

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
26 April 2007 (26.04.2007)

PCT

(10) International Publication Number
WO 2007/045904 A1

(51) International Patent Classification:
G06M 1/08 (2006.01) *A61M 15/00* (2006.01)
G06M 1/14 (2006.01)

Nicholas, John [GB/GB]; 95 Dunsberry, Bretton, Peterborough, Cambridgeshire PE3 8LB (GB).

(21) International Application Number:
PCT/GB2006/003923

(74) Agent: LAMB, Richard, Andrew; Urquhart-Dykes & Lord LLP, New Priestgate House, 57 Priestgate, Peterborough, Cambridgeshire PE1 1JX (GB).

(22) International Filing Date: 20 October 2006 (20.10.2006)

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, 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, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0521586.8 22 October 2005 (22.10.2005) GB
0521587.6 22 October 2005 (22.10.2005) GB

(71) Applicant (for all designated States except US): 42 TECHNOLOGY LIMITED [GB/GB]; Meadow Lane, St Ives, Cambridgeshire PE27 4LE (GB).

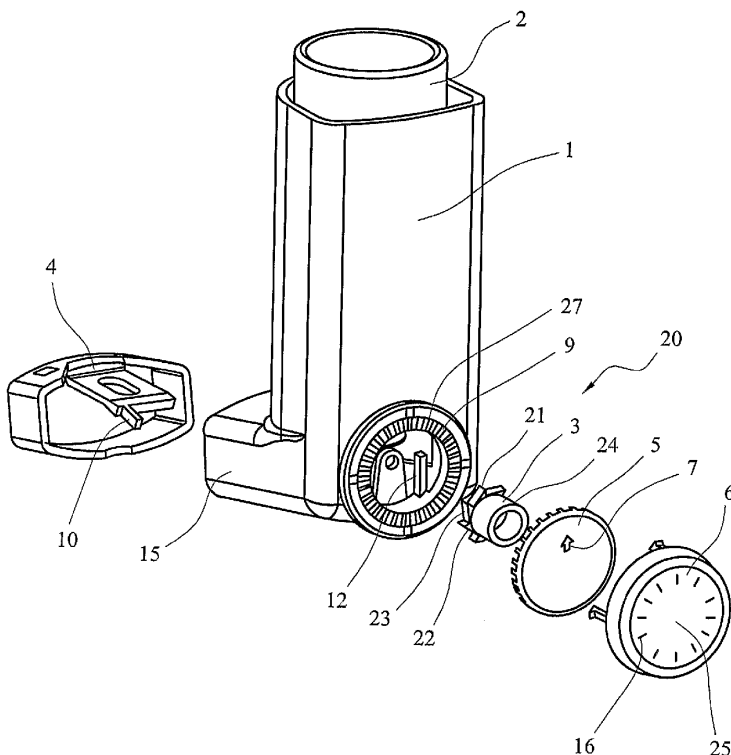
(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,

(72) Inventor; and

(75) Inventor/Applicant (for US only): CAMPLING,

[Continued on next page]

(54) Title: DOSE COUNTER FOR INHALATION DEVICES



(57) Abstract: A dose counter (20) for a medicament delivery device, in particular an inhaler, comprises two interengaged gears (5, 27) having different numbers of teeth (8, 9). One of the gears (27) is rotationally fixed and the gears (27, 5) are mounted so that actuation of medicament delivery device gyrates the engagement of one of the gears (5) around the other gear (27), and causes one of the gears (5) to rotate about its own axis with such rotation rotating a dose indicator (7). The gears may be crown gears (27, 5) with one mounted at an angle to the other, or an external gear (115/104) mounted eccentrically within an internal gear (102).

WO 2007/045904 A1



FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT,
RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA,
GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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.

Published:

— *with international search report*

DOSE COUNTER FOR INHALATION DEVICES

This invention relates to counting the number of doses delivered or remaining in a medicament dispensing device and in particular in a dry powder or "pressurised metered dose" inhaler devices.

Inhaler devices are traditionally used to treat pulmonary diseases and have recently been used to deliver other drugs such as insulin. Users of inhaler devices which do not include a means to count and indicate the number of doses used or remaining find it hard to know when their medication may run out, and hence when to replace the inhaler or drug canister.

The FDA (Food and Drug Administration) in the USA issued guidelines ("Integration of Dose-Counting Mechanisms into MDI Drug Products" March 2003) which say that new applications should include a dose counter.

A number of device with dose counters are therefore appearing on the market. Many of these dose counters however comprise complex mechanisms requiring high accuracy in manufacture and assembly. Indeed it has in fact proven difficult to convert the intermittent motion in the inhaler device which delivers the drug into a suitable motion to drive and increment a counter and dose display. This is particularly so since a large number of doses may be delivered by the inhaler and so the display needs to only be incremented by a relatively small amount for each actuation of the inhaler. In addition it is problematic to convert the intermittent, and relatively large (by comparison to the incrementation of the display wheel) motion in the inhaler device which delivers the drug, into a suitable motion to drive and operate a counter and dose display. It is also not generally possible, nor desirable

CONFIRMATION COPY

to use electronic counters or displays in such devices.

WO 2006/004497 describes a dose counter including a pointer gauge type display which rotates to indicate the number of dose remaining or used. This document does not
5 however describe how the pointer is incrementally moved.

EP1237603 and EP 1119383 describe further dose counter arrangements with pointer or indicator dials. These arrangements include ratchet mechanisms to increment the pointer or indicator dials. These ratchet mechanisms are
10 however relatively complex, and difficult to assemble, and can generally be improved.

WO 01/31578 describes a slightly different dose counter which uses multiple concentrically arranged numbered display wheels which are used together to indicate
15 the number of doses used or remaining, with one disc indicating the 'units' and the other indicator the 'tens' such that in combination the number of doses is displayed. The display wheels are again incremented by a ratchet drive. However in this case by using multiple display
20 wheels the reduction in movement does not need to be as much as in other single indicator wheel arrangements. However the use of multiple wheels adds to the complexity, and a simpler single display disc may in some situations be preferable.

25

It is therefore desirable to provide an improved dose counter which addresses the above described problems and/or which more generally offers improvements or an alternative to existing arrangements.

30 In particular an object of this invention is to provide a simple mechanical means to count the doses used and provide indication of doses used or remaining to the user. It is also desirable to provide such mechanical means that has only a few components. More specifically, and as

recognised as part of the invention, it is desirable to provide a dose counter with an improved means to convert an intermittent motion in the inhaler device which delivers the drug, into a suitable relatively small intermittent rotary motion of a dial or pointer which indicates the doses remaining or used.

According to the present invention there is therefore provided a dose counter, and a medicament delivery device including a dose counter, as described in the accompanying claims.

In particular in an embodiment of one aspect of the invention there is provided a dose counter for a medicament delivery device comprising a first gear which interengages a second gear at a point around the circumference of the first gear. The first and second gears have different numbers of teeth. One of the first and second gears is rotationally fixed, preferably such that it does not rotate about its own axis. The first and second gears are mounted such that an actuator, in use, when the medicament is dispensed, moves one of the first and second gears relative to the other and point of engagement between the first and second gears around the first gear thereby causing the other of the second and first gears to rotate about its own axis and rotate a dose indicator.

In an embodiment of another aspect of the invention there is provided a dose counter for a medicament delivery device comprising two interengaged gears having different numbers of teeth. One of the gears is rotationally fixed. The gears are mounted so that actuation of medicament delivery device gyrates the engagement of one of the gears around the other gear so that one of the gears rotates

about its own axis with such rotation rotating a dose indicator. rotates relative to other with such rotation rotating a dose indicator.

5 Such dose counters comprise a relatively simple easy
to make and assemble assembly with relatively few parts,
yet which provides a reliable and accurate rotation of a
dose indicator to provide an indication of the number of
doses dispensed and/or remaining. In addition the gear
10 arrangement of such dose counters provides a significant
reduction in the motion between the gears, and so of the
indicator such that for each activation the indicator is
only moved a small amount enabling a large number of doses
to be indicated by the full rotation of the indicator.

15

The first and second gears may comprise crown gears
with the first gear being mounted at an angle to the second
gear. The second gear is then moved conically relative to
the first gear.

20

Alternatively the first and second gears may comprise
corresponding internal and external gears having generally
radially teeth, with the second gear being mounted
eccentrically to the first gear. The second gear then being
moved around the first gear. The second gear may then
25 comprise first and second concentric sets of gear teeth
with the dose counter further comprises a third gear
coaxial with the first gear. The first set of gear teeth of
the second gear engage the first gear. The second set of
gear teeth of the second gear then engage the third gear at
30 a point around the circumference of the second gear. The
third gear has a different number of teeth to the second
set of teeth on the second gear, and is mounted such that,
in use, when the medicament is dispensed, the second gear
and point of engagement between the third gear and second

gears moves around the third gear thereby causing the third gear to rotate about its own axis. The dose indicator is then mounted on the third gear.

