

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp.,

Petitioners

v.

AptarFrance S.A.S.,

Patent Owner

Patent No. 9,370,631

Filing Date: October 9, 2014

Issue Date: June 21, 2016

Title: FLUID PRODUCT DISPENSER

Case No. To Be Assigned

PETITION FOR *INTER PARTES* REVIEW

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EXHIBITS

Exhibit No.	Description
1001	U.S. Patent No. 9,370,631 (the “’631 patent”)
1002	Declaration of S. David Piper
1003	Curriculum Vitae of S. David Piper
1004	Prosecution History of Application No. 10/556,432 that led to U.S. Patent No. 8,936,177, the parent of the ’631 Patent
1005	Prosecution History of Application No. 14/510,324 that led to the ’631 Patent
1006	International Publication No. WO 00/59806 (“ <i>Allsop</i> ”)
1007	U.S. Patent No. 6,283,365 (“ <i>Bason</i> ”)
1008	European Patent No. EP 0480488 (“ <i>Marelli</i> ”)
1009	U.S. Patent No. 3,205,863 (“ <i>Rhoades</i> ”)
1010	U.S. Patent No. 6,474,331
1011	U.S. Patent No. 6,752,153
1012	U.S. Food and Drug Administration, Division of Pulmonary and Allergy Drug Products in the Center for Drug Evaluation and Research (CDER), <i>Draft Guidance for Industry Integration of Dose-Counting Mechanisms into MDI Drug Products</i> (November 2001)
1013	United States Food and Drug Administration, Division of Pulmonary and Allergy Drug Products in the Center for Drug Evaluation and Research (CDER), <i>Final Guidance for Industry Integration of Dose-Counting Mechanisms into MDI Drug Products</i> (March 2003)
1014	International Publication No. WO 95/26769

1015	International Publication No. WO 96/03172
1016	RESERVED
1017	European Publication No. EP 0949584 A2 (“ <i>Bason</i> Publication”)
1018	A.R. Clark, <i>Medical Aerosol Inhalers: Past, Present, and Future</i> , 22 AEROSOL SCI. & TECH., 374 (1995)
1019	U.S. Patent No. 2,721,010
1020	U.S. Patent No. 5,290,539
1021	U.S. Patent No. 5,992,309
1022	U.S. Patent No. 2,126,626
1023	U.S. Patent No. 4,414,891
1024	U.S. Patent No. 7,195,134
1025	RESERVED
1026	RESERVED
1027	Andrew G. Weinstein, <i>When Should Your Asthmatic Patients Refill Their MDI Propelled with Chlorofluorocarbons?</i> , 70 DEL. MED. J., 293 (1998)
1028	Tina Penick Brock et al., <i>Accuracy of Float Testing for Metered-Dose Inhaler Canisters</i> , 42 J. OF THE AM. PHARM. ASS’N, 582 (2002)
1029	Excerpt from Joseph Edward Shigley and Larry D. Mitchell, <i>Mechanical Engineering Design</i> , 16 (McGraw-Hill, Inc., 4th ed., 1983)
1030	Excerpt from Robert E. Parr, <i>Principles of Mechanical Design</i> , 112-113 (McGraw-Hill, Inc., 1970)
1031	U.S. Patent No. 5,243,970
1032	U.S. Patent No. 7,090,662

1033	International Publication No. WO 2007/045904
1034	U.S. Patent No. 9,439,648
1035	RESERVED
1036	British Patent GB 1317315
1037	U.S. Patent No. 5,349,945
1038	U.S. Patent No. 6,142,339
1039	U.S. Patent No. 6,161,724
1040	International Publication No. WO 1998/56444
1041	Lewis, Metered-dose inhalers: actuators old and new, 4(3) EXPERT OPIN. DRUG. DELIV. 235 (May 2007)
1042	Stein and Thiel, The History of Therapeutic Aerosols: A Chronological Review 2017
1043	Excerpts from Federal Register Vol. 66
1044	Excerpts from Federal Register Vol. 68
1045	W. Travis Cain & John J. Oppenheimer, <i>The misconception of using floating patterns as an accurate means of measuring the contents of metered-dose inhaler devices</i> , 87 ANNALS OF ALLERGY, ASTHMA, & IMMUNOLOGY, 417 (2001)
1046	RESERVED
1047	Excerpt of Douglas M. Bryce, Plastic Injection Molding, Vol. 1 (1996)
1048	R. K. Schultz, <i>Drug delivery characteristics of metered-dose inhalers</i> , 96 J. ALLERGY CLIN. IMMUNOL. 284 (1995)
1049	D. B. Price <i>et al.</i> , <i>Historical cohort study examining comparative effectiveness of albuterol inhalers with and without integrated dose counter for patients with asthma or chronic obstructive pulmonary disease</i> , 9 J. ASTHMA & ALLERGY 145 (2016)

I. INTRODUCTION

Petitioners 3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp. (“Petitioners”) request *inter partes* review (“IPR”) of claims 1-4 (the “Challenged Claims”) of U.S. Patent No. 9,370,631 (the “’631 patent”) (Ex. 1001), pursuant to 35 U.S.C. §§311-319 and 37 C.F.R. §42.100 *et seq.*

The ’631 patent is directed to a fluid dispenser including a dose indicator device. Ex. 1001 at 1:16-20. Dose indicator devices—sometimes referred to as dose counters—keep track of the number of doses dispensed from a fluid dispenser. *Id.* at 1:24-30; Ex. 1002 ¶23. One purported feature of the ’631 patent’s dose indicator is the ability to prevent undercounting of the number of doses dispensed so a user does not believe there are doses left in an empty device—a dangerous situation for patients with conditions like asthma. The dose indicator disclosed in the ’631 patent purportedly prevents undercounting by: (1) counting a dose so long as the user has actuated the device a sufficient amount; and/or by (2) preventing release of a second dose of fluid until the counter has reset. Ex. 1004 at 1279:9-1280:19; Ex. 1001 at 2:18-31; 2:39-51.

The ’631 patent added nothing to what was already known in the art. Not only were “fluid dispensers having counting mechanisms [] well known” by the ’631 patent’s priority date, a fact admitted by the patentee (Ex. 1004 at 1281:19-1282:4), but the precise fluid dispenser of the Challenged Claims was disclosed in

multiple prior art references. As explained in Grounds 1 and 2 in this petition and supporting documents, every element of the Challenged Claims was disclosed in both *Allsop* (Ex. 1006) and *Marelli* (Ex. 1008).

There are additional reasons the Challenged Claims are unpatentable. As described in Grounds 3 and 4, the Challenged Claims reflect nothing more than simple and predictable modifications to other well-known metered dose inhalers (“MDIs”), including the device disclosed in *Bason*. The motivation to make such modifications was clear. By the early 2000s, the industry recognized that existing methods of monitoring medication in an MDI were insufficient. Ex. 1002 ¶18; Ex. 1027 at 5-6; Ex. at 1028 at 7; Ex. 1041 at 6; Ex. 1042 at 13; Ex. 1045 at 3. The U.S. Food and Drug Administration (“FDA”) agreed, issuing draft guidance in 2001 and final guidance in 2003 recommending that manufacturers “integrate a dose-counting device into the development of their MDI drug product.” Ex. 1002 ¶18; Ex. 1012 at 5; Ex. 1013 at 6; Ex. 1043 at 7-8; Ex. 1044 at 8; *see also* Ex. 1041 at 6; Ex. 1042 at 13. The draft and final guidance went a step further advising that, if 100% accuracy is not possible, the MDI “should be designed to specifically avoid under-counting.” Ex. 1002 ¶18; Ex. 1012 at 6; Ex. 1013 at 6. The FDA’s guidance not only provided the motivation to include a dose counter with specific design features in an MDI, the guidance expressly acknowledged the biggest design incentive facing a person having ordinary skill in the art (“POSA”) (and, in

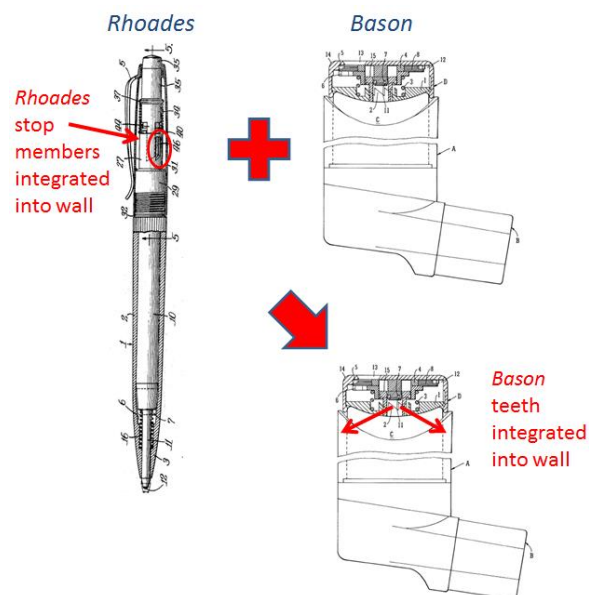
fact, the entire industry)—“it is recognized that the economics of [incorporating dose counters into MDIs] may be burdensome.” Ex. 1002 ¶133; Ex. 1012 at 6; Ex. 1013 at 6.

In light of the FDA’s guidance from as early as 2001, a POSA would have been motivated to incorporate dose counters that err on the side of avoiding undercounting into MDIs by no later than May 15, 2003 (the ’631 patent’s earliest priority date), and to do so in the most cost-effective and economical way since dose counters were to be standard in MDIs coming to market. Ex. 1002 ¶133. These motivations would have led a POSA to improve the counting mechanism of MDIs, which in many existing devices, involved converting the axial movement of an actuator or canister into rotational movement of a number wheel showing the remaining doses. *See* Ex. 1014 at 4:31-5:5; Ex. 1011 at 4:9-13.

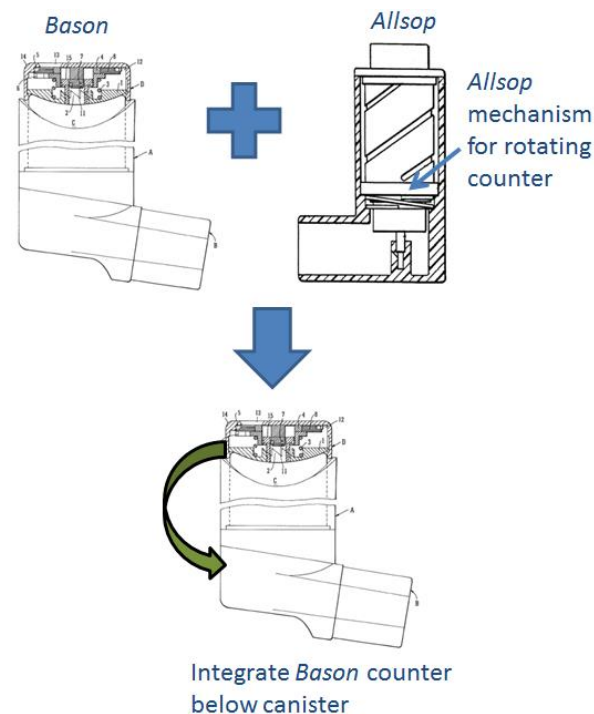
Mechanisms capable of converting axial motion into rotational motion were, of course, known prior to 2003 and had been utilized in many simple mechanical devices suitable for large-scale production. One such mechanism existed in a mass-produced pen. *Rhoades* (Ex. 1009), which was not considered by the Patent Office, discloses an inexpensive, small, easily-manufactured mechanical pen with a mechanism to convert axial movement into rotational movement. Ex. 1002 ¶25; *see generally* Ex. 1009. A POSA would have been motivated to look to analogous art (*e.g.*, mechanical pen art like *Rhoades*) that contained those desired features

rather than designing a mechanism from scratch. Ex. 1002 ¶¶25. This is consistent with the experience of Petitioner's expert who, when faced with the very problem of designing and building a dose indicator prior to 2001, drew from the mechanism in a simple, plastic, inexpensive mechanical pen. *Id.* ¶¶17, 135. And others working on the design and development of counting mechanisms for use in medical devices, including MDIs, looked to simple pen technology. *Id.* ¶135; Ex. 1031 at 2:36-47; Ex. 1032 at 1:40-48; Ex. 1033 at 15:10-25; Ex. 1034 at [56], Abstract, 3:29-39.

Accordingly, as described in Ground 3 and depicted below, a POSA would have been motivated to modify the MDI of *Bason* in light of the *Rhoades* mechanism—forming the stationary gear directly on the inhaler body to make a less expensive, easier to manufacture, and more reliable device.



Similarly, Ground 4 explains why and how one would have made a simple modification to *Bason* in light of the rotating counting mechanism used in the inhaler disclosed in *Allsop*—integrating the counter element into the inhaler body below the canister, again to make a less expensive, easier to manufacture, and more reliable device.



Petitioners respectfully request institution of IPR of the Challenged Claims on Grounds 1-4.

II. MANDATORY NOTICES, STANDING, AND FEES

A. Real Party-In-Interest

Petitioners 3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp. are real parties-in-interest.

B. Related Matters

Petitioners also filed a petition for IPR of U.S. Patent No. 8,936,177 (“the ’177 patent”), purportedly owned by Aptar France S.A.S. The ’177 patent and ’631 patent were asserted against Petitioners in a patent infringement litigation captioned *AptarGroup, Inc. et al. v. 3M Company et al.*, No. 1:17-cv-06294-VMK (N.D. Ill. filed Aug. 30, 2017) (the “Litigation”), currently pending in the United States District Court for the Northern District of Illinois.

C. Lead and Backup Counsel

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D. Service Information

Powers of Attorney accompany this Petition pursuant to 37 C.F.R. §42.10(b).

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E. Certification of Grounds for Standing

Petitioners certify that the '631 patent is available for IPR, and Petitioners are not barred or estopped from requesting IPR on the asserted grounds. Specifically, Petitioners state that: (1) Petitioners are not owners of the '631 patent; (2) Petitioners have not filed a civil action challenging the validity of any claim of

the '631 patent; and (3) Petitioners were served with the complaint in the Litigation on September 8, 2017, and an amended complaint on September 27, 2017.

F. Fees

Under 37 C.F.R. §42.103(a), Petitioners authorize the Office to charge the fee set forth in 37 C.F.R. §42.15(a) to Deposit Account No. 50-2310, as well as any additional fees that might be due in connection with this petition.

III. OVERVIEW OF THE '631 PATENT

A. Summary of Challenged Claims

The '631 patent relates to a fluid dispenser containing a dose indicator. Ex. 1001 at 1:16-20. The Challenged Claims broadly recite a fluid dispenser with components that move relative to each other in specific ways. The below chart summarizes the elements of independent claims 1 and 3. Whereas claim 1 includes a limitation relating to axial movement of the fluid reservoir as part of limitation [g] (highlighted), the similar limitation [h] (in claim 3) does not mention reservoir movement. Instead, that is addressed in limitation [d] of claim 3 (highlighted).

	Claim 1	Claim 3	Limitation Name
[a]	A fluid dispenser comprising:	[identical element]	“preamble”
[b]	a plurality of displayable dose values;	[identical element]	
[c]	a stationary body comprising at least one stationary multi-toothed gear;	[identical element]	
[d]	[no corresponding element]	a fluid reservoir disposed on said	

		stationary body so as to be axially displaceable relative to said stationary body;	
[e]	a first member that is displaceable axially relative to said stationary body;	[identical element]	The “first member limitation”
[f]	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	[identical element]	The “second member limitation”
[g]	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,	[no corresponding element]	The “fluid reservoir/displacement limitation”
[h]	[no corresponding element]	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	The “displacement limitation”

		among the plurality of displayable dose values,	
[i]	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 along [sic] the central longitudinal axis and is displaceable rotationally around the central longitudinal axis.	[identical element]	The “common central axis limitation”

B. Prosecution History of the ’631 Patent

The ’631 patent’s application was filed on October 9, 2014 and is a continuation of Application No. 10/556,432, which issued as the ’177 patent. *See* Ex. 1001 at [63]. The ’631 patent claims priority to FR 03 05858 filed on May 15, 2003, and has a priority date no earlier than May 15, 2003. *See id.* at [30].

