheiten zapfenartig in Richtung auf die dritte und vierte Scheibeneinheit 3 und 4 erstreckt.

Der zapfenartig in Richtung dritte und vierte Scheibeneinheit überstehenden Federnocken 6 kann in Wechselwirkung mit den anderen Elementen des Zählwerks, die insbesondere unter Bezugnahme auf Fig. 3 und 4 genauer erläutert werden, mit einer ersten Verzahnung 13 der vierten Scheibeneinheit 4 in Eingriff treten (siehe Fig. 2).

Die in Richtung dritte und vierte Scheibeneinheit weisende Seite der zweiten Scheibeneinheit 2 weist eine Innenverzahnung 7 auf, die symmetrisch um die Achse der Scheibeneinheiten angeordnet ist. Die Innenverzahnung 7, die in Fig. 2 zu sehen ist, nicht aber in Fig.1, weist die gleiche Anzahl von Zähnen wie die außenverzahnte Scheibeneinheit 1 auf. In der in Fig. 1 bzw. 2 dargestellten Ausführungsform beträgt die Anzahl der Zähne zehn, um zusammen mit einer ersten Innenverzahnung 13 der vierten Scheibeneinheit 4 mit 24 Zähnen insgesamt 240 diskrete Zählsschritte zu realisieren. Jedoch können problemlos andere Werte verwendet werden.

Der Radius der dritten Scheibeneinheit 3 ist gleich oder vorzugsweise geringfügig kleiner als der Radius der zweiten Scheibeneinheit 2. Ferner ist an dem Außenumfang der dritten Scheibeneinheit 3 eine keilförmige Schulter 11 angebracht, die zur Betätigung des an der zweiten Scheibeneinheit 2 angeordneten Federnocken 6 dient, was im folgenden noch genauer erklärt wird. Wird eine weitere Schulter angebracht, so ändert sich das Übersetzungsverhältnis. Die dritte Scheibeneinheit 3 ist mit einem Lagerbolzen 8 fest verbunden.

Der Lagerbolzen 8 weist bezogen auf die dritte Scheibeneinheit 3 drei unterschiedliche Bereiche auf, nämlich den in Richtung vierte Scheibeneinheit 4 weisenden Abschnitt 8a und die in Richtung erste und zweite Scheibeneinheit weisenden Abschnitte 8b und 8c. Der Durchmesser des Lagerbolzenabschnitts 8b ist mit dem des Abschnittes 8a identisch, und der des Abschnitts 8c ist im Vergleich dazu reduziert. Der Lagerbolzen 8 dient der drehfesten Anbringung der dritten Scheibeneinheit 3 an der Betätigungsvorrichtung 10 und zur drehbaren Lagerung der ersten, zweiten und vierten Scheibeneinheit 1, 2 und 4. Hierzu ist der Lagerbolzenabschnitt mit kleinerem Radius 8c in eine entsprechende Öffnung 18 der Befestigungseinheit 10 eingeführt und derart befestigt, daß die Position der dritten Scheibeneinheit 3 bezogen auf die Betätigungsvorrichtung 10 fest ist. Die in der ersten und zweiten Scheibeneinheiten 1 und 2 vorgesehenen Öffnungen sind so auf den Durchmesser des Lagerbolzenabschnittes 8b abgestimmt, daß die ersten und zweiten Scheibeneinheiten 1 und 2 auf dem Lagerbolzenabschnitt 8b gleitend drehbar sind. Es sei angemerkt, daß die Durchmesser der Abschnitte 8a, 8b und 8c nicht auf das in Fig. 1 bzw. Fig. 2 dargestellte Verhältnis beschränkt sind. Wesentlich ist, daß die jeweiligen Öffnungen

der Scheibeneinheiten und die Durchmesser der Lagerbolzenabschnitte aufeinander abgestimmt sind.

Ferner sind an dem Lagerbolzen 8 zwei L-förmige Verriegelungselemente 9 angeordnet, die am Außenumfang des Lagerbolzenabschnitts 8b angeordnet sind und die in die Innenverzahnung 7 der zweiten Scheibeneinheit 2 eingreifen. Die Öffnung der vierten Scheibeneinheit 4 ist so auf den Durchmesser des Lagerbolzenabschnittes 8a abgestimmt, daß die vierte Scheibeneinheit 4 auf dem Lagerbolzenabschnitt 8a gleitend drehbar ist. An dem Abschnitt 8a sind zudem, in Richtung vierte Scheibeneinheit 4 weisend, zwei Schnapphaken 12a symmetrisch angeordnet, die zur axialen Fixierung der Scheibeneinheit 4 dienen.

Auf der in Richtung vierte Scheibeneinheit 4 weisenden Seite der dritten Scheibeneinheit 3 ist eine Rastverzahnung 12 angebracht, die in Fig. 2 zu sehen ist. In dem in Fig. 2 dargestellten Ausführungsbeispiel besteht die Rastverzahnung 12 aus vier Elementen, die um 90° zueinander beabstandet sind. Die Rastverzahnung kann aber auch aus einem oder aus mehreren Elementen bestehen, die zentrisch um die Achse des Lagerbolzens 8 angeordnet sind. Diese Rastverzahnung 12 greift in eine zweite Verzahnung 14 der vierten Scheibeneinheit 4 ein und dient im wesentlichen der Sicherung der Drehstellung der Scheibeneinheit 4.

Die Ausgestaltung der vierten Scheibeneinheit 4 ist insbesondere aus Fig. 1 ersichtlich. Die in Richtung der anderen Scheibeneinheiten weisende Seite der vierten Scheibeneinheit 4 weist eine erste Verzahnung 13 auf, die an der Umfangsinnenseite angeordnet ist, und eine zweite Verzahnung 14, die kreisförmig um den Mittelpunkt der vierten

Scheibeneinheit 4 verläuft. Der Radius der zweiten Verzahnung 14 ist abgestimmt auf die Lage der Elemente der Rastverzahnung 12, die an der dritten Scheibeneinheit 3 vorgesehen ist.

Im montierten Zustand sind die erste und zweite Scheibeneinheit 1 und 2 auf dem Lagerbolzenabschnitt 8b angeordnet; dabei liegen die L-förmigen Verringerungselemente 9 in der Ausnehmung der Innenverzahnung 7 der zweiten Scheibeneinheit 2. Der Federnocken 6 ragt über die Außenkontur der dritten Scheibeneinheit 3. Die vierte Scheibeneinheit 4 ist auf dem Lagerbolzenabschnitt 8a angeordnet und nimmt aufgrund der kappenartigen Gestalt die dritte Scheibeneinheit 3 auf; dabei liegt der Federnocken 6 zwischen der Außenkontur der dritten Scheibeneinheit 3 und der ersten Innenverzahnung der vierten Scheibeneinheit 4.

Im folgenden wird die Funktionsweise des zuvor beschriebenen Zählwerks erläutert. Da, wie in Fig. 2 gezeigt, der Betätigungsarm 5 der erfindungsgemäßen Betätigungseinrichtung 10 in die Außenverzahnung der ersten Scheibeneinheit 1 eingreift, wird durch eine Bewegung des Betätigungsarmes 5 die erste Scheibeneinheit 1 in die in Fig. 1 und 2 angedeutete Pfeilrichtung gedreht. Hierbei bewegt sich die zweite Scheibeneinheit 2 mit, da die erste und zweite Scheibeneinheit 1 und 2 fest miteinander verbunden sind. Die erste und zweite Scheibeneinheit 1 und 2 gleiten dabei auf dem Lagerbolzenabschnitt 8b. Im Gegensatz dazu ist die dritte Scheibeneinheit 3 über den Lagerbolzen 8 mit der Betätigungseinrichtung 10 fest verbunden, so daß die Position der dritten Scheibeneinheit 3 bezogen auf die Betätigungseinrichtung 10 zu jedem Zeitpunkt unverändert bleibt. Gleichzeitig sind die an dem Lagerbolzenabschnitt 8b

angebrachten L-förmigen Verriegelungselemente 9 in Eingriff mit der Innenverzahnung 7 der Scheibeneinheit 2; jedoch gestattet die Gestaltung der Verriegelungselemente 9 und der Innenverzahnung 7 eine Drehung der ersten und zweiten Scheibeneinheiten 1 und 2 in der in Fig. 1 und 2 gezeigten Richtung. Bei einer Drehung der ersten und zweiten Scheibeneinheit 1 und 2 in Pfeilrichtung rasten die Verriegelungselemente 9 in die jeweils nächste Verzahnung der Innenverzahnung 7 ein. Bei einer erneuten Betätigung des Armes 5 drehen sich Scheibeneinheiten 1 und 2 genau einen Zahn weiter und der Verriegelungsarm rastet in den nächsten Zahn ein. Durch ein derartiges Eingreifen der Verriegelungselemente 9 in die Innenverzahnung 7 wird sichergestellt, daß sich die erste und somit auch die zweite Scheibeneinheit beim Lösen des Betätigungsarms 5 aus dem Eingriff mit der zahnradförmigen Scheibeneinheit 1 nicht zurückdreht, d.h. sich nicht entgegen der Pfeilrichtung zurückbewegt.

Bei der in Fig. 1 und 2 angedeuteten Drehung der ersten und zweiten Scheibeneinheit 1 und 2 in Pfeilrichtung läuft der an der zweiten Scheibeneinheit 2 angeordnete Federnocken 6 auf der Außenkontur der dritten Scheibeneinheit 3 entlang. Geht man von einem Zahnrad, das zehn Zähne aufweist aus, so überstreicht der Federnocken 6 bei 10-maliger Betätigung des Armes 5 einen Winkel von 360° , d.h. der Federnocken macht einen vollen Umlauf und gelangt wieder an seine Ausgangsposition. Solange der Federnocken 6 nicht von der Schulter 11 der dritten Scheibeneinheit 3 beeinflußt wird, greift der Federnocken 6 nicht in die an der Innenumfangseite der vierten Scheibeneinheit 4 angebrachte erste Verzahnung 13 ein. Erst wenn die Schulter 11 den Federnocken 6 in radialer Richtung anhebt, gelangt der Federnocken 6 in Eingriff mit

der ersten Innenverzahnung der vierten Scheibeneinheit 4 und bewirkt eine Drehung der vierten Scheibeneinheit um eine Drehstellung.

Die schrittweise Drehung der Scheibeneinheit 2 bezogen auf die dritte Scheibeneinheit 3, sowie das Eingreifen des Federnockens 6 der zweiten Scheibeneinheit 2 in die Innenverzahnung 13 der vierten Scheibeneinheit 4 werden im folgenden unter Bezugnahme auf Fig. 3 und 4 genauer beschrieben. Fig. 3 und 4 zeigen schematische Querschnittsansichten, die insbesondere das Zusammenwirken von zweiter und dritter Scheibeneinheit 2 und 3 detaillierter erläutern. In Fig. 3 und 4 sind die Scheibeneinheiten 2 und 3 aus der in Fig. 2 gezeigten Blickrichtung dargestellt. Die dritte Scheibeneinheit 3 ist in beiden Abbildungen aus Gründen der besseren Übersicht lediglich gestrichelt angedeutet. Fig. 3 zeigt die oben erwähnte Ausgangsposition bzw. Ruheposition der zweiten Scheibeneinheit 2 in Bezug auf die fest mit der Betätigungseinrichtung 10 verbundene dritte Scheibeneinheit 3. In dieser Position ist das Verriegelungselement 9 in den ersten Zahn 7-1 der Innenverzahnung 7 eingerastet. Durch Betätigung des Betätigungsarmes 5, der in die zahnradförmige erste Scheibeneinheit 1 eingreift (in Fig. 3 nicht dargestellt), wird die Scheibeneinheit 2 schrittweise, d.h. Zahn für Zahn, in der in Fig. 3 angedeuteten Pfeilrichtung gedreht. Das Verriegelungselement 9 rastet hierbei, beginnend vom ersten Innenzahn 7-1 in aufsteigender Reihenfolge in die Zähne 7-2 bis 7-9 ein. Bei der durch den Betätigungsarm 5 initiierten Drehbewegung der ersten und zweiten Scheibeneinheit 1 und 2 läuft der Federnocken 6 auf dem Umfang der in Fig. 3 gestrichelt dargestellten dritten Scheibeneinheit 3 entlang, ohne daß der Federnocken 6 ausgelenkt wird. In diesem Fall

;

greift der Federnocken 6 nicht in die erste Verzahnung 13 der vierten Scheibeneinheit 4 ein.

Ist der Betätigungsarm 5 so oft betätigt worden, daß das Verriegelungselement 9 in den Zahn 7-10 der Innenverzahnung 7 einrastet, d.h wenn ausgehend von der in Fig. 3 dargestellten Ausgangsposition der Betätigungsarm 5 zum neunten Mal betätigt worden ist, dann ist der Federnocken 6 in Kontakt mit der Schulter 11. Dies bewirkt, daß der Federnocken 6, wie in Fig. 4 dargestellt, in radialer Richtung ausgelenkt wird. Mit anderen Worten, der Federnocken 6 wird in dieser Position durch die Schulter 11 betätigt und der Federnocken 6 greift in die Innenumfangsverzahnung 13 ein und dreht die vierte Scheibeneinheit 4 um einen Zahn der ersten Verzahnung 13 in Pfeilrichtung weiter.

Bei dieser durch das Zusammenwirken der Schulter 11 und des Federnocken 6 bewirkten Drehung der vierten Scheibeneinheit 4 rastet die an der in Richtung erste, zweite und dritte Scheibeneinheit weisenden Innenseite der vierten Scheibeneinheit 4 angeordnete zweite Verzahnung 14 mit der Rastverzahnung 12 ein. Die Rastverzahnung 12 und die zweite Verzahnung 14 der vierten Scheibeneinheit 4 dienen hierbei der Sicherung der vierten Scheibeneinheit 4 gegen Verdrehen, und durch die Schnapphaken 12a ist eine axiale Fixierung der vierten Scheibeneinheit 4 gewährleistet.

Bei der nachfolgenden Betätigung der ersten bzw. zweiten Scheibeneinheit durch den Betätigungsarm 5 nimmt die zweite Scheibeneinheit 2 wieder die in Fig. 3 dargestellte Ausgangsposition ein und die zuvor unter Bezugnahme auf Fig. 3 beschriebene Bewegung des Federnocken 6 wird wieder durchlaufen, ohne daß der Federnocken 6 in Eingriff mit der

ersten Verzahnung 13 der vierten Scheibeneinheit 4 tritt. Erst nachdem das Verriegelungselement wieder in den Zahn 7-10 der Innenverzahnung 7 einrastet, wird der Federnocken 6 durch die Schulter 11 erneut ausgelenkt, so daß dieser wieder in Eingriff mit der Innenverzahnung 13 tritt und daraufhin die vierte Scheibeneinheit 4 um einen Zahn der ersten Innenverzahnung 13 weiterdreht. Auf diese Weise wird bei einer 10-zahnigen ersten Scheibeneinheit die vierte Scheibeneinheit 4 jeweils nach 10 Betätigungen des Betätigungsarms 5 um genau einen Zahn der ersten Verzahnung 13 weitergedreht. Wenn die erste Innenverzahnung 13 der vierten Scheibeneinheit 4 beispielsweise 24 Zähne aufweist, beträgt die maximale Anzahl der Zählstellungen in diesem Fall 240, d.h. wenn sich die vierte Scheibeneinheit 4 um 360° gedreht hat, sind 240 Betätigungen des Betätigungsarms 5 gezählt worden. Die zweite Verzahnung 14 der vierten Scheibeneinheit 4 weist die gleiche Anzahl von Zähnen wie die erste Innenverzahnung 13 auf.

Es sei angemerkt, daß die Anzahl der Zähne der ersten und zweiten Verzahnung 13 und 14 entsprechend an die gewünschte Übersetzung angepaßt werden kann. Eine 30-zahnige erste bzw. zweite Verzahnung 13 bzw. 14 dient somit zur Zählung von bis zu 300 Betätigungen. Das Übersetzungsverhältnis des erfindungsgemäßen Zählwerks bzw. die Anzahl der Zählungen kann aber auch durch ein Anordnen einer weiteren Schulter bzw. mehrerer Schultern am Außenrand der dritten Scheibeneinheit 3 variiert werden. Dies ermöglicht insbesondere ein unkompliziertes und schnelles Anpassen des erfindungsgemäßen Zählwerks an ein gewünschtes Übersetzungsverhältnis.

Die vierte Scheibeneinheit 4 kann in Form einer Anzeigescheibe ausgebildet sein, um entsprechend die Zählungen anzuzeigen. Dies kann beispielsweise durch einen Aufdruck eines Zeigers oder einer Farbmarkierung sowohl auf der Stirnseite als auch auf dem Rand der vierten Scheibeneinheit 4 erreicht werden. In dem in Fig. 2 dargestellten Ausführungsbeispiel ist ein Zeiger-Anzeigeelement 4a angedeutet. Der Zeiger gibt entsprechend der Drehstellung der vierten Scheibeneinheit 4 die Anzahl der Betätigungen an.

Im folgenden wird die Betätigungseinrichtung 10 gemäß der Erfindung beispielhaft genauer erläutert, die in vorteilhafter Weise mit dem zuvor beschriebenen Zählwerk ggf. aber auch mit anderen Zählwerken zusammenarbeitet.

Die in Fig. 1 und 2 dargestellte Betätigungseinrichtung 10 besteht aus einer zylinderförmigen Hülse 15 und einem zylinderförmigen Unterteil 16, bei dem es sich ebenfalls um eine Hülse handelt. An der Außenseite der Hülse 15 ist ein Betätigungsarm 5 angebracht. Hülse 15 und Unterteil 16 sind über eine bogenförmigen Feder 17 miteinander verbunden. Bei Betätigung der Feder 17, d.h. beim Zusammendrücken von Hülse 15 und Unterteil 16 in axialer Richtung, wird durch geeignete Führungselemente 19, die an der Hülse 15 in Richtung Unterteil 16 weisend angebracht sind, eine geradlinige Bewegung der Hülse 15 bezogen auf des Unterteil 16 gewährleistet. Dabei gleiten die Innenumfangsseite der Hülse 15 auf der Außenseite der Führungselemente 19. Wesentlich ist, daß eine geradlinige Bewegung der Hülse 15 und somit auch eine geradlinige Bewegung des Betätigungsarms 5 beim Zusammendrücken der Betätigungseinrichtung 10 gewährleistet ist, und ein zuverlässiges Eingreifen des Betätigungsarmes 5

in die zahnradförmige erste Scheibeneinheit 1 erzielt wird. Durch die Gestaltung der bogenförmigen Feder 17, beispielsweise wie in Fig. 1 und 2 gezeigt, als flaches gebogenes Federelement kann eine geradlinige Bewegung der Hülse 15 in Bezug auf das Unterteil erreicht werden, ohne daß Führungselemente erforderlich sind. Zur Verdeutlichung ist eine entsprechende Gestaltung der Betätigungseinrichtung 10 in Fig. 5 dargestellt, wobei das Zählwerk in der Darstellung der Fig. 5 weggelassen wurde.

In Fig. 6 ist in einer Gesamtansicht die Anordnung der erfindungsgemäßen Betätigungseinrichtung und des zuvor beschriebenen Zählwerks in einer Dosieraerosolabgabevorrichtung dargestellt. Fig. 6 zeigt ein Gehäuse 21 der Dosieraerosolabgabevorrichtung, das mit einem Mundstück 22 versehen ist. Das Mundstück 22 ist an dem unteren Bereich des Gehäuses 21 in abgewinkelter Stellung angeordnet. Im oberen Bereich des Gehäuses 21 befindet sich ein Dosieraerosolbehälter 23 zur Aufnahme eines zu zerstäubenden Aerosols. An den unteren Bereich des Aerosolbehälters 23 schließt sich ein Düsenbereich an, der in die Führungshülse 15 der Betätigungsvorrichtung 10 eingeführt ist. Die Düse selbst ist zur Verdeutlichung der Lage der erfindungsgemäßen Betätigungseinrichtung in Fig. 6 nicht dargestellt. Die Betätigungsvorrichtung 10 ist mit dem erfindungsgemäßen Zählwerk, bestehend aus den Scheibeneinheiten 1, 2, 3 und 4, verbunden, um die abgegebenen bzw. noch verbleibenden Dosierungen zu zählen und anzuzeigen. Bei jedem Pumpstoß, der, wie zuvor beschrieben, durch die Betätigung der Dosieraerosolabgabevorrichtung ausgelöst wird, wird eine bestimmte Aerosolmenge ausgegeben und über eine Düse zerstäubt, deren Aufbau und Verwendung mit derartigen herkömmlichen Dosieraerosolabgabevorrichtungen

allgemein bekannt ist. Das erzeugte Aerosol kann von einem Patienten über das Mundstück 22 eingeatmet werden. Die Betätigung der Dosieraerosolvorrichtung bewirkt, daß sich die Führungshülse 15 zusammen mit dem Betätigungsarm der Betätigungsvorrichtung 10 sich gegenüber dem Unterteil 16 verschiebt. Dadurch führt die Betätigung der Dosieraerosolabgabevorrichtung zu einer Weiterschaltung des Zählwerks.

Wie aus Fig. 6 hervorgeht, kann das Zählwerk mit der erfindungsgemäßen Betätigungseinrichtung unterhalb des Aerosolbehälters in einer herkömmlichen Dosieraerosolabgabevorrichtung problemlos angeordnet werden. Dies wird vorrangig dadurch erreicht, daß, wie schon aus Fig. 6 entnehmbar ist, sowohl die Hülse 15 als auch das Unterteil 16 der Betätigungsvorrichtung 10 im Inneren des Raums für insbesondere den Anschlußstutzen (nicht sichtbar) des Aerosolbehälters 23 und für den Düsenkörper der Dosieraerosolabgabevorrichtung aufweist. In Fig. 7 ist dargestellt, wie ein zylindrischer Düsenkörper 30 der Dosieraerosolabgabevorrichtung 21 in der Hülse 15 und dem Unterteil 16 der Betätigungseinrichtung 10 angeordnet werden kann. Man erkennt den (geschnitten dargestellten) zylindrischen Düsenkörper 30, die trichterförmige Düsenöffnung 31, einen Verbindungskanal 32, der die trichterförmige Düsenöffnung 31 mit einer Düsenkammer 33 verbindet, in die der Anschlußstutzen 25 des Aerosolbehälters 23 das Aerosol bei einem Pumpstoß abgibt. Da erfindungsgemäß die Hülse 15 und das Unterteil 16 der Betätigungseinrichtung 10 im Inneren ausreichend Raum sowohl für die Düse 30 als auch für den Anschluß des Aerosolbehälters 23 zur Verfügung stellen und da das Unterteil 16 so gestaltet ist, daß es die Düse 31 vollständig freigibt und die Aerosolerzeugung und -

ausbreitung nicht beeinflusst, kann die Betätigungseinrichtung 10 problemlos am Düsenkörper einer gegebenen Dosieraerosolabgabevorrichtung angeordnet werden, ohne daß Änderungen an dem Düsenkörper 30 bzw. der Düse 31, 32 oder dem Anschluß 25 für den Aerosolbehälter vorgenommen werden müssen. Das bedeutet, daß ein für die Dosieraerosolabgabevorrichtung durchlaufendes Zulassungsverfahren nicht erneut erforderlich ist, da keine Modifikationen an der Düsengestaltung 30, 31, 32, 33 aufgrund der erfindungsgemäßen Betätigungseinrichtung 10 vorgenommen werden müssen.

Die Freigabe der Düse 31 wird bei dem gezeigten Beispiel einer erfindungsgemäßen Betätigungseinrichtung dadurch erreicht, dass die das Unterteil 16 bildende Hülse an der der Düse zugewandten Seite eine entsprechende Aussparung aufweist, wie die Fig. 1, 2, 5, 6 und 7 zeigen. Alternativ kann auch eine Öffnung vorgesehen werden, die der Öffnung 8 ähnelt, die aber so ausgebildet ist, dass sie die Düse 31 freigibt.

Vorteilhaft ist somit, daß beim Einsatz eines Zählwerks mit einer erfindungsgemäßen Betätigungseinrichtung 10 eine herkömmliche Dosieraerosolabgabevorrichtung nicht in ihren wesentlichen Komponenten, insbesondere nicht die Düse, verändert werden muß. Durch eine einfache Anordnung einer Betätigungsvorrichtung zum Betätigen des Zählwerks in einer gegebenen Gerätegestaltung wird ein einfacher und unkomplizierter Aufbau ermöglicht, der universell mit bereits bekannten Geräten verwendet werden kann. Auf diese Weise kann auf eine aufwendige Modifikation der bereits bekannten Dosieraerosolabgabevorrichtungen verzichtet werden. Dies ist wesentlich von Vorteil, da beispielsweise bei einer Änderung

der Düsenform derartige Inhalatoren erneut medizinische Prüfungen zur Erlangung der Zulassung durchlaufen müßten, die in der Regel langwierig, aufwendig und somit kostspielig sind.

PATENTANSPRÜCHE

1. Dosieraerosolabgabevorrichtung mit einem Aerosolbehälter (23), einer in einem Düsenkörper (30) angeordneten Düse (31, 32), über die ein Aerosol abgegeben wird, wenn der Aerosolbehälter (23) gegenüber dem Düsenkörper (30) bei einer Betätigung der Dosieraerosolabgabevorrichtung verschoben wird, einem Zählwerk (1, 2, 3, 4) zur Zählung der Betätigungen der Dosieraerosolabgabevorrichtung und einer Betätigungsvorrichtung (10) zur Weiterschaltung des Zählwerks (1, 2, 3, 4) bei einer Betätigung der Dosieraerosolabgabevorrichtung, dadurch gekennzeichnet, dass die Betätigungsvorrichtung (10) so ausgestaltet und in der Dosieraerosolabgabevorrichtung angeordnet ist, dass der Düsenkörper (30) im Innern der Betätigungsvorrichtung (10) aufgenommen und die Düse (31) zur unbeeinflussten Aerosolerzeugung freigegeben ist.

2. Dosieraerosolabgabevorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Betätigungsvorrichtung (10) aus zwei gegeneinander verschiebbaren Hülsen (15, 16) besteht, die im Inneren den Düsenkörper (30) der Dosieraerosolabgabevorrichtung aufnehmen.

3. Dosieraerosolabgabevorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Hülsen (15, 16) der Betätigungsvorrichtung (10) durch Federelemente (17) miteinander verbunden sind, die die Hülsen (15, 16) der Betätigungsvorrichtung (10) in eine Ausgangsposition zurück bewegen.

4. Dosieraerosolabgabevorrichtung nach Anspruch 3, dadurch gekennzeichnet, dass die Federelemente (17) in Form von flachen, gebogenen Federelementen realisiert sind, die an den Außenseiten der Hülsen (15, 16) befestigt oder einstückig angeformt sind.

5. Dosieraerosolabgabevorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass an den Hülsen (15, 16) der Betätigungsvorrichtung (10) Führungselemente (19) vorgesehen sind, die eine geradlinige Verschiebung der beiden Hülsen (15, 16) gegeneinander gewährleisten.

6. Dosieraerosolabgabevorrichtung nach Ansprüche 3 oder 4, dadurch gekennzeichnet, dass die Federelemente (17) derart ausgestaltet sind, dass sie eine geradlinige Verschiebung der beiden Hülsen (15, 16) gegeneinander gewährleisten.

7. Dosieraerosolabgabevorrichtung nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass die Betätigungsvorrichtung (10) einen Betätigungsarm (5) umfasst, der auf das Zählwerk einwirkt, um das Zählwerk weiterzuschalten.

8. Dosieraerosolabgabevorrichtung nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, dass das Zählwerk aus mehreren parallel angeordneten Scheibeneinheiten (1, 2, 3, 4) aufgebaut ist und eine erste Scheibeneinheit eine Außenverzahnung (1a) aufweist, die mit der Betätigungsvorrichtung (10) zusammenwirkt.

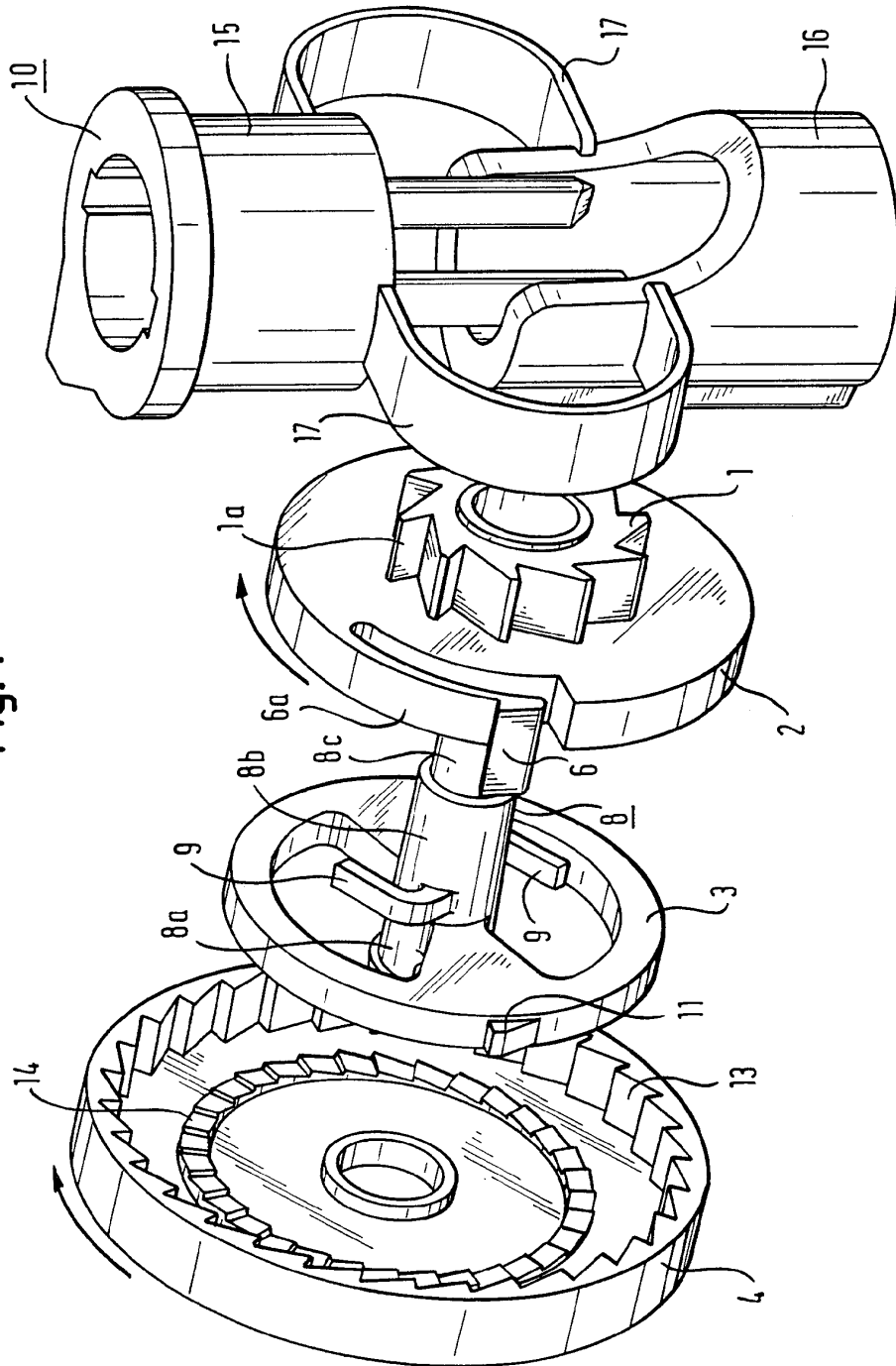
9. Dosieraerosolabgabevorrichtung nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, dass die Betätigungsvorrichtung (10) eine Öffnung (18) aufweist, in

der ein Lagerbolzen (8c) des Zählwerks zur Halterung des Zählwerks an der Betätigungsvorrichtung (10) befestigbar ist.

10. Dosieraerosolabgabevorrichtung nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, dass die Betätigungseinrichtung (10) eine Aussparung oder eine Öffnung aufweist, durch die die Düse (31) freigegeben ist.

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Fig. 1



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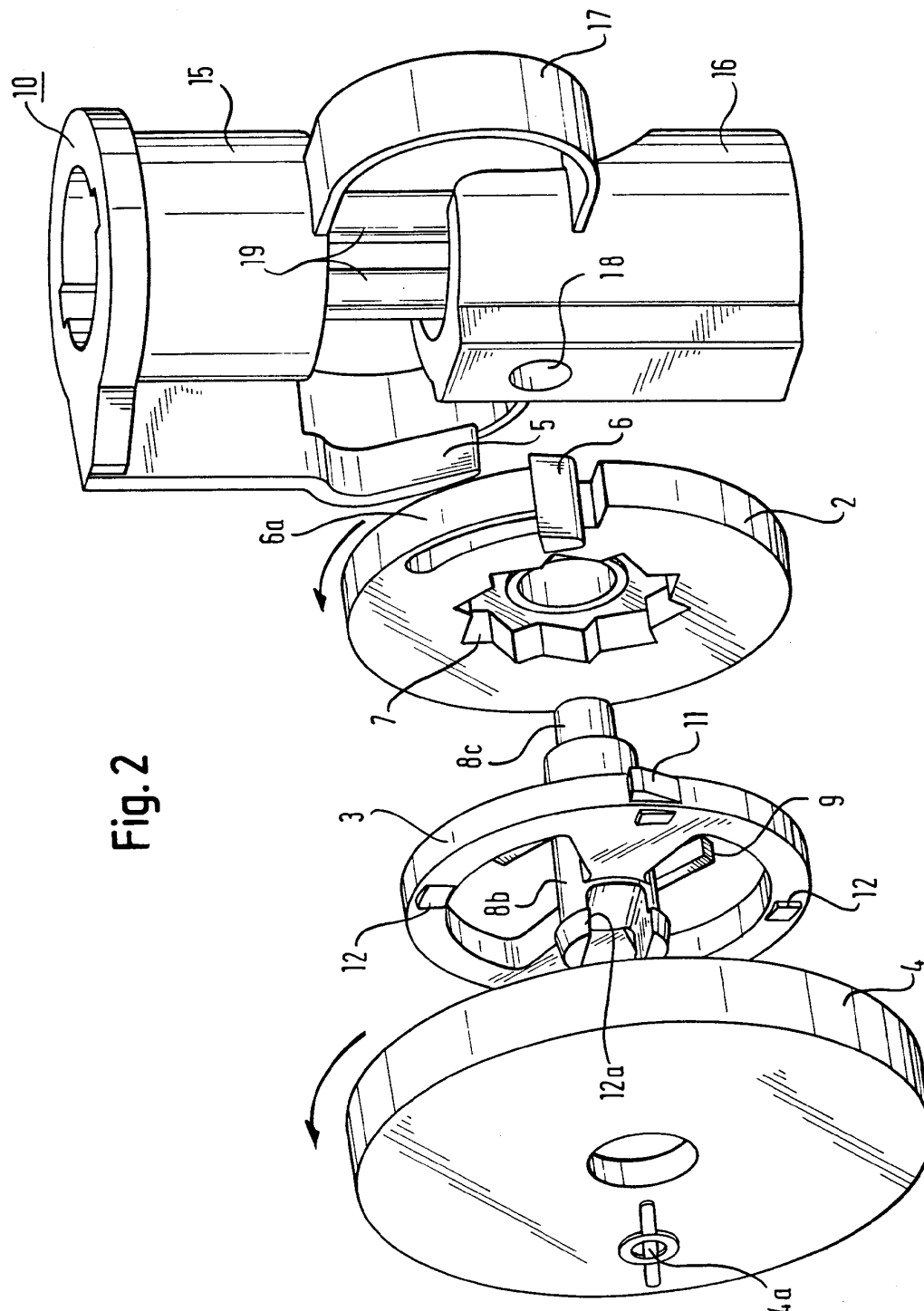


Fig. 2

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Fig. 3

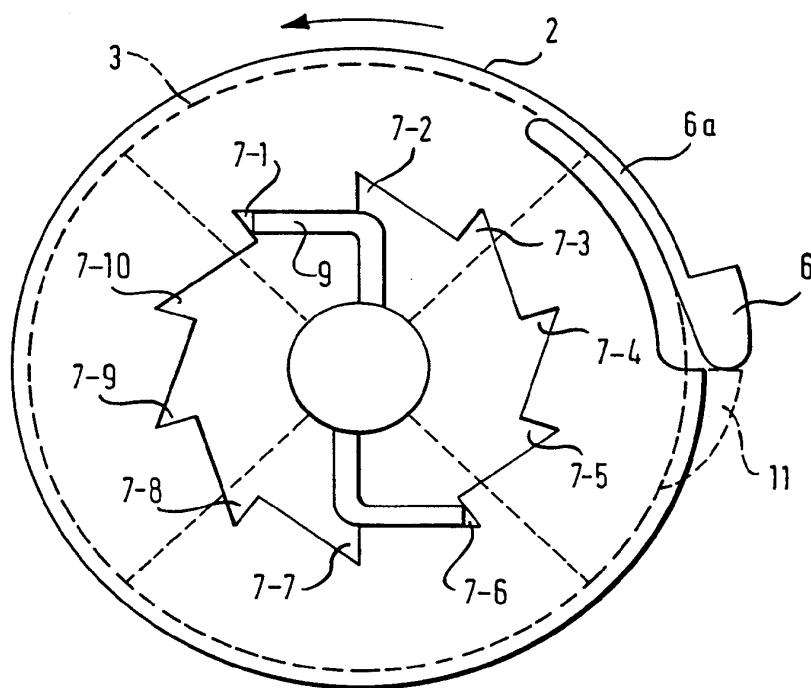
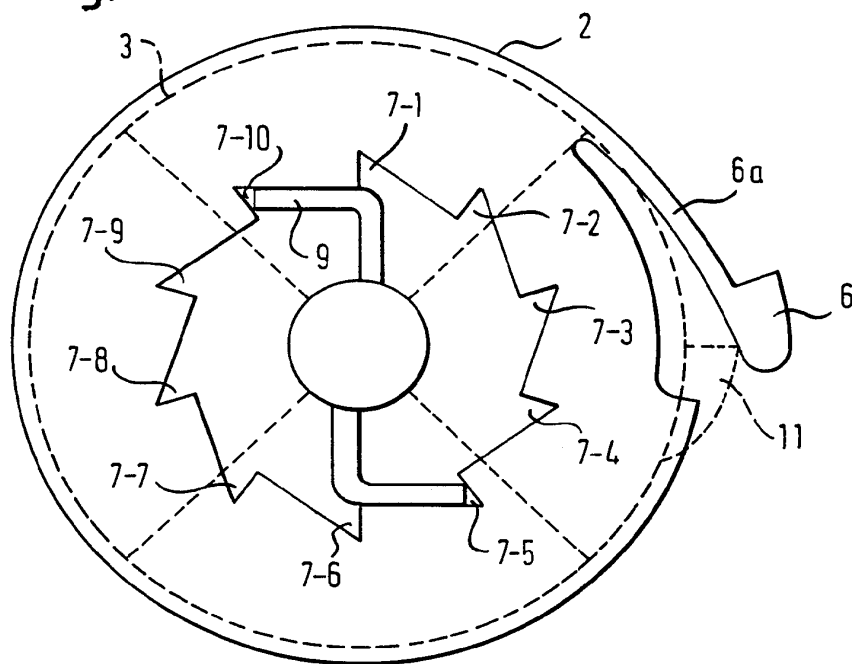


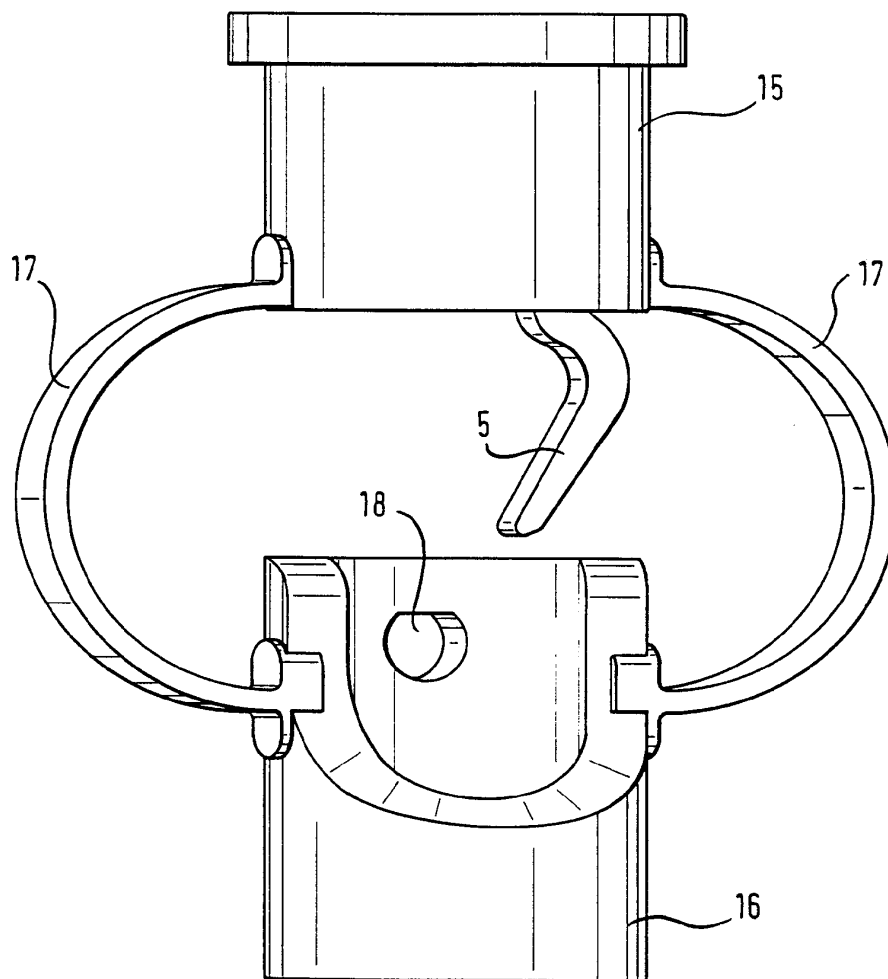
Fig. 4



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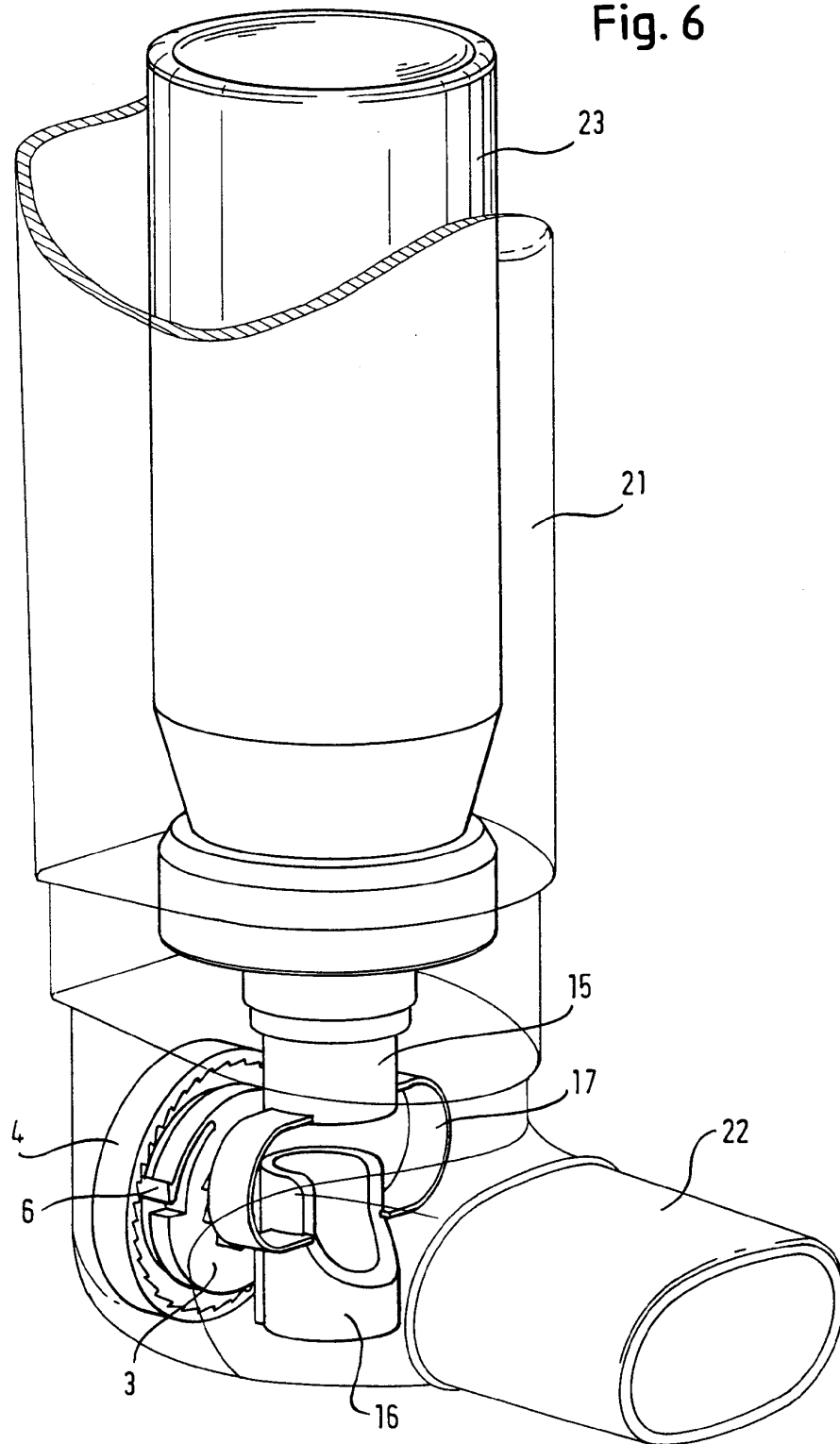
Fig. 5



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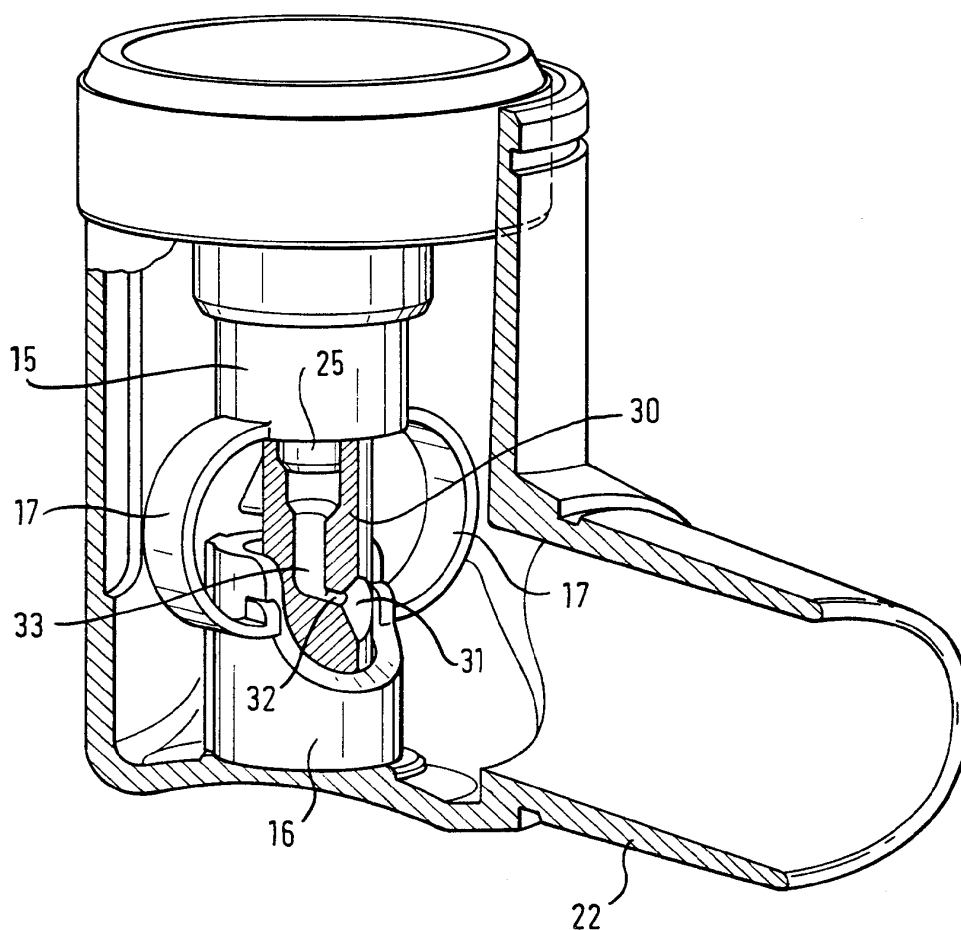
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Fig. 6



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Fig. 7



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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 99/06205

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 349 945 A (LAW BRIAN R ET AL) 27 September 1994 (1994-09-27)	1-3,7
Y	column 8, line 12 -column 9, line 3; figures 9-11	8
Y	GB 1 317 315 A (ENGLISH NUMBERING MACHINES) 16 May 1973 (1973-05-16) cited in the application figures	8
A	FR 2 022 212 A (VANTOREX LTD) 31 July 1970 (1970-07-31) claim 1; figure 2	1
A	US 5 482 030 A (KLEIN DAVID) 9 January 1996 (1996-01-09) claim 1; figures 3,4	1

☐ Further documents are listed in the continuation of box C.

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INTERNATIONAL SEARCH REPORT

Information on patent family members

In International Application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5349945 A	27-09-1994	AU 9060491 A DE 69108929 D DE 69108929 T EP 0559757 A WO 9209324 A	25-06-1992 18-05-1995 23-11-1995 15-09-1993 11-06-1992
GB 1317315 A	16-05-1973	NONE	
FR 2022212 A	31-07-1970	AU 6168869 A GB 1290484 A ZA 6906865 A	08-04-1971 27-09-1972 27-05-1971
US 5482030 A	09-01-1996	NONE	

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INTERNATIONALER RECHERCHENBERICHT

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C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 5 349 945 A (LAW BRIAN R ET AL) 27. September 1994 (1994-09-27)	1-3,7
Y	Spalte 8, Zeile 12 -Spalte 9, Zeile 3; Abbildungen 9-11	8
Y	GB 1 317 315 A (ENGLISH NUMBERING MACHINES) 16. Mai 1973 (1973-05-16) in der Anmeldung erwähnt Abbildungen	8
A	FR 2 022 212 A (VANTOREX LTD) 31. Juli 1970 (1970-07-31) Anspruch 1; Abbildung 2	1
A	US 5 482 030 A (KLEIN DAVID) 9. Januar 1996 (1996-01-09) Anspruch 1; Abbildungen 3,4	1

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PCT/EP 99/06205

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US 5349945 A	27-09-1994	AU 9060491 A DE 69108929 D DE 69108929 T EP 0559757 A WO 9209324 A	25-06-1992 18-05-1995 23-11-1995 15-09-1993 11-06-1992
GB 1317315 A	16-05-1973	KEINE	
FR 2022212 A	31-07-1970	AU 6168869 A GB 1290484 A ZA 6906865 A	08-04-1971 27-09-1972 27-05-1971
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : B65D 83/14, A61M 15/00		A1	(11) International Publication Number: WO 00/59806
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(21) International Application Number: PCT/GB00/01180 (22) International Filing Date: 28 March 2000 (28.03.00) (30) Priority Data: 9907928.7 7 April 1999 (07.04.99) GB (71) Applicant (for all designated States except US): BESPAC PLC [GB/GB]; Bergen Way, North Lynn Industrial Estate, King's Lynn, Norfolk PE30 2JJ (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): ALLSOP, Paul, Michael [GB/GB]; 6 Tyndale, North Wootton, King's Lynn, Norfolk PE30 3XD (GB). EAMES, Christopher, John [GB/GB]; 28 Saxon Way, Dersingham, King's Lynn, Norfolk PE31 6LY (GB). CLARK, David, John [GB/GB]; 323 Wootton Road, King's Lynn, Norfolk PE30 3AX (GB). (74) Agent: BOULT WADE TENNANT; Verulam Gardens, 70 Gray's Inn Road, London WC1X 8BT (GB).			(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: DISPENSING APPARATUS COMPRISING A DOSAGE COUNTING DEVICE			
(57) Abstract The present invention relates to dispensing apparatus comprising a housing (10) for receiving a pressurised container (15) containing product for dispensation, series of markings (172) indicative of quantities of product in the container, indicator means (160; 200) for indicating one of the markings of the series, and means for effecting relative movement between the indicator means and the series of markings on actuation of the pressurised container, so as to designate a subsequent marking of the series.			

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DISPENSING APPARATUS COMPRISING A DOSAGE COUNTING DEVICE

5 The present invention relates to improvements in
dispensing apparatus and, in particular, to
improvements in apparatus providing means for
measuring the quantity of product remaining in a
pressurised dispensing container.

10 Pressurised dispensing containers are widely used
in the pharmaceutical industry for storing medications
and other products to be dispensed in aerosol form.
Such containers usually contain a propellant, such as
HFC 134a, in which the product is suspended or
15 dissolved. Solvents, such as ethanol, may also be
present in the formulation. It is known to provide
pressurised dispensing apparatus capable of dispensing
metered doses of product from the containers upon each
actuation of the container valve, for example, metered
20 dose inhalers. The reliability and consistency of the
metered dose is especially important where the product
comprises or includes a medication. Inconsistent or
unreliable dispensation could result in a user of the
dispensing apparatus receiving too great or too little
medication.

25 A problem found by many users of such apparatus
is the inability to determine the quantity of product
remaining in the container. Many types of apparatus
continue to allow the dispensing of quantities of
propellant and/or solvent when the container is nearly
30 empty, even though the dose of product contained in
the propellant is below the required level, thereby
exacerbating the problem. Thus, users are often
unaware that the dispensing apparatus is operating

inadequately. This has potentially dangerous consequences where the product or medication dispensed is required urgently and no time is available to locate a replacement dispenser, such as in the treatment of asthmatic conditions. Sufferers of asthma often carry dispensers with them for extended periods of time, which may only be used on an occasional basis. Therefore, there is a danger that, where the user is unable to determine the contents of the pressurised dispensing container and the device is required in an emergency situation, the contents of the container may be inadequate.

It is an object of the present invention to provide apparatus for quickly and easily determining the quantity of product remaining in a pressurised dispensing container without the need for special testing equipment. Also, to provide apparatus suitable for use with conventional pressurised dispensing containers.

Accordingly, the present invention provides dispensing apparatus comprising a housing for receiving a pressurised container containing product for dispensation, a series of markings indicative of quantities of product in the container, indicator means for indicating one of the markings of the series, and means for effecting relative movement between the indicator means and the series of markings on actuation of the pressurised container so as to designate a subsequent marking of the series.

Embodiments of the present invention will now be described, by way of example only, with reference to the following drawings, in which:

Figure 1 is a side elevation of a first embodiment of dispensing apparatus according to the present invention;

Figure 2 is a rear elevation of a second
5 embodiment of dispensing apparatus according to the present invention;

Figure 3 is a sectional side elevation of the apparatus of Figure 1;

Figure 4 is a perspective view of an inner
10 housing of the apparatus of Figure 1 containing a dispensing device;

Figure 5 is a schematic diagram of lugs of the apparatus of Figure 1;

Figure 6 is a perspective view of a collar of the
15 apparatus of Figure 1;

Figure 7 is a plan view of a ring of the apparatus of Figure 1;

Figure 8 is a perspective view of a cap of the apparatus of Figure 1;

Figure 9 is a plan view of another version of
20 ring;

Figure 10 is a side elevation of the cap shown in Figure 8 assembled with a dispensing device;

Figure 11 is a schematic view of a part of the
25 outer housing of the apparatus of Figure 1;

Figure 12 is a schematic cross-sectional view of the outer housing of the apparatus of Figure 1;

Figure 13 is a side elevation of an alternative apparatus according to the present invention;

Figure 14 is a perspective view of a marker of an
30 alternative apparatus according to the present invention; and

Figure 15 is a side elevation, showing some

- 4 -

hidden detail, of the marker of Figure 14 assembled with the dispensing apparatus of the present invention.

5 Figures 1 to 12 show a dispensing apparatus according to the present invention. The apparatus comprises a housing 10 having a generally cylindrical portion 11, defining a chamber to slidably receive a pressurised dispensing container 15 and a mouthpiece 12, which extends laterally from a lower end of the cylindrical portion 11. The mouthpiece 12 may extend at a slight downward angle from the cylindrical portion 11. The pressurised dispensing container 15 comprises a metering valve attached to a can, for storing the product to be dispensed, by means of a ferrule which is placed over a valve stem of the metering valve and crimped to the open mouth of the can. A valve stem 16 extends axially from the metering valve and defines an outlet through which product is dispensed. The valve stem 16 is received in a valve stem receiving block 13 provided at a distal end of the generally cylindrical portion 11 as the dispensing container 15 is inserted therein. The valve stem receiving block 13 comprises a duct and an orifice such that product dispensed through the outlet of the valve stem 16 is directed through the duct and out of the orifice in the direction of the mouthpiece 12 in the form of an aerosol. Optionally the mouthpiece 12 may be covered by a mouthpiece cover when the apparatus is not being used, in order to protect the mouthpiece 12 from dust, dirt or other matter. In addition, the mouthpiece 12 may be detachable from the generally cylindrical portion 11 to allow for washing

- 5 -

and cleaning of the mouthpiece. Preferably, the detachable portion would include the valve stem receiving block 13 which is the component most prone to becoming clogged with deposits from the pressurised dispensing container 15. An internal lip in the generally cylindrical portion 11 may be provided to retain the pressurised dispensing container 15 within the generally cylindrical portion 11 when the mouthpiece 12 is detached.

In the apparatus of the present invention the housing 10 is provided with means to indicate to a user of the apparatus the quantity of product in the pressurised dispensing container.

The apparatus comprises an inner cylindrical housing 140 open at both ends as shown in Figure 4. The inner cylindrical housing 140 is provided with a number of inwardly directed ribs which act to reduce the effective diameter of the aperture. The other end 144 is unobstructed, as shown in Figure 4. In use the pressurised dispensing container 15 is located in the inner housing 140 with valve stem 16 protruding through the aperture. The ribs prevent the container 15 from passing through the aperture. The pressurised dispensing container 15 may be inserted and removed from the inner housing 140, during assembly of the apparatus, through the aperture 144.

The inner housing 140 is provided with an annular flange 142. The flange 142 has a number of protrusions 143 equidistantly spaced around its circumference. An exterior surface of the inner housing 140 has a helical groove 141 extending from the large open end 144 to the flange 142.

Around the inner housing 140 is located a ring

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160. As shown in Figure 7, the ring 160 has two pins 161 located on opposite sides thereof. The pins 161 penetrate the ring 160 or are two part elements having an outer portion 164 on an outer surface of the ring 160 and an inner portion 162 on an inner surface of the ring 160. The ring 160 is located around the inner housing 140 such that the inner portion 162 of each pin 161 is received in the groove 141 of the inner housing 140. The ring 160 is thus rotatable about and slidable along the inner housing 140 with the pins 161 constrained to move along helical groove 141. The ring 160 may, in addition, have an arcuate member 163 joined at each end to the outer portions 164 of each pin 161 as shown in Figures 2 and 9.

15 The cylindrical portion 11 of the housing 10 is provided with one or two longitudinally orientated slots 170, as shown in Figure 1. The slots 170 may extend upwardly to contact the open end of the cylindrical portion 11 of housing 10 as shown in Figure 12. The slots 170 may be provided with inserts 173 at their lower ends as shown in Figure 11 to limit the degree to which the pins 161 may move down the slots 170. In this way the number of potential doses dispensed by the apparatus may be reduced so as to ensure that the apparatus is disposed of before there is any danger of reduction in the quantity of product dispensed in each dose. Alternatively the actuator may be moulded with a slot 170 of shorter length so as to reduce the number of potentially deliverable doses.

30 The housing 10 further comprises a collar 155, shown in Figure 6, having a plurality of inwardly directed lugs 156. The lugs 156 have angled upper and lower surfaces, shown schematically in Figure 5. An

outer surface of the collar 155 comprises a notch 157. The internal diameter of the collar 155 is marginally greater than the external diameter of the flange 142 of the inner housing 140. The collar 155 is inserted
5 in housing 10 near a lower end of cylindrical housing portion 11. Notch 157 engages a detent (not shown) on the cylindrical housing portion 11 to prevent rotational movement of the collar 155. Alternatively, collar 155 may be integrally moulded with the
10 generally cylindrical portion 11. As an alternative the protrusions 143 may be provided as inwardly directed protrusions on the collar 155 and the lugs 156 may be provided as outwardly directed lugs on the flange 142.

15 The inner housing 140 is assembled with the main housing 10 such that the valve stem 16 of the pressurised dispensing container 15, which protrudes through the aperture of the inner housing 140 provided with the ribs, is received in the valve stem block 13,
20 as shown in Figure 3. A spring is provided between the inner housing 140 and the main housing 10 to bias the inner housing 140 upwardly away from the valve stem block 13. This may be achieved by means of a compression spring extending between the flange 142,
25 or other part of inner housing 140, and a lower part of the housing 10 or by a tensile spring extending between the flange 142 and an upper part of the housing 10. Alternatively, the internal spring force of the metering valve of the pressurised dispensing
30 container 15, which is used to bias the pressurised dispensing container 15, could be used to bias the inner housing 140 away from the valve stem receiving block 13.

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The flange 142 is received in collar 155 with the flange protrusions 143 adjacent to, or contacting the inwardly directed collar lugs 156. The outer portions 164 of pins 161 of ring 160 are located in the slots 170 in the main housing 10 as shown in Figure 1. In the embodiment provided with the arcuate member 163 attached to the ring 160, the arcuate member 163 is positioned around an exterior of the main housing 10 as shown in Figure 2.

A cap 150 as shown in Figures 8 and 10 may be fitted over the open end of the housing 10 on the cylindrical portion 11 to retain the container 15, inner housing 140 and other components in position. The cap 150 comprises two flexible legs 151 which extend downwardly from cap 150 within the housing 10. The legs 151 flex apart as a pressurised dispensing container 15 is inserted through cap 150 into the inner housing 140. As the distal end of the legs pass over the ferrule of the pressurised dispensing container 15 they flex inwardly, thereby trapping the container 15 and preventing its withdrawal.

A push-button cap (not shown) may be provided as part of the main housing 10 to cover the upper portion of the pressurised dispensing container 15. Advantageously, this prevents the ingress of dust, contaminants and moisture into the apparatus.

Markings 172 are printed or embossed on an exterior surface of the housing 10 adjacent the slots 170. The markings 172 may comprise numbers indicating the quantity of product in the pressurised dispensing container 15 in terms of the number of dosages remaining. Alternatively they may comprise a series of descriptive statements indicating how full the

- 9 -

pressurised dispensing container 15 is, such as "FULL", "3/4 FULL", "½ FULL" etc.

Depression of the pressurised dispensing container 15 results in downward movement of the container 15 relative to the housing 10. As the container 15 moves downwardly, the inner housing 140 is caused to move downwardly such that the protrusions 143 contact the angled surfaces of the inwardly directed lugs 156 of collar 155. As a result the inner housing 140 is urged to incrementally rotate about its longitudinal axis. Since pins 161 are received in the slots 170 the ring 160 is incrementally moved vertically relative to the inner housing 140. As a result, the outer portions 164 of pins 160 and/or the arcuate member 163 are moved into alignment with a subsequent marking 172 indicating that the pressurised dispensing container 15 contains one less dose. The angled surfaces of the inwardly directed lugs 156 are dimensioned such that the inner housing 140 is urged to rotate on upward vertical movement of the protrusions 143, as occurs when the pressurised dispensing container 15 is released due to the biasing force of the spring, as well as downward vertical movement, as occurs when the pressurised dispensing container 15 is depressed.

When the pins 162 reach the bottom of the helical groove 141 the device locks-out preventing any further dispensation.

The following variations to the invention may advantageously be incorporated, either singly or in combination, in the apparatus described above.

The inner housing 140 may be dispensed with and the helical groove 141 be provided in the container

- 10 -

wall of the pressurised dispensing container 15 and the protrusions 143 provided on the ferrule of the pressurised dispensing container 15.

5 The ring 160 may be replaced with a series of numbers or other markings spaced around the inner housing 140 or pressurised dispensing container 15 in a helical arrangement and spaced such that only a single number or marking is visible at any one time through the slots 170.

10 The inner housing may be non-rotatable and the collar 155 may be rotatable on interaction with the protrusions 143 of the inner housing 140. A series of markings or numbers are printed around the collar 155 and arranged such that at any one time a single number
15 or marking is visible to a user of the apparatus through, for example, a sight window in the main housing 10.

The inner housing 140 may be non-rotatable and a helical slot be provided in the generally cylindrical
20 portion 11 of the main housing 10 in which the ring 160 is deployed as shown in Figure 13. The ring 160 is operatively connected to the collar 155. Actuation of the apparatus causes the collar 155 and ring 160 to rotate about the inner housing 140 such that the pins
25 161 of the ring 160 move downwardly and around the helical slot.

The ring 160 may be replaced by a marker 200 having protrusions 202, 203 on each side as shown in Figure 14. The inwardly directed protrusion 203 is
30 disposed at an angle to the edges of the marker 200 such that it is received slidingly in the helical groove 141 of the inner housing. The outwardly directed protrusion 202 is disposed parallel to the

- 11 -

edges of the marker 200 such that it is received
slidingly in the vertical slot 170 of the main housing
10 when positioned between the inner housing 140 and
the main housing 10 as shown in Figure 15. An
5 indicating dot 204 may be provided to indicate which
marking 172 is designated.

Similarly to ring 160 relative movement of the
inner housing 140 and the cylindrical portion 11 of
the main housing 10 causes the marker 200 to move
10 along the longitudinal axis of the cylindrical portion
11 in the direction of arrow 205.

The protrusions 143 and the collar 155 may be
provided aligned with the top end of the inner housing
140 remote from the valve stem receiving block 13
15 rather than at the bottom end.

Claims:

1. Dispensing apparatus comprising a housing (10)
for receiving a pressurised container (15) containing
5 product for dispensation, a series of markings (172)
indicative of quantities of product in the container,
indicator means (160; 200) for indicating one of the
markings of the series, and means for effecting
relative movement between the indicator means and the
10 series of markings on actuation of the pressurised
container so as to designate a subsequent marking of
the series.
2. Dispensing apparatus as claimed in claim 1
15 wherein a cylindrical member (140) is located in the
housing (10), one of the housing and the cylindrical
member being provided with a longitudinal slot (170)
and the other of the housing and the cylindrical
member having a helical channel (141) along its
20 longitudinal axis, the indicator means (160; 200)
being operatively connected to both the longitudinal
slot and helical channel such that rotation of the
cylindrical member relative to the housing moves the
indicator means along the longitudinal axis of the
25 cylindrical member.
3. Dispensing apparatus as claimed in claim 2
wherein the housing (10) and the cylindrical member
(140) are provided with co-operating formations (143,
30 156) having angled abutment surfaces such that
relative longitudinal movement between the housing and
the cylindrical member causes relative rotation
between the housing and cylindrical member.

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4. Dispensing apparatus as claimed in claim 1 wherein one of the housing and the pressurised container (15) is provided with a longitudinal slot (170) and the other of the housing and the pressurised
5 container is provided with a helical channel (141) along its longitudinal axis, the indicator means (160; 200) being operatively connected to both the longitudinal slot and helical channel such that rotation of the pressurised container relative to the
10 housing moves the indicator means along the longitudinal axis of the housing.

5. Dispensing apparatus as claimed in claim 4 wherein the housing (10) and the pressurised container
15 (15) are provided with co-operating formations (143, 156) having angled abutment surfaces such that relative longitudinal movement between the housing and the pressurised container causes relative rotation between the housing and pressurised container.

20 6. Dispensing apparatus as claimed in any of claims 2 to 5 wherein the housing (10) comprises a collar (155) having one of the co-operating formations (143; 156) formed thereon.

25 7. Dispensing apparatus as claimed in any of claims 2 to 6 wherein the indicator means is a ring having one or more pins located in the longitudinal slot (170) and the helical channel (141).

30 8. Dispensing apparatus as claimed in any of claims 2 to 6 wherein the indicator means is a marker (200) having a first protrusion (203) engaged in the helical

channel (141) and a second protrusion (202) located in the longitudinal slot (170).

9. Dispensing apparatus as claimed in claim 1
5 wherein the housing (10) comprises a longitudinal slot (170) and the series of markings (172) are provided in a helical arrangement around the pressurised container (15) or other member (140; 155) located in the housing, such that only one of the series of markings
10 is visible through the slot at any one time.

10. Dispensing apparatus as claimed in any preceding claim comprising means (173) for locking out operation of the pressurised container after a pre-determined
15 number of actuations.

11. Dispensing apparatus as claimed in any preceding claim wherein the housing (10) comprises a mouthpiece (12) which is detachable.
20

12. Dispensing apparatus as claimed in any preceding claim further comprising a pressurised dispensing container (15) located in the housing (10).

FIG. 1.

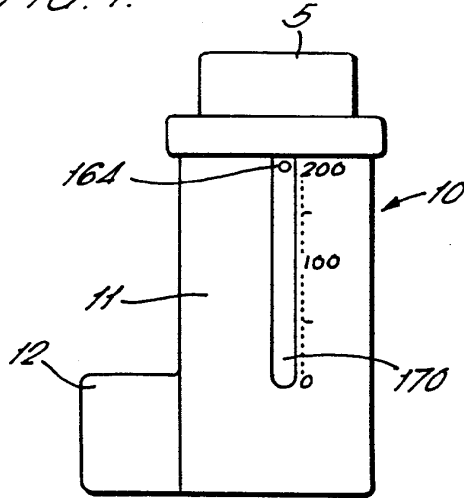


FIG. 2.

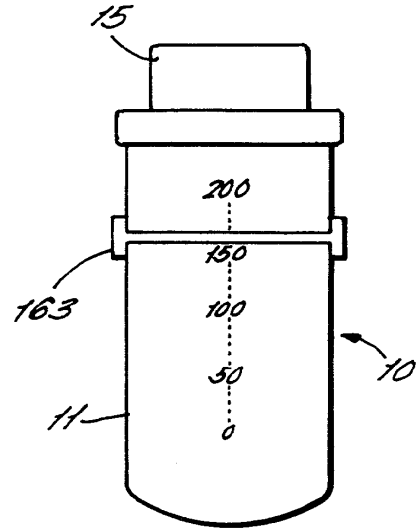


FIG. 3.

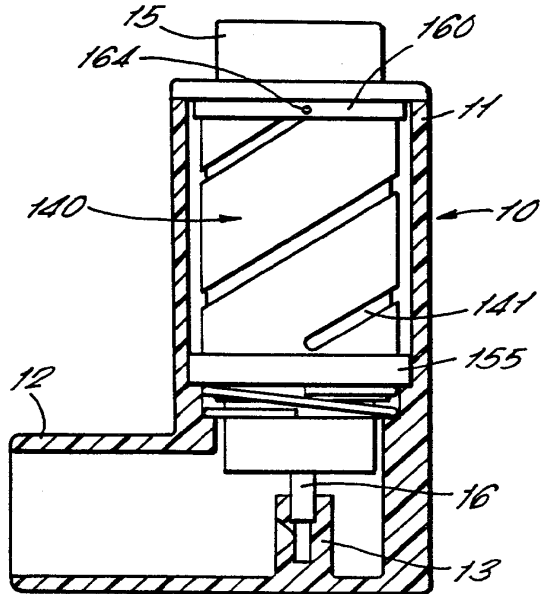


FIG. 4.

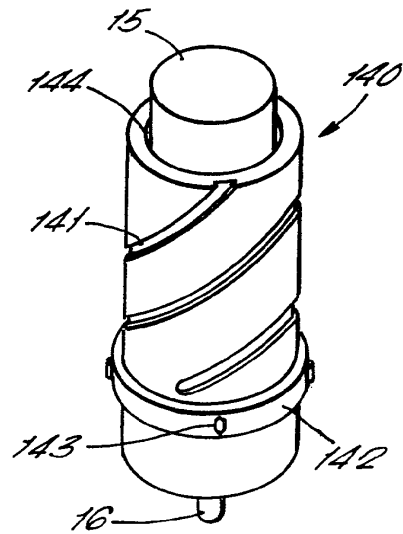


FIG. 5.

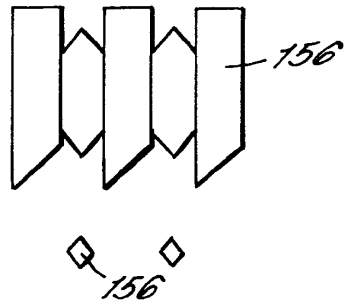


FIG. 6.

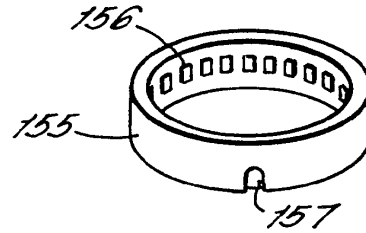


FIG. 7.

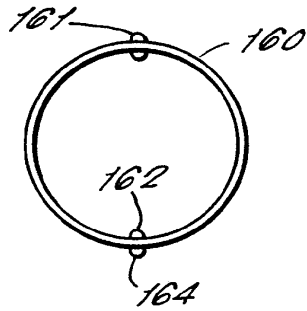


FIG. 8.

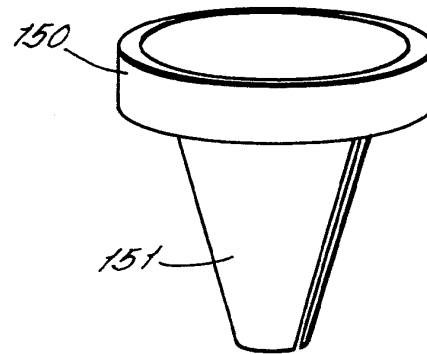
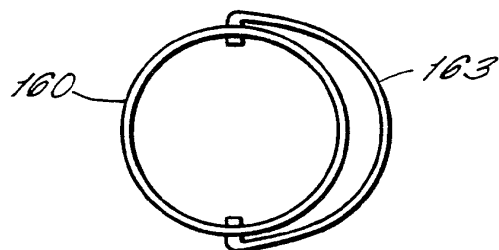


FIG. 9.



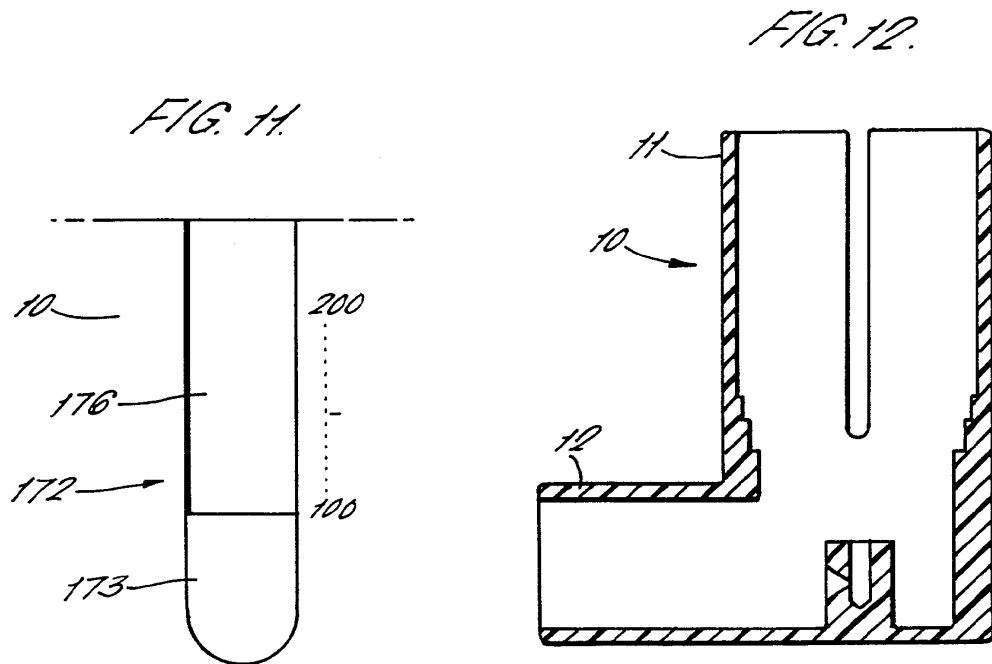
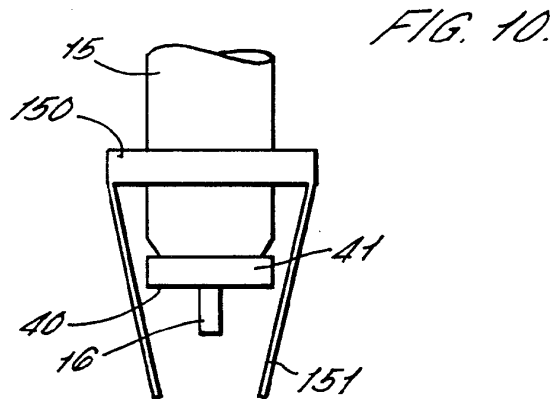
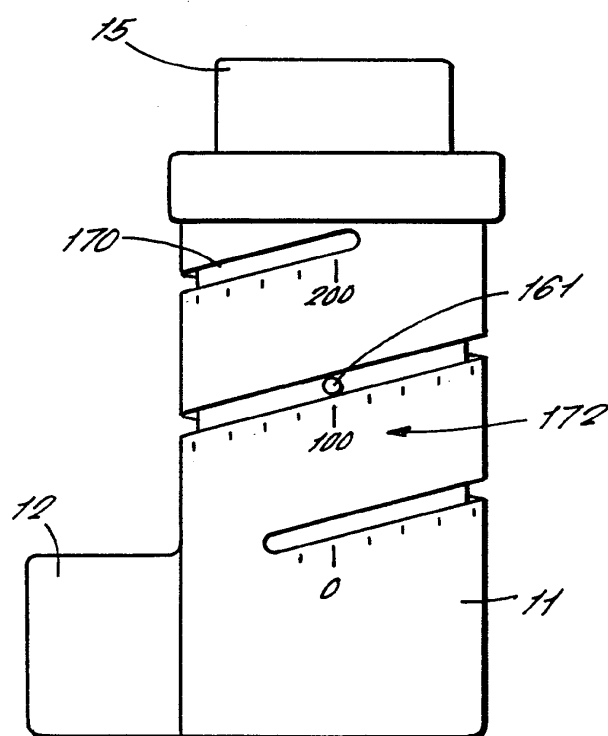


FIG. 13.



INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER IPC 7 B65D83/14 A61M15/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 349 945 A (WASS ET AL.) 27 September 1994 (1994-09-27) the whole document	1, 12
X	WO 98 56444 A (GLAXO) 17 December 1998 (1998-12-17) abstract; figures	1, 12
☐ Further documents are listed in the continuation of box C. ☒ Patent family members are listed in annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 28 June 2000		Date of mailing of the international search report 06/07/2000
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Gino, C

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5349945 A	27-09-1994	AU 9060491 A	25-06-1992
		DE 69108929 D	18-05-1995
		DE 69108929 T	23-11-1995
		EP 0559757 A	15-09-1993
		WO 9209324 A	11-06-1992
WO 9856444 A	17-12-1998	AU 8213798 A	30-12-1998
		AU 8213898 A	30-12-1998
		AU 8436498 A	30-12-1998
		WO 9856445 A	17-12-1998
		WO 9856446 A	17-12-1998
		EP 0988077 A	29-03-2000
		EP 0988078 A	29-03-2000
		EP 0986412 A	22-03-2000
		HR 980304 A	30-04-1999
		NO 996085 A	09-02-2000

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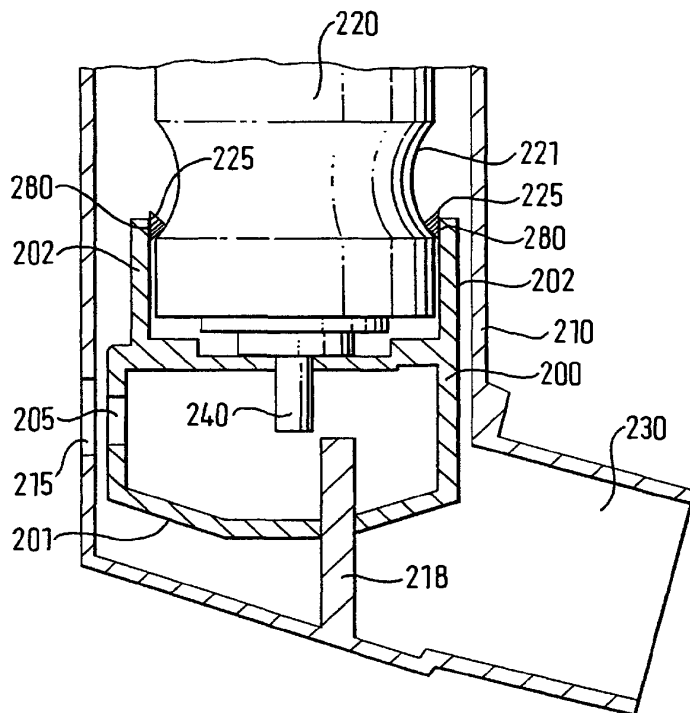
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- (74) Agent: **PIKE, Christopher, Gerard**; Pike & Co., Hayes Loft, 68A Hayes Place, Marlow, Buckinghamshire SL7 2BT (GB).
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[Continued on next page]

(54) Title: DEVICE HOUSING FOR AN AEROSOL CONTAINER



(57) Abstract: A housing (200) for a mechanical or electrical device for use with an aerosol canister (220) for containing chemical comprising a sleeve (202) for receipt of the aerosol canister; a collar (225) affixable around the neck of the canister; and a joint (280) between the sleeve and the collar to secure the housing to the canister.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DEVICE HOUSING FOR A AEROSOL CONTAINER

Technical Field

5 The present invention relates to a housing for a mechanical or electrical device which is joinable to a collar affixed around the neck of an aerosol canister to form a chemical dispenser. In particular, it relates to a medicament dispenser formable by
10 welding a housing for a dose counter to a collar affixed around the neck of an aerosol canister.

Background to the Invention

15 Aerosol canisters are widely used in domestic, commercial and industrial situations for the application of a range of chemicals. Typical examples of chemical products which are dispensable in this way include cosmetics, health products, paints, pharmaceuticals and agrochemicals. Frequently there is a need to attach
20 mechanical or electrical devices to such aerosol canisters, for example to regulate or record the flow of chemical from the canister, or to act as environmental sensors. Such devices may be affixed to the canisters by a range of technologies including the use of adhesives and heat treatment, such as soldering or welding. However, the attachment of such devices to aerosol canisters poses difficulties in terms of
25 producing a secure joint without affecting the integrity of the chemical by the application of excess heat during the heating or welding process. Similarly, the use of adhesives may lead to contamination problems due to the presence of low concentrations of volatiles from the adhesive on dispensing the chemical.

30 Medicament dispensers are extensively used in the administration of medicines, particularly those for the treatment of respiratory disorders. Medicaments which are

contained in an aerosol and are administered to a patient by means of an inhalation device are widely used in such therapy. These inhalation devices typically comprise a tubular housing or sleeve in which the aerosol canister is located and an outlet tube leading from the housing. The aerosol canisters used in such inhalation devices are designed to deliver a predetermined dose of medicament upon actuation; the valves can be opened either by depression of the valve member itself or by depression of the canister while the valve member is held stationary. In the use of such devices, the aerosol canister is placed in the tubular housing with the outlet valve member of the canister communicating via a support with the outlet tube, for example a nozzle or mouthpiece.

A recent development in this field of technology is the use of mechanical or electrical dose counters to register the number of medicament doses used or remaining within the medicament dispenser. Dose counters can be positioned within the tubular housing and operate by means of detecting movement of the housing relative to the aerosol canister on actuation of the dispenser by the patient. The indexing mechanism of the dose counter registers the actuation of the dispenser and the counter displays how many doses have been used or remain within the aerosol canister.

Some dose counters are detachable from the aerosol dispenser. One disadvantage of such devices is that the individual components may become separated and used in isolation from each other. Another disadvantage of these devices is that once the dose counter is removed from the aerosol canister it may be tampered with, typically by young children, to give a false reading. Detachment of the dose counter from the aerosol canister could therefore result in false readings on re-attachment to the canister. Furthermore, with patients having several different inhalers, the indicating device could be re-attached to the wrong dispenser.

Other dose counters are essentially irreversibly attached to the aerosol dispenser. One means of affixing dose counters to aerosol canisters is to use a 'snap-fit'

mechanism whereby a tubular grip assembly on the dose counter housing is pushed into position around the neck of the valve ferrule thereby locking the two components together. Whilst this arrangement holds the two structures securely together there can, on occasions, be some lateral movement or 'play' of one component relative to the other. As mechanical dose counters operate by registering relative movement of the aerosol canister to the dose counter housing, any play or lateral movement can result in false readings being registered on the dose counter. A key factor in the successful operation and functioning of such dose counters is that there be minimal movement of the housing relative to the aerosol canister outwith the actuation cycle.

10

Dimensional variation resulting from manufacturing tolerances of aerosol canisters and dose counter housings poses additional problems in the assembly and operation of medicament dispensers. In order that the dose indicator mechanism functions correctly the canister and the counter housing must fit together tightly. Thus any variations in the dimensions of either of these components which result in a loose fit between the counter housing and the canister can lead to increased relative movement and the problems of false readings discussed above.

To overcome these problems of dimensional variation, stringent tolerance levels must be set for the manufacture of both the counter housing and the aerosol canister. This approach, together with the high levels of quality control necessary to ensure that both components meet the required engineering standards, is expensive for the manufacturer.

It is an object of the present invention to address the aforementioned problems associated with attachment of a mechanical or electrical device to an aerosol canister, in particular for the attachment of a dose counter housing thereto. The present invention involves joining the device housing to a ring or collar affixed around the neck of an aerosol canister to minimise the relative movement of the component parts. This joining can be achieved by a variety of technologies, including melting the components together by means of 'hot staking', soldering the

30

surfaces together, or using adhesives to bind the housing to the collar. Welding technologies are particularly well suited for this purpose.

5

Summary of Invention

According to the present invention there is provided a housing for a mechanical or electrical device for use with an aerosol canister for containing chemical comprising a sleeve for receipt of the aerosol canister; a collar affixable around the neck of the
10 canister; and a joint between the sleeve and the collar to secure the housing to the canister.

In one aspect, the collar is a split collar.

15 In another aspect, the collar comprises the same material as the sleeve.

In a further aspect, the joint is a weld.

In yet another aspect, the weld is an ultrasound weld.

20

In a further aspect, the weld is a single continuous weld.

Optionally the weld comprises a plurality of spot welds. Preferably the number of welds is from 2 to 100, more preferably 6.

25

In another aspect, the weld is obtainable by energy generated by a sonitrode head, of energy output 100-200 Watts, frequency 20-50 kHz and duration 100-200 milliseconds. A typical sonitrode head would be a converter.

30 In one aspect, the housing additionally comprises a mechanical or electrical device.

Preferably the mechanical or electrical device is a dose counter.

Preferably the electrical device is a sensor.

- 5 Preferably the sensor is for sensing the pressure profile associated with the breath cycle. Pressure transducers are suitable sensors of this type.

More preferably the sensor is for sensing the airflow profile associated with the breath cycle. Sprung vane sensors and sensors including anemometers are suitable
10 sensors of this type.

More preferably the sensor is for sensing the temperature profile associated with the breath cycle. The temperature of the inhaled and exhaled part of the breath cycle varies and may, thus, be used as a measurement tool.

15 Most preferably the sensor is for sensing the moisture profile associated with the breath cycle. The moisture content of the inhaled and exhaled part of the breath cycle varies and this also may be used as a measurement tool.

20 In a further aspect, the electrical device comprises a transceiver for transmitting and receiving data. Preferably, the transceiver comprises a radiofrequency identifier comprising an antenna for transmitting or receiving radiofrequency energy, and an integrated circuit chip connecting with said antenna.

25 The radiofrequency identifier can be any known radiofrequency identifier. Such identifiers are sometimes known as radiofrequency transponders or radiofrequency identification (RFID) tags or labels. Suitable radiofrequency identifiers include those sold by Phillips Semiconductors of the Netherlands under the trade marks Hitag and Icode, those sold by Amtech Systems Corporation of the United States of America
30 under the trade mark Intellitag, and those sold by Texas Instruments of the United States of America under the trade mark Tagit.

Preferably the transceiver comprises a magnetic label or tag comprising an antenna for transmitting or receiving magnetic field energy; and an integrated circuit chip connecting with the antenna.

5

A suitable magnetic label or tag comprises plural magnetic elements in mutual association whereby the magnetic elements move relative to each other in response to an interrogating magnetic field. A magnetic label or tag of this type is described in U.S. Patent No. 4,940,966. Another suitable magnetic label or tag comprises a
10 magnetorestrictive element which is readable by application of an interrogating alternating magnetic field in the presence of a magnetic bias field which results in resonance of the magnetorestrictive elements at different predetermined frequencies. A magnetic label of this type is described in PCT Patent Application No. WO92/12402. Another suitable magnetic label or tag comprising plural discrete
15 magnetically active regions in a linear array is described in PCT Patent Application No. WO96/31790. Suitable magnetic labels and tags include those making use of Programmable Magnetic Resonance (PMR) (trade name) technology.

In another aspect, the electrical device comprises a microelectronic memory chip.
20 The microelectronic memory chip may be selected from the group consisting of programmable read only memory (PROM), erasable programmable read only memory (EPROM), electrically erasable programmable read only memory (EEPROM) and a SIM card-type memory chip. The microelectronic memory chip may alternatively be a random access memory (RAM) chip, powered by a suitable
25 source such as a battery.

In one aspect, the housing additionally comprises a window for viewing a reading from the mechanical or electrical device. The reading may typically be in the form of a digital readout on a visual display unit or counter, or may take the form of a
30 flashing coloured light to indicate, for example, the doses remaining within the canister.

In another aspect of the present invention there is provided a method for securing a housing for a mechanical or electrical device to an aerosol canister comprising placing a collar around the neck of the canister; positioning a sleeve around the collar; and joining the collar to the sleeve.

5

In one aspect, the method additionally comprises associating the mechanical or electrical device with the sleeve. The device may be associated with the sleeve using a snap-fit mechanism. Preferably the method additionally comprises sealing the mechanical or electrical device within the sleeve. The device may be sealed within the sleeve using a range of sealing means, such as welding, soldering or adhesive means. Welding means are particularly suitable for sealing the device within the sleeve.

Preferably the method comprises inserting the mechanical or electrical device into the sleeve before joining the collar to the sleeve. More preferably the method comprises sealing the mechanical or electrical device within the sleeve before joining the collar to the sleeve.

Preferably the method comprises inserting the mechanical or electrical device into the housing after joining the collar to the sleeve. More preferably the method comprises sealing the mechanical or electrical device within the housing after joining the collar to the sleeve.

In one aspect, the device is a dose counter. In another aspect, the device is a sensor. In a further aspect, the device is a transceiver for transmitting or receiving data. In another aspect, the device is a microelectronic memory chip.

In one aspect, the collar is a split collar. Preferably, the collar comprises the same material as the sleeve around the canister.

30

In another aspect, the method comprises joining the collar to the sleeve by welding. Preferably, the welding comprises ultra sound welding.

More preferably, the method comprises applying a single continuous weld. More preferably, the method comprises applying a plurality of spot welds. More preferably, it comprises applying from 2 to 100 welds, most preferably applying 6 welds.

In a further aspect, the method comprises using a sonitrode head to produce a weld condition of output 100 to 200 Watts, frequency 20 to 50 kilo Hertz and duration 100 to 200 milli seconds.

In another aspect of the present invention there is provided a dispenser comprising a housing according to the invention securable to an aerosol canister.

Preferably the dispenser additionally comprises an actuator body.

Preferably the dispenser is a medicament dispenser wherein the aerosol canister comprises a medicament in a propellant. More preferably the propellant is liquefied HFA134a or HFA-227. Most preferably the medicament is selected from the group consisting of albuterol, salmeterol, ipratropium bromide, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof and any mixtures thereof.

The present invention further provides a kit of parts comprising a housing according to the present invention and an aerosol canister for containing chemical. Preferably the kit additionally comprising an actuator body. More preferably the chemical is a medicament.

In a further aspect of the present invention there is provided the use of medicament dispenser according to the present invention for the administration of medicament to a patient.

Brief Description of Drawings

5 The invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a schematic representation of a section through a standard metered dose inhalation device.

10

Figure 2 is a schematic representation of a section through an aerosol canister affixed to a housing according to the present invention.

15

Figure 3 is a schematic representation of a medical dispenser according to the present invention.

20

Figures 4a - c is a schematic illustration of the process whereby a dose counter housing is secured to a standard metered dose inhalation device by ultrasound welding.

Figures 5a & b show a housing for a transceiver affixed to an aerosol container and a cross section of the housing according to the present invention.

25

Detailed Description of Drawings

The standard metered dose inhaler shown in Fig 1 comprises a housing 10 in which an aerosol canister 20 can be located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. An outlet 30 leads laterally from the closed end of the housing 10. In the embodiment illustrated, the outlet 30 is in the form of a

30

mouthpiece intended for insertion into the mouth of the patient but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

5 The aerosol canister 20, comprising a neck region 21 and ferrule 22, has an outlet valve stem 40 at one end. This valve member can be depressed to release a measured dose from the aerosol canister or, alternatively, the valve stem 40 can be fixed and the main body of the canister can be moved relative to the valve member to release the dose.

10 As shown in Figure 1, the aerosol canister 20 is located in the housing 10 so that one end protrudes from its open top, the canister being positioned such that the neck 21 and valve ferrule 22 are enclosed within housing 10. Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the canister 20 spaced from the internal surface of the housing 10. A support 50 is provided at the
15 lower end of the housing 10 and has a passage 60 in which the valve stem 40 of the aerosol canister 20 can be located and supported. A second passage 70 is provided in the support 50 and is directed towards the interior of the outlet 30. Thus, when the parts are in the positions shown in Figure 1, the protruding portion of the aerosol canister 20 can be depressed to move the canister relative to the valve stem 40 to
20 open the valve and a dose of medicament contained in the aerosol will be discharged through the passage 70 and into the outlet 30 from which it can be inhaled by a patient. One dose will be released from the aerosol canister each time it is fully depressed.

25 Figure 2 is a schematic diagram showing a housing for a dose indicating device 100 (internal details not shown) connected to an aerosol canister 120 according to the present invention. The housing comprises a cradle 101 for supporting the counter mechanism, located within the body of the counter (details not shown), and a housing 100 having a tubular sleeve 102 to receive aerosol canister 120 and valve
30 stem 140. Collar 125, which is typically a split ring, is secured around the neck 121 of the aerosol canister 120. Tubular sleeve 102 fits over valve ferrule 122 and

engages collar 125 which is tightly affixed around neck 121 of aerosol canister 120. Thus the tubular sleeve 102 and collar 125 form a tight connection between housing 100 and aerosol canister 120. Collar 125 is welded to sleeve 102 by application of ultrasound energy. The sleeve 102 is secured to the collar 125 by a series of spot welds 180. Two sonitrodes (not shown) are generally employed in the welding process, each sonitrode having three pins which are pushed into contact with the sleeve 102. Energy is transferred through the sonitrode pins, causing them to vibrate and fusing the sleeve 102 to the collar 125. The vibrating pins are pushed through the sleeve 102 to a depth of approximately 2mm into the body of the collar 125, melting and fusing the materials together, to form a series of spot welds. In an alternative herein, one continuous weld may be employed by either moving the sonitrode head around the sleeve or vice versa.

Figure 3 is a schematic diagram showing the lower part of a device similar to that of Figure 1 but incorporating the housing for a dose indicating device 200 affixed to an aerosol canister according to the invention as shown in Figure 2. The counter mechanism (not shown) is supported on a cradle 201 and engages post 218. Ultrasound welds 280 secure collar 225 around neck 221 of canister 220 to tubular sleeve 202, thereby affixing aerosol canister 220 to dose counter housing 200. The resulting assembly is positioned within housing 210. Thus on depression of the aerosol canister 220, the canister moves relative to the valve stem 240 and opens the canister valve (not shown) to discharge a predetermined dose of medicament to the patient through valve stem 240 and thence to outlet 230. The relative movement of canister 220 to counter housing 200 is registered by the counter mechanism (not shown) and the number of doses of medicament used or remaining within canister 220 is displayed on counter window 205 and can be viewed through housing window 215.

Figures 4a – c illustrate, with another embodiment of the present invention, the process whereby the collar 325 is fitted around neck 321 of the canister 320 and welded to tubular sleeve 302 of the dose counter housing 300. Figure 4a is an

exploded diagram showing collar 325 being positioned between canister 320 and dose counter housing 300 displaying counter window 305. The collar 325 is slipped around neck 321 of canister 320 (Figure 4b). As shown in Figure 4c, the collar 325 is then pushed in the direction of arrow A to locate against the base of ferrule 322 at the top of neck 321, while dose counter housing 300 is positioned over the top of canister 320 by being pressed down in the direction of arrow B. In this way, collar 325 is wedged between tubular sleeve 302 and the neck of canister 321. The collar 325 is joined to tubular sleeve 302 by ultra sound welding at the points indicated by arrows C, thereby securing the dose counter housing 300 to canister 320.

Figures 5a and 5b show a housing 400 for a passive transceiver in the form of an electrically erasable programmable read only memory (EEPROM) chip 490. In Figure 5a the housing 400 is welded at points 480 to collar 425 (not shown) which has been secured to the neck 421 of the aerosol canister 420 having outlet 440 as described above. The chip 490, located within housing 400, communicates with electrical contact pad 495. Figure 5b is a cut-away section of Figure 5a, the aerosol canister having been removed to show collar 425 welded to housing 400. In this sectional view, EEPROM chip 490 and electrical contact pad 495 are clearly shown.

Whilst the present invention has been described in detail in respect of a metered dose inhaler it will be appreciated that other mechanical and electronic devices, such as electronic sensors and readers, may be attached to an aerosol canister in an identical manner. For example, a temperature/pressure sensor for use with a paint dispenser could also be affixed to the aerosol canister in this way.

It may be appreciated that any of the parts of the dispenser which contact the chemical suspension may be coated with materials such as fluoropolymer materials which reduce the tendency of chemical to adhere thereto. Any movable parts may also have coatings applied thereto which enhance their desired movement characteristics. Frictional coatings may therefore be applied to enhance frictional contact and lubricants used to reduce frictional contact as necessary.

The medicament dispenser of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders such as asthma and chronic obstructive pulmonary disease. Appropriate medicaments may thus be selected

5 from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate (e.g. as the sodium salt), ketotifen or nedocromil (e.g. as the sodium salt); anti-infectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti-

10 inflammatories, e.g., beclomethasone (e.g. as the dipropionate ester), fluticasone (e.g. as the propionate ester), flunisolide, budesonide, rofleponide, mometasone e.g. as the furoate ester), ciclesonide, triamcinolone (e.g. as the acetonide) or 6 α , 9 α -difluoro-11 β -hydroxy-16 α -methyl-3-oxo-17 α -propionyloxy-androsta-1,4-diene-17 β -carbothioic acid S-(2-oxo-tetrahydro-furan-3-yl) ester; antitussives, e.g., noscapine;

15 bronchodilators, e.g., albuterol (e.g. as free base or sulphate), salmeterol (e.g. as xinafoate), ephedrine, adrenaline, fenoterol (e.g. as hydrobromide), formoterol (e.g. as fumarate), isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol (e.g. as acetate), reproterol (e.g. as hydrochloride), rimiterol, terbutaline (e.g. as sulphate), isoetharine, tulobuterol or 4-hydroxy-7-[2-[[[3-(2-

20 phenylethoxy)propyl]sulfonyl]ethyl]amino]ethyl-2(3H)-benzothiazolone; adenosine 2a agonists, e.g. 2R,3R,4S,5R)-2-[6-Amino-2-(1S-hydroxymethyl-2-phenyl-ethylamino)-purin-9-yl]-5-(2-ethyl-2H-tetrazol-5-yl)-tetrahydro-furan-3,4-diol (e.g. as maleate); α 4 integrin inhibitors e.g. (2S)-3-[4-({[4-(aminocarbonyl)-1-piperidinyl] carbonyl}oxy)phenyl]-2-(((2S)-4-methyl-2-[[2-(2-methylphenoxy)

25 acetyl]amino}pentanoyl)amino] propanoic acid (e.g. as free acid or potassium salt), diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium (e.g. as bromide), tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or

30 glucagon; vaccines, diagnostics and gene therapies. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form

of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament and/or to minimise the solubility of the medicament in the propellant. Preferred medicaments are selected from albuterol, salmeterol,
5 fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free
10 base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) or formoterol (e.g. as the fumarate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate) or budesonide. A particularly preferred combination is a combination of fluticasone propionate and salmeterol, or a salt thereof (particularly the xinafoate
15 salt). A further combination of particular interest is budesonide and formoterol (e.g. as the fumarate salt).

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.
20

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and
25 may include, by way of example and without limitation, one or more of the following claims:

Claims

- 5 1. A housing for a mechanical or electrical device for use with an aerosol
canister for containing chemical comprising
- a sleeve for receipt of said aerosol canister;
- 10 a collar affixable around the neck of the canister; and
- a joint between said sleeve and said collar to secure said housing to the
canister.
- 15 2. Housing according to claim 1, wherein the collar is a split collar.
3. Housing according to either of claims 1 or 2, wherein the collar comprises the
same material as the sleeve.
- 20 4. Housing according to any of claims 1 to 3, wherein said joint is a weld.
5. Housing according to claim 4, wherein said weld is an ultrasound weld.
6. Housing according to either of claims 4 or 5, wherein the weld is a single
25 continuous weld.
7. Housing according to either of claims 4 or 5, wherein the weld comprises a
plurality of spot welds.
- 30 8. Housing according to claim 7, wherein the number of welds is from
2 to 100.

9. Housing according to claim 8, wherein the number of welds is 6.
10. Housing according to any of claims 4 to 9, wherein the weld is obtainable by
5 energy generated by a sonitrode head, of energy output 100-200 Watts, frequency 20-50 kilo Hertz and duration 100-200 milliseconds.
11. Housing according to any of the preceding claims, additionally comprising said mechanical or electrical device.
- 10 12. Housing according to any of the preceding claims, wherein the mechanical or electrical device is a dose counter.
13. Housing according to any of the preceding claims, wherein the electrical
15 device is a sensor.
14. Housing according to claim 13, wherein said sensor is for sensing the pressure profile associated with the breath cycle.
- 20 15. Housing according to claim 13, wherein the sensor is for sensing the airflow profile associated with the breath cycle.
16. Housing according to claim 13, wherein the sensor is for sensing the temperature profile associated with the breath cycle.
- 25 17. Housing according to claim 13, wherein the sensor is for sensing the moisture profile associated with the breath cycle.
18. Housing according to any of the preceding claims, wherein the electrical
30 device comprises a transceiver for transmitting and receiving data.

19. Housing according to any of the preceding claims, wherein the electrical device comprises a microelectronic memory chip.

20. Housing according to claim 19, wherein said chip is selected from the group
5 consisting of random access memory (RAM), programmable read only memory (PROM), erasable programmable read only memory (EPROM), electrically erasable programmable read only memory (EEPROM) and a SIM card-type memory chip.

21. Housing according to any of the preceding claims, additionally comprising a
10 window for viewing a reading from the mechanical or electrical device.

22. Method for securing a housing for a mechanical or electrical device to an aerosol canister comprising

15 placing a collar around the neck of said canister;

positioning a sleeve around said collar; and

20 joining the collar to said sleeve.

23. Method according to claim 22, additionally comprising associating said mechanical or electrical device with said sleeve.

24. Method according to claim 23, additionally comprising sealing the mechanical
25 or electrical device within the sleeve.

25. Method according to claim 23, comprising inserting the mechanical or electrical device into the sleeve before joining the collar to the sleeve.

30 26. Method according to claim 25, comprising sealing the mechanical or electrical device within the sleeve before joining the collar to the sleeve.

27. Method according to claim 23, comprising inserting the mechanical or electrical device into the housing after joining the collar to the sleeve.

5 28. Method according to claim 27, comprising sealing the mechanical or electrical device into the housing after joining the collar to the sleeve.

29. Method according to any of claims 23 or 28, wherein the device is a dose counter.

10

30. Method according to any of claims 23 to 29, wherein the device is a sensor.

31. Method according to any of claims 23 to 30, wherein the device is a transceiver for transmitting or receiving data.

15

32. Method according to any of claims 23 to 31, wherein the device is a microelectronic memory chip.

33. Method according to any of claims 22 to 32, wherein the collar is a split collar.

20

34. Method according to any of claims 22 to 33, wherein the collar comprises the same material as the sleeve around the canister.

35. Method according to any of claims 22 to 34, comprising joining the collar to
25 the sleeve by welding.

36. Method according to claim 35, wherein said welding comprises ultra sound welding.

30 37. Method according to either of claims 35 or 36, comprising applying a single continuous weld.

38. Method according to either of claims 35 or 36, comprising applying a plurality of spot welds.

5 39. Method according to claim 38, comprising applying from 2 to 100 welds.

40. Method according to either of claims 38 or 39, comprising applying 6 welds.

41. Method according to any of claims 35 to 40, comprising using a sonitrode
10 head to produce a weld condition, of output 100 to 200 Watts, frequency 20 to 50 kilo Hertz and duration 100 to 200 milli seconds.

42. Dispenser comprising a housing according to any of claims 1 to 21 securable to an aerosol canister.

15 43. Dispenser according to claim 42, additionally comprising an actuator body.

44. Medicament dispenser according to either of claims 42 or 43, wherein said aerosol canister comprises a medicament in a propellant.

20 45. Medicament dispenser according to claim 44, wherein said propellant is liquefied HFA134a or HFA-227.

46. Medicament dispenser according to claim 44, wherein said medicament is
25 selected from the group consisting of albuterol, salmeterol, ipratropium bromide, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof and any mixtures thereof.

30 47. Kit of parts comprising
a housing according to any of claims 11 to 21; and

an aerosol canister for containing chemical.

48. Kit of parts according to claim 47, additionally comprising an actuator body.

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49. Kit of parts according to either of claims 47 or 48, wherein said chemical is a medicament.

50. Use of medicament dispenser according to any of claims 44 to 46 for the administration of medicament to a patient.

10

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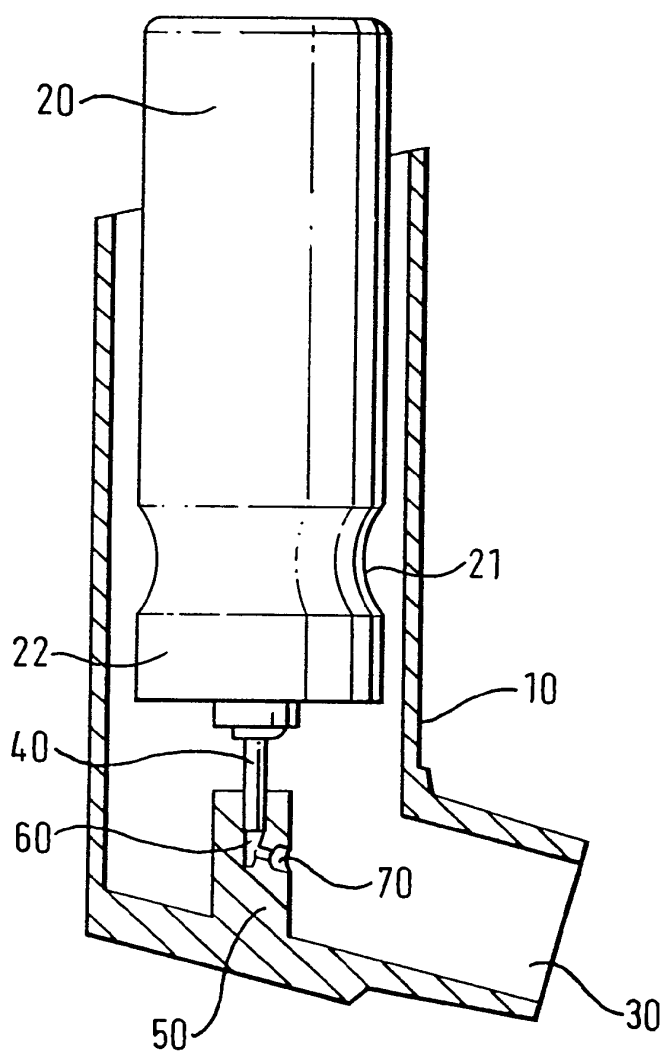


FIG. 1

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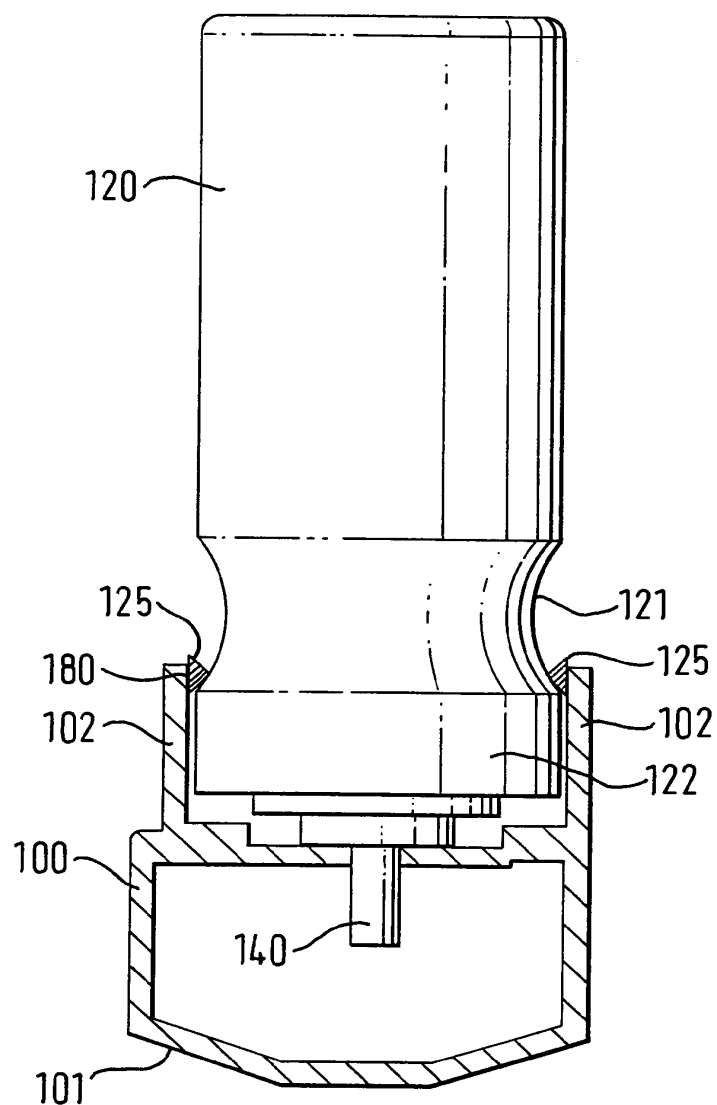


FIG. 2

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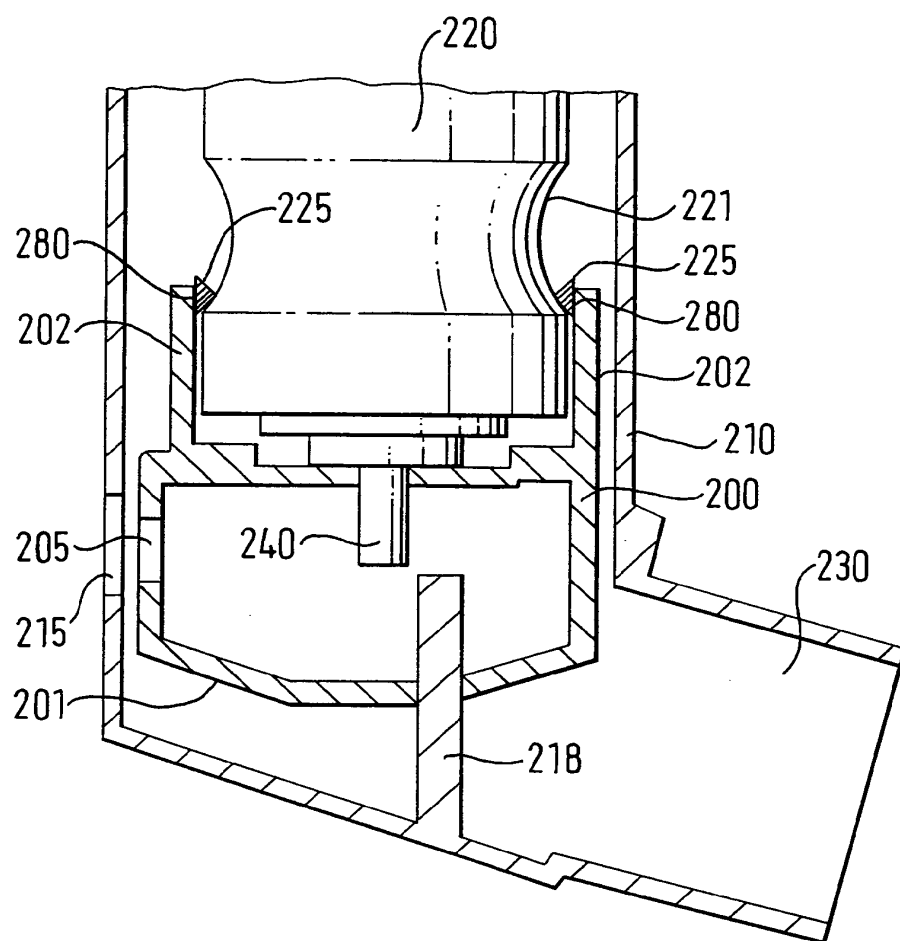


FIG. 3

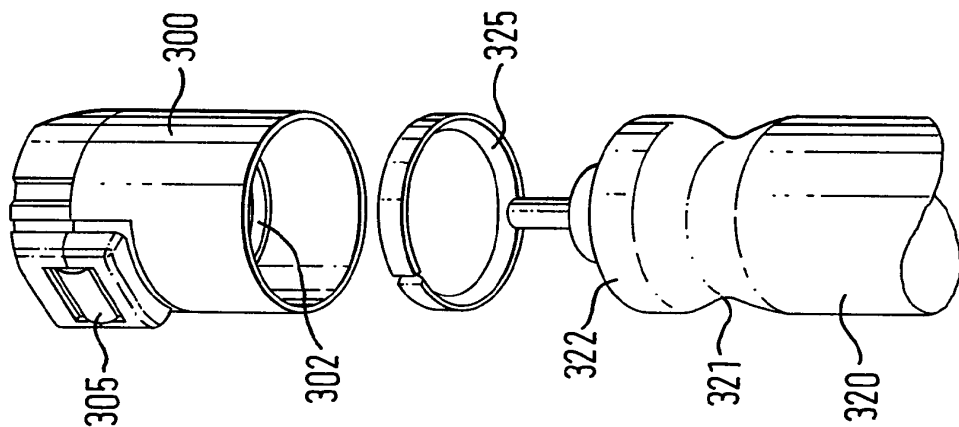


FIG. 4a

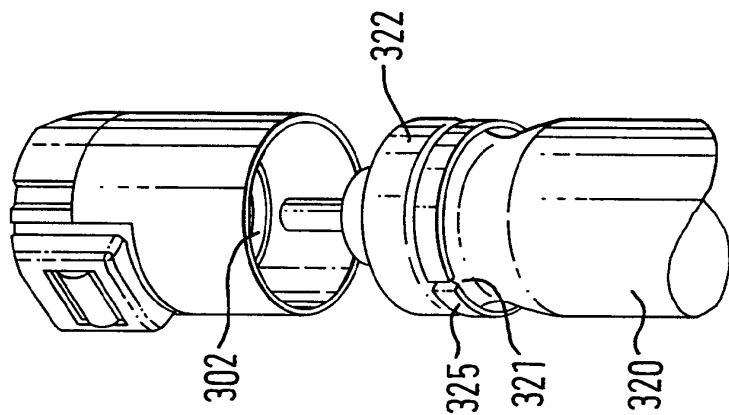


FIG. 4b

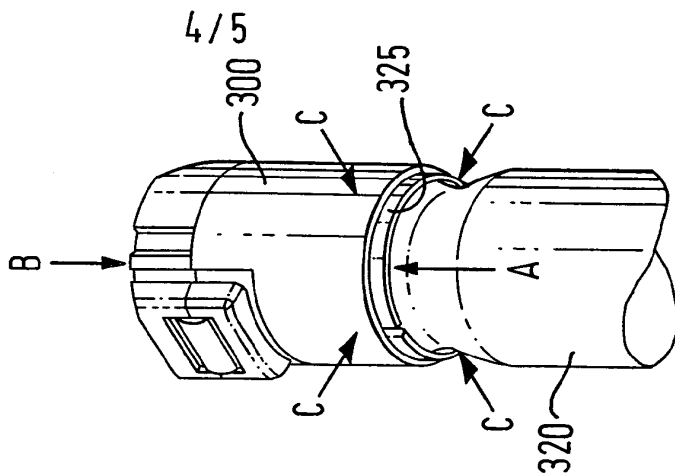
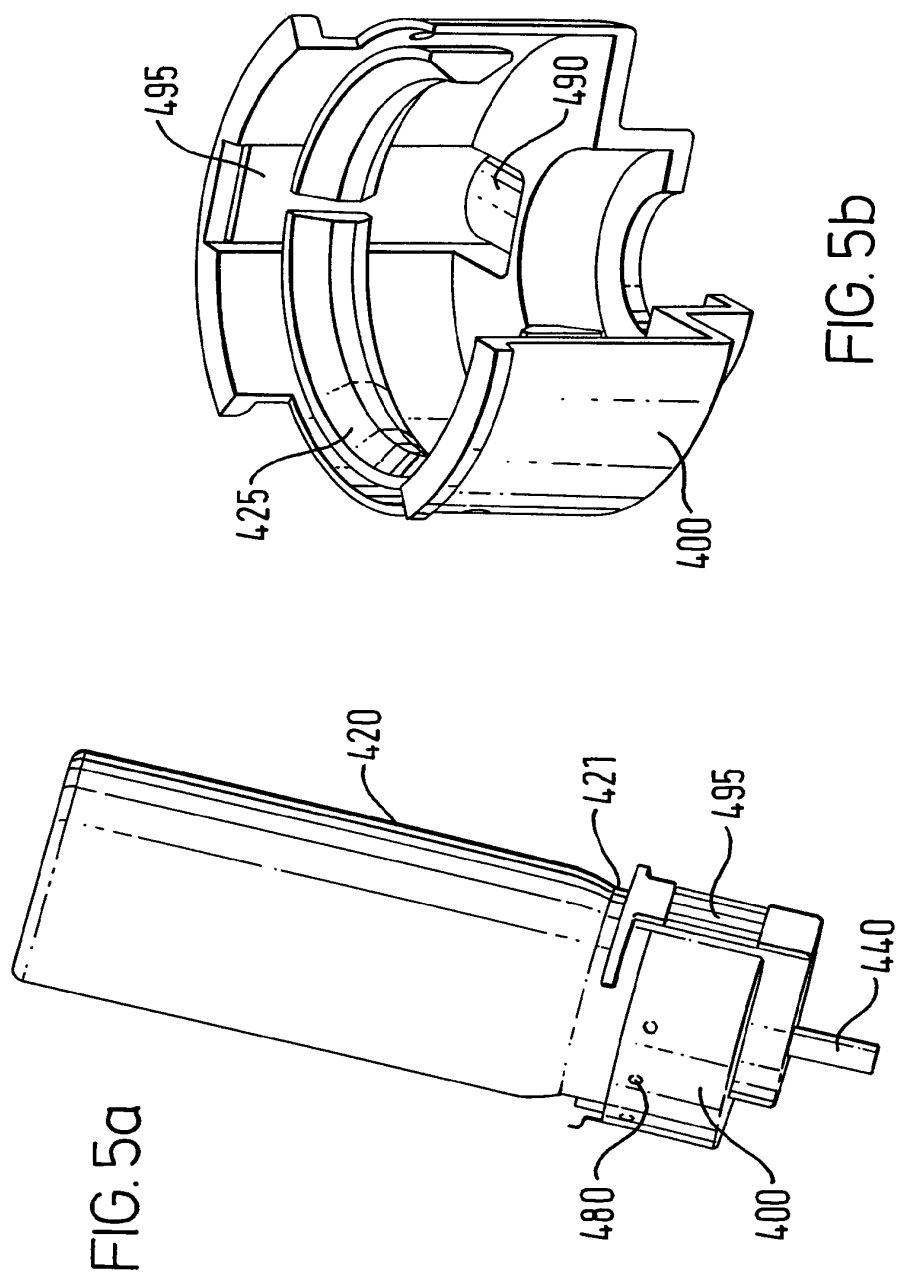


FIG. 4c

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 00/09991

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 B65D83/14 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 B65D A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 743 055 A (FRAPPE DOMINIQUE) 4 July 1997 (1997-07-04) page 4, line 24 -page 5, line 4; figures 1,4,5 page 4, line 6 - line 7 ---	1,12-21, 42-50
A	WO 86 02275 A (DRACO AB) 24 April 1986 (1986-04-24) claim 1; figures 3,5 ---	12,21
A,P	WO 00 53247 A (ANDERSON GREGOR JOHN MCLENNAN ;JONES ANTHONY PATRICK (GB); GLAXO G) 14 September 2000 (2000-09-14) claims 1-5 ---	13-17
A	GB 2 263 873 A (NORTON HEALTHCARE LTD) 11 August 1993 (1993-08-11) page 5, last paragraph ---	14,15
-/--		

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

18 January 2001

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 00/09991

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 363 842 A (MISHELEVICH DAVID J ET AL) 15 November 1994 (1994-11-15) column 6, line 21 - column 7, line 12 column 7, line 53 - line 55 ---	18-21
A	WO 99 06303 A (GLAXO GROUP LTD ;RIEBE MICHAEL THOMAS (US)) 11 February 1999 (1999-02-11) claims 6,7 ---	44-46, 49
A	WO 99 36115 A (1263152 ONTARIO INC) 22 July 1999 (1999-07-22) page 34, line 5 - line 15 page 35, line 5 - line 15; claim 1; figure 21 -----	1, 12

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

page 2 of 2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 00/09991

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2743055 A	04-07-1997	NONE	
WO 8602275 A	24-04-1986	AU 4969885 A DE 8590143 U DK 269086 A EP 0197113 A ES 547668 D ES 8701660 A FI 862440 A JP 62500361 T NO 862098 A PT 81272 A,B ZA 8507761 A	02-05-1986 02-04-1987 09-06-1986 15-10-1986 01-12-1986 01-03-1987 06-06-1986 19-02-1987 27-05-1986 01-11-1985 28-05-1986
WO 0053247 A	14-09-2000	NONE	
GB 2263873 A	11-08-1993	NONE	
US 5363842 A	15-11-1994	AT 166236 T CA 2126331 A,C DE 69225604 D DE 69225604 T EP 0617628 A JP 7509378 T JP 3085586 B WO 9312823 A	15-06-1998 08-07-1993 25-06-1998 25-02-1999 05-10-1994 19-10-1995 11-09-2000 08-07-1993
WO 9906303 A	11-02-1999	GB 2332712 A AU 9255098 A BR 9811060 A CN 1261854 T EP 0999987 A HR 990418 A NO 20000365 A PL 337519 A	30-06-1999 22-02-1999 19-09-2000 02-08-2000 17-05-2000 30-04-2000 25-01-2000 28-08-2000
WO 9936115 A	22-07-1999	US 6142339 A US 6161724 A AU 1777499 A EP 1047467 A	07-11-2000 19-12-2000 02-08-1999 02-11-2000

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(19) World Intellectual Property Organization
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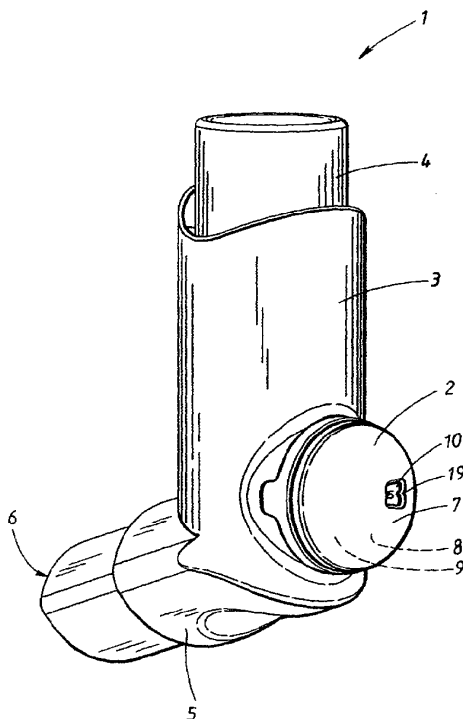
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[Continued on next page]

(54) Title: COUNTING MECHANISM, AND SPRAY DOSE INHALER WITH SAID COUNTING MECHANISM



(57) Abstract: The invention relates to a counting mechanism (2) for counting the number of spray doses, for example in combination with spray dose inhalers. A counting mechanism according to the invention comprises a cap (7), a counting wheel (8), and a control wheel (9), all of which have a substantially circular shape, are concentric in relation to each other and, upon each spraying, are acted upon via a rod-shaped pin (32), which is arranged at right angles to the inner surface of the control wheel (9) and is connected to the control wheel (9) via a spring member (33), such that a dosing step is counted by the counting mechanism (2). The counting mechanism (2) has a minimal effect on the spray flow and on the dose size of the sprayed substance since only the rod-shaped pin (32) is introduced into the spray channel.

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TITLE

COUNTING MECHANISM, AND SPRAY DOSE INHALER WITH SAID
COUNTING MECHANISM

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TECHNICAL FIELD

The invention relates to a counting mechanism for counting the number of
doses delivered from a container and comprising means for connection to
10 the container. The invention also concerns a spray dose inhaler into which a
spray container can be introduced and comprising a counting mechanism for
counting the number of doses delivered from the spray container.

BACKGROUND ART

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It has become increasingly common for medicines to be administered by
being sprayed into the mouth or nose. For this purpose, spray dose inhalers
have been developed which deliver one dose of medication per spray.
However, a considerable problem with the spray dose inhalers which have
20 hitherto been made available is that they do not have means for indicating
how many doses remain in the spray container. This means that many spray
containers are discarded long before they are empty, and in many cases
even when they are only half empty. There is therefore a great need for a
counting mechanism in order to be able to monitor the spray consumption in
25 a spray dose inhaler.

However, it has proven very difficult to obtain a reliable counting mechanism
which does not adversely affect the function of the inhaler since spray
administration is a method which is very sensitive to external disturbances. A
30 counting mechanism for a spray dose inhaler must therefore have a structure
which does not cause variations in the size of the delivered doses, which

does not create spaces where the active substance can accumulate, and which does not in any other way interfere with the function of the inhaler.

No satisfactory solution to the above problems has as yet been put forward.

5

DISCLOSURE OF THE INVENTION

The present invention nevertheless makes available a counting mechanism which is of the type discussed in the introduction and which largely avoids
10 the problems mentioned above. An arrangement according to the invention is mainly characterized in that the counting mechanism comprises a cap, a counting wheel, and a control wheel, all of which have a substantially circular shape and are concentric in relation to each other, the cap having an outer surface and an inner surface, and a flange-like cap edge projecting
15 from the periphery of the inner surface, and comprising a gear ring which is arranged inside the flange-like cap edge on the inner surface of the cap, an indicator window in the form of a through-opening in the cap, two concentrically arranged inner flanges which project centrally from the inner surface of the cap and of which a first inner flange is arranged radially inside
20 a second inner flange and projects a distance beyond the second inner flange, and in that the first inner flange has a radially projecting locking tooth, and the counting wheel has an outer surface and an inner surface and is arranged directly next to the cap with the outer surface of the counting wheel directed towards the inner surface of the cap, the counting wheel
25 comprising a centrally arranged through-hole with a shape and size corresponding to the shape and size of the second inner flange of the cap, at least one stop tongue which projects from the periphery of the counting wheel and is arranged to engage in and cooperate with the gear ring arranged on the inner surface of the cap, and a gear ring arranged on the
30 inner surface of the counting wheel, near the periphery of the counting wheel, and a measurement scale arranged on the outer surface and placed

so that it is visible through the indicator window, and in that the control wheel has an outer surface and an inner surface and is arranged directly next to the counting wheel, with the outer surface of the control wheel directed towards the inner surface of the counting wheel, the control wheel comprising a centrally arranged through-hole with a shape and size corresponding to the shape and size of the first inner flange of the cap and having a recess arranged on the periphery of the hole, which recess has a shape which substantially corresponds to the shape of the locking tooth arranged on the cap and with a size which slightly exceeds the size of the locking tooth, so that a predetermined clearance exists between the locking tooth and the edges of the recess, at least one stop tongue which projects from the periphery of the control wheel and which is arranged to engage in and cooperate with the gear ring arranged on the inner surface of the counting wheel, and a rod-shaped pin which is arranged at right angles to the inner surface of the control wheel and is connected to the control wheel via a spring member, and in that the stop tongue of the control wheel is oriented in a tangential direction which is opposite to the direction of the gear ring and stop tongue of the counting wheel, and in that the direction of the teeth in the gear ring of the cap coincides with the tangential direction of the stop tongue of the control wheel, and furthermore in that the number of stop tongues and the number of teeth are identical for the counting wheel and for the control wheel.

Although not essential to the invention, it may be expedient, for production reasons and assembly reasons, that the first and second inner flanges of the cap, and the centrally arranged through-holes in the counting wheel and control wheel, are substantially circular with a radius corresponding to the radius of the first and second inner flange, respectively, of the cap.

It is also advantageous for the stop tongues on the counting wheel and control wheel to be arranged to spring in the radial direction, as a result of

which the stop tongues bear with a certain spring force against the teeth of the gear rings of the counting wheel and cap. Radial direction is understood as a radial direction in towards or out from a centre axis running through the counting mechanism.

5

The number of doses which the counting mechanism is able to count depends on the clearance between the locking tooth, arranged on the inside of the cap, and the corresponding recess in the control wheel, and also on the number of teeth in the gear rings of the counting wheel and cap. For
10 counting mechanisms intended to count up to 130 doses, the clearance should be about 3° and the number of teeth should be 46. For counting mechanisms intended to count 130 to 240 doses, the clearance should be 1.5° and the number of teeth should be 82. The clearance is calculated by
15 dividing 360° by the number of doses which the counting mechanism is intended to be able to count, after which a whole 1° is added to the result. The number of teeth must be evenly divisible by the number of stop tongues, plus one extra tooth.

A suitable spring member for connecting the rod-shaped pin to the control
20 wheel, and for transferring forces acting on the rod-shaped pin to the control wheel, is a flat spring. The spring member can be a separately manufactured component, but it is advantageously made integral with the rod-shaped pin and the control wheel, for example by injection-moulding of plastic.

25 The invention also concerns a complete spray dose inhaler of the type discussed in the introduction. A spray dose inhaler according to the invention is characterized mainly in that the counting mechanism is arranged substantially on the outside of the inhaler and comprises a cap, a counting wheel, and a control wheel, all of which have a substantially
30 circular shape and are concentric in relation to each other, the cap having an outer surface and an inner surface, and a flange-like cap edge projecting

from the periphery of the inner surface, and comprising a gear ring which is arranged inside the flange-like cap edge on the inner surface of the cap, an indicator window in the form of a through-opening in the cap, two concentrically arranged inner flanges which project centrally from the inner surface of the cap and of which a first inner flange is arranged radially inside a second inner flange and projects a distance beyond the second inner flange, and in that the first inner flange has a radially projecting locking tooth, and the counting wheel has an outer surface and an inner surface and is arranged directly next to the cap with the outer surface of the counting wheel directed towards the inner surface of the cap, the counting wheel comprising a centrally arranged through-hole with a shape and size corresponding to the shape and size of the second inner flange of the cap, at least one stop tongue which projects from the periphery of the counting wheel and is arranged to engage in and cooperate with the gear ring arranged on the inner surface of the cap, and a gear ring arranged on the inner surface of the counting wheel, near the periphery of the counting wheel, and a measurement scale arranged on the outer surface and placed so that it is visible through the indicator window, and in that the control wheel has an outer surface and an inner surface and is arranged directly next to the counting wheel, with the outer surface of the control wheel directed towards the inner surface of the counting wheel, the counting wheel comprising a centrally arranged through-hole with a shape and size corresponding to the shape and size of the second inner flange of the cap and having a recess arranged on the periphery of the hole, which recess has a shape which substantially corresponds to the shape of the locking tooth arranged on the cap and with a size which is slightly greater than the locking tooth, so that a predetermined clearance exists between the locking tooth and the edges of the recess, at least one stop tongue which projects from the periphery of the control wheel and which is arranged to engage in and cooperate with the gear ring arranged on the inner surface of the counting wheel, and a rod-shaped pin which is arranged at right angles to the inner

surface of the control wheel and is connected to the control wheel via a spring member, and in that the stop tongue of the control wheel is oriented in a tangential direction which is opposite to the direction of the gear ring and stop tongue of the counting wheel, and in that the direction of the teeth in the gear ring of the cap coincides with the tangential direction of the stop tongue of the control wheel, and furthermore in that the number of stop tongues and the number of teeth are identical for the counting wheel and for the control wheel, and in that the outside of the spray dose inhaler is provided with coupling members for connecting the counting mechanism to the spray dose inhaler, the coupling members comprising a through-hole through which the rod-shaped pin of the counting mechanism can be introduced, the hole being positioned so that the rod-shaped pin is in contact with the spray container and is acted upon and deflected and/or changes position when the spray container moves in the first part of the spray dose inhaler.

Since the invention allows the counting mechanism to be arranged almost entirely on the outside of the inhaler, with only the very small rod-shaped pin situated inside the inhaler, the counting mechanism by and large does not in any way affect the flow through the inhaler. This means that the doses delivered retain a constant size, and that the risk of active substance accumulating in the inhaler as a result of the action of the counting mechanism is practically nonexistent.

The dose scale arranged on the counting wheel is placed in an annular configuration on the outside of the counting wheel and is either ascending or descending, depending on whether the counting mechanism is to indicate how many doses have been administered or how many doses remain. The dose scale is preferably a numerical scale, with the dose number being indicated in steps of 1, 2, 5, 10, 25 doses or in other dose steps if deemed appropriate. Alternatively, or in addition to this, it is however possible to imagine using a colour scale, for example ranging from green through yellow

to red. For example, the last 10% of the doses can be indicated by red or another differing colour. As the counting wheel is turned round during use, new parts of the dose scale successively appear through the indicator window in the counting mechanism cap. The indicator window is preferably
5 provided with an arrow which points to the dose number in each position.

The counting mechanism can be provided with a built-in stop position. Such a counting mechanism is discarded when it has counted the predetermined number of doses for which it has been designed. It is also possible to
10 produce re-usable counting mechanisms without built-in stop devices. Such a stop device can be provided, for example, by arranging a pin on the inside of the cap, which pin runs in a groove in the counting wheel.

BRIEF DESCRIPTION OF THE FIGURES

15

The invention will be described in greater detail below with reference to the illustrative embodiments shown in the attached figures, where:

Figure 1 shows a spray dose inhaler with a counting mechanism according
20 to the invention;

Figures 2a and 2b show an outer casing for a counting mechanism according to the invention;

25 Figures 3a and 3b show a counting wheel for a counting mechanism according to the invention;

Figures 4a and 4b show a control wheel for a counting mechanism according to the invention;

30

Figure 5 shows an exploded view of a spray dose inhaler with associated components;

Figure 6 shows a spray dose inhaler with an attachment arrangement for a
5 counting mechanism according to the invention;

Figure 7 shows a cross section through a spray dose inhaler and a counting mechanism according to the invention; and

10 Figure 8 shows an exploded view of a counting mechanism according to the invention.

DETAILED DESCRIPTION OF EMBODIMENTS

15 Figure 1 shows a spray dose inhaler 1 which is provided with a counting mechanism 2 arranged substantially on the outside of the inhaler. The spray dose inhaler 1 has an upper tubular part 3 into which a spray container 4 is introduced. The spray dose inhaler 1 also has a lower tubular mouthpiece part 5 which is angled in relation to the upper part 3 and which emerges via
20 an opening 6 from which the contents of the spray container 4 are delivered. When using the spray dose inhaler 1, the mouthpiece part 5 is placed in the user's mouth and the spray container 4 is pressed further down in the upper part 3 of the inhaler 1. A dose is thereby released and is sprayed into the user's oral cavity.

25

The counting mechanism 2 consists of three main components, namely a cap 7, a counting wheel 8, and a control wheel 9. Arranged on the outside is the substantially circular cap 7, the latter thus serving as an outer casing for the counting mechanism 2. The cap 7 is provided with an indicator window
30 10, and on the inside of the cap 7 there is a gear ring 11 in which the number of teeth 12 is adapted to the number of doses in the spray container.

Such a cap is shown in Figures 2a and 2b. Figure 2a shows the outside of the cap 7, i.e. the side directed away from the inhaler when the counting mechanism is fitted on an inhaler, and Figure 2b shows the inside of the cap, i.e. the side directed towards the inhaler when the counting mechanism 2 is fitted. The teeth 12 are inclined and slope in a first tangential direction. In Figure 2a the teeth 12 are shown with an inclination anti-clockwise in the figure. The cap 7 is additionally provided with a coupling arrangement comprising several parts and intended to cooperate with a corresponding coupling arrangement on the inhaler 1. The coupling arrangement on the inhaler 1 is shown in detail in Figure 6 and will be described in detail in the description of Figure 6. The coupling arrangement on the cap 7 comprises, on the one hand, a cap edge 13 projecting at right angles from the plane of the cap 7 and an almost rectangular pin 14 projecting from the cap edge 13, and, on the other hand, a centrally arranged cylindrical first inner flange 15. Moreover, the cylindrical inner flange 15 has a locking tooth 16 projecting radially from the outer surface of the inner flange 15.

Arranged concentrically to the outside of the cylindrical inner flange 15 there is an annular second inner flange 17 which has less height above the inner surface of the cap than does the cylindrical first inner flange 15, and which is intended to serve as coupling member between the cap 7 and the counting wheel 8. The cylindrical first inner flange 15 here fulfills the additional purpose of being a coupling member between the cap 7 and the control wheel 9.

Arranged inside of the cap 7, or outer casing, there is a counting wheel 8 of the type shown in Figures 3a and 3b. The counting wheel 8 has a substantially circular shape, with a central and circular through-hole 20. In the same way as in Figures 2a and 2b, the counting wheel 8 in Figure 3a is shown from the outside, which is the side directed outwards and away from the inhaler 1, and Figure 3b shows the inside, which is the side of the

counting wheel 8 directed inwards and towards the inhaler 1. As can be seen from Figure 3a, the outside of the counting wheel 8 is provided with a numerical scale 21 which is intended to continuously indicate the number of doses remaining in the spray container 4. In the illustrative embodiment shown, the doses are indicated in intervals of 5. In some cases it can of course be expedient to count the doses in another way, for example in individual doses or in intervals of two doses, ten doses, 25 doses, and so on, depending on how many doses in total are present in the spray container 4. The counting wheel 8 is either numbered in ascending sequence, so that the number of doses used is indicated, or in descending sequence, so that the number of doses remaining is indicated. The numerical scale 21 is visible through the indicator window 10 on the cap. As can be seen for example from Figure 2, the indicator window 10 can be provided with an indicator arrow 19 which points to the current number of doses. Moreover, the last doses, for example the last 10% of the doses, are marked in a different way, preferably with a different colour such as red.

As with the cap 7, a gear ring 22 is arranged on the inside of the counting wheel 8, about its periphery. The number of teeth 23 is adapted to the number of doses which are to be counted, and the teeth 23 are oriented in the opposite direction in relation to the teeth 12 on the cap 7, which means that the teeth 23 in Figure 3b slope clockwise. In addition, the counting wheel 8 is provided with three stop tongues 25 arranged symmetrically about the outer edge 24 of the counting wheel 8. The stop tongues 25 are designed in such a way that they have a certain spring capacity, upon radial loading, in towards or out from the centre of the counting wheel 8. As will be observed in Figures 3a and 3b, the stop tongues 25 have a free pin-shaped part which is directed along the periphery of the counting wheel 8 and which ends in a stop edge 26. In the example shown, the free parts of the stop tongues 25, as can be seen from Figure 3b, are directed clockwise about the

periphery of the counting wheel 8. The stop tongues 25 thus have the same direction as the teeth 23 of the counting wheel 8.

The third part of the counting mechanism 2 is the control wheel 9 shown in
5 Figures 4a and 4b. The control wheel 9 is also substantially circular in shape and is provided with three resilient stop tongues 30 which are distributed symmetrically about the periphery of the wheel 9 and have a free part which springs radially and ends in a stop edge 31. However, the stop tongues 30 of the control wheel 9 are directed in the opposite direction in relation to the
10 stop tongues 25 of the counting wheel 8. In addition, the control wheel 9 has a rod-shaped pin 32 which is arranged at right angles to the inside of the control wheel 9, which is the side of the control wheel 9 intended to be directed towards the inhaler 1. The pin 32 is connected to the control wheel 9 via a flat spring member 33. A circular hole 34 is arranged centrally
15 through the control wheel 9 and has a recess 35 arranged on the periphery of the hole 34, which recess 35 has a shape corresponding substantially to the shape of the locking tooth 16 arranged on the cap 7. When the counting mechanism 2 is assembled, the locking tooth 16 is in fact intended to be introduced into the recess 35 of the control wheel 9, in the manner of a key
20 in a lock. As has previously been mentioned, it is intended that there should be a certain clearance or play between the locking tooth 16 and the edges of the recess 35, which clearance has a predetermined size and contributes to defining the size of the counting steps which the counting mechanism 2 registers.

25

Figure 5 shows how the different parts are joined together to form a complete inhaler 1 with counting mechanism 2 and spray container 4. The spray container 4 is introduced into the upper tubular part 3 of the spray dose inhaler 1, and the counting mechanism 2 is fitted on the outside of the
30 upper tubular part 3 of the spray dose inhaler 1, near the transition to the mouthpiece part 5.

Figure 6 shows in detail the appearance of the coupling arrangement provided on the spray dose inhaler 1. The coupling arrangement comprises a circular outer flange 40, which projects from the surface of the inhaler 1 and which has an outer ring 41 and also an inner ring 42 which projects farther than the outer ring 41 and has an external radius corresponding to the internal radius of the projecting cap edge 13 on the cap 7 of the counting mechanism 2. A recess 43 is also provided in the outer ring 41 for cooperation with the substantially rectangular pin 14 arranged on the cap edge 13. Thus, the counting mechanism 2 is fitted with the cap 7 tight over the outer ring 41 of the coupling arrangement of the spray dose inhaler 1, and with the pin 14 on the cap edge 13 inserted into the recess 43 on the outer ring 41 of the coupling arrangement.

The spray dose inhaler 1 also has a centrally arranged annular inner flange 45 whose internal diameter corresponds to the external diameter of the cylindrical first inner flange 15 on the counting mechanism cap 7. The annular inner flange 45 arranged on the spray dose inhaler 1 has a gap 46 through which the locking tooth 16 arranged on the cylindrical first inner flange 15 of the counting mechanism cap 7 can project.

The spray dose inhaler 1 finally has a through-hole 47 arranged between the inner flange 45 and outer flange 40 of the coupling arrangement. The through-hole 47 is designed such that the rod-shaped pin 32 arranged on the control wheel 9 can be introduced through the wall of the spray dose inhaler 1 and into the inside of the spray dose inhaler. The hole has a diameter which is substantially the same as the diameter of the rod-shaped pin 32. Although the hole 47 and the rod-shaped pin in the illustrative embodiment shown have a circular cross section, it is possible, within the scope of the invention, to use holes/pins with edged or oval cross sections.

Figure 7 shows how the spray dose inhaler 1 looks when the counting mechanism 2 has been fitted and the spray container 4 has been introduced into the upper tubular part 3 of the inhaler 1. The rod-shaped pin 32 of the control wheel 9 is introduced through the hole 47 in the inhaler wall, and the hole 47 is positioned in such a way that the pin 32 is thereby in contact with the spray container 4 in such a way that, when the spray container 4 is pressed into the inhaler 1, the spray container 4 presses the pin 32 in its direction of movement. In so doing, that part of the pin 32 located inside the inhaler 1 is deflected and/or angled in the downward direction in Figure 7. This means that the flat spring 33 connecting the pin 32 to the control wheel 9 acts on the control wheel 9 in a direction opposite to the direction of movement of the pin 32 and spray container 4. The cooperation between the various parts of the counting mechanism 2 will be readily understood by referring to Figure 8, from which figure it clearly emerges how the directions of movement of the different gear rings 11, 22 and stop tongues 25, 30 relate to each other. When the rod-shaped pin 32 is pressed downwards in the inhaler (as is shown in Figure 7), the control wheel 9 is therefore rotated clockwise, viewed axially in the direction from within the inhaler 1. However, the rotation can only occur as far as is permitted by the clearance between the locking tooth 16 of the cap 7 and the corresponding recess 35 on the control wheel 9. By means of this rotation, one of the three stop tongues 30 arranged on the control wheel is additionally moved to a new position between two teeth 23 of the counting wheel 8. When the load exerted by the spray container 4 on the rod-shaped pin 32 ceases, the pin 32 returns to the substantially horizontal position shown in Figure 7 and the control wheel 9 springs back to its initial position, which corresponds to the control wheel 9 rotating anti-clockwise as far as is permitted by the clearance between the locking tooth 16 of the cap 7 and the corresponding recess 35 on the control wheel 9. During this movement, one of the stop tongues 30 of the control wheel 9 rests with its outer stop edge 31 against a tooth 23 of the counting wheel 8. In this way, the return movement is transmitted to the counting

wheel 8 which thus rotates anti-clockwise and counts one step, which can be observed in the indicator window 10 of the cap 7. At the same time, one of the locking tongues 25 on the periphery of the counting wheel 8 is moved to a stop position between two teeth 12 of the gear ring 11 of the cap 7, which means that a subsequent clockwise rotation of the control wheel 9 does not act on the counting wheel 8, since clockwise rotation of the counting wheel 8 is prevented by the fact that the outer stop edge 26 of one of the locking tongues 25 of the counting wheel bears against one of the teeth 12 of the cap 7 and prevents clockwise rotation.

10

In the examples shown in the figures, the position of the rod-shaped pin 32 is such that the control wheel 9 rotates clockwise when the spray container 4 is pressed into the inhaler 1 upon administration of a spray dose. However, this is not a necessary condition for the invention. It is therefore possible to envisage the pin 32 being positioned instead on the diametrically opposite side of the control wheel 9. Such positioning would mean that the control wheel 9 first rotated anti-clockwise when the spray container 4 was pressed into the inhaler 1. Of course, such an arrangement would additionally mean that the direction of rotation, like the direction of the different gear rings 11, 22 and stop tongues 25, 30, would be opposite to those directions described above.

A counting mechanism 2 according to the invention can advantageously be produced by injection moulding of plastic. It is of course also possible to envisage combinations of plastic components and other materials, or counting mechanisms made completely or partially of metal.

Although the counting mechanism has been described in association with a spray dose inhaler, it is of course possible to use the counting mechanism in all contexts where a substance is to be sprayed in doses. For example, the counting mechanism can be used for spraying cosmetics or the like. In

addition, spray dose inhalers in which the dosed substance is administered into the nose are of course also intended to come within the scope of the invention.

CLAIMS

1. Counting mechanism (2) for counting the number of doses delivered from a container (4) and comprising means for connection to the container (4), characterized in that the counting mechanism (2) comprises a cap (7), a counting wheel (8), and a control wheel (9), all of which have a substantially circular shape and are concentric in relation to each other, the cap (7) having an outer surface and an inner surface, and a flange-like cap edge (13) projecting from the periphery of the inner surface, and comprising a gear ring (11) which is arranged inside the flange-like cap edge (13) on the inner surface of the cap (7), an indicator window (10) in the form of a through-opening in the cap (7), two concentrically arranged inner flanges (15, 17) which project centrally from the inner surface of the cap (7) and of which a first inner flange (15) is arranged radially inside a second inner flange (17) and projects a distance beyond the second inner flange (17), and in that the first inner flange (15) has a radially projecting locking tooth (16), and the counting wheel (8) has an outer surface and an inner surface and is arranged directly next to the cap (7) with the outer surface of the counting wheel (8) directed towards the inner surface of the cap (7), the counting wheel (8) comprising a centrally arranged through-hole (20) with a shape and size corresponding to the shape and size of the second inner flange (17) of the cap (7), at least one stop tongue (25) which projects from the periphery of the counting wheel and is arranged to engage in and cooperate with the gear ring (11) arranged on the inner surface of the cap (7), and a gear ring (22) arranged on the inner surface of the counting wheel (8), near the periphery of the counting wheel (8), and a measurement scale (21) arranged on the outer surface and placed so that it is visible through the indicator window (10), and in that the control wheel (9) has an outer surface and an inner surface and is arranged directly next to the counting wheel (8), with the outer surface of the control wheel (9) directed towards the inner surface of the counting wheel (8), the control wheel (9) comprising a

centrally arranged through-hole (34) with a shape and size corresponding to the shape and size of the first inner flange (15) of the cap (7) and having a recess (35) arranged on the periphery of the hole (34), which recess (35) has a shape which substantially corresponds to the shape of the locking tooth (16) arranged on the cap (7) and with a size which slightly exceeds the size of the locking tooth (16), so that a predetermined clearance exists between the locking tooth (16) and the edges of the recess (35), at least one stop tongue (30) which projects from the periphery of the control wheel (9) and which is arranged to engage in and cooperate with the gear ring (22) arranged on the inner surface of the counting wheel (8), and a rod-shaped pin (32) which is arranged at right angles to the inner surface of the control wheel (9) and is connected to the control wheel (9) via a spring member (33), and in that the stop tongue (30) of the control wheel (9) is oriented in a tangential direction which is opposite to the direction of the gear ring (22) and stop tongue (25) of the counting wheel (8), and in that the direction of the teeth (12) in the gear ring (11) of the cap (7) coincides with the tangential direction of the stop tongue (30) of the control wheel (9), and furthermore in that the number of stop tongues (25, 30) and the number of teeth (12, 23) are identical for the counting wheel (8) and for the control wheel (9).

20

2. Counting mechanism according to Claim 1, characterized in that the number of stop tongues (25, 30) on the periphery of the counting wheel (8) and of the control wheel (9) is a prime number, and in that the stop tongues (25, 30) are symmetrically distributed about the periphery of the respective wheel (8, 9).

25

3. Counting mechanism according to Claim 1 or 2, characterized in that the first and second inner flange (15, 17) of the cap (7), and the centrally arranged through-holes (20, 34) in the counting wheel (8) and the control wheel (9), are substantially circular with a radius corresponding with the

30

radius of the first and second inner flange (15, 17), respectively, of the cap (7).

4. Counting mechanism according to Claim 1, 2 or 3, characterized in that the stop tongues (25, 30) on the counting wheel (8) and the control wheel (9) are arranged to spring in the radial direction.

5. Counting mechanism according to any of Claims 1 to 4, characterized in that the number of teeth (12, 23) on the counting wheel (8) and the control wheel (9) is 46, and in that the number of stop tongues (25, 30) on the counting wheel (8) and the control wheel (9) is 3, and in that the clearance between the locking tooth (16) and the recess (35) is approximately 3°.

6. Counting mechanism according to Claim 1, characterized in that the spring member (33) is a flat spring.

7. Spray dose inhaler (1) with an inside and an outside, comprising a first tubular part (3) into which a spray container (4) can be introduced, a second tubular mouthpiece part (5) which is angled in relation to the first part (3) and which emerges into an opening (6) from which the contents of the spray container (4) can be delivered, and comprising a counting mechanism (2), characterized in that the counting mechanism (2) is arranged substantially on the outside of the inhaler (1) and comprises a cap (7), a counting wheel (8), and a control wheel (9), all of which have a substantially circular shape and are concentric in relation to each other, the cap (7) having an outer surface and an inner surface, and a flange-like cap edge (13) projecting from the periphery of the inner surface, and comprising a gear ring (11) which is arranged inside the flange-like cap edge (13) on the inner surface of the cap (7), an indicator window (10) in the form of a through-opening in the cap (7), two concentrically arranged inner flanges (15, 17) which project centrally from the inner surface of the cap (7) and of

which a first inner flange (15) is arranged radially inside a second inner flange (17) and projects a distance beyond the second inner flange (17), and in that the first inner flange (15) has a radially projecting locking tooth (16), and the counting wheel (8) has an outer surface and an inner surface and is arranged directly next to the cap (7) with the outer surface of the counting wheel (8) directed towards the inner surface of the cap (7), the counting wheel (8) comprising a centrally arranged through-hole (20) with a shape and size corresponding to the shape and size of the second inner flange (17) of the cap (7), at least one stop tongue (25) which projects from the periphery of the counting wheel and is arranged to engage in and cooperate with the gear ring (11) arranged on the inner surface of the cap (7), and a gear ring (22) arranged on the inner surface of the counting wheel (8), near the periphery of the counting wheel (8), and a measurement scale (21) arranged on the outer surface and placed so that it is visible through the indicator window (10), and in that the control wheel (9) has an outer surface and an inner surface and is arranged directly next to the counting wheel (8), with the outer surface of the control wheel (9) directed towards the inner surface of the counting wheel (8), the control wheel (9) comprising a centrally arranged through-hole (34) with a shape and size corresponding to the shape and size of the first inner flange (15) of the cap (7) and having a recess (35) arranged on the periphery of the hole (34), which recess (35) has a shape which substantially corresponds to the shape of the locking tooth (16) arranged on the cap (7) and with a size which slightly exceeds the size of the locking tooth (16), so that a predetermined clearance exists between the locking tooth (16) and the edges of the recess (35), at least one stop tongue (30) which projects from the periphery of the control wheel (9) and which is arranged to engage in and cooperate with the gear ring (22) arranged on the inner surface of the counting wheel (8), and a rod-shaped pin (32) which is arranged at right angles to the inner surface of the control wheel (9) and is connected to the control wheel (9) via a spring member (33), and in that the stop tongue (30) of the control wheel (9) is oriented in a

tangential direction which is opposite to the direction of the gear ring (22) and stop tongue (25) of the counting wheel (8), and in that the direction of the teeth (12) in the gear ring (11) of the cap (7) coincides with the tangential direction of the stop tongue (30) of the control wheel (9), and furthermore in
5 that the number of stop tongues (25, 30) and the number of teeth (12, 23) are identical for the counting wheel (8) and for the control wheel (9), and in that the outside of the spray dose inhaler (1) is provided with coupling members (40, 43, 45, 47) for connecting the counting mechanism (2) to the
10 spray dose inhaler (1), the coupling members comprising a through-hole (47) through which the rod-shaped pin (32) of the counting mechanism (2) can be introduced, the hole (47) being positioned so that the rod-shaped pin (32) is in contact with the spray container and is acted upon and deflected and/or changes position when the spray container (4) moves in the first part (3) of the spray dose inhaler (1).

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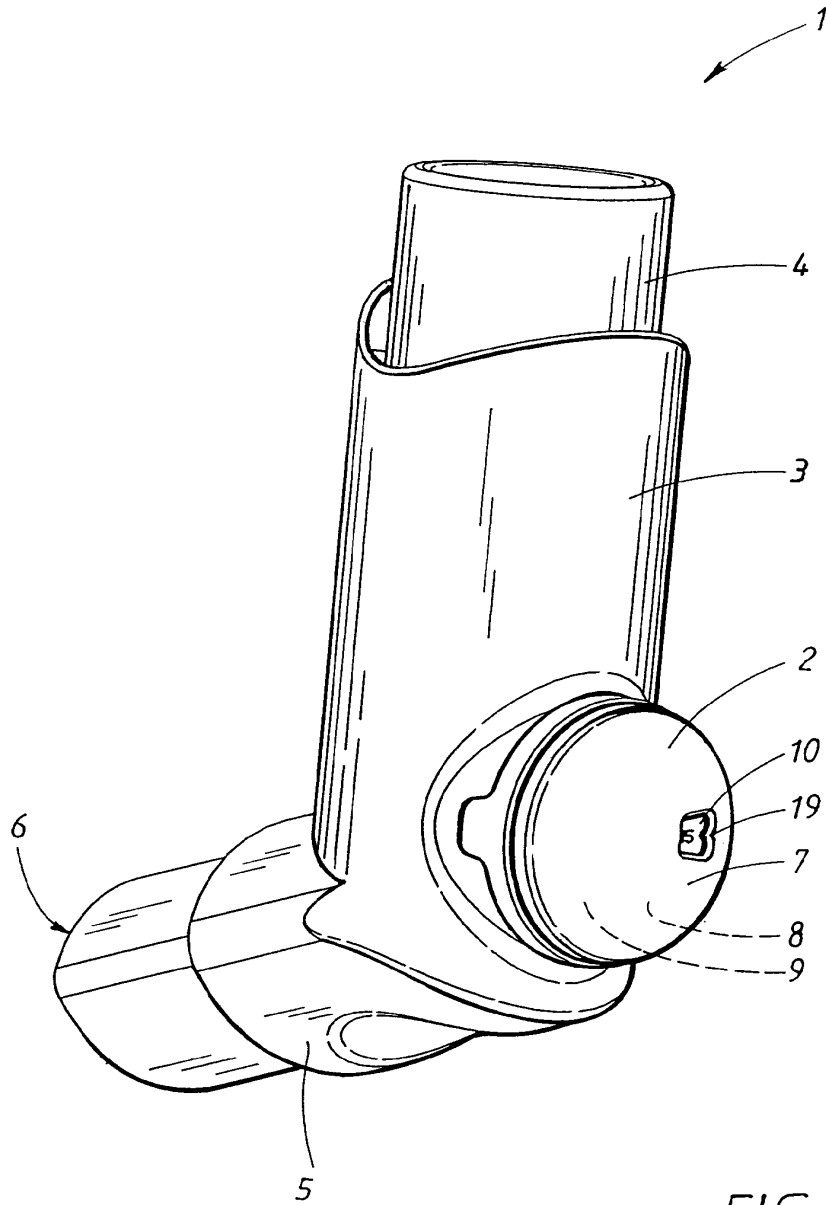


FIG. 1

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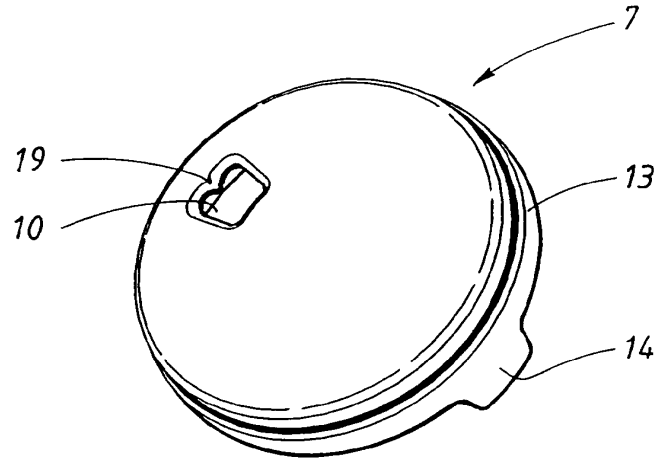


FIG. 2a

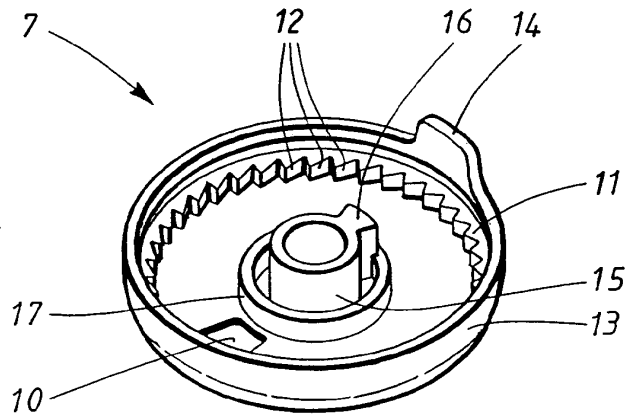


FIG. 2b

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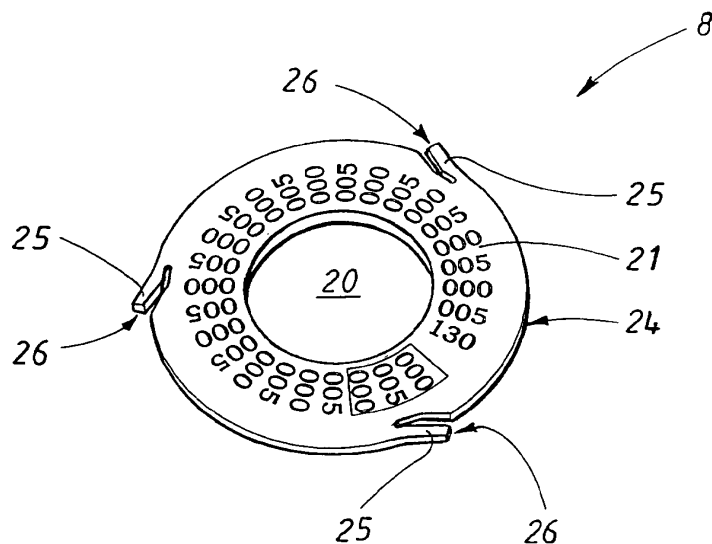


FIG. 3a

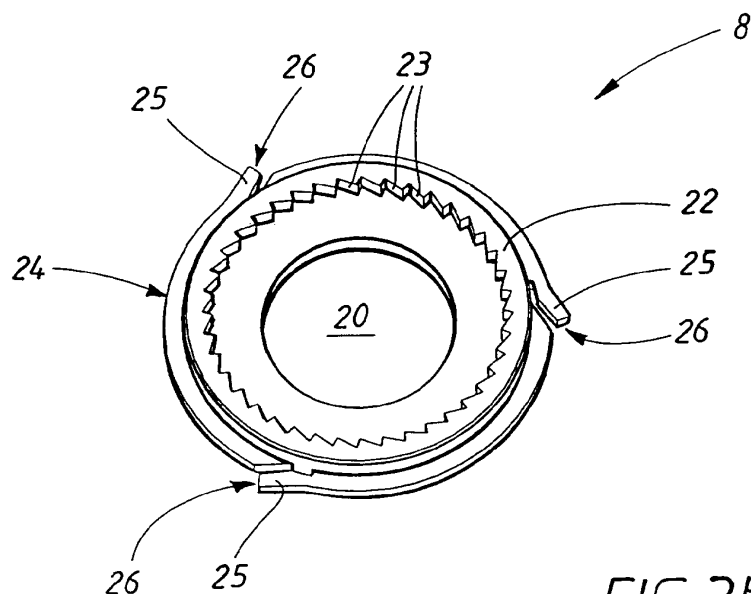


FIG. 3b

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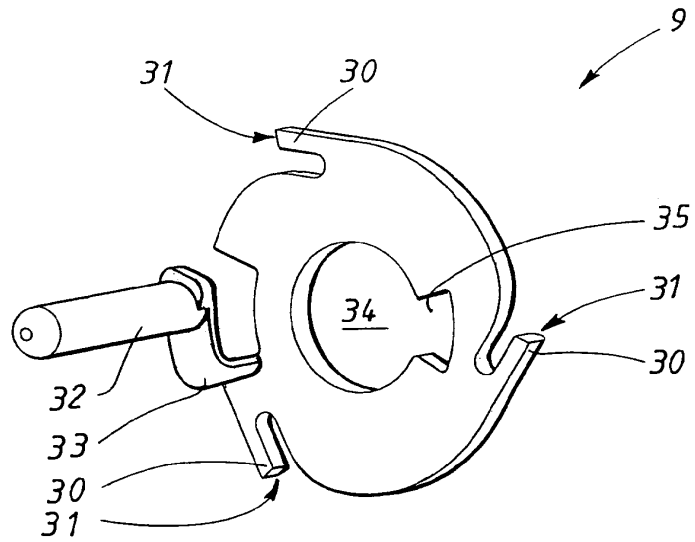


FIG. 4a

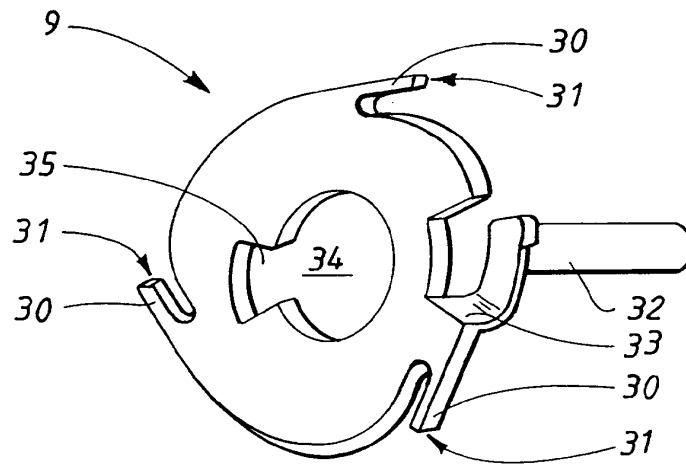


FIG. 4b

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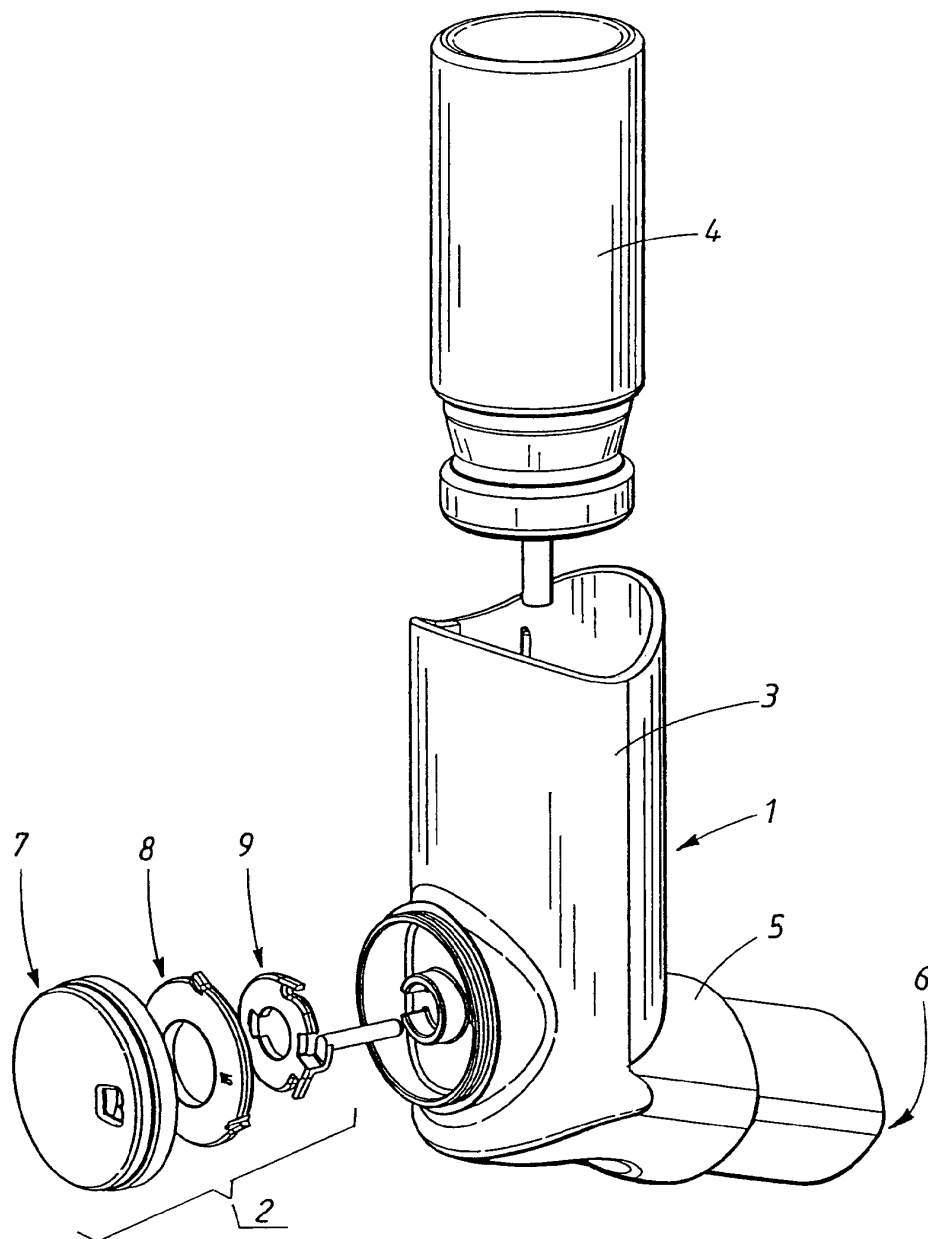


FIG. 5

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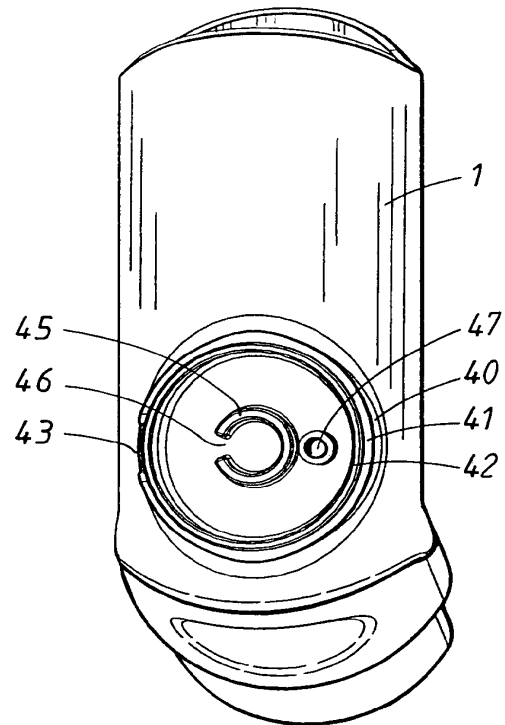


FIG. 6

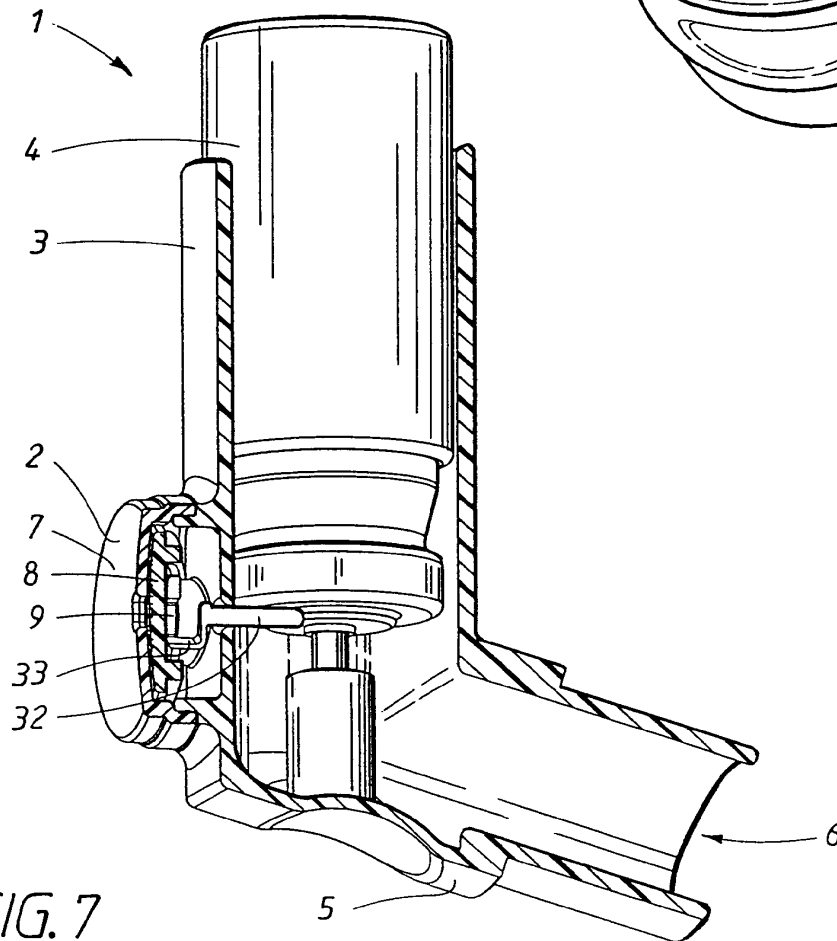


FIG. 7

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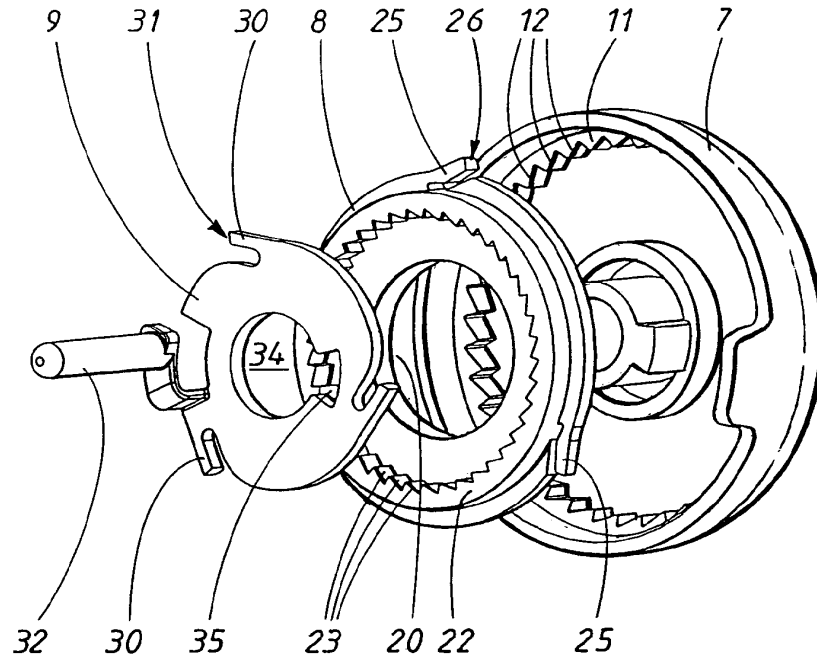


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/02319

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 11/00, A61M 15/00, G06M 1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M, G06M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 19549033 C1 (BOEHRINGER INGELHEIM INTERNATIONAL GMBH), 28 May 1998 (28.05.98), figure 1, claims 1-18 --	1-7
A	WO 8602275 A1 (AKTIEBOLAGET DRACO), 24 April 1986 (24.04.86), figures 1-7, claims 1-8 -- -----	1-7

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

23 January 2001

Date of mailing of the international search report

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Name and mailing address of the ISA/

Swedish Patent Office

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INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/SE 00/02319

Patent document cited in search report			Publication date	Patent family member(s)		Publication date
DE	19549033	C1	28/05/98	AU	1303597 A	28/07/97
				BG	102540 A	30/12/98
				BR	9612394 A	13/07/99
				CA	2238760 A	10/07/97
				CZ	9802049 A	11/11/98
				EP	0870178 A	14/10/98
				HR	960617 A,B	31/10/97
				HU	9903725 A	28/03/00
				IL	124573 D	00/00/00
				NO	982992 A	26/06/98
				PL	327571 A	21/12/98
				SK	89098 A	04/11/98
				US	6149054 A	21/11/00
				WO	9724586 A	10/07/97
WO	8602275	A1	24/04/86	AU	4969885 A	02/05/86
				DE	8590143 U	02/04/87
				DK	269086 A	09/06/86
				DK	481884 D	00/00/00
				EP	0197113 A	15/10/86
				ES	547668 A	01/12/86
				ES	8701660 A	01/03/87
				FI	862440 A	06/06/86
				JP	62500361 T	19/02/87
				NO	862098 A	27/05/86
				PT	81272 A,B	01/11/85
				ZA	8507761 A	28/05/86

Form PCT/ISA/210 (patent family annex) (July 1998)



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12

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⑤ Int. Cl. 4: **A61M 15/00**

② Date of filing: 24.04.87

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11.08.86 GB 8619516

④³ Date of publication of application:
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⑤⁴ Indicating device for aerosol dispensers.