Furthermore an embodiment of the invention provides a means to convert an intermittent motion in the inhaler device which delivers the drug into an intermittent rotary motion of a dial or pointer which indicates the doses remaining or used. Preferably such means comprises the actuator of the above described dose counter arrangements which converts linear intermittent motion to actuate the medicament dispenser into rotary motion to move the second gear. In particular the actuator may comprise a drive lug with a co-operating drive wheel having at least one projection around its periphery which is engageable, in use, by the drive lug to rotate the drive wheel and move the second gear. The drive lug and a drive wheel being mounted and arranged to, in use, when the medicament is dispensed, move relative to each other.

The dose counter of the invention is preferably used with an inhaler.

A particular aspect of an embodiment of this invention makes use of a wobble reduction gear similar to that described in US patent 544,796 of August 20th 1895. In this aspect of the invention, just two gears are required. The first is a stationery crown gear and the second is also a crown gear having a slightly different number of teeth. This second gear is mounted such that its axis can move conically. The second gear is forced to oscillate conically by, for example, pressure applied progressively in a circular motion to the gear face. As the gear oscillates conically, the gear teeth engaged at the rim effectively roll around the rim of the stationery gear and since there is a difference in the number of teeth, the moving gear rotates a small amount on its axis. This type of gear

arrangement is able to provide a large reduction between the input rotary motion and the output.

It is further possible to use the arrangement in US patent 544,796 to provide an output where the indicator is parallel to the viewing window to avoid parallax distortion of the readout. However, this requires an extra component; namely a third crown gear. The wobble gear will also require another set of teeth.

In yet another particular aspect and embodiment of this invention a dose counter mechanism incorporates an alternative reduction gear mechanism to achieve the required rotation of an indicator. This reduction gear mechanism achieves a high ratio by virtue of an internal and external gear pair with a small difference in numbers of teeth (typically one or two teeth difference). One of the gears is fixed with respect to some adjacent component and the other constrained to move in an eccentric rotary motion and gyrate within the stationary gear, whilst being allowed to rotate on its own axis. In this way, the moving gear will rotate on its own axis by the number of teeth differential for each full eccentric rotary motion of the moving gear. The eccentric motion may be generated in a number of ways from the motion of the inhaler mechanism. This causes slow rotation of moving gear about its axis which can then be used to provide an indication of the doses used or remaining.

In a preferred arrangement a second gear pair where one of the gears is part of or fixed to the moving gear in the first gear pair gives an output rotation on the same axis as the first fixed gear. Such a reduction gear arrangement is similar to that described in US 1770035. The final gear then provides indication of the doses used or remaining.

The present invention will now be described by way of example only with reference to the following figures in which:

Figure 1 shows an exploded view of an inhaler and dose counter of a first embodiment showing the component parts;

Figure 2 shows a side elevation of the ratchet wheel of the dose counter of figure 1;

Figure 3 shows a view of the indicator wheel of the dose counter shown in figure 1 showing the gear teeth and recess;

Figure 4 shows a cross section through the assembled dose counter shown in figure 1;

Figure 5 shows a more detailed exploded view of the mechanism of the dose counter of figure 1 with the inhaler body omitted to reveal the internal parts;

Figure 6 shows an exploded view of an inhaler and dose counter of a second embodiment showing the component parts;

Figure 7 shows a detailed view of the protrusion of the inhaler shown in figure 6 which drives the input rotational movement from the vertical movement of the cap;

Figure 8 shows the gear wheel, having two external sets of gear teeth, of the inhaler shown in figure 6;

Figure 9 shows the inside of the cap of the inhaler shown in figure 6 with only the indicator disc installed;

Figure 10 shows the inside of the cap of the inhaler similar to figure 9 but now also with the gear wheel installed; and

Figures 11 and 12 illustratively show the gear mechanism, in isolation, of the inhaler shown in figure 6, with the surrounding elements and parts removed.

Referring to a first embodiment of the invention as shown in figures 1 to 5, a pressurised metered dose inhaler includes a drug canister 2 located in the body 1 which is

activated by depression of the canister 2 with respect to the body 1. When activated and depressed a metered quantity of the drug is expelled as an aerosol through the mouth piece 15. As such the inhaler is generally conventional.

5 The pressurised metered dose inhaler also includes a dose counter assembly 20 which is activated with each depression of the canister, and delivery of a dose, to provide an indication of the number of doses dispensed or remaining.

10 The dose counter assembly 20 comprises a dose counter ratchet wheel 3 rotatably mounted in the inhaler body 1. The dose counter ratchet wheel 3 is rotated by a lever 10, mounted for ease of assembly on a component 4, and which is operated by depressing the inhaler canister 2. Specifically
15 lever 10, as shown in figure 4, is mounted underneath and supports the bottom of the canister 2. The cantilevered lever 10 is resilient and is deflected downwards when the canister 2 is depressed into the inhaler body 1 to expel the drug. The distal end of the lever 10 is located
20 adjacent and tangentially to the circumference of the ratchet wheel 3 and engages flat, generally radially extending, drive faces 21 of ratchet projections 23 of the ratchet wheel 3. Accordingly as the lever 10 is depressed it rotates the ratchet wheel 3 in a first, forwards,
25 direction. When the canister 2 is released the lever 10 springs back and upwards urging the canister 2 upwards. The outer face of the ratchet wheel 3 and a reverse side of the ratchet projections 23 have a sloping profile 22 allowing the end of the lever 10 to pass over them as the lever 10
30 springs back. The ratchet wheel 3 is prevented from counter rotation by a resilient pawl 12 moulded into the inhaler body 1. The pawl 12 is located adjacent and tangentially to the circumference of the ratchet wheel 3 and engages the flat drive faces 21 of the ratchet projections. The pawl

12, similarly to the end of the lever 10 passes over the sloping reverse profile 23 of the ratchet projections 23 when the ratchet wheel 3 is rotated by the lever 10 in the forwards direction.

5 The ratchet wheel 3 has a tubular extension 24 extending coaxially from an axial end of the ratchet wheel 3. An axial distal end of the tubular extension has a sloping face 13 disposed at an angle to the axial plane of the ratchet wheel 3.

10 An indicator wheel 5 is mounted on the end of the tubular extension 24 of the ratchet wheel 3 with the sloping face 13 of the ratchet wheel 3 in a circular or annular recess 11 of the indicator wheel 5, and abutting against an axial face of the indicator wheel 5. A cap 6
15 having a transparent viewing window 25 is fixed onto the inhaler body 1, and holds the indicator wheel 5 against the sloping face 13 of the ratchet wheel 3. An outer conical surface 14 of the indicator wheel 5 bears on the inner surface of the cap 6. The indicator wheel 5 is thereby held
20 and mounted at an angle to the axial plane of the ratchet wheel 3.

 The indicator wheel 5 has a plurality of teeth 8 disposed around the circumference of and extending from an axial inner end face of the wheel 5 forming crown gear 26
25 on the axial end face of the wheel 5, as shown in figure 3. A corresponding fixed crown gear 27 having a plurality of teeth 9 disposed around the circumference of and extending from an axial inner end face of crown gear 27 is provided on, or fixedly attached to, the inhaler body 1. The fixed
30 crown gear 27 is located coaxially, surrounding the ratchet wheel 3 and perpendicular to the axis of the ratchet wheel 3. The indicator wheel 5 mounted on the sloping face 13 the ratchet wheel 3 is accordingly mounted at an angle to the fixed crown gear 27 so that some of the teeth 8 of the

indicator wheel 5 engage with the teeth 9 of the fixed crown gear 27 at only one point around the circumference of the fixed crown gear 27. There is a small difference in the number of teeth 8,9 on the fixed crown gear 27 and indicator wheel 5, typically 1 or 2 teeth, and for example in this embodiment there is one less tooth on the indicator wheel 5 than on fixed crown gear 27.

The indicator wheel 5 mounted on the sloping end 13 of the ratchet wheel 3 is accordingly mounted such that its axis can move conically. As the ratchet wheel 3 rotates, the indicator wheel 5 moves or oscillates conically and "wobbles", following the sloping face 13 on the ratchet wheel 3. In other words the indicator wheel 5 is moved such that an axis of the indicator wheel 5 traces out a cone, with the base of the cone corresponding to the fixed, stationary, gear 27 and point of contact between the indicator wheel 5 and stationary fixed gear 27. As the indicator wheel 5 moves conically, the gear teeth 8,9 engaged at the rim effectively roll around the rim of the fixed stationery gear 27, and the point of engagement between the teeth 8,9 of the indicator wheel 5 and fixed crown gear 27 accordingly rotates and gyrates around the circumference of the fixed gear 27. As there is a difference between the number of teeth 8,9 on the indicator wheel 5 and on the fixed gear 27, the indicator wheel 5 will rotate a small amount about its axis. In particular in this embodiment as there is one less tooth on the indicator wheel 5 than on the fixed gear 27, the indicator wheel 5 will turn through one tooth pitch for a complete revolution of the ratchet drive 3. Each single operation of the ratchet 3 thereby incrementally rotates the indicator wheel 5 and so moves an indicator mark and pointer 7 on the indicator wheel 5 so as to indicate that one dose has been administered from the canister 2. Graduations 16 around the

circumference of the cap 6 show the number of doses remaining in the canister by reference to the indicator mark 7.