In response to repeated rejections under 35 U.S.C. §112 during prosecution of the ’177 patent (*e.g.*, Ex. 1004 at 210-215, 1103-1111), the patentee explained “[this] technology is considered to be of the predicable arts,” and “fluid dispensers having counting mechanisms [were] well known.” *Id.* at 1281:19-1282:4; *see also id.* at 255, 281, 1137-1139, 1149-1150, 1158-1166, 1229-1233; 1281:19-20, 1282:1-4, 1292:13-15. One of the named inventors of the ’631 patent submitted a

declaration explaining that “[o]ne of ordinary skill in the art would understand the improved portion of the fluid dispenser because the general concept of gears and actuators in a fluid dispenser is known.” *Id.* at 1192. He also asserted that “one of ordinary skill in the art would understand how the various elements could be connected with each other, as evidenced in Attachment A [a listing of prior art references], which shows the level of ordinary skill in the art with respect to the use of reservoirs and counter elements in dispenser bodies and how dispensers function.” *Id.* at 1192-1193. Attachment A included several patents depicting a dose counter below the fluid reservoir. *See id.* at 1194; Ex. 1037; Ex. 1038; Ex. 1039; Ex. 1040.

The Examiner also finally rejected the pending claims as anticipated by EP 0949584A2 (“Bason Publication”) (Ex. 1017), and the patentee appealed to the Patent Trial and Appeal Board (“PTAB”). Ex. 1004 at 1111-1112, 1117. At the PTAB, the patentee explained that the claim limitation “a stationary body (1) including at least one stationary gear” called for a stationary body and stationary gear having a unitary structure. *Id.* at 1285:12-20, 1286:6-14; *see also id.* at 1166-1167, 1192, 1196-1205, 1233-1234. Based on the specification, drawings, and patentee’s arguments, the PTAB expressly construed this element as “a stationary body including, *as a unitary or monolithic part of the stationary body*, at least one stationary gear.” *Id.* at 1273 (emphasis added). The PTAB explained that Bason’s

“teeth 2 are shown as being part of a secondary part 1, which is a *separate part* from the structure shown as corresponding to *stationary body ‘A.’*” *Id.* (emphasis added). Accordingly, the PTAB determined the application was patentable over the Bason Publication. *Id.* at 1272-1273.

During prosecution of the ’631 patent, the examiner rejected the claims as anticipated by U.S. Patent No. 6,283,365 (“*Bason*”), a U.S. family member of the Bason Publication. Ex. 1005 at 70-71. The patentee amended the claims to require the fluid reservoir move axially relative to the stationary body and argued “canister C is **bonded** to the domed base 1 [in *Bason*],” 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.” *Id.* at 85 (emphasis in original). Despite the patentee’s previous urging that a POSA would understand how to connect the claimed improved counter to a fluid reservoir, (Ex. 1004 at 255, 281, 1137-1139, 1149-1150, 1158-1166, 1190-1205, 1229-1233; 1281:19-20, 1282:1-4, 1292:13-15), the examiner never issued an obviousness rejection.

IV. CLAIM CONSTRUCTION

A. Terms to be Construed under 37 C.F.R. §42.100(b)

Each term of a claim in an unexpired patent subject to IPR is given its broadest reasonable interpretation (“BRI”) in light of the specification of the patent in which it appears. 37 C.F.R. §42.100(b). Accordingly, to the extent these terms

can be construed in light of the '631 patent's specification, Petitioners submit constructions under the BRI standard for the following terms, and submit that all remaining terms should also be given their BRI construction.¹

1. **“a stationary body comprising at least one multi-toothed gear”**

The '631 patent does not explicitly define the term “stationary body comprising at least one multi-toothed gear.” Using the same BRI standard applicable here, the PTAB construed a nearly identical term during prosecution of the '177 patent as “a stationary body including, as a unitary or monolithic part of the stationary body, at least one stationary gear.”² Ex. 1004 at 1273. That construction was based on the “[s]pecification and drawings, and with Appellant's

¹ These claim constructions are not a concession by Petitioners as to the proper scope of any claim term in any litigation. These proposed constructions are not a waiver of any argument that claim terms in the '631 patent fail to meet the requirements of 35 U.S.C. §112, or that a different claim scope is appropriate under the claim construction standard applied in litigation.

² The term construed in the '177 patent was “a stationary body (1) including at least one stationary gear (110, 122).” Neither the word “comprising,” nor the phrase “multi-toothed” change the scope of the term. The number of teeth has no bearing on whether they are unitary with the stationary body.

contentions.” *Id.* at 1273, 1285. The PTAB relied on its construction to determine that pending claims were patentable over the Bason Publication. *See supra* §III.C. The PTAB should apply that same construction here.

2. “disposed on”

The ’631 patent does not define “a fluid reservoir disposed on said stationary body,” used in the ’631 patent’s claim 3.³ Petitioners propose the term “disposed on” encompass cases where two components are either in direct or indirect contact with each other.

The ’631 patent’s figures suggest the reservoir can be indirectly “disposed on” the stationary body via counter element 20. Ex. 1001 at Figs. 1-8. The specification explains “[t]he displacement of the reservoir 2 causes the counter element 20 to be axially displaced, so that the first gear 210 [on the counter element] comes to co-operate once again with the stationary gear 110 of the body 1.” *Id.* at 7:23-26. In the context of this specification, “disposed on” is naturally read to allow an indirect connection where the reservoir is movable, yet “on” the stationary body.

³ In the Litigation, Petitioners contend that the term “disposed on” in claim 3 of the ’631 patent is indefinite. Petitioners have proposed their alternative construction because indefiniteness is beyond the scope of IPR. *See* 35 U.S.C. §311(b).

Moreover, the PTAB has repeatedly construed similar “on” or “disposed on” terms as not requiring direct contact. *See, e.g., LG Elecs., Inc. & LG Elecs. USA, Inc. v. Toshiba Samsung Storage Tech. Korea Corp.*, IPR2015-01642, Paper 37, Final Written Dec., at 16-17 (Jan. 25, 2017); *Samsung Elecs. Co. Ltd. et al. v. Home Semiconductor Inc.*, IPR2015-00466, Paper 11, Institution Dec., at 6-7 (June 17, 2015); *TPK Am., LLC v. Wintek Corp.*, IPR2013-00436, Paper 10, Institution Dec., at 10 (Jan. 10, 2014).

“Disposed on” should be construed to allow indirect contact—two pieces that are connected via an intermediary are disposed on each other.

V. LEVEL OF ORDINARY SKILL IN THE ART

A person of ordinary skill in the art at the time of the alleged invention of the ’631 patent would have had a bachelor’s degree in industrial design, mechanical engineering or a related discipline and at least three to five years of industry experience in the design or manufacture of mechanical devices, or equivalent experience, education, or both. *See* Ex. 1002 ¶12.

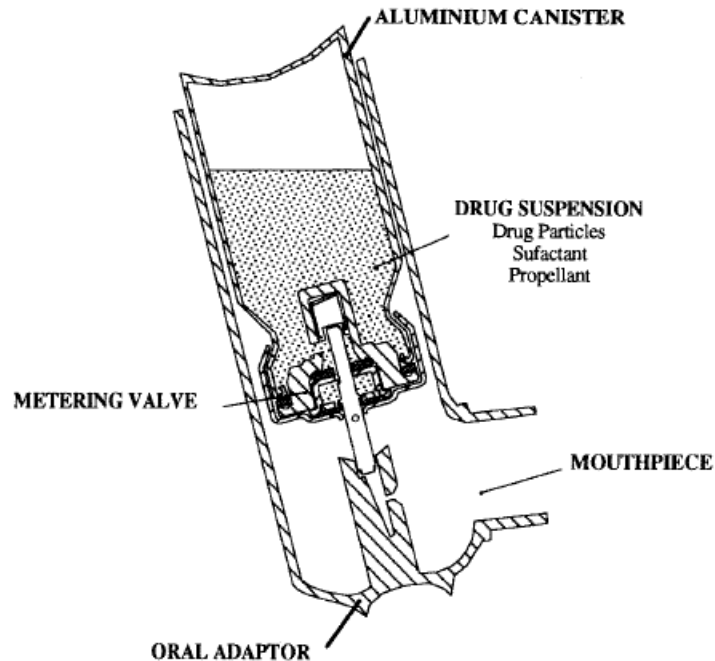
VI. SUMMARY OF THE PRIOR ART

A. The State of the Art as of May 2003

MDIs have been known and used in the art for at least 50 years. *See, e.g.,* Ex. 1012 at 4; Ex. 1018 at 6; Ex. 1042 at 8; Ex. 1002 ¶14. Dose counters have been designed for use with fluid dispensers since the early 1970s. *See, e.g.,* Ex.

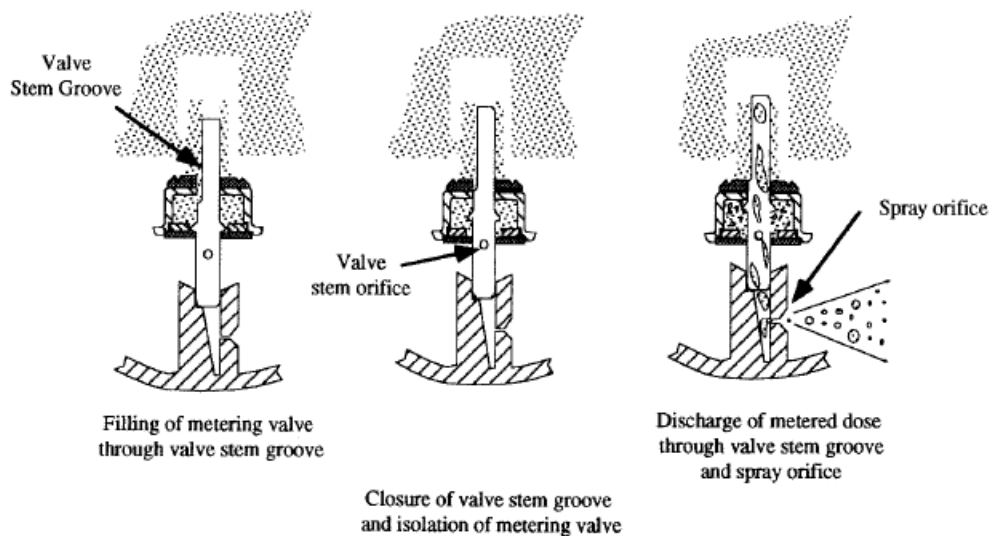
1036; Ex. 1002 ¶14. During prosecution of the parent '177 patent, the patentee explained that fluid dispensers and how to incorporate dose counters into fluid dispensers would have been known by a POSA. *See, e.g.*, Ex. 1004 at 255, 258-259, 281-285, 1190-1205, 1137-1139, 1149-1150, 1158-1166, 1190-1205, 1229-1233; 1281:19-20, 1282:1-4, 1292:13-15. Nonetheless, in the absence of a regulatory recommendation to include a dose counter, commercial MDIs did not include an integrated dose counter. Ex. 1002 ¶14; Ex. 1041 at 6; Ex. 1042 at 13. Even before the 2003 FDA guidance, however, a POSA was aware that the industry was moving towards including dose counters in future products.

MDIs have seen little mechanical change since their inception. *See* Ex. 1002 ¶15; Ex. 1041 at 1; Ex. 1048 at 1. They were generally known to include a canister assembly and mouthpiece (often referred to as an actuator or a boot). Ex. 1002 ¶15.



Ex. 1018 at 8, Fig. 2 (excerpt).

A POSA would have understood that the canister assembly consists of a metering valve mounted in combination with a reservoir where fluid is stored. Ex. 1002 ¶16. The mouthpiece includes a valve stem receptacle which is in fluid communication with a jet or spray orifice. *Id.* When not in use, the valve stem of the metering valve is fully engaged with the valve stem receptacle. *Id.* Upon depression of the reservoir relative to the mouthpiece, the metering valve causes a dose of fluid to be dispensed from the reservoir to the jet and out the mouthpiece where the resulting release can be inhaled by the patient. *Id.*



Ex. 1018 at 8, Fig. 2 (excerpt).

The prior art described a variety of dose counters. Ex. 1002 ¶17; *see, e.g.*, Ex. 1004 at 1192-1194; Ex. 1006; Ex. 1007; Ex. 1008; Ex. 1010; Ex. 1037; Ex. 1038; Ex. 1039; Ex. 1040. These devices, including the references relied on in Grounds 1-4, typically convert axial motion from a user into rotational motion of another component, often a number wheel. Ex. 1002 ¶17; Ex. 1006 at 9:3-11; Ex. 1007 at 3:15-26; Ex. 1008 at 4:9-48. This was a common mechanism used in a variety of mechanical devices by 2001-2003, including mechanical pens. Ex. 1002 ¶17; *see, e.g.*, Ex. 1009 at 1:9-12; 4:22-27 (mechanical pen); *see also* Ex. 1021 (device for drying foods); Ex. 1022 (push drill); Ex. 1023 (crushing apparatus (converting rotational into axial motion)). Indeed, Petitioner's expert was asked to design and build a dose indicator prior to 2001 and, like others in the industry, looked to the mechanism of a mechanical pen.

By 2001, the industry recognized that methods of monitoring the medication remaining in an MDI were insufficient. Ex. 1002 ¶18; Ex. 1027 at 5-6; Ex. at 1028 at 7; Ex. 1041 at 6; Ex. 1042 at 13; Ex. 1045 at 3. In December 2001, the FDA issued draft guidance suggesting “manufacturers with metered-dose inhalers under development for oral inhalation *integrate a dose-counting device*,” and “[d]ose-counters should be engineered to reliably track actuations and . . . if some low frequency of error is unavoidable, the device should be designed to specifically avoid under-counting.” Ex. 1012 at 5-6 (emphasis added); Ex. 1043 at 7-8. In light of the known deficiencies in then existing methods of monitoring medication level, and the FDA’s 2001 draft guidance, a POSA would have known by 2001 that inclusion of dose counters on future MDIs was more than a mere suggestion. Ex. 1002 ¶18. In March of 2003, the FDA issued final guidance, recommending the same. Ex. 1013 at 6-7; Ex. 1044 at 7-8. As a result of the draft and final guidance, manufacturers began implementing dose counters on commercial MDIs. Ex. 1002 ¶18; Ex. 1041 at 6, Ex. 1042 at 13. Inclusion of dose counters led to improvements for patients, including fewer emergency room visits. Ex. 1002 ¶18; Ex. 1049 at 1, 9.

It was well-understood by 2001 that undercounting the number of dispensed doses could lead to a patient unknowingly running out of medication. Ex. 1002 ¶19; *see, e.g.*, Ex. 1001 at 1:36-43; Ex. 1012 at 5; Ex. 1006 at 2:8-12; Ex. 1024 at

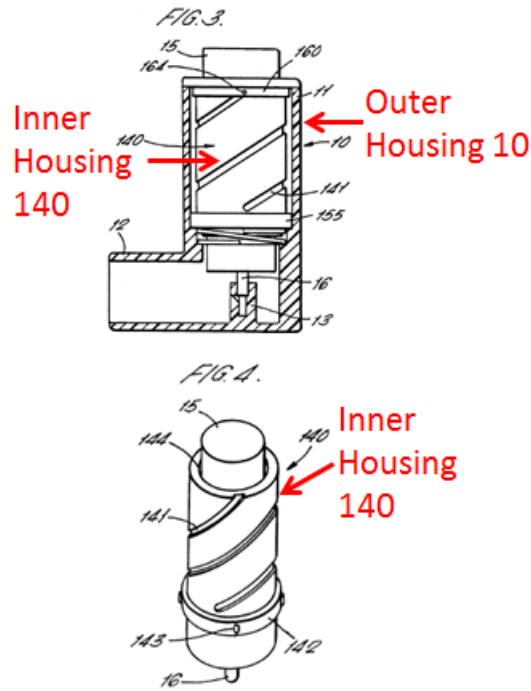
1:12-21 Ex. 1010 at 1:39-43; Ex. 1013 at 5-6. This was particularly problematic for rescue medications that a patient might need during, for example, an asthma attack. Ex. 1002 ¶19; *see, e.g.*, Ex. 1006 at 2:1-12; Ex. 1024 at 1:12-21; Ex. 1010 at 1:39-43; Ex. 1012 at 5; Ex. 1013 at 5-6. It was also known that undercounting could be avoided by coordinating the tolerances of the counter with the tolerances of the dispenser valve to trigger counting before fluid was dispensed. Ex. 1002 ¶19-22; Ex. 1001 at 1:41-43; *see also* Ex. 1011 at 4:9-12 (“[F]irst counting ring is actuated and rotated farther even when a dispensing stroke has been performed only incompletely.”); Ex. 1014 at 4:31-5:5; Ex. 1015 at 4:22-23 (“The force required to actuate the switching device may be less than that required to actuate the dispenser.”); Ex. 1020 at 5:47-6:3.