(57) A device is described for indicating the number of doses dispensed from an aerosol container (2) having an outlet valve member (4) movable relative to the body of the container (2) to dispense its contents in measured doses. Relative movement between the aerosol container body (2) and the outlet member (4) are detected by a ratchet wheel (14) and ratchet driving member (11A) which move with the body and outlet member respectively or vice versa. The ratchet wheel (14) may in turn drive an indicating member in the form of a linear rack (20) or rotatable wheel (116).

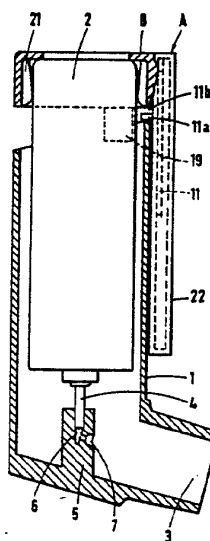


Fig. 1

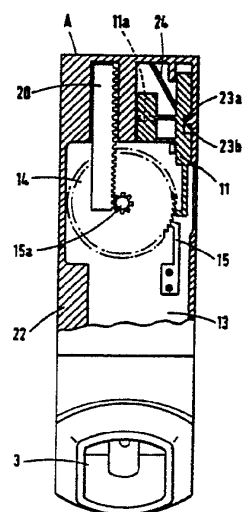


Fig.2

EP 0 254 391 A1

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INDICATING DEVICE

The present invention relates to a device for indicating the number of doses dispensed from an aerosol container, and, also, to aerosol devices, for example, inhalation devices by which medicaments contained in an aerosol may be administered to a patient.

It is well known to treat patients with medicaments contained in an aerosol, for example, in bronchodilator therapy. It is also known to use for such therapy, medicaments which are contained in an aerosol and are administered to a patient by means of an inhalation device comprising a tubular housing or sleeve in which the aerosol container is located and an outlet tube leading out of the tubular housing. The aerosol containers used in such inhalation devices have an outlet valve member at one end which can be opened either by depressing the valve member while the container is held stationary or by depressing the container while the valve member is held stationary. In the use of such devices, the aerosol container is placed in the tubular housing with the outlet valve member of the container communicating via a support with the outlet tube, for example, a nozzle or mouthpiece. When used for dispensing medicaments, for example in bronchodilation therapy, the housing is then held by the patient in a more or less upright condition and the mouthpiece or nozzle of the inhalation device is placed in the mouth or nose of the patient. The aerosol container is pressed towards the support to dispense a dose of medicament from the container which is then inhaled by the patient.

A disadvantage arising from use of such known devices is that the patient cannot determine the amount of medicament in the aerosol container at any given time. In an extreme case this could mean that the patient, possibly suffering from severe bronchospasm and needing a dose of medicament, will find that the aerosol container will not dispense a dose because its contents have already been exhausted.

An object of the present invention is to provide means of overcoming this disadvantage.

Accordingly, the present invention provides a device for indicating the number of doses dispensed from an aerosol container having a body and an outlet member movable relative to the body to dispense its contents in measured doses, said device comprising movement detection means responsive to relative movement between the body and the outlet member, and indicating means responsive to the movement detection means so that the indicator means is indicative of the number of

movements of the body relative to the outlet member and, therefore, of the quantity of the contents of the container remaining therein or which have been discharged therefrom.

The device of the present invention is preferably adapted for removable mounting to an aerosol container located in the housing of the medical inhalation device.

In one preferred embodiment, an actuator member is provided which comprises a ring-form member for mounting to the body of the aerosol container. A further member is provided which during at least a portion of the movement of the actuator member, is held stationary with respect to the outlet member. In a preferred embodiment, this further member is held stationary by abutment with a housing in which the aerosol container is received and in which the outlet member of the aerosol container is supported during relative movement of the container body.

The device preferably comprises a ratchet wheel which is caused to rotate, by relative movement between the container body and the container housing, through a pre-determined angle. This wheel may itself bear markings to indicate the number of relative movements made between the aerosol container and outlet member but is preferably adapted to drive, for example, an indicator rack or toothed wheel bearing such markings, employing a suitable step-down gear ratio. This latter arrangement permits the number of doses indicated to exceed many times the number of teeth on the ratchet wheel and, hence the production of a compact device.

According to a further aspect of the present invention there is provided an aerosol dispensing device comprising a housing in which an aerosol container can be located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the aerosol container and having a passage through which the contents of the aerosol container may pass to the outlet, the aerosol dispensing device being provided with a dose indicating device according to the invention.

Embodiments of the present invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a side view, partially in section, of a first embodiment of the indicating device of the present invention mounted to a medical inhalation device;

Figure 2 is a front view of the arrangement shown in Figure 1 in which the indicating device is shown in section;

Figure 2a shows part of modified embodiment from one side;

Figure 2b shows a view, from the opposite side to Figure 2 of a feature applicable both to the embodiment of Figures 1 and 2, and the modified embodiment of Figure 2a;

Figure 3 is a front view of a further embodiment of the invention, part of a front wall of the device being broken away;

Figure 4 is a sectional view of the device of Figure 3;

Figures 5 and 6 are similar views illustrating one modification of the device illustrated in Figures 3 and 4; and

Figures 7 and 8 are similar views of another modification.

The inhalation device shown in Figures 1 and 2 comprises a tubular housing 1 in which an aerosol container 2 can be located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. An outlet 3 leads laterally from the closed end of the housing 1. In the embodiment illustrated, the outlet 3 is in the form of a mouthpiece intended for insertion into the mouth of the patient, but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

The aerosol container 2 has an outlet valve member 4 at one end. This valve member can be depressed to release a measured dose from the aerosol container or, alternatively, the valve member 4 can be fixed and the main body of the container can be moved relative to the valve member to release the dose.

As shown clearly in Figure 1, the aerosol container 2 is located in the housing 1 so that one end protrudes from its open top. Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1. A support 5 is provided at the lower end of the housing 1 and has a passage 6 in which the valve member 4 of the aerosol container 2 can be located and supported. A second passage 7 is provided in the support 5 and is directed towards the interior of the outlet 3. Thus, when the parts are in the positions shown in Figures 1 and 2, the protruding portion of the aerosol container 2 can be depressed to move the container relative to the valve member 4 to open the valve and a dose of medicament contained in the aerosol will be discharged through the passage 7 and into the outlet 3 from which it can be inhaled by a patient. One dose will be released from the aerosol container each time it is fully depressed.

Figures 1 and 2 also show an embodiment of the dose indicating device of the present invention. This device A comprises an actuator member in the form of a ring-shaped cap member 8 which is removably located on the end of the protruding portion of the body of the aerosol container 2. The cap member 8 is retained on the body of the aerosol container 2 by means of longitudinal ribs 21 on its internal surface so that once it is on the body it cannot be removed too easily. The top of the cap abuts the end of the body of the container 2 and moves with the body throughout its displacement towards and away from the support 5. A pair of symmetrically placed spacing elements 19, of which one can be seen in Figure 1, extend from the lip of the cap member 8 into the housing 1 and slide against the internal wall of this housing so as to guide the movement of the aerosol container body therein.

Attached to the side of the cap member 8 and movable therewith is a housing 22 which defines an indicator compartment 13. This housing 22 extends from the cap member 8 along the external surface of the tubular housing 1. The length of this indicator housing 22 is such that when mounted to the tubular housing 1, it does not abut the outlet 3 as it moves downwardly with the container body.

A driving arm 11 is slidably retained within the housing 22 and is guided for movement between two limit positions defined by stop surfaces 23a and 23b. The driving arm 11 supports a projection 11a which extends through and is movable within a slot 11b in the wall of the indicator housing 22 mounted adjacent the tubular housing 1. In this embodiment, projection 11a rests on the top edge 1a of the wall of the tubular housing 1.

The driving arm 11 engages a ratchet wheel 14 which is mounted to the wall of the indicator housing 22. This ratchet wheel cooperates with a ratchet pawl 15. Whenever the body of the aerosol container 2 is depressed to open the valve member 4, the ratchet wheel 14 moves downwards with the cap member 8 while the driving arm 11 remains stationary with respect to the support 5 by virtue of the abutment of projection 11a with the wall of the tubular housing 1. In view of the engagement of the driving arm 11 with the ratchet wheel 14, this relative linear movement between these two elements results in rotation of the ratchet wheel 14 in an anticlockwise direction (as viewed in Figure 2) through the angle subtended by a ratchet wheel tooth.

A spur wheel 15a which is rotatable with the ratchet wheel 14, engages a toothed indicator rack 20. The gear ratio between the ratchet and spur wheel is such that the indicator rack moves through one "step" for a predetermined number of ratchet wheel "steps" and, hence, doses dispensed.

The front of the housing 22 has a window (not shown) through which a portion of the indicator rack 20 is visible. This indicator rack carries suitable markings which are displayed through the window when the given marking registers with this window. Any suitable markings may be employed, though preferably not letters, numbers or like characters which require to be read. For example, the rack can be marked with different colours of different portions so that, for example, when a red portion is displayed through the window, the patient will know that a new aerosol container must be obtained. In other alternatives, however, the indicator rack may be marked with numbers to indicate the proportion of the contents still remaining or the number of doses dispensed from or remaining in the aerosol container. In a convenient arrangement, the markings on the indicator rack indicate that the aerosol container is empty after a predetermined number of doses, for example 200, have been dispensed, this predetermined number being less than the number of doses with which the container has been charged, say 220, so as to allow for a margin of error.

With displacement of the cap member 8 and housing 22 towards the support 5, a resilient member 24 attached to or part of driving arm 11, extends obliquely between the driving arm 11 and the top wall of the housing 22 is placed under compression and distorts. Once the pressure applied to the cap member 8 has been released, the device A returns to the position illustrated in Figures 1 and 2. The force exerted by the resilient member 24 pushes the driving arm 11 downwards within the housing 22 so as to engage a subsequent tooth of the ratchet wheel 14.

The device illustrated in Figures 1 and 2 may be modified by replacing the indicator rack 20 by a toothed indicator wheel which is engaged by the spur wheel 15A. Thus, on rotation of the ratchet wheel 14 the spur wheel 15A drives this indicator wheel.

In a further modification of the device illustrated in Figures 1 and 2, the spur wheel 15A is replaced on the ratchet wheel 14 by a single start worm and the toothed indicator rack 20 is replaced by an indicator rack having a row of projections engageable by this single start worm. Thus, in this case, rotations of the ratchet wheel 14 rotates the single start worm which in turn drives the indicator rack.

Figure 2a shows a modification of part of what is shown in Figure 2, the resilient member 24 being replaced by a compression spring 24'.

Figure 2b shows a device according to the invention viewed from the opposite side to Figure 2. The view shows a plate 30 which forms a cover for the mechanism visible in Figure 2b. A slot 31 is

formed in the plate 30 to define a tongue 32, having the shape of an inverted L, connected to the remainder of the cover only by a narrow bridge 33. An upstanding lug 34 is formed on the base of the L and a similar lug 35 is formed on the remainder of the cover on the opposite side of the slot to the lug 34. The material, e.g. plastics material, of which the plate is formed is sufficiently resilient that a user can urge the lugs towards one another, for example by gripping them between a thumb and finger, in which process flexing about the bridge 33 occurs. The axle 14a on which the wheel 14 rotates is mounted in the tongue 32, so that urging the lugs 34 and 35 together moves the wheel out of engagement with the rack 20. This enables the rack 20 to slide down to the end position in which it represents a value of zero doses having been dispensed. In this way the counter is reset to zero. Thus, when one container has been dispensed the counter can be removed, reset to zero, and mounted on a full container, and in this way can be reused many times. The housing 101 is open at one end which will hereinafter be considered the top of the device for convenience of description. The housing 101 is closed at the other end. An outlet 103 leads laterally from near the closed end of the housing 101. In the illustrated embodiment, the outlet 103 is in the form of a mouthpiece intended for insertion into the mouth of a patient, but it may, if desired, be designed as a nozzle for insertion into the nostril of a patient.

The aerosol container 102 has an outlet valve member 104 at one end. This valve member can be depressed to release a dose from the aerosol container or, alternatively, the valve member 104 can be fixed and the main body of the container can be moved relatively to the valve member 104 to release a dose. The aerosol container 102 is located in the housing 101 so that one end protrudes from the open top of the housing as shown clearly in Figure 4. Spacer ribs, not shown, may be provided inside the housing to hold the external surface of the container spaced from the internal surface of the housing. A support or stem block 105 is provided at the lower end of the housing 101 and has a passage 106 in which the valve member 104 of the aerosol container 102 can be located and supported. A second passage 107 is provided in the support 105 and is directed towards the interior of the outlet 103. Thus, when the parts are in positions shown in Figures 3 and 4, the protruding portion of the aerosol container 102 can be depressed to move the container 102 relatively to the valve member 104 so that the valve will be opened and a dose of medicament contained in the

aerosol will be discharged through the passage 107 into the outlet 103 from which it can be inhaled by the patient. One dose will be released from the aerosol container each time it is fully depressed.

An actuator and container retainer member in the form of a ring 108 is guided for sliding movement in the housing 101. Locating lugs 109 protrude from the ring 108 and slide in slots 110 in the wall of the housing. The aerosol container 102 is fitted in the ring 108 in such a way that once it is fitted therein it cannot be removed therefrom and also so that the ring will move with the container 102 when it is depressed to open the outlet valve of the aerosol container. The fact that the aerosol container cannot be removed once it has been fitted prevents misuse or abuse of the product by replacement with an alternative product which may be detrimental or even dangerous to the wellbeing of a patient and contrary to medical instructions.

A driving arm 111 extends from the ring 108 through a slot 112 in the wall of the housing 101 into an indicator compartment 113. The driving arm 111 engages a ratchet wheel 114 in the indicator compartment. The ratchet wheel co-operates with a ratchet pawl 115. When the aerosol container 102 is depressed, the driving arm 111 moves downwards and forwards to the centre of the ratchet wheel 114, so engaging the next adjacent ratchet tooth. When the aerosol container 102 is released, the driving arm 111 moves upwards causing the ratchet wheel 114 to rotate the distance of one tooth. Rotatable with the ratchet wheel 114 is a spur gear 115A which engages a toothed indicator wheel 116. Thus, the indicator wheel 116 rotates one step for each dose dispensed by depression of the body of the aerosol container 112. The front of the indicator housing 113 has a window 117 through which a portion of the indicator wheel 116 is indicated. This indicator wheel can be given suitable markings which are displayed through the window when the given markings registers with the window. Thus, in the embodiment illustrated the indicator wheel has markings "1/4", "1/2", "3/4", "F", and "E". The markings "F" and "E" respectively denoting full and empty. Any suitable markings may be made on the indicator wheel. For example, the wheel can be marked with different colours at different positions so that, for example, when a red portion is displayed through the window, the patient will know that a new inhalation device must be obtained. In other alternatives, the indicator wheel may be marked with numbers to indicate either the number of doses dispensed from the aerosol container or the number of doses remaining to be dispensed. In a convenient arrangement, the indicator wheel is arranged to dis-

play that the aerosol container is empty after 200 doses have been dispensed, in that case the container having been charged with, say, 220 doses, to allow a margin of error.

The device illustrated in Figures 5 and 6 is modified so that the ratchet wheel 114 will drive a single start worm 118 which in turn drives an indicator rack 119 having a row of projections engageable by the worm. The other parts of the device designated by the same references are used with reference to Figures 3 and 4.

In the modified device illustrated in Figures 7 and 8, the ratchet wheel 114 again rotates a spur wheel 115A which engages and drives an indicator rack 120. Other parts of the device have the same reference numerals that are used in the description with reference to Figures 3 and 4.

The invention has hereinbefore been described in relation to medical inhalation devices but it is apparent that the invention may be applied to any container having a depressable dispensing valve, to determine the quantity of product used or that which is left in the container.

Claims

1. A device for indicating the number of doses dispensed from an aerosol container having a body and an outlet member movable relative to the body to dispense its contents in measured doses, said device comprising movement detection means responsive to relative movement between the body and the outlet member, and indicating means responsive to the movement detection means so that the indicator means is indicative of the number of movements of the body relative to the outlet member and, therefore, of the quantity of the contents of the container remaining therein or which have been discharged therefrom.

2. A device according to Claim 1, wherein the movement detection means comprises a ratchet wheel movable with one of the aerosol container and outlet member, and a ratchet wheel driving member movable with the other of the aerosol container and outlet member and arranged to rotate the ratchet wheel through a predetermined step upon relative movement of the aerosol container and outlet member.

3. A device according to Claim 1 or 2, wherein the indicator means is arranged to move linearly.

4. A device according to Claim 3, wherein the indicator means comprises a toothed rack, and the ratchet wheel carries a spur gear which meshes with the toothed rack and drives it.

5. A device according to Claim 3, wherein the indicator means comprises an indicator rack having a row of projections, and the ratchet wheel carries a worm which engages the row of projections and drives the rack.

6. A device according to Claim 2, wherein the indicating means comprises a rotatable toothed indicating wheel, and the ratchet wheel carries a spur gear which meshes with the indicating wheel and drives it.

7. A device according to Claim 2, wherein the ratchet wheel itself constitutes the indicating means.

8. A device according to any preceding claim, comprising an actuator member adapted to be removably mounted on the body of the aerosol container so as to be displaceable with respect to the outlet member, the actuator member comprising a further member which, during at least a portion of the movement of the actuator member, is held stationary with respect to the outlet member.

9. A device according to Claim 8, wherein the said further member is arranged to be held stationary with respect to the outlet member by abutment with a housing in which the aerosol container is received and in which the outlet member is supported during relative movement of the container body.

10. A device according to Claim 8 or 9, wherein the actuator member comprises a ring-shaped cap adapted to be mounted on an end of the body of the aerosol container.

11. A device according to any one of claims 8 to 10, comprising means for resetting the indicator means to zero.

12. A device according to any preceding claim, wherein the indicating means carries no numbers, letters, or like characters.

13. An aerosol dispensing device comprising a housing in which an aerosol container can be located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the aerosol container and having a passage through which the contents of the aerosol container may pass to the outlet, the outlet member being movable relative to the body of the container to dispense its contents in measured doses; and a dose indicating device according to any one of Claims 1 to 7.

14. An aerosol dispensing device according to Claim 13, wherein the dose indicating device comprises an indicator compartment disposed on a wall of the container-receiving housing, the dose indicating device comprising an actuator member mounted on, and carried by, the body of the aerosol container so as to be displaceable with respect to the outlet member, and hence with respect to the container-receiving housing, the said

actuator member carrying an arm which extends into the said indicator compartment to operate the said indicating means.

15. An aerosol dispensing device according to Claim 14, wherein the said actuator member is arranged to be so mounted on the body of the aerosol container that it cannot be removed therefrom.

16. A dose indicating device substantially as herein described with reference to any of the embodiments shown in the accompanying drawings.

Nouveau brevet de France
Nouvellement d'usage

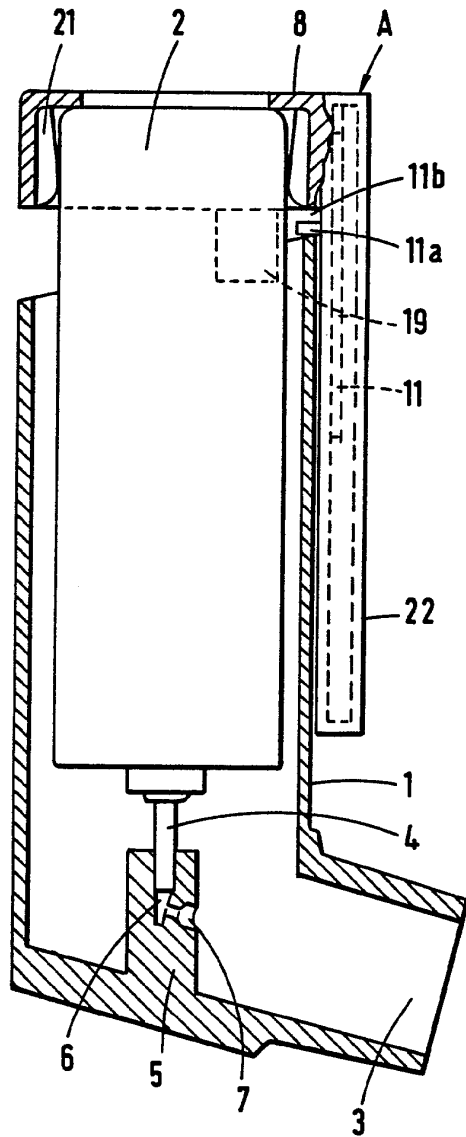


Fig. 1

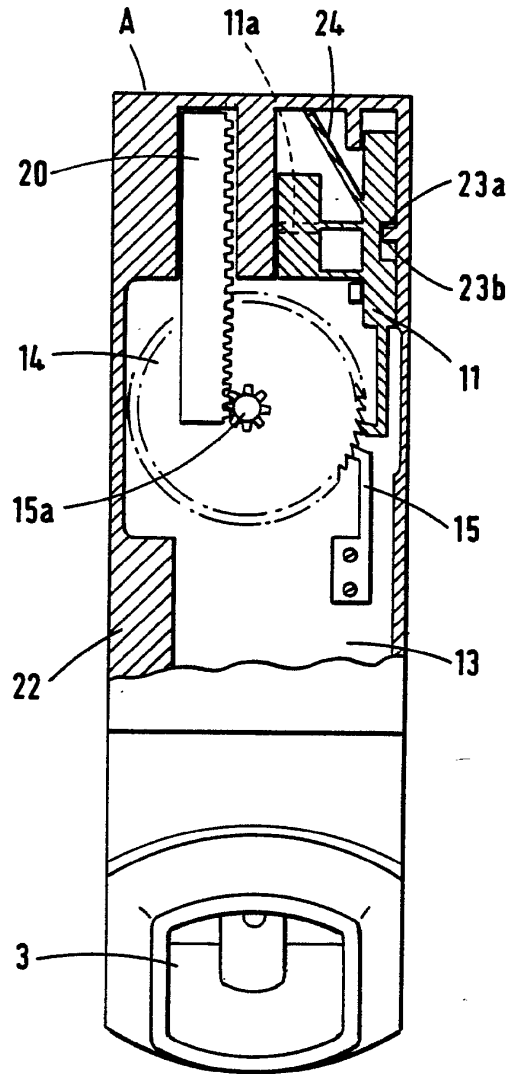


Fig. 2

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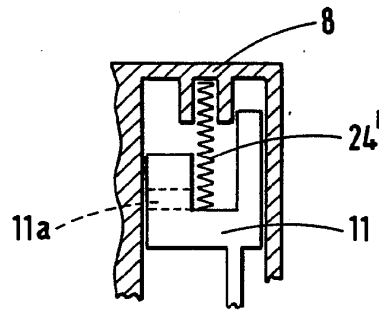


Fig. 2a

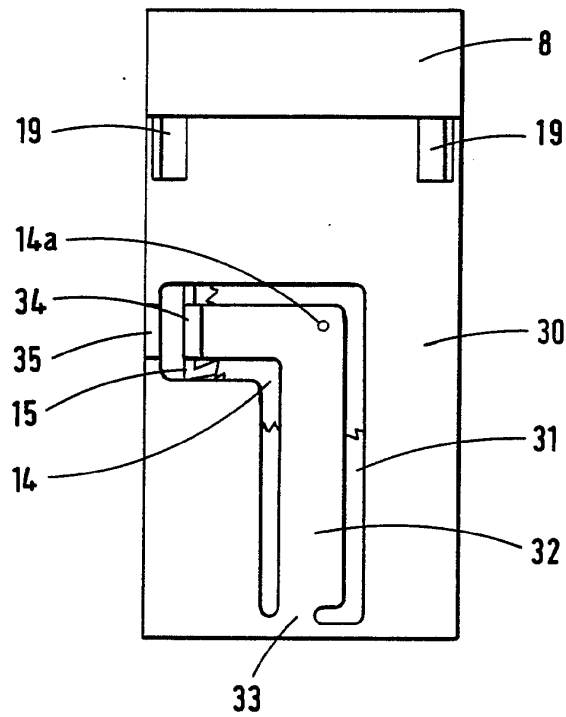


Fig. 2b

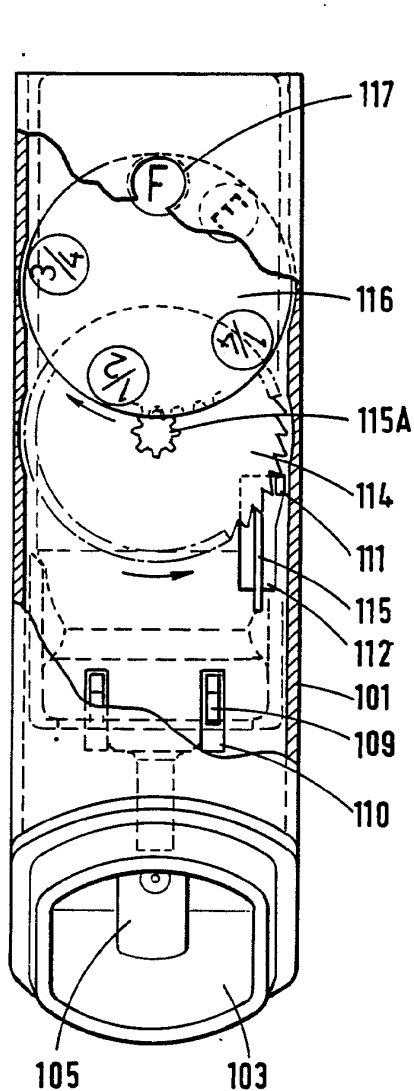


Fig. 3

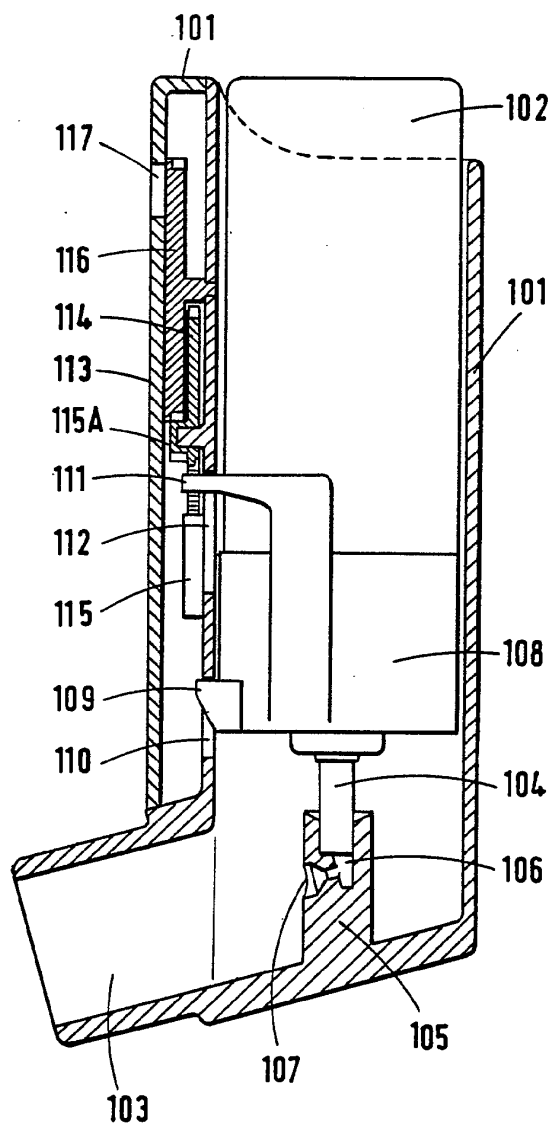


Fig. 4

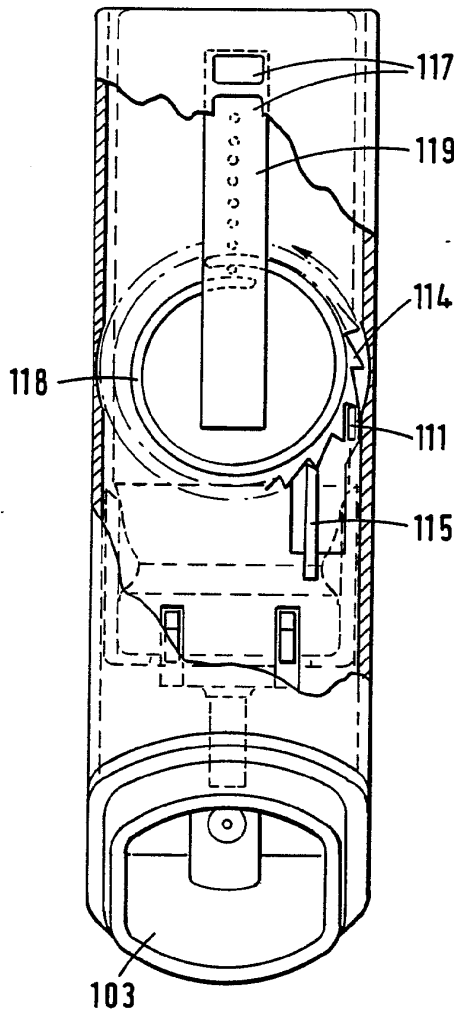


Fig. 5

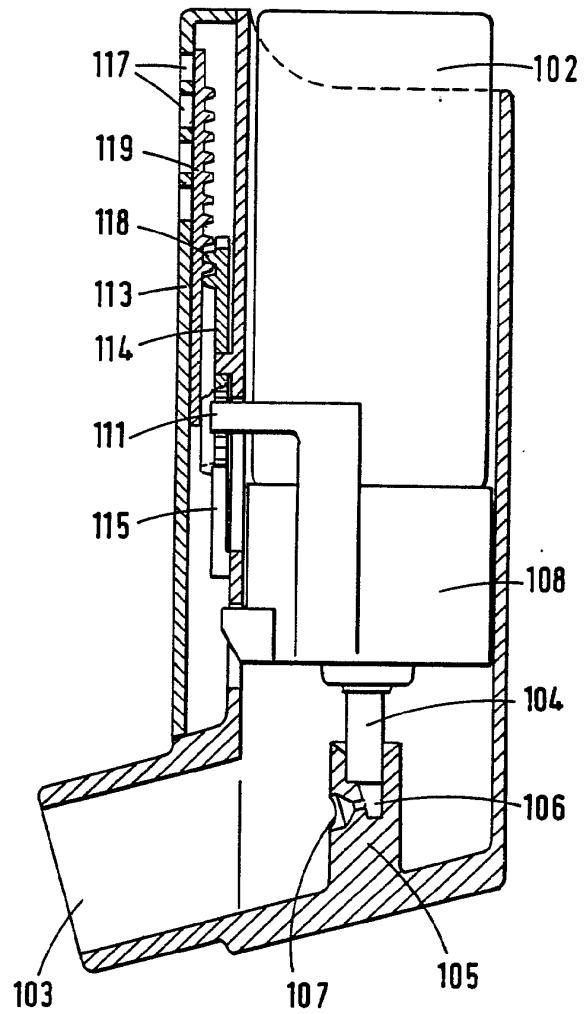


Fig. 6

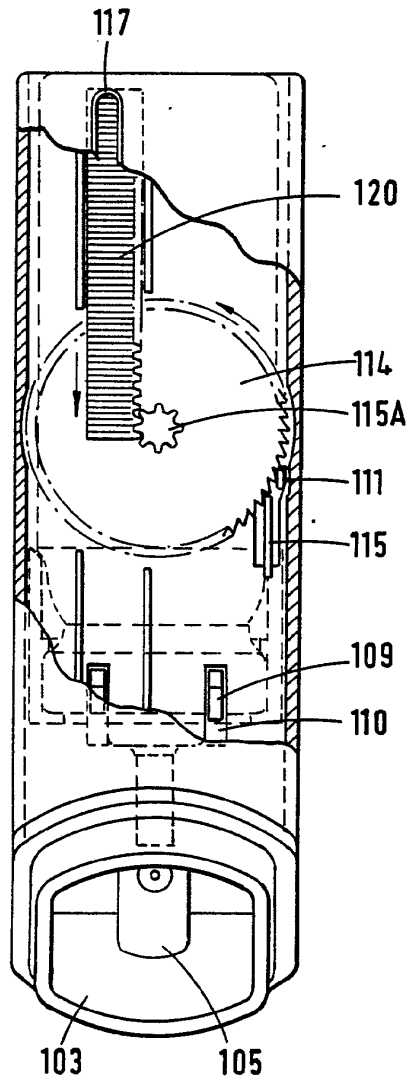


Fig. 7

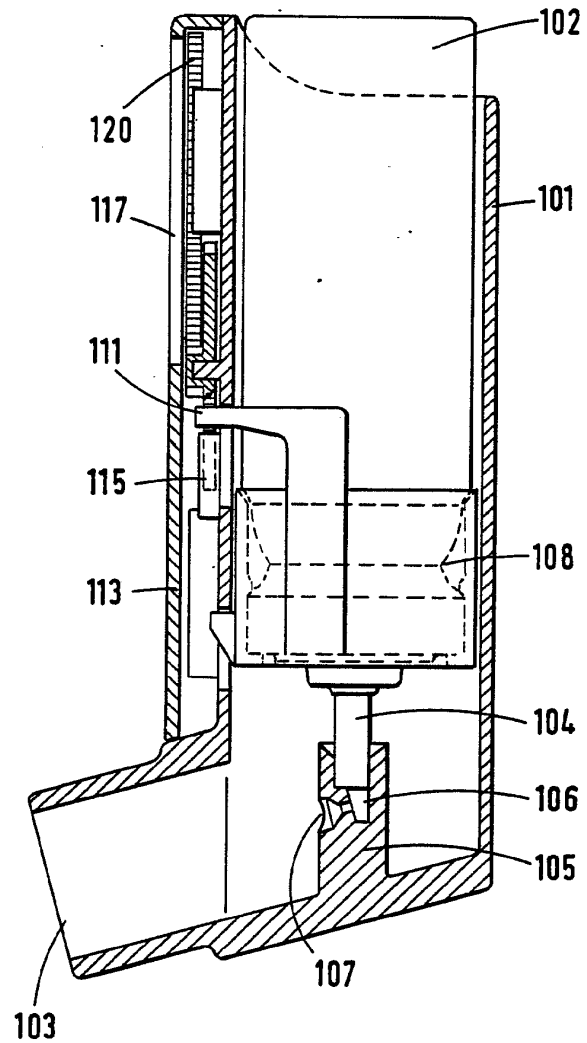


Fig. 8



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which under Rule 45 of the European Patent Convention
shall be considered, for the purposes of subsequent
proceedings, as the European search report

Application number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 87303617.2
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
X	WO - A1 - 86/02 275 (AKTIEBOLAGET DRACO)	1,12, 13	A 61 M 15/00
A	* Totality; especially page 6, line 35 - page 10, line 3 *	2,6-8, 14	
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X	GB - A - 1 317 315 (ENGL. NUMB. MACH.)	1,13	
A	* Totality; especially page 2, lines 15-22,66-97,114-117 *	2,6,7, 11,14	TECHNICAL FIELDS SEARCHED (Int. Cl.4)
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X	GB - A - 2 063 075 (STERVIN AG)	1	
A	* Totality; page 1, lines 107-126; page 2, lines 39-43 *	12,13	
	--		A 61 M 15/00
A	GB - A - 2 104 393 (GLAXO GROUP)	13	
	* Fig. 1; page 1, lines 92-108 *		

INCOMPLETE SEARCH			
The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims. Claims searched completely: 1-15 Claims searched incompletely: - Claims not searched: 16 Reason for the limitation of the search: (in order to rule 29(6))			
Place of search VIENNA		Date of completion of the search 17-09-1987	Examiner LUDWIG
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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(54) An indicator device

(57) A dose counter attached or attachable to the base of a pressurised canister for a metered dose inhaler and comprising a spring-loaded cap (14) which may be depressed in relation to a second part (1) mounted on the domed base of the canister (C). Within the cap (14) is a pair of independently rotatable rings, each carrying on its upper surface indicia visible through a window (13) in the cap. For each depression of the cap (14) relative to the canister, the first ring (4) is indexed in rotation, and for each complete revolution of the first ring (4), the second ring (8) is indexed in rotation. The first ring (4) carries the numbers 0 to 9 and the second ring (8) carries the numbers 00 to 20 so that the device counts down progressively from 200 to 000 thus providing an incremental indication of the number of doses remaining in the canister.

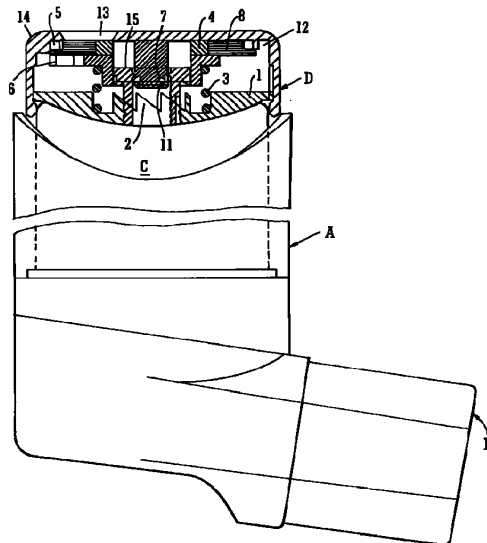


FIG. 1

EP 0 949 584 A2

Description

[0001] THIS INVENTION concerns an indicator device, and particularly, though not exclusively, such a device adapted to serve as a dose counter for metered dose inhalers (MDI's).

[0002] MDI's include pressurised canisters containing drugs to be inhaled for the relief of, for example, the symptoms of asthma. Typically each canister contains 200 doses but conventionally provides no indication to the user as to how many doses remain available for use at a particular time. This results in considerable inconvenience and risk to the user who must, inevitably, carry a fresh replacement MDI in addition to the one currently in use thus to ensure that if the current one becomes empty there is a spare supply.

[0003] Thus there is a need for a dose counter for an MDI to indicate the number of times the pressurised canister is depressed to dispense a dose of the drug. Such a counter must count down, typically from 200 to zero, progressively as doses are administered so that the user can readily see how many doses remain.

[0004] According to the present invention there is provided an indicator device to provide a count of a series of like linear movements of a first part of the device with respect to a second part thereof; the first part comprising first and second rotational rings carrying indicia progressively visible on the first part; the first and second parts having inter-engaging spaced projections such that upon each linear movement of the first part the first rotational ring is indexed in rotation, and such that a upon a predetermined number of linear movements of the first part, the second rotational ring is indexed in rotation.

[0005] Preferably, the second part is adapted to be affixed to the base of a pressurised canister of an MDI, and the first part is captive on the second part and spring-loaded thus to be capable of depression relative to the second part and to the canister.

[0006] Still further, the rotational rings are concentrically arranged, and the first rotational ring includes an annular array of spaced projections engageable successively with two further annular sets of projections fixed with respect to the second part of the device such that the projections on the first rotational ring successively engage the fixed projections to cause the first rotational ring to index in rotation twice for each depression and release thereof.

[0007] Furthermore, the second rotational ring comprises a further set of projections engageable successively by a pawl attached to the first rotational ring upon each complete revolution thereof thus to index the second rotational ring by one increment for each revolution of the first ring.

[0008] Still further, the first part of the device comprises a cap adapted for linear movement but prevented from rotational movement in relation to the second part of the device, the cap including a profiled channel in

which the pawl is adapted to travel during rotation of the first rotational ring, the profile of said channel causing the pawl to engage the projections of the second rotational ring once for each revolution of the first rotational ring, the cap including a window through which respective surfaces of the first and second rotational rings are visible in one radial location thereof whereby numeric indicia on said surfaces are progressively visible through said window.

[0009] An embodiment of the invention will now be described, by way of example only, with reference to the accompany drawings, in which:-

Fig. 1 is a part cross-sectional view of a meter dose inhaler having thereon an indicator device in accordance with the invention;

Fig. 2 is an enlarged cross-sectional view of the indicator device;

Fig. 3 is an exploded perspective view of the parts of the device;

Fig. 4 is a plan view of the device taken on line IV-IV of Fig. 2;

Fig. 5 is a cross-sectional view of part of the device illustrating the action thereof.

and Figs. 6a to 6d are partial plan views similar to Fig. 4, showing different operational conditions of the device.

[0010] Referring to Figs. 1 to 3, a meter dose inhaler A includes a mouth-piece B through which a user may inhale a drug dispensed from a canister C removably contained within the inhaler. A counter in accordance with the invention is illustrated generally at D.

[0011] The counter consists of a first part or base 1 which, in manufacture of the canister C is bonded to the domed base thereof. It will be appreciated that the canister C and counter D comprise a replaceable item within the inhaler.

[0012] Disposed in fixed position on the base 1 is a central bush 15 which in assembly of the device has a part 22 located on the base 1 by of a key way 23 and is thus non-movably attached thereto. The base 1 defines an annular cavity 1a intended to house the bottom of a coil spring 3, the top of which engages beneath a radially outwardly directed flange of a first rotational ring 4, an inner annular part of which may be accommodated within the cavity 1a.

[0013] The ring 4 defines an inner cylindrical space within the lower end of which there is located an annular series of projections formed as inwardly directed triangular teeth 7.

[0014] At the inner extremity of the cavity 1a of base 1 there is an annular series of projections formed as

upwardly directed teeth 2, and on the underside of an upper flange of the central bush 15 there is an annular series of projections formed as downwardly directed teeth 14a. When ring 4 is assembled with central bush 15, the triangular teeth 7 are movable therewith between the teeth 2 and the teeth 14a for a purpose to be described.

[0015] At one circumferential position on the outwardly directed flange of ring 4 is an outwardly projecting curved arm 6 carrying at its free end an upwardly directed pawl 5 for a purpose to be described.

[0016] Concentrically disposed above and around the ring 4 is a second rotational ring 8 having a circumferential series of projections formed as outwardly directed curvilinear teeth 9 and a further series of angular teeth 10 disposed on a reduced circumference of the ring 8. It will therefore be seen that the base 1, the central bush 15, the ring 4 and the ring 8 may be assembled in concentric relationship and surrounded by a cap 14 having a flat top and depending cylindrical wall, and having a central boss 11 which locates within the central bush 15. The cap 14 becomes captive with the base 1 by means thereon of an annular series of outwardly projecting lugs 27 which locate within arcuate and radially directed recesses 20 on the inner face of the cylindrical wall of the cap 14. The upper circular part of the cap 14 includes a window 13 of elongate rectangular form extending radially across one part of the top for a purpose to be described.

[0017] Within the cap 14 close to its circumference is a downwardly directed wall 12 defining an outer profiled channel which receives the pawl 5 of ring 4 when the device is fully assembled. The channel is profiled such that in one radial position which coincides with the position of window 13, the channel has a radially inwardly directed kink 26 (Fig. 3) for a purpose to be described.

[0018] When the entire device is assembled there is visible through the window 13 one radial location of the upper faces 24 and 25 respectively of the rotational rings 4 and 8. These faces carry respectively two numeric series such that face 24 carries the series 0 to 9 while face 25 carries the series 00 to 20. Thus, through the window 13 there may be visible progressively the numbers 000 to 200. As will be described the device counts down so that when the MDI is new and unused the number 200 will be visible thus indicating that there are 200 doses available within the canister to which the device is attached. As the MDI is progressively used the available doses will count down eventually to zero indicating that the canister is empty. The user may therefore determine at any time how many doses remain available from the canister.

[0019] The device operates as follows:

[0020] Upon depression of the cap 14 with respect to the base 1, the rings 4 and 8 are also depressed linearly causing, upon each depression, the teeth 7 to engage the lower fixed set of teeth 2. Owing to the triangular formation of the teeth 7 and 2 this causes the ring 4 to be

indexed in rotation, (See Fig. 5) and upon return or release of the cap, the teeth 7 then engage the upper teeth 14a causing a further rotational movement of the ring 4. Each of these rotational movements represents one half of a complete movement of the ring 4 so that the number visible through the window 13 on face 24 will change by one point for a complete depression and release of the cap. Thus the user can see the progressive movement of the inner ring indicating a count down from 9 to 0 for a complete revolution of the ring 4. During such revolution the pawl 5 on arm 6 travels around the channel defined by the wall 12 in cap 14. After ten rotational movements of the ring 4 the pawl 5 engages the kink 26 in the channel and thus moves inwardly to engage an adjacent trough between two of the teeth 9 on the second rotational ring 8 causing the latter to move rotationally by one position before the pawl 5 leaves the kink 26 and returns to the main part of the channel. (See Figs. 6a to 6d). Except when moved by the pawls, the ring 8 is prevented from rotational movement by engagement of one of the teeth 10 in a V-notch 30 in the inner face of the wall 12 coincident with the kink 26 therein (See Fig. 6a). Also, the ring 4 is prevented from rotation, except when being inclined, by engagement of the teeth 7 with the teeth 1 and 14a.

[0021] Thus it will be seen that for each complete revolution of the ring 4 the ring 8 is moved one position. When the device is new and unused the number 200 will appear in the window 13. The first actuation of the device moves rings 4 and 8 simultaneously thus revealing the number 199. Thereafter for ten operations the ring 4 alone will move to display a count down from 199 to 190 whereupon the outer ring 8 is moved once again to reveal the number 189 and so on, the device providing a continuously diminishing count of 200 doses from the MDI.

[0022] Figure 5 serves to illustrate how depression and release movements of the device cause the teeth 7 to engage the teeth 2 and 14a progressively. Figures 6a to 6d illustrate how the pawl 5 enters the kink 26 and engages the teeth 9 of the ring 8 once for each complete revolution of the ring 4.

[0023] Preferably, the entire device with the possible exception of spring 3 is made from individual pieces moulded from a plastics material and assembly is initiated by passing the central bush 15 downwardly through the ring 4 and fixing it within the base 1, the ring 8 then being superimposed on the ring 4 and finally the cap 14 being introduced over the entire assembly with the central boss 11 located within the central bush 15.

[0024] Conceivably, the counter may be removably attached to the base of a canister thus to be re-usable, but from an economic point of view it is more likely that the counter will be permanently attached to a canister and thus supplied and disposed of along with it.

Claims

1. An indicator device to provide a count of a series of like linear movements of a first part of the device with respect to a second part thereof; the first part comprising first and second rotational rings carrying indicia progressively visible on the first part; the first and second parts having inter-engaging spaced projection such that upon each linear movement of the first part the first rotational ring is indexed in rotation, and such that a upon a predetermined number of linear movements of the first part, the second rotational ring is indexed in rotation. 5
2. An indicator device according to Claim 1, wherein the second part is adapted to be affixed to the base of a pressurised canister of an MDI, and the first part is captive on the second part and spring-loaded thus to be capable of depression relative to the second part and to the canister. 10
3. An indicator device according to Claim 1 or Claim 2, wherein the rotational rings are concentrically arranged, and the first rotational ring includes an annular array of spaced projections engageable successively with two further annular sets of projections fixed with respect to the second part of the device such that the projections on the first rotational ring successively engage the fixed projections to cause the first rotational ring to index in rotation twice for each depression and release thereof. 15
4. An indicator device according to Claim 3, wherein the second rotational ring comprises a further set of projections engageable successively by a pawl attached to the first rotational ring upon each complete revolution thereof thus to index the second rotational ring by one increment for each revolution of the first ring. 20
5. An indicator device according to Claim 4, wherein the first part of the device comprises a cap adapted for linear movement but prevented from rotational movement in relation to the second part of the device, the cap including a profiled channel in which the pawl is adapted to travel during rotation of the first rotational ring, the profile of said channel causing the pawl to engage the projections of the second rotational ring once for each revolution of the first rotational ring, the cap including a window through which respective surfaces of the first and second rotational rings are visible in one radial location thereof whereby numeric indicia on said surfaces are progressively visible through said window. 25
6. An indicator device according to Claim 5, wherein the surface of the first ring carries a numeric series from 0 to 9, the surface of the second ring carries the numeric series 00 to 20, said surfaces being arranged concentrically such that through the window there may be visible progressively the numbers 000 to 200. 30
7. An indicator device according to any preceding claim, wherein the first and second rotational rings include means for preventing rotation thereof except when being indexed in rotation by the inter-engaging spaced projections. 35
8. An indicator device according to any preceding claim, being non-removably attached to the base of a pressurised canister for a metered dose inhaler. 40
9. An indicator device according to any one of Claims 1 to 7, being adapted for removable attachment to a pressurised canister for a metered dose inhaler. 45

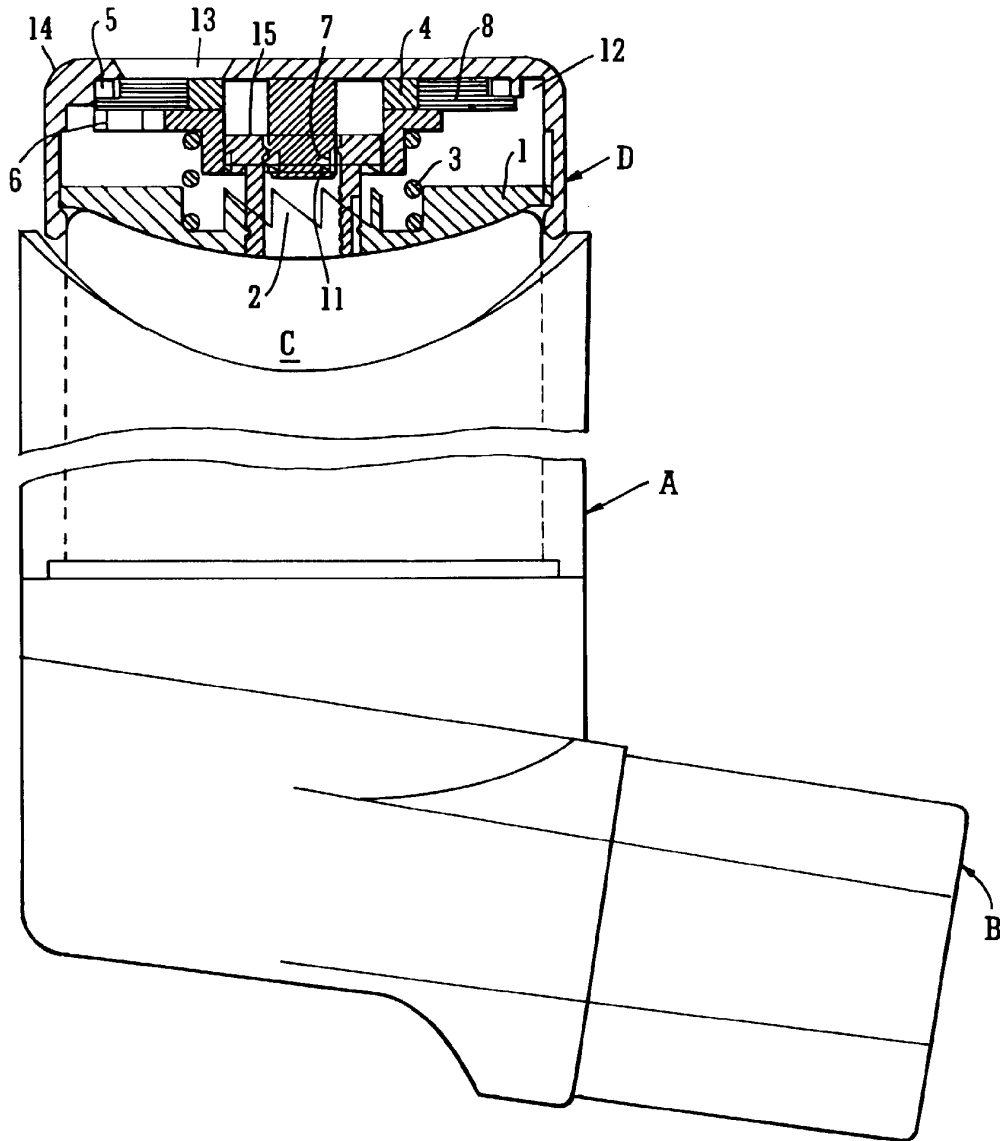


FIG. 1

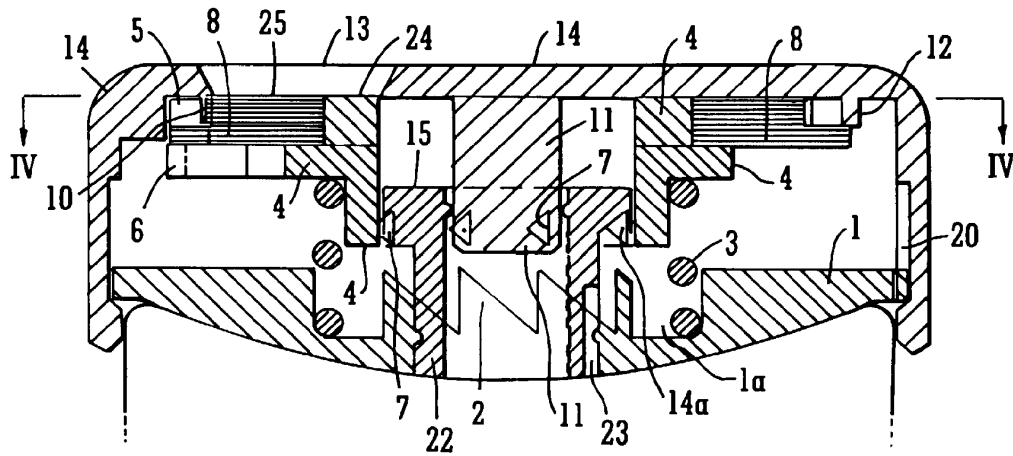


FIG. 2

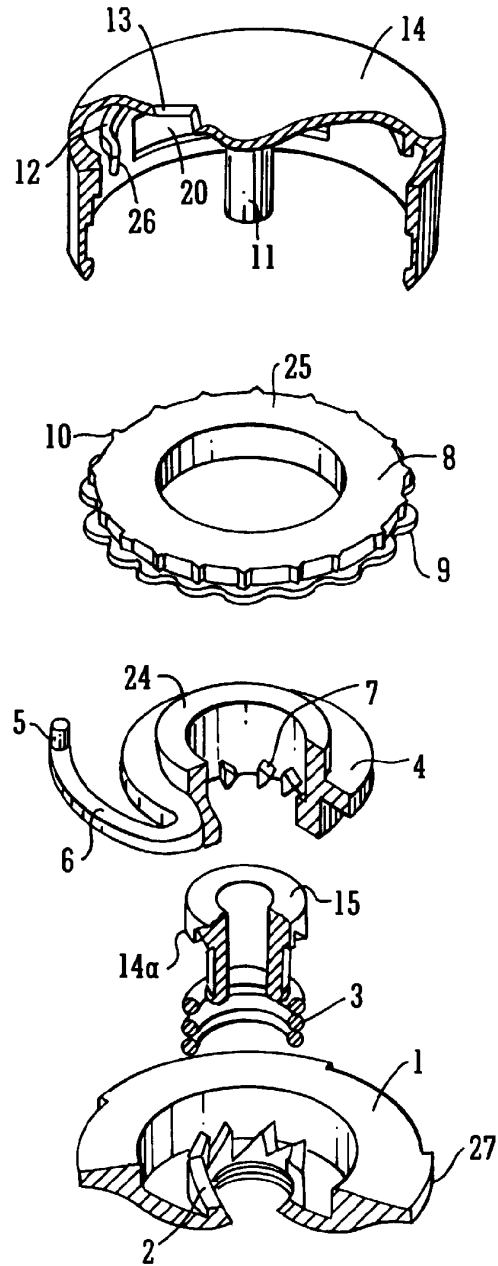


FIG. 3

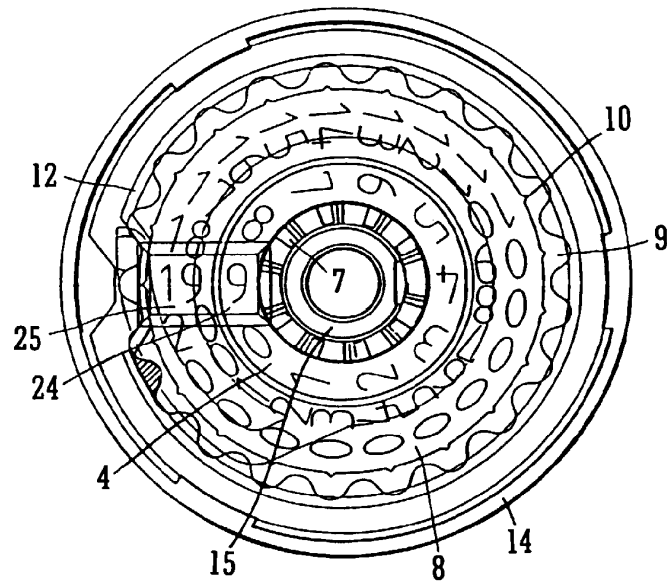


FIG. 4

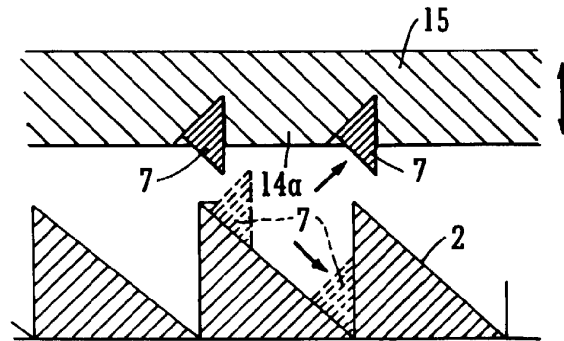
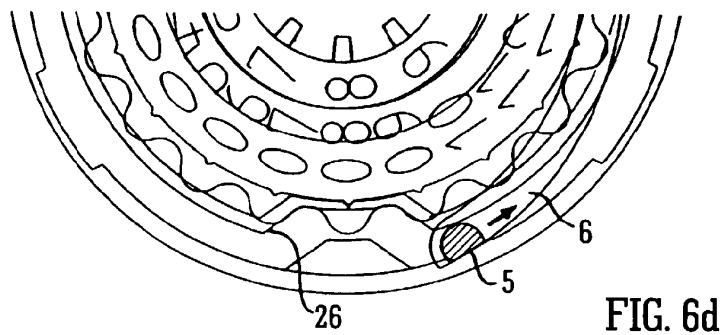
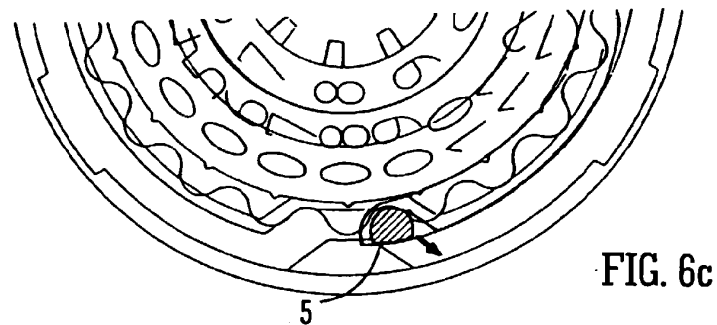
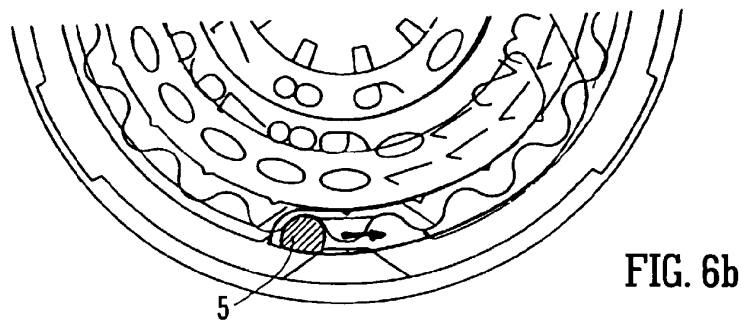
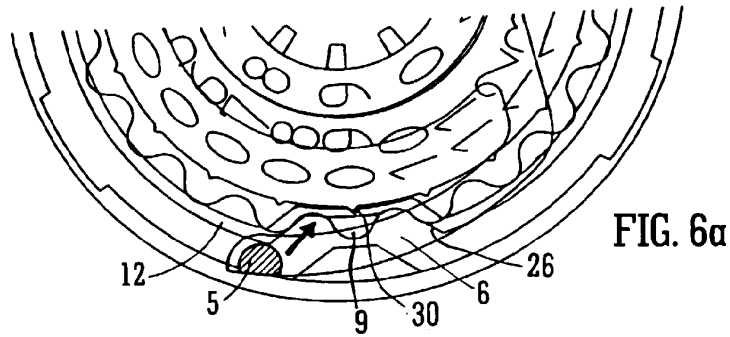


FIG. 5





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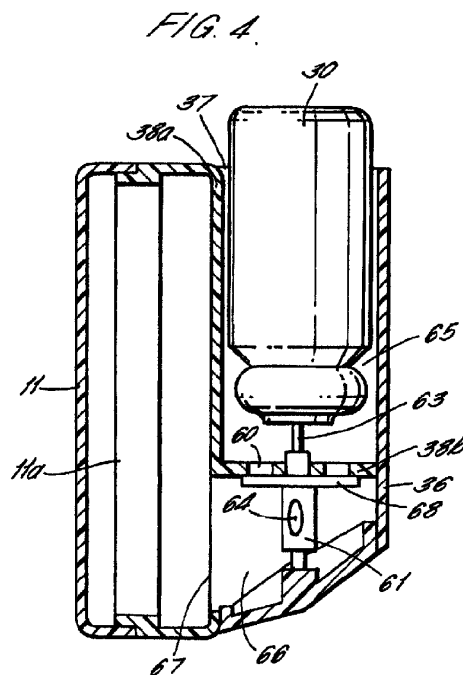
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(30) Priority: **11.12.1998 GB 9827402**

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(54) **Inhalation apparatus**

(57) The present invention relates to an inhalation apparatus for dispensing substances for inhalation and, in particular, but not exclusively, for dispensing medicinal products. Inhalation apparatus (1) comprises a housing (11) defining a socket (37) for receiving a pressurised dispensing container (30). The actuator means (61; 80) are provided for receiving a valve stem (63) of the pressurised dispensing container and a cylindrical chamber (11a) having an inlet (67) and an outlet (16). The actuator means defining duct means to direct product dispensed from the valve stem of the pressurised dispensing container through the inlet of the cylindrical chamber in a direction substantially tangential to the major axis of the cylindrical chamber. The outlet of the cylindrical chamber communicating with the mouthpiece (12), characterised in that the inlet is located at a periphery of the chamber and the outlet is located at or near a centre of the chamber such that inhalation by a user on the mouthpiece creates a cyclonic airflow in the cylindrical chamber between the inlet and outlet from which the dispensed product is entrained for inhalation.



EP 1 010 438 A1

Description

[0001] This invention relates to an inhalation apparatus for dispensing substances for inhalation and, in particular, but not exclusively, for dispensing medicinal products.

[0002] Known dispensing apparatus for use in inhalation apparatus include metered dose inhalers and dry powder inhalers. In known metered dose inhalers, the aerosol stream from a pressurised dispensing container is fired towards a patient or user of the inhaler into an airflow travelling in the same direction. A user inhales through a mouthpiece of the inhaler and creates an airflow through the container from air inlet holes which are generally at a part of the inhaler well spaced from the mouthpiece. Medicament is then released into this airflow at a point between the air inlet holes and the mouthpiece so that it is travelling in the same direction as the airflow. Typically, in such devices, there is no restriction in the airflow between the air inlet holes and the mouthpiece. Because of this, a substantial airflow can be created by the user of the device and, because the medicament is fired into the airflow in the same direction as the airflow, the effect is that particles of medicament can attain quite substantial velocities. As inhalers of this type are normally designed to be as small as practical for the convenience of the user, the distance between the point at which the medicament is fired and the patient's mouth is usually quite small so that there is little distance for the inertia of the particles of medicament to decrease with the result that the particles may impact in the oropharynx of a user with quite high velocity. This can be a problem with certain medicaments.

[0003] In known dry powder inhalers, powdered medicament, which is often combined with a powdered carrier, such as lactose, is stored within a delivery device until delivery of the medicament is required. It is known to store the medicament in a bulk holding reservoir in the delivery device. The drug is removed from the reservoir on an as required basis. It is also known to provide dry powder inhalers wherein the medicament is contained within discrete doses within a dosage unit such as a gelatine capsule. A problem with both types of known dry powder inhaler is that the medicament and carrier can form relatively large particles which when inhaled by the user do not reach deep into the lungs, which has been shown to be necessary for the most advantageous medical result to be obtained. It is known to provide baffle plates within an airflow passageway of a dry powder inhaler such that the medicament and carrier impact on the baffle plates and are, to a degree, separated and the particle size reduced. However, a problem with such baffle plates is that the medicament and carrier only pass through the baffle plates once and, as a result, a significant proportion of larger particles still exit the inhaler and are inhaled by the user.

[0004] According to the present invention there is provided inhalation apparatus comprising a housing defin-

ing a socket for receiving a pressurised dispensing container, actuator means for receiving a valve stem of the pressurised dispensing container and a cylindrical chamber having an inlet located at a periphery of the chamber and an outlet at or near a centre of the chamber, the actuator means defining duct means to direct product dispensed from the valve stem of the pressurised dispensing container through the inlet of the cylindrical chamber in a direction substantially tangential to the major axis of the cylindrical chamber, the outlet of the cylindrical chamber communicating with a mouthpiece, such that inhalation by a user on the mouthpiece creates a cyclonic airflow in the cylindrical chamber between the inlet and outlet in which the dispensed product is entrained for inhalation.

[0005] The present invention also provides a method of inhaling product dispensed from a pressurised dispensing container comprising the steps of inhaling on a mouthpiece of an inhalation apparatus comprising a cylindrical chamber having an inlet at a periphery thereof and an outlet at or near a centre thereof which communicates with the mouthpiece, to thereby create a cyclonic airflow from the inlet to the outlet, actuating the pressurised dispensing container to dispense a dose of product through the inlet of the cylindrical chamber in a direction substantially tangential to the major axis of the cylindrical chamber such that the product is entrained in the airflow and inhaled through the mouthpiece.

[0006] Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a side elevation of a first embodiment of dispensing apparatus according to the present invention;

Figure 2 is a front elevation of the apparatus of Figure 1;

Figure 3 is a cross-sectional elevation taken on line V-V of Figure 1;

Figure 4 is a schematic cross-section taken on line VI-VI of Figure 1;

Figure 5 shows the apparatus of Figure 4 immediately prior to dispensing of medicament;

Figure 6 shows the apparatus of Figure 4 during dispensation of medicament;

Figure 7 shows a side elevation of a second embodiment of dispensing apparatus according to the present invention;

Figure 8 shows a cross-sectional schematic elevation of a third embodiment of dispensing apparatus according to the present invention; and

Figure 9 shows an enlarged cross-sectional schematic elevation of part of the apparatus of Figure 8.

[0007] The dispensing apparatus 1 of the present invention as shown in Figures 1 to 9 comprises a spacer unit generally denoted by reference 10 which is either permanently or releasably connected in use to a dis-

dispensing unit generally designated by reference numeral 30.

[0008] The dispensing unit 30 comprises a pressurised dispensing container 30 of the type consisting of a pressurised container, metering valve attached thereto having a valve stem 63 extending axially to protrude from the metering valve. The pressurised dispensing container 30 typically contains medicament either in solution or suspension and a propellant system.

[0009] The spacer unit 10 of the first embodiment as shown in Figures 1 to 6 comprises a generally cylindrical housing 11 defining a spacer chamber 11a. The spacer chamber 11a has a major axis aligned with a centre of housing 11.

[0010] A hollow mouthpiece duct 13 extends radially outwardly from the centre of the housing 11 terminating in a substantially tubular mouthpiece 12 which extends beyond the periphery 17 of the housing 11. The mouthpiece 12 defines an outlet 19. The spacer chamber 11a communicates with the mouthpiece duct 13 through an aperture 16 in one side of the housing 11 positioned at or near the centre as best shown in Figure 3.

[0011] Preferably, the width of the chamber 11a, as measured in the direction of the major axis, decreases from the periphery of the chamber 11a to the centre.

[0012] The housing 11, inlet duct 15 and mouthpiece duct 13 may all be moulded from suitable plastics materials and are preferably moulded as a single unit.

[0013] A generally cylindrical housing 36 is integrally formed on one side of housing 11. As shown in Figure 4, the cylindrical housing 36 is divided into upper and lower sections 65 and 66 by an annular partition 38b. Airflow holes 60 are provided in the partition to allow air to pass from the upper to lower section. The upper section 65 of the cylindrical housing 36 defines a socket 37, in which in use the pressurised dispensing container 30 is inserted, and is separated from spacer chamber 11a by a partition 38a. The pressurised dispensing container 30 fits loosely in the upper section 65 of the cylindrical housing 36 such that air may readily pass between the pressurised dispensing container 30 and the walls of the cylindrical housing.

[0014] The lower section 66 of the cylindrical housing 36 communicates with the spacer chamber 11a through an aperture 67 which opens into the chamber 11a tangentially.

[0015] The lower section 66 of the cylindrical housing 36 contains an actuator 61. The actuator 61 has a cylindrical body, in an upper end of which is a bore for receiving a valve stem of the pressurised dispensing container 30 when the pressurised dispensing container 30 is inserted in socket 37 with the valve stem 63 lowermost. The valve stem receiving bore communicates via a duct with an opening 64 in the side wall of the actuator body which is arranged to direct an aerosol through 90° on discharge in a direction towards the aperture 67 connecting the lower section 66 with the spacer chamber 11a. The actuator 61 also comprises a radially extending

flange 68 of a large enough diameter to sealingly cover and close the airflow holes 60. A helical compression spring is provided between a lower end of the actuator 61 and a base of the cylindrical housing to bias the actuator 61 upwardly such that, in the rest position, the annular flange 68 contacts the partition 38b and seals the airflow holes 60.

[0016] In use, the user inserts the mouthpiece 12 of the spacer unit 10 into their mouth and inhales. Initially, as the airflow holes 60 are sealed by the flange 68, there is no airflow. Whilst continuing to inhale, the user manually depresses the dispensing container 30 causing the valve stem 63 to move downwardly. In turn, this causes the actuator 61 to slide axially downwards and compress the spring. The flange 68 of the actuator 61 is thus moved out of contact with the airflow holes 60 allowing the passage of air from an exterior of the device through the upper section 65 between the pressurised dispensing container 30 and walls, through the airflow holes 60, lower section 66 and aperture 67 into spacer chamber 11a.

[0017] The airflow entering the spacer chamber 11a enters in a direction having a substantial tangential component relative to the major axis such that the airflow is constrained to move in a rotational manner around the spacer chamber 11a due to the cylindrical shape of housing 11. As the user inhales air is drawn towards the centre of the spacer chamber 11a and out through aperture 16, along mouthpiece duct 13 and exits outlet 19 where it is inhaled by the user. Thus, inhalation by the user creates a cyclonic, rotating air flow within spacer chamber 11a. The product when entrained in the air flow passes with the air into spacer chamber 11a. Due to the cyclonic nature of the air flow within spacer chamber 11a, larger particles of product are held in the peripheral region 17 of the spacer chamber 11 whilst smaller particles are drawn towards the centre of the spacer chamber 11a where they exit the chamber 11a through aperture 16 into mouthpiece duct 13 and out mouthpiece 12 where they are inhaled. Thus, the cyclonic air flow in chamber 11a acts on the medicament as a classifier separating relatively small particles from relatively large particles and only passing relatively small particles through aperture 16 for inhalation.

[0018] Further depression of the dispensing container 30 causes the lower end of the actuator 61 to come into contact with the base of the cylindrical housing at which point further axial movement of the actuator 61 is prevented. Thus, the valve stem 63 is depressed inwardly relative to the metering valve of the pressurised dispensing container 30 and a dose of product is discharged as a fine aerosol mist which is then entrained in the airflow.

[0019] The cyclonic flow of the entrained aerosol acts to classify the aerosol as described above. Larger aerosol droplets are held in the periphery of the spacer chamber 11a and only the relatively smaller aerosol droplets are drawn to the centre and exit through aper-

ture 16 for inhalation. This has the beneficial effect that smaller aerosol droplets are able to be inhaled deeper into the lungs than larger droplets. This has been found to have beneficial medical results, especially for medicaments for treating respiratory disorders such as asthma. The cyclonic nature of the flow also results in the flow path length of the aerosol being greatly increased when compared to a linear spacer. The airflow and entrained aerosol pass round the spacer chamber 11a many times before exiting through aperture 16. This provides a greatly increased time for the speed and inertia of the aerosol droplets to decrease before they are delivered to the user. As a result there is a greatly reduced risk of the aerosol droplets forcibly impacting on the oropharynx region of the throat of the user with its associated discomfort and potential damage.

[0020] It should be noted that this embodiment is suitable for use with many types of dispensing unit in which actuation of the pressurised dispensing container is co-ordinated with the inhalation cycle of the user and is not restricted to the particular device herein described.

[0021] Figure 7 shows a second embodiment of dispensing apparatus according to the present invention. The dispensing unit 30 and spacer unit 10 are the same as those described in the first embodiment. However, in addition, the dispensing apparatus 1 is provided with a counter module 50 comprising a dose counting mechanism linked to the dispensing unit 30. A counter window 51 is provided viewable from an exterior of the housing 11 through which is displayed in use a counter indication 52 indicating either the number of doses dispensed or the number of doses remaining to be dispensed. The counter module is linked to the dispensing unit 30 such that each actuation of the dispensing unit actuates the counter module to either increment or decrement the counter indication as appropriate.

[0022] Figures 8 and 9 show a third embodiment of dispensing apparatus according to the present invention. The dispensing unit 30 is a pressurised dispensing container and is identical to that described in the first embodiment. The spacer unit 10 is also the same as that described in the first embodiment. The difference with the second embodiment lies in the means of actuating the pressurised dispensing container 30.

[0023] As in the second embodiment, the cylindrical housing 36 is divided into upper and lower sections 65 and 66 by a partition having airflow holes 60.

[0024] The valve stem 63 of the pressurised dispensing container 30 is received sealingly in a tubular actuator 80 which defines an annular shoulder which acts as stop limiting the extent to which the valve stem 63 extends within the actuator 80.

[0025] The actuator 80 is received as a snug fit within a downwardly extending tubular projection 81 formed integrally with the cylindrical housing 36. The tubular projection 81 has a lower end wall 94 defining an aperture 95 communicating with an annular space 96 formed between the lower end wall and the actuator 80. A nozzle

97 defined by the tubular projection 81 communicates with the annular space 96 and is orientated to release product from the annular space into the lower section 66 in the direction of the aperture 67 into the spacer chamber 11a.

[0026] A secondary valve means is formed in the tubular projection 81 by an annular valve seat 99 at the lower end of the actuator 80 and a resilient valve member 90 which extends from the lower section 66 into the annular space 96 and is normally urged into sealing contact with the valve seat 99 by a spigot 91. The valve member 90 has a cylindrical body which is recessed to accommodate the spigot 91 as an interference fit so that the spigot and valve member are sufficiently firmly connected to enable the valve member to be positively unseated from the valve seat when the spigot is retracted. The valve member is a sliding fit within the aperture 95 and is provided with a radially projecting flange 107 of greater diameter than the aperture 95 so that the flange acts as a stop limiting downward motion of the valve member 90 through the aperture.

[0027] The actuator 80 is provided with a radially extending flange 82 of external diameter slightly less than the internal diameter of the cylindrical housing 36 such that a restricted annular air passageway is defined between the flange 82 and the housing 36.

[0028] The actuator 80 and the hollow tubular valve stem together define a first chamber which is normally closed at its upper end by the internal valve means of the pressurised dispensing container and at its lower end by the secondary valve means.

[0029] In use, a user depresses the pressurised dispensing container 30 relative to the housing 36 so as to actuate the pressurised dispensing container 30 by relative movement between the container and the valve stem 63 which is prevented from downward movement by abutment with the annular shoulder in the actuator 80.

[0030] Actuation of the pressurised dispensing container 30 results in a pressurised metered dose of fluid entering the first chamber from which it is prevented from escaping by the secondary valve means. The user then inhales through the mouthpiece 12 thereby reducing air pressure within the spacer chamber 11a and the lower section 66 of the cylindrical housing 36. The annular flange 82 is subject to a downward force because of an imbalance of air pressure above and below the flange, since the air pressure above the flange is maintained at ambient air pressure by the airflow holes which are open to atmosphere. The flange 82 is thereby urged downwardly against the spring pressure provided by the spring. As the flange moves downwardly, the spigot 91 also moves downwardly thereby unseating the resilient valve member 90 from the valve seat 99 so that the pressurised fluid escapes from the first chamber into the annular space 96 which constitutes a second chamber. As fluid begins to escape, dissolved propellant in liquid form boils off from the dispensed dose causing the fluid to

rapidly expand. This expansion assists in further displacing the valve member 90 away from the seat 99. Displacement of the valve member 90 away from the seat 99 is limited by engagement between the flange 107 and the lower end wall 94 of the tubular projection 81. The pressurised fluid in the second chamber, i.e., annular space 96, then escapes via the nozzle, and is drawn into the spacer chamber 11a.

[0031] The spacer chamber 11a imparts a cyclonic action to the dispensed product as described in the previous embodiments with the same beneficial results of classification of the aerosol droplets and slowing of the droplets.

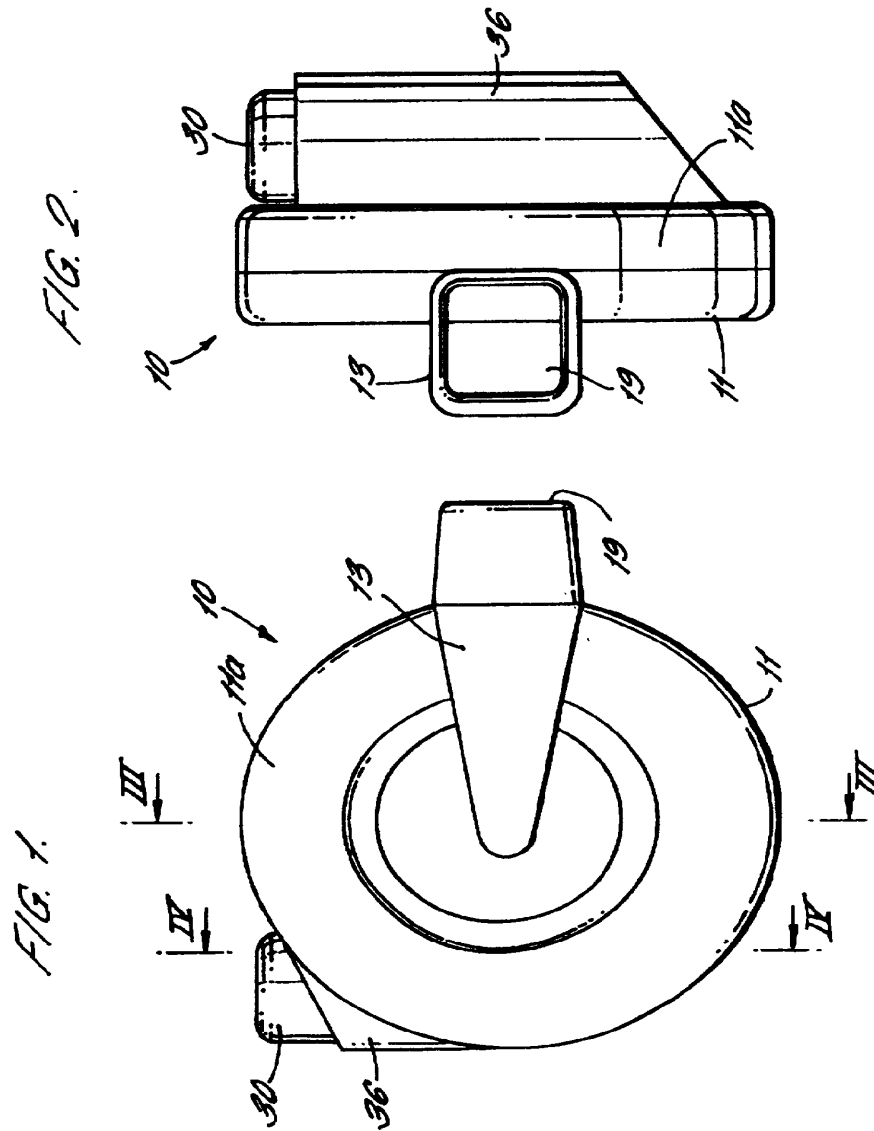
[0032] It should be noted that the dispensing apparatus 1 is suitable for use with other dispensing units which comprise means for actuating the pressurised dispensing container by the inhalation force produced by the user and is not restricted to the specific embodiment described herein.

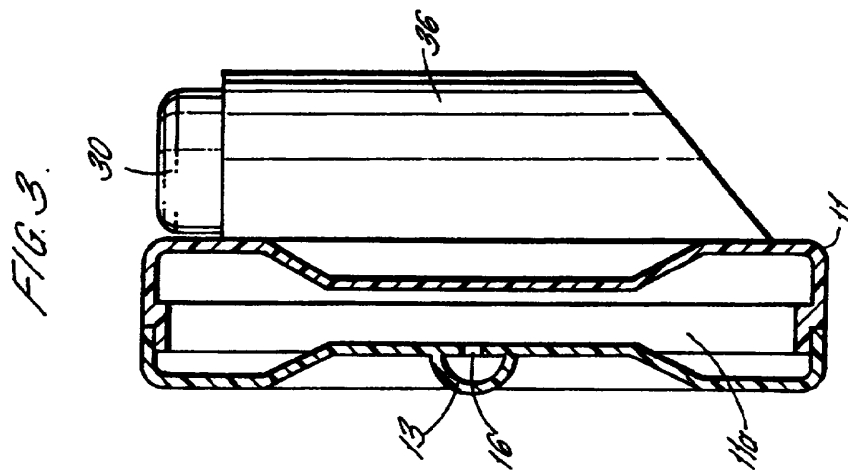
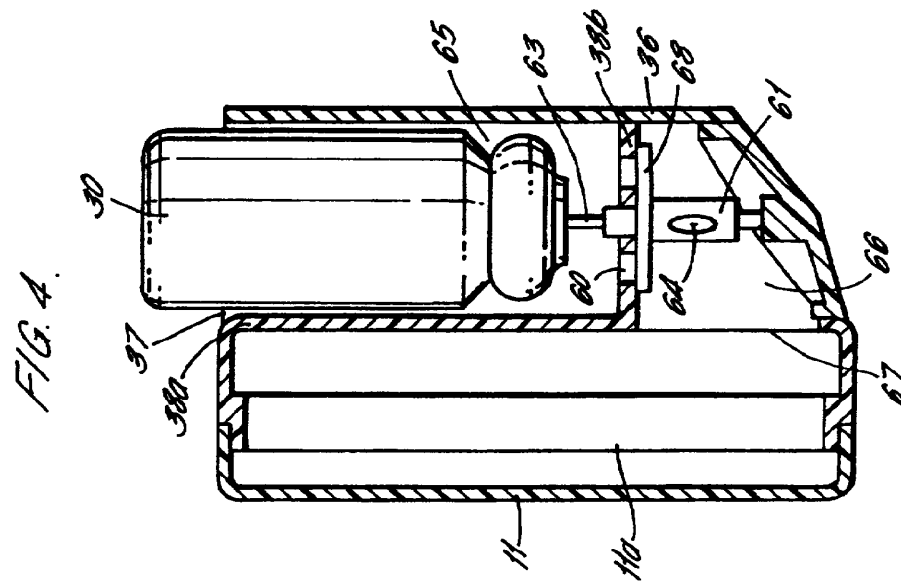
[0033] A fourth embodiment of dispensing apparatus according to the present invention comprises the dispensing unit 30 and spacer unit 10 of the third embodiment. However, in addition, the dispensing apparatus 1 is provided with a counter module 50 as described in the second embodiment.

Claims

1. Inhalation apparatus (1) comprising a housing (11) defining a socket (37) for receiving a pressurised dispensing container (30), actuator means (61; 80) for receiving a valve stem (63) of the pressurised dispensing container and a cylindrical chamber (11a) having an inlet (67) and an outlet (16), the actuator means defining duct means to direct product dispensed from the valve stem of the pressurised dispensing container through the inlet of the cylindrical chamber in a direction substantially tangential to the major axis of the cylindrical chamber, the outlet of the cylindrical chamber communicating with a mouthpiece (12), characterised in that the inlet is located at a periphery of the chamber and the outlet is located at or near a centre of the chamber, such that inhalation by a user on the mouthpiece creates a cyclonic airflow in the cylindrical chamber between the inlet and outlet in which the dispensed product is entrained for inhalation.
2. Inhalation apparatus as claimed in claim 1, wherein the width of the chamber, as measured in the direction of the cylindrical chamber's major axis, decreases from the periphery of the chamber to the centre.
3. Inhalation apparatus as claimed in claim 1 or claim 2, wherein the outlet (16) is formed at or near the centre on one side of the cylindrical chamber.

4. Inhalation apparatus as claimed in any preceding claim, wherein the socket (37) comprises an upper section (65) separated by a partition (38b) from a lower section (66) which communicates with the inlet to the cylindrical chamber, airflow holes (60) being provided in the partition.
5. Inhalation apparatus as claimed in any preceding claim, wherein the actuator means (61; 80) is actuated by inhalation of the user on the mouthpiece.
6. Inhalation apparatus as claimed in any of claims 1 to 4, wherein the actuation of the actuator means (61; 80) is co-ordinated with inhalation of the user on the mouthpiece.
7. Inhalation apparatus as claimed in any preceding claim further comprising means (50) for counting the number of actuations of the dispensing unit and displaying a visual indicator (52) correlated to the number of actuations.
8. Inhalation apparatus as claimed in claim 7, wherein the visual indicator (52) is a number indicating the number of actuations.
9. Inhalation apparatus as claimed in claim 7, wherein the visual indicator (52) is a number indicating the number of actuations remaining before the pressurised dispensing container is empty.
10. Inhalation apparatus as claimed in any preceding claim formed as a unitary moulding.
11. A method of inhaling product dispensed from a pressurised dispensing container (30) comprising the steps of inhaling on a mouthpiece (12) of an inhalation apparatus (1) comprising a cylindrical chamber (11a) having an inlet (67) at a periphery thereof and an outlet (16) at or near a centre thereof which communicates with the mouthpiece, to thereby create a cyclonic airflow from the inlet to the outlet, actuating the pressurised dispensing container to dispense a dose of product through the inlet of the cylindrical chamber in a direction substantially tangential to the major axis of the cylindrical chamber such that the product is entrained in the airflow and inhaled through the mouthpiece.
12. A method as claimed in claim 11, wherein inhalation on the mouthpiece (12) actuates the pressurised dispensing apparatus (30).





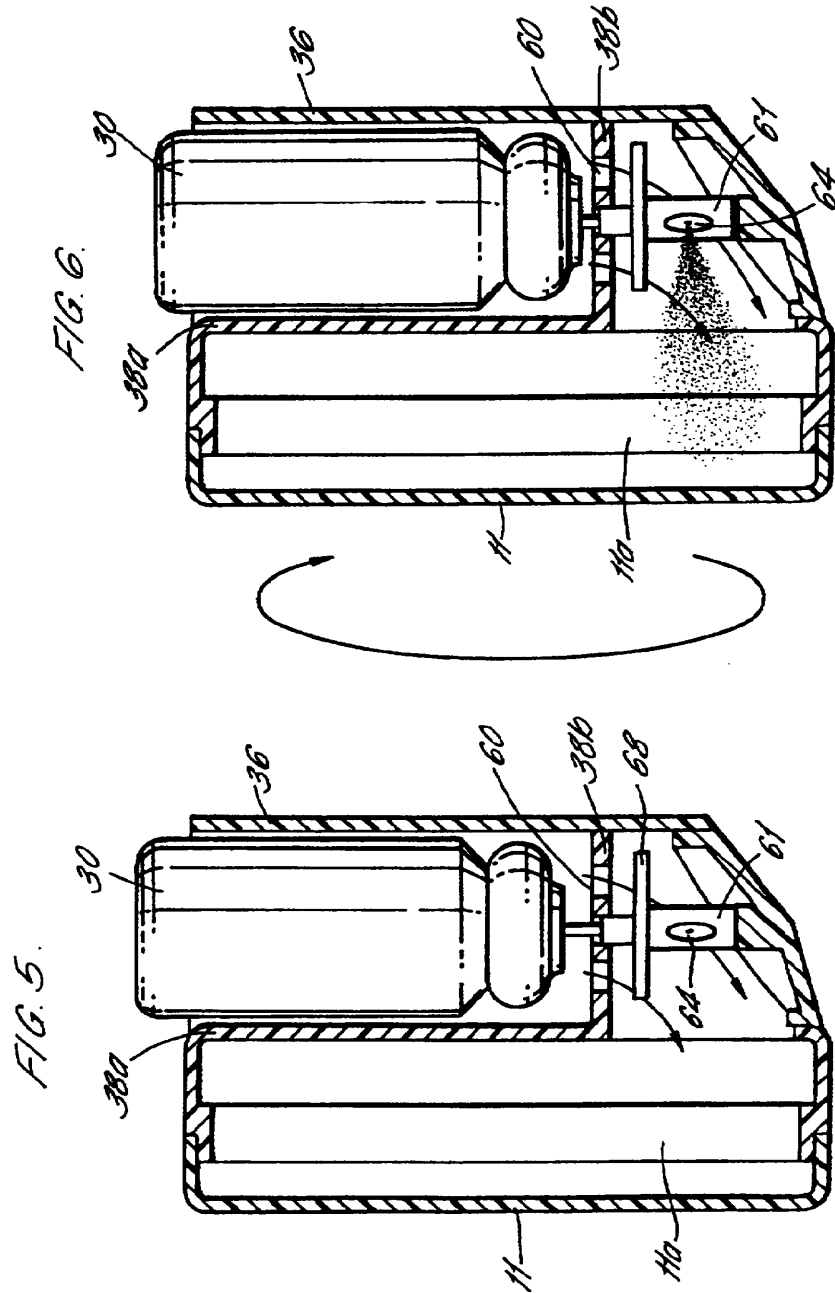


FIG. 7.

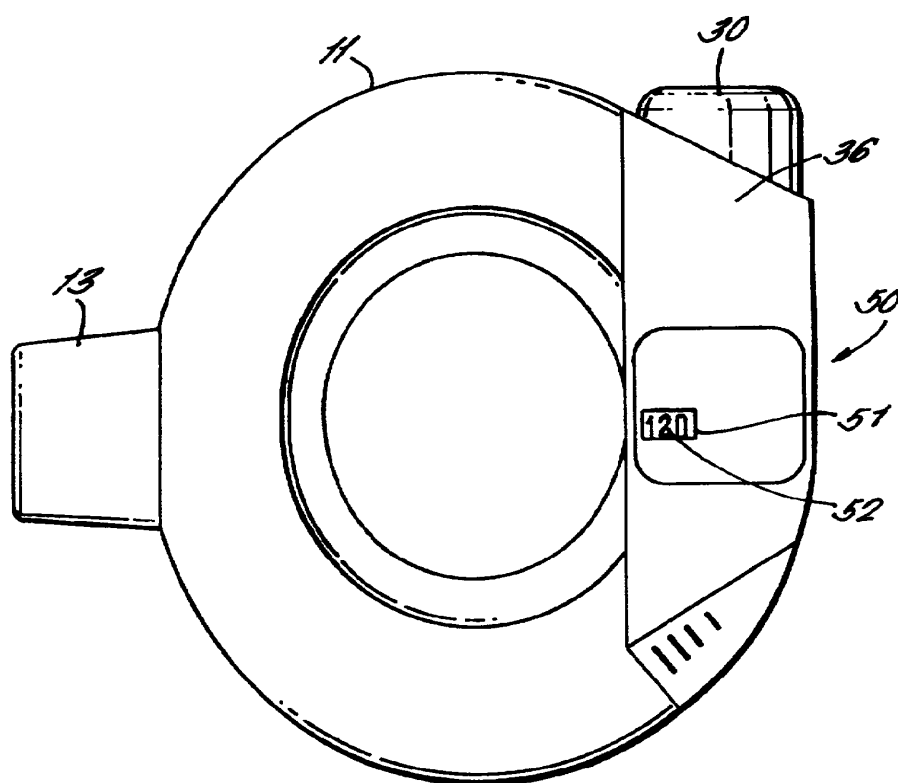


FIG. 8.

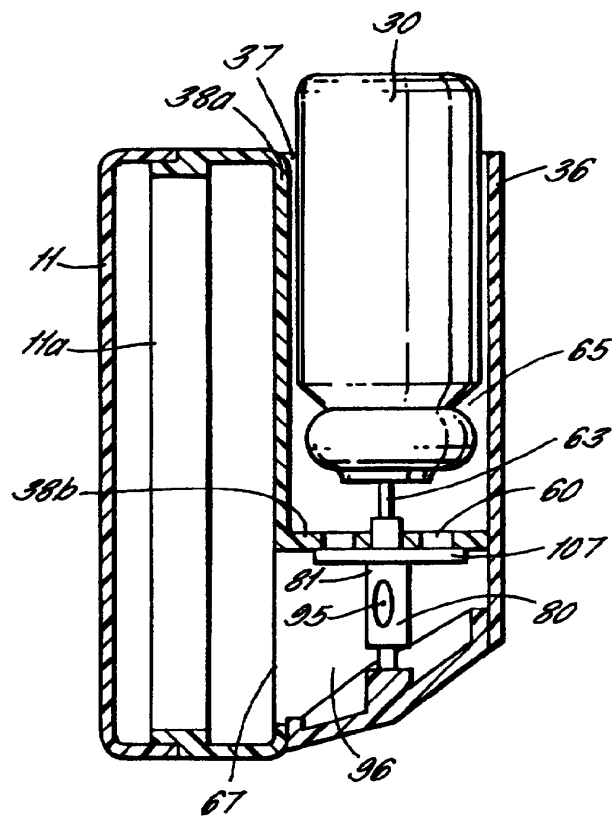
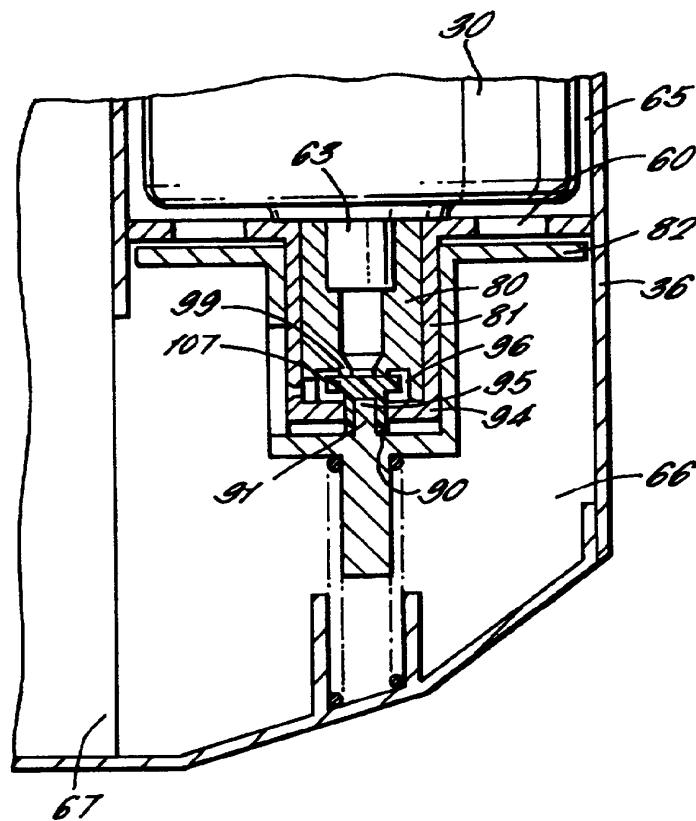


FIG. 9.





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PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 99 30 9783
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proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	FR 2 352 556 A (PASTEUR INSTITUT) 23 December 1977 (1977-12-23)	1-3, 10	A61M15/00 A61M11/00
Y	* page 1, line 38 - page 2, line 22 * * page 4, line 34 - page 5, line 8 * * page 5, line 18-20, 28-31 * * figures *	4-9	
Y	--- WO 88 03419 A (HUHTAMAEKI OY) 19 May 1988 (1988-05-19) * figures 5, 6 *	4	
Y	--- WO 93 24167 A (NORTON HEALTHCARE LTD ; HOLROYD MICHAEL JOHN (GB)) 9 December 1993 (1993-12-09)	5, 6	
A	* the whole document * ---	7-9	
		-/-	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61M
INCOMPLETE SEARCH			
The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims. Claims searched completely : 1-10 Claims searched incompletely : 11-12 Reason for the limitation of the search: Article 52 (4) EPC - Method for treatment of the human or animal body by therapy			
Place of search		Date of completion of the search	Examiner
MUNICH		9 March 2000	Lager, J
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

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European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

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EP 99 30 9783

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
Y	WO 93 00951 A (INHALE INC) 21 January 1993 (1993-01-21)	7-9	
A	* abstract * * figures * * page 4, line 37 - page 5, line 1 * * page 5, line 27-35 * * page 6, line 15-27 * * page 7, line 17-31 * * page 7, line 36 - page 8, line 4 * * page 9, line 10-19 * * page 11, line 37 - page 12, line 12 * * page 15, line 6-25 * ---	1-6,10	
A	EP 0 504 459 A (RITZAU PARI WERK GMBH PAUL) 23 September 1992 (1992-09-23) * abstract; figures * ---	1-10	TECHNICAL FIELDS SEARCHED (Int.Cl.7)
A	EP 0 682 955 A (RITZAU PARI WERK GMBH PAUL) 22 November 1995 (1995-11-22) * abstract; figures * ---	1-10	
A	WO 90 15635 A (HUHTAMAEKI OY) 27 December 1990 (1990-12-27) * abstract; figures * ---	1-10	
A	US 5 363 842 A (MISHELEVICH DAVID J ET AL) 15 November 1994 (1994-11-15) * abstract; figures * -----	4-9	

EPO FORM 1509 03.02 (p.04/05)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 99 30 9783

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

09-03-2000

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2352556 A	23-12-1977	NONE	
WO 8803419 A	19-05-1988	FI 864505 A	07-05-1988
		FI 870678 A,B,	07-05-1988
		AT 63828 T	15-06-1991
		AU 612333 B	11-07-1991
		AU 8236187 A	01-06-1988
		BG 60007 A	15-06-1993
		CA 1305001 A	14-07-1992
		DK 374888 A,C	06-07-1988
		EP 0289563 A	09-11-1988
		HU 48470 A	28-06-1989
		JP 1501290 T	11-05-1989
		KR 9605817 B	01-05-1996
		NO 882826 A,B,	27-06-1988
		NZ 222446 A	21-12-1990
		SU 1828403 A	15-07-1993
WO 9324167 A	09-12-1993	AU 4083993 A	30-12-1993
		CN 1079167 A	08-12-1993
		TR 26757 A	15-05-1995
		ZA 9303639 A	20-12-1993
WO 9300951 A	21-01-1993	AT 189124 T	15-02-2000
		AU 662919 B	21-09-1995
		AU 2309192 A	11-02-1993
		CA 2112674 A	21-01-1993
		DE 69230613 D	02-03-2000
		EP 0592540 A	20-04-1994
		EP 0940154 A	08-09-1999
		JP 7501231 T	09-02-1995
		US 5775320 A	07-07-1998
		US 5458135 A	17-10-1995
EP 0504459 A	23-09-1992	DE 59107894 D	11-07-1996
		JP 4325163 A	13-11-1992
		US 5309900 A	10-05-1994
EP 0682955 A	22-11-1995	CA 2149722 A	20-11-1995
		JP 8266626 A	15-10-1996
		US 5596982 A	28-01-1997
WO 9015635 A	27-12-1990	FI 892956 A	17-12-1990
		AU 641659 B	30-09-1993
		AU 5746990 A	08-01-1991
		CA 2058954 A	14-12-1991

EPO FORM P448

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 99 30 9783

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

09-03-2000

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9015635 A		EP 0477222 A	01-04-1992
		HU 213187 B	28-03-1997
		JP 4506018 T	22-10-1992
		KR 9411441 B	15-12-1994
		MX 173780 B	25-03-1994
		NO 303528 B	27-07-1998
		NZ 234031 A	26-10-1993
		RU 2089227 C	10-09-1997
US 5363842 A	15-11-1994	AT 166236 T	15-06-1998
		CA 2126331 A,C	08-07-1993
		DE 69225604 D	25-06-1998
		DE 69225604 T	25-02-1999
		EP 0617628 A	05-10-1994
		JP 7509378 T	19-10-1995
		WO 9312823 A	08-07-1993

EPO FORM PUSI

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

(19)



Europäisches Patentamt
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(11)

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(12)

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Remarks:

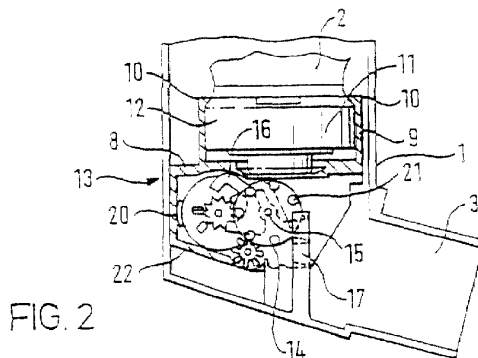
This application was filed on 06 - 08 - 2001 as a
divisional application to the application mentioned
under INID code 62.

(72) Inventors:
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(54) Dispenser with dose counter

(57) There is provided a dispenser suitable for dispensing medicament, particularly medicament for use in the treatment of respiratory disorders. The dispenser comprises a housing having a support; a container, locatable within said housing, having an outlet member, wherein said container is movable relative to the hous-

ing to enable dispensing therefrom and said outlet member is connectable with said support to prevent relative movement therebetween; and a dose indicator, locatable within said housing. The container and dose indicator are reversably removable from the housing as a single unit.



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Description

[0001] The present invention relates to a dispenser having an actuation indicator for indicating the number of actuations thereof. In particular, the invention relates to metered dose inhalers by means of which medicaments contained in an aerosol container may be administered to a patient.

[0002] It is well known to treat patients with medicaments contained in an aerosol, for example, in bronchodilator therapy. It is also known to use for such therapy, medicaments which are contained in an aerosol and are administered to a patient by means of an inhalation device comprising a tubular housing or sleeve in which the aerosol container is located and an outlet tube leading out of the tubular housing. The aerosol containers used in such inhalation devices are designed to deliver a predetermined dose of medicament upon each actuation by means of an outlet valve member at one end which can be opened either by depressing the valve member while the container is held stationary or by depressing the container while the valve member is held stationary. In the use of such devices, the aerosol container is placed in the tubular housing with the outlet valve member of the container communicating via a support with the outlet tube, for example a nozzle or mouthpiece. When used for dispensing medicaments, for example in bronchodilation therapy, the housing is then held by the patient in a more or less upright condition and the mouthpiece or nozzle of the inhalation device is placed in the mouth or nose of the patient. The aerosol container is pressed towards the support to dispense a dose of medicament from the container which is then inhaled by the patient.

[0003] A disadvantage arising from use of such known devices is that the patient cannot determine the amount of medicament in the container at any given time. In an extreme case this could mean that the patient, possibly suffering from severe bronchospasm and needing a dose of medicament, will find that the container will not dispense a dose because its contents have already been exhausted.

[0004] US Patent No. 4817822 describes an aerosol dispenser of the type described above having a dose indicating device which, in a first embodiment is removably attached to the end of the protruding portion of the aerosol container. The operating mechanism of the dose counter is located within a housing which extends from the end of the aerosol container along the external surface of the tubular housing. It is important with inhalation devices containing medicament that the contents of the aerosol container are clearly marked to ensure that the patient knows exactly what medication is contained. One disadvantage associated with this positioning of the dose indicating device is that the device obscures at least a part of the aerosol container and housing which creates labelling difficulties.

[0005] A further disadvantage of the device described

is that if the dose indicating device is removably attached to the aerosol container, it is possible that the dose indicating device may become separated from its aerosol container with the result that the aerosol dispenser could be used without the dose indicating device, or the actuating mechanism of the indicating device could be tampered with leading to a false reading when the indicating device is re-attached to the dispenser. With patients having several different inhalers, it could even result in the indicating device being re-attached to the wrong dispenser.

[0006] In a second embodiment described in US4817822 the operating mechanism of the dose indicating device is located within a compartment in the housing and is actuated by means of an actuator member attached to the aerosol container. In this embodiment, once the aerosol container is fitted into the housing it cannot be removed. This makes cleaning of the housing very difficult. Even if the container were removable, the operating mechanism of the dose indicating device would be vulnerable to damage when washing with water, soap, disinfectant or antiseptic solutions. This is important because sprays of many aerosol formulations leave residues which can entrap dust and dirt particles. Some provide a media for the growth of undesired micro-organisms. If the growth of these micro-organisms is unchecked, they can serve as a source of infection for the patient and will often introduce pathogens into the patient's respiratory tract.

[0007] US-A-5,622,163 describes an actuation indicator for a metered dose inhaler locatable on the upturned base of the dispensing canister thereof.

[0008] DE 86 02 238 U describes a metered dose inhaler with an actuation indicating device.

[0009] WO96/16686 describes an aerosol dispenser wherein the operating mechanism of the dose indicating device is electronic and wherein the actuating member comprises a microswitch set into the wall of the housing. The electronic counting mechanism and microswitch are contained within a hermetically sealed enclosure. However, electronic assemblies of this type are relatively expensive compared to equivalent mechanical mechanisms, typically costing five or six times as much to produce depending on quantities manufactured. Such expense must ultimately be borne by the customer and may be prohibitive.

[0010] US5482030 describes an aerosol dispenser having a mechanical dose indicator device located in and connected to the housing in the vicinity of the outlet tube of the aerosol container when fitted. Its mechanical construction makes it difficult to seal against moisture ingress and so this dispenser again is difficult to wash without damaging the operating mechanism of the dose indicating device.

[0011] Many different pharmaceutical products are sold in the form of aerosol containers as discussed above, requiring different sized container bodies and/or valves according to the required specifications. It is

therefore normal for there to be dimensional variations between different aerosol containers. Even between the same products there can be dimensional variations due to manufacturing tolerances. One problem which is common to all of the dose indicating devices discussed above is that the indicator mechanism, which is actuated by means of a switch which detects relative movement between the container body and housing, lacks any means of compensating for dimensional variations between different aerosol containers. Hence, the indicators described must be dimensioned according to the product with which they are to be used, and so will not be interchangeable with other products. Furthermore, in order for the dose indicators to work properly, the dimensions of the indicator, aerosol container and housing must be accurate.

[0012] It is an object to provide a dispenser having an actuation indicator which overcomes at least some of the above described disadvantages. It is a further object to provide such a dispenser which from the point of view of the patient closely resembles currently marketed dispensers in both external appearance and operation.

[0013] According to one aspect of the present invention there is provided a dispenser for dispensing medicament comprising a housing having a support; a container, locatable within said housing, having an outlet member, wherein said container is movable relative to the housing to enable dispensing therefrom and said outlet member is connectable with said support to prevent relative movement therebetween; and an actuation indicator, locatable within said housing, wherein the container and dose indicator are reversably removable from the housing as a single unit.

[0014] Suitably, the actuation indicator is engagable with the container in the vicinity of the outlet member. More preferably, the actuation indicator is engagable with the outlet member.

[0015] Suitably, the actuation indicator is provided with a grip member which is engagable with a neck portion of the container. Preferably, the neck portion is adjacent to or on the outlet member.

[0016] Suitably, the container is an aerosol container.

[0017] Suitably, the housing is provided with an outlet, more preferably in the form of a mouthpiece. Preferably, the dispenser comprises a passage through which dispensed doses may pass from the container to the outlet.

[0018] Suitably, the container provides measured doses.

[0019] Suitably, the actuation indicator indicates the number of doses dispensed from or remaining in the container.

[0020] Suitably, the actuation indicator comprises an indexing mechanism actuated by a predetermined movement of the aerosol container relative to the housing.

[0021] Preferably, the indexing mechanism comprises a lost motion coupling to allow and compensate for excess movement ('overtravel') of the aerosol container

relative to the housing.

[0022] By use of a lost motion coupling it is possible to create an actuation indicator of one size which can accommodate valves and actuators made within a wide range of manufacturing tolerances and can even fit a range of dispensers made to different dimensions.

[0023] Suitably, the indexing mechanism indexes the actuation indicator by means of a predetermined rotary movement of a first member driven by movement relative to a second member during actuation of the aerosol dispenser.

[0024] Suitably, the second member remains stationary relative to the housing during actuation of the aerosol dispenser.

[0025] Suitably, the first member comprises a pinion carried by a shaft through the lost motion coupling and the second member comprises a rack. Alternatively, the first member comprises a yoke and the second member comprises a post engaged by the yoke through the lost motion coupling.

[0026] Preferably, the lost motion coupling comprises a friction drive mechanism.

[0027] Suitably, the dispenser is a breath operated inhaler which is actuable in response to the inward breath of a user.

[0028] According to a particularly preferred aspect of the present invention there is provided an aerosol dispenser comprising a housing in which a container is removably located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the container and having a passage through which the contents of the container may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being movable relative to the outlet and housing to dispense its contents in measured doses, and a dose indicating device having a dose indicator for indicating the number of doses dispensed from or remaining in the container, characterised in that the dose indicating device is tightly connected to the container in the vicinity of the outlet member, such that the container and dose indicating device may be removed from the housing as a single unit.

[0029] According to a further aspect of the present invention there is provided an actuation indicating device for use with a dispenser comprising a housing and a container, locatable within said housing, having an outlet member, the actuation indicating device comprising attachment means to enable attachment to the container.

[0030] Suitably, the attachment means comprises a grip member which firmly engages a neck portion formed around the container. More preferably, the neck portion is located at the connection between the container and outlet member.

[0031] According to a particularly preferred aspect of the present invention the actuation indicating device has an actuation indicator for indicating the number of doses dispensed from or remaining in the container, wherein

the actuation indicating device comprises attachment means to enable tight connection to the container in the vicinity of the outlet member.

[0032] By fixing the actuation indicating device to the container in the vicinity of the outlet member may be possible to make use of the physical dimensions of the crimped ferrule of standard containers to provide a tight snap fit between the dose indicating device and aerosol container for easy assembly yet which once assembled cannot be easily separated. This ensures that the actuation indicator presents accurate information concerning the container with which it is assembled.

[0033] In a preferred aspect, the dispenser is a metered dose inhaler comprising a housing in which the container is removably located, an outlet leading from the housing, a support in the housing arranged to receive the outlet member of the container and having a passage through which the contents of the container may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being moveable relative to the outlet and housing to dispense its contents in measured doses, and a window through which the dose indicator may be viewed.

[0034] The location of the dose indicator in the vicinity of the outlet member of the container in a metered dose inhaler provides the advantage that visually and operationally the device may appear very similar to current marketed metered dose inhalers without dose indicating devices such that when switched to the metered dose inhaler according to the invention, patients perceive little change over their conventional dispensers, so creating minimal impact upon patients and their use of the device.

[0035] A dispenser according to the invention will now be described with reference to the accompanying drawings in which:

Fig. 1 is a section through a standard inhalation device comprising an aerosol dispenser;

Fig. 2 is a section through the dose indicating device as fitted to an aerosol dispenser in an inhalation device;

Fig 2a is a sectional view of an aspect of a dose indicating device herein;

Fig. 3 is a perspective view of a counting mechanism used in the dose indicating device of Fig. 2;

Fig. 4 shows the sequence of operation of the counting mechanism of Fig. 3;

Fig. 5 shows a lateral and a longitudinal section through a second embodiment of the dose indicating device as fitted into the housing of an inhalation device;

Fig. 6 shows an exploded view of a dose indicating device according to a third embodiment of the invention;

Fig. 7 shows another exploded view of the dose indicating device of figure 6 together with an aerosol container and housing;

Fig. 8 shows a schematic section through an inhalation device comprising the dose indicating device of figure 6 in a rest position; and

Fig. 9 shows a schematic section through the inhalation device of figure 8 in an actuated position.

[0036] The standard metered dose inhaler shown in Fig 1 comprises a tubular housing 1 in which an aerosol container 2 can be located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. An outlet 3 leads laterally from the closed end of the housing 1. In the embodiment illustrated, the outlet 3 is in the form of a mouthpiece intended for insertion into the mouth of the patient but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

[0037] The aerosol container 2 has an outlet valve stem 4 at one end. This valve member can be depressed to release a measured dose from the aerosol container or, alternatively, the valve stem 4 can be fixed and the main body of the container can be moved relative to the valve member to release the dose.

[0038] As shown clearly in Fig 1, the aerosol container 2 is located in the housing 1 so that one end protrudes from its open top. Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1. A support 5 is provided at the lower end of the housing 1 and has a passage 6 in which the valve stem 4 of the aerosol container 2 can be located and supported. A second passage 7 is provided in the support 5 and is directed towards the interior of the outlet 3. Thus, when the parts are in the positions shown in Fig 1, the protruding portion of the aerosol container 2 can be depressed to move the container relative to the valve stem 4 to open the valve and a dose of medication contained in the aerosol will be discharged through the passage 7 and into the outlet 3 from which it can be inhaled by a patient. One dose will be released from the aerosol container each time it is fully depressed.

[0039] Fig 2 shows the lower part of a device similar to that of Fig 1 but incorporating a dose indicating device according to the invention. The dose indicating device comprises a body 8 firmly attached to the aerosol container by means of tubular portion 9 formed with grips 10. Tubular portion 9 tightly engages the periphery of valve ferrule 11 while a grip in the form of lip 10 engages around neck 12 of valve ferrule 11 which is formed dur-

ing assembly when valve ferrule 11 is crimped onto aerosol container 2. Thus the tubular portion 9 and lip 10 form a tight connection to the aerosol container which once assembled by pushing the tubular portion 9 over the valve ferrule 11 cannot easily be disassembled.

[0040] Below tubular portion 9, body 8 forms a cradle 22 for mounting counter mechanism 13 and drive pinion 14. Drive pinion 14 is friction mounted on counter mechanism drive shaft 15. Drive pinion 14 is formed with a number of teeth or pegs 21 which can engage with a number of recesses or grooves formed on post 17 in the form of a rack moulded inside housing 1 and extending from the base of the housing 1 parallel to valve stem 4.

[0041] Whilst in the embodiment shown in Fig 2 the post 17 forms a moulded part of the housing other variations can be envisaged in which the post 17 forms a part of the dose indicating device itself. For example, Fig 2a shows a simplified representation of a dose indicating device in which the head of post 17 is receivable within a recess provided in the body 8 of the device. Teeth formed on the post 17 engage corresponding teeth on drive pinion 14. Spring 28 acts such as to urge the post from the recess. The protruding lip 24 of the post 17, however, abuts stop 26, thereby retaining at least a portion of the post 17 within the recess.

[0042] As shown in Figs 3 and 4, drive shaft 15 is connected to driver yoke 16 of counter mechanism 13. Driver yoke 16 has two switching latches 18a and 18b spaced either side of star wheel 19 such that driver yoke 16 may tilt about the axis of drive shaft 15 between a first position shown in Fig 4b in which switching latch 18a engages one side of star wheel 19, and a second position shown in Fig 4d in which switching latch 18b engages the other side of star wheel 19. Star wheel 19 is connected through a mechanism, similar to that described with reference to reference numerals 2 to 8 in Figs 1 to 3 of European Patent No. 0280104, to three digit wheels 33, which have numbers printed on their circumferential faces as described below. When located in the housing 1, counter mechanism 13 is small enough to be located to the sides of and behind support 5 so as not to interfere with the aerosol flume as it emerges from passage 7.

[0043] The aerosol container 2 may be supplied to the patient with the dose indicating device ready assembled thereto. Alternatively, the housing 1 may be supplied to the patient with the dose indicating device located in the position shown in Fig 2 and the aerosol container 2 supplied separately. In this case, the patient is instructed to insert the aerosol container 2 into the housing 1 with the valve stem first. Upon first insertion of the container into the housing, the tubular portion 9 and lip 10 of the dose indicating device ride over the periphery of valve ferrule 11 of the aerosol container 2 until lip 10 snaps around neck 12. Thereafter, the dose indicating device is attached to the aerosol container 2.

[0044] Other means of attachment of the dose indicator to the container are envisaged including adhesive

attachment; use of welded shrink sleeves; heat forming; crimping; ultra-sonic welding; and by the presence of an o-ring elastomer on the container which is fixedly pierceable by barbs on the attachment member of the dose indicator. In one aspect, permanent means of attachment are preferred.

[0045] To actuate the device, the protruding portion of the aerosol container is depressed as described above with reference to Fig. 1. As the aerosol container carrying the dose indicating mechanism moves within housing 1, drive pinion 14 starts to turn, through its engagement with post 17, causing rotation of drive shaft 15 and driver yoke 16. As driver yoke 16 tilts with rotation of drive shaft 15 switching latch 18a moves into engagement with star wheel 19 (Fig 4a) causing an incremental anti-clockwise rotation of a half tooth pitch of the star wheel until the switching latch 18a can move no further in this direction, the switching latch being positioned between two adjacent teeth of the star wheel (Fig 4b). At this point, drive shaft 15 cannot rotate any further and any further movement of the aerosol container into housing 1 results in drive pinion 14 continuing to rotate through its engagement with post 17 by virtue of the friction coupling between pinion 14 and drive shaft 15.

[0046] When the valve stem 4 has reached its fully depressed position and a metered dose of medicament has been discharged from the aerosol container, the aerosol container is allowed to return to its original position. As the aerosol container and dose indicating mechanism return to their original position, drive pinion 14 starts to rotate in the opposite direction together with drive shaft 15 and driver yoke 16. Thus, driver yoke 16 tilts such that switching latch 18a moves out of engagement with star wheel 19 while switching latch 18b moves into engagement therewith (Fig 4c), causing further incremental anti-clockwise rotation of a half tooth pitch of the star wheel until switching latch 18b can move no further in this direction (Fig 4d). Again, drive shaft 15 cannot rotate any further at this point and any further movement of the aerosol container out of housing 1 results in drive pinion 14 continuing to rotate through its engagement with post 17 by virtue of the friction coupling between pinion 14 and drive shaft 15. In this way it can be seen that the friction coupling acts as a lost motion coupling which allows the dose indicating device to be used with aerosol containers having valves with different lengths of travel of valve stem during actuation.

[0047] Each time the aerosol dispenser is actuated the star wheel is made to rotate through two incremental anti-clockwise movements as described above. These movements are translated through the counter mechanism into appropriate movements of the digit wheels 33, one number on each of the printed circumferential faces of the digit wheels being clearly visible through the window 20 at the back of the housing 1 (as shown in Fig 2), to indicate that a further dose of medicament has been dispensed. By having three digit wheels 33 it is possible for the dose counter to be used to count hundreds of

doses. Clearly if fewer than one hundred doses are to be contained within the dispenser, the dose counter could comprise fewer digit wheels. Alternatively, if a thousand or more doses are to be contained, then one or more additional digit wheels could be added as appropriate.

[0048] To remove the aerosol container 2 from the housing for cleaning, the aerosol container 2 may be withdrawn from the housing 1 in the usual manner. As the container is withdrawn, the friction coupling between drive pinion 14 and drive shaft 15 allows such further movement as is required for the drive pinion to come out of engagement with the post 17 without causing any further indexing of the counter mechanism. Once removed, the housing 1 may be cleaned as described without fear of interfering with or damaging the dose indicating device, which remains firmly connected to the aerosol container 2.

[0049] When the housing 1 is clean, the aerosol container 2 with dose indicating device may be re-inserted into the housing 1. During insertion, drive pinion 14 will engage post 17 and start to rotate until the aerosol container reaches its normal rest position with the valve stem 4 located in support 5. As the drive pinion 14 rotates, the friction coupling will act as a lost motion mechanism as described above, allowing for any travel of the aerosol container as between first engagement of drive pinion 14 and post 17, and location of valve stem 14 in support 5. In this way, the friction coupling automatically accommodates and compensates for different lengths of valve stems protruding from the ferrule.

[0050] Fig 5 shows an alternative lost motion coupling mechanism which may be used in an aerosol dispenser according to the invention. In this embodiment, instead of a pinion, driver yoke 16 is formed with two resilient arms 30 between which post 17 is grippingly engaged (Fig 5a). Post 17 is formed with ribs on its surface (not shown) which provide a rough surface finish to create the level of friction required between arms 30 and post 17 such that arms 30 will grip post 17 until the load applied overcomes the friction.

[0051] Upon actuation of the device, as the aerosol container and dose indicating mechanism move, the friction engagement between arms 30 and post 17 cause driver yoke 16 to tilt about the axis of shaft 15 (not shown in Fig 5), so moving switching latch 18a into engagement with star wheel 19 as discussed in relation to the first embodiment. As switching latch 18a reaches its limit of travel, driver yoke 16 can move no further, and any further movement of the aerosol container into housing 1 results in arms 30 slipping down post 17 by virtue of the friction coupling. Upon return to its original position, driver yoke 16 tilts in the other direction until switching latch 18b moves into engagement with star wheel 19 and can move no further. Any further movement of the aerosol container out of housing 1 results in arms 30 slipping up post 17.

[0052] Figures 6 to 9 show an inhalation device fitted

with an electro-mechanical dose indicating device according to the invention. As with the mechanical embodiments discussed above, the dose indicating device comprises a body 40 firmly attached to the aerosol container by means of tubular portion 41 formed with grips (not shown). Tubular portion 41 tightly engages the periphery of valve ferrule 11 while a grip in the form of a lip engages around neck 12 of valve ferrule 11. Thus the tubular portion 41 and lip form a tight connection to the aerosol container which once assembled by pushing the tubular portion 41 over the valve ferrule 11 cannot easily be disassembled.

[0053] Below tubular portion 41, body 40 forms a cradle for mounting counter mechanism 43, and defines a chamber for accommodating switch slide 44. Switch slide 44 is a cylindrical washer made of silicone rubber and having a bore of such a diameter that, with the can and dose indicating device mounted within the actuator housing, it provides a friction fit on pin 45, which is moulded in the housing and protrudes through a hole in body 40. The friction fit of switch slide 44 on pin 45 ensures the switch slide will not move along the pin unless pushed. Two contact members 46, 47, both of which comprise a switch contact and a circuit board contact, and one of which further comprises a battery contact, are mounted such that the battery and circuit board contacts are in constant contact with a first terminal of the battery 48 and printed circuit board (PCB) 49 respectively. The switch contacts do not contact each other but are positioned either side of pin 45, and define the upper limit of movement of the switch slide 44 within its chamber. Thus, when switch slide 44 is in its upper position as shown in figure 9, it makes contact with both switch contacts, so closing the circuit between them due to the electrical conductivity of the silicone rubber of the switch slide. Although in the embodiment described the switch slide is made of silicone rubber, it will be appreciated that it could alternatively be made of a non-conductive rubber having an insert at its upper face made of metal or some other conductive material.

[0054] In addition to its connections with contact members 46, 47, PCB 49 also has connections to the other terminal of the battery and to a three digit liquid crystal display (LCD) 50 in a conventional manner. The PCB comprises an application specific integrated circuit (ASIC), which provides the logic by which the dose indicator can be checked, programmed and made operational, as discussed in more detail below, to keep a record of how many times the switch contact circuit is closed and drives the LCD to display the number of doses remaining in the aerosol container. The ASIC is thus designed and programmed accordingly in a known manner.

[0055] Instead of a digital display, the LCD could alternatively be formatted to display an analogue indication. When the aerosol container is mounted in the actuator housing, LCD 50 is visible through window 20. In the embodiment depicted in figure 7, the LCD and win-

dow are located at the back of the housing, but they could equally be located at the front or some other part of the housing.

[0056] The Counter mechanism 43 is small enough to be located to the sides of and behind the stem block (support 5) moulded in housing so as not to interfere with the aerosol flume as it emerges.

[0057] To actuate the device, the protruding portion of the aerosol container when fitted into the actuator housing is depressed as described above. As the aerosol container carrying the dose indicating mechanism moves within the housing from its rest position (shown in figure 8), the chamber accommodating switch slide 44 moves down until the upper face of switch slide 44, which is mounted on pin 45, meets switch contacts 46, 47 and the switch circuit is closed. This causes the ASIC to decrement the number displayed by the LCD 50. As the aerosol container continues to move, a metered dose of medicament is discharged from the valve, while switch slide 44 is pushed down along pin 45 by virtue of the friction fit of the switch slide on the pin until the valve stem reaches its limit of travel and the aerosol container moves no further (figure 9). In this way, it can be seen that the friction fit of the switch slide 44 on pin 45 allows for over-travel of the valve stem after the switch circuit has been closed, so acting as a lost motion coupling. The aerosol container is then allowed to return to its original position within the housing, and as it returns, the chamber accommodating switch slide 44 moves up breaking the switch circuit as switch contacts 46, 47 move away from switch slide 44. Body 40 then meets the lower face of switch slide 44 and draws the switch slide up along pin 45 until the valve stem returns to its rest position (figure 8).

[0058] Because the dose indicating device is designed to be suitable for use in connection with different sized aerosol containers containing different numbers of doses to be delivered, the ASIC is designed to be factory set in accordance with the size of aerosol container with which the dose indicating device is assembled. After assembly of the dose indicating device and first connection of the battery, the ASIC enters a self-test mode. After this, the programming mode may be entered by activating the switch, allowing it to be programmed to count down from the appropriate number of doses (e.g. 200, 120, 80 or 60). This may be done automatically on a packing line. After programming has taken place, the ASIC enters the counting mode, where the LCD decrements upon closing of the switch contact circuit. When the count of zero is reached, the ASIC is designed to prevent the count from decrementing any further in a known manner. In order to prevent spurious readings due to the effects of switch 'bounce', the ASIC may be designed to decrement only after the switch circuit has been closed for a predetermined length of time in a known manner. In the event of the aerosol container getting jammed in the actuated position after operation, or the switch circuit jamming closed due to mechanical

damage or contamination, the ASIC may be designed to blank the LCD to alert the user that there is a problem.

[0059] As with the other embodiments of the invention described above, the aerosol container may be withdrawn from the actuator housing in the usual manner. As the container is withdrawn, body 40 draws the switch slide up along pin 45 until it clears the pin altogether. Once removed, the housing may be cleaned without interfering with or damaging the dose indicating device, which remains firmly connected to the aerosol container.

[0060] During re-insertion of the aerosol container, which can only occur when the body of the dose indicating device is correctly orientated with respect to the housing by virtue of their respective shapes, switch slide 44 engages and is pushed up by pin 45 until the upper face meets the switch contacts. Further insertion of the aerosol container results in switch slide 44 being pushed down along pin 45 until the valve stem is seated back within support 5.

[0061] It will be appreciated that by programming of the ASIC, one design of dose indicating device could be used in conjunction with a range of aerosol containers of various capacities. By virtue of the switch mechanism, the same design of dose indicating device can also be used in conjunction with a range of different valves having different lengths of valve stem and different stem travel specifications.

[0062] Whilst the present invention has been described in detail in respect of a metered dose inhaler actuatable manually by the patient it will be appreciated that other actuation mechanisms can be substituted. In particular, the use of a breath operated inhaler in which the actuation is assisted, and is responsive to, preferably triggered by, the inward breath of the patient, is also envisaged.

[0063] The dispenser of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders. Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or nedocromil; anti-infectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti-inflammatory, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetanide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimeterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro- α -[[6-[2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate,

lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

[0064] Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

[0065] Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

[0066] It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

[0067] The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

Claims

1. An aerosol dispenser comprising a housing (1) in which a container (2) is removably located, an outlet (3) leading from the housing (1) and a support (5) in the housing (1) arranged to receive an outlet member (4) of the container (2) and having a passage (7) through which the contents of the container (2) may pass to the outlet (3), the outlet member (4) being held stationary in the housing support (5) and the body of the container (2) being moveable relative to the outlet member (4) and housing (1) to dispense its contents in measured doses, and a dose indicating device having a dose indicator for indicating the number of doses dispensed from or remaining in the container (2), **characterised in that** the dose indicating device (13) tightly connects to the container (2) in the vicinity of the outlet member (4), such that the container (2) and dose indicating device (13) may be reversibly removed from the housing (1) as a single unit.

2. A dispenser according to claim 1 wherein the dose

indicating device (13) tightly connects with the outlet member (4).

3. A dispenser according to claim 1, wherein the dose indicating device (13) is provided with a grip member (10) which tightly connects with a neck portion of the container (2).

4. A dispenser according to claim 3, wherein the neck portion is adjacent to or on the outlet member (4).

5. A dispenser according to any of claims 1 to 4, wherein the outlet (3) is in the form of a mouthpiece.

6. A dispenser according to any of claims 1 to 5, wherein the dose indicating device (13) comprises an indexing mechanism actuated by a predetermined movement of the container (2) relative to the housing (1).

7. A dispenser according to claim 6, wherein the indexing mechanism comprises a lost motion coupling to allow and compensate for excess movement of the container (2) relative to the housing (1).

8. A dispenser according to either of claims 6 or 7, wherein the indexing mechanism indexes the actuation indicator (13) by means of a predetermined rotary movement of a first member (14;16) driven by movement relative to a second member (17) during actuation of the dispenser.

9. A dispenser according to claim 8, wherein the second member remains stationary relative to the housing during actuation of the dispenser.

10. A dispenser according to either of claims 8 or 9, wherein the first member comprises a pinion (14) carried by a shaft through the lost motion coupling and the second member comprises a rack (17).

11. A dispenser according to either of claims 8 or 9, wherein the first member comprises a yoke (16) for engagement with the second member (17) through the lost motion coupling.

12. A dispenser according to any of claims 7 to 11, wherein the lost motion coupling comprises a friction drive mechanism.

13. A dispenser according to any of claims 1 to 12, actuable in response to the inward breath of a user.

14. A dispenser according to any of claims 1 to 13, wherein the actuation indicator comprises a mechanical actuation indicating mechanism.

15. A dispenser according to any of claims 1 to 13,

wherein the actuation indicator comprises an electromechanical actuation indicating mechanism.

16. A dispenser according to any of claims 1 to 15, wherein the container (2) comprises medicament selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate and any salts or solvates thereof, and any mixtures thereof.

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17. A dispenser according to claim 16, wherein the medicament comprises salmeterol xinafoate.

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18. A dispenser according to claim 16, wherein the medicament comprises fluticasone propionate.

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19. A dispenser according to claim 16, wherein the medicament comprises a combination of salmeterol xinafoate and fluticasone propionate.

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20. An aerosol container assembly comprising

an aerosol container (2) having an outlet member (4) for dispensing measured doses of medicament; and

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a dose indicating device (13) having a dose indicator for indicating the number of doses of medicament dispensed from or remaining in the container (2),

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characterised in that the dose indicating device (13) tightly connects to the container (2) in the vicinity of the outlet member (4).

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21. An assembly according to claim 20, wherein the container (2) comprises medicament selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate and any salts or solvates thereof, and any mixtures thereof.

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22. A dispenser according to claim 21, wherein the medicament comprises salmeterol xinafoate.

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23. A dispenser according to claim 21, wherein the medicament comprises fluticasone propionate.

24. A dispenser according to claim 21, wherein the medicament comprises a combination of salmeterol xinafoate and fluticasone propionate.

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25. An aerosol container assembly in kit of parts form comprising

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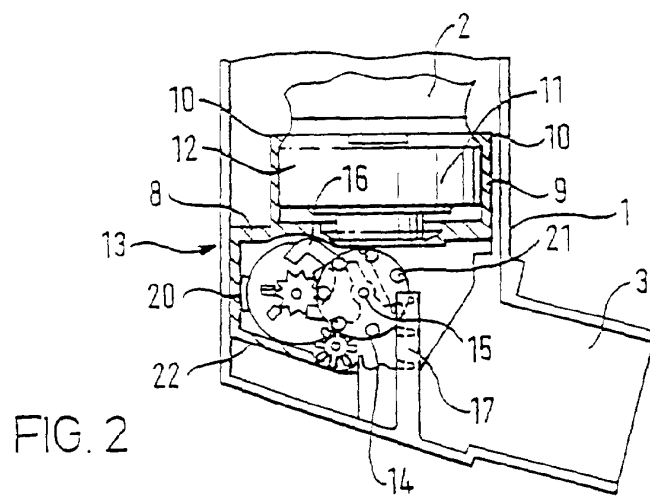
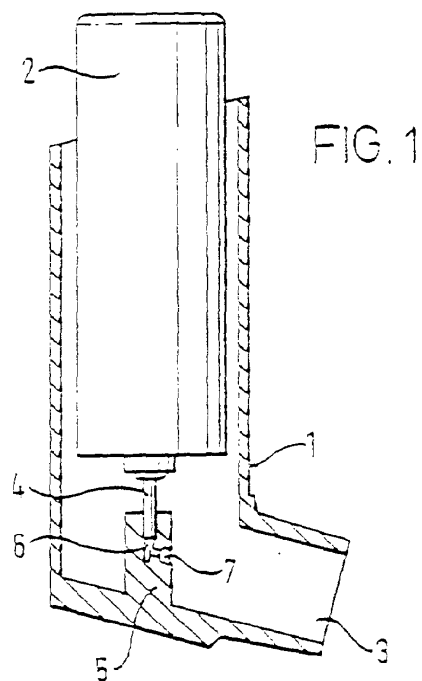
(a) an aerosol container (2) having an outlet member (4) for dispensing measured doses of medicament; and

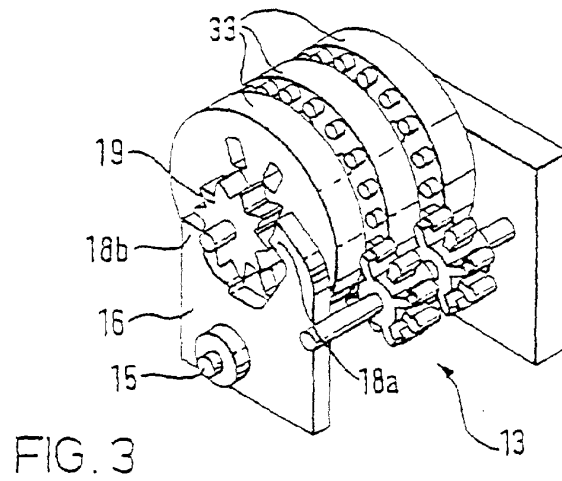
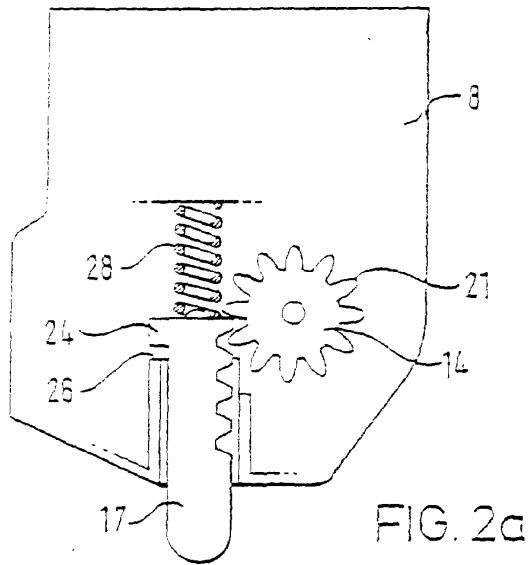
(b) a dose indicating device (13) having a dose indicator for indicating the number of doses of medicament dispensed from or remaining in the container (2),

characterised in that the dose indicating device (13) comprises attachment means (10) to enable its tight connection to the container (2) in the vicinity of the outlet member (4).

26. A kit of parts according to claim 25, wherein the attachment means comprises a grip member (10) for firmly engaging a neck portion formed around the container (2).

27. A kit of parts according to claim 26, wherein the neck portion is located at the connection between the container (2) and outlet member (4).





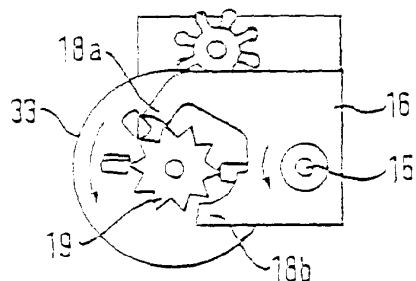


FIG. 4a

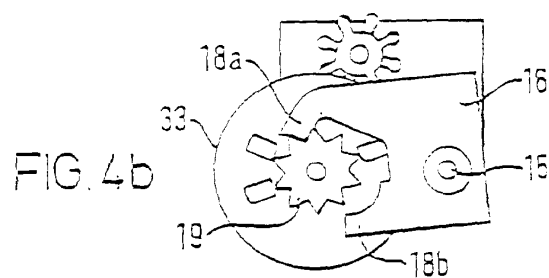


FIG. 4b

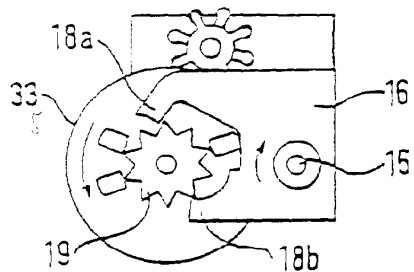


FIG. 4c

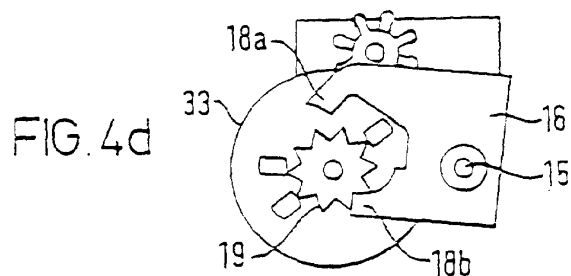


FIG. 4d

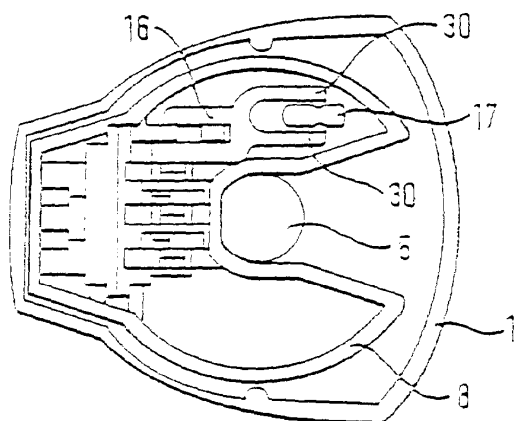


FIG. 5a

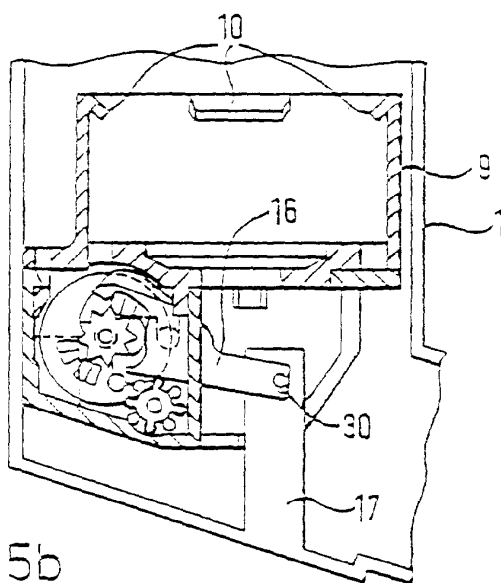
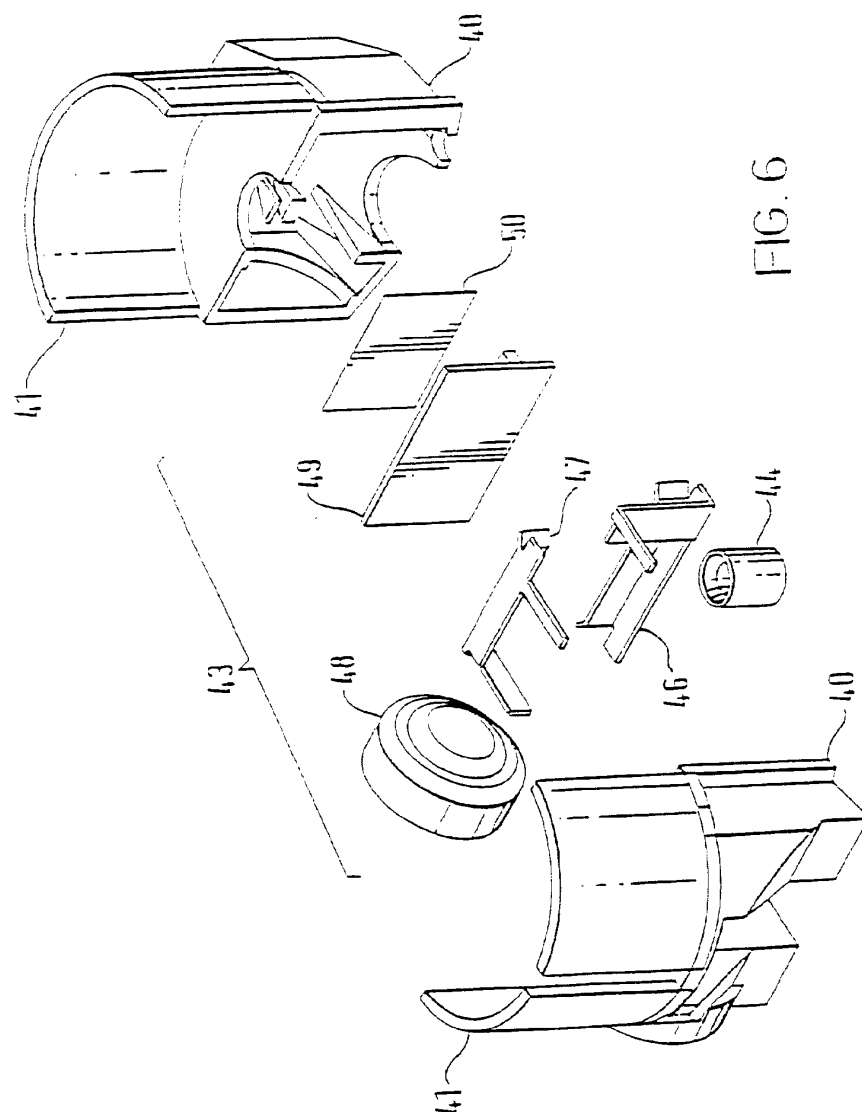


FIG. 5b



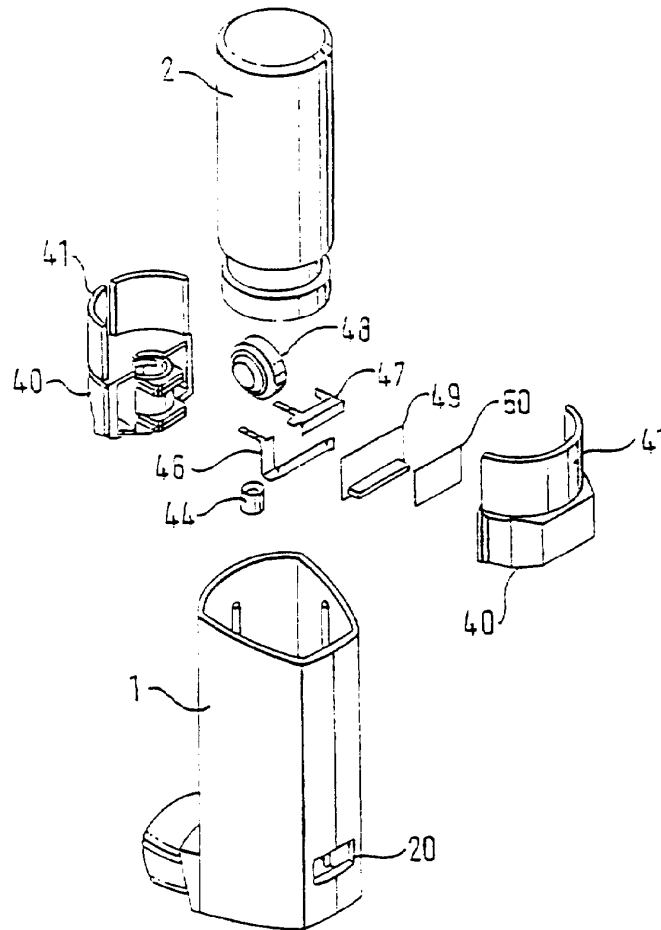


FIG. 7

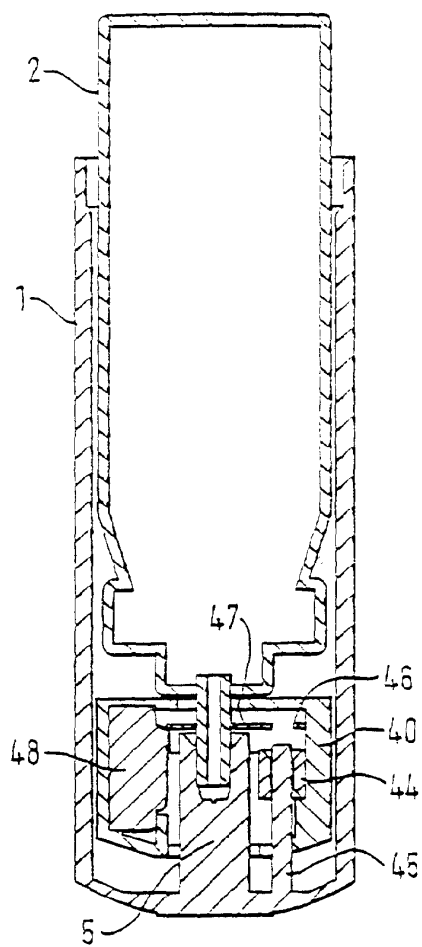


FIG. 8

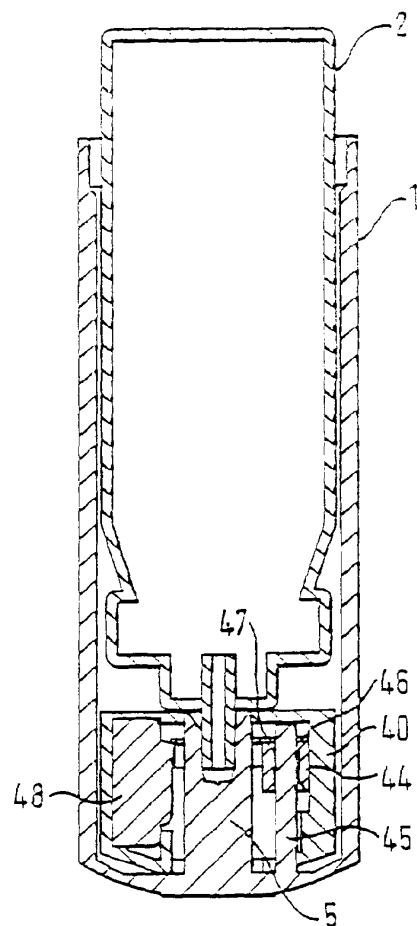


FIG. 9



(11) **EP 1 065 477 A2**

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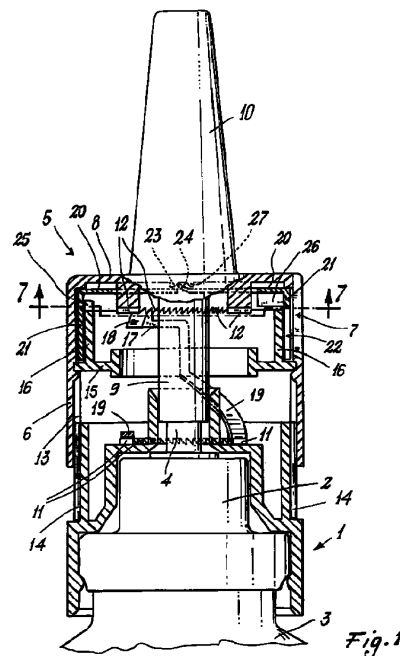
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(30) Priority: **30.06.1999 IT MI991448**

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(54) **Liquid dose dispenser with device for counting a large number of dispensed doses**

(57) A dispenser for measured quantities of a liquid product delivered under pressure by a metering pump or valve on which the dispenser is fitted, the dispenser having a device comprising discs on which there are reproduced two separate progressive successions of numbers which are selectively visible through a window in the dispenser, firstly the numbers of one disc and then the numbers of the other, to count the doses dispensed.



EP 1 065 477 A2

Description

[0001] This invention relates to a dispenser for dispensing measured quantities of a liquid, provided with a device for counting a large number of dispensed doses.

[0002] Many liquids, in particular pharmaceutical substances, are dispensed in measured quantities which have to be counted, each dose being dispensed by manually operating a dispenser applied to the stem of a pump or dispensing valve mounted on the mouth of a container containing the liquid to be used.

[0003] Liquid dose dispensers provided with devices for counting the number of doses already dispensed are described in the literature, for example in EP-B-114617, EP-B-269496, EP-A-472915 and EP-B-480488.

[0004] The device for counting the number of doses dispensed by the dispensers covered by the aforesaid patents comprises a discoidal body mounted rotatable about the longitudinal axis of the respective dispenser and having a continuous succession of numbers (increasing from 1 to about 20) reproduced along the periphery of the discoidal body, which is rotated through one step each time the dispenser is operated. One number at a time (in the increasing direction) is visible through a window provided in the dispenser, so making it possible to count the number of doses dispensed.

[0005] Known dispensers with a counting device have only one discoidal body. As these discoidal bodies are necessarily of small dimensions, the numbers reproduced along their periphery are necessarily limited in quantity, in general to about twenty. This means that dispensers of known type enable only a relatively small number of dispensed doses to be counted, thus limiting their application to small-volume liquid containers able to contain a liquid quantity equivalent to about twenty individual doses.

[0006] The main object of the invention is to provide a liquid dose dispenser having a device which enables a number of dispensed doses to be counted which is much larger (at least about double) than that achievable with similar known dispensers.

[0007] A further object is to provide a dispenser of the aforesaid type which is of simple structure, low production cost and reliable operation.

[0008] These and further objects are attained by a dispenser comprising:

- a base body with a seat for housing the free end of a pump or valve for delivering doses of a liquid contained in a container on which the pump is mounted;
- an operating body superposed on the base body and secured to it by guide elements which allow axial movement, but prevent rotation, of one body on the other, the operating body having a substantially cylindrical wall in which a window or aperture is provided, and a top wall with a hole about which

there extends a tubular element having at one end a seat for the free end of the pump stem and at its other end a nozzle for discharging the liquid dispensed by the dispenser;

- a first discoidal body housed in and rotatable within the operating body and having a substantially cylindrical surface facing the surface of the lateral wall of the operating body, through the window of which there is selectively positioned one of a first succession of numbers, letters or the like reproduced on the cylindrical surface of the first discoidal body;
 - two sawtooth-shaped annular surfaces provided one on the base body and the other on the top wall of the operating body, the teeth of one of the two surfaces pointing towards the teeth of the other surface;
 - flexible tangs projecting from the first discoidal body, and having their profiled free ends engaging the toothed surface of the base body and toothed surface of the operating body respectively, to cause the first discoidal body to rotate through one step each time the operating body is moved axially relative to the base body, with consequent initial flexure of said tangs and their subsequent return to an unflexed rest position;
- characterised by also comprising a second discoidal body housed between the top wall of the operating body and the first discoidal body, and having a cylindrical lateral wall on which a second succession of numbers is reproduced, and which extends between and is rotatable between the lateral wall of the operating body and the cylindrical surface of the first discoidal body, on the operating body and on the first discoidal body there being provided retention members which mutually cooperate to transiently maintain a window provided in the lateral wall of the second discoidal body facing the window in the operating body, the first discoidal body having a drive tooth which, when said first body has undergone a complete revolution about its axis, interferes with a tooth provided on the second discoidal body to drag it into rotation, to disengage said retention members and position in succession one of the numbers of said second succession of numbers in front of the window in the operating body.

[0009] Preferably said retention members comprise a first projection provided on the inside of the top wall of the operating body and bounded laterally by an inclined surface on which there rests a flexible tang projecting from the second discoidal body, this projection being overcome, with the flexing of said tang, when the drive tooth of the first discoidal body moves the second discoidal body away from its rest position.

[0010] Again preferably, said first projection in the form of a sawtooth is flanked by a stop tooth on which the flexible tang of the second discoidal body rests to block the movement of this latter after it has undergone

a complete revolution about its axis.

[0011] The structure and operation of the dose dispenser of the invention will be more apparent from the description of a preferred embodiment thereof given hereinafter by way of non-limiting example with reference to the accompanying drawings, on which:

Figure 1 is a partial axial section through the dose dispenser to an enlarged scale;

Figures 2 and 3 are respectively a perspective side view and a plan view of the first annular body forming part of the dispenser;

Figure 4 is a perspective side view of the second annular body of the dispenser;

Figures 5 and 6 schematically represent an inner portion of the dispenser in various positions assumed during dispenser operation;

Figure 7 is a cross-section through the dispenser on the line 7-7 of Figure 1; and

Figure 8 is a partial side view of the dispenser.

[0012] Reference will firstly be made to Figure 1, which shows a liquid dose dispenser comprising a base body 1 defining a seat for receiving and retaining the free end of a metering pump or valve 2 applied to the mouth of a container 3 containing the liquid to be delivered through the pump stem 4.

[0013] Onto the base body 1 there is fitted a operating body 5 having a cylindrical lateral wall 6 (in which a window or aperture 7 is provided) and a top wall 8 traversed by a hole (not visible on the drawing) about which there extends a tube, of which the downwardly facing portion 9 presents a seat into which the free end of the pump stem is inserted and retained, and the portion 10 extending outwards from the dispenser presents a nozzle (not shown) through which the dose of liquid originating from the pump is dispensed in atomized form. In the embodiment of Figure 1, the tube portion 10 has the elongate tapering form of a nasal insert used for spraying doses of a pharmaceutical product into a person's nostrils.

[0014] From the base body 1 there projects upwards (with reference to Figure 1) a succession of sawteeth 11 distributed in the manner of an annular surface. A similar succession of sawteeth 12, also distributed in the manner of an annular surface, projects from the top wall 8 of the operating body 5, the individual teeth of the two successions of teeth pointing towards each other.

[0015] Finally it should be noted that the two bodies 1 and 5 are connected together by a series of longitudinal grooves 13 and respective longitudinal ribs 14 inserted into and slidable within these grooves, to enable one body to move axially on the other, while preventing them from rotating relative to each other.

[0016] In the space delimited by the two bodies 1 and 5 there is housed a first discoidal body 15 having a cylindrical wall 16, on the outer surface of which there is

reproduced a first continuous succession of numbers (in the case shown on the drawings the numbers extend from 1 to 24) which are visible selectively, one at a time, through the window 7.

[0017] From the top of the discoidal body 15 there projects a pair of flexible tangs 17 the free ends of which are shaped as a sawtooth 18 which engages the teeth of the ring of teeth 12. The inclined surface of each tooth 18 of the tangs 17 is in contact with, and can slide (hence causing the tang to flex) along, the inclined surface of the teeth 12 (so enabling the body 15 to rotate relative to the body 5), and jump over these teeth. The other surface of the tooth 18 and that surface of the teeth 12 which faces it are shaped to mutually interfere, and prevent rotation of the body 15 in the opposite direction to the preceding.

[0018] Likewise, from the bottom of the discoidal body 15 there projects a pair of flexible tangs 19, the free ends of which each extend between two consecutive teeth of the ring of teeth 11, sliding on their inclined surfaces when the body 15 is rotated in one direction, while jamming against the straight surfaces of these teeth to prevent rotation of the body 15 in the opposite direction.

[0019] To better understand how the discoidal body 15 is made to rotate through one step each time the dispenser is operated, reference will be made to Figures 5 and 6, which show schematically the developments of the teeth 11 and 12, between which there is also shown schematically a portion of the discoidal body 15 with a flexible tang 17 and a flexible tang 19.

[0020] When in the rest state the aforesaid component parts assume the position shown by full lines in Figure 5.

[0021] When the operating body is pressed towards the base body to operate the pump and dispense a dose of liquid, the toothing 12 approaches the toothing 11 until it attains the position shown by dashed lines in Figure 5. During this approach, the profiled end of the tang 19 remains locked on that tooth indicated by the letter d, whereas the tang 17 flexes to rotate the body 15 towards the left (with reference to the figure) through one step, and with it the tang 17, the profiled end 18 of which jumps over the inclined surface of that tooth indicated by the letter b in the toothing 12, and becomes positioned between the teeth b and c, as shown by dashed lines in Figure 5.

[0022] When the pressure exerted by the two fingers on the top of the operating body 5 ceases, this latter is returned to its raised position by the action of the pump spring. However the profiled end 18 of the tang 17 remains fixed at the tooth b, between the two teeth b and c, to hence prevent the return of the discoidal body to that angular position which it had prior to the operation of the dispenser. While the toothing 12 returns to its rest position raised from the toothing 11 (Figure 6), the profiled end of the tang 19 is dragged to jump over the inclined surface of the tooth d and become positioned

between the teeth d and e.

[0023] The cycle can be repeated in this manner, with the window 7 each time showing the next number in the succession of numbers reproduced on the cylindrical surface 16 of the body 15, so enabling the number of dispensed liquid doses to be counted.

[0024] The dispenser with dose counter as described up to this point is similar to that described in EP-B-480488, in which the number of dispensed liquid doses which can be counted is equal to the highest number reproduced on the outer surface of the cylindrical wall 16 of the first rotatable body. In the case illustrated here this first body enables a maximum number of 24 doses to be counted.

[0025] The dispenser of the present invention comprises however a second discoidal body formed with a top annular wall 20 and a cylindrical lateral wall 21 which extends between and is rotatable between the lateral wall 6 of the operating body 5 and the cylindrical wall 16 of the first discoidal body (Figure 1), the top wall 20 being positioned between and rotatable between the wall 8 of the body 5 and the first discoidal body 15, 16.

[0026] In the cylindrical wall 21 there is provided a window 22 which can be transiently retained facing the window 7 of the body 5 by the retention members described hereinafter. On the outer surface of said cylindrical wall 22 there is reproduced a second succession of increasing numbers the lowest of which, in the example shown here, is the number 25, ie one more than the highest number reproduced on the first discoidal body.

[0027] The dispenser is mounted such that before dispensing the first dose of liquid, the window 22 is positioned in front of the window 7, and through this the lowest (0 or 1) of the numbers of that series of numbers reproduced on the wall 16 is visible.

[0028] To prevent the second discoidal body 20, 21 from being dragged into rotation by the first body 15, 16 while dispensing the first series of liquid doses, retention members are provided consisting of a tooth or projection 23 projecting downwards (with reference to Figure 1) from the top wall 8 of the body 5, this tooth or projection being bounded on one side by an inclined surface on which there rests the free end of an upwardly curved flexible tang 24 formed by cutting it from the annular wall 20. The friction exerted by the first discoidal body 15, 16 on the second discoidal body 20, 21 is insufficient to cause the tang 24 to flex and its free end to rise along the inclined surface of the tooth 23, so that the second discoidal body remains at rest while the first discoidal body undergoes a complete revolution about its axis, allowing all the numbers (in our case from 1 to 24) reproduced on the cylindrical wall 16 to be seen through the windows 7 and 22.

[0029] As can be seen from Figure 1 and more clearly from Figure 2, from the cylindrical wall 16 of the first discoidal body there projects a drive tooth 25 which, on termination of a complete revolution of this first body about its axis, interferes with a tooth or small rib 26 pro-

jecting below the wall 20 of the second discoidal body, which is dragged into rotation (causing the flexible tang 24 to jump over the retention tooth 23) by the first discoidal body, in step with it.

[0030] If it is required for the two discoidal bodies not to be able to undergo further rotation on termination of a complete revolution of the second discoidal body, adjacent to the tooth 23 a stop tooth 27 can be provided having a surface which the tang 24 cannot jump over.

[0031] It can be seen that as soon as the second discoidal body is dragged to undergo its first advancement step, the window 22 is moved away from the window 7 from which only the outer surface of the cylindrical wall 21 of the second discoidal body will then be visible (this hiding the cylindrical wall 16 of the first discoidal body from view), with the numbers (one at a time in succession) reproduced on it.