It will be appreciated that in this arrangement the amount, and direction, of rotation of the indicator wheel 5 rotates is determined by the tooth difference between the crown gears 26,27. If there is a larger tooth difference then the indicator wheel 5 will rotate more than if there is a smaller tooth difference.

This dose counter 20 and gear arrangement is accordingly able to provide a large reduction between the input rotary motion provided by the ratchet wheel 3 drive and the output rotation of the indicator wheel 5 whose rotational position can be used to then indicate the number of doses dispensed or remaining. Furthermore this arrangement only comprises a few moving parts and can be relatively easily assembled.

In this arrangement and embodiment the indicator wheel 5 upon which has the indicator mark and pointer 7 is at an angle. Where the indicator mark comprises a single pointer 7 type mark this is not a problem. However if other indicator marks are to be used, and in other embodiments it may be desirable to provide an output where the indicator wheel is parallel to the viewing window to avoid parallax distortion of the readout. It will be appreciated that this could be achieved by providing a further set of crown teeth on the opposite side of the indicator wheel 5 (which now becomes an intermediate crown gear wheel) with then a further third crown gear wheel mounted parallel to the axial plane of the ratchet wheel 3 as an indicator wheel. This third crown gear wheel engages the intermediate crown gear wheel diametrically opposite the engagement between the fixed crown gear and intermediate crown gear and is similarly incrementally rotated. There may be a difference

in number of teeth between the third crown gear and intermediate crown gear and this provides a further reduction in the incremental rotation of the indicator wheel about its axis. However the third crown gear could
5 have the small number of teeth as the intermediate crown gear such that the rotation is simply replicated and the third crown gear simply removes the parallax and provides a rotating pointed that is parallel to the fixed gear and perpendicular to the axis of rotation. Such a gear
10 arrangement is similar to that described in US patent 544,796 of August 20th 1895.

While this alternative arrangement and embodiment provides a parallel indicator wheel and further reduction in the incremental rotation which enables, it requires an
15 extra component: namely the third crown gear, and another set of teeth adding to the complexity. It does however provide a further reduction in the incremental rotation for each The wobble gear will also require another set of teeth.

20

Referring now to figures 6 to 12 a second embodiment of the invention, and pressurised metered dose inhaler with a dose counter mechanism 100 is shown. The inhaler is generally similar to that described above in relation to
25 figures 1 to 5, and conventional inhalers. A drug canister 124 is located in the inhaler body 125. Depressing the canister 124 causes a metered dose of drug to be expelled through the mouthpiece 126.

The dose counter mechanism 100 of this embodiment is
30 contained within the cap 110 of the inhaler such that when the cap 110 is depressed, the force is transmitted through the dose counter 100 to the canister 124 and a drug dose is expelled. Depression of the cap also rotates a drive wheel 119 which then via a reduction gear arrangement

incrementally rotates an indicator disc 111 to indicate the number of doses dispensed or remaining.

More specifically the dose counter mechanism 100 of this embodiment comprises a canister cap 123, a drive wheel 119 with an eccentric boss 118 fixed to it, a gear wheel 115, an indicator wheel 111, and the cap 110. The canister cap 123 provides a means to contain the mechanism 100 within the cap 110.

A central spindle 114 projects from the cap 110 and defines a central axis 150 of the dose counter mechanism 100 upon which the various other elements are mounted as will be described below. Alternatively a spindle can project from the canister cap 123.

The indicator disc 111 is mounted in the cap 110, and is free to rotate about the spindle 114 protruding from the inner surface of the cap 110. The cap 110 has a transparent viewing window 128 through which the indicator disc 111 can be viewed. The indicator disc 111 has a radial indicator mark or pointer 130. As will be explained further below the indicator disc 111 is arranged to rotate within the cap 110 with the pointer 130 pointing to graduations (not shown) around the circumference of the cap 110 to show the number of doses remaining in the canister 124 as the indicator disc 111 rotates.

Both the cap 110 and the indicator disc 111 have internal gear teeth 112 and 113 respectively forming two internal gears 102, 107. The indicator wheel 111 internal gear 107 when the indicator wheel 111 is fitted in the cap 110, is coaxial and concentric with the spindle 114 and central axis 150 of the dose counter 100. The cap internal gear 102 is disposed around the inside of the cap 110 and is coaxial and concentric with the spindle 114, and central axis 150 of the dose counter 100. The cap internal gear 102 is fixed and preferably comprises an internal moulding

within the cap 110. Alternatively the cap gear 102 may comprise a separate gear fixed into the cap 110. The cap gear 102 is disposed radially outside of the indicator wheel 111 and extends at least partially axially below the indicator wheel 111 when the indicator wheel 111 is installed in the cap 110 as shown in figure 9.

The gear wheel 115, shown in isolation in figure 8, comprises two concentric external gear sets of teeth 116,117 forming two concentric external gears 104,105 one on top of the other and which are fixed together. The gear wheel 115 preferably comprises a single moulding, but may comprise two separate gear wheels which are joined together. The gear wheel 115 includes a central bore 130.

The drive wheel 119 is located on top of the canister cap 123 and is coaxially mounted on the spindle 114 so as to freely rotate about on the spindle 114. The eccentric boss 118 comprises a cylindrical projection which projects from and is fixed to the drive wheel 119 and is located off centre from the axis of the ratchet drive wheel and central axis 150 of the dose counter 100. The gear wheel 115, and central bore 130 of the gear wheel 115, is coaxially mounted on the eccentric boss 118 which projects from an axial face of the drive wheel 119 such that the gear wheel 115 is located on the eccentric boss 118 but is free to rotate on and about the eccentric boss 118 and axis 152,154 of the boss 118 and of the gear wheel 115.

When the dose counter mechanism 100 is assembled in the cap 110 the gear wheel 115 is thereby eccentrically mounted and installed within the cap 110 such that the axis 154 of the gear wheel 115 is eccentric to the axis 150 of the spindle 114 and central axis 150 of the dose counter mechanism 100. The teeth 116 of the upper, smaller set, and gear 105 of the gear wheel 115 mesh with some of the teeth 113 in the indicator disc 111 at one point around the

circumference of the internal gear 107 of the indicator disc 111. The teeth 117 in the lower set and gear 104 and gear wheel 115 mesh with some of the teeth 112 in the cap 110 at one point around the circumference of the internal gear 102 in the cap 110. This is shown more clearly in figures 11 and 12 in which the other parts of the cap 110, indicator disc 110 and drive wheel 119 are omitted and removed to leave and show the gear portions more clearly in isolation.

10 The drive wheel 119 includes two rows 132,134 of projections 121,122 around the circumference of the drive wheel 119. The two rows 132,134 of projections 121,122 are axially spaced apart and the projections 121 are circumferentially staggered with respect to each other. The
15 projections 121,122 have opposite facing angled faces 136,138. A fixed protrusion and lug 120 which has corresponding opposed angled faces 140,142 is mounted on the inhaler body 125 tangentially of the drive wheel 119 and is arranged to engage the corresponding faces 132,134
20 of the protrusions 121,122 of the drive wheel 119. This arrangement of protrusions 121,122 on the drive wheel 119 is similar, and operates in a similar way, to the retraction mechanism on a ball point pen where such mechanism is activated by the depression of the top of the
25 pen.

 In operation when the cap 110 is depressed to cause a metered dose of drug to be expelled, the drive wheel 119 is moved axially and downwards relative to the inhaler body 125. The upper angled face 142 of the fixed protrusion 120
30 then abuts against the angled face 138 of the upper row 134 of protrusions 122 on the drive wheel 119 causing the drive wheel 119 to rotate. When the cap 110 is released it moves upwards and the lower angled face 140 of the fixed protrusion 120 then abuts against the angled face 136 of

the lower row 136 of protrusions 121 on the drive wheel 119 causing the drive wheel 119 to further rotate. Accordingly the drive wheel 119 is turned by the engagement of the protrusion 120 on the inhaler body progressively with those
5 on the wheel 121 and 122 as the inhaler is activated repeatedly. Rotation of the drive wheel 119 in the reverse direction is prevented by the location of the fixed protrusions 120 on the inhaler body 125 between the adjacent projections 121,122 on the drive wheel 119.

