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

IPR2018-01054 (U.S. Patent No. 8,936,177)
IPR2018-01055 (U.S. Patent No. 9,370,631)

Petitioners' Demonstratives

August 12, 2019 Oral Hearing

Introduction

1. **Unpatentability of Claims 1-3, 9 and 21 of the ’177 Patent**
    - Ground 1: Obviousness in view of Elliott + Rhoades
    - Ground 2: Obviousness in view of Bason + Rhoades

2. **Unpatentability of Claims 1-4 of the ’631 Patent**
    - Ground 1: Anticipation by Allsop
    - Ground 2: Anticipation by Marelli
    - Ground 3: Obviousness in view of Bason + Rhoades
    - Ground 4: Obviousness in view of Bason + Allsop

Instituted Grounds of Unpatentability –'177 Patent

Trial instituted for the '177 Patent (Ex. 1001)

- ***Ground 1:*** Claims 1, 2, 3, 9 and 21 are obvious over Elliott (Ex. 1006) in view of Rhoades (Ex. 1007).
- ***Ground 2:*** Claims 1, 2, 3, 9 and 21 are obvious over Bason (Ex. 1005) in view of Rhoades (Ex. 1007).

Institution Decision (Paper 11) at 2

The ’177 Patent (May 15, 2003)

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

The claims require:

(1) a fluid dispenser comprising

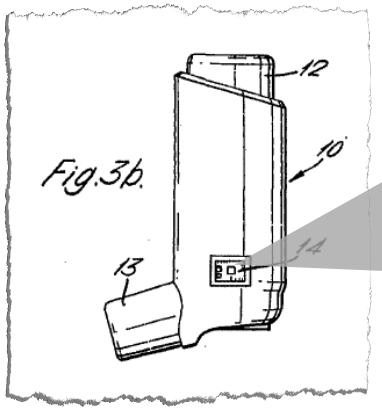
(2) a dose counter (i.e., a device for converting axial to rotational motion)

(3) wherein the dose counter functions during incomplete strokes (to prevent undercounting)

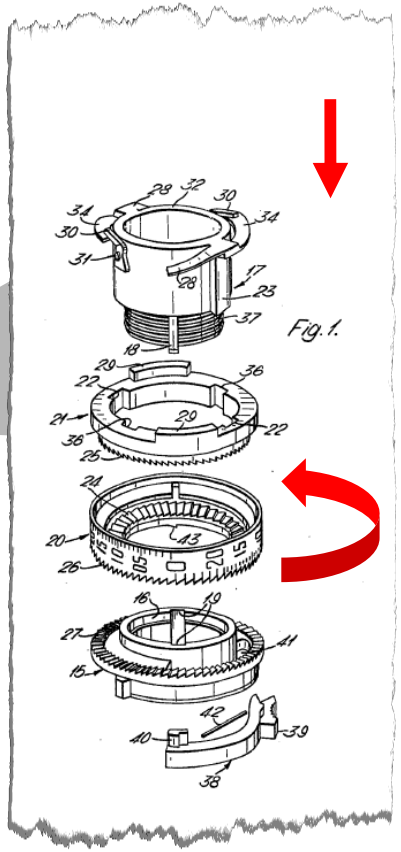
’177 Patent (Ex. 1001) at Claim 1
’177 Petition (Paper 1) at 1

Fluid Dispensers Comprising Dose Counters were Disclosed in the Prior Art

Elliott



Elliott (Ex. 1006) at Fig. 3b
'177 Petition (Paper 1) at 19



- For example, Elliott discloses a fluid dispenser having a dose counter

'177 Petition (Paper 1) at 17
Piper Decl. (Ex. 1002) at ¶ 54

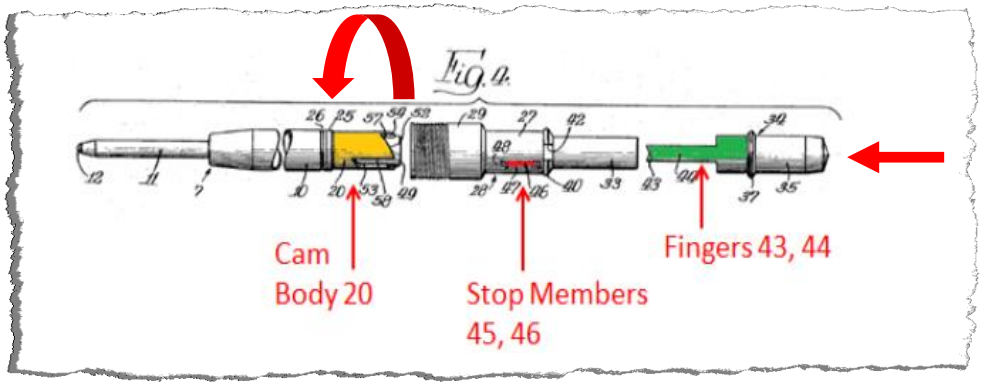
- The dose counter is a device that converts axial motion into rotational motion

'177 Petition (Paper 1) at 17
Piper Decl. (Ex. 1002) at ¶ 54

Elliott (Ex. 1006) at Fig. 1
'177 Petition (Paper 1) at 18

Rotating Mechanisms that Function During Incomplete Strokes were Disclosed in the Prior Art

Rhoades:



Rhoades (Ex. 1007) at Fig. 4
'177 Petition (Paper 1) at 23-28

- For example, Rhoades's cam body rotates before the plunger is completely depressed or released

'177 Petition (Paper 1) at 41-46
Piper Decl. (Ex. 1002) at ¶ 97
'177 Reply (Paper 28) at 13-20, 22-24

The FDA Required Manufacturers to Incorporate Those Components into MDIs

- The FDA's 2001 Draft Guidance and 2003 Final Guidance, published just two months before Aptar's priority date, required MDIs to (1) integrate dose counters and (2) avoid under-counting

'177 Petition (Paper 1) at 16

- Aptar admits it was simply "answer[ing] the FDA's call"

'177 Corrected Patent Owner Response (Paper 27) at 3

> The Agency recommends that manufacturers with metered-dose inhalers under development for oral inhalation integrate a dose-counting device into the development of their MDI drug product.

Ex. 1013 (2003 Final Guidance) at 6; '177 Petition (Paper 1) at 29

> Dose counters should be engineered to reliably track actuations and should be designed to be as close to 100 percent reliable as possible. However, if some low frequency of error is unavoidable, the device should be designed to specifically avoid undercounting (i.e., the MDI sprays, but the counter does not advance). Undercounting could result in patients assuming they have medication left in their MDI when they do not, a circumstance that is potentially dangerous.

Ex. 1013 (2003 Final Guidance) at 6; '177 Petition (Paper 1) at 33

Aptar Filed its Priority Application Two Months After FDA's Final Guidance

(12) **United States Patent**
Poulard

(10) **Patent No.: US 8,936,177 B2**
(45) **Date of Patent: Jan. 20, 2015**

(54) **FLUID PRODUCT DISPENSER**

(75) Inventor: **Fabien Poulard**, Rouen (FR)

(73) Assignee: **Aptar France SAS**, Le Neubourg (FR)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 2401 days.

(21) Appl. No.: **10/556,432**

(22) PCT Filed: **May 14, 2004**

(86) PCT No.: **PCT/FR2004/001189**
§ 371 (c)(1),
(2), (4) Date: **Nov. 9, 2005**

(87) PCT Pub. No.: **WO2004/101042**
PCT Pub. Date: **Nov. 25, 2004**

(65) **Prior Publication Data**
US 2007/0051745 A1 Mar. 8, 2007

(30) **Foreign Application Priority Data**
May 15, 2003 (FR) 03 05858

(51) **Int. Cl.**
B67D 7/22 (2010.01)
A61M 15/00 (2006.01)
G06M 1/08 (2006.01)
G06M 3/12 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 15/0065*** (2013.01); ***G06M 1/083*** (2013.01); ***G06M 3/12*** (2013.01); ***A61M 15/0068*** (2014.02)
USPC **222/36**; 128/205.23

(58) **Field of Classification Search**
CPC G06M 1/083; G06M 3/12; A61M 15/0068
USPC 222/36, 38, 162; 128/200.14, 200.23, 128/205.23
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,565,302 A * 1/1986 Pfeiffer et al. 222/38
4,817,822 A * 4/1989 Rand et al. 222/38
5,349,945 A 9/1994 Wass et al.
5,611,444 A * 3/1997 Garby et al. 215/230
5,718,355 A 2/1998 Garby et al.
5,904,139 A 5/1999 Hauser
5,988,496 A * 11/1999 Bruna ..... 235/91 R
6,142,339 A * 11/2000 Blacker et al. 222/23
6,155,251 A 12/2000 Hauser
6,161,724 A 12/2000 Blacker et al.
(Continued)

FOREIGN PATENT DOCUMENTS

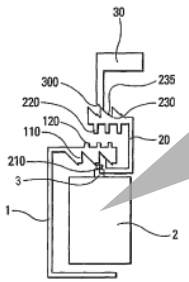
DE 100 61 723 A1 7/2002
EP 0 254 391 A1 1/1988
EP 0 480 488 A1 4/1992
EP 0 949 584 A2 10/1999
(Continued)

Primary Examiner — Lien Ngo
(74) *Attorney, Agent, or Firm* — Sughrue Mion, PLLC

(57) **ABSTRACT**

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.

22 Claims, 13 Drawing Sheets



Foreign Application Priority Data

May 15, 2003 (FR)

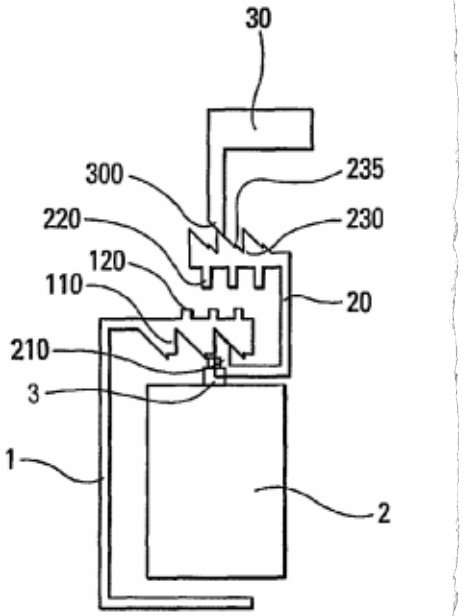


Fig. 1

'177 Patent (Ex. 1001) at cover

’177 Patent – Overview of Key Issues

Issues not in dispute

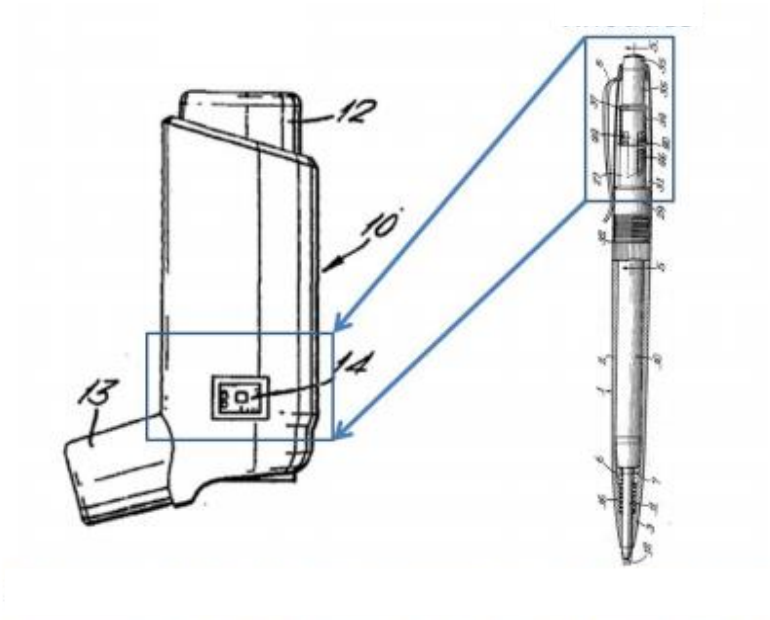
- Fluid dispensers having dose counters were known in the prior art

Issues in dispute:

- Rhoades’s disclosure of “incomplete actuation stroke” limitation (independent claim 1)
- Rhoades’s disclosure of “incomplete return stroke” limitations (dependent claim 2)
- Rhoades is analogous art
- Motivation to combine
- Operability of combinations

’177 Ground 1 – Introduction

Elliott **Rhoades**



’177 Petition (Paper 1) at 5

- Elliott discloses a fluid dispenser with a dose counter that converts axial motion to rotational motion

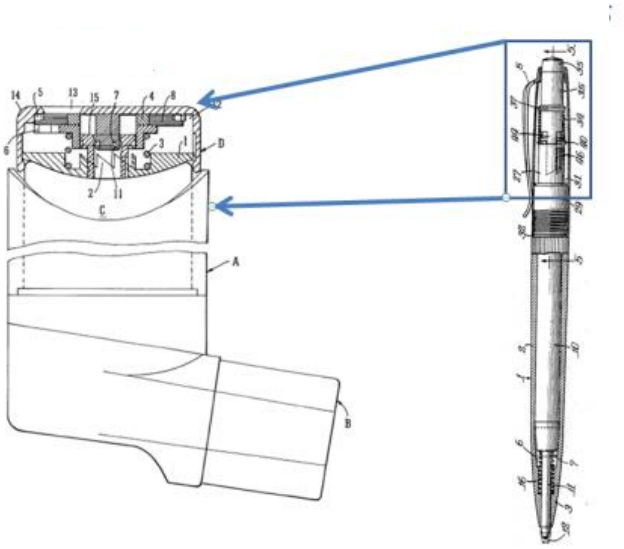
’177 Petition (Paper 1) at 17

- Rhoades discloses a fluid dispenser having a mechanism for converting axial to rotational motion that rotates upon incomplete strokes