[0032] Figures 2 and 3 show the first discoidal body in perspective view and in plan view from above, whereas Figure 4 shows the second discoidal body only in perspective view.

[0033] Figure 7 is a cross-section through the device on the line 7-7 of Figure 1 to facilitate the understanding of the dispenser structure and operation, no further explanation being necessary.

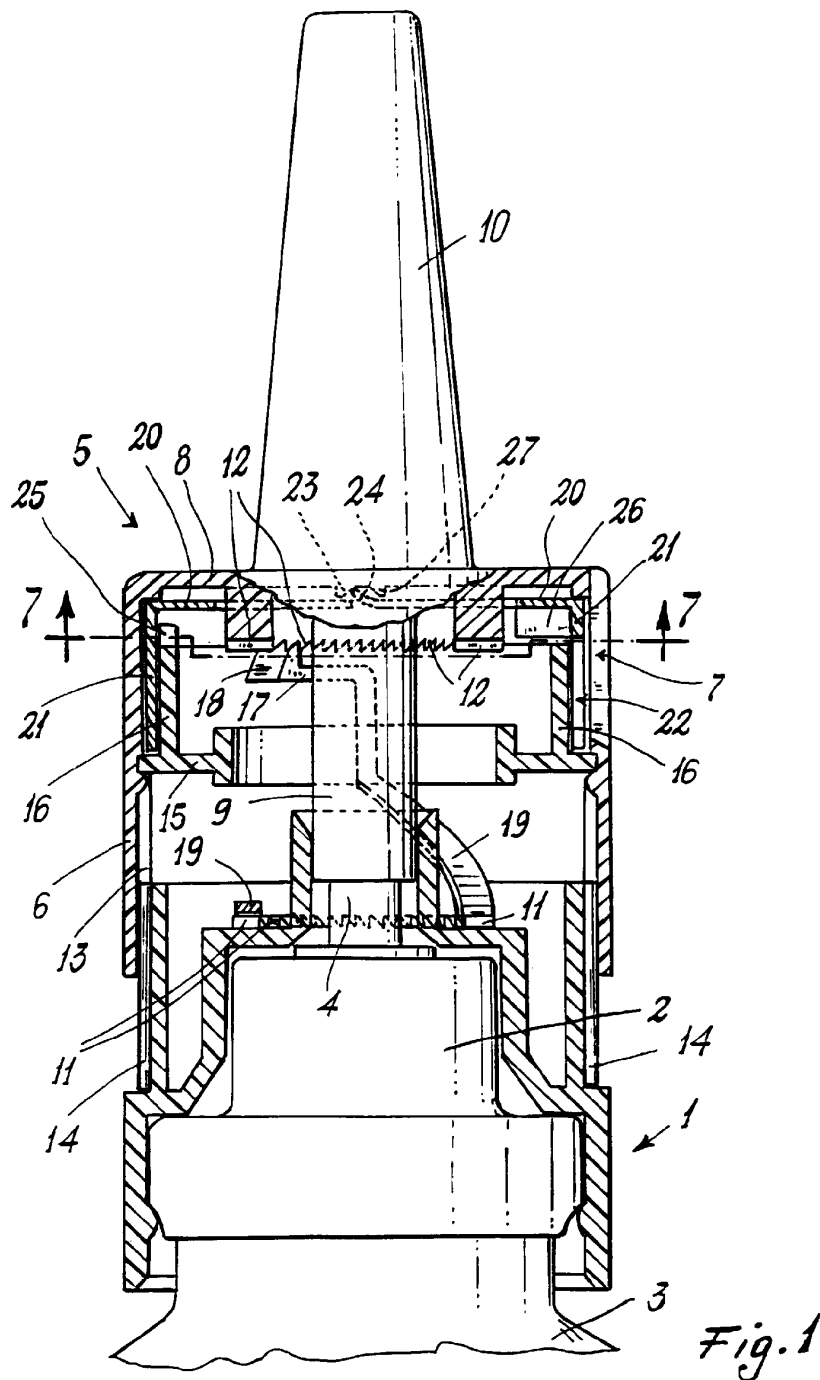
[0034] It is important to note that the dimensions of the device described and claimed herein are totally comparable to those of the device having a single rotatable discoidal body (EP-B-480488) while enabling twice the number of dispensed liquid doses to be counted.

Claims

1. A liquid dose dispenser with a device for counting the dispensed doses, comprising:

- a base body with a seat for housing the free end of a pump or valve for delivering doses of a liquid contained in a container on which the pump is mounted;
- an operating body superposed on the base body and secured to it by guide elements which allow axial movement, but prevent rotation, of one body on the other, the operating body having a substantially cylindrical wall in which a window or aperture is provided, and a top wall with a hole about which there extends a tubular element having at one end a seat for the free end of the pump stem and at its other end a nozzle for discharging the liquid dispensed by the dispenser;
- a first discoidal body housed in and rotatable within the operating body and having a substantially cylindrical surface facing the surface of the lateral wall of the operating body, through the window of which there is selectively positioned one of a first succession of numbers, letters or the like reproduced on the cylindrical

- surface of the first discoidal body;
- two sawtooth-shaped annular surfaces provided one on the base body and the other on the top wall of the operating body, the teeth of one of the two surfaces pointing towards the teeth of the other surface;
 - flexible tangs projecting from the first discoidal body, and having their profiled free ends engaging the toothed surface of the base body and toothed surface of the operating body respectively, to cause the first discoidal body to rotate through one step each time the operating body is moved axially relative to the base body, with consequent initial flexure of said tangs and their subsequent return to an unflexed rest position;
- characterised by also comprising a second discoidal body housed between the top wall of the operating body and the first discoidal body, and having a cylindrical lateral wall on which a second succession of numbers is reproduced, and which extends between and is rotatable between the lateral wall of the operating body and the cylindrical surface of the first discoidal body, on the operating body and on the first discoidal body there being provided retention members which mutually cooperate to transiently maintain a window provided in the lateral wall of the second discoidal body facing the window in the operating body, the first discoidal body having a drive tooth which, when said first body has undergone a complete revolution about its axis, interferes with a tooth provided on the second discoidal body to drag it into rotation, to disengage said retention members and position in succession one of the numbers of said second succession of numbers in front of the window in the operating body.
2. A device as claimed in claim 1, characterised in that said retention members comprise a first projection provided on the inside of the top wall of the operating body and bounded laterally by an inclined surface on which there rests a flexible tang projecting from the second discoidal body, this projection being overcome, with the flexing of said tang, when the drive tooth of the first discoidal body moves the second discoidal body away from its rest position.
3. A device as claimed in claim 2, characterised in that said first projection in the form of a sawtooth is flanked by a stop tooth on which the flexible tang of the second discoidal body rests to block the movement of this latter after it has undergone a complete revolution about its axis.



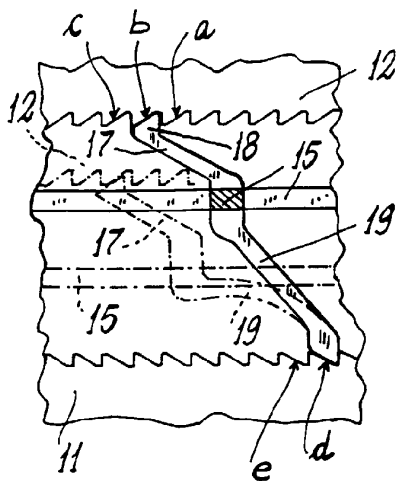


Fig. 5

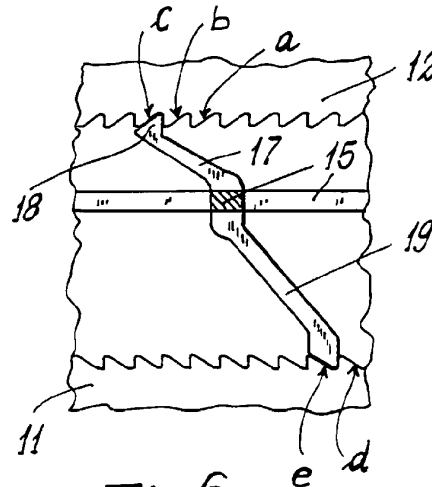


Fig. 6

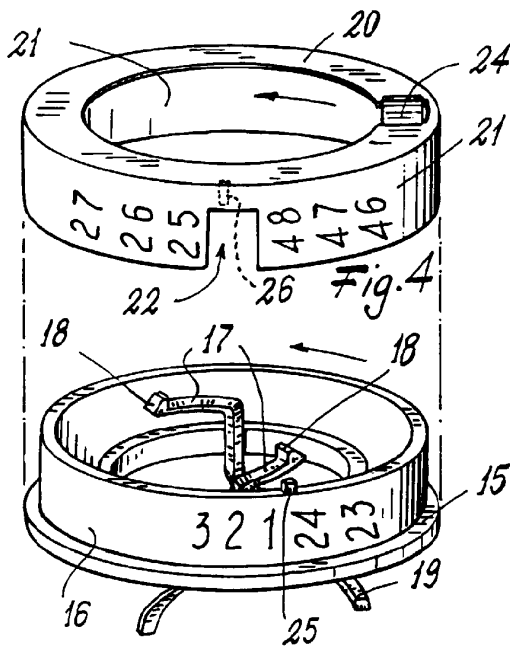


Fig. 2

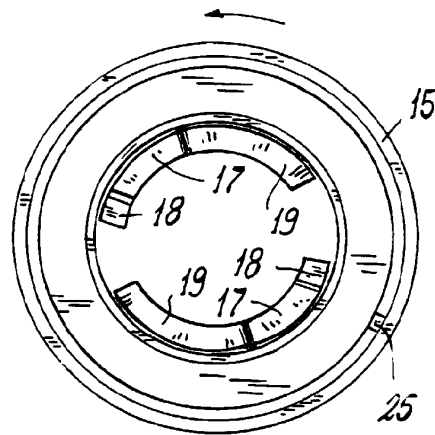
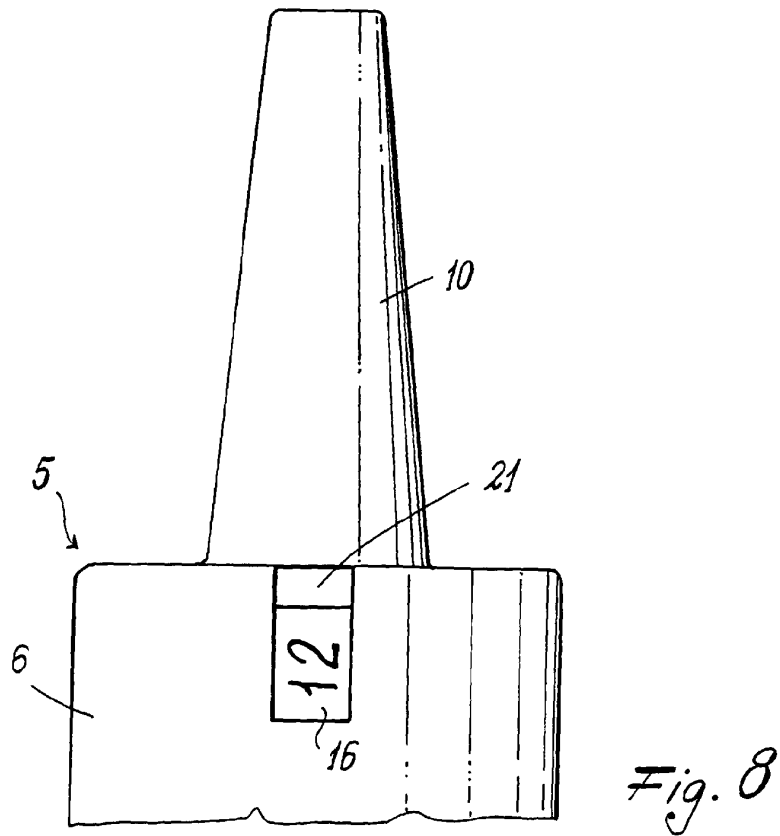
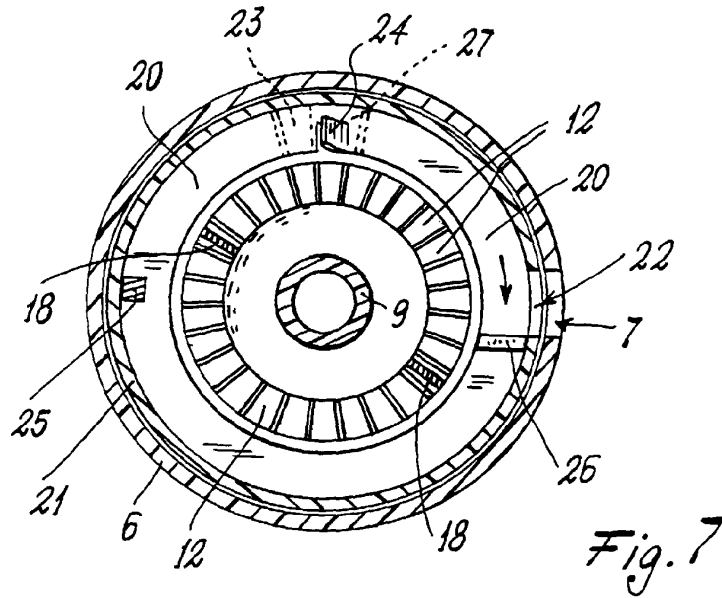


Fig. 3



Electronic Patent Application Fee Transmittal				
Application Number:		10556432		
Filing Date:		09-Nov-2005		
Title of Invention:		Fluid product dispenser		
First Named Inventor/Applicant Name:		Fabien Poulard		
Filer:		Ellen Resnick Smith		
Attorney Docket Number:		Q91404		
Filed as Large Entity				
U.S. National Stage under 35 USC 371 Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Claims in excess of 20	1615	2	52	104
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension - 3 months with \$0 paid	1253	1	1110	1110
Miscellaneous:				
Submission- Information Disclosure Stmt	1806	1	180	180
Total in USD (\$)				1394

Electronic Acknowledgement Receipt	
EFS ID:	8970123
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	Fluid product dispenser
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Ellen Resnick Smith
Filer Authorized By:	
Attorney Docket Number:	Q91404
Receipt Date:	06-DEC-2010
Filing Date:	09-NOV-2005
Time Stamp:	15:09:54
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1394
RAM confirmation Number	1448
Deposit Account	194880
Authorized User	SUGHRUE MION, PLLC
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Rule 130, 131 or 132 Affidavits	Q91404_executed312Declaration.PDF	265663 7fae069909a230281aefbdc5f5ac569bf6cb33c	no	4
Warnings:					
Information:					
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	Applicant Arguments/Remarks Made in an Amendment		13	30	

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Warnings:					
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14	Foreign Reference	16_WO0128887A1.pdf	1031902	no	30
			4ccedf3f8989d4d375f04b41ae7c4ab4d81dff12		
Warnings:					
Information:					
15	Foreign Reference	17_WO0137909A1.pdf	1180810	no	31
			0894717a6dda44b389d76467ae44ae11762f72c3		
Warnings:					
Information:					
16	Foreign Reference	18_EP0254391A1.pdf	678405	no	12
			063ca92f42d03fdac72d3b713c0a8a1ada122fab		
Warnings:					
Information:					
17	Foreign Reference	19_EP0949584A2.pdf	393331	no	9
			b2a05ea0efb2348cd1ecc36192d9af51ccedd8890		
Warnings:					
Information:					
18	Foreign Reference	20_EP1010438A1.pdf	625102	no	15
			dbb4261fe3ed83e347906c96d1e261656be499b5		
Warnings:					
Information:					
19	Foreign Reference	21_EP1163922A2.pdf	873496	no	16
			4a73e673d7ace6f64785ef55caedb34677dd2ee6		
Warnings:					
Information:					
20	Foreign Reference	22_EP1065477A2.pdf	434634	no	8
			75bd8c8c27c32250937e22aa3e005adff4dd7429d		
Warnings:					
Information:					
21	Fee Worksheet (PTO-875)	fee-info.pdf	33532	no	2
			ad0777616d8be2b09226dad96deab5d7dd6d861		
Warnings:					
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

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If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Fabien Poulard, hereby declare and state:

THAT I am the inventor of U.S. Application 10/556,432;

THAT I am a citizen of France;

THAT I have received the degree of Engineer in 1996 from ISPA;

THAT I have been employed by Valois since 05/03/2001, where I hold a position as

Design Engineering Leader, with responsibility for Dose Indicator Design;

I also hereby further declare and state:

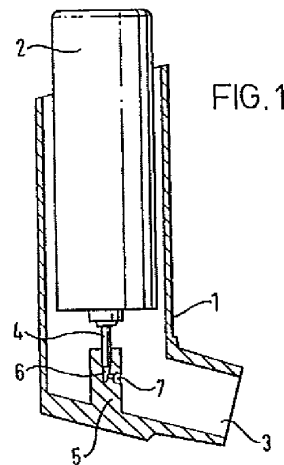
1. I am familiar with the June 4, 2010 Office Action, including the objections to the drawings and specification, and the rejections to the claims.

2. My invention provides a fluid dispenser including a dose indicator device that prevents any risk of under-counting. My invention guarantees that the indicator device is actuated each time

fluid is dispensed by the fluid dispenser, and prevents actuation of the indicator device when a dose is not dispensed. (See Specification at page 2, line 14-23.)

3. Fluid dispensers having dose indicator devices are well known. (See originally filed Specification at page 1, lines 1-8.)

4. With respect to the objection to the drawings in paragraph number 2 of the Office Action, the inclusion of a dispenser member on the reservoir was originally recited in claim 1 when the application was filed. Moreover, the placement of a dispenser member, such as a pump or valve, on top of a reservoir for use in a fluid dispenser, is well known in the art. The axial displacement of the reservoir relative to the stationary body actuates the dispenser member to cause a dose of fluid to be dispensed from the reservoir. (Specification at page 9, lines 3-5.) This type of pump or valve actuation is understood by those of ordinary skill in the art, as evidenced by numerous patents and patent applications published by the U.S Patent and Trademark Office and the European Patent Office. (See for example, U.S. Pub. No. 2002/0195102, FIG. 1 (reproduced to the right), cited by the Examiner in the Office Action dated July 22, 2008 and cited by Applicant in the Information Disclosure Statement filed on November 9, 2005, showing a dispenser member 4 mounted on a top of a reservoir 2). A list of such sample publications showing the placement of a dispenser member on top of a reservoir is provided in **Attachment A**. As such, one of ordinary skill in the art would have known the placement of the dispenser member on the reservoir.



5. With respect to the objection to the drawings in paragraph number 3, the drawings filed with the instant application, U.S. Application No. 10/556,432, were purposefully simplified to reduce the complexity of the drawings in order to increase the understanding of my invention. (Specification at page 8, lines 9-19.) I used diagrammatic drawings to illustrate the body, gears, reservoir, actuator and counter, to increase understanding of my invention because the use of diagrammatic drawings for such elements is well known and understood by those of ordinary skill in the art. This level of skill in the art is evidenced by the attached list of sample publications utilizing diagrammatic drawings to represent such elements as provided in **Attachment B**.

6. A set of pictures of an embodiment of the present invention is provided in **Attachment C**. One of ordinary skill in the art would understand how to interpret the diagrammatic drawings of the pending application to represent a device such as the one in these pictures.

7. With respect to the objection stated in paragraph number 4 of the Office Action, one of ordinary skill in the art would understand how the improved portion of the present invention is connected with the old portion and structure. By evidence of the publications provided in **Attachment A and Attachment B**, the old structure of gears and actuators in fluid dispensers is known. One of ordinary skill in the art would understand the improved portion of the fluid dispenser because the general concept of gears and actuators in a fluid dispenser is known.

8. With respect to the objections stated in paragraph number 7 of the Office Action, one of ordinary skill in the art would understand how the various elements could be connected with each other, as evidenced in **Attachment A**, which shows the level of ordinary skill in the art with

respect to the use of reservoirs and counter elements in dispenser bodies and how dispensers function. The illustration of an oblique tooth to simply represent a gear is understood by those of ordinary skill in the art. See **Attachment B**.

9. With respect to the rejection of the claims stated in paragraph number 9, the level of skill in the art has been established by the evidence provided in **Attachments A and B**. The determination of enablement should take the state of the prior art into consideration. The state of the prior art is evidenced in Attachments A and B. In view of such, one skilled in the art would readily understand how to make and use the present invention in a fluid dispenser without any undue experimentation.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 29/11/2010



Fabien Poulard

ATTACHMENT A

(US Refs Not Submitted)

US 5,349,945
US 5,718,355
US 5,904,139
US 6,161,724
US 6,142,339
US 6,155,251
US 6,328,037
US 6,446,627

(Submitted as Part 1)

WO 93/24167
WO 98/52634
WO 98/56444
WO 00/09187
WO 00/21593
WO 00/59806
WO 01/28887
WO 01/37909

(Submitted as Part 2)

EP 0 254 391
EP 0 949 584
EP 1 010 438
EP 1 163 922



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 15/00		A1	(11) International Publication Number: WO 93/24167
			(43) International Publication Date: 9 December 1993 (09.12.93)
(21) International Application Number: PCT/GB93/01064 (22) International Filing Date: 24 May 1993 (24.05.93) (30) Priority data: 9211436.2 29 May 1992 (29.05.92) GB (71) Applicant (for all designated States except US): NORTON HEALTHCARE LIMITED [GB/GB]; Gemini House, Flex Meadow, Harlow, Essex CM19 5TS (GB). (72) Inventor; and (75) Inventor/Applicant (for US only): HOLROYD, Michael, John [GB/GB]; 1 The Green, Thriplow, Royston, Hertfordshire SG8 7QX (GB). (74) Agent: BEN-NATHAN, Laurence, Albert; Urquhart-Dykes & Lord, 91 Wimpole Street, London W1M 8AH (GB).			(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published With international search report.
(54) Title: DOSE INDICATING DEVICE			
(57) Abstract A medicament dispensing device comprises a housing (400) for receiving a medicament delivery system (25), e.g., an aerosol can, actuable to deliver discrete doses of medicament. An actuation device has a spring loaded sleeve (420) for engaging the aerosol can at its base end, when the actuation device is released on inhalation at a mouthpiece (405) of the housing. A dose counter comprises a rotary dose indicating ring (101) surrounding the sleeve (420) to be indexed incrementally by a resilient indexing member provided on the sleeve, on each actuation of the aerosol can (25) to discharge a dose of medicament.			

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DOSE INDICATING DEVICE

This invention relates to a dose indicating device for a dispensing device suitable for dispensing discrete amounts of fluid or particulate material entrained in an air stream.

Metered dose inhalers are well known in medicine for treatment, or alleviation of the effects of respiratory complaints, for example asthma. Breath-actuated devices are also known.

Aerosol dispensers provided with dose counting devices are also known. Some of these devices require substantial modification of the body part or housing of the dispenser to accommodate the counters or require additional containing structures. EP-0,197,113 provides a counter device which is mounted on top of the dispenser housing. US-4,817,822 utilizes a linear or rotary scale accommodated in a separate compartment outside to the dispenser housing. EP-0,258,238 utilizes a vertically disposed numbered wheel which projects upwardly of the dose metering device.

EP-0,269,496 describes a push button actuator for mounting on the neck of an aerosol dispenser, having a stroke counter comprising a counting ring with axially facing teeth which are engaged by an axially inclined flexible blade on the push button for actuating the aerosol valve.

GB-1,317,315; GB-1,290,484 and WO 92/09324 relate to counters for basic dispensers having an open ended housing in which aerosol cans are slidably mounted such that when the cans are manually depressed, a dose of medicament is released from the aerosol and inhaled through a mouthpiece at the opposite end of the housing. However, the counters are located beneath the cans and must be engaged by the lower, valve ends of the cans to cause the counters to index on each manual depression of the cans. Such arrangements have the disadvantages that modification of the housing geometry is

required at the critical area of the housing lower end where atomization takes place, the counter is accessible to a patient and could lead to misuse and its disposition could result in the inhalation of foreign matter if breakage of parts of the counter mechanism takes place.

Therefore, although several dose counting devices have been proposed the prior art devices are subject to many technical disadvantages.

It is an object of this invention to provide an improved dispensing device having actuating means, which may be breath actuated, capable of actuating a pressurized aerosol container or a dry powder drug delivery system, and a dose indicating means operated in association with the actuating means, the indicating means being relatively simple and convenient in structure and capable of being readily accommodated within the dispenser housing without substantial modification thereof as well as reducing the risks of incorrect actuation by a patient and of inhalation of small components which could become separated from the mechanism.

The invention provides a dispensing device for use with a medicament delivery system which can be actuated to deliver discrete doses of medicament, the dispensing device comprising a housing for receiving the medicament delivery system, the housing having an inhalation nozzle and a dose indicating device comprising an annular or arcuate dose indicating element rotatably mounted in the housing with a section of the indicating element being visible from outside the housing, and an indexing member movable on discharge of a dose of medicament to index the indicating element incrementally, characterized in that actuating means are provided in the housing for acting on an end of a medicament delivery system remote from said nozzle, to cause dispensing of doses of medicament; in that the indicating element is located in the housing around a part associated with the actuating means and in that the indexing member is carried by said part for movement in one axial direction through the indicating element on actuation of the medicament delivery system and in the

opposite axial direction for resetting the actuating means, with the indicating element being incrementally indexed on each movement of the indexing member in said one direction only.

Said actuating means are preferably breath-actuated on inhalation through the nozzle.

The indicating element may have internal teeth which are engaged by an indexing member which is resiliently mounted on the aforesaid part so that it can move inwardly of the teeth when it moves in said opposite direction, being the teeth and the engagement portion of said indexing member inclined with respect to the axis of rotation of the indicating element.

Preferably there may be provided means for restraining said actuating means, and means to release said restraining means. The release means are preferably breath actuated.

The actuation means may comprise means for applying a preload capable of actuating said drug delivery system.

The restraining means may comprise means for applying a resisting pneumatic force capable of preventing actuation of the actuation means. The pneumatic resisting means may be provided by a gas, e.g. air, which is either held at a positive pressure greater than atmospheric or a negative pressure below atmospheric prior to release. The release means will act to return the pressure to atmospheric or prior equilibrium, thus allowing the full force of the preload to act.

The means for applying a resisting pneumatic force may comprise an expandable gas tight chamber, the release means including valve means which can be opened to release a negative pressure prevailing in said low pressure chamber.

Although this device has been described in particular relation to a system using air, it will be realised that in a closed system any suitable gas could be used.

A device according to the invention is particularly suited for use with pressurized inhalation aerosols having valves which can be actuated to dispense a dose of medicament. However in other embodiments, a device according to the

invention can be used with a dry powder drug delivery system disposed within said housing, in which a dose of powdered medicament is dispensed by said system into an air flow in said housing created by inhalation at an outlet nozzle associated with the housing.

In some arrangements according to the invention for use with an aerosol dispensing container or a dry powder delivery system, the housing may include a slidable inner sleeve for enclosing the top portion of the main body of the aerosol container or the dry powder delivery system with the depending member being associated with the inner sleeve, with the indexing member being carried on the sleeve. This inner sleeve is preferably arranged to form one end of a gas tight piston cylinder, bellows or diaphragm, such that movement of the inner sleeve will result in an increase in the enclosed volume within the piston cylinder, bellows or diaphragm producing a vacuum or low pressure volume to form the resisting force capable of preventing the actuation of the drug delivery system.

A preferred breath-actuating release means comprises a movable vane mechanism. A valve seal is preferably attached to said vane, such that on inhalation the vane moves from its rest position closing said inlet means to its actuating position, thus moving the valve seal out of contact with the valve port, causing the opening of the valve to release the aforesaid resisting force. The vane mechanism is preferably dynamically balanced, and may be biased towards its closed position, e.g., by a spring.

Air inlets into the housing may take the form of slots in an upper end wall of said housing.

The medicament may be a drug per se or in any form of carrier, e.g., including a powder or a gaseous carrier.

Preferably the actuating means act on the aforesaid inner sleeve, and are reset by causing the inner sleeve member to move in said opposite direction.

Preferably a cover for an outlet nozzle of the housing is movably mounted on the housing, and a cam formation on the

cover cooperates with the lower end of at least one depending member associated with the inner sleeve such that, when the cover is closed, the depending member moves the inner sleeve to reset the actuating means.

An embodiment of the invention will now be described by way of example and with reference to the accompanying drawings, in which:-

Figure 1 is a diagrammatic sectional view through a metered dose inhaler having a dose indicating mechanism in accordance with the present invention;

Figures 2A, 2B and 2C are sectional details of the inhaler showing the diaphragm in the pre-actuated, cocked, and actuated states, respectively;

Figure 3 is a diagrammatic perspective view of the dose counting mechanism of Figure 1; and

Figure 4 is a diagrammatic perspective detail of parts of the mechanism of Figure 3.

Referring to Figure 1, an inhalation device consists of a main body 400 which is generally cylindrical in cross section, with a mouthpiece section 405 at one end and an end cap section 407 housing air inlets 419 at the other end. A known type of aerosol dispensing container 25 of generally cylindrical shape is housed within the main body of the device. The aerosol dispensing container has a stem 40 which contains an aerosol dispensing valve (not shown). The bore 15 of a pedestal 16 in the housing, is such that it forms an airtight seal on the stem 40 of the aerosol dispensing container 25. A shoulder 45 limits and locates the position of the stem 40, which in turn locates the aerosol dispensing container 25 in position in the main body 400. A passage 50 extends from the bore 15, continuing from the shoulder 45 to interconnect with a dispensing nozzle 55.

The opposite end of the dispensing container is contained within a sleeve 420 of slightly smaller cross section to the main body 400. The longitudinal axis of both the sleeve 420 and main body 400 is generally coaxial. The sleeve is slidable within the inner wall of the main body to allow free

passage of air in the main body past the sleeve. The sleeve 420 may be held in place by connection with a diaphragm 440 held in connection with the top of the main body 400, as will now be described. Thus, the sleeve 420 effectively hangs from the top of the main body.

One end of an e.g., moulded flexible diaphragm 440 (as indicated in Figure 2C) comprising a rigid disc-like section 441, a flexible generally cylindrical wall section 445 and a stiffer annular connector flange 447. The sleeve 420 has a cooperating annular connection flange 450. An annular U-section clip 470 snaps over the flanges 447 and 450 to hold them together in an air-tight manner. A further lip 418 on the clip provides a snug fit for one end of a compression spring 460. The compression spring is thus located and free to act on the sleeve. The other end of the compression spring is located by an annular flange of a predominantly cylindrical flanged insert 480 housed in the top section of the main body 400. This insert includes a groove 485 into which the disc-like section 441 of the flexible diaphragm 440 is snap-fitted.

The shape of the top surface 422 of the closed end of the sleeve to conform to the internal shape of the diaphragm such that in the rest (preactuated) position of the inhaler (Figure 2A) the two surfaces are in close proximity, and the enclosed space between them very small.

The cylindrical insert 480 is retained in place by the end cap 407 comprising the upper part of the main body 400 of the device. This forms a chamber 590 between the air inlet slots 419 and the rigid part 441 of the diaphragm. The chamber is provided with one or more air pathways 580 such that air may pass from the air inlet slots 419 to the mouthpiece 405. The rigid disc-like section 441 of the diaphragm also includes a small valve port 495 which is normally covered by a diaphragm valve seal 540 housed in a vane 550 pivotally connected to the insert 480.

The vane 550 in its rest position divides the chamber 590 between the air inlets 419 and the air pathways 580 that link to the mouthpiece such that it may move from its rest position

by means of a pressure drop between the air inlets and the mouthpiece. On movement of the vane to the actuated position (Figure 2C) the valve seal 540 is moved sufficiently to open the valve port 495. The vane 550 may be biased closed by a light spring flexure, a weight or a magnet not shown.

As shown in Figure 1, the lower end of the main body has a moulded section 500 beneath the mouthpiece 405 to which a dust cap is pivotally connected. A cam 520 is integrally formed on each side of a dust cap 510, one on each side of the moulded section 500. An annular yoke member 425 is secured to the lower end of the sleeve 420 and has a pair of downwardly depending legs 530, the lower ends of which act on the cams 520 such that when the dust cap is in the closed position the inner sleeve is forced by the cam follower to its uppermost position.

When the dust cap is rotated to its open position the cam profile is such that the cam follower is free to move downwards by an amount sufficient to allow actuation of the device.

In its rest position (Figure 2A) the dust cap 510 is closed, the legs 530 of the yoke member restrain the inner sleeve 420 in its uppermost position such that the enclosed space trapped between the diaphragm 440 and the top surface 422 of the inner sleeve is at a minimum and the spring 460 is compressed. The valve port 495 is closed by the valve seal 540 and the sleeve 420 is clear of the top of the aerosol can 25 which is thus unloaded.

The dust cap is opened rotating the integral cam 520 allowing the cam follower 530 to drop by an initial amount of downward movement. The inner sleeve is forced downwards under the action of the spring 460. As the inner sleeve moves downwards the enclosed volume between the diaphragm 440 and inner sleeve is increased. Since the valve port 495 is closed this creates a low pressure volume or near vacuum in the space 600 then defined between the upper surface 422 of the sleeve 420 and the diaphragm 440. The effect of the pressure differential between the enclosed volume 600 and atmospheric

pressure is such that the inner sleeve tends to resist the action of the spring 460. As the inner sleeve moves downwards it contacts the aerosol can 25 and begins compression of the aerosol valve (not shown).

Downward movement of the inner sleeve 420 will continue until there is a balance of forces between the compressive force in the spring 460 and resisting forces created by the pressure differential and compression of the aerosol valve. This represents the cocked position shown in Figure 2B. The geometry of the device is arranged such that this balance occurs before the aerosol valve has been sufficiently compressed to actuate it.

A typical aerosol requires about 20N force to actuate. The spring 460 should accordingly provide a greater force, preferably 10% to 50% greater.

It may also be possible to arrange for the balance of forces to take place before the inner sleeve has contacted the aerosol can, such that the spring force is balanced by the resisting force produced on the inner sleeve by virtue of the pressure differential.

On inhalation by the patient through the mouthpiece 405, a small pressure differential is created across the vane 550 which is pivoted towards one end. The pressure differential causes the vane to move from the rest position to the actuated position. The vane and design of the air passageway 580 in the chamber 590 are such that in the actuated position air can flow freely from the air inlets 419 to the patient.

The movement of the vane 550 causes the valve seal 540 to be moved out of a sealing position with the valve port 495. Opening the valve port allows air into the space defined between the diaphragm 440 and inner sleeve 420 such that the enclosed space reaches atmospheric pressure. This causes an imbalance of forces acting on the sleeve 420 and the container 25. The sleeve and the container are thus forced downwards (Figure 2C) by the spring 460 resulting in the release of a measured dose of medicament through the dispensing nozzle 55 and into the mouthpiece at the same time as the patient

breathes in. Thus the patient inhales air with a metered dose of medicament.

After the inhalation of the dose by the patient, the dust cap 510 is returned to its closed position. This rotates the cam 520 and causes the legs 530 of the yoke 425 to be forced upwards. This in turn acts on the inner sleeve 420 moving it upwards to compress the spring 460 and to close the space between the diaphragm 440 and the inner sleeve top surface 422. This forces air out of that space, which escapes through the valve port 495 lifting the valve seal 540. Since the valve seal is only lightly biased to its closed position it presents little resistance to air flow out of the enclosed space. The aerosol can is free to return to the rest position under the action of its own aerosol valve spring.

In use the patient loads the aerosol dispensing container into the main body. The aerosol container may be loaded by forming the main body 400 in two separable parts 350, 360, which are joined by a threaded coupling. When the upper part 350 of the main body 400 has been unscrewed, the aerosol can be inserted. The upper part 350 can then be replaced locating the inner sleeve 420 over the top end of the can, and the device is ready for use. As described previously, the device could be manufactured as a sealed unit.

The construction and operation of the inhalation device is also described in WO 92/09323, to which reference should be made for further details.

The inhalation device is provided with a dose indicating mechanism in accordance with the present invention. The upper part 407 of the main body 400 of the inhaler is formed with a viewing window 100 through which numbers or other dose indication markings provided on a rotary ring 101, can be viewed. The ring 101 is located in annular recess defined in the upper body part 407.

The ring 101 is formed at its upper end with a set of internal, axially inclined ratchet teeth 103.

The ring 101 is rotationally indexed, in the direction of the arrow in Figure 3, by a predetermined amount, each time a

dose is dispensed from the aerosol container 25. This is achieved by providing an indexing member 109 on the sleeve 420 to cooperate with the internal teeth 103 on the ring 101. The member 109 is made of a strip of a suitable resilient material, e.g., spring steel, and has a flat base portion 108 secured to the outer wall of the sleeve 420. The free edge of the strip is bent outwardly and shaped to form the indexing member 109 which is also inclined with respect to the axis of the ring 101. A rectangular portion 107 is cut out of the flexible arm portion connecting the indexing member 109 to the base portion 108 so the connection is made by upper and lower limbs 105, 106. This construction produces a resilient support structure for the indexing member 109 which is torsionally relatively rigid but is relatively flexible along its length. In this way the indexing member can readily flex radially inwardly of the ring 101 during each return stroke, as described below.

The teeth 103 and the indexing face 110 of the member 109 are similarly inclined to the axis of the body part 400. When the sleeve 420 is moved downwardly sufficiently to dispense a dose from the aerosol container 25, the indexing member 109 moves to its lower position as shown in Figure 4, thereby causing the indicating ring 101 to index by a predetermined increment to change the dose number displayed in the window 100.

In practice, with the indexing member 109 at its uppermost position, there is a small amount of play between the member 109 and the tooth 103 with which it is engaged. This play is taken up over an initial movement of the sleeve 420 as the breath actuating means is set on opening the cover 510, as described above. This accounts for an initial stroke of about 1 mm of the movement of the indexing member 109.

When the device is triggered by inhalation at the mouthpiece 405 to dispense a dose of medicament, the indexing member 109 completes its stroke of about 4.5 mm. At the end of its stroke the indexing member 109, which has a height of about 8 mm, remains still engaged with the teeth 103, as

indicated in Figure 4. On the return stroke, the indexing member 109 first engages the next inclined tooth 103, and then resiliently rides over that tooth to engage in the gap behind that tooth, ready for the next indexing operation. The indexing member at the beginning of its stroke is engaged with the teeth 103, which have a depth of about 2 mm, over a distance of about 1.5 mm.

As the yoke 425 is lifted to reset the device, by closing the mouthpiece cover 510, the indexing member 109 flexes radially inwardly of the ratchet teeth 103 on the ring 101 until, in its upper position, it engages in the next notch defined between the teeth 103 ready for a subsequent indexing operation.

It will be appreciated that the dose indicating mechanism is only actuated when the inner sleeve 420 moves downwards sufficiently to cause a dose to be dispensed from the aerosol 25. Therefore merely opening the mouthpiece cover 510 to reach the cocked position (Figure 2B) will not cause the dose indicating mechanism to be indexed.

Moreover a gap 600' is formed in the set of teeth 103 so that after the maximum number of doses have been dispensed from the aerosol can 25 the indicating ring 101 is no longer indexed by the indexing member 109. At this point an "empty" indication could be shown in the window 100.

The device may also be provided with a means such that it will not operate below a certain predetermined air flow rate, e.g., 10 to 30 litres per minute. In one embodiment the vane 550 will be biased by a spring such that the predetermined minimum air flow is necessary for it to move to its actuated position and enable the valve seal to open.

The main body of a dispensing device is preferably manufactured from a plastic such as polypropylene, acetal or moulded polystyrene. It may however be manufactured from metal or other suitable material.

CLAIMS

1. A dispensing device for use with a medicament delivery system (25) which can be actuated to deliver discrete doses of medicament, the dispensing device comprising a housing (400) for receiving the medicament delivery system (25), the housing having an inhalation nozzle (405) and a dose indicating device comprising an annular or arcuate dose indicating element (101) rotatably mounted in the housing (400) with a section of the indicating element being visible from outside the housing, and an indexing member (109) movable on discharge of a dose of medicament to index the indicating element (101) incrementally, characterized in that actuating means (420,440,460,550) are provided in the housing for acting on an end of a medicament delivery system (25) remote from said nozzle (405), to cause dispensing of doses of medicament; in that the indicating element (101) is located in the housing around a part (420) associated with the actuating means and in that the indexing member (109) is carried by said part (420) for movement in one axial direction through the indicating element (101) on actuation of the medicament delivery system and in the opposite axial direction for resetting the actuating means, with the indicating element being incrementally indexed on each movement of the indexing member (109) in said one direction only.

2. A dispensing device according to Claim 1 wherein said actuating means (420,440,460,550) are breath-actuated, on inhalation at said nozzle (405).

3. A dispensing device according to Claim 1 wherein the indicating element (101) has internal teeth (103) which are engaged by the indexing member (109), the teeth (103) and the engagement portion of the indexing member (109) being inclined with respect to the axis of rotation of the indicating member (101), and the indexing member (109) being resiliently mounted

so that it can move inwardly of the teeth (103) when moved in said opposite axial direction.

4. A dispensing device according to Claim 3 wherein a predetermined number of teeth (103) are provided so that said indexing member (109) disengages therefrom after a corresponding number of indexing operations of said indicating element (101) which then gives an empty indication on said section thereof visible from outside the housing.

5. A dispensing device according to Claim 3 wherein said indexing member (109) is carried by a connecting portion (105,106) which is attached to said part (420) and is resiliently biased towards said teeth (103).

6. A dispensing device according to Claim 5 wherein said connecting portion is made of a resilient material so as to bias the indexing member towards said teeth (103).

7. A dispensing device according to Claim 5 wherein said connecting portion comprises two spaced apart resilient, connecting limbs (105,106).

8. A dispensing device according to Claim 1 wherein said actuating means comprise a loading member (420) for engaging said end of the medicament delivery system (25), said indexing member (109) being carried by said loading member, means (460) to load said loading member (420) to actuate said medicament delivery system, means (440) to restrain said loading means (46), and means (550) to release said restraining means (440).

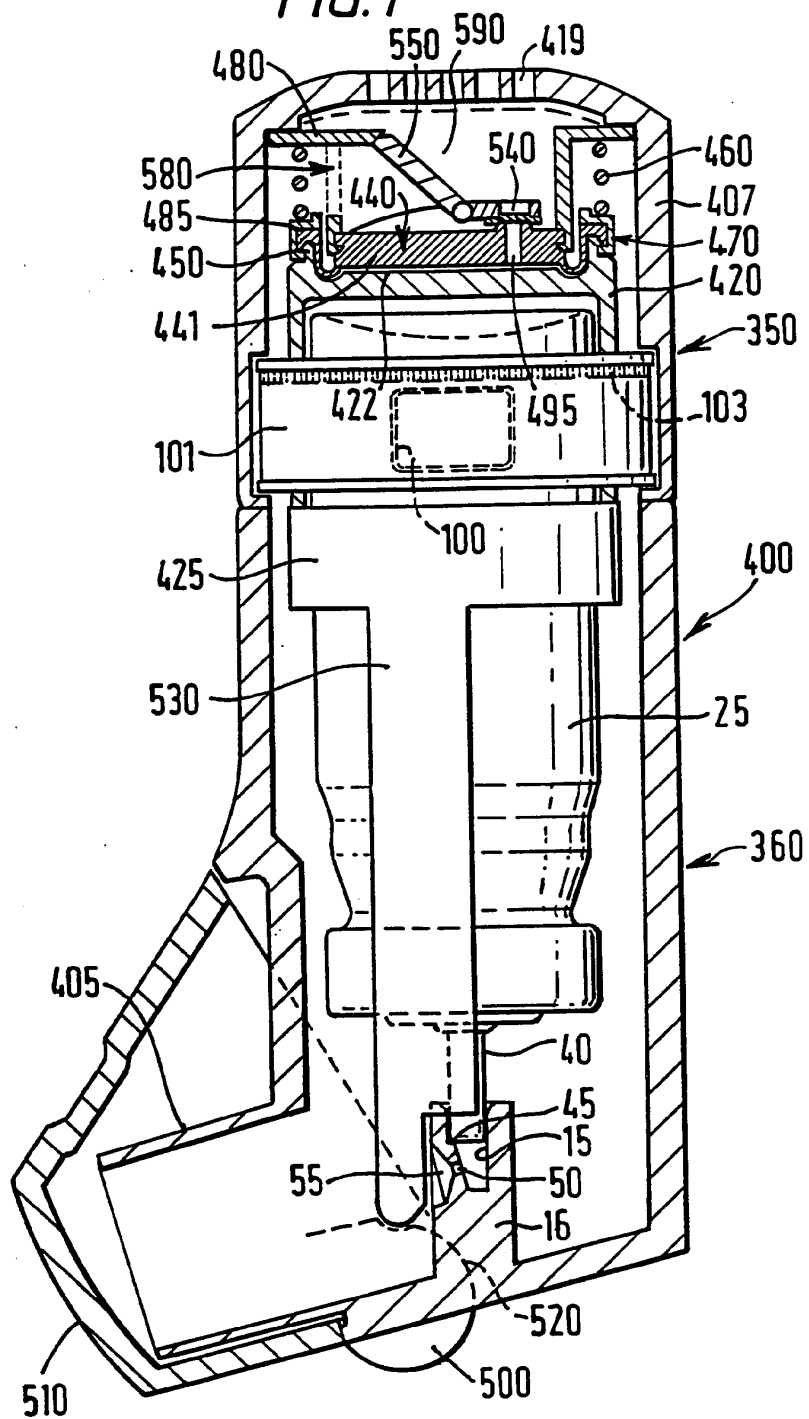
9. A dispensing device according to Claim 8 wherein said restraining means (440) comprise means for applying a resisting pneumatic force capable of preventing said loading means (460) from actuating the medicament delivery system (25).

10. A dispensing device according to Claim 1 wherein a cover (510) for said nozzle (405) of the housing is movably mounted on the housing, and a cam formation (520) on the cover (510) cooperates with the lower end of a depending member (530) associated with said part of the actuating means such that, when the cover is closed, the depending member moves said part to reset the actuating means and thereby to move said indexing member (109) in said axial direction.

11. A dispensing device according to Claim 1 in combination with a drug delivery system in the form of an aerosol dispensing container (25) having a valve capable of being actuated to release a metered amount of the pressurized aerosol contents.

12. A dispensing device according to Claim 1 in combination with a dry powder drug delivery system disposed within said housing and adapted to dispense, when actuated, a dose of powdered medicament into an air flow in said housing created by inhalation at said nozzle (405).

FIG. 1



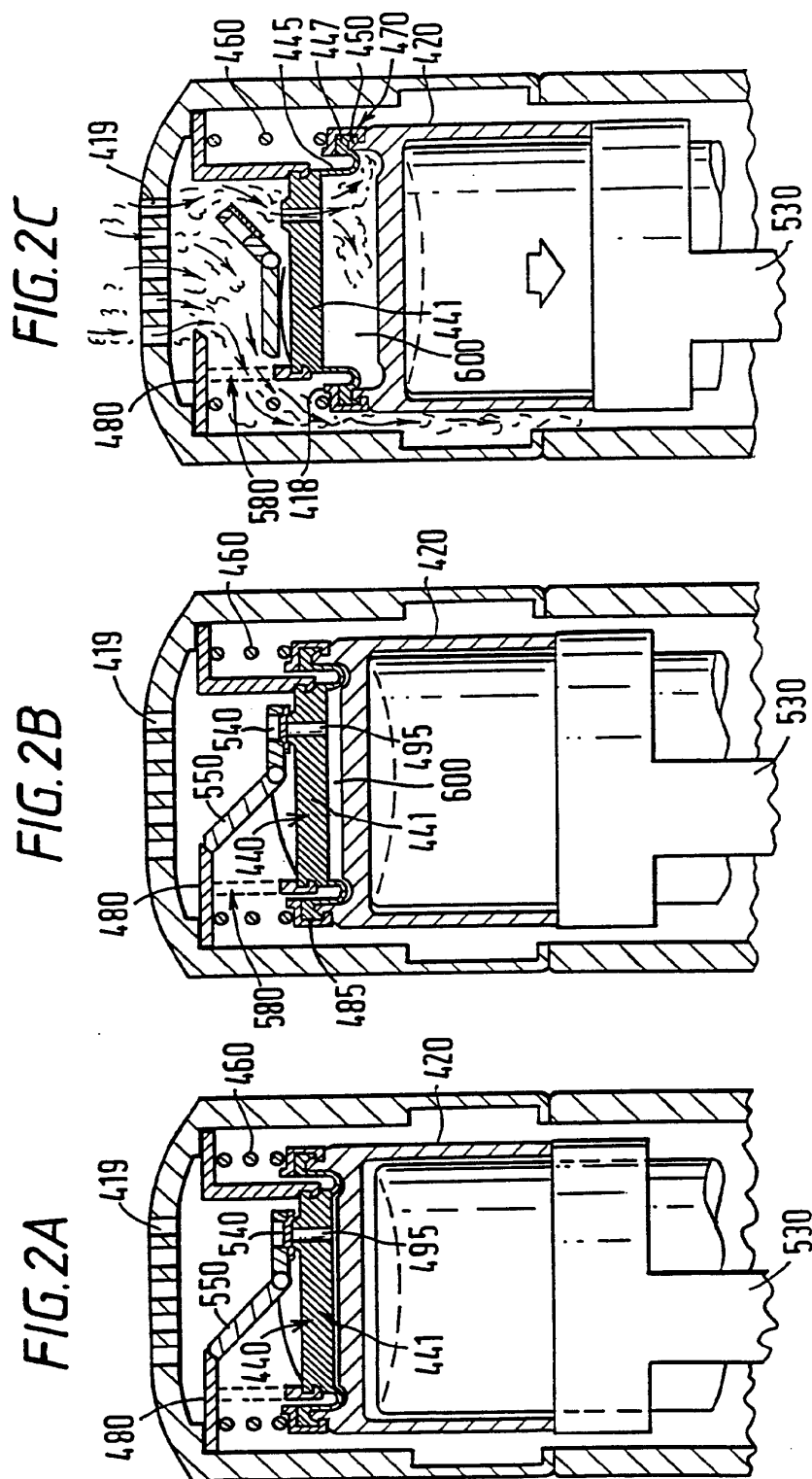
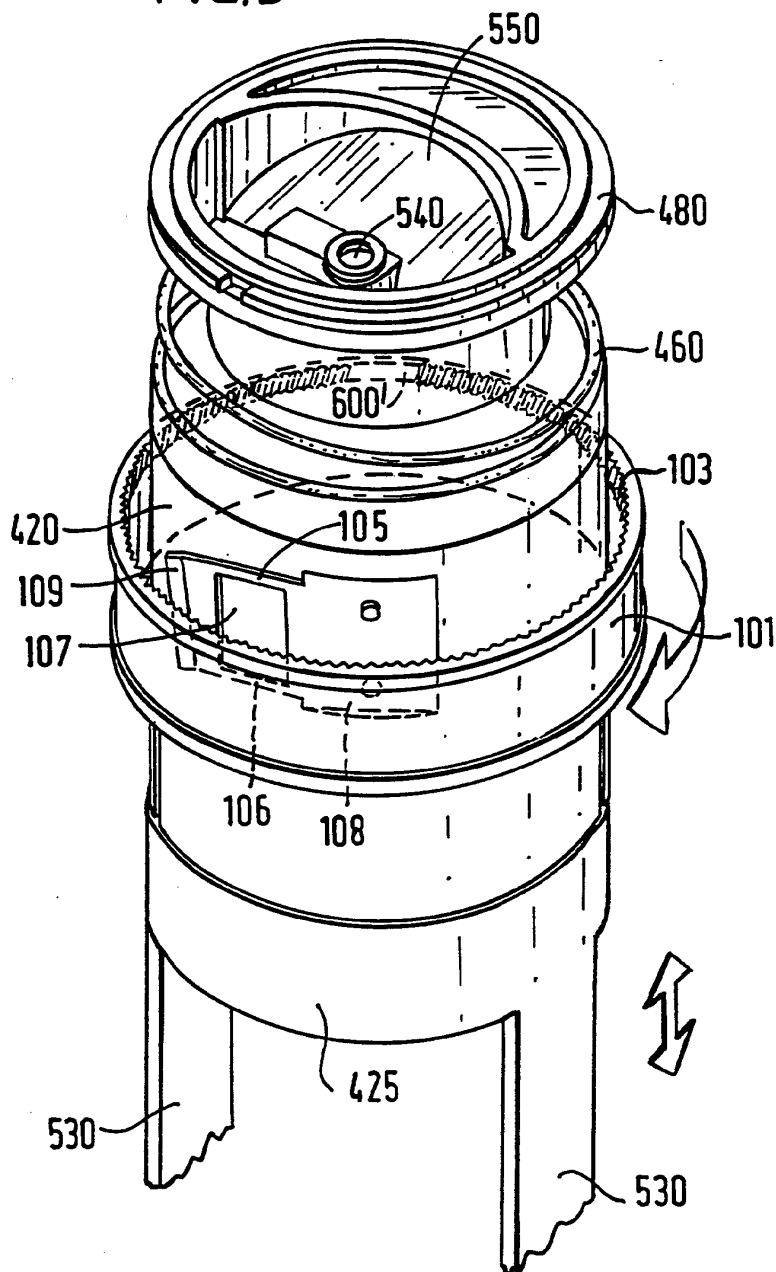
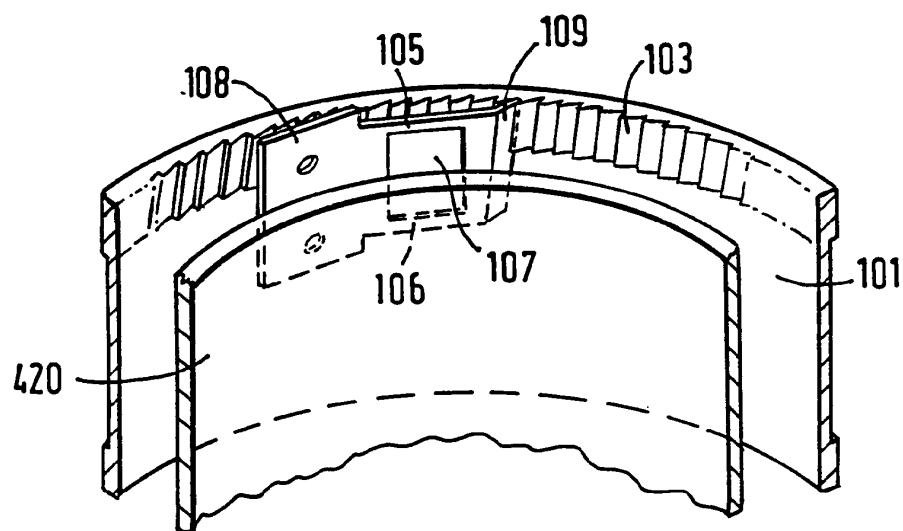


FIG. 3



4/4

FIG. 4



INTERNATIONAL SEARCH REPORT

PCT/GB 93/01064

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61M15/00		
II. FIELDS SEARCHED		
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Classification System	Classification Symbols	
Int.Cl. 5	A61M ; G06M	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
A	GB,A,1 317 315 (ENDLISH NUMBERING MACHINES LTD) 16 May 1973 cited in the application see page 2, line 6 - page 3, line 11 see figures 1-3	1, 3, 11
P,A	WO,A,9 209 324 (MINNESOTA MINING AND MANUFACTURING COMPANY) 11 June 1992 cited in the application see page 9, line 23 - page 10, line 3 see page 13, line 12 - page 14, line 35 see figures 5,6,9	1, 2, 4, 10, 11
¹⁰ Special categories of cited documents :¹⁰ "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "&" document member of the same patent family		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search 18 AUGUST 1993		Date of Mailing of this International Search Report 24. 08. 93
International Searching Authority EUROPEAN PATENT OFFICE		Signature of Authorized Officer SCHOENLEBEN J.

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III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
P,A	WO,A,9 209 323 (NORTON HEALTHCARE LTD.) 11 June 1992 cited in the application see page 9, line 27 - page 13, line 29 see figures 3-5 ---	1,2,8-11
A	EP,A,0 269 496 (VALOIS) 1 June 1988 cited in the application see figures 6,7 ---	3
A	WO,A,8 605 991 (AKTIEBOLGET DRACO) 23 October 1986 see page 2, line 10 - line 17 -----	12

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**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

GB 9301064
SA 74380

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
GB-A-1317315	16-05-73	None		
WO-A-9209324	11-06-92	AU-A-	9060491	25-06-92
WO-A-9209323	11-06-92	AU-A-	9034091	25-06-92
		CA-A-	2091367	02-06-92
		CN-A-	1062091	24-06-92
EP-A-0269496	01-06-88	FR-A-	2606506	13-05-88
		DE-A-	3774539	19-12-91
WO-A-8605991	23-10-86	SE-B-	448277	09-02-87
		AU-B-	587460	17-08-89
		AU-A-	5771686	05-11-86
		CA-A-	1250503	28-02-89
		EP-A, B	0258238	09-03-88
		JP-T-	62502451	24-09-87
		SE-A-	8501806	13-10-86
		US-A-	4668218	26-05-87

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/GB98/01501 (22) International Filing Date: 22 May 1998 (22.05.98) (30) Priority Data: 9710634.8 23 May 1997 (23.05.97) GB 9720594.2 30 September 1997 (30.09.97) GB 9800862.6 15 January 1998 (15.01.98) GB (71) Applicant (for all designated States except US): PA CONSULTING SERVICES LIMITED [GB/GB]; 123 Buckingham Palace Road, London SW1W 9SR (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): MACMICHAEL, Donald, Bruce, Atherton [GB/GB]; 104 Bedford Road, Hitchin, Hertfordshire SG5 2UE (GB). HEARNE, David, John [GB/GB]; 27 Church Road, Harlington, Bedfordshire LU5 6LE (GB). (74) Agent: KEITH W. NASH & CO.; 90-92 Regent Street, Cambridge CB2 1DP (GB).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: INHALER MECHANISM (57) Abstract A dosing device comprising a dispensing means (24, 26, 12) for dispensing a dose material, and a dose actuation mechanism, in which the dose actuation mechanism (42) comprises a readily deflectable member (40), and a cascade of at least two pivoted elements (46, 48), movement of one causing movement of the other, wherein the deflectable member (40) is movable by the user, and its movement is transferred to the first of the cascade of pivoted elements, so as to actuate the dispensing means. A first biasing means (56) communicates with one pivoted element (48) so that as movement is transferred between the pivoted elements (46, 48), energy stored in the first biasing means (50) is released to increase the force associated with the movement. A dose actuating mechanism for use in a dosing inhaler is also provided.		

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Title: Inhaler Mechanism**Field of Invention**

This invention concerns a dosing device and in particular relates to dosing devices for drug delivery such as injectors and inhalers, and a mechanism for use in such devices.

Background to the Invention

In treatment for asthma and other respiratory problems, a patient may take medication into his lungs by inhaling either an aerosol mist or a cloud of fine particles from an inhaler. Conventional asthma inhalers fall into two categories: 'dry powder inhalers' and 'metered dose inhalers' (MDI's).

Breath operated MDI's are known. For example US patent 3565070 describes an 'inhalation actuatable aerosol dispenser' and in addition WO 92/09232 and European patent 0147028 disclose further examples of breath operated MDI's.

An MDI consists of a small canister containing medication with a metering valve and a valve stem. The MDI delivers a metered dose to the patient when the valve stem is pressed. The fundamental problem in the design of breath operated MDI's is that a large force (of the order of 30 N) is required to depress the valve stem and actuate an MDI. However only a very small force is available from the patient's breath. This problem is partly overcome in the prior art by manually compressing a large spring to a sufficient force to actuate the device. The spring is compressed by the patient, either by a positive 'cocking' process or automatically when the patient opens the mouthpiece cover. The spring is then released by a trigger operated by the patient's breath. The operation of the trigger is however difficult to engineer reliably and cheaply

since releasing a spring with a stored force of 30N using a low force from the patient's breath is a difficult technical challenge.

WO 92/09323 describes a pneumatic system for holding the stored force. This requires a number of components which must be carefully manufactured to maintain a satisfactory vacuum seal during operation. European patent 0147028 describes a mechanical trigger design which requires extremely tight manufacturing tolerances and which to some extent depends on consistent levels of friction for repeatable operation.

The present invention seeks to provide an inhaler with a dose actuation mechanism which provides a very substantial amplification of the force being available from a patient's breath, whilst not being vulnerable to changes in the coefficient of friction between moving parts.

Summary of the Invention

According to the present invention, there is provided a dosing device comprising a dispensing means for dispensing a dose material, and a dose actuation mechanism, in which the dose actuation mechanism comprises a readily deflectable member, and a series of at least two movable elements which transmit and magnify movement of the first element in the series to the last element in the series by a cascade effect, wherein the deflectable member is movable by airflow, and its movement is transferred to the first element of the said series so as to actuate the dispensing means.

Preferably the moveable elements are pivoted and arranged sequentially to inter-communicate, movement of a first pivoted element by the deflectable member effecting movement of at least another pivoted element so as to actuate the dispensing means.

The deflectable member is preferably movable in response to inhalation by a patient. Thus in use only inhalation by the patient is required to activate the dose actuation mechanism and thus cause the measured dose to be dispensed.

The use of a cascade of moveable pivoted elements provides a form of amplification of the originating force created by the intake of breath, and whilst any number of such elements may be employed in the cascade, in general two such elements are sufficient.

As a preferred feature of the invention, this amplification may be achieved by a first biasing means which communicates with one moveable element so that as movement is transferred between the moveable elements, energy stored in the first biasing means is released to increase the force associated with the movement. This ensures that a small initial force exerted on the deflectable member is increased in magnitude as it cascades through the moveable elements. In such a way, a small initial force is magnified to allow actuation of the dispensing means.

Preferably one moveable element remote from the deflectable member is attached to, or acts on, the dispensing means so as to restrain actuation thereof until the said moveable element is deflected as a result of a cascade action. In this way the movement of the deflectable member and the pivoted elements can be used to release stored energy to provide sufficient force to dispense a dose from the dispensing means. In particular the dispensing means may be associated with a second biasing means, in which energy is stored in compression, which stored energy is released on movement of a pivoted element.

The invention also lies in a dose actuating mechanism for use in a dosing device, comprising a deflectable member and a cascade of at least two moveable elements, movement of the deflectable member being transferred to and between the moveable elements, in such a manner as to trigger the release

of stored energy sufficient to release a dose.

Preferably the dosing device is also provided with a lid including at least one cam surface, wherein movement of the lid results in the pivoted elements being restored to positions of unstable equilibrium ready to cause actuation of the dispensing means when the cascade is triggered.

The pivoted elements are preferably movable into a first position of unstable equilibrium, which movement is translated into stored energy, in the second biasing means, and when triggered, move into a second position of equilibrium, during which movement the stored energy is released from the second biasing means to dispense a dose from the dispensing means.

Preferably the moveable pivoted elements each comprise over-centre mechanisms. Thus where the over-centre mechanisms are arranged sequentially, movement of a first over-centre mechanism in the cascade, triggered by movement of the deflectable member, results in subsequent movement of the next, and in turn, any subsequent over-centre mechanisms, the last of which allows for actuation of the dispensing means.

Particularly preferred is the use of a first and a second over-centre mechanism as the moveable elements, the first over-centre mechanism communicating with first biasing means and the second over-centre mechanism communicating, via the dispensing means, with a second biasing means.

The use of two over-centre mechanisms in this way provides a force cascade which eventually results in actuation of the dispensing means. Thus an initial small force produced by movement of air due to inhalation, moves the deflectable member, which movement causes a first over-centre mechanism to shift over-centre, to produce an increased intermediate force because of the action of the first biasing means, this intermediate force in turn causes a second over-centre

mechanism to shift over-centre to release a larger stored force, typically 30N, from a second biasing means, so as to operate the inhaler. The use of over-centre mechanisms allows for a very substantial force amplification whilst reducing the effect of changes in the co-efficient of friction between moving parts.

The dose actuation mechanism of the present invention is applicable to various inhalers where breath actuation is desirable and where the drug is delivered by the release of stored energy in a spring. For example there is a family of devices known as pump jets in which the drug is delivered under pressure through a nozzle by the action of a mechanical pump, typically a piston pump. These have been used in the past for nasal drug delivery and for perfumes where the droplet size is not as critical as for inhaled drugs but they are now being developed to the point where very small droplets can be produced, suitable for inhalation. The mechanical pump may be driven by a powerful spring which is released by the patient's inhalation. The present invention is suitable for this type of inhaler either used in the mouth or for nasal drug delivery.

There are also some types of dry powder inhaler (DPI) in which the release of the drug particles is assisted by air movement caused by a piston driven by the release of a compressed spring or the drug particles are mechanically released by the direct action of a triggered spring. Again there is a need for a trigger mechanism capable of being reliably triggered by a small force, and thus the present invention is also applicable for these inhalers.

The present invention is also applicable in other fields where force amplification is valuable, for example other drug delivery and medical devices where stored energy is released by a manually operated trigger. Examples of this are needle-free injection systems (both with liquid drug and powder) in which the drug is accelerated towards the patient's skin

through the release of stored energy, auto-injectors in which a conventional syringe and needle are actuated by the release of stored energy and nasal or topical sprays in which the dosing pump is spring actuated.

The invention will now be described by way of example, and with reference to the accompanying drawings in which:

Figure 1 is a section through a base of a breath operated meter dose inhaler according to the preset invention illustrating a first chamber and a second chamber;

Figure 2 is a partial sectional view on the line II-II of Figure 1 showing the second chamber of the inhaler before a dose has been supplied;

Figure 3 is a partial sectional view on the line III-III of Figure 1 showing the first chamber of the inhaler before a dose has been supplied, line I-I is the section along which Figure 1 is taken;

Figure 4 is a partial sectional view on the line II-II of Figure 1 after a dose has been supplied;

Figure 5 is a partial sectional view on the line III-III of Figure 1 after a dose has been supplied;

Figure 6 is a sectional view, to an enlarged scale, on the line II-II of Figure 1 illustrating the interaction of linkage components in the second chamber when delivering a dose;

Figures 7 and 8 are a partial sectional view on the line VII-VII of Figure 1 illustrating the positioning of a cam feature during operation of the inhaler;

Figures 9 and 10 are a sectional view, to an enlarged scale, on the line VII-VII of Figure 1 showing an alternative cam feature;

Figures 11 and 12 show alternative arrangements of the link mechanism and their interaction when delivering a dose;

Figure 13 shows a series of views illustrating a dose counter mechanism used with the meter dose inhaler; and

Figure 14 is a schematic illustration showing individual components of the metered dose inhaler prior to assembly.

Referring to Figures 1, 2 and 3, a preferred embodiment of a breath operated metered dose inhaler (MDI) in accordance with the present invention comprises a hollow outer body 10, typically made of plastics material, which includes a protruding portion 12 with a central aperture 14. The protruding portion 12 and aperture 14 form a mouthpiece from which a dose may be inhaled on operation of the MDI. A mouthpiece cover 16 is pivotally attached to the outer body 10 and in Figure 1 the mouthpiece cover 16 is shown pivoted away from the body 10 to allow access to the mouthpiece.

Internally the body 10 is provided with a supporting platform 18 bearing boss 20. A biasing means 22, such as a spring, is positioned at one end to an inner base wall of body 10 with the other end of the spring 22 engaging with a canister 24 which contains the dosing medium. The canister 24 is held between the spring 22 and the boss 20 provided on the supporting platform 18. The canister 24 is provided with a stem 26 which connects with a passage 28 within boss 20 providing a nozzle 30 through which the dose is emitted.

Two adjacent chambers 32, 34 as shown in Figure 1 are defined within the outer body 10 by the supporting platform 18 and part of the inner wall of the lower part of outer body 10. Chamber 34 as shown in Figure 3 provides an actuation chamber with two apertures, an inlet aperture 36 and an outlet aperture 38, so as to provide an air passage through the first chamber 34 over vane 40. An actuation mechanism 42 is contained in the second chamber 32 shown in Figure 2 and comprises a shaft 44 which is rotatable and attached to vane 40, over-centre links 46, 48 and a biasing means 50. The shaft 44 is attached to the over-centre link 48 by a push rod 52 with over-centre link 46 being attached at one end to a neck of the canister 24 via a push rod 54 and yoke 56.

In Figures 2 and 3, the MDI is shown with the mouthpiece cover 16 opened and is ready for operating to provide a dose. Over-

centre link 46 is held in place by the pressure of the spring 22 acting on canister 24, and thus on push rod 54. The second over-centre link 48 is held in place by the action of the small 7 spring 50. The vane 40 is shown in Figure 3 and not in Figure 2 because typically the vane is mounted in a separate compartment to that containing the over-centre links 46, 48, the shaft 44 and push rod 52.

In use, a patient places his mouth over mouthpiece 12, 14 and inhales. This creates a flow of air through the chambers 32, 34, air entering from inlet aperture 36 and passing via aperture 38 into aperture 14 and thus the patient's mouth. The resulting flow of air over the vane 40 causes the vane to rotate as shown in Figure 5 and so apply a compressive force to the push rod 52. Providing the air flow has reached a pre-determined level which is sufficient to overcome the effect of spring 50, the second over-centre link 48 moves over-centre as shown in Figure 4. Thus the effect of the small spring 50 is to drive linkage 48 against linkage 46. The relative sizes of the springs 22 and 50 and the geometry of both the actuating chambers 32, 34 and the general internal body of the device, are selected to ensure that linkage 46 is driven over-centre by the action of linkage 48.

Figures 4 and 5 show the breath operated MDI after a dose has been released, with corresponding reference numerals to those used in Figure 1, 2 and 3 having been used for the common features. Figures 4 and 5 show how movement of the vane 40 results in over-centre movement of linkage 48 and subsequently linkage 46. The springs 22 and 50 are seen in their extended unbiased positions, where less energy is stored.

A detailed view of how the mechanism 42 works is given in Figure 6. Figure 6a) shows the actuation mechanism before inhalation. As inhalation occurs, a relatively small force, for example of the order of 0.25 N, in rod 52 is sufficient to displace link 48 to the right, even though a larger force, for

example 3.5 N, may be stored in spring 50. In Figure 6b), link 48 now has moved to the right and is pressing against link 46. The force of spring 50, which may have reduced to perhaps 2.5N because the spring has expanded, is sufficient to displace link 46 to the right, although link 46 is supporting a much greater force of perhaps 30N through pushrod 54. In this way the can 24 is released when the mechanism 42 collapses into the final position shown in Figure 6c).

As linkage 46 is driven over-centre, the restraining force on the canister 24 due to the force exerted by the push rod 54 is removed and the spring 22 is free to urge the canister 24 downwards against boss 20, causing a dose to be released through stem 26.

It can be seen that over-centre link 46 exerts a force on the neck of the canister 24 so storing compressive energy in the spring 22, and similarly over-centre link 48 stores compressive energy in spring 50. On inhalation, the vane 40 is deflected by a small force from the patient inhaling, and the vane 40 moves linkage 48 releasing the stored energy in spring 50.

This results in a force cascade, the lesser force of inhalation causing an increased intermediate force at the link 48. This intermediate force is sufficient to deflect link 46, as seen in Figure 6. As link 46 is deflected, rod 54 moves away from the neck of container 24, releasing the stored compressive energy in spring 22 and so providing a further increase in the force. Thus a force of the order of 30N is achieved, which is sufficient to dispense a dose from the stem 26.

After use, the patient closes the mouthpiece cover 16 and thereby replaces the linkages to their original position. The replacement is achieved by reset link 100 as shown in Figures 7 and 8. At one end of the link there is a slot 102 which engages with one drive pin 104 at the pivot of the mouthpiece cover. At the other end of the reset link 100 there are two

pins 106, 108 which are positioned underneath the linkages of the over-centre mechanism 46, 48. A drive pin 110 on the opposite side of the mouthpiece cover seen in Figure 3 and Figure 5 acts against yoke 56 to lift the canister and compress spring 22.

Figure 7 shows the mechanism after the device has been actuated. The over-centre mechanism is dropped and the reset link 100 is in the lower position. The user then closes the mouthpiece cover.

As the mouthpiece cover closes, the two drive pins 104, 110 in the mouthpiece cover take effect. Drive pin 110 engages with yoke 56 and lifts the canister 24 upwards, compressing spring 22. Drive pin 104 is engaged in reset link 100 and lifts this link upwards. The two pins 106, 108 on the reset link then press on features in the over-centre mechanism linkage and return the linkage to an upright position. Figure 8 shows the linkage 340 and the reset link 100 in this position.

The position of the two drive pins 104, 110 in the mouthpiece cover is arranged such that the action of pin 110 is to lift the canister 24 first, before pin 104 takes effect and reset link 100 starts to move the over-centre linkage, thus avoiding an over-stressed condition for the linkages.

When the mouthpiece cover is opened, the process is largely reversed. However the size of slot 102 in the reset link 100 is larger than the diameter of pin 104, thus causing the reset link 100 to remain in position and retain the over-centre link 46 in an upright position until can 24 is lowered in place, then holding the mechanism 42 in position as shown in Figure 8.

An alternative arrangement for resetting the inhaler mechanism is illustrated in Figures 9 and 10. In this case, after use, the patient closes the mouthpiece cover 16, and cam feature 60

inside the cover 16, compresses springs 22 and 50 and also returns the linkages 46 and 48 and the vane 40 to the rest, or cocked position, of Figure 2. Cam feature 62 only acts to compress spring 22 at the same time. Figures 9 and 10 illustrate the cam profiles for cam 60. Cams 60 and 62 are positioned on opposite sides of the cover 16. Cam feature 60 is provided on an internal wall of the mouthpiece cover 16, with cam feature 62 being provided in the corresponding position on the opposite inner wall of the cover 16. The cam features 60, 62 are designed such that during storage the smaller plastics components of the actuation mechanism 42 are not held under stress.

The cam 60 is positioned within the outer body 10, adjacent to the actuation mechanism 42. The lower part of the cam 60 has toothed portions 64, 66 and 68 which engage against pegs 70, 72 and 74 which extend to the side of the linkage mechanisms 46 and 48. In Figure 9, the linkage mechanisms are shown dotted for clarity and this Figure shows the post-triggered condition, i.e. after delivery of a dose.

When the mouthpiece cover 16 is closed as shown in Figure 10, the cam 60, which is directly attached to the cover 16, rotates clockwise and returns the over-centre mechanisms, or links, 46 and 48, to their starting position as required for operation of the inhaler to produce a dose. At the same time a lobe 76 provided on the cam 60 engages on a yoke 78 to lift the canister 24 and so compress the spring 22. The corresponding cam 62 provided within the mouthpiece cover 16 has a lobe identical with lobe 76, but does not have any toothed portions. By setting dimensions correctly, toothed portion 68 and lobe 76 hold the stored force from springs 50 and 22 respectively. By this means, there will be no stress on the linkages 46 and 48 during storage with the mouthpiece cover 16 closed.

The action of closing the cover 16 restores compressed energy within the biasing means so that the breath operated MDI is

once again in the pre-triggering position and is capable of providing a single dose on inhalation. Thus the action of closing the cover 16 ensures the breath operated MDI is primed, priming being achieved by the interaction of the cam surfaces with the pegs and the yoke.

In the present invention, two over-centre mechanisms are used to store and release energy in the springs 22 and 50. The use of at least two over-centre mechanisms which can cascade together ensures that a very small force, as provided by a patient inhaling, can release an intermediate force stored in an intermediate spring 50 and that the intermediate force can then be used to release a larger stored force, typically 30N, which then operates the inhaler. The use of two over-centre mechanisms ensures that the inhaling force does not need to be great and that tight manufacturing tolerances are not required. The two over-centre mechanical linkages can be constructed from a very small number of parts with moulded-in flexible hinges. Thus a breath operated MDI can be provided with a trigger mechanism which does not require precise dimensions for manufacture and which is cost effective.

Figure 11 shows an alternative arrangement of the link mechanism with an additional flexing piece 201 between links 52 and 48. This allows the linkage to be driven with a higher mechanical advantage as follows. Figure 11a) shows the mechanism in the primed position. When the user inhales, the vane pivots around shaft 44 and link 52 presses to the right against link 48. When over-centre mechanism 48 collapses to the right, link 201 allows link 48 to accelerate away from link 52 as Figure 11b). Link 48 then strikes link 46 causing the device to operate as in Figure 11c).

The additional link 201 means that the travel required from arm 202 on shaft 44 is less than the travel required from the mechanism shown in Figure 6. This means that arm 202 is shorter and hence the mechanical advantage available to drive

the trigger mechanism is greater.

Figure 12 shows a different alternative arrangement. In this case there is no spring 50. Instead, there is a link 203 bridging the top of mechanisms 48 and 46 and having a hinged connection to push rod 54. The effect of this is that links 48 and 46 are both held in compression by the compressive force transmitted by push rod 54 as shown in Figure 12a) with the mechanism primed before triggering. In this position, by way of example, the compressive force in push rod 54 may be 30N. If link 203 is constructed with a 10:1 lever ratio, then the compressive forces in links 48 and 46 would be approximately 27N and 2.7N respectively. This means that link 48 can be collapsed by the use of a very low force such as 0.2 or 0.3 N in push rod 52, as described previously. Figures 12b) and 12c) shows the device during operation.

The benefit of this arrangement is that spring 50 is eliminated which not only saves the cost of that component but also reduces the amount of space required by the mechanism.

Figure 13 illustrates operation of a dose counter used with the inhaler and as shown in Figure 14. The count indication is given by two wheels 112, 114. Each wheel comprises a toothed disc portion and a smooth disc, the smooth disc of wheel 112 bearing digits 00 to 20 and wheel 114 bearing digits 0 to 9. When the wheels are viewed together through window 116, the display can show any number from 000 to 209. Typically the display is used as an indication of doses remaining for the patient, ie the display starts at, for example, 200 and counts down to 000.

Wheel 114 is driven round by the action of flexible lever 118 acting on the ratchet teeth moulded on the wheel 114. Reverse movement is prevented by the action of sprung pawl 120 acting against the same ratchet teeth.

Lever 118 contains a pin feature 122 which engages with yoke 56. When the inhaler device is actuated and reset, the can 24 moves first downwards, then upwards. This action causes lever 118 to move, which drives round wheel 114 thereby causing the counter indication to change by one unit. The design ensures that a count is only made when a dose is taken by the user. In the event of the mouthpiece cover 16 being opened and closed without a dose being taken, the can 24 will not have dropped and therefore the counter will not have been actuated.

The smooth disc of wheel 114 has a single protruding feature 124 which is designed to engage in teeth moulded into wheel 112. Once per revolution, this feature will cause wheel 112 to index its position by a single count. Thus, for example wheel 114 may change from 0 to 9, wheel 112 may change from 17 to 16 and the display would change from 170 to 169.

Sprung lever 126 is provided to engage in tooth features 128 in wheel 112 to provide a 'detent' action, retaining the wheel in its correct orientation at all times except when engaged with and driven by the wheel 114.

All the features of the counter are moulded in a single component from plastics material, thus providing a construction which is very simple and low cost.

Figure 14 shows how a breath operated MDI in accordance with the invention could be manufactured with the actuation mechanism being composed of few separate components. Figure 12 is an exploded view of a typical breath operated MDI, comprising an outer body 150, biasing means 22, canister 24, a yoke 78 with protruding leg 152, a mouthpiece element 154, biasing means 50, an actuating section 158, a lower cap element 160 and mouthpiece cover 16. The actuating section 158 is moulded in one piece to include both linkages 46 and 48, push rod 52, shaft 44 and vane 40. The making of multiple parts of the actuation mechanism by moulding in plastics material as a

one piece actuating section 158 simplifies assembly of the breath operated MDI and reduces costs. Drive pin feature 104 is provided on an internal wall of the mouthpiece cover 16, with drive pin 110 being provided in the corresponding position on the opposite inner wall of the cover 16.

It will be apparent to a skilled person that the same effect could be achieved by counters of different physical construction including, for example, concentric indicating wheels or cylindrical indicating wheels which might provide different user benefits in terms of the size of the display digits, the size of the counter package and the number of components.

It will also be apparent to a skilled person in the art that the actuation mechanism 42 as described above may be positioned in various places within the outer body 10, for example above the canister 24, inside the biasing means 22, or alongside the canister 24. The actuation mechanism may also release the main spring 22 by the use of push rods, levers or other links as is readily apparent. The vane 40 could also be independently positioned elsewhere and linked to the two over-centre links by means other than push rod 52. The upper end of linkage 46 could be supported by a flexing arm similar to the arm linked to the upper end of linkage 48 and in such a case the connection to canister 24 could be by push rod or other mechanical link.

Claims

1. A dosing device comprising a dispensing means for dispensing a dose material, and a dose actuation mechanism, in which the dose actuation mechanism comprises a readily deflectable member, and a series of at least two movable elements which transmit and magnify movement of the first element in the series to the last element in the series by a cascade effect, wherein the deflectable member is movable by airflow, and its movement is transferred to the first element of the said series so as to actuate the dispensing means.
2. A dosing device according to claim 1, wherein the moveable elements are pivoted.
3. A dosing device according to claim 1, wherein the moveable elements are arranged to inter-communicate sequentially, so as to actuate the dispensing means.
4. A dosing device according to claim 1, or 2 or 3, wherein the deflectable member is movable in response to inhalation by a patient.
5. A dosing device according to any of the preceding claims, wherein a first biasing means communicates with one moveable element so that as movement is transferred between the moveable elements, energy stored in the first biasing means is released to increase the force associated with the movement.
6. A dosing device according to any of the preceding claims, wherein one moveable element remote from the deflectable member is attached to, or acts on, the dispensing means so as to restrain actuation thereof until the said moveable element is deflected as a result of a cascade action.

7. A dosing device according to any of the preceding claims, wherein the dispensing means is associated with a second biasing means, in which energy is stored in compression, which stored energy is released on movement of a moveable element.

8. A dosing device according to any of the preceding claims, further comprising a lid including at least one cam surface, wherein movement of the lid results in the moveable elements being restored to positions of unstable equilibrium ready to cause actuation of the dispensing means when the cascade is triggered.

9. A dosing device according to any of the preceding claims, wherein the moveable elements are movable into a first position of unstable equilibrium, which movement is translated into stored energy, in the second biasing means, and when triggered, move into a second position of equilibrium, during which movement the stored energy is released from the second biasing means to dispense a dose from the dispensing means.

10. A dosing device according to any preceding claims, wherein the moveable elements each comprise over-centre mechanisms.

11. A dosing device according to any preceding claims, wherein the moveable elements are a first and a second over-centre mechanism, the first over-centre mechanism communicating with first biasing means and the second over-centre mechanism communicating, via the dispensing means, with a second biasing means.

12. A dose actuating mechanism for use in a dosing inhaler, comprising a deflectable member and a cascade of at least two moveable elements, movement of the deflectable member being transferred to and between the moveable elements, in such a manner as to trigger the release of stored energy sufficient to release a dose.

13. A dose actuating mechanism according to claim 12, wherein each moveable element is pivoted and comprises an over-centre mechanism.

14. A dose actuating mechanism according to claim 12 or claim 13, wherein first biasing means and second biasing means communicate with the over-centre mechanisms.

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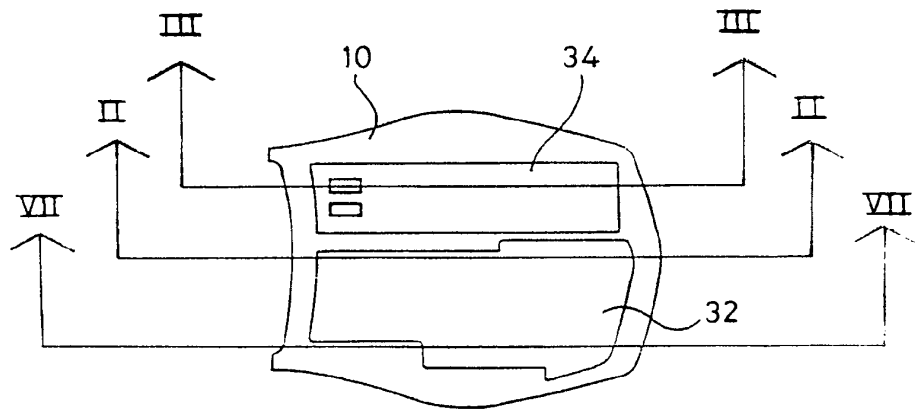


Fig. 1

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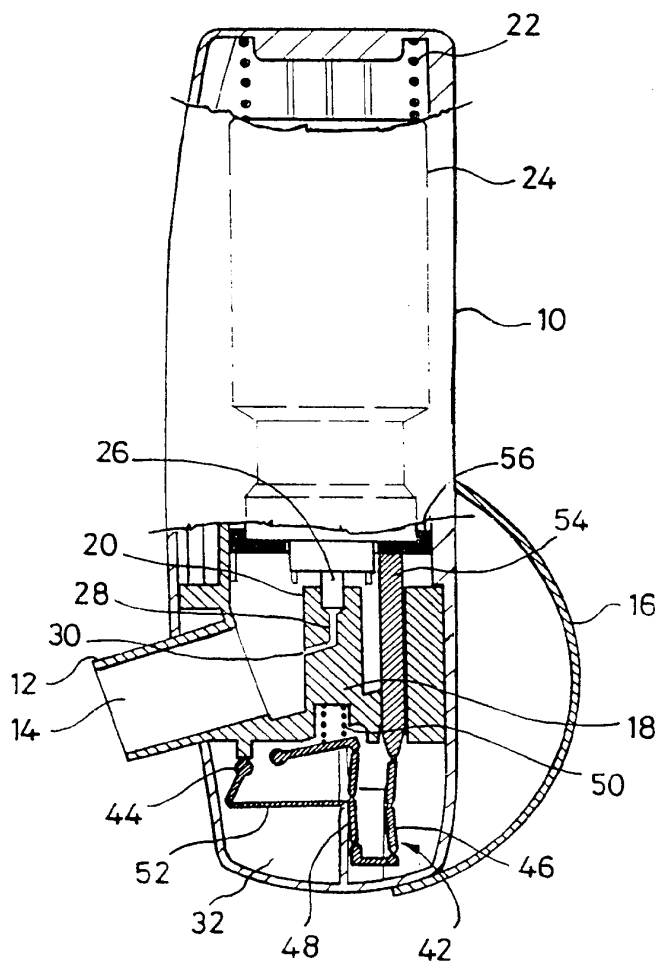


Fig. 2

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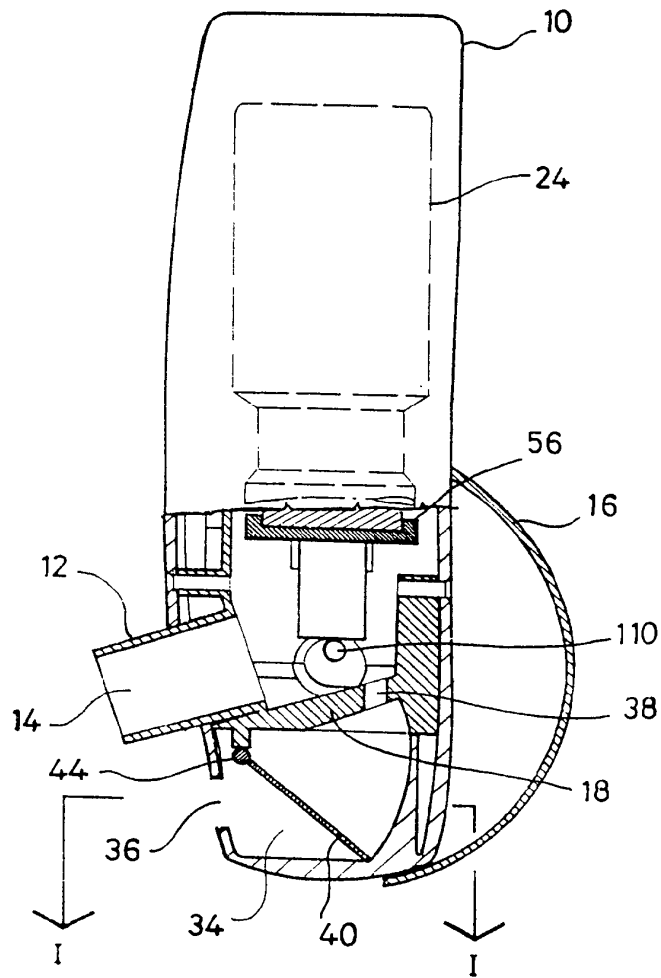


Fig. 3

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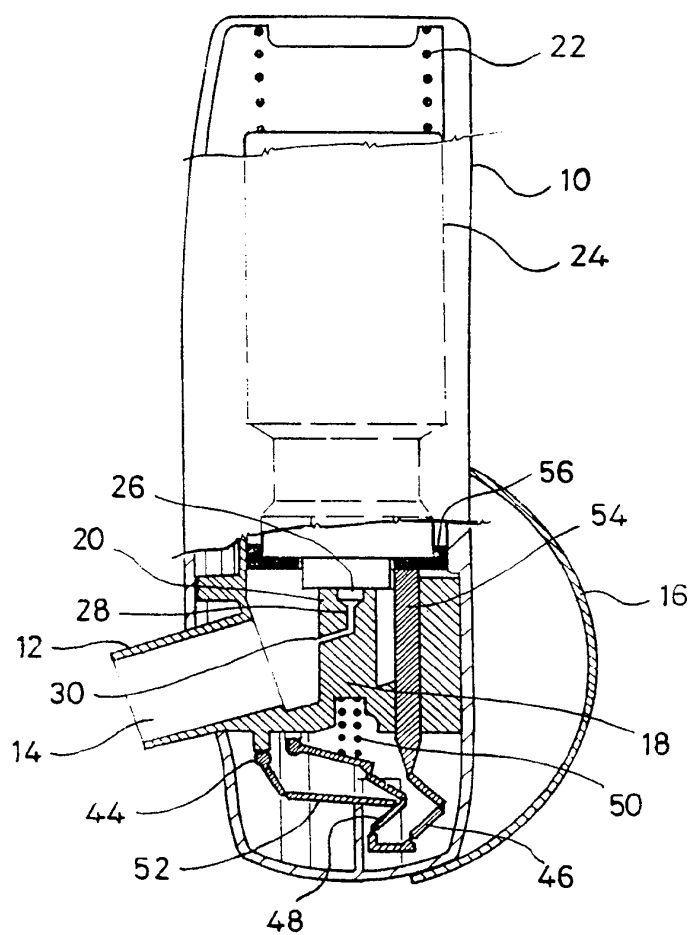


Fig. 4

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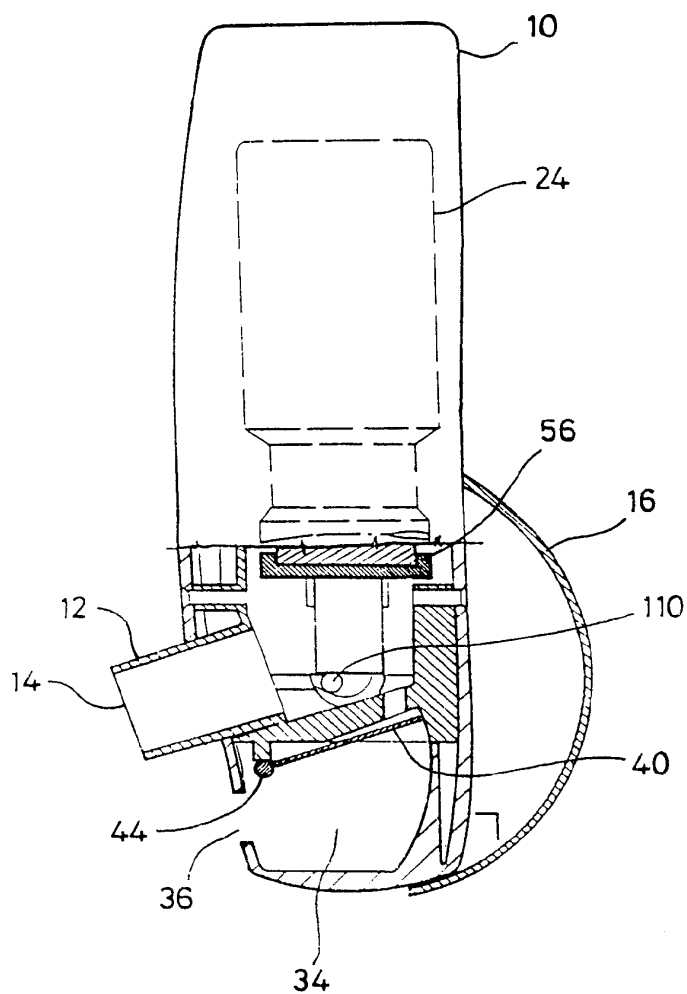


Fig. 5

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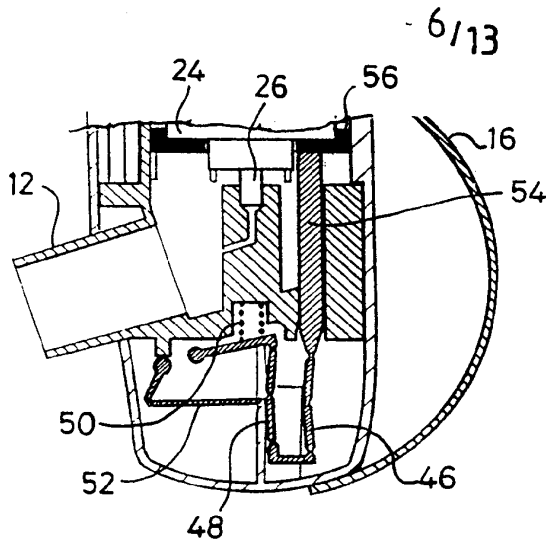


Fig. 6a

Fig. 6b

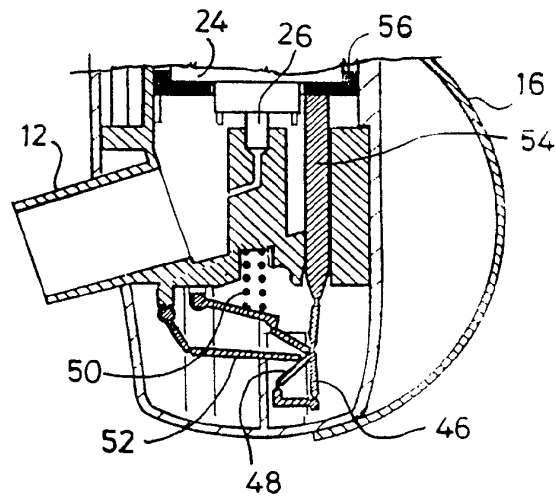
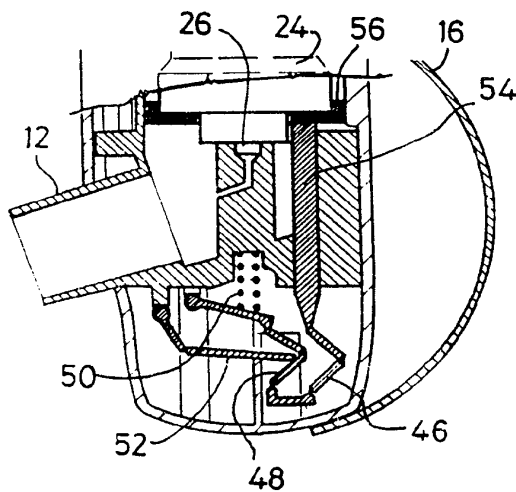


Fig. 6c



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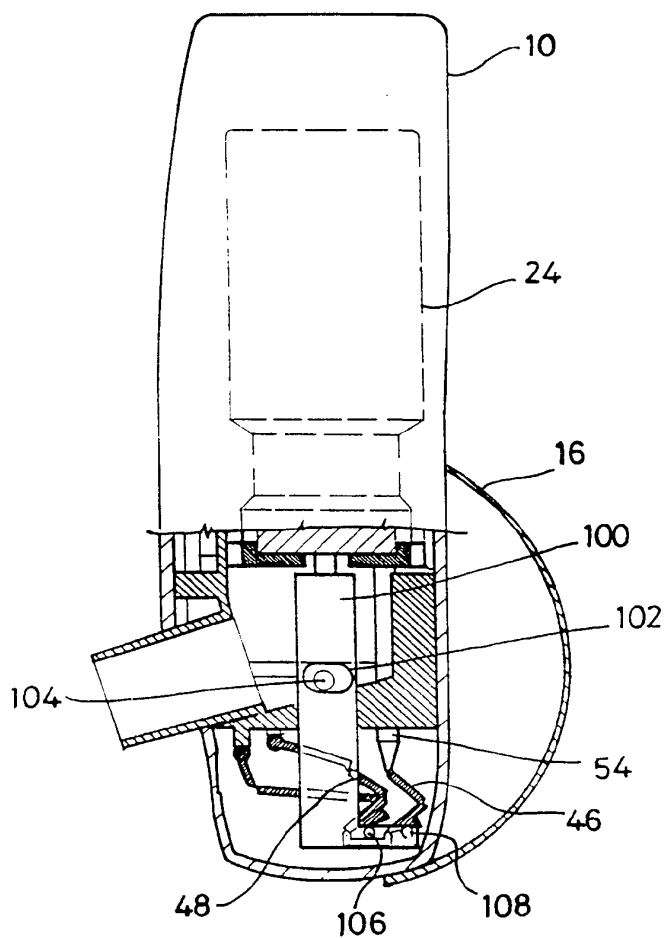


Fig. 7

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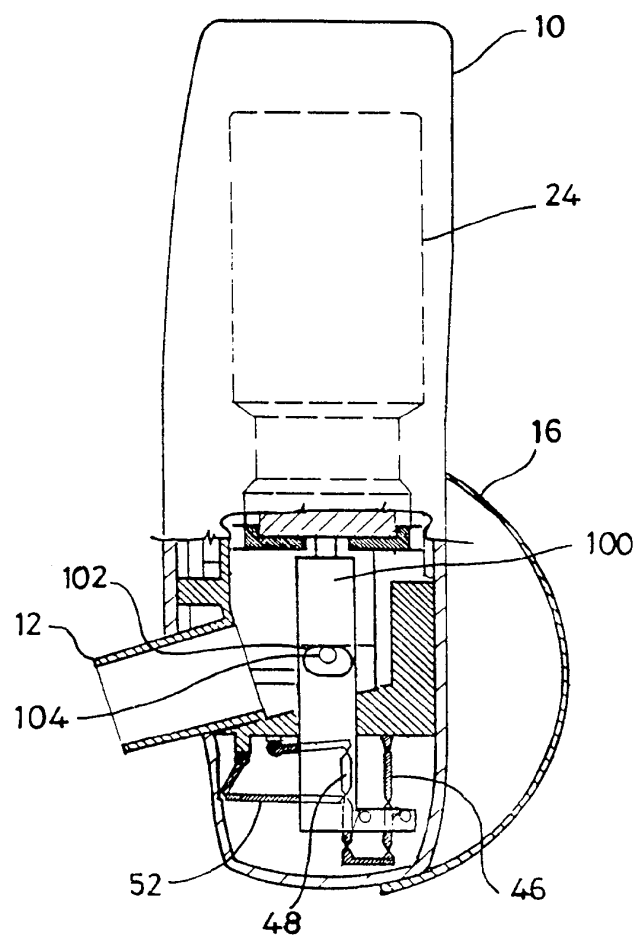


Fig. 8

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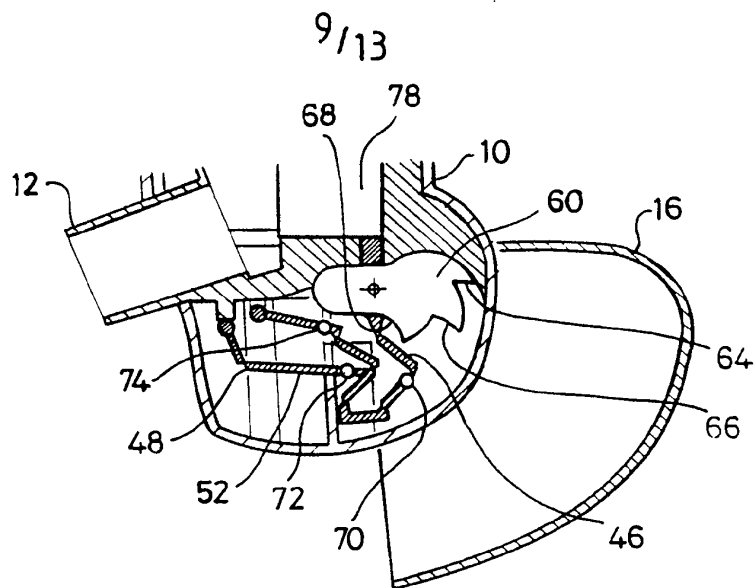


Fig. 9

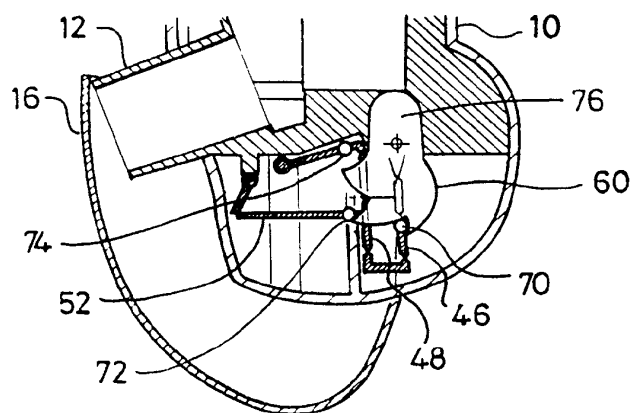


Fig. 10

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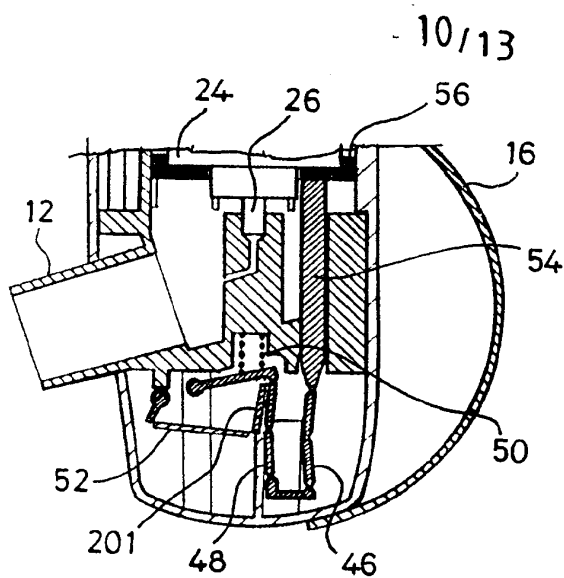


Fig. 11a

Fig. 11b

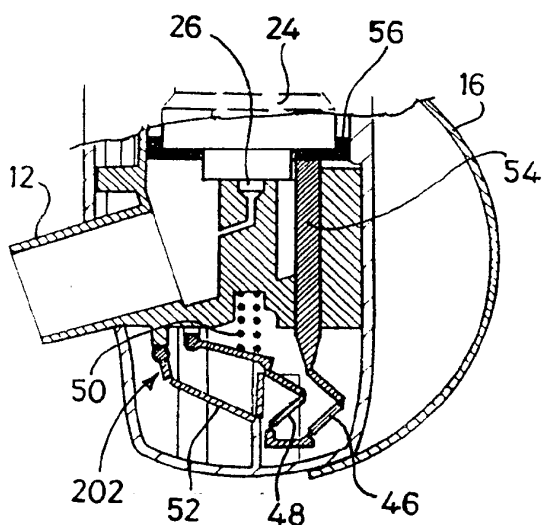
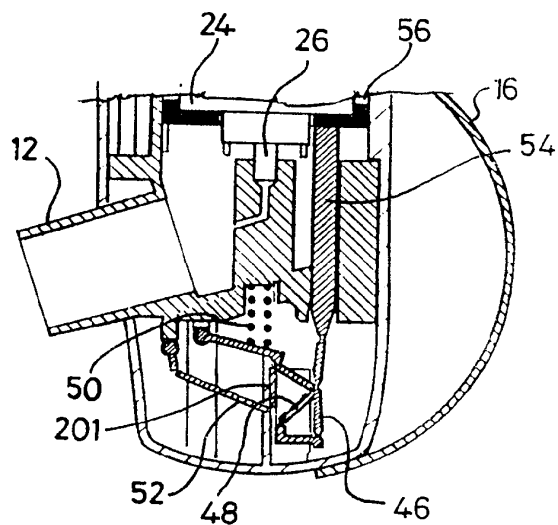


Fig. 11c

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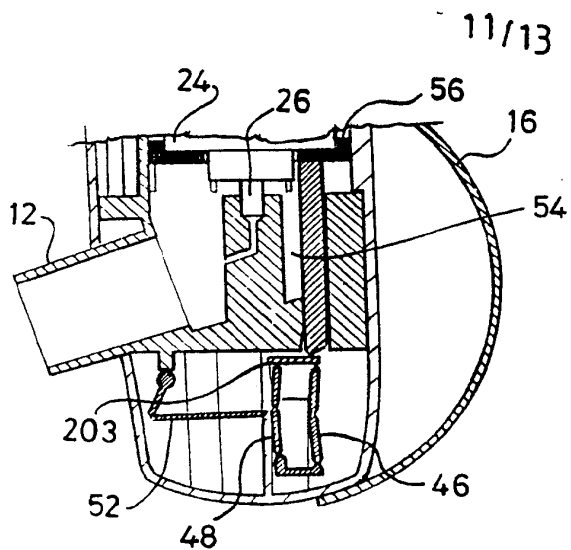


Fig. 12a

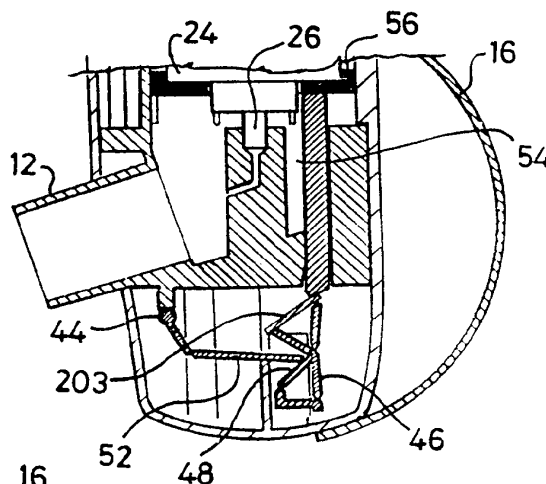


Fig. 12b

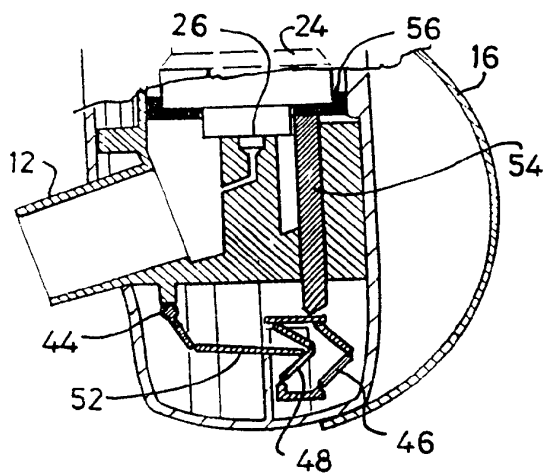


Fig. 12c

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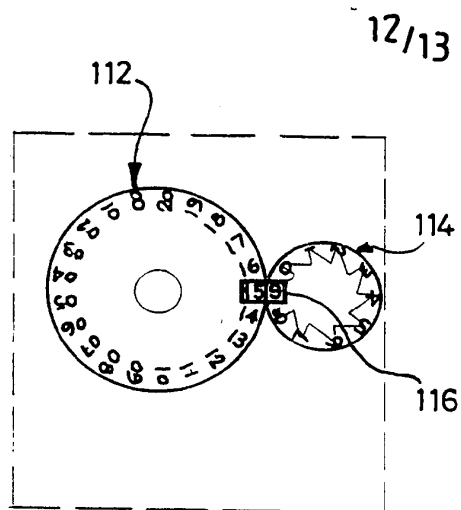


Fig. 13a

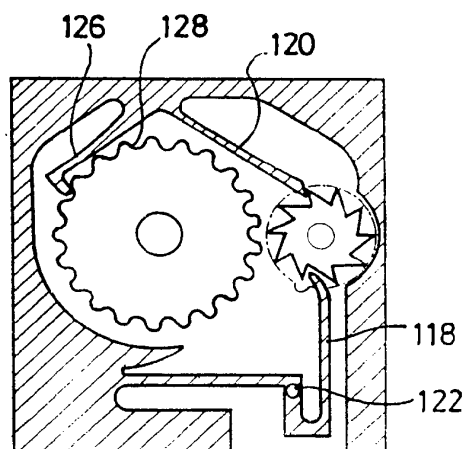


Fig. 13b

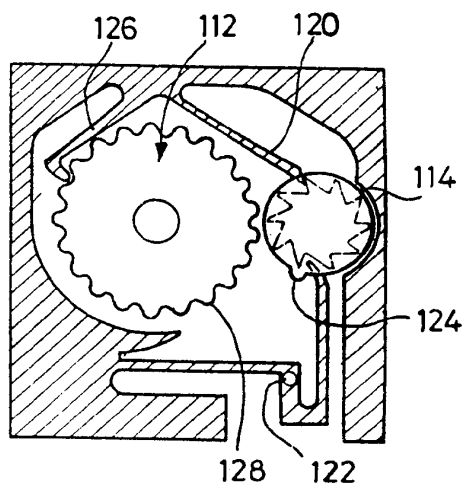
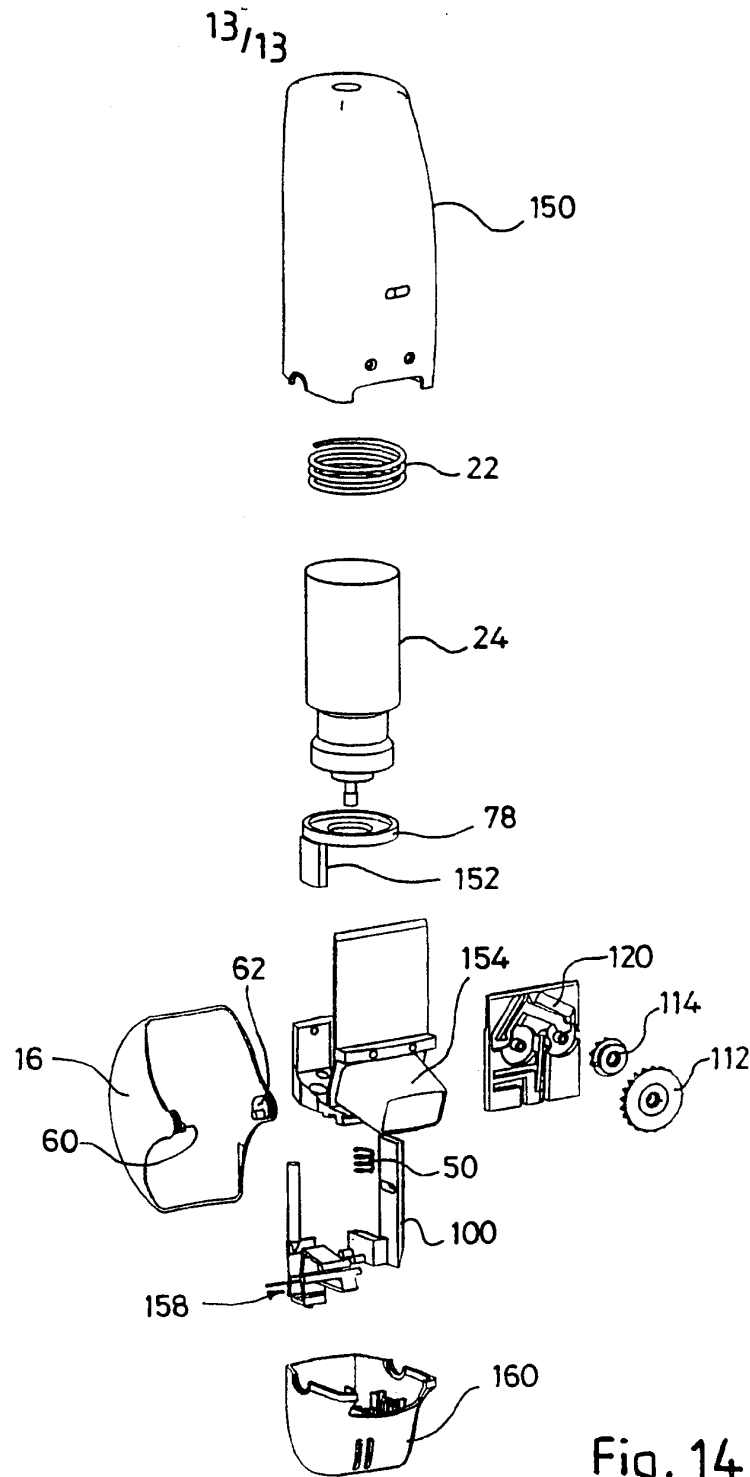


Fig. 13c

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INTERNATIONAL SEARCH REPORT

In ternational Application No
PCT/GB 98/01501

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 546 932 A (GALLI ROSARIA) 20 August 1996 see column 8, line 10 - line 32; figures 7-11	1,4-7,12
A	US 5 060 643 A (RICH MICHAEL ET AL) 29 October 1991 see figures 2,4	1,10,13

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Information on patent family members

International Application No

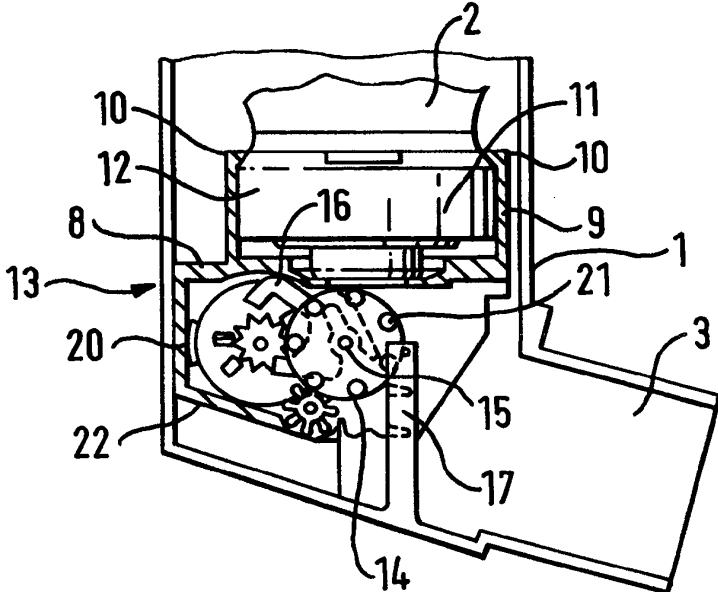
PCT/GB 98/01501

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5546932 A	20-08-1996	IT 1257321 B IT 1257471 B DE 69319107 D EP 0632734 A WO 9318812 A JP 7505075 T	15-01-1996 25-01-1996 16-07-1998 11-01-1995 30-09-1993 08-06-1995
US 5060643 A	29-10-1991	NONE	

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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61M 15/00	A1	(11) International Publication Number: WO 98/56444 (43) International Publication Date: 17 December 1998 (17.12.98)						
(21) International Application Number: PCT/EP98/03377 (22) International Filing Date: 8 June 1998 (08.06.98) (30) Priority Data: <table border="0"> <tr> <td>9711889.7</td> <td>10 June 1997 (10.06.97)</td> <td>GB</td> </tr> <tr> <td>9721875.4</td> <td>16 October 1997 (16.10.97)</td> <td>GB</td> </tr> </table> (71) Applicant (for all designated States except US): GLAXO GROUP LIMITED [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): RAND, Paul, Kenneth [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts SG12 0DP (GB). BRAND, Peter, John [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts SG12 0DP (GB). GODFREY, James, William [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts SG12 0DP (GB). BONNEY, Stanley, George [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Herts SG12 0DP (GB). (74) Agent: PIKE, Christopher, G.; Glaxo Wellcome plc, Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).		9711889.7	10 June 1997 (10.06.97)	GB	9721875.4	16 October 1997 (16.10.97)	GB	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
9711889.7	10 June 1997 (10.06.97)	GB						
9721875.4	16 October 1997 (16.10.97)	GB						
(54) Title: DISPENSER WITH DOSES' COUNTER (57) Abstract There is provided a dispenser suitable for dispensing medicament, particularly medicament for use in the treatment of respiratory disorders. The dispenser comprises a housing (1) having a support (5); a container (2), locatable within said housing (1), having an outlet member, wherein said container (2) is movable relative to the housing (1) to enable dispensing therefrom and said outlet member is connectable with said support (5) to prevent relative movement therebetween; and a dose indicator (13, 43), locatable within said housing (1). The container (2) and dose indicator (13, 43) are reversibly removable from the housing (1) as a single unit. 								

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DISPENSER WITH DOSES' COUNTER

5 The present invention relates to a dispenser having an actuation indicator for indicating the number of actuations thereof. In particular, the invention relates to metered dose inhalers by means of which medicaments contained in an aerosol container may be administered to a patient.

10 It is well known to treat patients with medicaments contained in an aerosol, for example, in bronchodilator therapy. It is also known to use for such therapy, medicaments which are contained in an aerosol and are administered to a patient by means of an inhalation device comprising a tubular housing or sleeve in which the aerosol container is located and an outlet tube leading out of the tubular housing. The aerosol containers used in such inhalation devices are
15 designed to deliver a predetermined dose of medicament upon each actuation by means of an outlet valve member at one end which can be opened either by depressing the valve member while the container is held stationary or by depressing the container while the valve member is held stationary. In the use of such devices, the aerosol container is placed in the tubular housing with the
20 outlet valve member of the container communicating via a support with the outlet tube, for example a nozzle or mouthpiece. When used for dispensing medicaments, for example in bronchodilation therapy, the housing is then held by the patient in a more or less upright condition and the mouthpiece or nozzle of the inhalation device is placed in the mouth or nose of the patient. The
25 aerosol container is pressed towards the support to dispense a dose of medicament from the container which is then inhaled by the patient.

A disadvantage arising from use of such known devices is that the patient cannot determine the amount of medicament in the container at any given time.
30 In an extreme case this could mean that the patient, possibly suffering from severe bronchospasm and needing a dose of medicament, will find that the container will not dispense a dose because its contents have already been exhausted.

US Patent No. 4817822 describes an aerosol dispenser of the type described above having a dose indicating device which, in a first embodiment is removably attached to the end of the protruding portion of the aerosol container. The operating mechanism of the dose counter is located within a housing which
5 extends from the end of the aerosol container along the external surface of the tubular housing. It is important with inhalation devices containing medicament that the contents of the aerosol container are clearly marked to ensure that the patient knows exactly what medication is contained. One disadvantage associated with this positioning of the dose indicating device is that the device
10 obscures at least a part of the aerosol container and housing which creates labelling difficulties.

A further disadvantage of the device described is that if the dose indicating device is removably attached to the aerosol container, it is possible that the
15 dose indicating device may become separated from its aerosol container with the result that the aerosol dispenser could be used without the dose indicating device, or the actuating mechanism of the indicating device could be tampered with leading to a false reading when the indicating device is re-attached to the dispenser. With patients having several different inhalers, it could even result in
20 the indicating device being re-attached to the wrong dispenser.

In a second embodiment described in US4817822 the operating mechanism of the dose indicating device is located within a compartment in the housing and is actuated by means of an actuator member attached to the aerosol container. In
25 this embodiment, once the aerosol container is fitted into the housing it cannot be removed. This makes cleaning of the housing very difficult. Even if the container were removable, the operating mechanism of the dose indicating device would be vulnerable to damage when washing with water, soap, disinfectant or antiseptic solutions. This is important because sprays of many
30 aerosol formulations leave residues which can entrap dust and dirt particles. Some provide a media for the growth of undesired micro-organisms. If the growth of these micro-organisms is unchecked, they can serve as a source of infection for the patient and will often introduce pathogens into the patient's respiratory tract.

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WO96/16686 describes an aerosol dispenser wherein the operating mechanism of the dose indicating device is electronic and wherein the actuating member comprises a microswitch set into the wall of the housing. The electronic counting mechanism and microswitch are contained within a hermetically sealed enclosure. However, electronic assemblies of this type are relatively expensive compared to equivalent mechanical mechanisms, typically costing five or six times as much to produce depending on quantities manufactured. Such expense must ultimately be borne by the customer and may be prohibitive.

US5482030 describes an aerosol dispenser having a mechanical dose indicator device located in and connected to the housing in the vicinity of the outlet tube of the aerosol container when fitted. Its mechanical construction makes it difficult to seal against moisture ingress and so this dispenser again is difficult to wash without damaging the operating mechanism of the dose indicating device.

Many different pharmaceutical products are sold in the form of aerosol containers as discussed above, requiring different sized container bodies and/or valves according to the required specifications. It is therefore normal for there to be dimensional variations between different aerosol containers. Even between the same products there can be dimensional variations due to manufacturing tolerances. One problem which is common to all of the dose indicating devices discussed above is that the indicator mechanism, which is actuated by means of a switch which detects relative movement between the container body and housing, lacks any means of compensating for dimensional variations between different aerosol containers. Hence, the indicators described must be dimensioned according to the product with which they are to be used, and so will not be interchangeable with other products. Furthermore, in order for the dose indicators to work properly, the dimensions of the indicator, aerosol container and housing must be accurate.

It is an object to provide a dispenser having an actuation indicator which overcomes at least some of the above described disadvantages. It is a further object to provide such a dispenser which from the point of view of the patient closely resembles currently marketed dispensers in both external appearance and operation.

According to one aspect of the present invention there is provided a dispenser for dispensing medicament comprising a housing having a support; a container, locatable within said housing, having an outlet member, wherein said container is movable relative to the housing to enable dispensing therefrom and said outlet member is connectable with said support to prevent relative movement therebetween; and an actuation indicator, locatable within said housing, wherein the container and dose indicator are reversably removable from the housing as a single unit.

Suitably, the actuation indicator is engagable with the container in the vicinity of the outlet member. More preferably, the actuation indicator is engagable with the outlet member.

Suitably, the actuation indicator is provided with a grip member which is engagable with a neck portion of the container. Preferably, the neck portion is adjacent to or on the outlet member.

Suitably, the container is an aerosol container.

Suitably, the housing is provided with an outlet, more preferably in the form of a mouthpiece. Preferably, the dispenser comprises a passage through which dispensed doses may pass from the container to the outlet.

Suitably, the container provides measured doses.

Suitably, the actuation indicator indicates the number of doses dispensed from or remaining in the container.

Suitably, the actuation indicator comprises an indexing mechanism actuated by a predetermined movement of the aerosol container relative to the housing.

Preferably, the indexing mechanism comprises a lost motion coupling to allow and compensate for excess movement ('overtravel') of the aerosol container relative to the housing.

By use of a lost motion coupling it is possible to create an actuation indicator of one size which can accomodate valves and actuators made within a wide range of manufacturing tolerances and can even fit a range of dispensers made to different dimensions.

Suitably, the indexing mechanism indexes the actuation indicator by means of a predetermined rotary movement of a first member driven by movement relative to a second member during actuation of the aerosol dispenser.

Suitably, the second member remains stationary relative to the housing during actuation of the aerosol dispenser.

Suitably, the first member comprises a pinion carried by a shaft through the lost motion coupling and the second member comprises a rack. Alternatively, the first member comprises a yoke and the second member comprises a post engaged by the yoke through the lost motion coupling.

Preferably, the lost motion coupling comprises a friction drive mechanism.

Suitably, the dispenser is a breath operated inhaler which is actuatable in response to the inward breath of a user.

According to a particularly preferred aspect of the present invention there is provided an aerosol dispenser comprising a housing in which a container is removably located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the container and having a passage through which the contents of the container may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being moveable relative to the outlet and housing to dispense its contents in measured doses, and a dose indicating device having a dose indicator for indicating the number of doses dispensed from or remaining in the container, characterised in that the dose indicating device is tightly connected to the container in the vicinity of the outlet member, such that the container and dose indicating device may be removed from the housing as a single unit.

According to a further aspect of the present invention there is provided an actuation indicating device for use with a dispenser comprising a housing and a container, locatable within said housing, having an outlet member, the actuation
5 indicating device comprising attachment means to enable attachment to the container.

Suitably, the attachment means comprises a grip member which firmly engages a neck portion formed around the container. More preferably, the neck portion is
10 located at the connection between the container and outlet member.

According to a particularly preferred aspect of the present invention the actuation indicating device has an actuation indicator for indicating the number of doses dispensed from or remaining in the container, wherein the actuation
15 indicating device comprises attachment means to enable tight connection to the container in the vicinity of the outlet member.

By fixing the actuation indicating device to the container in the vicinity of the outlet member may be possible to make use of the physical dimensions of the crimped ferrule of standard containers to provide a tight snap fit between the
20 dose indicating device and aerosol container for easy assembly yet which once assembled cannot be easily separated. This ensures that the actuation indicator presents accurate information concerning the container with which it is assembled.

25 In a preferred aspect, the dispenser is a metered dose inhaler comprising a housing in which the container is removably located, an outlet leading from the housing, a support in the housing arranged to receive the outlet member of the container and having a passage through which the contents of the container
30 may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being moveable relative to the outlet and housing to dispense its contents in measured doses, and a window through which the dose indicator may be viewed.

5 The location of the dose indicator in the vicinity of the outlet member of the container in a metered dose inhaler provides the advantage that visually and operationally the device may appear very similar to current marketed metered dose inhalers without dose indicating devices such that when switched to the metered dose inhaler according to the invention, patients perceive little change over their conventional dispensers, so creating minimal impact upon patients and their use of the device.

10 A dispenser according to the invention will now be described with reference to the accompanying drawings in which:

Fig. 1 is a section through a standard inhalation device comprising an aerosol dispenser;

15 Fig. 2 is a section through the dose indicating device as fitted to an aerosol dispenser in an inhalation device;

Fig 2a is a sectional view of an aspect of a dose indicating device herein;

20 Fig. 3 is a perspective view of a counting mechanism used in the dose indicating device of Fig. 2;

Fig. 4 shows the sequence of operation of the counter mechanism of Fig. 3;

25 Fig. 5 shows a lateral and a longitudinal section through a second embodiment of the dose indicating device as fitted into the housing of an inhalation device;

Fig. 6 shows an exploded view of a dose indicating device according to a third embodiment of the invention;

30 Fig. 7 shows another exploded view of the dose indicating device of figure 6 together with an aerosol container and housing;

35 Fig. 8 shows a schematic section through an inhalation device comprising the dose indicating device of figure 6 in a rest position; and

Fig. 9 shows a schematic section through the inhalation device of figure 8 in an actuated position.

5 The standard metered dose inhaler shown in Fig 1 comprises a tubular housing 1 in which an aerosol container 2 can be located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. An outlet 3 leads laterally from the closed end of the housing 1. In the embodiment illustrated, the outlet 3 is in the form of a mouthpiece intended for insertion into the mouth of the patient but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

15 The aerosol container 2 has an outlet valve stem 4 at one end. This valve member can be depressed to release a measured dose from the aerosol container or, alternatively, the valve stem 4 can be fixed and the main body of the container can be moved relative to the valve member to release the dose.

20 As shown clearly in Fig 1, the aerosol container 2 is located in the housing 1 so that one end protrudes from its open top. Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1. A support 5 is provided at the lower end of the housing 1 and has a passage 6 in which the valve stem 4 of the aerosol container 2 can be located and supported. A second passage 7 is provided in the support 5 and is directed towards the interior of the outlet 3.

25 Thus, when the parts are in the positions shown in Fig 1, the protruding portion of the aerosol container 2 can be depressed to move the container relative to the valve stem 4 to open the valve and a dose of medicament contained in the aerosol will be discharged through the passage 7 and into the outlet 3 from which it can be inhaled by a patient. One dose will be released from the aerosol container each time it is fully depressed.

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Fig 2 shows the lower part of a device similar to that of Fig 1 but incorporating a dose indicating device according to the invention. The dose indicating device comprises a body 8 firmly attached to the aerosol container by means of tubular portion 9 formed with grips 10. Tubular portion 9 tightly engages the periphery

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of valve ferrule 11 while a grip in the form of lip 10 engages around neck 12 of valve ferrule 11 which is formed during assembly when valve ferrule 11 is crimped onto aerosol container 2. Thus the tubular portion 9 and lip 10 form a tight connection to the aerosol container which once assembled by pushing the tubular portion 9 over the valve ferrule 11 cannot easily be disassembled.

Below tubular portion 9, body 8 forms a cradle 22 for mounting counter mechanism 13 and drive pinion 14. Drive pinion 14 is friction mounted on counter mechanism drive shaft 15. Drive pinion 14 is formed with a number of teeth or pegs 21 which can engage with a number of recesses or grooves formed on post 17 in the form of a rack moulded inside housing 1 and extending from the base of the housing 1 parallel to valve stem 4.

Whilst in the embodiment shown in Fig 2 the post 17 forms a moulded part of the housing other variations can be envisaged in which the post 17 forms a part of the dose indicating device itself. For example, Fig 2a shows a simplified representation of a dose indicating device in which the head of post 17 is receivable within a recess provided in the body 8 of the device. Teeth formed on the post 17 engage corresponding teeth on drive pinion 14. Spring 28 acts such as to urge the post from the recess. The protruding lip 24 of the post 17, however, abuts stop 26, thereby retaining at least a portion of the post 17 within the recess.

As shown in Figs 3 and 4, drive shaft 15 is connected to driver yoke 16 of counter mechanism 13. Driver yoke 16 has two switching latches 18a and 18b spaced either side of star wheel 19 such that driver yoke 16 may tilt about the axis of drive shaft 15 between a first position shown in Fig 4b in which switching latch 18a engages one side of star wheel 19, and a second position shown in Fig 4d in which switching latch 18b engages the other side of star wheel 19. Star wheel 19 is connected through a mechanism, similar to that described with reference to reference numerals 2 to 8 in Figs 1 to 3 of European Patent No. 0280104, to three digit wheels 33, which have numbers printed on their circumferential faces as described below. When located in the housing 1, counter mechanism 13 is small enough to be located to the sides of and behind

support 5 so as not to interfere with the aerosol flume as it emerges from passage 7.

5 The aerosol container 2 may be supplied to the patient with the dose indicating device ready assembled thereto. Alternatively, the housing 1 may be supplied to the patient with the dose indicating device located in the position shown in Fig 2 and the aerosol container 2 supplied separately. In this case, the patient is instructed to insert the aerosol container 2 into the housing 1 with the valve stem first. Upon first insertion of the container into the housing, the tubular portion 9
10 and lip 10 of the dose indicating device ride over the periphery of valve ferrule 11 of the aerosol container 2 until lip 10 snaps around neck 12. Thereafter, the dose indicating device is attached to the aerosol container 2.

15 Other means of attachment of the dose indicator to the container are envisaged including adhesive attachment; use of welded shrink sleeves; heat forming; crimping; ultra-sonic welding; and by the presence of an o-ring elastomer on the container which is fixedly piercable by barbs on the attachment member of the dose indicator. In one aspect, permanent means of attachment are preferred.

20 To actuate the device, the protruding portion of the aerosol container is depressed as described above with reference to Fig. 1. As the aerosol container carrying the dose indicating mechanism moves within housing 1, drive pinion 14 starts to turn, through its engagement with post 17, causing rotation of drive shaft 15 and driver yoke 16. As driver yoke 16 tilts with rotation of drive shaft 15 switching latch 18a moves into engagement with star wheel 19 (Fig 4a)
25 causing an incremental anti-clockwise rotation of a half tooth pitch of the star wheel until the switching latch 18a can move no further in this direction, the switching latch being positioned between two adjacent teeth of the star wheel (Fig 4b). At this point, drive shaft 15 cannot rotate any further and any further
30 movement of the aerosol container into housing 1 results in drive pinion 14 continuing to rotate through its engagement with post 17 by virtue of the friction coupling between pinion 14 and drive shaft 15.

35 When the valve stem 4 has reached its fully depressed position and a metered dose of medicament has been discharged from the aerosol container, the

aerosol container is allowed to return to its original position. As the aerosol container and dose indicating mechanism return to their original position, drive pinion 14 starts to rotate in the opposite direction together with drive shaft 15 and driver yoke 16. Thus, driver yoke 16 tilts such that switching latch 18a moves out of engagement with star wheel 19 while switching latch 18b moves into engagement therewith (Fig 4c), causing further incremental anti-clockwise rotation of a half tooth pitch of the star wheel until switching latch 18b can move no further in this direction (Fig 4d). Again, drive shaft 15 cannot rotate any further at this point and any further movement of the aerosol container out of housing 1 results in drive pinion 14 continuing to rotate through its engagement with post 17 by virtue of the friction coupling between pinion 14 and drive shaft 15. In this way it can be seen that the friction coupling acts as a lost motion coupling which allows the dose indicating device to be used with aerosol containers having valves with different lengths of travel of valve stem during actuation.

Each time the aerosol dispenser is actuated the star wheel is made to rotate through two incremental anti-clockwise movements as described above. These movements are translated through the counter mechanism into appropriate movements of the digit wheels 33, one number on each of the printed circumferential faces of the digit wheels being clearly visible through the widow at the back of the housing 1 (as shown in Fig 2), to indicate that a further dose of medicament has been dispensed. By having three digit wheels 33 it is possible for the dose counter to be used to count hundreds of doses. Clearly if fewer than one hundred doses are to be contained within the dispenser, the dose counter could comprise fewer digit wheels. Alternatively, if a thousand or more doses are to be contained, then one or more additional digit wheels could be added as appropriate.

To remove the aerosol container 2 from the housing for cleaning, the aerosol container 2 may be withdrawn from the housing 1 in the usual manner. As the container is withdrawn, the friction coupling between drive pinion 14 and drive shaft 15 allows such further movement as is required for the drive pinion to come out of engagement with the post 17 without causing any further indexing of the counter mechanism. Once removed, the housing 1 may be cleaned as

described without fear of interfering with or damaging the dose indicating device, which remains firmly connected to the aerosol container 2.

5 When the housing 1 is clean, the aerosol container 2 with dose indicating device may be re-inserted into the housing 1. During insertion, drive pinion 14 will engage post 17 and start to rotate until the aerosol container reaches its normal rest position with the valve stem 4 located in support 5. As the drive pinion 14 rotates, the friction coupling will act as a lost motion mechanism as described above, allowing for any travel of the aerosol container as between first
10 engagement of drive pinion 14 and post 17, and location of valve stem 14 in support 5. In this way, the friction coupling automatically accommodates and compensates for different lengths of valve stems protruding from the ferrule.

15 Fig 5 shows an alternative lost motion coupling mechanism which may be used in an aerosol dispenser according to the invention. In this embodiment, instead of a pinion, driver yoke 16 is formed with two resilient arms 30 between which post 17 is grippingly engaged (Fig 5a). Post 17 is formed with ribs on its surface (not shown) which provide a rough surface finish to create the level of friction required between arms 30 and post 17 such that arms 30 will grip post 17 until
20 the load applied overcomes the friction.

Upon actuation of the device, as the aerosol container and dose indicating mechanism move, the friction engagement between arms 30 and post 17 cause driver yoke 16 to tilt about the axis of shaft 15 (not shown in Fig 5), so moving
25 switching latch 18a into engagement with star wheel 19 as discussed in relation to the first embodiment. As switching latch 18a reaches its limit of travel, driver yoke 16 can move no further, and any further movement of the aerosol container into housing 1 results in arms 30 slipping down post 17 by virtue of the friction coupling. Upon return to its original position, driver yoke 16 tilts in the other
30 direction until switching latch 18b moves into engagement with star wheel 19 and can move no further. Any further movement of the aerosol container out of housing 1 results in arms 30 slipping up post 17.

35 Figures 6 to 9 show an inhalation device fitted with an electro-mechanical dose indicating device according to the invention. As with the mechanical

embodiments discussed above, the dose indicating device comprises a body 40 firmly attached to the aerosol container by means of tubular portion 41 formed with grips (not shown). Tubular portion 41 tightly engages the periphery of valve ferrule 11 while a grip in the form of a lip engages around neck 12 of valve ferrule 11. Thus the tubular portion 41 and lip form a tight connection to the aerosol container which once assembled by pushing the tubular portion 41 over the valve ferrule 11 cannot easily be disassembled.

Below tubular portion 41, body 40 forms a cradle for mounting counter mechanism 43, and defines a chamber for accommodating switch slide 44. Switch slide 44 is a cylindrical washer made of silicone rubber and having a bore of such a diameter that, with the can and dose indicating device mounted within the actuator housing, it provides a friction fit on pin 45, which is moulded in the housing and protrudes through a hole in body 40. The friction fit of switch slide 44 on pin 45 ensures the switch slide will not move along the pin unless pushed. Two contact members 46, 47, both of which comprise a switch contact and a circuit board contact, and one of which further comprises a battery contact, are mounted such that the battery and circuit board contacts are in constant contact with a first terminal of the battery 48 and printed circuit board (PCB) 49 respectively. The switch contacts do not contact each other but are positioned either side of pin 45, and define the upper limit of movement of the switch slide 44 within its chamber. Thus, when switch slide 44 is in its upper position as shown in figure 9, it makes contact with both switch contacts, so closing the circuit between them due to the electrical conductivity of the silicone rubber of the switch slide. Although in the embodiment described the switch slide is made of silicone rubber, it will be appreciated that it could alternatively be made of a non-conductive rubber having an insert at its upper face made of metal or some other conductive material.

In addition to its connections with contact members 46, 47, PCB 49 also has connections to the other terminal of the battery and to a three digit liquid crystal display (LCD) 50 in a conventional manner. The PCB comprises an application specific integrated circuit (ASIC), which provides the logic by which the dose indicator can be checked, programmed and made operational, as discussed in more detail below. to keep a record of how many times the switch contact circuit

is closed and drives the LCD to display the number of doses remaining in the aerosol container. The ASIC is thus designed and programmed accordingly in a known manner.

5 Instead of a digital display, the LCD could alternatively be formatted to display an analogue indication. When the aerosol container is mounted in the actuator housing, LCD 50 is visible through window 20. In the embodiment depicted in figure 7, the LCD and window are located at the back of the housing, but they could equally be located at the front or some other part of the housing.

10 The Counter mechanism 43 is small enough to be located to the sides of and behind the stem block (support 5) moulded in housing so as not to interfere with the aerosol flume as it emerges.

15 To actuate the device, the protruding portion of the aerosol container when fitted into the actuator housing is depressed as described above. As the aerosol container carrying the dose indicating mechanism moves within the housing from its rest position (shown in figure 8), the chamber accommodating switch slide 44 moves down until the upper face of switch slide 44, which is mounted
20 on pin 45, meets switch contacts 46, 47 and the switch circuit is closed. This causes the ASIC to decrement the number displayed by the LCD 50. As the aerosol container continues to move, a metered dose of medicament is discharged from the valve, while switch slide 44 is pushed down along pin 45 by virtue of the friction fit of the switch slide on the pin until the valve stem reaches
25 its limit of travel and the aerosol container moves no further (figure 9). In this way, it can be seen that the friction fit of the switch slide 44 on pin 45 allows for over-travel of the valve stem after the switch circuit has been closed, so acting as a lost motion coupling. The aerosol container is then allowed to return to its original position within the housing, and as it returns, the chamber
30 accommodating switch slide 44 moves up breaking the switch circuit as switch contacts 46, 47 move away from switch slide 44. Body 40 then meets the lower face of switch slide 44 and draws the switch slide up along pin 45 until the valve stem returns to its rest position (figure 8).

Because the dose indicating device is designed to be suitable for use in connection with different sized aerosol containers containing different numbers of doses to be delivered, the ASIC is designed to be factory set in accordance with the size of aerosol container with which the dose indicating device is assembled. After assembly of the dose indicating device and first connection of the battery, the ASIC enters a self-test mode. After this, the programming mode may be entered by activating the switch, allowing it to be programmed to count down from the appropriate number of doses (e.g. 200, 120, 80 or 60). This may be done automatically on a packing line. After programming has taken place, the ASIC enters the counting mode, where the LCD decrements upon closing of the switch contact circuit. When the count of zero is reached, the ASIC is designed to prevent the count from decrementing any further in a known manner. In order to prevent spurious readings due to the effects of switch 'bounce', the ASIC may be designed to decrement only after the switch circuit has been closed for a predetermined length of time in a known manner. In the event of the aerosol container getting jammed in the actuated position after operation, or the switch circuit jamming closed due to mechanical damage or contamination, the ASIC may be designed to blank the LCD to alert the user that there is a problem.

As with the other embodiments of the invention described above, the aerosol container may be withdrawn from the actuator housing in the usual manner. As the container is withdrawn, body 40 draws the switch slide up along pin 45 until it clears the pin altogether. Once removed, the housing may be cleaned without interfering with or damaging the dose indicating device, which remains firmly connected to the aerosol container.

During re-insertion of the aerosol container, which can only occur when the body of the dose indicating device is correctly orientated with respect to the housing by virtue of their respective shapes, switch slide 44 engages and is pushed up by pin 45 until the upper face meets the switch contacts. Further insertion of the aerosol container results in switch slide 44 being pushed down along pin 45 until the valve stem is seated back within support 5.

It will be appreciated that by programming of the ASIC, one design of dose indicating device could be used in conjunction with a range of aerosol containers

of various capacities. By virtue of the switch mechanism, the same design of dose indicating device can also be used in conjunction with a range of different valves having different lengths of valve stem and different stem travel specifications.

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Whilst the present invention has been described in detail in respect of a metered dose inhaler actuable manually by the patient it will be appreciated that other actuation mechanisms can be substituted. In particular, the use of a breath operated inhaler in which the actuation is assisted, and is responsive to,

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The dispenser of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders. Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or nedocromil; antiinfectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti- inflammatories, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimiterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro- α -[[[6-[2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate,

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the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclometasone dipropionate and salts or sovents thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

- 5 Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

- 10 It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

- 15 The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more
- 20 of the following claims:

CLAIMS:

1. A dispenser for dispensing medicament comprising
5 a housing having a support;

a container, locatable within said housing, having an outlet member, wherein
said container is movable relative to the housing to enable dispensing therefrom
and said outlet member is connectable with said support to prevent relative
10 movement therebetween; and

an actuation indicator, locatable within said housing,

wherein the container and actuation indicator are reversably removable from the
15 housing as a single unit.
2. A dispenser according to claim 1 wherein the actuation indicator is
engagable with the container in the vicinity of said outlet member.
- 20 3. A dispenser according to claim 2 wherein the actuation indicator is
engagable with the outlet member.
4. A dispenser according to any of claims 1 to 3, wherein the actuation
indicator is provided with a grip member which is engagable with a neck portion
25 of the container.
5. A dispenser according to claim 4, wherein the neck portion is adjacent
to or on the outlet member.
- 30 6. A dispenser according to any of claims 1 to 5 wherein the container is
an aerosol container.
7. A dispenser according to any of claims 1 to 6 wherein the housing is
provided with an outlet, preferably in the form of a mouthpiece.
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8. A dispenser according to claim 7 comprising a passage through which dispensed doses may pass from the container to said outlet.

5 9. A dispenser according to any of claims 1 to 8 wherein said container provides measured doses.

10 10. A dispenser according to any of claims 1 to 9 wherein said actuation indicator indicates the number of doses dispensed from or remaining in the container.

11 11. A dispenser according to any of claims 1 to 10, wherein the actuation indicator comprises an indexing mechanism actuated by a predetermined movement of the container relative to the housing.

15 12. A dispenser according to claim 11, wherein the indexing mechanism comprises a lost motion coupling to allow and compensate for excess movement of the container relative to the housing.

20 13. A dispenser according to either of claims 11 or 12, wherein the indexing mechanism indexes the actuation indicator by means of a predetermined rotary movement of a first member driven by movement relative to a second member during actuation of the dispenser.

25 14. A dispenser according to claim 13, wherein the second member remains stationary relative to the housing during actuation of the dispenser.

30 15. A dispenser according to claim 13 or 14, wherein the first member comprises a pinion carried by a shaft through the lost motion coupling and the second member comprises a rack.

16. A dispenser according to claim 13 or 14, wherein the first member comprises a yoke for engagement with the second member through the lost motion coupling.

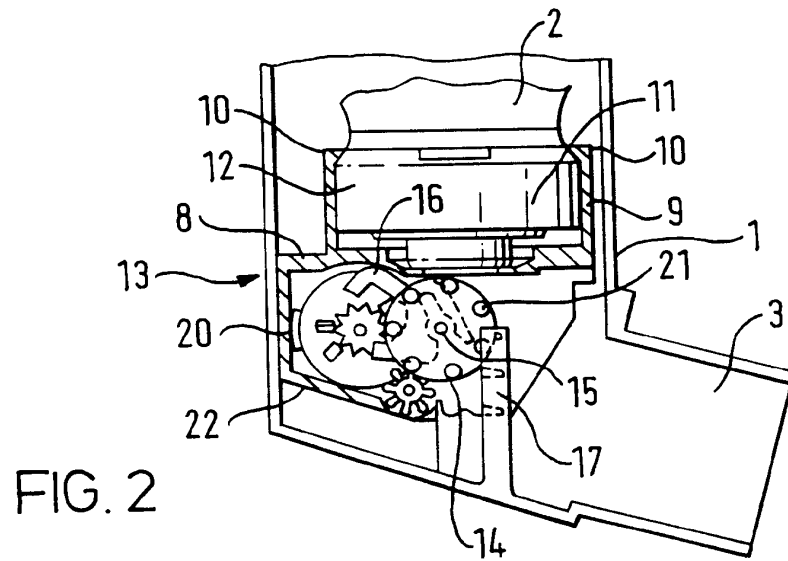
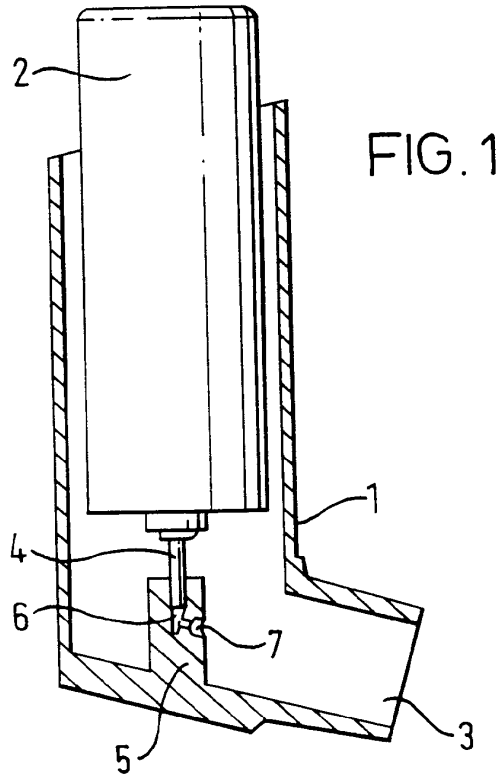
17. A dispenser according to any of claims 12 to 16, wherein the lost motion coupling comprises a friction drive mechanism.
18. A dispenser according to any of claims 1 to 17, actuatable in response to the inward breath of a user.
19. An aerosol dispenser according to claim 1 comprising a housing in which a container is removably located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the container and having a passage through which the contents of the container may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being moveable relative to the outlet member and housing to dispense its contents in measured doses, and a dose indicating device having a dose indicator for indicating the number of doses dispensed from or remaining in the container, characterised in that the dose indicating device is tightly connected to the container in the vicinity of the outlet member, such that the container and dose indicating device may be removed from the housing as a single unit.
20. An actuation indicating device for use with a dispenser comprising a housing and a container, locatable within said housing, having an outlet member, the actuation indicating device comprising attachment means to enable attachment to the container.
21. An actuation indicating device according to claim 20, wherein the attachment means comprises a grip member which firmly engages a neck portion formed around the container.
22. An actuation indicating device according to claim 21, wherein the neck portion is located at the connection between the container and outlet member.
23. An actuation indicating device according to claim 20, wherein the actuation indicating device has an actuation indicator for indicating the number of doses dispensed from or remaining in the container, wherein the actuation

indicating device comprises attachment means to enable tight connection to the container in the vicinity of the outlet member.

24. Electromechanical dose indicating device according to any of claims
5 20 to 23.

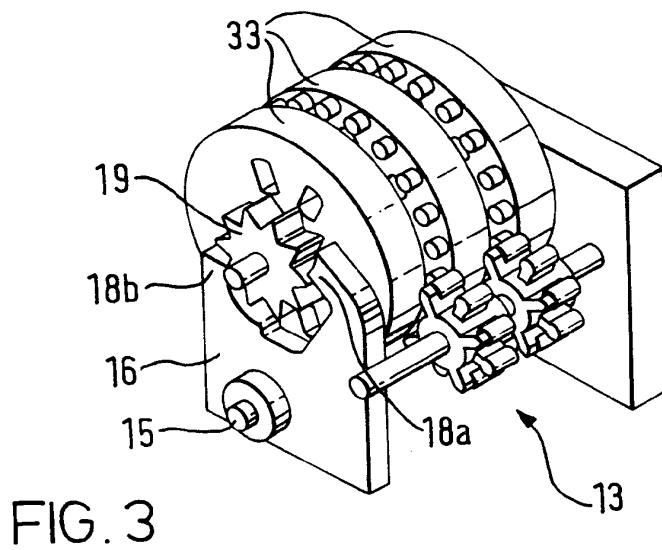
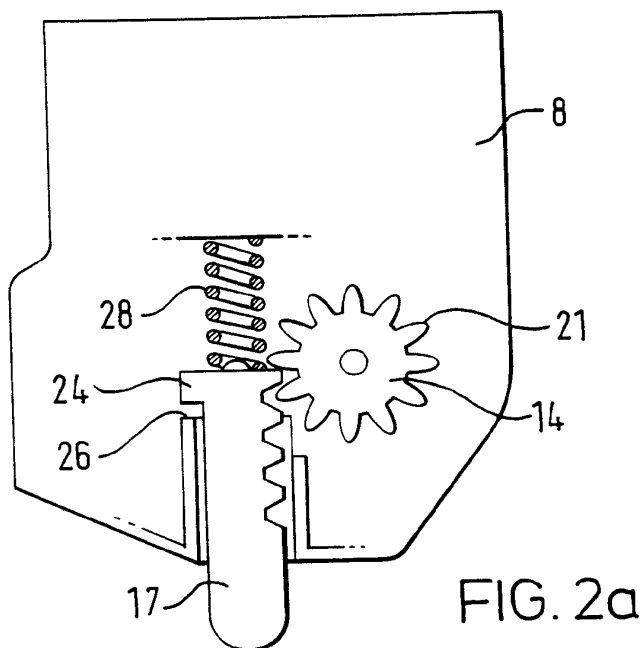
25. Use of a dispenser according to any of claims 1 to 18 for dispensing
medicament.

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SUBSTITUTE SHEET (rule 26)

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SUBSTITUTE SHEET (rule 26)

3 / 7

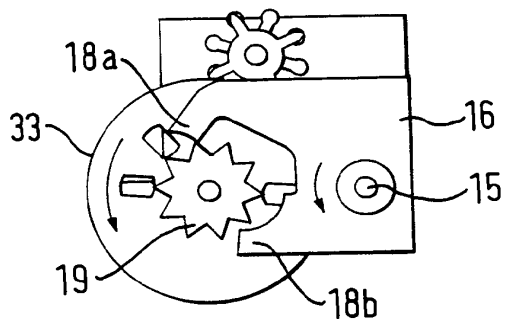


FIG. 4a

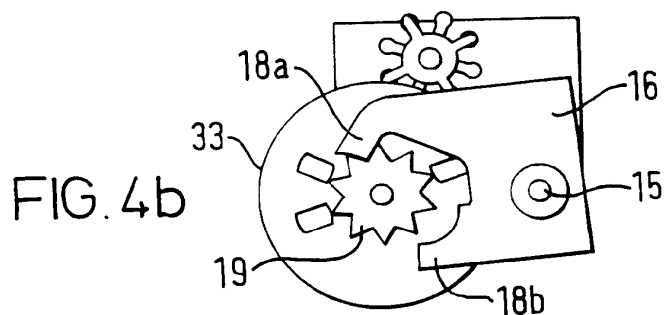


FIG. 4b

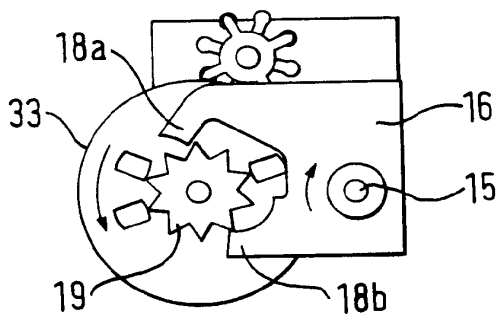


FIG. 4c

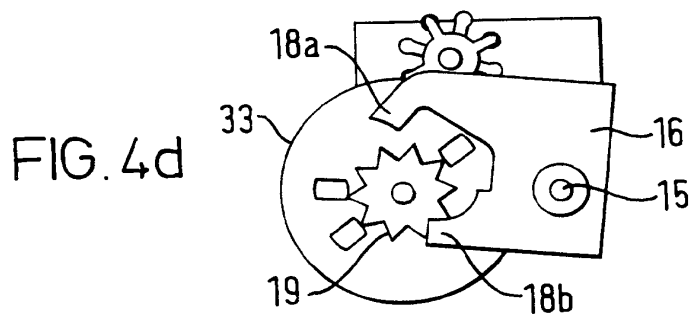


FIG. 4d

SUBSTITUTE SHEET (rule 26)

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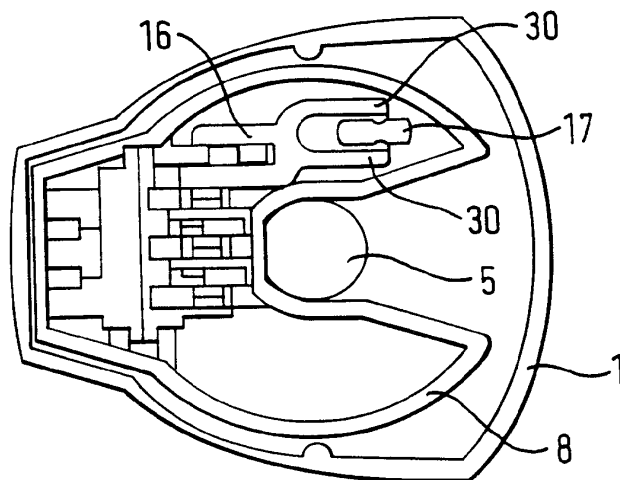


FIG. 5a

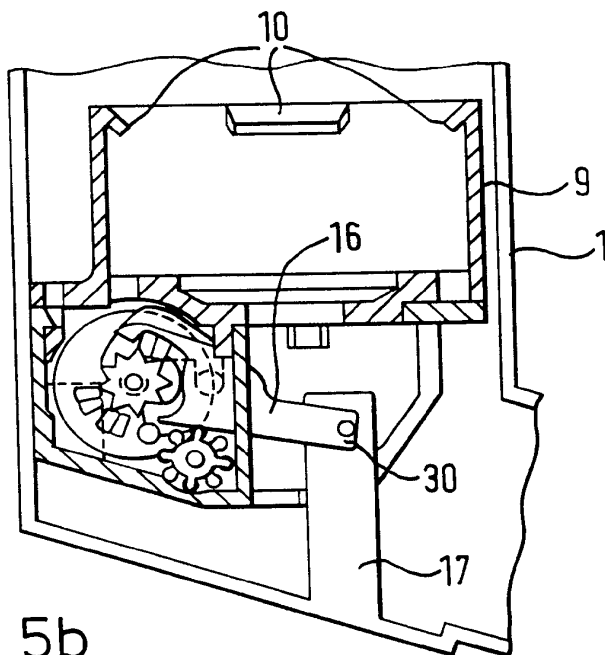


FIG. 5b

SUBSTITUTE SHEET (rule 26)

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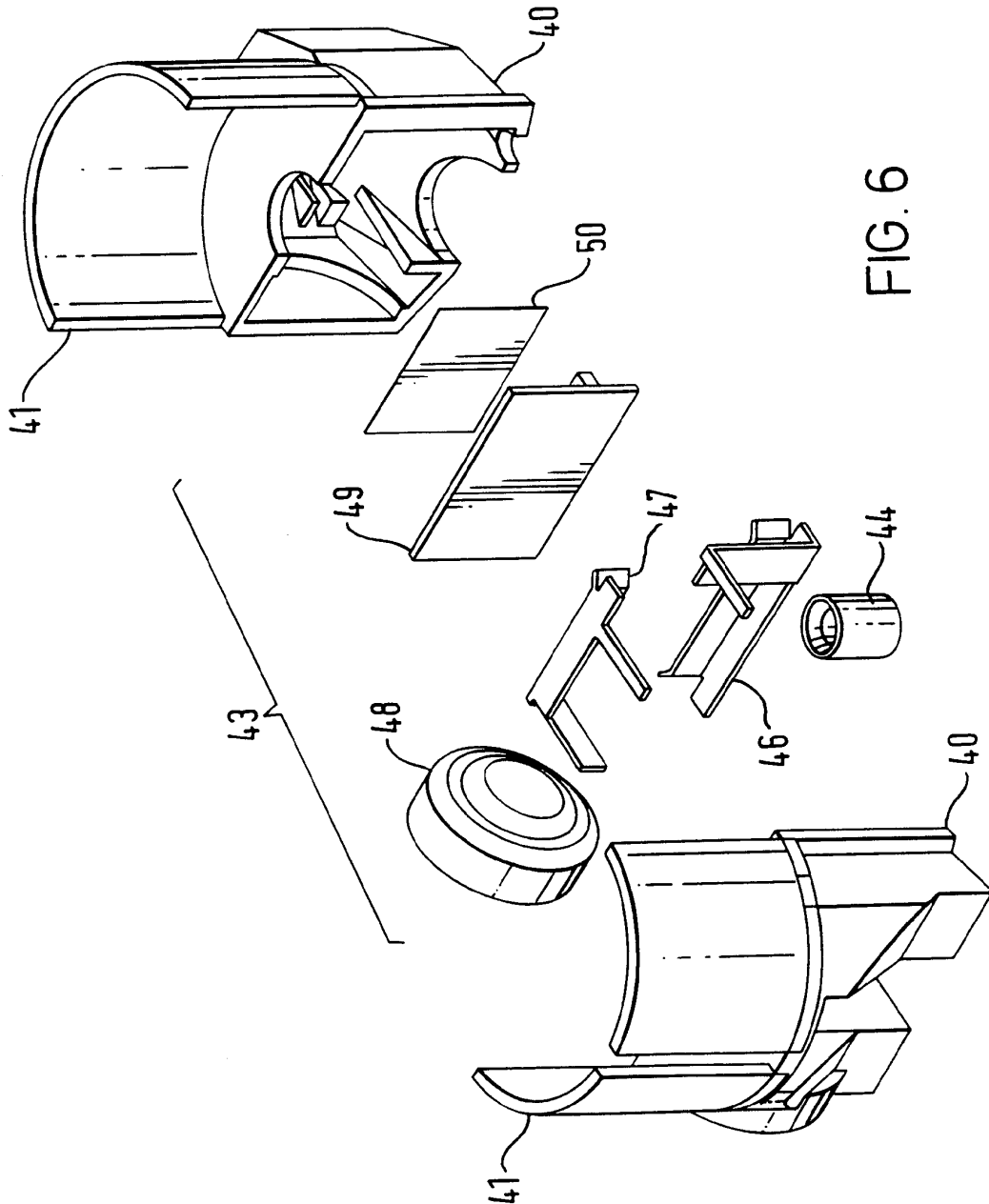


FIG. 6

SUBSTITUTE SHEET (rule 26)

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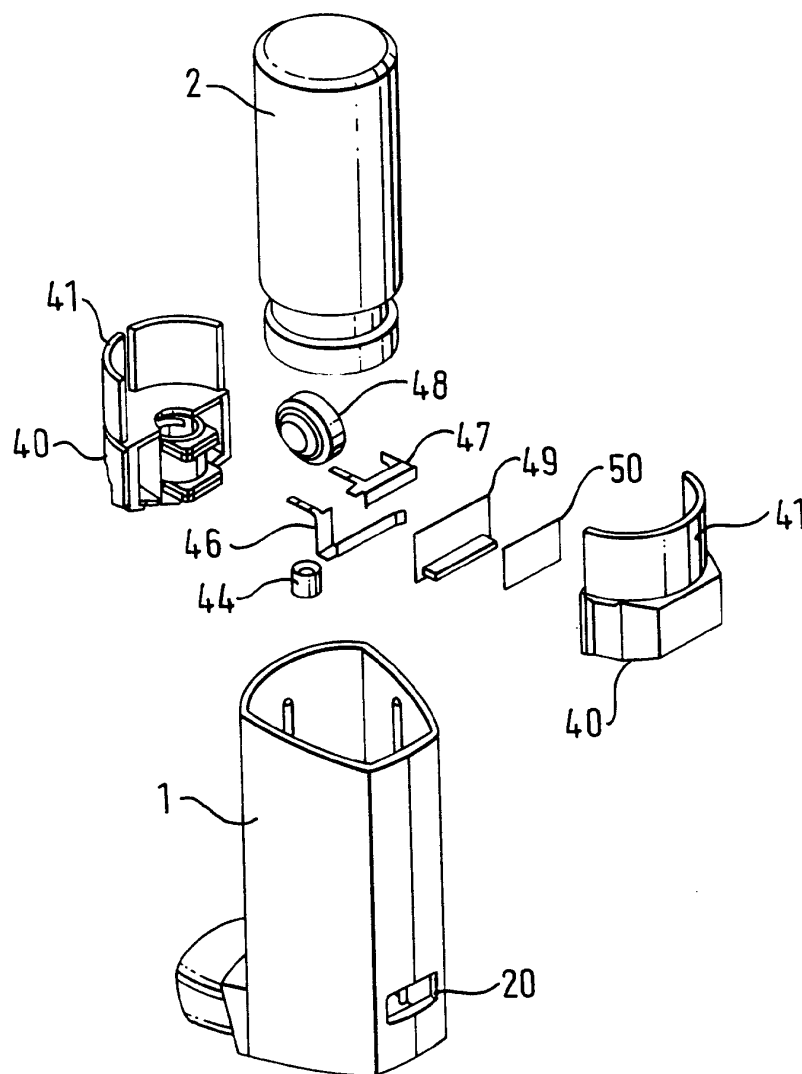


FIG. 7

SUBSTITUTE SHEET (rule 26)

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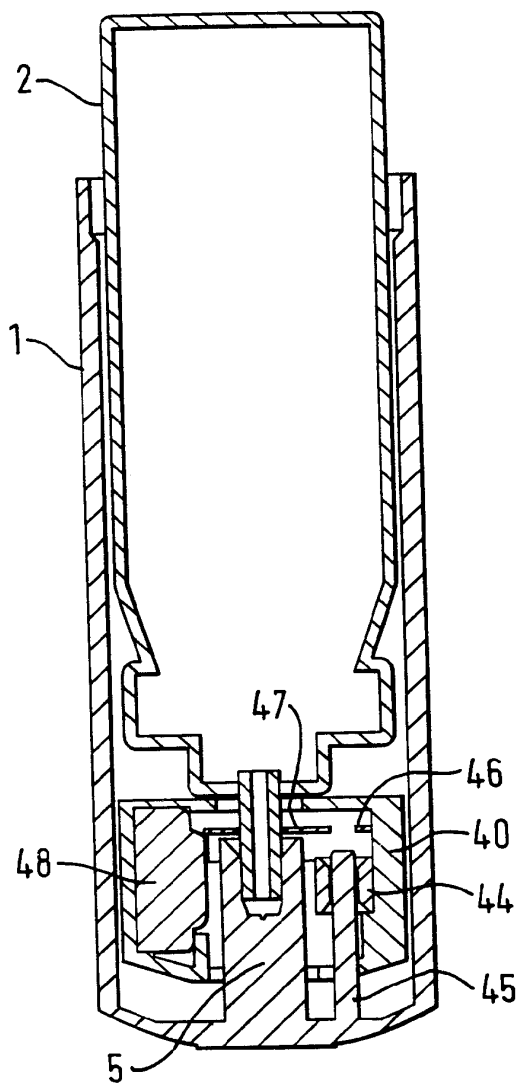


FIG. 8

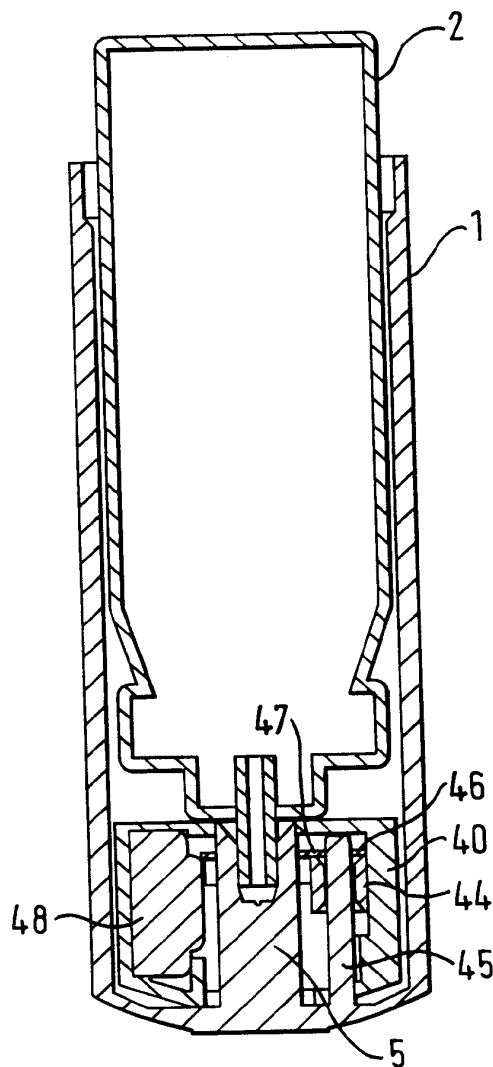


FIG. 9

SUBSTITUTE SHEET (rule 26)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 98/03377

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 622 163 A (JEWETT ET AL) 22 April 1997 see column 4, line 4 - column 5, line 64; figures 1-3 & WO 96 16686 A (IEP GROUP INC) 6 June 1996 cited in the application ----	20, 21, 24 1, 6-10, 19, 25
X A	DE 86 02 238 U (JOSEF WISCHERATH GMBH & CO) 10 April 1986 see page 3, line 8 - page 5, line 27; figures 1-3 ----- -/-	20-22 1-9, 11, 19, 23, 25

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

21 October 1998

Date of mailing of the international search report

30/10/1998

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Levert, C

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 98/03377

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 92 17231 A (INNOMED INC) 15 October 1992 see page 4, line 9 - page 6, line 4 see page 8, line 17 - page 10, line 3; figures 1-5 -----	1,2, 6-11,19, 25

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 98/03377

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5622163 A	22-04-1997	US 5544647 A	13-08-1996
		AU 7174596 A	29-05-1997
		CA 2190204 A	23-05-1997
		EP 0775499 A	28-05-1997
		JP 9168593 A	30-06-1997
		NO 964943 A	23-05-1997
		NZ 299619 A	24-11-1997
		AU 687290 B	19-02-1998
		AU 4236096 A	19-06-1996
		CA 2181789 A	06-06-1996
		EP 0746366 A	11-12-1996
		JP 9508845 T	09-09-1997
		NO 963134 A	28-08-1996
		NZ 297246 A	22-09-1997
		WO 9616686 A	06-06-1996
		ZA 9510129 A	06-06-1996
DE 8602238 U	10-04-1986	NONE	
WO 9217231 A	15-10-1992	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)

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 INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT)



(51) Internationale Patentklassifikation ⁷ : A61M 15/00, G06M 1/08, 1/14	A1	(11) Internationale Veröffentlichungsnummer: WO 00/09187 (43) Internationales Veröffentlichungsdatum: 24. Februar 2000 (24.02.00)
(21) Internationales Aktenzeichen: PCT/EP99/05939 (22) Internationales Anmeldedatum: 13. August 1999 (13.08.99) (30) Prioritätsdaten: 298 14 647.9 14. August 1998 (14.08.98) DE (71) Anmelder (für alle Bestimmungsstaaten ausser US): JOSEPH WISCHERATH GMBH & CO. KG [DE/DE]; Donatusstrasse 102, D-50259 Pulheim (DE). (72) Erfinder; und (75) Erfinder/Anmelder (nur für US): ECKERT, Joseph [DE/DE]; Suhlesstrasse 69, D-97638 Mellrichstadt (DE). (74) Anwalt: GRÜNECKER, KINKELDEY, STOCKMAIR & SCHWANHÄUSSER; Maximilianstrasse 58, D-80538 München (DE).	(81) Bestimmungsstaaten: DE, JP, US, europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Veröffentlicht <i>Mit internationalem Recherchenbericht.</i>	

(54) Title: INHALATOR COMPRISING A DOSAGE COUNTING DEVICE

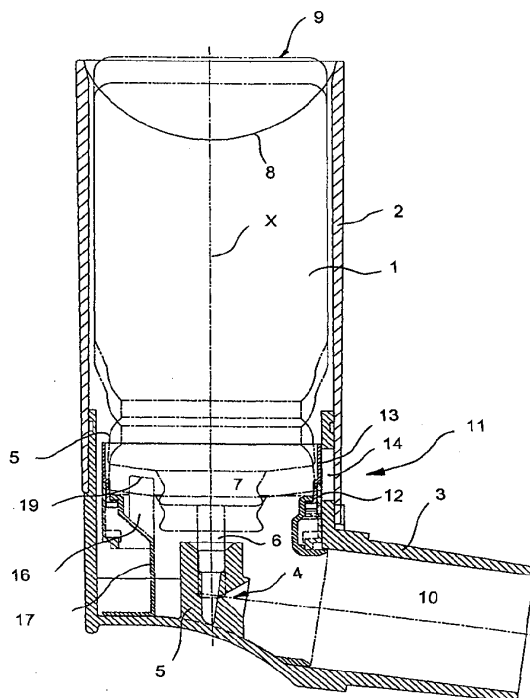
(54) Bezeichnung: INHALATOR MIT EINER DOSIERZÄHLEINRICHTUNG

(57) Abstract

The invention relates to an inhalator for discharging an aerosol comprising a dosage counting device (11). The dosage counting device comprises a first (12) and a second (13) counting ring and has a coupling device (24, 25, 26, 27) located between the counting rings.