10 The rotation of the drive wheel 119 as the inhaler is activated, progressively rotates the eccentric boss 118 around the central axis 150. The gear wheel 115 is thereby driven in an eccentric motion by the eccentric 118, with the gear wheel 115 moving in a circular path around the
15 spindle 114. The point of engagement between the teeth 117 of lower gear 104 of the gear wheel 115 and the teeth 112 on the fixed internal gear 102 in the cap 110, accordingly moves and gyrates around the circumference of the fixed internal cap gear 102. As the cap 110 will not rotate, and
20 since there is a small difference in numbers of teeth 117,112 (typically one or two teeth difference) on the lower gear 104 and the cap gear 102, the gear wheel 115 is rotated about its own axis 154 in the opposite direction to the circular motion of the gear wheel 115 about the spindle
25 114 axis by the number of teeth differential for each full eccentric rotary motion of the gear wheel 115 and drive wheel 119. Similarly the point of engagement between the teeth 116 of upper gear 105 of the gear wheel 115 and the teeth 113 on the indicator gear 107 moves and gyrates
30 around the circumference of the indicator gear 107. As there is a similar difference in numbers of teeth 116,113 on the upper gear 105 and the indicator gear 107 the indicator gear 107, and so indicator wheel 111, is rotated about its own axis by the number of teeth differential for

each full eccentric rotary motion of the moving gear wheel 115 and drive wheel 119. The upper row of teeth 116 will thereby drive the indicator disc 111 round. As a result the indicator wheel 111 slowly rotates following each actuation
5 of the inhaler thereby indicate the number of doses dispensed or remaining.

The ratio of the number of teeth 112,113,116,117 in each gear 102,104,105,107 (for gear wheel, cap and indicator disc) is calculated to give the required
10 reduction to get a sensible rotation of the indicator wheel 111 (300-330°) for the required number of actuations of the inhaler.

In a variation of this embodiment the indicator wheel 111 and the upper gear 105 of the gear wheel 115 may be
15 omitted and a dose indicator mark (pointer) 130 directly applied to the gear wheel 115 which slowly rotates within the cap 110. This would advantageously reduce the number of parts. However since the gear wheel 115 both rotates and moves eccentrically the dose indication will be less clear
20 and accurate. In addition the reduction in movement is reduced such the gear wheel 115 and indicator mark 130 will complete a full revolution under fewer activation of the inhaler and so the number of doses that can be indicated is reduced.

25 These embodiments of the invention all utilise relatively few parts. In addition all of these embodiments utilise reduction gear arrangements to slowly rotate a dose indicator. Such reduction gear arrangements provide a more positive and direct movement of an indicator dial or wheel
30 with the drive being constantly engaged leading to improved accuracy and less chance of breakage or jamming.

It will also be appreciated that while the detailed arrangement of the first and second embodiments differ, and they each have specific advantages, the actual reduction

gear arrangements operate in principle in a similar manner. Specifically both embodiments comprise two interengaged gears having different numbers of teeth with one of the gears being rotationally fixed and the gears being mounted so that actuation of inhaler gyrates the engagement of one of the gears around the other gear causing one to rotate relative to other with such rotation rotating a dose indicator.

Various modifications to the specific embodiments described above can of course be made. In particular the ratchet drive 3 of the first embodiment could be used in the arrangement of the second embodiment in place of the drive wheel 119. Similarly the drive wheel 115 arrangement of the second embodiment could be used in the arrangement of the first embodiment. Various other drive mechanisms for actuating and driving the dose counter, and specifically moving the respective gears of the dose counter could also be used. Indeed it will be appreciated that the particular ratchet drive and drive wheel arrangements of these embodiments simply comprises an actuator means to convert the actuation of the inhaler, and depression of the canister, into rotary motion to drive the counter mechanism and dose indicator. The particular ratchet 3 and drive wheel 119 arrangements of these embodiments are however preferred and are particularly advantageous in their own right, and indeed may comprise a further aspect of the invention.

While the dose counter in the first embodiment is located at the bottom of the inhaler and is actuated by movement of the bottom of the canister 2, the dose counter could be mounted at the top and activated by a cap in a similar manner to that described and shown in relation to the second embodiment.

It will also be recognised that the specific

arrangement of the various gears in these embodiments could be reversed and the location of the gears altered without departing from the principal of operation of the invention. For example in the second embodiment the external gear
5 wheel 115 could comprise an internal gear wheel with the fixed internal cap gear 102 and indicator gear 107 comprising external gear arrangements.

As shown in the preferred embodiments the dose indicator mark 7,130 comprise a radial pointer on the
10 indicator wheel 5,111 which rotates and points to fixed gradations 116. Other indicator arrangements are however possible. For example numbers, or other bar indications, could be printed around the periphery of the indicator wheels which are rotated passed a single fixed pointer
15 printed on the cap 6,110 or cap window 25,128. Alternatively only a small window could be provided in the cap 6,110 with such printed numbers or bars on the indicator being rotated behind the window such that they are only visible one at a time. The indicator wheel 5,111
20 could also alternatively be used to drive other further counter wheels. The dose indicator can also be arranged to either (or both) indicate the number of doses dispensed and/or the number of doses remaining.

The dose counter has been described, and is
25 particularly applicable for use with inhaler types medicament delivery devices. The dose counter could however be used in other types of medicament delivery devices which deliver repeated multiple discrete doses.

While the principle and mode of operation of this
30 invention have been explained and illustrated in its preferred embodiments it must be understood that this invention may be practised otherwise than as specifically explained and illustrated without departing from its scope.

CLAIMS

1. A dose counter for a medicament delivery device comprising a first gear which interengages a second gear at a point around the circumference of the first gear, the first and second gears having different numbers of teeth, one of the first and second gears is rotationally fixed, and the first and second gears are mounted such that an actuator, in use, when the medicament is dispensed, moves one of the first and second gears relative to the other and point of engagement between the first and second gears around the first gear thereby causing the other of the second and first gears to rotate about its own axis and rotate a dose indicator.
2. A dose counter of claim 1 wherein the first gear is fixed and the second gear, in use, rotates.
3. A dose counter of claim 1 or 2 wherein the actuator is arranged to move the second gear relative to the first gear when, in use, when the medicament is dispensed.
4. A dose counter of any preceding claim wherein there is only one tooth difference in the number of teeth on the first and second gears.
5. A dose counter of any preceding claim wherein the first and second gears comprise crown gears with teeth extending from facing axial end faces of the gears, and in which the first gear is mounted at an angle to the second gear.
6. A dose counter of claim 5 wherein the second gear is moved conically relative to the first gear.
7. A dose counter of claim 5 or 6 wherein the second crown gear has a further set of crown gear teeth extending from the opposite facing axial end face, and the dose counter further comprises a third crown gear with teeth extending from an axial end face and which interengages the

further set of crown gear teeth of the second gear at a point around the circumference of the second gear, the third crown gear being mounted such that, in use, when the medicament is dispensed, the second gear and point of engagement between the third gear and second gear moves around the third gear thereby causing the third gear to rotate about its own axis, and wherein the dose indicator is mounted on the third gear.

8. A dose counter of claim 7 wherein the third crown gear has a different number of teeth to the further set of crown gear teeth on the second gear.

9. A dose counter of any one of claim 1 to 4 wherein the first and second gears comprise corresponding internal and external gears having generally radially teeth, and in which the second gear is mounted eccentrically to the first gear.

10. A dose counter of claim 9 wherein the actuator, in use, moves the second gear around the first gear.

11. A dose counter of claim 9 or 10 wherein the first gear comprises an internal gear and the second gear comprises an external gear.

12. A dose counter of any one of claims 9 to 11 wherein the second gear comprises first and second concentric sets of gear teeth, the first set of gear teeth of the second gear engage the first gear, and the dose counter further comprises a third gear with teeth which interengage the second set of gear teeth of the second gear at a point around the circumference of the second gear, the third gear being mounted such that, in use, when the medicament is dispensed, the second gear and point of engagement between the third gear and second gears moves around the third gear thereby causing the third gear to rotate about its own axis, and wherein the dose indicator is mounted on the third gear.

13. A dose counter of claim 12 wherein the third gear has a different number of teeth to the second set of teeth on the second gear.
14. A dose counter of claim 12 or 13 the third gear is
5 coaxial with the first gear.
15. A dose counter of any preceding claim wherein the actuator converts linear intermittent motion to actuate the medicament dispenser into rotary motion to move the second gear.
- 10 16. A dose counter of claim 15 wherein the actuator comprises a drive lug and a drive wheel having at least one projection around its periphery which is engageable, in use, by the drive lug to rotate the drive wheel and move the second gear.
- 15 17. A dose counter of claim 16 wherein the drive lug and a drive wheel are mounted and arranged to, in use, when the medicament is dispensed, move relative to each other.
18. A dose counter of any preceding claim wherein the actuator comprises a ratchet mechanism.
- 20 19. A dose counter of any preceding claim wherein the dose indicator comprises a pointer.
20. A dose counter of any preceding claim further comprising an outer housing within which the first and second gears are mounted.
- 25 21. A dose counter of claim 20 wherein the outer housing includes a window through which the dose indicator is viewable.
22. A dose counter for a medicament delivery device comprising two interengaged gears having different numbers
30 of teeth with one of the gears rotationally fixed and the gears mounted so that actuation of medicament delivery device gyrates the engagement of one of the gears around the other gear so that one of the gears rotates about its own axis with such rotation rotating a dose indicator.