’177 Petition (Paper 1) at 41-46

’177 Ground 2 – Introduction

Bason **Rhoades**



’177 Petition (Paper 1) at 6

- Bason discloses a fluid dispenser with a dose counter that converts axial motion to rotational motion

  ’177 Petition (Paper 1) at 20

- Rhoades discloses a fluid dispenser having a mechanism for converting axial to rotational motion that rotates upon incomplete strokes

  ’177 Petition (Paper 1) at 41-46

Rhoades Teaches an Incomplete Actuation Stroke

The Rhoades mechanism rotates upon an incomplete depression—i.e., an "incomplete actuation stroke"

'177 Petition (Paper 1) at 41-43
Piper Decl., Ex. 1002 at ¶ 97

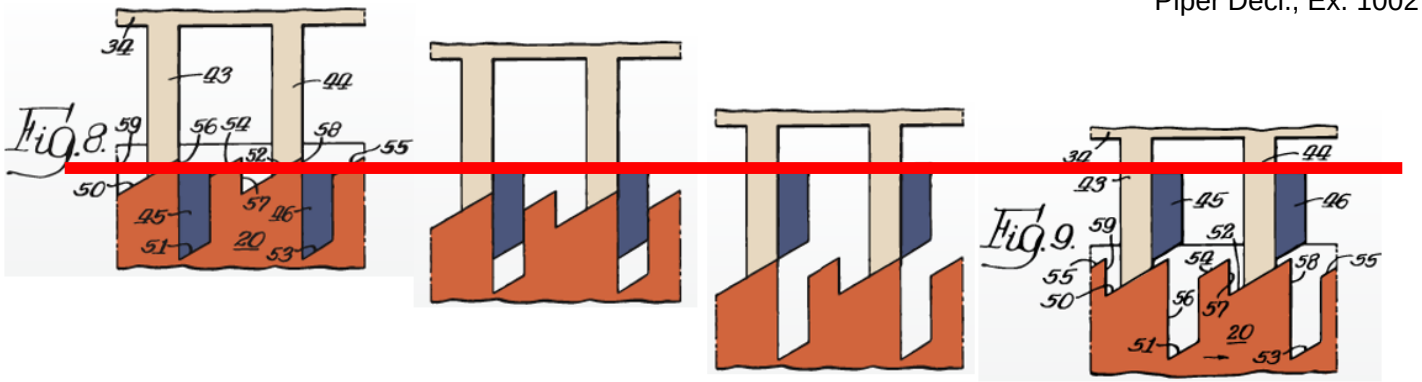


Figure 8 showing pen at rest

partial depression

stop members clear relief allowing cam body to rotate

Figure 9 showing cam body mid-rotation

Piper Decl., Ex. 1058 at ¶ 37
'177 Reply (Paper 28) at 13-20

When the cam body **20** has been depressed to an extent sufficient to permit the rearward edges of stop surfaces **56** and **58** to clear the forward edges of stop members **45** and **46** (FIG. 9), the cam body **20** is free to rotate

Rhoades (Ex. 1007) at 5:51-54
'177 Petition (Paper 1) at 42

Rhoades Teaches an Incomplete Actuation Stroke

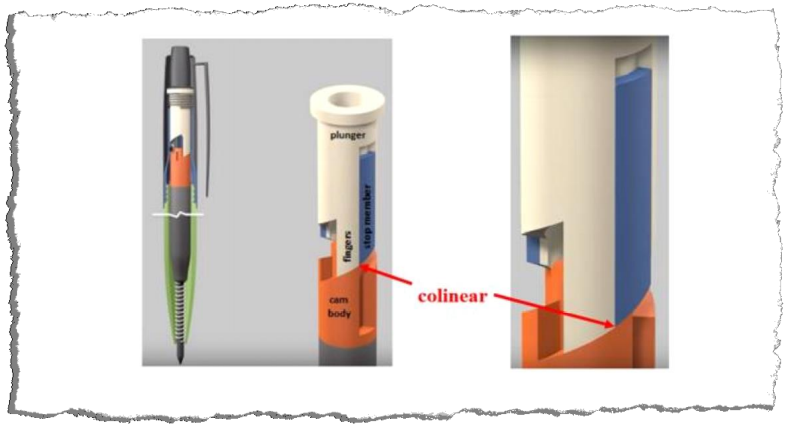
Aptar argues: a computer animation on "TheKidShouldSeeThis" website shows that Rhoades does not disclose an incomplete actuation stroke

'177 Corrected Patent Owner Response (Paper 27) at 19-24

- Aptar presents an irrelevant screenshot from the animation that clearly differs from Rhoades

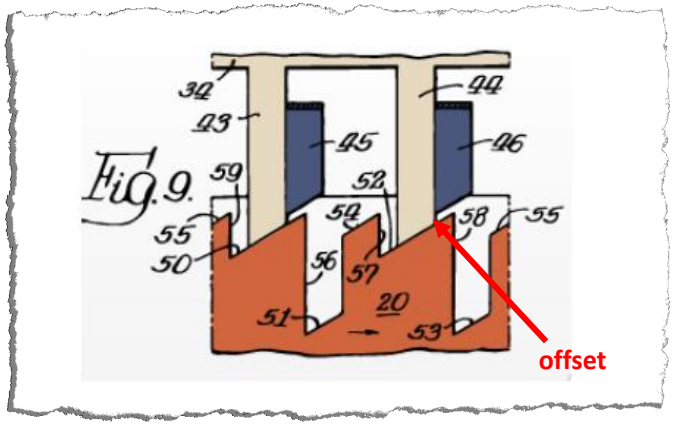
'177 Reply (Paper 28) at 13-18
Piper Decl. (Ex. 1058) at ¶ 35-37, 39-41

"TheKidShouldSeeThis.com" animation



Animation (Ex. 2020) at 1:58, 2:18; '177 Reply (Paper 28) at 16

Rhoades

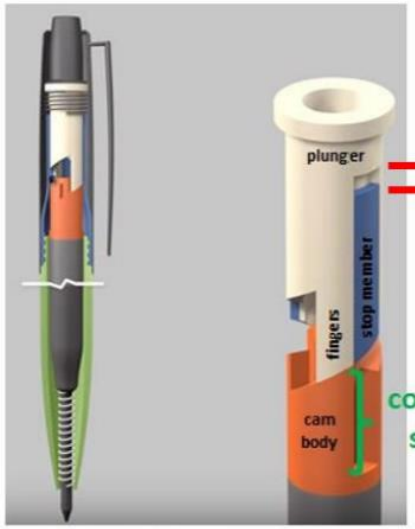


Rhoades (Ex. 1007) at Fig. 9; '177 Reply (Paper 28) at 17

Rhoades Teaches an Incomplete Actuation Stroke

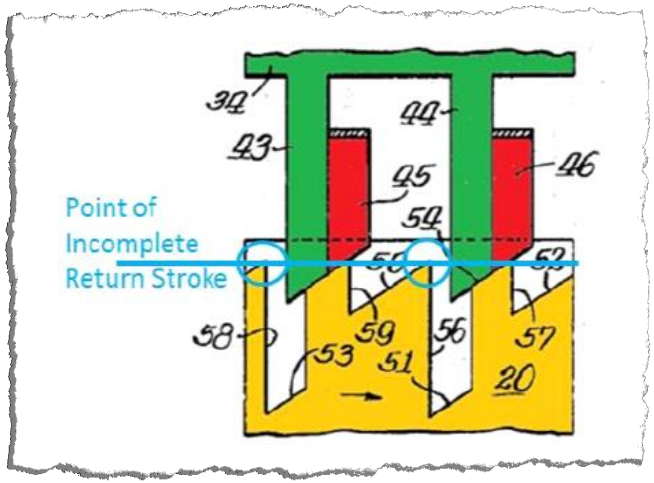
Even the animation on "TheKidShouldSeeThis.com" is not inconsistent with an "incomplete actuation stroke"

'177 Reply (Paper 28) at 14-15
Piper Decl. (Ex. 1058) at ¶ 36



'177 Reply (Paper 28) at 14-15
Piper Decl. (Ex. 1058) at ¶ 36

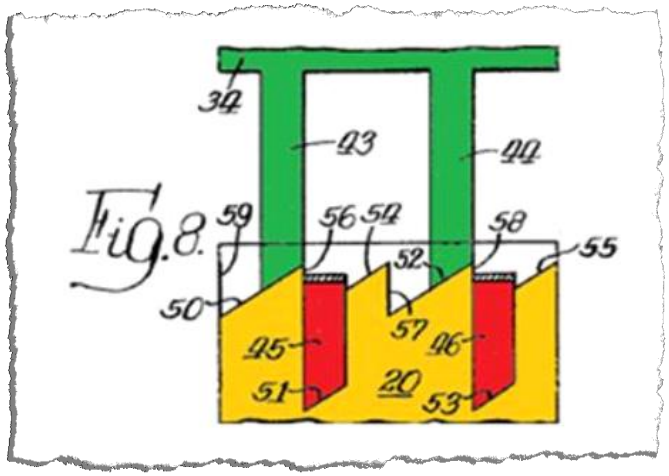
Rhoades Teaches an Incomplete Return Stroke (Claim 2)



- The point where fingers 43 and 44 pass the tip of sloped faces 50 and 52 (blue circles) is the point of the incomplete return stroke

'177 Petition (Paper 1) at 43-46
Piper Decl. (Ex. 1002) at ¶¶ 102-105

Rhoades (Ex. 1007) at Fig. 11
'177 Petition (Paper 1) at 45



- The plunger may be further released after that point

'177 Petition (Paper 1) at 43-46
Piper Decl. (Ex. 1002) at ¶¶ 102-105

Rhoades (Ex. 1007) at Fig. 8
'177 Petition (Paper 1) at 42

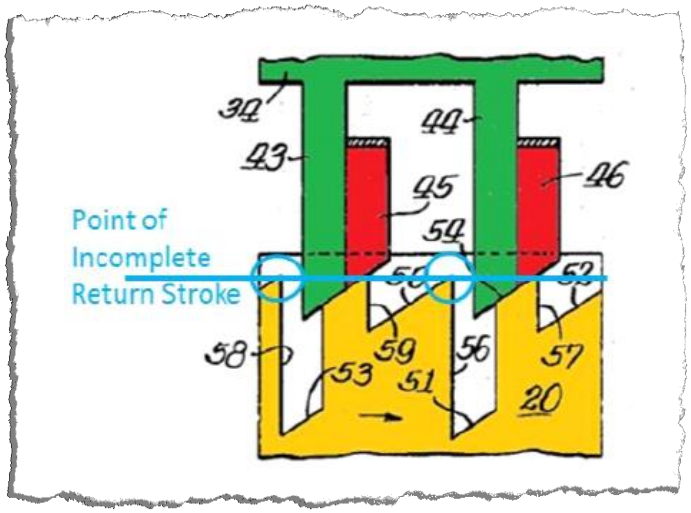
Rhoades Teaches an Incomplete Return Stroke (Claim 2)

- To prevent another dispensing of fluid before counter resets, if chamber refills with fluid at a distance X from rest, the point of the incomplete return stroke would be set to a distance of X+Y

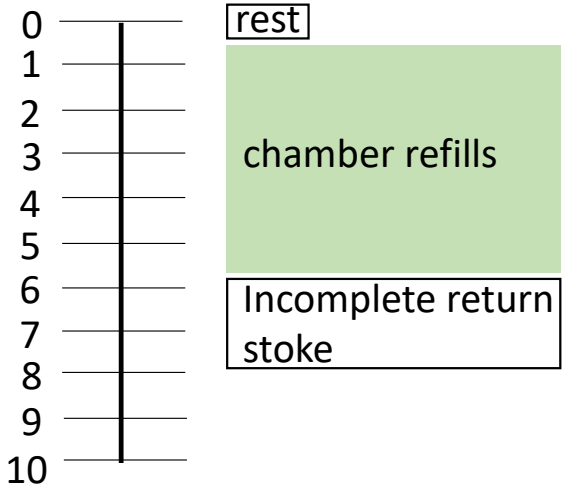
'177 Petition (Paper 1) at 33-34, 44
Piper Decl. (Ex. 1002) at ¶¶ 102-105

- Once the fingers clear the blue circles, and even if the fingers are not permitted to return to the rest position, depressing the plunger will actuate the device

'177 Petition (Paper 1) at 46
Piper Decl. (Ex. 1002) at ¶ 106



Rhoades (Ex. 1007) at Fig. 11;
'177 Petition (Paper 1) at 45; Piper Decl. (Ex. 1002) at ¶ 103



Motivation to Combine: The FDA Guidance

The FDA Guidance required all future MDIs to integrate dose counters that would avoid undercounting

'177 Petition (Paper 1) at 30
Piper Decl. (Ex. 1002) at ¶ 73

FDA Guidance:

> The Agency recommends that manufacturers with metered-dose inhalers under development for oral inhalation integrate a dose-counting device into the development of their MDI drug product.

2001 Draft Guidance (Ex. 1012) at 5; 2003 Final Guidance (Ex. 1013) at 6; '177 Petition (Paper 1) at 29

> Dose counters should be engineered to reliably track actuations and should be designed to be as close to 100 percent reliable as possible. However, if some low frequency of error is unavoidable, the device should be designed to specifically avoid undercounting (i.e., the MDI sprays, but the counter does not advance). Undercounting could result in patients assuming they have medication left in their MDI when they do not, a circumstance that is potentially dangerous.