(57) Zusammenfassung

Die Erfindung betrifft einen Inhalator zur Abgabe eines Aerosols mit einer Dosierzähleinrichtung (11), die einen ersten (12) und einen zweiten (13) Zählring aufweist und mit einer Koppelungsvorrichtung (24, 25, 26, 27) zwischen den Zählringen.



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Codes zur Identifizierung von PCT-Vertragsstaaten auf den Kopfbögen der Schriften, die internationale Anmeldungen gemäss dem PCT veröffentlichen.

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Inhalator mit einer Dosierzähleinrichtung

Die Erfindung betrifft einen Inhalator zur Abgabe eines Aerosols mit einer Dosierzähleinrichtung, einem Gehäuseteil und einem relativ zu dem Gehäuseteil entlang seiner Längsachse verschiebbar angeordneten Aerosol-Abgabebehälter.

Ein derartiger Inhalator ist aus EP-A1-0 254 391 bekannt. Bei diesem herkömmlichen Inhalator ist ein Aerosol-Abgabebehälter verschiebbar in einen rohrförmigen Abschnitt eines Gehäuseteils eingesetzt. Der Abgabebehälter umfaßt ein aus einem Kopfbereich des Abgabebehälters herausgeführtes Sprührohr, das in abdichtender Weise in einen Sprühsockelabschnitt eingesetzt ist, der einstückig mit dem Gehäuse ausgebildet ist. Zur Abgabe einer festgelegten Dosis eines in dem Abgabebehälter bevorrateten Mediums wird auf einen Bodenabschnitt des Abgabebehälters eine Druckkraft ausgeübt und der Behälter kurzzeitig in das Gehäuse hineingedrängt. Über das in den Sprühsockel eingesetzte Sprührohr wird kurzzeitig ein Ventilmechanismus geöffnet und eine vorbestimmte Menge des in dem Abgabebehälter bevorrateten Mediums aus dem Sprühkopf abgesprüht. In einem Seitenbereich des Gehäuses ist ein drehbewegbar gelagertes Anzeigerad vorgesehen, das bei jedem Abgabehub des Inhalators über ein Untersetzungsgetriebe um einen geringen Drehbetrag weitergedreht wird. Das Anzeigerad ist mit mehreren Füllstandsangaben versehen, die bei sukzessiver Drehung des Anzeigerades über einen Fensterabschnitt ablesbar sind. Wenn der Abgabebehälter nahezu vollständig entleert ist, wird in dem Fenster ein entsprechendes Symbol sichtbar und dem Benutzer damit signalisiert, daß der Abgabebehälter im wesentlichen vollständig entleert ist. Durch eine werkseitig vorgenommene Überfüllung des Abgabebehälters um ca. 10 bis 15 % ist gewährleistet, daß bei Erreichen dieser End-Markierung noch eine ausreichende Wirkstoffmenge in dem Abgabebehälter bevorratet ist.

Diese werkseitig vorgenommene Überfüllung des Abgabebehälters führt insbesondere bei der Abfüllung von vergleichsweise teuren Wirkstoffen zu einer Verteuerung des Inhalators. Auch unter Umweltverträglichkeitsaspekten erscheint eine Überfüllung des Abgabebehälters im bislang üblichen Umfang als problematisch.

Der Erfindung liegt daher die Aufgabe zugrunde, einen Inhalator zur Abgabe eines Aerosols zu schaffen, welcher sich durch eine hohe Funktions-Zuverlässigkeit und eine

hinsichtlich Ablesbarkeit und Anzeigegenauigkeit verbesserte Dosiermengen Zähleinrichtung auszeichnet.

Diese Aufgabe wird erfindungsgemäß durch einen Inhalator mit den im Schutzanspruch 1 angegebenen Merkmalen gelöst.

Dadurch wird es auf vorteilhafte Weise möglich, einen unter fertigungstechnischen Gesichtspunkten günstig herstellbaren Inhalator zu schaffen, bei welchem bedarfsweise jeder einzelne Dosierhub gezählt und angezeigt wird. Neben der damit erreichten zuverlässigen Überwachung der Restfüllmenge eines in dem Inhalator bevorrateten Wirkmediums wird es ferner möglich, die rezeptgemäße Einnahme eines Dosieraerosols besser im Auge zu behalten. Die erfindungsgemäß ausgebildete Dosierzähleinrichtung erlaubt beispielsweise eine von 0 bis ca. 200 aufsteigende Zählung der einzelnen Dosierungen. Alternativ dazu ist es auch möglich, die Zifferanordnung auf den beiden Zählringen derart vorzunehmen, daß eine von der maximalen Hubzahl abwärts laufende Dosierzählung erfolgt. Die Zählung kann beispielsweise von der Zahl 200 abwärts laufend erfolgen, wobei beispielsweise dann, wenn die Resthubzahl ≤ 50 ist, in der Anzeigeeinrichtung eine Farbmarkierung, beispielsweise in Form eines Signalbalkens, sichtbar wird, der dem entsprechenden Benutzer rechtzeitig die Nachbeschaffung eines entsprechenden Inhalators signalisiert.

Die vermittels der erfindungsgemäßen Dosierzähleinrichtung erreichte Verbesserung der Anzeigegenauigkeit erlaubt es, die aus Sicherheitsgründen vorgenommene Überfüllung des Abgabebehälters und damit die ggf. in dem Abgabebehälter verbleibende Wirkstoffrestmenge zu verringern.

Eine im Hinblick auf eine besonders zuverlässige Weiterschaltung des ersten Zählrings vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß der Schaltfinger von der Rotationsachse beabstandet und zu dieser geneigt angeordnet ist. Dadurch wird es auf kinematisch günstige Weise möglich, den Schaltfinger mit zählringseitig vorgesehenen Stellelementen in Eingriff zu bringen und den Schaltfinger anschließend um eine im wesentlichen quer zur Längsrichtung des Schaltfingers verlaufende Kippachse zu kippen. Der Anstellwinkel des Schaltfingers relativ zu einer durch den Zählring definier-

ten Radialebene liegt vorzugsweise im Bereich von 30 bis 60°. Hierbei ergeben sich bei günstigen Kräfteverhältnissen hinreichend große Transportwege des Schaltfingers.

Gemäß einer bevorzugten Ausführungsform der Erfindung ist der Schaltfinger aus einer Ausgangsstellung in eine zu dieser Ausgangsstellung geneigte Endstellung auslenkbar, wobei ein Eingriffsabschnitt des Schaltfingers bereits in der Ausgangsstellung desselben federnd nachgiebig in eine Eingriffsstellung mit dem ersten Zählring gedrängt ist. Dadurch wird auf zuverlässige Weise gewährleistet, daß jeder einzelne Abgabehub des Inhalators durch die Dosierzähleinrichtung erfaßt wird.

Eine im Hinblick auf eine besonders günstige Umsetzung der Abgabehubbewegung des Abgabebehälters des Inhalators in eine zum Betrieb der Dosierzähleinrichtung erforderliche Weiterschaltbewegung vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß ein Armteil vorgesehen ist, das mit dem Schaltfinger gekoppelt ist, wobei das Armteil und der Schaltfinger einen Kniegelenkmechanismus bilden. Dadurch wird bei weiterhin vorteilhaften Kräfteverhältnissen ein vergleichsweise großer Schaltfinger-Transportweg gewährleistet, wodurch es möglich wird, die auf dem ersten Zählring vorgesehenen Ziffern derart weit voneinander beabstandet anzuordnen, daß stets nur eine einzige Ziffer des Zählrings in einem Fensterabschnitt sichtbar ist.

Die zur Zurückstellung des Schaltfingers erforderlichen Rückstellkräfte können auf vorteilhafte Weise durch elastische Verformung des Schaltfingers oder der mit dem Schaltfinger gekoppelten Betätigungselemente aufgebracht werden. Der Schaltfinger besteht in vorteilhafter Weise aus einem Kunststoffmaterial, vorzugsweise einem thermoplastisch umformbaren Kunststoffmaterial.

Eine im Hinblick auf eine zuverlässige Betätigung des Schaltfingers vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß das Armteil und der Schaltfinger über einen Betätigungsabschnitt miteinander verbunden sind. Der Betätigungsabschnitt bildet in vorteilhafter Weise eine einem Schulterabschnitt des Abgabebehälters des Inhalators zugewandte Anlagefläche, die beim Absenken des Abgabebehälters im Rahmen eines Dosierhubs aus einer Ausgangsstellung ausgelenkt, insbesondere im wesentlichen in Axialrichtung des Abgabebehälters, verschoben wird.

Das Armteil und der Schaltfinger sind gemäß einer bevorzugten Ausführungsform der Erfindung einstückig ausgebildet. Vorteilhafterweise ist bei dieser Ausführungsform der Betätigungsabschnitt in einem Verbindungsbereich zwischen Armteil und Schaltfinger vorgesehen. Die Bewegbarkeit von Armteil und Schaltfinger zueinander resultiert im wesentlichen aus der Elastizität des Werkstoffes im Bereich der entsprechenden Übergangsstellen. Die Geometrie dieser Übergangsabschnitte ist derart gewählt, daß zumindest im Rahmen der vorgesehenen Anzahl an Dosierhüben keine erhebliche Materialermüdung oder Querschnittsschwächung in den entsprechenden Verbindungsabschnitten auftritt.

Eine im Hinblick auf eine besonders hohe Funktionszuverlässigkeit der Dosierzähleinrichtung vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß zumindest der erste Zählring, vorzugsweise auch der zweite Zählring, und in besonders vorteilhafter Weise auch der Schaltfinger aus POM gefertigt sind. Die restlichen Komponenten des Inhalators können aus vergleichsweise preiswerten Kunststoffen, wie beispielsweise Polystyrol oder Polyethylen oder sonstigen, vorzugsweise thermoplastisch umformbaren Kunststoffen gebildet sein.

Eine im Hinblick auf eine besonders kompakte und funktionszuverlässige Ausführungsform der Erfindung vorteilhafte Ausgestaltung der Dosierzähleinrichtung ist dadurch gegeben, daß der Schaltfinger, der Betätigungsabschnitt und das Armteil sich im wesentlichen bogenförmig um die Rotationsachse des ersten Zählrings erstrecken. Der Radius dieses Bogens entspricht in vorteilhafter Weise im wesentlichen dem halben Durchmesser der an dem Abgabebehälter ausgebildeten Schulter. Dadurch wird es auf vorteilhafte Weise möglich, die Zählring-Weiterschaltvorrichtung unmittelbar im Bereich des Abgabeventils des Inhalators anzuordnen. Dadurch wird es auf weiterhin vorteilhafte Weise möglich, einen zur Führung des Abgabebehälters des Inhalators vorgesehenen Gehäuseabschnitt durch ein separat ausgebildetes und auf ein Mundstück des Inhalators aufgestecktes Rohrelement auszubilden.

Eine im Hinblick auf eine zuverlässige Zählung der einzelnen Dosierhübe vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß eine Rücklaufsperrvorrichtung vorgesehen ist, die eine Rastklinke aufweist, die spätestens beim Weitertransport des ersten Zählrings um einen Zählschritt in einen entsprechenden zählringseitig ausgebilde-

ten Eingriffsabschnitt eingreift. Alternativ dazu oder auch in Kombination mit einer derartigen Rastklinke ist es möglich, eine Drehung des ersten Zählrings entgegen der Zählring-Weiterschalttrichtung auch durch einen reibschlüssig sperrenden Mechanismus zu verhindern. Die Zählring-Weiterschaltvorrichtung und in vorteilhafter Weise auch die Rücklaufsperrvorrichtung sind gemäß eines besonderen Aspekts der vorliegenden Erfindung derart ausgebildet, daß diese jeden Abgabe- bzw. Dosierhub zählt.

In vorteilhafter Weise ist der Weiterschaltmechanismus derart ausgebildet, daß der erste Zählring auch dann betätigt bzw. weitergedreht wird, wenn ein Abgabehub nur unvollständig ausgeführt wurde. Eine im Hinblick auf eine besonders leichtgängige Ausgestaltung der Rücklaufsperrvorrichtung vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß mehrere Rastklinken vorgesehen sind, die mit entsprechenden am ersten Zählring ausgebildeten Eingriffsabschnitten in Eingriff bringbar sind, wobei die einzelnen Rastklinken derart versetzt ausgebildet sind, daß diese Rastklinken sich jeweils in unterschiedlichen Eingriffszuständen befinden.

Die Länge des Armteils und die Länge des Schaltfingers sowie die Position des Armteils und des Schaltfingers sind in vorteilhafter Weise derart abgestimmt, daß bei einer Verlagerung des Betätigungselementes um eine vorgegebene Wegstrecke der Eingriffsabschnitt des Schaltfingers sich in Umfangsrichtung des ersten Zählrings um eine Wegstrecke verlagert, deren Länge im wesentlichen der Schrittlänge einer umfangsseitig an dem ersten Zählring vorgesehenen Skalierung entspricht. Dadurch wird es auf vorteilhafte Weise möglich, die zur Anzeige jedes einzelnen Zählschrittes erforderliche Nummernkombination eindeutig zur Anzeige zu bringen.

Eine im Hinblick auf eine besonders zuverlässige Zählung und Anzeige der einzelnen Dosierhübe vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß die Skalierung des ersten Zählringes die Ziffern 0, 1, 2... bis 9 trägt, wobei diese Ziffern in gleicher Umfangsteilung am Umfang des ersten Zählrings ausgebildet sind. Diese Ziffern können beispielsweise durch ein Siebdruckverfahren auf den Zählring aufgebracht werden. Gemäß einer besonders bevorzugten Ausführungsform der Erfindung wird die Skalierung jedoch über ein Laser-Beschriftungsverfahren unmittelbar in das Kunststoffmaterial des Zählrings eingebrannt.

Auch die Skalierung des zweiten Zählrings trägt in vorteilhafter Weise die Ziffern 0, 1, 2... bis 9. Die Beschriftung des zweiten Zählrings kann in der gleichen Weise erfolgen wie dies bezüglich des ersten Zählring vorangehend beschrieben wurde.

Eine im Hinblick auf die Zählung einer vergleichsweise großen Hubzahl vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß die Skalierung des zweiten Zählrings die Zahlen 0, 1, 2... bis 20 trägt. Dadurch wird es auf vorteilhafte Weise möglich, mit lediglich zwei Zählringen insgesamt 200 Dosierhübe zu zählen. Insbesondere bei dieser Ausführungsform ist an dem ersten Zählring die Ziffernfolge 0, 1, 2... bis 9 mehrfach, insbesondere 2- oder 3fach, abfolgend angeordnet. Dadurch wird der erforderliche Weiterschalttransportweg des ersten Zählrings erheblich verkürzt.

Die Koppelungsvorrichtung zur Koppelung des zweiten Zählrings mit dem ersten Zählring zur schrittweisen Drehung des zweiten Zählrings gemeinsam mit dem ersten Zählring umfaßt in vorteilhafter Weise eine an dem ersten Zählring ausgebildete, elastisch auslenkbare und mit einem Eingriffsabschnitt des zweiten Zählrings unmittelbar in Eingriff bringbare Zunge. Diese Zunge wird gemäß einer bevorzugten Ausführungsform der Erfindung durch eine relativ zum ersten Zählring stationär angeordnete Anlaufnase ausgelenkt, welche die elastisch auslenkbare Zunge mit dem zweiten Zählring über ein Winkelintervall in Eingriff hält, das exakt dem Weiterschalt-Schrittwinkel des zweiten Zählrings entspricht. Zur Realisierung entsprechender Übersetzungsverhältnisse können bedarfsweise mehrere derartige Anlaufnasen an einem relativ zum ersten Zählring stationär angeordneten Bauteil des Inhalators ausgebildet sein. Gegebenenfalls ist es auch möglich, mehrere elastisch auslenkbare und mit dem zweiten Zählring unmittelbar in Eingriff bringbare Zungenelemente an dem ersten Zählring auszubilden.

Eine im Hinblick auf eine besonders zuverlässige Betriebsweise dieser Koppelungsvorrichtung vorteilhafte Ausführungsform des Inhalators ist dadurch gegeben, daß der zweite Zählring einen Lagerungsabschnitt aufweist, der in den ersten Zählring drehbar eingesetzt oder auf den ersten Zählring aufgesetzt ist. Durch Ausbildung entsprechender Umfangsnuten und Eingriffsabschnitte zwischen den beiden Zählringen ist es möglich, die beiden Zählringe zueinander drehbar zu lagern und ein axiales Auseinanderziehen der beiden Zählringe zu verhindern. Die Position des ersten Zählrings relativ zu der An-

laufnase kann auf vorteilhafte Weise durch eine an dem ersten Zählring ausgebildete Umfangsnut eingehalten werden.

Die Drehung des zweiten Zählringes entgegen der Weiterschalttrichtung wird in vorteilhafter Weise durch eine weitere Rücklaufsperrvorrichtung verhindert.

Weitere Einzelheiten und Merkmale der Erfindung ergeben sich aus der nachfolgenden Beschreibung eines bevorzugten Ausführungsbeispiels in Verbindung mit der Zeichnung. Es zeigen:

Fig. 1 eine Längsschnittansicht durch einen Inhalator mit Mundstück und verschiebbar angeordnetem Abgabebehälter,

Figuren 2a, 2b und 2c eine Schemadarstellung zur Erläuterung der Transportmechanik der bei dem Inhalator gem. Fig. 1 vorgesehenen Zählring-Weiterschaltvorrichtung,

Figuren 3a und 3b Schemadarstellungen zur näheren Beschreibung einer bevorzugten Geometrie eines Schaltfingers, eines Betätigungsabschnittes und eines Armteiles,

Figuren 4a, 4b und 4c Axialschnittansichten durch den ersten und den zweiten Zählring zur Erläuterung der Funktionsweise der zur unmittelbaren Koppelung der ersten und zweiten Zählringe vorgesehenen Koppelungseinrichtung,

Fig. 5 eine Längsschnittansicht durch ein Blendenteil mit integral ausgebildetem Schaltfinger sowie integral ausgebildeter Rücklaufsperrvorrichtung,

Fig. 6 eine Radialschnittansicht entlang der Linie A-A in Fig. 5 zur Erläuterung des Aufbaus der Rücklaufsperrvorrichtung und

Fig. 7 eine vereinfachte Seitenansicht des Inhalators gemäß Fig. 1 mit einem im wesentlichen rechteckig ausgebildeten und entlang der Längsachse des Inhalators ausgerichtet verlaufenden Ablesefenster.

Der in Fig. 1 vereinfacht dargestellte Inhalator zur Abgabe eines Aerosols umfaßt einen entlang seiner Axialrichtung verschiebbar gelagerten Abgabebehälter 1, und einen zur Lagerung des Abgabebehälters 1 vorgesehenen Führungsschaft 2, der passend auf einen entsprechend ausgebildeten Verbindungsabschnitt eines Winkelstückes 3 aufgesetzt ist.

In dem Winkelstück 3 ist eine Sprühdüseneinrichtung 4 angeordnet, die in einem einstückig mit dem Winkelstück 3 ausgebildeten Zapfenabschnitt 5 ausgebildet ist. In diesen Zapfenabschnitt 5 ist ein Abgaberohr 6 des Abgabebehälters 1 in abdichtender Weise eingesetzt. Das Abgaberohr 6 ist in einem Kopfbereich 7 des Abgabebehälters 1 in axialer Richtung nachgiebig aufgenommen und durch eine Federeinrichtung (nicht sichtbar) derart vorgespannt, daß der Abgabebehälter 1 über das Abgaberohr 6 von dem Zapfenabschnitt 5 hinweggedrängt wird.

Im oberen Bereich des Führungsschaftes 2 ist eine Ausmuldung 8 vorgesehen, aus welcher ein Bodenbereich 9 des Abgabebehälters 1 hervorragt. Durch Aufbringen einer Druckkraft auf diesen Bodenbereich 9 kann der Abgabebehälter 1 zu dem Zapfenabschnitt 5 hin verschoben werden, wie dies durch Strichpunktlinien vereinfacht angedeutet ist. Sobald das Abgaberohr 6 an einer entsprechend in dem Zapfenabschnitt 5 ausgebildeten Anlagefläche ansteht, wird das Abgaberohr 6 in den Abgabebehälter 1 hineingedrängt und wirkt dabei mit einem Ventilmechanismus zusammen, über welchen eine vorbestimmte Menge eines in dem Abgabebehälters 1 bevorrateten Mediums aus diesem entströmen und über das Abgaberohr 6 zur Sprühdüseneinrichtung 4 und von dort aus in einen in dem Winkelstück 3 gebildeten Ansaugbereich 10 vordringen kann. Diese nachfolgend als Abgabehub bezeichnete Eintauchbewegung des Abgabebehälters 1 wird durch eine Dosierzähleinrichtung 11 gezählt.

Die Dosierzähleinrichtung 11 umfaßt hierzu einen ersten Zählring 12 und einen zweiten Zählring 13. Der erste Zählring 12 und der zweite Zählring 13 sind zueinander drehbar angeordnet. Der zweite Zählring 13 weist einen Dreh-Lagerungsabschnitt auf, der in einen entsprechenden Öffnungsbereich des ersten Zählrings 12 eingesetzt ist.

Der erste Zählring 12 und der zweite Zählring 13 sind coaxial zur Längsachse X des Abgabebehälters 1 angeordnet. Die beiden Zählringe 12, 13 sind in einem rohrförmigen Abschnitt des Winkelstückes 3 drehbewegbar angeordnet. An den Außenumfangsflächen der beiden Zählringe 12, 13 sind in nachfolgend noch näher erläuteter Weise Ziffern vorgesehen, die über eine Fensteröffnung 14, die in dem Winkelstück 3 ausgebildet ist, ablesbar sind.

Bei der in Fig. 1 dargestellten Ausführungsform des Inhalators befindet sich der zweite Zählring in etwa auf Höhe einer an dem Aufnahmebehälter 1 ausgebildeten Schulter 15. Der zweite Zählring 13 ist hinsichtlich seines Innendurchmessers derart dimensioniert, daß die Schulter 15 des Abgabebehälters 1 über eine der Abgabehublänge entsprechende Wegstrecke in den zweiten Führungsring 13 hinein eindringen kann.

In einem zwischen den beiden Zählringen 12, 13 und dem Kopfbereich 7 des Abgabebehälters verbleibenden Ringraum ist eine Zählring-Weiterschaltvorrichtung 16 vorgesehen, welche den coaxial zum Abgabebehälter 1 angeordneten Zählring 12 bei jedem Abgabehub um einen vorbestimmten Drehwinkel weiterdreht.

Die Zählring-Weiterschaltvorrichtung 16 ist bei der hier dargestellten Ausführungsform einstückig mit einem Blendenteil 17 ausgebildet, das in dem Winkelstück 3 eingesetzt ist. Das Blendenteil 17 bildet einen sich im wesentlichen ringförmig um die Längsachse X erstreckenden Lagerungsabschnitt, an welchem der zweite Zählring 13 gelagert ist.

An dem Blendenteil 17 ist einstückig mit diesem je eine Rücklaufsperrvorrichtung zum Sperren einer Drehbewegung der Zählringe 12, 13 in Gegenrichtung vorgesehen.

Das Blendenteil 17 ist ferner mit einer Anlaufnase versehen, die Teil einer im folgenden, ausführlich beschriebenen Koppelungsvorrichtung zur direkten Koppelung der beiden Zählringe 12, 13 bildet.

Die Zählring-Weiterschaltvorrichtung ist innerhalb der beiden Zählringe 12, 13 derart angeordnet, daß ein Betätigungsabschnitt 19 derselben mit der an dem Abgabebehälter 1 ausgebildeten Schulter in Berührungskontakt bringbar ist.

Die Funktionsweise der Zählring-Weiterschaltvorrichtung wird durch die Figuren 2a, 2b und 2c verdeutlicht. Die in den Figuren 2a, 2b und 2c dargestellte Zählring-Weiterschaltvorrichtung 16 umfaßt ein nachfolgend als Schaltfinger 20 bezeichnetes Getriebeglied, das bei der hier dargestellten Ausführungsform über den Betätigungsabschnitt 19 mit einem Armteil 21 gekoppelt ist. Bei der hier dargestellten Ausführungsform sind der Schaltfinger 20, der Betätigungsabschnitt 19 und das Armteil 21 einstückig miteinander ausgebildet und aufgrund der Eigenelastizität des hierbei verwendeten Kunststoffmaterials bewegbar miteinander gekoppelt.

Das Armteil 21 weist ein dem Betätigungsabschnitt 19 abgewandtes, stationäres Ende auf, über welches sich der gesamte durch Armteil 21, Betätigungsabschnitt 19 und Schaltfinger 20 gebildete Gelenkmechanismus in Umfangsrichtung des ersten Zählrings 12 abstützt.

Bei der hier gezeigten Anordnung bilden das Armteil 21 und der Schaltfinger 20 einen Kniehebel-Gelenkmechanismus. Durch allmähliches Niederdrücken des Betätigungsabschnittes entlang der hier angedeutet dargestellten Längsachse X des Abgabebehälters 1 werden das Armteil 21 und der Schaltfinger 20 allmählich in die in Fig. 2 dargestellte Endlage geschwenkt. Bezogen auf eine zu der Achse X senkrechte Projektionsfläche ergibt sich zwischen der Projektion der Position des bewegbaren Endes des Armteils 21 gegenüber der Projektion der Position dieses Endes in der Endstellung ein Versatz. Entsprechend diesem Versatz wird der Betätigungsabschnitt in Umfangsrichtung des ersten Zählrings verlagert. Auch der Schaltfinger 20 wird beim Niederdrücken des Betätigungsabschnittes geschwenkt, so daß sich dabei insgesamt eine Verlängerung der Projektion des Schaltfingers 20 in die zur genannten Längsachse X senkrechte Projektionsfläche ergibt. Nachdem der Schaltfinger 20 mit seinem dem ersten Zählring 12 abgewandten Endabschnitt ebenfalls mit dem Betätigungsabschnitt gekoppelt ist, ergibt sich eine Addition der durch Schwenken des Armteils und des Schaltfingers 20 erreichten Versatzstrecken. Zur Übertragung der entsprechenden in Umfangsrichtung des ersten Zählrings wirksamen Bewegungskomponente auf den ersten Zählring ist der Schaltfinger 20 mit einem Eingriffsabschnitt 22 versehen, der mit zählringseitig ausgebildeten Stellelementen in Eingriff bringbar ist. Durch entsprechende Verlagerung des Eingriffsabschnittes 22 des Schaltfingers 20 in Umfangsrichtung des ersten Zählrings 12 wird aufgrund des Eingriffs mit den Stellelementen 23 der erste Zählring 12 in Umfangsrichtung um eine vor-

bestimmte Wegstrecke weitertransportiert. Diese vorbestimmte Wegstrecke entspricht im wesentlichen dem Abstand zwischen zwei benachbarten Stellelementen 23. Nachdem der Betätigungsabschnitt 19 durch die an dem Abgabebehälter 1 ausgebildete Schulter in eine untere Endlage verlagert ist, federt beim Zurückfahren des Abgabebehälters 1 in dem Führungsschaft 2 auch der Betätigungsabschnitt 19 aufgrund der Eigenelastizität des Armteils 21 wieder in seine Ausgangsstellung zurück. Bei dieser Rückzugsbewegung überspringt der Schaltfinger 20 bzw. dessen Eingriffsabschnitt das beim nächsten Zählhub mit diesem in Eingriff tretende Stellelement 23 und federt unmittelbar hinter diesem Stellelement 23 wieder in eine Eingriffsstellung. Bei erneutem Niederdrücken des Betätigungsabschnittes 19 schiebt der Eingriffsabschnitt 22 des Schaltfingers das an dem ersten Zählring ausgebildete Stellelement 23 wieder um ein Transportintervall in Umfangsrichtung weiter. Hierbei tritt die nächstfolgende, an der Umfangsfläche des ersten Zählrings 12 vorgesehene Ziffer in die Fensteröffnung 14.

Bei den Darstellungen gemäß Fig. 2a, Fig. 2b und Fig. 2c ist die zur Weiterschaltung des ersten Zählrings vorgesehene Zählring-Weiterschaltvorrichtung in Form einer Abwicklung dargestellt.

Bei der in Fig. 1 dargestellten Ausführungsform erstreckt sich wie in Fig. 3b dargestellt der durch das Armteil 21, dem Betätigungsabschnitt 19 und den Schaltfinger 20 gebildete Gelenkmechanismus der Zählring-Weiterschaltvorrichtung im wesentlichen bogenförmig um die Längsachse X des Abgabebehälters 1 (in Fig. 3b nicht dargestellt). Durch Niederdrücken des in Fig. 3b dargestellten Betätigungsabschnittes 19 wird ein Versatz des Eingriffsabschnittes 22 des Schaltfingers 21 in Umfangsrichtung erreicht. Durch den Versatz des Eingriffsabschnittes 22 des Schaltfingers 20 in Umfangsrichtung kann der erste Zählring 12 um einen Weiterschaltwinkel α weitergedreht werden. Für den Fall, daß am Außenumfang des ersten Zählrings 12 drei Ziffern-Folgen der Ziffern 0 bis 9 vorgesehen sind, beträgt der Weiterschaltwinkel α ca. 12° . Bei einem derartigen Drehwinkel ergibt sich bereits bei einem dem Durchmesser des Abgabebehälters 1 entsprechenden Durchmesser des ersten Zählrings 12 ein hinreichend großer Abstand zwischen den benachbarten Ziffern, wodurch eine gute Ablesbarkeit der einzelnen Ziffern in der Fensteröffnung 14 gewährleistet ist. Entsprechend der Anzahl der am Umfang des ersten Zählrings 12 abgebildeten Ziffernfolgen wird das Übersetzungsverhältnis zwischen dem ersten Zählring 12 und dem zweiten Zählring 13 bestimmt. Das erforderliche

Übersetzungsverhältnis zwischen den beiden Zählringen kann in vorteilhafter Weise durch die nachfolgend in Verbindung mit den Figuren 4a, 4b und 4c beschriebene Koppelungsvorrichtung erreicht werden.

Die in den Figuren 4a, 4b und 4c in unterschiedlichen Koppelungszuständen dargestellte Koppelungsvorrichtung umfaßt ein einstückig mit dem ersten Zählring 12 ausgebildetes Zungenelement 24, das sich bei der Darstellung gemäß Fig. 4a in einer Neutralstellung befindet. An dem Zungenelement 24 ist ein Mitnehmerabschnitt 25 ausgebildet. Dieser Mitnehmerabschnitt 25 ist mit Eingriffsvorsprüngen 26, die einstückig mit dem zweiten Zählring 13 ausgebildet sind, in Eingriff bringbar. Hierzu ist eine am Blendenteil 17 ausgebildete Anlaufnase 27 vorgesehen, die das Zungenelement in eine Kopplungsposition drängt, in welcher der am Ende des Zungenelementes 24 ausgebildete Mitnehmerabschnitt 25 mit dem unmittelbar benachbarten Eingriffsvorsprung 26 des zweiten Zählrings 13 in Eingriff tritt. Sobald ein entsprechender Eingriffszustand hergestellt ist, wird der zweite Zählring 13 gemeinsam mit dem ersten Zählring 12 solange weitergedreht, bis das Zungenelement 24 von der Anlaufnase 27 abfällt und damit der Eingriffszustand zwischen dem Mitnehmerabschnitt 25 und dem entsprechenden Eingriffsvorsprung 26 aufgehoben ist. Sobald dieser Eingriffszustand aufgehoben ist, kann der erste Zählring 12 über eine vorbestimmte Wegstrecke, unabhängig von dem zweiten Zählring 13, weitergedreht werden.

In Fig. 4b ist das Zungenelement 24 durch die in dieser Darstellung nicht sichtbare Anlaufnase 27 in die genannte Koppelungsstellung gedrängt. Die Länge der hier durch den Buchstaben b angegebenen Koppelungsstrecke ist durch die Geometrie der Anlaufnase 27 bestimmt.

In Fig. 4c ist das Zungenelement 24 bereits in seine Ausgangsstellung zurückgefedert und der Eingriff zwischen dem Mitnehmerabschnitt 25 und dem entsprechenden Eingriffsvorsprung 26 des zweiten Zählrings 13 aufgehoben.

Das bei der hier dargestellten Ausführungsform vorgesehene Zungenelement 24 ist einstückig mit dem ersten Zählring 12 als im wesentlichen flachblattfederartiges Bauteil ausgebildet. Im Hinblick auf die erforderlichen mechanischen Eigenschaften des Zungenelementes sowie im Hinblick auf eine besonders hohe Maßhaltigkeit des ersten

Zählrings 12 ist dieser vorzugsweise aus POM-Kunststoffmaterial gebildet. Bei der hier dargestellten Ausführungsform sind an der Außenumfangsfläche des zweiten Zählrings 13 die Zahlen 1 bis 20 angeordnet. Durch die beiden Zählringe 12, 13 können in dieser Ausführungsform 200 Dosierungen einzeln gezählt werden. Mit zwei Zählringen ist eine Zählung bis 999 möglich. Unter Verwendung eines dritten Zählrings sind 9.999 Zählungen möglich. Die Koppelungsvorrichtung zur Koppelung eines dritten Zählrings mit dem zweiten Zählring entspricht in ihrem Aufbau in vorteilhafter Weise der zwischen dem ersten Zählring 12 und dem zweiten Zählring 13 vorgesehenen Koppelungsvorrichtung.

Zur Verhinderung einer Drehbewegung des zweiten Zählrings 13 relativ zu dem ersten Zählring 12 entgegen der durch die Koppelungsvorrichtung 24, 25, 26 sowie die Anlaufnase 27 bestimmten Transportrichtung ist für die Zählringe 12 und 13 eine Rücklaufsperrvorrichtung 29 vorgesehen, die mit entsprechenden Rastabschnitten in Eingriff bringbar ist. Bei der hier dargestellten Ausführungsform werden diese Rastabschnitte der Rücklaufsperrvorrichtung auf einfache Weise durch die Eingriffsvorsprünge 23 und 26 gebildet.

In Fig. 5 sind das bei dem Inhalator gemäß Fig.1 vorgesehene Blendenteil 17 und der darauf aufgesetzte erste Zählring 12 vergrößert dargestellt. Bei der gezeigten Ausführungsform umfaßt die zur Verhinderung einer Drehbewegung des ersten Zählrings 12 entgegen der Zählringweiterrichtung vorgesehene Rücklaufsperrvorrichtung 28 ein einstückig mit dem Blendenteil 17 ausgebildetes Federelement 29, das mit Rastvorsprüngen 30, die am Innenumfang des ersten Zählrings 12 ausgebildet und der Zählringrotationsachse X zugewandt sind, in Eingriff bringbar ist. Die bei dieser Ausführungsform verwirklichte spezielle Geometrie des einstückig mit dem Blendenteil 17 ausgebildeten Federelementes geht aus der in Fig.6 vereinfacht dargestellten Radialschnittansicht entlang der Linie A-A hervor.

Wie aus der Darstellung gemäß Fig.5 weiter ersichtlich, weist das zur direkten Weiterdrehung des zweiten Zählrings 13 (nicht dargestellt) vorgesehene Zungenelement 24 einen flach rechteckförmigen Querschnitt auf und ragt von einer Innenumfangswandung des ersten Zählrings 12 in einen zwischen dem ersten Zählring 12 und dem Blendenteil 17 gebildeten Ringraum hinein. Dieser Ringraum ist in seinem oberen Bereich von einem Anlaufabschnitt 31 begrenzt, welcher den hier nicht dargestellten

zweiten Zählring 13 in axialer Richtung lagert. Das hier gezeigte Blendenteil 17 bildet ferner einen zweiten Anlaufabschnitt 32, durch welchen der erste Zählring 12 in axialer Richtung gelagert ist. Im Hinblick darauf, daß sich die ersten und zweiten Zählringe 12, 13 gegeneinander in axialer Richtung aufgrund der in Fig. 1 gezeigten Schulterstruktur abstützen, sind durch die genannten ersten und zweiten Anlaufabschnitte 31 und 32 die beiden Zählringe 12, 13 insgesamt in axialer Richtung gelagert.

Lediglich in Strichpunktlinien ist in der Schnittansicht gemäß Fig. 5 auch die zur Auslenkung des am Endabschnitt des Zungenelementes 24 vorgesehenen Mitnehmerabschnittes 25 vorgesehene Anlaufnase 27 gezeigt. Die einstückig mit dem Blendenteil 17 ausgebildete Zählringweitschaltvorrichtung 16, insbesondere deren Armteil 21, ist ebenfalls in Strichpunktlinien angedeutet dargestellt.

Die Ausbildung der angesprochenen Filigranstrukturen an einem in einem Hauptgehäuseabschnitt des Inhalators einsetzbaren Blendenteil erweist sich unter fertigungstechnischen Gesichtspunkten als vorteilhaft. Grundsätzlich ist es jedoch auch möglich, auf das Blendenteil 17 zu verzichten und die zur Sperrung der Rücklaufdrehbewegung des ersten Zählrings 12 vorgesehene Rücklaufsperrvorrichtung 28, die Zählringweitschaltvorrichtung und die entsprechenden Lagerungsabschnitte zur Lagerung der ersten und zweiten Zählringe 12, 13 unmittelbar, d.h. einstückig mit dem Winkelstück 3 auszubilden.

Die in der Schnittansicht gemäß Fig. 6 erkennbare Teilung der an dem ersten Zählring 12 vorgesehenen Rastvorsprünge 30 ist derart festgelegt, daß die durch das Federelement 23 gebildete Rücklaufsperrvorrichtung den ersten Zählring 12 nach jedem Zählschritt erneut verrastet. Durch entsprechende Verkleinerung der Rastvorsprünge 30 und Verkleinerung der Abstände zwischen den abfolgenden Rastvorsprüngen ist es möglich, das Rastintervall der Rücklaufsperrvorrichtung zu verkleinern und damit eine Drehbewegung des ersten Zählrings auch dann zu verhindern, wenn dieser erste Zählring 12 nicht um einen vollständigen Zählschritt weitergedreht ist. Durch entsprechende Auslegung der Geometrie des Federelementes 29 kann der durch die Rücklaufsperrvorrichtung 28 erzeugte Drehwiderstand auf einem vergleichsweise geringen Wert gehalten werden.

In Fig.7 ist eine Seitenansicht (Seitenansicht von rechts) des in Fig.1 dargestellten Inhalators gezeigt. In der auf seiten des Ansaugbereiches 10 angeordneten Fensteröffnung 14 ist hier die Nummernangabe „200“ ablesbar. Diese Nummernangabe wird gebildet durch die über den ersten Zählring 12 in die Fensteröffnung 14 geschobene Ziffer „0“ und die über den zweiten Zählring 13 in die Fensteröffnung geschobene Zahl „20“. Im Falle einer beispielsweise abwärts laufenden Zählung wird bei der nächsten Betätigung des Inhalators sowohl der erste Zählring 12 als auch der zweite Zählring 13 um ein Winkelintervall (α) um die Längsachse X des Inhalators weitergedreht. Hierbei gelangt über den ersten Zählring 12 die Ziffer „9“ und über den zweiten Zählring 13 die Zahl „19“ in die Fensteröffnung 14. Damit wird in der Fensteröffnung 14 die Zahl „199“ angezeigt. Bei der nächsten Betätigung des Inhalators wird nur der erste Zählring 12 weitergedreht und die Ziffer „8“ gelangt in die Fensteröffnung 14. In der Fensteröffnung 14 wird nunmehr die Zahl „198“ angezeigt. Im Rahmen der nachfolgenden Dosierhübe wird zunächst nur der erste Zählring 12 jeweils um einen Zählschritt weitergedreht, bis die Ziffer „1“ in die Fensteröffnung 14 eintritt und in der Fensteröffnung 14 die Zahl „191“ angezeigt wird. Bei der nächstfolgenden Betätigung des Inhalators wird über den in den Fig.4a bis 4c gezeigten Koppelungsmechanismus der erste Zählring 12 unmittelbar mit dem zweiten Zählring gekoppelt und der erste Zählring 12 gemeinsam mit dem zweiten Zählring 13 um einen Zählschritt weitergedreht. Hierbei gelangt die umfangsseitig an dem ersten Zählring vorgesehene Ziffer 0 und die umfangsseitig an dem zweiten Zählring 13 vorgesehene Zahl „19“ in die Fensteröffnung 14. In der Fensteröffnung 14 wird nunmehr die Zahl „190“ angezeigt. Sobald die Zahl „19“ vollständig in die Fensteröffnung 14 gelangt ist, tritt der zur direkten Koppelung der ersten und zweiten Zählringe 12,13 vorgesehene Koppelungsmechanismus wieder in eine Freigabestellung und der erste Zählring 12 wird im Rahmen der nächsten Dosierhübe unabhängig von dem zweiten Zählring 13 gedreht, bis erneut die an dem ersten Zählring 12 vorgesehene Ziffer „1“ in die Fensteröffnung 14 gelangt.

Um eine im wesentlichen gleiche Teilung der Ziffernfolgen an dem ersten Zählring 12 und dem zweiten Zählring 13 zu erreichen, ist die Ziffernfolge 0 bis 9 zweifach abfolgend am Außenumfang des ersten Zählrings 12 ausgebildet. Bei einer, bezogen auf die Umfangsrichtung der Zählringe schmalere Ausgestaltung der Fensteröffnung 14 können an dem zweiten Zählring 13 beispielsweise die Zahlen 0 bis 40 ausgebildet

werden. Bei entsprechender Abstimmung des Übersetzungsverhältnisses zwischen dem ersten und dem zweiten Zählring 12, 13, beispielsweise durch Vervielfachung der zum Weitertransport des zweiten Zählrings vorgesehenen Anzahl an Anlaufnasen 27 können mit lediglich zwei Zählringen Hubzahlen von 0 bis 400 aufsteigend oder bedarfsweise auch abfallend gezählt werden.

Die Erfindung ist nicht auf das vorgehend beschriebene Ausführungsbeispiel beschränkt. Beispielsweise ist es auch möglich, auf das bei dem vorangehend beschriebenen bevorzugten Ausführungsbeispiel des Inhalators vorgesehene Blendenteil 17 zu verzichten und die entsprechenden Funktionsteile integral mit dem Gehäuse des Inhalators auszubilden. Bedarfsweise können durch den beschriebenen Inhalator auch aerosolfreie Wirkstoffe abgegeben werden. Zur Bereitstellung eines noch größeren Zählbereiches ist es möglich, einen dritten Zählring vorzusehen, der über einen entsprechenden Koppelungsmechanismus mit dem zweiten Zählring koppelbar ist.

Schutzansprüche:

1. Inhalator zur Abgabe eines Aerosols, mit:

- einer Dosierzähleinrichtung (11),
- einer Gehäuseeinrichtung (2, 3), und
- einem relativ zu der Gehäuseeinrichtung (2, 3) entlang seiner Längsachse verschiebbar angeordneten Aerosol-Abgabebehälter (1),

gekennzeichnet durch

- einen ersten Zählring (12), der coaxial zur Längsachse (X) des Aerosol-Abgabebehälters (1) angeordnet ist und um diese Längsachse (X) drehbar ist,
- einen zweiten Zählring (13), der coaxial zu dem ersten Zählring (12) angeordnet und mit diesem direkt koppelbar und relativ zu diesem drehbar ist,
- einer Zählringweitschaltvorrichtung (16) zur Drehung des ersten Zählringes (12) bei Betätigung des Inhalators, und
- einer Koppelungsvorrichtung (24, 25, 26, 27) zur Koppelung des zweiten Zählringes (13) mit dem ersten Zählring (12), zur schrittweisen Drehung des zweiten Zählringes (13) gemeinsam mit dem ersten Zählring (12),
- wobei die Zählringweitschaltvorrichtung (16) einen Betätigungsabschnitt (19) und einen mit diesem gekoppelten Schaltfinger (20) aufweist, der zur Drehung des zugehörigen Zählringes (12) mit Stellelementen (23) desselben in Eingriff bringbar ist.

2. Inhalator nach Anspruch 1, **dadurch gekennzeichnet**, daß der Schaltfinger (20) von der Rotationsachse (X) beabstandet und zu dieser geneigt angeordnet ist.

3. Inhalator nach Anspruch 1 oder 2 **dadurch gekennzeichnet**, daß der Schaltfinger (20) aus einer Ausgangsstellung in eine zu dieser Ausgangsstellung geneigte Endstellung auslenkbar ist, und in der Ausgangsstellung ein Eingriffsabschnitt des Schaltfingers (20) federnd nachgiebig in eine Eingriffsstellung mit dem ersten Zählring (12) gedrängt ist.

4. Inhalator nach mindestens einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet**, daß ein Armteil (21) vorgesehen ist das mit dem Schaltfinger (20) gekoppelt

ist, und daß das Armteil (21) und der Schaltfinger (20) einen Kniegelenkmechanismus bilden.

5. Inhalator nach mindestens einem der Ansprüche 1 bis 4, **dadurch gekennzeichnet**, daß das Armteil (21) elastisch nachgiebig ausgebildet ist und an einem stationären Teil (17) insbesondere einem mit der Gehäuseeinrichtung (2, 3) gekoppelten Teil abgestützt ist.

6. Inhalator nach mindestens einem der Ansprüche 1 bis 5, **dadurch gekennzeichnet**, daß das Armteil (21) und der Schaltfinger (20) über den Betätigungsabschnitt (17) miteinander verbunden sind.

7. Inhalator nach mindestens einem der Ansprüche 1 bis 6, **dadurch gekennzeichnet**, daß das Armteil (21) und der Schaltfinger (20) einstückig ausgebildet sind.

8. Inhalator nach mindestens einem der Ansprüche 1 bis 7, **dadurch gekennzeichnet**, daß das Armteil (21) und der Schaltfinger (20) aus einem Kunststoffmaterial insbesondere POM ausgebildet sind.

9. Inhalator nach mindestens einem der Ansprüche 1 bis 8, **dadurch gekennzeichnet**, daß der Betätigungsabschnitt (19) in eine zur Rotationsachse des ersten Zählringes (12) im wesentlichen parallele Richtung geführt ist, und daß das Armteil (21) ein Federelement bildet das den Schaltfinger (20) in seine Ausgangsstellung drängt.

10. Inhalator nach mindestens einem der Ansprüche 1 bis 9, **dadurch gekennzeichnet**, daß der Betätigungsabschnitt (19) eine Anlagefläche bildet die mit einer Schulter (19) des Aerosol-Abgabebehälters (1) in Anlage bringbar ist.

11. Inhalator nach mindestens einem der Ansprüche 1 bis 10, **dadurch gekennzeichnet**, daß der Schaltfinger (20), der Betätigungsabschnitt (19) und das Armteil (21) sich im wesentlichen bogenförmig um die Rotationsachse (X) des ersten Zählringes (12) erstrecken.

12. Inhalator nach mindestens einem der Ansprüche 1 bis 11, **dadurch gekennzeichnet**, daß eine Rücklaufsperrvorrichtung (28) vorgesehen ist, zum Verhindern einer Drehbewegung des ersten Zählrings (12) entgegen der Zählrichtung.

13. Inhalator nach Anspruch 12, **dadurch gekennzeichnet**, daß die Rücklaufsperrvorrichtung (28) eine Rastklinke aufweist.

14. Inhalator nach mindestens einem der Ansprüche 1 bis 13, **dadurch gekennzeichnet**, daß die Länge des Armteiles (21) und die Länge des Schaltfingers (20) sowie die Position des Armteiles (21) und des Schaltfingers (2a) derart abgestimmt sind, daß bei einer Verlagerung des Betätigungselementes (19) um eine vorgegebene Wegstrecke der Eingriffsabschnitt (22) des Schaltfingers (20) sich in Umfangsrichtung des ersten Zählrings (12) um eine Wegstrecke verlagert deren Länge im wesentlichen der Schrittlänge einer umfangsseitig an dem ersten Zählring (12) vorgesehenen Skalierung entspricht.

15. Inhalator nach mindestens einem der Ansprüche 1 bis 14, **dadurch gekennzeichnet**, daß die Skalierung des ersten Zählrings (12) die Ziffern 0, 1, 2... bis 9 trägt.

16. Inhalator nach mindestens einem der Ansprüche 1 bis 15, **dadurch gekennzeichnet**, daß die Skalierung des zweiten Zählrings (13) die Ziffern 0, 1, 2,... bis 9 trägt.

17. Inhalator nach mindestens einem der Ansprüche 1 bis 15, **dadurch gekennzeichnet**, daß die Skalierung des zweiten Zählrings (13) die Zahlen 0, 1, 2,...9, 10, 11,... 19 und 20 trägt.

18. Inhalator nach Anspruch 15, **dadurch gekennzeichnet**, daß die Ziffernfolge 0, 1...9 am Umfang des ersten Zählrings (12) mehrfach; insbesondere dreimal abfolgend vorgesehen ist.

19. Inhalator nach mindestens einem der Ansprüche 1 bis 18, **dadurch gekennzeichnet**, daß der zweite Zählring (13) einen Lagerungsabschnitt aufweist, der in den ersten Zählring (12) drehbar eingesetzt oder auf diesen aufgesetzt ist.

20. Inhalator nach mindestens einem der Ansprüche 1 bis 19, **dadurch gekennzeichnet**, daß die Koppelungsvorrichtung (24, 25, 26, 27) ein Mitnehmerelement aufweist das mit dem ersten Zählring (12) gekoppelt ist.

21. Inhalator nach Anspruch 20, **dadurch gekennzeichnet**, daß das Mitnehmerelement durch ein elastisch nachgiebiges Zungenelement (24) gebildet ist, das einstückig mit dem ersten Zählring (12) ausgebildet ist.

22. Inhalator nach Anspruch 20 oder 21, **dadurch gekennzeichnet**, daß der zweite Zählring (13) einen Verzahnungsabschnitt aufweist der mit dem Zungenelement (24) in Eingriff bringbar ist.

23. Inhalator nach einem der Ansprüche 20 bis 22, **dadurch gekennzeichnet**, daß die Koppelungsvorrichtung eine stationäre Anlauf-Nase (27) aufweist, zum Auslenken des Zungenelements (24) derart, daß dieses über eine, einem Zählschritt entsprechende Umfangslänge mit dem zweiten Zählring (13) in Eingriff tritt und den zweiten Zählring (13) um diese Umfangslänge weiterdreht.

24. Inhalator nach Anspruch 23, **dadurch gekennzeichnet**, daß drei in Umfangsrichtung gleichmäßig beabstandete stationäre Anlauf-Nasen (27) vorgesehen sind derart, daß der zweite Zählring (13) bei einem vollständigen Umlauf den zweiten Zählring (13) um drei Zählschritte weiterdreht.

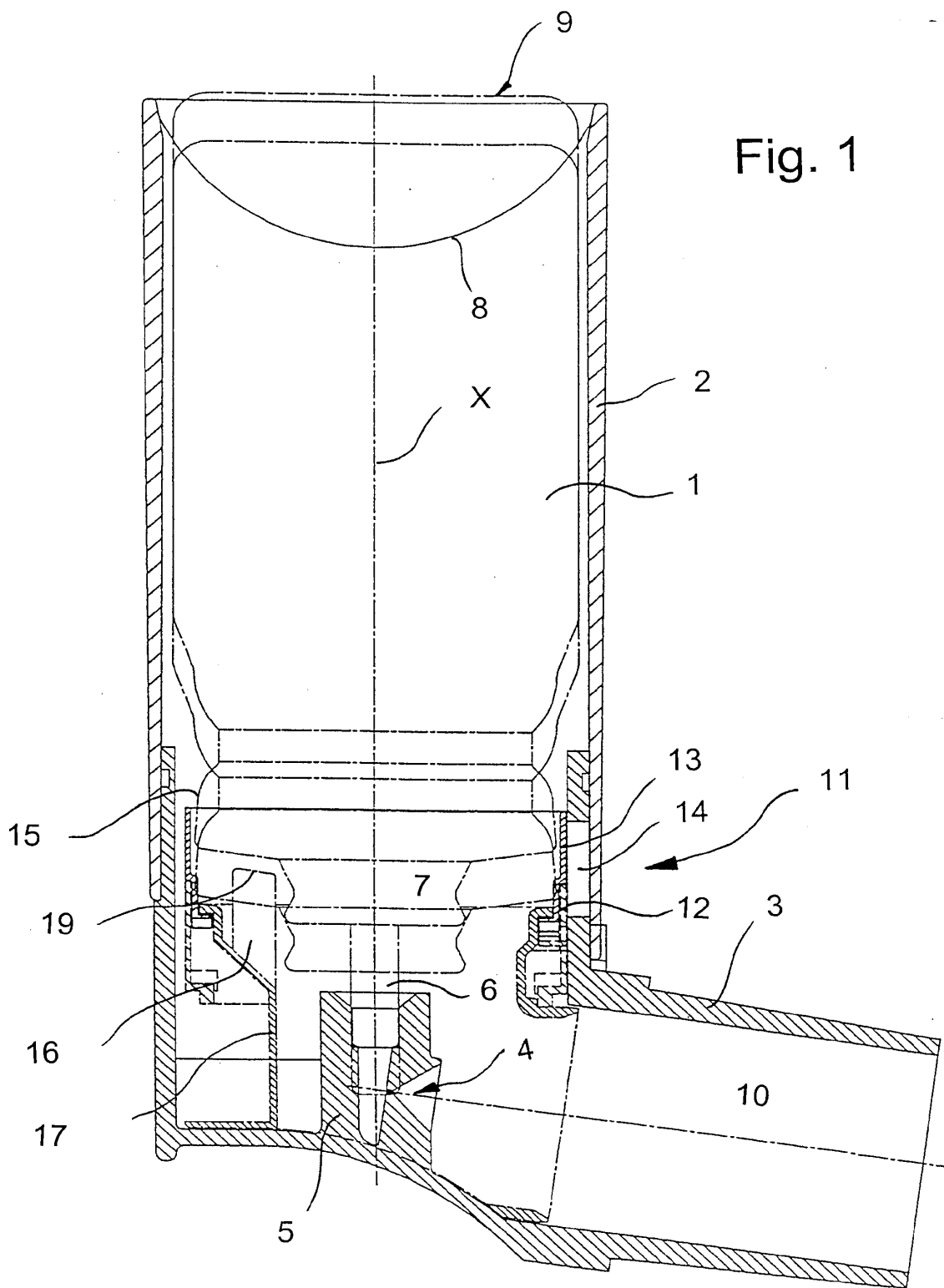


Fig. 2a

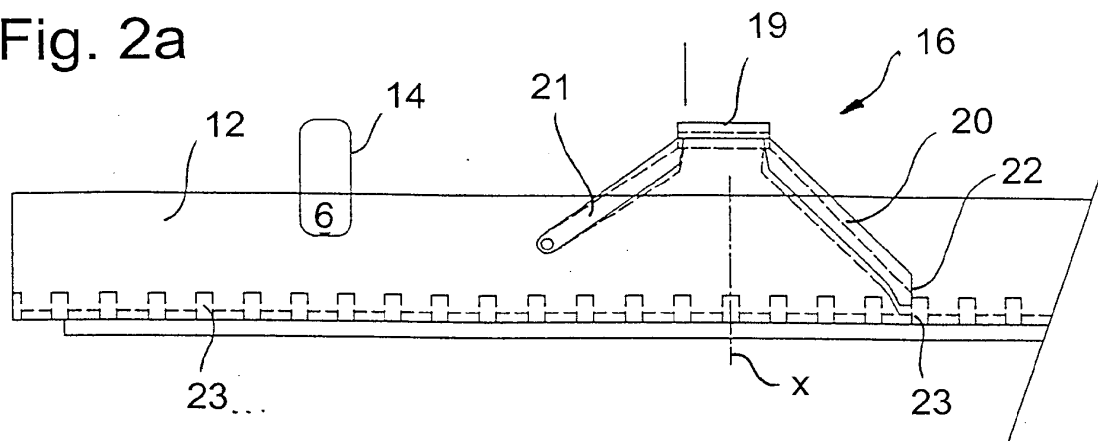


Fig. 2b

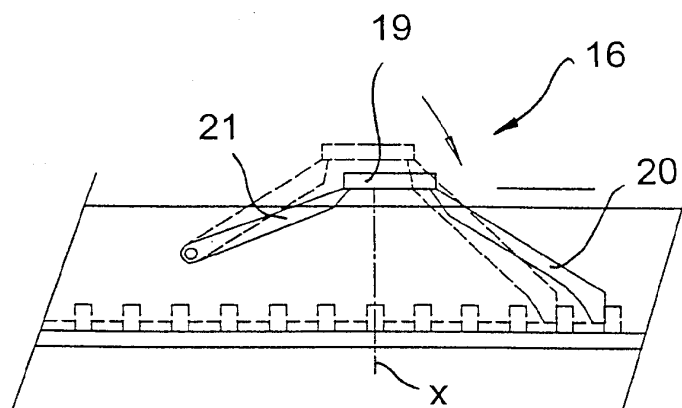


Fig. 2c

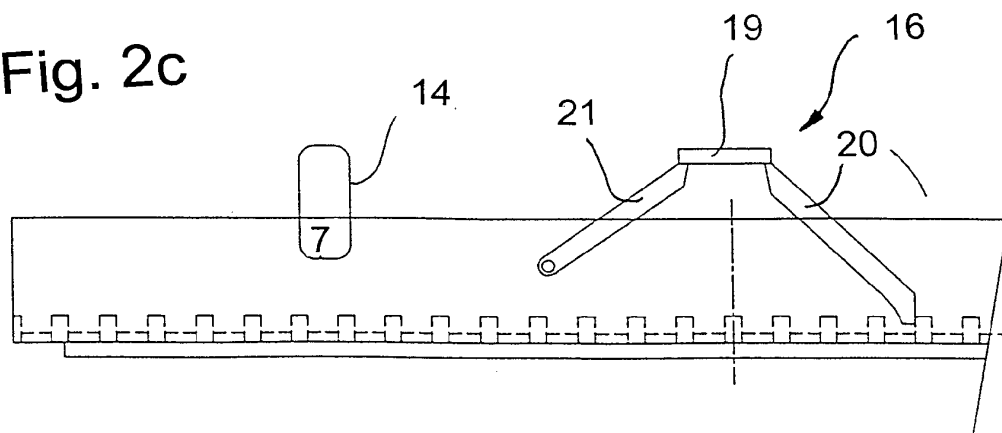


Fig. 3a

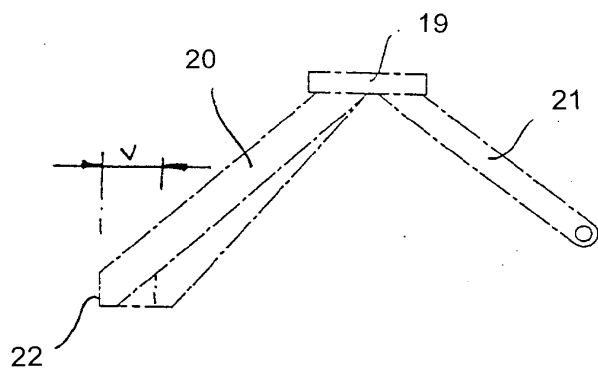
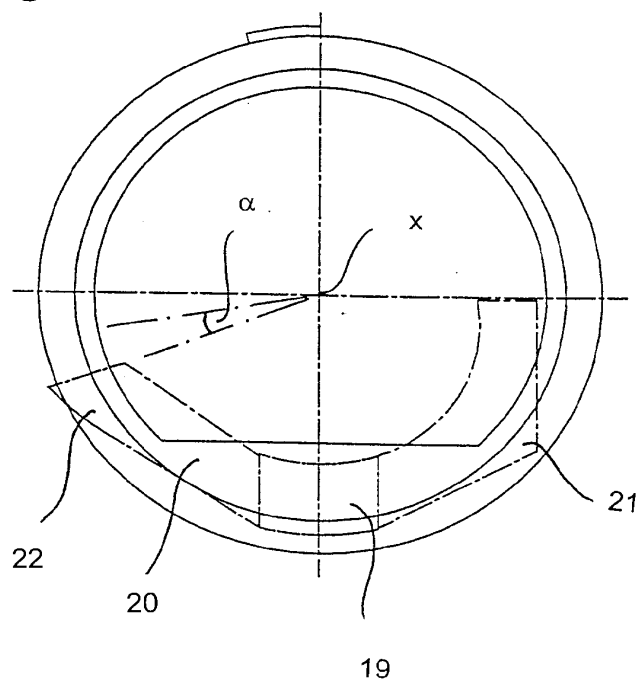


Fig. 3b



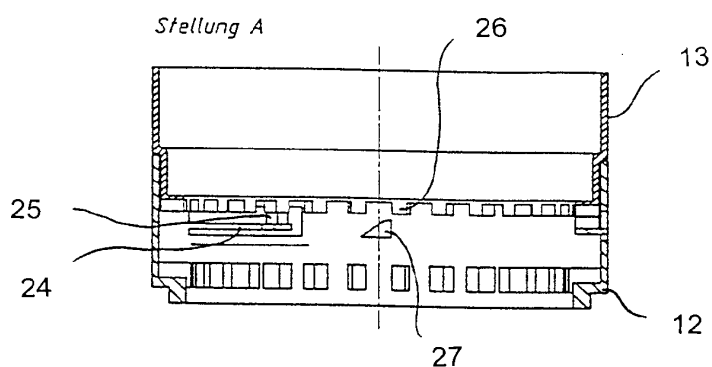


Fig. 4a

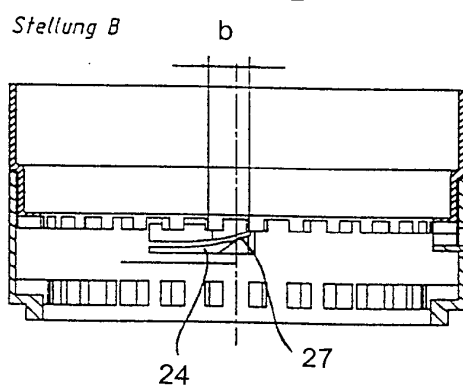


Fig. 4b

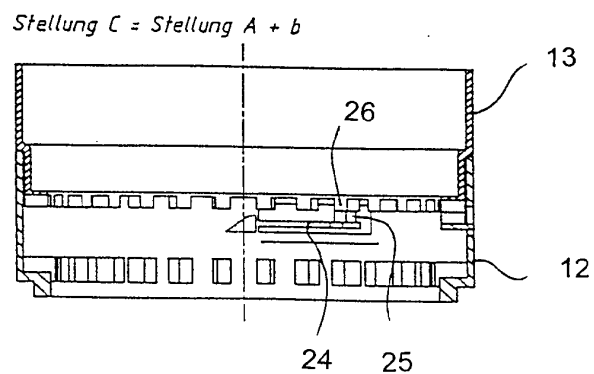


Fig. 4c

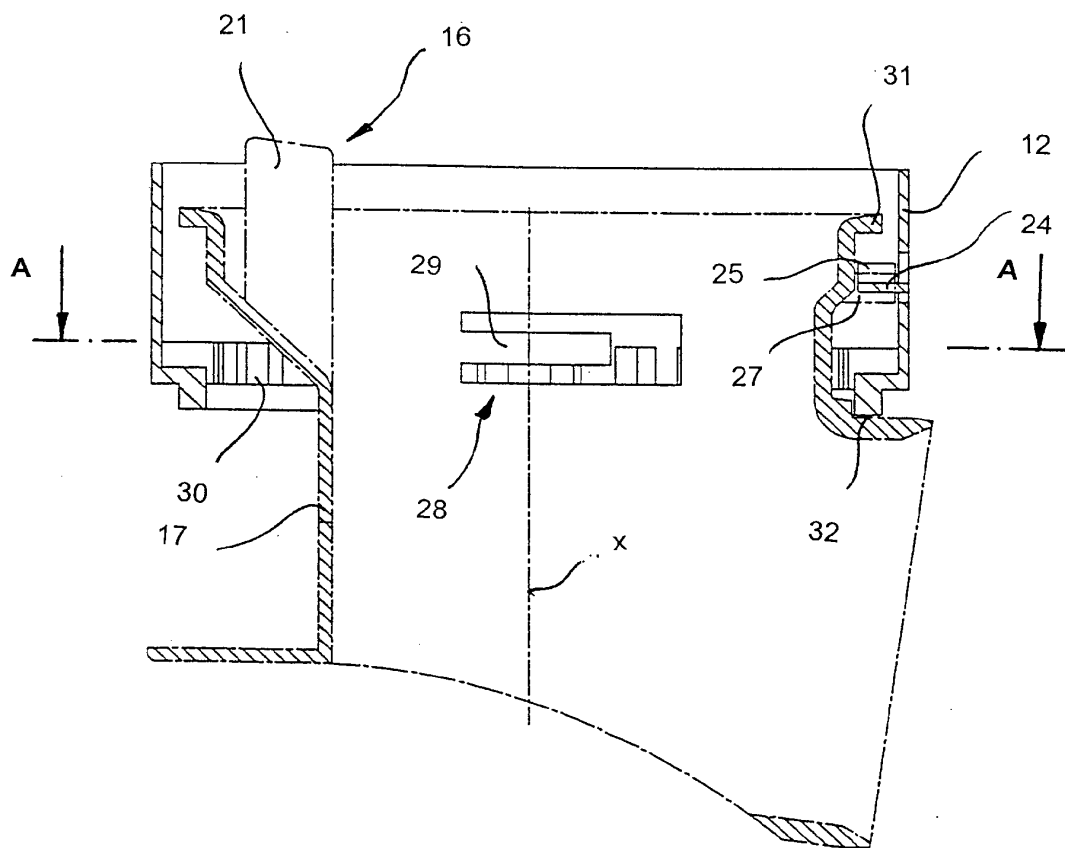


Fig. 5

A-A

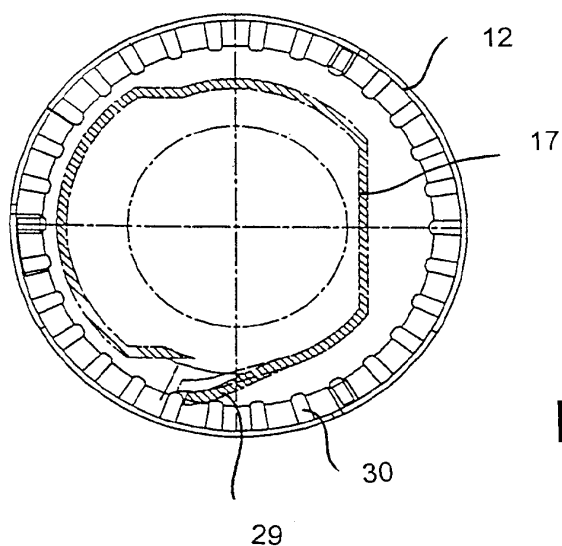


Fig. 6

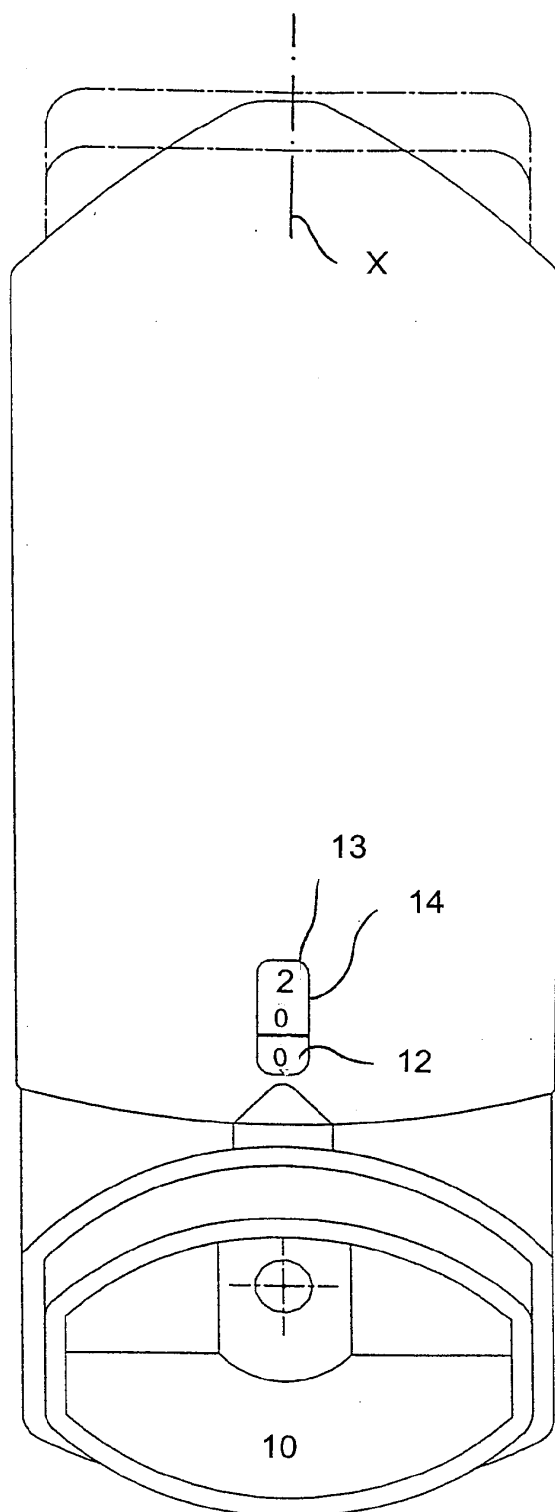


Fig. 7

INTERNATIONAL SEARCH REPORT

International Application No
PC/EP 99/05939

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M15/00 G06M1/08 G06M1/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M G06M B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 022 212 A (VANTOREX LTD) 31 July 1970 (1970-07-31) page 3, line 37 -page 4, line 24 figures 1,2	1, 15, 16, 20
Y		2-7, 9, 12-14, 17-19
Y	EP 0 480 488 A (ELETTRIO PLASTICA SPA) 15 April 1992 (1992-04-15) column 4, line 4 - line 33 figures 4,5	2-7, 9, 14
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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Date of the actual completion of the international search

24 November 1999

Date of mailing of the international search report

01/12/1999

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Authorized officer

Lakkis, A

INTERNATIONAL SEARCH REPORT

International Application No
PC1, EP 99/05939

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 94 14492 A (AMBROSIO THOMAS J ;MANTHENA SRINIVAS (US); SCHERING CORP (US); WIL) 7 July 1994 (1994-07-07) page 30, line 5 -page 31, line 5 page 49, line 26 - line 30 page 50, line 13 - line 25 page 65, line 35 -page 66, line 14 figures 3,4,67,71,75,105	12,13, 17-19
A	----	2,3,5,11
A	WO 96 29278 A (SENETICS INC) 26 September 1996 (1996-09-26) ----	
E	EP 0 949 584 A (BASON NEIL PETER) 13 October 1999 (1999-10-13) paragraphs '0018!-'0021! figures 2,3 -----	1,15-17, 19-22

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

page 2 of 2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PC, EP 99/05939

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2022212 A	31-07-1970	AU 6168869 A	08-04-1971
		GB 1290484 A	27-09-1972
		ZA 6906865 A	27-05-1971
EP 0480488 A	15-04-1992	IT 1243820 B	28-06-1994
		AT 113486 T	15-11-1994
		AU 646873 B	10-03-1994
		AU 8025891 A	16-04-1992
		CA 2046806 A	10-04-1992
		DE 69104950 D	08-12-1994
		DE 69104950 T	09-03-1995
		ES 2066336 T	01-03-1995
		JP 5228213 A	07-09-1993
		US 5174473 A	29-12-1992
WO 9414492 A	07-07-1994	AT 177323 T	15-03-1999
		AU 683036 B	30-10-1997
		AU 5748794 A	19-07-1994
		CA 2152088 A	07-07-1994
		CN 1091321 A	31-08-1994
		CZ 9501535 A	15-05-1996
		DE 69323897 D	15-04-1999
		DE 69323897 T	04-11-1999
		EP 0674533 A	04-10-1995
		ES 2128550 T	16-05-1999
		FI 952976 A	16-06-1995
		GR 3030035 T	30-07-1999
		HU 73522 A, B	28-08-1996
		IL 108061 A	10-06-1997
		JP 2924924 B	26-07-1999
		JP 8500756 T	30-01-1996
		NO 952429 A	18-08-1995
		NZ 259241 A	20-12-1996
		PL 309401 A	02-10-1995
		SG 52237 A	28-09-1998
		SK 80695 A	07-02-1996
		US 5829434 A	03-11-1998
		US 5687710 A	18-11-1997
		US 5740792 A	21-04-1998
		ZA 9309472 A	19-06-1995
WO 9629278 A	26-09-1996	US 5421482 A	06-06-1995
		AU 7732794 A	10-04-1995
		EP 0720568 A	10-07-1996
		WO 9508484 A	30-03-1995
		AU 688794 B	19-03-1998
		BR 9407608 A	14-01-1997
		CA 2172537 A	30-03-1995
		CN 1133584 A	16-10-1996
		JP 9502951 T	25-03-1997
		US 5611444 A	18-03-1997
		US 5718355 A	17-02-1998
		US 5799651 A	01-09-1998
EP 0949584 A	13-10-1999	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PC./EP 99/05939

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES

IPK 7 A61M15/00 G06M1/08 G06M1/14

Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)

IPK 7 A61M G06M B65D

Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	FR 2 022 212 A (VANTOREX LTD) 31. Juli 1970 (1970-07-31) Seite 3, Zeile 37 -Seite 4, Zeile 24 Abbildungen 1,2	1,15,16, 20
Y	---	2-7,9, 12-14, 17-19
Y	EP 0 480 488 A (ELETTRIO PLASTICA SPA) 15. April 1992 (1992-04-15) Spalte 4, Zeile 4 - Zeile 33 Abbildungen 4,5 ---	2-7,9,14
	--- -/--	

☒ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen

☒ Siehe Anhang Patentfamilie

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Datum des Abschlusses der internationalen Recherche

24. November 1999

Absenddatum des internationalen Recherchenberichts

01/12/1999

Name und Postanschrift der internationalen Recherchenbehörde

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Fax: (+31-70) 340-3016

Bevollmächtigter Bediensteter

Lakkis, A

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PC 1, EP 99/05939

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN		
Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	WO 94 14492 A (AMBROSIO THOMAS J ;MANTHENA SRINIVAS (US); SCHERING CORP (US); WIL) 7. Juli 1994 (1994-07-07) Seite 30, Zeile 5 -Seite 31, Zeile 5 Seite 49, Zeile 26 - Zeile 30 Seite 50, Zeile 13 - Zeile 25 Seite 65, Zeile 35 -Seite 66, Zeile 14 Abbildungen 3,4,67,71,75,105	12,13, 17-19
A	----	2,3,5,11
A	WO 96 29278 A (SENETICS INC) 26. September 1996 (1996-09-26) ----	
E	EP 0 949 584 A (BASON NEIL PETER) 13. Oktober 1999 (1999-10-13) Absätze '0018!-'0021! Abbildungen 2,3 -----	1,15-17, 19-22

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Seite 2 von 2

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichung, die zur selben Patentfamilie gehören

Internationales Aktenzeichen

PC 17 EP 99/05939

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
FR 2022212 A	31-07-1970	AU 6168869 A	08-04-1971
		GB 1290484 A	27-09-1972
		ZA 6906865 A	27-05-1971
EP 0480488 A	15-04-1992	IT 1243820 B	28-06-1994
		AT 113486 T	15-11-1994
		AU 646873 B	10-03-1994
		AU 8025891 A	16-04-1992
		CA 2046806 A	10-04-1992
		DE 69104950 D	08-12-1994
		DE 69104950 T	09-03-1995
		ES 2066336 T	01-03-1995
		JP 5228213 A	07-09-1993
		US 5174473 A	29-12-1992
WO 9414492 A	07-07-1994	AT 177323 T	15-03-1999
		AU 683036 B	30-10-1997
		AU 5748794 A	19-07-1994
		CA 2152088 A	07-07-1994
		CN 1091321 A	31-08-1994
		CZ 9501535 A	15-05-1996
		DE 69323897 D	15-04-1999
		DE 69323897 T	04-11-1999
		EP 0674533 A	04-10-1995
		ES 2128550 T	16-05-1999
		FI 952976 A	16-06-1995
		GR 3030035 T	30-07-1999
		HU 73522 A,B	28-08-1996
		IL 108061 A	10-06-1997
		JP 2924924 B	26-07-1999
		JP 8500756 T	30-01-1996
		NO 952429 A	18-08-1995
		NZ 259241 A	20-12-1996
		PL 309401 A	02-10-1995
		SG 52237 A	28-09-1998
		SK 80695 A	07-02-1996
		US 5829434 A	03-11-1998
		US 5687710 A	18-11-1997
		US 5740792 A	21-04-1998
		ZA 9309472 A	19-06-1995
WO 9629278 A	26-09-1996	US 5421482 A	06-06-1995
		AU 7732794 A	10-04-1995
		EP 0720568 A	10-07-1996
		WO 9508484 A	30-03-1995
		AU 688794 B	19-03-1998
		BR 9407608 A	14-01-1997
		CA 2172537 A	30-03-1995
		CN 1133584 A	16-10-1996
		JP 9502951 T	25-03-1997
		US 5611444 A	18-03-1997
		US 5718355 A	17-02-1998
		US 5799651 A	01-09-1998
EP 0949584 A	13-10-1999	KEINE	

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(54) Title: ACTUATING DEVICE FOR METERS AND METERING AEROSOL DISPENSING DEVICE WITH AN ACTUATING DEVICE FOR METERS (54) Bezeichnung: BETÄTIGUNGSVORRICHTUNG FÜR ZÄHLWERKE UND DOSIERAEROSOLABGABEVORRICHTUNG MIT EINER BETÄTIGUNGSEINRICHTUNG FÜR ZÄHLWERKE (57) Abstract A metering aerosol dispensing device comprising an aerosol container (23); a nozzle (31, 32) that is arranged in a nozzle body (30), whereby the aerosol is dispensed via said nozzle when the aerosol container (23) is pushed against the body (30) of the nozzle once the metering aerosol dispensing device is actuated; a meter (1, 2, 4) that counts the number of times that the metering aerosol dispensing device is actuated; and an actuating device (10) that enables the meter (1, 2, 3, 4) to move forward when the metering aerosol dispensing device is actuated. The invention is characterized in that the actuating device (10) is designed and arranged in the metering aerosol dispensing device in such a way that the body (30) of the nozzle is accommodated in the interior of the actuating device (10) and the nozzle (31) is released in order to produce aerosol in an unrestricted manner. (57) Zusammenfassung Dosieraerosolabgabevorrichtung mit einem Aerosolbehälter (23), einer in einem Düsenkörper (30) angeordneten Düse (31, 32), über die ein Aerosol abgegeben wird, wenn der Aerosolbehälter (23) gegenüber dem Düsenkörper (30) bei einer Betätigung der Dosieraerosolabgabevorrichtung verschoben wird, einem Zählwerk (1, 2, 3, 4) zur Zählung der Betätigungen der Dosieraerosolabgabevorrichtung und einer Betätigungsverrichtung (10) zur Weiterschaltung des Zählwerks (1, 2, 3, 4) bei einer Betätigung der Dosieraerosolabgabevorrichtung, dadurch gekennzeichnet, daß die Betätigungsverrichtung (10) so ausgestaltet und in der Dosieraerosolabgabevorrichtung angeordnet ist, dass der Düsenkörper (30) im Innern der Betätigungsverrichtung (10) aufgenommen und die Düse (31) zur unbeeinflussten Aerosolerzeugung freigegeben ist.		

LEDIGLICH ZUR INFORMATION

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BESCHREIBUNG

Betätigungsvorrichtung für Zählwerke und
Dosieraerosolabgabevorrichtung mit einer
Betätigungseinrichtung für Zählwerke

Die vorliegende Erfindung betrifft
Dosieraerosolabgabevorrichtungen, und insbesondere eine
Betätigungsvorrichtung für Zählwerke zur einfachen Verwendung
in Dosieraerosolabgabevorrichtungen.

Verschiedene Dosieraerosolabgabevorrichtungen für
Inhalationszwecke sind bekannt, die beispielsweise zur
Behandlung von Atemwegserkrankungen eine dosisgenaue
Medikamentenmenge in Form eines Sprühnebels oder Aerosols
abgeben. Hierbei kommt es insbesondere auf die zuverlässige
Dosierung des abgegebenen Medikaments an, damit ein gezielter
Therapieeffekt beim Patienten hervorgerufen wird. Derartige
Dosieraerosolvorrichtungen sind beispielsweise die allgemein
bekannten MDI (metered dose inhalers), die in der Regel ein
Gehäuse, einen Behälter zur Aufnahme eines flüssigen oder
pulverförmigen Medikaments, eine geeignet ausgebildete Düse
zum Zerstäuben und Verteilen des Medikaments und ein

Mundstück aufweisen, über das das erzeugte medikamentenhaltige Aerosol eingeatmet wird. Die Betätigung der Dosieraerosolvorrichtungen erfolgt beispielsweise bei Treibgasaerosolen derart, daß der Medikamentenbehälter gegenüber der in dem Gehäuse angeordneten Düse geradlinig verschoben wird, wodurch eine definierte Menge des Zerstäubungsguts freigesetzt wird. Eine Dosieraerosolvorrichtung dieser Art ist beispielsweise in EP 0 254 391 beschrieben.

Dosieraerosolabgabevorrichtungen sind in der Regel für Mehrfachdosierungen ausgelegt. Dabei ist es wünschenswert, dem Benutzer die Anzahl der abgegebenen Dosen, in anderen Worten der abgegebenen Sprühstöße, bzw. die noch zur Verfügung stehenden Sprühstöße anzuzeigen, um sicher zustellen, daß der Patient frühzeitig darauf hingewiesen wird, daß das Medikament verbraucht ist. Auf diese Weise wird vermieden, daß ein Patient, beispielsweise zur Vorbeugung eines akuten Asthmaanfalls, eine bereits nahezu leere Dosieraerosolabgabevorrichtung mit sich führt.

Aus diesem Grund sind Dosiervernebler bzw. Dosierinhalatoren mit unterschiedlichen Zählwerken ausgestattet worden. EP 0 254 391 beschreibt zum Beispiel einen Inhalator mit einem flachen Zählwerk, das auf der dem Patienten zugewandten Seite eines Aerosolspenders ausgebildet ist. Aus EP 0 505 321 ist ein wiederverwendbarer Inhalator mit rücksetztbarem Zähler bekannt, der beim Erreichen der ersten Relativposition von Vorratskammer und Dosierstift inkrementiert wird. Das in GB 1 317 315 offenbarte Zählwerk weist eine Vielzahl von ringförmigen Elementen auf, die mechanisch zusammenwirken, um an einem Anzeiger die noch zur Verfügung stehenden Dosierungen anzuzeigen. Weitere Medikamentenspender mit

mechanischem Zählwerk sind beispielsweise in WO 86/02275 und WO 93/24167 offenbart.

Die bekannten Lösungen für Dosierungsvorrichtungen weisen jedoch entweder einen komplexen, unhandlichen Aufbau auf oder erfordern, daß eine bereits vorhandene Dosisaerosolabgabevorrichtung in erheblichem Umfang modifiziert werden muß. Eine derartige Modifikation einer bereits vorhandenen Dosieraerosolabgabevorrichtung ist jedoch insofern von Nachteil, da diese dann erneut einem amtlichen Genehmigungsverfahren und den damit einhergehenden Versuchen für die medizinische Anwendbarkeit unterworfen werden muß. Dies ist jedoch in der Regel ein langwieriger und kostspieliger Prozess und daher unerwünscht.

Ausgehend vom Stand der Technik ist es daher die Aufgabe der vorliegenden Erfindung, für eine Dosieraerosolvorrichtung eine Betätigungsvorrichtung für Zählwerke mit kleinen Abmessungen zu schaffen, die mit unterschiedlichen Dosieraerosolabgabevorrichtungen zur Dosiszählung verwendet werden kann, ohne daß wesentliche Modifikationen an den Dosieraerosolvorrichtungen durchgeführt werden müssen. Die Aufgabe wird erfindungsgemäß gelöst durch eine Dosieraerosolabgabevorrichtung mit einem Aerosolbehälter, einer in einem Düsenkörper angeordneten Düse, über die ein Aerosol abgegeben wird, wenn der Aerosolbehälter gegenüber dem Düsenkörper bei einer Betätigung der Dosieraerosolabgabevorrichtung verschoben wird, einem Zählwerk zur Zählung der Betätigungen der Dosieraerosolabgabevorrichtung und einer Betätigungsvorrichtung zur Weiterschaltung des Zählwerks bei einer Betätigung der Dosieraerosolabgabevorrichtung, wobei die Betätigungsvorrichtung so ausgestaltet und in der

Dosieraerosolabgabevorrichtung angeordnet ist, dass der Düsenkörper im Innern der Betätigungsvorrichtung aufgenommen und die Düse zur unbeeinflussten Aerosolerzeugung freigegeben ist.

Vorteilhaft besteht die Betätigungsvorrichtung aus zwei gegeneinander verschiebbaren Hülsen, die im Inneren den Düsenkörper der Dosieraerosolabgabevorrichtung aufnehmen.

Die beiden Hülsen der Betätigungsvorrichtung sind vorteilhaft durch Federelemente miteinander verbunden, die die Hülsen der Betätigungsvorrichtung in eine Ausgangsposition zurück bewegen.

Die Federelemente sind vorteilhaft in Form von flachen, gebogenen Federelementen realisiert, die an den Außenseiten der Hülsen befestigt oder einstückig angeformt sind.

Um eine Verkantung der Hülsen zu vermeiden, sind an den Hülsen der Betätigungsvorrichtung Führungselemente vorgesehen sind, die eine geradlinige Verschiebung der beiden Hülsen gegeneinander gewährleisten. Alternativ können die Federelemente derart ausgestaltet werden, dass sie eine geradlinige Verschiebung der beiden Hülsen gegeneinander gewährleisten.

Für die Weiterschaltung des Zählwerks umfasst die Betätigungsvorrichtung einen Betätigungsarm umfasst, der auf das Zählwerk einwirkt.

Um ein möglichst kleines Zählwerk zu realisieren, besteht das Zählwerk aus mehreren parallel angeordneten Scheibeneinheiten wobei eine erste Scheibeneinheit eine Außenverzahnung

aufweist, die mit der Betätigungsverrichtung, insbesondere mit dem Betätigungsarm zusammenwirkt.

Um aus Zählwerk und Betätigungsverrichtung eine Einheit zu machen, weist die Betätigungsverrichtung eine Öffnung auf, in der ein Lagerbolzen des Zählwerks zur Halterung des Zählwerks an der Betätigungsverrichtung befestigbar ist.

Damit die Aerosolerzeugung und -ausbreitung nicht beeinflusst wird, weist die Betätigungseinrichtung, insbesondere das Unterteil eine Aussparung oder eine Öffnung auf, durch die die Düse freigegeben ist.

Weitere Merkmale und Vorteile der vorliegenden Erfindung ergeben sich aus der folgenden Beschreibung eines bevorzugten Ausführungsbeispiels, das im Zusammenhang mit den beigefügten Abbildungen erläutert wird, in denen zeigt:

- Fig. 1 eine Explosionsdarstellung eines Zählwerks, das mit einer erfindungsgemäßen Betätigungsverrichtung für eine Dosieraerosolabgabevorrichtung zusammenwirkt;
- Fig. 2 eine Explosionsdarstellung des in Fig. 1 gezeigten Zählwerks, betrachtet aus der zu Fig. 1 anderen Blickrichtung;
- Fig. 3 eine schematische Querschnittsansicht einer Ausgangs- bzw. Ruheposition der zweiten und dritten Scheibeneinheiten zur Erläuterung des Zusammenwirkens von zweiter und dritter Scheibeneinheit;

- Fig. 4 eine schematische Querschnittsansicht analog zu Fig.3, die die zweite und dritte Scheibeneinheit in einer Position zeigt, in der die zweite Scheibeneinheit durch die dritte Scheibeneinheit veranlaßt wird, mit der vierten Scheibeneinheit zusammenzuwirken;
- Fig. 5 eine separate Ansicht der in Fig. 1 und 2 dargestellten Betätigungsvorrichtung;
- Fig. 6 die Anordnung der erfindungsgemäßen Betätigungseinrichtung für Zählwerke in einer Dosieraerosolabgabevorrichtung; und
- Fig. 7 eine vergrößerte Darstellung der Anordnung der Betätigungseinrichtung an der Düse einer Dosieraerosolabgabevorrichtung.

Zur Einleitung und für ein besseres Verständnis der Erfindung wird im folgenden zunächst ein Zählwerk für Dosieraerosolabgabevorrichtungen unter Bezugnahme auf Fig. 1 und 2 beschrieben. Fig. 1 und 2 zeigen jeweils aus zwei unterschiedlichen Blickrichtungen betrachtete Explosionsdarstellungen des Zählwerks.

Das Zählwerk weist im wesentlichen vier Scheibeneinheiten 1, 2, 3 und 4 auf, die parallel zueinander angeordnet sind. Die Mittelpunkte der Scheibeneinheiten 1, 2, 3 und 4 liegen auf einer zu den Scheibeneinheiten senkrecht stehenden Achse und sind, wie nachstehend noch genauer erläutert wird, über einen Lagerbolzen 8 mit einer Betätigungsvorrichtung 10 eines Dosieraerosolerzeugers (nicht dargestellt) verbunden. Die erste, zweite und vierte Scheibeneinheit 1, 2 und 4 sind

bezogen auf die Betätigungsvorrichtung 10 drehbar angeordnet. Die dritte Scheibeneinheit 3 nimmt eine feste Position bezogen auf die Betätigungsvorrichtung 10 und damit auch auf die übrigen Scheibeneinheiten ein.

Die erste Scheibeneinheit 1 besitzt ein Mittel zur Aufnahme einer Kraft, die eine Drehung der ersten Scheibeneinheit hervorruft; dabei handelt es sich um eine Außenverzahnung 1a, in die ein an der Betätigungsvorrichtung 10 angebrachter Betätigungsarm 5 eingreift (siehe Fig. 1 und 2). Die erste Scheibeneinheit 1 weist einen kleineren Radius als die zweite Scheibeneinheit 2 auf und ist mit dieser fest verbunden. Durch diese feste Verbindung wird die Übertragung der Drehbewegung von der ersten Scheibeneinheit 1 auf die zweite Scheibeneinheit 2 realisiert. Es können aber auch andere Mittel zur Übertragung der Drehbewegung und zur Aufnahme der eine Drehbewegung hervorufenden Kraft an den beiden Scheibeneinheiten vorgesehen sein.

Um die Drehbewegung an eine vierte Scheibeneinheit 4 zu übertragen, ist als Übertragungsmittel am Außenumfang der zweiten Scheibeneinheit 2 ein keilförmiger Nocken 6 angebracht, der über ein Federelement 6a mit der zweiten Scheibeneinheit 2 verbunden ist und der im folgenden als Federnocken bezeichnet wird. Das Federelement 6a bildet im wesentlichen die Außenkontur der zweiten Scheibeneinheit 2 nach, besitzt aber ein frei schwingendes Ende. An dem frei schwingendem Ende ist der keilförmige Federnocken 6 derart angebracht, daß er in der Ruhestellung über die Außenkontur der zweiten Scheibeneinheit 2 in radialer Richtung übersteht. Die Geometrie des Federnocken ist so gewählt, daß der Nocken bzw. die Nase bei einer Auslenkung in radialer Richtung in

die Innenverzahnung 13 der vierten Scheibeneinheit 4 eingreift.

Dazu ist der keilförmige Federnocken 6 so angeordnet, daß die scharfe und die stumpfe Kante senkrecht zur Ebene der zweiten Scheibeneinheit 2 orientiert sind. Der Federnocken 6 weist ferner eine Breite auf, die größer ist als die Dicke der zweiten Scheibeneinheit 2, so daß sich der Federnocken 6 parallel zur Achse der Scheibeneinheiten zapfenartig in Richtung auf die dritte und vierte Scheibeneinheit 3 und 4 erstreckt.

Der zapfenartig in Richtung dritte und vierte Scheibeneinheit überstehenden Federnocken 6 kann in Wechselwirkung mit den anderen Elementen des Zählwerks, die insbesondere unter Bezugnahme auf Fig. 3 und 4 genauer erläutert werden, mit einer ersten Verzahnung 13 der vierten Scheibeneinheit 4 in Eingriff treten (siehe Fig. 2).

Die in Richtung dritte und vierte Scheibeneinheit weisende Seite der zweiten Scheibeneinheit 2 weist eine Innenverzahnung 7 auf, die symmetrisch um die Achse der Scheibeneinheiten angeordnet ist. Die Innenverzahnung 7, die in Fig. 2 zu sehen ist, nicht aber in Fig.1, weist die gleiche Anzahl von Zähnen wie die außenverzahnte Scheibeneinheit 1 auf. In der in Fig. 1 bzw. 2 dargestellten Ausführungsform beträgt die Anzahl der Zähne zehn, um zusammen mit einer ersten Innenverzahnung 13 der vierten Scheibeneinheit 4 mit 24 Zähnen insgesamt 240 diskrete Zählsschritte zu realisieren. Jedoch können problemlos andere Werte verwendet werden.

Der Radius der dritten Scheibeneinheit 3 ist gleich oder vorzugsweise geringfügig kleiner als der Radius der zweiten Scheibeneinheit 2. Ferner ist an dem Außenumfang der dritten Scheibeneinheit 3 eine keilförmige Schulter 11 angebracht, die zur Betätigung des an der zweiten Scheibeneinheit 2 angeordneten Federnocken 6 dient, was im folgenden noch genauer erklärt wird. Wird eine weitere Schulter angebracht, so ändert sich das Übersetzungsverhältnis. Die dritte Scheibeneinheit 3 ist mit einem Lagerbolzen 8 fest verbunden.

Der Lagerbolzen 8 weist bezogen auf die dritte Scheibeneinheit 3 drei unterschiedliche Bereiche auf, nämlich den in Richtung vierte Scheibeneinheit 4 weisenden Abschnitt 8a und die in Richtung erste und zweite Scheibeneinheit weisenden Abschnitte 8b und 8c. Der Durchmesser des Lagerbolzenabschnitts 8b ist mit dem des Abschnittes 8a identisch, und der des Abschnitts 8c ist im Vergleich dazu reduziert. Der Lagerbolzen 8 dient der drehfesten Anbringung der dritten Scheibeneinheit 3 an der Betätigungsvorrichtung 10 und zur drehbaren Lagerung der ersten, zweiten und vierten Scheibeneinheit 1, 2 und 4. Hierzu ist der Lagerbolzenabschnitt mit kleinerem Radius 8c in eine entsprechende Öffnung 18 der Befestigungseinheit 10 eingeführt und derart befestigt, daß die Position der dritten Scheibeneinheit 3 bezogen auf die Betätigungsvorrichtung 10 fest ist. Die in der ersten und zweiten Scheibeneinheiten 1 und 2 vorgesehenen Öffnungen sind so auf den Durchmesser des Lagerbolzenabschnittes 8b abgestimmt, daß die ersten und zweiten Scheibeneinheiten 1 und 2 auf dem Lagerbolzenabschnitt 8b gleitend drehbar sind. Es sei angemerkt, daß die Durchmesser der Abschnitte 8a, 8b und 8c nicht auf das in Fig. 1 bzw. Fig. 2 dargestellte Verhältnis beschränkt sind. Wesentlich ist, daß die jeweiligen Öffnungen

der Scheibeneinheiten und die Durchmesser der Lagerbolzenabschnitte aufeinander abgestimmt sind.

Ferner sind an dem Lagerbolzen 8 zwei L-förmige Verriegelungselemente 9 angeordnet, die am Außenumfang des Lagerbolzenabschnitts 8b angeordnet sind und die in die Innenverzahnung 7 der zweiten Scheibeneinheit 2 eingreifen. Die Öffnung der vierten Scheibeneinheit 4 ist so auf den Durchmesser des Lagerbolzenabschnittes 8a abgestimmt, daß die vierte Scheibeneinheit 4 auf dem Lagerbolzenabschnitt 8a gleitend drehbar ist. An dem Abschnitt 8a sind zudem, in Richtung vierte Scheibeneinheit 4weisend, zwei Schnapphaken 12a symmetrisch angeordnet, die zur axialen Fixierung der Scheibeneinheit 4 dienen.

Auf der in Richtung vierte Scheibeneinheit 4weisenden Seite der dritten Scheibeneinheit 3 ist eine Rastverzahnung 12 angebracht, die in Fig. 2 zu sehen ist. In dem in Fig. 2 dargestellten Ausführungsbeispiel besteht die Rastverzahnung 12 aus vier Elementen, die um 90° zueinander beabstandet sind. Die Rastverzahnung kann aber auch aus einem oder aus mehreren Elementen bestehen, die zentrisch um die Achse des Lagerbolzens 8 angeordnet sind. Diese Rastverzahnung 12 greift in eine zweite Verzahnung 14 der vierten Scheibeneinheit 4 ein und dient im wesentlichen der Sicherung der Drehstellung der Scheibeneinheit 4.

Die Ausgestaltung der vierten Scheibeneinheit 4 ist insbesondere aus Fig. 1 ersichtlich. Die in Richtung der anderen Scheibeneinheitenweisende Seite der vierten Scheibeneinheit 4 weist eine erste Verzahnung 13 auf, die an der Umfangsinnenseite angeordnet ist, und eine zweite Verzahnung 14, die kreisförmig um den Mittelpunkt der vierten

Scheibeneinheit 4 verläuft. Der Radius der zweiten Verzahnung 14 ist abgestimmt auf die Lage der Elemente der Rastverzahnung 12, die an der dritten Scheibeneinheit 3 vorgesehen ist.

Im montierten Zustand sind die erste und zweite Scheibeneinheit 1 und 2 auf dem Lagerbolzenabschnitt 8b angeordnet; dabei liegen die L-förmigen Verringerungselemente 9 in der Ausnehmung der Innenverzahnung 7 der zweiten Scheibeneinheit 2. Der Federnocken 6 ragt über die Außenkontur der dritten Scheibeneinheit 3. Die vierte Scheibeneinheit 4 ist auf dem Lagerbolzenabschnitt 8a angeordnet und nimmt aufgrund der kappenartigen Gestalt die dritte Scheibeneinheit 3 auf; dabei liegt der Federnocken 6 zwischen der Außenkontur der dritten Scheibeneinheit 3 und der ersten Innenverzahnung der vierten Scheibeneinheit 4.

Im folgenden wird die Funktionsweise des zuvor beschriebenen Zählwerks erläutert. Da, wie in Fig. 2 gezeigt, der Betätigungsarm 5 der erfindungsgemäßen Betätigungseinrichtung 10 in die Außenverzahnung der ersten Scheibeneinheit 1 eingreift, wird durch eine Bewegung des Betätigungsarmes 5 die erste Scheibeneinheit 1 in die in Fig. 1 und 2 angedeutete Pfeilrichtung gedreht. Hierbei bewegt sich die zweite Scheibeneinheit 2 mit, da die erste und zweite Scheibeneinheit 1 und 2 fest miteinander verbunden sind. Die erste und zweite Scheibeneinheit 1 und 2 gleiten dabei auf dem Lagerbolzenabschnitt 8b. Im Gegensatz dazu ist die dritte Scheibeneinheit 3 über den Lagerbolzen 8 mit der Betätigungseinrichtung 10 fest verbunden, so daß die Position der dritten Scheibeneinheit 3 bezogen auf die Betätigungseinrichtung 10 zu jedem Zeitpunkt unverändert bleibt. Gleichzeitig sind die an dem Lagerbolzenabschnitt 8b

angebrachten L-förmigen Verriegelungselemente 9 in Eingriff mit der Innenverzahnung 7 der Scheibeneinheit 2; jedoch gestattet die Gestaltung der Verriegelungselemente 9 und der Innenverzahnung 7 eine Drehung der ersten und zweiten Scheibeneinheiten 1 und 2 in der in Fig. 1 und 2 gezeigten Richtung. Bei einer Drehung der ersten und zweiten Scheibeneinheit 1 und 2 in Pfeilrichtung rasten die Verriegelungselemente 9 in die jeweils nächste Verzahnung der Innenverzahnung 7 ein. Bei einer erneuten Betätigung des Armes 5 drehen sich Scheibeneinheiten 1 und 2 genau einen Zahn weiter und der Verriegelungsarm rastet in den nächsten Zahn ein. Durch ein derartiges Eingreifen der Verriegelungselemente 9 in die Innenverzahnung 7 wird sichergestellt, daß sich die erste und somit auch die zweite Scheibeneinheit beim Lösen des Betätigungsarms 5 aus dem Eingriff mit der zahnradförmigen Scheibeneinheit 1 nicht zurückdreht, d.h. sich nicht entgegen der Pfeilrichtung zurückbewegt.

Bei der in Fig. 1 und 2 angedeuteten Drehung der ersten und zweiten Scheibeneinheit 1 und 2 in Pfeilrichtung läuft der an der zweiten Scheibeneinheit 2 angeordnete Federnocken 6 auf der Außenkontur der dritten Scheibeneinheit 3 entlang. Geht man von einem Zahnrad, das zehn Zähne aufweist aus, so überstreicht der Federnocken 6 bei 10-maliger Betätigung des Armes 5 einen Winkel von 360° , d.h. der Federnocken macht einen vollen Umlauf und gelangt wieder an seine Ausgangsposition. Solange der Federnocken 6 nicht von der Schulter 11 der dritten Scheibeneinheit 3 beeinflußt wird, greift der Federnocken 6 nicht in die an der Innenumfangseite der vierten Scheibeneinheit 4 angebrachte erste Verzahnung 13 ein. Erst wenn die Schulter 11 den Federnocken 6 in radialer Richtung anhebt, gelangt der Federnocken 6 in Eingriff mit

der ersten Innenverzahnung der vierten Scheibeneinheit 4 und bewirkt eine Drehung der vierten Scheibeneinheit um eine Drehstellung.

Die schrittweise Drehung der Scheibeneinheit 2 bezogen auf die dritte Scheibeneinheit 3, sowie das Eingreifen des Federnockens 6 der zweiten Scheibeneinheit 2 in die Innenverzahnung 13 der vierten Scheibeneinheit 4 werden im folgenden unter Bezugnahme auf Fig. 3 und 4 genauer beschrieben. Fig. 3 und 4 zeigen schematische Querschnittsansichten, die insbesondere das Zusammenwirken von zweiter und dritter Scheibeneinheit 2 und 3 detaillierter erläutern. In Fig. 3 und 4 sind die Scheibeneinheiten 2 und 3 aus der in Fig. 2 gezeigten Blickrichtung dargestellt. Die dritte Scheibeneinheit 3 ist in beiden Abbildungen aus Gründen der besseren Übersicht lediglich gestrichelt angedeutet. Fig. 3 zeigt die oben erwähnte Ausgangsposition bzw. Ruheposition der zweiten Scheibeneinheit 2 in Bezug auf die fest mit der Betätigungseinrichtung 10 verbundene dritte Scheibeneinheit 3. In dieser Position ist das Verriegelungselement 9 in den ersten Zahn 7-1 der Innenverzahnung 7 eingerastet. Durch Betätigung des Betätigungsarmes 5, der in die zahnradförmige erste Scheibeneinheit 1 eingreift (in Fig. 3 nicht dargestellt), wird die Scheibeneinheit 2 schrittweise, d.h. Zahn für Zahn, in der in Fig. 3 angedeuteten Pfeilrichtung gedreht. Das Verriegelungselement 9 rastet hierbei, beginnend vom ersten Innenzahn 7-1 in aufsteigender Reihenfolge in die Zähne 7-2 bis 7-9 ein. Bei der durch den Betätigungsarm 5 initiierten Drehbewegung der ersten und zweiten Scheibeneinheit 1 und 2 läuft der Federnocken 6 auf dem Umfang der in Fig. 3 gestrichelt dargestellten dritten Scheibeneinheit 3 entlang, ohne daß der Federnocken 6 ausgelenkt wird. In diesem Fall

;

greift der Federnocken 6 nicht in die erste Verzahnung 13 der vierten Scheibeneinheit 4 ein.

Ist der Betätigungsarm 5 so oft betätigt worden, daß das Verriegelungselement 9 in den Zahn 7-10 der Innenverzahnung 7 einrastet, d.h wenn ausgehend von der in Fig. 3 dargestellten Ausgangsposition der Betätigungsarm 5 zum neunten Mal betätigt worden ist, dann ist der Federnocken 6 in Kontakt mit der Schulter 11. Dies bewirkt, daß der Federnocken 6, wie in Fig. 4 dargestellt, in radialer Richtung ausgelenkt wird. Mit anderen Worten, der Federnocken 6 wird in dieser Position durch die Schulter 11 betätigt und der Federnocken 6 greift in die Innenumfangsverzahnung 13 ein und dreht die vierte Scheibeneinheit 4 um einen Zahn der ersten Verzahnung 13 in Pfeilrichtung weiter.

Bei dieser durch das Zusammenwirken der Schulter 11 und des Federnocken 6 bewirkten Drehung der vierten Scheibeneinheit 4 rastet die an der in Richtung erste, zweite und dritte Scheibeneinheit weisenden Innenseite der vierten Scheibeneinheit 4 angeordnete zweite Verzahnung 14 mit der Rastverzahnung 12 ein. Die Rastverzahnung 12 und die zweite Verzahnung 14 der vierten Scheibeneinheit 4 dienen hierbei der Sicherung der vierten Scheibeneinheit 4 gegen Verdrehen, und durch die Schnapphaken 12a ist eine axiale Fixierung der vierten Scheibeneinheit 4 gewährleistet.

Bei der nachfolgenden Betätigung der ersten bzw. zweiten Scheibeneinheit durch den Betätigungsarm 5 nimmt die zweite Scheibeneinheit 2 wieder die in Fig. 3 dargestellte Ausgangsposition ein und die zuvor unter Bezugnahme auf Fig. 3 beschriebene Bewegung des Federnocken 6 wird wieder durchlaufen, ohne daß der Federnocken 6 in Eingriff mit der

ersten Verzahnung 13 der vierten Scheibeneinheit 4 tritt. Erst nachdem das Verriegelungselement wieder in den Zahn 7-10 der Innenverzahnung 7 einrastet, wird der Federnocken 6 durch die Schulter 11 erneut ausgelenkt, so daß dieser wieder in Eingriff mit der Innenverzahnung 13 tritt und daraufhin die vierte Scheibeneinheit 4 um einen Zahn der ersten Innenverzahnung 13 weiterdreht. Auf diese Weise wird bei einer 10-zahnigen ersten Scheibeneinheit die vierte Scheibeneinheit 4 jeweils nach 10 Betätigungen des Betätigungsarms 5 um genau einen Zahn der ersten Verzahnung 13 weitergedreht. Wenn die erste Innenverzahnung 13 der vierten Scheibeneinheit 4 beispielsweise 24 Zähne aufweist, beträgt die maximale Anzahl der Zählstellungen in diesem Fall 240, d.h. wenn sich die vierte Scheibeneinheit 4 um 360° gedreht hat, sind 240 Betätigungen des Betätigungsarms 5 gezählt worden. Die zweite Verzahnung 14 der vierten Scheibeneinheit 4 weist die gleiche Anzahl von Zähnen wie die erste Innenverzahnung 13 auf.

Es sei angemerkt, daß die Anzahl der Zähne der ersten und zweiten Verzahnung 13 und 14 entsprechend an die gewünschte Übersetzung angepaßt werden kann. Eine 30-zahnige erste bzw. zweite Verzahnung 13 bzw. 14 dient somit zur Zählung von bis zu 300 Betätigungen. Das Übersetzungsverhältnis des erfindungsgemäßen Zählwerks bzw. die Anzahl der Zählungen kann aber auch durch ein Anordnen einer weiteren Schulter bzw. mehrerer Schultern am Außenrand der dritten Scheibeneinheit 3 variiert werden. Dies ermöglicht insbesondere ein unkompliziertes und schnelles Anpassen des erfindungsgemäßen Zählwerks an ein gewünschtes Übersetzungsverhältnis.

Die vierte Scheibeneinheit 4 kann in Form einer Anzeigescheibe ausgebildet sein, um entsprechend die Zählungen anzuzeigen. Dies kann beispielsweise durch einen Aufdruck eines Zeigers oder einer Farbmarkierung sowohl auf der Stirnseite als auch auf dem Rand der vierten Scheibeneinheit 4 erreicht werden. In dem in Fig. 2 dargestellten Ausführungsbeispiel ist ein Zeiger-Anzeigeelement 4a angedeutet. Der Zeiger gibt entsprechend der Drehstellung der vierten Scheibeneinheit 4 die Anzahl der Betätigungen an.

Im folgenden wird die Betätigungseinrichtung 10 gemäß der Erfindung beispielhaft genauer erläutert, die in vorteilhafter Weise mit dem zuvor beschriebenen Zählwerk ggf. aber auch mit anderen Zählwerken zusammenarbeitet.

Die in Fig. 1 und 2 dargestellte Betätigungseinrichtung 10 besteht aus einer zylinderförmigen Hülse 15 und einem zylinderförmigen Unterteil 16, bei dem es sich ebenfalls um eine Hülse handelt. An der Außenseite der Hülse 15 ist ein Betätigungsarm 5 angebracht. Hülse 15 und Unterteil 16 sind über eine bogenförmigen Feder 17 miteinander verbunden. Bei Betätigung der Feder 17, d.h. beim Zusammendrücken von Hülse 15 und Unterteil 16 in axialer Richtung, wird durch geeignete Führungselemente 19, die an der Hülse 15 in Richtung Unterteil 16 weisend angebracht sind, eine geradlinige Bewegung der Hülse 15 bezogen auf des Unterteil 16 gewährleistet. Dabei gleiten die Innenumfangsseite der Hülse 15 auf der Außenseite der Führungselemente 19. Wesentlich ist, daß eine geradlinige Bewegung der Hülse 15 und somit auch eine geradlinige Bewegung des Betätigungsarms 5 beim Zusammendrücken der Betätigungseinrichtung 10 gewährleistet ist, und ein zuverlässiges Eingreifen des Betätigungsarmes 5

in die zahnradförmige erste Scheibeneinheit 1 erzielt wird. Durch die Gestaltung der bogenförmigen Feder 17, beispielsweise wie in Fig. 1 und 2 gezeigt, als flaches gebogenes Federelement kann eine geradlinige Bewegung der Hülse 15 in Bezug auf das Unterteil erreicht werden, ohne daß Führungselemente erforderlich sind. Zur Verdeutlichung ist eine entsprechende Gestaltung der Betätigungseinrichtung 10 in Fig. 5 dargestellt, wobei das Zählwerk in der Darstellung der Fig. 5 weggelassen wurde.

In Fig. 6 ist in einer Gesamtansicht die Anordnung der erfindungsgemäßen Betätigungseinrichtung und des zuvor beschriebenen Zählwerks in einer Dosieraerosolabgabevorrichtung dargestellt. Fig. 6 zeigt ein Gehäuse 21 der Dosieraerosolabgabevorrichtung, das mit einem Mundstück 22 versehen ist. Das Mundstück 22 ist an dem unteren Bereich des Gehäuses 21 in abgewinkelter Stellung angeordnet. Im oberen Bereich des Gehäuses 21 befindet sich ein Dosieraerosolbehälter 23 zur Aufnahme eines zu zerstäubenden Aerosols. An den unteren Bereich des Aerosolbehälters 23 schließt sich ein Düsenbereich an, der in die Führungshülse 15 der Betätigungsvorrichtung 10 eingeführt ist. Die Düse selbst ist zur Verdeutlichung der Lage der erfindungsgemäßen Betätigungseinrichtung in Fig. 6 nicht dargestellt. Die Betätigungsvorrichtung 10 ist mit dem erfindungsgemäßen Zählwerk, bestehend aus den Scheibeneinheiten 1, 2, 3 und 4, verbunden, um die abgegebenen bzw. noch verbleibenden Dosierungen zu zählen und anzuzeigen. Bei jedem Pumpstoß, der, wie zuvor beschrieben, durch die Betätigung der Dosieraerosolabgabevorrichtung ausgelöst wird, wird eine bestimmte Aerosolmenge ausgegeben und über eine Düse zerstäubt, deren Aufbau und Verwendung mit derartigen herkömmlichen Dosieraerosolabgabevorrichtungen

allgemein bekannt ist. Das erzeugte Aerosol kann von einem Patienten über das Mundstück 22 eingeatmet werden. Die Betätigung der Dosieraerosolvorrichtung bewirkt, daß sich die Führungshülse 15 zusammen mit dem Betätigungsarm der Betätigungsvorrichtung 10 sich gegenüber dem Unterteil 16 verschiebt. Dadurch führt die Betätigung der Dosieraerosolabgabevorrichtung zu einer Weiterschaltung des Zählwerks.

Wie aus Fig. 6 hervorgeht, kann das Zählwerk mit der erfindungsgemäßen Betätigungseinrichtung unterhalb des Aerosolbehälters in einer herkömmlichen Dosieraerosolabgabevorrichtung problemlos angeordnet werden. Dies wird vorrangig dadurch erreicht, daß, wie schon aus Fig. 6 entnehmbar ist, sowohl die Hülse 15 als auch das Unterteil 16 der Betätigungsvorrichtung 10 im Inneren des Raums für insbesondere den Anschlußstutzen (nicht sichtbar) des Aerosolbehälters 23 und für den Düsenkörper der Dosieraerosolabgabevorrichtung aufweist. In Fig. 7 ist dargestellt, wie ein zylindrischer Düsenkörper 30 der Dosieraerosolabgabevorrichtung 21 in der Hülse 15 und dem Unterteil 16 der Betätigungseinrichtung 10 angeordnet werden kann. Man erkennt den (geschnitten dargestellten) zylindrischen Düsenkörper 30, die trichterförmige Düsenöffnung 31, einen Verbindungskanal 32, der die trichterförmige Düsenöffnung 31 mit einer Düsenkammer 33 verbindet, in die der Anschlußstutzen 25 des Aerosolbehälters 23 das Aerosol bei einem Pumpstoß abgibt. Da erfindungsgemäß die Hülse 15 und das Unterteil 16 der Betätigungseinrichtung 10 im Inneren ausreichend Raum sowohl für die Düse 30 als auch für den Anschluß des Aerosolbehälters 23 zur Verfügung stellen und da das Unterteil 16 so gestaltet ist, daß es die Düse 31 vollständig freigibt und die Aerosolerzeugung und -

ausbreitung nicht beeinflusst, kann die Betätigungseinrichtung 10 problemlos am Düsenkörper einer gegebenen Dosieraerosolabgabevorrichtung angeordnet werden, ohne daß Änderungen an dem Düsenkörper 30 bzw. der Düse 31, 32 oder dem Anschluß 25 für den Aerosolbehälter vorgenommen werden müssen. Das bedeutet, daß ein für die Dosieraerosolabgabevorrichtung durchlaufendes Zulassungsverfahren nicht erneut erforderlich ist, da keine Modifikationen an der Düsengestaltung 30, 31, 32, 33 aufgrund der erfindungsgemäßen Betätigungseinrichtung 10 vorgenommen werden müssen.

Die Freigabe der Düse 31 wird bei dem gezeigten Beispiel einer erfindungsgemäßen Betätigungseinrichtung dadurch erreicht, dass die das Unterteil 16 bildende Hülse ein der der Düse zugewandten Seite eine entsprechende Aussparung aufweist, wie die Fig. 1, 2, 5, 6 und 7 zeigen. Alternativ kann auch eine Öffnung vorgesehen werden, die der Öffnung 8 ähnelt, die aber so ausgebildet ist, dass sie die Düse 31 freigibt.

Vorteilhaft ist somit, daß beim Einsatz eines Zählwerks mit einer erfindungsgemäßen Betätigungseinrichtung 10 eine herkömmliche Dosieraerosolabgabevorrichtung nicht in ihren wesentlichen Komponenten, insbesondere nicht die Düse, verändert werden muß. Durch eine einfache Anordnung einer Betätigungsvorrichtung zum Betätigen des Zählwerks in einer gegebenen Gerätegestaltung wird ein einfacher und unkomplizierter Aufbau ermöglicht, der universell mit bereits bekannten Geräten verwendet werden kann. Auf diese Weise kann auf eine aufwendige Modifikation der bereits bekannten Dosieraerosolabgabevorrichtungen verzichtet werden. Dies ist wesentlich von Vorteil, da beispielsweise bei einer Änderung

der Düsenform derartige Inhalatoren erneut medizinische Prüfungen zur Erlangung der Zulassung durchlaufen müßten, die in der Regel langwierig, aufwendig und somit kostspielig sind.

PATENTANSPRÜCHE

1. Dosieraerosolabgabevorrichtung mit einem Aerosolbehälter (23), einer in einem Düsenkörper (30) angeordneten Düse (31, 32), über die ein Aerosol abgegeben wird, wenn der Aerosolbehälter (23) gegenüber dem Düsenkörper (30) bei einer Betätigung der Dosieraerosolabgabevorrichtung verschoben wird, einem Zählwerk (1, 2, 3, 4) zur Zählung der Betätigungen der Dosieraerosolabgabevorrichtung und einer Betätigungsvorrichtung (10) zur Weiterschaltung des Zählwerks (1, 2, 3, 4) bei einer Betätigung der Dosieraerosolabgabevorrichtung, dadurch gekennzeichnet, dass die Betätigungsvorrichtung (10) so ausgestaltet und in der Dosieraerosolabgabevorrichtung angeordnet ist, dass der Düsenkörper (30) im Innern der Betätigungsvorrichtung (10) aufgenommen und die Düse (31) zur unbeeinflussten Aerosolerzeugung freigegeben ist.

2. Dosieraerosolabgabevorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass die Betätigungsvorrichtung (10) aus zwei gegeneinander verschiebbaren Hülsen (15, 16) besteht, die im Inneren den Düsenkörper (30) der Dosieraerosolabgabevorrichtung aufnehmen.

3. Dosieraerosolabgabevorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass die Hülsen (15, 16) der Betätigungsvorrichtung (10) durch Federelemente (17) miteinander verbunden sind, die die Hülsen (15, 16) der Betätigungsvorrichtung (10) in eine Ausgangsposition zurück bewegen.

4. Dosieraerosolabgabevorrichtung nach Anspruch 3, dadurch gekennzeichnet, dass die Federelemente (17) in Form von flachen, gebogenen Federelementen realisiert sind, die an den Außenseiten der Hülsen (15, 16) befestigt oder einstückig angeformt sind.

5. Dosieraerosolabgabevorrichtung nach einem der Ansprüche 1 bis 4, dadurch gekennzeichnet, dass an den Hülsen (15, 16) der Betätigungsvorrichtung (10) Führungselemente (19) vorgesehen sind, die eine geradlinige Verschiebung der beiden Hülsen (15, 16) gegeneinander gewährleisten.

6. Dosieraerosolabgabevorrichtung nach Ansprüche 3 oder 4, dadurch gekennzeichnet, dass die Federelemente (17) derart ausgestaltet sind, dass sie eine geradlinige Verschiebung der beiden Hülsen (15, 16) gegeneinander gewährleisten.

7. Dosieraerosolabgabevorrichtung nach einem der Ansprüche 1 bis 6, dadurch gekennzeichnet, dass die Betätigungsvorrichtung (10) einen Betätigungsarm (5) umfasst, der auf das Zählwerk einwirkt, um das Zählwerk weiterzuschalten.

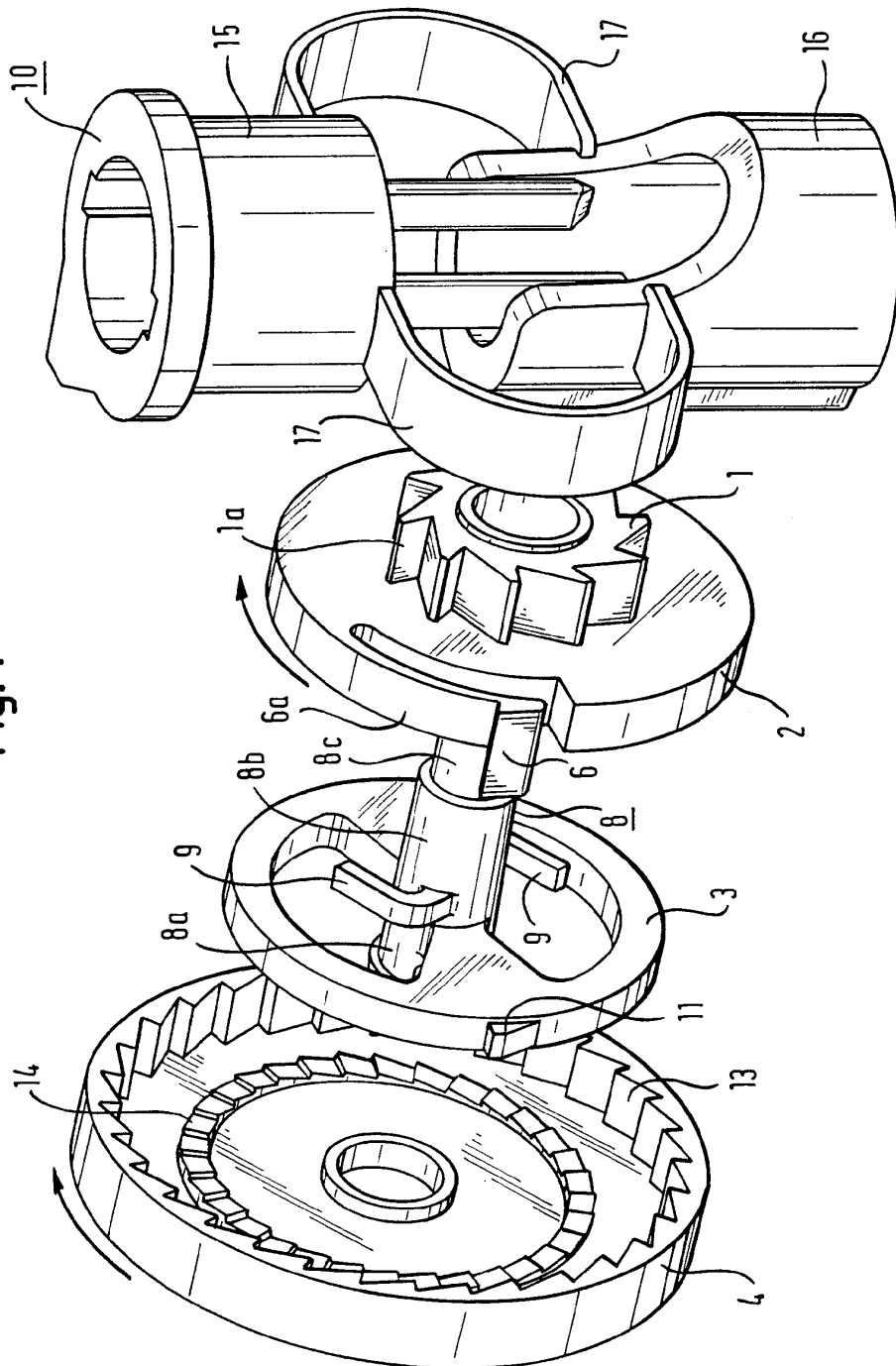
8. Dosieraerosolabgabevorrichtung nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, dass das Zählwerk aus mehreren parallel angeordneten Scheibeneinheiten (1, 2, 3, 4) aufgebaut ist und eine erste Scheibeneinheit eine Außenverzahnung (1a) aufweist, die mit der Betätigungsvorrichtung (10) zusammenwirkt.

9. Dosieraerosolabgabevorrichtung nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, dass die Betätigungsvorrichtung (10) eine Öffnung (18) aufweist, in

der ein Lagerbolzen (8c) des Zählwerks zur Halterung des Zählwerks an der Betätigungsvorrichtung (10) befestigbar ist.

10. Dosieraerosolabgabevorrichtung nach einem der Ansprüche 1 bis 9, dadurch gekennzeichnet, dass die Betätigungseinrichtung (10) eine Aussparung oder eine Öffnung aufweist, durch die die Düse (31) freigegeben ist.

Fig. 1



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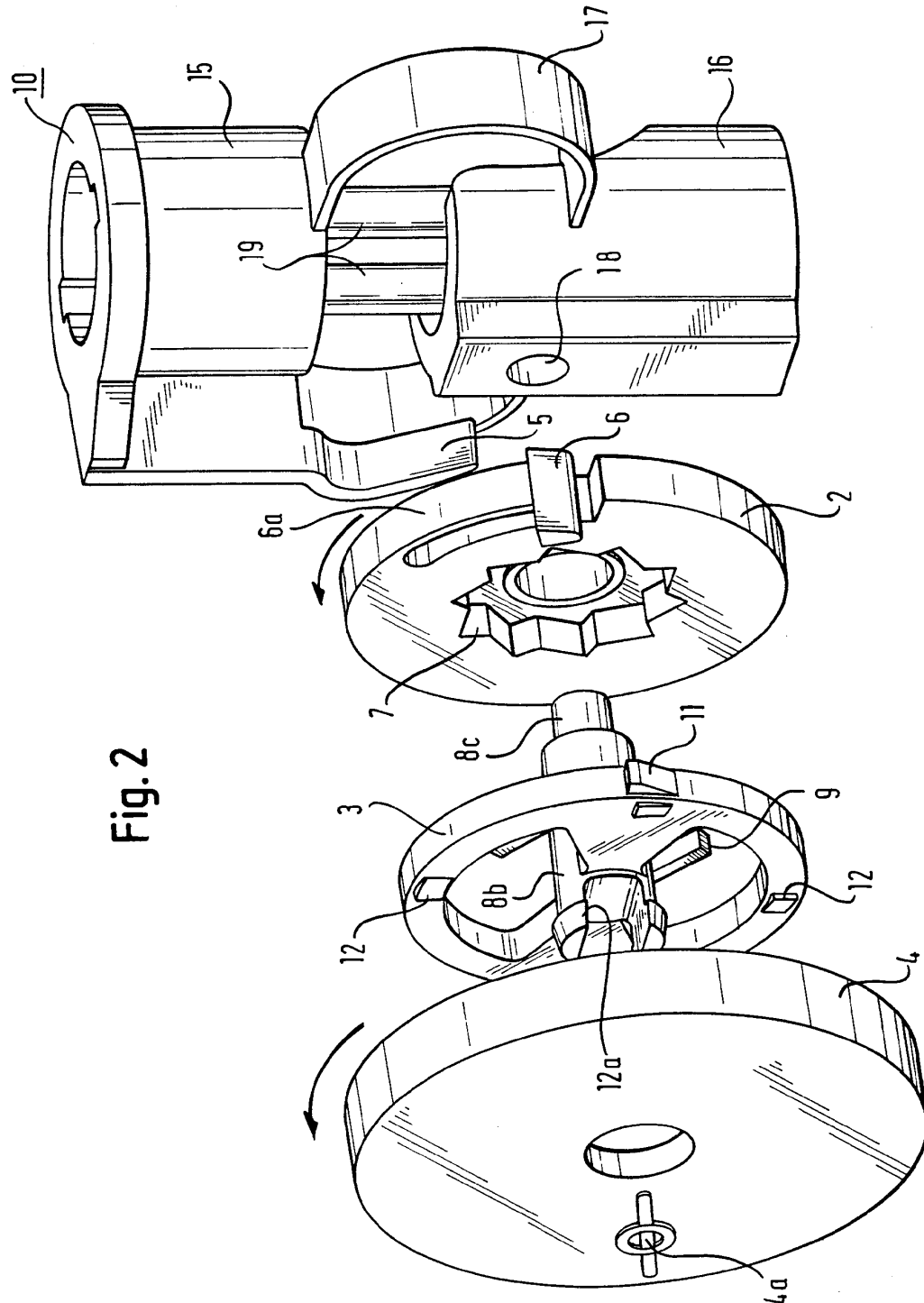


Fig. 2

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Fig. 3

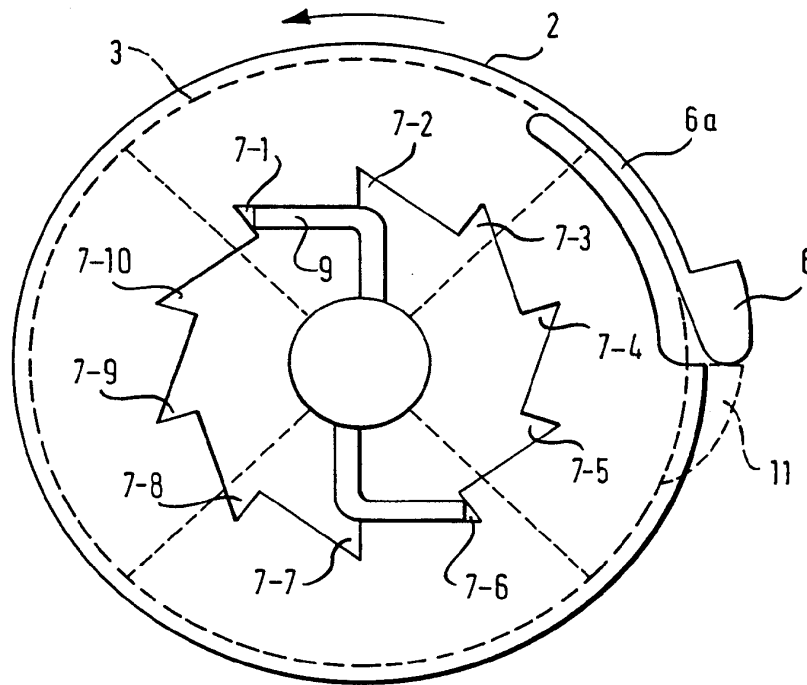
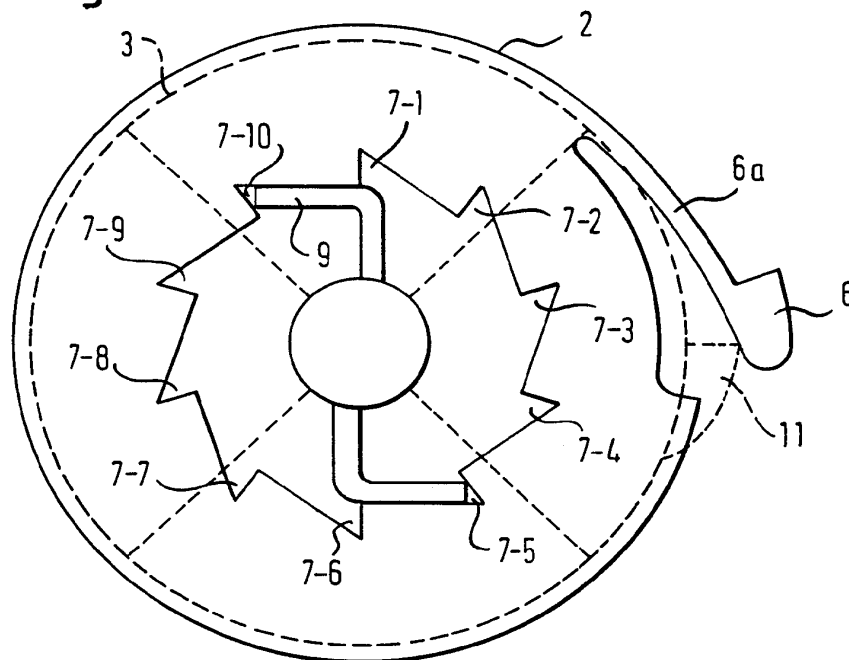


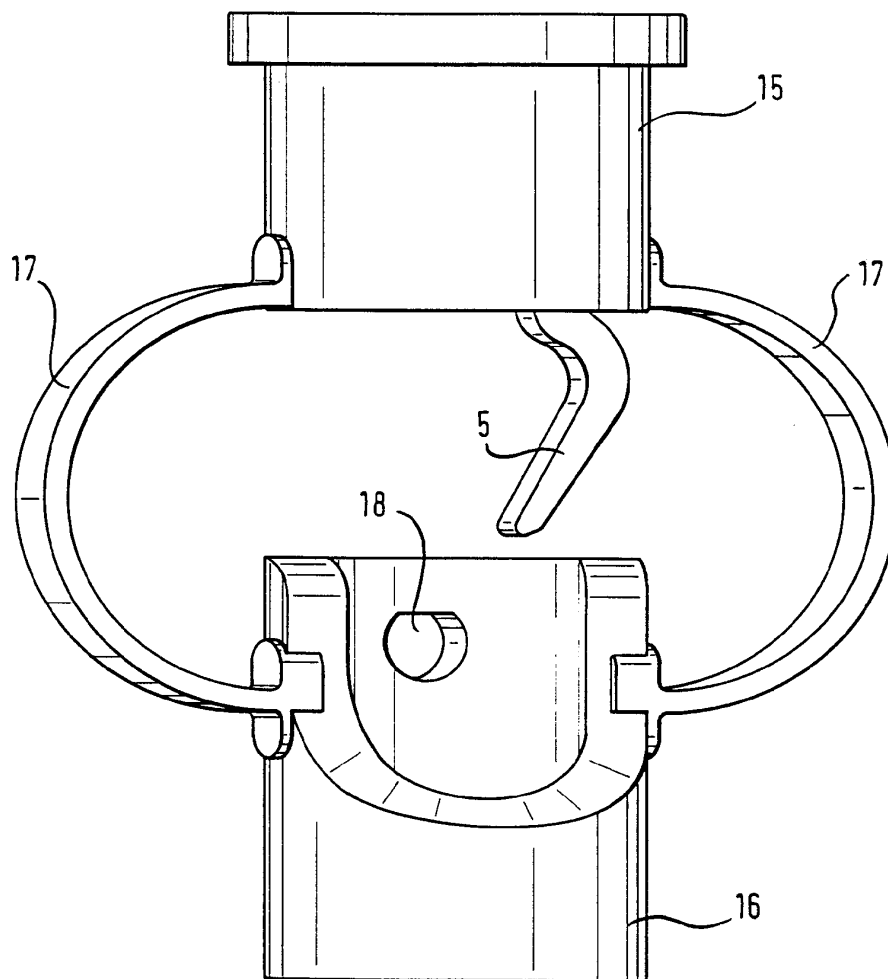
Fig. 4



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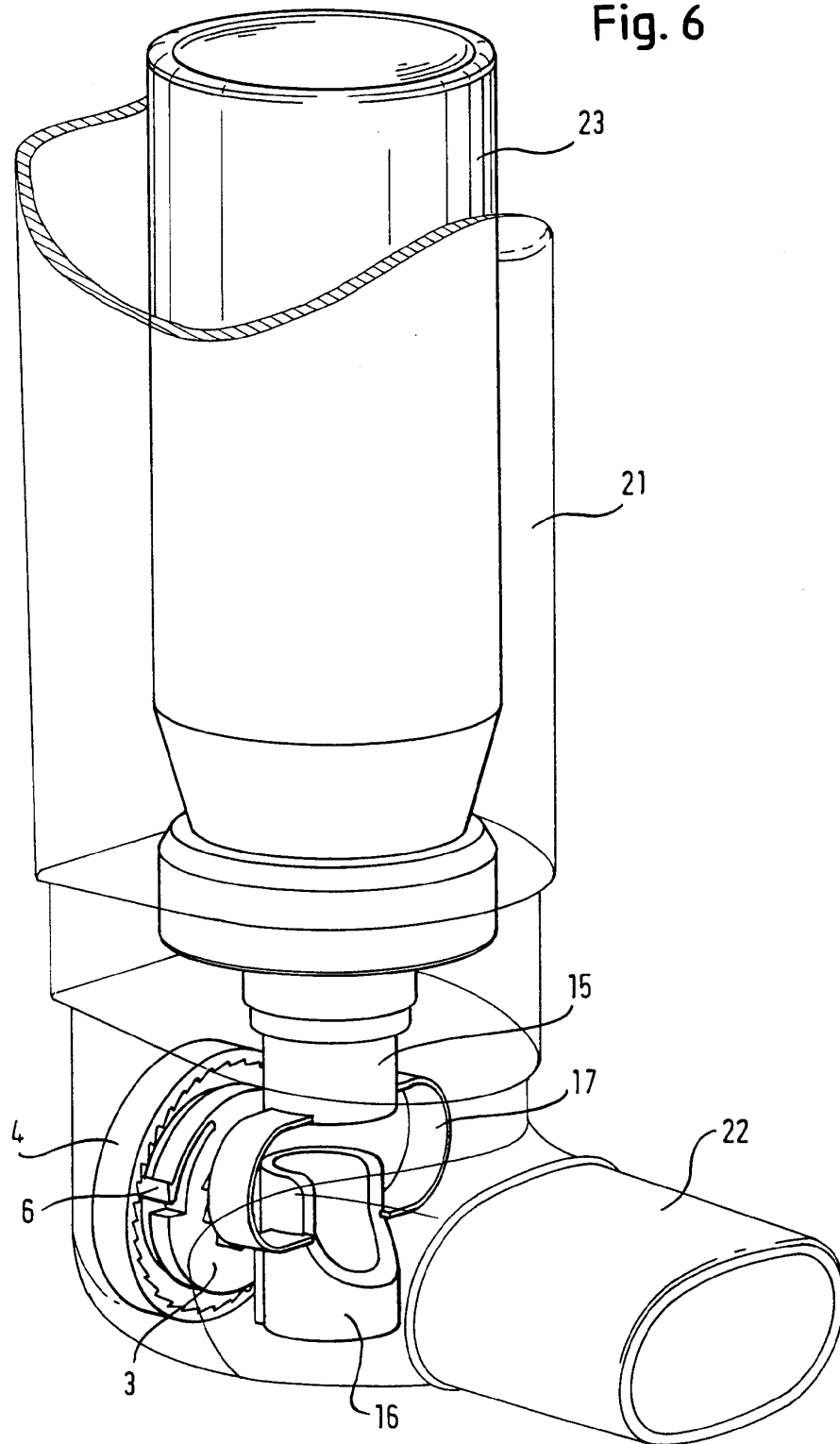
Fig. 5



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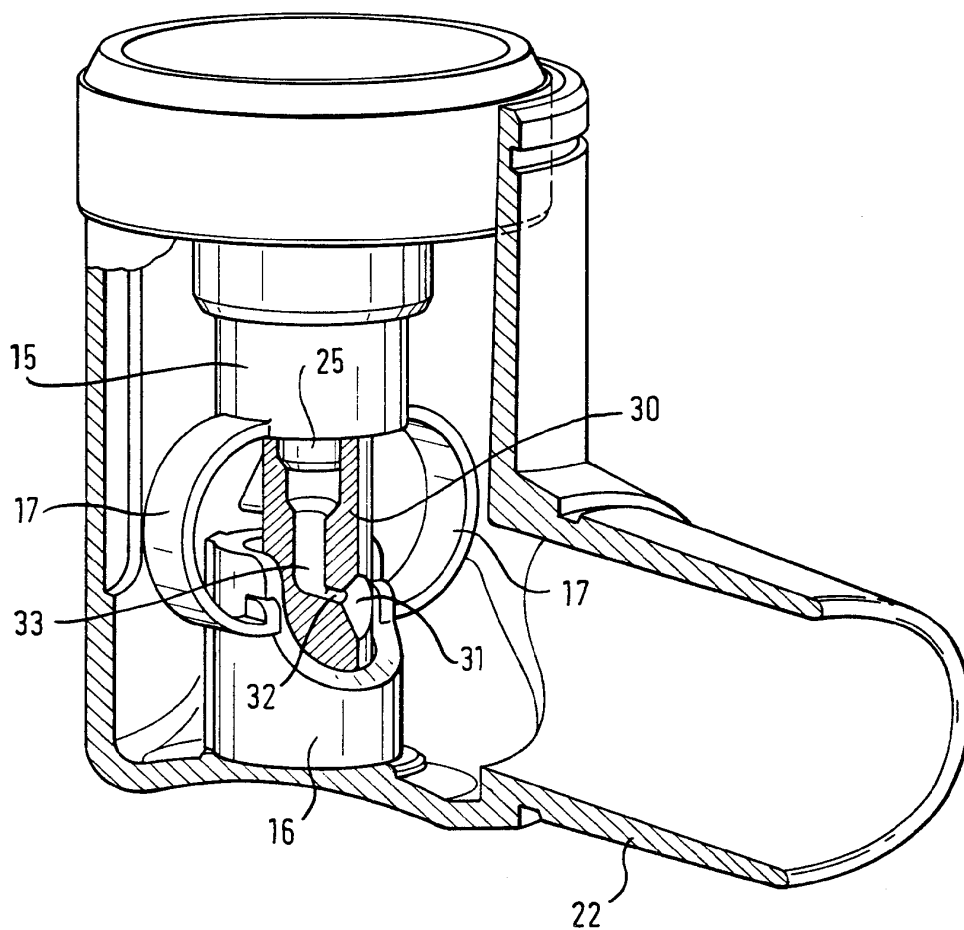
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Fig. 6



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Fig. 7



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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 99/06205

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61M15/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 349 945 A (LAW BRIAN R ET AL) 27 September 1994 (1994-09-27)	1-3,7
Y	column 8, line 12 -column 9, line 3; figures 9-11	8
Y	GB 1 317 315 A (ENGLISH NUMBERING MACHINES) 16 May 1973 (1973-05-16) cited in the application figures	8
A	FR 2 022 212 A (VANTOREX LTD) 31 July 1970 (1970-07-31) claim 1; figure 2	1
A	US 5 482 030 A (KLEIN DAVID) 9 January 1996 (1996-01-09) claim 1; figures 3,4	1
☐ Further documents are listed in the continuation of box C. ☒ Patent family members are listed in annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "G" document member of the same patent family		
Date of the actual completion of the international search 17 December 1999		Date of mailing of the international search report 11/01/2000
Name and mailing address of the ISA European Patent Office, P.B. 5618 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3018		Authorized officer Villeneuve, J-M

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INTERNATIONAL SEARCH REPORT

Information on patent family members

In International Application No
PCT/EP 99/06205

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5349945 A	27-09-1994	AU 9060491 A DE 69108929 D DE 69108929 T EP 0559757 A WO 9209324 A	25-06-1992 18-05-1995 23-11-1995 15-09-1993 11-06-1992
GB 1317315 A	16-05-1973	NONE	
FR 2022212 A	31-07-1970	AU 6168869 A GB 1290484 A ZA 6906865 A	08-04-1971 27-09-1972 27-05-1971
US 5482030 A	09-01-1996	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PCT/EP 99/06205

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Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	US 5 349 945 A (LAW BRIAN R ET AL) 27. September 1994 (1994-09-27)	1-3,7
Y	Spalte 8, Zeile 12 -Spalte 9, Zeile 3; Abbildungen 9-11	8
Y	GB 1 317 315 A (ENGLISH NUMBERING MACHINES) 16. Mai 1973 (1973-05-16) in der Anmeldung erwähnt Abbildungen	8
A	FR 2 022 212 A (VANTOREX LTD) 31. Juli 1970 (1970-07-31) Anspruch 1; Abbildung 2	1
A	US 5 482 030 A (KLEIN DAVID) 9. Januar 1996 (1996-01-09) Anspruch 1; Abbildungen 3,4	1
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Name und Postanschrift der Internationalen Recherchenbehörde Europäisches Patentamt, P.B. 5818 Patentaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3018		Bevollmächtigter Bediensteter Villeneuve, J-M

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INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

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PCT/EP 99/06205

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
US 5349945 A	27-09-1994	AU 9060491 A DE 69108929 D DE 69108929 T EP 0559757 A WO 9209324 A	25-06-1992 18-05-1995 23-11-1995 15-09-1993 11-06-1992
GB 1317315 A	16-05-1973	KEINE	
FR 2022212 A	31-07-1970	AU 6168869 A GB 1290484 A ZA 6906865 A	08-04-1971 27-09-1972 27-05-1971
US 5482030 A	09-01-1996	KEINE	

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(21) International Application Number: PCT/GB00/01180 (22) International Filing Date: 28 March 2000 (28.03.00) (30) Priority Data: 9907928.7 7 April 1999 (07.04.99) GB (71) Applicant (for all designated States except US): BESPAC PLC [GB/GB]; Bergen Way, North Lynn Industrial Estate, King's Lynn, Norfolk PE30 2JJ (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): ALLSOP, Paul, Michael [GB/GB]; 6 Tyndale, North Wootton, King's Lynn, Norfolk PE30 3XD (GB). EAMES, Christopher, John [GB/GB]; 28 Saxon Way, Dersingham, King's Lynn, Norfolk PE31 6LY (GB). CLARK, David, John [GB/GB]; 323 Wootton Road, King's Lynn, Norfolk PE30 3AX (GB). (74) Agent: BOULT WADE TENNANT; Verulam Gardens, 70 Gray's Inn Road, London WC1X 8BT (GB).			(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: DISPENSING APPARATUS COMPRISING A DOSAGE COUNTING DEVICE			
(57) Abstract The present invention relates to dispensing apparatus comprising a housing (10) for receiving a pressurised container (15) containing product for dispensation, series of markings (172) indicative of quantities of product in the container, indicator means (160; 200) for indicating one of the markings of the series, and means for effecting relative movement between the indicator means and the series of markings on actuation of the pressurised container, so as to designate a subsequent marking of the series.			

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DISPENSING APPARATUS COMPRISING A DOSAGE COUNTING DEVICE

5 The present invention relates to improvements in
dispensing apparatus and, in particular, to
improvements in apparatus providing means for
measuring the quantity of product remaining in a
pressurised dispensing container.

10 Pressurised dispensing containers are widely used
in the pharmaceutical industry for storing medications
and other products to be dispensed in aerosol form.
Such containers usually contain a propellant, such as
HFC 134a, in which the product is suspended or
15 dissolved. Solvents, such as ethanol, may also be
present in the formulation. It is known to provide
pressurised dispensing apparatus capable of dispensing
metered doses of product from the containers upon each
actuation of the container valve, for example, metered
20 dose inhalers. The reliability and consistency of the
metered dose is especially important where the product
comprises or includes a medication. Inconsistent or
unreliable dispensation could result in a user of the
dispensing apparatus receiving too great or too little
medication.

25 A problem found by many users of such apparatus
is the inability to determine the quantity of product
remaining in the container. Many types of apparatus
continue to allow the dispensing of quantities of
propellant and/or solvent when the container is nearly
30 empty, even though the dose of product contained in
the propellant is below the required level, thereby
exacerbating the problem. Thus, users are often
unaware that the dispensing apparatus is operating

inadequately. This has potentially dangerous consequences where the product or medication dispensed is required urgently and no time is available to locate a replacement dispenser, such as in the treatment of asthmatic conditions. Sufferers of asthma often carry dispensers with them for extended periods of time, which may only be used on an occasional basis. Therefore, there is a danger that, where the user is unable to determine the contents of the pressurised dispensing container and the device is required in an emergency situation, the contents of the container may be inadequate.

It is an object of the present invention to provide apparatus for quickly and easily determining the quantity of product remaining in a pressurised dispensing container without the need for special testing equipment. Also, to provide apparatus suitable for use with conventional pressurised dispensing containers.

Accordingly, the present invention provides dispensing apparatus comprising a housing for receiving a pressurised container containing product for dispensation, a series of markings indicative of quantities of product in the container, indicator means for indicating one of the markings of the series, and means for effecting relative movement between the indicator means and the series of markings on actuation of the pressurised container so as to designate a subsequent marking of the series.

Embodiments of the present invention will now be described, by way of example only, with reference to the following drawings, in which:

Figure 1 is a side elevation of a first embodiment of dispensing apparatus according to the present invention;

Figure 2 is a rear elevation of a second
5 embodiment of dispensing apparatus according to the present invention;

Figure 3 is a sectional side elevation of the apparatus of Figure 1;

Figure 4 is a perspective view of an inner
10 housing of the apparatus of Figure 1 containing a dispensing device;

Figure 5 is a schematic diagram of lugs of the apparatus of Figure 1;

Figure 6 is a perspective view of a collar of the
15 apparatus of Figure 1;

Figure 7 is a plan view of a ring of the apparatus of Figure 1;

Figure 8 is a perspective view of a cap of the apparatus of Figure 1;

Figure 9 is a plan view of another version of
20 ring;

Figure 10 is a side elevation of the cap shown in Figure 8 assembled with a dispensing device;

Figure 11 is a schematic view of a part of the
25 outer housing of the apparatus of Figure 1;

Figure 12 is a schematic cross-sectional view of the outer housing of the apparatus of Figure 1;

Figure 13 is a side elevation of an alternative apparatus according to the present invention;

Figure 14 is a perspective view of a marker of an
30 alternative apparatus according to the present invention; and

Figure 15 is a side elevation, showing some

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hidden detail, of the marker of Figure 14 assembled with the dispensing apparatus of the present invention.

5 Figures 1 to 12 show a dispensing apparatus according to the present invention. The apparatus comprises a housing 10 having a generally cylindrical portion 11, defining a chamber to slidably receive a pressurised dispensing container 15 and a mouthpiece 12, which extends laterally from a lower end of the cylindrical portion 11. The mouthpiece 12 may extend at a slight downward angle from the cylindrical portion 11. The pressurised dispensing container 15 comprises a metering valve attached to a can, for storing the product to be dispensed, by means of a ferrule which is placed over a valve stem of the metering valve and crimped to the open mouth of the can. A valve stem 16 extends axially from the metering valve and defines an outlet through which product is dispensed. The valve stem 16 is received in a valve stem receiving block 13 provided at a distal end of the generally cylindrical portion 11 as the dispensing container 15 is inserted therein. The valve stem receiving block 13 comprises a duct and an orifice such that product dispensed through the outlet of the valve stem 16 is directed through the duct and out of the orifice in the direction of the mouthpiece 12 in the form of an aerosol. Optionally the mouthpiece 12 may be covered by a mouthpiece cover when the apparatus is not being used, in order to protect the mouthpiece 12 from dust, dirt or other matter. In addition, the mouthpiece 12 may be detachable from the generally cylindrical portion 11 to allow for washing

- 5 -

and cleaning of the mouthpiece. Preferably, the detachable portion would include the valve stem receiving block 13 which is the component most prone to becoming clogged with deposits from the pressurised dispensing container 15. An internal lip in the generally cylindrical portion 11 may be provided to retain the pressurised dispensing container 15 within the generally cylindrical portion 11 when the mouthpiece 12 is detached.

10 In the apparatus of the present invention the housing 10 is provided with means to indicate to a user of the apparatus the quantity of product in the pressurised dispensing container.

The apparatus comprises an inner cylindrical housing 140 open at both ends as shown in Figure 4. The inner cylindrical housing 140 is provided with a number of inwardly directed ribs which act to reduce the effective diameter of the aperture. The other end 144 is unobstructed, as shown in Figure 4. In use the pressurised dispensing container 15 is located in the inner housing 140 with valve stem 16 protruding through the aperture. The ribs prevent the container 15 from passing through the aperture. The pressurised dispensing container 15 may be inserted and removed from the inner housing 140, during assembly of the apparatus, through the aperture 144.

The inner housing 140 is provided with an annular flange 142. The flange 142 has a number of protrusions 143 equidistantly spaced around its circumference. An exterior surface of the inner housing 140 has a helical groove 141 extending from the large open end 144 to the flange 142.

Around the inner housing 140 is located a ring

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160. As shown in Figure 7, the ring 160 has two pins 161 located on opposite sides thereof. The pins 161 penetrate the ring 160 or are two part elements having an outer portion 164 on an outer surface of the ring 160 and an inner portion 162 on an inner surface of the ring 160. The ring 160 is located around the inner housing 140 such that the inner portion 162 of each pin 161 is received in the groove 141 of the inner housing 140. The ring 160 is thus rotatable about and slidable along the inner housing 140 with the pins 161 constrained to move along helical groove 141. The ring 160 may, in addition, have an arcuate member 163 joined at each end to the outer portions 164 of each pin 161 as shown in Figures 2 and 9.

The cylindrical portion 11 of the housing 10 is provided with one or two longitudinally orientated slots 170, as shown in Figure 1. The slots 170 may extend upwardly to contact the open end of the cylindrical portion 11 of housing 10 as shown in Figure 12. The slots 170 may be provided with inserts 173 at their lower ends as shown in Figure 11 to limit the degree to which the pins 161 may move down the slots 170. In this way the number of potential doses dispensed by the apparatus may be reduced so as to ensure that the apparatus is disposed of before there is any danger of reduction in the quantity of product dispensed in each dose. Alternatively the actuator may be moulded with a slot 170 of shorter length so as to reduce the number of potentially deliverable doses.

The housing 10 further comprises a collar 155, shown in Figure 6, having a plurality of inwardly directed lugs 156. The lugs 156 have angled upper and lower surfaces, shown schematically in Figure 5. An

outer surface of the collar 155 comprises a notch 157. The internal diameter of the collar 155 is marginally greater than the external diameter of the flange 142 of the inner housing 140. The collar 155 is inserted
5 in housing 10 near a lower end of cylindrical housing portion 11. Notch 157 engages a detent (not shown) on the cylindrical housing portion 11 to prevent rotational movement of the collar 155. Alternatively, collar 155 may be integrally moulded with the
10 generally cylindrical portion 11. As an alternative the protrusions 143 may be provided as inwardly directed protrusions on the collar 155 and the lugs 156 may be provided as outwardly directed lugs on the flange 142.

15 The inner housing 140 is assembled with the main housing 10 such that the valve stem 16 of the pressurised dispensing container 15, which protrudes through the aperture of the inner housing 140 provided with the ribs, is received in the valve stem block 13,
20 as shown in Figure 3. A spring is provided between the inner housing 140 and the main housing 10 to bias the inner housing 140 upwardly away from the valve stem block 13. This may be achieved by means of a compression spring extending between the flange 142,
25 or other part of inner housing 140, and a lower part of the housing 10 or by a tensile spring extending between the flange 142 and an upper part of the housing 10. Alternatively, the internal spring force of the metering valve of the pressurised dispensing
30 container 15, which is used to bias the pressurised dispensing container 15, could be used to bias the inner housing 140 away from the valve stem receiving block 13.

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The flange 142 is received in collar 155 with the flange protrusions 143 adjacent to, or contacting the inwardly directed collar lugs 156. The outer portions 164 of pins 161 of ring 160 are located in the slots 170 in the main housing 10 as shown in Figure 1. In the embodiment provided with the arcuate member 163 attached to the ring 160, the arcuate member 163 is positioned around an exterior of the main housing 10 as shown in Figure 2.

10 A cap 150 as shown in Figures 8 and 10 may be fitted over the open end of the housing 10 on the cylindrical portion 11 to retain the container 15, inner housing 140 and other components in position. The cap 150 comprises two flexible legs 151 which
15 extend downwardly from cap 150 within the housing 10. The legs 151 flex apart as a pressurised dispensing container 15 is inserted through cap 150 into the inner housing 140. As the distal end of the legs pass over the ferrule of the pressurised dispensing
20 container 15 they flex inwardly, thereby trapping the container 15 and preventing its withdrawal.

A push-button cap (not shown) may be provided as part of the main housing 10 to cover the upper portion of the pressurised dispensing container 15.
25 Advantageously, this prevents the ingress of dust, contaminants and moisture into the apparatus.

Markings 172 are printed or embossed on an exterior surface of the housing 10 adjacent the slots 170. The markings 172 may comprise numbers indicating
30 the quantity of product in the pressurised dispensing container 15 in terms of the number of dosages remaining. Alternatively they may comprise a series of descriptive statements indicating how full the

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pressurised dispensing container 15 is, such as "FULL", "3/4 FULL", "½ FULL" etc.

Depression of the pressurised dispensing container 15 results in downward movement of the container 15 relative to the housing 10. As the container 15 moves downwardly, the inner housing 140 is caused to move downwardly such that the protrusions 143 contact the angled surfaces of the inwardly directed lugs 156 of collar 155. As a result the inner housing 140 is urged to incrementally rotate about its longitudinal axis. Since pins 161 are received in the slots 170 the ring 160 is incrementally moved vertically relative to the inner housing 140. As a result, the outer portions 164 of pins 160 and/or the arcuate member 163 are moved into alignment with a subsequent marking 172 indicating that the pressurised dispensing container 15 contains one less dose. The angled surfaces of the inwardly directed lugs 156 are dimensioned such that the inner housing 140 is urged to rotate on upward vertical movement of the protrusions 143, as occurs when the pressurised dispensing container 15 is released due to the biasing force of the spring, as well as downward vertical movement, as occurs when the pressurised dispensing container 15 is depressed.

When the pins 162 reach the bottom of the helical groove 141 the device locks-out preventing any further dispensation.

The following variations to the invention may advantageously be incorporated, either singly or in combination, in the apparatus described above.

The inner housing 140 may be dispensed with and the helical groove 141 be provided in the container

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wall of the pressurised dispensing container 15 and the protrusions 143 provided on the ferrule of the pressurised dispensing container 15.

5 The ring 160 may be replaced with a series of numbers or other markings spaced around the inner housing 140 or pressurised dispensing container 15 in a helical arrangement and spaced such that only a single number or marking is visible at any one time through the slots 170.

10 The inner housing may be non-rotatable and the collar 155 may be rotatable on interaction with the protrusions 143 of the inner housing 140. A series of markings or numbers are printed around the collar 155 and arranged such that at any one time a single number or marking is visible to a user of the apparatus through, for example, a sight window in the main housing 10.

20 The inner housing 140 may be non-rotatable and a helical slot be provided in the generally cylindrical portion 11 of the main housing 10 in which the ring 160 is deployed as shown in Figure 13. The ring 160 is operatively connected to the collar 155. Actuation of the apparatus causes the collar 155 and ring 160 to rotate about the inner housing 140 such that the pins 25 161 of the ring 160 move downwardly and around the helical slot.

30 The ring 160 may be replaced by a marker 200 having protrusions 202, 203 on each side as shown in Figure 14. The inwardly directed protrusion 203 is disposed at an angle to the edges of the marker 200 such that it is received slidingly in the helical groove 141 of the inner housing. The outwardly directed protrusion 202 is disposed parallel to the

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edges of the marker 200 such that it is received
slidingly in the vertical slot 170 of the main housing
10 when positioned between the inner housing 140 and
the main housing 10 as shown in Figure 15. An
5 indicating dot 204 may be provided to indicate which
marking 172 is designated.

Similarly to ring 160 relative movement of the
inner housing 140 and the cylindrical portion 11 of
the main housing 10 causes the marker 200 to move
10 along the longitudinal axis of the cylindrical portion
11 in the direction of arrow 205.

The protrusions 143 and the collar 155 may be
provided aligned with the top end of the inner housing
140 remote from the valve stem receiving block 13
15 rather than at the bottom end.

Claims:

1. Dispensing apparatus comprising a housing (10)
for receiving a pressurised container (15) containing
5 product for dispensation, a series of markings (172)
indicative of quantities of product in the container,
indicator means (160; 200) for indicating one of the
markings of the series, and means for effecting
relative movement between the indicator means and the
10 series of markings on actuation of the pressurised
container so as to designate a subsequent marking of
the series.
2. Dispensing apparatus as claimed in claim 1
15 wherein a cylindrical member (140) is located in the
housing (10), one of the housing and the cylindrical
member being provided with a longitudinal slot (170)
and the other of the housing and the cylindrical
member having a helical channel (141) along its
20 longitudinal axis, the indicator means (160; 200)
being operatively connected to both the longitudinal
slot and helical channel such that rotation of the
cylindrical member relative to the housing moves the
indicator means along the longitudinal axis of the
25 cylindrical member.
3. Dispensing apparatus as claimed in claim 2
wherein the housing (10) and the cylindrical member
(140) are provided with co-operating formations (143,
30 156) having angled abutment surfaces such that
relative longitudinal movement between the housing and
the cylindrical member causes relative rotation
between the housing and cylindrical member.

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4. Dispensing apparatus as claimed in claim 1 wherein one of the housing and the pressurised container (15) is provided with a longitudinal slot (170) and the other of the housing and the pressurised
5 container is provided with a helical channel (141) along its longitudinal axis, the indicator means (160; 200) being operatively connected to both the longitudinal slot and helical channel such that rotation of the pressurised container relative to the
10 housing moves the indicator means along the longitudinal axis of the housing.

5. Dispensing apparatus as claimed in claim 4 wherein the housing (10) and the pressurised container
15 (15) are provided with co-operating formations (143, 156) having angled abutment surfaces such that relative longitudinal movement between the housing and the pressurised container causes relative rotation between the housing and pressurised container.

20 6. Dispensing apparatus as claimed in any of claims 2 to 5 wherein the housing (10) comprises a collar (155) having one of the co-operating formations (143; 156) formed thereon.

25 7. Dispensing apparatus as claimed in any of claims 2 to 6 wherein the indicator means is a ring having one or more pins located in the longitudinal slot (170) and the helical channel (141).

30 8. Dispensing apparatus as claimed in any of claims 2 to 6 wherein the indicator means is a marker (200) having a first protrusion (203) engaged in the helical

channel (141) and a second protrusion (202) located in the longitudinal slot (170).

9. Dispensing apparatus as claimed in claim 1
5 wherein the housing (10) comprises a longitudinal slot (170) and the series of markings (172) are provided in a helical arrangement around the pressurised container (15) or other member (140; 155) located in the housing, such that only one of the series of markings
10 is visible through the slot at any one time.

10. Dispensing apparatus as claimed in any preceding claim comprising means (173) for locking out operation of the pressurised container after a pre-determined
15 number of actuations.

11. Dispensing apparatus as claimed in any preceding claim wherein the housing (10) comprises a mouthpiece (12) which is detachable.
20

12. Dispensing apparatus as claimed in any preceding claim further comprising a pressurised dispensing container (15) located in the housing (10).

FIG. 1.

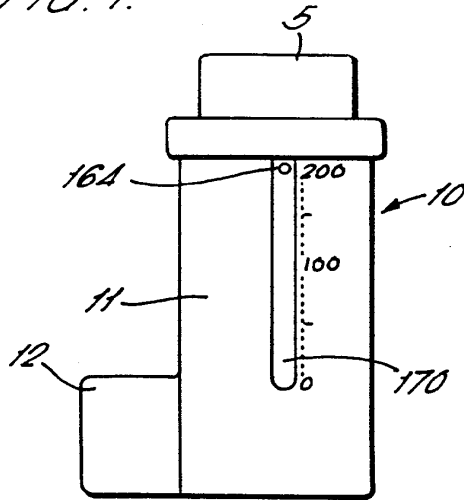


FIG. 2.

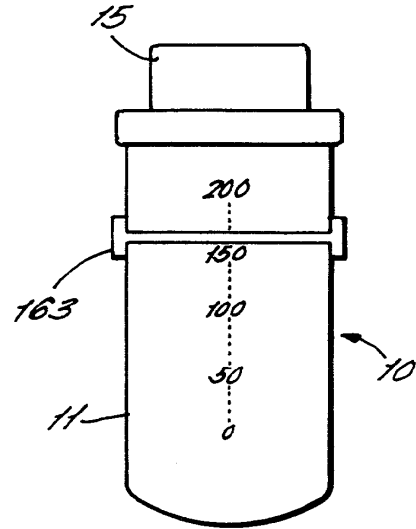


FIG. 3.

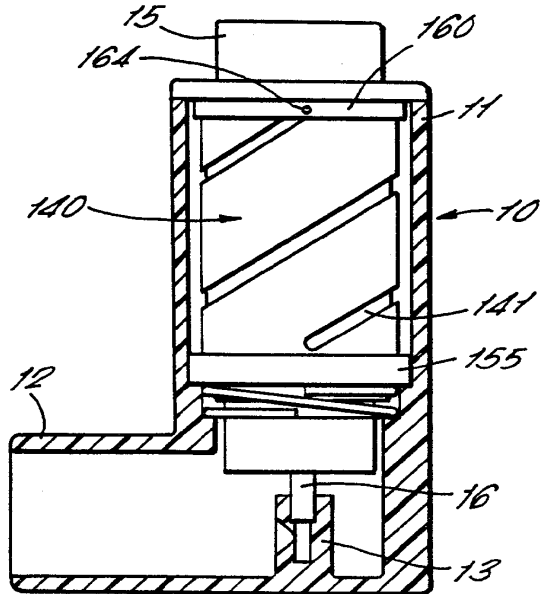


FIG. 4.

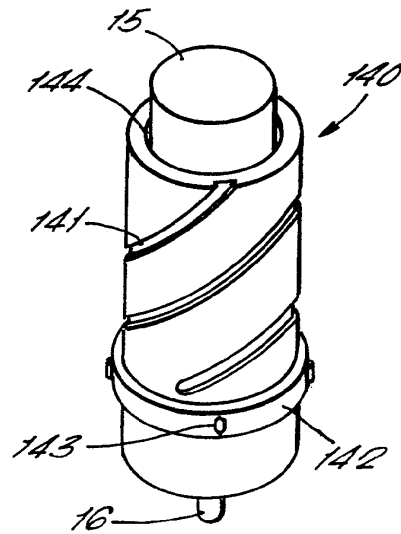


FIG. 5.

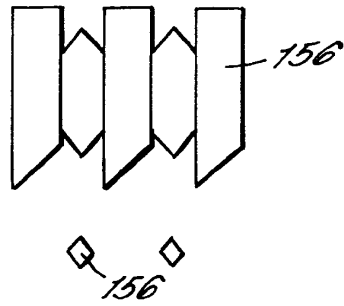


FIG. 6.

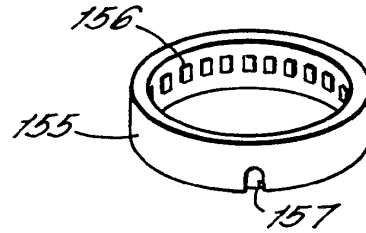


FIG. 7.

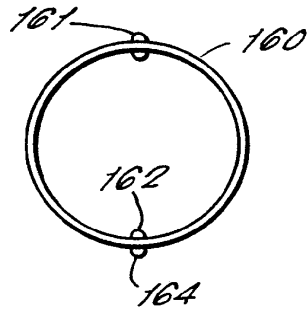


FIG. 8.