23. A dose counter of any preceding claim wherein the medicament delivery device comprises an inhaler.

24. A medicament delivery device including dose counter of any one of claims 1 to 20.

-1/7-

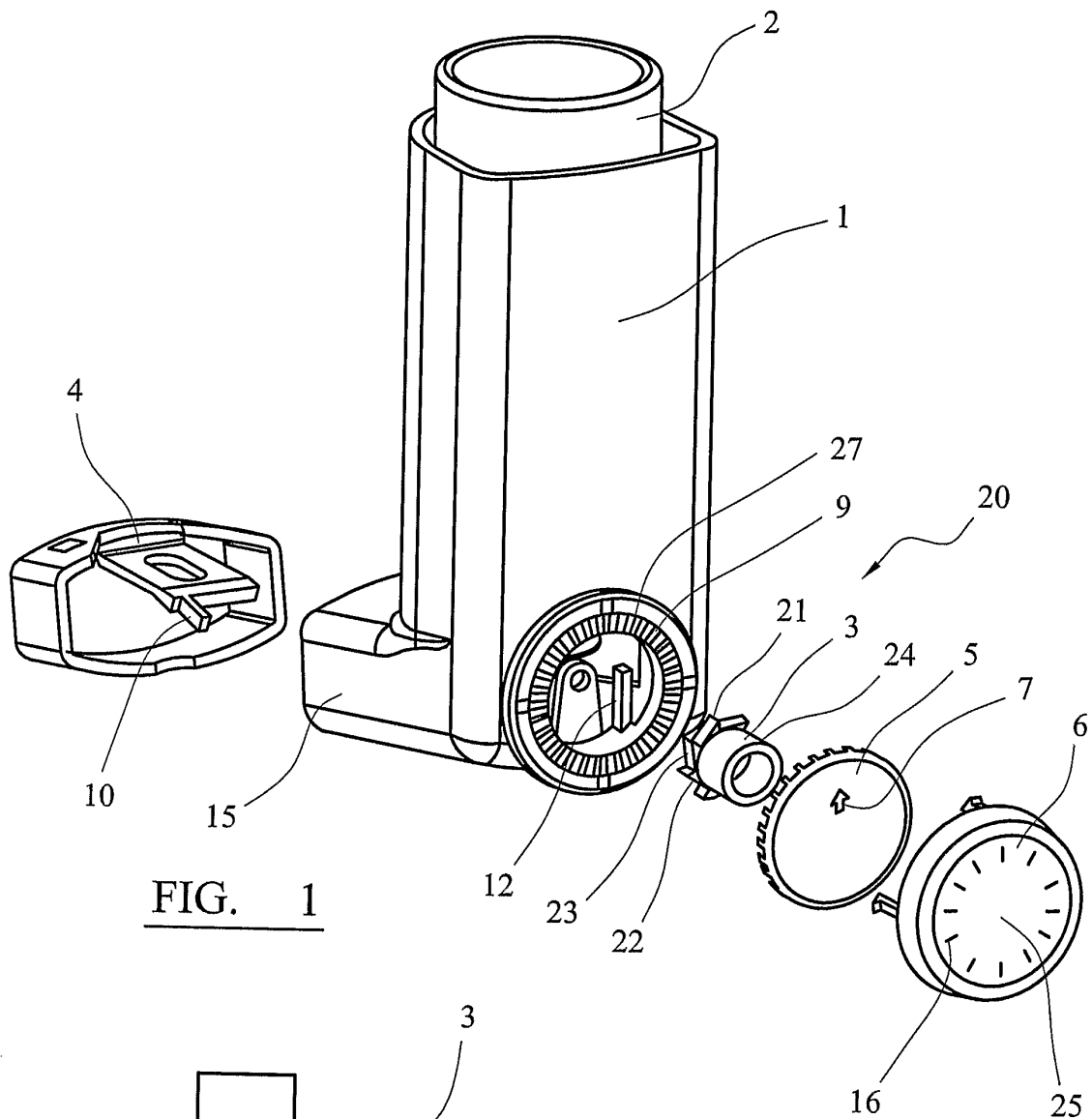


FIG. 1

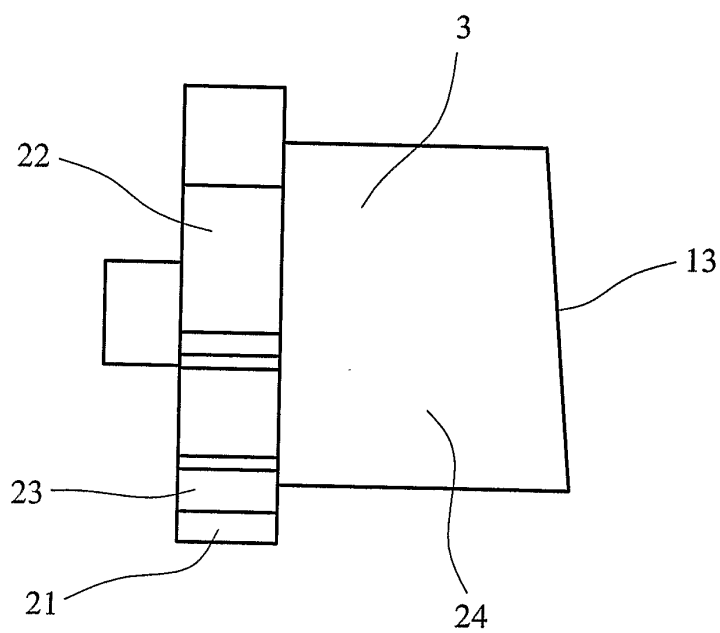


FIG. 2

SUBSTITUTE SHEET (RULE 26)

-2/7-

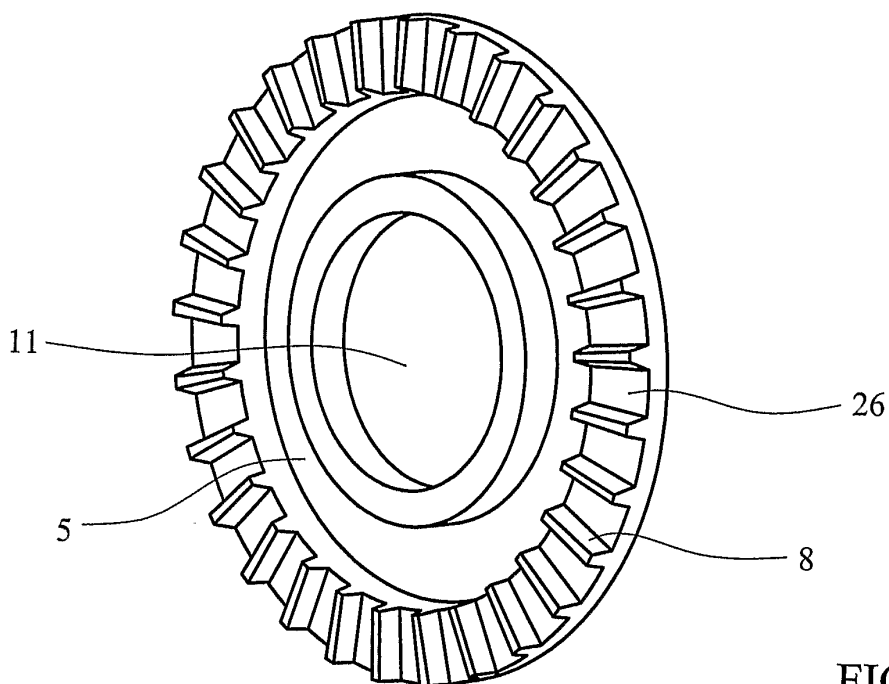


FIG. 3

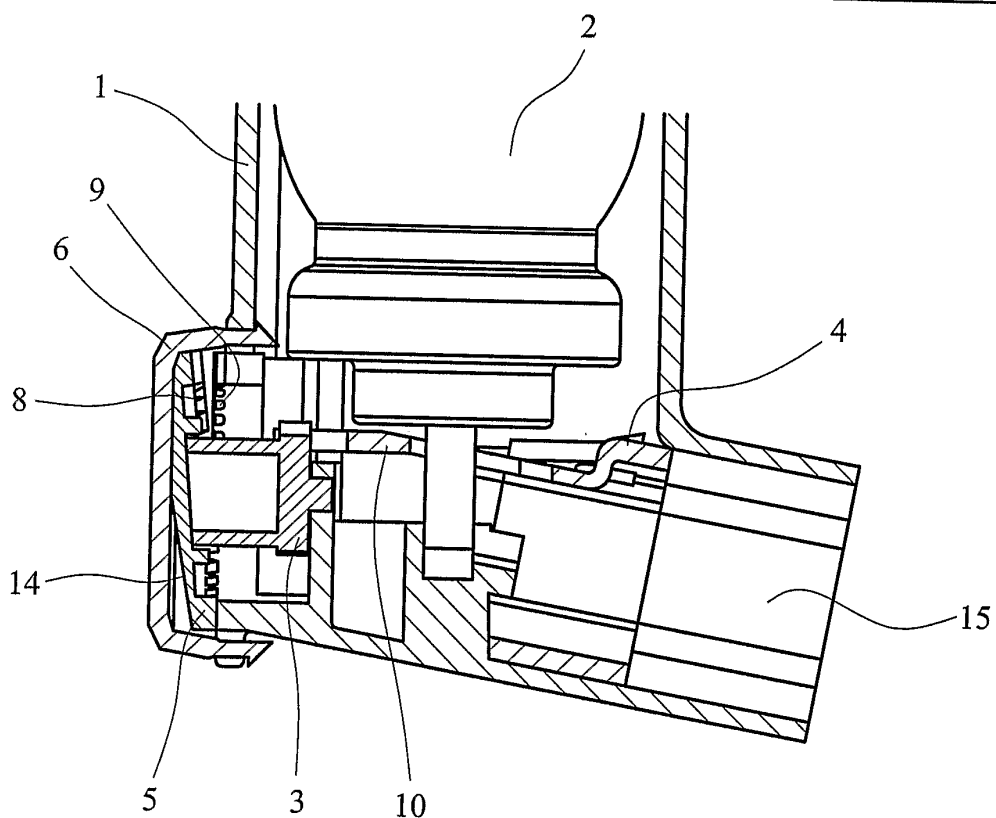


FIG. 4

SUBSTITUTE SHEET (RULE 26)