2001 Draft Guidance (Ex. 1012) at 6; 2003 Final Guidance (Ex. 1013) at 6; '177 Petition (Paper 1) at 33

Motivation to Combine: Well-Known Mechanisms with Same Mechanical Function

- Faced with the need to mass produce MDIs with integrated dose counters, A POSA would have looked to simple mechanisms that convert axial to rotational motion

'177 Petition (Paper 1) at 30, 54
Piper Decl. (Ex. 1002) at ¶ 73, 136

- A POSA would also have looked to mechanisms that were plastic, inexpensive, and mass-produced

'177 Petition (Paper 1) at 30, 54
Piper Decl. (Ex. 1002) at ¶ 73, 136

Motivation to Combine: Well-Known Mechanisms with Same Mechanical Function

Mr. Piper testified that he relied on the mechanism of a pen when asked to build a dose counter for an MDI in 1998

'177 Petition (Paper 1) at 15, 31
Piper Decl. (Ex. 1002) at ¶¶ 17, 74

Piper Declaration:

into axial motion)). Indeed, around 1998 and sometime before 2001, in my role at Piper Medical, I was asked to design and build a dose indicator and, like others in the industry, I looked to the mechanism of a simple, plastic, inexpensive mechanical pen that converted axial motion into rotational motion. And others

'177 Petition (Paper 1) at 15, 31
Piper Decl. (Ex. 1002) at ¶¶ 17, 74

Motivation to Combine: Well-Known Mechanisms with Same Mechanical Function

Mr. Clemens's prior testimony contradicts Aptar's position that a POSA designing a medical device would not look to basic mechanisms in the art for translating linear to rotational motion

Clemens's Prior Testimony (Ex. 1056) at 100; '177 Reply (Paper 28) at 25

Mr. Clemens's testimony in a district court proceeding involving a different medical device (an injection device):

Q. So so far what I have heard you say is -- and correct me if this is wrong, please -- but the ways that you can connect the tubular part to the nut are a gearbox, which is shown in the '278 patent, or gearing or threads.

Are there any other ways?

A. Well, I mean, yes, there are other ways of converting rotational motion into linear motion. You might use cams with springs. You

* * *

A. * * *

What I have described, gears, threads, cams, I mean, you could even -- well, there are other ways of translating rotational and linear motion. They may not be optimum for this particular design, but all I am saying is that engineers take these basic mechanisms and they apply it to whatever the product or whatever they are trying to achieve in a product.

Clemens's Prior Testimony (Ex. 1056) at 100; '177 Reply (Paper 28) at 25

Motivation to Combine: Well-Known Mechanisms with Same Mechanical Function

Mr. Clemens testified in that same district court case that by "basic mechanisms" he meant mechanisms that convert linear to rotational motion through the use of gears, cams, and springs – the same components found in Rhoades

Clemens's Prior Testimony (Ex. 1056) at 98-100
'177 Reply (Paper 28) at 25

Mr. Clemens's testimony in that same district court proceeding involving a different medical device (an injection device):

Q. How else would an engineer or one of ordinary skill in the art connect the tubular part to the nut?

* * *

A. * * *
You can do that through gearing, you can do that through threads, I mean, these are, you know, basic, typically basic machines that mechanical engineers use to do this kind of thing.

* * *

A. Well, I mean, yes, there are other ways of converting rotational motion into linear motion. You might use cams with springs. You

Clemens's Prior Testimony (Ex. 1056) at 98-99; '177 Reply (Paper 28) at 25

Motivation to Combine: Tolerances

Aptar argues: a POSA would not have been motivated to use the Rhoades mechanism because it is not suitable for use in a precision device requiring strict manufacturing tolerances

'177 Corrected Patent Owner Response (Paper 27) at 32-33

- But "[t]he challenged claims do not require expressly 'close manufacturing tolerances.'"

Institution Decision (Paper 11) at 18
'177 Reply (Paper 28) at 27

- Moreover, a POSA would have known how to coordinate the tolerances to produce a successful device

'177 Petition (Paper 1) at 33, 34
Piper Decl. (Ex. 1002) at ¶ 19-22, 78

Motivation to Combine: Tolerances

Aptar argues: Rhoades teaches away from using its mechanism in devices requiring close tolerances

'177 Corrected Patent Owner Response (Paper 27) at 32-33

Rhoades passage cited by Aptar:

> None of the operating parts of the projecting-retracting mechanism in accordance with my invention requires close manufacturing tolerances for dependable operation.

Rhoades (Ex. 1007) at 8:14-16

- But stating that close manufacturing tolerances may not be needed is not the same as discouraging the use of close tolerances if desired

'177 Reply (Paper 28) at 27

"A reference that merely expresses a general preference for an alternative invention but does not criticize, discredit, or otherwise discourage investigation into the claimed invention does not teach away."

Meiressone v. Google, Inc., 849 F.3d 1379, 1382 (Fed. Cir. 2017)

Motivation to Combine: Ease of Use

Aptar argues: a POSA would not have looked to Rhoades because it would have resulted in a "double click" inhaler

'177 Corrected Patent Owner Response (Paper 27) at 24

- Aptar presents insufficient evidence why a "double click" mechanism would be inadequate

'177 Corrected Patent Owner Response (Paper 27) at 24

- A "double click" inhaler would have the advantage of avoiding the problem of "loss of prime"

'177 Petition (Paper 1) at 35, 59; Piper Decl. (Ex. 1002) at ¶¶ 80, 142

- Mr. Piper testified that a POSA could have easily modified Rhoades to implement a single "depress-and-release" MDI

'177 Petition (Paper 1) at 35-36, 59-60
Piper Decl. (Ex. 1002) at ¶¶ 81, 143

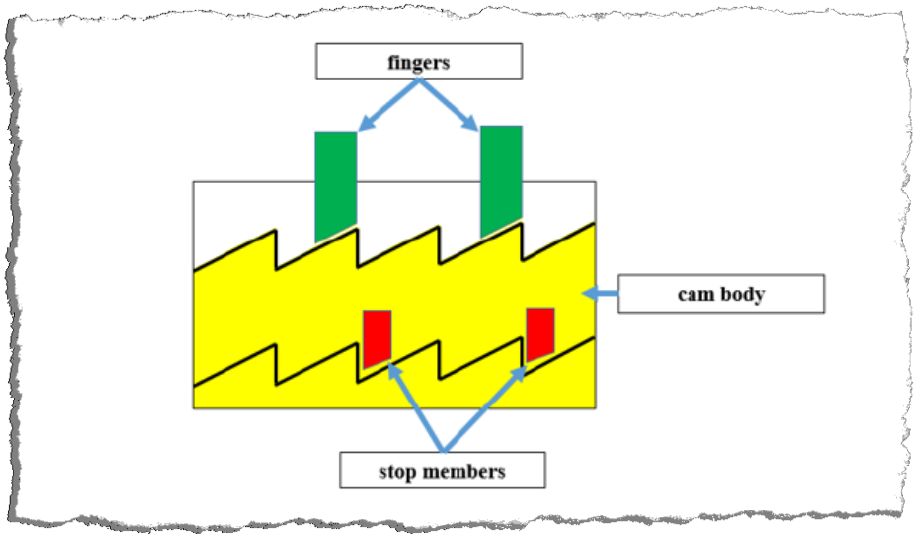
Motivation to Combine: Ease of Use

Mr. Piper described how a POSA would have implemented the single "depress-and-release" alternative:

- "Rather than two gears with separate heights, a POSA would have simply used a single row of teeth, all of the same height, and separately incorporated a second row of teeth of the same height to interact with stop members."

Piper Decl. (Ex. 1002) at ¶ 81
'177 Petition (Paper 1) at 35-36

Piper Declaration:



Piper Decl. (Ex. 1058) at ¶ 48
'177 Reply (Paper 28) at 21

Rhoades is Analogous Art

"Criteria for determining whether prior art is analogous may be summarized as (1) whether the art is from the same field of endeavor, regardless of the problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, ***whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved.***"

Sci. Plastic Prod., Inc. v. Biotage AB, 766 F.3d 1355, 1359 (Fed. Cir. 2014)

Rhoades is Analogous Art

1. **Mr. Piper:** Around 1998, when asked to build a dose counter for an MDI, Mr. Piper "looked to the mechanism of a simple, plastic, inexpensive mechanical pen that converted axial motion into rotational motion."

   Piper Decl. (Ex. 1002) at ¶ 17
   '177 Petition (Paper 1) at 15

2. **Mr. Clemens:** Testifying in another IPR regarding a safety device to protect needles, Mr. Clemens admitted the device has "simple mechanical structures and interfaces . . . [that] can be found in an age-old mechanisms of a retractable ball point pen."

   Clemens's Prior Testimony (Ex. 1055) at ¶ 47
   '177 Reply (Paper 28) at 25

3. **Prior Art MDIs:** "The device for rotating the rod [of the MDI] is an indexing mechanism much like that of a ball-point pen."

   Ambrosio (Ex. 1031) at 2:36-47
   '177 Petition (Paper 1) at 55

Rhoades is Analogous Art

Mr. Clemens's prior testimony contradicts Aptar's position that a POSA would not have looked to the Rhoades pen mechanism when designing a medical device

'177 Reply (Paper 28) at 25

Mr. Clemens in another IPR proceeding:

47. The safety device claimed by the challenged claims of the '011 Patent, thus, has simple mechanical structures and interfaces to protect the needle and prevent accidental needle sticks. *Id.*, 1:45-48. Such a mechanism can be found in an age-old mechanisms of a retractable ball point pen. It also has been utilized in needle safety devices, such as in the prior art Carrel and David-Hegerich references.

Clemens's Prior Testimony (Ex. 1055) at ¶ 47
'177 Reply (Paper 28) at 25

Rhoades is Analogous Art

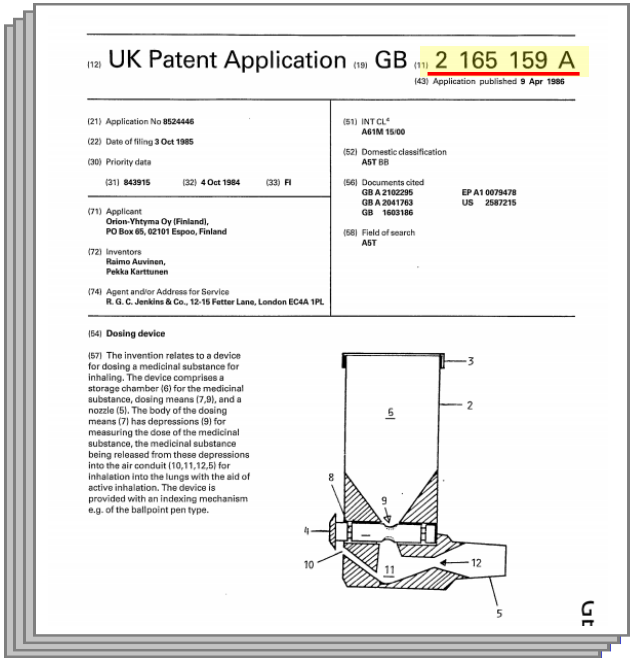
Ambrosio 1991 discusses a prior art MDI having a mechanism like that of a ball-point pen

'177 Petition (Paper 1) at 55;
Piper Decl. (Ex. 1002) at ¶ 75

Ambrosio 1991:

U.K. Patent No. 2,165,159 to Auvinent et al. discloses a dosing device having a fixed storage chamber for a medicinal powder, a mouthpiece and a venturi restriction between the mouthpiece and the storage chamber. A metering device is provided in the housing between the venturi restriction and the storage chamber and includes a rod having depressions therein for measuring the dose of the medicinal substance. The rod is rotatable to thereby deposit the medicinal powder in a depression thereof to the venture restriction. The device for rotating the rod is an indexing mechanism much like that of a ball-point pen. However, because of the cup-like arrangement of this patent, adhesion can occur along the walls of each depression, which is disadvantageous from a delivery viewpoint. See also European Patent

Ambrosio (Ex. 1031) at 2:36-47; '177 Petition (Paper 1) at 55



(12) UK Patent Application (19) GB (11) 2 165 159 A
(43) Application published 9 Apr 1986

(21) Application No 8524446
(22) Date of filing 3 Oct 1985
(30) Priority data
(31) 843915 (32) 4 Oct 1984 (33) FI
(71) Applicant
Orion-Yhtyma Oy (Finland),
PO Box 65, 02101 Espoo, Finland
(72) Inventors
Raimo Auvinen,
Pekka Karttunen
(74) Agent and/or Address for Service
R. G. C. Jenkins & Co., 12-15 Fetter Lane, London EC4A 1PL

(51) INT CL⁴
A61M 15/00
(52) Domestic classification
A5T BB
(56) Documents cited
GB A 2102295
GB A 2041763
GB 1603186
EP A1 0079478
US 2587215
(58) Field of search
A5T

(54) Dosing device

(57) The invention relates to a device for dosing a medicinal substance for inhaling. The device comprises a storage chamber (6) for the medicinal substance, dosing means (7,9), and a nozzle (5). The body of the dosing means (7) has depressions (9) for measuring the dose of the medicinal substance, the medicinal substance being released from these depressions into the air conduit (10,11,12,5) for inhalation into the lungs with the aid of active inhalation. The device is provided with an indexing mechanism e.g. of the ballpoint pen type.

The Ground 1 and 2 Combinations are Operable

"A person of ordinary skill is also a person of ordinary creativity, not an automaton."

KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007)

'177 Reply (Paper 28) at 1, 4

The Ground 1 and 2 Combinations are Operable

Aptar discussing the ’177 specification during prosecution:

> “One of ordinary skill would understand the structure and connection of a body, reservoir, actuator, counter and dispenser member … ***[they] need not be disclosed.***”

’177 Prosecution History (Ex. 1004) at 1134; ’177 Reply (Paper 28) at 2; *see also* ’177 Prosecution History (Ex. 1004) at 255, 258-259, 281-285, 1137-1139, 1149-1150, 1158-1166, 1190-1205, 1229-1233, 1281:10-1282:1-4, 1292:13-15; ’177 Petition (Paper 1) at 1-2, 10, 13, 62-63; ’177 Reply (Paper 28) at 2-3, 9, 30

Clemens testifying about the ’177 specification:

> Q Well, I guess what I'm asking you is: Where is that part of it coming from? Where is that knowledge about how to set the inhalation flow path coming from?
>
> A I guess it comes from -- what? -- over 50 years of development of metered-dose fluid-dispensing devices.

Clemens Tr. (Ex. 1077) at 43:23-44:16; ’177 Sur-Reply (Paper 45) at 3

The Ground 1 and 2 Combinations are Operable

When an applicant "did not provide the type of detail in his specification that he now argues is necessary in prior art references, [this] supports [a] finding that [a POSA] would have known how to implement the features of the references."

In re Epstein, 32 F.3d 1559, 1568 (Fed. Cir. 1994)

'177 Reply (Paper 28) at 1, 4

The Ground 1 and 2 Combinations are Operable: Snap-Fit Assembly

Aptar argues: the Ground 1 and 2 combinations would be inoperable because the cam body could not have been snap-fit past the stop members

'177 Corrected Patent Owner Response (Paper 27) at 37-38
'177 Sur-Reply (Paper 31) at 4-5

- But Mr. Clemens admitted that the use of snap-fits to connect the components of medical devices was known

Clemens Tr. (Ex. 1077) at 55:11-56:18, 71:3-7
'177 Sur-Sur-Reply (Paper 45) at 4-5

Mr. Clemens:

Q Have you ever utilized snap-fits in any of the devices that you've worked on?
A Sure.
* * *
Q Were any of these devices respiratory medical devices that have snap-fits that you worked on?
A I would refer to my previous answer that I gave just a few minutes ago, that some of those were related to inhaler devices.

Clemens Tr. (Ex. 1077) at 55:11-56:18, 71:3-7;
'177 Sur-Sur-Reply (Paper 45) at 4-5

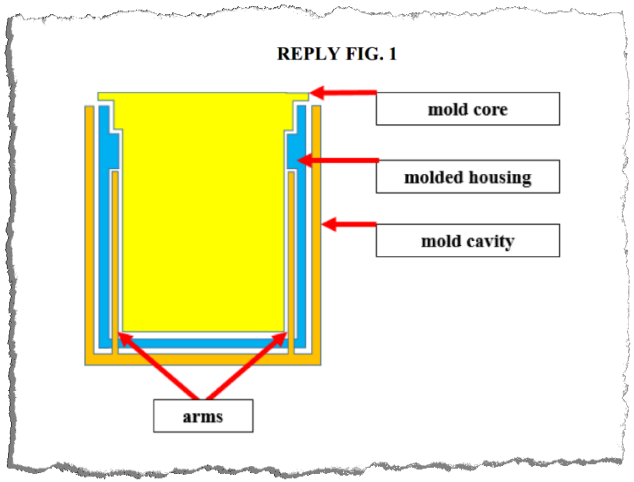
The Ground 1 and 2 Combinations are Operable: Injection Molding

Aptar argues: the Ground 1 and 2 combinations would be inoperable because no suitable injection molding tooling design existed to make them

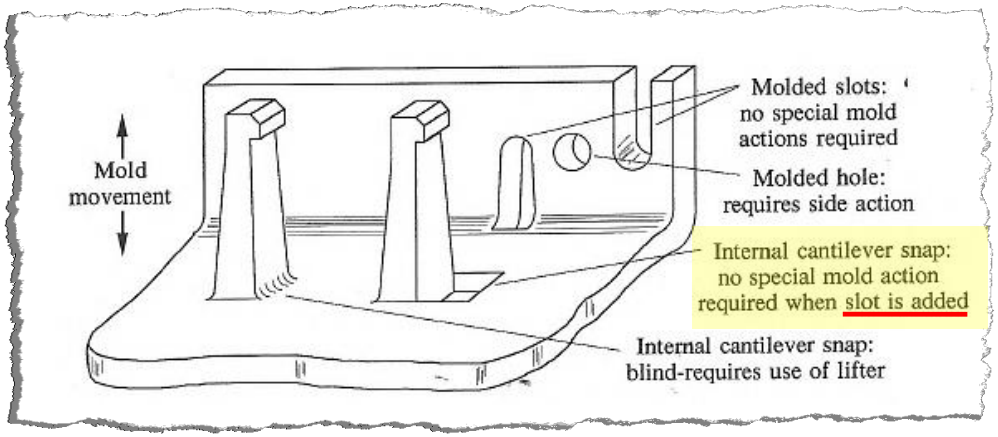
'177 Corrected Patent Owner Response (Paper 27) at 37-38

- But the 1994 treatise cited by Aptar describes how a POSA would have designed the injection molding tool

'177 Reply (Paper 28) at 6
Injection Molding Treatise (Ex. 2018) at 99



'177 Reply (Paper 28) at 6
Piper Dec. (Ex. 1058) at ¶ 11



Injection Molding Treatise (Ex. 2018) at 99
'177 Reply (Paper 28) at 6

The Ground 1 and 2 Combinations are Operable: Injection Molding

Aptar argues: the injection molding tool would be cost prohibitive

'177 Sur-Reply (Paper 31) at 7

- But Aptar's cited 1994 treatise teaches that this design, which has a slot in the line of draw, would eliminate added tooling cost

'177 Reply (Paper 28) at 6
Injection Molding Treatise (Ex. 2018) at 99
Clemens Tr. (Ex. 1077) at 22:23-23:11
'177 Sur-Sur-Reply (Paper 45) at 2

Aptar's Cited 1994 Treatise:

the cavity as the mold opens. The side action, and added tooling cost, could be eliminated if the part is designed with consideration towards ejection. For example, the hole could be replaced by a slot in the line of draw, and as a result, no special side actions or core pulls are required.

'177 Sur-Sur-Reply (Paper 45) at 2
Injection Molding Treatise (Ex. 2018) at 99

The Ground 1 and 2 Combinations are Operable: Injection Molding

Mr. Clemens agreed that the relevant tool included a slot in the line of draw

'177 Sur-Sur-Reply (Paper 45) at 2
Clemens Tr. (Ex. 1077) at 22:23-23:11

Mr. Clemens:

Q . . .

You agree that petitioners' tool design adds holes to the bottom of the housing; correct?

A Holes would be formed in some part of the housing, which is proximal to the flow path, not really

* * *

Q And those holes are in the line of draw; correct?

THE WITNESS: They would be in the line of draw. Correct.

Clemens Tr. (Ex. 1077) at 22:23-23:11

The Ground 1 and 2 Combinations are Operable: Injection Molding

Aptar argues: the Ground 1 and 2 combinations are inoperable because the tooling design would interfere with the inhalation flow path

'177 Corrected Patent Owner Response (Paper 27) at 12
'177 Sur-Reply (Paper 31) at 5-6

- But Mr. Clemens admitted a POSA would have known how to set a proper inhalation flow path

'177 Sur-Sur-Reply (Paper 45) at 3-4

Q How do through holes affect the inhalation flow path?

* * *

A . . .

I'm not going to be able to, you know, completely answer the question in terms of a particular instance, because we don't, you know, have the tools in front of us to run it and to actually define what those are, but, for instance, one of the effects could be -- well, necessarily would be the addition of high velocity fresh air being injected into an already established flow path, and that would -- in MDIs, it's

* * *

Q Are there any ways for skilled artisans to reduce the amount of fresh air being injected into a flow path?

A Certainly. There could be ways to do that.

Clemens Tr. (Ex. 1077) at 38:24-40:7

The Ground 1 and 2 Combinations are Operable: Injection Molding

Mr. Clemens admits that the ’177 specification lacks the type of detail for setting a proper inhalation flow path that he argues is necessary in the prior art

Mr. Clemens:

Clemens Tr. (Ex. 1057) at 137:16-138:16
’177 Reply (Paper 28) at 7

Q. (BY MR. WEIL) Mr. Clemens, can you turn back to the "177 Patent? That's Exhibit 1001. Earlier we were discussing the inhalation flow path and how modifications can affect the inhalation flow path. Does the "177 Patent describe the effect of these components on the inhalation flow path?

A. Again, no, I don't believe -- I believe that the patent is directed towards an invention which has been broadly -- broadly claimed, and so I believe that the intent is that you would have a flow path but that

* * *

Q. So it doesn't disclose anything about the flow path of that device. Is that right?

A. It's generally, or I should say broadly, written in terms of its claims relative to the safety features of a counter -- of a counting system. So I believe the intent is that the invention would apply to, you know, all the flow paths that you would design around it.

When an applicant “did not provide the type of detail in his specification that he now argues is necessary in prior art references, [this] supports [a] finding that [a POSA] would have known how to implement the features of the references.” *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994).

The Ground 1 Combination is Operable: Placement of Spring

Aptar argues: a POSA would not have known how to locate a biasing spring in the Elliott / Rhoades combination

'177 Corrected Patent Owner Response (Paper 27) at 15-17

- But Mr. Clemens admits that the '177 specification lacks the type of detail for properly locating a spring that he argues is necessary in the prior art

Clemens Tr. (Ex. 1077) at 102:25-103:15
'177 Sur-Sur-Reply (Paper 45) at 7

Mr. Clemens:

Q Despite the fact that the return spring is not shown, is it your position that a skilled artisan would be able to figure out where to place that return spring in order to operate the fluid dispenser disclosed in embodiment 1 of the '631 patent?

THE WITNESS: So given that the invention here is shown schematically, although the interactions are described and helpful features are shown to do that, it gives a skilled artisan the broad -- a broad approach to how this could be achieved. So there could be many solutions. So given that, it isn't being too specific on the reduction of art. I would say that, you know, there would be many, many options that could possibly work, and the skilled artisan would be able to latch onto one of those.

Clemens Tr. (Ex. 1077) at 102:25-103:15

The Ground 2 Combination is Operable: Rotation of Canister Relative to Valve Stem

Aptar argues: the Bason / Rhoades combination is inoperable because a canister cannot rotate relative to the valve stem

'177 Corrected Patent Owner Response (Paper 27) at 38-39

- But Mr. Piper explained why Aptar is incorrect and proved that prior art canisters rotated relative to the valve stem

'177 Reply (Paper 28) at 11
Piper Decl. (Ex. 1058) at ¶¶ 21-29

Prior Art MDI

Piper Decl. (Ex. 1058) at ¶¶ 21-29; '177 Reply (Paper 28) at 11

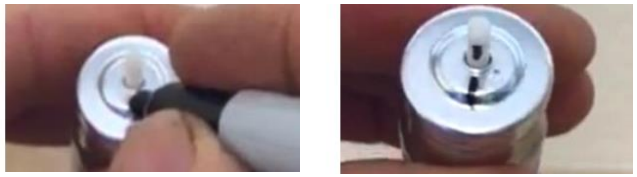
The Ground 2 Combination is Operable: Rotation of Canister Relative to Valve Stem

Mr. Piper demonstrated that prior art canisters rotated relative to the valve stem

'177 Reply (Paper 28) at 11
Piper Decl. (Ex. 1058) at ¶¶ 21-29

Albuterol MDI Demonstration (Ex. 1060):

1. Lines aligned on valve and canister



2. Rotation of canister

3. Lines no longer aligned

Piper Decl. (Ex. 1058) at ¶¶ 21-29
'177 Reply (Paper 28) at 11

There Was No Long-Felt Need

Aptar admitted that it responded to a shortly felt regulatory requirement

'177 Corrected Patent Owner Response (Paper 27) at 51

- Aptar admitted that in developing its alleged invention it "set out to answer the FDA's call"

'177 Corrected Patent Owner Response (Paper 27) at 3
'177 Reply (Paper 28) at 28

- Aptar has not sufficiently shown that there was a persistent, unmet need

'177 Reply (Paper 28) at 28-30

"Ecolochem's process was developed not in response to a long-felt need in the power industry, but in response to a shortly felt requirement imposed by EPRI's guidelines."

Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1377 (Fed. Cir. 2000)

There Was No Failure of Others

Aptar argues: "drug makers (including Petitioners) failed to create an accurate MDI dose counter"

'177 Corrected Patent Owner Response (Paper 27) at 51

- But Aptar fails to identify any evidentiary support for its conclusory assertion that ***anyone***, let alone Petitioners, tried and failed to create an accurate MDI dose counter with the claimed features

'177 Reply (Paper 28) at 30

The mere absence of a certain product in the marketplace is not evidence of failure of others.

Iron Grip Barbell Co. v. USA Sports, Inc., 392 F.3d 1317, 1324-25 (Fed. Cir. 2004)

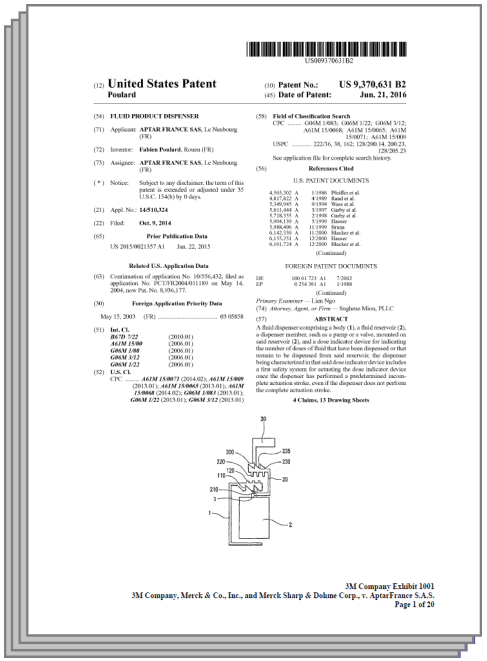
Instituted Grounds of Unpatentability – ’631 Patent

Trial instituted for the ’631 Patent (Ex. 1001)

- ***Ground 1:*** Claims 1-4 are anticipated by Allsop (Ex. 1006).
- ***Ground 2:*** Claims 1-4 are anticipated by Marelli (Ex. 1008).
- ***Ground 3:*** Claims 1-4 are obvious over Bason (Ex. 1007) in view of Rhoades (Ex. 1009).
- ***Ground 4:*** Claims 1-4 are obvious over Bason (Ex. 1007) in view of Allsop (Ex. 1006).

Institution Decision (Paper 11) at 2

’631 Patent: Claims 1 and 2



US009370631B2

(12) **United States Patent**
Poulard

(10) **Patent No.: US 9,370,631 B2**
(45) **Date of Patent: Jun. 21, 2016**

(54) **FLUID PRODUCT DISPENSER**

(71) Applicant: **APTAR FRANCE SAS**, Le Neubourg (FR)

(72) Inventor: **Fabien Poulard**, Rouen (FR)

(73) Assignee: **APTAR FRANCE SAS**, Le Neubourg (FR)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **14/510,324**

(22) Filed: **Oct. 9, 2014**

(65) **Prior Publication Data**

US 2015/0021357 A1 Jan. 22, 2015

Related U.S. Application Data

(63) Continuation of application No. 10/556,432, filed as application No. PCT/FR2004/011389 on May 14, 2004, now Pat. No. 8,936,173.

(30) **Foreign Application Priority Data**

May 15, 2003 (FR) 03 05858

(51) **Int. Cl.**
B67D 7/22 (2010.01)
A61M 15/00 (2006.01)
G06M 1/08 (2006.01)
G06M 1/12 (2006.01)
G06M 1/22 (2006.01)

(52) **U.S. Cl.**
CPC ***A61M 15/0071*** (2014.02); ***A61M 15/009*** (2013.01); ***A61M 15/0065*** (2013.01); ***A61M 15/0068*** (2014.02); ***G06M 1/083*** (2013.01); ***G06M 1/22*** (2013.01); ***G06M 1/12*** (2013.01)

(58) **Field of Classification Search**
CPC G06M 1/083; G06M 1/22; G06M 3/12; A61M 15/0068; A61M 15/0065; A61M 15/0071; A61M 15/009
USPC 222/36, 38, 162; 128/200.14, 200.21, 200.23, 205.23
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,565,302 A 1/1986 Pfeiffer et al.
4,817,822 A 4/1989 Rand et al.
5,349,945 A 9/1994 Wass et al.
5,611,444 A 3/1997 Clarke et al.
5,738,355 A 2/1998 Clarke et al.
5,868,130 A 2/1999 Hauser
6,116,237 A 9/2000 Klein
6,142,339 A 11/2000 Blacker et al.
6,155,251 A 12/2000 Hauser
6,161,724 A 12/2000 Blacker et al.
(Continued)

FOREIGN PATENT DOCUMENTS

DE 100 61 723 A1 7/2002
EP 0 254 501 A1 1/1988
(Continued)

Primary Examiner — Lien Ngo
(74) *Attorney, Agent, or Firm* — Sughrue Mion, PLLC

(57) **ABSTRACT**

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.

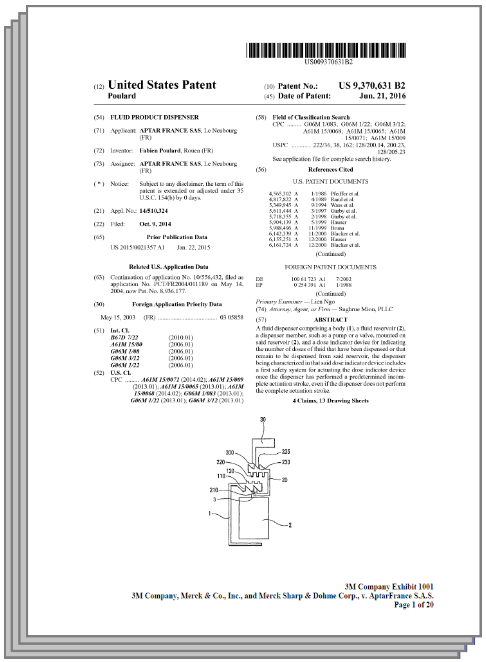
4 Claims, 13 Drawing Sheets

3M Company Exhibit 1001
3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp., v. Aptar France S.A.S.
Page 1 of 20

’631 Patent (Ex. 1001) at 10:2-26

1. A fluid dispenser comprising:
a plurality of displayable dose values;
a stationary body comprising at least one stationary multi-toothed gear;
a first member that is displaceable axially relative to said stationary body;
a second member that is displaceable axially and in rotation relative to said stationary body, said second member being engageable with said first member and said stationary body; and
when said first member displaces axially, the stationary body is configured to allow a fluid reservoir to be axially displaceable relative to said stationary body and said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values,
wherein the stationary body, the first member, and the second member are arranged to have a common central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable axially aloe the central longitudinal axis and is displaceable rotationally around the central longitudinal axis.
2. The fluid dispenser according to claim **1**, wherein the second member comprises at least one multi-toothed gear.

’631 Patent: Claims 3 and 4



’631 Patent (Ex. 1001) at 10:27-52

3. A fluid dispenser comprising:

a plurality of displayable dose values;

a stationary body comprising at least one stationary multi-toothed gear;

a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body;

a first member that is displaceable axially relative to said stationary body;

a second member that is displaceable axially and in rotation relative to said stationary body, said second member being engageable with said first member and said stationary body; and

when said first member displaces axially, said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values,

wherein the stationary body, the first member, and the second member are arranged to have a common central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis.

4. The fluid dispenser according to claim **3**, wherein the fluid reservoir is configured to be axially displaced relative to said stationary body during actuation of the fluid dispenser.

’631 Ground 1 – Introduction

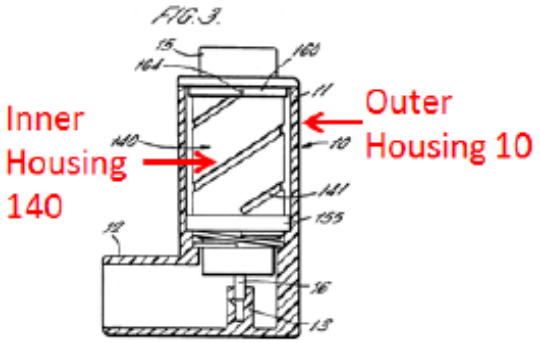
Ground 1: Claims 1-4 are anticipated by Allsop (Ex. 1006).

Issues in dispute

- Push-button cap (“first member”)
- “Displayable dose values”

Ground 1: Allsop Anticipates Claims 1-4 of the ’631 Patent

Allsop discloses every element of claims 1-4

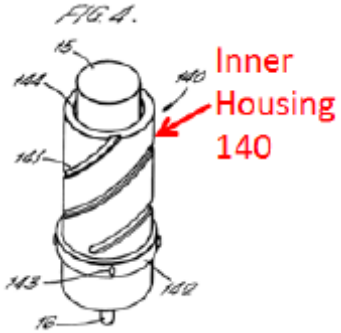


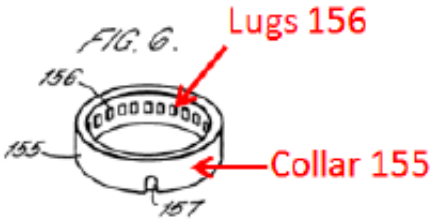
> A push-button cap (not shown) may be provided as part of the main housing 10 to cover the upper portion of the pressurised dispensing container 15. Advantageously, this prevents the ingress of dust, contaminants and moisture into the apparatus.

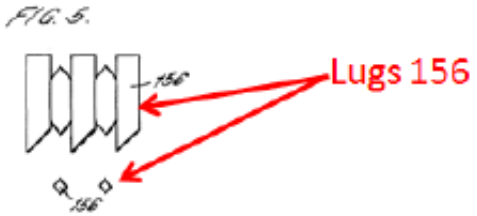
Allsop (Ex. 1006) at 8:22-26

> 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.

Allsop (Ex. 1006) at 10:4-9

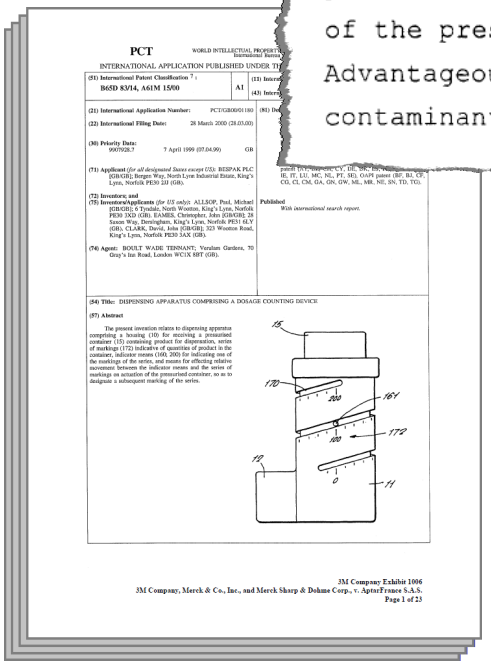






’631 Petition (Paper 1) at 21-22

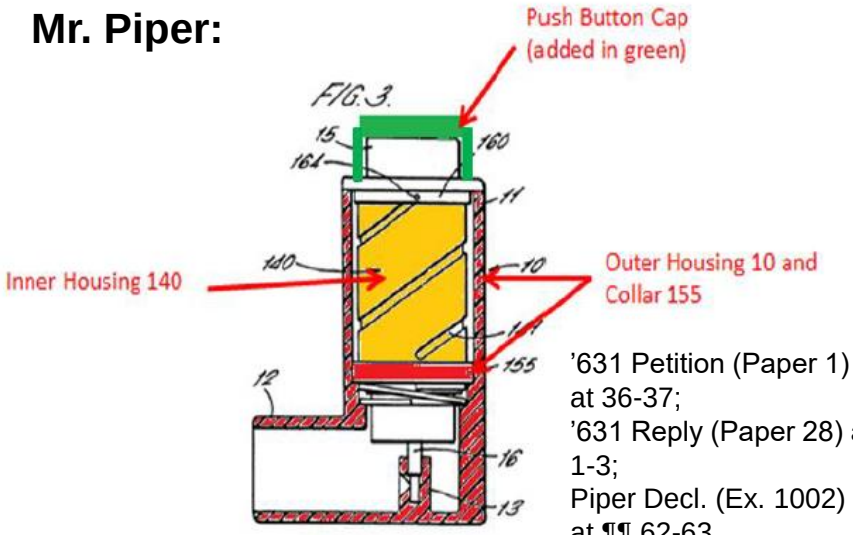
Allsop Discloses and Enables a First Member: The "Push-Button Cap" That can Move Axially



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.

Allsop (Ex. 1006) at 8:22-26

Mr. Piper:



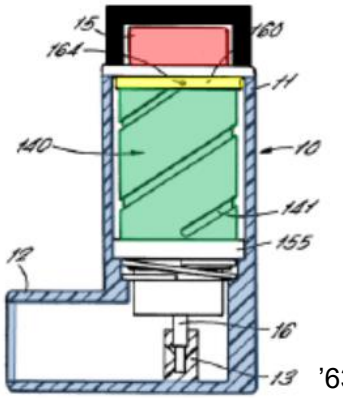
'631 Petition (Paper 1) at 36-37;
'631 Reply (Paper 28) at 1-3;
Piper Decl. (Ex. 1002) at ¶¶ 62-63

Allsop Discloses and Enables a First Member: The "Push-Button Cap" That can Move Axially

Aptar argues: The sides of the cap would recess into the device between the inner and outer housing, which would either prevent the cap from moving, or interfere with the ring and pins.

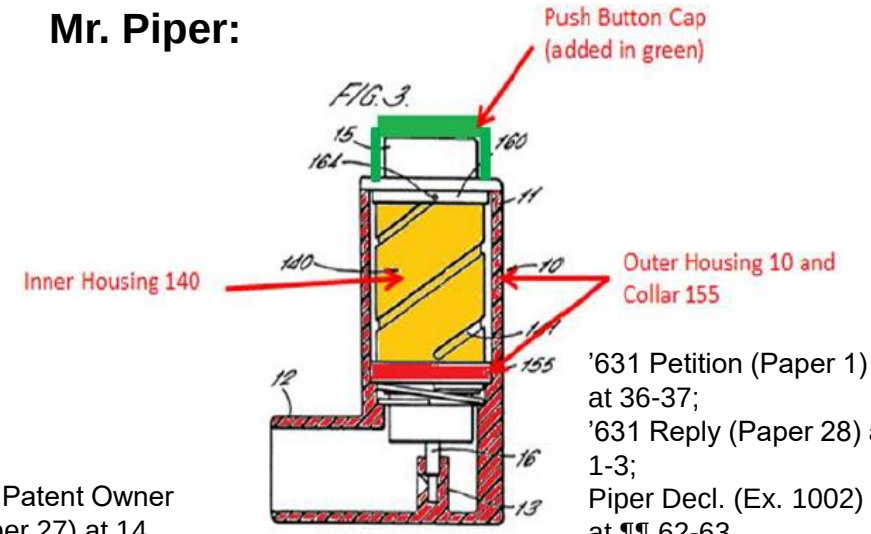
'631 Corrected Patent Owner Response (Paper 27) at 11-13

Mr. Clemens:



'631 Corrected Patent Owner Response (Paper 27) at 14

Mr. Piper:



'631 Petition (Paper 1) at 36-37;
'631 Reply (Paper 28) at 1-3;
Piper Decl. (Ex. 1002) at ¶¶ 62-63

Allsop Discloses and Enables a First Member: The "Push-Button Cap" That can Move Axially

> 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.

Allsop (Ex. 1006) at 8:22-26.

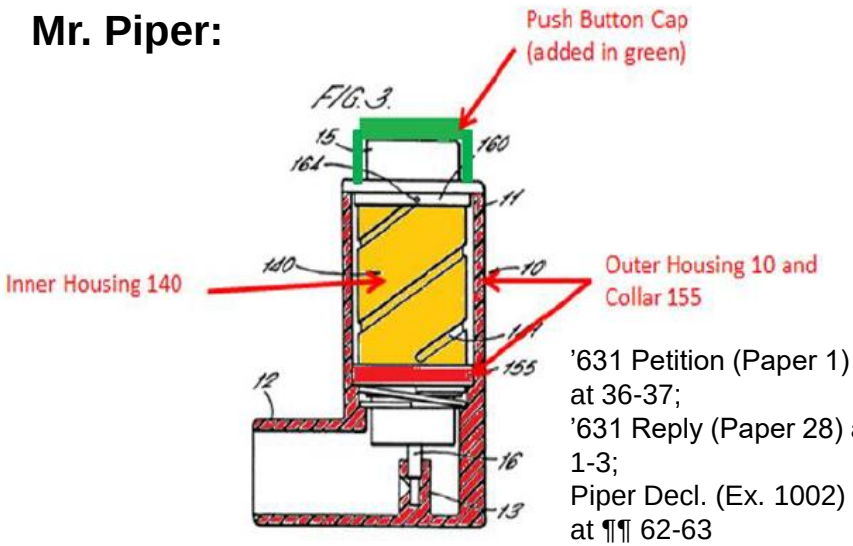
"[T]he push-button cap is located on the top rim of the outer housing where it 'cover[s] the upper portion of the pressurized dispensing container 15.' Allsop, Ex. 1006 at 8:22-26; Petition at 37."

'631 Reply (Paper 28) at 2

"[T]he sides of the push-button cap ***do not*** interfere with ring 160. Piper Decl., Ex. 1058 ¶ 10. The top 'push-button' portion of the cap moves axially."

'631 Reply (Paper 28) at 2

Mr. Piper:



'631 Petition (Paper 1) at 36-37;
'631 Reply (Paper 28) at 1-3;
Piper Decl. (Ex. 1002) at ¶¶ 62-63

A First Member (Push-Button Cap) Engages the Second Member (Inner Housing) in Allsop

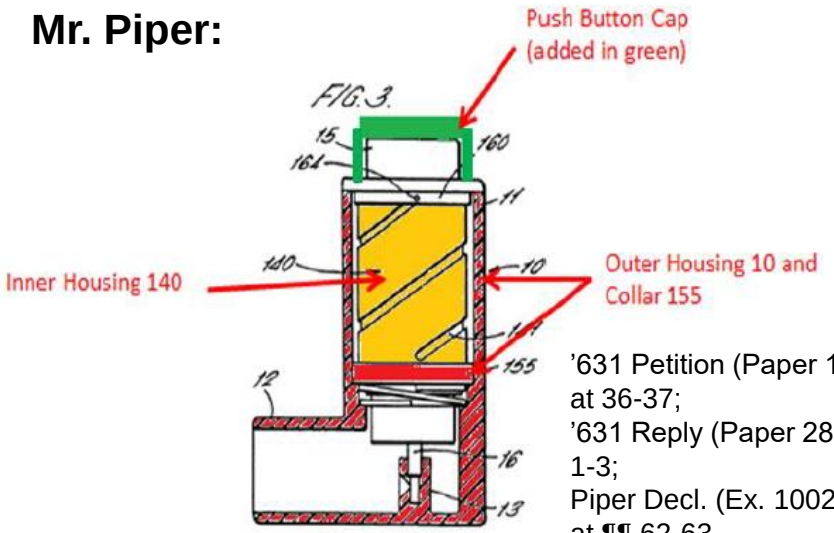
A push-button cap (not shown) may be provided as part of the main housing 10 to cover the upper portion of the pressurised dispensing container 15. Advantageously, this prevents the ingress of dust, contaminants and moisture into the apparatus.

Allsop (Ex. 1006) at 8:22-26.

The push-button would have engaged with the second member (the inner housing) either directly or indirectly. "Specifically, when the button is depressed, both the canister and inner housing move axially downward."

Piper Decl. (Ex. 1002) at ¶ 66;
'631 Petition (Paper 1) at 38

Mr. Piper:



'631 Petition (Paper 1) at 36-37;
'631 Reply (Paper 28) at 1-3;
Piper Decl. (Ex. 1002) at ¶¶ 62-63

Allsop Discloses Two Ways to Display and Change Dose Values

1. A ring for indicating that the container contains one less dose:

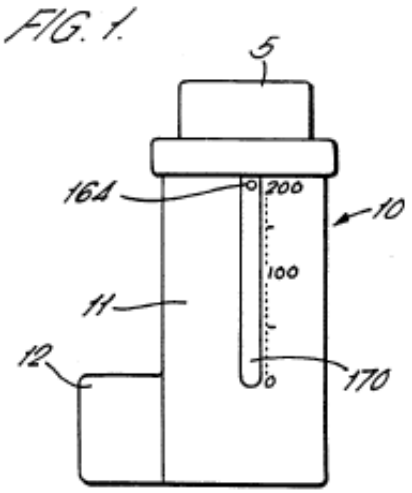
> slots 170 the ring 160 is incrementally moved vertically relative to the inner housing 140. As a result, the outer portions 164 of pins 160 and/or the arcuate member 163 are moved into alignment with a subsequent marking 172 indicating that the pressurised dispensing container 15 contains one less dose. The angled surfaces of the inwardly directed lugs 156 are

Allsop (Ex. 1006) at 9:13-17; *see also* '631 Petition (Paper 1) at 34-35, 39-40

2. A series of numbers spaced around the inner housing such that only a single number can be seen through the slots at any given time:

> 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.

Allsop (Ex. 1006) at 10:4-9 ; *see also* '631 Petition (Paper 1) at 34-35, 39-40



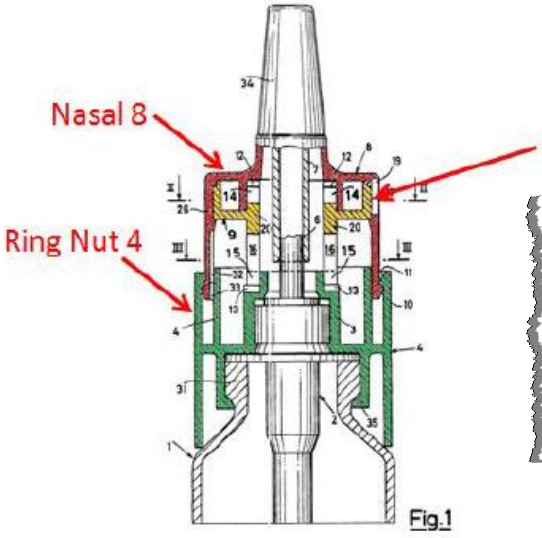
’631 Ground 2 – Introduction

Ground 2: Claims 1-4 are anticipated by Marelli (Ex. 1008).

Issue in dispute

- “[A] second member that is displaceable axially and in rotation relative to said stationary body.”

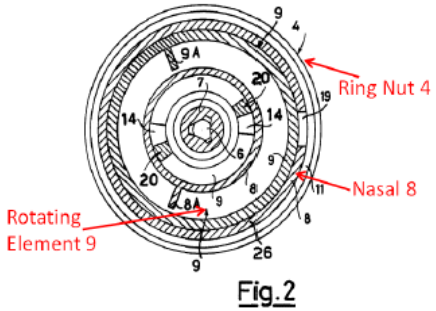
Ground 2: Marelli Anticipates Claims 1-4 of the ’631 Patent

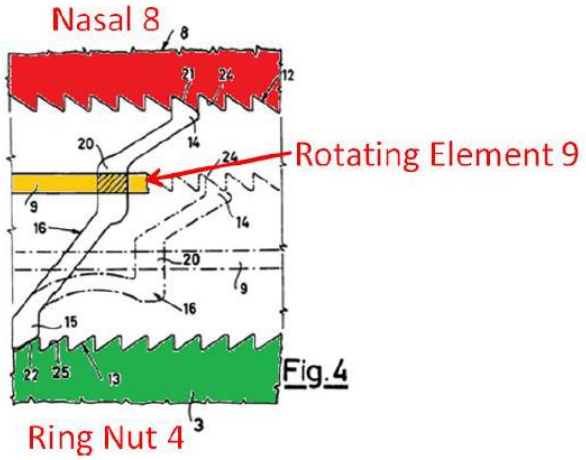


’631 Petition
(Paper 1) at 44, 49

Marelli teaches a rotating element 9 (second element). Rotating element 9 is integral with small flexible legs 16. Those small flexible legs engage with the saw tooth-shaped teeth 12 of nasal 8 via their upper part 14 and engage with the saw tooth shaped teeth 13 of ring nut 4 via their lower part 15. “Pressing on the nasal 8

’631 Petition (Paper 1) at 46



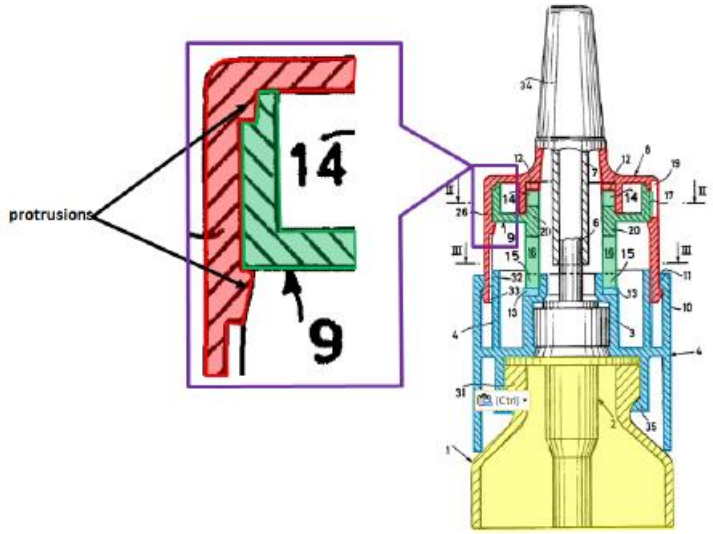


Marelli Anticipates Claims 1-4 of the ’631 Patent

Issue in dispute: “[A] second member that is displaceable axially and in rotation relative to said stationary body.”

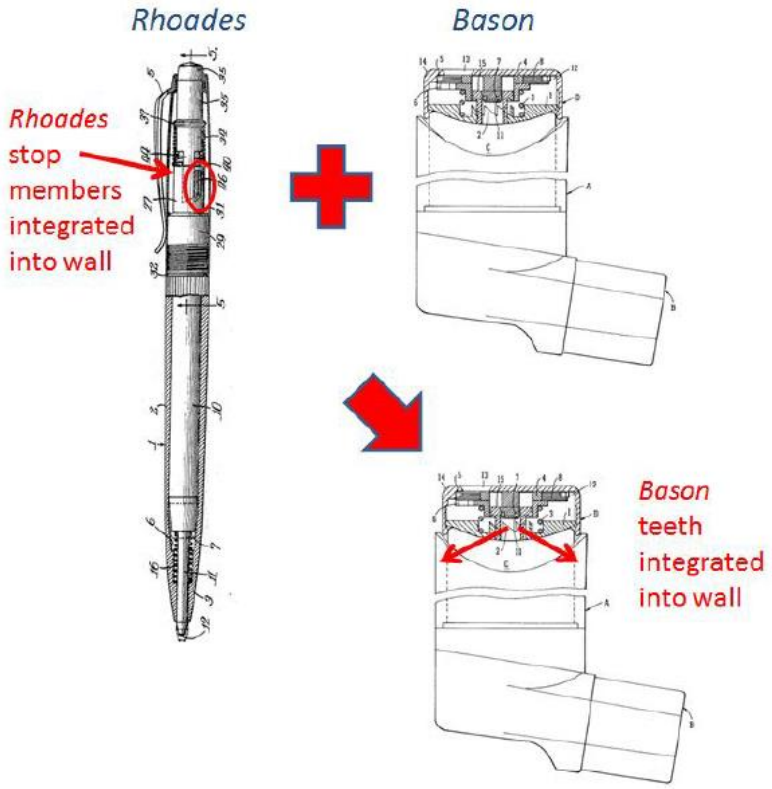
Marelli teaches a rotating element 9 (second element). Rotating element 9 is integral with small flexible legs 16. Those small flexible legs engage with the saw tooth-shaped teeth 12 of nasal 8 via their upper part 14 and engage with the saw tooth shaped teeth 13 of ring nut 4 via their lower part 15. “Pressing on the nasal 8

’631 Petition (Paper 1) at 46



Clemens Decl. (Ex. 2021) at ¶ 20

’631 Ground 3 – Introduction



’631 Petition (Paper 1) at 4

- Bason discloses a fluid dispenser with a dose counter that converts axial motion to rotational motion

’631 Petition (Paper 1) at 23

- Rhoades teaches a small, plastic, inexpensive mechanism for converting linear to rotational motion

’631 Petition (Paper 1) at 28

Overview of Key Issues for Ground 3

Ground 3: Claims 1-4 are obvious over Bason (Ex. 1007) in view of Rhoades (Ex. 1009).

Issues in dispute

- **Motivation to combine**
- **Bason cap** (disclosure of a "first member that is displaceable axially relative to [a] stationary body")
- **Bason gears** (disclosure of "when said first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate . . . .")
- **Rhoades is analogous art** (covered in '177 Patent; *see supra* slides 26-29)
- **Secondary considerations** (covered in '177 Patent; *see supra* slides 42-43)

No Obviousness Rejections During Prosecution

Aptar Amendment:

> when said first member displaces axially, the stationary body is configured to allow a fluid reservoir to be axially displaceable relative to said stationary body and said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values.

Aptar Remarks:

> **II. Claim Rejections - 35 USC §102**
>
> Claims 1-3 are rejected under pre-AIA 35 U.S.C. 102(b) as being anticipated by Bason (6,283,365).

> However, the canister C is **bonded** to the domed base 1. See col. 2, lines 16-18. Thus, the alleged stationary body 1 is not configured to allow the canister C to be axially displaced with respect to the alleged stationary body 1.

'631 Patent File History (Ex. 1005) at 83, 85

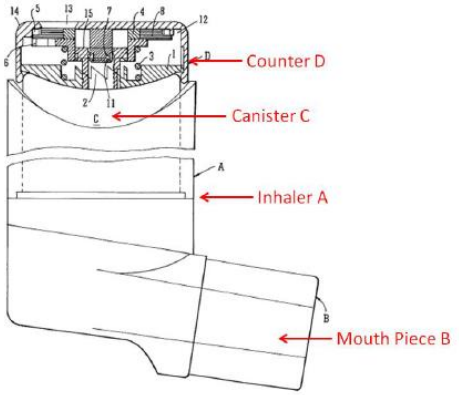


FIG. 1

Bason (Ex. 1007) at Fig. 1

Motivation to Combine: The FDA Guidance Provided Explicit Motivation to Combine

The FDA Guidance recommended all future MDIs to integrate dose counters:

'631 Petition (Paper 1) at 52-53

FDA Guidance

> The Agency recommends that manufacturers with metered-dose inhalers under development for oral inhalation integrate a dose-counting device into the development of their MDI drug product.

2001 Draft Guidance (Ex. 1012) at 5; 2003 Final Guidance (Ex. 1013) at 6; '631 Petition (Paper 1) at 19, 52-53

> Dose counters should be engineered to reliably track actuations and should be designed to be as close to 100 percent reliable as possible. However, if some low frequency of error is unavoidable, the device should be designed to specifically avoid undercounting (i.e., the MDI sprays, but the counter does not advance). Undercounting could result in patients assuming they have medication left in their MDI when they do not, a circumstance that is potentially dangerous.

2001 Draft Guidance (Ex. 1012) at 6; 2003 Final Guidance (Ex. 1013) at 6; '631 Petition (Paper 1) at 19, 52-53

Motivation to Combine: A POSA Would Have Looked to Existing Mechanisms to Improve Bason

- A POSA would have understood the need to improve prior art like Bason to scale up production, maximizing efficiency and reliability

'631 Petition (Paper 1) at 53-55;
Piper Decl. (Ex. 1002) at ¶¶ 134, 135

- Faced with the need to mass produce MDIs with integrated dose counters, A POSA would have looked to other simple, plastic, inexpensive, mass-produced mechanisms that convert linear to rotational motion such as the mechanical pen of Rhoades

'631 Petition (Paper 1) at 53-56;
Piper Decl. (Ex. 1002) at ¶¶ 134-138

Motivation to Combine: A POSA Would Have Looked to Existing Mechanisms to Improve Bason

- Mr. Piper looked to a pen mechanism when asked to build a dose counter in around 1998 (*see supra* slide 19)
- Mr. Clemens agreed POSAs know of and rely on basic mechanisms of a pen (*see supra* slides 20, 21)
- A POSA would have looked to a pen mechanism when designing a dose counter for an MDI (*see supra* slides 22-25).

Ground 3: A POSA Would Have Known How to Connect the Cap of Bason in the Combination

- In light of the industry's understanding leading up to and after the FDA's guidance market forces would have motivated a POSA to modify Bason by slightly extending Bason's inhaler body and integrating the stationary gear (tooth 2) of the Bason mechanism into the inhaler body.

  '631 Petition (Paper 1) at 55

- Such a modification was a simple variation known in the prior art and would have allowed one to injection mold the actuator with the stationary gear already included, decreasing the number of parts that would have had to have been assembled and tested. '631 Petition (Paper 1) at 55

- The rest of the components could be connected in the same way they are connected in Bason, or other ways well-understood in the art.

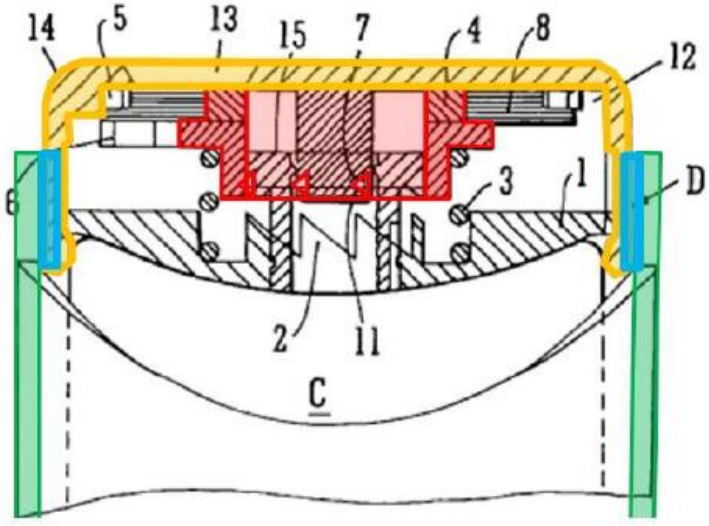
  '631 Petition (Paper 1) at 55

- "In such a configuration, the cap 14 would move axially relative to the stationary body. '631 Petition (Paper 1) at 61

Ground 3: A POSA Would Have Known How to Connect the Cap of Bason in the Combination

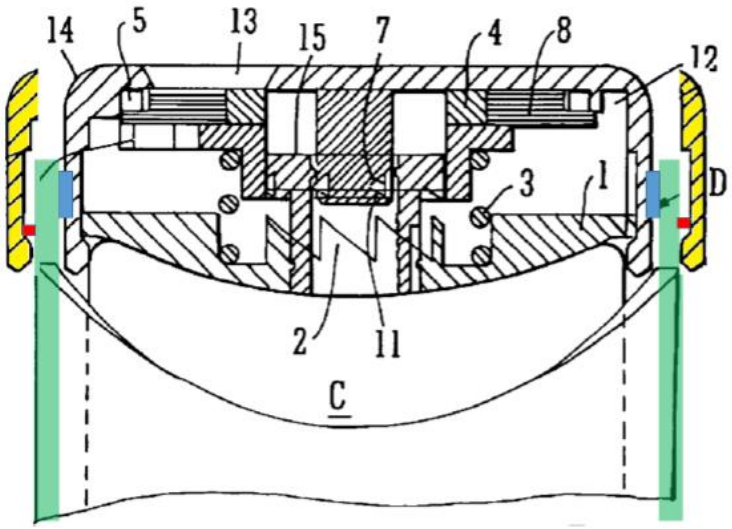
Aptar argues: The teeth molded onto the inhaler body would prevent the Bason cap from moving axially.

Aptar's Response:



'631 Corrected Patent Owner Response (Paper 27) at 35

Petitioners' Reply:



'631 Reply (Paper 28) at 11

Ground 3: A POSA Would Have Known How to Connect the Cap of Bason in the Combination

Aptar (2019) : The Bason cap "does not meet [the 'first member'] claim element because the teeth that purportedly would have been molded onto the inhaler body prevent the cap from moving axially as required by the claim."

'631 Corrected Patent Owner Response (Paper 27) at 35

Aptar (2011):

'177 File History (Ex. 1004) at 1149-50

> 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

'177 File History (Ex. 1004) at 1138

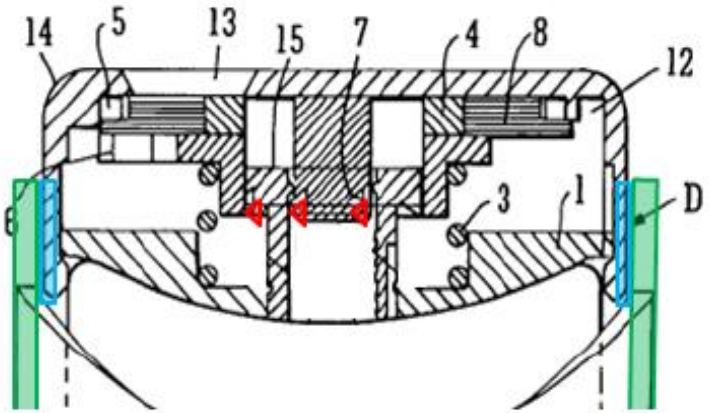
> As noted above and in the originally filed specification (*e.g.*, pages 1, 2 and 8), metered dose inhalers, dispenser members, dose indicator devices and actuation of a dispenser are well known in the art, and one of ordinary skill would understand the structure and connection of a body, reservoir, actuator, counter and dispenser member. Thus, such specific structural connections need not be disclosed in the specification.

Ground 3: A POSA Would Have Known How to Connect the Necessary Gears in the Combination

Aptar argues: Teeth 7 (red) cannot engage teeth 2 (blue) in the proposed combination.

'631 Corrected Patent Owner Response (Paper 27) at 38-39

Aptar's Response:



'631 Corrected Patent Owner Response (Paper 27) at 38

Petitioners' Reply:

Rhoades and Bason / Allsop combinations. Response at 37-39. As the Petition explains, "teeth 7 of ring 4 would ***interact with*** stationary teeth 2." Petition at 56; *see also id.* at 68. Furthermore, these "components would retain their same functions." *Id.* at 56, 68. In other words, a POSA would have connected the components so that they interact. *See* Ex. 1004 at 1233 ("One of ordinary skill in the art . . . would have understood how to shape and structure the gears and their novel interaction with each other.").[6] For example, a POSA would have extended

'631 Reply (Paper 28) at 14

Ground 3: A POSA Would Have Known How to Connect the Necessary Gears in the Combination

Aptar (2019): "[I]f Bason is modified as suggested by Petitioners (to move teeth 2 of base 1 to the inhaler body), then teeth 7 . . . cannot engage teeth 2."

'631 Corrected Patent Owner Response (Paper 27) at 38

Aptar (2011):

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.

'177 File History (Ex. 1004) at 1233

Ground 3: A POSA Would Have Known How to Connect the Cap and the Gears

Aptar's Expert, Mr. Clemens, testified:

Q. In paragraph 47, second to last sentence, you say "Petitioners state that the rest of the components would be connected in the same way they are connected in Bason."

Do you see that?

A. I do.

Q. I am going to hand you the petition from the '631 Patent IPR. If you could turn to page 55. Looking at the fourth line from the bottom, the petition says "The rest of the components could be connected in the same way they are connected in Bason or other ways well understood in the art."

Do you see that?

A. I do.

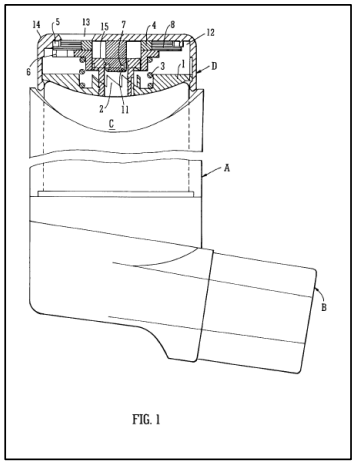
Q. Your opinion does not include that last clause, does it?

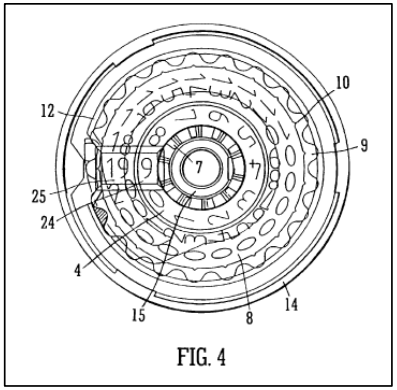
A. It does not.

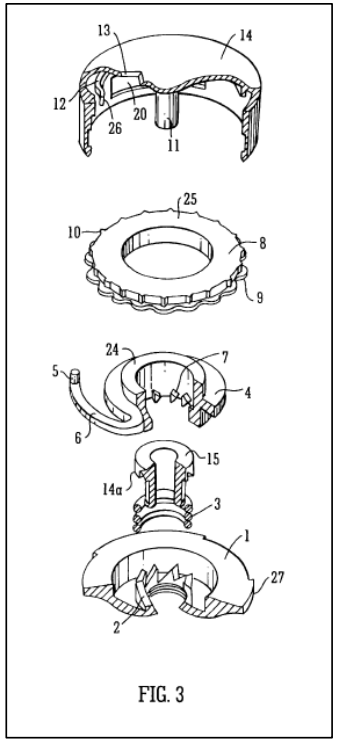
Clemens Tr. (Ex. 1057) at 231:6-22

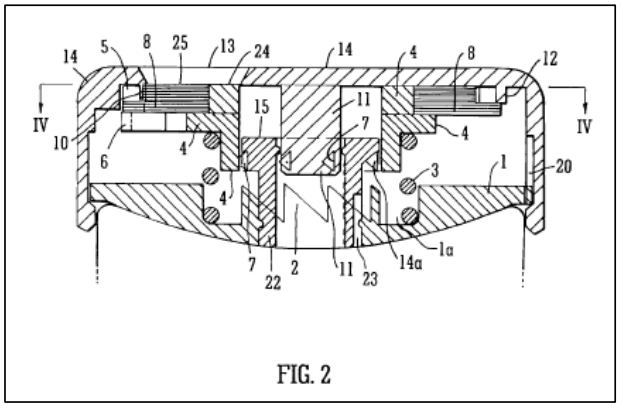
Details in Asserted Art vs. Details in Aptar's Patent

Bason (Ex. 1007):



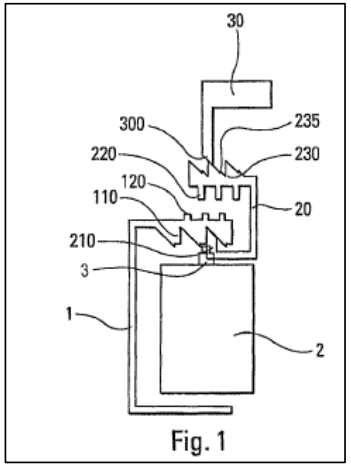


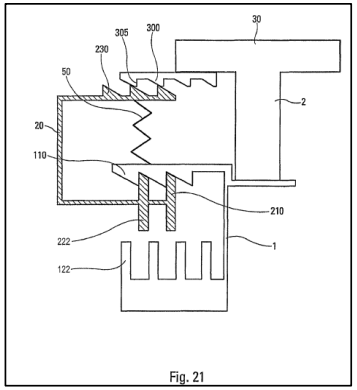




Bason (Ex. 1007) at Figs. 1-4;
'631 Reply (Paper 28) at 8

'631 Patent :





'631 Patent (Ex. 1001) at Figs. 3, 21

Aptar Discussed its Disclosure During Prosecution

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

'177 File History (Ex. 1004) at 255

When an applicant "did not provide the type of detail in his specification that he now argues is necessary in prior art references, [this] supports [a] finding that [a POSA] would have known how to implement the features of the references."

In re Epstein, 32 F.3d 1559, 1568 (Fed. Cir. 1994).

'631 Patent :

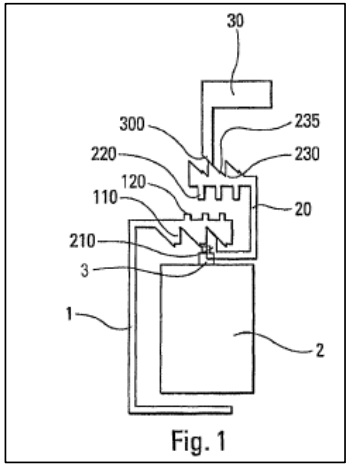


Fig. 1

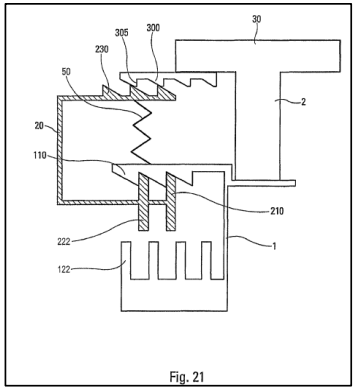
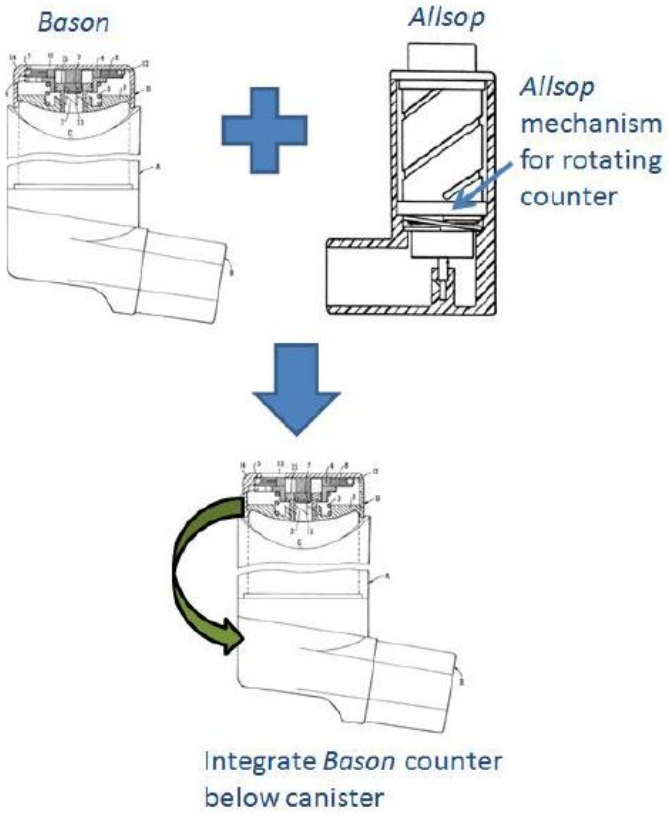


Fig. 21

'631 Patent (Ex. 1001) at Figs. 3, 21

’631 Ground 4 – Introduction



’631 Petition (Paper 1) at 5

- Bason discloses a fluid dispenser with a dose counter that converts axial motion to rotational motion

’631 Petition (Paper 1) at 23

- Allsop teaches a dispensing apparatus comprising a dosage counting device, for use in a fluid dispenser

’631 Petition (Paper 1) at 20-21

Overview of Key Issues for Ground 4

Ground 4: Claims 1-4 are obvious over Bason (Ex. 1007) in view of Allsop (Ex. 1006).

Issues in dispute

- **Motivation to combine**
- **Bason cap** (disclosure of a "first member that is displaceable axially relative to [a] stationary body")
- **Bason gears** (disclosure of "when said first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate . . . .")
- **"Displayable dose values"**
- **Secondary Considerations** (covered in '177 Patent; *see supra* slides 42-43)

Motivation to Combine: The FDA Guidance Provided Explicit Motivation to Combine

The FDA Guidance recommended all future MDIs to integrate dose counters:

'631 Petition (Paper 1) at 52-53

FDA Guidance

> The Agency recommends that manufacturers with metered-dose inhalers under development for oral inhalation integrate a dose-counting device into the development of their MDI drug product.

2001 Draft Guidance (Ex. 1012) at 5; 2003 Final Guidance (Ex. 1013) at 6; '631 Petition (Paper 1) at 19, 52-53, 66

> Dose counters should be engineered to reliably track actuations and should be designed to be as close to 100 percent reliable as possible. However, if some low frequency of error is unavoidable, the device should be designed to specifically avoid undercounting (i.e., the MDI sprays, but the counter does not advance). Undercounting could result in patients assuming they have medication left in their MDI when they do not, a circumstance that is potentially dangerous.

2001 Draft Guidance (Ex. 1012) at 6; 2003 Final Guidance (Ex. 1013) at 6; '631 Petition (Paper 1) at 19, 52-53, 66

Motivation to Combine: A POSA Would Have Looked to Existing Mechanisms Like Allsop

- Faced with the need to scale up production in response to the FDA's guidance, a POSA would have looked to similar devices like Allsop to maximize efficiency and reliability.

  '631 Petition (Paper 1) at 53-55, 66

- "To improve the *Bason* device . . ., a POSA would have simply moved the *Bason* dose counter below the *Bason* canister, where the rotational mechanism … is located in *Allsop*, and integrally molded the teeth 2 into the inhaler housing, just as Allsop teaches." '631 Petition (Paper 1) at 53-55, 66-67

- That improvement would have used fewer parts and required modulating fewer tolerances, decreasing cost and increasing reliability. '631 Petition (Paper 1) at 53-55, 67-69

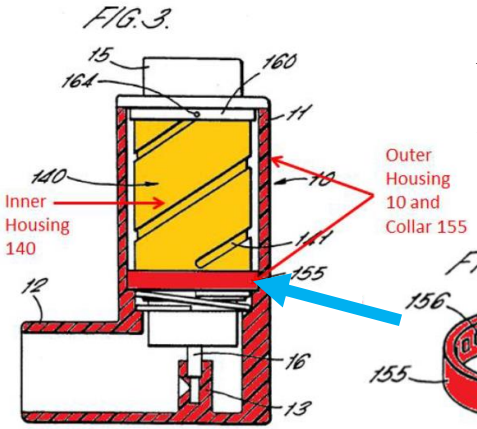
Motivation to Combine: A POSA Would Have Looked to Existing Mechanisms Like Allsop

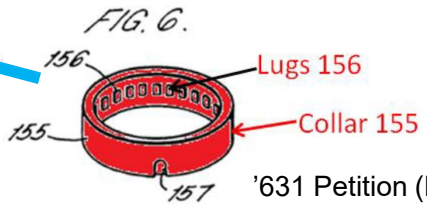
> One would have been motivated to make such a modification because the prior art explained that the fewer components and tolerances that needed to be modulated, the more accurate and reliable a device would be. Ex. 1002 ¶173; Ex.

'631 Petition (Paper 1) at 67

> Furthermore, the base 1 with stationary gear teeth 2 would be molded directly into the wall of the *Bason* inhaler, as taught in *Allsop*, decreasing costs even further. *Id.* ¶174; Ex. 1029 at 3; Ex. 1030 at 3. The counting device would be

'631 Petition (Paper 1) at 68





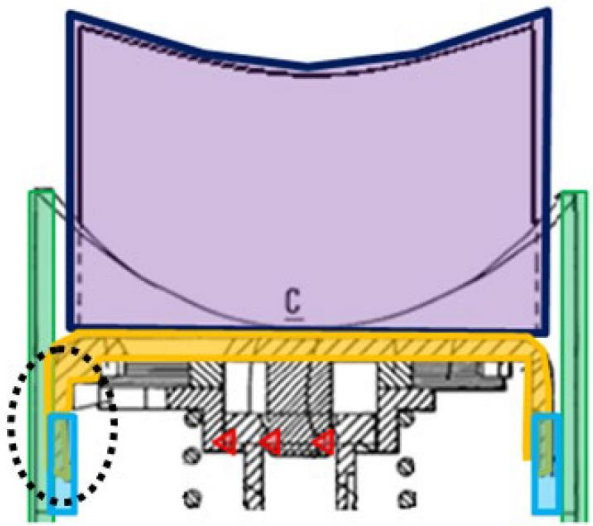
'631 Petition (Paper 1) at 35

> rotational movement of the collar 155. Alternatively, collar 155 may be integrally moulded with the generally cylindrical portion 11. As an alternative

Allsop (Ex. 1006) at 7:8-10;
'631 Petition (Paper 1) at 67, 70

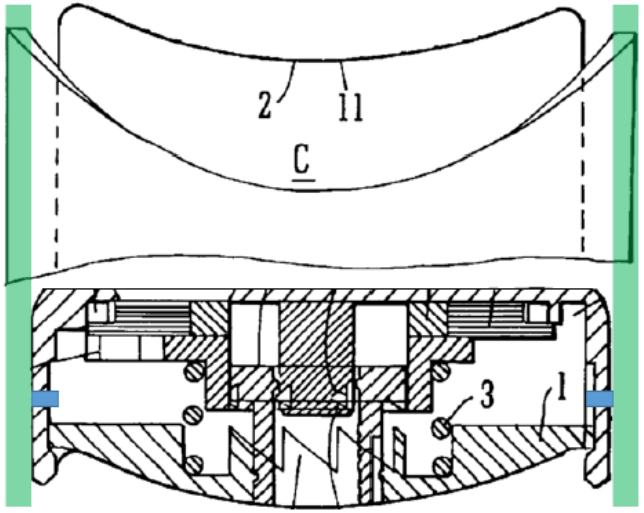
Bason Cap and Gears: A POSA Would Have Known How to Configure Them for Operation (Ground 4)

Aptar Response:



’631 Corrected Patent Owner Response (Paper 27) at 51

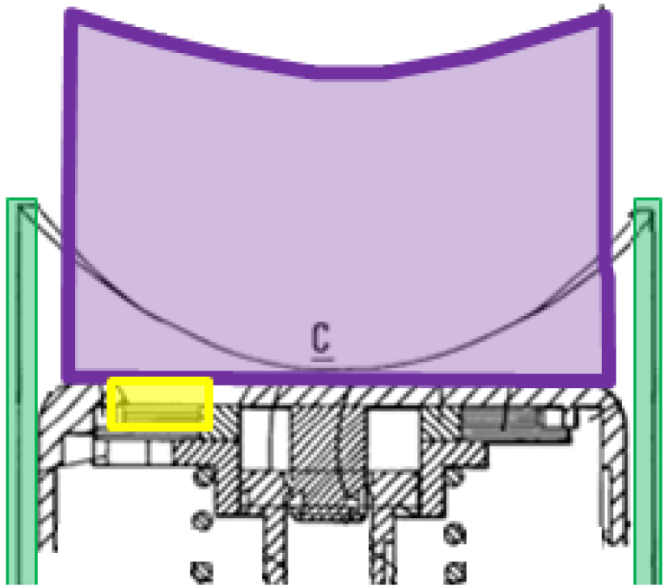
Petitioner Reply:



’631 Reply (Paper 28) at 12

Displayable Dose Values: A POSA Would Know How to Display the Dose Values (Ground 4)

Aptar Response:



'631 Corrected Patent Owner Response (Paper 27) at 51

Aptar: "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."

'177 File History (Ex. 1004) at 1138;
'631 Petition (Paper 1) at 12, 16, 69