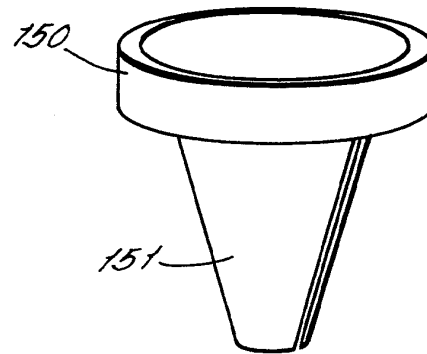
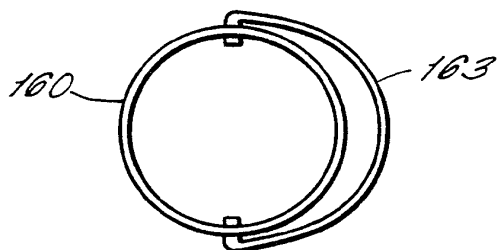


FIG. 9.



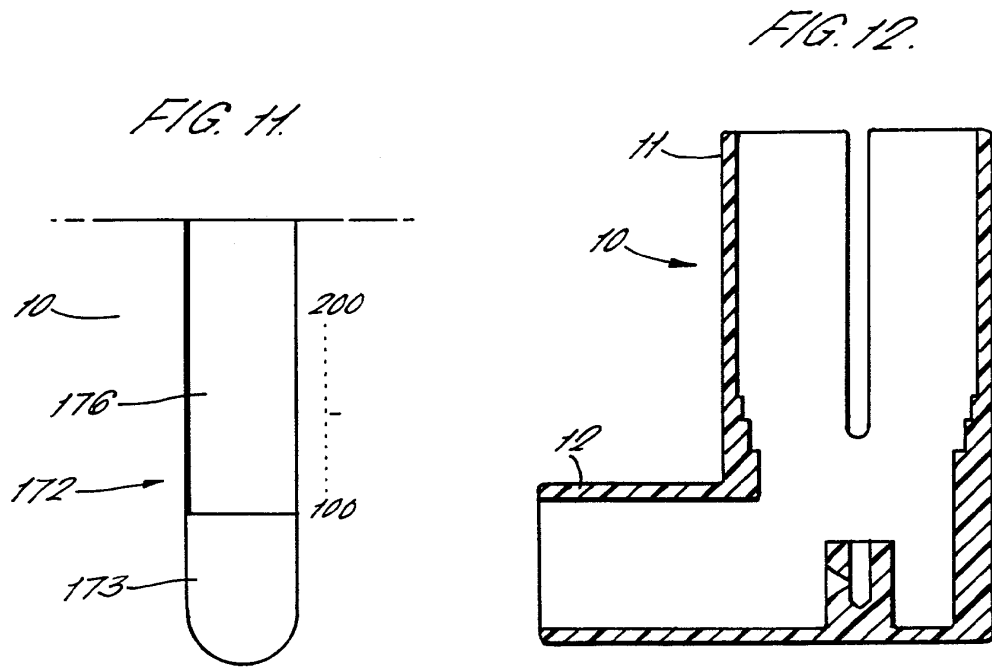
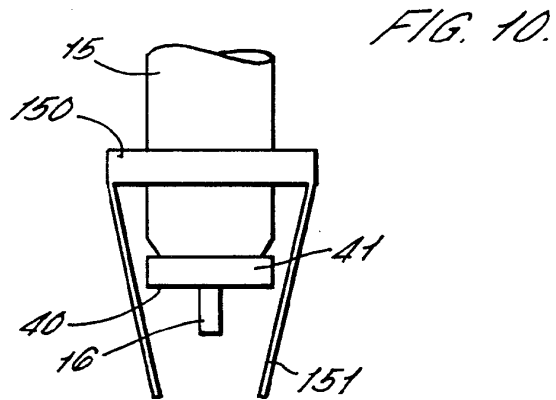


FIG. 13.

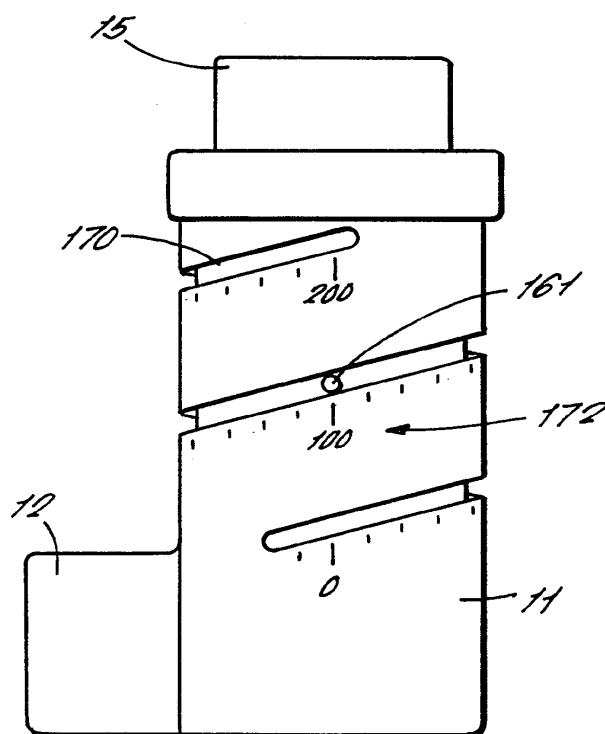


FIG. 14.

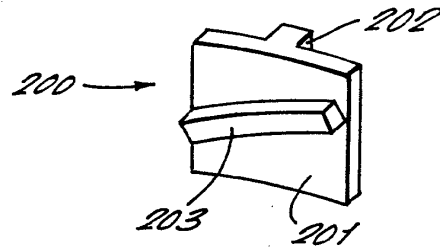
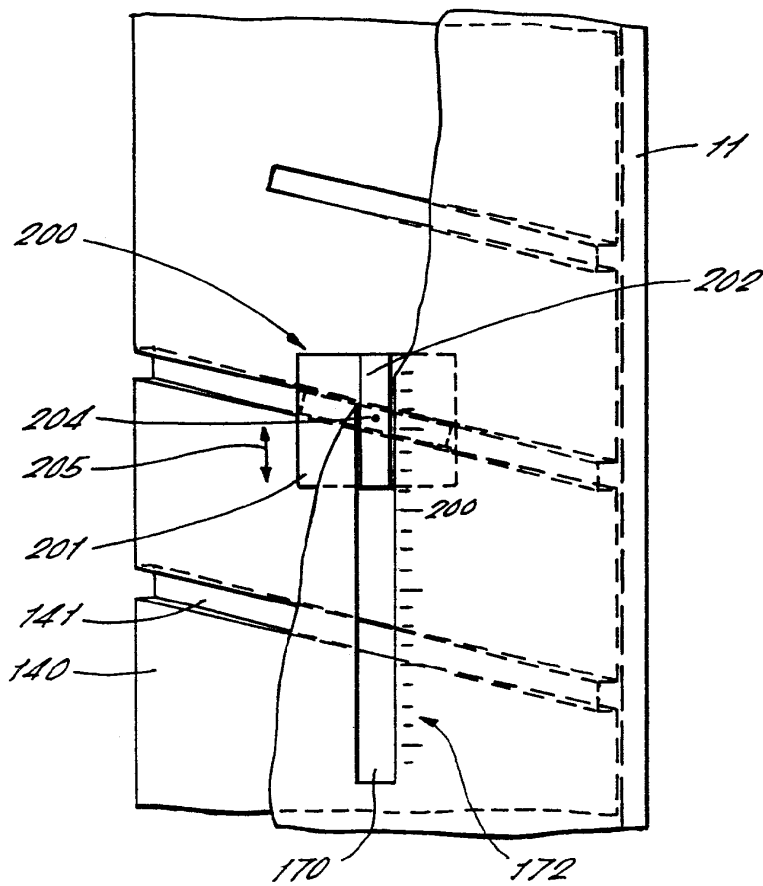


FIG. 15.



INTERNATIONAL SEARCH REPORT

International Application No
PCT/GB 00/01180

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 B65D83/14 A61M15/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 B65D A61M		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 349 945 A (WASS ET AL.) 27 September 1994 (1994-09-27) the whole document	1, 12
X	WO 98 56444 A (GLAXO) 17 December 1998 (1998-12-17) abstract; figures	1, 12
☐ Further documents are listed in the continuation of box C. ☒ Patent family members are listed in annex.		
* Special categories of cited documents : "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 28 June 2000		Date of mailing of the international search report 06/07/2000
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Authorized officer Gino, C

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5349945 A	27-09-1994	AU 9060491 A	25-06-1992
		DE 69108929 D	18-05-1995
		DE 69108929 T	23-11-1995
		EP 0559757 A	15-09-1993
		WO 9209324 A	11-06-1992
WO 9856444 A	17-12-1998	AU 8213798 A	30-12-1998
		AU 8213898 A	30-12-1998
		AU 8436498 A	30-12-1998
		WO 9856445 A	17-12-1998
		WO 9856446 A	17-12-1998
		EP 0988077 A	29-03-2000
		EP 0988078 A	29-03-2000
		EP 0986412 A	22-03-2000
		HR 980304 A	30-04-1999
		NO 996085 A	09-02-2000

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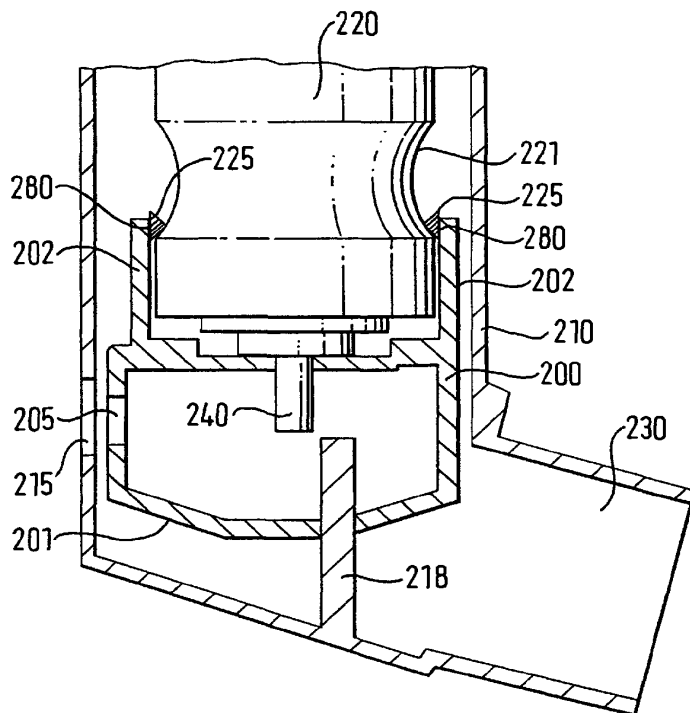
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- (74) Agent: **PIKE, Christopher, Gerard**; Pike & Co., Hayes Loft, 68A Hayes Place, Marlow, Buckinghamshire SL7 2BT (GB).
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[Continued on next page]

(54) Title: DEVICE HOUSING FOR AN AEROSOL CONTAINER



(57) Abstract: A housing (200) for a mechanical or electrical device for use with an aerosol canister (220) for containing chemical comprising a sleeve (202) for receipt of the aerosol canister; a collar (225) affixable around the neck of the canister; and a joint (280) between the sleeve and the collar to secure the housing to the canister.

WO 01/28887 A1



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DEVICE HOUSING FOR A AEROSOL CONTAINER

Technical Field

5 The present invention relates to a housing for a mechanical or electrical device which is joinable to a collar affixed around the neck of an aerosol canister to form a chemical dispenser. In particular, it relates to a medicament dispenser formable by
10 welding a housing for a dose counter to a collar affixed around the neck of an aerosol canister.

Background to the Invention

15 Aerosol canisters are widely used in domestic, commercial and industrial situations for the application of a range of chemicals. Typical examples of chemical products which are dispensable in this way include cosmetics, health products, paints, pharmaceuticals and agrochemicals. Frequently there is a need to attach
20 mechanical or electrical devices to such aerosol canisters, for example to regulate or record the flow of chemical from the canister, or to act as environmental sensors. Such devices may be affixed to the canisters by a range of technologies including the use of adhesives and heat treatment, such as soldering or welding. However, the attachment of such devices to aerosol canisters poses difficulties in terms of
25 producing a secure joint without affecting the integrity of the chemical by the application of excess heat during the heating or welding process. Similarly, the use of adhesives may lead to contamination problems due to the presence of low concentrations of volatiles from the adhesive on dispensing the chemical.

30 Medicament dispensers are extensively used in the administration of medicines, particularly those for the treatment of respiratory disorders. Medicaments which are

contained in an aerosol and are administered to a patient by means of an inhalation device are widely used in such therapy. These inhalation devices typically comprise a tubular housing or sleeve in which the aerosol canister is located and an outlet tube leading from the housing. The aerosol canisters used in such inhalation devices are designed to deliver a predetermined dose of medicament upon actuation; the valves can be opened either by depression of the valve member itself or by depression of the canister while the valve member is held stationary. In the use of such devices, the aerosol canister is placed in the tubular housing with the outlet valve member of the canister communicating via a support with the outlet tube, for example a nozzle or mouthpiece.

A recent development in this field of technology is the use of mechanical or electrical dose counters to register the number of medicament doses used or remaining within the medicament dispenser. Dose counters can be positioned within the tubular housing and operate by means of detecting movement of the housing relative to the aerosol canister on actuation of the dispenser by the patient. The indexing mechanism of the dose counter registers the actuation of the dispenser and the counter displays how many doses have been used or remain within the aerosol canister.

Some dose counters are detachable from the aerosol dispenser. One disadvantage of such devices is that the individual components may become separated and used in isolation from each other. Another disadvantage of these devices is that once the dose counter is removed from the aerosol canister it may be tampered with, typically by young children, to give a false reading. Detachment of the dose counter from the aerosol canister could therefore result in false readings on re-attachment to the canister. Furthermore, with patients having several different inhalers, the indicating device could be re-attached to the wrong dispenser.

Other dose counters are essentially irreversibly attached to the aerosol dispenser. One means of affixing dose counters to aerosol canisters is to use a 'snap-fit'

mechanism whereby a tubular grip assembly on the dose counter housing is pushed into position around the neck of the valve ferrule thereby locking the two components together. Whilst this arrangement holds the two structures securely together there can, on occasions, be some lateral movement or 'play' of one component relative to the other. As mechanical dose counters operate by registering relative movement of the aerosol canister to the dose counter housing, any play or lateral movement can result in false readings being registered on the dose counter. A key factor in the successful operation and functioning of such dose counters is that there be minimal movement of the housing relative to the aerosol canister outwith the actuation cycle.

10

Dimensional variation resulting from manufacturing tolerances of aerosol canisters and dose counter housings poses additional problems in the assembly and operation of medicament dispensers. In order that the dose indicator mechanism functions correctly the canister and the counter housing must fit together tightly. Thus any variations in the dimensions of either of these components which result in a loose fit between the counter housing and the canister can lead to increased relative movement and the problems of false readings discussed above.

To overcome these problems of dimensional variation, stringent tolerance levels must be set for the manufacture of both the counter housing and the aerosol canister. This approach, together with the high levels of quality control necessary to ensure that both components meet the required engineering standards, is expensive for the manufacturer.

It is an object of the present invention to address the aforementioned problems associated with attachment of a mechanical or electrical device to an aerosol canister, in particular for the attachment of a dose counter housing thereto. The present invention involves joining the device housing to a ring or collar affixed around the neck of an aerosol canister to minimise the relative movement of the component parts. This joining can be achieved by a variety of technologies, including melting the components together by means of 'hot staking', soldering the

30

surfaces together, or using adhesives to bind the housing to the collar. Welding technologies are particularly well suited for this purpose.

5

Summary of Invention

According to the present invention there is provided a housing for a mechanical or electrical device for use with an aerosol canister for containing chemical comprising a sleeve for receipt of the aerosol canister; a collar affixable around the neck of the
10 canister; and a joint between the sleeve and the collar to secure the housing to the canister.

In one aspect, the collar is a split collar.

15 In another aspect, the collar comprises the same material as the sleeve.

In a further aspect, the joint is a weld.

In yet another aspect, the weld is an ultrasound weld.

20

In a further aspect, the weld is a single continuous weld.

Optionally the weld comprises a plurality of spot welds. Preferably the number of welds is from 2 to 100, more preferably 6.

25

In another aspect, the weld is obtainable by energy generated by a sonitrode head, of energy output 100-200 Watts, frequency 20-50 kHz and duration 100-200 milliseconds. A typical sonitrode head would be a converter.

30 In one aspect, the housing additionally comprises a mechanical or electrical device.

Preferably the mechanical or electrical device is a dose counter.

Preferably the electrical device is a sensor.

- 5 Preferably the sensor is for sensing the pressure profile associated with the breath cycle. Pressure transducers are suitable sensors of this type.

- More preferably the sensor is for sensing the airflow profile associated with the breath cycle. Sprung vane sensors and sensors including anemometers are suitable
10 sensors of this type.

- More preferably the sensor is for sensing the temperature profile associated with the breath cycle. The temperature of the inhaled and exhaled part of the breath cycle varies and may, thus, be used as a measurement tool.

- 15 Most preferably the sensor is for sensing the moisture profile associated with the breath cycle. The moisture content of the inhaled and exhaled part of the breath cycle varies and this also may be used as a measurement tool.

- 20 In a further aspect, the electrical device comprises a transceiver for transmitting and receiving data. Preferably, the transceiver comprises a radiofrequency identifier comprising an antenna for transmitting or receiving radiofrequency energy, and an integrated circuit chip connecting with said antenna.

- 25 The radiofrequency identifier can be any known radiofrequency identifier. Such identifiers are sometimes known as radiofrequency transponders or radiofrequency identification (RFID) tags or labels. Suitable radiofrequency identifiers include those sold by Phillips Semiconductors of the Netherlands under the trade marks Hitag and Icode, those sold by Amtech Systems Corporation of the United States of America
30 under the trade mark Intellitag, and those sold by Texas Instruments of the United States of America under the trade mark Tagit.

Preferably the transceiver comprises a magnetic label or tag comprising an antenna for transmitting or receiving magnetic field energy; and an integrated circuit chip connecting with the antenna.

5

A suitable magnetic label or tag comprises plural magnetic elements in mutual association whereby the magnetic elements move relative to each other in response to an interrogating magnetic field. A magnetic label or tag of this type is described in U.S. Patent No. 4,940,966. Another suitable magnetic label or tag comprises a
10 magnetorestrictive element which is readable by application of an interrogating alternating magnetic field in the presence of a magnetic bias field which results in resonance of the magnetorestrictive elements at different predetermined frequencies. A magnetic label of this type is described in PCT Patent Application No. WO92/12402. Another suitable magnetic label or tag comprising plural discrete
15 magnetically active regions in a linear array is described in PCT Patent Application No. WO96/31790. Suitable magnetic labels and tags include those making use of Programmable Magnetic Resonance (PMR) (trade name) technology.

In another aspect, the electrical device comprises a microelectronic memory chip.
20 The microelectronic memory chip may be selected from the group consisting of programmable read only memory (PROM), erasable programmable read only memory (EPROM), electrically erasable programmable read only memory (EEPROM) and a SIM card-type memory chip. The microelectronic memory chip may alternatively be a random access memory (RAM) chip, powered by a suitable
25 source such as a battery.

In one aspect, the housing additionally comprises a window for viewing a reading from the mechanical or electrical device. The reading may typically be in the form of a digital readout on a visual display unit or counter, or may take the form of a
30 flashing coloured light to indicate, for example, the doses remaining within the canister.

In another aspect of the present invention there is provided a method for securing a housing for a mechanical or electrical device to an aerosol canister comprising placing a collar around the neck of the canister; positioning a sleeve around the collar; and joining the collar to the sleeve.

5

In one aspect, the method additionally comprises associating the mechanical or electrical device with the sleeve. The device may be associated with the sleeve using a snap-fit mechanism. Preferably the method additionally comprises sealing the mechanical or electrical device within the sleeve. The device may be sealed
10 within the sleeve using a range of sealing means, such as welding, soldering or adhesive means. Welding means are particularly suitable for sealing the device within the sleeve.

Preferably the method comprises inserting the mechanical or electrical device into
15 the sleeve before joining the collar to the sleeve. More preferably the method comprises sealing the mechanical or electrical device within the sleeve before joining the collar to the sleeve.

Preferably the method comprises inserting the mechanical or electrical device into
20 the housing after joining the collar to the sleeve. More preferably the method comprises sealing the mechanical or electrical device within the housing after joining the collar to the sleeve.

In one aspect, the device is a dose counter. In another aspect, the device is a
25 sensor. In a further aspect, the device is a transceiver for transmitting or receiving data. In another aspect, the device is a microelectronic memory chip.

In one aspect, the collar is a split collar. Preferably, the collar comprises the same material as the sleeve around the canister.

30

In another aspect, the method comprises joining the collar to the sleeve by welding. Preferably, the welding comprises ultra sound welding.

More preferably, the method comprises applying a single continuous weld. More preferably, the method comprises applying a plurality of spot welds. More preferably, it comprises applying from 2 to 100 welds, most preferably applying 6 welds.

In a further aspect, the method comprises using a sonitrode head to produce a weld condition of output 100 to 200 Watts, frequency 20 to 50 kilo Hertz and duration 100 to 200 milli seconds.

In another aspect of the present invention there is provided a dispenser comprising a housing according to the invention securable to an aerosol canister.

Preferably the dispenser additionally comprises an actuator body.

Preferably the dispenser is a medicament dispenser wherein the aerosol canister comprises a medicament in a propellant. More preferably the propellant is liquefied HFA134a or HFA-227. Most preferably the medicament is selected from the group consisting of albuterol, salmeterol, ipratropium bromide, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof and any mixtures thereof.

The present invention further provides a kit of parts comprising a housing according to the present invention and an aerosol canister for containing chemical. Preferably the kit additionally comprising an actuator body. More preferably the chemical is a medicament.

In a further aspect of the present invention there is provided the use of medicament dispenser according to the present invention for the administration of medicament to a patient.

Brief Description of Drawings

5 The invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a schematic representation of a section through a standard metered dose inhalation device.

10

Figure 2 is a schematic representation of a section through an aerosol canister affixed to a housing according to the present invention.

15

Figure 3 is a schematic representation of a medical dispenser according to the present invention.

20

Figures 4a - c is a schematic illustration of the process whereby a dose counter housing is secured to a standard metered dose inhalation device by ultrasound welding.

Figures 5a & b show a housing for a transceiver affixed to an aerosol container and a cross section of the housing according to the present invention.

25

Detailed Description of Drawings

The standard metered dose inhaler shown in Fig 1 comprises a housing 10 in which an aerosol canister 20 can be located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. An outlet 30 leads laterally from the closed end of the housing 10. In the embodiment illustrated, the outlet 30 is in the form of a

30

mouthpiece intended for insertion into the mouth of the patient but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

5 The aerosol canister 20, comprising a neck region 21 and ferrule 22, has an outlet valve stem 40 at one end. This valve member can be depressed to release a measured dose from the aerosol canister or, alternatively, the valve stem 40 can be fixed and the main body of the canister can be moved relative to the valve member to release the dose.

10 As shown in Figure 1, the aerosol canister 20 is located in the housing 10 so that one end protrudes from its open top, the canister being positioned such that the neck 21 and valve ferrule 22 are enclosed within housing 10. Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the canister 20 spaced from the internal surface of the housing 10. A support 50 is provided at the
15 lower end of the housing 10 and has a passage 60 in which the valve stem 40 of the aerosol canister 20 can be located and supported. A second passage 70 is provided in the support 50 and is directed towards the interior of the outlet 30. Thus, when the parts are in the positions shown in Figure 1, the protruding portion of the aerosol canister 20 can be depressed to move the canister relative to the valve stem 40 to
20 open the valve and a dose of medicament contained in the aerosol will be discharged through the passage 70 and into the outlet 30 from which it can be inhaled by a patient. One dose will be released from the aerosol canister each time it is fully depressed.

25 Figure 2 is a schematic diagram showing a housing for a dose indicating device 100 (internal details not shown) connected to an aerosol canister 120 according to the present invention. The housing comprises a cradle 101 for supporting the counter mechanism, located within the body of the counter (details not shown), and a housing 100 having a tubular sleeve 102 to receive aerosol canister 120 and valve
30 stem 140. Collar 125, which is typically a split ring, is secured around the neck 121 of the aerosol canister 120. Tubular sleeve 102 fits over valve ferrule 122 and

engages collar 125 which is tightly affixed around neck 121 of aerosol canister 120. Thus the tubular sleeve 102 and collar 125 form a tight connection between housing 100 and aerosol canister 120. Collar 125 is welded to sleeve 102 by application of ultrasound energy. The sleeve 102 is secured to the collar 125 by a series of spot welds 180. Two sonitrodes (not shown) are generally employed in the welding process, each sonitrode having three pins which are pushed into contact with the sleeve 102. Energy is transferred through the sonitrode pins, causing them to vibrate and fusing the sleeve 102 to the collar 125. The vibrating pins are pushed through the sleeve 102 to a depth of approximately 2mm into the body of the collar 125, melting and fusing the materials together, to form a series of spot welds. In an alternative herein, one continuous weld may be employed by either moving the sonitrode head around the sleeve or vice versa.

Figure 3 is a schematic diagram showing the lower part of a device similar to that of Figure 1 but incorporating the housing for a dose indicating device 200 affixed to an aerosol canister according to the invention as shown in Figure 2. The counter mechanism (not shown) is supported on a cradle 201 and engages post 218. Ultrasound welds 280 secure collar 225 around neck 221 of canister 220 to tubular sleeve 202, thereby affixing aerosol canister 220 to dose counter housing 200. The resulting assembly is positioned within housing 210. Thus on depression of the aerosol canister 220, the canister moves relative to the valve stem 240 and opens the canister valve (not shown) to discharge a predetermined dose of medicament to the patient through valve stem 240 and thence to outlet 230. The relative movement of canister 220 to counter housing 200 is registered by the counter mechanism (not shown) and the number of doses of medicament used or remaining within canister 220 is displayed on counter window 205 and can be viewed through housing window 215.

Figures 4a – c illustrate, with another embodiment of the present invention, the process whereby the collar 325 is fitted around neck 321 of the canister 320 and welded to tubular sleeve 302 of the dose counter housing 300. Figure 4a is an

exploded diagram showing collar 325 being positioned between canister 320 and dose counter housing 300 displaying counter window 305. The collar 325 is slipped around neck 321 of canister 320 (Figure 4b). As shown in Figure 4c, the collar 325 is then pushed in the direction of arrow A to locate against the base of ferrule 322 at the top of neck 321, while dose counter housing 300 is positioned over the top of canister 320 by being pressed down in the direction of arrow B. In this way, collar 325 is wedged between tubular sleeve 302 and the neck of canister 321. The collar 325 is joined to tubular sleeve 302 by ultra sound welding at the points indicated by arrows C, thereby securing the dose counter housing 300 to canister 320.

Figures 5a and 5b show a housing 400 for a passive transceiver in the form of an electrically erasable programmable read only memory (EEPROM) chip 490. In Figure 5a the housing 400 is welded at points 480 to collar 425 (not shown) which has been secured to the neck 421 of the aerosol canister 420 having outlet 440 as described above. The chip 490, located within housing 400, communicates with electrical contact pad 495. Figure 5b is a cut-away section of Figure 5a, the aerosol canister having been removed to show collar 425 welded to housing 400. In this sectional view, EEPROM chip 490 and electrical contact pad 495 are clearly shown.

Whilst the present invention has been described in detail in respect of a metered dose inhaler it will be appreciated that other mechanical and electronic devices, such as electronic sensors and readers, may be attached to an aerosol canister in an identical manner. For example, a temperature/pressure sensor for use with a paint dispenser could also be affixed to the aerosol canister in this way.

It may be appreciated that any of the parts of the dispenser which contact the chemical suspension may be coated with materials such as fluoropolymer materials which reduce the tendency of chemical to adhere thereto. Any movable parts may also have coatings applied thereto which enhance their desired movement characteristics. Frictional coatings may therefore be applied to enhance frictional contact and lubricants used to reduce frictional contact as necessary.

The medicament dispenser of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders such as asthma and chronic obstructive pulmonary disease. Appropriate medicaments may thus be selected

5 from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate (e.g. as the sodium salt), ketotifen or nedocromil (e.g. as the sodium salt); anti-infectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti-

10 inflammatories, e.g., beclomethasone (e.g. as the dipropionate ester), fluticasone (e.g. as the propionate ester), flunisolide, budesonide, rofleponide, mometasone e.g. as the furoate ester), ciclesonide, triamcinolone (e.g. as the acetonide) or 6 α , 9 α -difluoro-11 β -hydroxy-16 α -methyl-3-oxo-17 α -propionyloxy-androsta-1,4-diene-17 β -carbothioic acid S-(2-oxo-tetrahydro-furan-3-yl) ester; antitussives, e.g., noscapine;

15 bronchodilators, e.g., albuterol (e.g. as free base or sulphate), salmeterol (e.g. as xinafoate), ephedrine, adrenaline, fenoterol (e.g. as hydrobromide), formoterol (e.g. as fumarate), isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol (e.g. as acetate), reproterol (e.g. as hydrochloride), rimiterol, terbutaline (e.g. as sulphate), isoetharine, tulobuterol or 4-hydroxy-7-[2-[[[3-(2-

20 phenylethoxy)propyl]sulfonyl]ethyl]amino]ethyl-2(3H)-benzothiazolone; adenosine 2a agonists, e.g. 2R,3R,4S,5R)-2-[6-Amino-2-(1S-hydroxymethyl-2-phenyl-ethylamino)-purin-9-yl]-5-(2-ethyl-2H-tetrazol-5-yl)-tetrahydro-furan-3,4-diol (e.g. as maleate); α 4 integrin inhibitors e.g. (2S)-3-[4-({[4-(aminocarbonyl)-1-piperidinyl] carbonyl}oxy)phenyl]-2-(((2S)-4-methyl-2-[[2-(2-methylphenoxy)

25 acetyl]amino}pentanoyl)amino] propanoic acid (e.g. as free acid or potassium salt), diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium (e.g. as bromide), tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate, lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or

30 glucagon; vaccines, diagnostics and gene therapies. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form

of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament and/or to minimise the solubility of the medicament in the propellant. Preferred medicaments are selected from albuterol, salmeterol,
5 fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free
10 base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) or formoterol (e.g. as the fumarate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate) or budesonide. A particularly preferred combination is a combination of fluticasone propionate and salmeterol, or a salt thereof (particularly the xinafoate
15 salt). A further combination of particular interest is budesonide and formoterol (e.g. as the fumarate salt).

It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.
20

The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and
25 may include, by way of example and without limitation, one or more of the following claims:

Claims

- 5 1. A housing for a mechanical or electrical device for use with an aerosol
canister for containing chemical comprising
- a sleeve for receipt of said aerosol canister;
- 10 a collar affixable around the neck of the canister; and
- a joint between said sleeve and said collar to secure said housing to the
canister.
- 15 2. Housing according to claim 1, wherein the collar is a split collar.
3. Housing according to either of claims 1 or 2, wherein the collar comprises the
same material as the sleeve.
- 20 4. Housing according to any of claims 1 to 3, wherein said joint is a weld.
5. Housing according to claim 4, wherein said weld is an ultrasound weld.
6. Housing according to either of claims 4 or 5, wherein the weld is a single
25 continuous weld.
7. Housing according to either of claims 4 or 5, wherein the weld comprises a
plurality of spot welds.
- 30 8. Housing according to claim 7, wherein the number of welds is from
2 to 100.

9. Housing according to claim 8, wherein the number of welds is 6.
10. Housing according to any of claims 4 to 9, wherein the weld is obtainable by
5 energy generated by a sonitrode head, of energy output 100-200 Watts, frequency 20-50 kilo Hertz and duration 100-200 milliseconds.
11. Housing according to any of the preceding claims, additionally comprising said mechanical or electrical device.
- 10 12. Housing according to any of the preceding claims, wherein the mechanical or electrical device is a dose counter.
13. Housing according to any of the preceding claims, wherein the electrical
15 device is a sensor.
14. Housing according to claim 13, wherein said sensor is for sensing the pressure profile associated with the breath cycle.
- 20 15. Housing according to claim 13, wherein the sensor is for sensing the airflow profile associated with the breath cycle.
16. Housing according to claim 13, wherein the sensor is for sensing the temperature profile associated with the breath cycle.
- 25 17. Housing according to claim 13, wherein the sensor is for sensing the moisture profile associated with the breath cycle.
18. Housing according to any of the preceding claims, wherein the electrical
30 device comprises a transceiver for transmitting and receiving data.

19. Housing according to any of the preceding claims, wherein the electrical device comprises a microelectronic memory chip.

20. Housing according to claim 19, wherein said chip is selected from the group
5 consisting of random access memory (RAM), programmable read only memory (PROM), erasable programmable read only memory (EPROM), electrically erasable programmable read only memory (EEPROM) and a SIM card-type memory chip.

21. Housing according to any of the preceding claims, additionally comprising a
10 window for viewing a reading from the mechanical or electrical device.

22. Method for securing a housing for a mechanical or electrical device to an aerosol canister comprising

15 placing a collar around the neck of said canister;

positioning a sleeve around said collar; and

20 joining the collar to said sleeve.

23. Method according to claim 22, additionally comprising associating said mechanical or electrical device with said sleeve.

24. Method according to claim 23, additionally comprising sealing the mechanical
25 or electrical device within the sleeve.

25. Method according to claim 23, comprising inserting the mechanical or electrical device into the sleeve before joining the collar to the sleeve.

30 26. Method according to claim 25, comprising sealing the mechanical or electrical device within the sleeve before joining the collar to the sleeve.

27. Method according to claim 23, comprising inserting the mechanical or electrical device into the housing after joining the collar to the sleeve.

5 28. Method according to claim 27, comprising sealing the mechanical or electrical device into the housing after joining the collar to the sleeve.

29. Method according to any of claims 23 or 28, wherein the device is a dose counter.

10

30. Method according to any of claims 23 to 29, wherein the device is a sensor.

31. Method according to any of claims 23 to 30, wherein the device is a transceiver for transmitting or receiving data.

15

32. Method according to any of claims 23 to 31, wherein the device is a microelectronic memory chip.

33. Method according to any of claims 22 to 32, wherein the collar is a split collar.

20

34. Method according to any of claims 22 to 33, wherein the collar comprises the same material as the sleeve around the canister.

25 35. Method according to any of claims 22 to 34, comprising joining the collar to the sleeve by welding.

36. Method according to claim 35, wherein said welding comprises ultra sound welding.

30 37. Method according to either of claims 35 or 36, comprising applying a single continuous weld.

38. Method according to either of claims 35 or 36, comprising applying a plurality of spot welds.

5 39. Method according to claim 38, comprising applying from 2 to 100 welds.

40. Method according to either of claims 38 or 39, comprising applying 6 welds.

41. Method according to any of claims 35 to 40, comprising using a sonitrode
10 head to produce a weld condition, of output 100 to 200 Watts, frequency 20 to 50 kilo Hertz and duration 100 to 200 milli seconds.

42. Dispenser comprising a housing according to any of claims 1 to 21 securable to an aerosol canister.

15

43. Dispenser according to claim 42, additionally comprising an actuator body.

44. Medicament dispenser according to either of claims 42 or 43, wherein said aerosol canister comprises a medicament in a propellant.

20

45. Medicament dispenser according to claim 44, wherein said propellant is liquefied HFA134a or HFA-227.

46. Medicament dispenser according to claim 44, wherein said medicament is
25 selected from the group consisting of albuterol, salmeterol, ipratropium bromide, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof and any mixtures thereof.

47. Kit of parts comprising

30

a housing according to any of claims 11 to 21; and

an aerosol canister for containing chemical.

48. Kit of parts according to claim 47, additionally comprising an actuator body.

5

49. Kit of parts according to either of claims 47 or 48, wherein said chemical is a medicament.

50. Use of medicament dispenser according to any of claims 44 to 46 for the administration of medicament to a patient.

10

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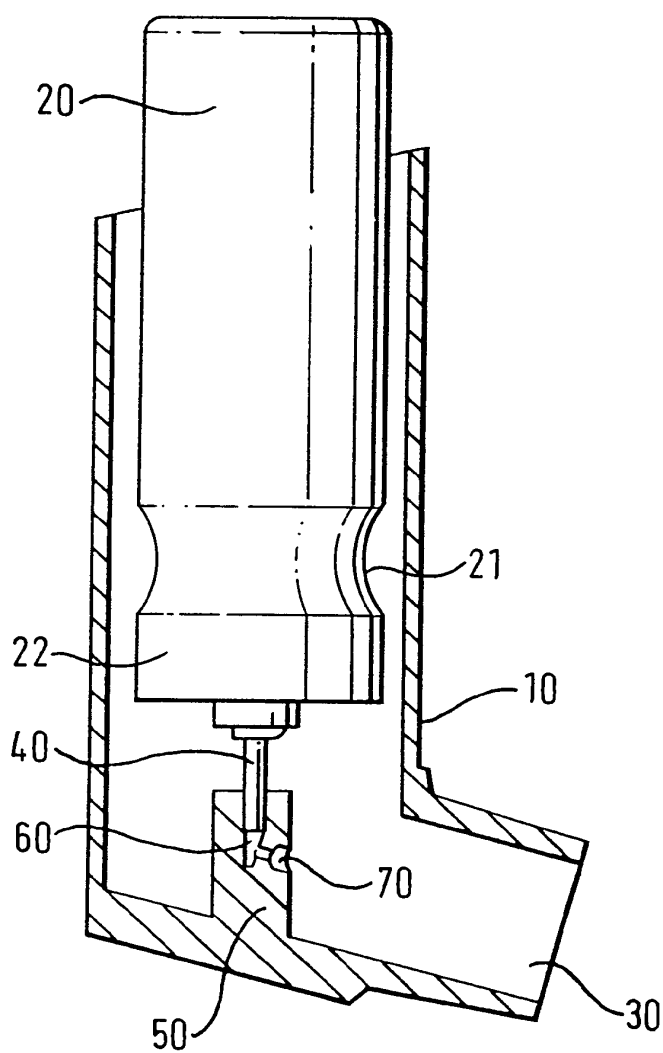


FIG. 1

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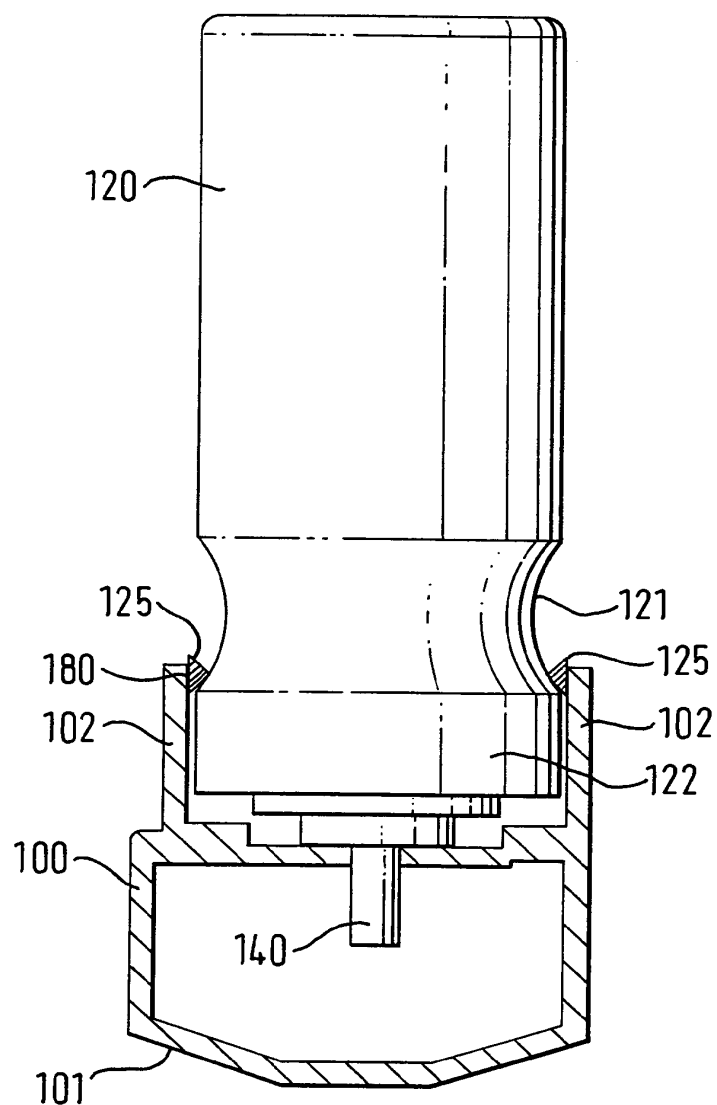


FIG. 2

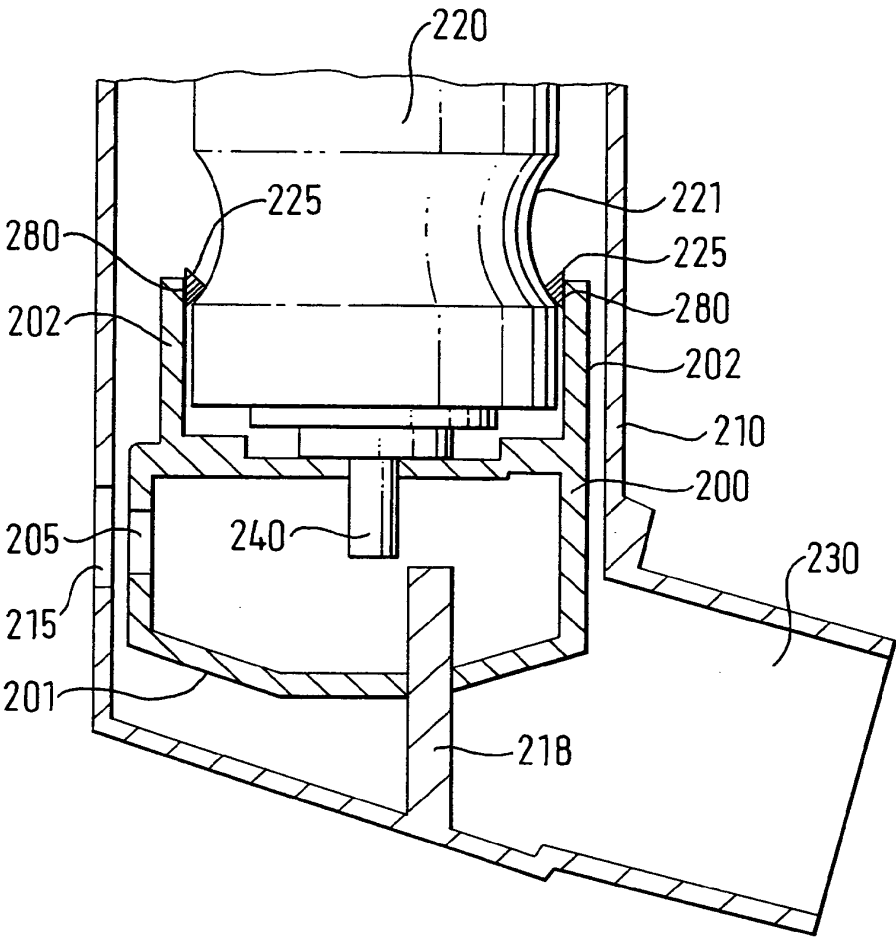


FIG. 3

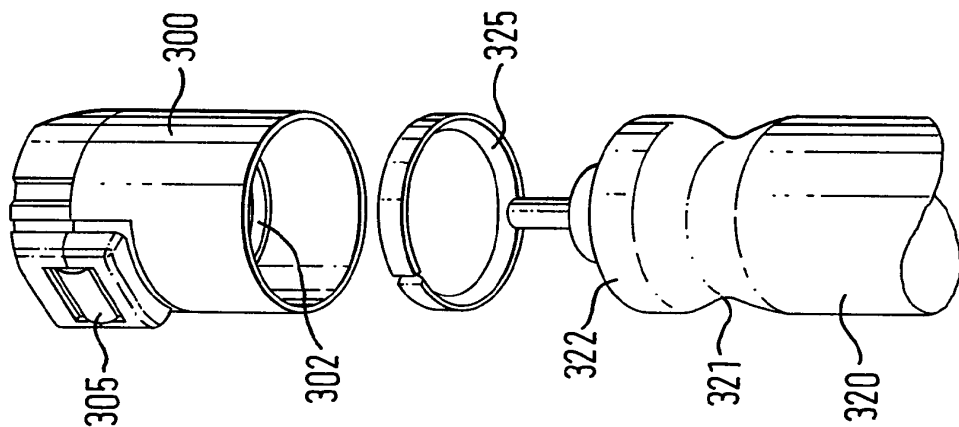


FIG. 4a

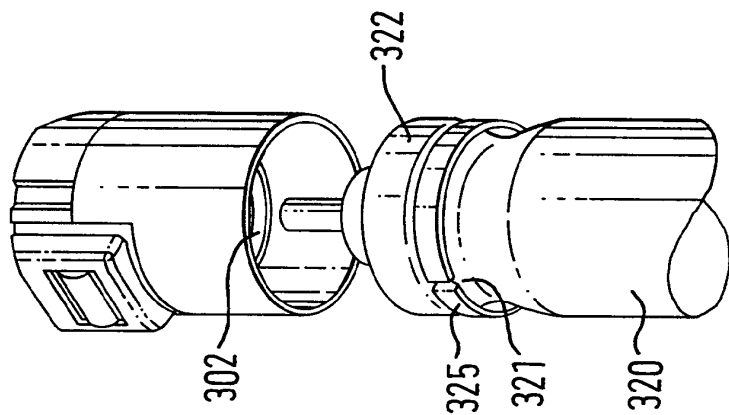


FIG. 4b

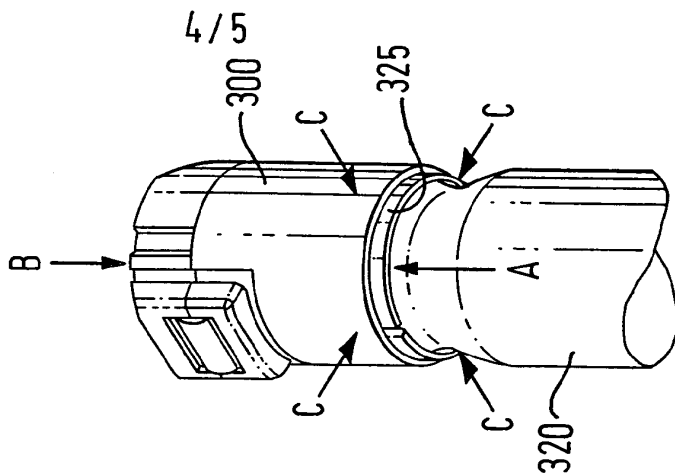
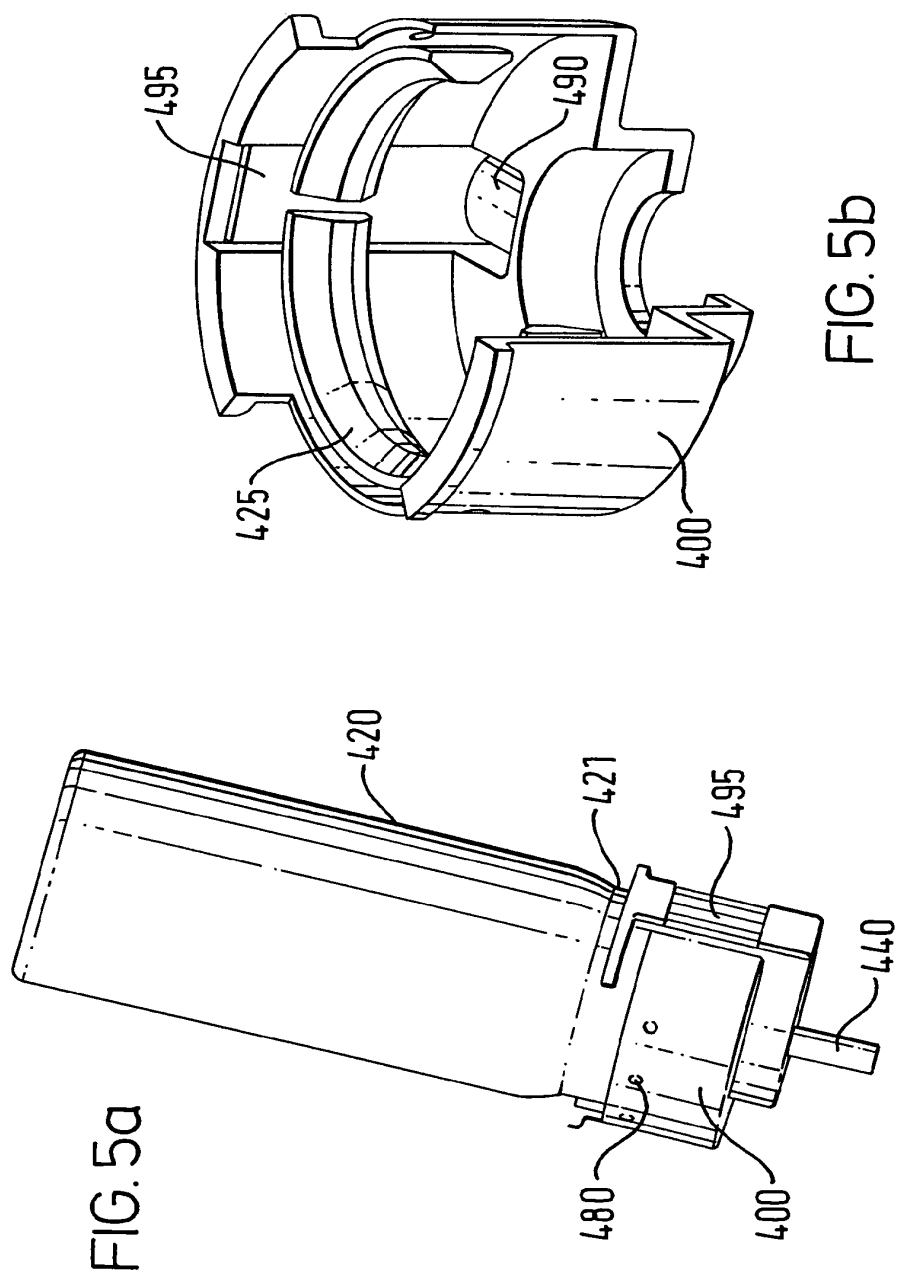


FIG. 4c

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 00/09991

A. CLASSIFICATION OF SUBJECT MATTER

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 B65D A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 743 055 A (FRAPPE DOMINIQUE) 4 July 1997 (1997-07-04) page 4, line 24 -page 5, line 4; figures 1,4,5 page 4, line 6 - line 7 ---	1,12-21, 42-50
A	WO 86 02275 A (DRACO AB) 24 April 1986 (1986-04-24) claim 1; figures 3,5 ---	12,21
A,P	WO 00 53247 A (ANDERSON GREGOR JOHN MCLENNAN ;JONES ANTHONY PATRICK (GB); GLAXO G) 14 September 2000 (2000-09-14) claims 1-5 ---	13-17
A	GB 2 263 873 A (NORTON HEALTHCARE LTD) 11 August 1993 (1993-08-11) page 5, last paragraph ---	14,15
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 00/09991

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 363 842 A (MISHELEVICH DAVID J ET AL) 15 November 1994 (1994-11-15) column 6, line 21 - column 7, line 12 column 7, line 53 - line 55 ---	18-21
A	WO 99 06303 A (GLAXO GROUP LTD ;RIEBE MICHAEL THOMAS (US)) 11 February 1999 (1999-02-11) claims 6,7 ---	44-46, 49
A	WO 99 36115 A (1263152 ONTARIO INC) 22 July 1999 (1999-07-22) page 34, line 5 - line 15 page 35, line 5 - line 15; claim 1; figure 21 -----	1, 12

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

page 2 of 2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 00/09991

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2743055 A	04-07-1997	NONE	
WO 8602275 A	24-04-1986	AU 4969885 A DE 8590143 U DK 269086 A EP 0197113 A ES 547668 D ES 8701660 A FI 862440 A JP 62500361 T NO 862098 A PT 81272 A,B ZA 8507761 A	02-05-1986 02-04-1987 09-06-1986 15-10-1986 01-12-1986 01-03-1987 06-06-1986 19-02-1987 27-05-1986 01-11-1985 28-05-1986
WO 0053247 A	14-09-2000	NONE	
GB 2263873 A	11-08-1993	NONE	
US 5363842 A	15-11-1994	AT 166236 T CA 2126331 A,C DE 69225604 D DE 69225604 T EP 0617628 A JP 7509378 T JP 3085586 B WO 9312823 A	15-06-1998 08-07-1993 25-06-1998 25-02-1999 05-10-1994 19-10-1995 11-09-2000 08-07-1993
WO 9906303 A	11-02-1999	GB 2332712 A AU 9255098 A BR 9811060 A CN 1261854 T EP 0999987 A HR 990418 A NO 20000365 A PL 337519 A	30-06-1999 22-02-1999 19-09-2000 02-08-2000 17-05-2000 30-04-2000 25-01-2000 28-08-2000
WO 9936115 A	22-07-1999	US 6142339 A US 6161724 A AU 1777499 A EP 1047467 A	07-11-2000 19-12-2000 02-08-1999 02-11-2000

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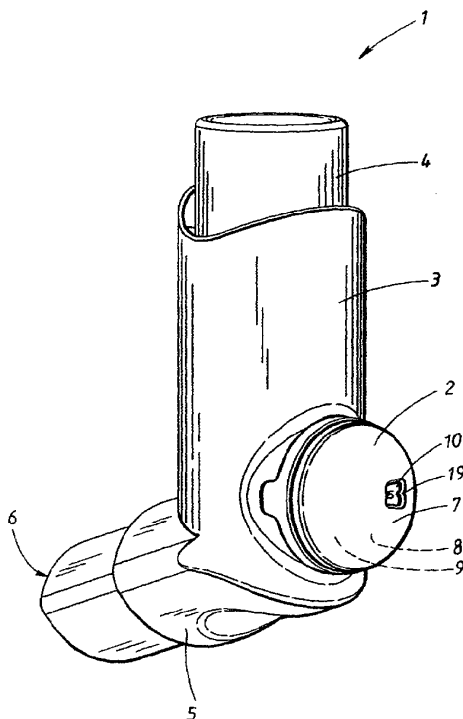
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(75) Inventor/Applicant (for US only): HÖRLIN, Ernst [SE/SE]; Svartmossevägen 2, S-436 39 Askim (SE).
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- (30) Priority Data: 9904278-0 26 November 1999 (26.11.1999) SE (71) Applicant (for all designated States except US): ERNST HÖRLINS INGENJÖRSBYRÅ AB [SE/SE]; Svartmossevägen 2, S-436 39 Askim (SE).

[Continued on next page]

(54) Title: COUNTING MECHANISM, AND SPRAY DOSE INHALER WITH SAID COUNTING MECHANISM



(57) Abstract: The invention relates to a counting mechanism (2) for counting the number of spray doses, for example in combination with spray dose inhalers. A counting mechanism according to the invention comprises a cap (7), a counting wheel (8), and a control wheel (9), all of which have a substantially circular shape, are concentric in relation to each other and, upon each spraying, are acted upon via a rod-shaped pin (32), which is arranged at right angles to the inner surface of the control wheel (9) and is connected to the control wheel (9) via a spring member (33), such that a dosing step is counted by the counting mechanism (2). The counting mechanism (2) has a minimal effect on the spray flow and on the dose size of the sprayed substance since only the rod-shaped pin (32) is introduced into the spray channel.

WO 01/37909 A1



Published:

— With international search report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

TITLE

COUNTING MECHANISM, AND SPRAY DOSE INHALER WITH SAID
COUNTING MECHANISM

5

TECHNICAL FIELD

The invention relates to a counting mechanism for counting the number of
doses delivered from a container and comprising means for connection to
10 the container. The invention also concerns a spray dose inhaler into which a
spray container can be introduced and comprising a counting mechanism for
counting the number of doses delivered from the spray container.

BACKGROUND ART

15

It has become increasingly common for medicines to be administered by
being sprayed into the mouth or nose. For this purpose, spray dose inhalers
have been developed which deliver one dose of medication per spray.
However, a considerable problem with the spray dose inhalers which have
20 hitherto been made available is that they do not have means for indicating
how many doses remain in the spray container. This means that many spray
containers are discarded long before they are empty, and in many cases
even when they are only half empty. There is therefore a great need for a
counting mechanism in order to be able to monitor the spray consumption in
25 a spray dose inhaler.

However, it has proven very difficult to obtain a reliable counting mechanism
which does not adversely affect the function of the inhaler since spray
administration is a method which is very sensitive to external disturbances. A
30 counting mechanism for a spray dose inhaler must therefore have a structure
which does not cause variations in the size of the delivered doses, which

does not create spaces where the active substance can accumulate, and which does not in any other way interfere with the function of the inhaler.

No satisfactory solution to the above problems has as yet been put forward.

5

DISCLOSURE OF THE INVENTION

The present invention nevertheless makes available a counting mechanism which is of the type discussed in the introduction and which largely avoids
10 the problems mentioned above. An arrangement according to the invention is mainly characterized in that the counting mechanism comprises a cap, a counting wheel, and a control wheel, all of which have a substantially circular shape and are concentric in relation to each other, the cap having an outer surface and an inner surface, and a flange-like cap edge projecting
15 from the periphery of the inner surface, and comprising a gear ring which is arranged inside the flange-like cap edge on the inner surface of the cap, an indicator window in the form of a through-opening in the cap, two concentrically arranged inner flanges which project centrally from the inner surface of the cap and of which a first inner flange is arranged radially inside
20 a second inner flange and projects a distance beyond the second inner flange, and in that the first inner flange has a radially projecting locking tooth, and the counting wheel has an outer surface and an inner surface and is arranged directly next to the cap with the outer surface of the counting wheel directed towards the inner surface of the cap, the counting wheel
25 comprising a centrally arranged through-hole with a shape and size corresponding to the shape and size of the second inner flange of the cap, at least one stop tongue which projects from the periphery of the counting wheel and is arranged to engage in and cooperate with the gear ring arranged on the inner surface of the cap, and a gear ring arranged on the
30 inner surface of the counting wheel, near the periphery of the counting wheel, and a measurement scale arranged on the outer surface and placed

so that it is visible through the indicator window, and in that the control wheel has an outer surface and an inner surface and is arranged directly next to the counting wheel, with the outer surface of the control wheel directed towards the inner surface of the counting wheel, the control wheel comprising a centrally arranged through-hole with a shape and size corresponding to the shape and size of the first inner flange of the cap and having a recess arranged on the periphery of the hole, which recess has a shape which substantially corresponds to the shape of the locking tooth arranged on the cap and with a size which slightly exceeds the size of the locking tooth, so that a predetermined clearance exists between the locking tooth and the edges of the recess, at least one stop tongue which projects from the periphery of the control wheel and which is arranged to engage in and cooperate with the gear ring arranged on the inner surface of the counting wheel, and a rod-shaped pin which is arranged at right angles to the inner surface of the control wheel and is connected to the control wheel via a spring member, and in that the stop tongue of the control wheel is oriented in a tangential direction which is opposite to the direction of the gear ring and stop tongue of the counting wheel, and in that the direction of the teeth in the gear ring of the cap coincides with the tangential direction of the stop tongue of the control wheel, and furthermore in that the number of stop tongues and the number of teeth are identical for the counting wheel and for the control wheel.

Although not essential to the invention, it may be expedient, for production reasons and assembly reasons, that the first and second inner flanges of the cap, and the centrally arranged through-holes in the counting wheel and control wheel, are substantially circular with a radius corresponding to the radius of the first and second inner flange, respectively, of the cap.

It is also advantageous for the stop tongues on the counting wheel and control wheel to be arranged to spring in the radial direction, as a result of

which the stop tongues bear with a certain spring force against the teeth of the gear rings of the counting wheel and cap. Radial direction is understood as a radial direction in towards or out from a centre axis running through the counting mechanism.

5

The number of doses which the counting mechanism is able to count depends on the clearance between the locking tooth, arranged on the inside of the cap, and the corresponding recess in the control wheel, and also on the number of teeth in the gear rings of the counting wheel and cap. For
10 counting mechanisms intended to count up to 130 doses, the clearance should be about 3° and the number of teeth should be 46. For counting mechanisms intended to count 130 to 240 doses, the clearance should be 1.5° and the number of teeth should be 82. The clearance is calculated by dividing 360° by the number of doses which the counting mechanism is
15 intended to be able to count, after which a whole 1° is added to the result. The number of teeth must be evenly divisible by the number of stop tongues, plus one extra tooth.

A suitable spring member for connecting the rod-shaped pin to the control
20 wheel, and for transferring forces acting on the rod-shaped pin to the control wheel, is a flat spring. The spring member can be a separately manufactured component, but it is advantageously made integral with the rod-shaped pin and the control wheel, for example by injection-moulding of plastic.

25 The invention also concerns a complete spray dose inhaler of the type discussed in the introduction. A spray dose inhaler according to the invention is characterized mainly in that the counting mechanism is arranged substantially on the outside of the inhaler and comprises a cap, a counting wheel, and a control wheel, all of which have a substantially
30 circular shape and are concentric in relation to each other, the cap having an outer surface and an inner surface, and a flange-like cap edge projecting

from the periphery of the inner surface, and comprising a gear ring which is arranged inside the flange-like cap edge on the inner surface of the cap, an indicator window in the form of a through-opening in the cap, two concentrically arranged inner flanges which project centrally from the inner surface of the cap and of which a first inner flange is arranged radially inside a second inner flange and projects a distance beyond the second inner flange, and in that the first inner flange has a radially projecting locking tooth, and the counting wheel has an outer surface and an inner surface and is arranged directly next to the cap with the outer surface of the counting wheel directed towards the inner surface of the cap, the counting wheel comprising a centrally arranged through-hole with a shape and size corresponding to the shape and size of the second inner flange of the cap, at least one stop tongue which projects from the periphery of the counting wheel and is arranged to engage in and cooperate with the gear ring arranged on the inner surface of the cap, and a gear ring arranged on the inner surface of the counting wheel, near the periphery of the counting wheel, and a measurement scale arranged on the outer surface and placed so that it is visible through the indicator window, and in that the control wheel has an outer surface and an inner surface and is arranged directly next to the counting wheel, with the outer surface of the control wheel directed towards the inner surface of the counting wheel, the counting wheel comprising a centrally arranged through-hole with a shape and size corresponding to the shape and size of the second inner flange of the cap and having a recess arranged on the periphery of the hole, which recess has a shape which substantially corresponds to the shape of the locking tooth arranged on the cap and with a size which is slightly greater than the locking tooth, so that a predetermined clearance exists between the locking tooth and the edges of the recess, at least one stop tongue which projects from the periphery of the control wheel and which is arranged to engage in and cooperate with the gear ring arranged on the inner surface of the counting wheel, and a rod-shaped pin which is arranged at right angles to the inner

surface of the control wheel and is connected to the control wheel via a spring member, and in that the stop tongue of the control wheel is oriented in a tangential direction which is opposite to the direction of the gear ring and stop tongue of the counting wheel, and in that the direction of the teeth in the gear ring of the cap coincides with the tangential direction of the stop tongue of the control wheel, and furthermore in that the number of stop tongues and the number of teeth are identical for the counting wheel and for the control wheel, and in that the outside of the spray dose inhaler is provided with coupling members for connecting the counting mechanism to the spray dose inhaler, the coupling members comprising a through-hole through which the rod-shaped pin of the counting mechanism can be introduced, the hole being positioned so that the rod-shaped pin is in contact with the spray container and is acted upon and deflected and/or changes position when the spray container moves in the first part of the spray dose inhaler.

Since the invention allows the counting mechanism to be arranged almost entirely on the outside of the inhaler, with only the very small rod-shaped pin situated inside the inhaler, the counting mechanism by and large does not in any way affect the flow through the inhaler. This means that the doses delivered retain a constant size, and that the risk of active substance accumulating in the inhaler as a result of the action of the counting mechanism is practically nonexistent.

The dose scale arranged on the counting wheel is placed in an annular configuration on the outside of the counting wheel and is either ascending or descending, depending on whether the counting mechanism is to indicate how many doses have been administered or how many doses remain. The dose scale is preferably a numerical scale, with the dose number being indicated in steps of 1, 2, 5, 10, 25 doses or in other dose steps if deemed appropriate. Alternatively, or in addition to this, it is however possible to imagine using a colour scale, for example ranging from green through yellow

to red. For example, the last 10% of the doses can be indicated by red or another differing colour. As the counting wheel is turned round during use, new parts of the dose scale successively appear through the indicator window in the counting mechanism cap. The indicator window is preferably
5 provided with an arrow which points to the dose number in each position.

The counting mechanism can be provided with a built-in stop position. Such a counting mechanism is discarded when it has counted the predetermined number of doses for which it has been designed. It is also possible to
10 produce re-usable counting mechanisms without built-in stop devices. Such a stop device can be provided, for example, by arranging a pin on the inside of the cap, which pin runs in a groove in the counting wheel.

BRIEF DESCRIPTION OF THE FIGURES

15

The invention will be described in greater detail below with reference to the illustrative embodiments shown in the attached figures, where:

Figure 1 shows a spray dose inhaler with a counting mechanism according
20 to the invention;

Figures 2a and 2b show an outer casing for a counting mechanism according to the invention;

25 Figures 3a and 3b show a counting wheel for a counting mechanism according to the invention;

Figures 4a and 4b show a control wheel for a counting mechanism according to the invention;

30

Figure 5 shows an exploded view of a spray dose inhaler with associated components;

Figure 6 shows a spray dose inhaler with an attachment arrangement for a
5 counting mechanism according to the invention;

Figure 7 shows a cross section through a spray dose inhaler and a counting mechanism according to the invention; and

10 Figure 8 shows an exploded view of a counting mechanism according to the invention.

DETAILED DESCRIPTION OF EMBODIMENTS

15 Figure 1 shows a spray dose inhaler 1 which is provided with a counting mechanism 2 arranged substantially on the outside of the inhaler. The spray dose inhaler 1 has an upper tubular part 3 into which a spray container 4 is introduced. The spray dose inhaler 1 also has a lower tubular mouthpiece part 5 which is angled in relation to the upper part 3 and which emerges via
20 an opening 6 from which the contents of the spray container 4 are delivered. When using the spray dose inhaler 1, the mouthpiece part 5 is placed in the user's mouth and the spray container 4 is pressed further down in the upper part 3 of the inhaler 1. A dose is thereby released and is sprayed into the user's oral cavity.

25

The counting mechanism 2 consists of three main components, namely a cap 7, a counting wheel 8, and a control wheel 9. Arranged on the outside is the substantially circular cap 7, the latter thus serving as an outer casing for the counting mechanism 2. The cap 7 is provided with an indicator window
30 10, and on the inside of the cap 7 there is a gear ring 11 in which the number of teeth 12 is adapted to the number of doses in the spray container.

Such a cap is shown in Figures 2a and 2b. Figure 2a shows the outside of the cap 7, i.e. the side directed away from the inhaler when the counting mechanism is fitted on an inhaler, and Figure 2b shows the inside of the cap, i.e. the side directed towards the inhaler when the counting mechanism 2 is fitted. The teeth 12 are inclined and slope in a first tangential direction. In Figure 2a the teeth 12 are shown with an inclination anti-clockwise in the figure. The cap 7 is additionally provided with a coupling arrangement comprising several parts and intended to cooperate with a corresponding coupling arrangement on the inhaler 1. The coupling arrangement on the inhaler 1 is shown in detail in Figure 6 and will be described in detail in the description of Figure 6. The coupling arrangement on the cap 7 comprises, on the one hand, a cap edge 13 projecting at right angles from the plane of the cap 7 and an almost rectangular pin 14 projecting from the cap edge 13, and, on the other hand, a centrally arranged cylindrical first inner flange 15. Moreover, the cylindrical inner flange 15 has a locking tooth 16 projecting radially from the outer surface of the inner flange 15.

Arranged concentrically to the outside of the cylindrical inner flange 15 there is an annular second inner flange 17 which has less height above the inner surface of the cap than does the cylindrical first inner flange 15, and which is intended to serve as coupling member between the cap 7 and the counting wheel 8. The cylindrical first inner flange 15 here fulfills the additional purpose of being a coupling member between the cap 7 and the control wheel 9.

Arranged inside of the cap 7, or outer casing, there is a counting wheel 8 of the type shown in Figures 3a and 3b. The counting wheel 8 has a substantially circular shape, with a central and circular through-hole 20. In the same way as in Figures 2a and 2b, the counting wheel 8 in Figure 3a is shown from the outside, which is the side directed outwards and away from the inhaler 1, and Figure 3b shows the inside, which is the side of the

counting wheel 8 directed inwards and towards the inhaler 1. As can be seen from Figure 3a, the outside of the counting wheel 8 is provided with a numerical scale 21 which is intended to continuously indicate the number of doses remaining in the spray container 4. In the illustrative embodiment shown, the doses are indicated in intervals of 5. In some cases it can of course be expedient to count the doses in another way, for example in individual doses or in intervals of two doses, ten doses, 25 doses, and so on, depending on how many doses in total are present in the spray container 4. The counting wheel 8 is either numbered in ascending sequence, so that the number of doses used is indicated, or in descending sequence, so that the number of doses remaining is indicated. The numerical scale 21 is visible through the indicator window 10 on the cap. As can be seen for example from Figure 2, the indicator window 10 can be provided with an indicator arrow 19 which points to the current number of doses. Moreover, the last doses, for example the last 10% of the doses, are marked in a different way, preferably with a different colour such as red.

As with the cap 7, a gear ring 22 is arranged on the inside of the counting wheel 8, about its periphery. The number of teeth 23 is adapted to the number of doses which are to be counted, and the teeth 23 are oriented in the opposite direction in relation to the teeth 12 on the cap 7, which means that the teeth 23 in Figure 3b slope clockwise. In addition, the counting wheel 8 is provided with three stop tongues 25 arranged symmetrically about the outer edge 24 of the counting wheel 8. The stop tongues 25 are designed in such a way that they have a certain spring capacity, upon radial loading, in towards or out from the centre of the counting wheel 8. As will be observed in Figures 3a and 3b, the stop tongues 25 have a free pin-shaped part which is directed along the periphery of the counting wheel 8 and which ends in a stop edge 26. In the example shown, the free parts of the stop tongues 25, as can be seen from Figure 3b, are directed clockwise about the

periphery of the counting wheel 8. The stop tongues 25 thus have the same direction as the teeth 23 of the counting wheel 8.

The third part of the counting mechanism 2 is the control wheel 9 shown in
5 Figures 4a and 4b. The control wheel 9 is also substantially circular in shape and is provided with three resilient stop tongues 30 which are distributed symmetrically about the periphery of the wheel 9 and have a free part which springs radially and ends in a stop edge 31. However, the stop tongues 30 of the control wheel 9 are directed in the opposite direction in relation to the
10 stop tongues 25 of the counting wheel 8. In addition, the control wheel 9 has a rod-shaped pin 32 which is arranged at right angles to the inside of the control wheel 9, which is the side of the control wheel 9 intended to be directed towards the inhaler 1. The pin 32 is connected to the control wheel 9 via a flat spring member 33. A circular hole 34 is arranged centrally
15 through the control wheel 9 and has a recess 35 arranged on the periphery of the hole 34, which recess 35 has a shape corresponding substantially to the shape of the locking tooth 16 arranged on the cap 7. When the counting mechanism 2 is assembled, the locking tooth 16 is in fact intended to be introduced into the recess 35 of the control wheel 9, in the manner of a key
20 in a lock. As has previously been mentioned, it is intended that there should be a certain clearance or play between the locking tooth 16 and the edges of the recess 35, which clearance has a predetermined size and contributes to defining the size of the counting steps which the counting mechanism 2 registers.

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Figure 5 shows how the different parts are joined together to form a complete inhaler 1 with counting mechanism 2 and spray container 4. The spray container 4 is introduced into the upper tubular part 3 of the spray dose inhaler 1, and the counting mechanism 2 is fitted on the outside of the
30 upper tubular part 3 of the spray dose inhaler 1, near the transition to the mouthpiece part 5.

Figure 6 shows in detail the appearance of the coupling arrangement provided on the spray dose inhaler 1. The coupling arrangement comprises a circular outer flange 40, which projects from the surface of the inhaler 1 and which has an outer ring 41 and also an inner ring 42 which projects farther than the outer ring 41 and has an external radius corresponding to the internal radius of the projecting cap edge 13 on the cap 7 of the counting mechanism 2. A recess 43 is also provided in the outer ring 41 for cooperation with the substantially rectangular pin 14 arranged on the cap edge 13. Thus, the counting mechanism 2 is fitted with the cap 7 tight over the outer ring 41 of the coupling arrangement of the spray dose inhaler 1, and with the pin 14 on the cap edge 13 inserted into the recess 43 on the outer ring 41 of the coupling arrangement.

The spray dose inhaler 1 also has a centrally arranged annular inner flange 45 whose internal diameter corresponds to the external diameter of the cylindrical first inner flange 15 on the counting mechanism cap 7. The annular inner flange 45 arranged on the spray dose inhaler 1 has a gap 46 through which the locking tooth 16 arranged on the cylindrical first inner flange 15 of the counting mechanism cap 7 can project.

The spray dose inhaler 1 finally has a through-hole 47 arranged between the inner flange 45 and outer flange 40 of the coupling arrangement. The through-hole 47 is designed such that the rod-shaped pin 32 arranged on the control wheel 9 can be introduced through the wall of the spray dose inhaler 1 and into the inside of the spray dose inhaler. The hole has a diameter which is substantially the same as the diameter of the rod-shaped pin 32. Although the hole 47 and the rod-shaped pin in the illustrative embodiment shown have a circular cross section, it is possible, within the scope of the invention, to use holes/pins with edged or oval cross sections.

Figure 7 shows how the spray dose inhaler 1 looks when the counting mechanism 2 has been fitted and the spray container 4 has been introduced into the upper tubular part 3 of the inhaler 1. The rod-shaped pin 32 of the control wheel 9 is introduced through the hole 47 in the inhaler wall, and the hole 47 is positioned in such a way that the pin 32 is thereby in contact with the spray container 4 in such a way that, when the spray container 4 is pressed into the inhaler 1, the spray container 4 presses the pin 32 in its direction of movement. In so doing, that part of the pin 32 located inside the inhaler 1 is deflected and/or angled in the downward direction in Figure 7. This means that the flat spring 33 connecting the pin 32 to the control wheel 9 acts on the control wheel 9 in a direction opposite to the direction of movement of the pin 32 and spray container 4. The cooperation between the various parts of the counting mechanism 2 will be readily understood by referring to Figure 8, from which figure it clearly emerges how the directions of movement of the different gear rings 11, 22 and stop tongues 25, 30 relate to each other. When the rod-shaped pin 32 is pressed downwards in the inhaler (as is shown in Figure 7), the control wheel 9 is therefore rotated clockwise, viewed axially in the direction from within the inhaler 1. However, the rotation can only occur as far as is permitted by the clearance between the locking tooth 16 of the cap 7 and the corresponding recess 35 on the control wheel 9. By means of this rotation, one of the three stop tongues 30 arranged on the control wheel is additionally moved to a new position between two teeth 23 of the counting wheel 8. When the load exerted by the spray container 4 on the rod-shaped pin 32 ceases, the pin 32 returns to the substantially horizontal position shown in Figure 7 and the control wheel 9 springs back to its initial position, which corresponds to the control wheel 9 rotating anti-clockwise as far as is permitted by the clearance between the locking tooth 16 of the cap 7 and the corresponding recess 35 on the control wheel 9. During this movement, one of the stop tongues 30 of the control wheel 9 rests with its outer stop edge 31 against a tooth 23 of the counting wheel 8. In this way, the return movement is transmitted to the counting

wheel 8 which thus rotates anti-clockwise and counts one step, which can be observed in the indicator window 10 of the cap 7. At the same time, one of the locking tongues 25 on the periphery of the counting wheel 8 is moved to a stop position between two teeth 12 of the gear ring 11 of the cap 7, which means that a subsequent clockwise rotation of the control wheel 9 does not act on the counting wheel 8, since clockwise rotation of the counting wheel 8 is prevented by the fact that the outer stop edge 26 of one of the locking tongues 25 of the counting wheel bears against one of the teeth 12 of the cap 7 and prevents clockwise rotation.

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In the examples shown in the figures, the position of the rod-shaped pin 32 is such that the control wheel 9 rotates clockwise when the spray container 4 is pressed into the inhaler 1 upon administration of a spray dose. However, this is not a necessary condition for the invention. It is therefore possible to envisage the pin 32 being positioned instead on the diametrically opposite side of the control wheel 9. Such positioning would mean that the control wheel 9 first rotated anti-clockwise when the spray container 4 was pressed into the inhaler 1. Of course, such an arrangement would additionally mean that the direction of rotation, like the direction of the different gear rings 11, 22 and stop tongues 25, 30, would be opposite to those directions described above.

A counting mechanism 2 according to the invention can advantageously be produced by injection moulding of plastic. It is of course also possible to envisage combinations of plastic components and other materials, or counting mechanisms made completely or partially of metal.

Although the counting mechanism has been described in association with a spray dose inhaler, it is of course possible to use the counting mechanism in all contexts where a substance is to be sprayed in doses. For example, the counting mechanism can be used for spraying cosmetics or the like. In

addition, spray dose inhalers in which the dosed substance is administered into the nose are of course also intended to come within the scope of the invention.

CLAIMS

1. Counting mechanism (2) for counting the number of doses delivered from a container (4) and comprising means for connection to the container (4), characterized in that the counting mechanism (2) comprises a cap (7), a counting wheel (8), and a control wheel (9), all of which have a substantially circular shape and are concentric in relation to each other, the cap (7) having an outer surface and an inner surface, and a flange-like cap edge (13) projecting from the periphery of the inner surface, and comprising a gear ring (11) which is arranged inside the flange-like cap edge (13) on the inner surface of the cap (7), an indicator window (10) in the form of a through- opening in the cap (7), two concentrically arranged inner flanges (15, 17) which project centrally from the inner surface of the cap (7) and of which a first inner flange (15) is arranged radially inside a second inner flange (17) and projects a distance beyond the second inner flange (17), and in that the first inner flange (15) has a radially projecting locking tooth (16), and the counting wheel (8) has an outer surface and an inner surface and is arranged directly next to the cap (7) with the outer surface of the counting wheel (8) directed towards the inner surface of the cap (7), the counting wheel (8) comprising a centrally arranged through-hole (20) with a shape and size corresponding to the shape and size of the second inner flange (17) of the cap (7), at least one stop tongue (25) which projects from the periphery of the counting wheel and is arranged to engage in and cooperate with the gear ring (11) arranged on the inner surface of the cap (7), and a gear ring (22) arranged on the inner surface of the counting wheel (8), near the periphery of the counting wheel (8), and a measurement scale (21) arranged on the outer surface and placed so that it is visible through the indicator window (10), and in that the control wheel (9) has an outer surface and an inner surface and is arranged directly next to the counting wheel (8), with the outer surface of the control wheel (9) directed towards the inner surface of the counting wheel (8), the control wheel (9) comprising a

centrally arranged through-hole (34) with a shape and size corresponding to the shape and size of the first inner flange (15) of the cap (7) and having a recess (35) arranged on the periphery of the hole (34), which recess (35) has a shape which substantially corresponds to the shape of the locking tooth (16) arranged on the cap (7) and with a size which slightly exceeds the size of the locking tooth (16), so that a predetermined clearance exists between the locking tooth (16) and the edges of the recess (35), at least one stop tongue (30) which projects from the periphery of the control wheel (9) and which is arranged to engage in and cooperate with the gear ring (22) arranged on the inner surface of the counting wheel (8), and a rod-shaped pin (32) which is arranged at right angles to the inner surface of the control wheel (9) and is connected to the control wheel (9) via a spring member (33), and in that the stop tongue (30) of the control wheel (9) is oriented in a tangential direction which is opposite to the direction of the gear ring (22) and stop tongue (25) of the counting wheel (8), and in that the direction of the teeth (12) in the gear ring (11) of the cap (7) coincides with the tangential direction of the stop tongue (30) of the control wheel (9), and furthermore in that the number of stop tongues (25, 30) and the number of teeth (12, 23) are identical for the counting wheel (8) and for the control wheel (9).

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2. Counting mechanism according to Claim 1, characterized in that the number of stop tongues (25, 30) on the periphery of the counting wheel (8) and of the control wheel (9) is a prime number, and in that the stop tongues (25, 30) are symmetrically distributed about the periphery of the respective wheel (8, 9).

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3. Counting mechanism according to Claim 1 or 2, characterized in that the first and second inner flange (15, 17) of the cap (7), and the centrally arranged through-holes (20, 34) in the counting wheel (8) and the control wheel (9), are substantially circular with a radius corresponding with the

30

radius of the first and second inner flange (15, 17), respectively, of the cap (7).

4. Counting mechanism according to Claim 1, 2 or 3, characterized in that the stop tongues (25, 30) on the counting wheel (8) and the control wheel (9) are arranged to spring in the radial direction.

5. Counting mechanism according to any of Claims 1 to 4, characterized in that the number of teeth (12, 23) on the counting wheel (8) and the control wheel (9) is 46, and in that the number of stop tongues (25, 30) on the counting wheel (8) and the control wheel (9) is 3, and in that the clearance between the locking tooth (16) and the recess (35) is approximately 3°.

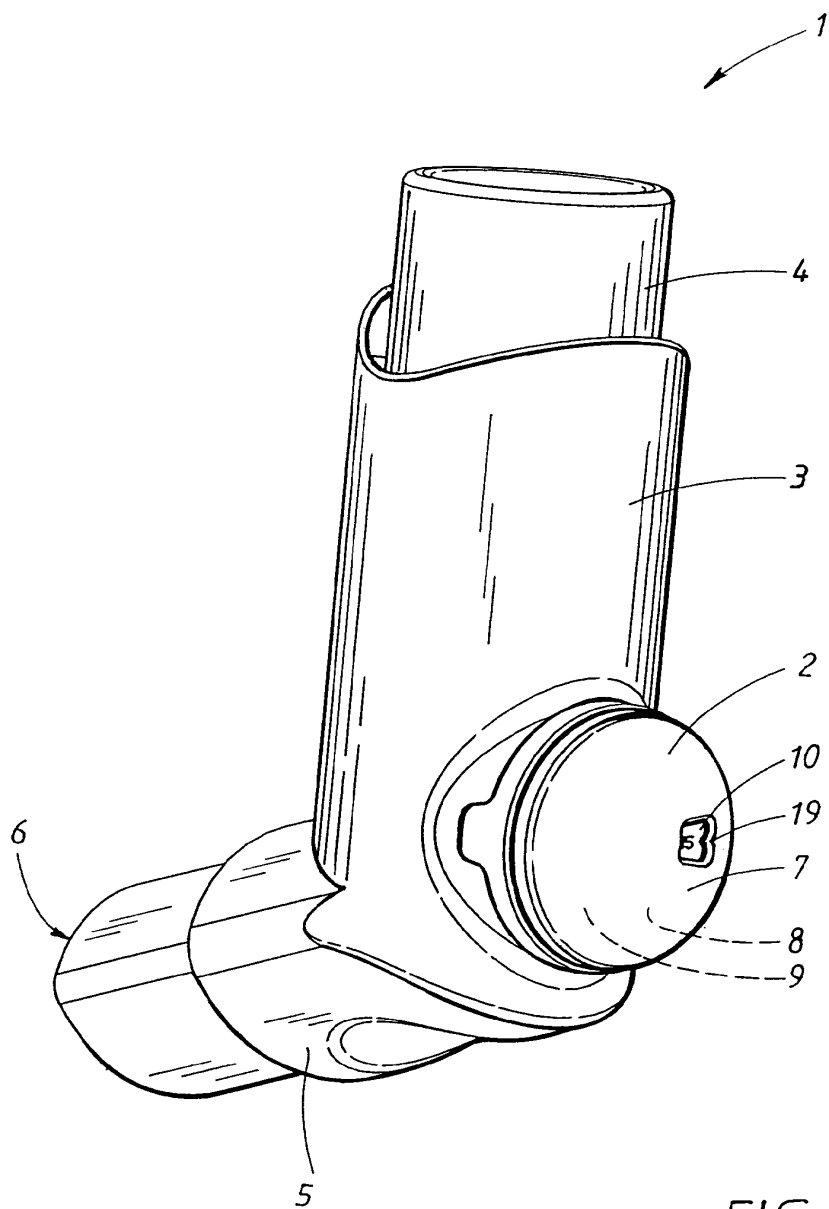
6. Counting mechanism according to Claim 1, characterized in that the spring member (33) is a flat spring.

7. Spray dose inhaler (1) with an inside and an outside, comprising a first tubular part (3) into which a spray container (4) can be introduced, a second tubular mouthpiece part (5) which is angled in relation to the first part (3) and which emerges into an opening (6) from which the contents of the spray container (4) can be delivered, and comprising a counting mechanism (2), characterized in that the counting mechanism (2) is arranged substantially on the outside of the inhaler (1) and comprises a cap (7), a counting wheel (8), and a control wheel (9), all of which have a substantially circular shape and are concentric in relation to each other, the cap (7) having an outer surface and an inner surface, and a flange-like cap edge (13) projecting from the periphery of the inner surface, and comprising a gear ring (11) which is arranged inside the flange-like cap edge (13) on the inner surface of the cap (7), an indicator window (10) in the form of a through-opening in the cap (7), two concentrically arranged inner flanges (15, 17) which project centrally from the inner surface of the cap (7) and of

which a first inner flange (15) is arranged radially inside a second inner flange (17) and projects a distance beyond the second inner flange (17), and in that the first inner flange (15) has a radially projecting locking tooth (16), and the counting wheel (8) has an outer surface and an inner surface and is arranged directly next to the cap (7) with the outer surface of the counting wheel (8) directed towards the inner surface of the cap (7), the counting wheel (8) comprising a centrally arranged through-hole (20) with a shape and size corresponding to the shape and size of the second inner flange (17) of the cap (7), at least one stop tongue (25) which projects from the periphery of the counting wheel and is arranged to engage in and cooperate with the gear ring (11) arranged on the inner surface of the cap (7), and a gear ring (22) arranged on the inner surface of the counting wheel (8), near the periphery of the counting wheel (8), and a measurement scale (21) arranged on the outer surface and placed so that it is visible through the indicator window (10), and in that the control wheel (9) has an outer surface and an inner surface and is arranged directly next to the counting wheel (8), with the outer surface of the control wheel (9) directed towards the inner surface of the counting wheel (8), the control wheel (9) comprising a centrally arranged through-hole (34) with a shape and size corresponding to the shape and size of the first inner flange (15) of the cap (7) and having a recess (35) arranged on the periphery of the hole (34), which recess (35) has a shape which substantially corresponds to the shape of the locking tooth (16) arranged on the cap (7) and with a size which slightly exceeds the size of the locking tooth (16), so that a predetermined clearance exists between the locking tooth (16) and the edges of the recess (35), at least one stop tongue (30) which projects from the periphery of the control wheel (9) and which is arranged to engage in and cooperate with the gear ring (22) arranged on the inner surface of the counting wheel (8), and a rod-shaped pin (32) which is arranged at right angles to the inner surface of the control wheel (9) and is connected to the control wheel (9) via a spring member (33), and in that the stop tongue (30) of the control wheel (9) is oriented in a

tangential direction which is opposite to the direction of the gear ring (22) and stop tongue (25) of the counting wheel (8), and in that the direction of the teeth (12) in the gear ring (11) of the cap (7) coincides with the tangential direction of the stop tongue (30) of the control wheel (9), and furthermore in
5 that the number of stop tongues (25, 30) and the number of teeth (12, 23) are identical for the counting wheel (8) and for the control wheel (9), and in that the outside of the spray dose inhaler (1) is provided with coupling members (40, 43, 45, 47) for connecting the counting mechanism (2) to the
10 spray dose inhaler (1), the coupling members comprising a through-hole (47) through which the rod-shaped pin (32) of the counting mechanism (2) can be introduced, the hole (47) being positioned so that the rod-shaped pin (32) is in contact with the spray container and is acted upon and deflected and/or changes position when the spray container (4) moves in the first part (3) of the spray dose inhaler (1).

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FIG. 1

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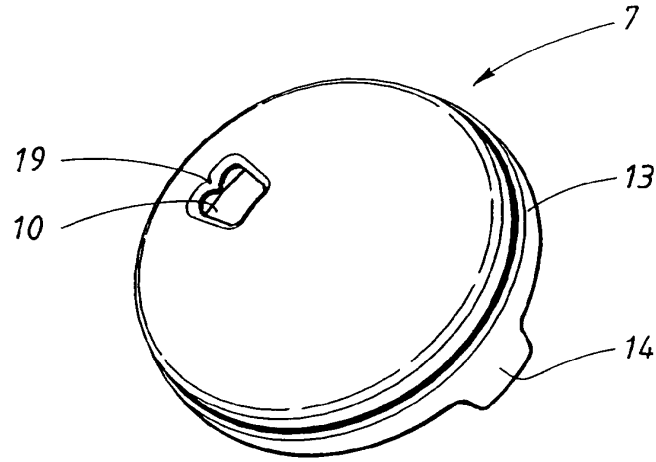


FIG. 2a

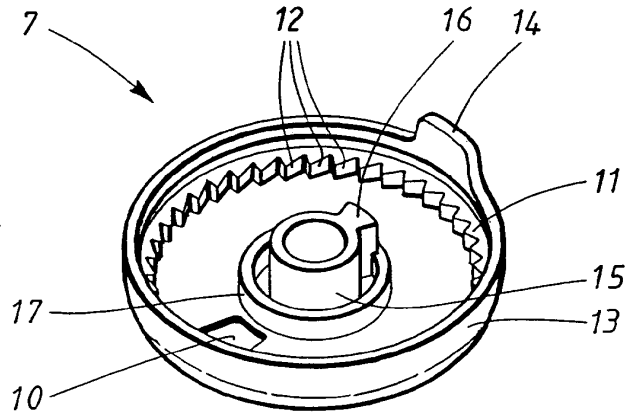


FIG. 2b

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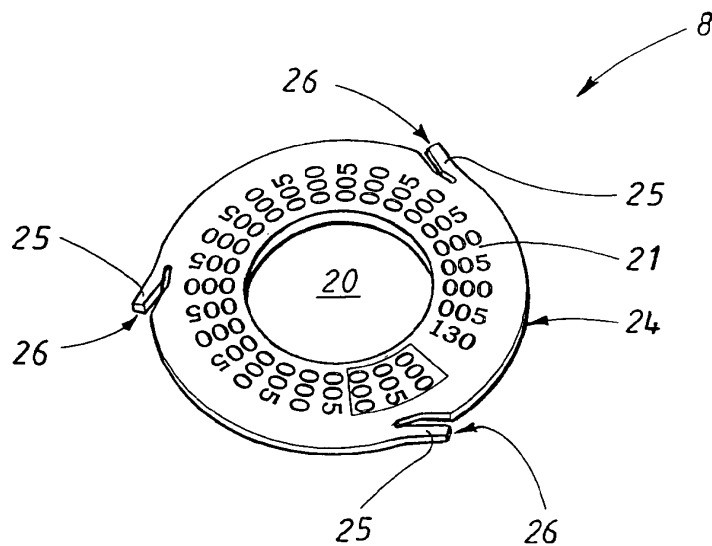


FIG. 3a

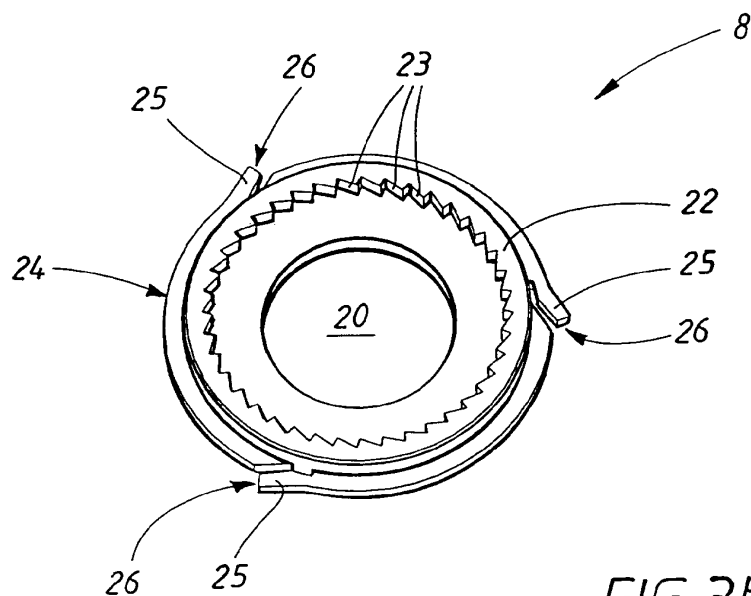


FIG. 3b

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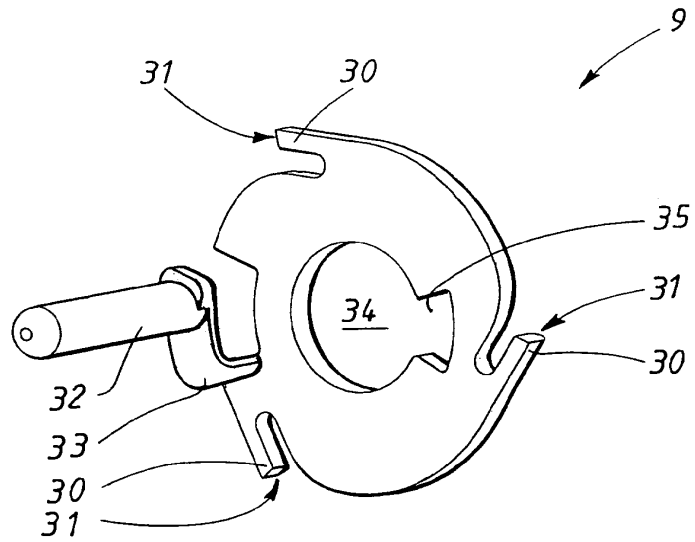


FIG. 4a

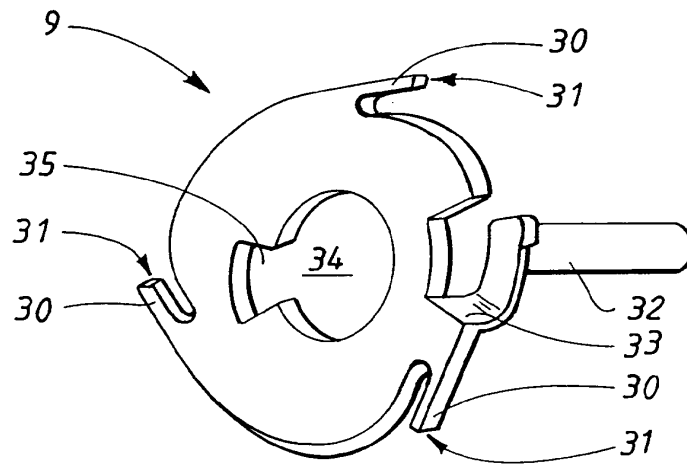


FIG. 4b

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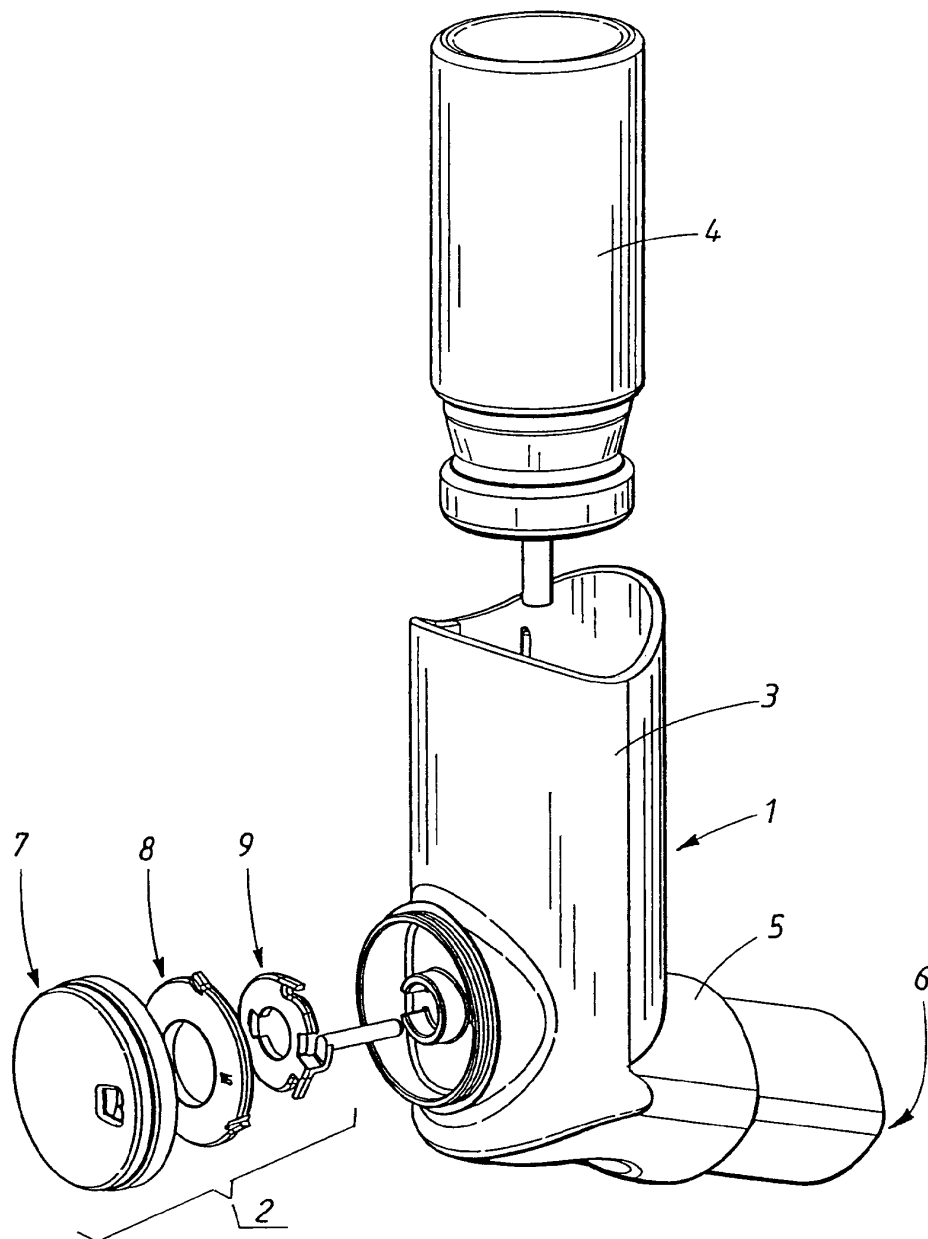


FIG. 5

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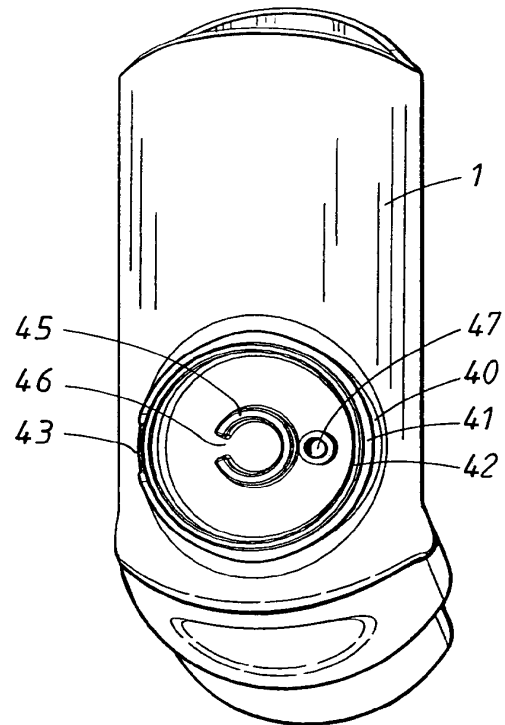


FIG. 6

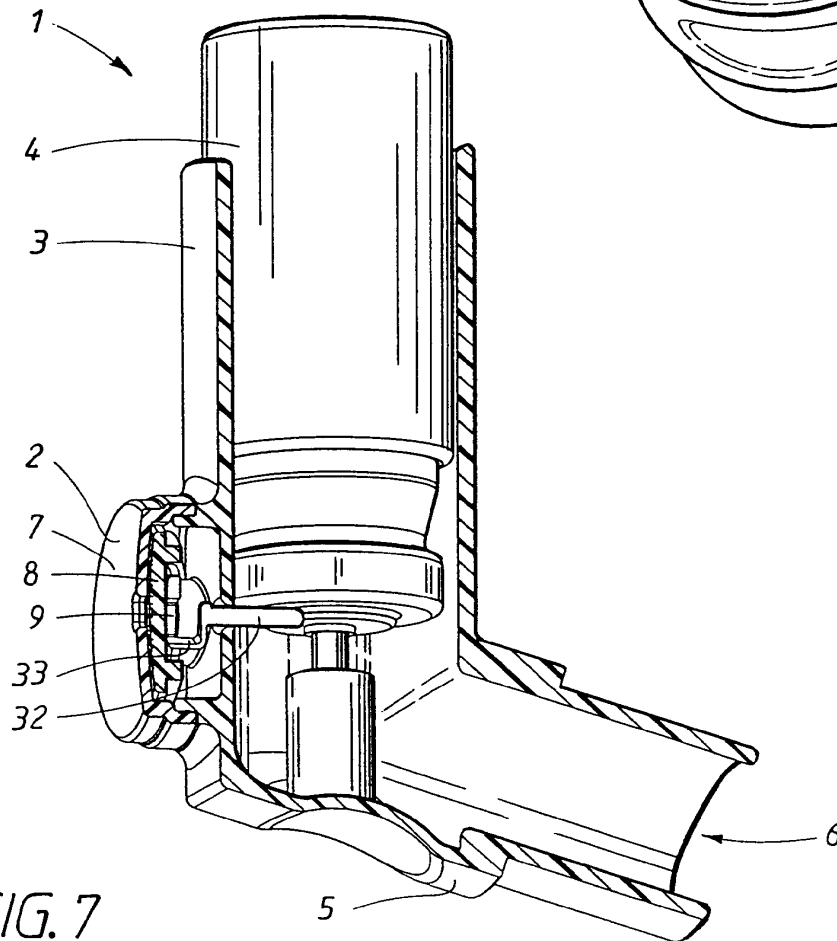


FIG. 7

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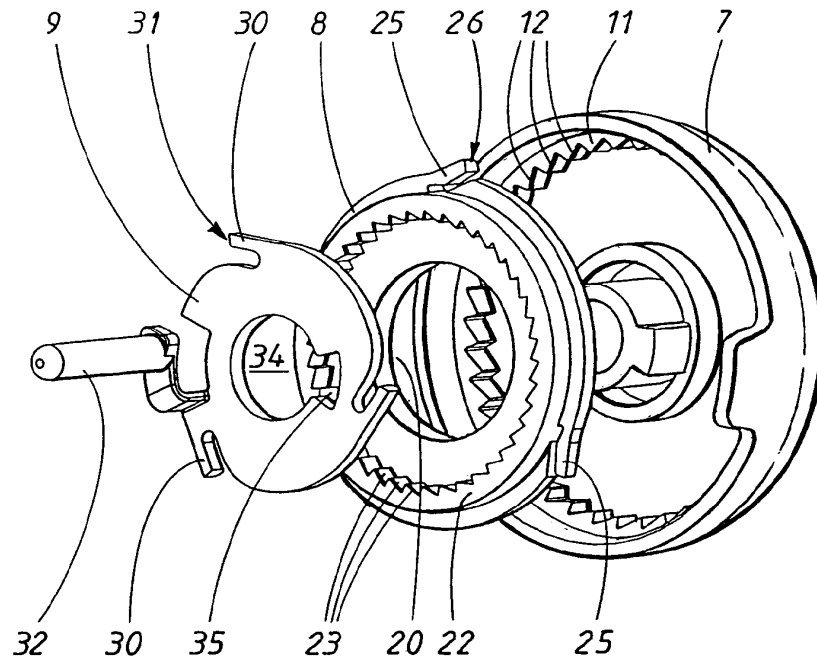


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 00/02319

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61M 11/00, A61M 15/00, G06M 1/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61M, G06M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 19549033 C1 (BOEHRINGER INGELHEIM INTERNATIONAL GMBH), 28 May 1998 (28.05.98), figure 1, claims 1-18 --	1-7
A	WO 8602275 A1 (AKTIEBOLAGET DRACO), 24 April 1986 (24.04.86), figures 1-7, claims 1-8 -- -----	1-7

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

23 January 2001

Date of mailing of the international search report

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Swedish Patent Office

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Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/SE 00/02319

Patent document cited in search report			Publication date	Patent family member(s)		Publication date
DE	19549033	C1	28/05/98	AU	1303597 A	28/07/97
				BG	102540 A	30/12/98
				BR	9612394 A	13/07/99
				CA	2238760 A	10/07/97
				CZ	9802049 A	11/11/98
				EP	0870178 A	14/10/98
				HR	960617 A,B	31/10/97
				HU	9903725 A	28/03/00
				IL	124573 D	00/00/00
				NO	982992 A	26/06/98
				PL	327571 A	21/12/98
				SK	89098 A	04/11/98
				US	6149054 A	21/11/00
				WO	9724586 A	10/07/97
WO	8602275	A1	24/04/86	AU	4969885 A	02/05/86
				DE	8590143 U	02/04/87
				DK	269086 A	09/06/86
				DK	481884 D	00/00/00
				EP	0197113 A	15/10/86
				ES	547668 A	01/12/86
				ES	8701660 A	01/03/87
				FI	862440 A	06/06/86
				JP	62500361 T	19/02/87
				NO	862098 A	27/05/86
				PT	81272 A,B	01/11/85
				ZA	8507761 A	28/05/86

Form PCT/ISA/210 (patent family annex) (July 1998)

ATTACHMENT A

(US Refs Not Submitted)

US 5,349,945
US 5,718,355
US 5,904,139
US 6,161,724
US 6,142,339
US 6,155,251
US 6,328,037
US 6,446,627

(Submitted as Part 1)

WO 93/24167
WO 98/52634
WO 98/56444
WO 00/09187
WO 00/21593
WO 00/59806
WO 01/28887
WO 01/37909

(Submitted as Part 2)

EP 0 254 391
EP 0 949 584
EP 1 010 438
EP 1 163 922

EUROPEAN PATENT APPLICATION

Application number: **87303617.2**

Int. Cl.4: **A61M 15/00**

Date of filing: **24.04.87**

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(Guidelines for Examination in the EPO, A-III,
7.3).

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Date of publication of application:
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Indicating device for aerosol dispensers.

A device is described for indicating the number of doses dispensed from an aerosol container (2) having an outlet valve member (4) movable relative to the body of the container (2) to dispense its contents in measured doses. Relative movement between the aerosol container body (2) and the outlet member (4) are detected by a ratchet wheel (14) and ratchet driving member (11A) which move with the body and outlet member respectively or vice versa. The ratchet wheel (14) may in turn drive an indicating member in the form of a linear rack (20) or rotatable wheel (116).

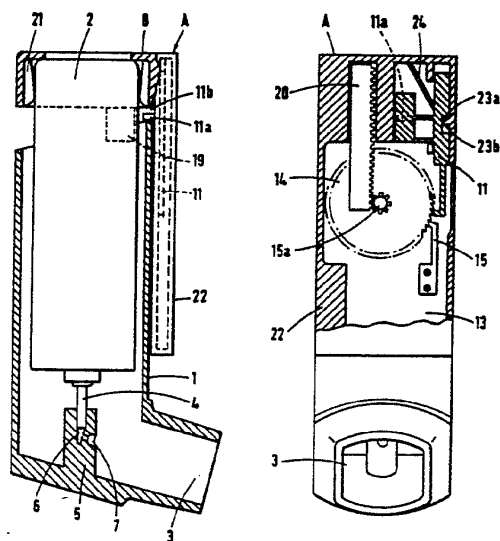


Fig.1

Fig.2

EP 0 254 391 A1

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INDICATING DEVICE

The present invention relates to a device for indicating the number of doses dispensed from an aerosol container, and, also, to aerosol devices, for example, inhalation devices by which medicaments contained in an aerosol may be administered to a patient.

It is well known to treat patients with medicaments contained in an aerosol, for example, in bronchodilator therapy. It is also known to use for such therapy, medicaments which are contained in an aerosol and are administered to a patient by means of an inhalation device comprising a tubular housing or sleeve in which the aerosol container is located and an outlet tube leading out of the tubular housing. The aerosol containers used in such inhalation devices have an outlet valve member at one end which can be opened either by depressing the valve member while the container is held stationary or by depressing the container while the valve member is held stationary. In the use of such devices, the aerosol container is placed in the tubular housing with the outlet valve member of the container communicating via a support with the outlet tube, for example, a nozzle or mouthpiece. When used for dispensing medicaments, for example in bronchodilation therapy, the housing is then held by the patient in a more or less upright condition and the mouthpiece or nozzle of the inhalation device is placed in the mouth or nose of the patient. The aerosol container is pressed towards the support to dispense a dose of medicament from the container which is then inhaled by the patient.

A disadvantage arising from use of such known devices is that the patient cannot determine the amount of medicament in the aerosol container at any given time. In an extreme case this could mean that the patient, possibly suffering from severe bronchospasm and needing a dose of medicament, will find that the aerosol container will not dispense a dose because its contents have already been exhausted.

An object of the present invention is to provide means of overcoming this disadvantage.

Accordingly, the present invention provides a device for indicating the number of doses dispensed from an aerosol container having a body and an outlet member movable relative to the body to dispense its contents in measured doses, said device comprising movement detection means responsive to relative movement between the body and the outlet member, and indicating means responsive to the movement detection means so that the indicator means is indicative of the number of

movements of the body relative to the outlet member and, therefore, of the quantity of the contents of the container remaining therein or which have been discharged therefrom.

The device of the present invention is preferably adapted for removable mounting to an aerosol container located in the housing of the medical inhalation device.

In one preferred embodiment, an actuator member is provided which comprises a ring-form member for mounting to the body of the aerosol container. A further member is provided which during at least a portion of the movement of the actuator member, is held stationary with respect to the outlet member. In a preferred embodiment, this further member is held stationary by abutment with a housing in which the aerosol container is received and in which the outlet member of the aerosol container is supported during relative movement of the container body.

The device preferably comprises a ratchet wheel which is caused to rotate, by relative movement between the container body and the container housing, through a pre-determined angle. This wheel may itself bear markings to indicate the number of relative movements made between the aerosol container and outlet member but is preferably adapted to drive, for example, an indicator rack or toothed wheel bearing such markings, employing a suitable step-down gear ratio. This latter arrangement permits the number of doses indicated to exceed many times the number of teeth on the ratchet wheel and, hence the production of a compact device.

According to a further aspect of the present invention there is provided an aerosol dispensing device comprising a housing in which an aerosol container can be located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the aerosol container and having a passage through which the contents of the aerosol container may pass to the outlet, the aerosol dispensing device being provided with a dose indicating device according to the invention.

Embodiments of the present invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a side view, partially in section, of a first embodiment of the indicating device of the present invention mounted to a medical inhalation device;

Figure 2 is a front view of the arrangement shown in Figure 1 in which the indicating device is shown in section;

Figure 2a shows part of modified embodiment from one side;

Figure 2b shows a view, from the opposite side to Figure 2 of a feature applicable both to the embodiment of Figures 1 and 2, and the modified embodiment of Figure 2a;

Figure 3 is a front view of a further embodiment of the invention, part of a front wall of the device being broken away;

Figure 4 is a sectional view of the device of Figure 3;

Figures 5 and 6 are similar views illustrating one modification of the device illustrated in Figures 3 and 4; and

Figures 7 and 8 are similar views of another modification.

The inhalation device shown in Figures 1 and 2 comprises a tubular housing 1 in which an aerosol container 2 can be located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. An outlet 3 leads laterally from the closed end of the housing 1. In the embodiment illustrated, the outlet 3 is in the form of a mouthpiece intended for insertion into the mouth of the patient, but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

The aerosol container 2 has an outlet valve member 4 at one end. This valve member can be depressed to release a measured dose from the aerosol container or, alternatively, the valve member 4 can be fixed and the main body of the container can be moved relative to the valve member to release the dose.

As shown clearly in Figure 1, the aerosol container 2 is located in the housing 1 so that one end protrudes from its open top. Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1. A support 5 is provided at the lower end of the housing 1 and has a passage 6 in which the valve member 4 of the aerosol container 2 can be located and supported. A second passage 7 is provided in the support 5 and is directed towards the interior of the outlet 3. Thus, when the parts are in the positions shown in Figures 1 and 2, the protruding portion of the aerosol container 2 can be depressed to move the container relative to the valve member 4 to open the valve and a dose of medicament contained in the aerosol will be discharged through the passage 7 and into the outlet 3 from which it can be inhaled by a patient. One dose will be released from the aerosol container each time it is fully depressed.

Figures 1 and 2 also show an embodiment of the dose indicating device of the present invention. This device A comprises an actuator member in the form of a ring-shaped cap member 8 which is removably located on the end of the protruding portion of the body of the aerosol container 2. The cap member 8 is retained on the body of the aerosol container 2 by means of longitudinal ribs 21 on its internal surface so that once it is on the body it cannot be removed too easily. The top of the cap abuts the end of the body of the container 2 and moves with the body throughout its displacement towards and away from the support 5. A pair of symmetrically placed spacing elements 19, of which one can be seen in Figure 1, extend from the lip of the cap member 8 into the housing 1 and slide against the internal wall of this housing so as to guide the movement of the aerosol container body therein.

Attached to the side of the cap member 8 and movable therewith is a housing 22 which defines an indicator compartment 13. This housing 22 extends from the cap member 8 along the external surface of the tubular housing 1. The length of this indicator housing 22 is such that when mounted to the tubular housing 1, it does not abut the outlet 3 as it moves downwardly with the container body.

A driving arm 11 is slidably retained within the housing 22 and is guided for movement between two limit positions defined by stop surfaces 23a and 23b. The driving arm 11 supports a projection 11a which extends through and is movable within a slot 11b in the wall of the indicator housing 22 mounted adjacent the tubular housing 1. In this embodiment, projection 11a rests on the top edge 1a of the wall of the tubular housing 1.

The driving arm 11 engages a ratchet wheel 14 which is mounted to the wall of the indicator housing 22. This ratchet wheel cooperates with a ratchet pawl 15. Whenever the body of the aerosol container 2 is depressed to open the valve member 4, the ratchet wheel 14 moves downwards with the cap member 8 while the driving arm 11 remains stationary with respect to the support 5 by virtue of the abutment of projection 11a with the wall of the tubular housing 1. In view of the engagement of the driving arm 11 with the ratchet wheel 14, this relative linear movement between these two elements results in rotation of the ratchet wheel 14 in an anticlockwise direction (as viewed in Figure 2) through the angle subtended by a ratchet wheel tooth.

A spur wheel 15a which is rotatable with the ratchet wheel 14, engages a toothed indicator rack 20. The gear ratio between the ratchet and spur wheel is such that the indicator rack moves through one "step" for a predetermined number of ratchet wheel "steps" and, hence, doses dispensed.

The front of the housing 22 has a window (not shown) through which a portion of the indicator rack 20 is visible. This indicator rack carries suitable markings which are displayed through the window when the given marking registers with this window. Any suitable markings may be employed, though preferably not letters, numbers or like characters which require to be read. For example, the rack can be marked with different colours of different portions so that, for example, when a red portion is displayed through the window, the patient will know that a new aerosol container must be obtained. In other alternatives, however, the indicator rack may be marked with numbers to indicate the proportion of the contents still remaining or the number of doses dispensed from or remaining in the aerosol container. In a convenient arrangement, the markings on the indicator rack indicate that the aerosol container is empty after a predetermined number of doses, for example 200, have been dispensed, this predetermined number being less than the number of doses with which the container has been charged, say 220, so as to allow for a margin of error.

With displacement of the cap member 8 and housing 22 towards the support 5, a resilient member 24 attached to or part of driving arm 11, extends obliquely between the driving arm 11 and the top wall of the housing 22 is placed under compression and distorts. Once the pressure applied to the cap member 8 has been released, the device A returns to the position illustrated in Figures 1 and 2. The force exerted by the resilient member 24 pushes the driving arm 11 downwards within the housing 22 so as to engage a subsequent tooth of the ratchet wheel 14.

The device illustrated in Figures 1 and 2 may be modified by replacing the indicator rack 20 by a toothed indicator wheel which is engaged by the spur wheel 15A. Thus, on rotation of the ratchet wheel 14 the spur wheel 15A drives this indicator wheel.

In a further modification of the device illustrated in Figures 1 and 2, the spur wheel 15A is replaced on the ratchet wheel 14 by a single start worm and the toothed indicator rack 20 is replaced by an indicator rack having a row of projections engageable by this single start worm. Thus, in this case, rotations of the ratchet wheel 14 rotates the single start worm which in turn drives the indicator rack.

Figure 2a shows a modification of part of what is shown in Figure 2, the resilient member 24 being replaced by a compression spring 24'.

Figure 2b shows a device according to the invention viewed from the opposite side to Figure 2. The view shows a plate 30 which forms a cover for the mechanism visible in Figure 2b. A slot 31 is

formed in the plate 30 to define a tongue 32, having the shape of an inverted L, connected to the remainder of the cover only by a narrow bridge 33. An upstanding lug 34 is formed on the base of the L and a similar lug 35 is formed on the remainder of the cover on the opposite side of the slot to the lug 34. The material, e.g. plastics material, of which the plate is formed is sufficiently resilient that a user can urge the lugs towards one another, for example by gripping them between a thumb and finger, in which process flexing about the bridge 33 occurs. The axle 14a on which the wheel 14 rotates is mounted in the tongue 32, so that urging the lugs 34 and 35 together moves the wheel out of engagement with the rack 20. This enables the rack 20 to slide down to the end position in which it represents a value of zero doses having been dispensed. In this way the counter is reset to zero. Thus, when one container has been dispensed the counter can be removed, reset to zero, and mounted on a full container, and in this way can be reused many times. The housing 101 is open at one end which will hereinafter be considered the top of the device for convenience of description. The housing 101 is closed at the other end. An outlet 103 leads laterally from near the closed end of the housing 101. In the illustrated embodiment, the outlet 103 is in the form of a mouthpiece intended for insertion into the mouth of a patient, but it may, if desired, be designed as a nozzle for insertion into the nostril of a patient.

The aerosol container 102 has an outlet valve member 104 at one end. This valve member can be depressed to release a dose from the aerosol container or, alternatively, the valve member 104 can be fixed and the main body of the container can be moved relatively to the valve member 104 to release a dose. The aerosol container 102 is located in the housing 101 so that one end protrudes from the open top of the housing as shown clearly in Figure 4. Spacer ribs, not shown, may be provided inside the housing to hold the external surface of the container spaced from the internal surface of the housing. A support or stem block 105 is provided at the lower end of the housing 101 and has a passage 106 in which the valve member 104 of the aerosol container 102 can be located and supported. A second passage 107 is provided in the support 105 and is directed towards the interior of the outlet 103. Thus, when the parts are in positions shown in Figures 3 and 4, the protruding portion of the aerosol container 102 can be depressed to move the container 102 relatively to the valve member 104 so that the valve will be opened and a dose of medicament contained in the

aerosol will be discharged through the passage 107 into the outlet 103 from which it can be inhaled by the patient. One dose will be released from the aerosol container each time it is fully depressed.

An actuator and container retainer member in the form of a ring 108 is guided for sliding movement in the housing 101. Locating lugs 109 protrude from the ring 108 and slide in slots 110 in the wall of the housing. The aerosol container 102 is fitted in the ring 108 in such a way that once it is fitted therein it cannot be removed therefrom and also so that the ring will move with the container 102 when it is depressed to open the outlet valve of the aerosol container. The fact that the aerosol container cannot be removed once it has been fitted prevents misuse or abuse of the product by replacement with an alternative product which may be detrimental or even dangerous to the wellbeing of a patient and contrary to medical instructions.

A driving arm 111 extends from the ring 108 through a slot 112 in the wall of the housing 101 into an indicator compartment 113. The driving arm 111 engages a ratchet wheel 114 in the indicator compartment. The ratchet wheel co-operates with a ratchet pawl 115. When the aerosol container 102 is depressed, the driving arm 111 moves downwards and forwards to the centre of the ratchet wheel 114, so engaging the next adjacent ratchet tooth. When the aerosol container 102 is released, the driving arm 111 moves upwards causing the ratchet wheel 114 to rotate the distance of one tooth. Rotatable with the ratchet wheel 114 is a spur gear 115A which engages a toothed indicator wheel 116. Thus, the indicator wheel 116 rotates one step for each dose dispensed by depression of the body of the aerosol container 112. The front of the indicator housing 113 has a window 117 through which a portion of the indicator wheel 116 is indicated. This indicator wheel can be given suitable markings which are displayed through the window when the given markings registers with the window. Thus, in the embodiment illustrated the indicator wheel has markings "1/4", "1/2", "3/4", "F", and "E". The markings "F" and "E" respectively denoting full and empty. Any suitable markings may be made on the indicator wheel. For example, the wheel can be marked with different colours at different positions so that, for example, when a red portion is displayed through the window, the patient will know that a new inhalation device must be obtained. In other alternatives, the indicator wheel may be marked with numbers to indicate either the number of doses dispensed from the aerosol container or the number of doses remaining to be dispensed. In a convenient arrangement, the indicator wheel is arranged to dis-

play that the aerosol container is empty after 200 doses have been dispensed, in that case the container having been charged with, say, 220 doses, to allow a margin of error.

The device illustrated in Figures 5 and 6 is modified so that the ratchet wheel 114 will drive a single start worm 118 which in turn drives an indicator rack 119 having a row of projections engageable by the worm. The other parts of the device designated by the same references are used with reference to Figures 3 and 4.

In the modified device illustrated in Figures 7 and 8, the ratchet wheel 114 again rotates a spur wheel 115A which engages and drives an indicator rack 120. Other parts of the device have the same reference numerals that are used in the description with reference to Figures 3 and 4.

The invention has hereinbefore been described in relation to medical inhalation devices but it is apparent that the invention may be applied to any container having a depressable dispensing valve, to determine the quantity of product used or that which is left in the container.

Claims

1. A device for indicating the number of doses dispensed from an aerosol container having a body and an outlet member movable relative to the body to dispense its contents in measured doses, said device comprising movement detection means responsive to relative movement between the body and the outlet member, and indicating means responsive to the movement detection means so that the indicator means is indicative of the number of movements of the body relative to the outlet member and, therefore, of the quantity of the contents of the container remaining therein or which have been discharged therefrom.

2. A device according to Claim 1, wherein the movement detection means comprises a ratchet wheel movable with one of the aerosol container and outlet member, and a ratchet wheel driving member movable with the other of the aerosol container and outlet member and arranged to rotate the ratchet wheel through a predetermined step upon relative movement of the aerosol container and outlet member.

3. A device according to Claim 1 or 2, wherein the indicator means is arranged to move linearly.

4. A device according to Claim 3, wherein the indicator means comprises a toothed rack, and the ratchet wheel carries a spur gear which meshes with the toothed rack and drives it.

5. A device according to Claim 3, wherein the indicator means comprises an indicator rack having a row of projections, and the ratchet wheel carries a worm which engages the row of projections and drives the rack.

6. A device according to Claim 2, wherein the indicating means comprises a rotatable toothed indicating wheel, and the ratchet wheel carries a spur gear which meshes with the indicating wheel and drives it.

7. A device according to Claim 2, wherein the ratchet wheel itself constitutes the indicating means.

8. A device according to any preceding claim, comprising an actuator member adapted to be removably mounted on the body of the aerosol container so as to be displaceable with respect to the outlet member, the actuator member comprising a further member which, during at least a portion of the movement of the actuator member, is held stationary with respect to the outlet member.

9. A device according to Claim 8, wherein the said further member is arranged to be held stationary with respect to the outlet member by abutment with a housing in which the aerosol container is received and in which the outlet member is supported during relative movement of the container body.

10. A device according to Claim 8 or 9, wherein the actuator member comprises a ring-shaped cap adapted to be mounted on an end of the body of the aerosol container.

11. A device according to any one of claims 8 to 10, comprising means for resetting the indicator means to zero.

12. A device according to any preceding claim, wherein the indicating means carries no numbers, letters, or like characters.

13. An aerosol dispensing device comprising a housing in which an aerosol container can be located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the aerosol container and having a passage through which the contents of the aerosol container may pass to the outlet, the outlet member being movable relative to the body of the container to dispense its contents in measured doses; and a dose indicating device according to any one of Claims 1 to 7.

14. An aerosol dispensing device according to Claim 13, wherein the dose indicating device comprises an indicator compartment disposed on a wall of the container-receiving housing, the dose indicating device comprising an actuator member mounted on, and carried by, the body of the aerosol container so as to be displaceable with respect to the outlet member, and hence with respect to the container-receiving housing, the said

actuator member carrying an arm which extends into the said indicator compartment to operate the said indicating means.

15. An aerosol dispensing device according to Claim 14, wherein the said actuator member is arranged to be so mounted on the body of the aerosol container that it cannot be removed therefrom.

16. A dose indicating device substantially as herein described with reference to any of the embodiments shown in the accompanying drawings.

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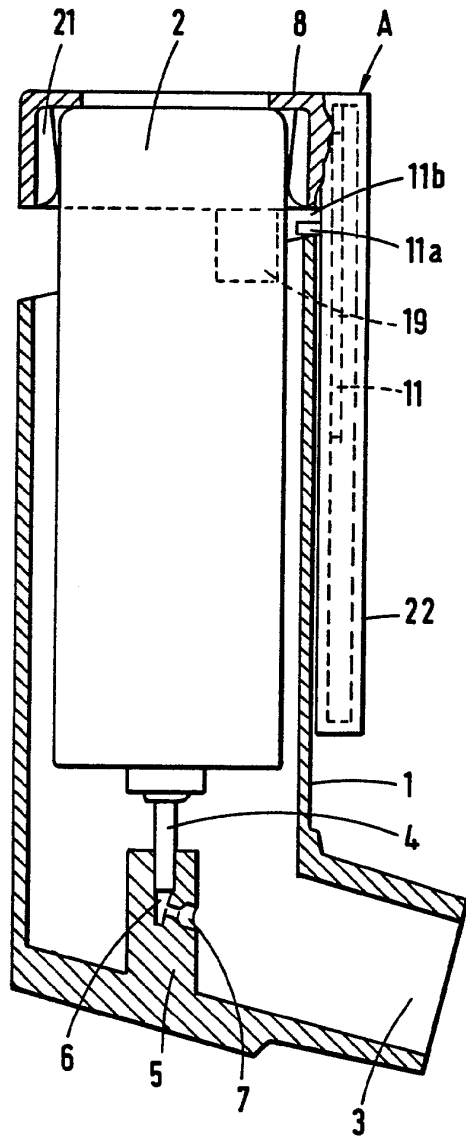


Fig. 1

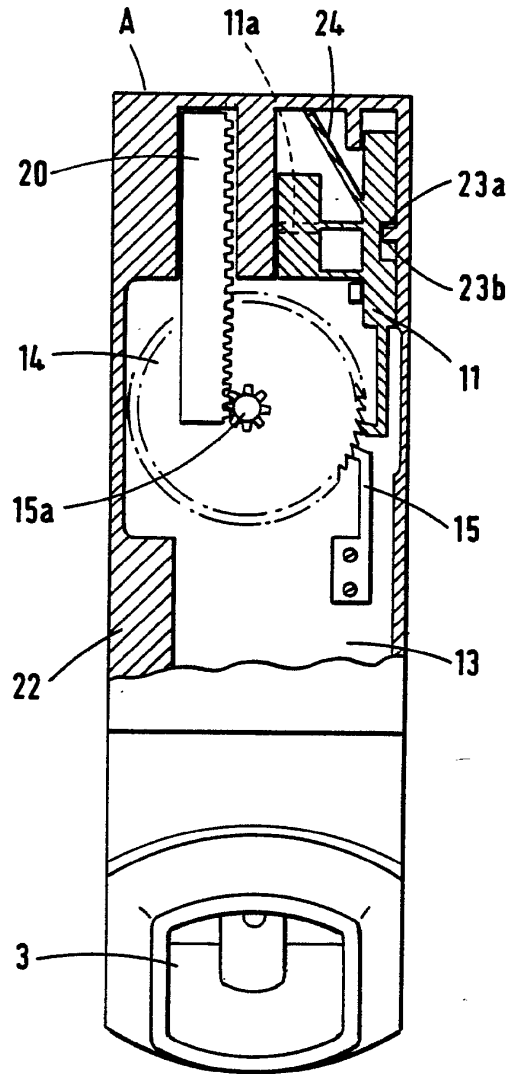


Fig. 2

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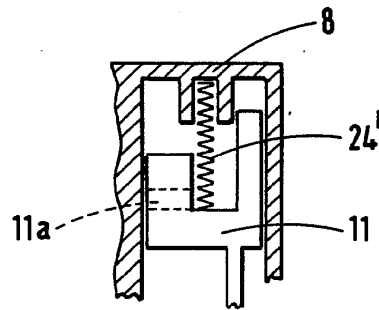


Fig. 2a

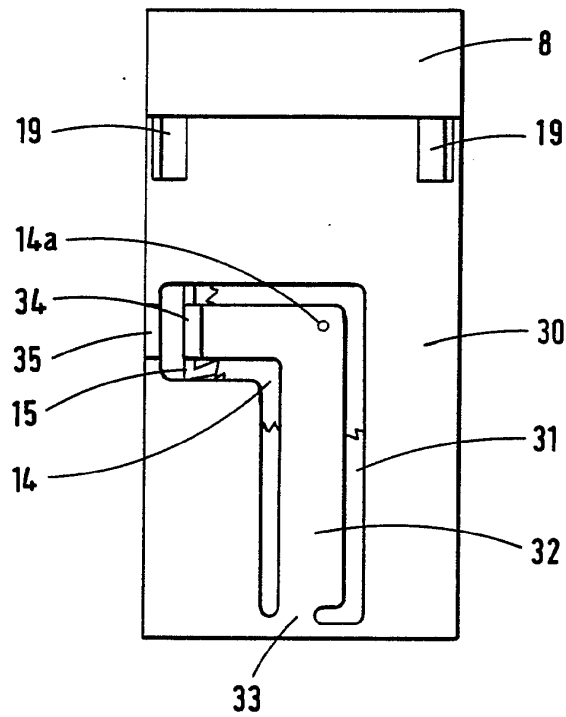


Fig. 2b

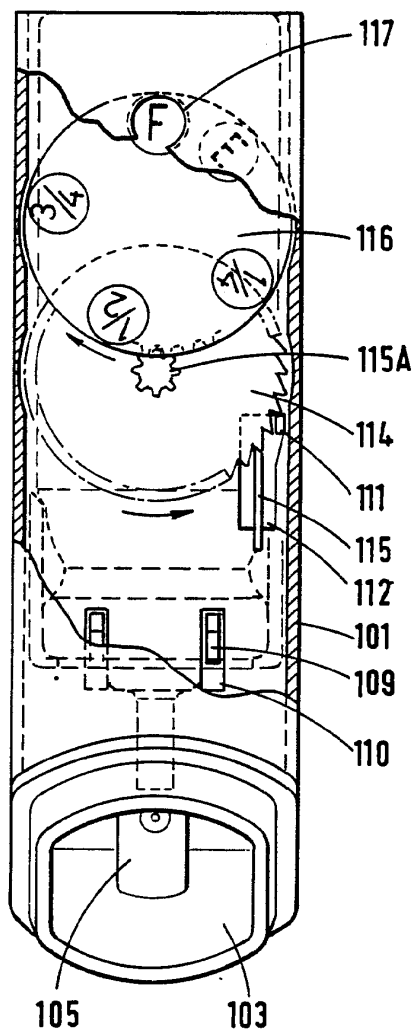


Fig. 3

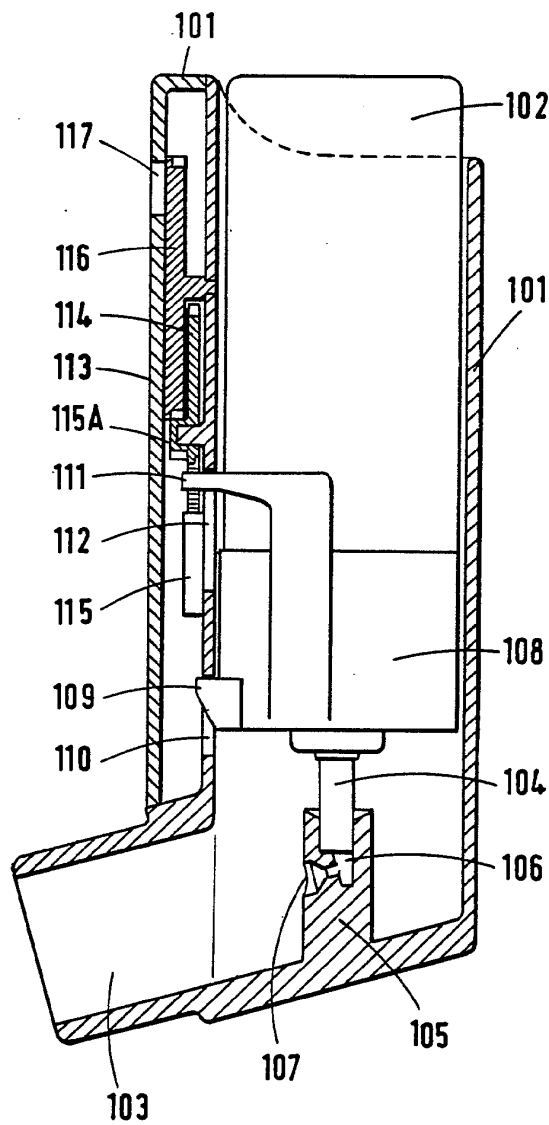


Fig. 4

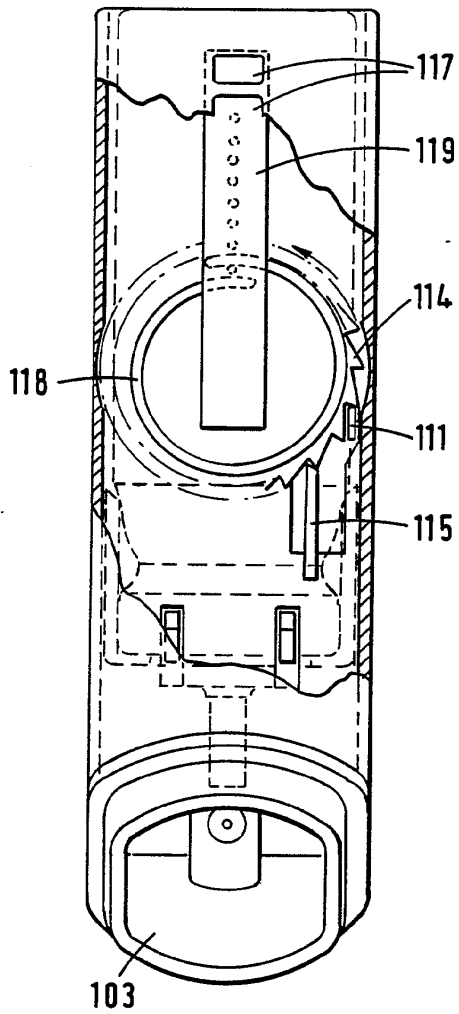


Fig. 5

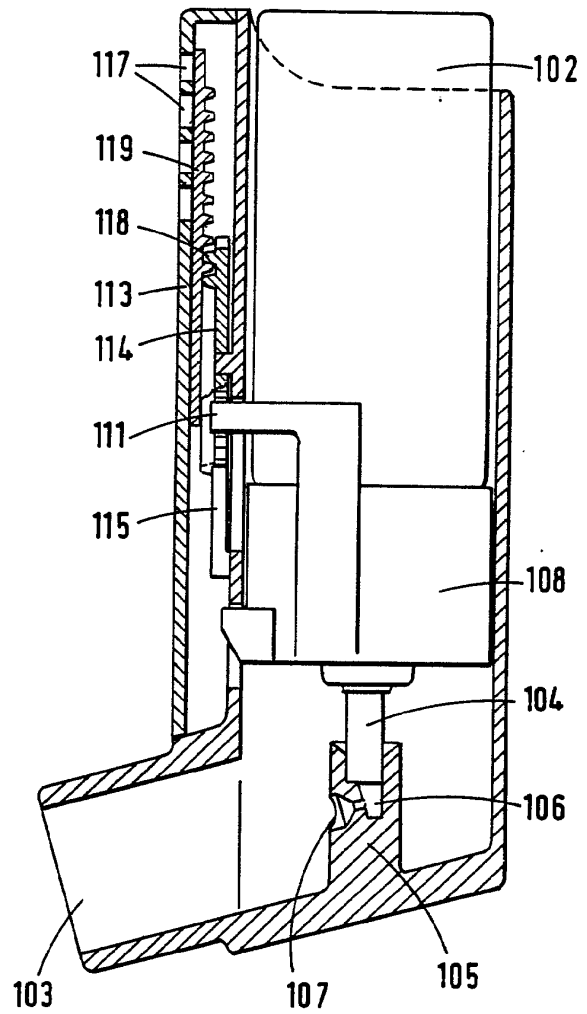


Fig. 6

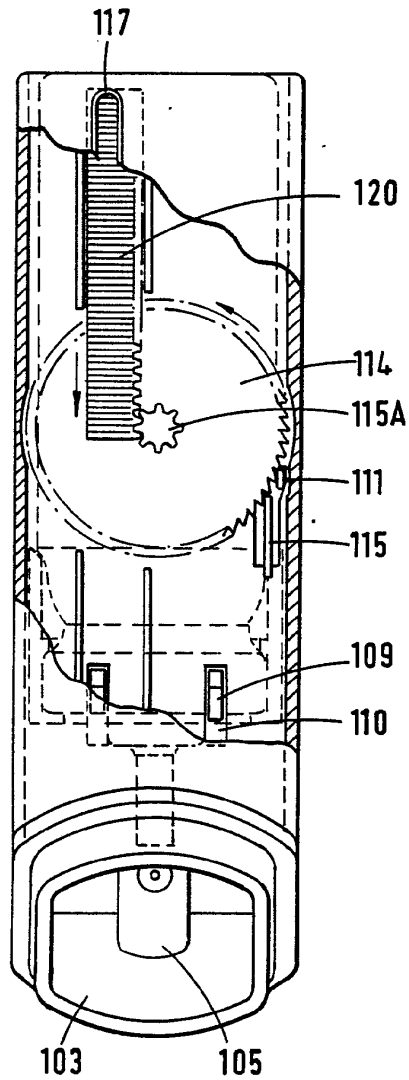


Fig. 7

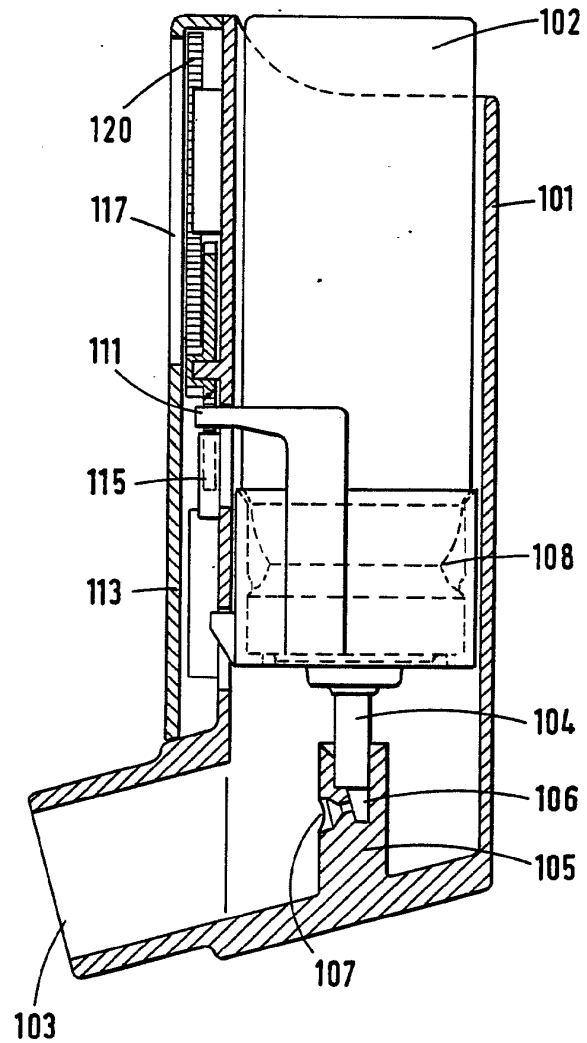


Fig. 8



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which under Rule 45 of the European Patent Convention
shall be considered, for the purposes of subsequent
proceedings, as the European search report

Application number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 87303617.2
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
X	WO - A1 - 86/02 275 (AKTIEBOLAGET DRACO)	1,12; 13	A 61 M 15/00
A	* Totality; especially page 6, line 35 - page 10, line 3 * --	2,6-8, 14	
X	GB - A - 1 317 315 (ENGL. NUMB. MACH.)	1,13	
A	* Totality; especially page 2, lines 15-22,66-97,114-117 * --	2,6,7, 11,14	
X	GB - A - 2 063 075 (STERVIN AG)	1	TECHNICAL FIELDS SEARCHED (Int. Cl.4)
A	* Totality; page 1, lines 107-126; page 2, lines 39-43 * --	12,13	
A	GB - A - 2 104 393 (GLAXO GROUP) * Fig. 1; page 1, lines 92-108 * ----	13	
			A 61 M 15/00
INCOMPLETE SEARCH			
The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims. Claims searched completely: 1-15 Claims searched incompletely: - Claims not searched: 16 Reason for the limitation of the search: (in order to rule 29(6))			
Place of search VIENNA		Date of completion of the search 17-09-1987	Examiner LUDWIG
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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(54) An indicator device

(57) A dose counter attached or attachable to the base of a pressurised canister for a metered dose inhaler and comprising a spring-loaded cap (14) which may be depressed in relation to a second part (1) mounted on the domed base of the canister (C). Within the cap (14) is a pair of independently rotatable rings, each carrying on its upper surface indicia visible through a window (13) in the cap. For each depression of the cap (14) relative to the canister, the first ring (4) is indexed in rotation, and for each complete revolution of the first ring (4), the second ring (8) is indexed in rotation. The first ring (4) carries the numbers 0 to 9 and the second ring (8) carries the numbers 00 to 20 so that the device counts down progressively from 200 to 000 thus providing an incremental indication of the number of doses remaining in the canister.

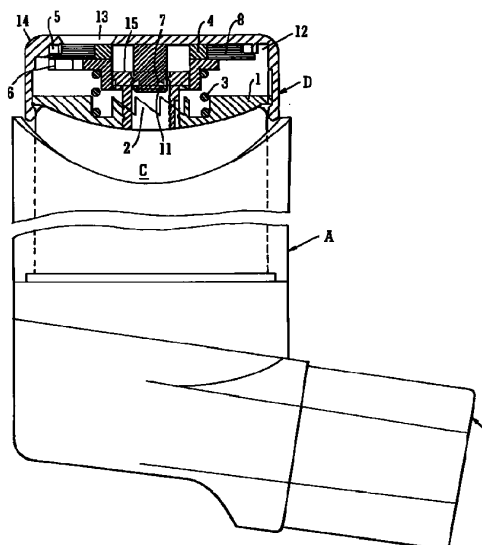


FIG. 1

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Description

[0001] THIS INVENTION concerns an indicator device, and particularly, though not exclusively, such a device adapted to serve as a dose counter for metered dose inhalers (MDI's).

[0002] MDI's include pressurised canisters containing drugs to be inhaled for the relief of, for example, the symptoms of asthma. Typically each canister contains 200 doses but conventionally provides no indication to the user as to how many doses remain available for use at a particular time. This results in considerable inconvenience and risk to the user who must, inevitably, carry a fresh replacement MDI in addition to the one currently in use thus to ensure that if the current one becomes empty there is a spare supply.

[0003] Thus there is a need for a dose counter for an MDI to indicate the number of times the pressurised canister is depressed to dispense a dose of the drug. Such a counter must count down, typically from 200 to zero, progressively as doses are administered so that the user can readily see how many doses remain.

[0004] According to the present invention there is provided an indicator device to provide a count of a series of like linear movements of a first part of the device with respect to a second part thereof; the first part comprising first and second rotational rings carrying indicia progressively visible on the first part; the first and second parts having inter-engaging spaced projections such that upon each linear movement of the first part the first rotational ring is indexed in rotation, and such that a upon a predetermined number of linear movements of the first part, the second rotational ring is indexed in rotation.

[0005] Preferably, the second part is adapted to be affixed to the base of a pressurised canister of an MDI, and the first part is captive on the second part and spring-loaded thus to be capable of depression relative to the second part and to the canister.

[0006] Still further, the rotational rings are concentrically arranged, and the first rotational ring includes an annular array of spaced projections engageable successively with two further annular sets of projections fixed with respect to the second part of the device such that the projections on the first rotational ring successively engage the fixed projections to cause the first rotational ring to index in rotation twice for each depression and release thereof.

[0007] Furthermore, the second rotational ring comprises a further set of projections engageable successively by a pawl attached to the first rotational ring upon each complete revolution thereof thus to index the second rotational ring by one increment for each revolution of the first ring.

[0008] Still further, the first part of the device comprises a cap adapted for linear movement but prevented from rotational movement in relation to the second part of the device, the cap including a profiled channel in

which the pawl is adapted to travel during rotation of the first rotational ring, the profile of said channel causing the pawl to engage the projections of the second rotational ring once for each revolution of the first rotational ring, the cap including a window through which respective surfaces of the first and second rotational rings are visible in one radial location thereof whereby numeric indicia on said surfaces are progressively visible through said window.

[0009] An embodiment of the invention will now be described, by way of example only, with reference to the accompany drawings, in which:-

Fig. 1 is a part cross-sectional view of a meter dose inhaler having thereon an indicator device in accordance with the invention;

Fig. 2 is an enlarged cross-sectional view of the indicator device;

Fig. 3 is an exploded perspective view of the parts of the device;

Fig. 4 is a plan view of the device taken on line IV-IV of Fig. 2;

Fig. 5 is a cross-sectional view of part of the device illustrating the action thereof.

and Figs. 6a to 6d are partial plan views similar to Fig. 4, showing different operational conditions of the device.

[0010] Referring to Figs. 1 to 3, a meter dose inhaler A includes a mouth-piece B through which a user may inhale a drug dispensed from a canister C removably contained within the inhaler. A counter in accordance with the invention is illustrated generally at D.

[0011] The counter consists of a first part or base 1 which, in manufacture of the canister C is bonded to the domed base thereof. It will be appreciated that the canister C and counter D comprise a replaceable item within the inhaler.

[0012] Disposed in fixed position on the base 1 is a central bush 15 which in assembly of the device has a part 22 located on the base 1 by of a key way 23 and is thus non-movably attached thereto. The base 1 defines an annular cavity 1a intended to house the bottom of a coil spring 3, the top of which engages beneath a radially outwardly directed flange of a first rotational ring 4, an inner annular part of which may be accommodated within the cavity 1a.

[0013] The ring 4 defines an inner cylindrical space within the lower end of which there is located an annular series of projections formed as inwardly directed triangular teeth 7.

[0014] At the inner extremity of the cavity 1a of base 1 there is an annular series of projections formed as

upwardly directed teeth 2, and on the underside of an upper flange of the central bush 15 there is an annular series of projections formed as downwardly directed teeth 14a. When ring 4 is assembled with central bush 15, the triangular teeth 7 are movable therewith between the teeth 2 and the teeth 14a for a purpose to be described.

[0015] At one circumferential position on the outwardly directed flange of ring 4 is an outwardly projecting curved arm 6 carrying at its free end an upwardly directed pawl 5 for a purpose to be described.

[0016] Concentrically disposed above and around the ring 4 is a second rotational ring 8 having a circumferential series of projections formed as outwardly directed curvilinear teeth 9 and a further series of angular teeth 10 disposed on a reduced circumference of the ring 8. It will therefore be seen that the base 1, the central bush 15, the ring 4 and the ring 8 may be assembled in concentric relationship and surrounded by a cap 14 having a flat top and depending cylindrical wall, and having a central boss 11 which locates within the central bush 15. The cap 14 becomes captive with the base 1 by means thereon of an annular series of outwardly projecting lugs 27 which locate within arcuate and radially directed recesses 20 on the inner face of the cylindrical wall of the cap 14. The upper circular part of the cap 14 includes a window 13 of elongate rectangular form extending radially across one part of the top for a purpose to be described.

[0017] Within the cap 14 close to its circumference is a downwardly directed wall 12 defining an outer profiled channel which receives the pawl 5 of ring 4 when the device is fully assembled. The channel is profiled such that in one radial position which coincides with the position of window 13, the channel has a radially inwardly directed kink 26 (Fig. 3) for a purpose to be described.

[0018] When the entire device is assembled there is visible through the window 13 one radial location of the upper faces 24 and 25 respectively of the rotational rings 4 and 8. These faces carry respectively two numeric series such that face 24 carries the series 0 to 9 while face 25 carries the series 00 to 20. Thus, through the window 13 there may be visible progressively the numbers 000 to 200. As will be described the device counts down so that when the MDI is new and unused the number 200 will be visible thus indicating that there are 200 doses available within the canister to which the device is attached. As the MDI is progressively used the available doses will count down eventually to zero indicating that the canister is empty. The user may therefore determine at any time how many doses remain available from the canister.

[0019] The device operates as follows:

[0020] Upon depression of the cap 14 with respect to the base 1, the rings 4 and 8 are also depressed linearly causing, upon each depression, the teeth 7 to engage the lower fixed set of teeth 2. Owing to the triangular formation of the teeth 7 and 2 this causes the ring 4 to be

indexed in rotation, (See Fig. 5) and upon return or release of the cap, the teeth 7 then engage the upper teeth 14a causing a further rotational movement of the ring 4. Each of these rotational movements represents one half of a complete movement of the ring 4 so that the number visible through the window 13 on face 24 will change by one point for a complete depression and release of the cap. Thus the user can see the progressive movement of the inner ring indicating a count down from 9 to 0 for a complete revolution of the ring 4. During such revolution the pawl 5 on arm 6 travels around the channel defined by the wall 12 in cap 14. After ten rotational movements of the ring 4 the pawl 5 engages the kink 26 in the channel and thus moves inwardly to engage an adjacent trough between two of the teeth 9 on the second rotational ring 8 causing the latter to move rotationally by one position before the pawl 5 leaves the kink 26 and returns to the main part of the channel. (See Figs. 6a to 6d). Except when moved by the pawls, the ring 8 is prevented from rotational movement by engagement of one of the teeth 10 in a V-notch 30 in the inner face of the wall 12 coincident with the kink 26 therein (See Fig. 6a). Also, the ring 4 is prevented from rotation, except when being inclined, by engagement of the teeth 7 with the teeth 1 and 14a.

[0021] Thus it will be seen that for each complete revolution of the ring 4 the ring 8 is moved one position. When the device is new and unused the number 200 will appear in the window 13. The first actuation of the device moves rings 4 and 8 simultaneously thus revealing the number 199. Thereafter for ten operations the ring 4 alone will move to display a count down from 199 to 190 whereupon the outer ring 8 is moved once again to reveal the number 189 and so on, the device providing a continuously diminishing count of 200 doses from the MDI.

[0022] Figure 5 serves to illustrate how depression and release movements of the device cause the teeth 7 to engage the teeth 2 and 14a progressively. Figures 6a to 6d illustrate how the pawl 5 enters the kink 26 and engages the teeth 9 of the ring 8 once for each complete revolution of the ring 4.

[0023] Preferably, the entire device with the possible exception of spring 3 is made from individual pieces moulded from a plastics material and assembly is initiated by passing the central bush 15 downwardly through the ring 4 and fixing it within the base 1, the ring 8 then being superimposed on the ring 4 and finally the cap 14 being introduced over the entire assembly with the central boss 11 located within the central bush 15.

[0024] Conceivably, the counter may be removably attached to the base of a canister thus to be re-usable, but from an economic point of view it is more likely that the counter will be permanently attached to a canister and thus supplied and disposed of along with it.

Claims

1. An indicator device to provide a count of a series of like linear movements of a first part of the device with respect to a second part thereof; the first part comprising first and second rotational rings carrying indicia progressively visible on the first part; the first and second parts having inter-engaging spaced projection such that upon each linear movement of the first part the first rotational ring is indexed in rotation, and such that a upon a predetermined number of linear movements of the first part, the second rotational ring is indexed in rotation. 5
2. An indicator device according to Claim 1, wherein the second part is adapted to be affixed to the base of a pressurised canister of an MDI, and the first part is captive on the second part and spring-loaded thus to be capable of depression relative to the second part and to the canister. 10
3. An indicator device according to Claim 1 or Claim 2, wherein the rotational rings are concentrically arranged, and the first rotational ring includes an annular array of spaced projections engageable successively with two further annular sets of projections fixed with respect to the second part of the device such that the projections on the first rotational ring successively engage the fixed projections to cause the first rotational ring to index in rotation twice for each depression and release thereof. 15
4. An indicator device according to Claim 3, wherein the second rotational ring comprises a further set of projections engageable successively by a pawl attached to the first rotational ring upon each complete revolution thereof thus to index the second rotational ring by one increment for each revolution of the first ring. 20
5. An indicator device according to Claim 4, wherein the first part of the device comprises a cap adapted for linear movement but prevented from rotational movement in relation to the second part of the device, the cap including a profiled channel in which the pawl is adapted to travel during rotation of the first rotational ring, the profile of said channel causing the pawl to engage the projections of the second rotational ring once for each revolution of the first rotational ring, the cap including a window through which respective surfaces of the first and second rotational rings are visible in one radial location thereof whereby numeric indicia on said surfaces are progressively visible through said window. 25
6. An indicator device according to Claim 5, wherein the surface of the first ring carries a numeric series from 0 to 9, the surface of the second ring carries the numeric series 00 to 20, said surfaces being arranged concentrically such that through the window there may be visible progressively the numbers 000 to 200. 30
7. An indicator device according to any preceding claim, wherein the first and second rotational rings include means for preventing rotation thereof except when being indexed in rotation by the inter-engaging spaced projections. 35
8. An indicator device according to any preceding claim, being non-removably attached to the base of a pressurised canister for a metered dose inhaler. 40
9. An indicator device according to any one of Claims 1 to 7, being adapted for removable attachment to a pressurised canister for a metered dose inhaler. 45

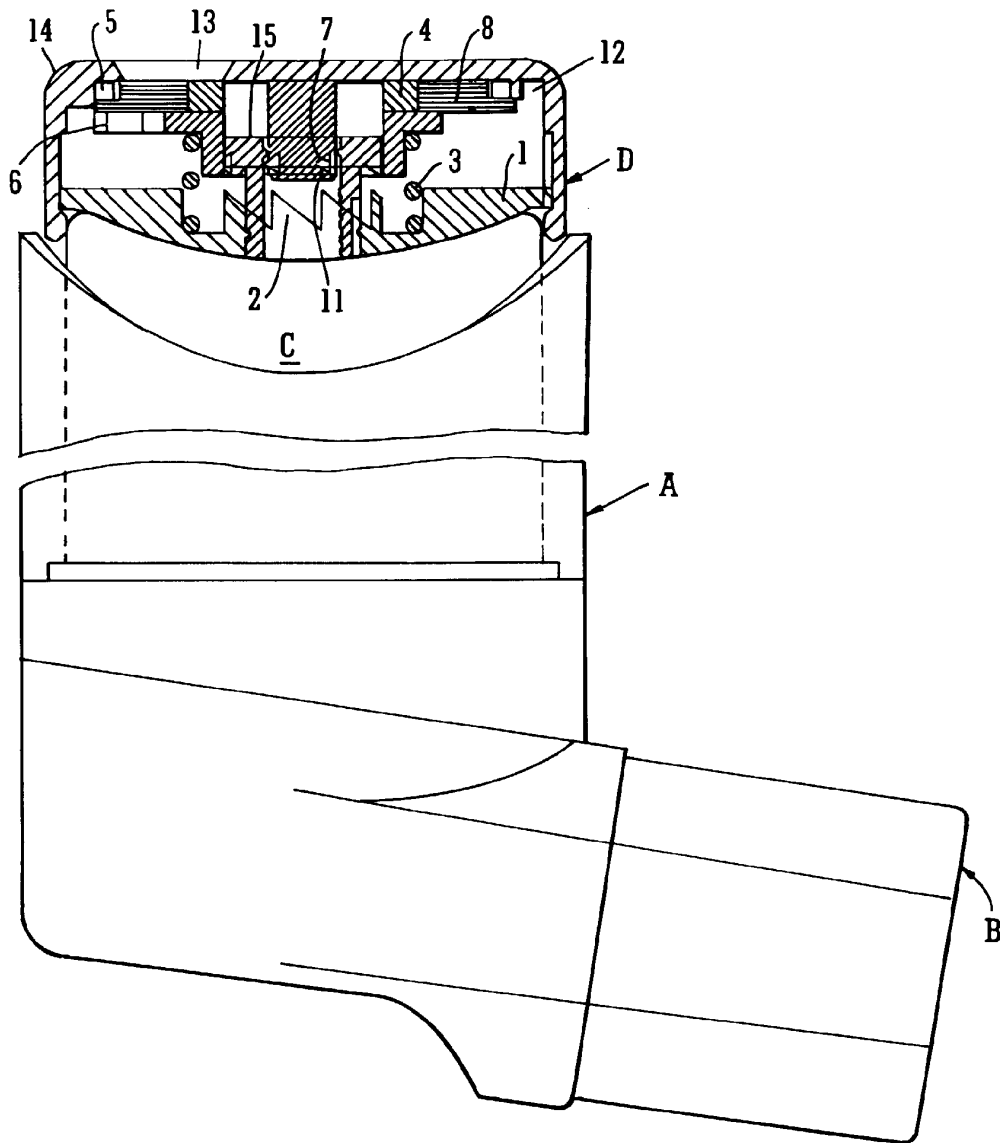


FIG. 1

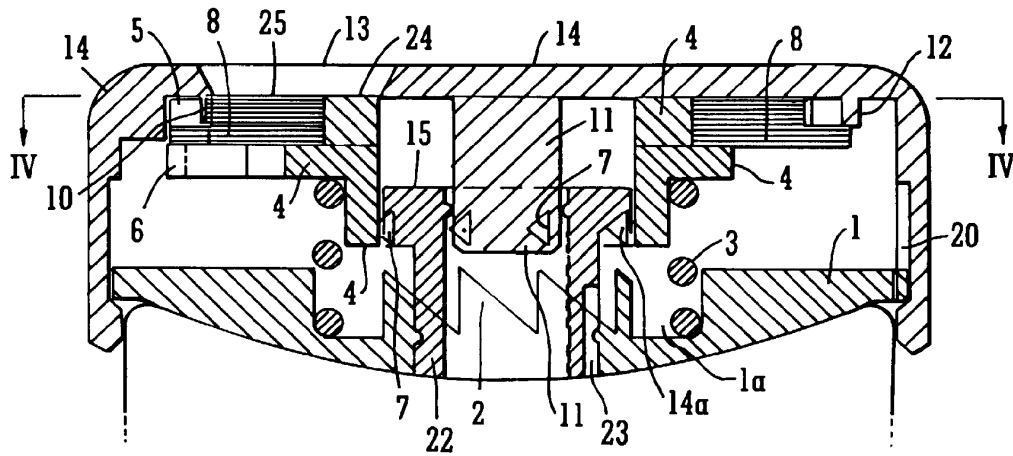


FIG. 2

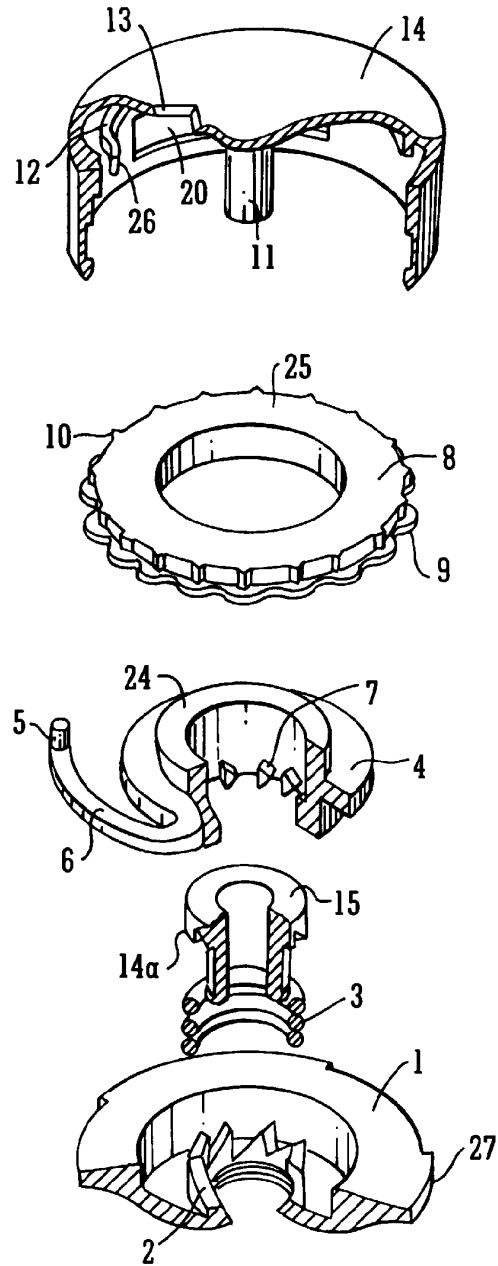


FIG. 3

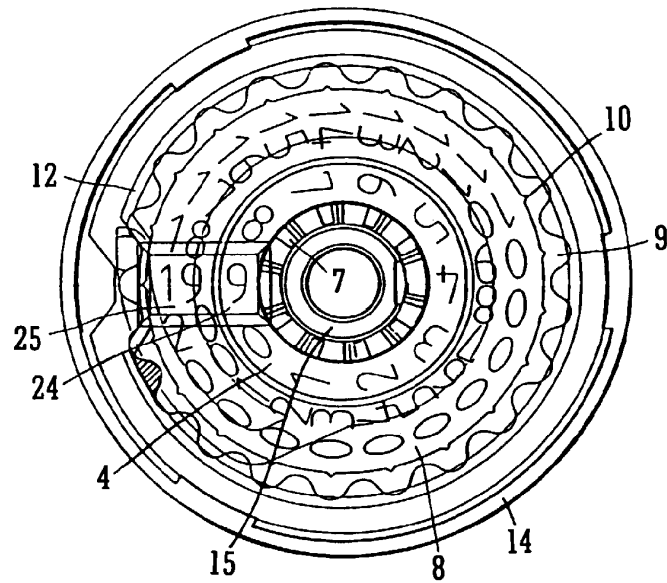


FIG. 4

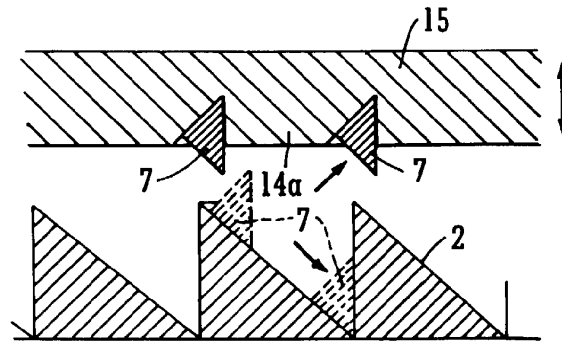
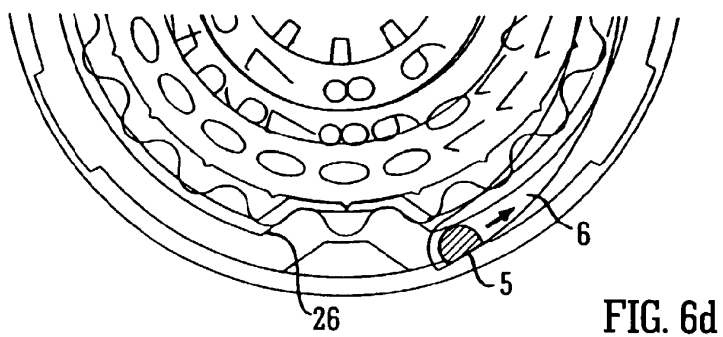
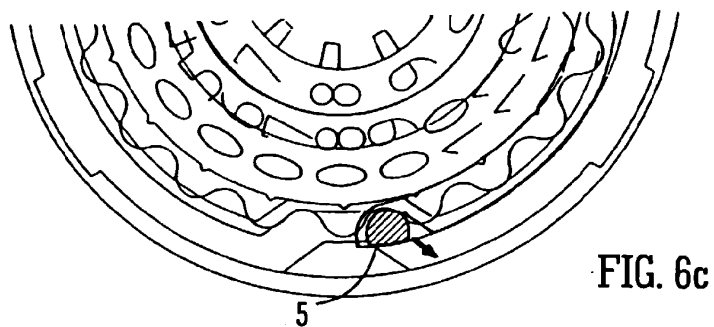
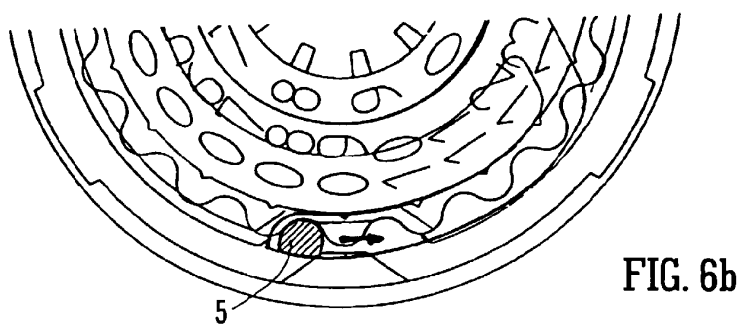
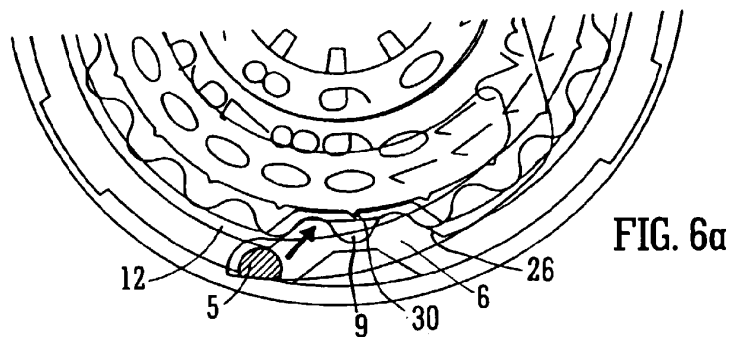


FIG. 5





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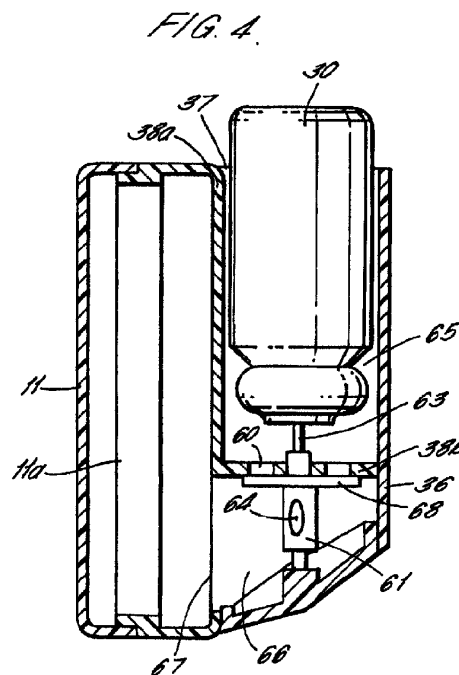
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(54) **Inhalation apparatus**

(57) The present invention relates to an inhalation apparatus for dispensing substances for inhalation and, in particular, but not exclusively, for dispensing medicinal products. Inhalation apparatus (1) comprises a housing (11) defining a socket (37) for receiving a pressurised dispensing container (30). The actuator means (61; 80) are provided for receiving a valve stem (63) of the pressurised dispensing container and a cylindrical chamber (11a) having an inlet (67) and an outlet (16). The actuator means defining duct means to direct product dispensed from the valve stem of the pressurised dispensing container through the inlet of the cylindrical chamber in a direction substantially tangential to the major axis of the cylindrical chamber. The outlet of the cylindrical chamber communicating with the mouthpiece (12), characterised in that the inlet is located at a periphery of the chamber and the outlet is located at or near a centre of the chamber such that inhalation by a user on the mouthpiece creates a cyclonic airflow in the cylindrical chamber between the inlet and outlet from which the dispensed product is entrained for inhalation.