-3/7-

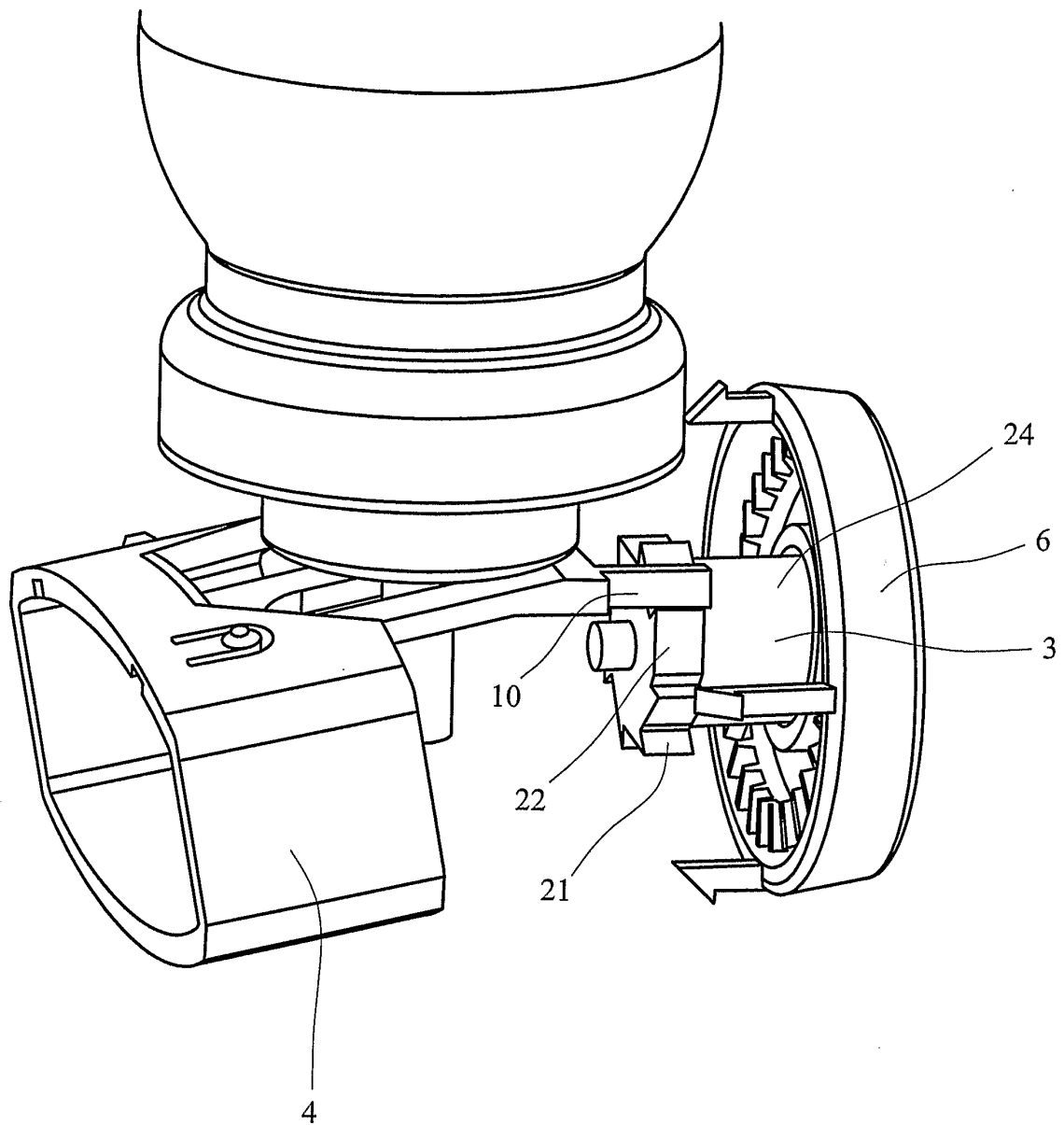


FIG. 5

SUBSTITUTE SHEET (RULE 26)

-4/7-

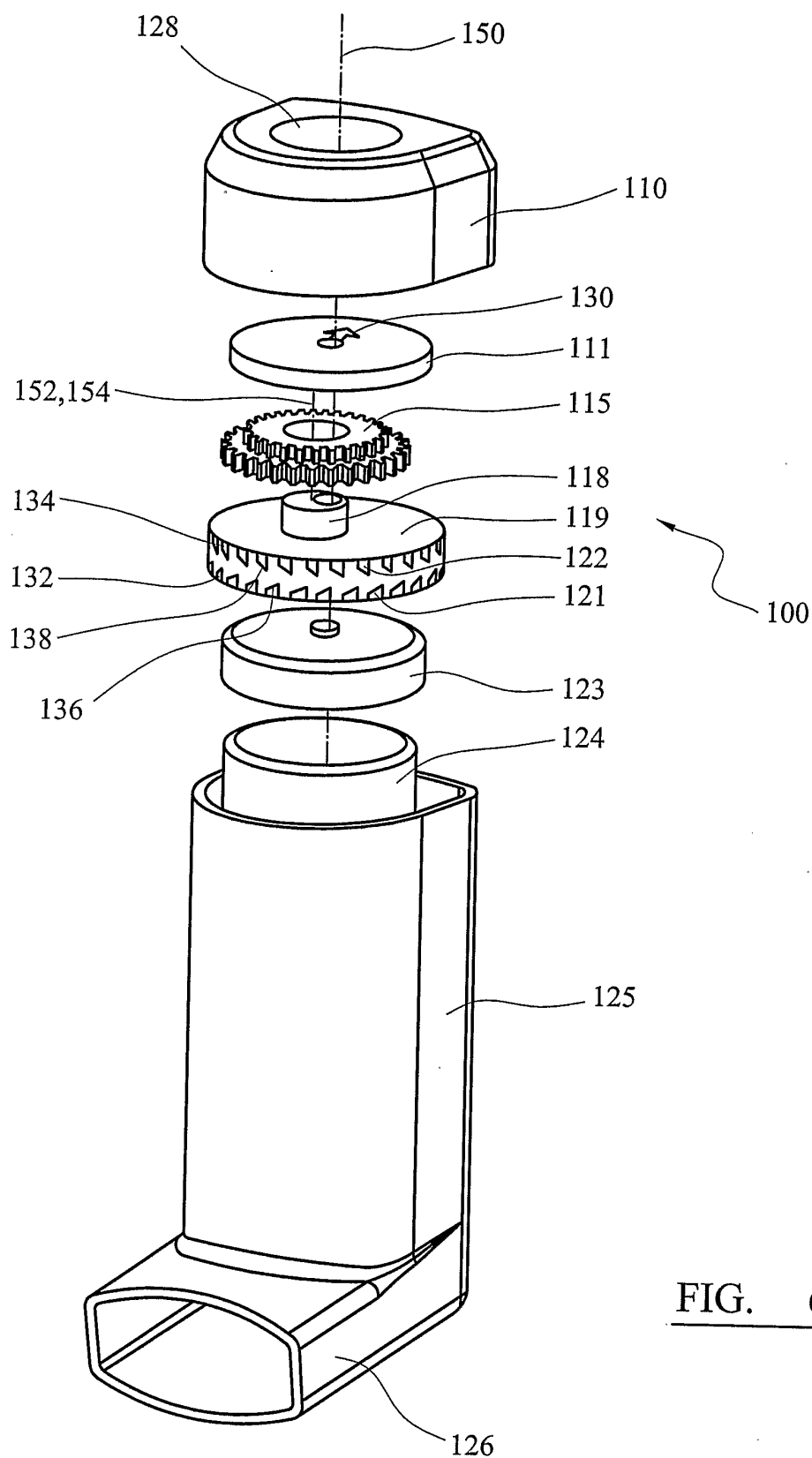


FIG. 6

SUBSTITUTE SHEET (RULE 26)

-5/7-

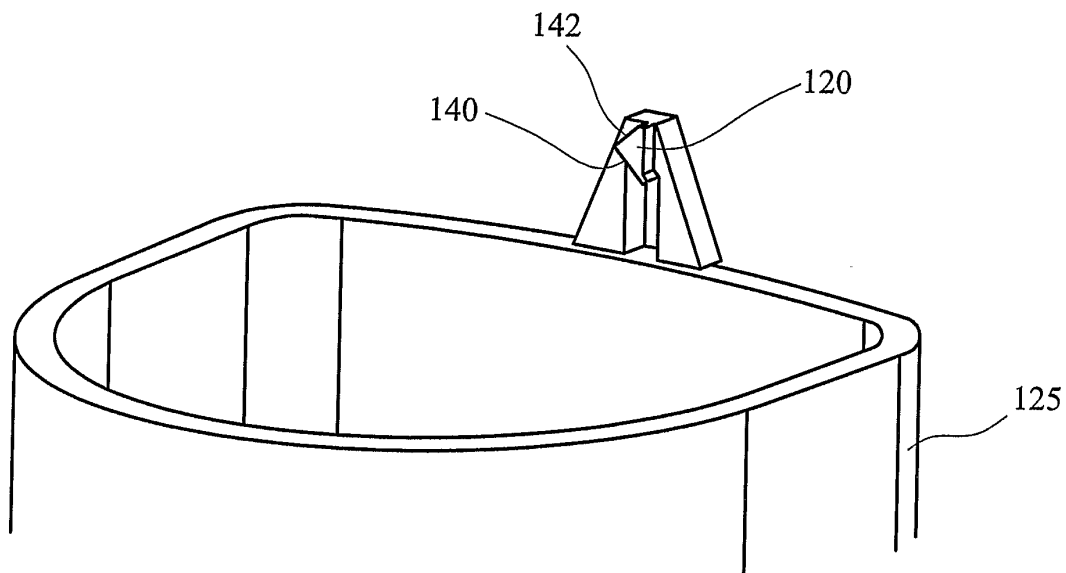


FIG. 7

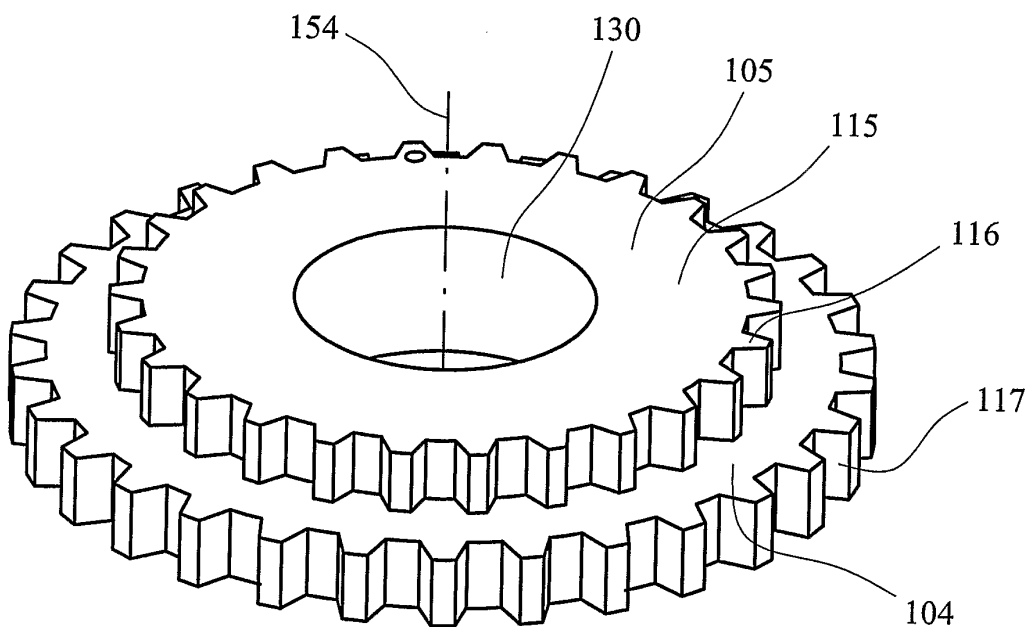


FIG. 8

SUBSTITUTE SHEET (RULE 26)

-6/7-

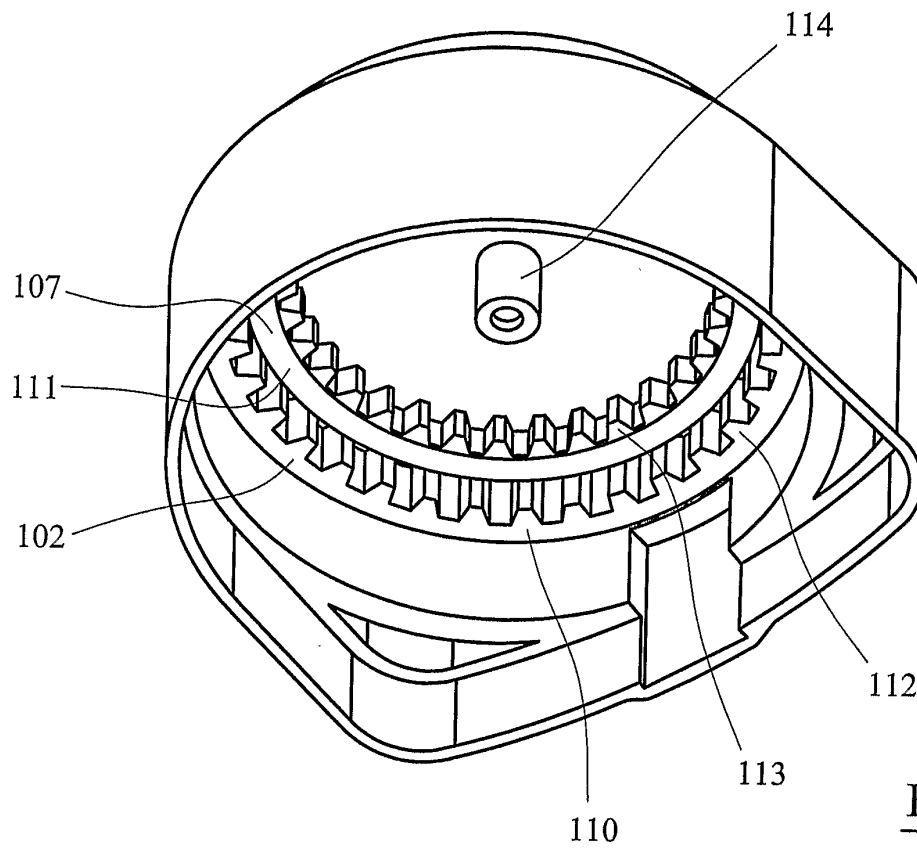


FIG. 9

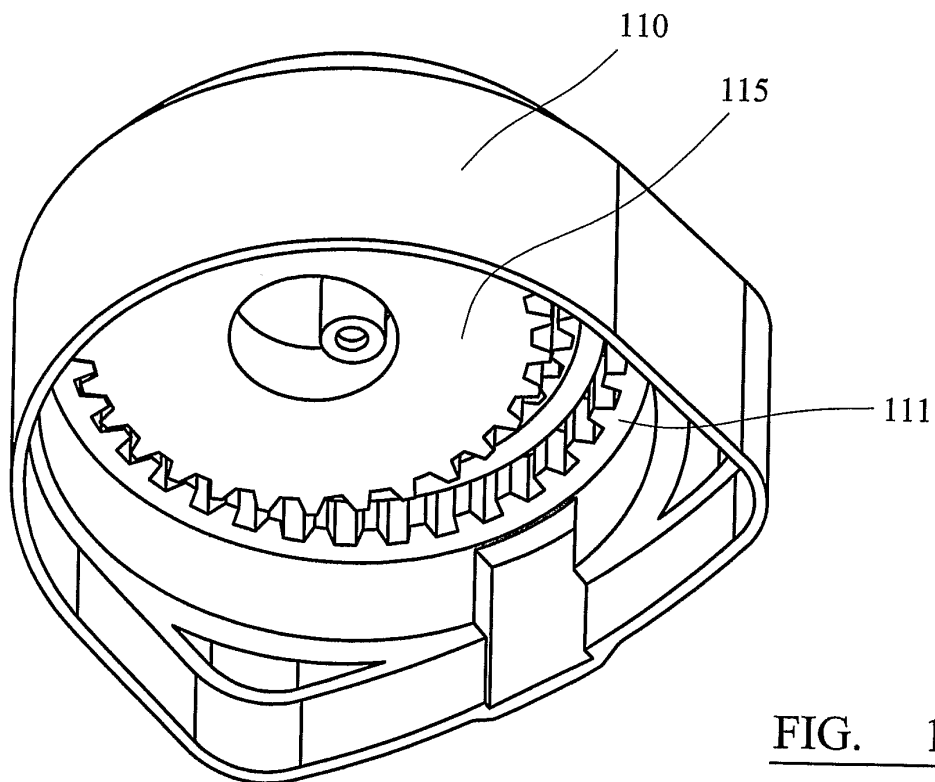


FIG. 10

SUBSTITUTE SHEET (RULE 26)

-7/7-

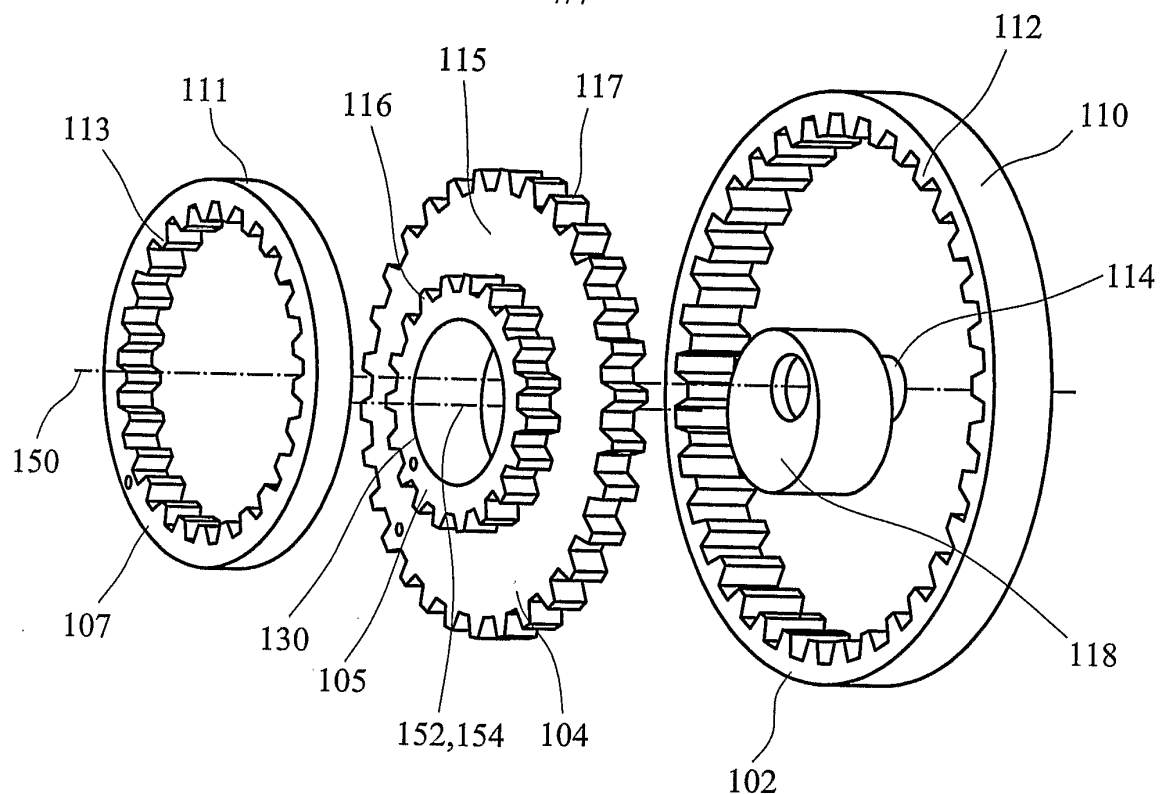


FIG. 11

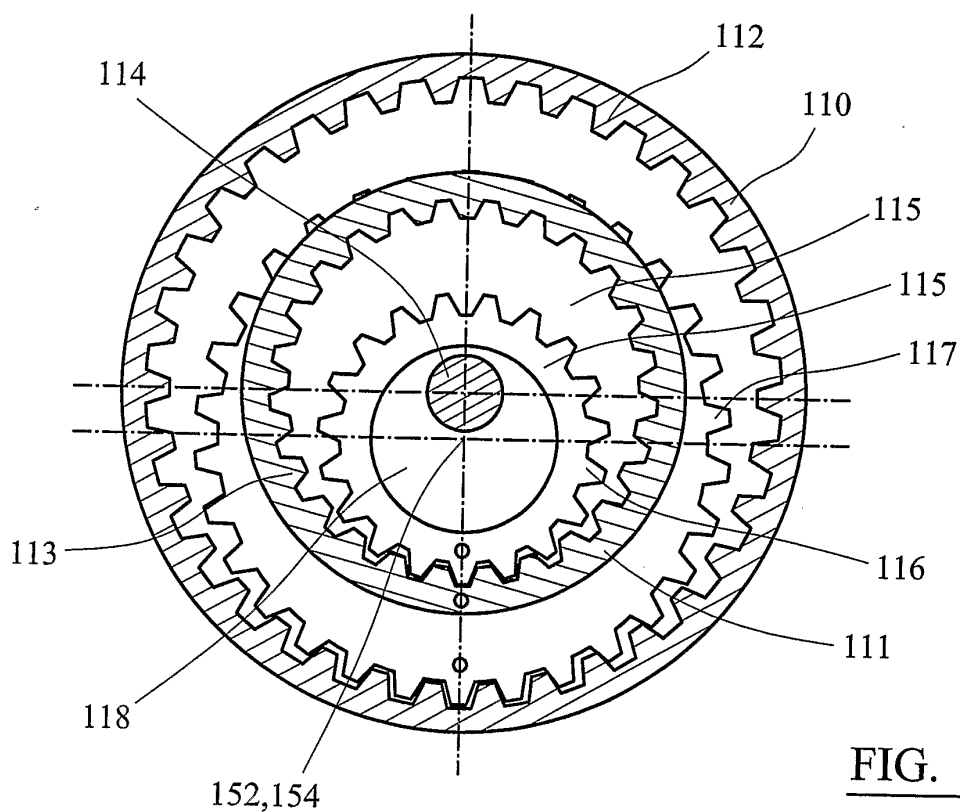


FIG. 12

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2006/003923

A. CLASSIFICATION OF SUBJECT MATTER

INV. G06M1/08 G06M1/14 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)

A61M G06M

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2004/089451 A (ERNST HOERLINS INGENJOERSBYRAA [SE]; HOERLIN ERNST [SE]) 21 October 2004 (2004-10-21) page 9, line 21 - page 10, line 17 page 17, line 23 - page 24, line 32 figures 1-3	1-24
X	EP 0 826 386 A2 (MINNESOTA MINING & MFG [US]) 4 March 1998 (1998-03-04) column 22, line 21 - column 24, line 6 figures 10,14-18	1-3, 9-11, 15-24
P, X	WO 2006/051073 A (VON SCHUCKMANN ALFRED [DE]) 18 May 2006 (2006-05-18) the whole document	1-3, 9-11, 15-18, 20-24
----- -/--		

☒ 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 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.

Z document member of the same patent family

Date of the actual completion of the international search

11 December 2006

Date of mailing of the international search report

12/01/2007

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

Azaizia, Mourad

2

Form PCT/ISA/210 (second sheet) (April 2005)

page 1 of 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2006/003923

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 2006/054083 A (CLINICAL DESIGNS LTD [GB]; BACON RAYMOND [GB]) 26 May 2006 (2006-05-26) page 9, line 32 - page 10, line 32 figures 5-8 -----	1-3, 9-11, 15-18, 20-24
A	WO 92/09324 A (MINNESOTA MINING & MFG [US]) 11 June 1992 (1992-06-11) page 8, line 20 - page 14, line 35 figures 1-11 -----	1-24
A	WO 99/36115 A2 (1263152 ONTARIO INC [CA]) 22 July 1999 (1999-07-22) the whole document -----	1-24
A	WO 2005/084736 A2 (SANNER FRIEDR GMBH CO KG [DE] SANNER FRIEDR GMBH CO KG [DE]; GIEBEL LU) 15 September 2005 (2005-09-15) pages 13-15; figures 6a-6i; example VI -----	1-24

2

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

page 2 of 2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2006/003923

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 2004089451	A	21-10-2004	SE 525061 C2 SE 0301039 A	23-11-2004 09-10-2004
EP 0826386	A2	04-03-1998	NONE	
WO 2006051073	A	18-05-2006	DE 102005033398 A1 WO 2006051006 A1	11-05-2006 18-05-2006
WO 2006054083	A	26-05-2006	NONE	
WO 9209324	A	11-06-1992	AU 9060491 A DE 69108929 D1 DE 69108929 T2 EP 0559757 A1 US 5349945 A	25-06-1992 18-05-1995 23-11-1995 15-09-1993 27-09-1994
WO 9936115	A2	22-07-1999	AU 753568 B2 AU 1777499 A CA 2315777 A1 DE 69918267 D1 DE 69918267 T2 EP 1449557 A2 EP 1047467 A2 JP 2002528144 T US 2002170920 A1 US 2006086749 A1	24-10-2002 02-08-1999 22-07-1999 29-07-2004 28-07-2005 25-08-2004 02-11-2000 03-09-2002 21-11-2002 27-04-2006
WO 2005084736	A2	15-09-2005	NONE	

Form PCT/ISA/210 (patent family annex) (April 2005)