B. International Publication WO 00/59806 (“*Allsop*”) (Ex. 1006)

Allsop published on October 12, 2000 from International Application PCT/GB00/01180, filed on March 28, 2000. Ex. 1006. *Allsop* is prior art to the ’631 patent under 35 U.S.C. §102(b). *Allsop* was listed on an Information Disclosure Statement, but not relied on by the examiner in any office action during prosecution of the ’631 patent.

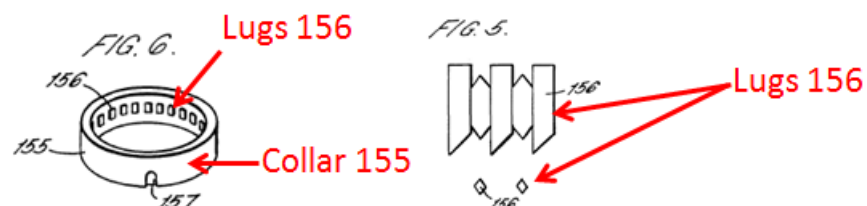
Allsop discloses a “dispensing apparatus comprising a dosage counting device.” *Id.* at Title. Specifically, *Allsop* teaches a dispenser comprising a

stationary outer housing 10 and a slidable and rotatable inner housing 140 located within the outer housing. Ex. 1002 ¶53.



Ex. 1006 at Figs. 3 and 4 (annotated).

Near the base of the outer housing is a collar 155, which “may be integrally moulded with the generally cylindrical portion 11” of outer housing 10. *Id.* at 7:8-10. Collar 155 contains a plurality of inwardly directed lugs 156 having angled upper and lower surfaces. *Id.* at 6:30-33.



See *id.* at Figs. 5 and 6 (annotated).

The inner housing 140 includes “an annular flange 142,” which has “a number of protrusions 143 equidistantly spaced around its circumference” near the base. *Id.* at 5:28-29. A pressurized dispensing container 15 is within the inner housing and a valve stem 16 protrudes from the container, through the inner housing, and into a stem block 13 from where product is dispensed. *Id.* at 4:5-28. *Allsop* also discloses a “push-button cap” (not shown in figure) that may cover the upper portion of the container. *Id.* at 8:22-24.

To operate *Allsop*, a user depresses the pressurized container 15, causing the reservoir and inner housing to move downward. As protrusions 143 of the inner housing contact the angled surfaces of the stationary lugs 156 on the outer housing, the inner housing rotates. Upon release of the canister, a spring forces the inner housing upwards and protrusions 143 again engage angled surfaces of lugs 156, causing further rotation of the inner housing 140. *Id.* at 9:3-25, Fig. 5.

Allsop discloses a ring 160 for “indicating that the pressurised dispensing container 15 contains one less dose.” *Id.* at 9:14-17. *Allsop* alternatively discloses, “a series of numbers . . . spaced around the inner housing 140 . . . such that only a single number” can be seen through slots 170 at any given time. *Id.* at 10:4-9.

C. U.S. Patent No. 6,283,365 (“*Bason*”) (Ex. 1007)

Bason issued on September 4, 2001 from Application No. 09/288,163, filed on April 8, 1999. Ex. 1007. *Bason* is prior art to the ’631 patent under 35 U.S.C.

§102(b). The examiner relied on *Bason* in an anticipation rejection during prosecution of the '631 patent, but it was never cited in an obviousness rejection. Ex. 1005 at 70-71, 85-86.

Bason discloses a dose counter for an MDI that is attached to the base of a pressurized canister near the top of the inhaler. Ex. 1007 at 1:3-5, 2:16-18, Fig. 1. The counter in *Bason* also converts axial motion into rotational motion. Ex. 1002 ¶118.

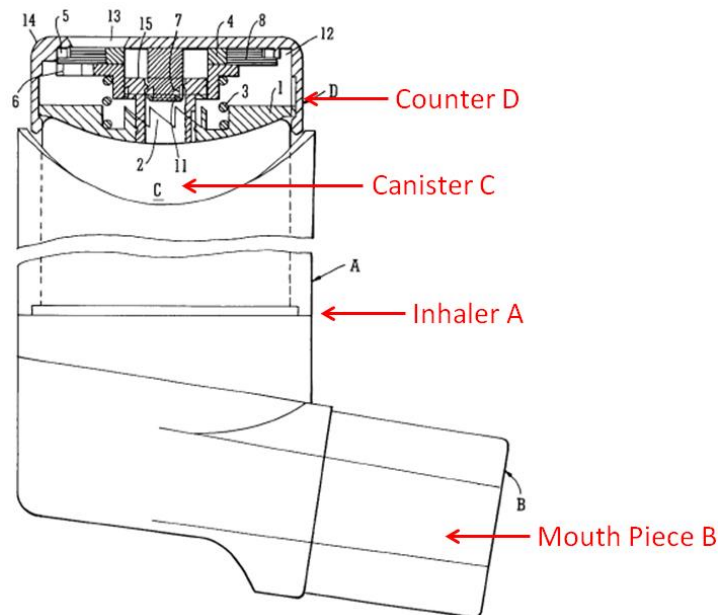
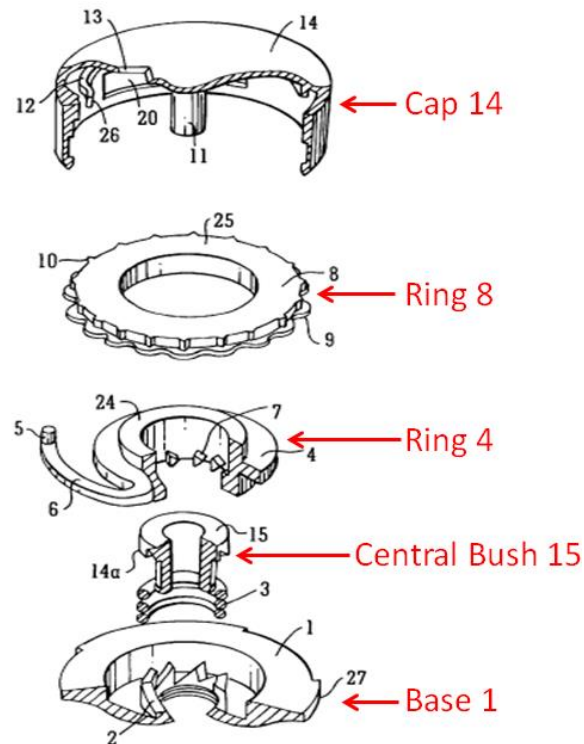


FIG. 1

Ex. 1007 at Fig. 1 (annotated), 1:3-6, 2:11-15.

The *Bason* dose counter has of a central bush 15 that is “[d]isposed in fixed position on base 1,” (*id.* at 2:20, Figs. 1 & 3), with “downwardly directed teeth 14a,” (*id.* at 2:33-35). Base 1 includes “upwardly directed teeth 2.” *Id.* at 2:31-33,

Fig. 3. Rings 4 and 8 include numerals on faces 24 and 25, and are located between teeth 2 of the base and teeth 14a of the central bush. *Id.* at 2:66-3:4; Ex. 1002 ¶119. Above ring 8 is an axially movable cap. Ex. 1007 at 2:47-50; Ex. 1002 ¶119.



Ex. 1007 at Fig. 3 (annotated).

“Upon depression of the cap 14 with respect to the base 1, the rings 4 and 8 are also depressed linearly,” and teeth 7 of ring 4 engage the angled face of teeth 2 on the base 1, causing ring 4 to rotate (which can cause ring 8 to rotate as well). *Id.* at 3:15-22. When the user releases the cap, spring 3 causes ring 4 and the cap to move upwards, where teeth 7 on ring 4 engage teeth 14a of the central bush, rotating ring 4 further and into position for the next actuation. *Id.* at 3:15-26; Ex.

1002 ¶120. Rotation of rings 4 and 8 changes the displayed dose value. Ex. 1007 at 3:15-24. Figure 5 shows how teeth 7 (on ring 4) sequentially engage teeth 2 and 14a, causing rotation of ring 4 (not shown). Ex. 1002 ¶120.

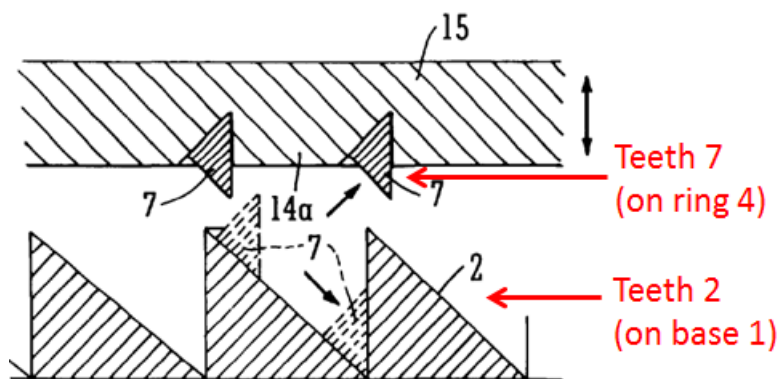


FIG. 5

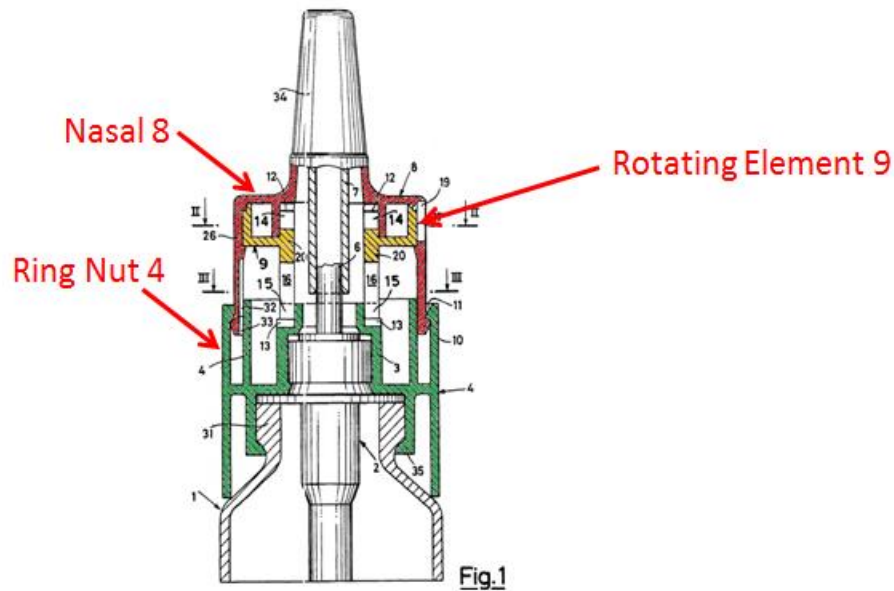
Ex. 1007 at Fig. 5 (annotated).

D. EP 0480488 (“*Marelli*”) (Ex. 1008)

Marelli published on April 15, 1992 and issued as a patent on November 2, 1994. Ex. 1008. *Marelli* is prior art to the ’631 patent under 35 U.S.C. §102(b). *Marelli* was listed on an Information Disclosure Statement, but it was not cited by the examiner during prosecution of the ’631 patent.

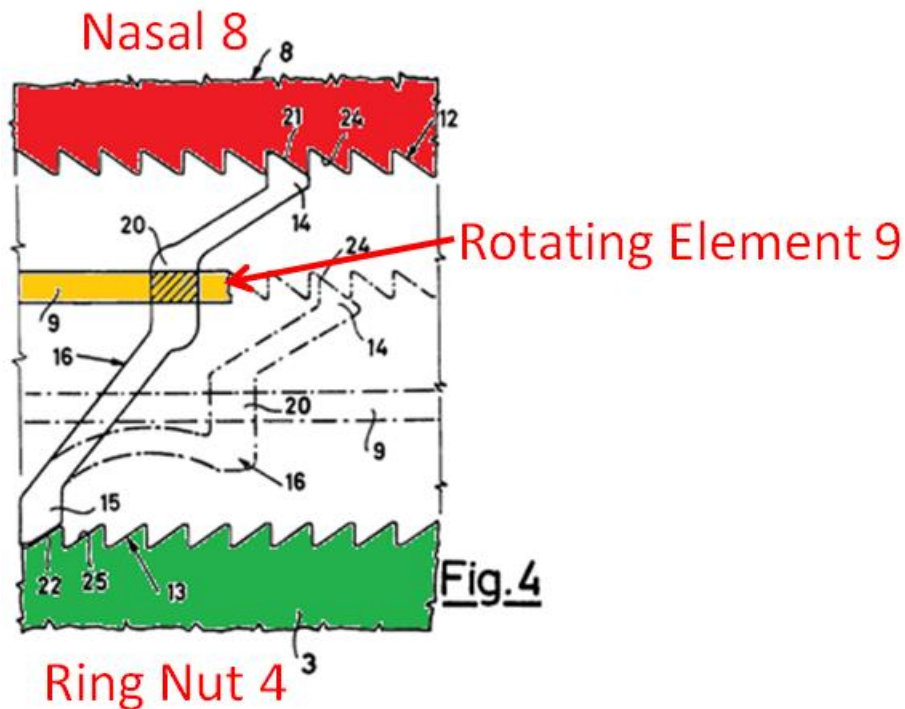
Marelli discloses a dose counting device for a fluid distributor, with a particular application to nasal distributors. *Id.* at 1:3-7. *Marelli* comprises ring nut 4, nasal 8, and distribution valve 2. *Id.* at 3:9-25. Ring nut 4 is fastened to a fluid filled container. *Id.* at 4:3-4. Nasal 8 extends from the valve and can be inserted into the nostrils for distribution of the fluid. *Id.* at 3:34-38. Nasal 8 (red, below)

and ring nut 4 (green, below) are movable axially relative to each other. *Id.* at 3:26-38. “Every stroke imparted to the nasal causes the distribution of a given dose of product.” *Id.* at 1:26-27.



Id. at Fig. 1 (annotated).

“Inside both the nasal 8 and the ring nut 4 there are accomplished internal sets of saw-tooth shaped teeth 12, 13.” *Id.* at 3:39-41. Between those rows of teeth is intermediate part 20, integral with a rotating element 9, which has small flexible legs 16 that interact with the rows of saw tooth-shaped teeth. *Id.* at 3:39-46.



Id. at Fig. 4 (annotated).

As a stroke is imparted to nasal 8, rows of teeth 12 and 13 are moved towards each other and the upper part 14 of flexible leg 16 slips to the next tooth in row of teeth 12. *Id.* at 4:9-30, Fig. 4. Upon release of the device, lower part 15 of flexible leg 16 is pulled into the next tooth of row 13. *Id.* at 4:30-36, Fig. 4. This causes rotating element 9, which contains numerical indices 17, to rotate circumferentially one position, changing the displayed dose value. *Id.* at 4:9-48, Fig. 4.

E. U.S. Patent No. 3,205,863 (“*Rhoades*”) (Ex. 1009)

Rhoades was filed on December 29, 1953 and issued on September 14, 1965, and is prior art under §102(b). Ex. 1009. *Rhoades* was not cited during prosecution of the '631 patent.

Rhoades discloses a ball point pen having a projecting and retracting mechanism that converts axial motion into rotational motion. Ex. 1009 at 1:9-12; 4:22-27. When a user pushes button 35, forwardly-directed teeth move a cam body and attached ink reservoir forward. Ex. 1002 ¶122. Once the cam body has moved past stop members, the cam body will rotate. *Id.* Stop members then cause the reservoir to remain in an extended position. *Id.* Pushing the button again moves the cam body axially until it clears the stop members, and release of the button allows the cam body to rotate again, fully retracting the reservoir. *Id.*

Figure 1 shows the pen in the retracted position. *See* Ex. 1009 at Fig. 1 (annotated):

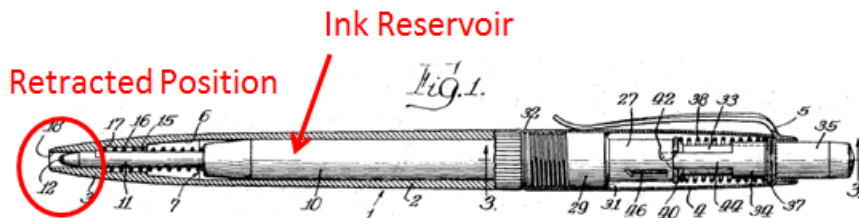
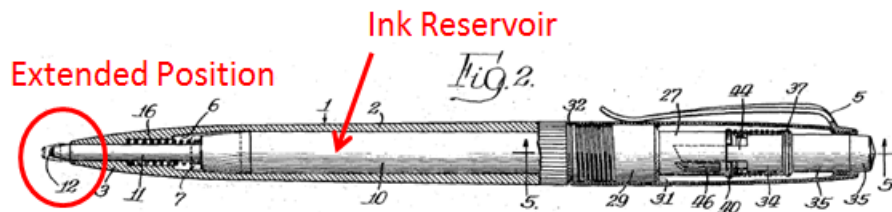
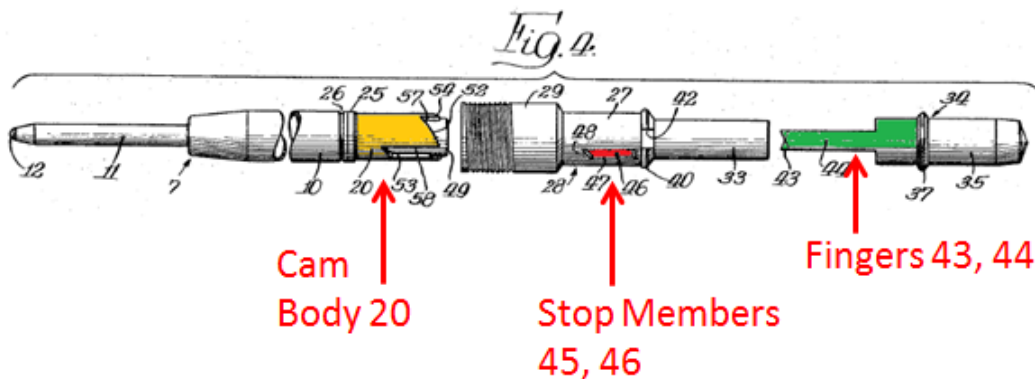


Figure 2 shows the pen in the extended position. *See id.* at Fig. 2 (annotated):

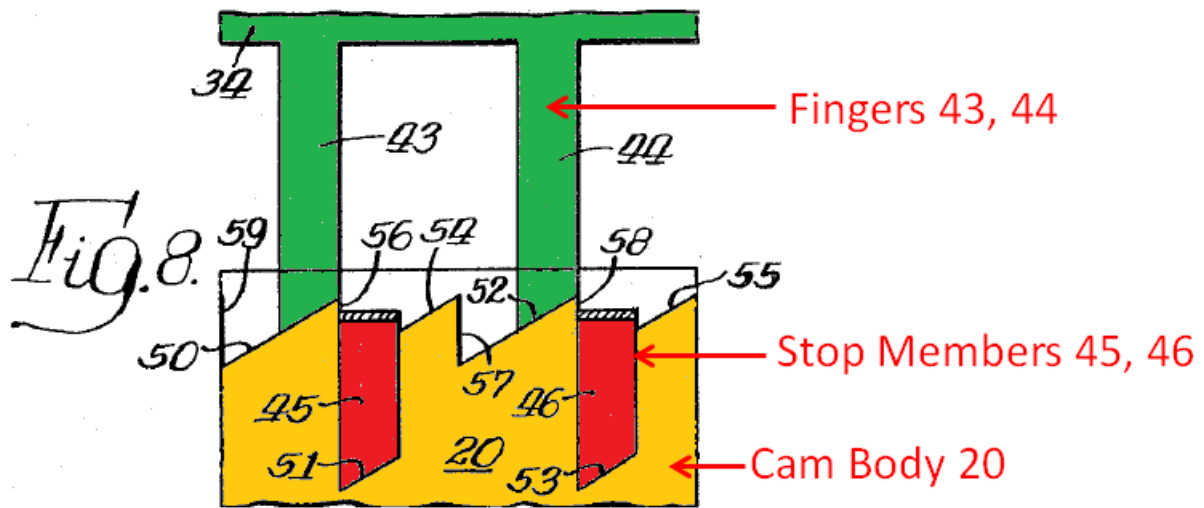


Ink reservoir section 10 containing the fluid (ink) that will be dispensed from the ball point is connected directly to the cam body 20 (yellow, below), which is rotatably and slidably disposed within the stationary guide member 28. *Id.* at 3:36-38, 60-67. At the end of the device is push button 35, connected to a plunger 34, which includes two fingers 43 and 44 (green, below) extending forwardly from the plunger. Guide member 28 includes stop members 45 and 46, which are two inwardly directed tabs (red, below). *Id.* at 4:13-19.



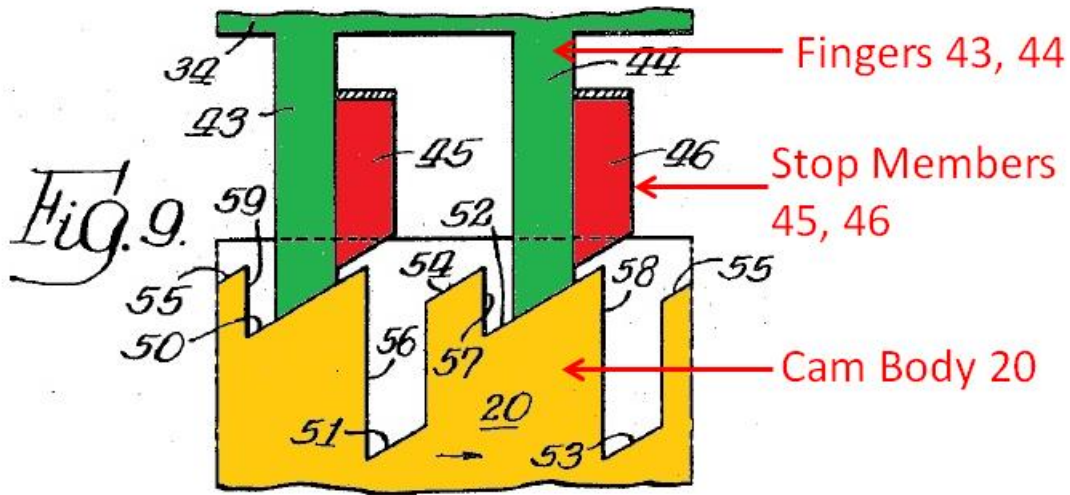
Id. at Fig. 4 (annotated).

The cam body 20, fingers 43 and 44, and stop members 45 and 46 all have sloped faces that cooperate in causing the axial and rotational movement of cam body 20 under the force of spring 16. *Id.* at 5:55-58; Ex. 1002 ¶126.

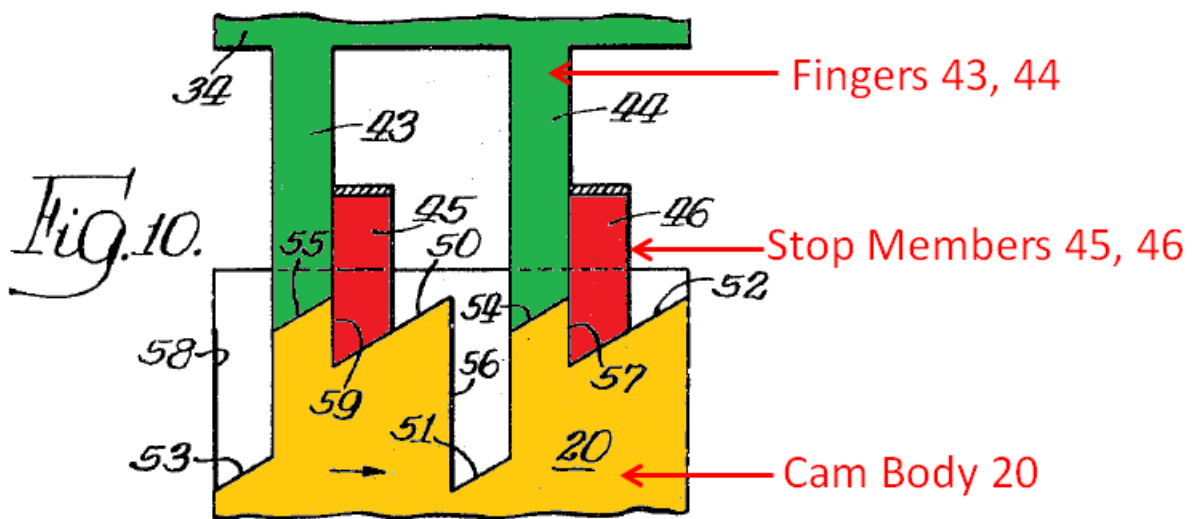


Ex. 1009 at Fig. 8 (annotated).

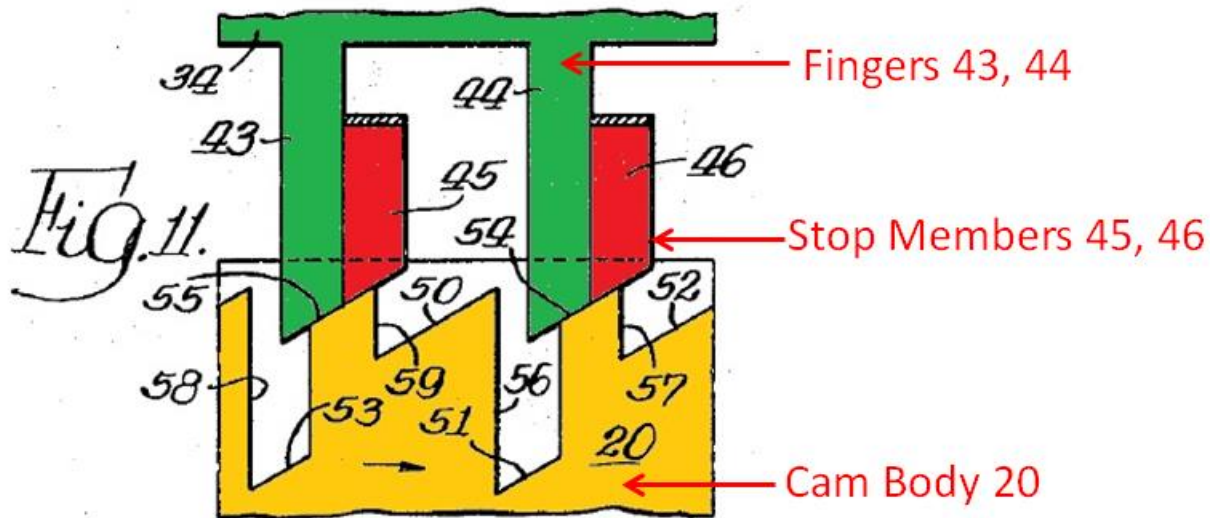
Figure 8 above shows the *Rhoades* mechanism fully retracted. Ex. 1009 at 5:15-22. Stop members 45 and 46 reside in the deep grooves with bottom surfaces 51 and 53, while fingers 43 and 44 rest against cam body faces 50 and 52. Ex. 1002 ¶127. As fingers 43 and 44 are depressed by the plunger 34 and push button 35, they move cam body 20 axially downward. Despite the force exerted by the sloped faces of the fingers 43 and 44, cam body 20 cannot rotate until it moves past stop members 45 and 46. *Id.*; Ex. 1009 at 5:47-50, Fig. 9 (annotated):



Once cam body 20 has moved axially a sufficient distance to clear the stop members 45 and 46, it begins to rotate. Ex. 1002 ¶128; Ex. 1009 at 5:51-54, Fig. 9. When plunger 35 is released, the cam body continues to rotate until the stop members abut faces 57 and 59, and the fingers rest on faces 54 and 55. Ex. 1002 ¶128. Here, the pen is in its extended conformation. See Ex. 1009 at Fig. 10 (annotated):



Finally, when the plunger 35 is depressed again, it causes vertical faces 59 and 57 to slide along stop members 45 and 46. Once cam body 20 has moved a sufficient distance axially so that faces 59 and 57 clear the stop members, cam body 20 again rotates. Ex. 1002 ¶129; see Ex. 1009 at Fig. 11 (annotated):



Once cam body 20 rotates enough for fingers 43 and 44 to align with the deep grooves containing bottoms 51 and 53, fingers 43 and 44 will move freely up and down as plunger 35 is released and depressed unless and until the plunger is released a sufficient distance to allow the tips of fingers 43 and 44 to clear the tips of sloped faces 50 and 52. Ex. 1002 ¶130. At that point, cam body 20 rotates until stop members 45 and 46 are aligned with deep grooves having bottoms 53 and 51. *Id.* Complete release of the plunger causes the completion of an actuation, and stop members 45 and 46 come to rest in the bottoms of the deep grooves, against faces 51 and 53—the same configuration shown above in Figure 8. *Id.*

VII. STATEMENT OF PRECISE RELIEF REQUESTED AND REASONS THEREFOR UNDER 37 C.F.R. §§42.104(b)(1) AND (2)

Petitioners request review of the Challenged Claims under 37 C.F.R. §42.108 and cancellation of these claims as unpatentable on the following grounds:

Ground	Proposed Statutory Rejections for the '631 Patent
1	Claims 1-4 are anticipated under §102(b) by <i>Allsop</i>
2	Claims 1-4 are anticipated under §102(b) by <i>Marelli</i>
3	Claims 1-4 are rendered obvious under §103(a) by <i>Bason</i> in view of <i>Rhoades</i>
4	Claims 1-4 are rendered obvious under §103(a) by <i>Bason</i> in view of <i>Allsop</i>

VIII. EACH CHALLENGED CLAIM OF THE '631 PATENT IS UNPATENTABLE

Pursuant to 37 C.F.R. §42.104(b)(4)-(5), the Challenged Claims are unpatentable for the reasons set forth in detail below. The majority of elements in independent claims 1 and 3 are identical. *See supra* §III.B. Those identical elements will be addressed concurrently.

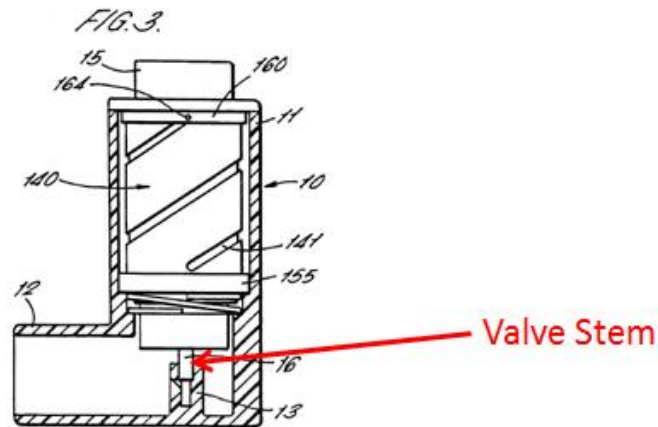
A. GROUND 1: Claims 1-4 of the '631 Patent are Anticipated by *Allsop* under 35 U.S.C. §102(b)

Allsop teaches each element and anticipates the Challenged Claims. Ex. 1002 ¶58.

1. **Claims 1 through 4**

(a) **Claims 1 and 3 Preamble:** “A fluid dispenser”

To the extent the preamble is deemed limiting, *Allsop* discloses a fluid dispenser. “[T]he present invention provides [a] dispensing apparatus.” Ex. 1006 at 2:20-21. The device depicted in *Allsop* Fig. 1 is an inhaler that dispenses aerosolized medicament through a valve stem 16. Ex. 1002 ¶¶59, 73.



Ex. 1006 at Fig. 3 (annotated), 4:18-20.

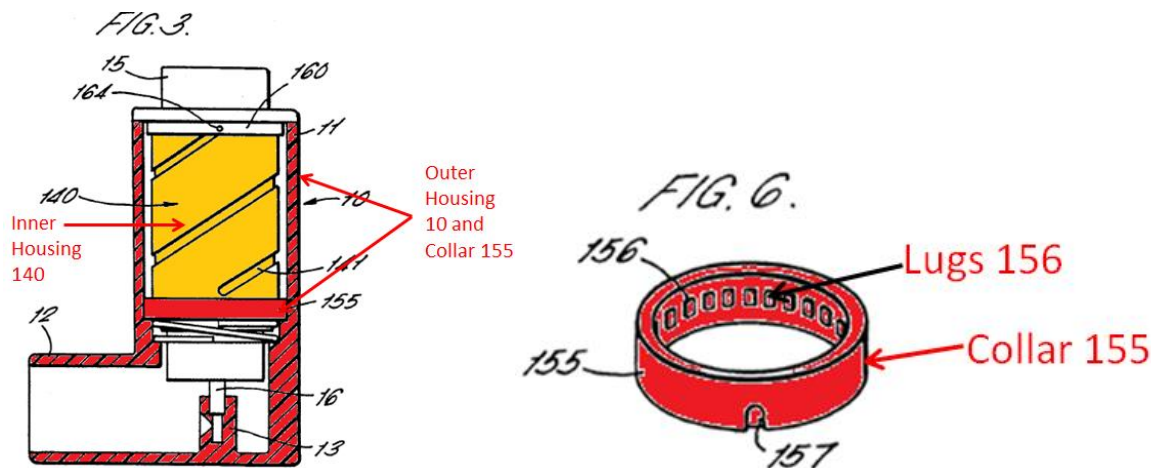
(b) **Claims 1 and 3:** “a plurality of displayable dose values”

Allsop discloses an outer housing that contains a series of values corresponding to doses remaining in the pressurized canister. Ex. 1006 at 2:20-29; *Id.* at Fig. 1. The current value is indicated by a ring at the value corresponding to the remaining doses, or a series of numbers spaced around the inner housing so

only a single number is visible at any one time. *Id.* at 9:13-17, 10:4-9; Ex. 1002 ¶¶60, 74.

(c) **Claims 1 and 3:** “a stationary body comprising at least one stationary multi-toothed gear”

Allsop discloses a collar with “a plurality of inwardly directed lugs 156 . . . hav[ing] angled upper and lower surfaces” near the lower end of the cylindrical portion 11 of housing 10. Ex. 1006 at 6:30-7:6. The *Allsop* collar can be “integrally moulded,” and therefore unitary, with the outer cylindrical housing. *Id.* at 7:9-10. A POSA would have understood the housing 10 with an integrally molded collar 155 containing inwardly directed lugs 156 to be the claimed stationary body with at least one stationary multi-toothed gear (depicted in red below). Ex. 1002 ¶¶61, 75.



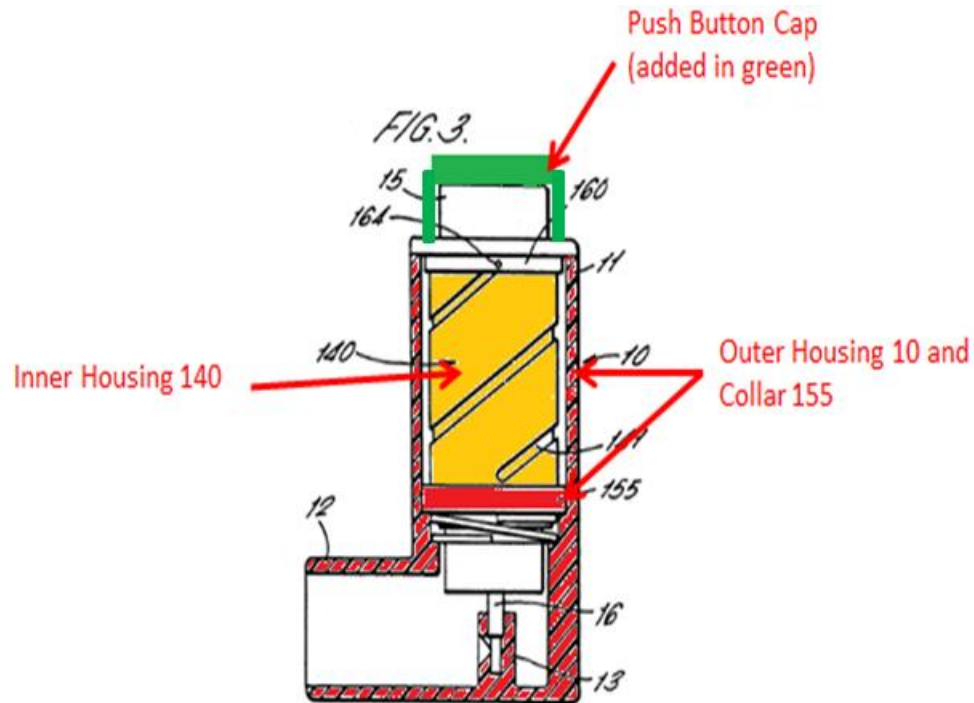
Ex. 1006 at Figs. 3, 6 (annotated).

- (d) **Claim 3:** “a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”

Allsop discloses a housing having a generally cylindrical portion 11, which defines “a chamber to slidably receive a pressurized dispensing container 15.” Ex. 1006 at 4:8-9. Figure 3 depicts the container within the housing body 10. Ex. 1002 ¶76. As explained in §IV.A.2, the fluid reservoir is disposed on the stationary body so long as it is at least indirectly connected to the stationary body. The container 15 sits within the inner housing, protrusions 143 of which are directly in contact with lugs 156 on the outer housing (stationary body). *Id.* “Depression of the pressurised dispensing container 15 results in downward movement of the container 15 relative to the housing 10.” Ex. 1006 at 9:3-5. Accordingly, the container in *Allsop* is the fluid reservoir, and it is disposed on the stationary body so as to be axially displaceable relative to the stationary body. Ex. 1002 ¶76.

- (e) **Claims 1 and 3:** element [e]—“first member limitation” (*see supra* §III.B)

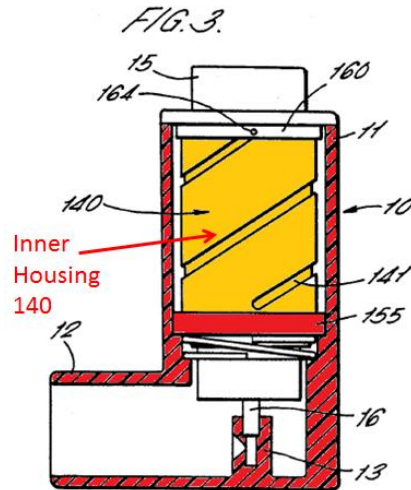
Allsop discloses use of a “push-button cap” that covers the upper portion of the pressurized container 15. The push-button cap is not shown in the figure, but its location above the container is labeled and depicted in green below. Ex. 1002 ¶¶62, 77; Ex. 1006 at 8:22-24, Fig. 3 (annotated):



A POSA would have understood that the button could be depressed axially, moving the canister axially. Ex. 1002 ¶¶63, 78. Accordingly, he or she would have understood *Allsop* to disclose the claimed first member by disclosing a push-button cap. *Id.*

(f) **Claims 1 and 3:** element [f]—“second member limitation” (*see supra* §III.B)

Allsop discloses inner housing 140, which is the claimed “second member” (depicted in yellow below). Ex. 1002 ¶¶64, 79; *see* Ex. 1006 at Fig. 3 (annotated):



The inner housing 140 directly houses the pressurized canister. Ex. 1006 at 5:14-26. Near the bottom of the inner housing 140 are a plurality of outwardly directed protrusions 143. *Id.* at 5:27-32. Inner housing 140 is located within outer housing 10 and is moved downward as the canister is depressed. Ex. 1002 ¶¶65, 80; Ex. 1006 at 9:3-9. As the inner housing moves downward, protrusions 143 interact with inwardly directed lugs 156 of the outer housing, causing the inner housing to rotate. Ex. 1006 at 9:3-11, 17-25. The inner housing directly engages with the stationary body via the interaction between protrusions 143 of the inner housing 140 and lugs 156 of the stationary body. *Id.* at 9:5-9.

A POSA would have understood the depressible button of the push button cap would engage with the inner housing as the button was depressed. Ex. 1002 ¶¶66, 81. And if the button does not directly engage the inner housing, the button indirectly engages the inner housing via the pressurized canister when the button is depressed. *Id.*

(g) **Claim 1:** element [g]—“fluid reservoir/displacement limitation” (*see supra* §III.B)

As explained above, *Allsop* discloses a pressurised dispensing container (fluid reservoir) that is axially displaceable within the outer housing 10 (stationary body). Ex. 1006 at 4:5-13, 19-26.

When the push-button cap (first member) is depressed, the pressurized canister (fluid reservoir) and inner housing (second member) are depressed axially. Ex. 1006 at 4:5-13, 19-26; 8:22-26; Ex. 1002 ¶68. As the inner housing moves downwards, protrusions 143 engage lugs 156 and the inner housing rotates. Ex. 1006 at 9:5-9. As the inner housing rotates, ring 160 slides axially downwards to the next displayable dose value, indicating there is one less dose remaining. *Id.* at 9:13-17. Alternatively, the subsequent dose values can be printed directly on the inner housing. *Id.* at 10:4-9.

A POSA would have understood that as the push-button cap (first member) displaces axially, a container 15 (fluid reservoir) displaces axially, the inner housing (second member) displaces axially, and upon contacting lugs 156 of the outer housing (stationary body), the inner housing is rotated to change a displayed dose value. Ex. 1002 ¶69.

- (h) **Claim 3:** element [h]—“displacement limitation” (*see supra* §III.B)

As shown in the chart in §III.B, this limitation [h] is identical to claim 1’s limitation [g] except that this limitation [h] does not require a fluid reservoir as part of the limitation. Accordingly, *Allsop* discloses this limitation for the same reasons described immediately above. *See* §VIII.A.1.g.

- (i) **Claims 1 and 3:** element [i]—“common central axis limitation” (*see supra* §III.B)

Allsop discloses an outer housing 10 (stationary body) that has a generally cylindrical portion 11. Ex. 1006 at 4:7-8. Within that generally cylindrical portion is the cylindrical inner housing 140 (second member), which interacts with the circular collar 155 of the stationary body. Ex. 1002 ¶¶70, 83; *see* Ex. 1006 at 9:3-11, 17-25, Figs. 3 and 4. Accordingly, the stationary body and inner housing have a common central longitudinal axis. Ex. 1002 ¶¶70, 83; Ex. 1006 at Figs. 3, 4. The push button cap (first member) covers the top of the cylindrical fluid reservoir, and therefore shares the same longitudinal axis. Ex. 1006 at 8:22-24; Ex. 1002 ¶¶70, 83.

As described above, the push-button cap moves axially along the longitudinal axis running through the outer housing. Similarly, as the cylindrical inner housing moves axially, the protrusions 143 contact and engage the lugs 156

of the outer housing, causing the inner housing to rotate about that same axis. Ex. 1002 ¶¶71, 84; Ex. 1006 at 9:3-11, 17-25, Figs. 3-4.

- (j) **Claim 2:** “The fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear”

Allsop teaches that the inner housing 140 (second member) has a number of protrusions 143 equidistantly spaced around its circumference. Ex. 1006 at 5:28-29, Fig. 4. Those protrusions are the multiple gear teeth of a multi-toothed gear located on the second member. Ex. 1002 ¶72.

- (k) **Claim 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”

Allsop teaches that “[t]he pressurised dispensing container 15 comprises a metering valve attached to a can,” and “[a] valve stem 16 extends axially from the metering valve and defines an outlet through which product is dispensed.” Ex. 1006 at 4:13-20. “Depression of the pressurised dispensing container 15 results in downward movement of the container 15 relative to the housing 10.” *Id.* at 9:3-5. A POSA would have understood that as a pressurized canister with a valve as disclosed in *Allsop* is depressed, fluid will be dispensed from the canister. *See* Ex. 1002 ¶85; Ex. 1018 at 6-8; Ex. 1019 at 2:34-50, Figs. 1-2; Ex. 1020 at 5:47-6:8, Figs. 1-2.

B. GROUND 2: Claims 1-4 of the '631 Patent are Anticipated by *Marelli* under 35 U.S.C. §102(b)

Marelli teaches each element and anticipates the Challenged Claims. *See* Ex. 1002 ¶90.

1. Claims 1 through 4

(a) Claims 1 and 3 Preamble: “A fluid dispenser”

To the extent the preamble is deemed limiting, *Marelli* discloses a fluid dispenser. The device disclosed in *Marelli* “relates to a dose counting device for a distributor of doses of fluid products.” Ex. 1008 at 1:3-5.

(b) Claims 1 and 3: “a plurality of displayable dose values”

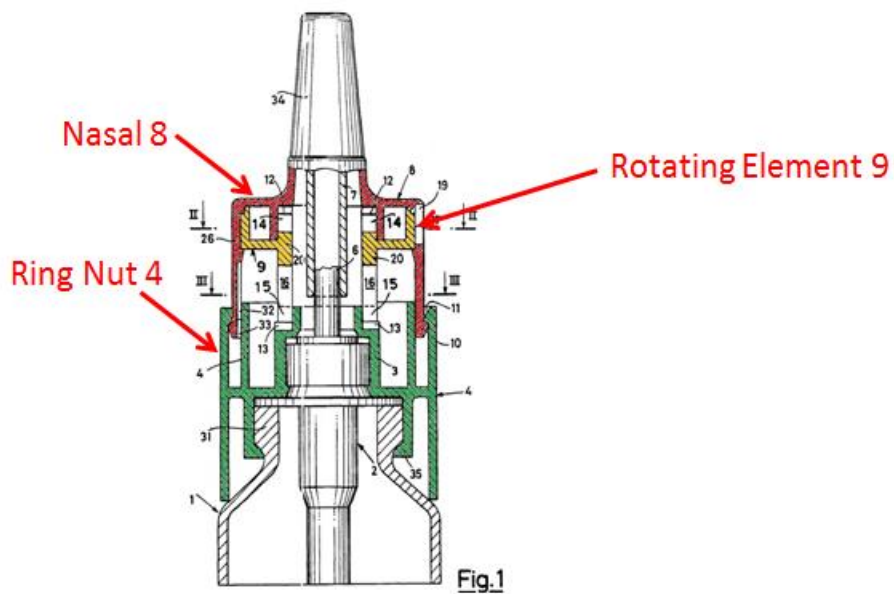
Marelli discloses “progressive numerical indices 17” on rotating element 9, which are displayed through an observation window 19 in the annular part 26 of the nasal 8, for “indicating the number of strokes that have been imparted to the nasal 8 up to that time.” Ex. 1008 at 3:45-52, 4:42-46.

(c) Claims 1 and 3: “a stationary body comprising at least one stationary multi-toothed gear”

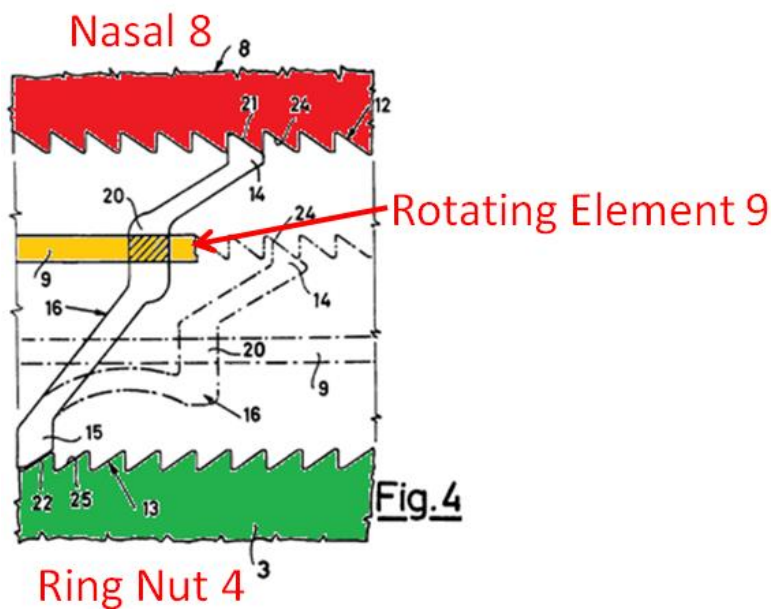
Marelli discloses a container 1 with a distribution valve that is fastened to the container through a flange 3. Ex. 1008 at 3:9-17. That flange is part of ring nut 4 fastened to the container by means of an annular protrusion 35. *Id.* at 3:16-19. The valve 2 leads to “nasal 8,” through which the fluid product is delivered to a patient’s nose. *Id.* at 3:19-25; Ex. 1002 ¶¶93, 106. “[T]he nasal 8 is moved in an axial translation with respect to the ring nut 4 by axial depression of the same . . .

.” Ex. 1008 at 4:9-11. Nasal distributors like the one disclosed in *Marelli* are generally used by placing two fingers on the top of the distributor and the user’s thumb on the bottom of the distributor. Ex. 1002 ¶¶93, 106. The user inserts the terminal spout (34 in the figure below) into his or her nostril, and squeezes the distributor, moving the nasal and ring nut 4 towards each other. *Id.*

A POSA would have understood the terms “stationary” and “moving” are relative terms. *Id.* ¶¶94, 107. A body is only stationary or moving with respect to another body. *Id.* Accordingly, he or she would have understood that either the nasal 8 (red), or ring nut 4 (green) would be considered a stationary body and the other an axially moving piece. *Id.* The specification of *Marelli* describes the nasal as “axially translatable.” Ex. 1008 at 3:23-24. However, because the user inserts the terminal spout (translatable with the nasal) in his or her nostril, a POSA would have understood it is really the ring nut and fluid reservoir that move, while the nasal remains stationary with respect to the user with the spout inserted in the user’s nostril during use. Ex. 1002 ¶¶94, 107. In other words, a user does not pull the nasal down (and out of the nose) during operation, but rather moves the ring nut 4 (green) and canister towards the nasal 8 (red). *Id.* Accordingly, a POSA would have understood *Marelli* to disclose a stationary body, the nasal 8 (red, below). *Id.*



Ex. 1008 at Fig. 1 (annotated). Inside nasal 8 there is an “internal set[] of saw-tooth shaped teeth.” *Id.* at 3:39-41.



Id. at Fig. 4 (annotated). Accordingly, nasal 8 is a stationary body that comprises at least one stationary multi-toothed gear. Ex. 1002 ¶¶96, 109.

- (d) **Claim 3:** “a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”

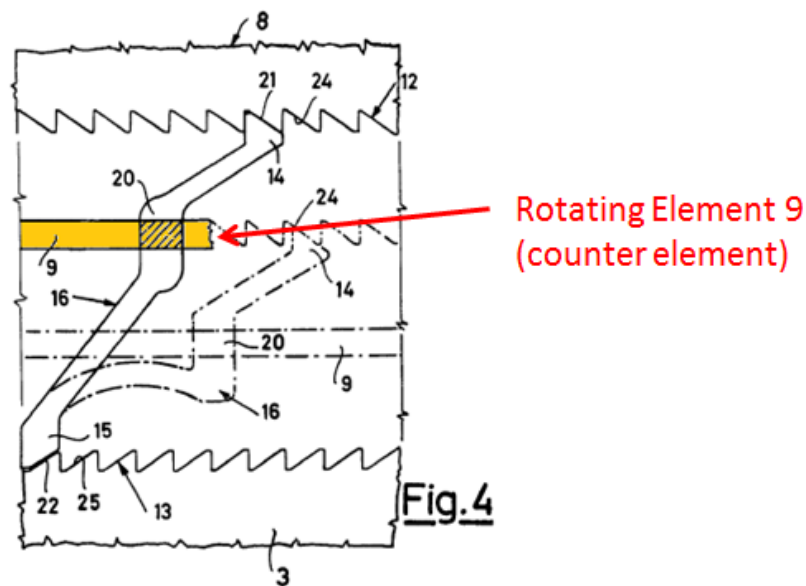
Marelli discloses a fluid reservoir attached to ring nut 4. As described immediately above, a POSA would have understood nasal 8 could be a stationary body. Ex. 1002 ¶110. As described in §IV.A.2, the fluid reservoir can be “disposed on” the stationary body indirectly. In *Marelli*, the container attached to ring nut 4 is disposed on the nasal 8 indirectly through the interaction between the ring nut 4 and the nasal 8. As strokes are imparted to the nasal 8, the fluid reservoir, attached to ring nut 4, is moved axially with ring nut 4. Ex. 1008 at 1:26-27, 3:26-38; 4:3-11, Fig. 1; Ex. 1002 ¶110.

- (e) **Claims 1 and 3:** element [e]—“first member limitation” (*see supra* §III.B)

Marelli teaches ring nut 4 (first element). “At each operation of the distributor the nasal 8 is moved in an axial translation with respect to the ring nut 4 by the axial depression of the same.” Ex. 1008 at 4:9-11. Accordingly, *Marelli* expressly discloses that nasal 8 and ring nut 4 displace axially relative to each other. A POSA would have understood that nasal 8 would be considered the stationary body, and therefore, ring nut 4 would be considered a first member that moves axially relative to nasal 8. Ex. 1002 ¶¶97, 111; *see* Ex. 1008 at 3:26-38.

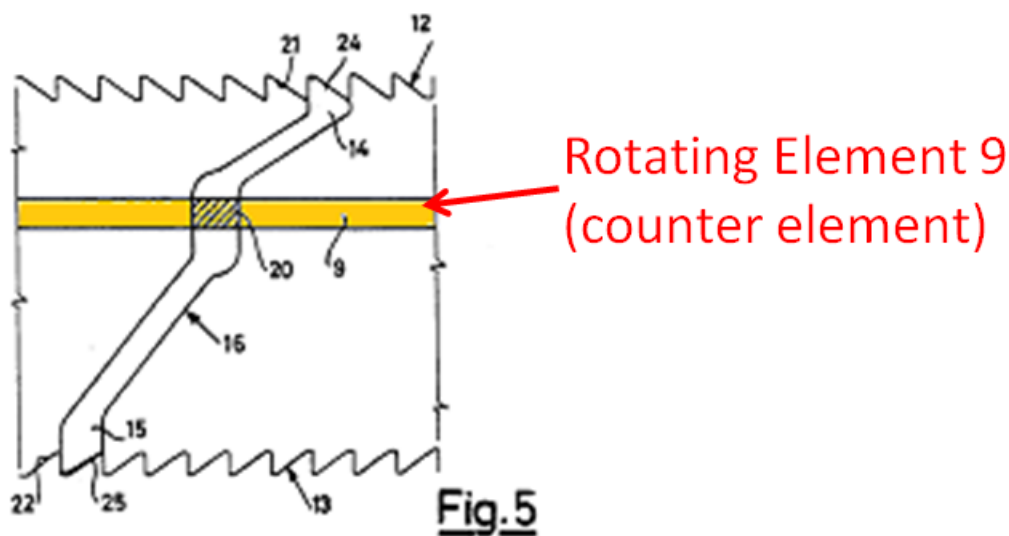
(f) **Claims 1 and 3:** element [f]—“second member limitation” (*see supra* §III.B)

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 . . . the small leg 16 is elastically urged by the approach of the set of teeth 12 towards the set of teeth 13 in the configuration illustrated by a dotted line in the same Figure 4.” Ex. 1008 at 4:22-28. Although described in the specification as the movement of the nasal 8, operation of the device effects the same result if the ring nut is moved axially while nasal 8 remains stationary. Ex. 1002 ¶¶98, 112. Whether a body is stationary or moving is a description of the body relative to another object. This axial motion causes axial movement of the counter element 9.



Ex. 1008 at Fig. 4 (annotated).

Upon actuation, “upper part 14 leaves the tooth 21 to position itself in a tooth 24 adjacent to it.” *Id.* at 4:29-30. On the return stroke, teeth 13 and teeth 12 move apart “and the lower part 15 of the small leg 16 leaves the tooth 22 to position itself in the tooth adjacent to it.” *Id.* at 4:34-36. This moves “the small leg 16 through one position.” *Id.* at 4:39. “During this forward movement the intermediate part 20 of the small leg 16 takes with it the rotating element 9 in a unitary rotation.” *Id.* at 4:39-42.



Id. at Fig. 5 (annotated).

(g) **Claim 1:** element [g]—“fluid reservoir/displacement limitation” (*see supra* §III.B)

As described in the immediately preceding claim element, axial displacement between ring nut 4 and nasal 8 causes axial displacement and rotation of element 9 in unitary rotation. Ex. 1008 at 3:39-52, 4:40-42; Ex. 1002 ¶100.

That rotation causes “[t]he numerical index 17 attached to the rotating element 9 [to] be rotated through one position and behind the window 19 there shall appear the immediately successive numerical index 17, updating the information related to the number of strokes imparted to the nasal 8 and thus to the number of doses distributed.” Ex. 1008 at 4:42-48. As noted above, the container is attached to ring nut 4, which moves axially relative to nasal 8. Accordingly, *Marelli* teaches that the container moves axially relative to the stationary body. Ex. 1002 ¶100.

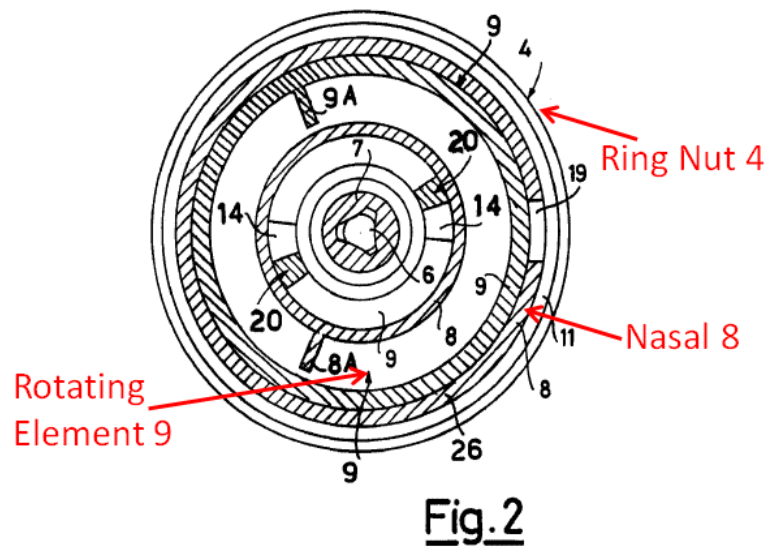
(h) **Claim 3:** element [h]—“displacement limitation” (*see supra* §III.B)

As shown in the chart in §III.B, this limitation [h] is identical to claim 1’s limitation [g] except that this limitation [h] does not require a fluid reservoir as part of the limitation. Accordingly, *Marelli* discloses this limitation for the same reasons described immediately above. *See* §VIII.B.1.g.

(i) **Claims 1 and 3:** element [i]—“common central axis limitation” (*see supra* §III.B)

Marelli discloses a dose counting device including a circular nasal 8 (stationary body), a circular ring nut 4 (first member), and a circular rotating element 9 (second member). Ex. 1008 at 3:26-52, 4:40-42, Fig. 2; Ex. 1002 ¶¶101, 115. These components are all circular and share the same axis, a feature depicted in Figure 2 (a view from above through a cross section of the device). Ex. 1008 at 2:52-53, Fig. 2. The axial movement of the first member and the axial and

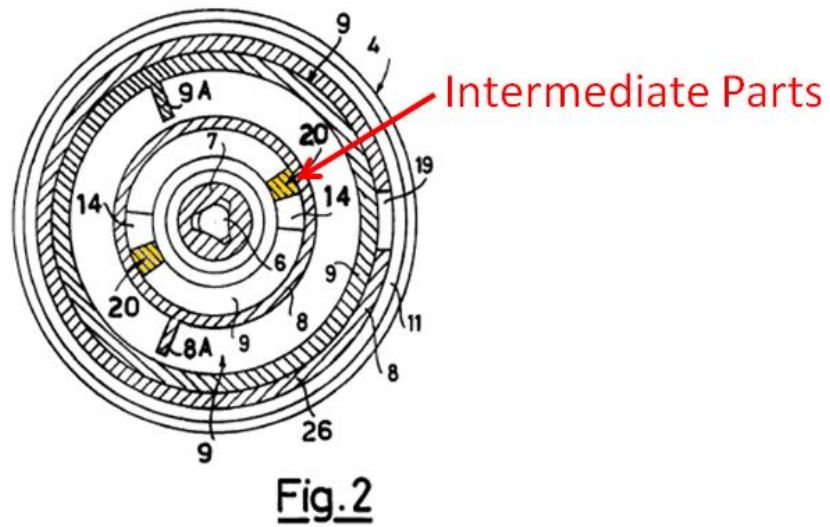
rotational movement of the second member is described above in §§VIII.B.1.f and VIII.B.1.g.



Id. at Fig. 2 (annotated).

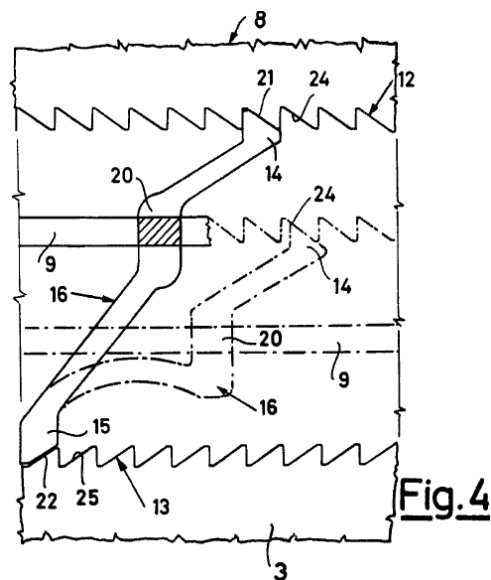
- (j) **Claim 2:** “The fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear”

Marelli teaches a rotating element 9 (second element). Rotating element 9 is connected to two pairs of small flexible legs 16 via intermediate parts 20. Ex. 1008 at 3:39-46, 4:19-22, 4:39-42; *see, e.g., id.* at Fig. 2 (annotated):



Each of those intermediate parts has a gear tooth 14 that cooperates with the row of teeth 12 on nasal 8 and a gear tooth 15 that cooperates with teeth 13 on ring nut 4.

Id. at 3:39-46, 4:13-30, Fig. 4:



- (k) **Claim 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”

Marelli discloses a fluid reservoir attached to ring nut 4. As described above, a POSA would have understood nasal 8 could be a stationary body. Ex. 1002 ¶116. “Every stroke imparted to the nasal causes the distribution of a given dose of product.” Ex. 1008 at 1:26-27. “At each operation of the distributor the nasal 8 is moved in an axial translation with respect to the ring nut 4 by the axial depression of the same.” *Id.* at 4:9-11. “Pressing on the nasal 8, while the same nasal operates through the slidable spout 6 [of] the valve 2 for the distribution of a dose of product.” *Id.* at 4:22-25.

C. GROUND 3: Claims 1-4 of the '631 Patent are Obvious under 35 U.S.C. §103 over *Bason* in view of *Rhoades*

During prosecution, the patentee traversed an anticipation rejection by arguing only that *Bason* failed to teach that “the stationary body is configured to allow a fluid reservoir to be axially displaceable with respect to the stationary body.” Ex. 1005 at 85-86. The fluid reservoir was axially displaceable with respect to the inhaler body, but the stationary gear was on base 1, and not unitary with the inhaler body. *See* Ex. 1002 ¶131. For the reasons below, market forces would have motivated a POSA to modify *Bason* by incorporating the stationary gear directly into the inhaler body, just as the stationary stop members are

incorporated into the body of *Rhoades*. *See id.* ¶¶134-137. In such a modification, the fluid reservoir would move axially with respect to the stationary body. Each element of claims 1-4 is taught by *Bason* in view of *Rhoades*. *See id.* ¶131.

1. A POSA would have been Motivated to Combine *Bason* with *Rhoades*

Bason teaches a dose counter located at the top of an inhaler (bonded to the base of the canister). Ex. 1007 at 2:16-18, Fig. 1; *supra* §VI.C. Such a configuration would have been useful to one designing a dose counter for use with a variety of different canisters and/or actuators. Ex. 1002 ¶132. By 2001, a POSA would have known that the methods being used to monitor the remaining doses in an MDI were insufficient, there was a market force to improve and incorporate dose counters into commercial MDIs, and the FDA would soon be addressing the issue. *Id.*; Ex. 1027 at 2-3, 6; Ex. 1028 at 3-5, Ex. 1045 at 3 (noting in November 2001 that “[m]anufacture[rs] must develop more reliable means [than the float test] to allow patients to evaluate . . . the number of actuations that remain”). Then, in December of 2001, the FDA issued draft guidance, and in 2003, the FDA issued final guidance recommending the inclusion of integrated dose counters in MDIs. Ex. 1002 ¶132; Ex. 1012 at 5-6; Ex. 1013 at 5-7. Despite the known deficiencies in prior methods of monitoring drug level and the longstanding interest in dose counter development up to that point, commercial MDIs did not include integrated dose counters. Ex. 1002 ¶132; Ex. 1041 at 6 (citing the 2003 FDA guidance and

noting that the “launch of Seretide Evohaler™ (GlaxoSmithKline) introduced the first MDI with a built-in dose counter in 2004.”); Ex. 1042 at 13.

Accordingly, by the time of the ’631 patent’s alleged invention, the market would have forced a POSA to scale up production of a device like *Bason* for manufacturing and use with a specific canister/actuator. Ex. 1002 ¶134. A POSA would also have been motivated to improve *Bason* to increase speed and decrease cost of manufacture while producing consistently acceptable and reliable products. *Id.*; Ex. 1007 at 3:66-4:3; Ex. 1022 at 1:43-45; Ex. 1029 at 3; Ex. 1030 at 3; Ex. 1047 at 89. It was well-known in the art that manufacturing costs would generally be lower, and reliability greater, if a device was comprised of as few separate components as possible. Ex. 1002 ¶134; Ex. 1007 at 3:66-4:3; Ex. 1022 at 1:43-45; Ex. 1029 at 3; Ex. 1030 at 3. Decreasing the number of separate components requires fewer manufacturing and validation steps and would require fewer steps and components that could fail. Ex. 1002 ¶134; Ex. 1030 at 3. Both *Bason* and the ’631 patent recognized the economic motive behind the design of such devices. Ex. 1007 at 3:66-4:3; Ex. 1001 at 2:9-11. A POSA would have routinely looked to other small inexpensive mechanical devices when seeking to improve devices like *Bason* in such ways. Ex. 1002 ¶134.

Rhoades teaches a mechanical pen—a small, plastic, inexpensive mechanical device that converts axial motion (depression of the button) into

rotational motion (rotation of the cam body and ink reservoir in the pen body), just like in *Bason* and in the claimed invention. *See id.* ¶135, *supra* §VI.E. A POSA in 2003 would have been familiar with the *Rhoades* mechanism and would look to this type of art when seeking to improve *Bason* as above. Ex. 1002 ¶135. Indeed, skilled artisans developing counting mechanisms in medical devices (including MDIs) would have looked to such analogous art (*i.e.*, mechanical pen technology) and did look to such art both before and after the '631 patent's priority date. *See, e.g., id.* ¶136; Ex. 1031 at 2:36-47 (disclosing a dosing device with a rod rotated by an indexing mechanism "much like that of a ball-point pen"); Ex. 1032 at 1:40-48 (describing a pen-type injector, and referring to a prior art reference "based on the ball point pen principle"); Ex. 1033 at 15:10-25 (disclosing an MDI with a dose counter having a drive wheel and explaining that an "arrangement of protrusions [] on the drive wheel [] is similar, and operates in a similar way, to the retraction mechanism on a ball point pen"); Ex. 1034 at [56], Abstract, 3:29-39 (disclosing a suturing device with a "sheath retraction and extension mechanism [] similar to that used in retractable tip ball point pens" and referring specifically to *Rhoades*). Moreover, Petitioner's own expert was asked to design and build a dose indicator prior to 2001, and like other skilled artisans in the field, he looked to the mechanism in a simple, plastic, and inexpensive mechanical pen that converted axial motion into rotational motion. Ex. 1002 ¶135. Accordingly, *Rhoades* is

analogous art to the claimed invention. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007); *Sci. Plastic Prods. v. Biotage AB*, 766 F.3d 1355, 1359-60 (Fed. Cir. 2014) (references about sealing carbonated beverage bottles relevant to claims directed to low pressure liquid chromatographic cartridges).

In light of the industry's understanding leading up to and after the FDA's guidance—that companies would need to start incorporating integrated dose counters into their MDIs—market forces would have motivated a POSA to improve a device like *Bason* to make it cheaper to manufacture and more reliable. Ex. 1002 ¶138. In view of *Rhoades*, a POSA would have slightly extended *Bason*'s inhaler body (just as guide member 28 in *Rhoades* extends beyond the reservoir) (*id.* ¶137), integrating the stationary gear (tooth 2) of *Bason* into the inhaler body, just as the stationary gears (stop members) of *Rhoades* are integrated directly on the *Rhoades* body (*id.*). Such a modification is a simple variation known in the prior art and would allow one to injection mold the actuator with the stationary gear already included, decreasing the number of parts that must be assembled and tested. By 2003, injection molding had long been used to manufacture mechanical devices. *Id.*; Ex. 1047. 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. Ex. 1002 ¶137. These are the types of connections the patentee stressed were well-known at the time of invention. *See, e.g.*, Ex. 1004 at 255, 281, 1137-1139, 1149-

1150, 1158-1166, 1190-1205, 1229-1233; 1281:19-20, 1282:1-4, 1292:13-15. Accordingly, a POSA would have been motivated to make the above modification and would have had a reasonable expectation of success in doing so; the modification was predictable because the manufacturability and connectivity of such components was well-understood by a POSA. Ex. 1002 ¶137.

Moreover, in such a modification, all of the components would retain their same functions—depressing the *Bason* cap would depress rings 4 and 8; teeth 7 of ring 4 would interact with stationary teeth 2 (now formed directly on the device housing) and rotate ring 4 to change the dose value the same way they do in *Bason*. *Id.* ¶138. And the cap would similarly depress the canister to cause a dose to be dispensed. *Id.* The resulting inhaler would have been predictable, well-understood by a POSA, less expensive to manufacture (no need to separately manufacture *Bason* base 1 and bond it to a canister), and more reliable (fewer parts that need to be manufactured and assembled). *See id.*; Ex. 1022 at 1:43-45; Ex. 1029 at 3; Ex. 1030 at 3.

The need to address these problems was particularly acute in the early 2000s in light of regulatory guidance that caused manufacturers to use dose counters in MDIs. *See KSR*, 550 U.S. at 424; *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1354-55 (Fed. Cir. 2016); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1377 (Fed. Cir. 2000) (patented process was developed in response to a

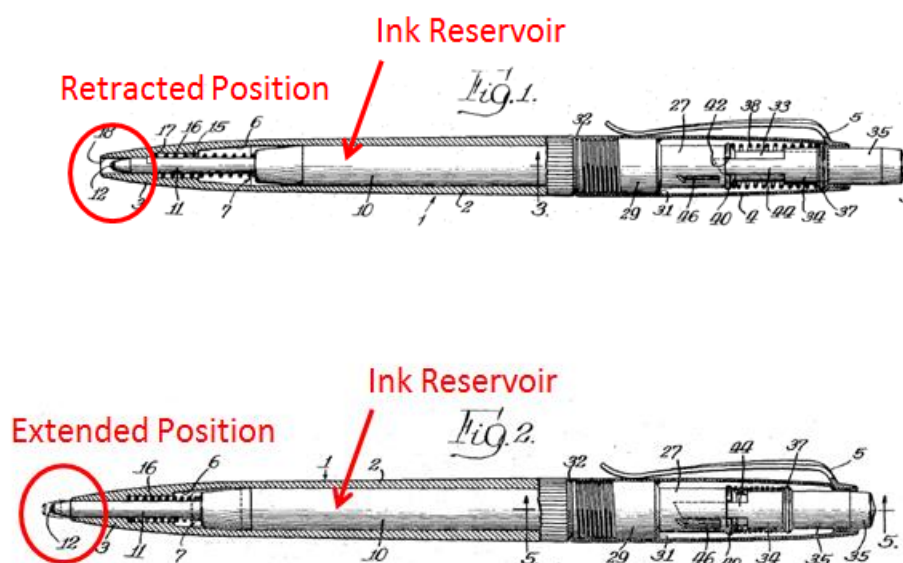
regulatory requirement). By May 2003, a POSA would have used well-known methods like injection molding to manufacture such a device. *See generally* Ex. 1047.

2. ***Bason* and *Rhoades* Disclose Each and Every Limitation of Claims 1-4 of the '631 Patent**

(a) **Claims 1 and 3 Preamble: “A fluid dispenser”**

To the extent the preamble is deemed limiting, *Bason* discloses a fluid dispenser. *Bason* discloses a dose counter that can be used with MDIs. Ex. 1007 at 1:3-5. MDIs are fluid dispensers. Ex. 1002 ¶¶139, 153.

Rhoades discloses a fluid dispenser. *Rhoades* describes a ball point pen having an ink reservoir section 10 connected to the ball writing point 12 via the ink feed section 11. Ex. 1009 at 3:34-42. Ink (i.e., fluid) is dispensed from the ink reservoir to the ball writing point. *Id.* at 11:60-63.



Id. at Figs. 1-2 (annotated).

(b) **Claims 1 and 3:** “a plurality of displayable dose values”

Bason discloses rotational rings 4 and 8, having upper faces 24 and 25 that carry “two numeric series such that face 24 carries the series 0 to 9 while face 25 carries the series 00 to 20. Thus, through the window 13 there may be visible progressively the numbers 000 to 200. . . . As the MDI is progressively used the available doses will count down eventually to zero” Ex. 1007 at 3:1-10.

(c) **Claims 1 and 3:** “a stationary body comprising at least one stationary multi-toothed gear”

As described in §IV.A.1, the claimed stationary body must be unitary and monolithic with at least one stationary multi-toothed gear. As described in §VI.C, *Bason* discloses a stationary counter component with gear teeth that is not unitary with the outer inhaler body. *Rhoades*, however, teaches a stationary guide member 28 that is the device housing. Ex. 1002 ¶¶142, 156. “Two stop members 45 and 46 extend longitudinally within the central portion 27 of the guide member 28 The stop members 45 and 46 may conveniently be formed by a pair of parallel, longitudinal cuts 47 and a diagonal cut 48 in the tubular wall of the central portion 27 of the guide member 28 to form a tab which then is displaced inwardly to depend at its rearward end from the guide member.” Ex. 1009 at 4:13-21. “[T]he stop members may be formed integrally with a stationary member and may be made of substantial size” *Id.* at 8:7-9. The stop members 43 and 44 are teeth

on the stationary gear of guide member 28. Ex. 1002 ¶¶142, 156. Accordingly, guide member 28 is a stationary body with at least one stationary multi-toothed gear.

- (d) **Claim 3:** “a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”

Bason teaches the use of a pressurized canister for use with an MDI. Ex. 1002 ¶157; Ex. 1007 at 1:3-8, Fig. 1. That canister is bonded to base 1 of the *Bason* dose counter and, accordingly, moves with base 1, axially relative to the *Bason* inhaler body A. Ex. 1002 ¶157.

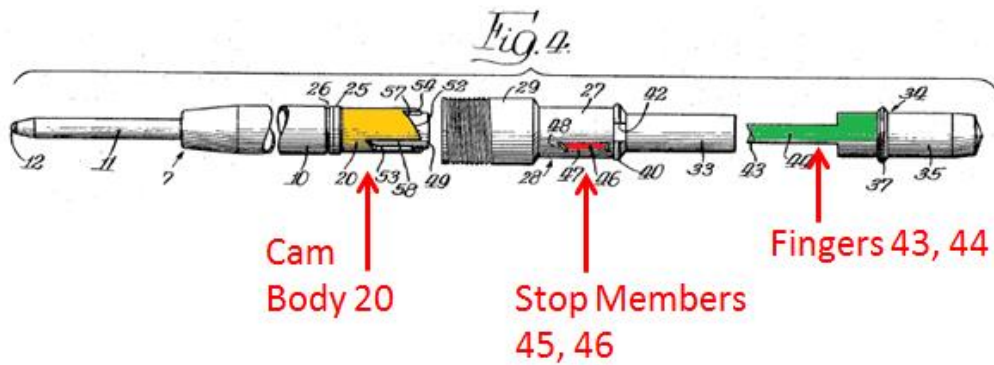
Rhoades teaches that a “writing unit of the instrument, includes an ink reservoir section 10 containing a quantity of ink.” Ex. 1009 at 3:35-37. The ink reservoir section is directly connected to the cam body 20. *Id.* at 3:49-52. The cam body is located within stationary body guide member 28 (which contains stationary stop members 45 and 46), and is moved axially by fingers 43 and 44 of plunger 34. *Id.* at 4:13-19, 5:13-19, 5:39-43, 5:51-58. When the cam body 20 displaces axially, the connected ink reservoir section also displaces axially. Ex. 1002 ¶158; Ex. 1009 at 5:39-43. Accordingly, the fluid reservoir (ink reservoir section) moves axially relative to the stationary body (guide member 28). Ex. 1002 ¶158. Cam body 20 and the directly connected ink reservoir also interact with stop members 45 and 46. *Id.*; Ex. 1009 at 4:29-33; 5:51-58. Because the

fluid reservoir can be disposed on a stationary body through an indirect interaction, the *Rhoades* ink reservoir is disposed on the guide member 28 through interactions between its connected cam body 20 and the stop members formed integrally on guide member 28. Ex. 1002 ¶158.

As described in §VIII.C.1, in view of *Rhoades* teaching the stationary gears are located directly on guide member 28, a POSA would have molded *Bason's* stationary gear teeth 2 directly on *Bason's* inhaler body. Ex. 1002 ¶159. In such a device, the inhaler body would be the claimed stationary body with at least one stationary multi-toothed gear. *Id.* The canister, moving axially relative to the inhaler body, as it always does, would therefore move axially relative to that stationary body. *Id.* The canister would also interact indirectly with the stationary body through interactions between the other components of the counter device, or through the bottom of the canister at the base of the inhaler body. *Id.*

(e) **Claims 1 and 3:** element [e]—“first member limitation”
(*see supra* §III.B)

Rhoades discloses a push button 35 that is formed integrally with a plunger 34 that has two integrally formed fingers 43 and 44. Ex. 1009 at 4:10-13. “When the push button 35 is depressed, the actuating fingers 43 and 44 will be moved downwardly (as viewed in FIG. 8) with respect to stationary stop members 45 and 46 and will carry with them the cylindrical cam body 20.” *Id.* at 5:39-43. *See id.* at Fig. 4 (annotated):



Bason discloses cap 14, which is depressed by the user to depress the canister and rings 4 and 8. Ex. 1007 at Abstract, Fig. 1, 3:15-16; Ex. 1002 ¶¶144, 161. In light of *Rhoades* and its integrated stop members, one would have incorporated *Bason*'s teeth 2 directly on the inhaler body, and the inhaler body would be the claimed stationary body. Ex. 1002 ¶¶144, 161. In such a configuration, the cap 14 would move axially relative to the stationary body. *Id.*

(f) **Claims 1 and 3:** element [f]—"second member limitation" (*see supra* §III.B)

As explained above in §§VI.E, VIII.C.2.d, and VIII.C.2.e, *Rhoades* teaches cam body 20, which engages both the axially moving fingers and the stationary stop members. When axial moving fingers push the cam body a sufficient distance, the cam body clears the stop members and rotates. Ex. 1009 at 4:22-33; 5:51-54. "The cam body 20 is rotatably and slidably disposed within a tubular central portion 27 of a stationary guide member 28 so as to in effect be 'floating' therein." *Id.* at 3:66-68. Cam body 20 can engage with stop members 45 and 46.

See, e.g., id. at 5:11-28. “The cylindrical cam body 20 is . . . engageable by the fingers 43 and 44 to impart unidirectional rotational movement as well as longitudinal reciprocating movement to the cam body and the connected unit 7.” *Id.* at 4:22-28; *see also* §VI.E.

Bason teaches rotational ring 4 (second member) that is moved axially by direct contact with the cap 14 (first member). Upon sufficient axial depression, teeth 7 of rotational ring 4 contact teeth 2 of the stationary body and rotational ring 4 begins to rotate. Ex. 1002 ¶¶146, 163.

(g) **Claim 1:** element [g]—“fluid reservoir/displacement limitation” (*see supra* §III.B)

The cooperation of the first and second members resulting in axial and rotational movement of the cam body 20 in *Rhoades* is described in §VIII.C.2.d-f. “The cam body 20 is secured to the rear end of reservoir section 10 in ink-tight relation” Ex. 1009 at 3:59-60. Accordingly, the ink reservoir section containing ink (the fluid reservoir) moves axially with the cam body, and therefore moves axially relative to the stationary body.

The cooperation of the first and second members resulting in axial and rotational movement of rotational ring 4 in *Bason* is described above. As described in §III.C, the canister in *Bason* moves axially relative to the inhaler housing. If the teeth of base 1 are molded into the inhaler body such that the inhaler body is the stationary body, the canister moves axially relative to the stationary body. Ex.

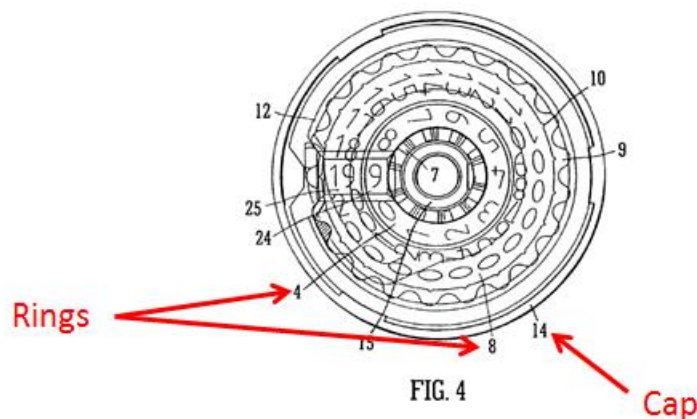
1002 ¶148. *Bason* discloses rings that carry with them numeric series, which a POSA would have included on cam body 20. Ex. 1007 at 3:1-10.

- (h) **Claim 3:** element [h]—“displacement limitation” (*see supra* §III.B)

As shown in the chart in §III.B, this limitation [h] is identical to claim 1’s limitation [g] except that this limitation [h] does not require a fluid reservoir as part of the limitation. Accordingly, both *Bason* and *Rhoades* disclose this limitation for the reasons described immediately above. *See* §VIII.C.2.g.

- (i) **Claims 1 and 3:** element [i]—“common central axis limitation” (*see supra* §III.B)

Bason discloses a dose counter including a circular base 1 (stationary body/gear), a cylindrical cap 14 (first member), and a circular rotational ring 4 (second member). Ex. 1002 ¶¶149, 165. These components are all circular and share the same axis. Ex. 1007 at 2:5-6, Fig. 4. The axial movement of the first member and the axial and rotational movement of the second member is described above. *See* §VIII.C.2.d-h.



Ex. 1007 at Fig. 4 (annotated).

In *Rhoades*, the guide member 28 (stationary body) is a hollow cylinder with a central longitudinal axis. The cylindrical cam body 20 (second member) and plunger with fingers 43 and 44 (first member) is generally cylindrical in shape. Both the cam body and plunger share the same axis as the guide member 28, and axial movement occurs along that axis while rotational movement occurs about the axis. Ex. 1002 ¶¶150, 166. Incorporating teeth 2 directly in the *Bason* inhaler body would not alter the common axis. *Id.* ¶¶149, 165.

- (j) **Claim 2:** “The fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear”

Bason teaches that rotational ring 4 “defines an inner cylindrical space within the lower end of which there is located an annular series of projections formed as inwardly directed triangular teeth 7.” Ex. 1007 at 2:28-30.

Rhoades teaches a cam body “with a plurality of cam surfaces 50, 52, 54, 55 diametrically opposite pairs of which are successively engageable by the fingers 43 and 44 to impart unidirectional rotational movement” to the cam body. Ex. 1009 at 4:23-26.

- (k) **Claim 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”

Bason discloses that the pressurized canister moves axially relative to the inhaler body A when used. Ex. 1002 ¶167; Ex. 1007 at Abstract, Fig. 1. It is that axial depression that causes the dispenser to actuate. Ex. 1002 ¶167.

Rhoades discloses that stop members (stationary gear teeth) can be formed integral with the *Rhoades* guide member 28 (stationary body). A POSA would have been motivated to combine *Bason* with *Rhoades* such that the *Bason* inhaler housing includes *Bason* teeth 2 and operates as the stationary body. See §VIII.C.1; Ex. 1002 ¶168. Thus, the *Bason* fluid reservoir moves axially relative to that stationary body, and it is that same axial motion that causes actuation of the fluid dispenser. Ex. 1002 ¶168.

D. GROUND 4: Claims 1-4 of the '631 Patent are Obvious under 35 U.S.C. §103 over *Bason* in view of *Allsop*

For the reasons below, a POSA would have been motivated to modify *Bason* by fixing the *Bason* dose counter below the canister in view of *Allsop*. See Ex.

1002 ¶169. Moreover, POSA would have had a reasonable expectation of success and the modification was predictable because the manufacturability and connectivity of components of MDIs with dose counter was well-understood by a POSA. *See id.*; *see supra* §VIII.C.1. In such a modification, the fluid reservoir would move axially with respect to the stationary body and would address the same element raised by the patentee during prosecution, as explained above in §III.C. Each element of claims 1-4 is taught by *Bason* in view of *Allsop*. *See* Ex. 1002 ¶169.

1. A POSA would have been Motivated to Combine *Bason* with *Allsop*

A POSA would have been motivated to improve *Bason* because of the same market forces and for the same reasons described in §VIII.C.1 above.

Allsop teaches a dispensing apparatus comprising a dosage counting device, for use in an MDI. Ex. 1006 at 1:4-8, 15-19. *Allsop* teaches the same type of device (a dose counter for an MDI) that the '631 patent allegedly improves upon. Ex. 1002 ¶171. A POSA would have looked to *Allsop* when considering ways to improve *Bason*. *Id.*

To improve the *Bason* device as described in §VIII.D.1, in light of the device disclosed in *Allsop*, a POSA would have simply moved the *Bason* dose counter below the *Bason* canister, where the rotational mechanism (outer housing collar 155 and inner housing flange 142) is located in *Allsop*, and integrally molded the

teeth 2 into the inhaler housing, just as *Allsop* teaches. *Id.* ¶172; Ex. 1006 at 7:8-10, Figs. 3, 4.⁴

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. 1030 at 3. Here, *Bason* teaches a dose counter located in the cap. Ex. 1002 ¶173; Ex. 1007 at Fig. 1. The axial force applied by a user to the cap in *Bason* is split between actuating the dose counter (and doing so prior to release of the medication), and moving the canister axially to cause dispensation of the fluid. Ex. 1002 ¶173. This requires coordination between a spring in the dose counter and a spring in the valve of the canister. *Id.* One would be motivated to improve *Bason* by moving the counter below the canister, as in *Allsop*, where the entire axial force

⁴ To the extent the Board understands the BRI of stationary body to encompass bodies other than the outer housing of an inhaler, such that the *Bason* dose counter could itself include a stationary body, this combination teaches every element of the Challenged Claims even if teeth 2 are *not* integrally molded into the outer housing. *I.e.*, fixing the *Bason* dose counter in place below the canister allows the fluid reservoir to move relative to a stationary body with an integral gear, negating patentee's arguments traversing the anticipation rejection during prosecution. *See* Ex. 1005 at 70-71, 85-86.

would be directed at moving the canister, requiring coordination of *only* the spring in the valve, and where the displacement of the canister would cause the dose counter to actuate. *Id.*

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 near the base of the inhaler, and the canister would sit on top of that counting device, poking out of the top of the inhaler body which, as the patentee noted, as is “sometimes [the case] in your asthma inhalers.” Ex. 1004 at 1285:2-4.

A POSA would have had a reasonable expectation of success because all of the components would retain their same functions—depressing the canister of *Bason* would depress the cap it would now be sitting on top of. The cap would depress rings 4 and 8, causing teeth 7 of ring 4 to interact with stationary teeth 2 and rotate ring 4 to change the dose value the same way they do in *Bason*. Ex. 1002 ¶175. The valve would extend through the counting mechanism just as it does in *Allsop*. *Id.* The resulting inhaler would have been predictable, well-understood by the POSA, less expensive to manufacture (no need to separately manufacture *Bason* base 1 and bond it to a canister if the teeth are molded into the housing), and more reliable (fewer parts that need to be manufactured and assembled and coordinated). *See id.*; Ex. 1001 at 1:24-59, 1:66-2:3, 2:9-11; Ex.

1022 at 1:43-45; Ex. 1028 at 3; Ex. 1029 at 3. Indeed, this is a simple, known variation known in the prior art and the type of modification is the same type of modification patentee stressed was well-known. *See, e.g.*, Ex. 1004 at 255, 281, 1137-1139, 1149-1150, 1158-1166, 1190-1205, 1229-1233; 1281:19-20, 1282:1-4, 1292:13-15. Accordingly, a POSA would have been motivated to make the above modification, and would have had a reasonable expectation of success in doing so; the modification would have been predictable because the manufacturability and connectivity of such components would have been well-understood by a POSA.

The need to address these problems was particularly acute in the early 2000s in light of regulatory guidance that caused manufacturers to use dose counters in MDIs. *See KSR*, 550 U.S. at 424; *Purdue Pharma*, 811 F.3d at 1354-55; *Ecolochem*, 227 F.3d at 1377. By May 2003, a POSA would have used well-known methods like injection molding to manufacture such a device. Ex. 1047.

2. *Bason* and *Allsop* Disclose Each and Every Limitation of Claims 1-4 of the '631 Patent

(a) Claims 1 and 3 Preamble: “A fluid dispenser”

To the extent the preamble is deemed limiting, both *Bason* and *Allsop* disclose a fluid dispenser. *See* §§VIII.C.2.a (*Bason*); VIII.A.1.a (*Allsop*).

(b) Claims 1 and 3: “a plurality of displayable dose values”

Both *Bason* and *Allsop* disclose a plurality of displayable dose values for the reasons above. *See* §§VIII.C.2.b (*Bason*); VIII.A.1.b (*Allsop*).

- (c) **Claims 1 and 3:** “a stationary body comprising at least one stationary multi-toothed gear”

Bason discloses an inhaler body and a dose counter with a stationary component base 1, which contains stationary teeth 2. *See* §VIII.C.2.c (*Bason*). *Allsop* discloses “a stationary body comprising at least one stationary multi-toothed gear” for the reasons above. *See* §VIII.A.1.c (*Allsop*).

For the reasons in §VIII.A.1.c above, in light of *Allsop*’s teaching that collar 155 containing lugs 156 could be molded directly onto the inhaler body, a POSA could have and would have been motivated to mold the teeth 2 of *Bason* directly onto the *Bason* inhaler body. Ex. 1002 ¶¶180, 191. *Allsop* expressly discloses this as an alternate conformation. Ex. 1006 at 7:8-10. Alternatively, he or she would also have been motivated to integrate the dose counter of *Bason* to a stationary position at the base of the inhaler—the location of the turning mechanism in *Allsop*.⁵ Ex. 1002 ¶¶180, 191.

⁵ To the extent the PTAB adopts a different construction for stationary body comprising at least one multi-toothed gear that does not require the stationary gear to be unitary with the stationary body, the claims would have been obvious based on an even simpler modification to *Bason*—fixing the existing counter below the canister—a configuration the patentee cited numerous times as present in the prior

- (d) **Claim 3:** “a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”

As noted above, the reservoir in *Bason* moves relative to the inhaler body. To the extent *Bason* is modified such that the inhaler body is the claimed stationary body, it would meet this limitation. Ex. 1002 ¶192; *see* §VIII.C.2.d (*Bason*).

Allsop discloses “a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body” for the reasons above. *See* §VIII.A.1.d (*Allsop*).

As described in §VIII.D.1, a POSA would have modified *Bason* in view of *Allsop* by either integrating the stationary teeth 2 on the inhaler body, or by integrating the dose counter to a position below the reservoir such that the reservoir would be axially displaceable relative to base 1 of the dose counter. Ex. 1002 ¶194.

- (e) **Claims 1 and 3:** element [e]—“first member limitation” (*see supra* §III.B)

Both *Bason* and *Allsop* disclose “a first member that is displaceable axially relative to said stationary body” for the reasons above. *See* §§VIII.C.2.e (*Bason*); VIII.A.1.e (*Allsop*).

art during prosecution. *See* Ex. 1004 at 1190-1205 (referring to Attachment A); *see, e.g.*, Ex. 1037; Ex. 1038; Ex. 1039; Ex. 1040.

- (f) **Claims 1 and 3:** element [f]—“second member limitation” (*see supra* §III.B)

Both *Bason* and *Allsop* disclose “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” for the reasons above. *See* §§VIII.C.2.f (*Bason*); VIII.A.1.f (*Allsop*).

- (g) **Claim 1:** element [g]—“fluid reservoir/displacement limitation” (*see supra* §III.B)

Both *Bason* and *Allsop* disclose the fluid reservoir/displacement limitation for the reasons above. *See* §§VIII.C.2.g (*Bason*); VIII.A.1.g (*Allsop*).

For the reasons described in §VIII.D.1, a POSA would have been motivated to, and easily could move the dose counter disclosed in *Bason* to a position immediately below the canister (the location of the rotation mechanism disclosed in *Allsop*) and/or integrate base 1 of *Bason* with the inhaler body (outer housing), as disclosed in *Allsop*. Ex. 1002 ¶184. The resulting device would include a fluid reservoir that moves axially relative to the stationary body.

- (h) **Claim 3:** element [h]—“displacement limitation” (*see supra* §III.B)

Both *Bason* and *Allsop* disclose the displacement limitation for the reasons above. *See* §§VIII.C.2.h (*Bason*); VIII.A.1.h (*Allsop*).

- (i) **Claims 1 and 3:** element [i]—“common central axis limitation” (*see supra* §III.B)

Both *Bason* and *Allsop* disclose the common central axis limitation for the reasons above. *See* §§VIII.C.2.i (*Bason*); VIII.A.1.i (*Allsop*).

As noted above, a POSA would have been motivated to combine *Bason* with *Allsop* to fix the counter below the canister, with teeth 2 molded into the base of the inhaler. *See* §VIII.D.1. Either modification would retain the shared axis of the stationary body and stationary gear as shown in both *Bason* and *Allsop*. Ex. 1002 ¶¶186, 199.

- (j) **Claim 2:** “The fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear”

Both *Bason* and *Allsop* disclose the fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear for the reasons above. *See* §§VIII.C.2.j (*Bason*); VIII.A.1.j (*Allsop*).

- (k) **Claim 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”

Allsop discloses a 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 for the reasons above. *See* §VIII.A.1.k (*Allsop*).

As noted above, a POSA would have been motivated to combine *Bason* with *Allsop* to fix the counter below the canister, with teeth 2 molded into the base of the inhaler. See §VIII.D.1. That modification would have resulted in a fluid dispenser wherein the fluid reservoir is configured to be axially displaced relative to said stationary body during actuation of the fluid dispenser. Ex. 1002 ¶201.

IX. CONCLUSION

Petitioners respectfully request that IPR of the '631 patent be instituted and that the Challenged Claims be cancelled as unpatentable under 35 U.S.C. §318(b).

Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. §42.24(d)

Under the provisions of 37 CFR §42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 13,908, which is less than the 14,000 allowed under 37 CFR §42.24(a)(i).

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petition for *Inter Partes* Review was served on counsel of record on May 10, 2018, by filing this document through the End-to-End System, as well as delivering a copy via overnight mail to the counsel of record for the Patent Owner at the following address:

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