EP 1 010 438 A1

Description

[0001] This invention relates to an inhalation apparatus for dispensing substances for inhalation and, in particular, but not exclusively, for dispensing medicinal products.

[0002] Known dispensing apparatus for use in inhalation apparatus include metered dose inhalers and dry powder inhalers. In known metered dose inhalers, the aerosol stream from a pressurised dispensing container is fired towards a patient or user of the inhaler into an airflow travelling in the same direction. A user inhales through a mouthpiece of the inhaler and creates an airflow through the container from air inlet holes which are generally at a part of the inhaler well spaced from the mouthpiece. Medicament is then released into this airflow at a point between the air inlet holes and the mouthpiece so that it is travelling in the same direction as the airflow. Typically, in such devices, there is no restriction in the airflow between the air inlet holes and the mouthpiece. Because of this, a substantial airflow can be created by the user of the device and, because the medicament is fired into the airflow in the same direction as the airflow, the effect is that particles of medicament can attain quite substantial velocities. As inhalers of this type are normally designed to be as small as practical for the convenience of the user, the distance between the point at which the medicament is fired and the patient's mouth is usually quite small so that there is little distance for the inertia of the particles of medicament to decrease with the result that the particles may impact in the oropharynx of a user with quite high velocity. This can be a problem with certain medicaments.

[0003] In known dry powder inhalers, powdered medicament, which is often combined with a powdered carrier, such as lactose, is stored within a delivery device until delivery of the medicament is required. It is known to store the medicament in a bulk holding reservoir in the delivery device. The drug is removed from the reservoir on an as required basis. It is also known to provide dry powder inhalers wherein the medicament is contained within discrete doses within a dosage unit such as a gelatine capsule. A problem with both types of known dry powder inhaler is that the medicament and carrier can form relatively large particles which when inhaled by the user do not reach deep into the lungs, which has been shown to be necessary for the most advantageous medical result to be obtained. It is known to provide baffle plates within an airflow passageway of a dry powder inhaler such that the medicament and carrier impact on the baffle plates and are, to a degree, separated and the particle size reduced. However, a problem with such baffle plates is that the medicament and carrier only pass through the baffle plates once and, as a result, a significant proportion of larger particles still exit the inhaler and are inhaled by the user.

[0004] According to the present invention there is provided inhalation apparatus comprising a housing defin-

ing a socket for receiving a pressurised dispensing container, actuator means for receiving a valve stem of the pressurised dispensing container and a cylindrical chamber having an inlet located at a periphery of the chamber and an outlet at or near a centre of the chamber, the actuator means defining duct means to direct product dispensed from the valve stem of the pressurised dispensing container through the inlet of the cylindrical chamber in a direction substantially tangential to the major axis of the cylindrical chamber, the outlet of the cylindrical chamber communicating with a mouthpiece, such that inhalation by a user on the mouthpiece creates a cyclonic airflow in the cylindrical chamber between the inlet and outlet in which the dispensed product is entrained for inhalation.

[0005] The present invention also provides a method of inhaling product dispensed from a pressurised dispensing container comprising the steps of inhaling on a mouthpiece of an inhalation apparatus comprising a cylindrical chamber having an inlet at a periphery thereof and an outlet at or near a centre thereof which communicates with the mouthpiece, to thereby create a cyclonic airflow from the inlet to the outlet, actuating the pressurised dispensing container to dispense a dose of product through the inlet of the cylindrical chamber in a direction substantially tangential to the major axis of the cylindrical chamber such that the product is entrained in the airflow and inhaled through the mouthpiece.

[0006] Preferred embodiments of the present invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

Figure 1 is a side elevation of a first embodiment of dispensing apparatus according to the present invention;

Figure 2 is a front elevation of the apparatus of Figure 1;

Figure 3 is a cross-sectional elevation taken on line V-V of Figure 1;

Figure 4 is a schematic cross-section taken on line VI-VI of Figure 1;

Figure 5 shows the apparatus of Figure 4 immediately prior to dispensing of medicament;

Figure 6 shows the apparatus of Figure 4 during dispensation of medicament;

Figure 7 shows a side elevation of a second embodiment of dispensing apparatus according to the present invention;

Figure 8 shows a cross-sectional schematic elevation of a third embodiment of dispensing apparatus according to the present invention; and

Figure 9 shows an enlarged cross-sectional schematic elevation of part of the apparatus of Figure 8.

[0007] The dispensing apparatus 1 of the present invention as shown in Figures 1 to 9 comprises a spacer unit generally denoted by reference 10 which is either permanently or releasably connected in use to a dis-

dispensing unit generally designated by reference numeral 30.

[0008] The dispensing unit 30 comprises a pressurised dispensing container 30 of the type consisting of a pressurised container, metering valve attached thereto having a valve stem 63 extending axially to protrude from the metering valve. The pressurised dispensing container 30 typically contains medicament either in solution or suspension and a propellant system.

[0009] The spacer unit 10 of the first embodiment as shown in Figures 1 to 6 comprises a generally cylindrical housing 11 defining a spacer chamber 11a. The spacer chamber 11a has a major axis aligned with a centre of housing 11.

[0010] A hollow mouthpiece duct 13 extends radially outwardly from the centre of the housing 11 terminating in a substantially tubular mouthpiece 12 which extends beyond the periphery 17 of the housing 11. The mouthpiece 12 defines an outlet 19. The spacer chamber 11a communicates with the mouthpiece duct 13 through an aperture 16 in one side of the housing 11 positioned at or near the centre as best shown in Figure 3.

[0011] Preferably, the width of the chamber 11a, as measured in the direction of the major axis, decreases from the periphery of the chamber 11a to the centre.

[0012] The housing 11, inlet duct 15 and mouthpiece duct 13 may all be moulded from suitable plastics materials and are preferably moulded as a single unit.

[0013] A generally cylindrical housing 36 is integrally formed on one side of housing 11. As shown in Figure 4, the cylindrical housing 36 is divided into upper and lower sections 65 and 66 by an annular partition 38b. Airflow holes 60 are provided in the partition to allow air to pass from the upper to lower section. The upper section 65 of the cylindrical housing 36 defines a socket 37, in which in use the pressurised dispensing container 30 is inserted, and is separated from spacer chamber 11a by a partition 38a. The pressurised dispensing container 30 fits loosely in the upper section 65 of the cylindrical housing 36 such that air may readily pass between the pressurised dispensing container 30 and the walls of the cylindrical housing.

[0014] The lower section 66 of the cylindrical housing 36 communicates with the spacer chamber 11a through an aperture 67 which opens into the chamber 11a tangentially.

[0015] The lower section 66 of the cylindrical housing 36 contains an actuator 61. The actuator 61 has a cylindrical body, in an upper end of which is a bore for receiving a valve stem of the pressurised dispensing container 30 when the pressurised dispensing container 30 is inserted in socket 37 with the valve stem 63 lowermost. The valve stem receiving bore communicates via a duct with an opening 64 in the side wall of the actuator body which is arranged to direct an aerosol through 90° on discharge in a direction towards the aperture 67 connecting the lower section 66 with the spacer chamber 11a. The actuator 61 also comprises a radially extending

flange 68 of a large enough diameter to sealingly cover and close the airflow holes 60. A helical compression spring is provided between a lower end of the actuator 61 and a base of the cylindrical housing to bias the actuator 61 upwardly such that, in the rest position, the annular flange 68 contacts the partition 38b and seals the airflow holes 60.

[0016] In use, the user inserts the mouthpiece 12 of the spacer unit 10 into their mouth and inhales. Initially, as the airflow holes 60 are sealed by the flange 68, there is no airflow. Whilst continuing to inhale, the user manually depresses the dispensing container 30 causing the valve stem 63 to move downwardly. In turn, this causes the actuator 61 to slide axially downwards and compress the spring. The flange 68 of the actuator 61 is thus moved out of contact with the airflow holes 60 allowing the passage of air from an exterior of the device through the upper section 65 between the pressurised dispensing container 30 and walls, through the airflow holes 60, lower section 66 and aperture 67 into spacer chamber 11a.

[0017] The airflow entering the spacer chamber 11a enters in a direction having a substantial tangential component relative to the major axis such that the airflow is constrained to move in a rotational manner around the spacer chamber 11a due to the cylindrical shape of housing 11. As the user inhales air is drawn towards the centre of the spacer chamber 11a and out through aperture 16, along mouthpiece duct 13 and exits outlet 19 where it is inhaled by the user. Thus, inhalation by the user creates a cyclonic, rotating air flow within spacer chamber 11a. The product when entrained in the air flow passes with the air into spacer chamber 11a. Due to the cyclonic nature of the air flow within spacer chamber 11a, larger particles of product are held in the peripheral region 17 of the spacer chamber 11 whilst smaller particles are drawn towards the centre of the spacer chamber 11a where they exit the chamber 11a through aperture 16 into mouthpiece duct 13 and out mouthpiece 12 where they are inhaled. Thus, the cyclonic air flow in chamber 11a acts on the medicament as a classifier separating relatively small particles from relatively large particles and only passing relatively small particles through aperture 16 for inhalation.

[0018] Further depression of the dispensing container 30 causes the lower end of the actuator 61 to come into contact with the base of the cylindrical housing at which point further axial movement of the actuator 61 is prevented. Thus, the valve stem 63 is depressed inwardly relative to the metering valve of the pressurised dispensing container 30 and a dose of product is discharged as a fine aerosol mist which is then entrained in the airflow.

[0019] The cyclonic flow of the entrained aerosol acts to classify the aerosol as described above. Larger aerosol droplets are held in the periphery of the spacer chamber 11a and only the relatively smaller aerosol droplets are drawn to the centre and exit through aper-

ture 16 for inhalation. This has the beneficial effect that smaller aerosol droplets are able to be inhaled deeper into the lungs than larger droplets. This has been found to have beneficial medical results, especially for medicaments for treating respiratory disorders such as asthma. The cyclonic nature of the flow also results in the flow path length of the aerosol being greatly increased when compared to a linear spacer. The airflow and entrained aerosol pass round the spacer chamber 11a many times before exiting through aperture 16. This provides a greatly increased time for the speed and inertia of the aerosol droplets to decrease before they are delivered to the user. As a result there is a greatly reduced risk of the aerosol droplets forcibly impacting on the oropharynx region of the throat of the user with its associated discomfort and potential damage.

[0020] It should be noted that this embodiment is suitable for use with many types of dispensing unit in which actuation of the pressurised dispensing container is co-ordinated with the inhalation cycle of the user and is not restricted to the particular device herein described.

[0021] Figure 7 shows a second embodiment of dispensing apparatus according to the present invention. The dispensing unit 30 and spacer unit 10 are the same as those described in the first embodiment. However, in addition, the dispensing apparatus 1 is provided with a counter module 50 comprising a dose counting mechanism linked to the dispensing unit 30. A counter window 51 is provided viewable from an exterior of the housing 11 through which is displayed in use a counter indication 52 indicating either the number of doses dispensed or the number of doses remaining to be dispensed. The counter module is linked to the dispensing unit 30 such that each actuation of the dispensing unit actuates the counter module to either increment or decrement the counter indication as appropriate.

[0022] Figures 8 and 9 show a third embodiment of dispensing apparatus according to the present invention. The dispensing unit 30 is a pressurised dispensing container and is identical to that described in the first embodiment. The spacer unit 10 is also the same as that described in the first embodiment. The difference with the second embodiment lies in the means of actuating the pressurised dispensing container 30.

[0023] As in the second embodiment, the cylindrical housing 36 is divided into upper and lower sections 65 and 66 by a partition having airflow holes 60.

[0024] The valve stem 63 of the pressurised dispensing container 30 is received sealingly in a tubular actuator 80 which defines an annular shoulder which acts as stop limiting the extent to which the valve stem 63 extends within the actuator 80.

[0025] The actuator 80 is received as a snug fit within a downwardly extending tubular projection 81 formed integrally with the cylindrical housing 36. The tubular projection 81 has a lower end wall 94 defining an aperture 95 communicating with an annular space 96 formed between the lower end wall and the actuator 80. A nozzle

97 defined by the tubular projection 81 communicates with the annular space 96 and is orientated to release product from the annular space into the lower section 66 in the direction of the aperture 67 into the spacer chamber 11a.

[0026] A secondary valve means is formed in the tubular projection 81 by an annular valve seat 99 at the lower end of the actuator 80 and a resilient valve member 90 which extends from the lower section 66 into the annular space 96 and is normally urged into sealing contact with the valve seat 99 by a spigot 91. The valve member 90 has a cylindrical body which is recessed to accommodate the spigot 91 as an interference fit so that the spigot and valve member are sufficiently firmly connected to enable the valve member to be positively unseated from the valve seat when the spigot is retracted. The valve member is a sliding fit within the aperture 95 and is provided with a radially projecting flange 107 of greater diameter than the aperture 95 so that the flange acts as a stop limiting downward motion of the valve member 90 through the aperture.

[0027] The actuator 80 is provided with a radially extending flange 82 of external diameter slightly less than the internal diameter of the cylindrical housing 36 such that a restricted annular air passageway is defined between the flange 82 and the housing 36.

[0028] The actuator 80 and the hollow tubular valve stem together define a first chamber which is normally closed at its upper end by the internal valve means of the pressurised dispensing container and at its lower end by the secondary valve means.

[0029] In use, a user depresses the pressurised dispensing container 30 relative to the housing 36 so as to actuate the pressurised dispensing container 30 by relative movement between the container and the valve stem 63 which is prevented from downward movement by abutment with the annular shoulder in the actuator 80.

[0030] Actuation of the pressurised dispensing container 30 results in a pressurised metered dose of fluid entering the first chamber from which it is prevented from escaping by the secondary valve means. The user then inhales through the mouthpiece 12 thereby reducing air pressure within the spacer chamber 11a and the lower section 66 of the cylindrical housing 36. The annular flange 82 is subject to a downward force because of an imbalance of air pressure above and below the flange, since the air pressure above the flange is maintained at ambient air pressure by the airflow holes which are open to atmosphere. The flange 82 is thereby urged downwardly against the spring pressure provided by the spring. As the flange moves downwardly, the spigot 91 also moves downwardly thereby unseating the resilient valve member 90 from the valve seat 99 so that the pressurised fluid escapes from the first chamber into the annular space 96 which constitutes a second chamber. As fluid begins to escape, dissolved propellant in liquid form boils off from the dispensed dose causing the fluid to

rapidly expand. This expansion assists in further displacing the valve member 90 away from the seat 99. Displacement of the valve member 90 away from the seat 99 is limited by engagement between the flange 107 and the lower end wall 94 of the tubular projection 81. The pressurised fluid in the second chamber, i.e., annular space 96, then escapes via the nozzle, and is drawn into the spacer chamber 11a.

[0031] The spacer chamber 11a imparts a cyclonic action to the dispensed product as described in the previous embodiments with the same beneficial results of classification of the aerosol droplets and slowing of the droplets.

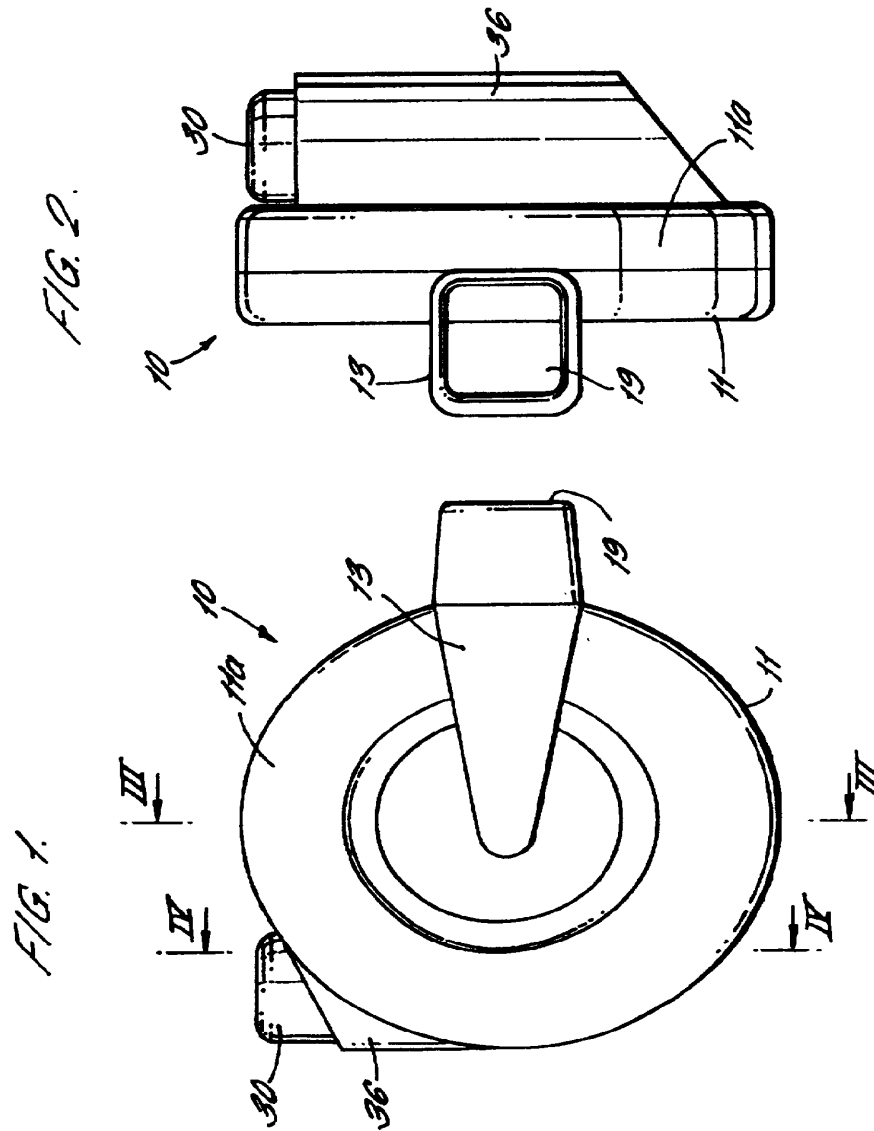
[0032] It should be noted that the dispensing apparatus 1 is suitable for use with other dispensing units which comprise means for actuating the pressurised dispensing container by the inhalation force produced by the user and is not restricted to the specific embodiment described herein.

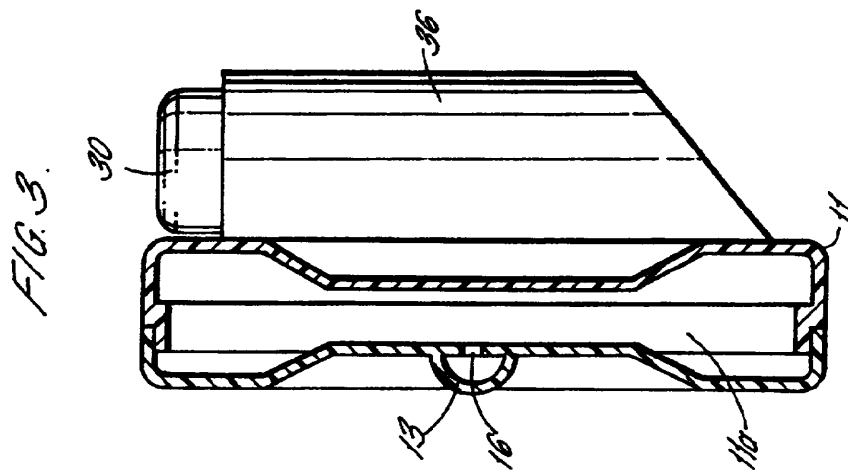
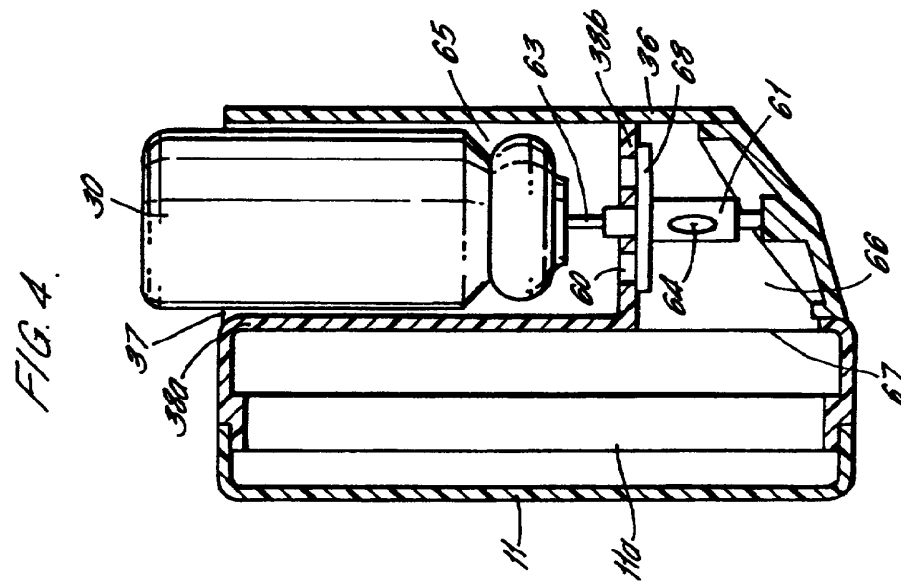
[0033] A fourth embodiment of dispensing apparatus according to the present invention comprises the dispensing unit 30 and spacer unit 10 of the third embodiment. However, in addition, the dispensing apparatus 1 is provided with a counter module 50 as described in the second embodiment.

Claims

1. Inhalation apparatus (1) comprising a housing (11) defining a socket (37) for receiving a pressurised dispensing container (30), actuator means (61; 80) for receiving a valve stem (63) of the pressurised dispensing container and a cylindrical chamber (11a) having an inlet (67) and an outlet (16), the actuator means defining duct means to direct product dispensed from the valve stem of the pressurised dispensing container through the inlet of the cylindrical chamber in a direction substantially tangential to the major axis of the cylindrical chamber, the outlet of the cylindrical chamber communicating with a mouthpiece (12), characterised in that the inlet is located at a periphery of the chamber and the outlet is located at or near a centre of the chamber, such that inhalation by a user on the mouthpiece creates a cyclonic airflow in the cylindrical chamber between the inlet and outlet in which the dispensed product is entrained for inhalation.
2. Inhalation apparatus as claimed in claim 1, wherein the width of the chamber, as measured in the direction of the cylindrical chamber's major axis, decreases from the periphery of the chamber to the centre.
3. Inhalation apparatus as claimed in claim 1 or claim 2, wherein the outlet (16) is formed at or near the centre on one side of the cylindrical chamber.

4. Inhalation apparatus as claimed in any preceding claim, wherein the socket (37) comprises an upper section (65) separated by a partition (38b) from a lower section (66) which communicates with the inlet to the cylindrical chamber, airflow holes (60) being provided in the partition.
5. Inhalation apparatus as claimed in any preceding claim, wherein the actuator means (61; 80) is actuated by inhalation of the user on the mouthpiece.
6. Inhalation apparatus as claimed in any of claims 1 to 4, wherein the actuation of the actuator means (61; 80) is co-ordinated with inhalation of the user on the mouthpiece.
7. Inhalation apparatus as claimed in any preceding claim further comprising means (50) for counting the number of actuations of the dispensing unit and displaying a visual indicator (52) correlated to the number of actuations.
8. Inhalation apparatus as claimed in claim 7, wherein the visual indicator (52) is a number indicating the number of actuations.
9. Inhalation apparatus as claimed in claim 7, wherein the visual indicator (52) is a number indicating the number of actuations remaining before the pressurised dispensing container is empty.
10. Inhalation apparatus as claimed in any preceding claim formed as a unitary moulding.
11. A method of inhaling product dispensed from a pressurised dispensing container (30) comprising the steps of inhaling on a mouthpiece (12) of an inhalation apparatus (1) comprising a cylindrical chamber (11a) having an inlet (67) at a periphery thereof and an outlet (16) at or near a centre thereof which communicates with the mouthpiece, to thereby create a cyclonic airflow from the inlet to the outlet, actuating the pressurised dispensing container to dispense a dose of product through the inlet of the cylindrical chamber in a direction substantially tangential to the major axis of the cylindrical chamber such that the product is entrained in the airflow and inhaled through the mouthpiece.
12. A method as claimed in claim 11, wherein inhalation on the mouthpiece (12) actuates the pressurised dispensing apparatus (30).





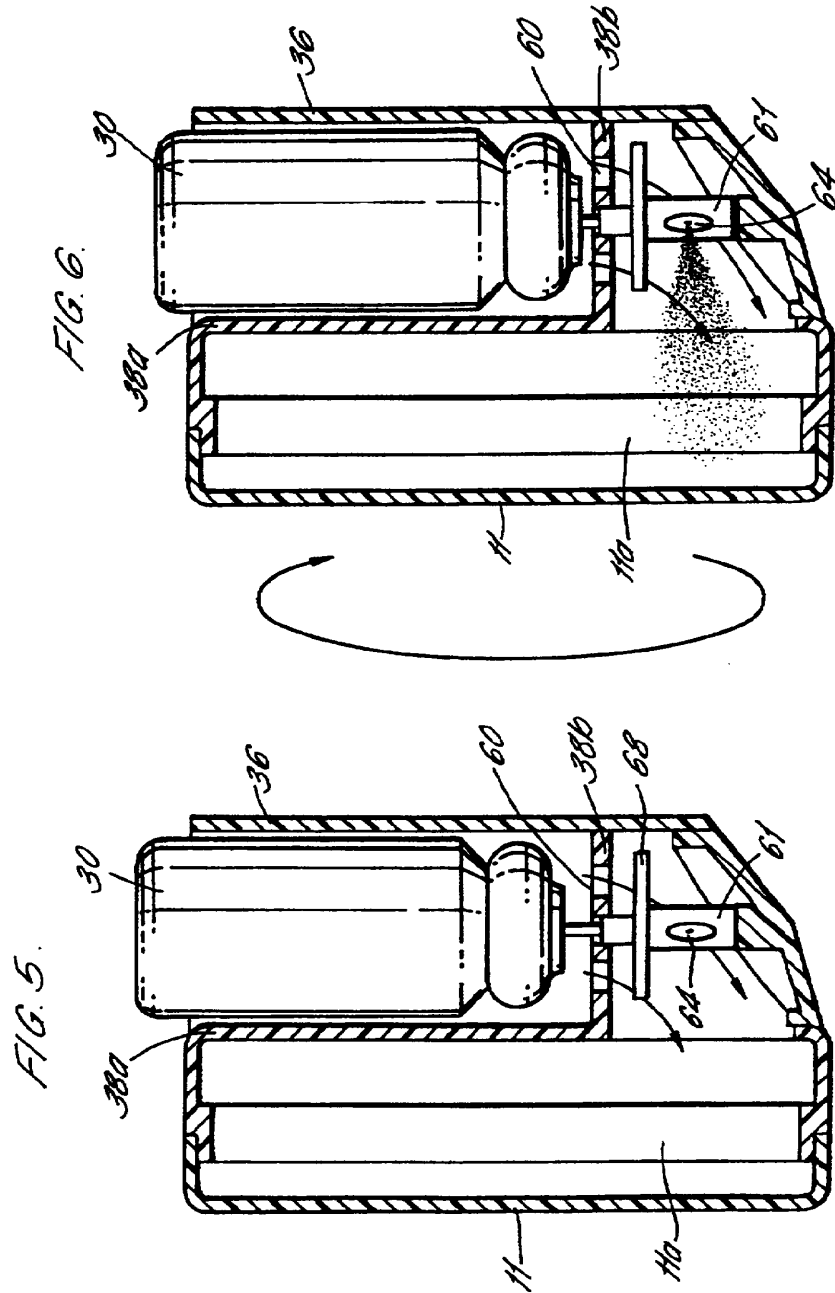


FIG. 7.

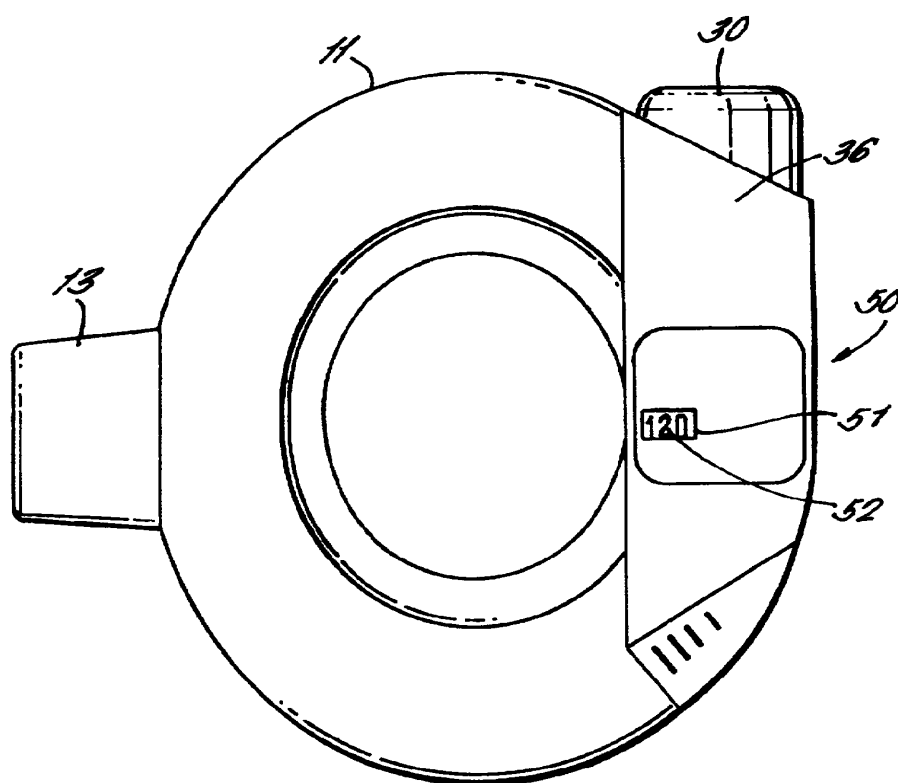


FIG. 8.

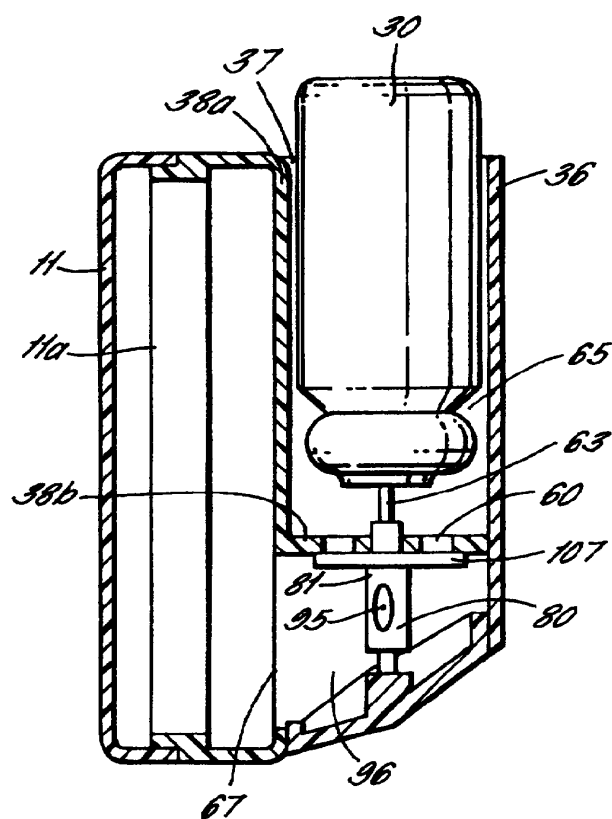
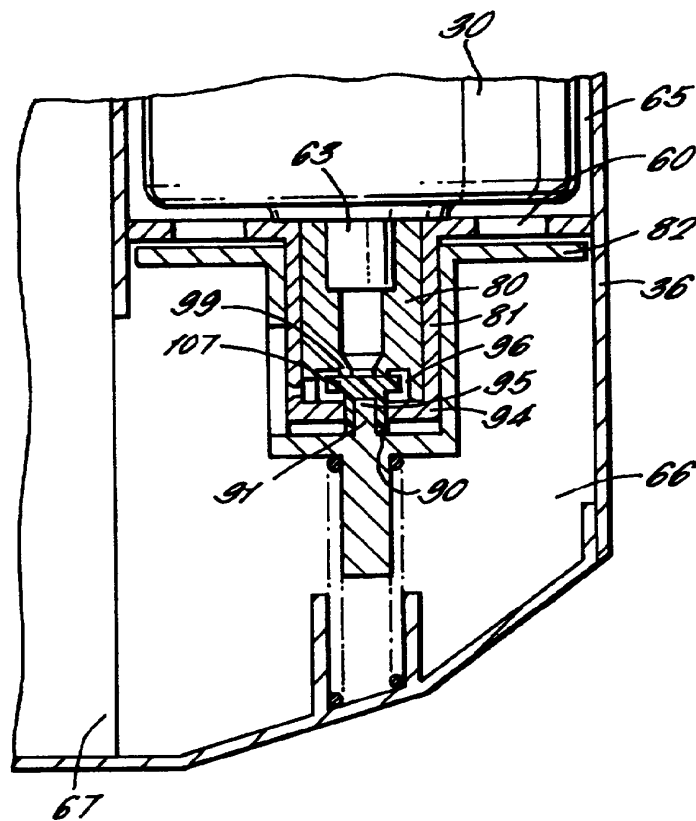


FIG. 9.





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PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 99 30 9783
shall be considered, for the purposes of subsequent
proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	FR 2 352 556 A (PASTEUR INSTITUT) 23 December 1977 (1977-12-23)	1-3, 10	A61M15/00 A61M11/00
Y	* page 1, line 38 - page 2, line 22 * * page 4, line 34 - page 5, line 8 * * page 5, line 18-20, 28-31 * * figures *	4-9	
Y	--- WO 88 03419 A (HUHTAMAEKI OY) 19 May 1988 (1988-05-19) * figures 5, 6 *	4	
Y	--- WO 93 24167 A (NORTON HEALTHCARE LTD ; HOLROYD MICHAEL JOHN (GB)) 9 December 1993 (1993-12-09)	5, 6	
A	* the whole document * ---	7-9	
		-/-	
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61M
INCOMPLETE SEARCH			
The Search Division considers that the present application, or one or more of its claims, does/do not comply with the EPC to such an extent that a meaningful search into the state of the art cannot be carried out, or can only be carried out partially, for these claims. Claims searched completely : 1-10 Claims searched incompletely : 11-12 Reason for the limitation of the search: Article 52 (4) EPC - Method for treatment of the human or animal body by therapy			
Place of search		Date of completion of the search	Examiner
MUNICH		9 March 2000	Lager, J
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

EPC FORM 1503 03 82 (P4/C07)

European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 99 30 9783

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
Y	WO 93 00951 A (INHALE INC) 21 January 1993 (1993-01-21)	7-9	
A	* abstract * * figures * * page 4, line 37 - page 5, line 1 * * page 5, line 27-35 * * page 6, line 15-27 * * page 7, line 17-31 * * page 7, line 36 - page 8, line 4 * * page 9, line 10-19 * * page 11, line 37 - page 12, line 12 * * page 15, line 6-25 *	1-6,10	
A	EP 0 504 459 A (RITZAU PARI WERK GMBH PAUL) 23 September 1992 (1992-09-23) * abstract; figures *	1-10	TECHNICAL FIELDS SEARCHED (Int.Cl.7)
A	EP 0 682 955 A (RITZAU PARI WERK GMBH PAUL) 22 November 1995 (1995-11-22) * abstract; figures *	1-10	
A	WO 90 15635 A (HUHTAMAEKI OY) 27 December 1990 (1990-12-27) * abstract; figures *	1-10	
A	US 5 363 842 A (MISHELEVICH DAVID J ET AL) 15 November 1994 (1994-11-15) * abstract; figures *	4-9	

EPO FORM 1509 03.02 (p.04/05)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 99 30 9783

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

09-03-2000

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2352556 A	23-12-1977	NONE	
WO 8803419 A	19-05-1988	FI 864505 A	07-05-1988
		FI 870678 A,B,	07-05-1988
		AT 63828 T	15-06-1991
		AU 612333 B	11-07-1991
		AU 8236187 A	01-06-1988
		BG 60007 A	15-06-1993
		CA 1305001 A	14-07-1992
		DK 374888 A,C	06-07-1988
		EP 0289563 A	09-11-1988
		HU 48470 A	28-06-1989
		JP 1501290 T	11-05-1989
		KR 9605817 B	01-05-1996
		NO 882826 A,B,	27-06-1988
		NZ 222446 A	21-12-1990
		SU 1828403 A	15-07-1993
WO 9324167 A	09-12-1993	AU 4083993 A	30-12-1993
		CN 1079167 A	08-12-1993
		TR 26757 A	15-05-1995
		ZA 9303639 A	20-12-1993
WO 9300951 A	21-01-1993	AT 189124 T	15-02-2000
		AU 662919 B	21-09-1995
		AU 2309192 A	11-02-1993
		CA 2112674 A	21-01-1993
		DE 69230613 D	02-03-2000
		EP 0592540 A	20-04-1994
		EP 0940154 A	08-09-1999
		JP 7501231 T	09-02-1995
		US 5775320 A	07-07-1998
		US 5458135 A	17-10-1995
EP 0504459 A	23-09-1992	DE 59107894 D	11-07-1996
		JP 4325163 A	13-11-1992
		US 5309900 A	10-05-1994
EP 0682955 A	22-11-1995	CA 2149722 A	20-11-1995
		JP 8266626 A	15-10-1996
		US 5596982 A	28-01-1997
WO 9015635 A	27-12-1990	FI 892956 A	17-12-1990
		AU 641659 B	30-09-1993
		AU 5746990 A	08-01-1991
		CA 2058954 A	14-12-1991

EPO FORM P448

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 99 30 9783

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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09-03-2000

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9015635 A		EP 0477222 A	01-04-1992
		HU 213187 B	28-03-1997
		JP 4506018 T	22-10-1992
		KR 9411441 B	15-12-1994
		MX 173780 B	25-03-1994
		NO 303528 B	27-07-1998
		NZ 234031 A	26-10-1993
		RU 2089227 C	10-09-1997
US 5363842 A	15-11-1994	AT 166236 T	15-06-1998
		CA 2126331 A,C	08-07-1993
		DE 69225604 D	25-06-1998
		DE 69225604 T	25-02-1999
		EP 0617628 A	05-10-1994
		JP 7509378 T	19-10-1995
		WO 9312823 A	08-07-1993

EPO FORM PUSI

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

(19)



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(11)

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(54) **Dispenser with dose counter**

(57) There is provided a dispenser suitable for dispensing medicament, particularly medicament for use in the treatment of respiratory disorders. The dispenser comprises a housing having a support; a container, locatable within said housing, having an outlet member, wherein said container is movable relative to the hous-

ing to enable dispensing therefrom and said outlet member is connectable with said support to prevent relative movement therebetween; and a dose indicator, locatable within said housing. The container and dose indicator are reversably removable from the housing as a single unit.

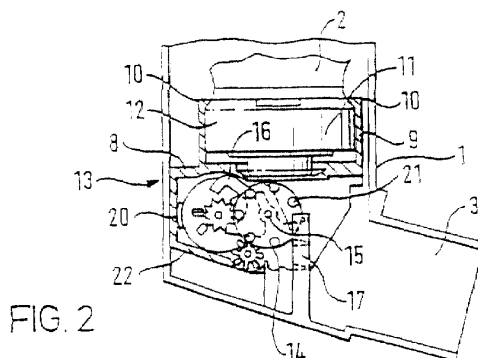


FIG. 2

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Description

[0001] The present invention relates to a dispenser having an actuation indicator for indicating the number of actuations thereof. In particular, the invention relates to metered dose inhalers by means of which medicaments contained in an aerosol container may be administered to a patient.

[0002] It is well known to treat patients with medicaments contained in an aerosol, for example, in bronchodilator therapy. It is also known to use for such therapy, medicaments which are contained in an aerosol and are administered to a patient by means of an inhalation device comprising a tubular housing or sleeve in which the aerosol container is located and an outlet tube leading out of the tubular housing. The aerosol containers used in such inhalation devices are designed to deliver a predetermined dose of medicament upon each actuation by means of an outlet valve member at one end which can be opened either by depressing the valve member while the container is held stationary or by depressing the container while the valve member is held stationary. In the use of such devices, the aerosol container is placed in the tubular housing with the outlet valve member of the container communicating via a support with the outlet tube, for example a nozzle or mouthpiece. When used for dispensing medicaments, for example in bronchodilation therapy, the housing is then held by the patient in a more or less upright condition and the mouthpiece or nozzle of the inhalation device is placed in the mouth or nose of the patient. The aerosol container is pressed towards the support to dispense a dose of medicament from the container which is then inhaled by the patient.

[0003] A disadvantage arising from use of such known devices is that the patient cannot determine the amount of medicament in the container at any given time. In an extreme case this could mean that the patient, possibly suffering from severe bronchospasm and needing a dose of medicament, will find that the container will not dispense a dose because its contents have already been exhausted.

[0004] US Patent No. 4817822 describes an aerosol dispenser of the type described above having a dose indicating device which, in a first embodiment is removably attached to the end of the protruding portion of the aerosol container. The operating mechanism of the dose counter is located within a housing which extends from the end of the aerosol container along the external surface of the tubular housing. It is important with inhalation devices containing medicament that the contents of the aerosol container are clearly marked to ensure that the patient knows exactly what medication is contained. One disadvantage associated with this positioning of the dose indicating device is that the device obscures at least a part of the aerosol container and housing which creates labelling difficulties.

[0005] A further disadvantage of the device described

is that if the dose indicating device is removably attached to the aerosol container, it is possible that the dose indicating device may become separated from its aerosol container with the result that the aerosol dispenser could be used without the dose indicating device, or the actuating mechanism of the indicating device could be tampered with leading to a false reading when the indicating device is re-attached to the dispenser. With patients having several different inhalers, it could even result in the indicating device being re-attached to the wrong dispenser.

[0006] In a second embodiment described in US4817822 the operating mechanism of the dose indicating device is located within a compartment in the housing and is actuated by means of an actuator member attached to the aerosol container. In this embodiment, once the aerosol container is fitted into the housing it cannot be removed. This makes cleaning of the housing very difficult. Even if the container were removable, the operating mechanism of the dose indicating device would be vulnerable to damage when washing with water, soap, disinfectant or antiseptic solutions. This is important because sprays of many aerosol formulations leave residues which can entrap dust and dirt particles. Some provide a media for the growth of undesired micro-organisms. If the growth of these micro-organisms is unchecked, they can serve as a source of infection for the patient and will often introduce pathogens into the patient's respiratory tract.

[0007] US-A-5,622,163 describes an actuation indicator for a metered dose inhaler locatable on the upturned base of the dispensing canister thereof.

[0008] DE 86 02 238 U describes a metered dose inhaler with an actuation indicating device.

[0009] WO96/16686 describes an aerosol dispenser wherein the operating mechanism of the dose indicating device is electronic and wherein the actuating member comprises a microswitch set into the wall of the housing. The electronic counting mechanism and microswitch are contained within a hermetically sealed enclosure. However, electronic assemblies of this type are relatively expensive compared to equivalent mechanical mechanisms, typically costing five or six times as much to produce depending on quantities manufactured. Such expense must ultimately be borne by the customer and may be prohibitive.

[0010] US5482030 describes an aerosol dispenser having a mechanical dose indicator device located in and connected to the housing in the vicinity of the outlet tube of the aerosol container when fitted. Its mechanical construction makes it difficult to seal against moisture ingress and so this dispenser again is difficult to wash without damaging the operating mechanism of the dose indicating device.

[0011] Many different pharmaceutical products are sold in the form of aerosol containers as discussed above, requiring different sized container bodies and/or valves according to the required specifications. It is

therefore normal for there to be dimensional variations between different aerosol containers. Even between the same products there can be dimensional variations due to manufacturing tolerances. One problem which is common to all of the dose indicating devices discussed above is that the indicator mechanism, which is actuated by means of a switch which detects relative movement between the container body and housing, lacks any means of compensating for dimensional variations between different aerosol containers. Hence, the indicators described must be dimensioned according to the product with which they are to be used, and so will not be interchangeable with other products. Furthermore, in order for the dose indicators to work properly, the dimensions of the indicator, aerosol container and housing must be accurate.

[0012] It is an object to provide a dispenser having an actuation indicator which overcomes at least some of the above described disadvantages. It is a further object to provide such a dispenser which from the point of view of the patient closely resembles currently marketed dispensers in both external appearance and operation.

[0013] According to one aspect of the present invention there is provided a dispenser for dispensing medicament comprising a housing having a support; a container, locatable within said housing, having an outlet member, wherein said container is movable relative to the housing to enable dispensing therefrom and said outlet member is connectable with said support to prevent relative movement therebetween; and an actuation indicator, locatable within said housing, wherein the container and dose indicator are reversably removable from the housing as a single unit.

[0014] Suitably, the actuation indicator is engagable with the container in the vicinity of the outlet member. More preferably, the actuation indicator is engagable with the outlet member.

[0015] Suitably, the actuation indicator is provided with a grip member which is engagable with a neck portion of the container. Preferably, the neck portion is adjacent to or on the outlet member.

[0016] Suitably, the container is an aerosol container.

[0017] Suitably, the housing is provided with an outlet, more preferably in the form of a mouthpiece. Preferably, the dispenser comprises a passage through which dispensed doses may pass from the container to the outlet.

[0018] Suitably, the container provides measured doses.

[0019] Suitably, the actuation indicator indicates the number of doses dispensed from or remaining in the container.

[0020] Suitably, the actuation indicator comprises an indexing mechanism actuated by a predetermined movement of the aerosol container relative to the housing.

[0021] Preferably, the indexing mechanism comprises a lost motion coupling to allow and compensate for excess movement ('overtravel') of the aerosol container

relative to the housing.

[0022] By use of a lost motion coupling it is possible to create an actuation indicator of one size which can accommodate valves and actuators made within a wide range of manufacturing tolerances and can even fit a range of dispensers made to different dimensions.

[0023] Suitably, the indexing mechanism indexes the actuation indicator by means of a predetermined rotary movement of a first member driven by movement relative to a second member during actuation of the aerosol dispenser.

[0024] Suitably, the second member remains stationary relative to the housing during actuation of the aerosol dispenser.

[0025] Suitably, the first member comprises a pinion carried by a shaft through the lost motion coupling and the second member comprises a rack. Alternatively, the first member comprises a yoke and the second member comprises a post engaged by the yoke through the lost motion coupling.

[0026] Preferably, the lost motion coupling comprises a friction drive mechanism.

[0027] Suitably, the dispenser is a breath operated inhaler which is actuable in response to the inward breath of a user.

[0028] According to a particularly preferred aspect of the present invention there is provided an aerosol dispenser comprising a housing in which a container is removably located, an outlet leading from the housing and a support in the housing arranged to receive an outlet member of the container and having a passage through which the contents of the container may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being movable relative to the outlet and housing to dispense its contents in measured doses, and a dose indicating device having a dose indicator for indicating the number of doses dispensed from or remaining in the container, characterised in that the dose indicating device is tightly connected to the container in the vicinity of the outlet member, such that the container and dose indicating device may be removed from the housing as a single unit.

[0029] According to a further aspect of the present invention there is provided an actuation indicating device for use with a dispenser comprising a housing and a container, locatable within said housing, having an outlet member, the actuation indicating device comprising attachment means to enable attachment to the container.

[0030] Suitably, the attachment means comprises a grip member which firmly engages a neck portion formed around the container. More preferably, the neck portion is located at the connection between the container and outlet member.

[0031] According to a particularly preferred aspect of the present invention the actuation indicating device has an actuation indicator for indicating the number of doses dispensed from or remaining in the container, wherein

the actuation indicating device comprises attachment means to enable tight connection to the container in the vicinity of the outlet member.

[0032] By fixing the actuation indicating device to the container in the vicinity of the outlet member may be possible to make use of the physical dimensions of the crimped ferrule of standard containers to provide a tight snap fit between the dose indicating device and aerosol container for easy assembly yet which once assembled cannot be easily separated. This ensures that the actuation indicator presents accurate information concerning the container with which it is assembled.

[0033] In a preferred aspect, the dispenser is a metered dose inhaler comprising a housing in which the container is removably located, an outlet leading from the housing, a support in the housing arranged to receive the outlet member of the container and having a passage through which the contents of the container may pass to the outlet, the outlet member being held stationary in the housing support and the body of the container being moveable relative to the outlet and housing to dispense its contents in measured doses, and a window through which the dose indicator may be viewed.

[0034] The location of the dose indicator in the vicinity of the outlet member of the container in a metered dose inhaler provides the advantage that visually and operationally the device may appear very similar to current marketed metered dose inhalers without dose indicating devices such that when switched to the metered dose inhaler according to the invention, patients perceive little change over their conventional dispensers, so creating minimal impact upon patients and their use of the device.

[0035] A dispenser according to the invention will now be described with reference to the accompanying drawings in which:

Fig. 1 is a section through a standard inhalation device comprising an aerosol dispenser;

Fig. 2 is a section through the dose indicating device as fitted to an aerosol dispenser in an inhalation device;

Fig 2a is a sectional view of an aspect of a dose indicating device herein;

Fig. 3 is a perspective view of a counting mechanism used in the dose indicating device of Fig. 2;

Fig. 4 shows the sequence of operation of the counting mechanism of Fig. 3;

Fig. 5 shows a lateral and a longitudinal section through a second embodiment of the dose indicating device as fitted into the housing of an inhalation device;

Fig. 6 shows an exploded view of a dose indicating device according to a third embodiment of the invention;

Fig. 7 shows another exploded view of the dose indicating device of figure 6 together with an aerosol container and housing;

Fig. 8 shows a schematic section through an inhalation device comprising the dose indicating device of figure 6 in a rest position; and

Fig. 9 shows a schematic section through the inhalation device of figure 8 in an actuated position.

[0036] The standard metered dose inhaler shown in Fig 1 comprises a tubular housing 1 in which an aerosol container 2 can be located. The housing is open at one end (which will hereinafter be considered to be the top of the device for convenience of description) and is closed at the other. An outlet 3 leads laterally from the closed end of the housing 1. In the embodiment illustrated, the outlet 3 is in the form of a mouthpiece intended for insertion into the mouth of the patient but it may, if desired, be designed as a nozzle for insertion into the patient's nostril.

[0037] The aerosol container 2 has an outlet valve stem 4 at one end. This valve member can be depressed to release a measured dose from the aerosol container or, alternatively, the valve stem 4 can be fixed and the main body of the container can be moved relative to the valve member to release the dose.

[0038] As shown clearly in Fig 1, the aerosol container 2 is located in the housing 1 so that one end protrudes from its open top. Spacer ribs (not shown) may be provided inside the housing to hold the external surface of the container 2 spaced from the internal surface of the housing 1. A support 5 is provided at the lower end of the housing 1 and has a passage 6 in which the valve stem 4 of the aerosol container 2 can be located and supported. A second passage 7 is provided in the support 5 and is directed towards the interior of the outlet 3. Thus, when the parts are in the positions shown in Fig 1, the protruding portion of the aerosol container 2 can be depressed to move the container relative to the valve stem 4 to open the valve and a dose of medication contained in the aerosol will be discharged through the passage 7 and into the outlet 3 from which it can be inhaled by a patient. One dose will be released from the aerosol container each time it is fully depressed.

[0039] Fig 2 shows the lower part of a device similar to that of Fig 1 but incorporating a dose indicating device according to the invention. The dose indicating device comprises a body 8 firmly attached to the aerosol container by means of tubular portion 9 formed with grips 10. Tubular portion 9 tightly engages the periphery of valve ferrule 11 while a grip in the form of lip 10 engages around neck 12 of valve ferrule 11 which is formed dur-

ing assembly when valve ferrule 11 is crimped onto aerosol container 2. Thus the tubular portion 9 and lip 10 form a tight connection to the aerosol container which once assembled by pushing the tubular portion 9 over the valve ferrule 11 cannot easily be disassembled.

[0040] Below tubular portion 9, body 8 forms a cradle 22 for mounting counter mechanism 13 and drive pinion 14. Drive pinion 14 is friction mounted on counter mechanism drive shaft 15. Drive pinion 14 is formed with a number of teeth or pegs 21 which can engage with a number of recesses or grooves formed on post 17 in the form of a rack moulded inside housing 1 and extending from the base of the housing 1 parallel to valve stem 4.

[0041] Whilst in the embodiment shown in Fig 2 the post 17 forms a moulded part of the housing other variations can be envisaged in which the post 17 forms a part of the dose indicating device itself. For example, Fig 2a shows a simplified representation of a dose indicating device in which the head of post 17 is receivable within a recess provided in the body 8 of the device. Teeth formed on the post 17 engage corresponding teeth on drive pinion 14. Spring 28 acts such as to urge the post from the recess. The protruding lip 24 of the post 17, however, abuts stop 26, thereby retaining at least a portion of the post 17 within the recess.

[0042] As shown in Figs 3 and 4, drive shaft 15 is connected to driver yoke 16 of counter mechanism 13. Driver yoke 16 has two switching latches 18a and 18b spaced either side of star wheel 19 such that driver yoke 16 may tilt about the axis of drive shaft 15 between a first position shown in Fig 4b in which switching latch 18a engages one side of star wheel 19, and a second position shown in Fig 4d in which switching latch 18b engages the other side of star wheel 19. Star wheel 19 is connected through a mechanism, similar to that described with reference to reference numerals 2 to 8 in Figs 1 to 3 of European Patent No. 0280104, to three digit wheels 33, which have numbers printed on their circumferential faces as described below. When located in the housing 1, counter mechanism 13 is small enough to be located to the sides of and behind support 5 so as not to interfere with the aerosol flume as it emerges from passage 7.

[0043] The aerosol container 2 may be supplied to the patient with the dose indicating device ready assembled thereto. Alternatively, the housing 1 may be supplied to the patient with the dose indicating device located in the position shown in Fig 2 and the aerosol container 2 supplied separately. In this case, the patient is instructed to insert the aerosol container 2 into the housing 1 with the valve stem first. Upon first insertion of the container into the housing, the tubular portion 9 and lip 10 of the dose indicating device ride over the periphery of valve ferrule 11 of the aerosol container 2 until lip 10 snaps around neck 12. Thereafter, the dose indicating device is attached to the aerosol container 2.

[0044] Other means of attachment of the dose indicator to the container are envisaged including adhesive

attachment; use of welded shrink sleeves; heat forming; crimping; ultra-sonic welding; and by the presence of an o-ring elastomer on the container which is fixedly pierceable by barbs on the attachment member of the dose indicator. In one aspect, permanent means of attachment are preferred.

[0045] To actuate the device, the protruding portion of the aerosol container is depressed as described above with reference to Fig. 1. As the aerosol container carrying the dose indicating mechanism moves within housing 1, drive pinion 14 starts to turn, through its engagement with post 17, causing rotation of drive shaft 15 and driver yoke 16. As driver yoke 16 tilts with rotation of drive shaft 15 switching latch 18a moves into engagement with star wheel 19 (Fig 4a) causing an incremental anti-clockwise rotation of a half tooth pitch of the star wheel until the switching latch 18a can move no further in this direction, the switching latch being positioned between two adjacent teeth of the star wheel (Fig 4b). At this point, drive shaft 15 cannot rotate any further and any further movement of the aerosol container into housing 1 results in drive pinion 14 continuing to rotate through its engagement with post 17 by virtue of the friction coupling between pinion 14 and drive shaft 15.

[0046] When the valve stem 4 has reached its fully depressed position and a metered dose of medicament has been discharged from the aerosol container, the aerosol container is allowed to return to its original position. As the aerosol container and dose indicating mechanism return to their original position, drive pinion 14 starts to rotate in the opposite direction together with drive shaft 15 and driver yoke 16. Thus, driver yoke 16 tilts such that switching latch 18a moves out of engagement with star wheel 19 while switching latch 18b moves into engagement therewith (Fig 4c), causing further incremental anti-clockwise rotation of a half tooth pitch of the star wheel until switching latch 18b can move no further in this direction (Fig 4d). Again, drive shaft 15 cannot rotate any further at this point and any further movement of the aerosol container out of housing 1 results in drive pinion 14 continuing to rotate through its engagement with post 17 by virtue of the friction coupling between pinion 14 and drive shaft 15. In this way it can be seen that the friction coupling acts as a lost motion coupling which allows the dose indicating device to be used with aerosol containers having valves with different lengths of travel of valve stem during actuation.

[0047] Each time the aerosol dispenser is actuated the star wheel is made to rotate through two incremental anti-clockwise movements as described above. These movements are translated through the counter mechanism into appropriate movements of the digit wheels 33, one number on each of the printed circumferential faces of the digit wheels being clearly visible through the window 20 at the back of the housing 1 (as shown in Fig 2), to indicate that a further dose of medicament has been dispensed. By having three digit wheels 33 it is possible for the dose counter to be used to count hundreds of

doses. Clearly if fewer than one hundred doses are to be contained within the dispenser, the dose counter could comprise fewer digit wheels. Alternatively, if a thousand or more doses are to be contained, then one or more additional digit wheels could be added as appropriate.

[0048] To remove the aerosol container 2 from the housing for cleaning, the aerosol container 2 may be withdrawn from the housing 1 in the usual manner. As the container is withdrawn, the friction coupling between drive pinion 14 and drive shaft 15 allows such further movement as is required for the drive pinion to come out of engagement with the post 17 without causing any further indexing of the counter mechanism. Once removed, the housing 1 may be cleaned as described without fear of interfering with or damaging the dose indicating device, which remains firmly connected to the aerosol container 2.

[0049] When the housing 1 is clean, the aerosol container 2 with dose indicating device may be re-inserted into the housing 1. During insertion, drive pinion 14 will engage post 17 and start to rotate until the aerosol container reaches its normal rest position with the valve stem 4 located in support 5. As the drive pinion 14 rotates, the friction coupling will act as a lost motion mechanism as described above, allowing for any travel of the aerosol container as between first engagement of drive pinion 14 and post 17, and location of valve stem 14 in support 5. In this way, the friction coupling automatically accommodates and compensates for different lengths of valve stems protruding from the ferrule.

[0050] Fig 5 shows an alternative lost motion coupling mechanism which may be used in an aerosol dispenser according to the invention. In this embodiment, instead of a pinion, driver yoke 16 is formed with two resilient arms 30 between which post 17 is grippingly engaged (Fig 5a). Post 17 is formed with ribs on its surface (not shown) which provide a rough surface finish to create the level of friction required between arms 30 and post 17 such that arms 30 will grip post 17 until the load applied overcomes the friction.

[0051] Upon actuation of the device, as the aerosol container and dose indicating mechanism move, the friction engagement between arms 30 and post 17 cause driver yoke 16 to tilt about the axis of shaft 15 (not shown in Fig 5), so moving switching latch 18a into engagement with star wheel 19 as discussed in relation to the first embodiment. As switching latch 18a reaches its limit of travel, driver yoke 16 can move no further, and any further movement of the aerosol container into housing 1 results in arms 30 slipping down post 17 by virtue of the friction coupling. Upon return to its original position, driver yoke 16 tilts in the other direction until switching latch 18b moves into engagement with star wheel 19 and can move no further. Any further movement of the aerosol container out of housing 1 results in arms 30 slipping up post 17.

[0052] Figures 6 to 9 show an inhalation device fitted

with an electro-mechanical dose indicating device according to the invention. As with the mechanical embodiments discussed above, the dose indicating device comprises a body 40 firmly attached to the aerosol container by means of tubular portion 41 formed with grips (not shown). Tubular portion 41 tightly engages the periphery of valve ferrule 11 while a grip in the form of a lip engages around neck 12 of valve ferrule 11. Thus the tubular portion 41 and lip form a tight connection to the aerosol container which once assembled by pushing the tubular portion 41 over the valve ferrule 11 cannot easily be disassembled.

[0053] Below tubular portion 41, body 40 forms a cradle for mounting counter mechanism 43, and defines a chamber for accommodating switch slide 44. Switch slide 44 is a cylindrical washer made of silicone rubber and having a bore of such a diameter that, with the can and dose indicating device mounted within the actuator housing, it provides a friction fit on pin 45, which is moulded in the housing and protrudes through a hole in body 40. The friction fit of switch slide 44 on pin 45 ensures the switch slide will not move along the pin unless pushed. Two contact members 46, 47, both of which comprise a switch contact and a circuit board contact, and one of which further comprises a battery contact, are mounted such that the battery and circuit board contacts are in constant contact with a first terminal of the battery 48 and printed circuit board (PCB) 49 respectively. The switch contacts do not contact each other but are positioned either side of pin 45, and define the upper limit of movement of the switch slide 44 within its chamber. Thus, when switch slide 44 is in its upper position as shown in figure 9, it makes contact with both switch contacts, so closing the circuit between them due to the electrical conductivity of the silicone rubber of the switch slide. Although in the embodiment described the switch slide is made of silicone rubber, it will be appreciated that it could alternatively be made of a non-conductive rubber having an insert at its upper face made of metal or some other conductive material.

[0054] In addition to its connections with contact members 46, 47, PCB 49 also has connections to the other terminal of the battery and to a three digit liquid crystal display (LCD) 50 in a conventional manner. The PCB comprises an application specific integrated circuit (ASIC), which provides the logic by which the dose indicator can be checked, programmed and made operational, as discussed in more detail below, to keep a record of how many times the switch contact circuit is closed and drives the LCD to display the number of doses remaining in the aerosol container. The ASIC is thus designed and programmed accordingly in a known manner.

[0055] Instead of a digital display, the LCD could alternatively be formatted to display an analogue indication. When the aerosol container is mounted in the actuator housing, LCD 50 is visible through window 20. In the embodiment depicted in figure 7, the LCD and win-

dow are located at the back of the housing, but they could equally be located at the front or some other part of the housing.

[0056] The Counter mechanism 43 is small enough to be located to the sides of and behind the stem block (support 5) moulded in housing so as not to interfere with the aerosol flume as it emerges.

[0057] To actuate the device, the protruding portion of the aerosol container when fitted into the actuator housing is depressed as described above. As the aerosol container carrying the dose indicating mechanism moves within the housing from its rest position (shown in figure 8), the chamber accommodating switch slide 44 moves down until the upper face of switch slide 44, which is mounted on pin 45, meets switch contacts 46, 47 and the switch circuit is closed. This causes the ASIC to decrement the number displayed by the LCD 50. As the aerosol container continues to move, a metered dose of medicament is discharged from the valve, while switch slide 44 is pushed down along pin 45 by virtue of the friction fit of the switch slide on the pin until the valve stem reaches its limit of travel and the aerosol container moves no further (figure 9). In this way, it can be seen that the friction fit of the switch slide 44 on pin 45 allows for over-travel of the valve stem after the switch circuit has been closed, so acting as a lost motion coupling. The aerosol container is then allowed to return to its original position within the housing, and as it returns, the chamber accommodating switch slide 44 moves up breaking the switch circuit as switch contacts 46, 47 move away from switch slide 44. Body 40 then meets the lower face of switch slide 44 and draws the switch slide up along pin 45 until the valve stem returns to its rest position (figure 8).

[0058] Because the dose indicating device is designed to be suitable for use in connection with different sized aerosol containers containing different numbers of doses to be delivered, the ASIC is designed to be factory set in accordance with the size of aerosol container with which the dose indicating device is assembled. After assembly of the dose indicating device and first connection of the battery, the ASIC enters a self-test mode. After this, the programming mode may be entered by activating the switch, allowing it to be programmed to count down from the appropriate number of doses (e.g. 200, 120, 80 or 60). This may be done automatically on a packing line. After programming has taken place, the ASIC enters the counting mode, where the LCD decrements upon closing of the switch contact circuit. When the count of zero is reached, the ASIC is designed to prevent the count from decrementing any further in a known manner. In order to prevent spurious readings due to the effects of switch 'bounce', the ASIC may be designed to decrement only after the switch circuit has been closed for a predetermined length of time in a known manner. In the event of the aerosol container getting jammed in the actuated position after operation, or the switch circuit jamming closed due to mechanical

damage or contamination, the ASIC may be designed to blank the LCD to alert the user that there is a problem.

[0059] As with the other embodiments of the invention described above, the aerosol container may be withdrawn from the actuator housing in the usual manner. As the container is withdrawn, body 40 draws the switch slide up along pin 45 until it clears the pin altogether. Once removed, the housing may be cleaned without interfering with or damaging the dose indicating device, which remains firmly connected to the aerosol container.

[0060] During re-insertion of the aerosol container, which can only occur when the body of the dose indicating device is correctly orientated with respect to the housing by virtue of their respective shapes, switch slide 44 engages and is pushed up by pin 45 until the upper face meets the switch contacts. Further insertion of the aerosol container results in switch slide 44 being pushed down along pin 45 until the valve stem is seated back within support 5.

[0061] It will be appreciated that by programming of the ASIC, one design of dose indicating device could be used in conjunction with a range of aerosol containers of various capacities. By virtue of the switch mechanism, the same design of dose indicating device can also be used in conjunction with a range of different valves having different lengths of valve stem and different stem travel specifications.

[0062] Whilst the present invention has been described in detail in respect of a metered dose inhaler actuatable manually by the patient it will be appreciated that other actuation mechanisms can be substituted. In particular, the use of a breath operated inhaler in which the actuation is assisted, and is responsive to, preferably triggered by, the inward breath of the patient, is also envisaged.

[0063] The dispenser of the invention is suitable for dispensing medicament, particularly for the treatment of respiratory disorders. Appropriate medicaments may thus be selected from, for example, analgesics, e.g., codeine, dihydromorphine, ergotamine, fentanyl or morphine; anginal preparations, e.g., diltiazem; antiallergics, e.g., cromoglycate, ketotifen or nedocromil; anti-infectives e.g., cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines and pentamidine; antihistamines, e.g., methapyrilene; anti-inflammatory, e.g., beclomethasone dipropionate, fluticasone propionate, flunisolide, budesonide, rofleponide, mometasone furoate or triamcinolone acetonide; antitussives, e.g., noscapine; bronchodilators, e.g., albuterol, salmeterol, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropanolamine, pirbuterol, reproterol, rimeterol, terbutaline, isoetharine, tulobuterol, or (-)-4-amino-3,5-dichloro- α -[[6-[2-(2-pyridinyl)ethoxy] hexyl]methyl] benzenemethanol; diuretics, e.g., amiloride; anticholinergics, e.g., ipratropium, tiotropium, atropine or oxitropium; hormones, e.g., cortisone, hydrocortisone or prednisolone; xanthines, e.g., aminophylline, choline theophyllinate,

lysine theophyllinate or theophylline; therapeutic proteins and peptides, e.g., insulin or glucagon. It will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of salts, (e.g., as alkali metal or amine salts or as acid addition salts) or as esters (e.g., lower alkyl esters) or as solvates (e.g., hydrates) to optimise the activity and/or stability of the medicament.

[0064] Preferred medicaments are selected from albuterol, salmeterol, fluticasone propionate and beclomethasone dipropionate and salts or solvates thereof, e.g., the sulphate of albuterol and the xinafoate of salmeterol.

[0065] Medicaments can also be delivered in combinations. Preferred formulations containing combinations of active ingredients contain salbutamol (e.g., as the free base or the sulphate salt) or salmeterol (e.g., as the xinafoate salt) in combination with an antiinflammatory steroid such as a beclomethasone ester (e.g., the dipropionate) or a fluticasone ester (e.g., the propionate).

[0066] It will be understood that the present disclosure is for the purpose of illustration only and the invention extends to modifications, variations and improvements thereto.

[0067] The application of which this description and claims form part may be used as a basis for priority in respect of any subsequent application. The claims of such subsequent application may be directed to any feature or combination of features described therein. They may take the form of product, method or use claims and may include, by way of example and without limitation, one or more of the following claims:

Claims

1. An aerosol dispenser comprising a housing (1) in which a container (2) is removably located, an outlet (3) leading from the housing (1) and a support (5) in the housing (1) arranged to receive an outlet member (4) of the container (2) and having a passage (7) through which the contents of the container (2) may pass to the outlet (3), the outlet member (4) being held stationary in the housing support (5) and the body of the container (2) being moveable relative to the outlet member (4) and housing (1) to dispense its contents in measured doses, and a dose indicating device having a dose indicator for indicating the number of doses dispensed from or remaining in the container (2), **characterised in that** the dose indicating device (13) tightly connects to the container (2) in the vicinity of the outlet member (4), such that the container (2) and dose indicating device (13) may be reversibly removed from the housing (1) as a single unit.

2. A dispenser according to claim 1 wherein the dose

indicating device (13) tightly connects with the outlet member (4).

3. A dispenser according to claim 1, wherein the dose indicating device (13) is provided with a grip member (10) which tightly connects with a neck portion of the container (2).

4. A dispenser according to claim 3, wherein the neck portion is adjacent to or on the outlet member (4).

5. A dispenser according to any of claims 1 to 4, wherein the outlet (3) is in the form of a mouthpiece.

6. A dispenser according to any of claims 1 to 5, wherein the dose indicating device (13) comprises an indexing mechanism actuated by a predetermined movement of the container (2) relative to the housing (1).

7. A dispenser according to claim 6, wherein the indexing mechanism comprises a lost motion coupling to allow and compensate for excess movement of the container (2) relative to the housing (1).

8. A dispenser according to either of claims 6 or 7, wherein the indexing mechanism indexes the actuation indicator (13) by means of a predetermined rotary movement of a first member (14;16) driven by movement relative to a second member (17) during actuation of the dispenser.

9. A dispenser according to claim 8, wherein the second member remains stationary relative to the housing during actuation of the dispenser.

10. A dispenser according to either of claims 8 or 9, wherein the first member comprises a pinion (14) carried by a shaft through the lost motion coupling and the second member comprises a rack (17).

11. A dispenser according to either of claims 8 or 9, wherein the first member comprises a yoke (16) for engagement with the second member (17) through the lost motion coupling.

12. A dispenser according to any of claims 7 to 11, wherein the lost motion coupling comprises a friction drive mechanism.

13. A dispenser according to any of claims 1 to 12, actuable in response to the inward breath of a user.

14. A dispenser according to any of claims 1 to 13, wherein the actuation indicator comprises a mechanical actuation indicating mechanism.

15. A dispenser according to any of claims 1 to 13,

wherein the actuation indicator comprises an electromechanical actuation indicating mechanism.

16. A dispenser according to any of claims 1 to 15, wherein the container (2) comprises medicament selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate and any salts or solvates thereof, and any mixtures thereof.

17. A dispenser according to claim 16, wherein the medicament comprises salmeterol xinafoate.

18. A dispenser according to claim 16, wherein the medicament comprises fluticasone propionate.

19. A dispenser according to claim 16, wherein the medicament comprises a combination of salmeterol xinafoate and fluticasone propionate.

20. An aerosol container assembly comprising

an aerosol container (2) having an outlet member (4) for dispensing measured doses of medicament; and

a dose indicating device (13) having a dose indicator for indicating the number of doses of medicament dispensed from or remaining in the container (2),

characterised in that the dose indicating device (13) tightly connects to the container (2) in the vicinity of the outlet member (4).

21. An assembly according to claim 20, wherein the container (2) comprises medicament selected from the group consisting of albuterol, salmeterol, fluticasone propionate, beclomethasone dipropionate and any salts or solvates thereof, and any mixtures thereof.

22. A dispenser according to claim 21, wherein the medicament comprises salmeterol xinafoate.

23. A dispenser according to claim 21, wherein the medicament comprises fluticasone propionate.

24. A dispenser according to claim 21, wherein the medicament comprises a combination of salmeterol xinafoate and fluticasone propionate.

25. An aerosol container assembly in kit of parts form comprising

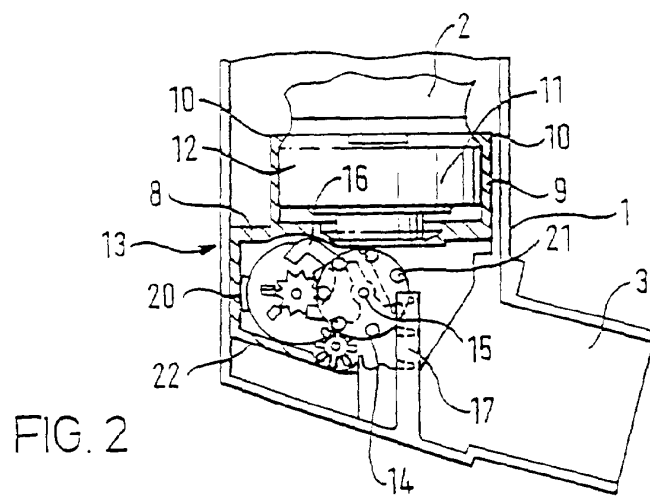
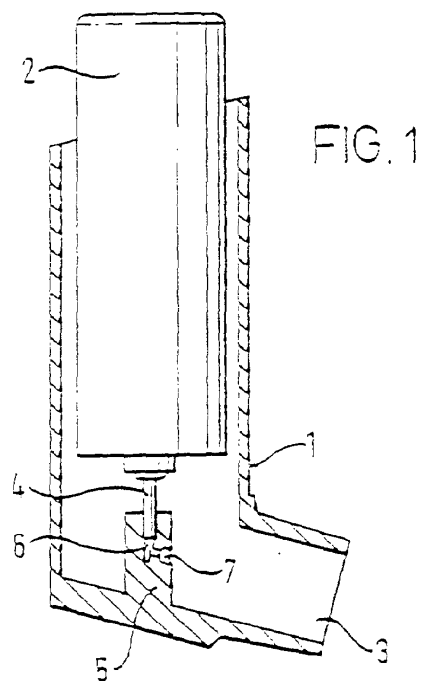
(a) an aerosol container (2) having an outlet member (4) for dispensing measured doses of medicament; and

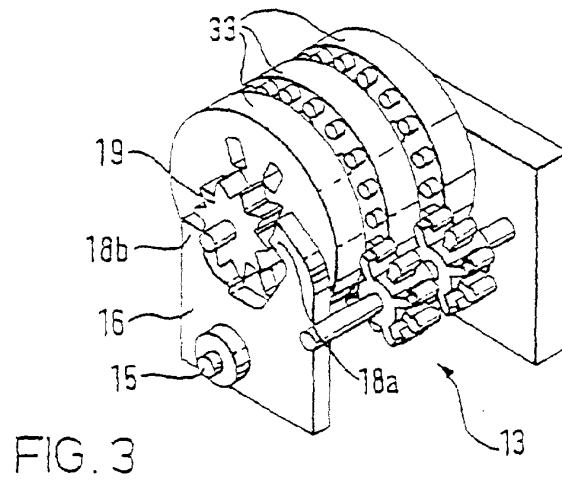
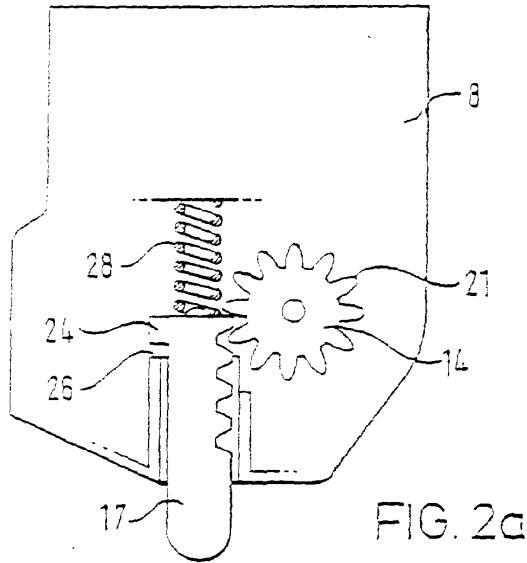
(b) a dose indicating device (13) having a dose indicator for indicating the number of doses of medicament dispensed from or remaining in the container (2),

characterised in that the dose indicating device (13) comprises attachment means (10) to enable its tight connection to the container (2) in the vicinity of the outlet member (4).

26. A kit of parts according to claim 25, wherein the attachment means comprises a grip member (10) for firmly engaging a neck portion formed around the container (2).

27. A kit of parts according to claim 26, wherein the neck portion is located at the connection between the container (2) and outlet member (4).





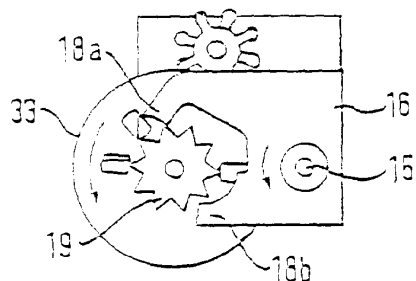


FIG. 4a

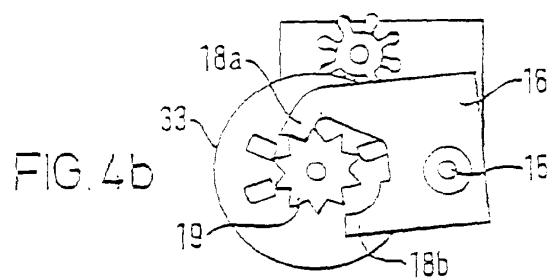


FIG. 4b

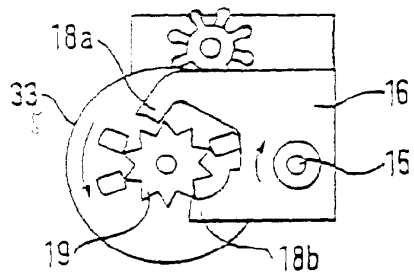


FIG. 4c

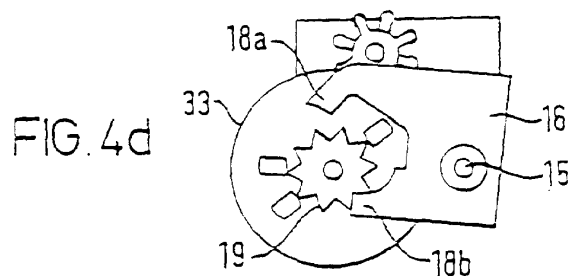


FIG. 4d

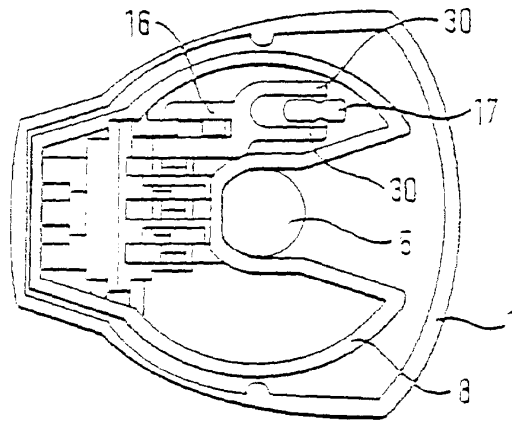


FIG. 5a

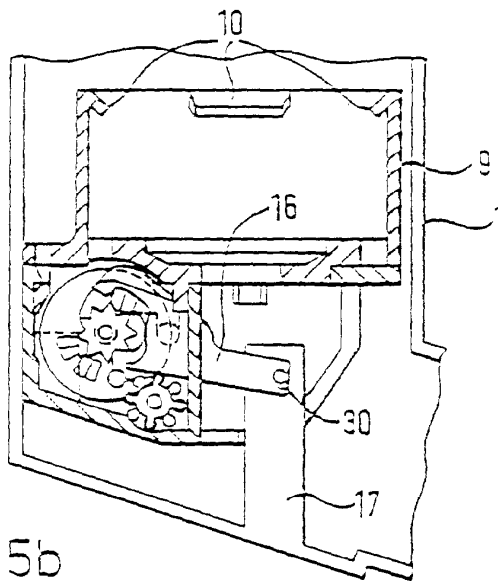
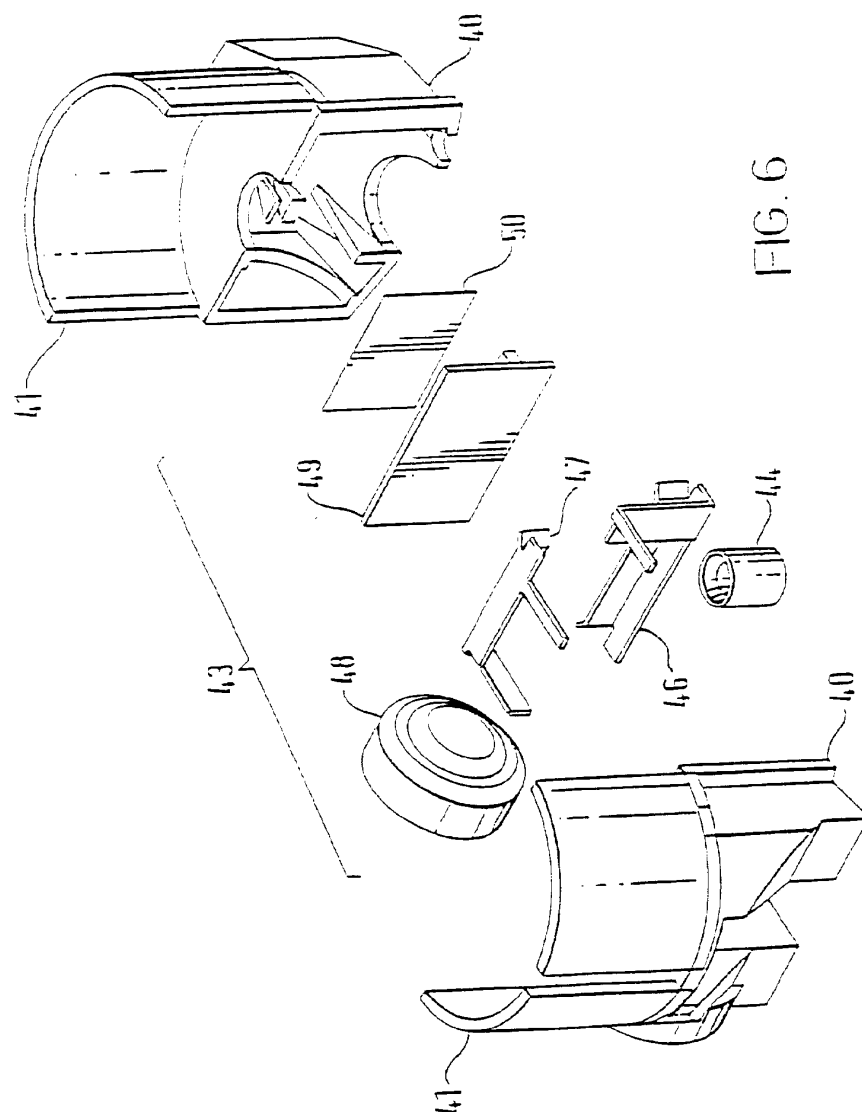


FIG. 5b



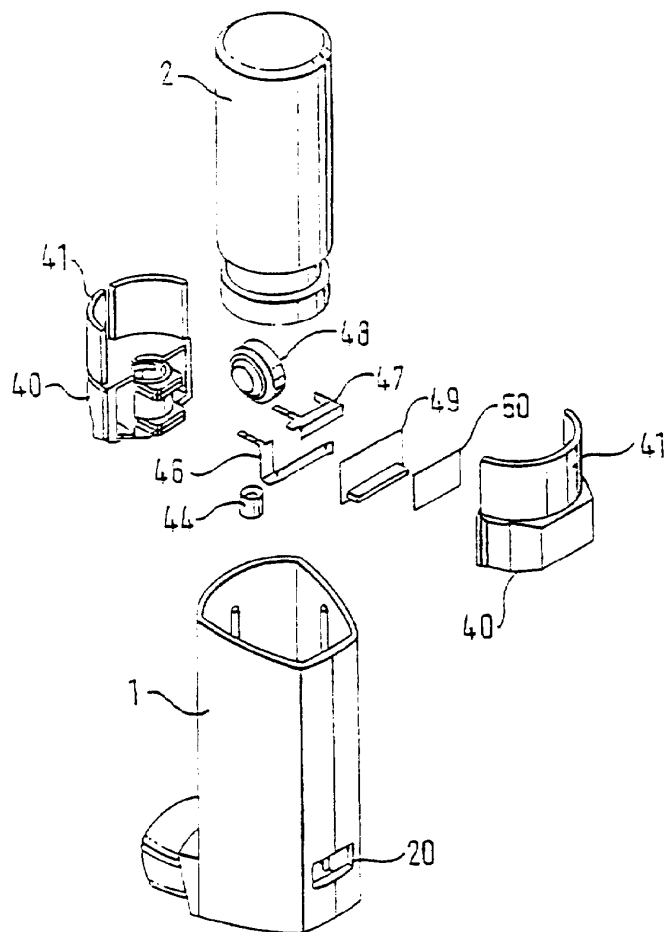


FIG. 7

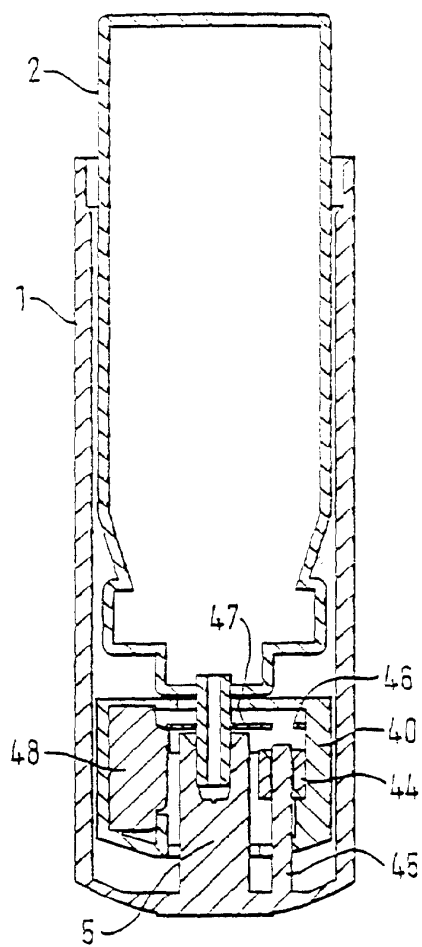


FIG. 8

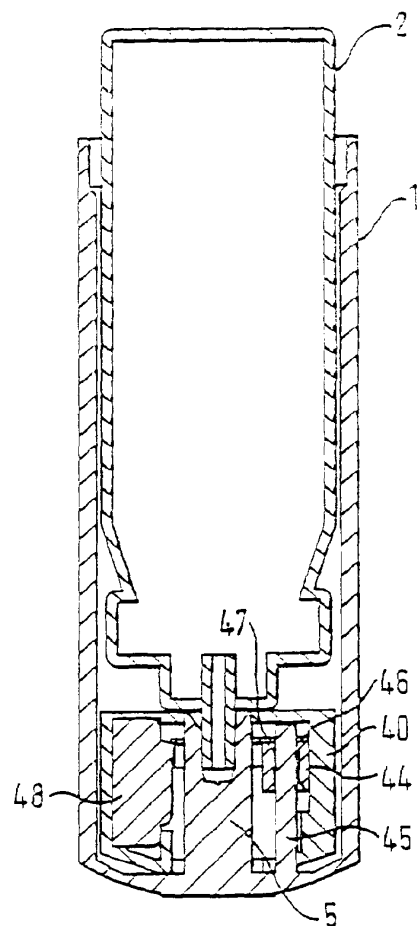


FIG. 9

ATTACHMENT B

(US Ref. Not Submitted)

US 5,718,355: Figures 3A, 3E, 3F, 3G, 3H

WO 00/09187: Figures 2a, 2b, 2c

EP 0 480 488: Figures 4, 5

EP 0 949 584: Figure 5

EP 1 065 477: Figures 5, 6

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(51) Internationale Patentklassifikation ⁷ : A61M 15/00, G06M 1/08, 1/14	A1	(11) Internationale Veröffentlichungsnummer: WO 00/09187 (43) Internationales Veröffentlichungsdatum: 24. Februar 2000 (24.02.00)
(21) Internationales Aktenzeichen: PCT/EP99/05939 (22) Internationales Anmeldedatum: 13. August 1999 (13.08.99) (30) Prioritätsdaten: 298 14 647.9 14. August 1998 (14.08.98) DE (71) Anmelder (für alle Bestimmungsstaaten ausser US): JOSEPH WISCHERATH GMBH & CO. KG [DE/DE]; Donatusstrasse 102, D-50259 Pulheim (DE). (72) Erfinder; und (75) Erfinder/Anmelder (nur für US): ECKERT, Joseph [DE/DE]; Suhlesstrasse 69, D-97638 Mellrichstadt (DE). (74) Anwalt: GRÜNECKER, KINKELDEY, STOCKMAIR & SCHWANHÄUSSER; Maximilianstrasse 58, D-80538 München (DE).		(81) Bestimmungsstaaten: DE, JP, US, europäisches Patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Veröffentlicht <i>Mit internationalem Recherchenbericht.</i>

(54) Title: INHALATOR COMPRISING A DOSAGE COUNTING DEVICE

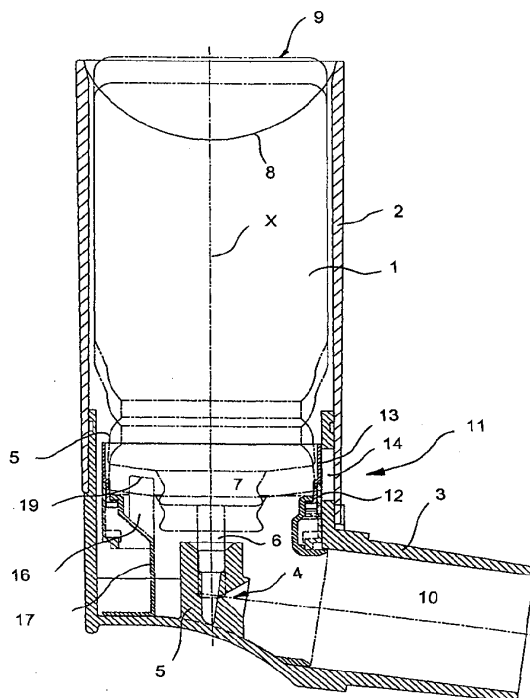
(54) Bezeichnung: INHALATOR MIT EINER DOSIERZÄHLEINRICHTUNG

(57) Abstract

The invention relates to an inhalator for discharging an aerosol comprising a dosage counting device (11). The dosage counting device comprises a first (12) and a second (13) counting ring and has a coupling device (24, 25, 26, 27) located between the counting rings.

(57) Zusammenfassung

Die Erfindung betrifft einen Inhalator zur Abgabe eines Aerosols mit einer Dosierzähleinrichtung (11), die einen ersten (12) und einen zweiten (13) Zählring aufweist und mit einer Koppelungsvorrichtung (24, 25, 26, 27) zwischen den Zählringen.



LEDIGLICH ZUR INFORMATION

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EE	Estland						

Inhalator mit einer Dosierzähleinrichtung

Die Erfindung betrifft einen Inhalator zur Abgabe eines Aerosols mit einer Dosierzähleinrichtung, einem Gehäuseteil und einem relativ zu dem Gehäuseteil entlang seiner Längsachse verschiebbar angeordneten Aerosol-Abgabebehälter.

Ein derartiger Inhalator ist aus EP-A1-0 254 391 bekannt. Bei diesem herkömmlichen Inhalator ist ein Aerosol-Abgabebehälter verschiebbar in einen rohrförmigen Abschnitt eines Gehäuseteils eingesetzt. Der Abgabebehälter umfaßt ein aus einem Kopfbereich des Abgabebehälters herausgeführtes Sprührohr, das in abdichtender Weise in einen Sprühsockelabschnitt eingesetzt ist, der einstückig mit dem Gehäuse ausgebildet ist. Zur Abgabe einer festgelegten Dosis eines in dem Abgabebehälter bevorrateten Mediums wird auf einen Bodenabschnitt des Abgabebehälters eine Druckkraft ausgeübt und der Behälter kurzzeitig in das Gehäuse hineingedrängt. Über das in den Sprühsockel eingesetzte Sprührohr wird kurzzeitig ein Ventilmechanismus geöffnet und eine vorbestimmte Menge des in dem Abgabebehälter bevorrateten Mediums aus dem Sprühkopf abgesprüht. In einem Seitenbereich des Gehäuses ist ein drehbewegbar gelagertes Anzeigerad vorgesehen, das bei jedem Abgabehub des Inhalators über ein Untersetzungsgetriebe um einen geringen Drehbetrag weitergedreht wird. Das Anzeigerad ist mit mehreren Füllstandsangaben versehen, die bei sukzessiver Drehung des Anzeigerades über einen Fensterabschnitt ablesbar sind. Wenn der Abgabebehälter nahezu vollständig entleert ist, wird in dem Fenster ein entsprechendes Symbol sichtbar und dem Benutzer damit signalisiert, daß der Abgabebehälter im wesentlichen vollständig entleert ist. Durch eine werkseitig vorgenommene Überfüllung des Abgabebehälters um ca. 10 bis 15 % ist gewährleistet, daß bei Erreichen dieser End-Markierung noch eine ausreichende Wirkstoffmenge in dem Abgabebehälter bevorratet ist.

Diese werkseitig vorgenommene Überfüllung des Abgabebehälters führt insbesondere bei der Abfüllung von vergleichsweise teuren Wirkstoffen zu einer Verteuerung des Inhalators. Auch unter Umweltverträglichkeitsaspekten erscheint eine Überfüllung des Abgabebehälters im bislang üblichen Umfang als problematisch.

Der Erfindung liegt daher die Aufgabe zugrunde, einen Inhalator zur Abgabe eines Aerosols zu schaffen, welcher sich durch eine hohe Funktions-Zuverlässigkeit und eine

hinsichtlich Ablesbarkeit und Anzeigegenauigkeit verbesserte Dosiermengenzähleinrichtung auszeichnet.

Diese Aufgabe wird erfindungsgemäß durch einen Inhalator mit den im Schutzanspruch 1 angegebenen Merkmalen gelöst.

Dadurch wird es auf vorteilhafte Weise möglich, einen unter fertigungstechnischen Gesichtspunkten günstig herstellbaren Inhalator zu schaffen, bei welchem bedarfsweise jeder einzelne Dosierhub gezählt und angezeigt wird. Neben der damit erreichten zuverlässigen Überwachung der Restfüllmenge eines in dem Inhalator bevorrateten Wirkmediums wird es ferner möglich, die rezeptgemäße Einnahme eines Dosieraerosols besser im Auge zu behalten. Die erfindungsgemäß ausgebildete Dosierzähleinrichtung erlaubt beispielsweise eine von 0 bis ca. 200 aufsteigende Zählung der einzelnen Dosierungen. Alternativ dazu ist es auch möglich, die Zifferanordnung auf den beiden Zählringen derart vorzunehmen, daß eine von der maximalen Hubzahl abwärts laufende Dosierzählung erfolgt. Die Zählung kann beispielsweise von der Zahl 200 abwärts laufend erfolgen, wobei beispielsweise dann, wenn die Resthubzahl ≤ 50 ist, in der Anzeigeeinrichtung eine Farbmarkierung, beispielsweise in Form eines Signalbalkens, sichtbar wird, der dem entsprechenden Benutzer rechtzeitig die Nachbeschaffung eines entsprechenden Inhalators signalisiert.

Die mittels der erfindungsgemäßen Dosierzähleinrichtung erreichte Verbesserung der Anzeigegenauigkeit erlaubt es, die aus Sicherheitsgründen vorgenommene Überfüllung des Abgabebehälters und damit die ggf. in dem Abgabebehälter verbleibende Wirkstoffrestmenge zu verringern.

Eine im Hinblick auf eine besonders zuverlässige Weiterschaltung des ersten Zählrings vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß der Schaltfinger von der Rotationsachse beabstandet und zu dieser geneigt angeordnet ist. Dadurch wird es auf kinematisch günstige Weise möglich, den Schaltfinger mit zählringseitig vorgesehenen Stellelementen in Eingriff zu bringen und den Schaltfinger anschließend um eine im wesentlichen quer zur Längsrichtung des Schaltfingers verlaufende Kippachse zu kippen. Der Anstellwinkel des Schaltfingers relativ zu einer durch den Zählring definier-

ten Radialebene liegt vorzugsweise im Bereich von 30 bis 60°. Hierbei ergeben sich bei günstigen Kräfteverhältnissen hinreichend große Transportwege des Schaltfingers.

Gemäß einer bevorzugten Ausführungsform der Erfindung ist der Schaltfinger aus einer Ausgangsstellung in eine zu dieser Ausgangsstellung geneigte Endstellung auslenkbar, wobei ein Eingriffsabschnitt des Schaltfingers bereits in der Ausgangsstellung desselben federnd nachgiebig in eine Eingriffsstellung mit dem ersten Zählring gedrängt ist. Dadurch wird auf zuverlässige Weise gewährleistet, daß jeder einzelne Abgabehub des Inhalators durch die Dosierzähleinrichtung erfaßt wird.

Eine im Hinblick auf eine besonders günstige Umsetzung der Abgabehubbewegung des Abgabebehälters des Inhalators in eine zum Betrieb der Dosierzähleinrichtung erforderliche Weiterschaltbewegung vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß ein Armteil vorgesehen ist, das mit dem Schaltfinger gekoppelt ist, wobei das Armteil und der Schaltfinger einen Kniegelenkmechanismus bilden. Dadurch wird bei weiterhin vorteilhaften Kräfteverhältnissen ein vergleichsweise großer Schaltfinger-Transportweg gewährleistet, wodurch es möglich wird, die auf dem ersten Zählring vorgesehenen Ziffern derart weit voneinander beabstandet anzuordnen, daß stets nur eine einzige Ziffer des Zählrings in einem Fensterabschnitt sichtbar ist.

Die zur Zurückstellung des Schaltfingers erforderlichen Rückstellkräfte können auf vorteilhafte Weise durch elastische Verformung des Schaltfingers oder der mit dem Schaltfinger gekoppelten Betätigungselemente aufgebracht werden. Der Schaltfinger besteht in vorteilhafter Weise aus einem Kunststoffmaterial, vorzugsweise einem thermoplastisch umformbaren Kunststoffmaterial.

Eine im Hinblick auf eine zuverlässige Betätigung des Schaltfingers vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß das Armteil und der Schaltfinger über einen Betätigungsabschnitt miteinander verbunden sind. Der Betätigungsabschnitt bildet in vorteilhafter Weise eine einem Schulterabschnitt des Abgabebehälters des Inhalators zugewandte Anlagefläche, die beim Absenken des Abgabebehälters im Rahmen eines Dosierhubs aus einer Ausgangsstellung ausgelenkt, insbesondere im wesentlichen in Axialrichtung des Abgabebehälters, verschoben wird.

Das Armteil und der Schaltfinger sind gemäß einer bevorzugten Ausführungsform der Erfindung einstückig ausgebildet. Vorteilhafterweise ist bei dieser Ausführungsform der Betätigungsabschnitt in einem Verbindungsbereich zwischen Armteil und Schaltfinger vorgesehen. Die Bewegbarkeit von Armteil und Schaltfinger zueinander resultiert im wesentlichen aus der Elastizität des Werkstoffes im Bereich der entsprechenden Übergangsstellen. Die Geometrie dieser Übergangsabschnitte ist derart gewählt, daß zumindest im Rahmen der vorgesehenen Anzahl an Dosierhüben keine erhebliche Materialermüdung oder Querschnittsschwächung in den entsprechenden Verbindungsabschnitten auftritt.

Eine im Hinblick auf eine besonders hohe Funktionszuverlässigkeit der Dosierzähleinrichtung vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß zumindest der erste Zählring, vorzugsweise auch der zweite Zählring, und in besonders vorteilhafter Weise auch der Schaltfinger aus POM gefertigt sind. Die restlichen Komponenten des Inhalators können aus vergleichsweise preiswerten Kunststoffen, wie beispielsweise Polystyrol oder Polyethylen oder sonstigen, vorzugsweise thermoplastisch umformbaren Kunststoffen gebildet sein.

Eine im Hinblick auf eine besonders kompakte und funktionszuverlässige Ausführungsform der Erfindung vorteilhafte Ausgestaltung der Dosierzähleinrichtung ist dadurch gegeben, daß der Schaltfinger, der Betätigungsabschnitt und das Armteil sich im wesentlichen bogenförmig um die Rotationsachse des ersten Zählrings erstrecken. Der Radius dieses Bogens entspricht in vorteilhafter Weise im wesentlichen dem halben Durchmesser der an dem Abgabebehälter ausgebildeten Schulter. Dadurch wird es auf vorteilhafte Weise möglich, die Zählring-Weiterschaltvorrichtung unmittelbar im Bereich des Abgabeventils des Inhalators anzuordnen. Dadurch wird es auf weiterhin vorteilhafte Weise möglich, einen zur Führung des Abgabebehälters des Inhalators vorgesehenen Gehäuseabschnitt durch ein separat ausgebildetes und auf ein Mundstück des Inhalators aufgestecktes Rohrelement auszubilden.

Eine im Hinblick auf eine zuverlässige Zählung der einzelnen Dosierhübe vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß eine Rücklaufsperrvorrichtung vorgesehen ist, die eine Rastklinke aufweist, die spätestens beim Weitertransport des ersten Zählrings um einen Zählschritt in einen entsprechenden zählringseitig ausgebilde-

ten Eingriffsabschnitt eingreift. Alternativ dazu oder auch in Kombination mit einer derartigen Rastklinke ist es möglich, eine Drehung des ersten Zählrings entgegen der Zählring-Weiterschalttrichtung auch durch einen reibschlüssig sperrenden Mechanismus zu verhindern. Die Zählring-Weiterschaltvorrichtung und in vorteilhafter Weise auch die Rücklaufsperrvorrichtung sind gemäß eines besonderen Aspekts der vorliegenden Erfindung derart ausgebildet, daß diese jeden Abgabe- bzw. Dosierhub zählt.

In vorteilhafter Weise ist der Weiterschaltmechanismus derart ausgebildet, daß der erste Zählring auch dann betätigt bzw. weitergedreht wird, wenn ein Abgabehub nur unvollständig ausgeführt wurde. Eine im Hinblick auf eine besonders leichtgängige Ausgestaltung der Rücklaufsperrvorrichtung vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß mehrere Rastklinken vorgesehen sind, die mit entsprechenden am ersten Zählring ausgebildeten Eingriffsabschnitten in Eingriff bringbar sind, wobei die einzelnen Rastklinken derart versetzt ausgebildet sind, daß diese Rastklinken sich jeweils in unterschiedlichen Eingriffszuständen befinden.

Die Länge des Armteils und die Länge des Schaltfingers sowie die Position des Armteils und des Schaltfingers sind in vorteilhafter Weise derart abgestimmt, daß bei einer Verlagerung des Betätigungselementes um eine vorgegebene Wegstrecke der Eingriffsabschnitt des Schaltfingers sich in Umfangsrichtung des ersten Zählrings um eine Wegstrecke verlagert, deren Länge im wesentlichen der Schrittlänge einer umfangsseitig an dem ersten Zählring vorgesehenen Skalierung entspricht. Dadurch wird es auf vorteilhafte Weise möglich, die zur Anzeige jedes einzelnen Zählschrittes erforderliche Nummernkombination eindeutig zur Anzeige zu bringen.

Eine im Hinblick auf eine besonders zuverlässige Zählung und Anzeige der einzelnen Dosierhübe vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß die Skalierung des ersten Zählringes die Ziffern 0, 1, 2... bis 9 trägt, wobei diese Ziffern in gleicher Umfangsteilung am Umfang des ersten Zählrings ausgebildet sind. Diese Ziffern können beispielsweise durch ein Siebdruckverfahren auf den Zählring aufgebracht werden. Gemäß einer besonders bevorzugten Ausführungsform der Erfindung wird die Skalierung jedoch über ein Laser-Beschriftungsverfahren unmittelbar in das Kunststoffmaterial des Zählrings eingebrannt.

Auch die Skalierung des zweiten Zählrings trägt in vorteilhafter Weise die Ziffern 0, 1, 2... bis 9. Die Beschriftung des zweiten Zählrings kann in der gleichen Weise erfolgen wie dies bezüglich des ersten Zählring vorangehend beschrieben wurde.

Eine im Hinblick auf die Zählung einer vergleichsweise großen Hubzahl vorteilhafte Ausführungsform der Erfindung ist dadurch gegeben, daß die Skalierung des zweiten Zählrings die Zahlen 0, 1, 2... bis 20 trägt. Dadurch wird es auf vorteilhafte Weise möglich, mit lediglich zwei Zählringen insgesamt 200 Dosierhübe zu zählen. Insbesondere bei dieser Ausführungsform ist an dem ersten Zählring die Ziffernfolge 0, 1, 2... bis 9 mehrfach, insbesondere 2- oder 3fach, abfolgend angeordnet. Dadurch wird der erforderliche Weiterschalttransportweg des ersten Zählrings erheblich verkürzt.

Die Koppelungsvorrichtung zur Koppelung des zweiten Zählrings mit dem ersten Zählring zur schrittweisen Drehung des zweiten Zählrings gemeinsam mit dem ersten Zählring umfaßt in vorteilhafter Weise eine an dem ersten Zählring ausgebildete, elastisch auslenkbare und mit einem Eingriffsabschnitt des zweiten Zählrings unmittelbar in Eingriff bringbare Zunge. Diese Zunge wird gemäß einer bevorzugten Ausführungsform der Erfindung durch eine relativ zum ersten Zählring stationär angeordnete Anlaufnase ausgelenkt, welche die elastisch auslenkbare Zunge mit dem zweiten Zählring über ein Winkelintervall in Eingriff hält, das exakt dem Weiterschalt-Schrittwinkel des zweiten Zählrings entspricht. Zur Realisierung entsprechender Übersetzungsverhältnisse können bedarfsweise mehrere derartige Anlaufnasen an einem relativ zum ersten Zählring stationär angeordneten Bauteil des Inhalators ausgebildet sein. Gegebenenfalls ist es auch möglich, mehrere elastisch auslenkbare und mit dem zweiten Zählring unmittelbar in Eingriff bringbare Zungenelemente an dem ersten Zählring auszubilden.

Eine im Hinblick auf eine besonders zuverlässige Betriebsweise dieser Koppelungsvorrichtung vorteilhafte Ausführungsform des Inhalators ist dadurch gegeben, daß der zweite Zählring einen Lagerungsabschnitt aufweist, der in den ersten Zählring drehbar eingesetzt oder auf den ersten Zählring aufgesetzt ist. Durch Ausbildung entsprechender Umfangsnuten und Eingriffsabschnitte zwischen den beiden Zählringen ist es möglich, die beiden Zählringe zueinander drehbar zu lagern und ein axiales Auseinanderziehen der beiden Zählringe zu verhindern. Die Position des ersten Zählrings relativ zu der An-

laufnase kann auf vorteilhafte Weise durch eine an dem ersten Zählring ausgebildete Umfangsnut eingehalten werden.

Die Drehung des zweiten Zählringes entgegen der Weiterschalttrichtung wird in vorteilhafter Weise durch eine weitere Rücklaufsperrvorrichtung verhindert.

Weitere Einzelheiten und Merkmale der Erfindung ergeben sich aus der nachfolgenden Beschreibung eines bevorzugten Ausführungsbeispiels in Verbindung mit der Zeichnung. Es zeigen:

Fig. 1 eine Längsschnittansicht durch einen Inhalator mit Mundstück und verschiebbar angeordnetem Abgabebehälter,

Figuren 2a, 2b und 2c eine Schemadarstellung zur Erläuterung der Transportmechanik der bei dem Inhalator gem. Fig. 1 vorgesehenen Zählring-Weiterschaltvorrichtung,

Figuren 3a und 3b Schemadarstellungen zur näheren Beschreibung einer bevorzugten Geometrie eines Schaltfingers, eines Betätigungsabschnittes und eines Armteiles,

Figuren 4a, 4b und 4c Axialschnittansichten durch den ersten und den zweiten Zählring zur Erläuterung der Funktionsweise der zur unmittelbaren Koppelung der ersten und zweiten Zählringe vorgesehenen Koppelungseinrichtung,

Fig. 5 eine Längsschnittansicht durch ein Blendenteil mit integral ausgebildetem Schaltfinger sowie integral ausgebildeter Rücklaufsperrvorrichtung,

Fig. 6 eine Radialschnittansicht entlang der Linie A-A in Fig. 5 zur Erläuterung des Aufbaus der Rücklaufsperrvorrichtung und

Fig. 7 eine vereinfachte Seitenansicht des Inhalators gemäß Fig. 1 mit einem im wesentlichen rechteckig ausgebildeten und entlang der Längsachse des Inhalators ausgerichtet verlaufenden Ablesefenster.

Der in Fig. 1 vereinfacht dargestellte Inhalator zur Abgabe eines Aerosols umfaßt einen entlang seiner Axialrichtung verschiebbar gelagerten Abgabebehälter 1, und einen zur Lagerung des Abgabebehälters 1 vorgesehenen Führungsschaft 2, der passend auf einen entsprechend ausgebildeten Verbindungsabschnitt eines Winkelstückes 3 aufgesetzt ist.

In dem Winkelstück 3 ist eine Sprühdüseneinrichtung 4 angeordnet, die in einem einstückig mit dem Winkelstück 3 ausgebildeten Zapfenabschnitt 5 ausgebildet ist. In diesen Zapfenabschnitt 5 ist ein Abgaberohr 6 des Abgabebehälters 1 in abdichtender Weise eingesetzt. Das Abgaberohr 6 ist in einem Kopfbereich 7 des Abgabebehälters 1 in axialer Richtung nachgiebig aufgenommen und durch eine Federeinrichtung (nicht sichtbar) derart vorgespannt, daß der Abgabebehälter 1 über das Abgaberohr 6 von dem Zapfenabschnitt 5 hinweggedrängt wird.

Im oberen Bereich des Führungsschaftes 2 ist eine Ausmuldung 8 vorgesehen, aus welcher ein Bodenbereich 9 des Abgabebehälters 1 hervorragt. Durch Aufbringen einer Druckkraft auf diesen Bodenbereich 9 kann der Abgabebehälter 1 zu dem Zapfenabschnitt 5 hin verschoben werden, wie dies durch Strichpunktlinien vereinfacht angedeutet ist. Sobald das Abgaberohr 6 an einer entsprechend in dem Zapfenabschnitt 5 ausgebildeten Anlagefläche ansteht, wird das Abgaberohr 6 in den Abgabebehälter 1 hineingedrängt und wirkt dabei mit einem Ventilmechanismus zusammen, über welchen eine vorbestimmte Menge eines in dem Abgabebehälters 1 bevorrateten Mediums aus diesem entströmen und über das Abgaberohr 6 zur Sprühdüseneinrichtung 4 und von dort aus in einen in dem Winkelstück 3 gebildeten Ansaugbereich 10 vordringen kann. Diese nachfolgend als Abgabehub bezeichnete Eintauchbewegung des Abgabebehälters 1 wird durch eine Dosierzähleinrichtung 11 gezählt.

Die Dosierzähleinrichtung 11 umfaßt hierzu einen ersten Zählring 12 und einen zweiten Zählring 13. Der erste Zählring 12 und der zweite Zählring 13 sind zueinander drehbar angeordnet. Der zweite Zählring 13 weist einen Dreh-Lagerungsabschnitt auf, der in einen entsprechenden Öffnungsbereich des ersten Zählrings 12 eingesetzt ist.

Der erste Zählring 12 und der zweite Zählring 13 sind coaxial zur Längsachse X des Abgabebehälters 1 angeordnet. Die beiden Zählringe 12, 13 sind in einem rohrförmigen Abschnitt des Winkelstückes 3 drehbewegbar angeordnet. An den Außenumfangsflächen der beiden Zählringe 12, 13 sind in nachfolgend noch näher erläuteter Weise Ziffern vorgesehen, die über eine Fensteröffnung 14, die in dem Winkelstück 3 ausgebildet ist, ablesbar sind.

Bei der in Fig. 1 dargestellten Ausführungsform des Inhalators befindet sich der zweite Zählring in etwa auf Höhe einer an dem Aufnahmebehälter 1 ausgebildeten Schulter 15. Der zweite Zählring 13 ist hinsichtlich seines Innendurchmessers derart dimensioniert, daß die Schulter 15 des Abgabebehälters 1 über eine der Abgabehublänge entsprechende Wegstrecke in den zweiten Führungsring 13 hinein eindringen kann.

In einem zwischen den beiden Zählringen 12, 13 und dem Kopfbereich 7 des Abgabebehälters verbleibenden Ringraum ist eine Zählring-Weiterschaltvorrichtung 16 vorgesehen, welche den coaxial zum Abgabebehälter 1 angeordneten Zählring 12 bei jedem Abgabehub um einen vorbestimmten Drehwinkel weiterdreht.

Die Zählring-Weiterschaltvorrichtung 16 ist bei der hier dargestellten Ausführungsform einstückig mit einem Blendenteil 17 ausgebildet, das in dem Winkelstück 3 eingesetzt ist. Das Blendenteil 17 bildet einen sich im wesentlichen ringförmig um die Längsachse X erstreckenden Lagerungsabschnitt, an welchem der zweite Zählring 13 gelagert ist.

An dem Blendenteil 17 ist einstückig mit diesem je eine Rücklaufsperrvorrichtung zum Sperren einer Drehbewegung der Zählringe 12, 13 in Gegenrichtung vorgesehen.

Das Blendenteil 17 ist ferner mit einer Anlaufnase versehen, die Teil einer im folgenden, ausführlich beschriebenen Koppelungsvorrichtung zur direkten Koppelung der beiden Zählringe 12, 13 bildet.

Die Zählring-Weiterschaltvorrichtung ist innerhalb der beiden Zählringe 12, 13 derart angeordnet, daß ein Betätigungsabschnitt 19 derselben mit der an dem Abgabebehälter 1 ausgebildeten Schulter in Berührungskontakt bringbar ist.

Die Funktionsweise der Zählring-Weiterschaltvorrichtung wird durch die Figuren 2a, 2b und 2c verdeutlicht. Die in den Figuren 2a, 2b und 2c dargestellte Zählring-Weiterschaltvorrichtung 16 umfaßt ein nachfolgend als Schaltfinger 20 bezeichnetes Getriebeglied, das bei der hier dargestellten Ausführungsform über den Betätigungsabschnitt 19 mit einem Armteil 21 gekoppelt ist. Bei der hier dargestellten Ausführungsform sind der Schaltfinger 20, der Betätigungsabschnitt 19 und das Armteil 21 einstückig miteinander ausgebildet und aufgrund der Eigenelastizität des hierbei verwendeten Kunststoffmaterials bewegbar miteinander gekoppelt.

Das Armteil 21 weist ein dem Betätigungsabschnitt 19 abgewandtes, stationäres Ende auf, über welches sich der gesamte durch Armteil 21, Betätigungsabschnitt 19 und Schaltfinger 20 gebildete Gelenkmechanismus in Umfangsrichtung des ersten Zählrings 12 abstützt.

Bei der hier gezeigten Anordnung bilden das Armteil 21 und der Schaltfinger 20 einen Kniehebel-Gelenkmechanismus. Durch allmähliches Niederdrücken des Betätigungsabschnittes entlang der hier angedeutet dargestellten Längsachse X des Abgabebehälters 1 werden das Armteil 21 und der Schaltfinger 20 allmählich in die in Fig. 2 dargestellte Endlage geschwenkt. Bezogen auf eine zu der Achse X senkrechte Projektionsfläche ergibt sich zwischen der Projektion der Position des bewegbaren Endes des Armteils 21 gegenüber der Projektion der Position dieses Endes in der Endstellung ein Versatz. Entsprechend diesem Versatz wird der Betätigungsabschnitt in Umfangsrichtung des ersten Zählrings verlagert. Auch der Schaltfinger 20 wird beim Niederdrücken des Betätigungsabschnittes geschwenkt, so daß sich dabei insgesamt eine Verlängerung der Projektion des Schaltfingers 20 in die zur genannten Längsachse X senkrechte Projektionsfläche ergibt. Nachdem der Schaltfinger 20 mit seinem dem ersten Zählring 12 abgewandten Endabschnitt ebenfalls mit dem Betätigungsabschnitt gekoppelt ist, ergibt sich eine Addition der durch Schwenken des Armteils und des Schaltfingers 20 erreichten Versatzstrecken. Zur Übertragung der entsprechenden in Umfangsrichtung des ersten Zählrings wirksamen Bewegungskomponente auf den ersten Zählring ist der Schaltfinger 20 mit einem Eingriffsabschnitt 22 versehen, der mit zählringseitig ausgebildeten Stellelementen in Eingriff bringbar ist. Durch entsprechende Verlagerung des Eingriffsabschnittes 22 des Schaltfingers 20 in Umfangsrichtung des ersten Zählrings 12 wird aufgrund des Eingriffs mit den Stellelementen 23 der erste Zählring 12 in Umfangsrichtung um eine vor-

bestimmte Wegstrecke weitertransportiert. Diese vorbestimmte Wegstrecke entspricht im wesentlichen dem Abstand zwischen zwei benachbarten Stellelementen 23. Nachdem der Betätigungsabschnitt 19 durch die an dem Abgabebehälter 1 ausgebildete Schulter in eine untere Endlage verlagert ist, federt beim Zurückfahren des Abgabebehälters 1 in dem Führungsschaft 2 auch der Betätigungsabschnitt 19 aufgrund der Eigenelastizität des Armteils 21 wieder in seine Ausgangsstellung zurück. Bei dieser Rückzugsbewegung überspringt der Schaltfinger 20 bzw. dessen Eingriffsabschnitt das beim nächsten Zählhub mit diesem in Eingriff tretende Stellelement 23 und federt unmittelbar hinter diesem Stellelement 23 wieder in eine Eingriffsstellung. Bei erneutem Niederdrücken des Betätigungsabschnittes 19 schiebt der Eingriffsabschnitt 22 des Schaltfingers das an dem ersten Zählring ausgebildete Stellelement 23 wieder um ein Transportintervall in Umfangsrichtung weiter. Hierbei tritt die nächstfolgende, an der Umfangsfläche des ersten Zählrings 12 vorgesehene Ziffer in die Fensteröffnung 14.

Bei den Darstellungen gemäß Fig. 2a, Fig. 2b und Fig. 2c ist die zur Weiterschaltung des ersten Zählrings vorgesehene Zählring-Weiterschaltvorrichtung in Form einer Abwicklung dargestellt.

Bei der in Fig. 1 dargestellten Ausführungsform erstreckt sich wie in Fig. 3b dargestellt der durch das Armteil 21, dem Betätigungsabschnitt 19 und den Schaltfinger 20 gebildete Gelenkmechanismus der Zählring-Weiterschaltvorrichtung im wesentlichen bogenförmig um die Längsachse X des Abgabebehälters 1 (in Fig. 3b nicht dargestellt). Durch Niederdrücken des in Fig. 3b dargestellten Betätigungsabschnittes 19 wird ein Versatz des Eingriffsabschnittes 22 des Schaltfingers 21 in Umfangsrichtung erreicht. Durch den Versatz des Eingriffsabschnittes 22 des Schaltfingers 20 in Umfangsrichtung kann der erste Zählring 12 um einen Weiterschaltwinkel α weitergedreht werden. Für den Fall, daß am Außenumfang des ersten Zählrings 12 drei Ziffern-Folgen der Ziffern 0 bis 9 vorgesehen sind, beträgt der Weiterschaltwinkel α ca. 12° . Bei einem derartigen Drehwinkel ergibt sich bereits bei einem dem Durchmesser des Abgabebehälters 1 entsprechenden Durchmesser des ersten Zählrings 12 ein hinreichend großer Abstand zwischen den benachbarten Ziffern, wodurch eine gute Ablesbarkeit der einzelnen Ziffern in der Fensteröffnung 14 gewährleistet ist. Entsprechend der Anzahl der am Umfang des ersten Zählrings 12 abgebildeten Ziffernfolgen wird das Übersetzungsverhältnis zwischen dem ersten Zählring 12 und dem zweiten Zählring 13 bestimmt. Das erforderliche

Übersetzungsverhältnis zwischen den beiden Zählringen kann in vorteilhafter Weise durch die nachfolgend in Verbindung mit den Figuren 4a, 4b und 4c beschriebene Koppelungsvorrichtung erreicht werden.

Die in den Figuren 4a, 4b und 4c in unterschiedlichen Koppelungszuständen dargestellte Koppelungsvorrichtung umfaßt ein einstückig mit dem ersten Zählring 12 ausgebildetes Zungenelement 24, das sich bei der Darstellung gemäß Fig. 4a in einer Neutralstellung befindet. An dem Zungenelement 24 ist ein Mitnehmerabschnitt 25 ausgebildet. Dieser Mitnehmerabschnitt 25 ist mit Eingriffsvorsprüngen 26, die einstückig mit dem zweiten Zählring 13 ausgebildet sind, in Eingriff bringbar. Hierzu ist eine am Blendenteil 17 ausgebildete Anlaufnase 27 vorgesehen, die das Zungenelement in eine Kopplungsposition drängt, in welcher der am Ende des Zungenelementes 24 ausgebildete Mitnehmerabschnitt 25 mit dem unmittelbar benachbarten Eingriffsvorsprung 26 des zweiten Zählrings 13 in Eingriff tritt. Sobald ein entsprechender Eingriffszustand hergestellt ist, wird der zweite Zählring 13 gemeinsam mit dem ersten Zählring 12 solange weitergedreht, bis das Zungenelement 24 von der Anlaufnase 27 abfällt und damit der Eingriffszustand zwischen dem Mitnehmerabschnitt 25 und dem entsprechenden Eingriffsvorsprung 26 aufgehoben ist. Sobald dieser Eingriffszustand aufgehoben ist, kann der erste Zählring 12 über eine vorbestimmte Wegstrecke, unabhängig von dem zweiten Zählring 13, weitergedreht werden.

In Fig. 4b ist das Zungenelement 24 durch die in dieser Darstellung nicht sichtbare Anlaufnase 27 in die genannte Koppelungsstellung gedrängt. Die Länge der hier durch den Buchstaben b angegebenen Koppelungsstrecke ist durch die Geometrie der Anlaufnase 27 bestimmt.

In Fig. 4c ist das Zungenelement 24 bereits in seine Ausgangsstellung zurückgefedert und der Eingriff zwischen dem Mitnehmerabschnitt 25 und dem entsprechenden Eingriffsvorsprung 26 des zweiten Zählrings 13 aufgehoben.

Das bei der hier dargestellten Ausführungsform vorgesehene Zungenelement 24 ist einstückig mit dem ersten Zählring 12 als im wesentlichen flachblattfederartiges Bauteil ausgebildet. Im Hinblick auf die erforderlichen mechanischen Eigenschaften des Zungenelementes sowie im Hinblick auf eine besonders hohe Maßhaltigkeit des ersten

Zählrings 12 ist dieser vorzugsweise aus POM-Kunststoffmaterial gebildet. Bei der hier dargestellten Ausführungsform sind an der Außenumfangsfläche des zweiten Zählrings 13 die Zahlen 1 bis 20 angeordnet. Durch die beiden Zählringe 12, 13 können in dieser Ausführungsform 200 Dosierungen einzeln gezählt werden. Mit zwei Zählringen ist eine Zählung bis 999 möglich. Unter Verwendung eines dritten Zählrings sind 9.999 Zählungen möglich. Die Koppelungsvorrichtung zur Koppelung eines dritten Zählrings mit dem zweiten Zählring entspricht in ihrem Aufbau in vorteilhafter Weise der zwischen dem ersten Zählring 12 und dem zweiten Zählring 13 vorgesehenen Koppelungsvorrichtung.

Zur Verhinderung einer Drehbewegung des zweiten Zählrings 13 relativ zu dem ersten Zählring 12 entgegen der durch die Koppelungsvorrichtung 24, 25, 26 sowie die Anlaufnase 27 bestimmten Transportrichtung ist für die Zählringe 12 und 13 eine Rücklaufsperrvorrichtung 29 vorgesehen, die mit entsprechenden Rastabschnitten in Eingriff bringbar ist. Bei der hier dargestellten Ausführungsform werden diese Rastabschnitte der Rücklaufsperrvorrichtung auf einfache Weise durch die Eingriffsvorsprünge 23 und 26 gebildet.

In Fig. 5 sind das bei dem Inhalator gemäß Fig.1 vorgesehene Blendenteil 17 und der darauf aufgesetzte erste Zählring 12 vergrößert dargestellt. Bei der gezeigten Ausführungsform umfaßt die zur Verhinderung einer Drehbewegung des ersten Zählrings 12 entgegen der Zählringweiterrichtung vorgesehene Rücklaufsperrvorrichtung 28 ein einstückig mit dem Blendenteil 17 ausgebildetes Federelement 29, das mit Rastvorsprüngen 30, die am Innenumfang des ersten Zählrings 12 ausgebildet und der Zählringrotationsachse X zugewandt sind, in Eingriff bringbar ist. Die bei dieser Ausführungsform verwirklichte spezielle Geometrie des einstückig mit dem Blendenteil 17 ausgebildeten Federelementes geht aus der in Fig.6 vereinfacht dargestellten Radialschnittansicht entlang der Linie A-A hervor.

Wie aus der Darstellung gemäß Fig.5 weiter ersichtlich, weist das zur direkten Weiterdrehung des zweiten Zählrings 13 (nicht dargestellt) vorgesehene Zungenelement 24 einen flach rechteckförmigen Querschnitt auf und ragt von einer Innenumfangswandung des ersten Zählrings 12 in einen zwischen dem ersten Zählring 12 und dem Blendenteil 17 gebildeten Ringraum hinein. Dieser Ringraum ist in seinem oberen Bereich von einem Anlaufabschnitt 31 begrenzt, welcher den hier nicht dargestellten

zweiten Zählring 13 in axialer Richtung lagert. Das hier gezeigte Blendenteil 17 bildet ferner einen zweiten Anlaufabschnitt 32, durch welchen der erste Zählring 12 in axialer Richtung gelagert ist. Im Hinblick darauf, daß sich die ersten und zweiten Zählringe 12, 13 gegeneinander in axialer Richtung aufgrund der in Fig. 1 gezeigten Schulterstruktur abstützen, sind durch die genannten ersten und zweiten Anlaufabschnitte 31 und 32 die beiden Zählringe 12, 13 insgesamt in axialer Richtung gelagert.

Lediglich in Strichpunktlinien ist in der Schnittansicht gemäß Fig. 5 auch die zur Auslenkung des am Endabschnitt des Zungenelementes 24 vorgesehenen Mitnehmerabschnittes 25 vorgesehene Anlaufnase 27 gezeigt. Die einstückig mit dem Blendenteil 17 ausgebildete Zählringweitschaltvorrichtung 16, insbesondere deren Armteil 21, ist ebenfalls in Strichpunktlinien angedeutet dargestellt.

Die Ausbildung der angesprochenen Filigranstrukturen an einem in einem Hauptgehäuseabschnitt des Inhalators einsetzbaren Blendenteil erweist sich unter fertigungstechnischen Gesichtspunkten als vorteilhaft. Grundsätzlich ist es jedoch auch möglich, auf das Blendenteil 17 zu verzichten und die zur Sperrung der Rücklaufdrehbewegung des ersten Zählrings 12 vorgesehene Rücklaufsperrvorrichtung 28, die Zählringweitschaltvorrichtung und die entsprechenden Lagerungsabschnitte zur Lagerung der ersten und zweiten Zählringe 12, 13 unmittelbar, d.h. einstückig mit dem Winkelstück 3 auszubilden.

Die in der Schnittansicht gemäß Fig. 6 erkennbare Teilung der an dem ersten Zählring 12 vorgesehenen Rastvorsprünge 30 ist derart festgelegt, daß die durch das Federelement 23 gebildete Rücklaufsperrvorrichtung den ersten Zählring 12 nach jedem Zählschritt erneut verrastet. Durch entsprechende Verkleinerung der Rastvorsprünge 30 und Verkleinerung der Abstände zwischen den abfolgenden Rastvorsprüngen ist es möglich, das Rastintervall der Rücklaufsperrvorrichtung zu verkleinern und damit eine Drehbewegung des ersten Zählrings auch dann zu verhindern, wenn dieser erste Zählring 12 nicht um einen vollständigen Zählschritt weitergedreht ist. Durch entsprechende Auslegung der Geometrie des Federelementes 29 kann der durch die Rücklaufsperrvorrichtung 28 erzeugte Drehwiderstand auf einem vergleichsweise geringen Wert gehalten werden.

In Fig.7 ist eine Seitenansicht (Seitenansicht von rechts) des in Fig.1 dargestellten Inhalators gezeigt. In der auf seiten des Ansaugbereiches 10 angeordneten Fensteröffnung 14 ist hier die Nummernangabe „200“ ablesbar. Diese Nummernangabe wird gebildet durch die über den ersten Zählring 12 in die Fensteröffnung 14 geschobene Ziffer „0“ und die über den zweiten Zählring 13 in die Fensteröffnung geschobene Zahl „20“. Im Falle einer beispielsweise abwärts laufenden Zählung wird bei der nächsten Betätigung des Inhalators sowohl der erste Zählring 12 als auch der zweite Zählring 13 um ein Winkelintervall (α) um die Längsachse X des Inhalators weitergedreht. Hierbei gelangt über den ersten Zählring 12 die Ziffer „9“ und über den zweiten Zählring 13 die Zahl „19“ in die Fensteröffnung 14. Damit wird in der Fensteröffnung 14 die Zahl „199“ angezeigt. Bei der nächsten Betätigung des Inhalators wird nur der erste Zählring 12 weitergedreht und die Ziffer „8“ gelangt in die Fensteröffnung 14. In der Fensteröffnung 14 wird nunmehr die Zahl „198“ angezeigt. Im Rahmen der nachfolgenden Dosierhübe wird zunächst nur der erste Zählring 12 jeweils um einen Zählschritt weitergedreht, bis die Ziffer „1“ in die Fensteröffnung 14 eintritt und in der Fensteröffnung 14 die Zahl „191“ angezeigt wird. Bei der nächstfolgenden Betätigung des Inhalators wird über den in den Fig.4a bis 4c gezeigten Koppelungsmechanismus der erste Zählring 12 unmittelbar mit dem zweiten Zählring gekoppelt und der erste Zählring 12 gemeinsam mit dem zweiten Zählring 13 um einen Zählschritt weitergedreht. Hierbei gelangt die umfangsseitig an dem ersten Zählring vorgesehene Ziffer 0 und die umfangsseitig an dem zweiten Zählring 13 vorgesehene Zahl „19“ in die Fensteröffnung 14. In der Fensteröffnung 14 wird nunmehr die Zahl „190“ angezeigt. Sobald die Zahl „19“ vollständig in die Fensteröffnung 14 gelangt ist, tritt der zur direkten Koppelung der ersten und zweiten Zählringe 12,13 vorgesehene Koppelungsmechanismus wieder in eine Freigabestellung und der erste Zählring 12 wird im Rahmen der nächsten Dosierhübe unabhängig von dem zweiten Zählring 13 gedreht, bis erneut die an dem ersten Zählring 12 vorgesehene Ziffer „1“ in die Fensteröffnung 14 gelangt.

Um eine im wesentlichen gleiche Teilung der Ziffernfolgen an dem ersten Zählring 12 und dem zweiten Zählring 13 zu erreichen, ist die Ziffernfolge 0 bis 9 zweifach abfolgend am Außenumfang des ersten Zählrings 12 ausgebildet. Bei einer, bezogen auf die Umfangsrichtung der Zählringe schmalere Ausgestaltung der Fensteröffnung 14 können an dem zweiten Zählring 13 beispielsweise die Zahlen 0 bis 40 ausgebildet

werden. Bei entsprechender Abstimmung des Übersetzungsverhältnisses zwischen dem ersten und dem zweiten Zählring 12, 13, beispielsweise durch Vervielfachung der zum Weitertransport des zweiten Zählrings vorgesehenen Anzahl an Anlaufnasen 27 können mit lediglich zwei Zählringen Hubzahlen von 0 bis 400 aufsteigend oder bedarfsweise auch abfallend gezählt werden.

Die Erfindung ist nicht auf das vorgehend beschriebene Ausführungsbeispiel beschränkt. Beispielsweise ist es auch möglich, auf das bei dem vorangehend beschriebenen bevorzugten Ausführungsbeispiel des Inhalators vorgesehene Blendenteil 17 zu verzichten und die entsprechenden Funktionsteile integral mit dem Gehäuse des Inhalators auszubilden. Bedarfsweise können durch den beschriebenen Inhalator auch aerosolfreie Wirkstoffe abgegeben werden. Zur Bereitstellung eines noch größeren Zählbereiches ist es möglich, einen dritten Zählring vorzusehen, der über einen entsprechenden Koppelungsmechanismus mit dem zweiten Zählring koppelbar ist.

Schutzansprüche:

1. Inhalator zur Abgabe eines Aerosols, mit:

- einer Dosierzähleinrichtung (11),
- einer Gehäuseeinrichtung (2, 3), und
- einem relativ zu der Gehäuseeinrichtung (2, 3) entlang seiner Längsachse verschiebbar angeordneten Aerosol-Abgabebehälter (1),

gekennzeichnet durch

- einen ersten Zählring (12), der coaxial zur Längsachse (X) des Aerosol-Abgabebehälters (1) angeordnet ist und um diese Längsachse (X) drehbar ist,
- einen zweiten Zählring (13), der coaxial zu dem ersten Zählring (12) angeordnet und mit diesem direkt koppelbar und relativ zu diesem drehbar ist,
- einer Zählringweitschaltvorrichtung (16) zur Drehung des ersten Zählringes (12) bei Betätigung des Inhalators, und
- einer Koppelungsvorrichtung (24, 25, 26, 27) zur Koppelung des zweiten Zählringes (13) mit dem ersten Zählring (12), zur schrittweisen Drehung des zweiten Zählringes (13) gemeinsam mit dem ersten Zählring (12),
- wobei die Zählringweitschaltvorrichtung (16) einen Betätigungsabschnitt (19) und einen mit diesem gekoppelten Schaltfinger (20) aufweist, der zur Drehung des zugehörigen Zählringes (12) mit Stellelementen (23) desselben in Eingriff bringbar ist.

2. Inhalator nach Anspruch 1, **dadurch gekennzeichnet**, daß der Schaltfinger (20) von der Rotationsachse (X) beabstandet und zu dieser geneigt angeordnet ist.

3. Inhalator nach Anspruch 1 oder 2 **dadurch gekennzeichnet**, daß der Schaltfinger (20) aus einer Ausgangsstellung in eine zu dieser Ausgangsstellung geneigte Endstellung auslenkbar ist, und in der Ausgangsstellung ein Eingriffsabschnitt des Schaltfingers (20) federnd nachgiebig in eine Eingriffsstellung mit dem ersten Zählring (12) gedrängt ist.

4. Inhalator nach mindestens einem der Ansprüche 1 bis 3, **dadurch gekennzeichnet**, daß ein Armteil (21) vorgesehen ist das mit dem Schaltfinger (20) gekoppelt

ist, und daß das Armteil (21) und der Schaltfinger (20) einen Kniegelenkmechanismus bilden.

5. Inhalator nach mindestens einem der Ansprüche 1 bis 4, **dadurch gekennzeichnet**, daß das Armteil (21) elastisch nachgiebig ausgebildet ist und an einem stationären Teil (17) insbesondere einem mit der Gehäuseeinrichtung (2, 3) gekoppelten Teil abgestützt ist.

6. Inhalator nach mindestens einem der Ansprüche 1 bis 5, **dadurch gekennzeichnet**, daß das Armteil (21) und der Schaltfinger (20) über den Betätigungsabschnitt (17) miteinander verbunden sind.

7. Inhalator nach mindestens einem der Ansprüche 1 bis 6, **dadurch gekennzeichnet**, daß das Armteil (21) und der Schaltfinger (20) einstückig ausgebildet sind.

8. Inhalator nach mindestens einem der Ansprüche 1 bis 7, **dadurch gekennzeichnet**, daß das Armteil (21) und der Schaltfinger (20) aus einem Kunststoffmaterial insbesondere POM ausgebildet sind.

9. Inhalator nach mindestens einem der Ansprüche 1 bis 8, **dadurch gekennzeichnet**, daß der Betätigungsabschnitt (19) in eine zur Rotationsachse des ersten Zählringes (12) im wesentlichen parallele Richtung geführt ist, und daß das Armteil (21) ein Federelement bildet das den Schaltfinger (20) in seine Ausgangsstellung drängt.

10. Inhalator nach mindestens einem der Ansprüche 1 bis 9, **dadurch gekennzeichnet**, daß der Betätigungsabschnitt (19) eine Anlagefläche bildet die mit einer Schulter (19) des Aerosol-Abgabebehälters (1) in Anlage bringbar ist.

11. Inhalator nach mindestens einem der Ansprüche 1 bis 10, **dadurch gekennzeichnet**, daß der Schaltfinger (20), der Betätigungsabschnitt (19) und das Armteil (21) sich im wesentlichen bogenförmig um die Rotationsachse (X) des ersten Zählringes (12) erstrecken.

12. Inhalator nach mindestens einem der Ansprüche 1 bis 11, **dadurch gekennzeichnet**, daß eine Rücklaufsperrvorrichtung (28) vorgesehen ist, zum Verhindern einer Drehbewegung des ersten Zählrings (12) entgegen der Zählrichtung.
13. Inhalator nach Anspruch 12, **dadurch gekennzeichnet**, daß die Rücklaufsperrvorrichtung (28) eine Rastklinke aufweist.
14. Inhalator nach mindestens einem der Ansprüche 1 bis 13, **dadurch gekennzeichnet**, daß die Länge des Armteiles (21) und die Länge des Schaltfingers (20) sowie die Position des Armteiles (21) und des Schaltfingers (2a) derart abgestimmt sind, daß bei einer Verlagerung des Betätigungselementes (19) um eine vorgegebene Wegstrecke der Eingriffsabschnitt (22) des Schaltfingers (20) sich in Umfangsrichtung des ersten Zählrings (12) um eine Wegstrecke verlagert deren Länge im wesentlichen der Schrittlänge einer umfangsseitig an dem ersten Zählring (12) vorgesehenen Skalierung entspricht.
15. Inhalator nach mindestens einem der Ansprüche 1 bis 14, **dadurch gekennzeichnet**, daß die Skalierung des ersten Zählrings (12) die Ziffern 0, 1, 2... bis 9 trägt.
16. Inhalator nach mindestens einem der Ansprüche 1 bis 15, **dadurch gekennzeichnet**, daß die Skalierung des zweiten Zählrings (13) die Ziffern 0, 1, 2,... bis 9 trägt.
17. Inhalator nach mindestens einem der Ansprüche 1 bis 15, **dadurch gekennzeichnet**, daß die Skalierung des zweiten Zählrings (13) die Zahlen 0, 1, 2,...9, 10, 11,... 19 und 20 trägt.
18. Inhalator nach Anspruch 15, **dadurch gekennzeichnet**, daß die Ziffernfolge 0, 1...9 am Umfang des ersten Zählrings (12) mehrfach; insbesondere dreimal abfolgend vorgesehen ist.
19. Inhalator nach mindestens einem der Ansprüche 1 bis 18, **dadurch gekennzeichnet**, daß der zweite Zählring (13) einen Lagerungsabschnitt aufweist, der in den ersten Zählring (12) drehbar eingesetzt oder auf diesen aufgesetzt ist.

20. Inhalator nach mindestens einem der Ansprüche 1 bis 19, **dadurch gekennzeichnet**, daß die Koppelungsvorrichtung (24, 25, 26, 27) ein Mitnehmerelement aufweist das mit dem ersten Zählring (12) gekoppelt ist.

21. Inhalator nach Anspruch 20, **dadurch gekennzeichnet**, daß das Mitnehmerelement durch ein elastisch nachgiebiges Zungenelement (24) gebildet ist, das einstückig mit dem ersten Zählring (12) ausgebildet ist.

22. Inhalator nach Anspruch 20 oder 21, **dadurch gekennzeichnet**, daß der zweite Zählring (13) einen Verzahnungsabschnitt aufweist der mit dem Zungenelement (24) in Eingriff bringbar ist.

23. Inhalator nach einem der Ansprüche 20 bis 22, **dadurch gekennzeichnet**, daß die Koppelungsvorrichtung eine stationäre Anlauf-Nase (27) aufweist, zum Auslenken des Zungenelements (24) derart, daß dieses über eine, einem Zählschritt entsprechende Umfangslänge mit dem zweiten Zählring (13) in Eingriff tritt und den zweiten Zählring (13) um diese Umfangslänge weiterdreht.

24. Inhalator nach Anspruch 23, **dadurch gekennzeichnet**, daß drei in Umfangsrichtung gleichmäßig beabstandete stationäre Anlauf-Nasen (27) vorgesehen sind derart, daß der zweite Zählring (13) bei einem vollständigen Umlauf den zweiten Zählring (13) um drei Zählschritte weiterdreht.

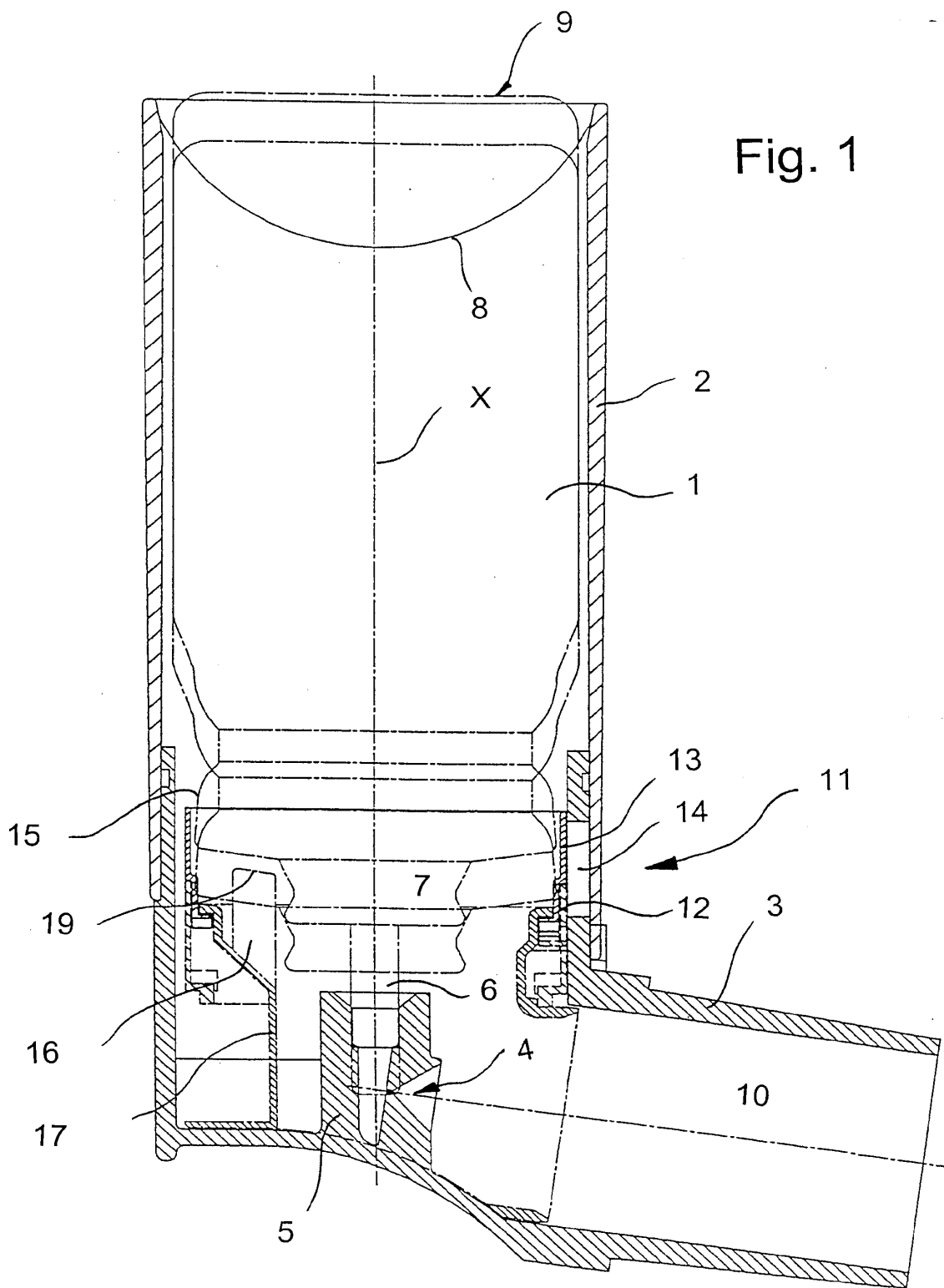


Fig. 2a

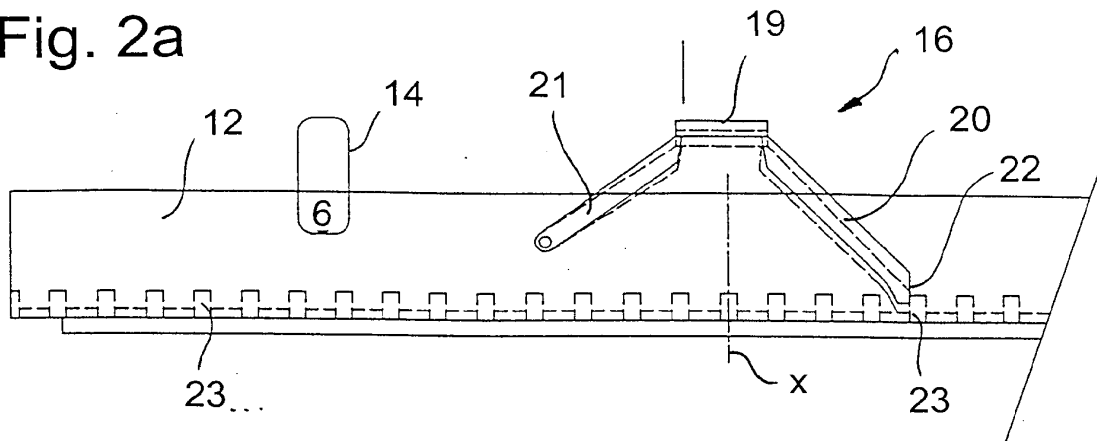


Fig. 2b

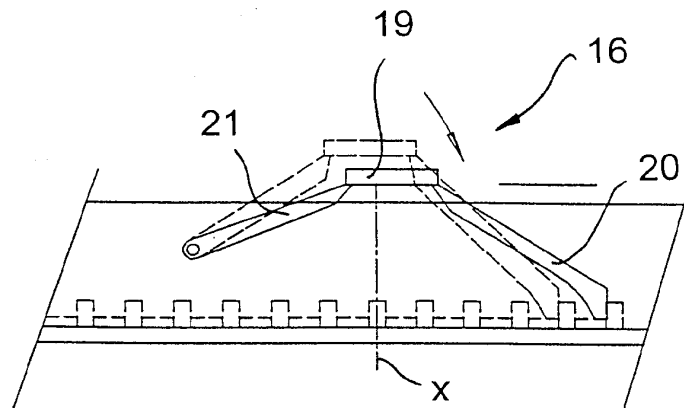


Fig. 2c

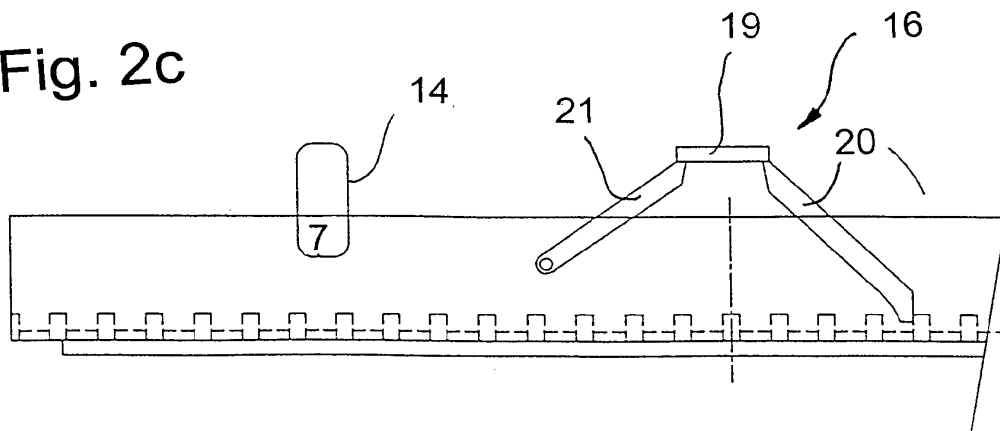


Fig. 3a

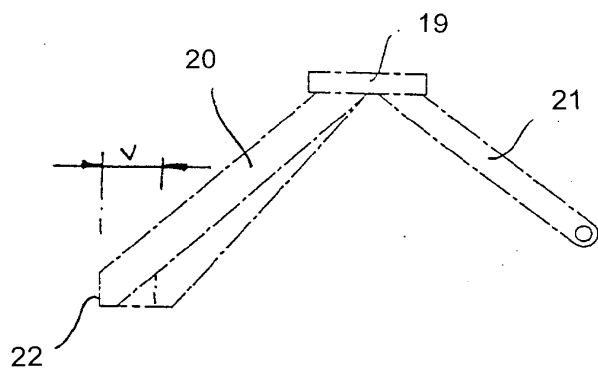
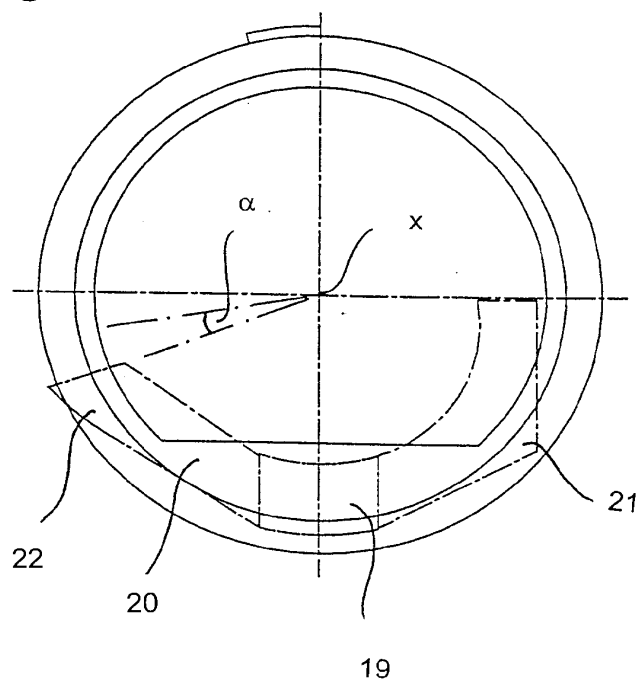


Fig. 3b



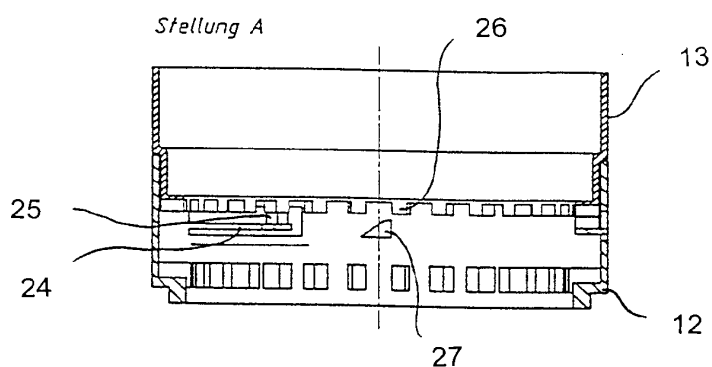


Fig. 4a

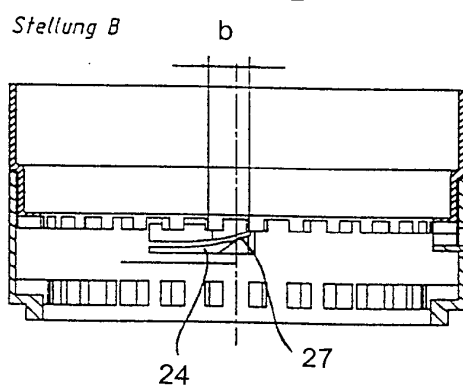


Fig. 4b

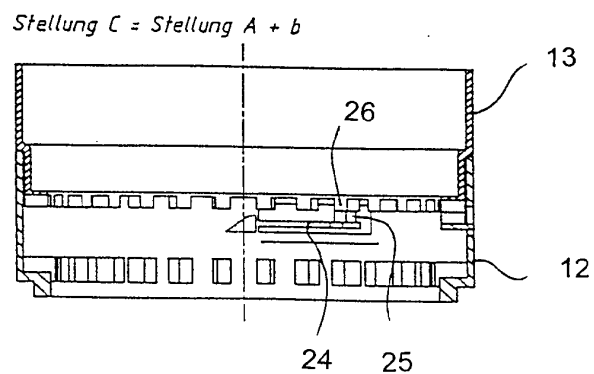


Fig. 4c

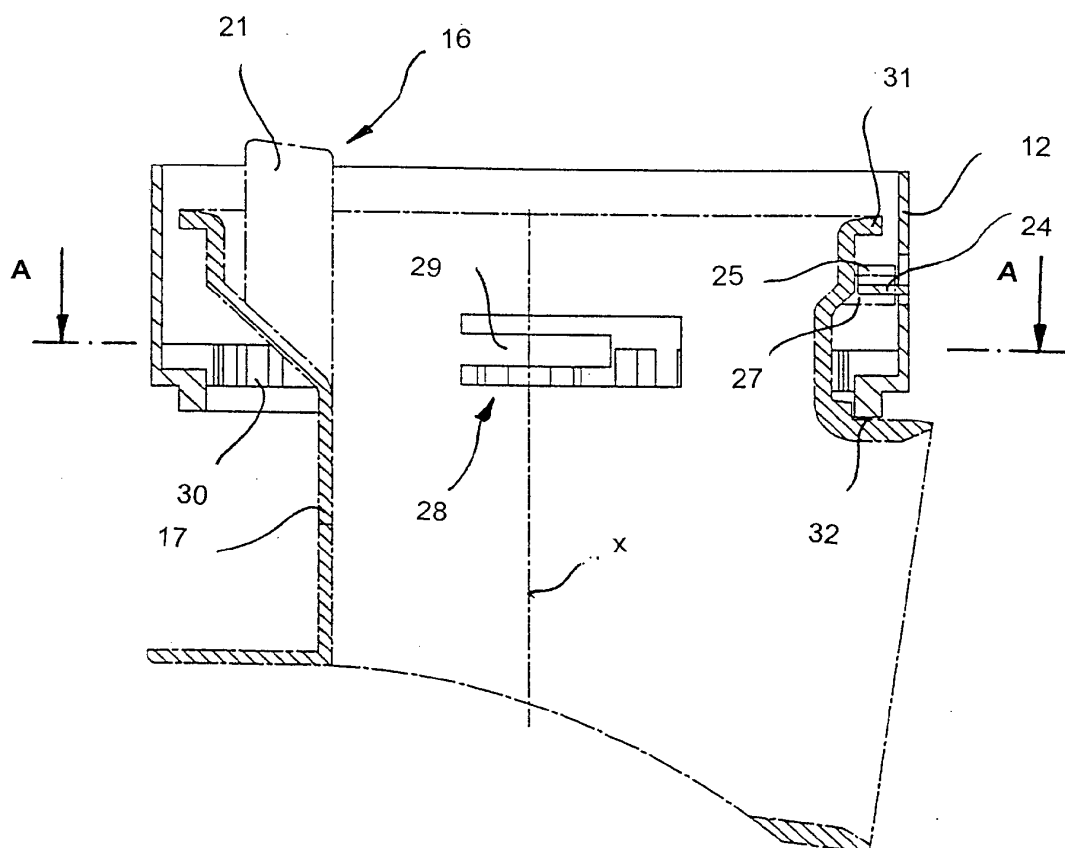


Fig. 5

A-A

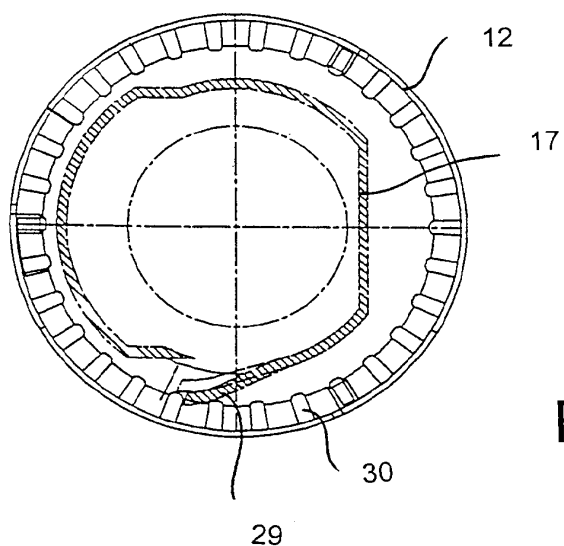


Fig. 6

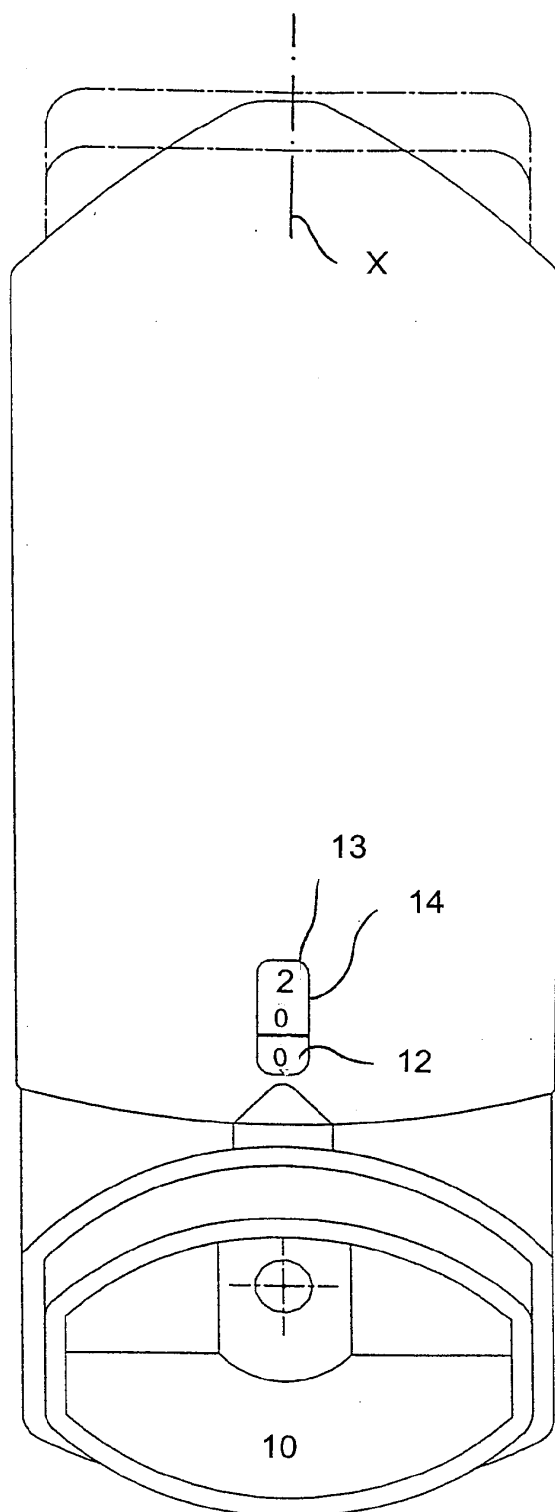


Fig. 7

INTERNATIONAL SEARCH REPORT

International Application No
PC/EP 99/05939

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M15/00 G06M1/08 G06M1/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M G06M B65D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2 022 212 A (VANTOREX LTD) 31 July 1970 (1970-07-31) page 3, line 37 -page 4, line 24 figures 1,2	1, 15, 16, 20
Y	---	2-7, 9, 12-14, 17-19
Y	EP 0 480 488 A (ELETTRIO PLASTICA SPA) 15 April 1992 (1992-04-15) column 4, line 4 - line 33 figures 4,5 --- -/--	2-7, 9, 14

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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Date of the actual completion of the international search

24 November 1999

Date of mailing of the international search report

01/12/1999

Name and mailing address of the ISA

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Lakkis, A

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 99/05939

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 94 14492 A (AMBROSIO THOMAS J ;MANTHENA SRINIVAS (US); SCHERING CORP (US); WIL) 7 July 1994 (1994-07-07) page 30, line 5 -page 31, line 5 page 49, line 26 - line 30 page 50, line 13 - line 25 page 65, line 35 -page 66, line 14 figures 3,4,67,71,75,105	12,13, 17-19
A	----	2,3,5,11
A	WO 96 29278 A (SENETICS INC) 26 September 1996 (1996-09-26) ----	
E	EP 0 949 584 A (BASON NEIL PETER) 13 October 1999 (1999-10-13) paragraphs '0018!-'0021! figures 2,3 -----	1,15-17, 19-22

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

page 2 of 2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PC, EP 99/05939

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR 2022212 A	31-07-1970	AU 6168869 A GB 1290484 A ZA 6906865 A	08-04-1971 27-09-1972 27-05-1971
EP 0480488 A	15-04-1992	IT 1243820 B AT 113486 T AU 646873 B AU 8025891 A CA 2046806 A DE 69104950 D DE 69104950 T ES 2066336 T JP 5228213 A US 5174473 A	28-06-1994 15-11-1994 10-03-1994 16-04-1992 10-04-1992 08-12-1994 09-03-1995 01-03-1995 07-09-1993 29-12-1992
WO 9414492 A	07-07-1994	AT 177323 T AU 683036 B AU 5748794 A CA 2152088 A CN 1091321 A CZ 9501535 A DE 69323897 D DE 69323897 T EP 0674533 A ES 2128550 T FI 952976 A GR 3030035 T HU 73522 A, B IL 108061 A JP 2924924 B JP 8500756 T NO 952429 A NZ 259241 A PL 309401 A SG 52237 A SK 80695 A US 5829434 A US 5687710 A US 5740792 A ZA 9309472 A	15-03-1999 30-10-1997 19-07-1994 07-07-1994 31-08-1994 15-05-1996 15-04-1999 04-11-1999 04-10-1995 16-05-1999 16-06-1995 30-07-1999 28-08-1996 10-06-1997 26-07-1999 30-01-1996 18-08-1995 20-12-1996 02-10-1995 28-09-1998 07-02-1996 03-11-1998 18-11-1997 21-04-1998 19-06-1995
WO 9629278 A	26-09-1996	US 5421482 A AU 7732794 A EP 0720568 A WO 9508484 A AU 688794 B BR 9407608 A CA 2172537 A CN 1133584 A JP 9502951 T US 5611444 A US 5718355 A US 5799651 A	06-06-1995 10-04-1995 10-07-1996 30-03-1995 19-03-1998 14-01-1997 30-03-1995 16-10-1996 25-03-1997 18-03-1997 17-02-1998 01-09-1998
EP 0949584 A	13-10-1999	NONE	

Form PCT/ISA/210 (patent family annex) (July 1992)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PC./EP 99/05939

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES IPK 7 A61M15/00 G06M1/08 G06M1/14		
Nach der Internationalen Patentklassifikation (IPK) oder nach der nationalen Klassifikation und der IPK		
B. RECHERCHIERTE GEBIETE Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole) IPK 7 A61M G06M B65D		
Recherchierte aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen		
Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)		
C. ALS WESENTLICH ANGESEHENE UNTERLAGEN		
Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	FR 2 022 212 A (VANTOREX LTD) 31. Juli 1970 (1970-07-31) Seite 3, Zeile 37 -Seite 4, Zeile 24 Abbildungen 1,2	1,15,16, 20
Y	---	2-7,9, 12-14, 17-19
Y	EP 0 480 488 A (ELETTRIO PLASTICA SPA) 15. April 1992 (1992-04-15) Spalte 4, Zeile 4 - Zeile 33 Abbildungen 4,5 ---	2-7,9,14
	--- -/--	
☒ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen ☒ Siehe Anhang Patentfamilie		
* Besondere Kategorien von angegebenen Veröffentlichungen "A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist "E" älteres Dokument, das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist "L" Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund angegeben ist (wie ausgeführt) "O" Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Ausstellung oder andere Maßnahmen bezieht "P" Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach dem beanspruchten Prioritätsdatum veröffentlicht worden ist "T" Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zum Verständnis des der Erfindung zugrundeliegenden Prinzips oder der ihr zugrundeliegenden Theorie angegeben ist "X" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erfinderscher Tätigkeit beruhend betrachtet werden "Y" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erfinderscher Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren anderen Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist "&" Veröffentlichung, die Mitglied derselben Patentfamilie ist		
Datum des Abschlusses der internationalen Recherche 24. November 1999		Absenddatum des internationalen Recherchenberichts 01/12/1999
Name und Postanschrift der internationalen Recherchenbehörde Europäisches Patentamt, P. B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016		Bevollmächtigter Bediensteter Lakkis, A

Formblatt PCT/ISA/210 (Blatt 2) (Juli 1992)

Seite 1 von 2

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen

PC 1, EP 99/05939

C.(Fortsetzung) ALS WESENTLICH ANGESEHENE UNTERLAGEN		
Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
Y	WO 94 14492 A (AMBROSIO THOMAS J ;MANTHENA SRINIVAS (US); SCHERING CORP (US); WIL) 7. Juli 1994 (1994-07-07) Seite 30, Zeile 5 -Seite 31, Zeile 5 Seite 49, Zeile 26 - Zeile 30 Seite 50, Zeile 13 - Zeile 25 Seite 65, Zeile 35 -Seite 66, Zeile 14 Abbildungen 3,4,67,71,75,105	12,13, 17-19
A	----	2,3,5,11
A	WO 96 29278 A (SENETICS INC) 26. September 1996 (1996-09-26) ----	
E	EP 0 949 584 A (BASON NEIL PETER) 13. Oktober 1999 (1999-10-13) Absätze '0018!-'0021! Abbildungen 2,3 -----	1,15-17, 19-22

Formblatt PCT/ISA/210 (Fortsetzung von Blatt 2) (Juli 1992)

Seite 2 von 2

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichung, die zur selben Patentfamilie gehören

Internationales Aktenzeichen

PC 1, EP 99/05939

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
FR 2022212 A	31-07-1970	AU 6168869 A	08-04-1971
		GB 1290484 A	27-09-1972
		ZA 6906865 A	27-05-1971
EP 0480488 A	15-04-1992	IT 1243820 B	28-06-1994
		AT 113486 T	15-11-1994
		AU 646873 B	10-03-1994
		AU 8025891 A	16-04-1992
		CA 2046806 A	10-04-1992
		DE 69104950 D	08-12-1994
		DE 69104950 T	09-03-1995
		ES 2066336 T	01-03-1995
		JP 5228213 A	07-09-1993
		US 5174473 A	29-12-1992
WO 9414492 A	07-07-1994	AT 177323 T	15-03-1999
		AU 683036 B	30-10-1997
		AU 5748794 A	19-07-1994
		CA 2152088 A	07-07-1994
		CN 1091321 A	31-08-1994
		CZ 9501535 A	15-05-1996
		DE 69323897 D	15-04-1999
		DE 69323897 T	04-11-1999
		EP 0674533 A	04-10-1995
		ES 2128550 T	16-05-1999
		FI 952976 A	16-06-1995
		GR 3030035 T	30-07-1999
		HU 73522 A, B	28-08-1996
		IL 108061 A	10-06-1997
		JP 2924924 B	26-07-1999
		JP 8500756 T	30-01-1996
		NO 952429 A	18-08-1995
		NZ 259241 A	20-12-1996
		PL 309401 A	02-10-1995
		SG 52237 A	28-09-1998
		SK 80695 A	07-02-1996
		US 5829434 A	03-11-1998
		US 5687710 A	18-11-1997
		US 5740792 A	21-04-1998
		ZA 9309472 A	19-06-1995
WO 9629278 A	26-09-1996	US 5421482 A	06-06-1995
		AU 7732794 A	10-04-1995
		EP 0720568 A	10-07-1996
		WO 9508484 A	30-03-1995
		AU 688794 B	19-03-1998
		BR 9407608 A	14-01-1997
		CA 2172537 A	30-03-1995
		CN 1133584 A	16-10-1996
		JP 9502951 T	25-03-1997
		US 5611444 A	18-03-1997
		US 5718355 A	17-02-1998
		US 5799651 A	01-09-1998
EP 0949584 A	13-10-1999	KEINE	

Formblatt PCT/ISA/210 (Anhang Patentfamilie)(Juli 1992)



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Publication number: **0 480 488 A1**

(12)

EUROPEAN PATENT APPLICATION

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G06M 1/04, B67D 5/08**

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A request for correction of the description has been filed pursuant to Rule 88 EPC. A decision on the request will be taken during the proceedings before the Examining Division (Guidelines for Examination in the EPO, A-V, 2.2).

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(54) **Dose counting device for a distributor of doses of fluid products, especially for pharmaceutical use.**

(57) The device comprises a distributor provided with an operating member (8) for a counting means of doses of fluid associated with a mouth (31) of a container (1), a ring nut (4) for fastening the distributor means (2) onto the mouth (31) and elastic means (16) suitable for transforming the translatory motion of said operating member (8) with respect to the ring nut (4) in a rotatory and axially reciprocating motion of a rotating and axially translatable element (9) to cause the appearance of a different numerical index provided on the rotating element (9) at an observation position (19) obtained in the operating member (8).

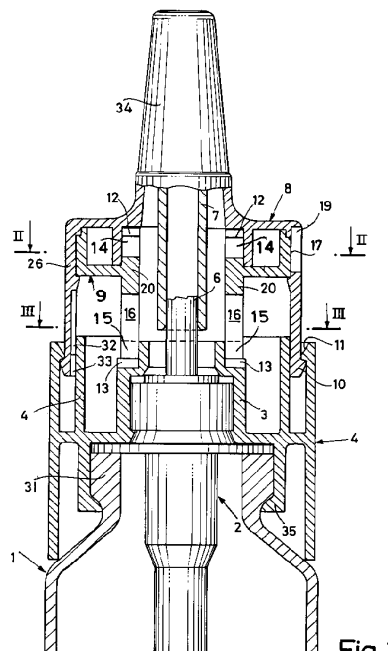


Fig.1

EP 0 480 488 A1

The present invention relates to a dose counting device for a distributor of doses of fluid products, especially for pharmaceutical use.

Such dose counting devices find particular application in the field of nasal distributors.

The latter essentially comprise a bottle open at its upper end and tapered for the introduction of a member for the distribution of the product contained inside it. The member for the distribution of the product has a terminal spout at its upper end from which the distributed product is introduced in a truncated-cone element, called «nasal», shaped so as to be able to be inserted in the nasal cavities and thus allow the product to be injected into the nostrils.

A ring nut screwed or fastened to the bottle accomplishes the connection between the bottle, the distribution member and the nasal.

In such distributors the distribution of the product is operated by successive strokes on the nasal so as to cause it to slide with respect to the coupling ring nut and to correspondingly activate the distribution member.

Every stroke imparted to the nasal causes the distribution of a given dose of product. Since the product contained in the nasal distributors consists mainly of substances to be administered in a controlled dose, it is particularly important to have available a dose counting device suitable for visualizing the total number of doses distributed.

The object of the present invention is to accomplish a dose counting device that is easy and safe to use as the distributor of doses of liquid products, especially but not exclusively for nasal distributors, with the possibility of indicating with a progressive numerical index the number of doses distributed over time.

According to the present invention such object is attained with a dose counting device for a dose distributor of fluid products, especially for pharmaceutical use, said distributor comprising a container of liquid product provided with a mouth, means for the distribution of doses of fluid from said container through said mouth, a ring nut for fastening said distributor means onto said mouth of the container, a translatable operating member for the operation of said distribution means, characterized in that it comprises elastic means suitable for transforming the translatory motion of said operating member with respect to the ring nut in a rotatory and axially reciprocating motion of a rotating and axially translatable element provided with progressive numerical indices which can be positioned in succession with every dose distributed in a pre-set observation position, said elastic means comprising a succession of small flexible circumferentially distanced legs having an upper part suitable for reacting with a first set of one-directional

teeth of the operating member, a lower part suitable for reacting with a second set of one-directional teeth of the ring nut and an intermediate part fastened to the rotating element, so that when said first set of one-directional teeth approaches said second set of one-directional teeth under the action of said operating member, the upper part of said small legs disengages from the corresponding tooth of the first set of teeth to be inserted in an immediately adjacent tooth and thus drives in rotation and axial forward movement said intermediate part of the small leg and when said first set of teeth is moved away from said second set of teeth when the action of said operating member ceases the lower part of said small legs disengages from the corresponding tooth of the second set of teeth to be inserted in an immediately adjacent tooth and thus drives in rotation and axial backward movement said intermediate part (20) of the small leg (16).

In particular the ring nut is provided with radial ridges suitable for their engagement in slots of the operating member in order to guide the latter's translation with respect to it.

The same dose counter, used in the case in question in the pharmaceutical field, can also find application in cosmetics when fluid products are to be distributed.

There is also the possibility of applying it to a distributor of pills with a controlled dosing.

Given the reduced dimensions wherein it is necessary to silk-screen the numerical indices there is lastly the possibility of using suitable colour hues for them giving an auxiliary and immediately understandable piece of information.

The features of the present invention shall be made more evident by an embodiment illustrated as a non-limiting example in the enclosed drawings, wherein:

Fig. 1 shows an axial sectional view of a dose counting device according to the present invention;

Fig. 2 is a transversal cross-sectional view taken along the line II-II of Fig. 1;

Fig. 3 is a transversal cross-sectional view taken along the line III-III of Fig. 1;

Fig. 4 illustrates with a full line a small flexible leg and the two sets of teeth in the starting position and in a dotted line the same small leg and the corresponding sets of teeth during the course of the operation of the operating member for the distribution of a dose of product;

Fig. 5 illustrates the same small leg of fig. 4 after the return of the operating member to the starting position;

Fig. 6 shows the upper part of the nasal, seen from the right hand side with respect to Fig. 1.

With reference to Figs 1 to 3 and 6, the device

comprises a container 1 of a fluid product, not shown, in the form of a bottle with its upper mouth open 31 to allow the introduction inside it of a distribution valve 2 for the fluid contained in it. Such valve 2, already described in the Italian patent application No. 22133 B/87 filed on 30 July 1987 in the name of the same applicant, is associated with the container 1 through a flange 3 forming part of a ring nut 4 fastened to the container 1 by means of an annular protrusion 35 of the same and terminates at the upper end with an axially slidable distribution spout 6 inserted and blocked in a guide channel 7 for the fluid, which forms part of and passes right through an axially translatable nasal 8, constituting the operating member of the valve 2.

The latter is an internally hollow cylinder 26 terminating at its lower end with an annular edge 10 turned outward, connected to a corresponding annular edge 11 of the ring nut 4 so as to prevent the separation of the nasal 8 from the ring nut 4 and provided with axial slots 32 in which there are slidably inserted radial ridges 33 of the ring nut 4 for the axial translation of the nasal 8 with respect to it. At its upper end and in its middle portion the nasal 8 extends in a protrusion 34 shaped in the form of a nose so that it can be inserted into the nostrils for the introduction of the fluid product to be distributed.

Inside both the nasal 8 and the ring nut 4 there are accomplished internal sets of saw-tooth shaped teeth 12, 13 in engagement with corresponding upper parts 14 and lower parts 15 of a circumferential succession of small elastically flexible legs 16 whose intermediate part 20 is integral with a rotating element 9 with progressive numerical indices 17. With reference to Fig. 6, such indices 17 during the rotation of the rotating element 9 are positioned in succession in an observation position constituted by a window 19 obtained in the annular part 26 of the nasal 8, indicating the number of strokes that have been imparted to the nasal 8 up to that time. The rotating element 9 is also provided with a radial locator 9A suitable for coming to a stop against a corresponding locator 8A protruding radially from the nasal 8 to prevent the rotation of the rotating element 9 after a given number of strokes has been imparted to the nasal 8 and thus a pre-set maximum number of doses distributed highlighted, as explained above, by the progressive numerical indices 17 in the window 19.

It should also be noted that in the specific case the ring nut 4 is fastened onto the container 1, but it is also possible for the ring nut 4 to be screwed down onto the container 1 itself.

The operation of the dose counting device according to the present invention is as follows.

At each operation of the distributor the nasal 8

is moved in an axial translation with respect to the ring nut 4 by the axial depression of the same and thanks to the engagement of the radial ridges 33 of the ring nut 4 in the slots 32 of the nasal 8. More accurately, with reference to Fig. 4, initially the small generic leg 16 of the succession of the small circumferentially distanced legs is with its upper part 14 engaged with a tooth 21 of the internal set of teeth 12 of the nasal 8. The same small leg 16 is now with one of its lower parts 15 engaged with a tooth 22 of the internal set of teeth 13 of the ring nut 4, while its middle portion 20 is integral with the rotating element 9. Pressing on the nasal 8, while the same nasal operates through the slidable spout 6 the valve 2 for the distribution of a dose of product, the small leg 16 is elastically urged by the approach of the set of teeth 12 towards the set of teeth 13 in the configuration illustrated by a dotted line in the same Figure 4. During this urging its upper part 14 leaves the tooth 21 to position itself in a tooth 24 adjacent to it. With reference to Fig. 5, when the pressure on the nasal 8 is released, the latter translates in a direction opposite to the ring nut 4, the set of teeth 12 moves away from the set of teeth 13 and the lower part 15 of the small leg 16 leaves the tooth 22 to position itself in the tooth adjacent to it. The displacement of the upper part 14 in the notch 24 and of the lower part 15 in the notch 25 is equivalent to the forward movement of the small leg 16 through one position. During this forward movement the intermediate part 20 of the small leg 16 takes with it the rotating element 9 in a unitary rotation. The numerical index 17 attached to the rotating element 9 shall be rotated through one position and behind the window 19 there shall appear the immediately successive numerical index 17, updating the information related to the number of strokes imparted to the nasal 8 and thus to the number of doses distributed. At the end of a given maximum number of strokes imparted to the nasal 8 and thus of a given maximum number of doses of product distributed, the radial locator 9A protruding from the rotating element 9 comes to a stop against the radial locator 8A protruding from the nasal 8. The rotation of the rotating element 9 is blocked and behind the window 19 there appears the progressive numerical index 17 corresponding to the maximum allowed number of doses distributed. Even after the blocking of the rotation of the rotating element 9 it is still possible to press against the nasal 8 in order to use up completely the product contained in the container.

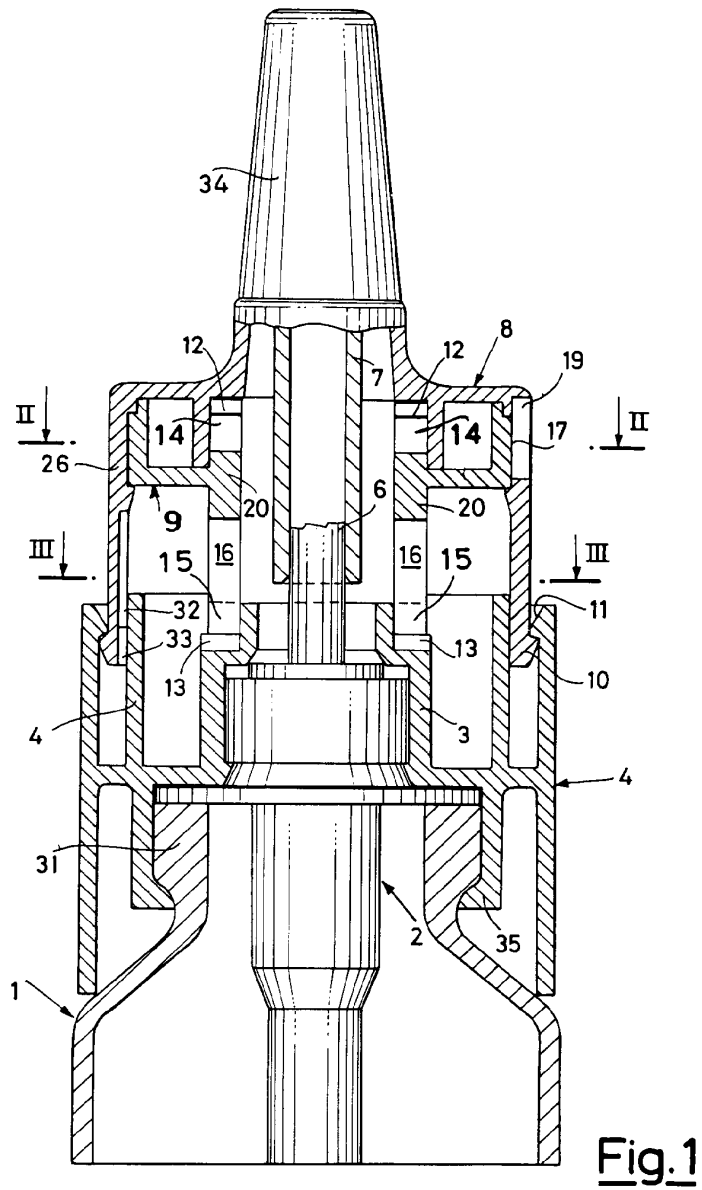
Claims

1. Dose counting device for a distributor of doses of fluid products, especially for pharmaceutical

use, said distributor comprising a container (1) of liquid product provided with a mouth (31), means (2) for the distribution of doses of fluid from said container (1) through said mouth (31), a ring nut (4) for fastening said distributor means (2) onto said mouth (31) of the container (1), a translatable operating member (8) for the operation of said distribution means (2), characterized in that it comprises elastic means (16) suitable for transforming the translatory motion of said operating member (8) with respect to the ring nut (4) in a rotatory and axially reciprocating motion of a rotating and axially translatable element (9) provided with progressive numerical indices (17) which can be positioned in succession with every dose distributed in a pre-set observation position (19), said elastic means comprising a succession of small flexible circumferentially distanced legs (16) having an upper part (14) suitable for reacting with a first set of one-directional teeth (12) of the operating member (8), a lower part (15) suitable for reacting with a second set of one-directional teeth (13) of the ring nut (4) and an intermediate part (20) fastened to the rotating element (9), so that when said first set of one-directional teeth (12) approaches said second set of one-directional teeth (13) under the action of said operating member (8), the upper part (14) of said small legs (16) disengages from the corresponding tooth (21) of the first set of teeth (12) to be inserted in an immediately adjacent tooth (24) and thus drives in rotation and axial forward movement said intermediate part (20) of the small leg (16) and when said first set of teeth (12) is moved away from said second set of teeth (13) when the action of said operating member (8) ceases the lower part (15) of said small legs (16) disengages from the corresponding tooth (22) of the second set of teeth (13) to be inserted in an immediately adjacent tooth (25) and thus drives in rotation and axial backward movement said intermediate part (20) of the small leg (16).

2. Device according to claim 1, characterised in that said ring nut (4) is provided with radial ridges (33) suitable for their engagement in longitudinal slots (32) of the operating member (8) in order to guide the latter's translation with respect to it.
3. Device according to claim 1, characterised in that said operating member (8) has a top portion (12) in the shape of a nose.
4. Device according to claim 1, characterised in

that said rotating element (9) is provided with a radial locator (9A) suitable for coming to a stop against a corresponding radial locator (8A) of the operating member (8) to prevent the rotation of the rotating element (9), but allowing its axial translation, after a given number of strokes has been imparted to the operating member (8) and thus after a given maximum number of doses distributed.



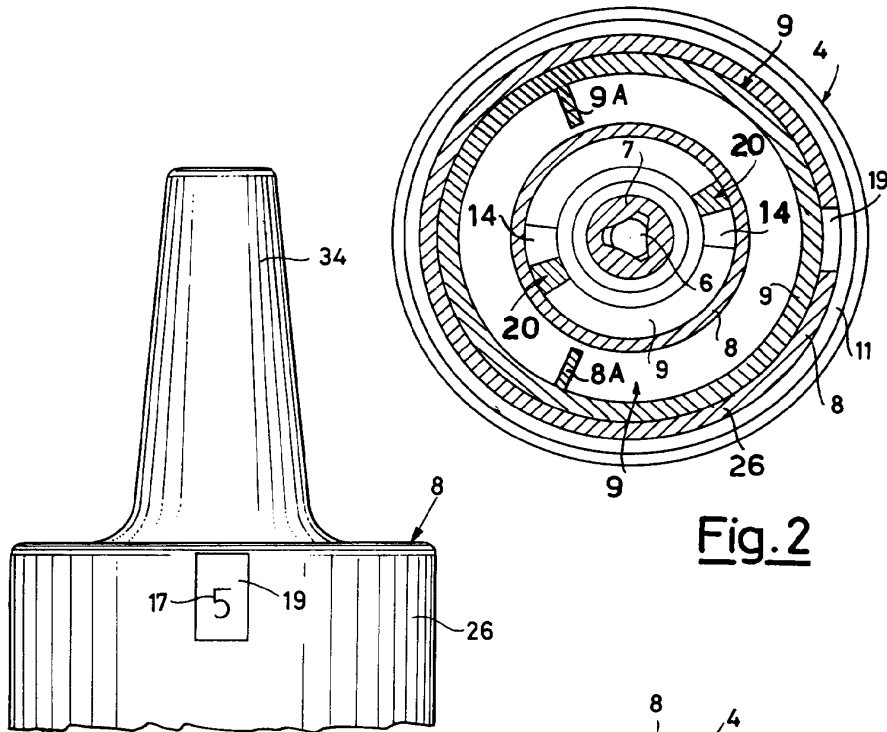


Fig. 2

Fig. 6

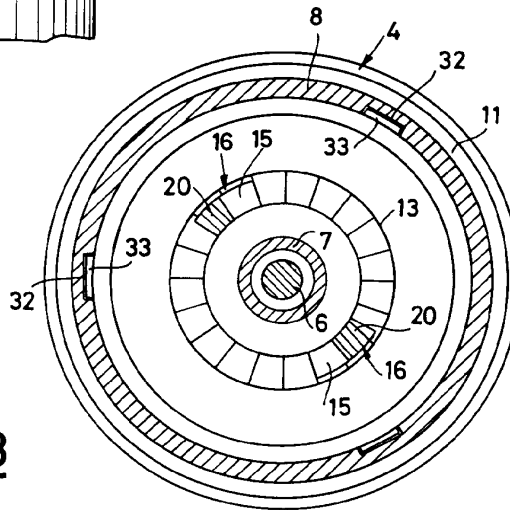
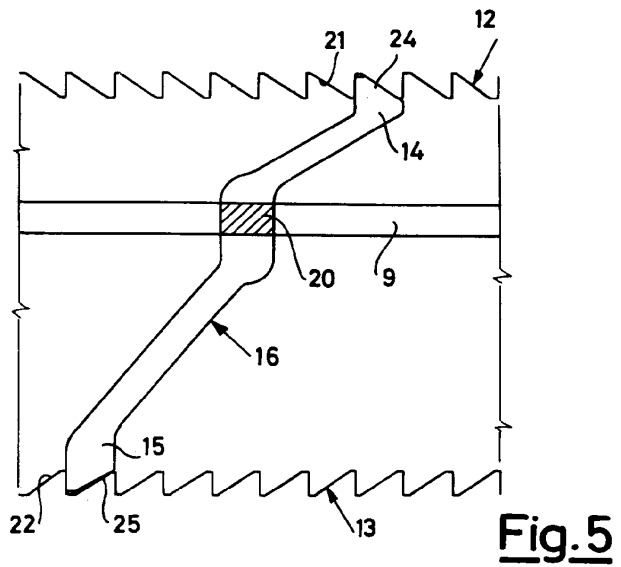
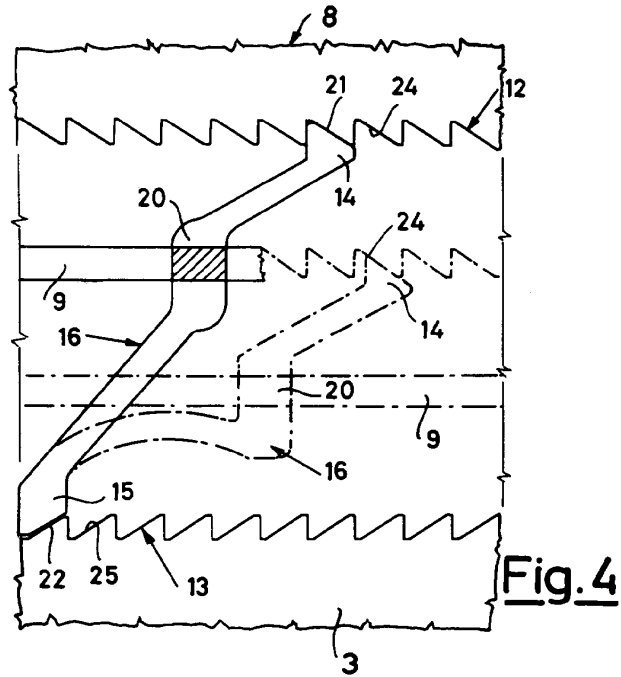


Fig. 3





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 91201759.7						
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)						
A	<u>GB - A - 1 317 315</u> (ENGL. NUMB.) * Totality; especially fig. 1-36; page 2, lines 6-113 * --	1,4	A 61 M 15/00 A 61 M 15/08 G 06 M 1/04 B 67 D 5/08						
A	<u>FR - A - 2 450 640</u> (PFEIFFER ZERST.) * Fig. 1,2 * --	1,2							
D,A	<u>EP - A - 0 301 615</u> (ELETTO PL.) * Fig. 1; column 3, line 6 - column 4, line 5 * ----	1							
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)						
			A 61 M B 67 D G 06 M						
The present search report has been drawn up for all claims									
Place of search VIENNA		Date of completion of the search 22-01-1992	Examiner LUDWIG						
<table border="0"><tr><td>CATEGORY OF CITED DOCUMENTS</td><td>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document</td></tr><tr><td>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</td><td></td><td></td><td></td></tr></table>				CATEGORY OF CITED DOCUMENTS	T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ----- & : member of the same patent family, corresponding document	X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			
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(54) An indicator device

(57) A dose counter attached or attachable to the base of a pressurised canister for a metered dose inhaler and comprising a spring-loaded cap (14) which may be depressed in relation to a second part (1) mounted on the domed base of the canister (C). Within the cap (14) is a pair of independently rotatable rings, each carrying on its upper surface indicia visible through a window (13) in the cap. For each depression of the cap (14) relative to the canister, the first ring (4) is indexed in rotation, and for each complete revolution of the first ring (4), the second ring (8) is indexed in rotation. The first ring (4) carries the numbers 0 to 9 and the second ring (8) carries the numbers 00 to 20 so that the device counts down progressively from 200 to 000 thus providing an incremental indication of the number of doses remaining in the canister.

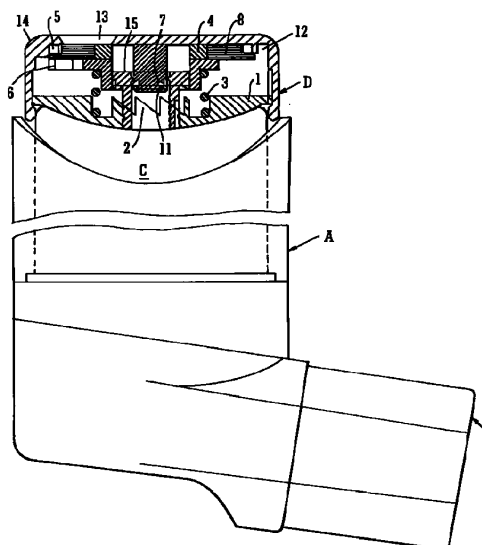


FIG. 1

EP 0 949 584 A2

Description

[0001] THIS INVENTION concerns an indicator device, and particularly, though not exclusively, such a device adapted to serve as a dose counter for metered dose inhalers (MDI's).

[0002] MDI's include pressurised canisters containing drugs to be inhaled for the relief of, for example, the symptoms of asthma. Typically each canister contains 200 doses but conventionally provides no indication to the user as to how many doses remain available for use at a particular time. This results in considerable inconvenience and risk to the user who must, inevitably, carry a fresh replacement MDI in addition to the one currently in use thus to ensure that if the current one becomes empty there is a spare supply.

[0003] Thus there is a need for a dose counter for an MDI to indicate the number of times the pressurised canister is depressed to dispense a dose of the drug. Such a counter must count down, typically from 200 to zero, progressively as doses are administered so that the user can readily see how many doses remain.

[0004] According to the present invention there is provided an indicator device to provide a count of a series of like linear movements of a first part of the device with respect to a second part thereof; the first part comprising first and second rotational rings carrying indicia progressively visible on the first part; the first and second parts having inter-engaging spaced projections such that upon each linear movement of the first part the first rotational ring is indexed in rotation, and such that a upon a predetermined number of linear movements of the first part, the second rotational ring is indexed in rotation.

[0005] Preferably, the second part is adapted to be affixed to the base of a pressurised canister of an MDI, and the first part is captive on the second part and spring-loaded thus to be capable of depression relative to the second part and to the canister.

[0006] Still further, the rotational rings are concentrically arranged, and the first rotational ring includes an annular array of spaced projections engageable successively with two further annular sets of projections fixed with respect to the second part of the device such that the projections on the first rotational ring successively engage the fixed projections to cause the first rotational ring to index in rotation twice for each depression and release thereof.

[0007] Furthermore, the second rotational ring comprises a further set of projections engageable successively by a pawl attached to the first rotational ring upon each complete revolution thereof thus to index the second rotational ring by one increment for each revolution of the first ring.

[0008] Still further, the first part of the device comprises a cap adapted for linear movement but prevented from rotational movement in relation to the second part of the device, the cap including a profiled channel in

which the pawl is adapted to travel during rotation of the first rotational ring, the profile of said channel causing the pawl to engage the projections of the second rotational ring once for each revolution of the first rotational ring, the cap including a window through which respective surfaces of the first and second rotational rings are visible in one radial location thereof whereby numeric indicia on said surfaces are progressively visible through said window.

[0009] An embodiment of the invention will now be described, by way of example only, with reference to the accompany drawings, in which:-

Fig. 1 is a part cross-sectional view of a meter dose inhaler having thereon an indicator device in accordance with the invention;

Fig. 2 is an enlarged cross-sectional view of the indicator device;

Fig. 3 is an exploded perspective view of the parts of the device;

Fig. 4 is a plan view of the device taken on line IV-IV of Fig. 2;

Fig. 5 is a cross-sectional view of part of the device illustrating the action thereof.

and Figs. 6a to 6d are partial plan views similar to Fig. 4, showing different operational conditions of the device.

[0010] Referring to Figs. 1 to 3, a meter dose inhaler A includes a mouth-piece B through which a user may inhale a drug dispensed from a canister C removably contained within the inhaler. A counter in accordance with the invention is illustrated generally at D.

[0011] The counter consists of a first part or base 1 which, in manufacture of the canister C is bonded to the domed base thereof. It will be appreciated that the canister C and counter D comprise a replaceable item within the inhaler.

[0012] Disposed in fixed position on the base 1 is a central bush 15 which in assembly of the device has a part 22 located on the base 1 by of a key way 23 and is thus non-movably attached thereto. The base 1 defines an annular cavity 1a intended to house the bottom of a coil spring 3, the top of which engages beneath a radially outwardly directed flange of a first rotational ring 4, an inner annular part of which may be accommodated within the cavity 1a.

[0013] The ring 4 defines an inner cylindrical space within the lower end of which there is located an annular series of projections formed as inwardly directed triangular teeth 7.

[0014] At the inner extremity of the cavity 1a of base 1 there is an annular series of projections formed as

upwardly directed teeth 2, and on the underside of an upper flange of the central bush 15 there is an annular series of projections formed as downwardly directed teeth 14a. When ring 4 is assembled with central bush 15, the triangular teeth 7 are movable therewith between the teeth 2 and the teeth 14a for a purpose to be described.

[0015] At one circumferential position on the outwardly directed flange of ring 4 is an outwardly projecting curved arm 6 carrying at its free end an upwardly directed pawl 5 for a purpose to be described.

[0016] Concentrically disposed above and around the ring 4 is a second rotational ring 8 having a circumferential series of projections formed as outwardly directed curvilinear teeth 9 and a further series of angular teeth 10 disposed on a reduced circumference of the ring 8. It will therefore be seen that the base 1, the central bush 15, the ring 4 and the ring 8 may be assembled in concentric relationship and surrounded by a cap 14 having a flat top and depending cylindrical wall, and having a central boss 11 which locates within the central bush 15. The cap 14 becomes captive with the base 1 by means thereon of an annular series of outwardly projecting lugs 27 which locate within arcuate and radially directed recesses 20 on the inner face of the cylindrical wall of the cap 14. The upper circular part of the cap 14 includes a window 13 of elongate rectangular form extending radially across one part of the top for a purpose to be described.

[0017] Within the cap 14 close to its circumference is a downwardly directed wall 12 defining an outer profiled channel which receives the pawl 5 of ring 4 when the device is fully assembled. The channel is profiled such that in one radial position which coincides with the position of window 13, the channel has a radially inwardly directed kink 26 (Fig. 3) for a purpose to be described.

[0018] When the entire device is assembled there is visible through the window 13 one radial location of the upper faces 24 and 25 respectively of the rotational rings 4 and 8. These faces carry respectively two numeric series such that face 24 carries the series 0 to 9 while face 25 carries the series 00 to 20. Thus, through the window 13 there may be visible progressively the numbers 000 to 200. As will be described the device counts down so that when the MDI is new and unused the number 200 will be visible thus indicating that there are 200 doses available within the canister to which the device is attached. As the MDI is progressively used the available doses will count down eventually to zero indicating that the canister is empty. The user may therefore determine at any time how many doses remain available from the canister.

[0019] The device operates as follows:

[0020] Upon depression of the cap 14 with respect to the base 1, the rings 4 and 8 are also depressed linearly causing, upon each depression, the teeth 7 to engage the lower fixed set of teeth 2. Owing to the triangular formation of the teeth 7 and 2 this causes the ring 4 to be

indexed in rotation, (See Fig. 5) and upon return or release of the cap, the teeth 7 then engage the upper teeth 14a causing a further rotational movement of the ring 4. Each of these rotational movements represents one half of a complete movement of the ring 4 so that the number visible through the window 13 on face 24 will change by one point for a complete depression and release of the cap. Thus the user can see the progressive movement of the inner ring indicating a count down from 9 to 0 for a complete revolution of the ring 4. During such revolution the pawl 5 on arm 6 travels around the channel defined by the wall 12 in cap 14. After ten rotational movements of the ring 4 the pawl 5 engages the kink 26 in the channel and thus moves inwardly to engage an adjacent trough between two of the teeth 9 on the second rotational ring 8 causing the latter to move rotationally by one position before the pawl 5 leaves the kink 26 and returns to the main part of the channel. (See Figs. 6a to 6d). Except when moved by the pawls, the ring 8 is prevented from rotational movement by engagement of one of the teeth 10 in a V-notch 30 in the inner face of the wall 12 coincident with the kink 26 therein (See Fig. 6a). Also, the ring 4 is prevented from rotation, except when being inclined, by engagement of the teeth 7 with the teeth 1 and 14a.

[0021] Thus it will be seen that for each complete revolution of the ring 4 the ring 8 is moved one position. When the device is new and unused the number 200 will appear in the window 13. The first actuation of the device moves rings 4 and 8 simultaneously thus revealing the number 199. Thereafter for ten operations the ring 4 alone will move to display a count down from 199 to 190 whereupon the outer ring 8 is moved once again to reveal the number 189 and so on, the device providing a continuously diminishing count of 200 doses from the MDI.

[0022] Figure 5 serves to illustrate how depression and release movements of the device cause the teeth 7 to engage the teeth 2 and 14a progressively. Figures 6a to 6d illustrate how the pawl 5 enters the kink 26 and engages the teeth 9 of the ring 8 once for each complete revolution of the ring 4.

[0023] Preferably, the entire device with the possible exception of spring 3 is made from individual pieces moulded from a plastics material and assembly is initiated by passing the central bush 15 downwardly through the ring 4 and fixing it within the base 1, the ring 8 then being superimposed on the ring 4 and finally the cap 14 being introduced over the entire assembly with the central boss 11 located within the central bush 15.

[0024] Conceivably, the counter may be removably attached to the base of a canister thus to be re-usable, but from an economic point of view it is more likely that the counter will be permanently attached to a canister and thus supplied and disposed of along with it.

Claims

1. An indicator device to provide a count of a series of like linear movements of a first part of the device with respect to a second part thereof; the first part comprising first and second rotational rings carrying indicia progressively visible on the first part; the first and second parts having inter-engaging spaced projection such that upon each linear movement of the first part the first rotational ring is indexed in rotation, and such that a upon a predetermined number of linear movements of the first part, the second rotational ring is indexed in rotation. 5
2. An indicator device according to Claim 1, wherein the second part is adapted to be affixed to the base of a pressurised canister of an MDI, and the first part is captive on the second part and spring-loaded thus to be capable of depression relative to the second part and to the canister. 10
3. An indicator device according to Claim 1 or Claim 2, wherein the rotational rings are concentrically arranged, and the first rotational ring includes an annular array of spaced projections engageable successively with two further annular sets of projections fixed with respect to the second part of the device such that the projections on the first rotational ring successively engage the fixed projections to cause the first rotational ring to index in rotation twice for each depression and release thereof. 15
4. An indicator device according to Claim 3, wherein the second rotational ring comprises a further set of projections engageable successively by a pawl attached to the first rotational ring upon each complete revolution thereof thus to index the second rotational ring by one increment for each revolution of the first ring. 20
5. An indicator device according to Claim 4, wherein the first part of the device comprises a cap adapted for linear movement but prevented from rotational movement in relation to the second part of the device, the cap including a profiled channel in which the pawl is adapted to travel during rotation of the first rotational ring, the profile of said channel causing the pawl to engage the projections of the second rotational ring once for each revolution of the first rotational ring, the cap including a window through which respective surfaces of the first and second rotational rings are visible in one radial location thereof whereby numeric indicia on said surfaces are progressively visible through said window. 25
6. An indicator device according to Claim 5, wherein the surface of the first ring carries a numeric series from 0 to 9, the surface of the second ring carries the numeric series 00 to 20, said surfaces being arranged concentrically such that through the window there may be visible progressively the numbers 000 to 200. 30
7. An indicator device according to any preceding claim, wherein the first and second rotational rings include means for preventing rotation thereof except when being indexed in rotation by the inter-engaging spaced projections. 35
8. An indicator device according to any preceding claim, being non-removably attached to the base of a pressurised canister for a metered dose inhaler. 40
9. An indicator device according to any one of Claims 1 to 7, being adapted for removable attachment to a pressurised canister for a metered dose inhaler. 45

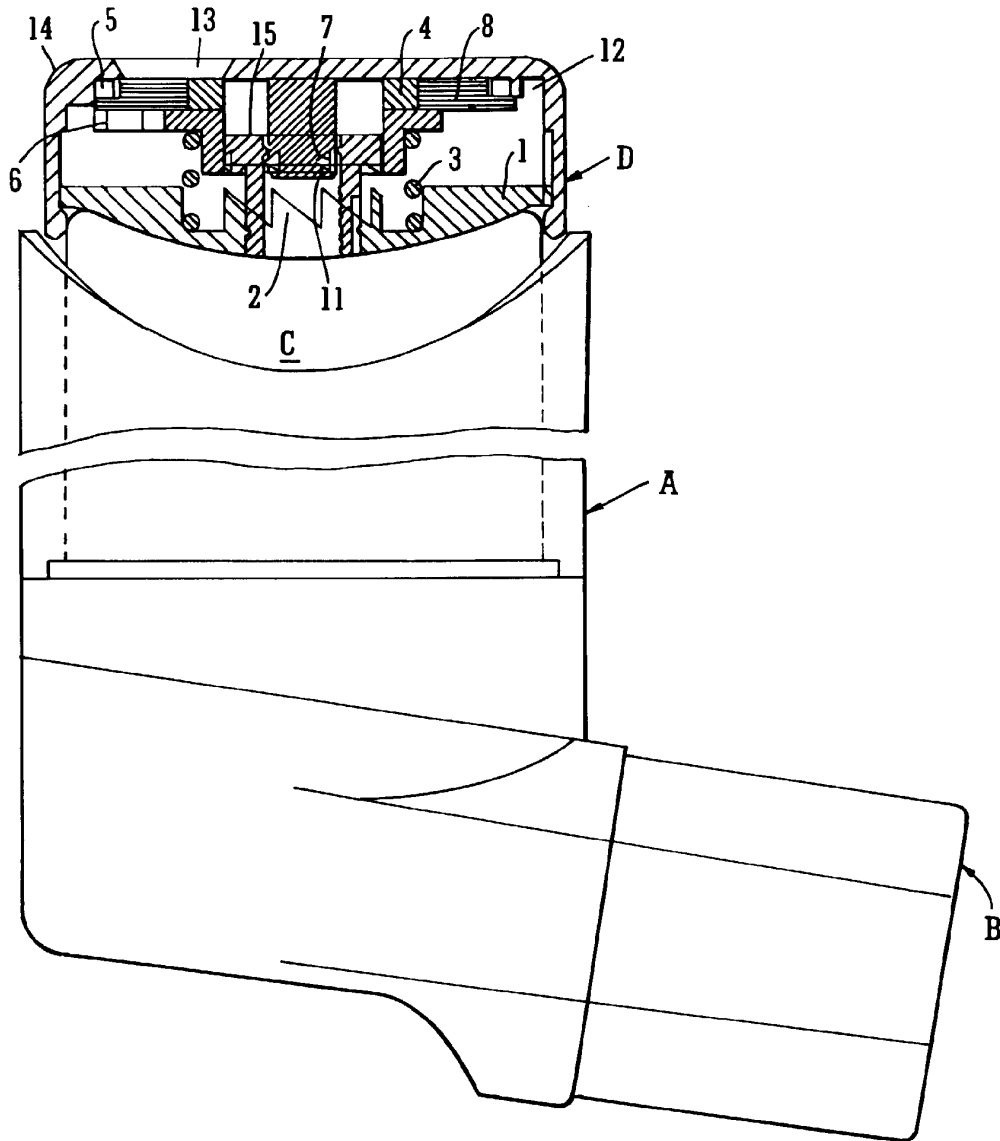


FIG. 1

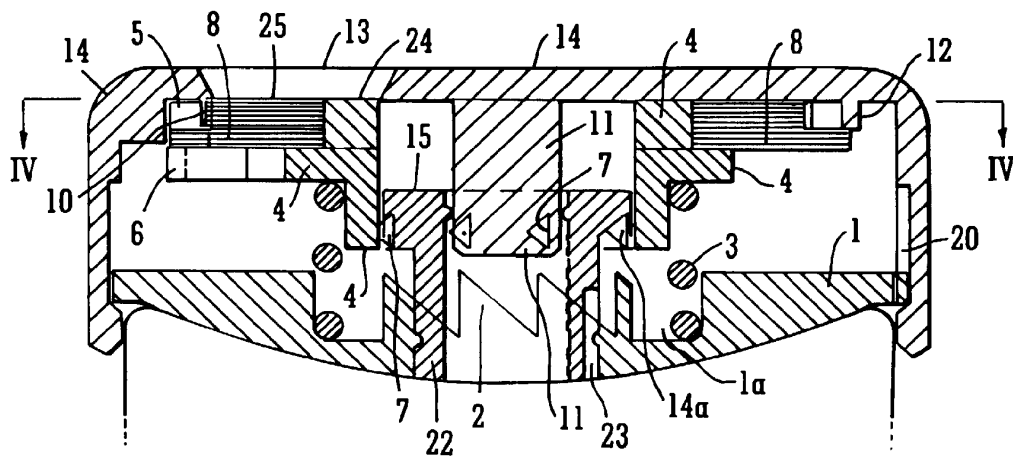


FIG. 2

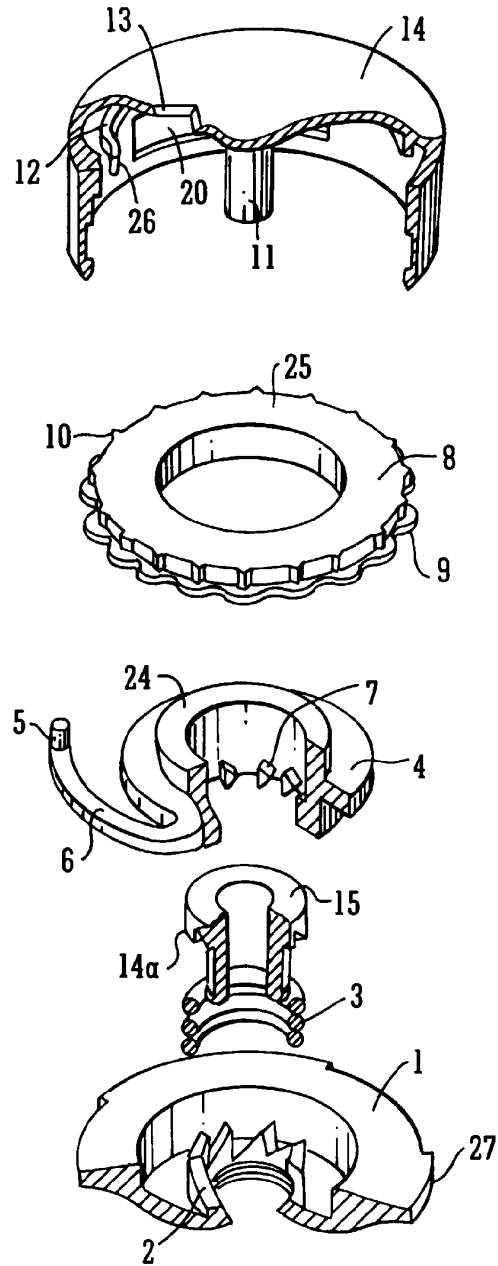


FIG. 3

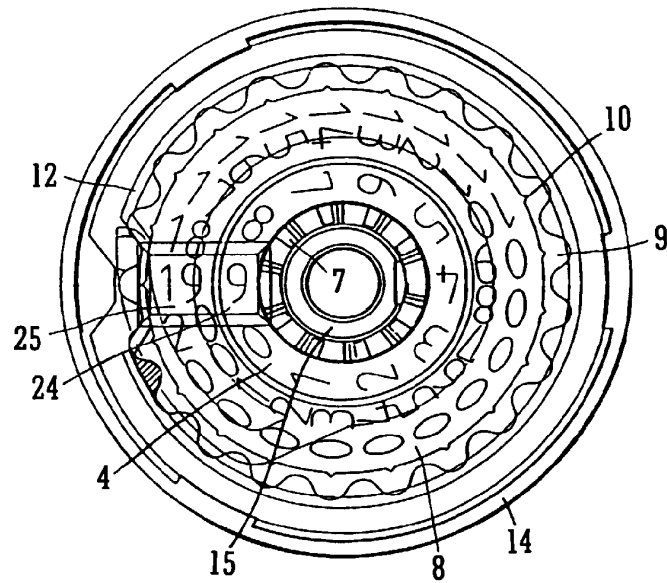


FIG. 4

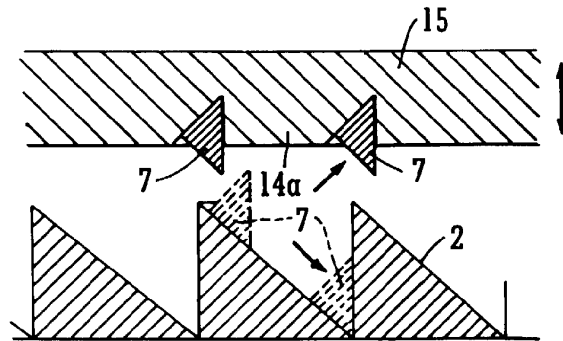
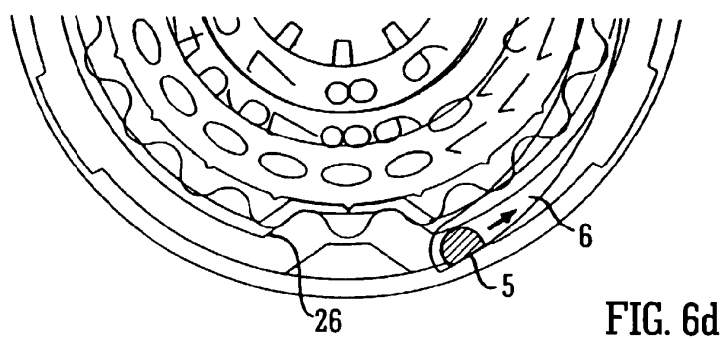
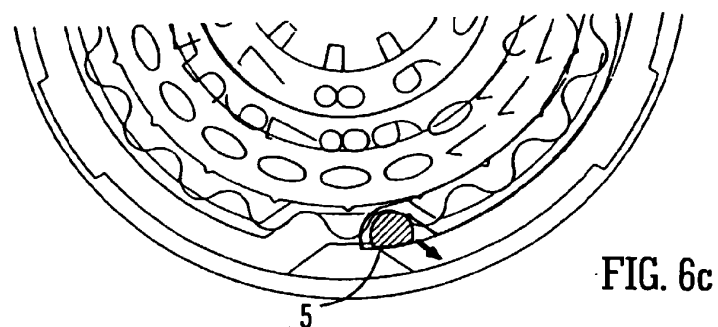
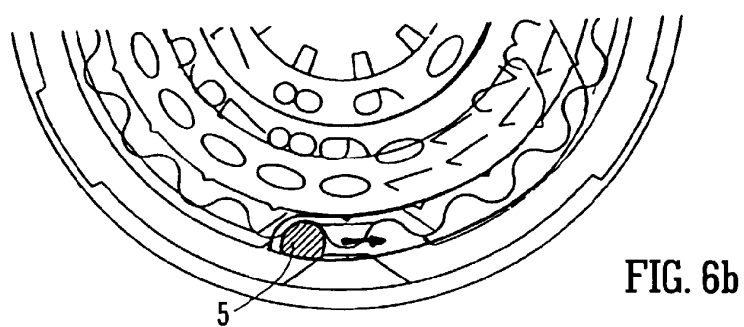
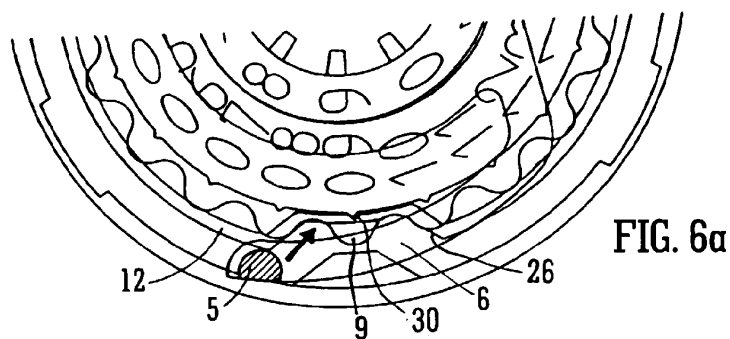


FIG. 5





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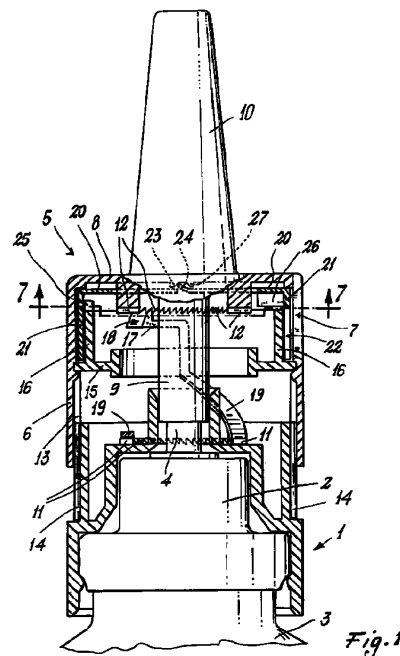
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(54) **Liquid dose dispenser with device for counting a large number of dispensed doses**

(57) A dispenser for measured quantities of a liquid product delivered under pressure by a metering pump or valve on which the dispenser is fitted, the dispenser having a device comprising discs on which there are reproduced two separate progressive successions of numbers which are selectively visible through a window in the dispenser, firstly the numbers of one disc and then the numbers of the other, to count the doses dispensed.



EP 1 065 477 A2

Description

[0001] This invention relates to a dispenser for dispensing measured quantities of a liquid, provided with a device for counting a large number of dispensed doses.

[0002] Many liquids, in particular pharmaceutical substances, are dispensed in measured quantities which have to be counted, each dose being dispensed by manually operating a dispenser applied to the stem of a pump or dispensing valve mounted on the mouth of a container containing the liquid to be used.

[0003] Liquid dose dispensers provided with devices for counting the number of doses already dispensed are described in the literature, for example in EP-B-114617, EP-B-269496, EP-A-472915 and EP-B-480488.

[0004] The device for counting the number of doses dispensed by the dispensers covered by the aforesaid patents comprises a discoidal body mounted rotatable about the longitudinal axis of the respective dispenser and having a continuous succession of numbers (increasing from 1 to about 20) reproduced along the periphery of the discoidal body, which is rotated through one step each time the dispenser is operated. One number at a time (in the increasing direction) is visible through a window provided in the dispenser, so making it possible to count the number of doses dispensed.

[0005] Known dispensers with a counting device have only one discoidal body. As these discoidal bodies are necessarily of small dimensions, the numbers reproduced along their periphery are necessarily limited in quantity, in general to about twenty. This means that dispensers of known type enable only a relatively small number of dispensed doses to be counted, thus limiting their application to small-volume liquid containers able to contain a liquid quantity equivalent to about twenty individual doses.

[0006] The main object of the invention is to provide a liquid dose dispenser having a device which enables a number of dispensed doses to be counted which is much larger (at least about double) than that achievable with similar known dispensers.

[0007] A further object is to provide a dispenser of the aforesaid type which is of simple structure, low production cost and reliable operation.

[0008] These and further objects are attained by a dispenser comprising:

- a base body with a seat for housing the free end of a pump or valve for delivering doses of a liquid contained in a container on which the pump is mounted;
- an operating body superposed on the base body and secured to it by guide elements which allow axial movement, but prevent rotation, of one body on the other, the operating body having a substantially cylindrical wall in which a window or aperture is provided, and a top wall with a hole about which

there extends a tubular element having at one end a seat for the free end of the pump stem and at its other end a nozzle for discharging the liquid dispensed by the dispenser;

- a first discoidal body housed in and rotatable within the operating body and having a substantially cylindrical surface facing the surface of the lateral wall of the operating body, through the window of which there is selectively positioned one of a first succession of numbers, letters or the like reproduced on the cylindrical surface of the first discoidal body;
- two sawtooth-shaped annular surfaces provided one on the base body and the other on the top wall of the operating body, the teeth of one of the two surfaces pointing towards the teeth of the other surface;
- flexible tangs projecting from the first discoidal body, and having their profiled free ends engaging the toothed surface of the base body and toothed surface of the operating body respectively, to cause the first discoidal body to rotate through one step each time the operating body is moved axially relative to the base body, with consequent initial flexure of said tangs and their subsequent return to an unflexed rest position;
- characterised by also comprising a second discoidal body housed between the top wall of the operating body and the first discoidal body, and having a cylindrical lateral wall on which a second succession of numbers is reproduced, and which extends between and is rotatable between the lateral wall of the operating body and the cylindrical surface of the first discoidal body, on the operating body and on the first discoidal body there being provided retention members which mutually cooperate to transiently maintain a window provided in the lateral wall of the second discoidal body facing the window in the operating body, the first discoidal body having a drive tooth which, when said first body has undergone a complete revolution about its axis, interferes with a tooth provided on the second discoidal body to drag it into rotation, to disengage said retention members and position in succession one of the numbers of said second succession of numbers in front of the window in the operating body.

[0009] Preferably said retention members comprise a first projection provided on the inside of the top wall of the operating body and bounded laterally by an inclined surface on which there rests a flexible tang projecting from the second discoidal body, this projection being overcome, with the flexing of said tang, when the drive tooth of the first discoidal body moves the second discoidal body away from its rest position.

[0010] Again preferably, said first projection in the form of a sawtooth is flanked by a stop tooth on which the flexible tang of the second discoidal body rests to block the movement of this latter after it has undergone

a complete revolution about its axis.

[0011] The structure and operation of the dose dispenser of the invention will be more apparent from the description of a preferred embodiment thereof given hereinafter by way of non-limiting example with reference to the accompanying drawings, on which:

Figure 1 is a partial axial section through the dose dispenser to an enlarged scale;

Figures 2 and 3 are respectively a perspective side view and a plan view of the first annular body forming part of the dispenser;

Figure 4 is a perspective side view of the second annular body of the dispenser;

Figures 5 and 6 schematically represent an inner portion of the dispenser in various positions assumed during dispenser operation;

Figure 7 is a cross-section through the dispenser on the line 7-7 of Figure 1; and

Figure 8 is a partial side view of the dispenser.

[0012] Reference will firstly be made to Figure 1, which shows a liquid dose dispenser comprising a base body 1 defining a seat for receiving and retaining the free end of a metering pump or valve 2 applied to the mouth of a container 3 containing the liquid to be delivered through the pump stem 4.

[0013] Onto the base body 1 there is fitted a operating body 5 having a cylindrical lateral wall 6 (in which a window or aperture 7 is provided) and a top wall 8 traversed by a hole (not visible on the drawing) about which there extends a tube, of which the downwardly facing portion 9 presents a seat into which the free end of the pump stem is inserted and retained, and the portion 10 extending outwards from the dispenser presents a nozzle (not shown) through which the dose of liquid originating from the pump is dispensed in atomized form. In the embodiment of Figure 1, the tube portion 10 has the elongate tapering form of a nasal insert used for spraying doses of a pharmaceutical product into a person's nostrils.

[0014] From the base body 1 there projects upwards (with reference to Figure 1) a succession of sawteeth 11 distributed in the manner of an annular surface. A similar succession of sawteeth 12, also distributed in the manner of an annular surface, projects from the top wall 8 of the operating body 5, the individual teeth of the two successions of teeth pointing towards each other.

[0015] Finally it should be noted that the two bodies 1 and 5 are connected together by a series of longitudinal grooves 13 and respective longitudinal ribs 14 inserted into and slidable within these grooves, to enable one body to move axially on the other, while preventing them from rotating relative to each other.

[0016] In the space delimited by the two bodies 1 and 5 there is housed a first discoidal body 15 having a cylindrical wall 16, on the outer surface of which there is

reproduced a first continuous succession of numbers (in the case shown on the drawings the numbers extend from 1 to 24) which are visible selectively, one at a time, through the window 7.

[0017] From the top of the discoidal body 15 there projects a pair of flexible tangs 17 the free ends of which are shaped as a sawtooth 18 which engages the teeth of the ring of teeth 12. The inclined surface of each tooth 18 of the tangs 17 is in contact with, and can slide (hence causing the tang to flex) along, the inclined surface of the teeth 12 (so enabling the body 15 to rotate relative to the body 5), and jump over these teeth. The other surface of the tooth 18 and that surface of the teeth 12 which faces it are shaped to mutually interfere, and prevent rotation of the body 15 in the opposite direction to the preceding.

[0018] Likewise, from the bottom of the discoidal body 15 there projects a pair of flexible tangs 19, the free ends of which each extend between two consecutive teeth of the ring of teeth 11, sliding on their inclined surfaces when the body 15 is rotated in one direction, while jamming against the straight surfaces of these teeth to prevent rotation of the body 15 in the opposite direction.

[0019] To better understand how the discoidal body 15 is made to rotate through one step each time the dispenser is operated, reference will be made to Figures 5 and 6, which show schematically the developments of the teeth 11 and 12, between which there is also shown schematically a portion of the discoidal body 15 with a flexible tang 17 and a flexible tang 19.

[0020] When in the rest state the aforesaid component parts assume the position shown by full lines in Figure 5.

[0021] When the operating body is pressed towards the base body to operate the pump and dispense a dose of liquid, the toothing 12 approaches the toothing 11 until it attains the position shown by dashed lines in Figure 5. During this approach, the profiled end of the tang 19 remains locked on that tooth indicated by the letter d, whereas the tang 17 flexes to rotate the body 15 towards the left (with reference to the figure) through one step, and with it the tang 17, the profiled end 18 of which jumps over the inclined surface of that tooth indicated by the letter b in the toothing 12, and becomes positioned between the teeth b and c, as shown by dashed lines in Figure 5.

[0022] When the pressure exerted by the two fingers on the top of the operating body 5 ceases, this latter is returned to its raised position by the action of the pump spring. However the profiled end 18 of the tang 17 remains fixed at the tooth b, between the two teeth b and c, to hence prevent the return of the discoidal body to that angular position which it had prior to the operation of the dispenser. While the toothing 12 returns to its rest position raised from the toothing 11 (Figure 6), the profiled end of the tang 19 is dragged to jump over the inclined surface of the tooth d and become positioned

between the teeth d and e.

[0023] The cycle can be repeated in this manner, with the window 7 each time showing the next number in the succession of numbers reproduced on the cylindrical surface 16 of the body 15, so enabling the number of dispensed liquid doses to be counted.

[0024] The dispenser with dose counter as described up to this point is similar to that described in EP-B-480488, in which the number of dispensed liquid doses which can be counted is equal to the highest number reproduced on the outer surface of the cylindrical wall 16 of the first rotatable body. In the case illustrated here this first body enables a maximum number of 24 doses to be counted.

[0025] The dispenser of the present invention comprises however a second discoidal body formed with a top annular wall 20 and a cylindrical lateral wall 21 which extends between and is rotatable between the lateral wall 6 of the operating body 5 and the cylindrical wall 16 of the first discoidal body (Figure 1), the top wall 20 being positioned between and rotatable between the wall 8 of the body 5 and the first discoidal body 15, 16.

[0026] In the cylindrical wall 21 there is provided a window 22 which can be transiently retained facing the window 7 of the body 5 by the retention members described hereinafter. On the outer surface of said cylindrical wall 22 there is reproduced a second succession of increasing numbers the lowest of which, in the example shown here, is the number 25, ie one more than the highest number reproduced on the first discoidal body.

[0027] The dispenser is mounted such that before dispensing the first dose of liquid, the window 22 is positioned in front of the window 7, and through this the lowest (0 or 1) of the numbers of that series of numbers reproduced on the wall 16 is visible.

[0028] To prevent the second discoidal body 20, 21 from being dragged into rotation by the first body 15, 16 while dispensing the first series of liquid doses, retention members are provided consisting of a tooth or projection 23 projecting downwards (with reference to Figure 1) from the top wall 8 of the body 5, this tooth or projection being bounded on one side by an inclined surface on which there rests the free end of an upwardly curved flexible tang 24 formed by cutting it from the annular wall 20. The friction exerted by the first discoidal body 15, 16 on the second discoidal body 20, 21 is insufficient to cause the tang 24 to flex and its free end to rise along the inclined surface of the tooth 23, so that the second discoidal body remains at rest while the first discoidal body undergoes a complete revolution about its axis, allowing all the numbers (in our case from 1 to 24) reproduced on the cylindrical wall 16 to be seen through the windows 7 and 22.

[0029] As can be seen from Figure 1 and more clearly from Figure 2, from the cylindrical wall 16 of the first discoidal body there projects a drive tooth 25 which, on termination of a complete revolution of this first body about its axis, interferes with a tooth or small rib 26 pro-

jecting below the wall 20 of the second discoidal body, which is dragged into rotation (causing the flexible tang 24 to jump over the retention tooth 23) by the first discoidal body, in step with it.

[0030] If it is required for the two discoidal bodies not to be able to undergo further rotation on termination of a complete revolution of the second discoidal body, adjacent to the tooth 23 a stop tooth 27 can be provided having a surface which the tang 24 cannot jump over.

[0031] It can be seen that as soon as the second discoidal body is dragged to undergo its first advancement step, the window 22 is moved away from the window 7 from which only the outer surface of the cylindrical wall 21 of the second discoidal body will then be visible (this hiding the cylindrical wall 16 of the first discoidal body from view), with the numbers (one at a time in succession) reproduced on it.

[0032] Figures 2 and 3 show the first discoidal body in perspective view and in plan view from above, whereas Figure 4 shows the second discoidal body only in perspective view.

[0033] Figure 7 is a cross-section through the device on the line 7-7 of Figure 1 to facilitate the understanding of the dispenser structure and operation, no further explanation being necessary.

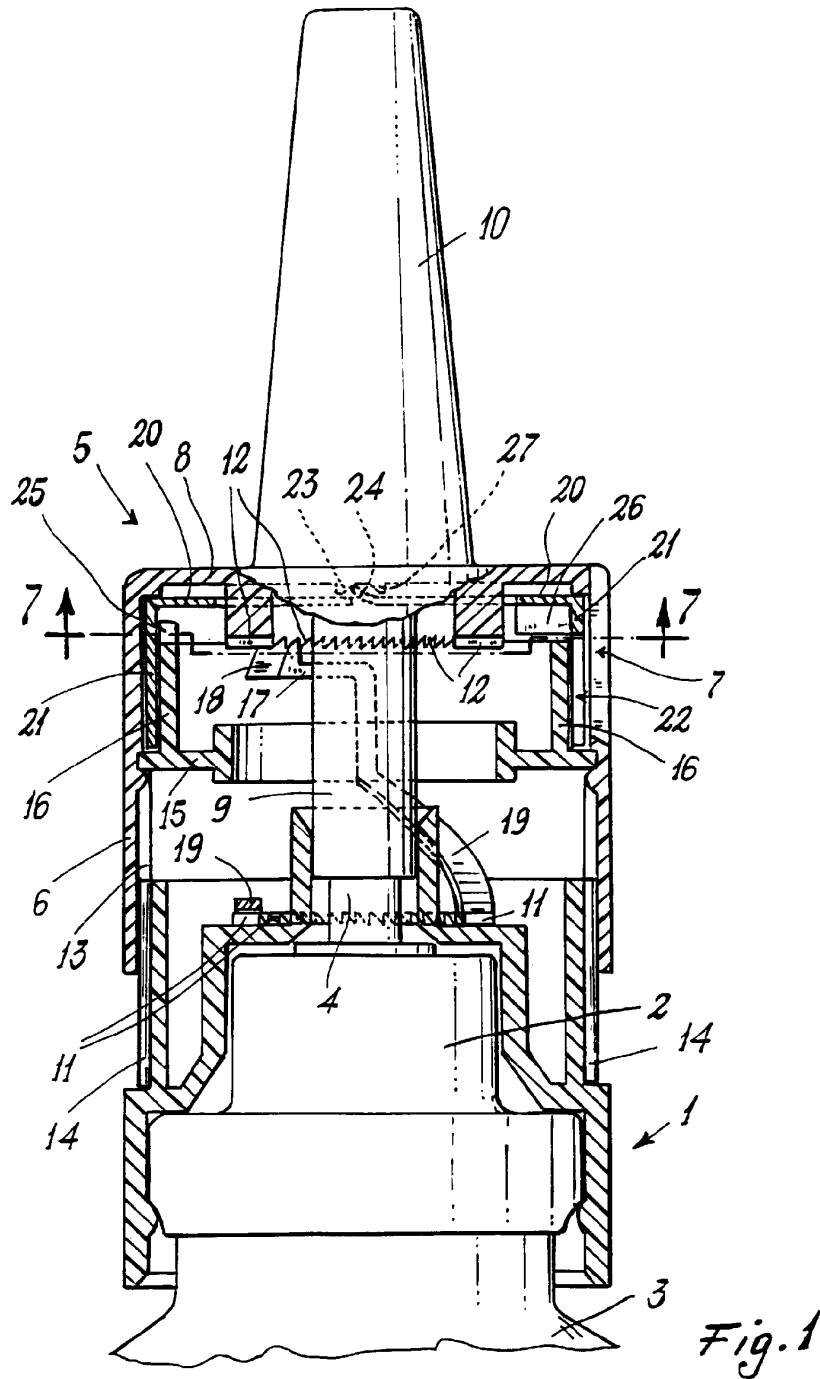
[0034] It is important to note that the dimensions of the device described and claimed herein are totally comparable to those of the device having a single rotatable discoidal body (EP-B-480488) while enabling twice the number of dispensed liquid doses to be counted.

Claims

1. A liquid dose dispenser with a device for counting the dispensed doses, comprising:

- a base body with a seat for housing the free end of a pump or valve for delivering doses of a liquid contained in a container on which the pump is mounted;
- an operating body superposed on the base body and secured to it by guide elements which allow axial movement, but prevent rotation, of one body on the other, the operating body having a substantially cylindrical wall in which a window or aperture is provided, and a top wall with a hole about which there extends a tubular element having at one end a seat for the free end of the pump stem and at its other end a nozzle for discharging the liquid dispensed by the dispenser;
- a first discoidal body housed in and rotatable within the operating body and having a substantially cylindrical surface facing the surface of the lateral wall of the operating body, through the window of which there is selectively positioned one of a first succession of numbers, letters or the like reproduced on the cylindrical

- surface of the first discoidal body;
- two sawtooth-shaped annular surfaces provided one on the base body and the other on the top wall of the operating body, the teeth of one of the two surfaces pointing towards the teeth of the other surface;
 - flexible tangs projecting from the first discoidal body, and having their profiled free ends engaging the toothed surface of the base body and toothed surface of the operating body respectively, to cause the first discoidal body to rotate through one step each time the operating body is moved axially relative to the base body, with consequent initial flexure of said tangs and their subsequent return to an unflexed rest position;
- characterised by also comprising a second discoidal body housed between the top wall of the operating body and the first discoidal body, and having a cylindrical lateral wall on which a second succession of numbers is reproduced, and which extends between and is rotatable between the lateral wall of the operating body and the cylindrical surface of the first discoidal body, on the operating body and on the first discoidal body there being provided retention members which mutually cooperate to transiently maintain a window provided in the lateral wall of the second discoidal body facing the window in the operating body, the first discoidal body having a drive tooth which, when said first body has undergone a complete revolution about its axis, interferes with a tooth provided on the second discoidal body to drag it into rotation, to disengage said retention members and position in succession one of the numbers of said second succession of numbers in front of the window in the operating body.
2. A device as claimed in claim 1, characterised in that said retention members comprise a first projection provided on the inside of the top wall of the operating body and bounded laterally by an inclined surface on which there rests a flexible tang projecting from the second discoidal body, this projection being overcome, with the flexing of said tang, when the drive tooth of the first discoidal body moves the second discoidal body away from its rest position.
 3. A device as claimed in claim 2, characterised in that said first projection in the form of a sawtooth is flanked by a stop tooth on which the flexible tang of the second discoidal body rests to block the movement of this latter after it has undergone a complete revolution about its axis.



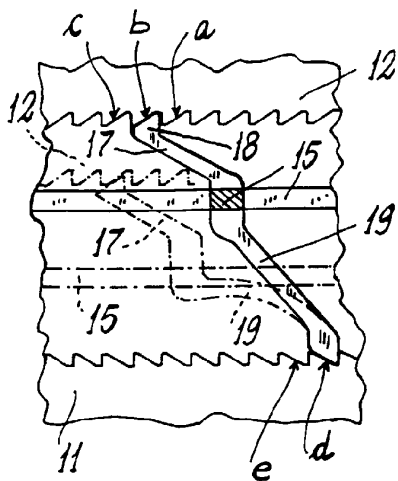


Fig. 5

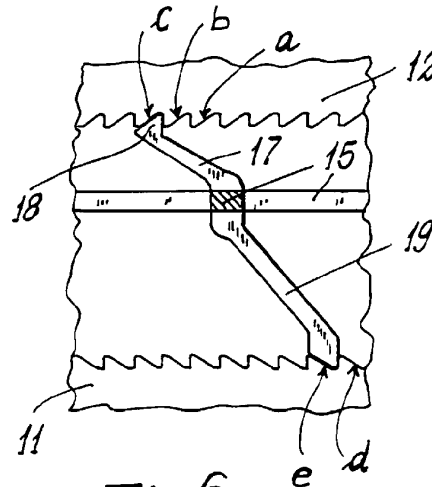


Fig. 6

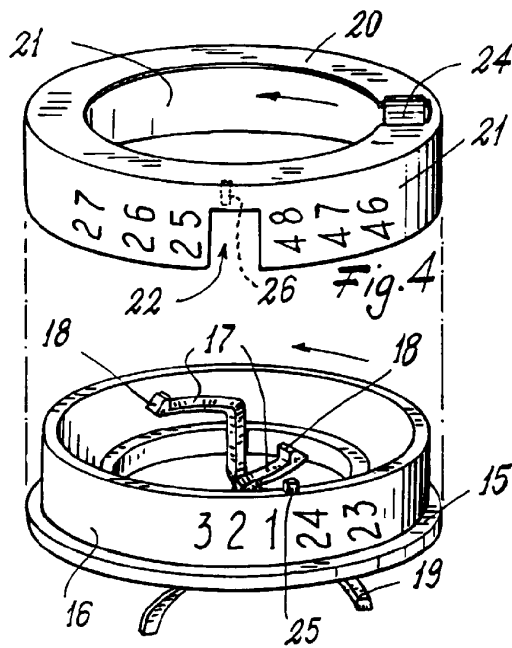


Fig. 2

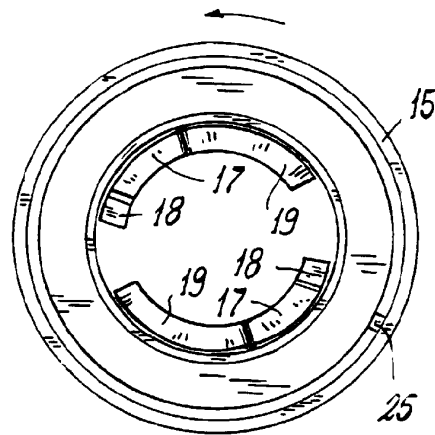
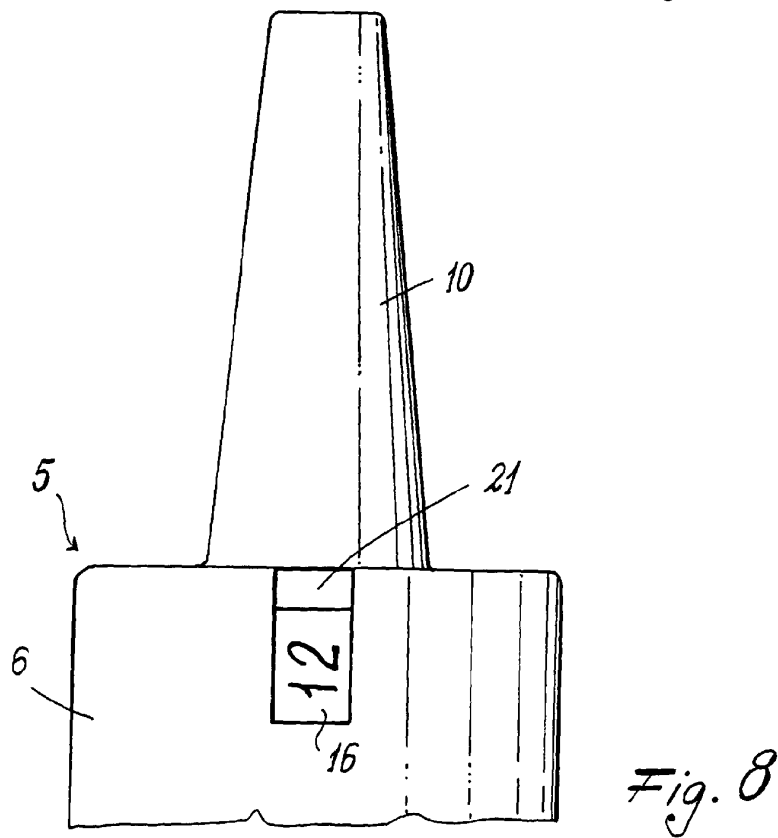
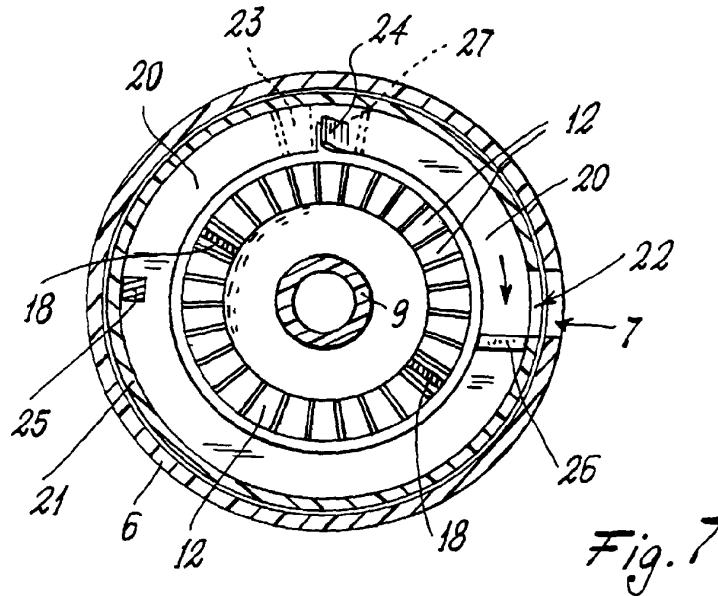
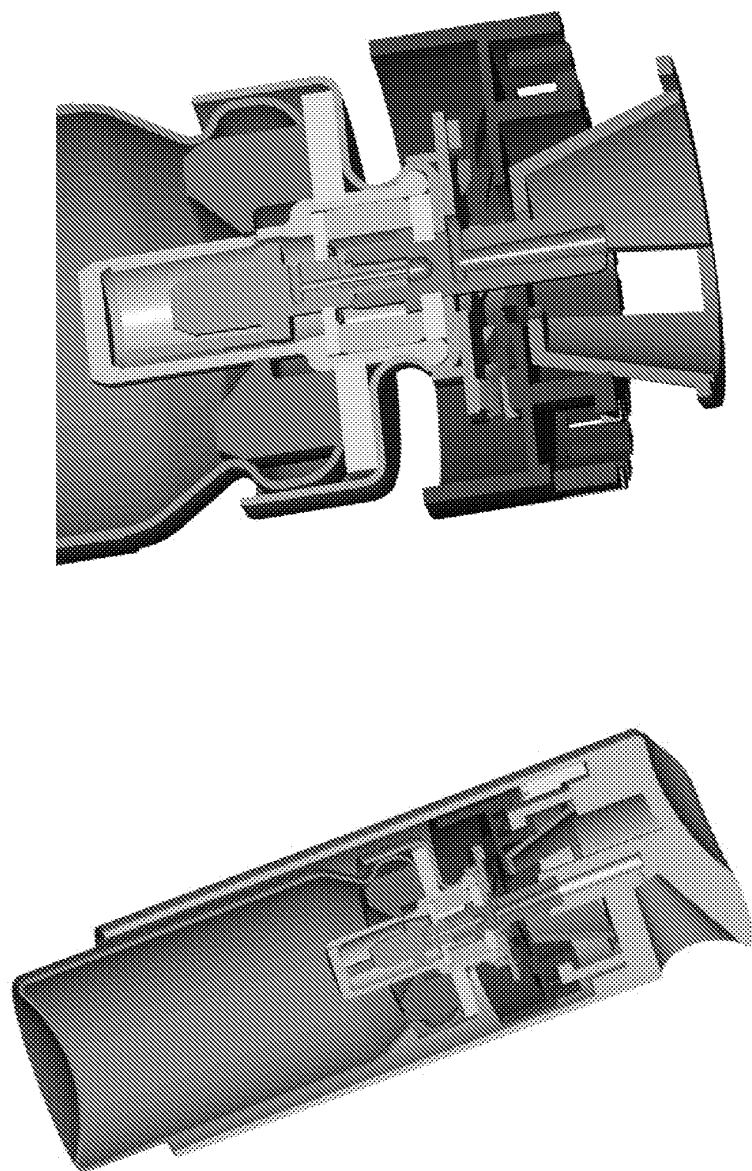
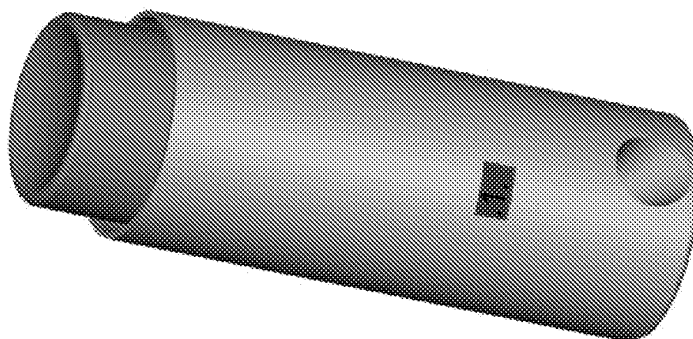


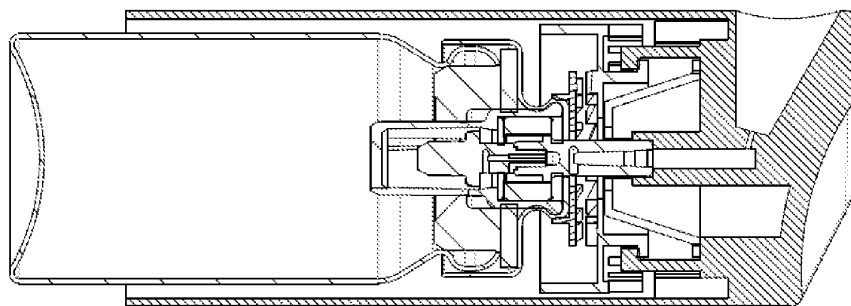
Fig. 3

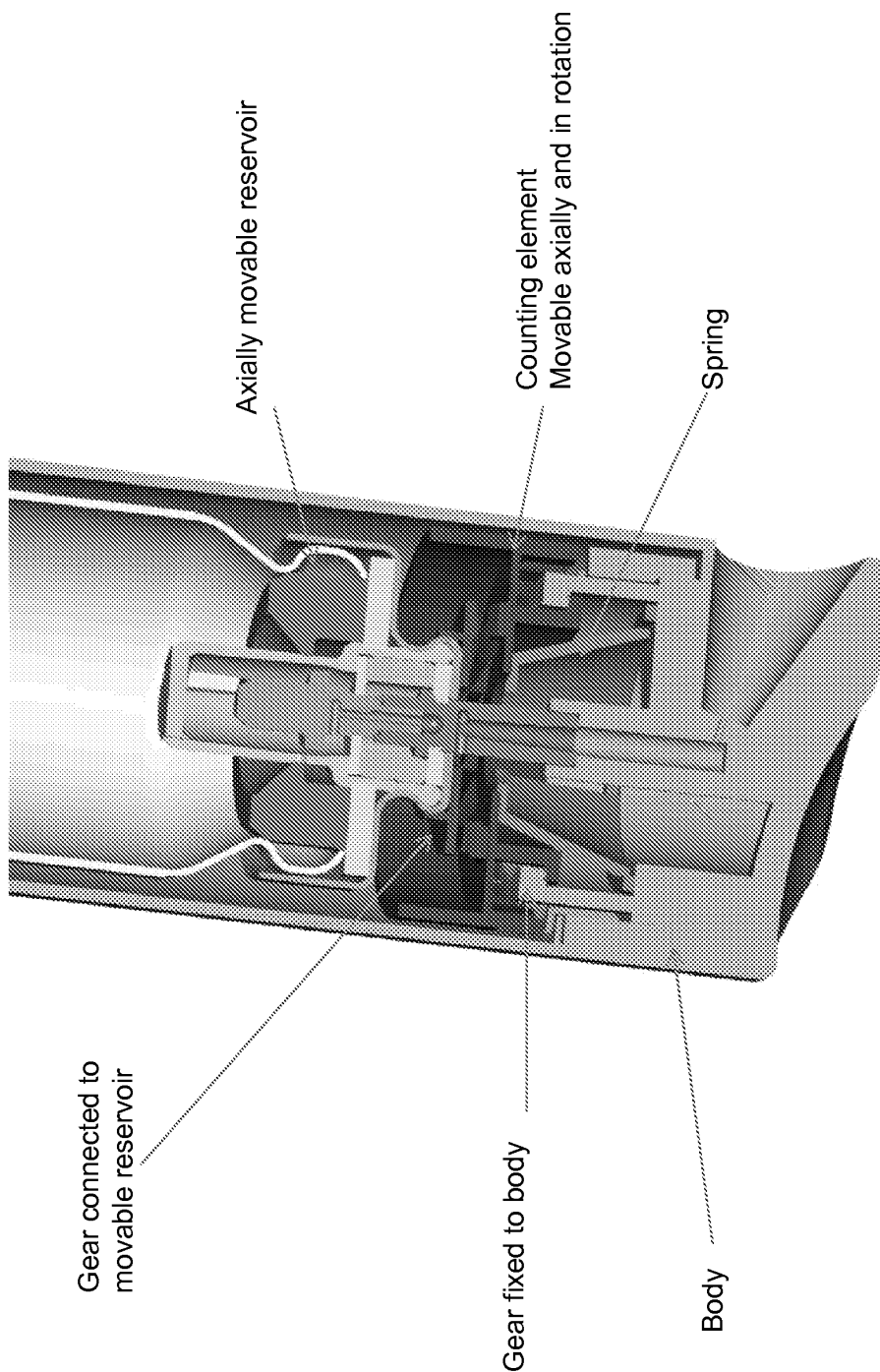


ATTACHMENT C









We're changing
our name but not
our commitment.

Pfetter | Valois

Fig 13

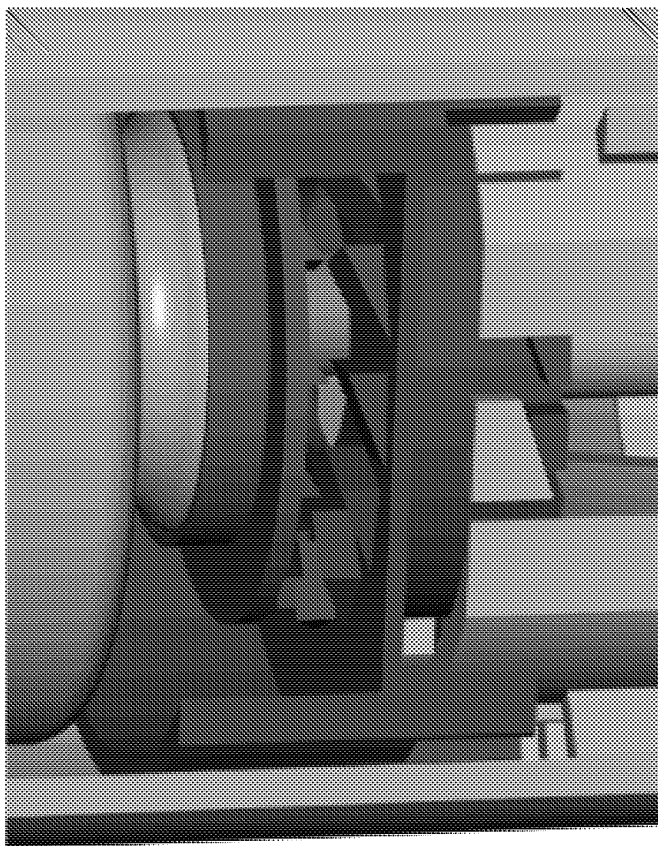


Fig 14

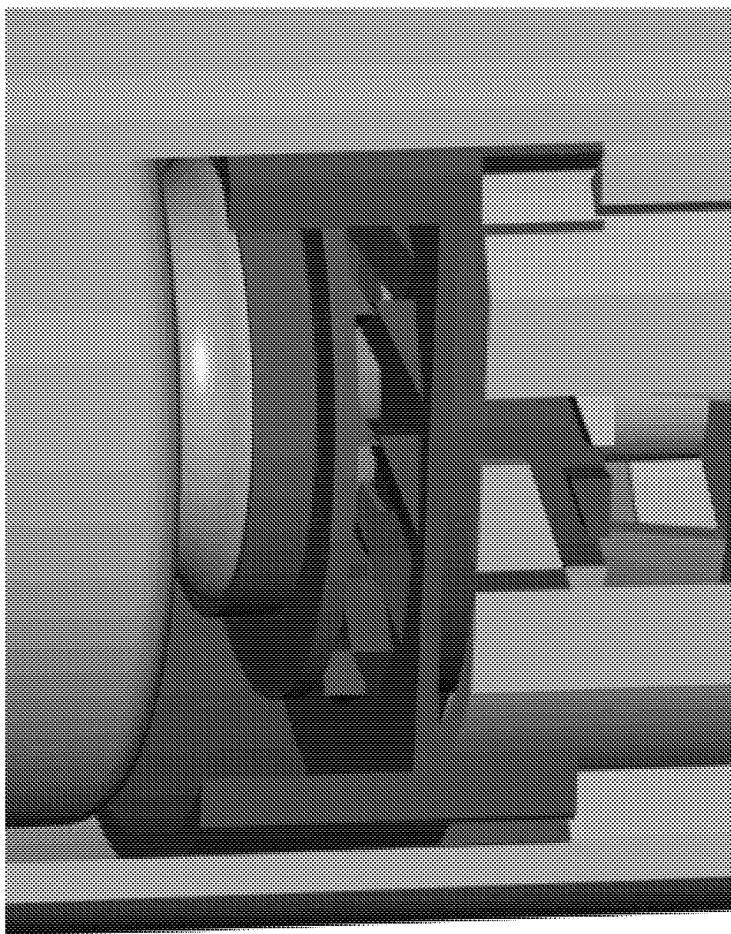


Fig 16

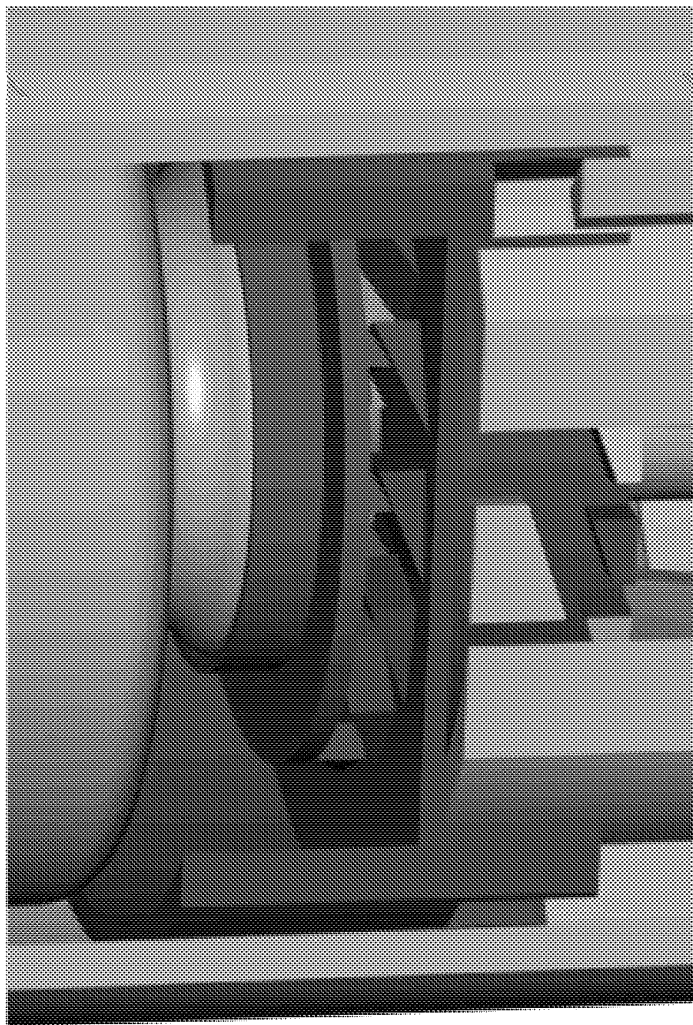


Fig 17

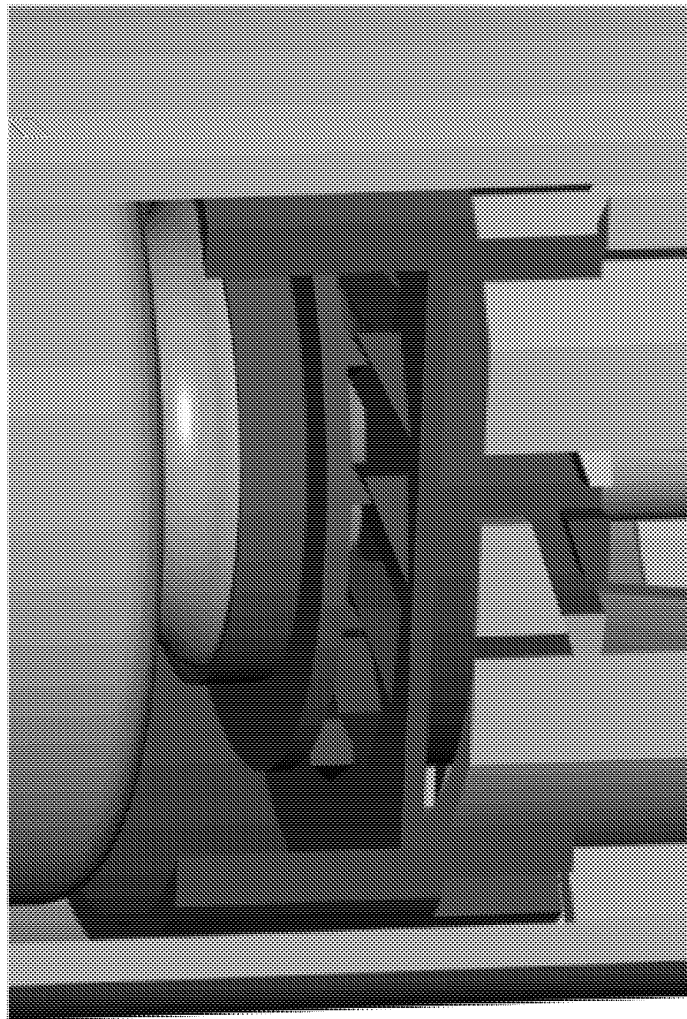
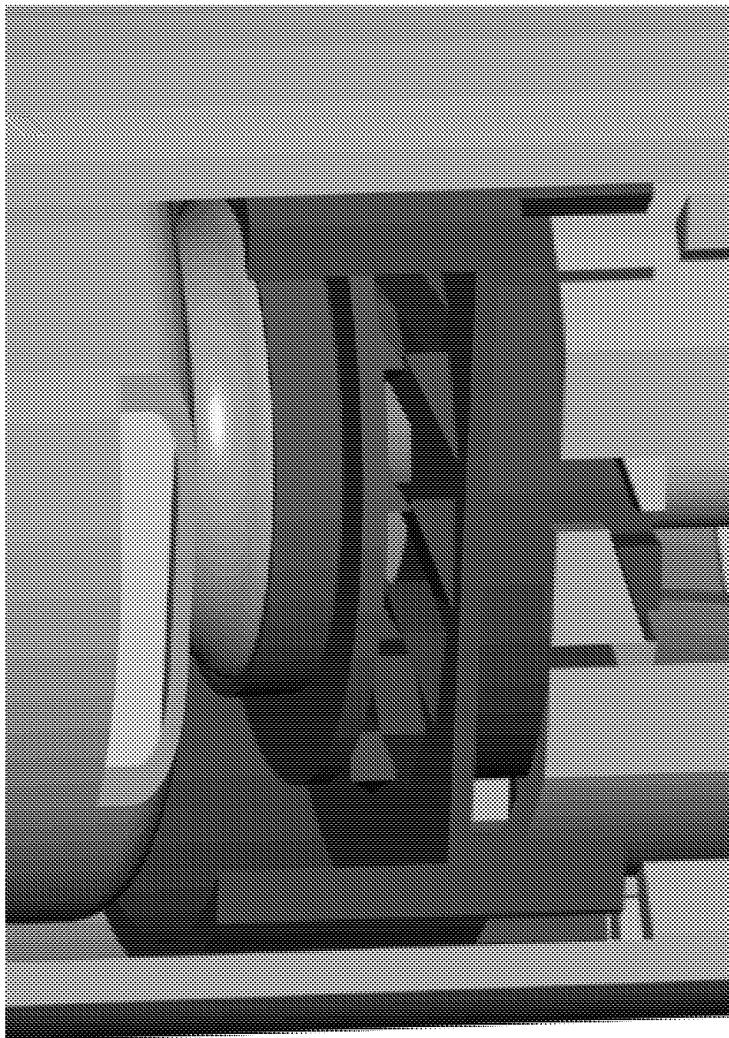


Fig 21



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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 10/556,432		Filing Date 11/09/2005		☐ To be Mailed	

APPLICATION AS FILED – PART I					OTHER THAN SMALL ENTITY					
(Column 1)		(Column 2)		SMALL ENTITY ☐		OR		SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	RATE (\$)	FEE (\$)	RATE (\$)	FEE (\$)	RATE (\$)	
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A		N/A		N/A		N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A		N/A		N/A		N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A		N/A		N/A		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$	=	OR	X \$	=	X \$	=	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$	=	OR	X \$	=	X \$	=	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))			If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).							
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
					TOTAL		TOTAL			

* If the difference in column 1 is less than zero, enter "0" in column 2.

APPLICATION AS AMENDED – PART II					OTHER THAN SMALL ENTITY						
(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR		SMALL ENTITY	
AMENDMENT	12/06/2010	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 23	Minus	** 21	=	2	OR	X \$52=	104		
	Independent (37 CFR 1.16(h))	* 3	Minus	***3	=	0	OR	X \$220=	0		
☐ Application Size Fee (37 CFR 1.16(s))											
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))											
					TOTAL ADD'L FEE		TOTAL ADD'L FEE		104		

(Column 1)		(Column 2)		(Column 3)		SMALL ENTITY		OR		SMALL ENTITY	
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$	=	OR	X \$	=	
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$	=	OR	X \$	=	
☐ Application Size Fee (37 CFR 1.16(s))											
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))											
					TOTAL ADD'L FEE		TOTAL ADD'L FEE				

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
 The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/JAMES ELLIOTT/

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AMENDMENTS TO THE SPECIFICATION

Please replace the third full paragraph on page 8 with the following amended paragraph:

The descriptions of the three embodiments below relate to actuation cycles of the dispenser, and to the various functional features of the indicator device that make it possible to guarantee operational and counting reliability of said indicator device. The drawings to which the present description refers are therefore highly simplified diagrams which do not show the fluid dispenser in detail, but only in very diagrammatic manner relating to the various portions that can be moved relative to one another, for explaining the actuation cycle of said dispenser and of said indicator device. ~~Thus, for example, the dispenser member, e.g. a pump or a valve, is only shown in Figure 1. In addition, the dispenser head including the dispenser orifice is also not shown, since these elements are not directly involved in the present invention.~~

Please replace the paragraph bridging pages 8-9 with the following amended paragraph:

With reference to FIGS. 1 to 8, a first embodiment of the present invention is described.
The dispenser includes the body 1, the reservoir 2, and a dispenser member 3 mounted on a reservoir 2. In this first embodiment, the dispenser includes a reservoir 2 that is axially displaceable in a body 1, which is considered below as being the stationary portion of the dispenser. The axial displacement of the reservoir 2 relative to the body 1 actuates the dispenser member 3 (shown in FIG. 1) and thus causes a dose of fluid to be dispensed from said reservoir. In this first embodiment, the dispenser includes an actuator member 30 on which the user exerts an axial actuation force so as to actuate the dispenser and thus displace said reservoir 2 relative to the body 1. The dispenser further includes a dose indicator device for counting or indicating the dispensing of one fluid dose each time the dispenser is actuated. Thus, by means of the

indicator device, the user can tell how many doses have been dispensed from said reservoir 2, or how many doses remain inside said reservoir 2. This information must be very accurate, in particular when the fluid is a pharmaceutical, and any risk of under-counting must be eliminated. In the event of under-counting, i.e. in the event of the indicator device failing to count one or more occasions on which a dose of fluid is dispensed in full or in part, the user can end up with a dispenser that indicates that one or two doses remain in the reservoir, whereas in reality, the reservoir is empty. In the event of an asthma attack, the user can thus end up with a dispenser that is no longer functional, and that does not enable the user to take the medicine.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1. (currently amended): A fluid dispenser comprising:
a stationary body (1) including at least one stationary gear (110, 122),
a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said
body,
a dispenser member mounted on said reservoir (2), and
a dose indicator device, including a counter element (20) that is displaceable axially and
in rotation relative to said body (1), for indicating the number of doses of fluid that have been
dispensed or that remain to be dispensed from said reservoir,
~~the dispenser being characterized in that said dose indicator device includes a first safety~~
~~system that actuates the dose indicator device once the dispenser has performed a predetermined~~
~~incomplete actuation stroke, even if the dispenser does not perform the a complete actuation~~
~~stroke, said reservoir (2) being axially displaceable relative to said body (1), said body (1)~~
~~including at least one stationary gear (110, 122), said dose indicator device including a counter~~
~~element (20) that is displaceable axially and in rotation relative to said body (1), wherein said~~
counter element (20) ~~co-operating~~cooperates, while the dispenser is being actuated, firstly with
said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so
that the dose indicator device is actuated once the dispenser has performed a pretermined
incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.

2. (currently amended): A dispenser according to claim 1, ~~in which said dose indicator device includes a second safety system which~~wherein, during the return stroke of the dispenser after dispensing a dose, said dose indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

3. (previously presented): A dispenser according to claim 1, in which said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20), said counter element (20) including a second gear (230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser, the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation, the stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

4. (original): A dispenser according to claim 3, in which the stationary gear (110) includes abutment means (115) preventing said counter element (20) from turning once said counter element (20) has turned at least in part, an additional axial displacement of said counter

element (20) being necessary to enable it to continue to turn and/or to return the indicator device to its rest position.

5. (original): A dispenser according to claim 4, in which said abutment means (115) comprise an axial projection.

6. (previously presented): A dispenser according to claim 1, in which said stationary gear (110) and/or said counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position after a preceding actuation, and until the dispenser has completed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

7. (previously presented): A dispenser according to claim 6, in which said blocking means comprise axial projections (120, 220) provided on the body (1) and on the counter element (20) respectively, each of said projections (120, 220) having an axial end-profile that is planar, said projections (120, 220) facing each other, at least in part, until the counter element has turned sufficiently to offset said projections (120, 220), with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

8. (previously presented): A dispenser according to claim 3, in which the teeth of the second gear (230) of the counter element (20) include an intermediate step (235), the actuator

member (30) co-operating with said step (235) while the dispenser is being actuated, and co-operating with the end wall of said second gear (230) while returning to the rest position, after being actuated, the displacement between the intermediate step (235) and the end wall being obtained by said counter element (20) turning.

9. (previously presented): A dispenser according to claim 3, in which, once the predetermined incomplete return stroke has been performed, the actuator member (30) is positioned facing the following tooth of the second gear (230) of the counter element (20), enabling the dispenser and the dose indicator device to be actuated once again.

10. (previously presented): A dispenser according to claim 1, in which said body (1) includes a first stationary gear (110) and a second stationary gear (122), said counter element (20) including a first gear (210) for co-operating with said first stationary gear (110) and a second gear (222) for co-operating with said second stationary gear (122), said counter element (20) being put axially into contact with an actuator member (30) of the dispenser by means of a return spring (50) and being turnable relative to said actuator member (30), the teeth of said second gear (222) and of said second stationary gear (122) being oblique, at least in part, so that an axial displacement of the actuator member (30) initially causes said counter element (20) to be displaced axially over a predetermined incomplete actuation stroke until the oblique portion (221) of said second gear (222) of the counter element (20) co-operates with said oblique portion (121) of said second stationary gear (122), causing the counter element (20) to be turned over a first portion of a turn cycle, the teeth of said first gear (210) and of said first stationary gear (110)

being oblique, at least in part, so that when the counter element (20) returns to its rest position, it is caused to turn so as to terminate its turn cycle, which corresponds to one actuation of the dispenser being counted.

11. (previously presented): A dispenser according to claim 10, in which said first and second stationary gears (110, 122) of the body (1) and/or said first and second gears (210, 222) of the counter element (20) are offset relative to each other, so that whenever the counter element (20) is displaceable in rotation, returning said counter element to its rest position without terminating the actuation stroke of the dispenser causes the counter element (20) to turn over its complete turn cycle, guaranteeing that one actuation of the dispenser is counted after said predetermined incomplete actuation stroke.

12. (previously presented): A dispenser according to claim 10, in which said second stationary gear (122) of the body (1) and/or said second gear (222) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, and until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

13. (previously presented): A dispenser according to claim 12, in which said blocking means have an axial end-profile that is planar, at least in part, and that is formed on the teeth of

said second stationary gear (122) of the body (1) and on the teeth of said second gear (222) of the counter element (20), said planar profiles of said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

14. (previously presented): A dispenser according to claim 10, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

15. (previously presented): A dispenser according to claim 1, in which said body (1) includes a first stationary gear (110) and a second stationary gear (122), said counter element (20) comprising a first gear (210) for co-operating with said first stationary gear (110), a second gear (222) for co-operating with said second stationary gear (122), and a third gear (230) for co-operating with an actuator gear (300) secured to an actuator member (30) of the dispenser, the teeth of said third gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member (30) causes said counter element (20) to be displaced axially and in rotation, the first stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

16. (previously presented): A dispenser according to claim 15, in which said second stationary gear (122) of the body (1) and/or said second gear (222) of the counter element (20)

include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

17. (previously presented): A dispenser according to claim 16, in which said blocking means have an axial end-profile that is planar and that is formed on the teeth of said second stationary gear (122) and on the teeth of said second gear (222), said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

18. (previously presented): A dispenser according to claim 16, in which said actuator gear (300) includes abutment means (305) limiting the extent to which the counter element (20) can turn, until the actuator member (30) has performed said predetermined incomplete return stroke.

19. (original): A dispenser according to claim 18, in which said abutment means (305) comprise an axial projection formed on said actuator gear (300).

20. (previously presented): A dispenser according to claim 15, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

21. (previously presented): A dispenser according to claim 1, wherein the dispenser member is a pump or a valve.

22. (new): A fluid dispenser comprising:

a stationary body (1) including at least one stationary gear (110, 122);

a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body;

a dispenser member mounted on said reservoir (2), being actuated when said reservoir is axially displaced relative to the stationary body by a predetermined amount, for dispensing a dose of fluid from said reservoir;

a dose indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, said dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to said body (1), wherein when the dispenser member is actuated, said counter element cooperates firstly with said at least one stationary gear (110, 122) and secondly with said reservoir (2);

first safety means for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke; and

second safety means for preventing the fluid from being expelled again until said dispenser has completed the predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined

incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

23. (new): A fluid dispenser comprising:
a stationary body including at least one stationary gear;
an actuator member that is displaceable axially with respect to said stationary body;
a dose indicator that is displaceable axially and in rotation relative to said body, said dose indicator being engageable with said actuator member and said stationary body, wherein when said actuator member displaces axially, said counter element is caused to be displaced axially and permitted to rotate relative to said body.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 02/18/2011 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER NGO, LIEN M	
			ART UNIT 3754	PAPER NUMBER
			NOTIFICATION DATE 02/18/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary	Application No.	Applicant(s)	
	10/556,432	POULARD, FABIEN	
	Examiner	Art Unit	
	LIEN TM NGO	3754	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 06 December 2010.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-23 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)	4) ☐ Interview Summary (PTO-413)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)	5) ☐ Notice of Informal Patent Application
Paper No(s)/Mail Date <u>12/6/10</u> .	6) ☐ Other: _____

DETAILED ACTION

1. This application has been treated as being obviously informal. Note, it is impractical to give a complete action on the merits because of the insufficiencies noted below. A reasonable search has been made in so far as the invention could be understood from the disclosure.

Drawings

2. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed 10/22/08 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.21 (a) (6) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of a pump or valve 3 located on top of the reservoir 2 and having a structure contacted with members 20 and 110 as amended in fig. 1.

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show the details of structure and connections of components of the invention as described in the specification as improvement of the prior art to make the invention work and function. Note, the drawings of figs. 1-21 only show a simplified diagrams of a reservoir, a body, an actuator member, a counter element, and fail to specially show such elements are structurally connected/mounted to one another in order to one having an ordinary skill to understand how the system of the invention can perform the functions and work as disclosed in the original specification, for example, what are actual structures of the body, reservoir, dispenser member, dose indicator device, actuator member, station gear(s), counter element gear(s), actuator gear(s) and how are

connections between the elements so that the body gear is stationary, the reservoir can be stored in the body and axially displaceable to the body, the counter element can indicate the number of doses dispensed or remained and can be axially displaceable and rotatable, why just a oblique tooth of the actuator and the counter element can be considered a gear, why the gear of the body is stationary but the gear of the actuator is axial displaceable and the gears of the counter element are axially and rotatably displaceable. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to under 37 CFR 1.83(b) because they are incomplete. 37 CFR 1.83(b) reads as follows:

When the invention consists of an improvement on an old machine the drawing must when possible exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith.

The specification of the application, pages 1 and 2, discloses the invention, which is a fluid dispenser comprising a dose indicator as an improvement on a prior art. Figs. 1-21 in the present application show only simplified diagrams without clearly providing the structural shapes and connections between one element to one another in order to one having an ordinary skill to understand the claimed invention functions, working and improvement as disclosed in the specification. The drawing does not exhibit, in one or more views, the improved portion itself, disconnected from the old structure, and also in another view, so much only of the old structure as will suffice to show the connection of the invention therewith.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement

sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the dispenser member mounted on the reservoir or a pump or a valve in claims 1 and 21, the counter element is in rotation relative to the body in claim 1, and the counter element is turnable relative to the actuator member, the counter element co-operating, while the dispenser being actuated, first with at least one station gear of the body and secondly with the reservoir in claims 10 and 15, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The amendment filed 12/6/10 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: (with reference to figs. 1-8,... a dispenser member 3 mounted on a reservoir 2). Amendment of Fig. 1 introduces new matter because the original disclosure does not support the showing of a dispenser member or a pump or valve 3 located on top of the reservoir 2, and having a structure contacted with members 20 and 110 as amended in fig. 1.

Applicant is required to cancel the new matter in the reply to this Office Action.

7. The disclosure is objected to under 37 CFR 1.71, as being so incomprehensible as to preclude a reasonable search of the prior art by the examiner. For example, the

following items are not understood: what are structural connections between the container, body, actuator and counter elements so that the reservoir can be stored in the body and axially displaceable to the body, the counter element can indicate the number of doses dispensed or remained and can be axially displaceable and rotatable; why just a oblique tooth of the actuator and the counter element can be considered a gear; why the gear of the body can be stationary but the gear of the actuator is axial displaceable and the gears of the counter element are axially and rotatably displaceable; what are actual structural shapes and connections of one element to one another in order to one having an ordinary skill to understand the invention functions, working and improvement, etc. as disclosed in the specification.

Applicant is required to submit an amendment which clarifies the disclosure so that the examiner may make a proper comparison of the invention with the prior art.

Applicant should be careful not to introduce any new matter into the disclosure (i.e., matter which is not supported by the disclosure as originally filed).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In regard to claims 1-9, 22 and 23, the claims recite the elements and their functions related one to another without actual structures and connections between them. The specification of the present application does not disclose in full, clear, concise of the actual structures of a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element and structural connections between them in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or perform the system in claims 1 and 23, so that the counter element is displaceable axially and in rotation relative to the body, the body gear is stationary, the reservoir is axially displaced relative to the body even if the dispenser does not perform a complete actuator stroke and the counter element co-operating, while the dispenser is being actuated, firstly with the at least one stationary gear and secondly with the reservoir; and the system as in claim 2 during the return stroke; and also claimed subject matter in claims 3-9 and 22. In regard to claims 10-14, the specification of the present application does not disclose in full, clear, concise of the actual structures of a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element and structural connections between them in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or perform the claimed subject matter of claims 10-14, which examiner

believe they are claimed directly from the embodiment of figs. 9-12 in the application. Moreover, the specification does not support the claimed subject matter of claim 10-14 as disclosed in figs. 9-12, which enables for the counter element co-operating, while the dispenser is being actuated, firstly with the at least one stationary gear and secondly with the reservoir, as claimed in claims 1 and 22.

In regard to claims 15-20 , the specification of the present application does not disclose in full, clear, concise of the actual structures of a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element and structural connections between them in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or perform the claimed subject mater of claims 15-20, which examiner believe they are claimed directly from the embodiment of figs. 13-21. Moreover, the specification does not support the claimed subject matter of claim 15-20 as disclosed in figs. 13-21, which enables for the counter element co-operating, while the dispenser is being actuated, firstly with the at least one stationary gear and secondly with the reservoir, as claimed in claim 1.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-23 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See

MPEP § 2172.01. The omitted structural cooperative relationships are: the claims comprising many elements but do not include structures or shapes of elements and structural connections between the elements, such omission amounting to a gap between the necessary structural connections.

12. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because it is not clear what are required for structures or shapes of the elements in the claims, such as a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element, etc., and structural connections between them to understand the claimed subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bason (EP 0949548). As best understood Bason discloses, in figs. 1-6, a fluid dispenser comprising a stationary body¹ including at least one stationary gear 2; a fluid reservoir C, a dispenser (inherent); a dose indicator device having a counter element 4, 8

displaceable axially and in rotation relative to the body; wherein the dispenser is actuated, the counter element cooperates firstly with the at least one stationary gear and secondly with said reservoir; first and second safety means 10, 5.

15. Claims 1 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Rand et al. (EP 0254391). As best understood Rand et al. disclose, in figs. 1 and 2, a fluid dispenser comprising a stationary body 11 including at least one stationary gear; a fluid reservoir 2, a dispenser member 4; a dose indicator device having a counter element 14, 20 displaceable axially and in rotation relative to the body; wherein the dispenser is actuated, the counter element cooperates firstly with the at least one stationary gear and secondly with said reservoir.

Response to Amendment

16. The Declaration under 37 CFR 1.132 filed 12/6/10 is insufficient to overcome the rejection of claims 1-23 based upon drawing objections, specification objection and 112 rejections as set forth in the last Office action because the structures, connections of the components of the application invention or claimed invention are well known or an understood by ordinary skill in the art by evidences with different prior art inventions having different structures, connections of components, etc, which is not readily understood by one ordinary skill in the art how to make and use of the present invention.

Response to Arguments

17. Applicant's arguments with respect to claims 1-23 have been considered but are moot in view of the new ground(s) of rejection.

18. Applicant's arguments filed 112/6/10 have been fully considered but they are not persuasive because the structures, connections of the components of the application invention or claimed invention are well known or an understood by ordinary skill in the art by evidences with different prior art inventions having different structures, connections of components, etc, which is not readily understood by one ordinary skill in the art how to make and use of the present invention.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LIEN TM NGO whose telephone number is 571-272-4545. The examiner can normally be reached on Monday through Friday from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, KEVIN SHAVER can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LIEN TM NGO/
Primary Examiner, Art Unit 3754

February 14, 2011

Receipt date: 12/06/2010

MODIFIED PTO/SB/08a (01-10)
Approved for use through 07/31/2012.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	10/556,432
	Confirmation Number	3524
	Filing Date	November 9, 2005
	First Named Inventor	Fabien POULARD
	Art Unit	3754
	Examiner Name	Lien M. Ngo
	Attorney Docket Number	Q91404

U.S. PATENTS						
Examiner Initials*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	5349945	A	1994-09-27	WASS et al.	
	2.	5718355	A	1998-02-17	GARBY et al.	
	3.	5904139	A	1999-05-18	HAUSER	
	4.	6161724	A	2000-12-19	BLACKER et al.	
	5.	6155251	A	2000-12-05	HAUSER	
	6.	6328037	B1	2001-12-11	SCARROTT et al.	
	7.	6752153	B1	2004-06-22	ECKERT	
	8.	6679251	B1	2004-01-20	GALLEM et al.	
	9.	6481438	B1	2002-11-19	GALLEM et al.	

U.S. PATENT APPLICATION PUBLICATIONS						
Examiner Initials*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
	10.	93/24167	WO	A1	1993-12-09	Norton Healthcare Limited		
	11.	98/52634	WO	A1	1998-11-26	PA Consulting Services Limited		
	12.	98/56444	WO	A1	1998-12-17	Glaxo Group Limited		
	13.	00/09187	WO	A1	2000-02-24	Joseph Wicherath GmbH & Co Kg		Abstract and US '153
	14.	00/21593	WO	A1	2000-04-20	Pari GmbH Spezialisten fur Eff		Abstract and Hauser US '251 and US '438
	15.	00/59806	WO	A1	2000-10-12	Bespak PLC		
	16.	01/28887	WO	A1	2001-04-26	Glaxo Group Limited		
	17.	01/37909	WO	A1	2001-05-31	Ernst Horlins Ingenjorbyra AB		
	18.	0 254 391	EP	A1	1988-01-27	Glaxo Group Limited		
	19.	0 949 584	EP	A2	1999-10-13	Bason, Neil Peter		
	20.	1 010 438	EP	A1	2000-06-21	Bespak PLC		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. 2 Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). 3 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 4 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 5 Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /LN/

[Page 1 of 3]

Receipt date: 12/06/2010

MODIFIED PTO/SB/08a (01-10)
Approved for use through 07/31/2012.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	Application Number	10/556,432
	Confirmation Number	3524
	Filing Date	November 9, 2005
	First Named Inventor	Fabien POULARD
	Art Unit	3754
	Examiner Name	Lien M. Ngo
	Attorney Docket Number	Q91404

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No	Foreign Document Number ³	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
	21.	1 163 922	EP	A2	2001-12-19	Glaxo Group Limited		
	22.	1 065 477	EP	A2	2001-01-03	Microspray Delta S.p.A.		

NON-PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	T ⁵

EXAMINER SIGNATURE			
Examiner Signature	/Lien Ngo/	Date Considered	02/14/2011

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. 2 Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). 3 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 4 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 5 Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /LN/

[Page 2 of 3]

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. NGO

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

NOTICE OF APPEAL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant hereby appeals to the Board of Patent Appeals and Interferences from the final Office Action dated February 18, 2011.

The statutory fee of \$540.00 was previously paid on May 20, 2009 and should be applied to this new appeal. Therefore no fee is believed due at this time. However, the USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880 if necessary. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

/Ellen R. Smith
Ellen R. Smith
Registration No. 43,042

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: June 17, 2011

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2009 <i>(Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)</i>		Docket Number Q91404 Confirmation Number 3524	
Application Number		10/556,432	
Filing Date		November 9, 2005	
For FLUID PRODUCT DISPENSER			
Art Unit		3754	
Examiner Name		Lien M. NGO	
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):			
		<u>Fee</u>	<u>Small Entity Fee</u>
☒	One month (37 CFR 1.17(a)(1))	\$130.00	\$65.00 \$130.00
☐	Two month (37 CFR 1.17(a)(2))	\$490.00	\$245.00 _____
☐	Three month (37 CFR 1.17(a)(3))	\$1110.00	\$555.00 _____
☐	Four month (37 CFR 1.17(a)(4))	\$1730.00	\$865.00 _____
☐	Five month (37 CFR 1.17(a)(5))	\$2350.00	\$1175.00 _____
☐	Previous Payment Amount	Date Submitted _____	
☐ Applicant claims small entity status. See 37 CFR 1.27			
☐ A check in the amount of the fee is enclosed.			
☒ Payment by credit card.			
☐ The Director has already been authorized to charge fees in this application to a Deposit Account.			
☒ The Director is hereby authorized to charge any fees, except for the Issue Fee and the Publication Fee , or credit any overpayment, to Deposit Account Number 19-4880.			
I am the ☐ applicant/inventor ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed (Form PTO/SB/96). ☒ attorney or agent of record. Registration Number <u>43,042</u> ☐ attorney or agent under 37 CFR 1.34. ☐ Registration number if acting under 37 CFR 1.34 _____			
WASHINGTON OFFICE 23373 CUSTOMER NUMBER			
_____ / Ellen R. Smith/ Signature		_____ June 17, 2011 Date	
_____ Ellen R. Smith Typed or printed name		_____ (202) 293-7060 Telephone Number	
Note: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			
☒ Total of <u>1</u> form is submitted.			

Electronic Patent Application Fee Transmittal				
Application Number:		10556432		
Filing Date:		09-Nov-2005		
Title of Invention:		Fluid product dispenser		
First Named Inventor/Applicant Name:		Fabien Poulard		
Filer:		Ellen Resnick Smith/Brenda Pugh		
Attorney Docket Number:		Q91404		
Filed as Large Entity				
U.S. National Stage under 35 USC 371 Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
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Miscellaneous-Filing:				
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Extension - 1 month with \$0 paid	1251	1	130	130

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				130

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Application Number:	10556432
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Title of Invention:	Fluid product dispenser
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Notice of Appeal Filed	Notice_of_Appeal.PDF	50903	no	1
			2851b9e599edec1e50b9dd0a52566d98be58e3c8		
Warnings:					
Information:					
2	Extension of Time	EOT.pdf	96121	no	1
			f7a25b52a63f1e288f34fdaf7604d50f86bb8c		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	29974	no	2
			30126c65dbf5906ff9e1f2a85cae5383e6c74275		
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. NGO

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. § 41.37, Appellant submits the following:

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I. REAL PARTY IN INTEREST

The real party in interest in this appeal is VALOIS SAS (assignee), of France, by virtue of an assignment executed by Fabien POULARD (inventor), of France, on October 20, 2005.

The assignment was previously submitted and was recorded on October 20, 2005, at Reel 017925, Frame 0909.

II. RELATED APPEALS AND INTERFERENCES

To the knowledge and belief of Appellant, the Assignee, and the Appellant's legal representative, there are no other appeals or interferences before the Board of Appeals and Interferences that will directly affect or be affected by the Board's decision in the instant Appeal.

III. STATUS OF CLAIMS

Claims 1-23 are all of the pending claims and all are rejected. The rejections of claims 1-23 are being appealed.

Claims 1-21 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate description of the invention that would enable one skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed subject matter.

Claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections.

Claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bason (EP 0949548).

Claims 1 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rand et al. (EP 0254391).

IV. STATUS OF AMENDMENTS

The status of all amendments filed after final rejection is as follows:

A Final Rejection was mailed on February 18, 2011. Appellant filed a Notice of Appeal on June 17, 2011 in response to the Final Rejection. Thus, no Amendments have been submitted after the Final Rejection.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 1, 22 and 23 are the only independent claims. The claimed subject matter will be explained with reference to three exemplary and non-limiting embodiments disclosed in the specification of the current application.

The subject matter of claim 1 concerns a fluid dispenser comprising a stationary body (1) including at least one stationary gear (110, 122) (*see e.g.*, original specification, 1st embodiment: page 10, lines 20-22; 2nd embodiment: page 14, lines 22-23; 3rd embodiment: page 16, lines 11-21; *see also* amendment to the specification filed October 22, 2008; *see also* FIGS. 1 and 13), a fluid reservoir (2) disposed in the body (1) so as to be axially displaceable relative to the body (1) (*see e.g.*, original specification, 1st embodiment: page 8, line 35 to page 9, line 5; FIGS. 1-4; 2nd embodiment: page 14, lines 28-32; 3rd embodiment: FIGS 13-21, showing the reservoir (2) being axially displaced relative to the body), a dispenser member (3) mounted on the reservoir (2) (*see e.g.*, original specification, claim 1; *see also*, amendment to FIG. 1 filed October 22, 2008), and a dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to the body (1) for indicating the number of doses that have been dispensed or remain to be dispensed from the reservoir (2) (*see e.g.*, original specification, 1st embodiment: page 8, line 36 to page 9, line 15 and page 10, lines 25-31; FIGS. 1-8; 2nd embodiment: page 14, lines 23-27; FIGS. 9-12; 3rd embodiment: page 16, lines 16-26; FIGS. 13-21; *see also* amendments to specification and drawings filed October 22, 2008.)

Claim 1 recites that the counter element (20) cooperates, while the dispenser is being

actuated, firstly with the at least one stationary gear (110, 122) of the body (1), and secondly with the reservoir (2) (*see e.g.*, original specification, 1st embodiment: page 10, lines 22-25; 2nd embodiment: page 14, line 22 to page 15, line 9; FIGS. 1-8; 3rd embodiment: page 16, lines 16-26), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete acutation stroke, even if the dispenser does not perform a complete actuation stroke (*see e.g.*, original specification, 1st embodiment: page 11, line 22 to page 12, line 3; page 12, lines 23-28; 2nd embodiment: page 15, lines 5-23; 3rd embodiment: page 16, lines 26-32).

The subject matter of independent claim 22 concerns a fluid dispenser comprising a stationary body (1) including at least one stationary gear (110, 122); (*see e.g.*, original specification, 1st embodiment: page 10, lines 20-22; 2nd embodiment: page 14, lines 22-23; 3rd embodiment: page 16, lines 15-18; *see also* amendment to the specification filed October 22, 2008; *see also* FIGS. 1 and 13), a fluid reservoir (2) disposed in the body (1) so as to be axially displaceable relative to the body (*see e.g.*, original specification, 1st embodiment: page 8, line 35 to page 9, line 5; FIGS. 1-4; 2nd embodiment: page 14, lines 28-32; 3rd embodiment: FIGS 13-21, showing the reservoir (2) being axially displaced relative to the body), a dispenser member (3) mounted on the reservoir (2) (*see e.g.*, original specification, claim 1; *see also*, amendment to FIG. 1 filed October 22, 2008), being actuated when the reservoir (2) is axially displaced relative to the stationary body (1) by a predetermined amount, for dispensing a dose of fluid from the reservoir (2) (*see e.g.*, original specification page 9, lines 1-5); and a dose indicator device for indicating the number of doses that have been dispensed or remain to be dispensed from the

reservoir (2) (*see e.g.*, original specification, 1st embodiment: page 8, line 36 to page 9, line 15 and page 10, lines 25-31; FIGS. 1-8; 2nd embodiment: page 14, line 23 to page 15, line 1; FIGS. 9-12; 3rd embodiment: page 16, lines 16-26; FIGS. 13-21; *see also* amendments to specification and drawings filed October 22, 2008) including a counter element (20) that is displaceable axially and in rotation relative to the body (1) wherein when the dispenser member is being actuated, the counter element cooperates firstly with the at least one stationary gear (110, 122) of the body (1), and secondly with the reservoir (2) (*see e.g.*, original specification, 1st embodiment: page 10, lines 20-31; 2nd embodiment: page 14, line 20 to page 15, line 9; 3rd embodiment: page 16, lines 15-26).

Claim 22 further includes first safety means and second safety means (*see e.g.*, original specification, page 9, lines 27-37), wherein first safety means actuates the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke and second safety means prevents the fluid from being expelled again until the dispenser has completed the predetermined incomplete return stroke, the dispenser and the dose indicator device being capable of being actuated once again (*see e.g.*, original specification, page 14, lines 4-14), once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and the dispenser is actuated once again before returning to its rest position (*see e.g.*, original specification, 1st embodiment: page 10, lines 15-19, “[i]nitially the first safety system is described below with reference to Figures 1-4;” *see also* page 10, line 20 to page 12, line 28, describing FIGS. 1-4 in detail; 2nd embodiment: page 15, lines 18-23, “[t]he first safety system is

thus provided [above];” *see also* page 14, line 20 to page 15, line 17 describing the first safety system; 3rd embodiment: page 16, lines 16-28, “[t]his takes place after said incomplete actuation stroke of the dispenser . . . ;” *see also* page 16, lines 4-32.)

The subject matter of claim 23 concerns a fluid dispenser having a stationary body (1) including at least one stationary gear (110, 122) (*see e.g.*, original specification, 1st embodiment: page 10, lines 20-22; 2nd embodiment: page 14, lines 22-23; 3rd embodiment: page 16, lines 15-18; *see also* amendment to the specification filed October 22, 2008; *see also* FIGS. 1 and 13), an actuator member (2, 30) that is displaceable axially with respect to the stationary body (*see e.g.*, original specification, 1st embodiment: page 8, line 35 to page 9, line 5; page 10, line 32 to page 11, line 1; FIGS. 1-4; 2nd embodiment: page 14, lines 28-32; 3rd embodiment: FIGS 13-21, showing the reservoir (2) being axially displaced relative to the body), and a dose indicator (*see e.g.*, counter element 20) that is displaceable axially and in rotation relative to the body (1) (*see e.g.*, original specification, 1st embodiment: page 8, line 36 to page 9, line 15 and page 10, lines 25-31; FIGS. 1-8; 2nd embodiment: page 14, lines 23-27; FIGS. 9-12; 3rd embodiment: page 16, lines 16-26; FIGS. 13-21; *see also* amendments to specification and drawings filed October 22, 2008), the dose indicator being engageable with the actuator member (2, 30) and the stationary body (1) (*see e.g.* original specification page 11, lines 6-22), wherein when the actuator member displaces axially, the counter element is caused to be displaced axially and permitted to rotate relative to the body (*see e.g.*, original specification page 11, lines 21-23; FIGS. 1-4).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues on appeal are summarized as follows:

1. Whether claims 1-23 are properly rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate description of the invention that would enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed subject matter.
2. Whether claims 1-23 are properly rejected under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections.
3. Whether claims 1-23 are properly rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Whether claim 1 is properly rejected under 35 U.S.C. § 102(b) as being anticipated by Bason (EP 0949548).
5. Whether claim 22 is properly rejected under 35 U.S.C. § 102(b) as being anticipated by Bason (EP 0949548).
6. Whether claim 23 is properly rejected under 35 U.S.C. § 102(b) as being anticipated by Bason (EP 0949548).
7. Whether claims 2-21 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by Bason (EP 0949548).

8. Whether claim 1 is properly rejected under 35 U.S.C. § 102(b) as being anticipated by Rand et al. (EP 0254391).

9. Whether claim 23 is properly rejected under 35 U.S.C. § 102(b) as being anticipated by Rand et al. (EP 0254391).

VII. ARGUMENT

1. Whether claims 1-23 are properly rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate description of the invention that would enable one skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed subject matter.

A. The Examiner's Rejection

The Examiner rejected claims 1-23 under 35 U.S.C. § 112, first paragraph, as allegedly failing to enable one skilled in the art to make and/or use the invention (*see*, Final Office Action dated February 18, 2011: page 7, last paragraph). It is noted that the Examiner has not specified claim 21 in the detailed rejection. Nevertheless, claim 22 is addressed below.

In rejecting claims 1-9, 22 and 23, the Examiner states (*see*, Final Office Action dated February 18, 2011: pages 7-9) that “the claims recite the elements and their functions related to one another without actual structures and connections between them [sic]. The specification does not disclose in full, clear, concise [sic] of the actual structures of a body, a reservoir, dispenser member, an indicator device, at least one station [sic] gear, a counter element and structural connections between them in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or perform the system in claims 1 and 23, so that the counter element is displaceable axially and in rotation relative to the body, the body gear is stationary, the reservoir is axially displaced relative to the body even if the dispenser does not perform a complete actuator stroke and the counter element co-operating, while the dispenser is being actuated, firstly with the at least one stationary gear and secondly with the reservoir; and

the system as in claim 2 during the return stroke; and also claimed subject matter in claims 3-9 and 22.”

The rejection continues on to state that claims 10-14 are not enabled because the specification does not disclose the structure of the body, reservoir, dispenser member, indicator device, stationary gear, counter element and structural connections between them in such a way to enable one skilled in the art. The Examiner also states that the specification does not support the claimed subject matter of claims 10-14 disclosed in FIGS. 9-12, which enables the counter element to co-operate with the stationary gear and then the reservoir.

Still further, the Examiner asserts the same rejections against claims 15-20 for failing to enable one of ordinary skill in the art to make and/or perform the claimed subject matter for the same reasons set forth for claims 10-14, stating that specification does not support the claimed subject matter of claims 15-20 as disclosed in Figs. 13-21.

Thus, the Examiner appears to essentially contend that all of the features recited in all of the claims 1-23 are not enabled.

B. The Test for Enablement

The test for enablement is whether one skilled in the art could make and use the claimed invention without undue experimentation. See *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916); *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (emphasis added). Thus, “[a] patent need not teach, and preferably omits, what is well known in the art.” MPEP § 2164.01 (citing *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*,

802 F.2d 1367, 1384 (Fed. Cir. 1986)) (emphasis added). It is not necessary to “enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim to that effect.” MPEP § 2164 (citing *CFMT, Inc. v. Yildup Int’l Corp.*, 349 F.3d 1333 (Fed. Cir. 2003)). As such, “[d]etailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention.” MPEP § 2164 (emphasis added). In fact,

[i]n examining a patent application, the PTO is **required** to assume that the specification complies with the enablement provision of Section 112 unless it has ‘acceptable evidence or reasoning’ to suggest otherwise. . . . The PTO thus must provide reasons supported by the record as a whole why the specification is not enabling. . . . Then and only then does the burden shift to the applicant to show that one of ordinary skill in the art could have practiced the claimed invention without undue experimentation. . . .”

Gould v. Mossinghoff, 229 USPQ 1, 13-14 (D.D.C. 1985) (citations omitted), *aff’d* in part, vacated in part on other grounds, and remanded sub nom. *Gould v. Quigg*, 3 USPQ2d 1302 (Fed. Cir. 1987) (emphasis added); *see also* MPEP § 2164.04.

In order to determine whether a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue,” the Examiner must consider the *Wands* factors, which are provided in MPEP § 2164.01(a). Among these factors, includes the nature of the invention, the state of the prior art, the level of one of ordinary skill, the amount of direction provided by the inventor, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

C. The Examiner has Not Overcome the Presumption that the Disclosure is Enabling and Has not Shifted the Burden to the Applicant

The Examiner does not apply any of the *Wands* factors discussed above for making a determination of enablement, and thus, does not apply the correct standard for establishing a prima facie case of lack of enablement.

For example, in considering the state of the prior art, the specification discloses that dose indicator devices are well known, including counters that display the number of doses (*see*, original specification at page 1, lines 8-15). The specification also discloses that once a dose has been dispensed, the next dose is loaded into the chamber of the dispenser member (pump or valve) (*see*, original specification at page 2, lines 2-4). Still further, the specification states that the present invention applies particularly well to “Metered Dose Inhaler” (MDI) devices which comprise a metering valve mounted on a reservoir containing the fluid and a propellant gas, the displacement of the reservoir relative to the valve member causing a dose of fluid to be dispensed by means of said propellant gas” (*see*, specification at page 8, lines 25-34).

Accordingly, one skilled in the art would readily understand an MDI or similar device and its structural configurations, including a dispenser member to dispense the pharmaceutical, a body to hold the reservoir therein, a counter to count dispensed doses, and how a counter could be actuated upon the dispensing of a dose.

MPEP 2164.01 states:

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with **information known in the art without undue experimentation**. A patent need not teach, and **preferably omits**, what is known in the art. (emphasis added)

In the original specification (page 8, lines 13-24), Appellant specifically stated that those features which are known in the art are omitted from the drawings for the sake of simplifying the understanding of the inventive aspect of the device: “The drawings to which the present description refers are highly simplified diagrams which do not show the fluid dispenser in detail, but only in very diagrammatic manner relating to the various portions that can be moved relative to one another, for explaining the actuation cycle of said dispenser and of said indicator device.”

As noted above and in the originally filed specification (*e.g.*, pages 1, 2 and 8), metered dose inhalers, dispenser members, dose indicator devices and actuation of a dispenser are well known in the art, and one of ordinary skill would understand the structure and connection of a body, reservoir, actuator, counter and dispenser member. Thus, such specific structural connections need not be disclosed in the specification.

In view of the context of the explanation provided by the specification that previous fluid dispensers included dose indicator devices, counters, reservoirs, dispenser members, etc., (*see*, specification at pages 1-2 and 8), one skilled in the art would readily understand how to make and use the present invention in a fluid dispenser without any undue experimentation.

Additionally, Appellant filed a Declaration under 37 C.F.R. 1.132 on December 6, 2010, providing evidence regarding the state of the prior art and the level of one of ordinary skill in the art.

The Examiner has not substantively responded to any of the detailed explanations and evidence submitted by Appellant on December 6, 2010, including the Remarks and Declaration provided thereon. The Examiner has not asserted why one of ordinary skill in the art would have been unable to make and/or use the recited invention without undue burden. *See In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993) (“When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application . . .”).

Thus, a prima facie case of lack of enablement has not been met.

D. Disclosure of the Current Application

In order to appreciate the fact that the claims are fully enabled, a proper understanding of the disclosure is required. To aid the Board in understanding the subject matter of the current application, Applicant is providing below a step-by-step description of the actuation of an embodiment of the dispenser and dose indicator *as disclosed in the current application*. The following detailed explanations were provided to the Examiner in the first Appeal Brief filed on November 19, 2009, and in the Amendment under 37 C.F.R. § 1.111 and Declaration under 37 C.F.R. § 1.132 which were filed on December 6, 2010.

As noted above, the Examiner has not substantively responded to these explanations.

In the “Response to Amendment” (Final Office Action, page 11) the Examiner merely states:

“The Declaration under 37 C.F.R. § 1.132 filed 12/6/10 is insufficient to overcome the rejection of claims 1-23 based upon drawing objections, specification objection [sic] and 112 rejections as set forth in the last Office action because the structures, connections of the components of the application invention or claimed invention are well known or an [sic] understand by ordinary skill in the art by evidences with different prior art inventions having different structures, connections of components, etc, which is not readily understood by one [of] ordinary skill in the art [sic] how to make and use of [sic] the present invention.”

In the “Response to Arguments” (Final Office Action, page 12) the Examiner states:

“Applicant’s arguments filed 112/6/10 [sic] have been fully considered but they are not persuasive because the structures, connections of the components of the application invention or claimed invention are well known or an [sic] understood by ordinary skill in the art by evidences with different prior art invention having different structures, connections of components, etc, which is not readily understood by one [sic] ordinary skill in the art how to make and use of [sic] the present invention.”

Appellant believes that the Examiner's rejection under 35 U.S.C. § 112, first paragraph, is predicated on her lack of understanding the technology to which the disclosure pertains. Following the PTO's mandate encouraging interviews, Appellant's attempts to explain the claimed invention to the Examiner during interviews were unsuccessful.

However, as explained in the following sections, one skilled in the art would readily comprehend the disclosure and particularly understand how the claimed invention functions and operates.

A first embodiment is described in detail from page 8, line 35 to page 14, line 19 of the specification of the present application. This portion of the written description also refers to FIGS. 1-8 of the application.

In this embodiment, "the dispenser includes a reservoir 2 that is axially displaceable in a body 1, which is considered as being the stationary portion of the dispenser." (Original specification, page 8, line 36, to page 9, line 2.) "The axial displacement of the reservoir 2 relative to the body 1 actuates the dispenser member and thus causes a dose of fluid to be dispensed from said reservoir." (Original specification, page 9, lines 3-5.)

Further this embodiment includes "an actuator member 30 on which the user exerts an axial actuation force so as to actuate the dispenser and thus displace said reservoir 2 relative to the body 1." (Original specification, page 9, lines 5-9; *see also* FIG. 1 of the current application, reproduced below.) Additionally, "the stationary body 1 includes a stationary gear 110." (Original specification, page 10, lines 21-22.) The "counter element 20 is displaceable both axially and in rotation relative to the body 1." (Original specification, page 10, lines 25-27.)

Figures 1-8, shown on the following page in sequence for a side-by-side comparison, depict the actuation of this embodiment. Furthermore, each figure will be discussed in greater detail individually on the following pages, and enlarged views of each figure are included in an attached appendix. The figures are color-coded to assist the Board in distinguishing the elements of this embodiment. A courtesy color copy of the Appeal Brief is being hand delivered to the Examiner. These color coded drawings were also previously delivered to the Examiner with the first Appeal Brief filed on November 19, 2009, and with the Amendment under 37 C.F.R. § 1.111 Further, courtesy color copies will be delivered to the Board, if necessary.

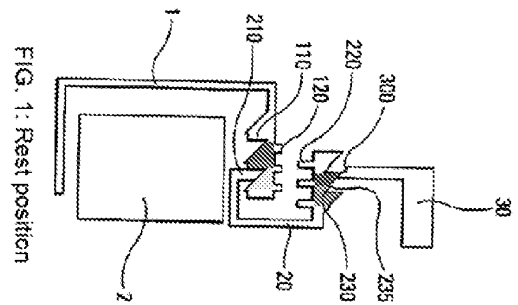


FIG. 1: Rest position

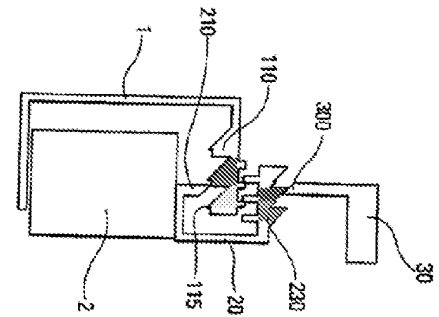


FIG. 2: initial axial displacement of counter element 20

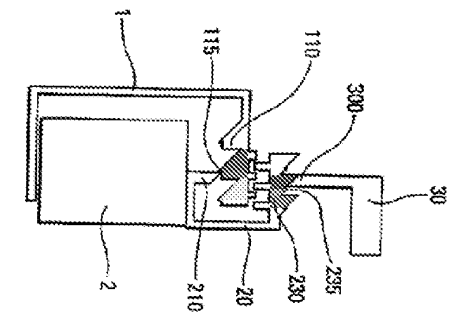


FIG. 3: initial rotation of the counter element 20

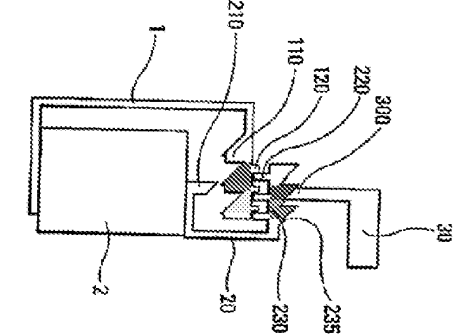


FIG. 4: completion of axial displacement of counter element 20 and incremental rotation of counter element 20

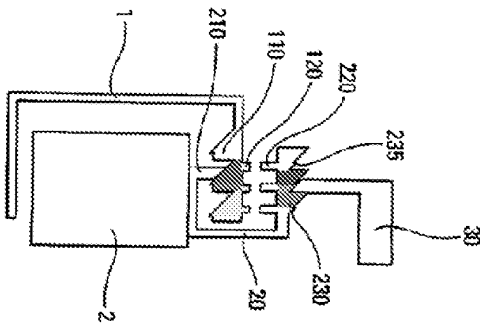


FIG. 5: partial upward release of actuator 30 and incremental rotation of counter element 20

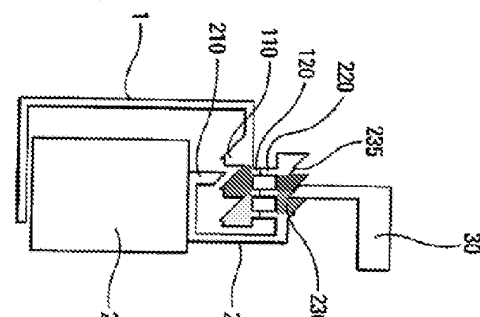


FIG. 6: prevention of actuation prior to complete release of actuator 30

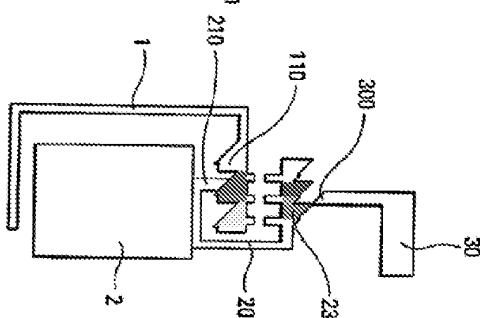


FIG. 7: continued release of actuator 30

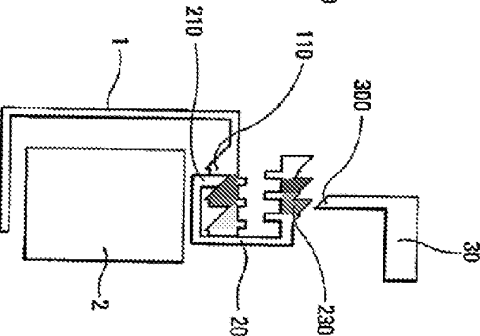


FIG. 8: completion of release of actuator 30, completion of rotation of counter element 20

This embodiment is described in the specification with respect to Figures 1-8 of the application.

Steps 1 and 2: see FIG. 1

- 1) Starting from a rest position, actuation begins by depressing the actuator 30 in the axial direction (downward in Fig. 1). (Original specification, page 10, line 35 to page 11, line 5.) The oblique portion of the tooth of the actuator gear 300 contacts the oblique portion of the first tooth (purple) of the second gear 230, which urges the counter element 20 downward and applies a force on the counter element 20 to the left. (Original specification, page 11, lines 1-5.)
- 2) While the oblique portions of the actuator gear 300 and the first tooth (purple) of the second gear 230 apply a force to the left on the counter element 20, the end wall (blue) of the stationary gear 110 prevents the counter element 20 from rotating to the left and only allows the counter element 20 to be displaced downward in an axial direction. (Original specification, page 11, lines 5-8.)

Step 3: see FIG. 2

- 3) The counter element 20 is displaced downward by the actuator 30 until the first gear 210 of the counter element 20 passes the end wall (blue) of the stationary gear in the axial direction. As the counter element 20 is displaced downward, the bottom of the counter element 20 contacts the reservoir 2 and displaces the reservoir 2 downward, thereby actuating the dispenser. (Original specification, page 11, lines 9-16.)

Steps 4 and 5: see FIG. 3

- 4) The counter element 20 is then urged to rotate to the left by the engagement of the oblique portions of the tooth of the actuator gear 300 and the first tooth (purple) of the second gear 230, thereby initiating the counting of one dose of fluid. (Original specification, page 11, lines 16-28.) Accordingly, the counter element 20 rotates before the complete actuation of the dispenser member, *thereby ensuring that a count is registered if there is any possibility that fluid was dispensed.* (Original specification, page 11, line 33 to page 12, line 3.)
- 5) The first gear 210 of the counter element 20 rotates until it contacts the abutment means 115 (tip of the red section extending past the end wall (blue section) in the axial direction) which again prevents the rotation of the counter element 20, and causes the vertical displacement of the counter element 20. (Original specification, page 12, lines 4-11.)

Step 6: see FIG. 4

- 6) Once the first gear 210 of the counter element 20 is displaced past the abutment means 115 (red) in the axial direction, the engagement of the oblique portions of the actuator gear 300 and the first tooth (purple) of the second gear 230 rotate the counter element 20 until the actuator gear 300 meshes with the first abutment 235 (orange) on the second gear 230. (Original specification, page 12, lines 7-11.) *This prevents the counter element 20 from rotating again.*

Steps 7 & 8: see FIG. 5

- 7) When the actuator 30 is released by the user, a spring (not shown in the drawings) displaces the reservoir 2 axially upward towards the rest position. (Original specification, page 12, line 32 to page 13, line 2.) The displacement of the reservoir 2 causes the counter 20 to be displaced axially upward until the oblique portion of the first gear 210 engages the oblique portion of the second tooth (red) of the stationary gear 110. (Original specification, page 13, lines 4-8.) At this point, the abutment 235 prevents rotation of the counter element 20, and the engagement of the first gear 210 and the stationary gear 110 prevents axial displacement of the counter element 20. Accordingly, the actuator 30 moves axially relative to the counter element 20 when the actuator 30 is further released, and the actuator gear 300 passes over the abutment 235 (orange). At this point, the chamber of the dispenser can be filled. (Original specification, page 12, lines 12-18.)
- 8) The engagement of the oblique portion of the first gear 210 with the oblique portion of second tooth (red) of the stationary gear 110 causes the counter element 20 to rotate until the actuator gear 300 contacts an end wall of the second tooth (green) of the second gear 230. (Original specification, page 13, lines 4-16.)

Step 9: see FIG. 6

- 9) If one were to attempt to actuate the dispenser at this point, before completing the return stroke, the axial projections 120 of the counter element 20 (shown in red on following page) would engage the axial projections 220 of the body 1 (shown in red on the

following page), *thereby preventing actuation of the dispenser member*. (Original specification, page 13, lines 17-29.)

Step 10: see FIG. 7

10) With the end wall of the second tooth (green) of the second gear 230 preventing rotation of the counter element 20, and with the first gear 210 and the second tooth (red) of the stationary gear 110 preventing axial displacement of the counter element 20, the actuator 30 will move in the axial direction relative to the end wall of the second tooth (green) of the second gear 230 when the actuator 30 is further released, and the actuator gear 300 will pass over the end wall of the second tooth (green) of the second gear 230. (Original specification, page 13, lines 29-37.)

In the position shown in Figure 6 (step 9 described above), a new action of the dispenser is not possible because of an insufficient return stroke.

Figure 7 (step 10 described above), however, shows a position before the completion of a return stroke where it is possible to have a new actuation of the dispenser despite the uncompleted return stroke of the first actuation.

In Figure 7 (step 10) the new actuation is possible because the actuator gear 300 has passed over the end wall of the second tooth (green) of the second gear 230. Thus, the engagement of the first gear 210 with the second tooth (red) of the stationary gear 110

further rotates counter element 20, and a new actuation stroke would make the actuator gear 300 cooperate with the oblique portion of the second tooth (green) of the second gear 230.

Step 11: see FIG. 8

- 11) Once the actuator gear 300 passes over the end wall of the second tooth (green) of the second gear 230, the oblique portions of the first gear 210 and the oblique portions of the second tooth (red) of the stationary gear 110, cause the counter element 20 to complete the rotation cycle. (See FIG. 8 on page 18, original specification, page 14, lines 18-19.)

E. Comparison of Claims with Disclosure

The Examiner rejects all of the claims because all of the elements allegedly are not fully and clearly disclosed and enabled. Below, each of the independent claims 1, 22 and 23 is discussed separately, and dependent claim 2 is discussed separately because the return stroke was mentioned separately by the Examiner on page 8, lines 15-16 of the Final Office Action. Claims 3-21 are addressed together in the interest of efficiency and because the Examiner has not set forth any additional reasons why claims 3-21 are not enabled.

i. Claim 1

The language of independent claim 1 will be compared with the first exemplary embodiment of the invention. It should be noted that the claims should not be limited to this embodiment, and that the comparison is only being done to show that the claimed subject matter is adequately enabled.

The specification of the original application discloses that “the dispenser includes a reservoir 2 that is axially displaceable in a body 1, which is considered as being the stationary portion of the dispenser.” (*See*, original specification, page 8, line 35, to page 9, line 2; *see also*, FIGS. 1-4 show the reservoir 2 moving downward with respect to the body 1.) “The axial displacement of the reservoir 2 relative to the body 1 actuates the dispenser member and thus causes a dose of fluid to be dispensed from said reservoir” (*see*, original specification, page 9, lines 3-5.) “[T]he stationary body 1 includes a stationary gear 110” (*see*, original specification, page 10, lines 21-22; FIG. 1).

As such, these features of claim 1 are fully and clearly described in the specification:

“...a stationary body (1) including at least one stationary gear (110, 122), a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body, a dispenser member mounted on said reservoir (2), a dose indicator device, including a counter element (20) that is displaceable axially and in rotation relative to said body (1) for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir....”

In view of the specification and the state of the art, one having ordinary skill in the art would know how to make and use a reservoir that is axially displaceable relative to a body to actuate a dispenser member on the reservoir without undue experimentation. (*See*, Declaration filed December 6, 2010, at paragraph number 9 (i.e., Attachment A of Amendment filed December 6, 2010).)

Still further, one having ordinary skill in the art would know how to make and use these claimed features without any undue experimentation. The details of known structural elements

for the “connections” between the reservoir 2, the body 1, the actuator 3, and the counter element 20 were intentionally omitted because they are not required to understand the claimed subject matter. (*See for example*, MPEP 2164.01; original specification, page 8, lines 13-24, “[t]he drawings to which the present description refers are highly simplified diagrams which do not show the fluid dispenser in detail, but only in very diagrammatic manner relating to the various portions that can be moved relative to one another, for explaining the actuation cycle of said dispenser and of said indicator device.”)

In fact, the inclusion of these features would unnecessarily complicate the disclosure, making it more difficult for one of ordinary skill in the art to understand the claimed subject matter. Thus, what the disclosure intentionally focuses on is the inventive aspects of providing a dispensing mechanism with a counter element with a safety system. With respect to the *Wands* factors, the amount of direction provided by the inventor is clearly sufficient in the filed application, and the quantity of experimentation needed to make or use the invention based on the content of the disclosure is not undue.

Turning to the next portion of claim 1, again, the specification adequately describes these features and one of ordinary skill in the art would have been enabled to make and/or use the claimed subject matter:

“...wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke”

FIGS. 1-4 illustrate the movement of the dispenser during the first half of an actuation cycle, wherein the dispenser is displaced from a rest position (FIG. 1) to an actuated position (FIG. 4). The counter element 20 firstly co-operates with the stationary gear 110 and then with the reservoir 2.

After the counter element 20 has been displaced in a downward axial direction, the bottom of the counter element 20 contacts the reservoir 2 to displace the reservoir. Accordingly, the counter element 20 firstly contacts the stationary gear 110 and secondly contacts the reservoir 2. (See e.g., original specification at page 10, line 32 to page 11, line 25.)

Even if the dispenser does not perform a complete actuation stroke, the dose is counted. After the counter element 20 (via first gear 210) disengages the stationary gear 110, which is at a position of an incomplete actuation stroke, the counter element 20 is rotated by the oblique surfaces of the actuator gear 300 engaging the oblique surface of the second gear 230. As such, the counter element 20 is actuated during a predetermined incomplete actuation stroke. (See, e.g. original specification, page 11, line 25 - page 12, line 3.)

In view of the above, independent claim 1 is fully disclosed and enabled by the original specification.

ii. Claim 22

The Examiner asserts that independent claim 22 fails to meet the enablement requirement. However, for reasons similar to those discussed above, one of ordinary skill in the art would be enabled to make and/or use the invention.

In particular:

“...a stationary body (1) including at least one stationary gear (110, 122); a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body; a dispenser member mounted on said reservoir (2), being actuated when said reservoir is axially displaced relative to the stationary body by a predetermined amount, for dispensing a dose of fluid from said reservoir...”

The structural connections between the body, the reservoir, and the dispenser member are discussed in the specification and any portions which have been omitted are already known in the art (*see, e.g.* Declaration paragraph 9). Specifically, the disclosure states that “the dispenser includes a reservoir 2 that is axially displaceable in a body 1, which is considered as being the stationary portion of the dispenser.” (*See, original specification, page 8, line 36, to page 9, line 2; see also, FIGS. 1-4 show the reservoir 2 moving downward with respect to the body 1.*) “The axial displacement of the reservoir 2 relative to the body 1 actuates the dispenser member and thus causes a dose of fluid to be dispensed from said reservoir” (*see, original specification, page 9, lines 3-5.*) “[T]he stationary body 1 includes a stationary gear 110” (*see, original specification, page 10, lines 21-22; FIG. 1.*)

Turning to the next portion of claim 22, again, the specification adequately describes these features, and any features which are omitted from the detailed description are known by those of ordinary skill in the art:

“..a dose indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, said dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to said body (1), wherein when the dispenser member is actuated, said counter element cooperates firstly with said at least one stationary gear (110, 122) and secondly with said reservoir (2)...”

FIGS. 1-4 illustrate the movement of the dispenser during the first half of an actuation cycle, wherein the dispenser is displaced from a rest position to an actuated position. The counter element is displaced in a downward axial direction wherein it co-operates first with the stationary gear 110 and then with the reservoir 2. As illustrated, the bottom of the counter element 20 contacts the reservoir 2 to displace the reservoir. Accordingly, the counter element 20 firstly contacts the stationary gear and secondly contacts the reservoir. (See e.g., original specification at page 10, line 32 to page 11, line 25.)

The next portion of claim 22 states:

“...first safety means for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke; and second safety means for preventing the fluid from being expelled again until said dispenser has completed the predetermined

incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.”

In the claimed invention, even if the dispenser does not perform a complete actuation stroke, the dose is counted. That is, after the counter element 20 (via first gear 210) disengages the stationary gear 110, which is at a position of an incomplete actuation stroke, the counter element 20 is rotated by the oblique surfaces of the actuator gear engaging the oblique surface of the second gear 230. Thus, the first safety means provides for the counter element to be actuated during a predetermined incomplete actuation stroke. (*See, e.g.* original specification, page 11, line 25 - page 12, line 3; FIG. 3, wherein the counter element rotates before the complete actuation of the dispenser member.)

The second safety means is illustrated, for example, in FIGS. 6-7 and discussed in the corresponding written description (*see, e.g.*, pages 9 and 13). As shown in FIG. 6, the axial projections 120 of the counter element 20 face the axial projections 220 of the body 1, thereby preventing actuation of the dispenser. The new actuation is possible once the actuator gear 300 has passed over the wall of the second tooth of the second gear 230. As shown in FIG. 7, the engagement of the first gear 210 with the second tooth of the stationary gear 110 further rotates counter element 20, and a new actuation stroke would make the actuator gear 300 cooperate with the oblique portion of the second tooth of the second gear 230.

In view of the foregoing, one of ordinary skill in the art would have been fully enabled to make and/or use the claimed invention according to claim 22.

iii. Claim 23

Claim 23 is enabled also. The first portion of claim 23 recites:

“...a stationary body including at least one stationary gear;...an actuator member that is displaceable axially with respect to said stationary body...”

As discussed earlier, the specification fully and clearly describes this feature, and moreover, one of ordinary skill in the art is well apprised of how an actuator member is displaced with respect to a stationary body in a dispensing device. The specification of the original application discloses “a body 1, which is considered as being the stationary portion of the dispenser” (see, specification, page 8, line 36 – page 9, line 2). The specification also states that “the stationary body 1 includes a stationary gear 110” (specification, page 10, lines 21-22). Still further, the specification states discloses “an actuator member 30” (specification, page 9, lines 5-9)... “so as to displace said actuator member axially downwards” (specification, page 10, lines 36-37). Also, FIGS. 1-8 illustrate the movement of the actuator member 30 with respect to the stationary body 1.

Claim 23 continues on to recite:

“...a dose indicator that is displaceable axially and in rotation relative to said body, said dose indicator being engageable with said actuator member and said

stationary body, wherein when said actuator member displaces axially, said counter element is caused to be displaced axially and permitted to rotate relative to said body.”

The specification of the original application discloses that “a dose indicator device for counting” (specification, page 9, lines 9-10)... “the counter element both axially and in rotation relative to the body 1” (specification, page 10, lines 26-27)... “cooperating with said stationary gear 110 of the body and..with an actuator gear 300 secured to the actuator member 30” (specification, page 10, lines 27-31)... “when a user presses on the actuator member 30 so as to displace said actuator member axially downwards in Figure 1, the oblique profile of the teeth of the actuator gear 300 and of the second gear 230 of the counter element urge the counter element 20 to be displaced axially downwards, and also in rotation...” (specification page 10, line 35 – page 11, line 5).

In view of the foregoing, claim 23 is fully disclosed and enabled.

iv. Dependent Claim 2

With respect to claim 2, the Examiner states that the “specification does not disclose in full clear, concise...the system as in claim 2 during the return stroke” (see Final Office Action, page 8). The Examiner does not provide any further details for the basis of this rejection of claim 2.

Claim 2 recites:

“...during the return stroke of the dispenser after dispensing a dose, said dose indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke...”

The language of claim 2 is fully disclosed and enabled by the originally filed application as follows. “Figure 6 is a diagram showing an attempt to perform a new actuation before the dispenser has completed its return stroke.” (Specification, page 13, lines 17-19.) If the return stroke is insufficient, it is impossible to expel a new dose of fluid (specification, page 13, lines 26-28), but once the actuator member 30 is freed from the end wall of the second gear 230, and the axial projections 120 and 220 are offset, the new actuation can be permitted (specification, page 13, line 29 to page 14, line 17).

Thus, claim 2 is fully disclosed and enabled.

v. Dependent claims 3-21

Moreover, dependent claims 3-21 are fully described and enabled by the disclosure of the original application, for similar reasons to those stated above with respect to claims 1 and 2.

The Examiner does not provide any further explanations for why the claims are not enabled. They appear to be rejected for lack of enablement for the same reasons as those discussed above. Thus, Appellant submits that the remaining claims 3-21 are fully disclosed and enabled for the same reasons discussed above for claims 1, 2, 22 and 23.

For at least the foregoing reasons, the connections between the elements is clear, and any aspects of the connections between the elements which are not explicitly stated would have been understood by one of ordinary skill in this field of art which pertains to fluid dispensers having counting mechanisms. See, e.g., Declaration filed December 6, 2010.

In the absence of any reasonable explanation as to why the scope of protection provided by claims 1-23 is not adequately enabled by the description of the invention provided in the specification of the application, Appellant respectfully requests that this rejection not be sustained.

2. Whether claims 1-23 are properly rejected under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections.

In paragraph number 11 of the Office Action, claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential structural cooperative relationships of elements.

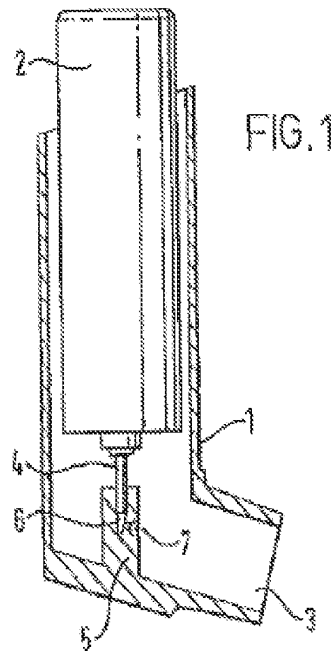
To support the rejection, the Examiner refers to MPEP § 2172.01, and states “[t]he omitted structural cooperative relationships are: the claims comprising [sic] many elements but do not include structures or shapes of elements and structural connections between the elements, such omission amounting to a gap between the necessary structural connections.” (Office Action, page 10, lines 1-4.)

It appears that the Examiner takes the position that the recited elements (1) do not have structures and shapes, and (2) that there is no structural connection between the elements.

Due to the general nature of the Examiner's comments, it is not clear if some or all the elements allegedly lack structure, shape, and connection. The Examiner has not addressed any particular aspect of the claim scope. It appears that this rejection is predicated by the Examiner's limited understanding of the field of art to which the invention pertains.

Claim 1:

Turning to the structures and shapes of the elements, claim 1 is directed to a fluid dispenser comprising, among other things, a stationary body, a fluid reservoir having dispenser member, and a dose indicator device. Fluid dispensers having dose indicator devices are well known (See, Declaration filed December 6, 2010 at paragraph no. 3). The general structures and shapes of a stationary body, a fluid reservoir held by such a body, a dispenser member mounted on a reservoir and a counting device for indicating the number of doses that have been dispensed or remain to be dispensed are known in the art. In fact, US Pub No 2002/0195102 (FIG. 1 reproduced below), was cited by the Examiner in the Office Action dated July 22, 2008, and cited by Appellant in the Information Disclosure Statement filed on November 9, 2005, showing a dispenser member mounted on a top of a reservoir held in a stationary body.



A list of such sample publications showing the structures and shapes of fluid dispensers having a stationary body, fluid reservoir with a dispenser member, and a dose indicator device was provided in Attachment A of the Declaration under 37 CFR 1.132 filed on December 6, 2010. Also, Appellant filed an IDS citing such documents. Thus, the structure and shape of these elements is known and the invention is not intended to be limited by these known structures.

Turning to whether there are missing structural connections between the elements, claim 1 recites that the reservoir is “axially displaceable relative to said stationary body”, having the stationary gear, and that that the counter element “is displaceable axially and in rotation relative

to said body”, and that the counter element cooperates with the stationary gear first and then the reservoir.

As such, the claims include structural connections between the elements, and there is no omission amounting to a gap between the elements.

With regard to the structural connection between the elements, it is not essential to a patentable invention that there be interdependency between the elements of the claimed device or that all of the elements operate concurrently toward the desired result. *Ex parte Nolden*, 149 USPQ 378, 380 (Bd. Pat. App. 1965). The claims require only a reasonable degree of particularity and distinction, when analyzed with respect to the specification, the prior art, and the claim interpretation given by one of ordinary skill in the art at the time of the invention.

Appellant respectfully submits that when analyzed with respect to the specification (*see*, detailed discussion and color drawings above) and the claim interpretation given by one of ordinary skill in the art at the time of the invention (*see*, Declaration and specification, e.g., pages 1 and 8), the claims possess a reasonable degree of particularity and distinction.

For example, claim 1 recites “wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.”

When analyzed with respect to the specification, the claim clearly sets forth the structural connection between the elements. While the dispenser is being actuated, the counter element

moves axially and rotatably with respect to the stationary body, so as to first cooperate with a stationary gear (110; FIG. 1) and secondly with the reservoir (2; FIG. 2). As discussed thoroughly with respect to the rejections under 112, first paragraph, this causes the dose indicator device to be actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.

Claims 2-21:

With respect to claims 2-21 Appellant respectfully submits that when analyzed with respect to the specification (*see*, detailed discussion and color drawings above) and the claim interpretation given by one of ordinary skill in the art at the time of the invention (*see*, Declaration and specification, e.g., pages 1 and 8), these claims possess a reasonable degree of particularity and distinction.

The explanations provided above in Section 1, including the detailed step by step explanation of the invention with respect to FIGS. 1-8, support the recitation of claims 2-21. The Examiner has not explained which structural connections are missing. As discussed above with respect to claim 1, however, each element is recited in such a manner to distinctly cooperate with other elements in the claim.

Thus, a *prima facie* case of rejection for omission of essential structural cooperative relationships of elements is not met in the Final Office Action against claims 2-21.

Claim 22:

Claim 22 clearly recites the essential cooperative relationships of the elements for similar reasons to those discussed above for claim 1. In particular, each of the stationary body, fluid reservoir, dispenser member and dose indicator device cooperate in claim 22.

As discussed in thorough detail in Section 1 above, a stationary body (1) includes at least one stationary gear (110, 122) and a fluid reservoir (2) is disposed in said body so as to be axially displaceable relative to said body. This cooperative relationship is clearly set forth. Moreover, one of ordinary skill in the art is well acquainted with having a fluid reservoir disposed in a body.

Claim 22 also clearly sets forth the cooperative relationship between the reservoir, dispenser member and body. A dispenser member is mounted on said reservoir (2) and actuated when said reservoir is axially displaced relative to the stationary body by a predetermined amount, for dispensing a dose of fluid from said reservoir.

Claim 22 further includes the dose indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir. The claim recites “said dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to said body (1), wherein when the dispenser member is actuated, said counter element cooperates firstly with said at least one stationary gear (110, 122) and secondly with said reservoir (2)”. The cooperative relationships of these elements is clear, particularly with respect to the written disclosure. (See Section 1 above).

The first safety means for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a

complete actuation stroke and the second safety means for preventing the fluid from being expelled again until said dispenser has completed the predetermined incomplete return stroke are also clearly set forth with respect to their cooperative relationship. Claim 22 states “said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.” It is not necessary to recite every surface that engages and abuts in order for this aspect of the invention to be clear. When the claims are read in light of the specification, the first and second safety means are recited in a clear manner, with any necessary structural connections provided within the claim by way of the body, reservoir, dispenser member and indicator device which cooperate together to achieve the first and second safety means.

Claim 23:

Claim 23 meets all requirements of 35 U.S.C. § 112, second paragraph, for similar reasons to those discussed above for claims 1-22. The structural cooperative relationships between the stationary body, the actuator member and the dose indicator are clear. As recited in claim 23, the “actuator member...is displaceable axially with respect to said stationary body”, and one of ordinary skill in the art would understand how an actuator member moves with respect to the body.

Moreover, a dose indicator that is displaceable axially and in rotation relative to said body is a clear recitation. The dose indicator is engageable with the actuator member and the stationary body. When the claim is read in light of the specification, the cooperation between

these elements is clear. When the actuator member displaces axially, the counter element is caused to be displaced axially and permitted to rotate relative to said body.

In the absence of any reasonable explanation as to why the scope of protection provided by claims 1-23 is not adequately recited, Appellant respectfully requests that this rejection not be sustained.

3. Whether claims 1-23 are properly rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In paragraph number 12 of the Office Action, claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

The Examiner asserts (Final Office Action, page 10), “[t]he claims are indefinite because it is not clear what are required for structures or shapes of the elements in the claims, such as a body, a reservoir, dispenser member, an indicator device, at least one station [sic] gear, a counter element, etc., and structural connections between them to understand the claimed subject matter which applicant regards as the invention.”

However, as discussed above, one of ordinary skill in the art would have already been apprised of how a conventional body, reservoir, dispenser member and indicator device could be shaped and structured. Additional detail is not necessary for an understanding of the claims.

Moreover, the stationary gear, counter element and the structural connections between them are provided in sufficient detail so that one of ordinary skill in the art would understand the invention, in light of the specification. As set forth clearly above, step by step in at least FIGS. 1-8, one of ordinary skill in the art, already having the knowledge of how conventional reservoirs, dispenser members and indicator devices are shaped and structured, would have understood how to shape and structure the gears and their novel interaction with each other in the claimed invention.

4. Whether claims 1-21 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by Bason (EP 0949548).

A. Claim 1

Appellant respectfully submits that claim 1 is distinguishable from Bason, because Bason fails to disclose each and every feature of the claims.

The Examiner provides one general statement of rejection for all of claims 1-23:

“As best understood Bason discloses, in figs. 1-6, a fluid dispenser comprising a stationary body 1 including at least one stationary gear 2; a fluid reservoir C, a dispenser (inherent); a dose indicator device having a counter element 4, 8 displaceable axially and in rotation relative to the body; wherein the dispenser is actuated, the counter element cooperates firstly with the at least one stationary gear and secondly with said reservoir; first and second safety means 10, 5.”

Notably, Appellant submitted Bason to the Examiner in the IDS filed December 6, 2010, as evidence of the state of the prior art, and to help the Examiner understand the technology to which the invention pertains. The Examiner succinctly dismissed this evidence with respect to the objections and rejections under 35 U.S.C. § 112 (see Final Office Action at page 11), but the Examiner uses this reference as prior art for teaching each and every feature of the claims 1-23.

Turning to the substance of Bason, this reference discloses a conventional indicator device. With regard to claim 1, a fluid dispenser comprises a stationary body A. The stationary body does not include a stationary gear. While the Examiner alleges that the base 1 is a stationary body, since the fluid reservoir C is not “disposed in said body so as to be axially displaceable relative to said body”, this base 1 cannot be considered to correspond to the claimed stationary body. In fact, “[t]he counter consists of a first part or base 1 which, in manufacture of the canister C is bonded to the domed base thereof.” In fact, the base 1 is replaceable/disposable with the canister C. (*See*, paragraph [0011].) As such, Bason fails to teach or suggest that the reservoir C is axially displaceable relative to the base 1. Thus, Bason fails to teach or suggest a stationary body (i.e., element A) including at least one stationary gear.

For at least this reason, Bason fails to anticipate claim 1.

Moreover, the counter element 4, 8 (first and second rings) that is displaceable axially and in rotation relative to the body A does not cooperate firstly with a stationary gear of the body A and secondly with the reservoir C, so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.

Rather, the count starts at the beginning of the actuation stroke, and the dose indicator device actuation could remain incomplete if the dispenser actuation is stopped before a complete actuation stroke. In Bason, a complete depression is necessary; it can be seen on Fig. 5 that actuating element 7 must be almost completely down tooth 2 in order to ensure that, upon release, it will enter upper tooth 14a. In any case, counting starts at the beginning of actuation stroke (element 7 slides down on tooth 2) and could remain incomplete if the actuation is stopped before element 7 has reached the bottom of tooth 2.

More specifically, upon depression of the cap 14 with respect to the base 1 and reservoir C, the rings 4, 8 move axially, causing upon each depression, the teeth 7 to engage with the lower fixed set of teeth 2 of the base 1. Owing to the triangular formation of the teeth 7 and 2, this causes the ring 4 to be indexed in rotation, and upon return or release of the cap, the teeth 7 then engage the upper teeth 14a causing a further rotational movement of the ring. Each of these rotational movements represents one half of a complete movement of the ring 4 **so that the number visible through the window 13 on the face 24 will change by one point for a complete depression and release of the cap.** See paragraph [0020].

As such, Bason fails to teach or suggest “so that the dose indicator device is actuated once the dispenser has performed a pretermined **incomplete** actuation stroke, **even if the dispenser does not perform a complete actuation stroke**”.

Thus, claim 1 is not anticipated by Bason.

B. Claim 2

Claim 2 is patentable for at least the same reasons as claim 1. Moreover, Bason is silent as to how the dispenser can be prevented from expelling fluid if a predetermined incomplete return stroke has not been completed. The Office Action provides no details as to which structure in Bason could provide this function.

Thus, Appellant respectfully submits that claim 2 is distinguishable from Bason.

C. Claims 3-5 and 8-9

Claim 3 is not anticipated by Bason for at least the same reasons as claim 1 discussed above. Bason fails to disclose that stationary body includes a stationary gear. As noted above, the so called body 1 is attached to the top surface of the reservoir and moves with the reservoir, and thus, is not stationary. Still further, Bason does not disclose the counter element includes two gears which cooperate with the stationary gear of a stationary body and an actuator gear of an actuator member, respectively. The Examiner has failed to point out which features of Bason allegedly disclose these structural aspects of the invention, and Appellant does not find support for these feature in the reference. At most, the teeth 7 on the counter engage with the teeth 2 and teeth 14a; however, this is a single gear cooperating with the two sets of teeth rather than the claimed invention having two gears for the counter cooperating with the stationary gear and the actuator gear.

Thus, claim 3 is patentable, as well as claims 4, 5, 8 and 9 by virtue of their dependency from claim 3.

D. Claims 6-7

Claim 6 is not anticipated by Bason for at least the reasons discussed above, by virtue of its dependency from claim 1.

Moreover, Bason fails to disclose the claimed blocking means. The claimed invention prevents the dispenser from being actuated again, until an incomplete return stroke has been completed. For example, see FIG. 6 of the pending application. There is no structurally or functionally equivalent means in Bason. See FIG. 3 of Bason.

Thus, claim 6 is patentable for this additional reason. Moreover, claim 7 is patentable at least by virtue of its dependency from claims 1 and 6.

E. Claims 10-14

Bason fails to teach or suggest a stationary body that includes two stationary gears, and a counter element that includes two gears, wherein the two stationary gear cooperate with the two counter gears. The Office Action fails to explain where these structural features are provided in Bason. Moreover, the drawings in Bason fail to support this anticipation rejection.

As noted earlier, Bason does not disclose a stationary body as in the claimed invention. Moreover, Bason fails to disclose a stationary body have two stationary gears. See FIGS. 1 and 3.

The claimed invention provides these two stationary gears for cooperating with the different gears of the counter element to control the axial and rotational movement. See FIGS. 1-8 of the pending application, wherein the stationary body 1 has the stationary gear 110 and the stationary gear 120, each cooperating with a gear 210, 220 of the counter 20.

Since Bason fails to disclose each and every feature of claim 10, claim 10 is patentable. Moreover, claims 11-14 are patentable at least by virtue of their dependency from claims 1 and 10.

F. Claims 15-20

Claim 15 is distinguishable from Bason for similar reasons to those mentioned above. Bason fails to disclose a stationary body having a first stationary gear and a second stationary gear. The so-called stationary body in Bason is not similar to the stationary body of the claimed invention since it does not hold the reservoir and does not include two gears.

In addition, Bason fails to disclose that the counter element includes a third gear. This feature is completely missing from Bason. See FIG. 3.

For at least the foregoing reasons, as well as by virtue of its dependency from claim 1, claim 15 is not anticipated by Bason. In addition, claims 16-20 are patentable for at least the same reasons as claim 15.

5. Whether claim 22 is properly rejected under 35 U.S.C. § 102(b) as being anticipated by Bason (EP 0949548).

Claim 22 is not anticipated by Bason for at least the same reasons as those discussed above for claim 1. Particularly, Bason does not disclose that the stationary body A, in which the reservoir C is disposed, has a stationary gear.

In addition, as discussed above, a completely actuation of the dispenser is required in order for the counting device to indicate a counted dose in Bason. Thus, Bason fails to disclose first safety means for actuating the dose indicator device once the dispenser has performed a

predetermined **incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.**

Still further, Bason does not disclose a second safety means for preventing the fluid from being expelled again until said dispenser has completed the predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

Bason is completely silent as to preventing the fluid from being expelled until the dispenser completes a predetermined incomplete return stroke.

In view of the foregoing, claim 22 is not anticipated by Bason.

6. Whether claim 23 is properly rejected under 35 U.S.C. § 102(b) as being anticipated by Bason (EP 0949548).

Claim 23 is not anticipated by Bason for similar reasons to those discussed above regarding claims 1 and 22. Namely, the stationary body C does not include a stationary gear.

7. Whether claim 1 is properly rejected under 35 U.S.C. § 102(b) as being anticipated by Rand et al. (EP 0254391).

Rand was cited by Appellant in an IDS submitted on December 6, 2010 in conjunction with the Declaration under 37 C.F.R. § 1.132, as evidence of the state of the prior art, with respect to the numerous objections and rejections under 35 U.S.C. § 112. The Examiner did not

consider Rand useful for understanding the state of the art, yet uses the reference for showing that each and every feature of claim 1 is anticipated.

The rejection states (Office Action at page 11) “[a]s best understood Rand et al. disclose in figs. 1 and 2, a fluid dispenser comprising a stationary body 11 including at least one stationary gear; a fluid reservoir 2, a dispenser member 4, a dose indicator device having a counter element 14, 20 displaceable axially and in rotation relative to the body; wherein the dispenser is actuated, the counter element cooperates firstly with the at least one stationary gear and secondly with the actuator.”

Rand discloses a fluid reservoir (aerosol container) 2 disposed in a stationary body (housing) 1. The reservoir 2 is axially displaceable relative to the body 1. (See col. 3, lines 36 – 50). The Examiner asserts that the fluid reservoir 2 is disposed in the driving arm 11. However, this is not an accurate interpretation of the driving arm 11 because the fluid reservoir is not “disposed in” the driving arm 11; rather the driving arm is disposed along one exterior side of the housing 1.

As such, the reservoir 2 is disposed in the housing 1, not the driving arm 11. (See also, col. 3, lines 36-38.)

The housing (body) 1 does not have a stationary gear. The ring-shaped cap member 8 is removably located on the end of the protruding portion of the reservoir 2, and moves up and down with the reservoir (col. 4, lines 4-13).

A housing 22, which defines an indicator compartment 13, extends from the cap member 8, thus moving up and down with the cap 8 and reservoir 2 (col. 4, lines 20-27). Various

components are housed within the compartment 13 of the housing 22, and in particular, the alleged counter element 14, 20. As such, the housing 22 is not stationary with respect to the reservoir 2; that is, the housing 22 is not a stationary body having at least one stationary gear since the reservoir 2 is not axially displaceable relative to the body.

The stationary driving arm 11 supports a projection 11a which extends through and is movable within a slot 11b and rests on the slot 1a of the body 1. Thus, at most, the body 1 has a stationary driving arm 11, which is not a gear.

For at least the foregoing reasons, Rand fails to disclose a stationary body including at least one stationary gear, in which the reservoir 2 is disposed in an axially displaceable manner.

Turning to other features of claim 1, the alleged counter element 14, 20 is a ratchet wheel 14 and a linear rack 20, which are provided in the compartment 13 of the housing 22.

The linear rack 20 is displaceable axially, and the ratchet wheel 14 is displaceable in rotation relative to the body 1 (see FIG. 2), for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from the reservoir (col. 4, lines 46-50).

However, the alleged counter element 14, 20 does not cooperate, while the dispenser is being actuated, firstly with said at least one stationary gear (not discussed in Office Action, but assumedly either arm 11 or ratchet pawl 15) of the body 1, and secondly with the reservoir, so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.

Rather, in Rand, the counter element never cooperates with the reservoir at all, and only cooperates with the depression of the cap 8/housing 22.

Moreover, operation of the counter is actuated by depression of the container which provides depression of the ratchet wheel 14 which is engaged with the fixed arm 11, thus resulting in rotation of the ratchet wheel, which itself actuates the linear indicator rack 20 (col. 4, lines 40-52). Thus, even if one were to consider the arm 11 to be a stationary gear of the body 1, counting starts at the beginning of the actuation stroke, and any incomplete actuation stroke would result in an incomplete rotation of the ratchet wheel, and thus an incomplete displacement of the indicator rack, providing incomplete counting. That is, the dose indicator device is not actuated by an incomplete actuation stroke as in the claimed invention. According to col. 4, whenever the body 2 is depressed to open the valve member 4, the ratchet wheel moves downwards to move through a step. There is no teaching or suggestion that the ratchet wheel moves through to the next step by an incomplete actuation stroke.

In view of the foregoing, Rand fails to disclose a dose indicator device including a counter element, that is actuated by an incomplete actuation stroke.

For at least the foregoing reasons, Rand fails to anticipate claim 1.

8. Whether claim 23 is properly rejected under 35 U.S.C. § 102(b) as being anticipated by Rand et al. (EP 0254391).

Rand fails to anticipate claim 23 because Rand fails to disclose a stationary body including at least one stationary gear.

There is no structure equivalent in Rand to a stationary gear. The driving arm 11 is an elongated arm structure with a projection 11a. This is not a gear, and thus, not equivalent to the stationary gear of the claimed invention.

Thus, claim 23 is not anticipated by Rand.

Conclusion

The fee required under 37 C.F.R. § 41.37(a) was previously submitted on November 19, 2009. The fee required under 1.17(c) is being remitted. The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: September 19, 2011

CLAIMS APPENDIX

CLAIMS 1-23 ON APPEAL:

1. (previously presented): A fluid dispenser comprising:

a stationary body (1) including at least one stationary gear (110, 122),

a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body,

a dispenser member mounted on said reservoir (2), and

a dose indicator device, including a counter element (20) that is displaceable axially and in rotation relative to said body (1), for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir,

wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a pretermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.

2. (previously presented): A dispenser according to claim 1, wherein, during the return stroke of the dispenser after dispensing a dose, said dose indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does

not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

3. (previously presented): A dispenser according to claim 1, in which said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20), said counter element (20) including a second gear (230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser, the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation, the stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

4. (original): A dispenser according to claim 3, in which the stationary gear (110) includes abutment means (115) preventing said counter element (20) from turning once said counter element (20) has turned at least in part, an additional axial displacement of said counter element (20) being necessary to enable it to continue to turn and/or to return the indicator device to its rest position.

5. (original): A dispenser according to claim 4, in which said abutment means (115) comprise an axial projection.

6. (previously presented): A dispenser according to claim 1, in which said stationary gear (110) and/or said counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position after a preceding actuation, and until the dispenser has completed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

7. (previously presented): A dispenser according to claim 6, in which said blocking means comprise axial projections (120, 220) provided on the body (1) and on the counter element (20) respectively, each of said projections (120, 220) having an axial end-profile that is planar, said projections (120, 220) facing each other, at least in part, until the counter element has turned sufficiently to offset said projections (120, 220), with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

8. (previously presented): A dispenser according to claim 3, in which the teeth of the second gear (230) of the counter element (20) include an intermediate step (235), the actuator member (30) co-operating with said step (235) while the dispenser is being actuated, and co-operating with the end wall of said second gear (230) while returning to the rest position, after being actuated, the displacement between the intermediate step (235) and the end wall being obtained by said counter element (20) turning.

9. (previously presented): A dispenser according to claim 3, in which, once the predetermined incomplete return stroke has been performed, the actuator member (30) is positioned facing the following tooth of the second gear (230) of the counter element (20), enabling the dispenser and the dose indicator device to be actuated once again.

10. (previously presented): A dispenser according to claim 1, in which said body (1) includes a first stationary gear (110) and a second stationary gear (122), said counter element (20) including a first gear (210) for co-operating with said first stationary gear (110) and a second gear (222) for co-operating with said second stationary gear (122), said counter element (20) being put axially into contact with an actuator member (30) of the dispenser by means of a return spring (50) and being turnable relative to said actuator member (30), the teeth of said second gear (222) and of said second stationary gear (122) being oblique, at least in part, so that an axial displacement of the actuator member (30) initially causes said counter element (20) to be displaced axially over a predetermined incomplete actuation stroke until the oblique portion (221) of said second gear (222) of the counter element (20) co-operates with said oblique portion (121) of said second stationary gear (122), causing the counter element (20) to be turned over a first portion of a turn cycle, the teeth of said first gear (210) and of said first stationary gear (110) being oblique, at least in part, so that when the counter element (20) returns to its rest position, it is caused to turn so as to terminate its turn cycle, which corresponds to one actuation of the dispenser being counted.

11. (previously presented): A dispenser according to claim 10, in which said first and second stationary gears (110, 122) of the body (1) and/or said first and second gears (210, 222) of the counter element (20) are offset relative to each other, so that whenever the counter element (20) is displaceable in rotation, returning said counter element to its rest position without terminating the actuation stroke of the dispenser causes the counter element (20) to turn over its complete turn cycle, guaranteeing that one actuation of the dispenser is counted after said predetermined incomplete actuation stroke.

12. (previously presented): A dispenser according to claim 10, in which said second stationary gear (122) of the body (1) and/or said second gear (222) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, and until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

13. (previously presented): A dispenser according to claim 12, in which said blocking means have an axial end-profile that is planar, at least in part, and that is formed on the teeth of said second stationary gear (122) of the body (1) and on the teeth of said second gear (222) of the counter element (20), said planar profiles of said teeth facing each other, at least in part, until the

counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

14. (previously presented): A dispenser according to claim 10, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

15. (previously presented): A dispenser according to claim 1, in which said body (1) includes a first stationary gear (110) and a second stationary gear (122), said counter element (20) comprising a first gear (210) for co-operating with said first stationary gear (110), a second gear (222) for co-operating with said second stationary gear (122), and a third gear (230) for co-operating with an actuator gear (300) secured to an actuator member (30) of the dispenser, the teeth of said third gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member (30) causes said counter element (20) to be displaced axially and in rotation, the first stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

16. (previously presented): A dispenser according to claim 15, in which said second stationary gear (122) of the body (1) and/or said second gear (222) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus

preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

17. (previously presented): A dispenser according to claim 16, in which said blocking means have an axial end-profile that is planar and that is formed on the teeth of said second stationary gear (122) and on the teeth of said second gear (222), said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

18. (previously presented): A dispenser according to claim 16, in which said actuator gear (300) includes abutment means (305) limiting the extent to which the counter element (20) can turn, until the actuator member (30) has performed said predetermined incomplete return stroke.

19. (original): A dispenser according to claim 18, in which said abutment means (305) comprise an axial projection formed on said actuator gear (300).

20. (previously presented): A dispenser according to claim 15, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

21. (previously presented): A dispenser according to claim 1, wherein the dispenser member is a pump or a valve.

22. (previously presented): A fluid dispenser comprising:
a stationary body (1) including at least one stationary gear (110, 122);
a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body;

a dispenser member mounted on said reservoir (2), being actuated when said reservoir is axially displaced relative to the stationary body by a predetermined amount, for dispensing a dose of fluid from said reservoir;

a dose indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, said dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to said body (1), wherein when the dispenser member is actuated, said counter element cooperates firstly with said at least one stationary gear (110, 122) and secondly with said reservoir (2);

first safety means for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke; and

second safety means for preventing the fluid from being expelled again until said dispenser has completed the predetermined incomplete return stroke, said dispenser and said

dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

23. (previously presented): A fluid dispenser comprising:

a stationary body including at least one stationary gear;

an actuator member that is displaceable axially with respect to said stationary body;

a dose indicator that is displaceable axially and in rotation relative to said body, said dose indicator being engageable with said actuator member and said stationary body, wherein when said actuator member displaces axially, said counter element is caused to be displaced axially and permitted to rotate relative to said body.

Appeal Brief under 37 C.F.R. § 41.37
U.S. Application No.: 10/556,432

Attorney Docket No.: Q91404

EVIDENCE APPENDIX:

Pursuant to 37 C.F.R. § 41.37(c)(1)(ix), submitted herewith are copies of any evidence submitted pursuant to 37 C.F.R. §§ 1.130, 1.131, or 1.132 or any other evidence entered by the Examiner and relied upon by Appellant in the appeal.

These documents have been submitted on December 6, 2010.

Appeal Brief under 37 C.F.R. § 41.37
U.S. Application No.: 10/556,432

Attorney Docket No.: Q91404

RELATED PROCEEDINGS APPENDIX

There are no related proceedings pursuant to 37 C.F.R. § 41.37(c)(1)(ii).

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. NGO

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

SUBMISSION OF APPEAL BRIEF

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an Appeal Brief. The statutory fee of \$540.00 was previously paid on November 19, 2009, and thus, no further fee is believed due. However, the USPTO is directed and authorized to charge all required fees, including the statutory fee if necessary, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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/Ellen R. Smith/
Ellen R. Smith
Registration No. 43,042

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: September 19, 2011

APPENDIX

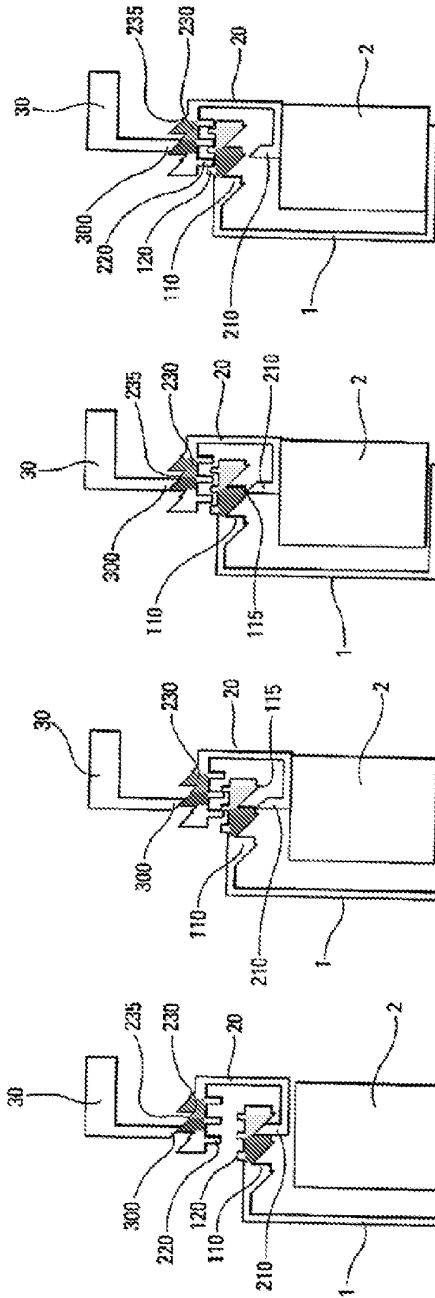


FIG. 1: Rest position

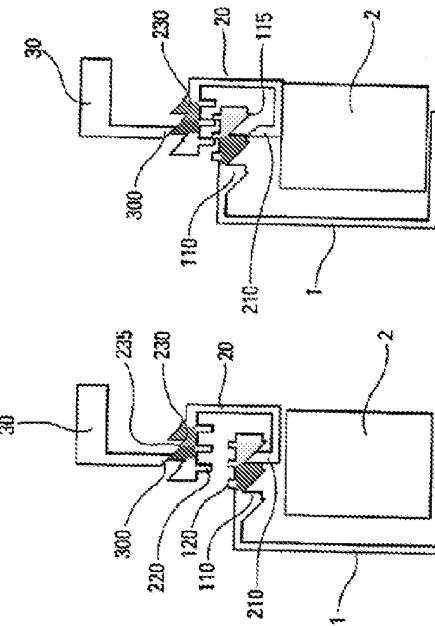


FIG. 2: initial axial displacement of counter element 20

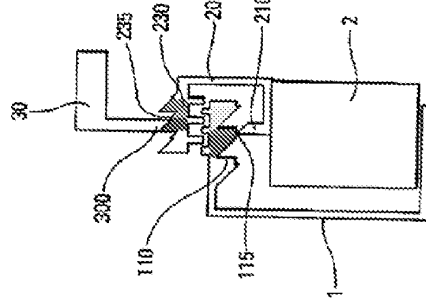


FIG. 3: initial rotation of the counter element 20

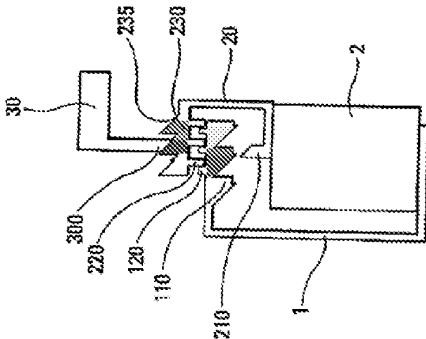


FIG. 4: completion of axial displacement of counter element 20 and incremental rotation of counter element 20

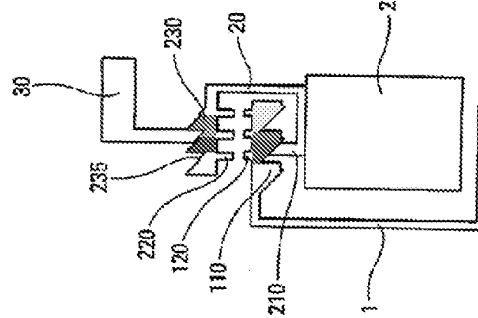


FIG. 5: partial upward release of actuator 30 and incremental rotation of counter element 20

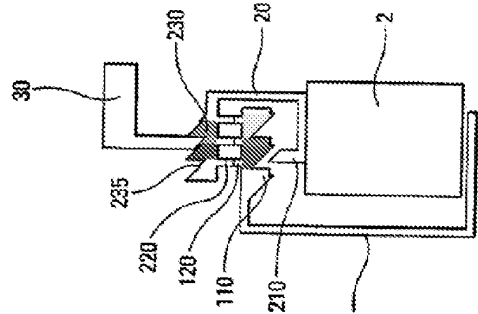


FIG. 6: prevention of actuation prior to complete release of actuator 30

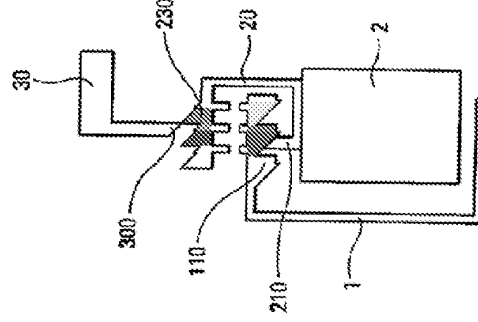


FIG. 7: continued release of actuator 30

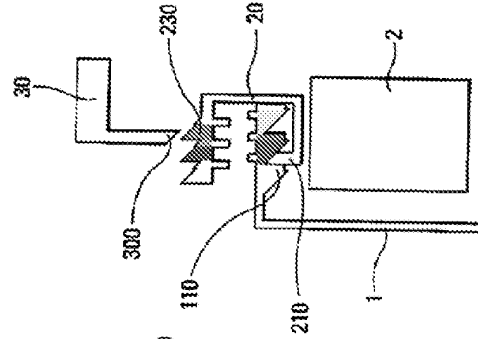


FIG. 8: completion of release of actuator 30, completion of rotation of counter element 20

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: Lien M. Ngo

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

DECLARATION UNDER 37 C.F.R. § 1.132

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Fabien Poulard, hereby declare and state:

THAT I am the inventor of U.S. Application 10/556,432;

THAT I am a citizen of France;

THAT I have received the degree of Engineer in 1996 from ISPA;

THAT I have been employed by Valois since 05/03/2001, where I hold a position as

Design Engineering Leader, with responsibility for Dose Indicator Design;

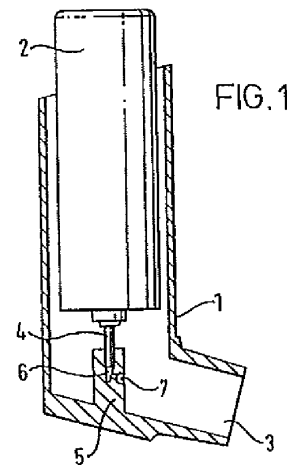
I also hereby further declare and state:

1. I am familiar with the June 4, 2010 Office Action, including the objections to the drawings and specification, and the rejections to the claims.
2. My invention provides a fluid dispenser including a dose indicator device that prevents any risk of under-counting. My invention guarantees that the indicator device is actuated each time

fluid is dispensed by the fluid dispenser, and prevents actuation of the indicator device when a dose is not dispensed. (See Specification at page 2, line 14-23.)

3. Fluid dispensers having dose indicator devices are well known. (See originally filed Specification at page 1, lines 1-8.)

4. With respect to the objection to the drawings in paragraph number 2 of the Office Action, the inclusion of a dispenser member on the reservoir was originally recited in claim 1 when the application was filed. Moreover, the placement of a dispenser member, such as a pump or valve, on top of a reservoir for use in a fluid dispenser, is well known in the art. The axial displacement of the reservoir relative to the stationary body actuates the dispenser member to cause a dose of fluid to be dispensed from the reservoir. (Specification at page 9, lines 3-5.) This type of pump or valve actuation is understood by those of ordinary skill in the art, as evidenced by numerous patents and patent applications published by the U.S Patent and Trademark Office and the European Patent Office. (See for example, U.S. Pub. No. 2002/0195102, FIG. 1 (reproduced to the right), cited by the Examiner in the Office Action dated July 22, 2008 and cited by Applicant in the Information Disclosure Statement filed on November 9, 2005, showing a dispenser member 4 mounted on a top of a reservoir 2). A list of such sample publications showing the placement of a dispenser member on top of a reservoir is provided in **Attachment A**. As such, one of ordinary skill in the art would have known the placement of the dispenser member on the reservoir.



5. With respect to the objection to the drawings in paragraph number 3, the drawings filed with the instant application, U.S. Application No. 10/556,432, were purposefully simplified to reduce the complexity of the drawings in order to increase the understanding of my invention. (Specification at page 8, lines 9-19.) I used diagrammatic drawings to illustrate the body, gears, reservoir, actuator and counter, to increase understanding of my invention because the use of diagrammatic drawings for such elements is well known and understood by those of ordinary skill in the art. This level of skill in the art is evidenced by the attached list of sample publications utilizing diagrammatic drawings to represent such elements as provided in **Attachment B**.

6. A set of pictures of an embodiment of the present invention is provided in **Attachment C**. One of ordinary skill in the art would understand how to interpret the diagrammatic drawings of the pending application to represent a device such as the one in these pictures.

7. With respect to the objection stated in paragraph number 4 of the Office Action, one of ordinary skill in the art would understand how the improved portion of the present invention is connected with the old portion and structure. By evidence of the publications provided in **Attachment A and Attachment B**, the old structure of gears and actuators in fluid dispensers is known. One of ordinary skill in the art would understand the improved portion of the fluid dispenser because the general concept of gears and actuators in a fluid dispenser is known.

8. With respect to the objections stated in paragraph number 7 of the Office Action, one of ordinary skill in the art would understand how the various elements could be connected with each other, as evidenced in **Attachment A**, which shows the level of ordinary skill in the art with

respect to the use of reservoirs and counter elements in dispenser bodies and how dispensers function. The illustration of an oblique tooth to simply represent a gear is understood by those of ordinary skill in the art. See **Attachment B**.

9. With respect to the rejection of the claims stated in paragraph number 9, the level of skill in the art has been established by the evidence provided in **Attachments A and B**. The determination of enablement should take the state of the prior art into consideration. The state of the prior art is evidenced in Attachments A and B. In view of such, one skilled in the art would readily understand how to make and use the present invention in a fluid dispenser without any undue experimentation.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 23/11/2010


Fabien Poulard

ATTACHMENT A

(US Refs Not Submitted)

US 5,349,945
US 5,718,355
US 5,904,139
US 6,161,724
US 6,142,339
US 6,155,251
US 6,328,037
US 6,446,627

(Submitted as Part 1)

WO 93/24167
WO 98/52634
WO 98/56444
WO 00/09187
WO 00/21593
WO 00/59806
WO 01/28887
WO 01/37909

(Submitted as Part 2)

EP 0 254 391
EP 0 949 584
EP 1 010 438
EP 1 163 922

ATTACHMENT B

(US Ref. Not Submitted)

US 5,718,355: Figures 3A, 3E, 3F, 3G, 3H

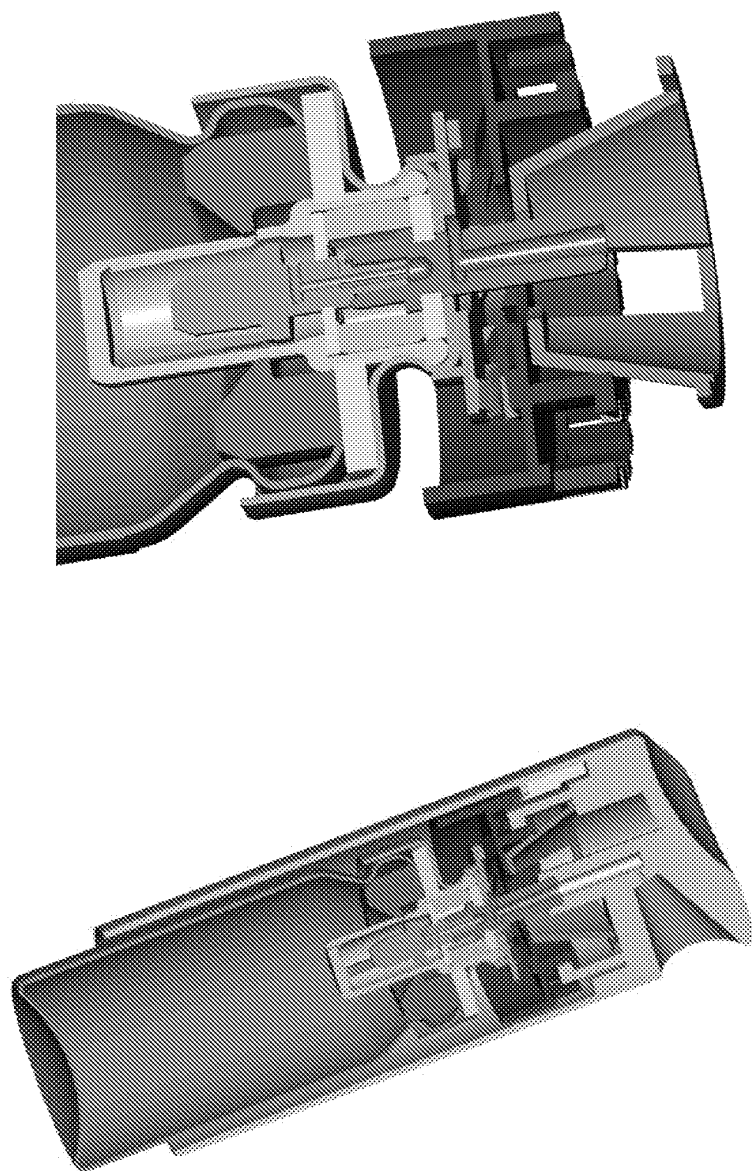
WO 00/09187: Figures 2a, 2b, 2c

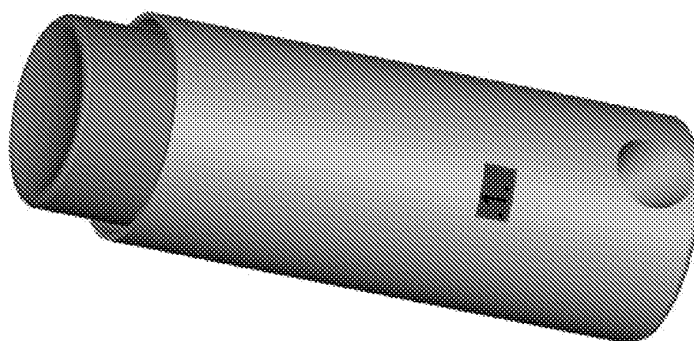
EP 0 480 488: Figures 4, 5

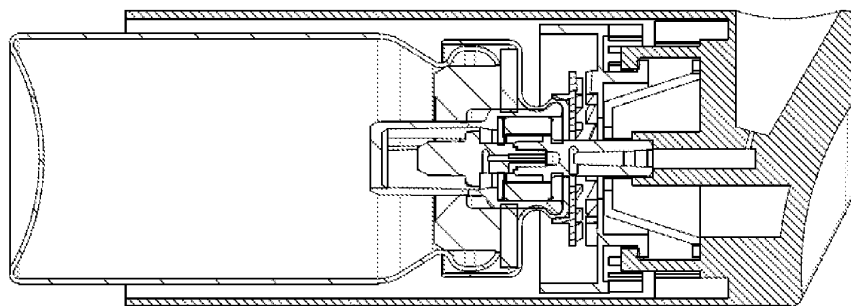
EP 0 949 584: Figure 5

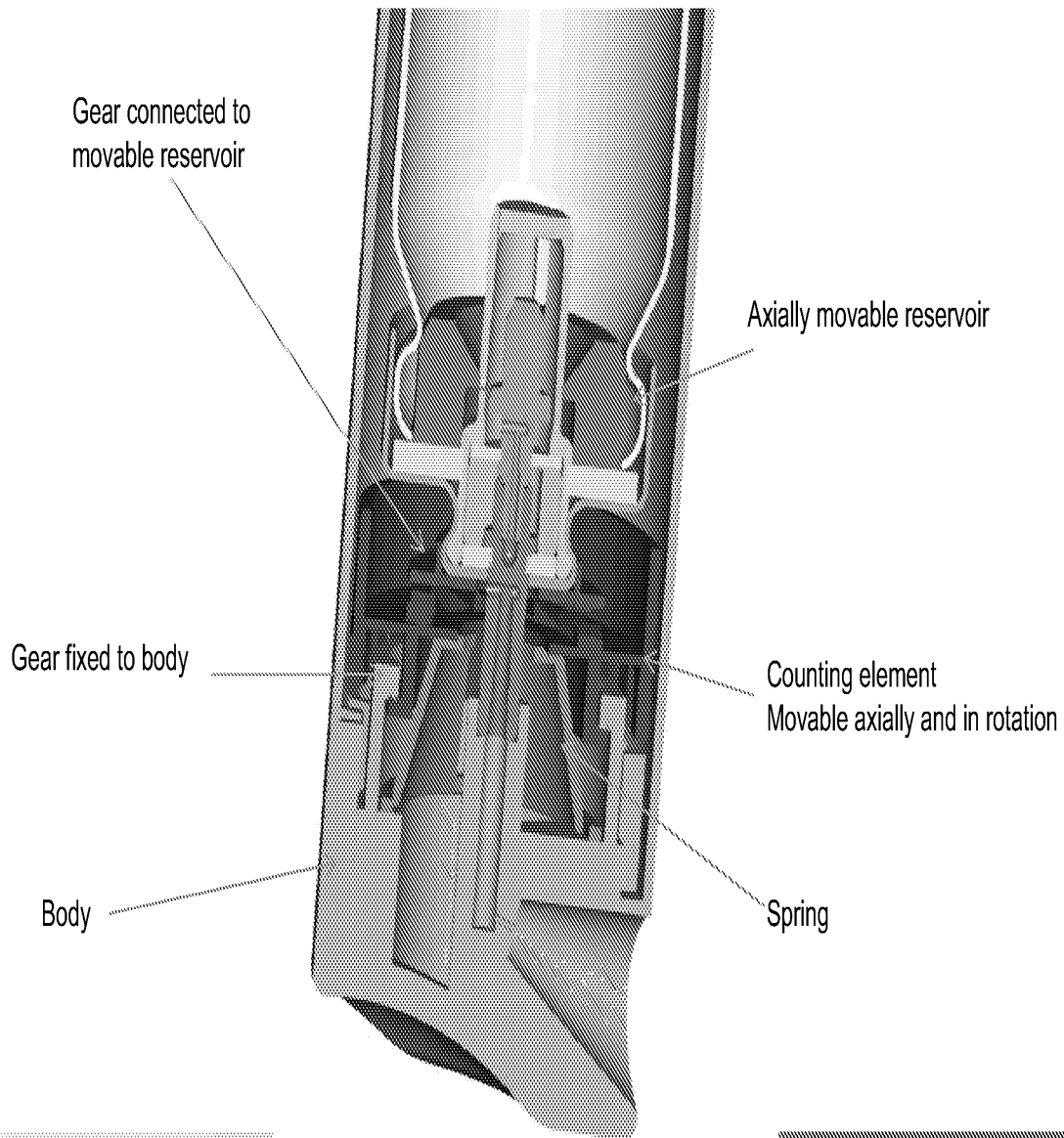
EP 1 065 477: Figures 5, 6

ATTACHMENT C









Pfeiffer Valois 

We're changing
our name but not
our commitment.

Fig 13

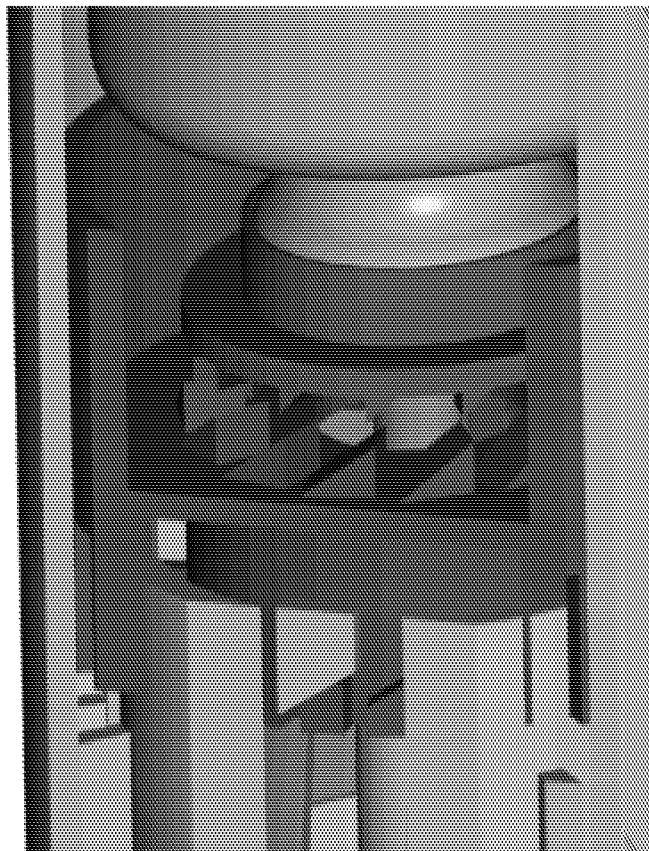


Fig 14

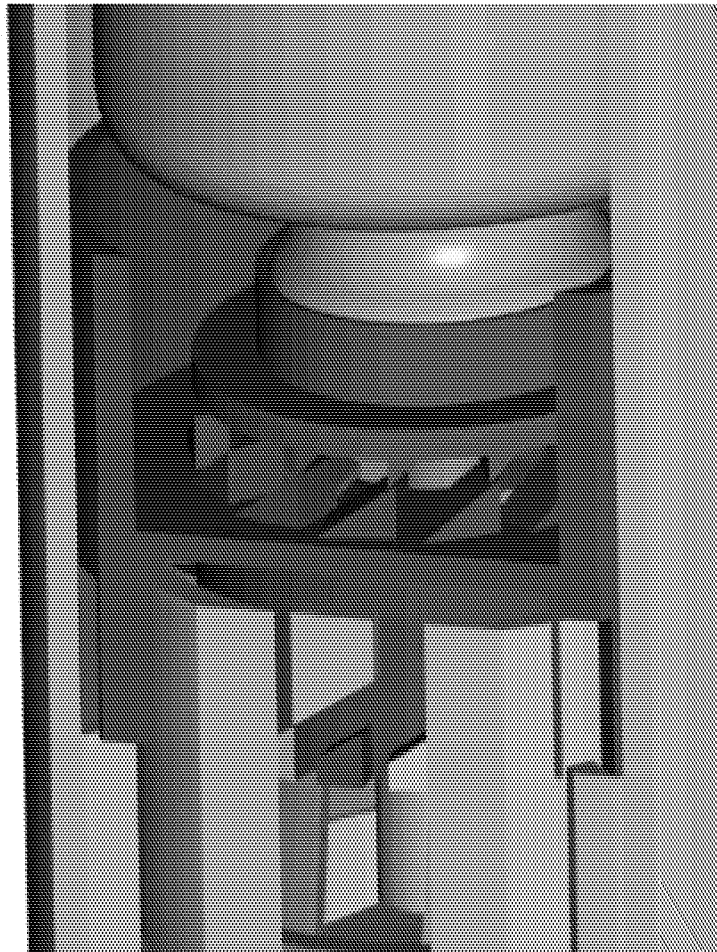


Fig 16

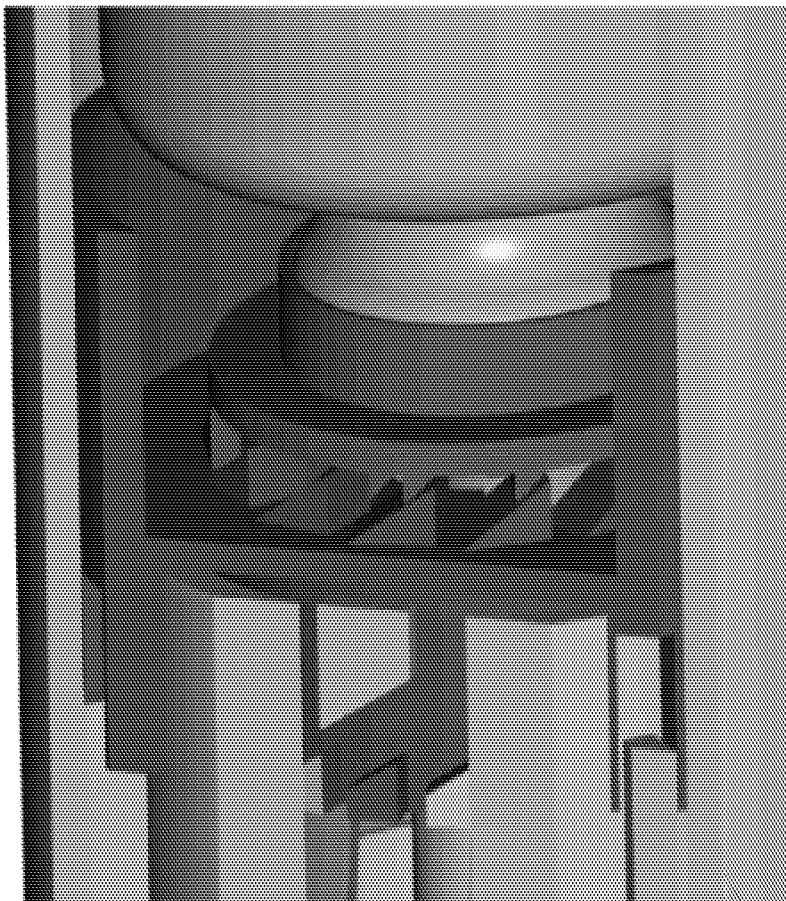


Fig 17

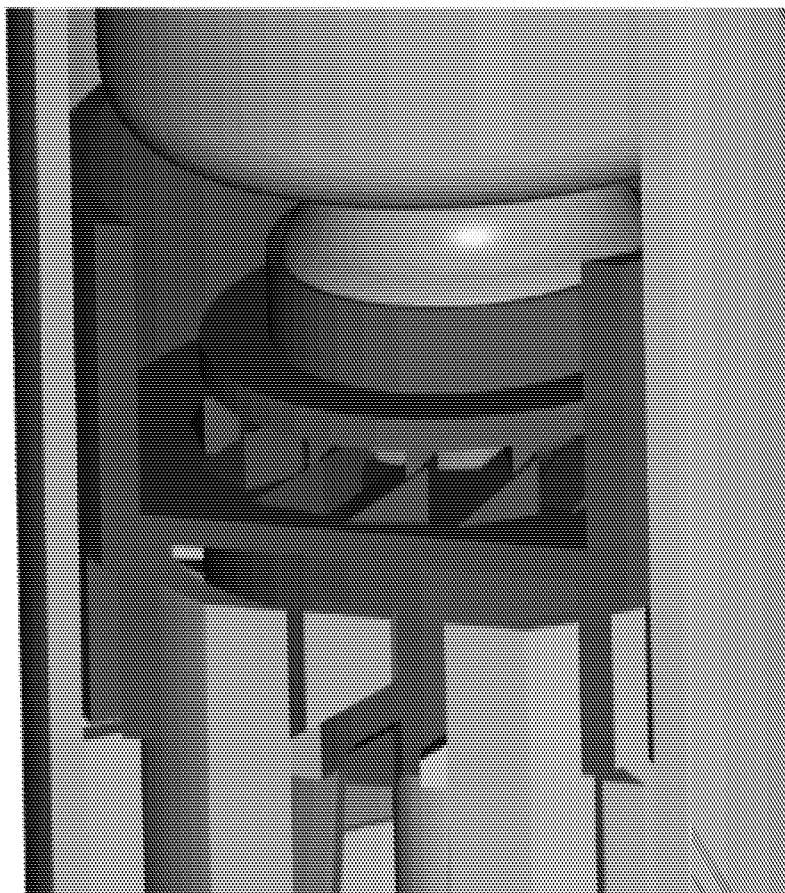
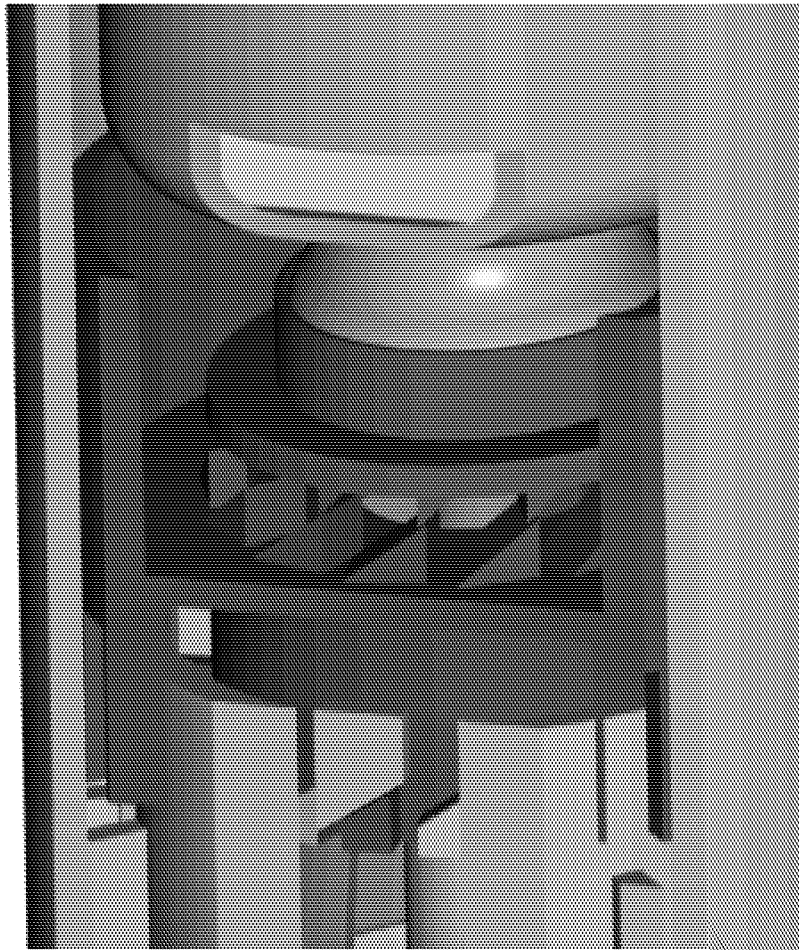


Fig 21



Electronic Patent Application Fee Transmittal				
Application Number:		10556432		
Filing Date:		09-Nov-2005		
Title of Invention:		Fluid product dispenser		
First Named Inventor/Applicant Name:		Fabien Poulard		
Filer:		Ellen Resnick Smith/Tiara Hill		
Attorney Docket Number:		Q91404		
Filed as Large Entity				
U.S. National Stage under 35 USC 371 Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 1 month with \$0 paid	1251	1	130	130

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				130

Electronic Acknowledgement Receipt	
EFS ID:	10981570
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	Fluid product dispenser
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Ellen Resnick Smith/Tiara Hill
Filer Authorized By:	Ellen Resnick Smith
Attorney Docket Number:	Q91404
Receipt Date:	19-SEP-2011
Filing Date:	09-NOV-2005
Time Stamp:	17:21:51
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$130
RAM confirmation Number	4588
Deposit Account	194880
Authorized User	SUGHRUE MION, PLLC
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. 1.492 (National application filing, search, and examination fees) Charge any Additional Fees required under 37 C.F.R. Section 1.17 (Patent application and reexamination processing fees)	

Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees)

Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Appeal Brief Filed	Q91404_Appeal_Brief_wAppen dix.pdf	1798628 fe1c8139ff9f9571845de84304a23a038d07848	no	67

Warnings:

Information:

2		Dec_attachments.pdf	848591 aa3d57b69b1def59a8554f2bed148aea874527eb	yes	16

Multipart Description/PDF files in .zip description

Document Description	Start	End
Rule 130, 131 or 132 Affidavits	1	4
Rule 130, 131 or 132 Affidavits	5	5
Rule 130, 131 or 132 Affidavits	6	6
Rule 130, 131 or 132 Affidavits	7	16

Warnings:

Information:

3	Fee Worksheet (SB06)	fee-info.pdf	29920 abaa2619fb67bc54478e4e168e7050c8cbb7c33d	no	2

Warnings:

Information:

Total Files Size (in bytes):			2677139

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 12/06/2011 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER	
			NGO, LIEN M	
			ART UNIT	PAPER NUMBER
			3754	
			NOTIFICATION DATE	DELIVERY MODE
			12/06/2011	ELECTRONIC

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The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/556,432
Filing Date: November 09, 2005
Appellant(s): POULARD, FABIEN

Ellen R. Smith
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/19/11 appealing from the Office action mailed 2/18/11.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-23 are all of the pending claims and all are rejected. The rejections of claims 1-23 are being appealed.

Claims 1-23 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate description of the invention that would enable one skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed subject matter.

Claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections.

Claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bason (EP 0949548).

Claims 1 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rand et al. (EP 0254391).

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

EP 0949584	BASON	10-1999
EP 0254391	RAND ET AL.	01-1988

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-23 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In regard to claims 1-9, 22 and 23, the claims recite the elements and their functions related one to another without actual structures and connections between them. The specification of the present application does not disclose in full, clear, concise of the actual structures of a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element, first and second safety means, and structural connections between them in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or perform the system in claims 1, 22 and 23, so that the counter element is displaceable axially and in rotation relative to the body, the body gear is stationary, the reservoir is axially displaced relative to the body even if the dispenser does not perform a complete actuator stroke and the counter element co-operating, while the dispenser is being actuated, firstly with the at

least one stationary gear and secondly with the reservoir; and the system as in claim 2 during the return stroke; and also claimed subject matter in claims 3-9.

In regard to claims 10-14, the specification of the present application does not disclose in full, clear, concise of the actual structures of a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element and structural connections between them in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or perform the claimed subject mater of claims 10-14, which examiner believe they are claimed directly from the embodiment of figs. 9-12 in the application. Moreover, the specification does not support the claimed subject matter of claim 10-14 as disclosed in figs. 9-12, which enables for the counter element co-operating, while the dispenser is being actuated, firstly with the at least one stationary gear and secondly with the reservoir, as claimed in claims 1 and 22. In figs. 9-12, the counter element 20 is attached to actuator 30 which is integral one piece with a reservoir 2; therefore, it is impossible to counter element 20 co-operating the reservoir 2.

In regard to claims 15-20 , the specification of the present application does not disclose in full, clear, concise of the actual structures of a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element and structural connections between them in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or perform the claimed subject mater of claims 15-20, which examiner believe they are claimed directly from the embodiment of figs. 13-21. Moreover, the specification does not support the claimed

subject matter of claim 15-20 as disclosed in figs. 13-21, which enables for the counter element co-operating, while the dispenser is being actuated, firstly with the at least one stationary gear and secondly with the reservoir, as claimed in claim 1. In figs. 13-21, the counter element 20 is engaged to actuator 30 and a stationary body 1 while the dispenser is being actuated, but it is separate from a reservoir 2; therefore, it is impossible to counter element 20 co-operating the reservoir 2.

Claims 1-23 stand rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the claims comprising many elements but do not include structures or shapes of elements and structural connections between the elements, such omission amounting to a gap between the necessary structural connections.

Claims 1-23 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because it is not clear what are required for structures or shapes of the elements in the claims, such as a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element, first safety means, second safety means, etc., and structural connections between

them to understand the claimed subject matter which applicant regards as the invention.

Claims 1-23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bason (EP 0949548). As best understood, Bason discloses, in figs. 1-6, a fluid dispenser comprising a stationary body A including at least one stationary gear 2; a fluid reservoir C, a dispenser (inherent); a dose indicator device having a counter element (4, 8) displaceable axially and in rotation relative to the body; wherein the dispenser is actuated, the counter element cooperates firstly with the at least one stationary gear and secondly with said reservoir; first and second safety means 10, 15.

Claims 1 and 23 stand rejected under 35 U.S.C. 102(b) as being anticipated by Rand et al. (EP 0254391). As best understood Rand et al. disclose, in figs. 1 and 2, a fluid dispenser comprising a stationary body 1 including at least one stationary gear 11; a fluid reservoir 2, a dispenser member 4; a dose indicator device having a counter element (A, 14, 20) displaceable axially and in rotation relative to the body; wherein the dispenser is actuated, the counter element cooperates firstly with the at least one stationary gear 11 and secondly with said reservoir.

(10) Response to Argument

In regard to Claims 1-23 as rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, Appellant argues that the claims are enablement because one skilled in the art would understand the structural configurations and connections of the claimed elements in the claims by filling a Declaration under 37 C.F.R. 1.132, dated 12/6/10 or 9/19/11, and providing evidences with different prior art inventions having different structures, connections of components, etc. However, that is not found persuasive because the evidences of the prior art, for example, the invention in the Attachment C, and Fig. 1 of US Pub No. 2000/0195102, one skilled in the art is unable to view the prior art above to understand and/or make the present claim inventions as claims 1-23 with in Figs. 1-8 (embodiment I, claims 1-9), Figs. 9-12 (embodiment II, claims 1 and 10-14), and Figs. 13-21 (embodiment III, claims 1 and 15-20). Claims 1 and 21-23 are genetic claims.

Figs. 1-21 show simplified diagrams of an actuator member 40, a counter element or a dose indicator device 20, a body 1, and a reservoir 2. The present specification does not disclose the actual structures, shapes and connections of and between the elements of the inventions (actually claimed inventions comprise three different embodiments). One skilled in the art is unable to view the structures, shapes and connections of and between the elements of the inventions of Attachment C and Fig. I of US Pub No. 2000/0195120 to figure out the actual structures, shapes and connections of and between the elements of the present claimed inventions to form a stationary body, an axially displaceable reservoir, and displaceable axially and rotatably

dose indicator device relatively to each other as claimed; wherein the counter element cooperates, while the dispenser is being actuated, firstly with the at least one stationary gear of said body, and secondly with said reservoir, so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke (claim 1); and wherein, during the return stroke of the dispenser after dispensing a dose, the dose indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position (claim 2); and also the same with claims 22 and 23.

In regard to claims 1-23 as rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, Appellant, again, relied on the prior art, for example, the inventions of Attachment C and Fig. I of US Pub No. 2000/0195120, and the present application drawing, figs. 1-21 to argue that no omitting essential structure cooperative relationships of element as being incomplete or no a gap between elements. That is not found convincing because the claimed inventions many elements are cooperative relationships, for example, a stationary body, an axially displaceable reservoir, and displaceable axially and rotatably dose indicator device; wherein the counter element

cooperates, while the dispenser is being actuated, firstly with the at least one stationary gear of said body, and secondly with said reservoir , so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke; and wherein, during the return stroke of the dispenser after dispensing a dose, the dose indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to it rest position. However the claims do not include structural connections between elements, which are essential cooperative relationships of elements, such omission amounting a gap between the necessary structural connections between a stationary body, an axially displaceable reservoir, and displaceable axially and rotatably dose indicator device; wherein the counter element cooperates, while the dispenser is being actuated, firstly with the at least one stationary gear of said body, and secondly with said reservoir , so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke (claim 1); and wherein, during the return stroke of the dispenser after dispensing a dose, the dose indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being

actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position (claim 2); and also the same with claims 22 and 23.

In regard to Claims 1-23 as rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, Appellant argues that one of ordinary skill in the art, already having the knowledge of how conventional reservoirs, dispenser members and indicator devices are shaped, structured and connected to form the claimed inventions. However, that is found not convincing because the claims are indefinite because it is not clear what are required for structures or shapes of the elements in the claims, such as a body, a reservoir, dispenser member, an indicator device, at least one station gear, a counter element, first and second safety means, etc., and structural connections between them to understand the claimed subject matter which applicant regards as the invention. One of ordinary skill in the art would not view to different inventions with different structural elements and connections of the prior art to understand the subject matters to require in the claims to be patentable over the prior art.

In regard to claims 1-23 as rejected under 35 U.S.C. 102(b) as being anticipated by Bason (EP 0949548), Appellant argues that Bason fails to

teach a stationary body including at least one station gear, a counter does not cooperate firstly with a stationary gear of the stationary body in claim 1, and limitations of claims 22-23. However, that is not found not convincing because Bason discloses, in figs.1-6, a comprising a stationary body A including at least one stationary gear 2; a fluid reservoir C, a dispenser (inherent); a dose indicator device having a counter element (4, 8) displaceable axially and in rotation relative to the body; wherein the dispenser is actuated, the counter element cooperates firstly with the at least one stationary gear 2 and secondly with said reservoir C; first and second safety means 10, 15. Because Bason discloses the fluid dispenser with limitations substantially as claimed; therefore, as appellant's arguments, it would have been inherent or known in the art, an ordinary skill in the art would understand the invention of Bason is capable perform the functions as claims 1-23.

In regard to Claims 1 and 23 as rejected under 35 U.S.C. 102(b) as being anticipated by Rand et al. (EP 0254391), Appellant argues that Rand et al. fail to teach a stationary body including at least one stationary gear, in which a reservoir is disposed in an axially displaceable manner. However, that is not found convincing because Rand et al. disclose, in figs. 1 and 2, a fluid dispenser comprising a stationary body 1 including at least one stationary gear 11; a fluid reservoir 2, a dispenser member 4; a dose indicator device having a counter element (A, 14, 20) displaceable axially and in

rotation relative to the body; wherein the dispenser is actuated, the counter element cooperates firstly with the at least one stationary gear 11 and secondly with said reservoir 2. Because Rand et al. disclose the fluid dispenser with limitations substantially as claimed; therefore, as appellant's arguments, it would have been inherent or known in the art, an ordinary skill in the art would understand the invention of Rand et al. is capable perform the function as claim 1.

In regard to claim 23, Appellant argues that Rand et al. fail to disclose a stationary body including at least one stationary gear. The arm 11 is an elongated arm structure with a projection, and thus, not equivalent to the stationary gear of the claimed invention. However, that is not found convincing because there is not further limitation required for the stationary gear. In view the present application in figs. 1-12, the gear 300 of the actuator 30, the gear 210 of the dose indicator device 20, the gear 210 and 220 of the actuator 20 are in the forms of elongated arm structures.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/LIEN TM NGO/

Primary Examiner, Art Unit 3754

Conferees:

/KEVIN P. SHAVER/

Supervisory Patent Examiner, Art Unit 3754

/Len Tran/

Supervisory Patent Examiner, Art Unit 3752

PATENT APPLICATION

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of:

Fabien POULARD

Appln. No.: 10/556,432

Confirmation No.: 3524

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

Docket No: Q91404

Group Art Unit: 3754

Examiner: Lien M. NGO

REPLY BRIEF PURSUANT TO 37 C.F.R. § 41.41

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. § 41.41, Appellant respectfully submits this Reply Brief in response to the Examiner's Answer dated December 6, 2011. Entry of this Reply Brief is respectfully requested.

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STATUS OF CLAIMS

Claims 1-23 are all the claims pending in the application. Claims 1-23 are rejected and the subject of this appeal.

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed, including the statute applied, the claims subject to each rejection, and the references relied upon by the examiner are as follows.

A. Claims 1-23 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate description of the invention that would enable one skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed subject matter.

B. Claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections.

C. Claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

D. Claims 1-23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bason (EP 0949548).

E. Claims 1 and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rand et al. (EP 0254391).

ARGUMENT

In addition to the arguments set forth in the Appeal Brief filed September 19, 2012, Appellants respond to certain points made in the Examiner's Answer as follows.

A. Concerning the rejection of claims 1-23 under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide an adequate description of the invention that would enable one skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed subject matter:

(i) Concerning the Examiner's response on pages 9-10 of the Examiner's Answer, the Examiner states that the Declarations and evidence of the level of skill in the art are not persuasive. The Examiner states (page 9, lines 10-11) "one skilled in the art is unable to view the prior art above to understand and/or make the present claim inventions as claims 1-23..."

As an initial matter, Appellants note that the Examiner has dismissed the Declaration summarily without any reasoned explanation for dismissing or rejecting the evidence of the Declaration. The Examiner did not respond to any of the points raised in the Declaration.

Also, it appears that, overall, the Examiner's position is based on her own understanding of the claims rather than from the perspective of one of ordinary skill in the art. In doing so, the Examiner has committed legal error. See MPEP 2141.03 and 2144.03. The Examiner must review the claims from the viewpoint of one of ordinary level of skill in the art rather than her own positions. The Examiner's interpretations do not reflect the interpretation of one of ordinary skill in the art.

The Examiner also states that the simplified diagrams provided by Appellants do not disclose the structures, shapes and connections of and between the elements.

However, the Examiner must consider the *Wands* factors when determining whether a disclosure satisfies the enablement requirement. The state of the prior art and the level of one of ordinary skill are two of the various factors. The examples provided in the Declarations (dated December 6, 2010 and September 19, 2011), show the state of the prior art and the understanding that one of ordinary skill in this field of technology would possess.

Appellants intentionally provided simplified diagrams to aid in the understanding of the claimed invention, since one of ordinary skill in the art is already well apprised of how an axially displaceable reservoir is generally provided in a stationary body for actuating doses from the reservoir.

One of ordinary skill in the art would certainly be able to view the prior art to understand and/or make the claimed invention based on the amount of direction provided by Appellants in the disclosure without an undue amount of experimentation to make or use the invention.

(ii) Concerning claims 10-14, the Examiner states (Examiner's Answer, page 6, lines 13-15): "In figs. 9-12, the counter element is attached to actuator 30 which is integral one piece with a reservoir 2; therefore, it is impossible to counter element 20 co-operating the reservoir 2 [sic]."

As best understood, the Examiner appears to state that it is impossible for the counter element to cooperate with the reservoir.

This new point made in the Examiner's Answer is an example of the Examiner's misunderstanding of the claimed invention.

As discussed on page 14, the user may perform the actuation by displacing the reservoir itself, i.e., there is not necessarily a separate actuator member in this embodiment. One of ordinary skill in the art understands that many fluid dispensing mechanisms in this field of art include dispenser systems in which the user presses on the

fluid reservoir to cause it to displace with respect to the body holding the reservoir in order to actuate a dose of the pharmaceutical product therein.

As shown in the step-by-step movement of FIGS. 9-11, the reservoir 2 (and actuator 30) moves downward with respect to the stationary gears 110, 122 of the body 1. The downward movement of the actuator *causes the counter element 20 to also move downward* with respect to the stationary gears. Thus, the counter element cooperates with the reservoir. See also FIGS. 1-8.

Since the stationary gears 110, 122 have oblique portions that cooperate with downward moving counter element 20, they cause the counter element to turn, and thus, initiate a counting cycle. (See specification at paragraph bridging pages 14-15.)

If the user stops actuating the dispenser, the system returns to its position by use of the return spring 50 (see transition from FIG. 11 to FIG. 12).

In view of the foregoing, the Examiner's above assertion is an inaccurate analysis of Appellants' device.

(iii) Concerning claims 15-20, the Examiner states (Examiner's Answer, page 7, lines 3-6): "In figs. 13-21, the counter element is engaged to actuator 30 and a stationary body 1 while the dispenser is being actuated, but it is separate from a reservoir 2; therefore, it is impossible to counter element 20 co-operating the reservoir 2."

As discussed on page 16 of the Specification, an actuator gear 300 is secured to the actuator member and a third gear 230 is introduced to the counter element 20 for co-operating with the actuator gear 300. Similar to the other embodiments, axial displacement of the actuator member 30 and reservoir 2 causes the counter element 20 to be displaced axially and when the gears of the counter element reach the oblique surfaces of the stationary gears, the counter element is also displaced in a rotational direction to initiate the counting cycle.

Axial displacement of the actuator member 30 (and thereby reservoir) causes the counter element 20 to be displaced axially and in rotation accordingly. Thus, the counter element 20 cooperates with the two stationary gears of the body 1 and the actuator gear of the actuator member 30 depending on its axial displacement position (see FIGS. 13-20). As such, the Examiner's assertion above is misplaced. It is not understood why the Examiner states that "it is impossible to counter element 20 co-operating the reservoir 2" or exactly what the Examiner means by this statement.

B. Concerning the rejection of claims 1-23 under 35 U.S.C. § 112, second paragraph, as allegedly being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections.

The Examiner is not convinced that the claims are complete "because the claimed inventions many elements are cooperative relationships, for example, a stationary body, an axially displaceable reservoir, and displaceable axially and rotatable dose indicator device; wherein the counter element cooperates, while the dispenser is being actuated,..."

However, the claimed elements cooperate in the clear manner recited in the claims and explained in the specification. The Examiner does not appear to understand the claimed invention, and thus, does not appear to understand how the axial and rotational displacement of the elements is performed in the claimed invention.

The claims include the required language necessary to convey the structural cooperative relationships of the elements. The Examiner has failed to provide any particular example of where there is a gap between the structural connections. Thus, Appellants are not afforded an opportunity to rebut any specific assertions of how any or all of the claims fail to meet the requirement.

C. Concerning the rejection of claims 1-23 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

The Examiner responds (Examiner's Answer, page 12, first full paragraph), that the claims are still considered indefinite because "it is not clear what are required for structures or shapes of the elements in the claims, such as a body, a reservoir, dispenser member, an indicator device...One of ordinary skill in the art would not view to different inventions with different structural elements and connections of the prior art to understand the subject matters to require in the claims to be patentable over the prior art."

The claims must be read in light of the specification. Appellant has provided a very detailed analysis of how the different elements in the claims structurally cooperate (see step by step analysis of FIGS. 1-8 in the Appeal Brief, as well as the specification). For instance, the oblique surfaces of the gears are provided so that as the counter element is axially displaced, it is caused to rotate by engagement with the surfaces of the stationary gears. One of ordinary skill in the art already having the knowledge of how conventional reservoirs, dispenser members and indicator devices are shaped and structured, would have understood how to shape and structure the gears and their novel interaction with each other in the claimed invention.

D. Concerning the rejection of claims 1-23 under 35 U.S.C. § 102(b) as being anticipated by Bason (EP 0949548):

The Examiner paraphrases the previous rejection and maintains that "Because Bason discloses the fluid dispenser with limitations substantially as claimed; therefore, as appellant's arguments, it would have been inherent or known in the art, an ordinary skill in the art would understand the invention of Bason is capable perform the functions as claims 1-23 [sic]."

However, Bason fails to disclose each and every feature, either explicitly or inherently, as is required in an anticipation rejection.

For example, Bason fails to disclose a stationary body including at least one stationary gear. The reservoir C is not axially displaceable relative to the base 1.

Also, for example, the number visible through the window 13 on the face 24 will change by one point for a complete depression and release of the cap. As, such it is not capable of changing the count if an incomplete actuation stroke is performed.

The Examiner has failed to address this point, or explained how Bason is capable of changing the count even if an incomplete actuation stroke is performed by Bason. Without the Examiner's explanation of this interpretation of Bason, Appellant is not afforded an opportunity to rebut the Examiner's position.

For at least the foregoing reasons in addition to the those provided in the Appeal Brief, Appellant respectfully submits that Bason fails to anticipate claims 1-23.

E. Concerning the rejection of claims 1 and 23 under 35 U.S.C. § 102(b) based on Rand:

The Examiner paraphrases the previous rejection, including that the arm 11 is a stationary gear of a stationary body 1, and maintains that the arguments presented by Appellants are not persuasive because no further limitations are required for the stationary gear and that the drawings of the present application show that "the gear 300 of the actuator gear 30, the gear 210 of the dose indicator device 20, the gear 210 and 220 of the actuator 20 are in the forms of elongated arm structures."

Initially, it is noted that Appellant has not characterized the gears 300, 210 and 220 as "elongated arm structures" in the drawings or written description. The Examiner does not appear to understand the drawings and how they represent the gears of the claimed invention.

As noted in the Appeal Brief (see page 28), the drawings are very diagrammatic. As discussed on page 8 of the specification, the drawings are highly simplified diagrams

so as to facilitate the understanding of how the various elements move relative to each other.

With respect to the Examiner's interpretation of Rand, Appellant maintains that the counter element never cooperates with the reservoir in Rand. It only cooperates with the depression of the cap 8/housing 22.

Moreover, the Examiner has failed to address the fact that even if one were to consider the arm 11 to be a stationary gear, Rand is not actuated by an incomplete actuation stroke as in the claimed invention. Any incomplete actuation stroke would result in an incomplete rotation of the ratchet wheel, and thus, an incomplete displacement of the indicator rack, providing incomplete counting.

The Examiner has not provided any guidance or explanation as to how Rand discloses this feature of the claimed invention, and thus, Appellant is not afforded an opportunity to specifically rebut the Examiner's position with respect to this feature of the claims.

As such, Appellant maintains that Rand fails to disclose each and every feature of claims 1 and 23 for the reasons discussed above in addition to those outlined the Appeal Brief.

CONCLUSION

For the above reasons as well as the reasons set forth in Appeal Brief, Appellant respectfully requests that the Board reverse the Examiner's rejections of all claims on Appeal. An early and favorable decision on the merits of this Appeal is respectfully requested.

Respectfully submitted,

/Ellen R. Smith/

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Ellen R. Smith
Registration No. 43,042

Date: February 6, 2012

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR ORAL HEARING BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES		Docket Number (Optional) Q91404									
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] On _____ Signature _____ Typed or printed name _____		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2" style="padding: 2px;">In re Application of Fabien POULARD</td> </tr> <tr> <td style="padding: 2px;">Application Number 10/556,432</td> <td style="padding: 2px;">Filed November 9, 2005</td> </tr> <tr> <td colspan="2" style="padding: 2px;">For FLUID PRODUCT DISPENSER</td> </tr> <tr> <td style="padding: 2px;">Art Unit 3754</td> <td style="padding: 2px;">Examiner Lien M. NGO</td> </tr> </table>		In re Application of Fabien POULARD		Application Number 10/556,432	Filed November 9, 2005	For FLUID PRODUCT DISPENSER		Art Unit 3754	Examiner Lien M. NGO
In re Application of Fabien POULARD											
Application Number 10/556,432	Filed November 9, 2005										
For FLUID PRODUCT DISPENSER											
Art Unit 3754	Examiner Lien M. NGO										

Applicant hereby requests an oral hearing before the Board of Patent Appeals and Interferences in the appeal of the above-identified application.

The fee for this Request for Oral Hearing is (37 CFR 41.20(b)(3)) \$ 1240.00

☐ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee shown above is reduced by half, and the resulting fee is: \$ _____

☐ A check in the amount of the fee is enclosed.

☒ Payment by credit card. Form PTO-2038 is attached.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account. I have enclosed a duplicate copy of this sheet.

☐ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 19-4880.

☐ A petition for an extension of time under 37 CFR 1.136(b) (PTO/SB/23) is enclosed. For extensions of time in reexamination proceedings, see 37 CFR 1.550.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

I am the

☐ applicant/inventor. ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96) ☒ attorney or agent of record. Registration number <u>43,042</u> ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34. _____	/Ellen R. Smith/ Signature Ellen R. Smith Typed or printed name February 6, 2012 Date 202-293-7060 Telephone number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of one (1) forms are submitted.

This collection of information is required by 37 CFR 41.20(b)(3). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Patent Application Fee Transmittal				
Application Number:		10556432		
Filing Date:		09-Nov-2005		
Title of Invention:		Fluid product dispenser		
First Named Inventor/Applicant Name:		Fabien Poulard		
Filer:		Ellen Resnick Smith/Hannah Lipman		
Attorney Docket Number:		Q91404		
Filed as Large Entity				
U.S. National Stage under 35 USC 371 Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Request for oral hearing	1403	1	1240	1240
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				1240

Electronic Acknowledgement Receipt	
EFS ID:	12010055
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	Fluid product dispenser
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Ellen Resnick Smith/Hannah Lipman
Filer Authorized By:	Ellen Resnick Smith
Attorney Docket Number:	Q91404
Receipt Date:	06-FEB-2012
Filing Date:	09-NOV-2005
Time Stamp:	17:22:26
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$1240
RAM confirmation Number	4527
Deposit Account	194880
Authorized User	SUGHRUE MION, PLLC
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: Charge any Additional Fees required under 37 C.F.R. Section 1.19 (Document supply fees) Charge any Additional Fees required under 37 C.F.R. Section 1.21 (Miscellaneous fees and charges)	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Reply Brief Filed	Reply_Brief.PDF	122039	no	11
			64f573091da8874eade21c53ae6ca85072b992f		
Warnings:					
Information:					
2	Request for Oral Hearing	Request_Oral_Hearing.PDF	97808	no	1
			277c3867e643d0299547a490b3adb44632671271		
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	29901	no	2
			1584808dff6e9c062823d8f746ed886b64a53e79		
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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373	7590	02/23/2012	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			NGO, LIEN M	
			ART UNIT	PAPER NUMBER
			3754	
			NOTIFICATION DATE	DELIVERY MODE
			02/23/2012	ELECTRONIC

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sughrue@sughrue.com
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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10/556,432	09 November 2005	POULARD, FABIEN	Q91404

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

LIEN NGO

ART UNIT	PAPER
3754	20120216

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

1. The reply brief filed 2/6/2012 has been entered and considered. The application has been forwarded to the Board of Patent Appeals and Interferences for decision on the appeal.

/LIEN TM NGO/
Primary Examiner, Art Unit 3754

PTO-90C (Rev.04-03)



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 02/27/2012 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER NGO, LIEN M	
			ART UNIT	PAPER NUMBER
			3754	
			NOTIFICATION DATE	DELIVERY MODE
			02/27/2012	ELECTRONIC

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

Appeal No: 2012-005156
Application: 10/556,432
Appellant: Fabien Poulard

**Board of Patent Appeals and Interferences
Docketing Notice**

Application 10/556,432 was received from the Technology Center at the Board on February 21, 2012 and has been assigned Appeal No: 2012-005156.

In all future communications regarding this appeal, please include both the application number and the appeal number.

The mailing address for the Board is:

BOARD OF PATENT APPEALS AND INTERFERENCES
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ALEXANDRIA, VIRGINIA 22313-1450

The facsimile number of the Board is 571-273-0052. Because of the heightened security in the Washington D.C. area, facsimile communications are recommended. Telephone inquiries can be made by calling 571-272-9797 and referencing the appeal number listed above.

By order of the Board of Patent Appeals and Interferences.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 03/12/2014 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER NGO, LIEN M	
			ART UNIT 3754	PAPER NUMBER
			NOTIFICATION DATE 03/12/2014	DELIVERY MODE ELECTRONIC

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sughrue@sughrue.com
USPTO@sughrue.com

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PATENT TRIAL AND APPEAL BOARD**



SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

Appeal No: 2012-005,156
Appellant: Fabien Poulard
Application No: 10/556,432
Hearing Room: A
Hearing Docket: B
Hearing Date: Thursday, May 08, 2014
Hearing Time: 09:00 AM
Location: Madison Building - East Wing
600 Dulany Street, 9th Floor
Alexandria, Virginia 22313-1450

**NOTICE OF HEARING
CONFIRMATION REQUIRED WITHIN TWENTY-ONE DAYS**

Your attention is directed to 37 CFR § 41.47. The above identified appeal will be heard by the Patent Trial and Appeal Board on the date indicated. Hearings will commence at the time set and as soon as the argument in one appeal is concluded, the succeeding appeal will be taken up. The time allowed for argument is twenty minutes unless additional time is requested and permitted before the argument is commenced. If there are any inquiries, please contact the Clerk of the Board at 571-272-9797.

The application involved in this appeal has been published. Accordingly, the hearing in this appeal is open to the public.

CONFIRMATION OR WAIVER OF THE HEARING IS REQUIRED. This form must be completed below and facsimile transmitted to both: (1) the USPTO Central fax number (official copy), and (2) the Patent Trial and Appeal Board fax number (courtesy copy) within TWENTY-ONE (21) DAYS from the mailing date of this notice indicating confirmation or waiver of the hearing. A copy of this notice may be alternately filed by mail if facsimile is not available.

PTAB HEARINGS FAX No: (571) 273-9797

USPTO Central Fax No: (571) 273-8300

PTAB Mailing Address: Patent Trial and Appeal Board
United States Patent and Trademark Office
P.O. BOX 1450
Alexandria, Virginia 22313-1450

In all communications relating to this appeal, please identify the appeal by its number.

CHECK ONE: () HEARING ATTENDANCE CONFIRMED () HEARING ATTENDANCE WAIVED

Signature of Attorney/Agent/Appellant

Date

Registration No.

Names of other visitors expected to accompany counsel: _____

For information on visitor access to hearing rooms and security procedures at the USPTO Alexandria Campus, see
http://www.uspto.gov/web/offices/dcom/gcounsel/contact.htm#bpai_contacts

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q91404
Fabien POULARD	Appeal No: 2012-005,156
Appln. No.: 10/556,432	Group Art Unit: 3754
Confirmation No.: 3524	Examiner: NGO, LIEN M
Filed: November 9, 2005	
For: FLUID PRODUCT DISPENSER	

REQUEST FOR POSTPONEMENT OF ORAL HEARING

Patent and Trial and Appeal Board
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

Appellant requests a resetting of the date of the Oral Hearing in the above-identified application before the Patent Trial and Appeal Board ("Board").

Appellant received the Notice of Hearing dated March 12, 2014, which set a May 8, 2014 date for the Oral Hearing on Appeal before the Board. The undersigned attorney, who has been handling the prosecution of the application, has a prior commitment overseas the week of May 5-12 of 2014. The only other attorney familiar with the application will be unavailable due to his spouse undergoing medical surgery that same week.

In view of the forgoing, we respectfully request that the May 8, 2014 date be rescheduled. Appellant suggests the week of May 19, 2014, or any week thereafter, which is convenient for the Board.

REQUEST FOR POSTPONEMENT OF ORAL HEARING
Appln. No.: 10/556,432

Attorney Docket No.: Q91404

Respectfully submitted,

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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: March 14, 2014

/Ellen R. Smith/

Ellen R. Smith

Registration No. 43,042

Electronic Acknowledgement Receipt	
EFS ID:	18479222
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	Fluid product dispenser
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Ellen Resnick Smith/Mariko Motomura
Filer Authorized By:	Ellen Resnick Smith
Attorney Docket Number:	Q91404
Receipt Date:	14-MAR-2014
Filing Date:	09-NOV-2005
Time Stamp:	15:51:56
Application Type:	U.S. National Stage under 35 USC 371

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Appeal Postponement of Oral Hearing Request	Q91404RequestforPostponementofOralHearingasfiled.pdf	5313 8ec191164bef30908dd820331a277239ecf60e31	no	2

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appeal No: 2012-005,156

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: NGO, LIEN M

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

REQUEST FOR POSTPONEMENT OF ORAL HEARING

Patent and Trial and Appeal Board
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

Appellant requests a resetting of the date of the Oral Hearing in the above-identified application before the Patent Trial and Appeal Board ("Board").

Appellant received the Notice of Hearing dated March 12, 2014, which set a May 8, 2014 date for the Oral Hearing on Appeal before the Board. The undersigned attorney, who has been handling the prosecution of the application, has a prior commitment overseas the week of May 5-12 of 2014. The only other attorney familiar with the application will be unavailable due to his spouse undergoing medical surgery that same week.

In view of the forgoing, we respectfully request that the May 8, 2014 date be rescheduled. Appellant suggests the week of May 19, 2014, or any week thereafter, which is convenient for the Board.

REQUEST FOR POSTPONEMENT OF ORAL HEARING
Appl. No.: 10/556,432

Attorney Docket No.: Q91404

Respectfully submitted,

SUGHRUE MION, PLLC
Telephone: 202.293.7060
Facsimile: 202.293.7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: March 14, 2014

/Ellen R. Smith/

Ellen R. Smith

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MAR 14 2014

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Date March 14, 2014

To: USPTO Patent Trial and Appeal Board

Fax 1-571-273-8300

From: Ellen R. Smith Reg. No. 43,042

Subject Request for Postponement of Oral Hearing

Our Ref Q91404 Appl. No. 10/556,432

Conf. No. 3524 Appeal No. 2012-005,156

Pages 3 (including cover sheet)

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524

23373	7590	03/21/2014
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037		

EXAMINER	
NGO, LIEN M	

ART UNIT	PAPER NUMBER
3754	

NOTIFICATION DATE	DELIVERY MODE
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FABIEN POULARD

Appeal 2012-005156
Application 10/556,432
Technology Center 3700

Before QUITA S. GOULD, *Deputy Clerk*, *Hearing Operations*.

ORDER GRANTING REQUEST TO RESCHEDULE ORAL HEARINGS

An oral hearing before a merits panel of the Patent Trial and Appeal Board had been set for Tuesday, May 8, 2014. The notice setting the hearing was mailed to Appellant on March 12, 2014. On March 14, 2014, Appellant filed a response requesting that the oral hearing be rescheduled. The stated reason for the request is due to a prior commitment overseas the week of May 5-12. The other attorney familiar with the case will also be unavailable due to a family commitment.

Appeal 2012-005156
Application 10/556,432

For the reason given above, it is:

Ordered that the request to reschedule the oral hearing is **GRANTED**.
The oral argument will be rescheduled to a date that will be determined later.
No further requests for postponement will be permitted. Any further
requests for postponement will be treated as a waiver of the Request for Oral
Hearing.

QSG

Ellen R. Smith
SUGHRUE MION, PLLC
2100 Pennsylvania Avenue, N.W.
Suite 800
Washington, DC 20037



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 04/10/2014 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER NGO, LIEN M	
			ART UNIT	PAPER NUMBER
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PATENT TRIAL AND APPEAL BOARD**



SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

Appeal No: 2012-005,156
Appellant: Fabien Poulard
Application No: 10/556,432
Hearing Room: D
Hearing Docket: B
Hearing Date: Thursday, June 19, 2014
Hearing Time: 09:00 AM
Location: Madison Building - East Wing
600 Dulany Street, 9th Floor
Alexandria, Virginia 22313-1450

**NOTICE OF HEARING
CONFIRMATION REQUIRED WITHIN TWENTY-ONE DAYS**

Your attention is directed to 37 CFR § 41.47. The above identified appeal will be heard by the Patent Trial and Appeal Board on the date indicated. Hearings will commence at the time set and as soon as the argument in one appeal is concluded, the succeeding appeal will be taken up. The time allowed for argument is twenty minutes unless additional time is requested and permitted before the argument is commenced. If there are any inquiries, please contact the Clerk of the Board at 571-272-9797.

The application involved in this appeal has been published. Accordingly, the hearing in this appeal is open to the public.

CONFIRMATION OR WAIVER OF THE HEARING IS REQUIRED. This form must be completed below and facsimile transmitted to both: (1) the USPTO Central fax number (official copy), and (2) the Patent Trial and Appeal Board fax number (courtesy copy) within TWENTY-ONE (21) DAYS from the mailing date of this notice indicating confirmation or waiver of the hearing. A copy of this notice may be alternately filed by mail if facsimile is not available.

PTAB HEARINGS FAX No: (571) 273-9797

USPTO Central Fax No: (571) 273-8300

PTAB Mailing Address: Patent Trial and Appeal Board
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Alexandria, Virginia 22313-1450

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Signature of Attorney/Agent/Appellant

Date

Registration No.

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APR 17 2014

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PATENT TRIAL AND APPEAL BOARD



SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

Appeal No: 2012-005,156
Appellant: Fabien Poulard
Application No: 10/556,432
Hearing Room: D
Hearing Docket: B
Hearing Date: Thursday, June 19, 2014
Hearing Time: 09:00 AM
Location: Madison Building - East Wing
600 Dulany Street, 9th Floor
Alexandria, Virginia 22313-1450

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 Signature of Attorney/Agent/Appellant: [Signature] Date: 4-17-14 Registration No. 43042

Names of other visitors expected to accompany counsel: _____

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Date April 17, 2014

To: USPTO

Fax 571-273-8300

From: Ellen R. Smith Reg. No.: 43,042

Subject Notice of Hearing Attendance Confirmation

Our Ref Q91404 Appl. No. 10/556,432

Conf. No. 3524 Appeal No. 2012-005,156

Pages 2 (including cover sheet)

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appeal No: 2012-005,156

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: NGO, LIEN M

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

REQUEST FOR ELMO PROJECTOR AT ORAL HEARING

Patent and Trial and Appeal Board
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

Appellant requests an **Elmo Projector** be provided in the hearing room for the oral hearing scheduled on **June 19, 2014 at 9:00 AM in Hearing Room D, Hearing Docket B**. Appellant will use the projector for the drawings of record (from the Appeal Brief, original Application and Declaration). The use of the projector is intended to facilitate the discussion during the oral hearing.

Respectfully submitted,

SUGHRUE MION, PLLC
Telephone: 202.293.7060
Facsimile: 202.293.7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: June 18, 2014

/Ellen R. Smith/

Ellen R. Smith

Registration No. 43,042

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Date June 18, 2014

To USPTO

Fax 571-273-8300

From Ellen R. Smith Reg. No. 43,042

Subject Request for Elmo Projector at Oral Hearing

Our Ref Q91404 Appl. No. 10/556,432

Conf. No. 3524 Appeal No. 2012-005,156

Pages 2
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 07/02/2014 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER	
			NGO, LIEN M	
			ART UNIT	PAPER NUMBER
			3754	
			NOTIFICATION DATE	DELIVERY MODE
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FABIEN POULARD

Appeal 2012-005156
Application 10/556,432¹
Technology Center 3700

Before EDWARD A. BROWN, MICHAEL L. HOELTER, and
ANNETTE R. REIMERS, *Administrative Patent Judges*.

BROWN, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant appeals under 35 U.S.C. § 134 from the Examiner's decision rejecting claims 1–23. Appeal Br. 4. Appellant's representative presented oral argument on June 19, 2014. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

¹ According to Appellant, the real party in interest is VALOIS SAS. Appeal Br. 2.

Claimed Subject Matter

Claims 1, 22, and 23 are independent. Claim 1, reproduced below, is illustrative of the claimed subject.

1. A fluid dispenser comprising:
a stationary body (1) including at least one stationary gear (110, 122),
a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body,
a dispenser member mounted on said reservoir (2), and
a dose indicator device, including a counter element (20) that is displaceable axially and in rotation relative to said body (1), for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a pretermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.²

REJECTIONS

I. Claims 1–23 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.³

II. Claims 1–23 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, and also as being indefinite.

III. Claims 1–23 are rejected under 35 U.S.C. § 102(b) as anticipated by Bason (EP 0949584 A2, published Oct. 13, 1999).

² In claim 1, it appears that “pretermined” should be “predetermined.”

³ We analyze rejections I and II below in the same order that both the Examiner and Appellant address them.

IV. Claims 1 and 23 are rejected under 35 U.S.C. § 102(b) as anticipated by Rand (EP 0254391 A1, published Jan. 27, 1988).

ANALYSIS

Rejection I

The Examiner found that the claims recite the elements and their functions in relation to one another, but not the “actual” structures and connections between the elements. Ans. 5. According to the Examiner, the Specification does not adequately disclose the actual structures of a body, reservoir, dispenser member, indicator device, at least one stationary gear, and counter element (claims 1 and 22), and first safety means and second safety means (claim 22) (claim 23 recites a stationary body, at least one stationary gear, dose indicator, and counter element), and the structural connections between these elements, so as to enable one skilled in the art to make and/or use the system recited in claims 1, 22, and 23, “so that the counter element is displaceable axially and in rotation relative to the body, the body gear is stationary, the reservoir is axially displaced relative to the body even if the dispenser does not perform a complete actuator stroke and the counter element co-operating, while the dispenser is being actuated, firstly with the at least one stationary gear and secondly with the reservoir.” Ans. 5-6.

In contrast, Appellant contends the Examiner did not consider the *Wands* factors. Appeal Br. 14. Appellant also contends the Specification discloses that the invention applies to Metered Dose Inhaler devices (Appeal Br. 15; *see* Spec. 8, ll. 25–34) and the drawings are simplified (Appeal Br. 16; *see* Spec. 8, ll. 13–24), and one skilled in the art would understand the

structure and connection of a body, reservoir, actuator, counter, and dispenser member and specific connections need not be disclosed (Appeal Br. 16).

“Although not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1989)(citations omitted). The *Wands* factors are factors for accessing whether a disclosure is sufficient to enable one of ordinary skill in the art to practice a claimed invention without having to engage in “undue experimentation” *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

We agree with Appellant that the Examiner did not articulate adequate reasoning why the claimed subject matter is not described in the Specification in such a way to enable one of ordinary skill in the art to make and use the invention. *See In re Wright*, 999 F.2d at 1561–62 (“the case law makes clear that properly reasoned and supported statements explaining any failure to comply with section 112 are a requirement to support a rejection”). Firstly, the Examiner did not mention or appear to apply the *Wands* factors in the enablement analysis. Secondly, Appellant explains that the structural components and the operation of the embodiment of the fluid dispenser depicted in Figures 1–8 are disclosed at page 8, line 35 to page 14, line 19 of the Specification. *See* Appeal Br. 19–29. This disclosure describes and depicts the operation of the fluid dispenser from a rest position (Fig. 1) to an actuated position (Fig. 4), where this operation includes the counting of a dose with “a predetermined incomplete actuation stroke of the dispenser.” *See* Spec. p. 10, l. 18 – p. 12, l. 28; Figs. 1–4. In light of this disclosure, the

Examiner does not provide adequate reasoning to establish that one of ordinary skill in the art would have been unable to make and use the fluid dispenser recited in claim 1 without undue experimentation, absent additional disclosure as to the “actual structures, shapes and connections of and between the elements of the invention.” Ans. 9.

We also find the Examiner’s non-enablement position to be unsupported in regard to claim 2, which depends from claim 1. *See* Ans. 10. Appellant explains that the subject matter recited in claim 2 is supported by the disclosure at page 13, line 17 – page 14, line 17, and Figure 6 of the Specification. Appeal Br. 34–35.

The Examiner does not identify any specific subject matter in claims 3–9 (Ans. 6) and 21, which depend from claim 1.

The Examiner’s position regarding claims 10–14 (Ans. 6) and 15–20 (Ans. 6–7) is similar to the position for claim 1. The Examiner also found that “[i]n figs. 9-12, the counter element 20 is attached to actuator 30 which is integral one piece with a reservoir 2; therefore, it is impossible to counter element 20 co-operating the reservoir 2 [sic].” Ans. 6, 7.

In response, Appellant explains that, as shown in Figures 9–11, “[t]he downward movement of the actuator *causes the counter element 20 to also move downward* with respect to the stationary gears. Thus, the counter element cooperates with the reservoir. *See also FIGS. 1-8.*” Reply Br. 6. Appellant’s explanation is consistent with the depicted subject matter, and is persuasive.

The Examiner's position for claim 22 is the same as that for claim 1. Ans. 5–6, 9–10.⁴

Thus, the Examiner did not establish a prima facie case of non-enablement for claims 1–22, and so the burden did not shift to Appellant to show that one of ordinary skill in the art could have practiced the claimed invention without undue experimentation. *See In re Strahilevitz*, 668 F.2d 1229, 1232 (CCPA 1982). However, although the burden did not shift, Appellant submitted a Declaration regarding the state of the art and the level of ordinary skill in the art. We agree with Appellant that the Examiner did not adequately respond to this submission. Appeal Br. 17; Reply Br. 4–5; *see* Ans. 9–10.

Therefore, we do not sustain the rejection of claims 1–22 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

However, for the reasons discussed below for Rejection II, we do not reach the rejection of claim 23 under 35 U.S.C. § 112, first paragraph.

Rejection II

Claims 1-22

The Examiner found that claims 1–23 are incomplete for omitting essential structural cooperative relationships of elements, in that “the claims compris[e] many elements but do not include structures or shapes of

⁴ Claim 22 recites, *inter alia*, “second safety means for preventing the fluid from being expelled again until said dispenser has completed *the predetermined incomplete return stroke*.” Emphasis added. We note there is no antecedent basis for “the predetermined incomplete return stroke” in this limitation.

elements and structural connections between the elements, such omission amounting to a gap between the necessary structural connections.” Ans. 7.

The Examiner does not specify any particular omitted “essential structural cooperative relationships of elements,” and provides reasoning that is similar to the non-enablement position described above. Ans. 10–12.

Appellant’s contentions in response to this rejection are similar to those discussed above in regard to Rejection I. Appeal Br. 36–43.

We agree with Appellant in that the Examiner did not adequately identify any “gap between the necessary structural connections” of the recited elements for claims 1–22.

The Examiner also determined that claims 1–22 are indefinite because it is unclear what are required for the structures or shapes, and the structural connections, of the claimed elements. Ans. 7.

In contrast, Appellant contends that the Specification provides sufficient details regarding the claimed elements and their structural connections. Appeal Br. 43–44.

The Examiner’s response does not specify any particular deficiencies as to the structure, shapes, or connections of the elements. Ans. 12. The Examiner does not explain why one of ordinary skill in the art would not understand the meaning of the claims, when read in light of the Specification, without adding further claim limitations regarding “structures or shapes of elements and structural connections between the elements.” Thus, we do not sustain the rejection of claims 1–22 under 35 U.S.C. § 112, second paragraph.

Claim 23

We find that claim 23 is indefinite because it recites “said counter element is caused to be displaced axially and permitted to rotate relative to said body,” but there is no antecedent basis for “said counter element.” Consequently, it is unclear to us whether “said counter element” should instead be another element recited previously in claim 23. If not, then it appears that additional limitations pertaining to “said counter element” have been omitted in this claim, making it incomplete. Lack of antecedent basis is a sufficient basis for rejecting a claim as indefinite when one of ordinary skill in the art would not understand the bounds of the claim as a whole when read in light of the specification. *See Energizer Holdings, Inc. v. Int’l Trade Comm’n*, 435 F.3d 1366, 1370–71 (Fed. Cir. 2006). We find the scope and meaning of claim 23 to be unclear, and thus, we sustain the rejection of this claim under 35 U.S.C. § 112, second paragraph.

Rejection III

Claims 1 and 22 recite “a stationary body (1) including at least one stationary gear (110, 122).”

The Examiner found that Bason discloses a fluid dispenser comprising, *inter alia*, a stationary body A including at least one stationary gear 2. Ans. 8.

Appellant contends that Bason’s stationary body A does not include a stationary gear. Appeal Br. 45. We agree.

Figures 1–8, 9–12, and 13–21 of Appellant’s application all show stationary gear 110 as being part of stationary body 1. In other words, the depicted stationary body 1 and stationary gear 110 form a unitary structure. Stationary gear 110 is also stationary with respect to stationary body 1.

Consistent with the Specification and drawings, and with Appellant's contentions, we construe "a stationary body (1) including at least one stationary gear (110, 122)" as a stationary body including, as a unitary or monolithic part of the stationary body, at least one stationary gear. In contrast, Bason's teeth 2 are shown as being part of a second part 1, which is a separate part from the structure shown as corresponding to stationary body "A." See ¶ 14; Figs. 1–3. Thus, we agree with Appellant that Bason's stationary body "A" does not include teeth 2.

We also agree with Appellant that the Examiner did not provide sufficient evidence to show that Bason's device meets the limitation "so that the dose indicator device is actuated once the dispenser has performed a pretermined [sic] incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke," in claim 1. See Appeal Br. 46.

Thus, because the Examiner did not establish by a preponderance of the evidence that Bason discloses each and every limitation of claim 1 or 22, we do not sustain the anticipation rejection of these claims, or of claims 2–21, which depend from claim 1.

Because the scope of claim 23 is indefinite, the rejection of claim 23 as anticipated by Bason must fall, *pro forma*, as it is necessarily based on speculative assumptions as to the claim's scope. See *In re Steele*, 305 F.2d 859, 862–63 (CCPA 1962). Therefore, we reverse, *pro forma*, the rejection of claim 23 as anticipated by Bason.

Rejection IV

The Examiner found that Rand discloses a fluid dispenser comprising, *inter alia*, a stationary body 1 including at least one stationary gear 11. Ans. 8 (citing Figs. 1, 2).

Figures 1 and 2 of Rand show driving arm 11 disposed within housing 22. *See also* col. 4, ll. 28–31. “This housing 22 extends from the cap member 8 along the external surface of the tubular housing 1.” Col. 4, ll. 22–24; Figs. 1, 2.

Appellant contends that Rand’s stationary housing 1 does not have a stationary gear. Appeal Br. 51–52.

We agree with Appellant that driving arm 11 of Rand is not a stationary gear of tubular housing 1. That is, driving arm 11 is not a unitary or monolithic part of tubular housing 1. Accordingly, the Examiner’s finding that Rand discloses “a stationary body (1) including at least one stationary gear (110, 122),” as claimed, is not supported by a preponderance of the evidence.

We also agree with Appellant that the Examiner did not establish that Rand’s device meets the limitation reciting “so that the dose indicator device is actuated once the dispenser has performed a pretermined [sic] incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke,” in claim 1. *See* Appeal Br. 52–53.

Therefore, we do not sustain the anticipation rejection of claim 1 based on Rand.

For the same reasons discussed above for rejection III, we reverse, *pro forma*, the rejection of claim 23 as anticipated by Rand.

DECISION

We AFFIRM the rejection of claim 23, and REVERSE the rejections of claims 1–22.

Appeal 2012-005156
Application 10/556,432

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART

Klh



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 08/04/2014 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER NGO, LIEN M	
			ART UNIT 3754	PAPER NUMBER
			NOTIFICATION DATE 08/04/2014	DELIVERY MODE ELECTRONIC

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RECORD OF ORAL HEARING
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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FABIEN POULARD

Appeal 2012-005156
Application 10/556,432
Technology Center 3700

Oral Hearing Held: June 19, 2014

Before EDWARD A. BROWN, MICHAEL L. HOELTER, and
ANNETTE R. REIMERS, *Administrative Patent Judges*.

APPEARANCES:

ON BEHALF OF THE APPELLANT:

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The above-entitled matter came on for hearing on Thursday,
June 19, 2014, commencing at 9:02 a.m. at the U.S. Patent and
Trademark Office, 600 Dulany Street, Alexandria, Virginia.

P-R-O-C-E-E-D-I-N-G-S

9:02 a.m.

MS. BOBO-ALLEN: Good morning. Calendar No. 21,
Appeal No. 2012-5156, Ms. Smith.

JUDGE BROWN: Good morning.

MS. SMITH: Good morning. How are you?

JUDGE BROWN: Hi. I'm Judge Brown. I'm here with
Judge Reimers and this is Judge Hoelter on video.

MS. SMITH: Good morning.

JUDGE BROWN: You'll have 20 minutes for presentation, so
proceed when you're ready.

MS. SMITH: Good morning. My name is Ellen Smith and I
represent the Appellant.

In the interest of time I would like to focus on the numerous 112
issues that have been raised during prosecution. I'll provide you with a
detailed explanation of the claimed invention, if this is helpful to the
Board, after I will explain the state of the art and the nature of the
invention.

Fluid dispensers have been well known for decades. Fluid
dispensers are used to dispense a product to a user such as a metered

1 dose inhaler, otherwise known as MDIs, asthma inhalers, rescue
2 inhalers and the like. These types of devices are used every day by
3 millions of people. Many of these dispensers have counting
4 mechanisms which show the user how many doses are remaining in the
5 device. These counting mechanisms were introduced to these
6 dispensers years ago and are generally known in the art. This case is
7 not about fluid dispensers generally. This case is about the
8 improvements to the counting mechanism in the dispenser.

9 Appellant has noted in the background of the specification; if
10 you want, you can look at pages 1 and 2, that there are several problems
11 with these counting mechanisms and thus the claimed invention is
12 directed to an improvement for these known counting mechanisms.
13 The problem addressed by applicant specifically solves the problem of
14 under-counting of the counting mechanism. In particular, two
15 scenarios may result in under-counting which I will refer to in layman's
16 terms as the half dose and the double dose.

17 The half dose problem refers to a situation when the user begins
18 the actuation stroke but doesn't complete the stroke, so less than a full
19 dose may be dispensed. But more importantly, because the actuation
20 stroke is not complete, the counting device fails to record the dose

1 count, thus the half dose is not counted and this results in inaccurate
2 indication that there's more fluid remaining in the reservoir than
3 actually is there, which could be dangerous in an emergency situation.

4 The double dose problem refers to a situation when the user
5 completes the actuation stroke to administer a full dose, but then
6 immediately actuates a second dose without allowing the actuator to
7 revert back to its original position. Because the actuation stroke
8 doesn't start at the initial position or at a position high enough to
9 activate the counting mechanism, once again the second dose is not
10 counted resulting in under-counting.

11 To address the half dose problem, Appellant has improved the
12 counting device to allow a dose to be counted even if the actuation
13 stroke is not completed. And to address the double dose problem, the
14 Appellant has improved the counting device to prevent a double dose
15 unless the actuator has been allowed to revert back enough to allow the
16 counter to be activated before that second dose is administered. These
17 two safety features are achieved by the interaction of the beveled teeth
18 and projections on the counting element gear in conjunction with the
19 gears on the stationary body and the actuator.

1 All of the 112 rejections appear to be a result of the Examiner's
2 apparent lack of understanding how these dispensing devices operate.
3 The rejections have been provided almost in a vacuum without any
4 reference to what one of ordinary skill in the art would have already
5 known.

6 I want to turn to the first paragraph 112 rejection regarding
7 enablement. The test for enablement is whether any necessary
8 experimentation is undue. In our case the Examiner has not shown
9 that any experimentation is necessary, much less undue
10 experimentation. The Examiner has not met the burden required for
11 showing lack of enablement. The Examiner failed to review any of the
12 Wands factors which are used to determine whether undue
13 experimentation would be needed to make or use the invention.

14 So as the Board is aware, the Wands factors are used to
15 determine whether experimentation is undue. There are numerous
16 Wands factors. I would like to address a few of them. The nature of
17 the invention and the state of the art.

18 Both of these have already been discussed. This is a
19 mechanical technology. The technology is considered to be of the
20 predictable arts and there's no issue of skepticism here. The inventive

1 aspect focuses on the counting element. And as discussed in the
2 declaration, which was filed during prosecution, fluid dispensers are
3 well known and fluid dispensers having counting mechanisms are well
4 known. Again, the inventive concepts relate to the counting
5 mechanism.

6 Other factors for Wands are the level of ordinary skill in the art,
7 the amount of direction provided by the inventor and the quantity of
8 experimentation required to make or use the invention based on the
9 disclosure.

10 I'm going to give you step-by-step, play-by-play of the first
11 embodiment to show that actually the inventor has provided explicit
12 instruction for how this invention works by focusing on the features
13 which provide the safety features to avoid the under-counting of the
14 double dose and the half dose.

15 Once again, I'd like to mention that the Examiner has failed to
16 indicate that any quantity of experimentation is required, much less
17 undue experimentation. Her statements are merely conclusory and she
18 has provided no evidence to support her positions. As I have
19 mentioned, this is a mechanical device. The Examiner has failed to
20 raise any issues of skepticism or unpredictability or any other reason

1 why a person of ordinary skill would require to conduct undue
2 experimentation.

3 Applicant is not required to explain how these dispensing
4 devices generally operate because this knowledge is already known.
5 In fact, applicant's explanation need not and should not include features
6 which are well known in the art. MPEP Section 2164 states that it is
7 preferable to omit the features which are already well known. The
8 applicant purposely omitted the details of elements which are already
9 well known in order to simplify the explanation of the invention and
10 allow a person of ordinary skill in the art to focus on the improvement
11 to the counting element.

12 In other words, the drawings and written description are
13 provided from the point of view of a person who already knows how
14 these dispensing devices operate and is looking at the solution to the
15 problem associated with the counter indicator. The drawings were
16 intentionally provided to simplify the explanation of the interaction
17 between the projection and teeth on the gears since this interaction is
18 the mechanical configuration which provides the safety features of
19 applicant's device; that is, to prevent miscounting the half dose and the
20 double dose.

1 I now want to take a few moments using the Elmo projector to
2 explain generally how the three embodiments look, and then I'll take
3 you through everything step-by-step.

4 Okay. So this is one of the figures from the first embodiment.
5 I've color coded it so it would be easy to visualize. You have your
6 fixed body with the stationary gear, 110. You have your axially
7 movable components, which here are the reservoir in your actuator.
8 And then you have your counter element, 20. That is what is axially
9 and rotationally displaceable.

10 JUDGE BROWN: How does that rotate?

11 MS. SMITH: It rotates by the movement of the actuator here,
12 300, when it presses on the bevel. That diagonal oblique surface will
13 cause it to rotate, which I'll explain in a second. It can't rotate until the
14 bottom gear, 210, gets dislodged from that stationary gear. So what
15 you're going to have is an axial movement first and then rotational
16 movement.

17 JUDGE BROWN: And translation?

18 MS. SMITH: Yes. Okay. So here is the second
19 embodiment. Again I've color coded similar parts the same way. The
20 blue is referring to your stationary fixed member with your stationary

1 gear, 110. You have your moveable reservoir which a user would
2 press. And here actually we don't have a separate actuator member,
3 because sometimes in your asthma inhalers your reservoir is sticking up
4 from the casing and you can just press directly on that reservoir. And
5 then again we have our counter element, 20, which is also the same way
6 as the first embodiment. You can move up and down or it can rotate.
7 And the third embodiment, again similar. Referring to these three
8 elements, you have your stationary body, 1, you have your counter
9 element, 20. Again, it's rotatable and it moves up and down. And
10 then you have your reservoir that moves up and down.

11 And as a matter of fact --

12 JUDGE BROWN: Excuse me. In the first embodiment is
13 that gear 110 actually part of the body?

14 MS. SMITH: Yes, it is.

15 JUDGE BROWN: It's unitary?

16 MS. SMITH: Yes.

17 JUDGE BROWN: Okay.

18 MS. SMITH: Here I have the CAD drawing. These were
19 submitted with the declaration during prosecution. And this is going
20 to correspond to this third embodiment. You can see both here.

1 Okay. So you can see how a person with skill in the art would
2 have visualized the gears, the rotating element and the reservoir. Here
3 what we have is the green -- which associates with the green. You
4 would show -- when we're showing -- just trying to show how the teeth,
5 the beveled features and the projections are engaging with each other.

6 So in our drawings we've pulled out a couple of teeth and the
7 gears, as you can see. Purple matches with the blue; I didn't have a
8 purple highlighter, and the red matches with the pink. And the green
9 matches with your counting mechanism. And here you can see here
10 matches here. Actuator is here. This moves down. It causes this to
11 rotate and move down and ultimately causes this to dislodge from your
12 stationary gear, which is attached to your stationary body. You're
13 going to have obviously a rotational axis in the middle. And these are
14 your projections.

15 When we talk about the means to prevent the under-counting
16 during a double dose, this is when you're going to have this planar
17 portion and this planar portion abut next to each other, and that's what
18 prevents your double dose from happening until your counting
19 mechanism has moved enough to -- and the actuator has moved back up
20 to actually get a count, so you could count that second double dose. So

1 the user won't be able to do a double dose until the actuator stroke is at
2 least partially moved up so that it can make that counter count.

3 So this, I think a person of ordinary skill in the art would take
4 these drawings, take the specification description, and they can use it in
5 a variety of fluid dispensers. The important parts that we're focusing
6 on right now are the manner in which that counting mechanism is
7 displaced axially, rotated a bit, a dose is counted, the actuation is
8 finished, a person -- and then so that's your count before you get your
9 full actuation stroke. So even if you stop and you never complete it,
10 they counted it. And then that second part is when you have your
11 abutment means there that are going to push together and prevent the
12 double dose from happening unless there's an opportunity to count that
13 second dose.

14 Now I wanted to take a minute to discuss this step-by-step
15 explanation. This is in the specification and it is outlined in the brief,
16 but I'll go through it as quickly as I can.

17 So this is the figure 1, the first embodiment. It's starting from a
18 rest position. Actuation would begin by pressing the actuator, 30, in
19 the axial direction, which is downward in Figure 1. The oblique
20 portion of the tooth of the actuator gear, 300, contacts the oblique

1 portion of the first tooth, which is purple, of that second gear, 230,
2 which urges the counter element, 20, downward and applies a force on
3 the counter element, 20, to the left. However, while the oblique
4 portion of actuator gear, 300, and that first tooth colored purple of the
5 second gear apply force to the left on the counter element, the end wall,
6 which is colored blue, of the stationary gear prevents the counter
7 element from rotating to the left and only allows the counter element,
8 20, to be displaced downward in the axial direction.

9 Here in Figure 2 the counter element is displaced downward by
10 the actuator, 30, until the first gear, 210, of the counter element, 20,
11 passes the end wall, which is shown in blue, of the stationary gear in the
12 axial direction. As the counter element, 20, gets displaced downward,
13 the bottom of the counter element, 20, contacts the reservoir and
14 displaces the reservoir, 2, downward, thereby actuating the dispenser.

15 In Figure 3 the counter element, 20, is then urged to rotate to the
16 left by the engagement of the oblique portions of the tooth of the
17 actuator gear, 300, and the first tooth, which is purple, of the second
18 gear, 230. This initiates the counting of one dose of fluid. Thus the
19 counter element, 20, rotates before the complete actuation of the
20 dispenser member, thereby ensuring that a count is registered if there's

1 any possibility that any fluid has been dispensed. The first gear, 210,
2 of the counter element rotates until it contacts the abutment means, 115.
3 That's the tip of the red section that extends past the end wall of the
4 blue. It causes the vertical displacement of the counter element again.

5 So here there's like a jagged point which is on these and that
6 causes that additional vertical displacement. Once the first gear, 210,
7 of the counter element is displaced past the abutment means, 115 in red,
8 the axial direction, the engagement of the oblique portions of the
9 actuator gear, 300, and the first tooth, shown in purple, of the second
10 gear, 230, rotate the counter element, 20, until the actuator gear, 300,
11 meshes with the first abutment, 235, which is shown in orange. So
12 you have a jagged gear tip on this one. This prevents the counter
13 element, 20, from rotating.

14 When the actuator, 30, is released by the user, a spring
15 displaces the reservoir, 2, axially upwards towards the rest position.
16 The displacement of the reservoir, 2, causes the counter to be displaced
17 axially upward until the oblique portion of the first gear, 210, engages
18 the oblique portion of the second tooth, shown in red, of the stationary
19 gear, 110. At this point the abutment, 235, which is the little jagged
20 piece there, prevents rotation of the counter element, 20, and the

1 engagement of the first gear, 210, and the stationary gear, 110, prevent
2 axial displacement of the counter element.

3 The actuator, 30, moves axially relative to the counter element,
4 20, when the actuator, 30, is further released and the actuator gear, 300,
5 passes over the abutment, 235, which is shown in orange. At this point
6 the chamber of the dispenser could be filled.

7 The engagement of the oblique portion of the first gear, 210,
8 with the oblique portion of the second tooth of the stationary gear
9 causes the counter element, 20, to rotate until the actuator gear, 300,
10 contacts an end wall of the second tooth, which is shown in green, of
11 the second gear, 230.

12 If one were to attempt to actuate the dispenser at this point
13 before completing the return stroke, the axial projections, 120, of the
14 counter element, 20, would engage the axial projections, 220, of the
15 body. This prevents actuation of the dispenser member.

16 With the end wall of the second tooth, shown in green, of the
17 second gear, 230, preventing rotation of the counter element, 20, and
18 with the first gear, 210, and the second tooth in red of the stationary
19 gear, 110, preventing axial displacement of the counter element, the
20 actuator, 30, will move in the axial direction relative to the end wall of

1 the second tooth, shown in green, of the second gear, 230, when the
2 actuator, 30, is further released and the actuator gear, 300, will pass
3 over the end wall of the second tooth in green of the second gear, 230.

4 In the position shown in Figure 6, a new action of the dispenser
5 is not possible because of the insufficient return stroke. Figure 7,
6 however, shows the position before the completion of a return stroke
7 where it is possible to have a new actuation of the dispenser despite the
8 uncompleted return stroke.

9 The new actuation is possible because the gear, 300, has passed
10 over the end wall of the second tooth shown in green of the second gear,
11 230. Thus, the engagement of the first gear, 210, with the second
12 tooth, red, of the stationary gear, 110, further rotates the counter
13 element, 20, and a new actuation stroke would make the actuator gear,
14 300, cooperate with that oblique portion of that green second tooth of
15 the second gear, 230.

16 Once the actuator gear, 300, passes over the end wall of that
17 second tooth shown in green of the second gear, 230, the oblique
18 portions of the first gear, 210, and the oblique portions of the second
19 tooth, shown in red, of the stationary gear, 110, cause the element to
20 complete the rotation cycle.

1 So if you were to look at the figures more quickly, you can see
2 this 20 is rotating. Starts out here. And as it's rotating it is moved
3 from here. It's moving around, continuing over the tooth until it's back
4 in two, the crevice there. Same with the top, because as the bottom is
5 moving, so is the top. So it's all rotating together. So if you sort of
6 look at them in succession, you could see the rotational movement from
7 the purple to the green due to the rotating of the element, 20.

8 Briefly I wanted to talk about the 112 second paragraph
9 rejection for the alleged omission of a central elements. The Examiner
10 provided two general reasons. She said that the recited elements do
11 not have structures and shapes and there are no structural connections
12 between the elements.

13 The structure and shape of these types of elements is known.
14 The declaration provided evidence that showed that these actuators,
15 reservoirs, etcetera, are already known. It's well established that
16 applicants can illustrate features using a black box to represent an
17 element.

18 In this case applicant has exaggerated the size of the gear teeth
19 on the rotating counting element, 20, and the stationary gear, 110.
20 Each tooth is shown enlarged. The figure illustrates the 3D rotation in

1 two dimensions. It's clear that the gear rotates to the left as I just
2 explained with the movement of the mechanism, 20. In fact, one of
3 the references which the Examiner used in the prior art rejection uses
4 the same type of schematic to illustrate teeth on a gear. That was the
5 Bason reference. They used the same type of schematic. It's Figure
6 5.

7 And referring to whether or not the structural connections
8 between the elements, it's established that structural connections do not
9 have to include interdependency between the elements, only a
10 reasonable degree of specificity. As discussed in MPEP Section 2712,
11 it's okay if the various elements do not directly inter-cooperate. The
12 applicant here has clearly provided enough for a person of ordinary
13 skill in the art to exploit this novel technology. One can use various
14 types of fluid dispensers to connect the elements as shown in the
15 different examples of the three embodiments. The essential novelty,
16 the essence of the invention is described in explicit detail. The prior
17 art setting is mentioned in general detail. This is sufficient for 112
18 purposes.

19 I don't know how much time I have left or if you have any
20 questions.

1 JUDGE BROWN: Your time is about over.

2 MS. SMITH: Yes, okay.

3 JUDGE HOELTER: If I may interrupt briefly?

4 MS. SMITH: Sure.

5 JUDGE HOELTER: If I could direct your attention to claim
6 23, the last two lines, starting with "said counter element is caused to be
7 displaced axially."

8 MS. SMITH: Yes.

9 JUDGE HOELTER: Could I ask you to address that recitation
10 of said counter element in that claim?

11 JUDGE BROWN: He means that there's no recitation.

12 JUDGE REIMERS: There's no --

13 JUDGE BROWN: Prior to that line.

14 JUDGE REIMERS: Right. It doesn't appear to have any
15 antecedent basis for the counter element.

16 MS. SMITH: Yes, I agree with you. I didn't notice that. In
17 the other claims we talk about the counter element being a part of the
18 dose indicator. This is all part of the counting mechanism. But
19 you're right, this claim has some antecedence problems.

20 JUDGE HOELTER: Again, I was just wanting to --

1 MS. SMITH: Yes.

2 JUDGE HOELTER: -- see if there's something maybe --

3 MS. SMITH: We could --

4 JUDGE HOELTER: -- I was overlooking.

5 MS. SMITH: No, I mean, it probably should say that it is the
6 dose indicator rather than the counter element. It's just using different
7 language to describe that counting mechanism.

8 JUDGE HOELTER: Okay. Thank you.

9 MS. SMITH: Sure.

10 JUDGE BROWN: Okay. Any questions?

11 JUDGE REIMERS: No.

12 JUDGE HOELTER: Okay. We're done. Thank you very
13 much.

14 MS. SMITH: Thank you.

15 (Whereupon, the above-entitled matter went off the record at
16 9:28 a.m.)

17

18

19

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 09/08/2014 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER	
			NGO, LIEN M	
			ART UNIT	PAPER NUMBER
			3754	
			NOTIFICATION DATE	DELIVERY MODE
			09/08/2014	ELECTRONIC

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<i>Applicant-Initiated Interview Summary</i>	Application No.	Applicant(s)	
	10/556,432	POULARD, FABIEN	
	Examiner	Art Unit	
	LIEN NGO	3754	

All participants (applicant, applicant's representative, PTO personnel):

(1) LIEN NGO. (3) _____.

(2) ELLEN R. SMITH (Attorney). (4) _____.

Date of Interview: 28 August 2014.

Type: ☒ Telephonic ☐ Video Conference
 ☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☐ No.
 If Yes, brief description: _____.

Issues Discussed ☐ 101 ☒ 112 ☒ 102 ☐ 103 ☒ Others
 (For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: 1-23.

Identification of prior art discussed: Rand (EP-0254391).

Substance of Interview
 (For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

A discussion of a proposed amendment sent on 8/26/14 was made. As a Patent Board Decision dated 7/02/2014, Examiner agreed that claims 1-9, 21 and 22 are allowed. However, examiner maintained the 112, 1st paragraph, rejection of claims 10-20, 112, and the 2nd paragraph, Rejection of claim 23; and the 102 Rejection of claim 23 by Rand (EP-0254391).

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/LIEN NGO/ Primary Examiner, Art Unit 3754	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Art Unit: 3754

ATTACHMENT

2100 Pennsylvania Avenue, NW
Washington, DC 20037-3213
T 202.293.7060
F 202.293.7860
www.sughrue.com

EMAIL

Date August 26, 2014

To Examiner Lien M. Ngo

Of U.S. Patent and Trademark Office Art Unit: 3754

Email lien.ngo@uspto.gov

From Ellen R. Smith Reg. No. 43,042

Subject Interview Agenda

Our Ref Q91404 Appln. No. 10/556,432

Pages 11 (including cover sheet)

Please call attention to problems with this transmission by return fax or telephone. Thank you.

THE INFORMATION CONTAINED IN THIS COMMUNICATION IS CONFIDENTIAL, MAY BE ATTORNEY-CLIENT PRIVILEGED, AND IS

INTENDED ONLY FOR THE USE OF THE ADDRESSEE. UNAUTHORIZED USE, DISCLOSURE OR COPYING IS STRICTLY PROHIBITED AND MAY BE UNLAWFUL. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE IMMEDIATELY NOTIFY US.

Please review the Interview Agenda for the telephone interview scheduled for **August 28, 2014 at 2:00**

PM for the above-identified application.

I look forward to speaking with you.

Respectfully submitted,

Ellen R. Smith

FOR DISCUSSION ONLY

U.S. Application No. 10/556,432

ISSUES FOR DISCUSSION ONLY; NOT TO BE ENTERED

☐ Status of the application.

☐ Minor proposed amendments to claims 1 and 23 to remove any ambiguities, as attached.

o Claim 1: replace "pretermind" with --predetermined--, to correct typographical error.

o Claim 23: replace "counter element" with --dose indicator--, to correct typographical error (since "counter element" should instead be "dose indicator" recited previously in claim 23).

FOR DISCUSSION ONLY

U.S. Application No. 10/556,432

CLAIMS FOR DISCUSSION ONLY; NOT TO BE ENTERED

1. (PROPOSED): A fluid dispenser comprising:

a stationary body (1) including at least one stationary gear (110, 122),

a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body,

a dispenser member mounted on said reservoir (2), and

a dose indicator device, including a counter element (20) that is displaceable axially and

in rotation relative to said body (1), for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir,

wherein said counter element (20) cooperates, while the dispenser is being actuated,

firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a

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[pretermine] predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.

2. (previously presented): A dispenser according to claim 1, wherein, during the return stroke of the dispenser after dispensing a dose, said dose indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke,

said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

3. (previously presented): A dispenser according to claim 1, in which said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20), said counter element (20) including a second gear (230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser, the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation, the stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

4. (original): A dispenser according to claim 3, in which the stationary gear (110) includes abutment means (115) preventing said counter element (20) from turning once said counter element (20) has turned at least in part, an additional axial displacement of said counter element (20) being necessary to enable it to continue to turn and/or to return the indicator device to its rest position.

5. (original): A dispenser according to claim 4, in which said abutment means (115) comprise an axial projection.

6. (previously presented): A dispenser according to claim 1, in which said stationary gear (110) and/or said counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position after a preceding actuation, and until the dispenser has completed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

7. (previously presented): A dispenser according to claim 6, in which said blocking means comprise axial projections (120, 220) provided on the body (1) and on the counter element (20) respectively, each of said projections (120, 220) having an axial end-profile that is planar, said projections (120, 220) facing each other, at least in part, until the counter element has turned sufficiently to offset said projections (120, 220), with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

8. (previously presented): A dispenser according to claim 3, in which the teeth of the second gear (230) of the counter element (20) include an intermediate step (235), the actuator member (30) co-operating with said step (235) while the dispenser is being actuated, and cooperating with the end wall of said second gear (230) while returning to the rest position, after being actuated, the displacement between the intermediate step (235) and the end wall being obtained by said counter element (20) turning.

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9. (previously presented): A dispenser according to claim 3, in which, once the predetermined incomplete return stroke has been performed, the actuator member (30) is positioned facing the following tooth of the second gear (230) of the counter element (20), enabling the dispenser and the dose indicator device to be actuated once again.

10. (previously presented): A dispenser according to claim 1, in which said body (1) includes a first stationary gear (110) and a second stationary gear (122), said counter element (20) including a first gear (210) for co-operating with said first stationary gear (110) and a second gear (222) for co-operating with said second stationary gear (122), said counter element (20) being put axially into contact with an actuator member (30) of the dispenser by means of a return spring (50) and being turnable relative to said actuator member (30), the teeth of said second gear (222) and of said second stationary gear (122) being oblique, at least in part, so that an axial displacement of the actuator member (30) initially causes said counter element (20) to be displaced axially over a predetermined incomplete actuation stroke until the oblique portion (221) of said second gear (222) of the counter element (20) co-operates with said oblique portion (121) of said second stationary gear (122), causing the counter element (20) to be turned over a first portion of a turn cycle, the teeth of said first gear (210) and of said first stationary gear (110) being oblique, at least in part, so that when the counter element (20) returns to its rest position, it is caused to turn so as to terminate its turn cycle, which corresponds to one actuation of the dispenser being counted.

11. (previously presented): A dispenser according to claim 10, in which said first and second stationary gears (110, 122) of the body (1) and/or said first and second gears (210, 222) of the counter element (20) are offset relative to each other, so that whenever the counter element (20) is displaceable in rotation, returning said counter element to its rest position without terminating the actuation stroke of the dispenser causes the counter element (20) to turn over its complete turn cycle, guaranteeing that one actuation of the dispenser is counted after said predetermined incomplete actuation stroke.

12. (previously presented): A dispenser according to claim 10, in which said second stationary gear (122) of the body (1) and/or said second gear (222) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, and until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

13. (previously presented): A dispenser according to claim 12, in which said blocking means have an axial end-profile that is planar, at least in part, and that is formed on the teeth of said second stationary gear (122) of the body (1) and on the teeth of said second gear (222) of the counter element (20), said planar profiles of said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

14. (previously presented): A dispenser according to claim 10, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

15. (previously presented): A dispenser according to claim 1, in which said body (1)

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includes a first stationary gear (110) and a second stationary gear (122), said counter element (20) comprising a first gear (210) for co-operating with said first stationary gear (110), a second gear (222) for co-operating with said second stationary gear (122), and a third gear (230) for cooperating

with an actuator gear (300) secured to an actuator member (30) of the dispenser, the teeth of said third gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member (30) causes said counter element (20) to be displaced axially and in rotation, the first stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

16. (previously presented): A dispenser according to claim 15, in which said second stationary gear (122) of the body (1) and/or said second gear (222) of the counter element (20) include(s) blocking means preventing the dispenser from being actuated once again, and thus preventing any pharmaceutical from being expelled once again, while the counter element (20) is returning to its rest position following a preceding actuation, until said dispenser has performed a predetermined incomplete return stroke, after which the indicator device can count the next dose.

17. (previously presented): A dispenser according to claim 16, in which said blocking means have an axial end-profile that is planar and that is formed on the teeth of said second stationary gear (122) and on the teeth of said second gear (222), said teeth facing each other, at least in part, until the counter element (20) has completed a turn that is sufficient to offset said teeth, with that sufficient turn corresponding to said predetermined incomplete return stroke of the dispenser.

18. (previously presented): A dispenser according to claim 16, in which said actuator gear (300) includes abutment means (305) limiting the extent to which the counter element (20) can turn, until the actuator member (30) has performed said predetermined incomplete return stroke.

19. (original): A dispenser according to claim 18, in which said abutment means (305) comprise an axial projection formed on said actuator gear (300).

20. (previously presented): A dispenser according to claim 15, in which said actuator member (30) of the dispenser is secured to said reservoir (2) and is displaced axially therewith.

21. (previously presented): A dispenser according to claim 1, wherein the dispenser member is a pump or a valve.

22. (previously presented): A fluid dispenser comprising:

a stationary body (1) including at least one stationary gear (110, 122);

a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body; a dispenser member mounted on said reservoir (2), being actuated when said reservoir is axially displaced relative to the stationary body by a predetermined amount, for dispensing a dose of fluid from said reservoir;

a dose indicator device for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir, said dose indicator device including a counter element (20) that is displaceable axially and in rotation relative to said body (1), wherein when the dispenser member is actuated, said counter element cooperates firstly with said at least one stationary gear (110, 122) and secondly with said reservoir (2);

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first safety means for actuating the dose indicator device once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke; and

second safety means for preventing the fluid from being expelled again until said dispenser has completed the predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

23. (PROPOSED): A fluid dispenser comprising:

a stationary body including at least one stationary gear;

an actuator member that is displaceable axially with respect to said stationary body;

a dose indicator that is displaceable axially and in rotation relative to said body, said dose indicator being engageable with said actuator member and said stationary body, wherein when said actuator member displaces axially, said [counter element] dose indicator is caused to be displaced axially and permitted to rotate relative to said body.



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

23373 7590 09/10/2014
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

NGO, LIEN M

ART UNIT

PAPER NUMBER

3754

DATE MAILED: 09/10/2014

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524

TITLE OF INVENTION: FLUID PRODUCT DISPENSER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	12/10/2014

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

23373 7590 09/10/2014
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524

TITLE OF INVENTION: FLUID PRODUCT DISPENSER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	UNDISCOUNTED	\$960	\$0	\$0	\$960	12/10/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
NGO, LIEN M	3754	222-036000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev. 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
- ☐ Applicant asserting small entity status. See 37 CFR 1.27
- ☐ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien Poulard	Q91404	3524
23373 7590 09/10/2014 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER NGO, LIEN M	
			ART UNIT	PAPER NUMBER
			3754	

DATE MAILED: 09/10/2014

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 10/556,432	Applicant(s) POULARD, FABIEN	
	Examiner LIEN NGO	Art Unit 3754	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Patent Board Decision dated 7/2/14.
☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are 1-22. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
Certified copies:
a) ☒ All b) ☐ Some *c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
* Certified copies not received: _____.

Applicant has **THREE MONTHS FROM THE "MAILING DATE"** of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in **ABANDONMENT** of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ **CORRECTED DRAWINGS** (as "replacement sheets") must be submitted.
☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ **DEPOSIT OF and/or INFORMATION** about the deposit of **BIOLOGICAL MATERIAL** must be submitted. Note the attached Examiner's comment regarding **REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL**.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)	5. ☒ Examiner's Amendment/Comment
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____	6. ☐ Examiner's Statement of Reasons for Allowance
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	7. ☐ Other _____
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____	

/LIEN NGO/ Primary Examiner, Art Unit 3754	

1. The present application is being examined under the pre-AIA first to invent provisions.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with attorney Ellen Smith on 9/5/2014.

The application has been amended as follows:

Claim 23 has been canceled.

In claim 1, line 12, "pretermine" has been changed to – predetermined --.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LIEN NGO whose telephone number is (571)272-4545. The examiner can normally be reached on Monday through Friday from 8:30 AM -6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, KEVIN SHAVER can be reached on 571-272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LIEN NGO/
Primary Examiner, Art Unit 3754

September 5, 2014

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	916	G06M1/083.CPC.	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	OFF	2014/09/05 10:30
L2	46	("20030015191" "20030209239" "20040065326" "20040089292" "20040094147" "20040139964" "20040149773" "20040211420" "20040222237" "20070181120" "20070210102" "20070246042" "20080017192" "20080265198" "20090139516" "3178110" "3622053" "3994421" "4414972" "4563574" "4565302" "4841964" "5174473" "5522378" "5562219" "5565861" "5772080" "5808337" "5833088" "5871007" "5984122" "5988496" "6189739" "6234168" "6360739" "7322352" "7448342" "7464708" "7500444" "7543582" "7571726" "7587988" "7827984" "7828172" "7832351").PN. OR ("8689785").URPN.	US- PGPUB; USPAT; USOCR	ADJ	OFF	2014/09/05 10:33
L3	538	G06M3/12.CPC.	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	OFF	2014/09/05 10:54
L4	37	2 NOT 1	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	OFF	2014/09/05 10:54
L5	2427	A61M15/0068.CPC.	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	OFF	2014/09/05 10:57
L6	2232	5 NOT 1	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	OFF	2014/09/05 10:57
L7	137	dispens\$4 same (dos\$4 or met\$4) same gear same (indicat\$4 or count\$4) same (station\$4 or fix\$5)	US- PGPUB; USPAT;	ADJ	ON	2014/09/05 11:29

			FPRS; EPO; JPO; DERWENT			
L8	3	(dispens\$4 and station\$5 and reservoir and dose and counter and gear and actuat\$4 and stroke).clm.	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	ON	2014/09/05 11:36
L9	4573	128/200.14,200.23,205.23.ccls.	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	OFF	2014/09/05 11:39
L10	4384	9 not 5	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	OFF	2014/09/05 11:39
L11	4360	10 not 1	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	OFF	2014/09/05 11:39
L12	4357	11 not 3	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	OFF	2014/09/05 11:39
L13	207	12 and gear and (dos\$4 or met\$4) and (indicat\$4 or counter\$4)	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	OFF	2014/09/05 11:41
L14	205	13 not 7	US- PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	ADJ	OFF	2014/09/05 11:42

9/ 5/ 2014 12:22:53 PM

C:\Users\Ingo\Documents\EAST\Workspaces\10556432.wsp

Issue Classification 	Application/Control No. 10556432	Applicant(s)/Patent Under Reexamination POULARD, FABIEN	
	Examiner LIEN NGO	Art Unit 3754	

CPC						
Symbol					Type	Version
A61M		15		0065	F	2013-01-01
G06M		1		083	I	2013-01-01
G06M		3		12	I	2013-01-01
A61M		15		0068	I	2014-02-04

CPC Combination Sets						
Symbol			Type	Set	Ranking	Version

NONE		Total Claims Allowed:	
(Assistant Examiner)		22	
(Date)			
/LIEN NGO/ Primary Examiner.Art Unit 3754	9//5/14	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification 	Application/Control No. 10556432	Applicant(s)/Patent Under Reexamination POULARD, FABIEN
	Examiner LIEN NGO	Art Unit 3754

US ORIGINAL CLASSIFICATION						INTERNATIONAL CLASSIFICATION													
CLASS			SUBCLASS			CLAIMED					NON-CLAIMED								
222			36			B	6	7	D	7 / 22 (2010.01.01)									
CROSS REFERENCE(S)																			
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																		
128	205.23																		

NONE		Total Claims Allowed:	
		22	
(Assistant Examiner)	(Date)		
/LIEN NGO/ Primary Examiner.Art Unit 3754	9//5/14	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification 	Application/Control No. 10556432	Applicant(s)/Patent Under Reexamination POULARD, FABIEN
	Examiner LIEN NGO	Art Unit 3754

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47															
Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
1	1	17	17												
2	2	18	18												
3	3	19	19												
4	4	20	20												
5	5	21	21												
6	6	22	22												
7	7		23												
8	8														
9	9														
10	10														
11	11														
12	12														
13	13														
14	14														
15	15														
16	16														

NONE (Assistant Examiner) _____ (Date) _____		Total Claims Allowed: 22	
/LIEN NGO/ Primary Examiner.Art Unit 3754 (Primary Examiner) _____ (Date) 9//5/14		O.G. Print Claim(s) 1	O.G. Print Figure 1

<i>Index of Claims</i> 	Application/Control No. 10556432	Applicant(s)/Patent Under Reexamination POULARD, FABIEN
	Examiner LIEN NGO	Art Unit 3754

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant				☐ CPA		☐ T.D.		☐ R.1.47	
CLAIM		DATE							
Final	Original	07/16/2008	09/05/2014						
1	1	✓	=						
2	2	✓	=						
3	3	✓	=						
4	4	✓	=						
5	5	✓	=						
6	6	✓	=						
7	7	✓	=						
8	8	✓	=						
9	9	✓	=						
10	10	✓	=						
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12	12	✓	=						
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15	15	✓	=						
16	16	✓	=						
17	17	✓	=						
18	18	✓	=						
19	19	✓	=						
20	20	✓	=						
21	21		=						
22	22		=						
	23		-						

Search Notes 	Application/Control No. 10556432	Applicant(s)/Patent Under Reexamination POULARD, FABIEN
	Examiner HYEA J CHOI	Art Unit 3754

CPC- SEARCHED		
Symbol	Date	Examiner
G06M1/083, G06M3/12	9/5/14	LN
A61M15/0068		

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
222	36, 38, and 162	July 2008	Hyea Jung Choi
128	200.14,200.23,205.23	9/5/14	LN

SEARCH NOTES		
Search Notes	Date	Examiner
Got search in class 222 from Kevin Shaver.	July 2008	Hyea Jung Choi
See attached EAST history.		
EAST text search	9/5/14	LN

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
All of above		9/5/14	LN



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 United States Patent and Trademark Office
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 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 3524

SERIAL NUMBER 10/556,432	FILING or 371(c) DATE 11/09/2005 RULE	CLASS 222	GROUP ART UNIT 3754	ATTORNEY DOCKET NO. Q91404		
APPLICANTS INVENTORS Fabien Poulard, Rouen, FRANCE; ** CONTINUING DATA ***** This application is a 371 of PCT/FR04/01189 05/14/2004 ** FOREIGN APPLICATIONS ***** FRANCE 03/05858 05/15/2003 ** IF REQUIRED, FOREIGN FILING LICENSE GRANTED ** 11/25/2006						
Foreign Priority claimed ☒ Yes ☐ No 35 USC 119(a-d) conditions met ☒ Yes ☐ No Verified and /LIEN M NGO/ Acknowledged Examiner's Signature		☒ Met after Allowance LN Initials	STATE OR COUNTRY FRANCE	SHEETS DRAWINGS 13	TOTAL CLAIMS 20	INDEPENDENT CLAIMS 1
ADDRESS SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037 UNITED STATES						
TITLE Fluid product dispenser						
FILING FEE RECEIVED 1056	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:			☐ All Fees		
				☐ 1.16 Fees (Filing)		
				☐ 1.17 Fees (Processing Ext. of time)		
				☐ 1.18 Fees (Issue)		
				☐ Other _____		
			☐ Credit			

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Appln. No.: 10/556,432

Group Art Unit: 3754

Confirmation No.: 3524

Examiner: NGO, LIEN M

Filed: November 9, 2005

For: FLUID PRODUCT DISPENSER

STATEMENT OF SUBSTANCE OF INTERVIEW

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Please review and enter the following remarks summarizing the telephone interview conducted on August 28, 2014:

REMARKS

An Examiner's Interview Summary Record (PTO-413) was mailed September 8, 2014.

During the interview, the following was discussed:

1. Brief description of exhibits or demonstration: None.
2. Identification of claims discussed: 1-23.
3. Identification of art discussed: Rand.
4. Identification of principal proposed amendments: Correcting typographical errors

in claims 1 and 23.

5. Brief Identification of principal arguments: The proposed amendments correct spelling error in claim 1, and overcome the antecedency issue in claim 23.

6. Indication of other pertinent matters discussed: None.

7. Results of Interview: Examiner disagreed with Patent Trial and Appeal Board decision; Applicant's representative noted that the Board's decision following a complete review of the record and applying the correct legal standard was proper. No agreement reached.

It is respectfully submitted that the instant STATEMENT OF SUBSTANCE OF INTERVIEW complies with the requirements of 37 C.F.R. §§1.2 and 1.133 and MPEP §713.04.

It is believed that no petition or fee is required. However, if the USPTO deems otherwise, Applicant hereby petitions for any extension of time which may be required to maintain the pendency of this case, and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,

SUGHRUE MION, PLLC
Telephone: 202.293.7060
Facsimile: 202.293.7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: October 6, 2014

/Ellen R. Smith/

Ellen R. Smith
Registration No. 43,042

Electronic Acknowledgement Receipt	
EFS ID:	20338870
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	FLUID PRODUCT DISPENSER
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Ellen Resnick Smith/Mariko Motomura
Filer Authorized By:	Ellen Resnick Smith
Attorney Docket Number:	Q91404
Receipt Date:	06-OCT-2014
Filing Date:	09-NOV-2005
Time Stamp:	16:09:19
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	no				
File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant summary of interview with examiner	Q91404\$SIasfiled.pdf	6822 730c6123e4ee1f61ae0d4c1ba90b8f430c3e05c6	no	2
Warnings:					
Information:					

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PART B - FEE(S) TRANSMITTALComplete and send this form, together with applicable fee(s), to: **Mail**Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
(571) 273-2885or **Fax**

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS
(Note: Use Block 1 for any change of address)

23373

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, NW
SUITE 800
WASHINGTON, DC 20037

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	11/09/2005	Fabien POULARD	Q91404	3524

TITLE OF INVENTION: FLUID PRODUCT DISPENSER

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	Undiscounted	\$960	\$0	\$0	\$960	12/10/2014

EXAMINER	ART UNIT	CLASS-SUBCLASS
NGO, LIEN M	3754	222-036000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363)
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached.
Use of a Customer Number is required.

2. For printing on the patent front page, list
(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Sughrue Mion, PLLC

2

3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

APTAR FRANCE SAS

Le Neubourg, France

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government**4a. The following fee(s) are submitted:**

- ☒ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached.
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 19-4880 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ Applicant certifying micro entity status. See 37 CFR 1.29
☐ Applicant asserting small entity status. See 37 CFR 1.27
☐ Applicant changing to regular undiscounted fee status

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature	<u>/Raja Saliba/</u>	Date	<u>December 9, 2014</u>
Typed or Printed Name	<u>Raja Saliba</u>	Registration No.	<u>43,078</u>

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Electronic Patent Application Fee Transmittal				
Application Number:		10556432		
Filing Date:		09-Nov-2005		
Title of Invention:		FLUID PRODUCT DISPENSER		
First Named Inventor/Applicant Name:		Fabien Poulard		
Filer:		Abraham Jacob Rosner/Sharon Slater		
Attorney Docket Number:		Q91404		
Filed as Large Entity				
Filing Fees for U.S. National Stage under 35 USC 371				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl Issue Fee	1501	1	960	960

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				960

Electronic Acknowledgement Receipt	
EFS ID:	20902472
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	FLUID PRODUCT DISPENSER
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Abraham Jacob Rosner/Sharon Slater
Filer Authorized By:	Abraham Jacob Rosner
Attorney Docket Number:	Q91404
Receipt Date:	09-DEC-2014
Filing Date:	09-NOV-2005
Time Stamp:	10:28:29
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$ 960
RAM confirmation Number	9826
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:					
Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	Q91404IssueFeeTransmittal.pdf	36157 188129905ea70d9ad310c261a113f036a98bae0d	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30456 c397255712f4c696e212ffbfba8640b6eb4e3b5	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			66613		
This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503. <u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application. <u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course. <u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.					



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/556,432	01/20/2015	8936177	Q91404	3524

23373 7590 12/30/2014
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment is 2401 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Fabien Poulard, Rouen, FRANCE;

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The USA offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to encourage and facilitate business investment. To learn more about why the USA is the best country in the world to develop technology, manufacture products, and grow your business, visit SelectUSA.gov.

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q91404
Fabien POULARD, et al.	Group Art Unit: 3754
Appln. No.: 10/556,432	Examiner: NGO, LIEN M
Confirmation No.: 3524	Patent No.: 8,936,177
Filed: November 9, 2005	Issue Date: January 20, 2015
For: FLUID PRODUCT DISPENSER	

**PETITION UNDER 37 C.F.R. § 1.324 TO CORRECT INVENTORSHIP IN PATENT TO ADD
OR DELETE INVENTOR(S), PURSUANT TO 35 U.S.C. § 256**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The undersigned, on behalf of the Inventors and the Assignee, petitions the Director in accordance with 37 C.F.R. § 1.324(a) to correct inventorship of the above-identified patent by adding the names Jean-Denis SAUZADE and Yann ROARD as co-inventors.

The failure to name the correct inventors arose through error without any deceptive intention.

REMARKS

In accordance with 37 C.F.R. § 1.324(b), submitted herewith are the following:

1. Where one or more persons are being added, a statement from each person who is being added as an inventor that the error in inventorship occurred without deceptive intent on his or her part.

PETITION UNDER 37 C.F.R. § 1.324 TO CORRECT INVENTORSHIP IN PATENT TO ADD
OR DELETE INVENTOR(S), PURSUANT TO 35 U.S.C. § 256

Attorney Docket No.: Q91404

Appln. No.: 10/556,432

2. A statement from the current named inventor who has not submitted a statement under paragraph (1) above, stating that they have no disagreement in regard to the requested change; and

3. A statement from all assignee(s) of the parties submitting a statement under paragraph (1) and paragraph (2) above agreeing to the change of inventorship, which statement complies with the requirements of §3.73(b); and

The processing fee of \$140.00 set forth in 37 C.F.R. § 1.20(b) is also being remitted.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Ellen R. Smith/

SUGHRUE MION, PLLC
Telephone: 202.293.7060
Facsimile: 202.293.7860

Ellen R. Smith
Registration No. 43,042

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: October 19, 2017

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of	Docket No: Q91404
Fabien POULARD	Group Art Unit: 3754
Appln. No.: 10/556,432	Examiner: NGO, LIEN M
Confirmation No.: 3524	Patent No.: 8,936,177
Filed: November 9, 2005	Issue Date: January 20, 2015
For: FLUID PRODUCT DISPENSER	

**STATEMENT OF ASSIGNEE OF RIGHTS FROM ALL ASSIGNEES OF PARTIES
SUBMITTING A STATEMENT UNDER ¶(1) & ¶(2) IN SUPPORT OF PETITION
UNDER 37 C.F.R. § 1.324 TO CORRECT INVENTORSHIP OF PATENT**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

The undersigned, a representative of APTAR FRANCE SAS, represents that APTAR FRANCE SAS is the owner of the entire right, title and interest of Application No. 10/556,432, (now United States Patent 8,936,177), filed on November 9, 2005 for FLUID PRODUCT DISPENSER by virtue of:

an Assignment from Mr. Fabien POULARD executed on October 20, 2005, recorded on November 9, 2005 at Reel No. 017925, Frame 0909, to VALOIS SAS, and by virtue of an Assignment from VALOIS SAS to APTAR FRANCE SAS executed on July 25, 2012, recorded on September 10, 2012 at Reel No. 028930, Frame No. 0848;

an Assignment from Mr. Jean-Denis SAUZADE executed on July 31, 2017, recorded on September 21, 2017, at Reel No. 043648, Frame 0791, to Telemaq SAS, and by virtue of an Assignment from Telemaq SAS to APTAR FRANCE SAS executed on August 13, 2017, recorded on September 21, 2017, at Reel 043650, Frame 0708, and for which a copy is attached herewith; and

an Assignment from Mr. Yann ROARD executed on August 10, 2017, recorded on September 21, 2017, at Reel No. 043648, Frame No. 0791, to Telemaq SAS, and by virtue of an Assignment from Telemaq SAS to APTAR FRANCE SAS, executed on August 13, 2017, recorded on September 21, 2017, at Reel No. 043650, Frame No. 0708, and for which a copy is attached herewith.

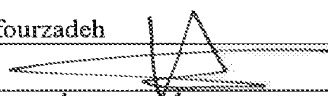
The undersigned hereby certifies that the above-mentioned Assignment has been reviewed and to the best of the undersigned's knowledge and belief, title is in who is seeking to take this action.

The undersigned (whose title is supplied below) is empowered to sign this consent statement on behalf of the assignee.

Yann Ghafourzadeh hereby agrees to the correction of inventorship in connection with the above-identified application whereby the names of Jean-Denis SAUZADE and Yann ROARD are added as co-inventors.



STATEMENT OF ASSIGNEE OF RIGHTS FROM ALL ASSIGNEES OF PARTIES
SUBMITTING A STATEMENT UNDER (1) & (2) IN SUPPORT OF PETITION
UNDER 37 C.F.R. § 1.324 TO CORRECT INVENTORSHIP OF PATENT
Attorney Docket No.: Q91404
Appln. No.: 10/556,432

Name	Yann Ghafourzadeh	Title	Vice President, Prescription Sales and Operations Europe
Signature			
Date	September 2017		

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Group Art Unit: 3754

Appln. No.: 10/556,432

Examiner.: NGO, LIEN M

Confirmation No.: 3524

Patent No.: 8,936,177

Filed: November 9, 2005

Issue Date: January 20, 2015

For: FLUID PRODUCT DISPENSER

STATEMENT FROM ADDED INVENTORS IN SUPPORT OF PETITION UNDER 37
C.F.R. § 1.324 TO CORRECT INVENTORSHIP OF PATENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Jean-Denis SAUZADE and Yann ROARD, the inventors being added to the above-identified patent do hereby declare that an error occurred in naming the inventors of the above-identified patent and that the error occurred without deceptive intention on our part.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief is believed to be true; and further that these statements were made with the knowledge that willful statements and the like so made are punishable by fine or imprisonment or both under 18 USC §1001, and may jeopardize the validity of the application or any patent issuing thereon.

Name of 1 st Added Inventor	Jean-Denis SAUZADE
Signature	<i>Jean-Denis Sauzade</i>
Date	<i>August 21st 2017</i>
Name of 2 nd Added Inventor	Yann ROARD
Signature	<i>Yann Roard</i>
Date	<i>August 17th 2017</i>

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q91404

Fabien POULARD

Group Art Unit: 3754

Appln. No.: 10/556,432

Examiner.: NGO, LIEN M

Confirmation No.: 3524

Patent No.: 8,936,177

Filed: November 9, 2005

Issue Date: January 20, 2015

For: FLUID PRODUCT DISPENSER

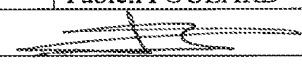
**STATEMENT FROM CURRENT NAMED INVENTOR, WHO IS NOT A PERSON
BEING ADDED AS AN INVENTOR, IN SUPPORT OF PETITION UNDER 37
C.F.R. § 1.324 TO CORRECT INVENTORSHIP OF PATENT**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Fabien POUARD, the current named inventor, of the above-identified patent who is not a person being added as an inventor do hereby declare that an error occurred in naming the inventors of the above-identified patent and that the error occurred without deceptive intention on my part.

I hereby declare that I have no disagreement in regard to the requested change in inventors.

Name of 1 st Inventor	Fabien POULARD
Signature	
Date	August 22, 2017

CERTIFICATION OF ACCURACY

1. My name is Michelle Louise Warmath. I am over eighteen years of age, have never been convicted of a felony or crime involving moral turpitude, suffer from no legal disability, and am in all other ways fully capable of making this affidavit. The facts stated herein are within my personal knowledge and are true and correct.
2. I am bilingual in the French and English languages and have been translating documents from French to English for over 45 years. I am therefore qualified to translate in said languages. I hold a Bachelor of Educational Science from the University of Nancy II in Nancy, France and have been a freelance vendor employed by Transperfect Translations International Inc. ("Transperfect") since August 2015.
3. I Michelle Louise Warmath hereby confirm that the document attached and incorporated hereto as Aptar - Road Assignment to Telemag, is, to the best of my knowledge and belief, a fair and accurate representation of 2017 08 10 Road to Telemag (French) EXECUTED Aptar - Road Assignment to Telemag from French into English.


Michelle L. Warmath

SWORN TO BEFORE ME, on Thursday, September 14, 2017.


Notary Public in and for
The State of Connecticut

My commission expires on 12/2019



PATENT ASSIGNMENT

This Patent Assignment is entered into as of August 10, 2017, between Yann Roard, 76 Chemin du Val Fleuri, Résidence Les Lauriers Bât. C, 06800 Cagnes sur Mer (“Assignor”); and Telemaq SAS, Athéna B, 1180 Route des Dolines, Sophia Antipolis, 06560 Valbonne (“Assignee”).

WHEREAS, to the extent Assignor’s right, title, and interest in the Patents and Inventions has not already been transferred by operation of French law, Assignor hereby agrees to sell, convey, transfer, assign, and deliver to Assignee all of Assignor’s right, title, and interest in, to, and under U.S. Patent No. 8,936,177, issued January 20, 2015, titled “Fluid Product Dispenser,” U.S. Patent No. 9,370,631, issued June 21, 2016, titled “Fluid Product Dispenser,” and all foreign and U.S. counterparts thereto (the “Patents”) and the inventions disclosed and/or claimed therein (the “Inventions”).

WHEREAS Assignee desires to acquire the entire right, title, and interest to the Patents and Inventions from Assignor to the extent not already acquired under French law.

NOW, THEREFORE, for good and sufficient consideration, the receipt of which is hereby acknowledged, Assignor hereby sells, assigns, and transfers to Assignee, its successors, representatives, and assigns, the entire right, title, and interest to (1) the Patents; (2) the Inventions; (3) all provisionals, non-provisionals, divisionals, continuations, continuations-in-part, reissues, reexaminations, extensions, foreign counterparts, or any other application(s) or patent(s) based on the Inventions or claiming priority to or from the Patents; and (4) any right to recover damages, including royalties and provisional damages, for prior, current, or future infringements of the Patents and Inventions identified in this paragraph.

Assignor authorizes and requests the Commissioner of Patents and Trademarks of the United States and all foreign countries to issue any and all aforementioned Patents and Inventions, including subsequently filed provisional, non-provisional, divisional, continuation, continuation-in-part, reissue, or other application(s), to Assignee for its use and on behalf of Assignee, its successors, representatives, and assigns.

The right, title, and interest conveyed in this Assignment is to be held and enjoyed by Assignee and Assignee’s successors, representatives, and assigns, as fully and exclusively as it would have been held and enjoyed by Assignor had this Assignment not been made.

IN WITNESS WHEREOF, Assignor has executed this Assignment on the date set forth below:

Yann Roard

Telemaq SAS

Signature: [signature]

Date: [handwritten:] August 10, 2017

Signature: [signature]

Date: [handwritten:] August 11, 2017

CESSION DE BREVETS

La présente Cession de brevets, qui entre en vigueur le 10 août 2017, intervient entre Yann Roard, 76 Chemin du Val Fleuri, Résidence Les Lauriers Bât C, 06800 Cagnes Sur Mer (le « Cédant ») et Telemaq SAS, Athéna B, 1180 Route des Dolines, Sophia Antipolis, 06560 Valbonne (le « Cessionnaire »).

ATTENDU QUE, dans la mesure où les droits, titres et intérêts du Cédant sur les Brevets et Inventions n'ont pas encore été transmis par l'effet de la législation française, le Cédant accepte par les présentes de vendre, transférer, attribuer, céder et fournir au Cessionnaire tous ses droits, titres et intérêts selon le brevet n° 8,936,177 délivré le 20 janvier 2015 et intitulé « Distributeur de produit fluide », et le brevet n° 9,370,631 délivré le 21 juin 2016 et intitulé « Distributeur de produit fluide » aux États-Unis, et tous les brevets américains et étrangers y afférents (les « Brevets »), ainsi que les inventions divulguées et/ou revendiquées (les « Inventions »).

ATTENDU QUE le Cessionnaire souhaite obtenir tous les droits, titres et intérêts sur les Brevets et Inventions du Cédant dans la mesure où il ne les a pas encore obtenus conformément à la législation française.

EN CONSÉQUENCE DE QUOI, à des fins de contrepartie satisfaisante et suffisante, dont la réception est reconnue par les présentes, le Cédant vend, cède et transfère selon celles-ci au Cessionnaire, ainsi qu'à ses successeurs, représentants et ayants droit, tous ses droits, titres et intérêts sur (1) les Brevets ; (2) les Inventions ; (3) les demandes de brevets complémentaires, temporaires ou autres, les demandes de brevets constituant une continuation ou une continuation en partie, le renouvellement et le réexamen des demandes de brevets, l'extension des brevets, les brevets étrangers ou tout autre brevet ou demande basé sur les Inventions ou dont la priorité sur les Brevets est revendiquée ; et (4) le droit de percevoir des dommages-intérêts, notamment des redevances et indemnités provisoires, en cas de non-respect antérieur, actuel ou ultérieur des Brevets et Inventions mentionnés dans le présent alinéa.

Le Cédant autorise et demande au Commissaire de l'Office des brevets et des marques aux États-Unis et dans tous les autres pays de délivrer l'ensemble des Brevets et Inventions susvisés, y compris les demandes de brevets complémentaires, temporaires ou autres, les demandes de brevets constituant une continuation ou une continuation en partie, le renouvellement des demandes de brevets ou autre(s) demande(s) déposée(s), au profit du Cessionnaire à des fins d'utilisation personnelle et en son nom, ainsi que pour le compte de ses successeurs, représentants et ayants droit.

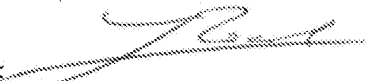
Le Cessionnaire, ainsi que ses successeurs, représentants et ayants droit, détiennent et bénéficient pleinement et exclusivement des droits, titres et intérêts transférés dans le cadre de la présente Cession comme si le Cédant les détenait et en bénéficiait en l'absence de cette Cession.

EN FOI DE QUOI, le Cédant exécute la présente Cession à la date suivante :

Yann Roard

Telemaq SAS

Signature :



Signature :



Date :

le 10 août 2017

Date :

le 11 Août 2017

PATENT ASSIGNMENT

This patent Assignment, in force as of July 31, 2017, takes place between Jean-Denis Sauzade, 32 Chemin de la Dragonnière 06130 Grasse (the "Assignor") and Telemaq SAS, Athéna B, 1180 route des Dolines, Sophia Antipolis, 06560 Valbonne (the "Assignee").

WHEREAS, to the extent that the rights, title, and interest of the Assignor in the Patents and Inventions have not yet been transferred by operation of French law, the Assignor hereunder agrees to sell, transfer, allocate, assign, and provide to the Assignee all its rights, title, and interest according to patent No. 8,936,177 issued on January 20, 2015 and titled "Fluid product dispenser", and patent No. 9,370,631 issued on June 21, 2016 and titled "Fluid product dispenser" in the United States, and all the related American and foreign patents (the "Patents"), as well as the disclosed and/or claimed inventions (the "Inventions").

WHEREAS, the Assignee wishes to obtain all the rights, title, and interest in the Patents and Inventions of the Assignor to the extent that it has not yet obtained them by operation of French law.

NOW THEREFORE, as satisfactory and sufficient compensation hereby acknowledged to have been received, the Assignor hereby sells, assigns, and transfers to the Assignee, as well as to its successors, representatives, and beneficiaries, all its rights, title, and interest in (1) the Patents; (2) the Inventions; (3) the additional, temporary, or other patent applications, the patent applications that constitute a continuation or partial continuation, renewal, or reexamination of the patent applications, the extension of the patents, the foreign patents, or any other patent or application based on the Inventions or whose priority on the Patents is claimed; and (4) the right to receive damages, especially temporary royalties and indemnifications, in the event of prior, current, or subsequent default on the Patents and Inventions mentioned in this paragraph.

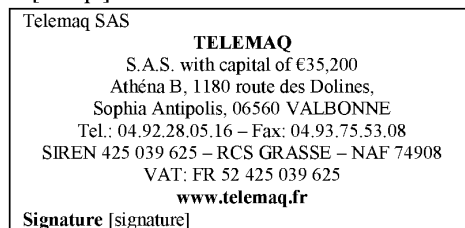
The Assignor authorizes and requests the Patent and Trademark Office Commissioner in the United States and all the other countries to deliver all the aforementioned Patents and Inventions, including the additional, temporary, or other patent applications, the patent applications that constitute a continuation or partial continuation, renewal of patent applications, or any other application(s) filed, to the benefit of the Assignee, for purposes of personal use and in its name, as well as to the benefit of its successors, representatives, and beneficiaries.

The Assignee, as well as its successors, representatives, and beneficiaries, fully and exclusively hold and benefit from the rights, title, and interest transferred as part of this Assignment as the Assignor would have held and benefitted from them in the absence of this Assignment.

IN WITNESS WHEREOF, the Assignor executed this Assignment on the following date:

Jean-Denis Sauzade

[stamp:]



Signature: [signature]

Date: [handwritten:] 07/31/2017

Date: [handwritten:] 07/31/2017



TRANSPERFECT

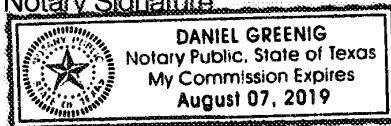
CERTIFICATE OF ACCURACY

I, Stacy Garrett of TransPerfect Translations, Inc. do hereby declare that the following are to the best of my knowledge and belief a true and accurate translation of the document "2017 07 31 Sauzade to Telemaq (French) EXECUTED" translated from French into English.

I so declare under penalty of perjury under the laws of the United States on this fifth day of September, 2017.

Stacy Garrett
TransPerfect Translations, Inc.
1717 Main Street, Suite 4450
Dallas, TX 75201

Notary Signature



Notary Stamp

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CESSION DE BREVETS

La présente Cession de brevets, qui entre en vigueur le 31 Juillet 2017, intervient entre Jean-Denis Sauzade, 32 Chemin de la Dragonnière 06130 Grasse (le « Cédant ») et Telemaq SAS, Athéna B, 1180 Route des Dolines, Sophia Antipolis, 06560 Valbonne (le « Cessionnaire »).

ATTENDU QUE, dans la mesure où les droits, titres et intérêts du Cédant sur les Brevets et Inventions n'ont pas encore été transmis par l'effet de la législation française, le Cédant accepte par les présentes de vendre, transférer, attribuer, céder et fournir au Cessionnaire tous ses droits, titres et intérêts selon le brevet n° 8,936,177 délivré le 20 janvier 2015 et intitulé « Distributeur de produit fluide », et le brevet n° 9,370,631 délivré le 21 juin 2016 et intitulé « Distributeur de produit fluide » aux États-Unis, et tous les brevets américains et étrangers y afférents (les « Brevets »), ainsi que les inventions divulguées et/ou revendiquées (les « Inventions »).

ATTENDU QUE le Cessionnaire souhaite obtenir tous les droits, titres et intérêts sur les Brevets et Inventions du Cédant dans la mesure où il ne les a pas encore obtenus conformément à la législation française.

EN CONSÉQUENCE DE QUOI, à des fins de contrepartie satisfaisante et suffisante, dont la réception est reconnue par les présentes, le Cédant vend, cède et transfère selon celles-ci au Cessionnaire, ainsi qu'à ses successeurs, représentants et ayants droit, tous ses droits, titres et intérêts sur (1) les Brevets ; (2) les Inventions ; (3) les demandes de brevets complémentaires, temporaires ou autres, les demandes de brevets constituant une continuation ou une continuation en partie, le renouvellement et le réexamen des demandes de brevets, l'extension des brevets, les brevets étrangers ou tout autre brevet ou demande basé sur les Inventions ou dont la priorité sur les Brevets est revendiquée ; et (4) le droit de percevoir des dommages-intérêts, notamment des redevances et indemnités provisoires, en cas de non-respect antérieur, actuel ou ultérieur des Brevets et Inventions mentionnés dans le présent alinéa.

Le Cédant autorise et demande au Commissaire de l'Office des brevets et des marques aux États-Unis et dans tous les autres pays de délivrer l'ensemble des Brevets et Inventions susvisés, y compris les demandes de brevets complémentaires, temporaires ou autres, les demandes de brevets constituant une continuation ou une continuation en partie, le renouvellement des demandes de brevets ou autre(s) demande(s) déposée(s), au profit du Cessionnaire à des fins d'utilisation personnelle et en son nom, ainsi que pour le compte de ses successeurs, représentants et ayants droit.

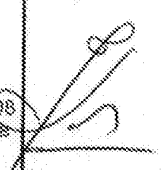
Le Cessionnaire, ainsi que ses successeurs, représentants et ayants droit, détiennent et bénéficient pleinement et exclusivement des droits, titres et intérêts transférés dans le cadre de la présente Cession comme si le Cédant les détenait et en bénéficiait en l'absence de cette Cession.

EN FOI DE QUOI, le Cédant exécute la présente Cession à la date suivante :

Jean-Denis Sauzade

Signature :

Date : 31/07/2017

Telemaq SAS TELEMAQ S.A.S. au capital de 35.200 € Athéna B - 1180 Route des Dolines Sophia Antipolis - 06560 VALBONNE Tél: 04 92 28 05 16 - Fax : 04 93 75 53 08 SIREN 425 039 925 - RCS GRASSE - NAF 7490Z TVA : FR 52 425 039 925 Signature:  www.telemaq.fr

Date : 31/07/2017

PATENT ASSIGNMENT

This Patent Assignment is entered into as of [INSERT DATE], between Telemaq SAS, Athéna B. 1180 Route des Dolines, Sophia Antipolis, 06560 Valbonne ("Assignor"); and Aptar France SAS, Lieudit Le Prieuré, 27110 Le Neubourg, France ("Assignee").

WHEREAS Assignor previously agreed to sell, convey, transfer, assign, and deliver to Assignee all of Assignor's right, title, and interest in, to, and under U.S. Patent No. 8,936,177, issued January 20, 2015, titled "Fluid Product Dispenser," U.S. Patent No. 9,370,631, issued June 21, 2016, titled "Fluid Product Dispenser," and all foreign and U.S. counterparts thereto (the "Patents") and the inventions disclosed and/or claimed therein (the "Inventions").

WHEREAS Assignee desires to acquire the entire right, title, and interest to the Patents and Inventions from Assignor.

NOW, THEREFORE, for good and sufficient consideration, the receipt of which is hereby acknowledged, Assignor hereby sells, assigns, and transfers to Assignee, its successors, representatives, and assigns, the entire right, title, and interest to (1) the Patents; (2) the Inventions; (3) all provisionals, non-provisionals, divisionals, continuations, continuations-in-part, reissues, reexaminations, extensions, foreign counterparts, or any other application(s) or patent(s) based on the Inventions or claiming priority to or from the Patents; and (4) any right to recover damages, including royalties and provisional damages, for prior, current, or future infringements of the Patents and Inventions identified in this paragraph.

Assignor authorizes and requests the Commissioner of Patents and Trademarks of the United States and all foreign countries to issue any and all aforementioned Patents and Inventions, including subsequently filed provisional, non-provisional, divisional, continuation, continuation-in-part, reissue, or other application(s), to Assignee for its use and on behalf of Assignee, its successors, representatives, and assigns.

The right, title, and interest conveyed in this Assignment is to be held and enjoyed by Assignee and Assignee's successors, representatives, and assigns, as fully and exclusively as it would have been held and enjoyed by Assignor had this Assignment not been made.

IN WITNESS WHEREOF, Assignor has executed this Assignment on the date set forth below:

Telemaq SAS:

Signature: Jean-Denis Saugade

Date: August 13th 2017



Aptar France SAS:

Signature: Yann GUAROUNLADY

Date: 15 Août 2017



McKool 1326598v1

Electronic Patent Application Fee Transmittal				
Application Number:		10556432		
Filing Date:		09-Nov-2005		
Title of Invention:		FLUID PRODUCT DISPENSER		
First Named Inventor/Applicant Name:		Fabien Poulard		
Filer:		Ellen Resnick Smith/Keyanna Honesty		
Attorney Docket Number:		Q91404		
Filed as Large Entity				
Filing Fees for U.S. National Stage under 35 USC 371				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Extension-of-Time:				
Miscellaneous:				
Total in USD (\$)				140

Electronic Acknowledgement Receipt	
EFS ID:	30708720
Application Number:	10556432
International Application Number:	
Confirmation Number:	3524
Title of Invention:	FLUID PRODUCT DISPENSER
First Named Inventor/Applicant Name:	Fabien Poulard
Customer Number:	23373
Filer:	Ellen Resnick Smith/Keyanna Honesty
Filer Authorized By:	Ellen Resnick Smith
Attorney Docket Number:	Q91404
Receipt Date:	19-OCT-2017
Filing Date:	09-NOV-2005
Time Stamp:	18:01:10
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	\$ 140
RAM confirmation Number	102017INTEFSW18020100
Deposit Account	194880
Authorized User	Keyanna Honesty
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows: 37 CFR 1.17 (Patent application and reexamination processing fees) 37 CFR 1.19 (Document supply fees)	

37 CFR 1.21 (Miscellaneous fees and charges)
 37 CFR 1.492 (National application filing, search, and examination fees)
 37 CFR 1.492(a) (Basic national fee only)

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Request under Rule 48 correcting inventorship	Q91404PetitiontoCorrectInventorshipforUS8936177withStateMentsandAssignments.pdf	3116083	no	14
			f63edc7a34a4d6ba22cd2b8a32be2c835b953b05		

Warnings:

Information:

2	Fee Worksheet (SB06)	fee-info.pdf	30730	no	2
			6ac88d7eeb85b8c08e3cc97bc7f8684946a2d821		

Warnings:

Information:

Total Files Size (in bytes):	3146813

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Illinois Northern District Court - Eastern Div. on the following

☐ Trademarks or ☒ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO. 17cv04295	DATE FILED 6/7/2017	U.S. DISTRICT COURT Illinois Northern District Court - Eastern Div.
PLAINTIFF Aptargroup, Inc		DEFENDANT 3M Co., Merck & Co., Inc.
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 9,370,631		
2 8,936,177		
3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

AO 120 (Rev. 08/10)

TO: Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court Northern District of Illinois on the following

☐ Trademarks or ☒ Patents. (☐ the patent action involves 35 U.S.C. § 292.):

DOCKET NO. 17-cv-4295	DATE FILED 6/7/2017	U.S. DISTRICT COURT Northern District of Illinois
PLAINTIFF AptarGroup, Inc., et al		DEFENDANT 3M Company et al
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1 8,936,177	1/20/2015	Aptar France
2 9,370,631	6/21/2016	Aptar France
3		
4		
5		

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT case terminated

CLERK Thomas G. Bruton	(BY) DEPUTY CLERK A. Scherer	DATE 9/8/2017

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
 Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy