

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.

Aptar France 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

EXPERT DECLARATION OF S. DAVID PIPER

I.	PERSONAL AND PROFESSIONAL BACKGROUND	1
II.	MATERIALS REVIEWED AND CONSIDERED	3
III.	LEVEL OF ORDINARY SKILL IN THE ART	6
IV.	THE BASICS OF METERED DOSE INHALERS WITH DOSE COUNTERS	8
V.	SUMMARY OF THE '631 PATENT	15
A.	Claim 1.....	19
1.	"a stationary body comprising at least one stationary multi-toothed gear,"	19
B.	Claim 2.....	21
C.	Claim 3.....	21
1.	"disposed on"	22
D.	Claim 4.....	23
VI.	SUMMARY OF THE RELEVANT LAW	23
A.	General	23
B.	Anticipation.....	24
C.	Obviousness.....	25
VII.	ALL CLAIMS OF THE '631 PATENT ARE UNPATENTABLE OVER THE IDENTIFIED PRIOR ART	28
A.	Ground 1: Claims 1-4 of the '631 Patent are Anticipated by Allsop (Ex. 1006).....	28
1.	Claim 1	30
a.	"A fluid dispenser"	31
b.	"a plurality of displayable dose values"	31

c.	“a stationary body comprising at least one stationary multi-toothed gear”	31
d.	“a first member that is displaceable axially relative to said stationary body”	32
e.	“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”	33
f.	“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”	35
g.	“wherein the stationary body, the first member, and the second member are arranged to have a common central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis”	36
2.	Claim 2: “The fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear.”	37
3.	Claim 3	37
a.	“A fluid dispenser”	37
b.	“a plurality of displayable dose values”	37
c.	“a stationary body comprising at least one stationary multi-toothed gear”	38

d.	“a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”	39
e.	“a first member that is displaceable axially relative to said stationary body”	39
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”	40
g.	“when said first member displaces axially, said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values”	42
h.	“wherein the stationary body, the first member, and the second member are arranged to have a common central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis”	42
4.	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.”	43
B.	Ground 2: Claims 1-4 of the ’631 Patent are Anticipated by Marelli (Ex. 1008)	43
1.	Claim 1	46
a.	“A fluid dispenser”	46
b.	“a plurality of displayable dose values”	46

c.	“a stationary body comprising at least one stationary multi-toothed gear”	46
d.	“a first member that is displaceable axially relative to said stationary body”	49
e.	“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”	49
f.	“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”	51
g.	“wherein the stationary body, the first member, and the second member are arranged to have a common central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis”	52
2.	Claim 2	53
a.	“The fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear”	53
3.	Claim 3	54
a.	“A fluid dispenser”	54
b.	“a plurality of displayable dose values”	54

c.	“a stationary body comprising at least one stationary multi-toothed gear”	54
d.	“a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”	57
e.	“a first member that is displaceable axially relative to said stationary body”	58
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”	58
g.	“when said first member displaces axially, said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values”	60
h.	“wherein the stationary body, the first member, and the second member are arranged to have a common central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis”	60
4.	Claim 4	61
a.	“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.”	61
C.	Ground 3: Claims 1-4 of the '631 Patent are Obvious over Bason (Ex. 1007) in view of Rhoades (Ex. 1009)	62
1.	Claim 1	78

a.	“A fluid dispenser”	78
b.	“a plurality of displayable dose values”	78
c.	“a stationary body comprising at least one stationary multi-toothed gear”	79
d.	“a first member that is displaceable axially relative to said stationary body”	80
e.	“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”	80
f.	“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”	81
g.	“wherein the stationary body, the first member, and the second member are arranged to have a common central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis”	82
2.	Claim 2	83
a.	“The fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear.”	84
3.	Claim 3	84
a.	“A fluid dispenser”	84

b.	“a plurality of displayable dose values”	85
c.	“a stationary body comprising at least one stationary multi-toothed gear”	85
d.	“a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”	86
e.	“a first member that is displaceable axially relative to said stationary body”	88
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”	89
g.	“when said first member displaces axially, said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values”	90
h.	“wherein the stationary body, the first member, and the second member are arranged to have a common central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis”	90
4.	Claim 4	91
a.	“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.”	91
D.	Ground 4: Claims 1-4 of the '631 Patent are Obvious over Bason (Ex. 1007) in view of Allsop (Ex. 1006)	92

1.	Claim 1	96
a.	“A fluid dispenser”	96
b.	“a plurality of displayable dose values”	96
c.	“a stationary body comprising at least one stationary multi-toothed gear”	96
d.	“a first member that is displaceable axially relative to said stationary body”	97
e.	“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”	98
f.	“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”	98
g.	“wherein the stationary body, the first member, and the second member are arranged to have a common central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis”	98
2.	Claim 2: “The fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear.”	99
3.	Claim 3	99
a.	“A fluid dispenser”	99

b.	“a plurality of displayable dose values”	99
c.	“a stationary body comprising at least one stationary multi-toothed gear”	100
d.	“a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”	101
e.	“a first member that is displaceable axially relative to said stationary body”	101
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”	102
g.	“when said first member displaces axially, said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values”	102
h.	“wherein the stationary body, the first member, and the second member are arranged to have a common central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis”	102
4.	Claim 4	103
a.	“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.”	103
VIII.	CONCLUSION	103

IX. SIGNATURE.....	104
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I, S. David Piper, declare as follows:

1. I am over the age of twenty-one and I am competent to testify as to the matters set forth in this Declaration.

2. I have been retained by Petitioners, 3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp., to assess U.S. Patent No. 9,370,631 (“the ’631 Patent”). I understand that Petitioners are accused of infringing the ’631 Patent in a pending District Court litigation. I further understand that this Declaration is being submitted in connection with a petition for *inter partes* review (“IPR”) challenging the patentability of claims 1-4 of the ’631 Patent (the “Challenged Claims”). I am being compensated at a rate of \$360 per hour, plus actual expenses. My compensation is not dependent in any way upon the substance of my testimony or the outcome of Petitioners’ IPR petitions or the litigation involving the ’631 Patent.

I. PERSONAL AND PROFESSIONAL BACKGROUND

3. My qualifications are stated more fully in my curriculum vitae (Ex. 1003). Here, I provide a brief summary of my qualifications.

4. I am the President, CEO and Founder of Piper Medical. Piper Medical is a leading tester of respiratory medical devices and provides United States Food and Drug Administration (“FDA”) regulatory assistance, product design and development support, and manufacturing assistance.

5. I earned a Bachelor of Science with honors in Mechanical Engineering from California Polytechnic State University (“Cal Poly”) in 1989. I am a registered professional mechanical engineer (No. M029026) with the State of California.

6. I am the author of numerous publications and presentations in the field of respiratory care and aerosol technologies. I am listed as an inventor or co-inventor on ten U.S. Patents directed to respiratory care and aerosol technologies. *See Ex. 1003.*

7. From 1990 to 1995, I was the Director of Research & Development for Vortran Medical. My work for Vortran involved the invention, development and bringing to market of various respiratory medical devices with a particular focus on products intended to deliver medication via patient inhalation. Such work included specifically the invention and development of a Metered Dose Inhaler (MDI) for the delivery of powder medicament and work on a novel MDI technology called the GentleHaler. From 2000 to 2006, I was the President, CEO and Founder of EVIT Labs, Inc. My work at EVIT Labs involved the development of an aerosol technology I invented for delivery of aerosolized liquid medication that can be characterized as a hybrid of a jet nebulizer and an MDI.

8. In the mid to late 1990s and early 2000s, in my role as President, CEO and Founder, my work at Piper Medical was focused on product development for

innovative respiratory products, and after EVIT Labs I continued on with this work. I have brought dozens of medical products to market. Products that I have developed and sold directly, or licensed to a partner, include the EZflow Nebulizer, the AeroTee, the Piper Pulmonary Modulation Technology, and the Quixie Breath Actuated Nebulizer. In addition, I have been contracted by customers to help bring numerous other products to market including: jet and ultrasonic nebulizers, spacer chambers, ventilators, manual resuscitators, oxygen blenders, oxygen concentrators, CO2 monitoring devices, specialized mask delivery systems, CPAP machines, BiPAP machines, Heat and Moisture Exchangers (HMEs), patient monitoring devices, cannulas, high humidity oxygen delivery systems, humidifiers, and atomizers.

II. MATERIALS REVIEWED AND CONSIDERED

9. In connection with my work on this matter, I have reviewed and considered the following documents:

Exhibit No.	Description
1001	U.S. Patent No. 9,370,631 (the “’631 Patent”)
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
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
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, MECHANICAL ENGINEERING DESIGN, 16 (McGraw-Hill, Inc., 4th ed., 1983)
1030	Excerpt from Robert E. Parr, PRINCIPLES OF MECHANICAL DESIGN, 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
1036	British Specification 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, <i>The History of Therapeutic Aerosols: A Chronological Review</i> , 30(1) J. AEROSOL MED. & PULMONARY DRUG DELIVERY 20 (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)
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)

III. LEVEL OF ORDINARY SKILL IN THE ART

10. For the purposes of assessing whether prior art references disclose every element of a patent claim and/or would have rendered the claimed invention obvious, I understand that the '631 Patent and the prior art references must be assessed from the perspective of the person having ordinary skill in the art ("POSA") to which the patent is related, based on the understanding of that person as of the date of the invention. I understand that a POSA is presumed to be aware of all pertinent prior art and the conventional wisdom of the art, and is a person having ordinary creativity. I have applied this standard throughout my Declaration.

11. I have been asked to provide my opinion as to the state of the art in the field of medical devices, including inhalation devices, in the early 2000s, and, specifically at the time of the invention in early 2003. I use the early 2003 timeframe because I have been informed that the earliest claimed priority date of the '631 Patent is May 15, 2003. Whenever I offer an opinion below about the knowledge of a POSA, the manner in which a POSA would have understood the claims of the '631 Patent, the manner in which a POSA would have understood the prior art, or what a POSA would have been led to do based on the prior art, I am referencing the early 2003 timeframe, even if I do not say so specifically in each instance. As explained herein, I am familiar with the state of the art and the industry in the years leading up to 2003, including the industry's understanding around the time of draft regulatory guidance in 2001, and my opinions would not change even if the Patent Owner establishes an earlier date of invention.

12. In my opinion, a POSA in the inhalation device field, to which the '631 Patent is directed, in the 2003 time period, 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. A POSA would have had the ability to understand and apply the prior art references discussed herein.

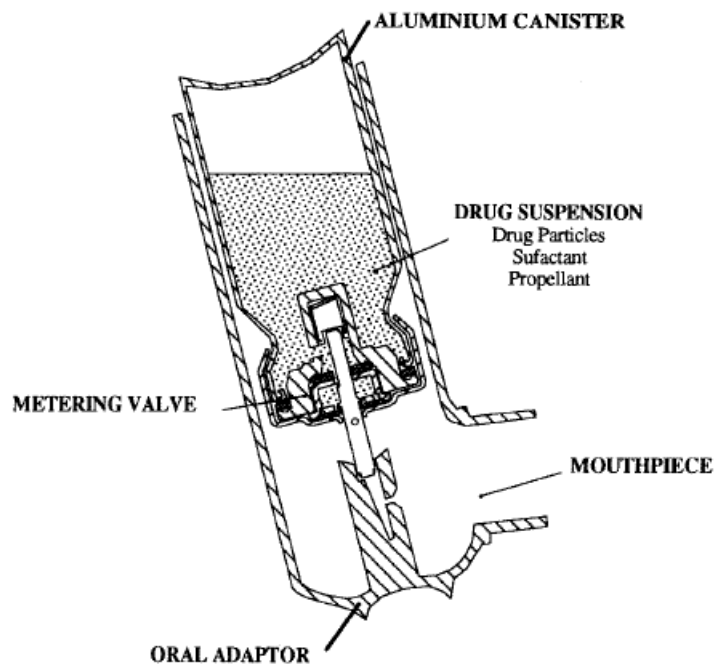
13. By 2003, I had a bachelor's degree in mechanical engineering, was a registered professional mechanical engineer with the State of California, and had 13 years of experience in the field of medical devices. Therefore, I was a person having more than ordinary skill in the art in the 2003 timeframe. However, I worked with many engineers who fit the characterization of a POSA, and am familiar with their level of skill. When developing the opinions set forth below, I assume the perspective of a POSA, as set forth above.

IV. THE BASICS OF METERED DOSE INHALERS WITH DOSE COUNTERS

14. 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. A POSA would have also known that dose counters had been designed for use with fluid dispensers since the early 1970s. *See, e.g.,* Ex. 1036. During prosecution of the '177 Patent (the '631 Patent's parent), 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. However, in the absence of a regulatory requirement to include a dose counter, commercial MDIs generally did not include a dose counter prior to the 2003 FDA guidance. Ex. 1041 at 6; Ex. 1042 at 13. As I will explain below, however, prior to the 2003 FDA

guidance, a POSA was aware that the industry was moving towards including dose counters in future products.

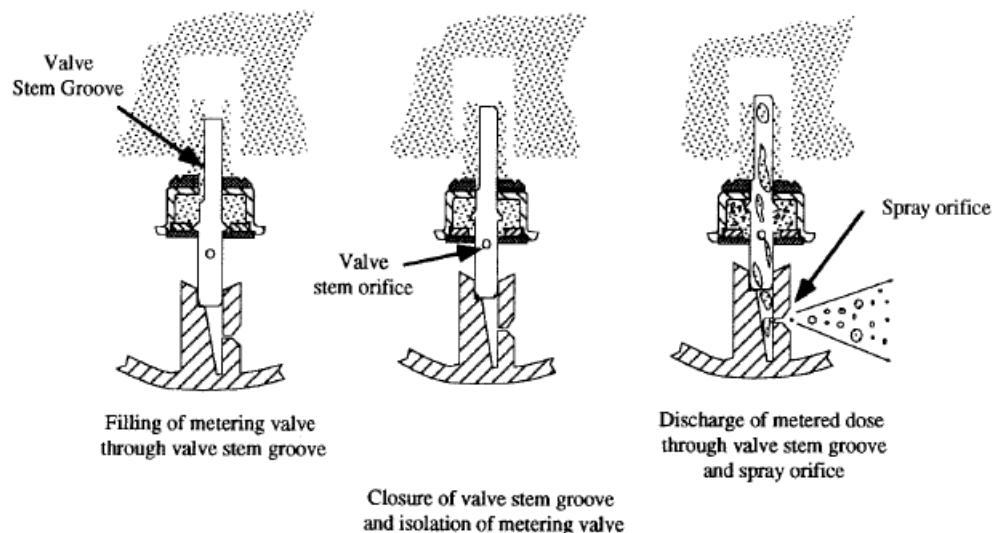
15. MDIs have seen little mechanical change over the past decades. *See* Ex. 1041 at 1; Ex. 1048 at 1. They were generally known to have included a canister assembly and mouthpiece (often referred to as an actuator or a boot).



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

16. A POSA would have understood that the canister assembly consists of a metering valve mounted in combination with a reservoir where fluid is stored. The mouthpiece would have included a valve stem receptacle which would have been in fluid communication with a jet or spray orifice. When not in use, the valve stem of the metering valve would have been fully engaged with the valve stem receptacle. Upon depression of the reservoir relative to the mouthpiece, the

metering valve would have caused a dose of fluid to be dispensed from the reservoir to the jet and out the mouthpiece where the resulting release could have been inhaled by the patient. Ex. 1018 at 6-9.



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

17. The prior art described a variety of dose counters. *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 discussed in Grounds 1-4, typically convert axial motion from a user into a rotational motion of another component, often a number wheel. Ex. 1006 at 9:3-11; Ex. 1007 at 3:15-26; Ex. 1008 at 4:9-48. This was a common mechanism known to POSAs and used in a variety of mechanical devices by 2001-2003, including mechanical pens. *See, e.g.*, Ex. 1009 at 1:9-12; 4:22-27 (mechanical pen); Ex. 1021 (device for drying foods); Ex. 1022 (push drill); Ex. 1023 (crushing apparatus (converting rotational motion into axial motion)). Indeed, around 1998 and sometime before 2001, in my role at

Piper Medical, I was asked to design and build a dose indicator and, like others in the industry, I looked to the mechanism of a mechanical pen that converted axial motion into rotational motion.

18. By 2001, the industry recognized that methods of monitoring the medication remaining in an MDI were insufficient. Without a dose indicator, a user could not easily determine the amount of medication remaining inside of an MDI reservoir. Ex. 1028. For example, a patient could not visually see the level of remaining drug. Accordingly, there was a risk that a patient would have used all of the medication in his or her MDI and not have known it. Patients had been instructed to either manually keep track of the doses they took, or to use the “float test.” Ex. 1028 at 3-4; Ex. 1045 at 1-3. By the late 1990s and early 2000s, the industry recognized these prior methods were insufficient. *See* Ex. 1027 at 5-6; Ex. at 1028 at 7; Ex. 1041 at 6; Ex. 1042 at 13; Ex. 1045 at 3. Then, in December 2001, the FDA issued draft guidance suggesting that “manufacturers with metered-dose inhalers under development for oral inhalation ***integrate a dose-counting device*** into the development of their MDI drug product,” 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). The FDA’s 2001 draft guidance was announced in the Federal Register on December 11, 2001. Ex. 1043 at 7-8. I

personally recall the FDA's draft guidance was issued around 2001. 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. I personally remember that the industry understood the draft FDA guidance to signal that new MDIs would be required to have dose counters, or there was a significant risk they would not be approved. Thus, the main effect of the FDA's guidance was to force manufacturers to sell MDIs that included a dose counter. In March of 2003, the FDA issued final guidance, recommending the same. Ex. 1013 at 6-7. The FDA's final guidance was announced in the Federal Register on March 13, 2003. Ex. 1044 at 7-8. As a result of the draft and final guidances, manufacturers began implementing dose counters on MDIs. Ex. 1041 at 6, Ex. 1042 at 13. Subsequent articles concluded that inclusion of dose counters on certain MDIs led to improvements for patients, including fewer emergency room visits. Ex. 1049 at 9.

19. It was well understood by 2001 that undercounting the number of dispensed doses could lead a patient to unknowingly run out of medication. *See, e.g.,* Ex. 1001 at 1:36-43; Ex. 1006 at 2:8-12; Ex. 1024 at 1:12-21 Ex. 1010 at 1:39-43; Ex. 1012 at 5; Ex. 1013 at 5-6. This was particularly problematic for rescue medications that a patient might need to take during an asthma attack. *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. By 2003, it was already known that the undercounting risk could be avoided by aligning the tolerances of the mechanism to the tolerances of the dispenser valve to trigger counting before fluid was dispensed. Ex. 1001 at 1:41-43; *see also* Ex. 1011 at 4:9-12 (“[T]he switching mechanism is formed such that the first 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.

20. At the time of the invention of the '631 Patent, a POSA would have designed an integrated dispenser to count prior to firing the valve and dispensing medication. *See* Ex. 1020 at 5:58-68 (release of dose after axial depression of valve); Ex. 1010 at 1:50-53 (preset amount of relative movement results in a count); Ex. 1014 at 4:31-5:5 (pressure to count should be less than pressure to dispense fluid); Ex. 1011 at 4:9-13 (counting ring actuated even when dispensing stroke is incomplete). For example, if a POSA knew that the valve would have dispensed medication after being depressed 100/1000 inch with a tolerance of plus or minus 2/1000 inch, that would have meant that for the canisters and valves to pass quality control standard, they would have had to dispense medication between 98/1000 inch and 102/1000 inch of depression. A POSA would have simply designed the gears of a dose counter to actuate counting at a point prior to 98/1000

inch. For example, the counter might have actuated after 80/1000 inch of depression, plus or minus 3/1000 inch. Thus, the counter would have actuated between 77/1000 and 83/1000 of an inch of depression, but the canister would not have dispensed medication until between 98/1000 and 102/1000 of an inch of depression. In such an arrangement there is no amount of depression or travel of the valve stem mechanism that would result in the release of medication without being counted because the travel distance of the indicator device to count (77/1000 – 83/1000 of an inch) is always less than the travel distance of the canister to release fluid containing medication (98/1000 – 102/1000 of an inch). The background section of the '631 Patent seems to recognize that this was the standard in the art at the time. *See* Ex. 1001 at 1:41-43.

21. Accordingly, a POSA would have adjusted the design, dimensions, and tolerances of the counter to ensure that the counter wheel would rotate before the medicine is expelled.

22. The same would have been true with respect to the return stroke. At some specific point (within a range of tolerances), the metering chamber would refill with medication. For similar reasons as above, a POSA would have designed the tolerances of the dose counter such that the counter would have reset prior to the metering chamber refilling. Thus, medication would have only been dispensed again after the counter had reset.

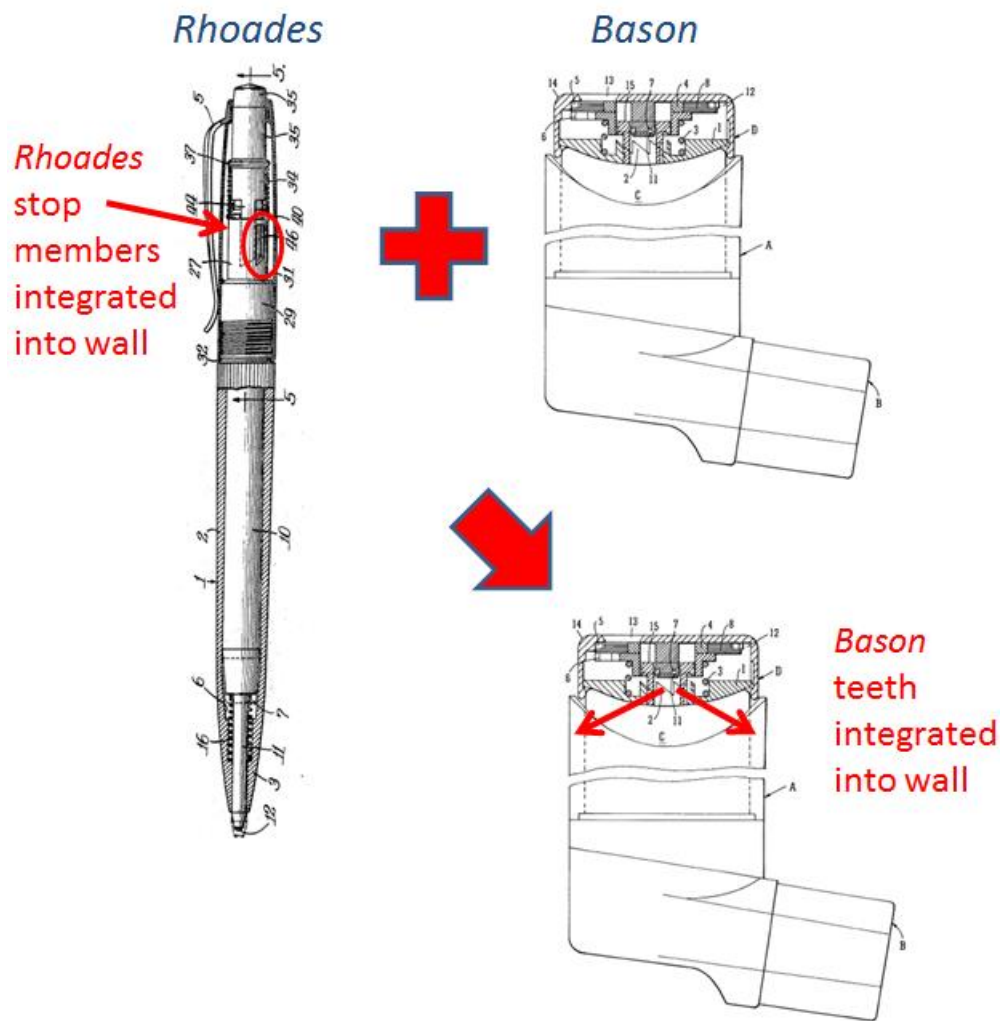
V. SUMMARY OF THE '631 PATENT

23. 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. Ex. 1001 at 1:24-30. The indicator disclosed in the '631 Patent can be used with a metered dose inhaler (“MDI”). Ex. 1001 at 5:9-10. MDIs include “a metering valve mounted on a reservoir . . . the displacement of the reservoir relative to the valve member causing a dose of fluid to be dispensed.” Ex. 1001 at 5:11-14. The disclosed indicator supposedly prevents errors of undercounting the number of dispensed doses 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. Even the '631 Patent recognizes that the concept of coordinating the point at which medication is released to occur before the point at which the counter counts was known. Ex. 1001 at 1:41-43; *see also* Ex. 1010 at 1:50-53; Ex. 1011 at 4:9-13; Ex. 1014 at 4:31-5:5; Ex. 1020 at 5:58-68.

24. In 2001, the United States Food and Drug Administration (FDA) issued draft guidance seeking comments on its proposed recommendation that manufacturers integrate dose counters directly into MDIs. Ex. 1012 at 4-6; Ex. 1043 at 7-8. The draft guidance was driven, in part, by the industry’s recognition

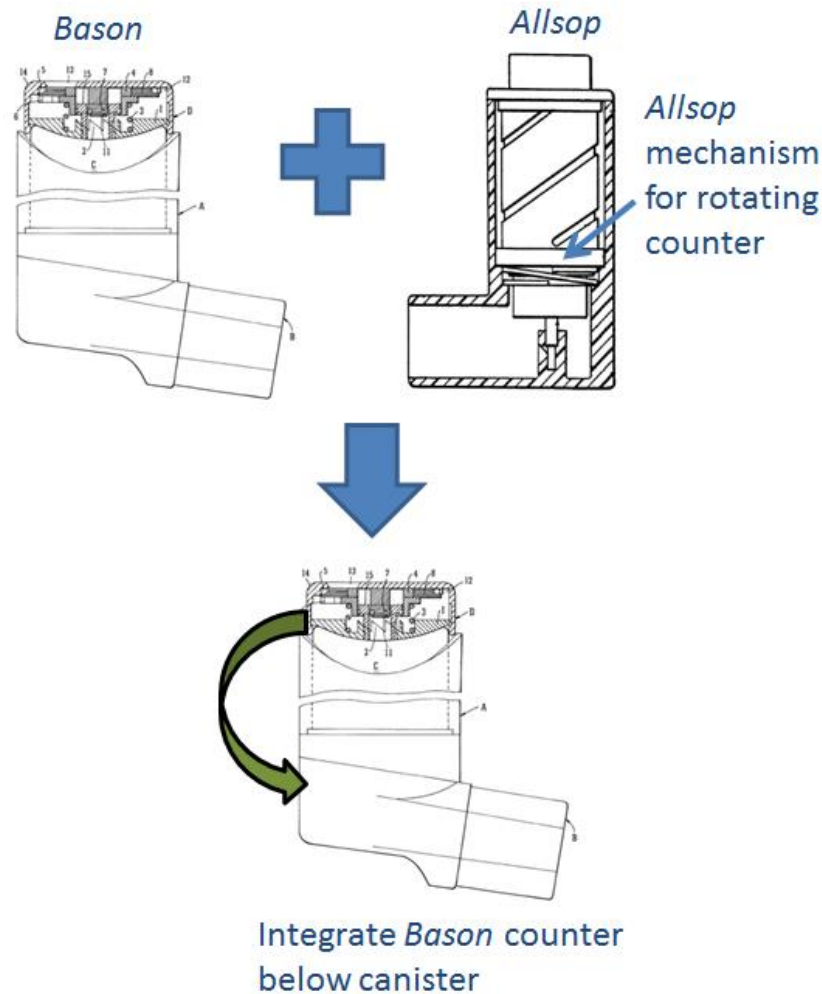
that existing methods of monitoring the medication remaining in an MDI were insufficient. Ex. 1027 at 5-6; Ex. 1028 at 7; Ex. 1041 at 6; Ex. 1042 at 13; Ex. 1045 at 3. By 2003, just before the '631 Patent's earliest possible priority date, the FDA finalized and issued that guidance. Ex. 1013 at 2-7; Ex. 1044 at 8. As a result of the draft and final guidance, manufacturers began including integrated dose counters into MDI products. Ex. 1041 at 6; Ex. 1042 at 13.

25. The prior art taught the specific elements of the Challenged Claims. Grounds 1 and 2 explain how every element of the Challenged Claims was already taught in *Allsop* (Ex. 1006) and *Marelli* (Ex. 1008) respectively. A POSA would also have been motivated to combine, in a predictable manner, known inhalers with known mechanisms that could easily serve as dose counters. *Rhoades* (Ex. 1009) teaches such an inexpensive, small, easily manufactured mechanical pen with a mechanism to convert axial movement into rotational movement. A POSA would have been motivated to look to such a reference that contained those design features rather than designing a mechanism from scratch. As described in Ground 3, a POSA would have been motivated to modify *Bason* in light of *Rhoades*—forming the stationary gear directly on the inhaler body—and that modification would teach a device having every element of the Challenged Claims.



Ex. 1009 at Fig. 2 (annotated); Ex. 1007 at Fig 1 (annotated).

26. Ground 4 explains why and how one would have made a simple modification to the *Bason* device in light of *Allsop*—integrating the counter element into the inhaler body below the canister—and why that modification would teach every element of the Challenged Claims.



Ex. 1007 at Fig. 1 (annotated); Ex. 1006 at Fig. 3 (annotated).

27. I understand that in an *inter partes* review proceeding, claim terms should be given their broadest reasonable interpretation consistent with the specification. I understand that if a term is expressly defined in the specification, the broadest reasonable interpretation is that definition and that otherwise the broadest reasonable interpretation is the plain and ordinary meaning, consistent with the specification, to a POSA, at the time of invention. In my analysis below, I apply that standard to the words and phrases of the Challenged Claims.

A. Claim 1

28. The '631 Patent includes independent claim 1, which is reproduced below.

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

Ex. 1001 at 10:1-24.

- 1. "a stationary body comprising at least one stationary multi-toothed gear,"**

29. The '631 Patent does not explicitly define the term “stationary body comprising at least one multi-toothed gear.” I understand that, 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.”¹ Ex. 1004 at 1273. That construction was based on the “[s]pecification and drawings, and with Appellant’s contentions.” Ex. 1004 at 1273, 1285:12-17. The PTAB relied on its construction to determine that pending claims were patentable over the Bason Publication. This interpretation is consistent with how a POSA would have understood this term. A POSA would have recognized that Fig. 1 of the '631 Patent shows the stationary body and stationary gear as a single, unitary structure. A POSA would further have relied on construction of the nearly identical term described above during prosecution of the '177 Patent in understanding the metes and bounds of the claim. The PTAB here should similarly require that a stationary

¹ The term construed in the '177 Patent was “a stationary body (1) including at least one stationary gear (110, 122).” Use of the word “comprising,” instead of “including” does not change the scope. Nor does the inclusion of the words “multi-toothed.” The number of teeth has no bearing on whether they are unitary with the stationary body.

body include as a unitary or monolithic part of the stationary body, at least one stationary multi-toothed gear. To the extent the PTAB adopts a different construction for this term that does not require the stationary gear to be unitary with the stationary body, my opinions would not change.

B. Claim 2

30. Claim 2 requires that in the fluid dispenser of claim 1, “the second member comprises at least one multi-toothed gear.” Ex. 1001 at 10:25-26

C. Claim 3

31. The '631 Patent includes independent claim 3, which is reproduced below.

A fluid dispenser comprising:

a plurality of displayable dose values;

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

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

displaceable relative to said stationary body;

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

a second member that is displaceable axially and in rotation relative to said

stationary body, said second member being engageable with said first

member and said stationary body; and

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

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

Ex. 1001 at 10:27-49.

1. "disposed on"

32. The '631 Patent does not define "a fluid reservoir disposed on said stationary body."² Petitioners propose the term "disposed on" encompass cases where two components are either in direct or indirect contact with each other.

33. The '631 Patent's figures suggest the reservoir can be indirectly "disposed on" the stationary body via counter element 20. The specification

² I understand that in the district court litigation Petitioners contend that the terms "disposed on" in claim 3 of the '631 Patent is indefinite, which is beyond the scope of *inter partes* review.

explains that “[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.” Ex. 1001 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.

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

D. Claim 4

35. Claim 4 requires that in the fluid dispenser of claim 3, “the fluid reservoir is configured to be axially displaced relative to said stationary body during actuation of the fluid dispenser.” Ex. 1001 at 10:50-52.

36. I understand that in an *inter partes* review proceeding, claim terms should be given their broadest reasonable interpretation consistent with the specification.

VI. SUMMARY OF THE RELEVANT LAW

A. General

37. In expressing my opinions and considering the subject matter of the ’631 Patent, I am relying upon legal principles that Petitioners’ attorneys have provided and/or explained to me.

38. I understand that in an *inter partes* review proceeding, Petitioners have the burden to prove the Challenged Claims of the '631 Patent are unpatentable by a preponderance of the evidence. I understand that "preponderance of the evidence" means that a fact or conclusion is more likely true than not.

39. I understand that a claim is unpatentable if the claimed subject matter was known before the invention was made or would have been obvious to a POSA at the time the invention was made. My understanding of the legal standards for "anticipation" and "obviousness" are set forth below.

B. Anticipation

40. I understand that the following standards govern the determination of whether a patent claim is "anticipated" by the prior art.

41. I understand that, for a patent to be "anticipated" by the prior art, each and every limitation of the claim must be found, expressly, implicitly or inherently, in a single prior art reference. I further understand that the requirement of strict identity between the claim and the reference is not met if a single element or limitation required by the claim is missing from the applied reference.

42. I understand that claim limitations that are not expressly described in a prior art reference may still be adequately disclosed for anticipation purposes if

they are implicitly disclosed by the reference or are inherent (*i.e.*, necessarily present) in what the reference describes.

43. I have been informed that in assessing whether a limitation is implicitly disclosed by a reference, I should take into account the knowledge possessed by a POSA and consider not only the specific teaching of the reference but also the inferences a POSA would reasonably have been expected to have drawn from those teachings in light of such knowledge.

C. Obviousness

44. I understand that for a single prior art reference or a combination of prior art references to render a claimed invention obvious, the Petitioners must prove a POSA would have arrived at the subject matter of the claimed invention by reviewing the reference or references.

45. I have been informed that a patent claim can be found unpatentable as obvious where the differences between the patented subject matter and the prior art reference or references are such that the subject matter as a whole would have been obvious to POSA at the time the invention was made. Specifically, I understand that the obviousness question involves a consideration of:

- a. the scope and content of the prior art;
- b. the differences between the prior art and the claims at issue;
- c. the knowledge of a POSA; and

d. whatever objective factors indicating obviousness or non-obviousness may be present in any particular case – referred to as “secondary considerations.”

46. I understand that the obviousness inquiry should not be done in hindsight, but must be done using the perspective of a POSA as of the effective filing date of the Challenged Claims (unless the Patent Owner establishes an earlier invention date).

47. I understand that in order for a claimed invention to be considered obvious, there must be some rationale for combining prior art references in the manner that renders the claimed invention obvious.

48. I understand that obviousness may also be shown by demonstrating that it would have been obvious to modify what is taught in a single prior art reference to create the patented invention, or otherwise implement what is taught in a reference in a manner that would have resulted in the patented subject matter.

49. I further understand that obviousness may be shown by establishing that it would have been obvious to combine the teachings of more than one prior art reference. In determining whether a prior art reference would have been combined with other prior art or with other information within the knowledge of a POSA, I have been informed the following are examples of approaches and rationales that may be considered:

- a. Combining prior art elements according to known methods to yield predictable results;
- b. Simple substitution of one known element for another to obtain predictable results;
- c. Use of a known technique to improve similar devices in the same way;
- d. Applying a known technique to a known device ready for improvement to yield predictable results;
- e. Applying a technique or approach that would have been “obvious to try,” *i.e.*, choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- f. Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to a POSA; or
- g. Some teaching, suggestion, or motivation in the prior art that would have led a POSA to modify the prior art reference or to combine prior art reference teaching to arrive at the claimed invention. I understand that this teaching, suggestion or motivation may come from prior art reference or from knowledge or common sense of a POSA.

50. I understand that an invention that might be considered an obvious variation of a prior art reference may be considered non-obvious if other prior art references teach away from that variation.

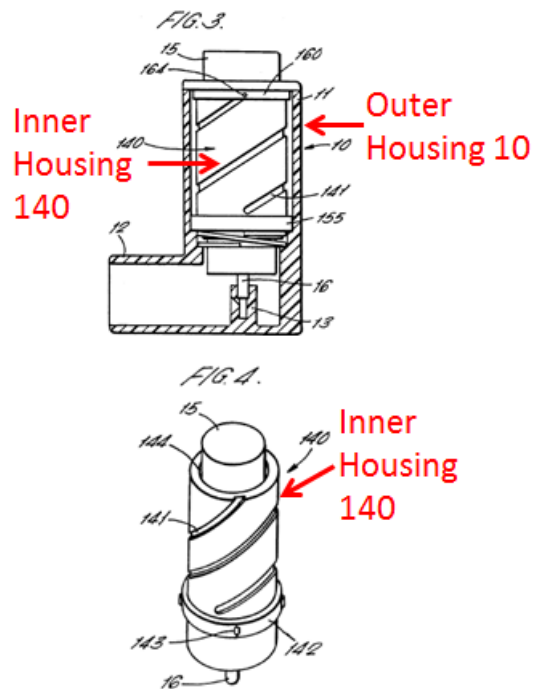
51. I also understand, however, that a reference does not “teach away” simply because it suggested that a different variation may be better or preferred; rather, to “teach away” the reference must have clearly indicated to a POSA that the variation should not have been attempted because, for example, it would not work.

VII. ALL CLAIMS OF THE '631 PATENT ARE UNPATENTABLE OVER THE IDENTIFIED PRIOR ART

A. Ground 1: Claims 1-4 of the '631 Patent are Anticipated by Allsop (Ex. 1006)

52. Allsop (Ex. 1006) is an international patent application publication that published on October 12, 2000. I have been informed by counsel that Allsop is prior art to the '631 Patent.

53. *Allsop* discloses a “dispensing apparatus comprising a dosage counting device.” Ex. 1006 at Title. Specifically, *Allsop* teaches a dispenser comprising a stationary outer housing 10 (having a cylindrical portion 11), and a slidable and rotatable inner housing 140 located within the outer housing.



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

54. 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. Ex. 1006 at 7:8-10. Collar 155 contains a plurality of inwardly directed lugs 156 having angled upper and lower surfaces. Ex. 1006 at 6:30-33.



See Ex. 1006 at Fig. 6 (collar 155 containing lugs 156) (annotated), Fig. 5 (inwardly directed lugs having angled upper and lower surfaces) (annotated).

55. The inner housing 140 includes “an annular flange 142,” which has “a number of protrusions 143 equidistantly spaced around its circumference” near the

base. Ex. 1006 at 5:28-29. A pressurized dispensing container 15 is located 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. Ex. 1006 at 4:5-28. *Allsop* also discloses a “push-button cap” (not shown in figure) that may cover the upper portion of the container. Ex. 1006 at 8:22-24.

56. To operate *Allsop*, a user depresses the pressurized container 15, causing the inner housing to move downward in conjunction with the reservoir. As protrusions 143 of the downwardly moving inner housing contact the angled surfaces of the stationary lugs 156 in the outer housing, the inner housing is caused to rotate. Upon release of the canister, the inner housing moves upwards under the force of a spring and protrusions 143 again engage angled surfaces of lugs 156, causing further rotation of the inner housing 140. Ex. 1006 at 9:3-25, Fig. 5.

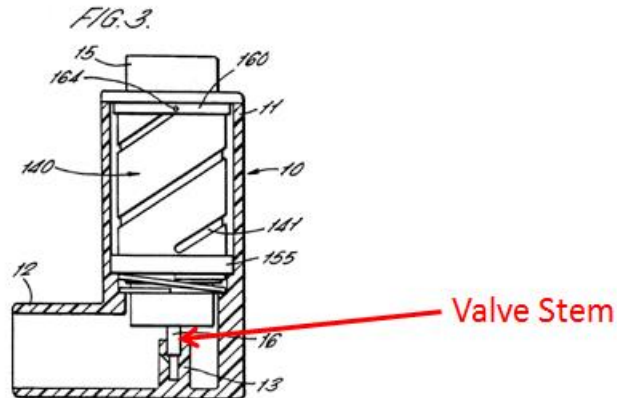
57. *Allsop* discloses a ring 160 for “indicating that the pressurised dispensing container 15 contains one less dose.” Ex. 1006 at 9:14-17. *Allsop* also discloses that “[t]he ring 160 may be replaced with a series of numbers . . . spaced around the inner housing 140 . . . such that only a single number” can be seen through slots 170 at any given time. Ex. 1006 at 10:4-9.

58. In my opinion, each element of the Challenged Claims is disclosed by *Allsop*, and thus the Challenged Claims are anticipated by *Allsop*.

1. **Claim 1**

a. “A fluid dispenser”

59. *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.



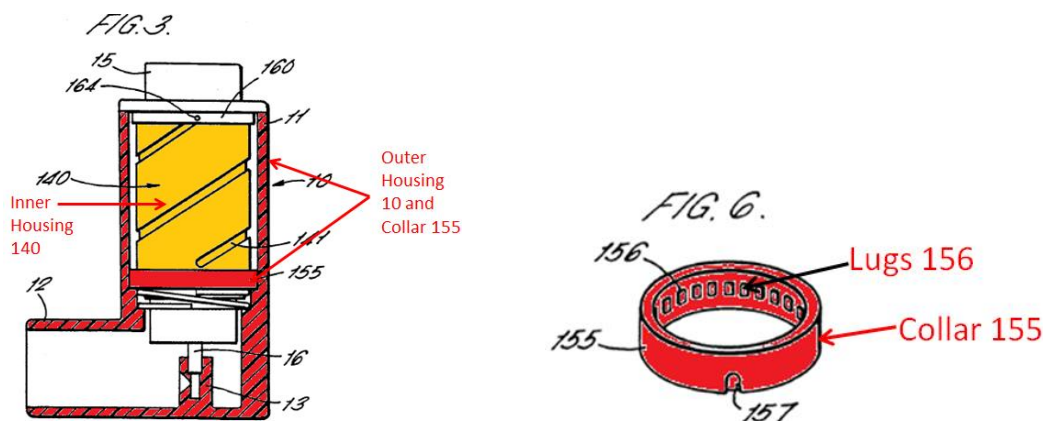
Ex. 1006 at Fig. 3 (annotated); *see also* Ex. 1006 at 4:18-20.

b. “a plurality of displayable dose values”

60. *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, Fig. 1. The current value is indicated by a ring at the value corresponding to the remaining doses. Ex. 1006 at 9:13-17. Alternatively, the ring may be replaced with a series of numbers spaced around the inner housing so only a single number is visible at any one time. Ex. 1006 at 10:4-9.

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

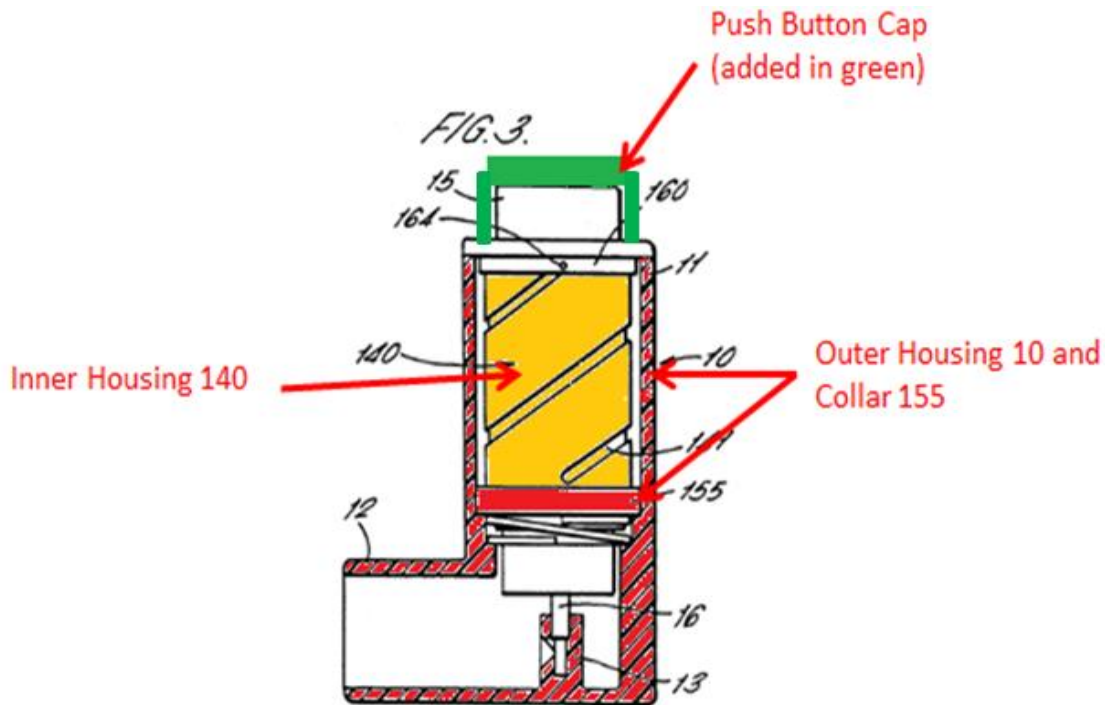
61. *Allsop* discloses a collar with “a plurality of inwardly directed lugs 156 . . . hav[ing] angled upper and lower surfaces,” near the lower end of the cylindrical portion 11 of housing 10. Ex. 1006 at 6:30-7:6. The *Allsop* collar can be “integrally moulded,” and therefore unitary, with the outer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



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

d. “a first member that is displaceable axially relative to said stationary body”

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

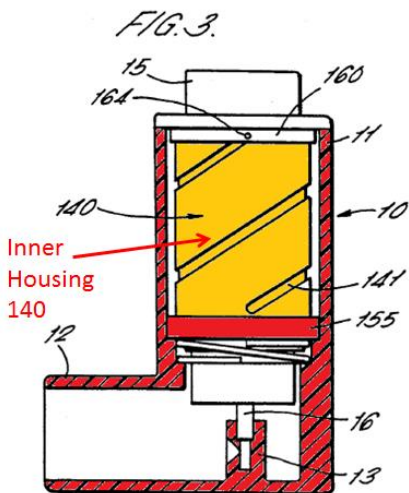


63. The button could be depressed axially, moving the canister axially.

Accordingly, *Allsop* discloses the claimed first member by disclosing a push-button cap.

- e. **“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”**

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



65. The inner housing 140 is the cylinder that 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. Ex. 1006 at 5:27-32. Inner housing 140 is located within outer housing 10 and is caused to move downward as the canister is depressed. Ex. 1006 at 9:3-9. As the inner housing is moved downward, outwardly directed protrusions 143 interact with the angled surfaces of inwardly directed lugs 156 on 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. Ex. 1006 at 9:5-9.

66. The depressible button of the push button cap would engage with the inner housing as the button was depressed. And if the button does not directly engage the inner housing, the button indirectly engages the inner housing via the

pressurized canister. Specifically, when the button is depressed, both the canister and inner housing move axially downward.

- f. **“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”**

67. 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.

68. 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. 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. Ex. 1006 at 9:13-17. Alternatively, the subsequent dose values can be printed directly on the inner housing. Ex. 1006 at 10:4-9.

69. As the push-button cap (first member) displaces axially, a container 15 (fluid reservoir) displaces axially, and 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. 1006 at 9:3-25.

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

70. *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. *See* Ex. 1006 at 9:3-11, 17-25, Figs. 3 and 4. Accordingly, the stationary body has a central longitudinal axis through the cylindrical portion. Ex. 1006 at Figs. 3, 4. The cylindrical inner housing shares that same longitudinal axis. *See* Ex. 1006 at Figs. 3 and 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.

71. 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. 1006 at 9:3-11, 17-25, Figs. 3-4.

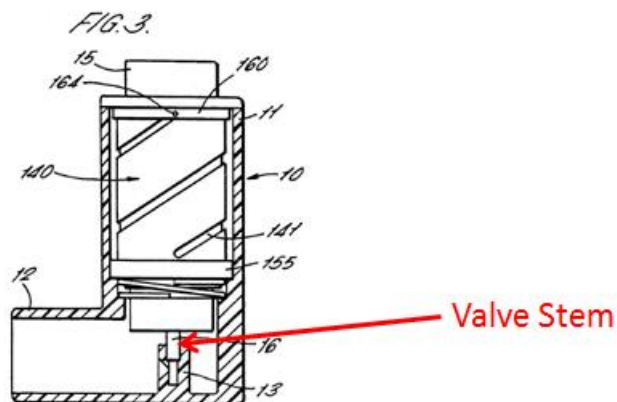
2. Claim 2: “The fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear.”

72. *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.

3. Claim 3

a. “A fluid dispenser”

73. *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.



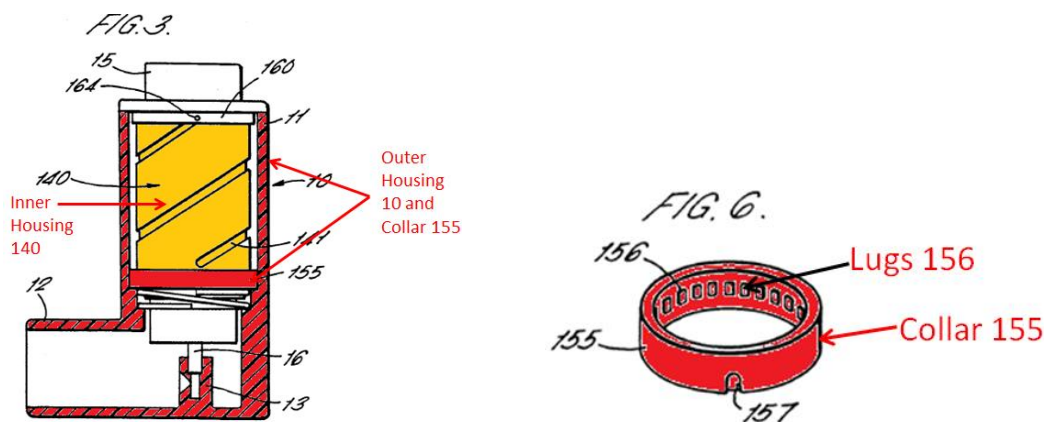
Ex. 1006 at Fig. 3 (annotated); *see also* Ex. 1006 at 4:18-20.

b. “a plurality of displayable dose values”

74. *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; Ex. 1006 at Fig. 1. The current value is indicated by a ring at the value corresponding to the remaining doses. Ex. 1006 at 9:13-17. Alternatively, the ring may be replaced with a series of numbers spaced around the inner housing so only a single number is visible at any one time. Ex. 1006 at 10:4-9.

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

75. *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. Ex. 1006 at 7:9-10. The housing 10 with an integrally molded collar 155 containing inwardly directed lugs 156 is the claimed stationary body with at least one stationary multi-toothed gear (depicted in red below).



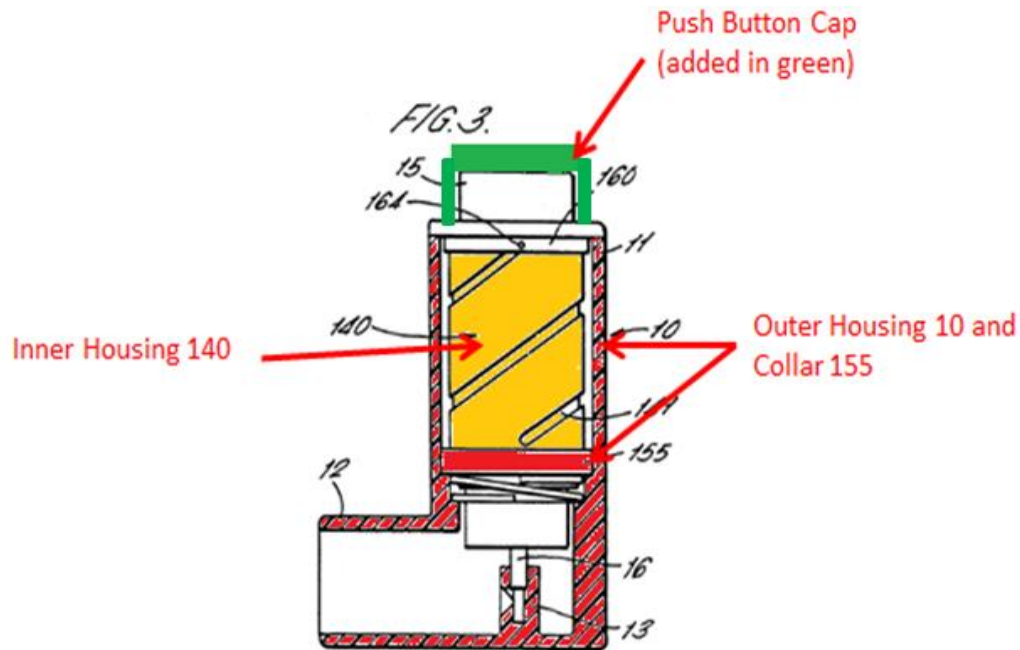
See Ex. 1006 at Figs. 3, 6 (annotated).

d. “a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”

76. *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, shown above, depicts the container within the housing body 10. As explained in ¶¶ 32-34, 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). “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.

e. “a first member that is displaceable axially relative to said stationary body”

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

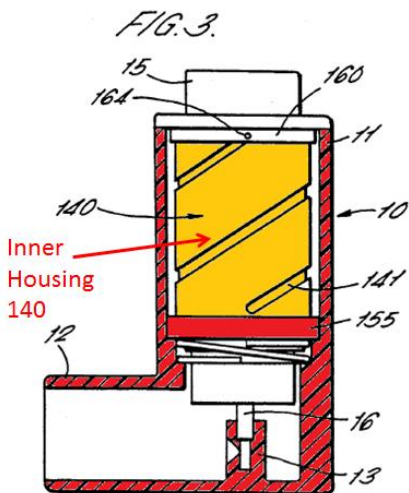


78. The button could be depressed axially, moving the canister axially.

Accordingly, *Allsop* discloses the claimed first member by disclosing a push-button cap.

- 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”**

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



80. The inner housing 140 is the cylinder that 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. Ex. 1006 at 5:27-32. Inner housing 140 is located within outer housing 10 and is caused to move downward as the canister is depressed. Ex. 1006 at 9:3-9. As the inner housing is moved downward, outwardly directed protrusions 143 interact with the angled surfaces of inwardly directed lugs 156 on 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. Ex. 1006 at 9:5-9.

81. The depressible button of the push button cap would engage with the inner housing as the button was depressed. And if the button does not directly engage the inner housing, the button indirectly engages the inner housing via the

pressurized canister. Specifically, when the button is depressed, both the canister and inner housing move axially downward.

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

82. This limitation is identical to a limitation of claim 1 except that this limitation does not require a fluid reservoir as part of the limitation. Accordingly, *Allsop* discloses this limitation for the same reasons described immediately above with respect to claim 1. *See* ¶¶ 67-70.

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

83. *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. *See* Ex. 1006 at 9:3-11, 17-25, Figs. 3 and 4. Accordingly, the stationary body has a central longitudinal axis through the cylindrical portion. Ex. 1006 at Figs. 3, 4. The cylindrical inner housing shares that same longitudinal axis. *See* Ex. 1006 at Figs.

3 and 4. The push button cap (first member) is made to cover the top of the cylindrical fluid reservoir, and therefore shares the same longitudinal axis. Ex. 1006 at 8:22-24.

84. 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. 1006 at 9:3-11, 17-25, Figs. 3-4.

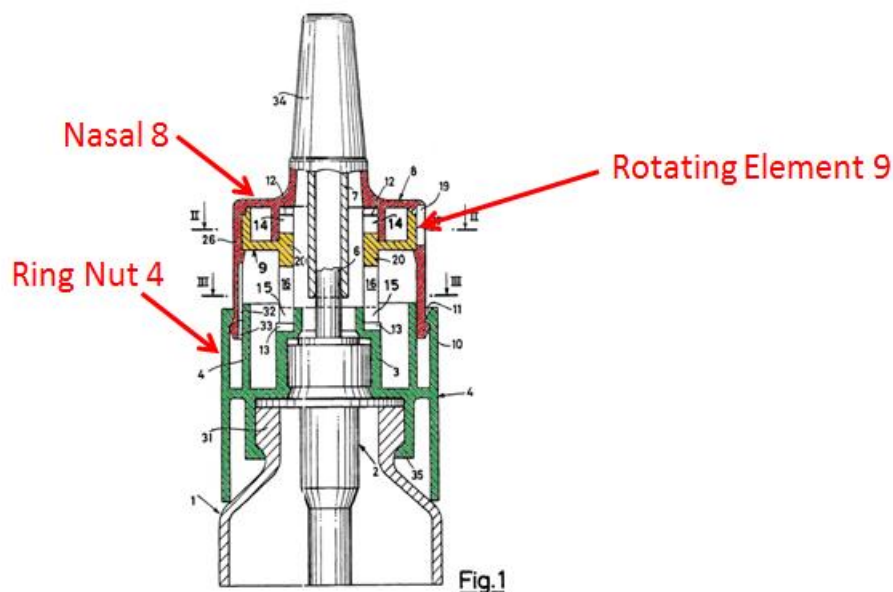
4. Claim 4: “The fluid dispenser according to claim 3, wherein the fluid reservoir is configured to be axially displaced relative to said stationary body during actuation of the fluid dispenser.”

85. *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.” Ex. 1006 at 9:3-5. As a pressurized canister with a valve as disclosed in *Allsop* is depressed, fluid will be dispensed from the canister. *See* 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 (Ex. 1008)

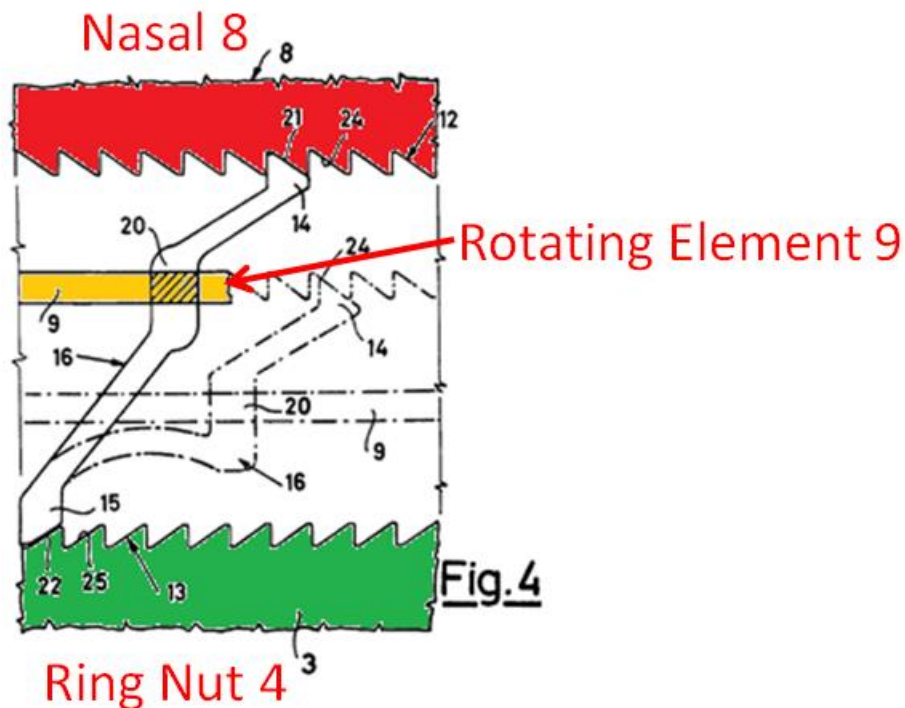
86. *Marelli* (Ex. 1008) issued on November 2, 1994. I have been informed by counsel that *Marelli* is prior art to the '631 Patent.

87. *Marelli* discloses a dose counting device for a distributor of fluid products, with a particular application to nasal distributors. Ex. 1008 at 1:3-7. *Marelli* discloses a device comprising a ring nut 4, a nasal 8, and a distribution valve 2. Ex. 1008 at 3:9-25. The ring nut 4 is fastened to a fluid filled container. Ex. 1008 at 4:3-4. The nasal 8 extends from the valve and can be inserted into the nostrils for distribution of the fluid. Ex. 1008 at 3:34-38. The nasal 8 (red, below) and ring nut 4 (green, below) are movable axially relative to each other. Ex. 1008 at 3:26-38. "Every stroke imparted to the nasal causes the distribution of a given dose of product." Ex. 1008 at 1:26-27.



Ex. 1008 at Fig. 1 (annotated).

88. “Inside both the nasal 8 and the ring nut 4 there are accomplished internal sets of saw-tooth shaped teeth 12, 13.” Ex. 1008 at 3:39-41. Between those two rows of teeth is an intermediate part 20 that is integral with a rotating element 9 (yellow), which has small flexible legs 16 that interact with the rows of saw-tooth shaped teeth 12 and 13 respectively. Ex. 1008 at 3:39-46.



Ex. 1008 at Fig. 4 (annotated).

89. As a stroke is imparted to the 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 the row of teeth 12. Ex. 1008 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. Ex. 1008 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 observed through window 19. Ex. 1008 at 4:9-48, Fig. 4.

90. In my opinion, each element of the Challenged Claims is taught by *Marelli*, and thus the Challenged Claims are anticipated by *Marelli*.

1. Claim 1

a. “A fluid dispenser”

91. 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. “a plurality of displayable dose values”

92. *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.

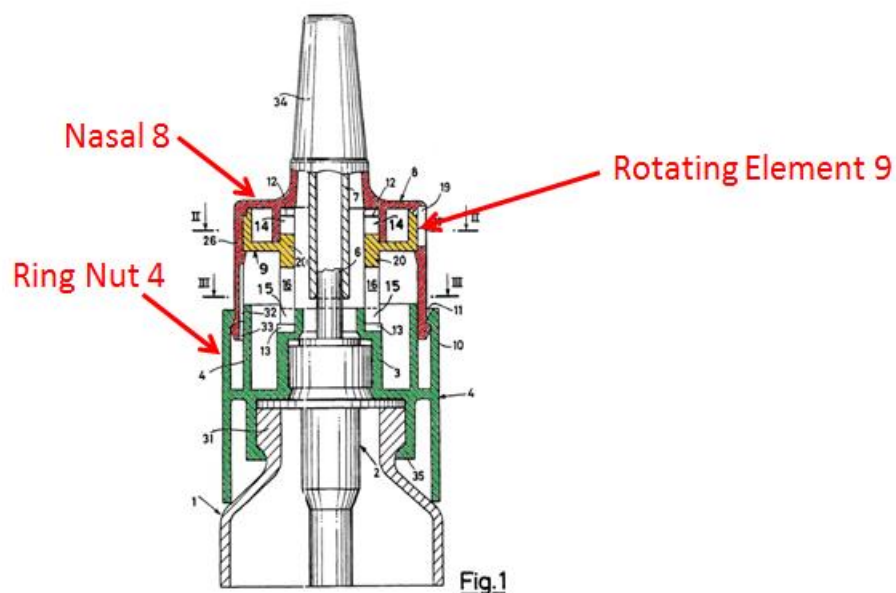
c. “a stationary body comprising at least one stationary multi-toothed gear”

93. *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 a ring nut 4 that is fastened to the container by means of an annular protrusion 35. Ex. 1008 at 3:16-19. The valve 2 leads to “nasal 8,” through which fluid product is delivered to a patient’s nose. Ex. 1008 at 3:19-25. “[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. 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.

94. A POSA would have understood that the terms “stationary” and “moving” are relative terms. A body is only stationary or moving with respect to another body. For example, if a book is inside a car that is driving at 65 miles per hour, the book is moving at 65 miles per hour relative to people outside the car; but the book is stationary relative to the occupants of that same vehicle. Accordingly, a POSA would have understood that either the nasal 8 (red), or the ring nut 4 (green) would be considered a stationary body and the other an axially moving piece. 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 would have really been the ring nut and fluid reservoir that moved with respect to the user, while the nasal remains stationary with respect to the user with the spout inserted in the user’s nostril during use. 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

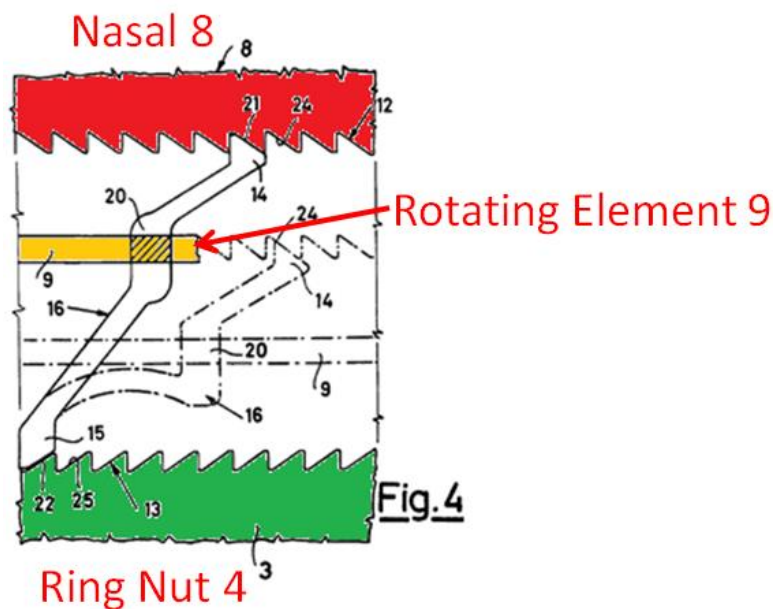
(green) and canister towards the nasal 8 (red). Accordingly, a POSA would have understood *Marelli* to disclose a stationary body, the nasal 8 (red, below).



Ex. 1008 at Fig. 1 (annotated).

95. Inside nasal 8 there is an “internal set[] of saw-tooth shaped teeth.”

Ex. 1008 at 3:39-41.



Ex. 1008 at Fig. 4 (annotated).

96. Accordingly, nasal 8 is a stationary body that comprises at least one stationary multi-toothed gear.

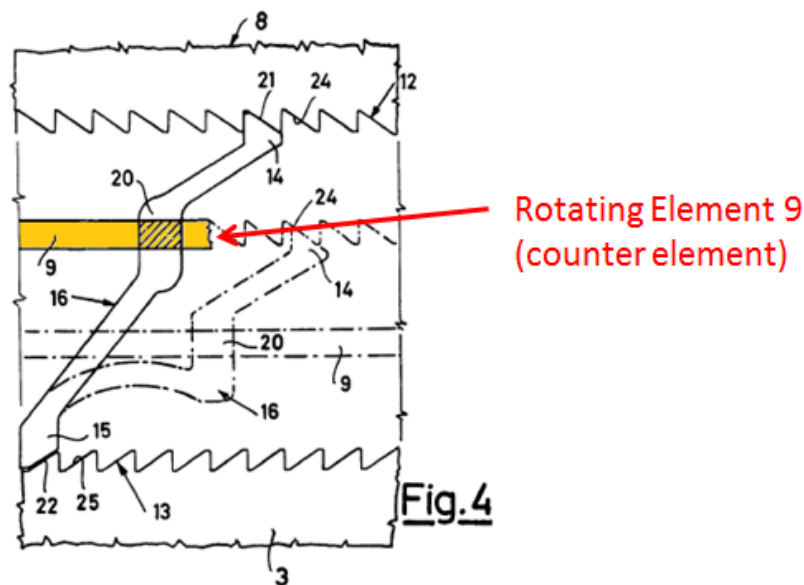
d. “a first member that is displaceable axially relative to said stationary body”

97. *Marelli* teaches ring nut 4 (first member). “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. *See* Ex. 1008 at 3:26-38.

e. “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”

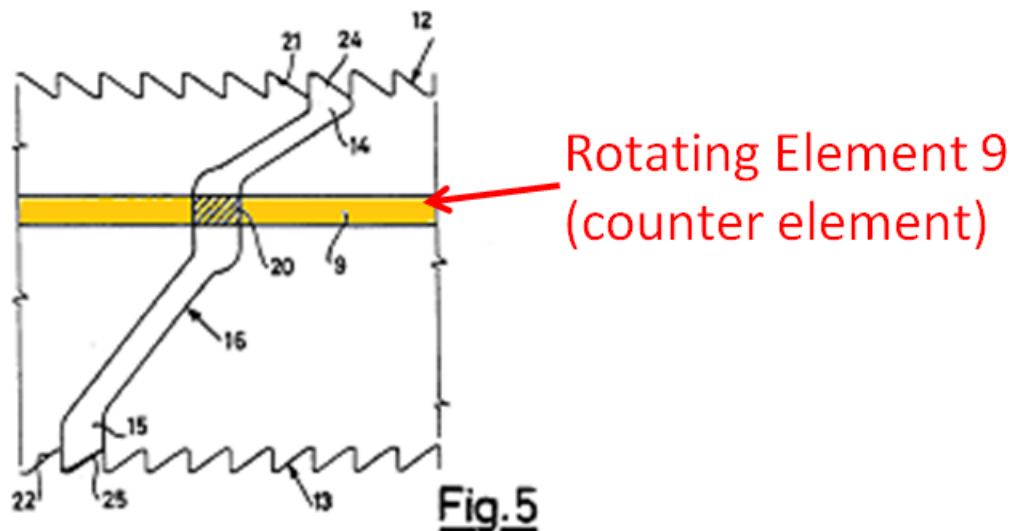
98. *Marelli* teaches a rotating element 9 (second member). Rotating element 9 is integral with small flexible legs 16. Those small flexible legs engage with the saw-tooth shaped teeth 12 of nasal 8 via their upper part 14 and engage with the saw-tooth shaped teeth 13 of ring nut 4 via their lower part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

99. Upon actuation, “upper part 14 leaves the tooth 21 to position itself in a tooth 24 adjacent to it.” Ex. 1008 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.” Ex. 1008 at 4:34-36. This moves “the small leg 16 through one position.” Ex. 1008 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.” Ex. 1008 at 4:39-42.



Ex. 1008 at Fig. 5 (annotated).

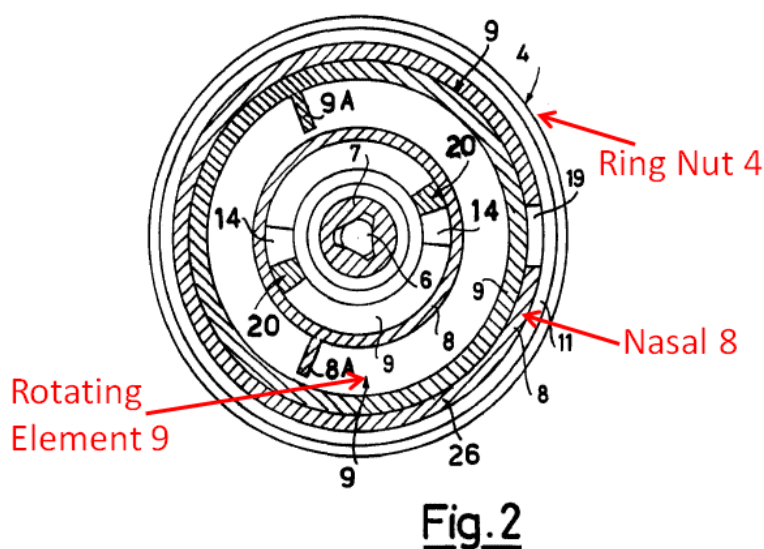
- f. **“when said first member displaces axially, the stationary body is configured to allow a fluid reservoir to be axially displaceable relative to said stationary body and said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change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

100. 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. 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.

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

101. *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. 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 are described above in ¶¶ 97-100.



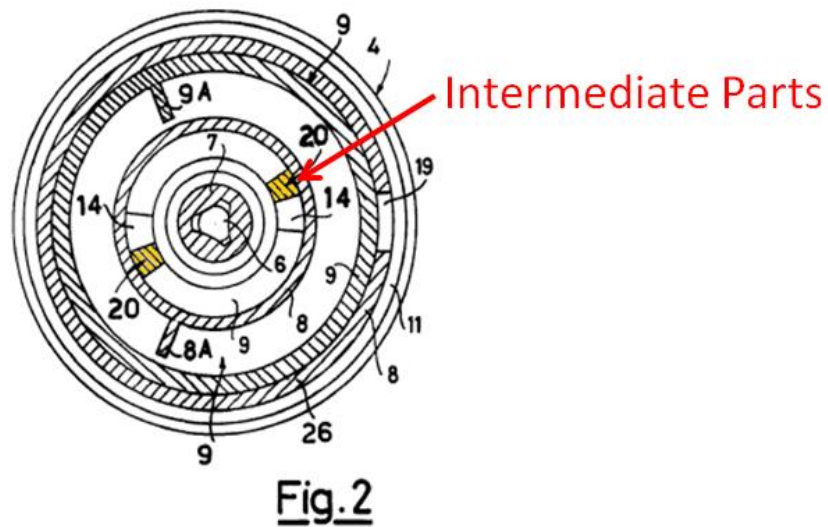
Ex. 1008 at Fig. 2 (annotated).

2. Claim 2

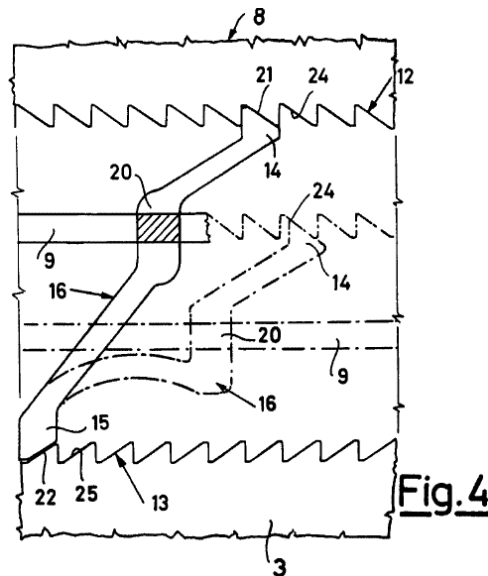
- a. “The fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear”

102. *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.*, Ex. 1008 at Fig. 2 (annotated):



103. 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. Ex. 1008 at 3:39-46, 4:13-30; *see, e.g.*, Ex. 1008 at Fig. 4:



Ex. 1008, Fig. 4.

3. Claim 3

a. “A fluid dispenser”

104. 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. “a plurality of displayable dose values”

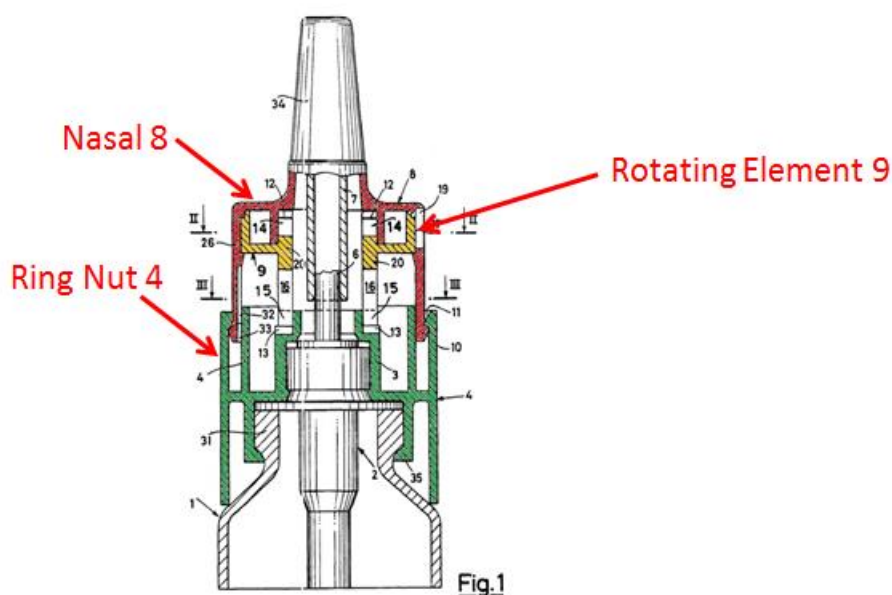
105. *Marelli* discloses “progressive numerical indices 17” on rotating element 9, which are displayed through an observation window 19 in the annular part 26 of the nasal 8, for “indicating the number of strokes that have been imparted to the nasal 8 up to that time.” Ex. 1008 at 3:45-52, 4:42-46.

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

106. *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 a ring nut 4 is fastened to the container by means of an annular protrusion 35. Ex. 1008 at 3:16-19. The valve 2 leads to “nasal 8,” through which fluid product is delivered to a patient’s nose. Ex. 1008 at 3:19-25. “[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. 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.

107. A POSA would have understood the terms “stationary” and “moving” are relative terms. A body is only stationary or moving with respect to another body. For example, if a book is inside a car that is driving at 65 miles per hour, the book is moving at 65 miles per hour relative to people outside the car; but the book is stationary relative to the occupants of that same vehicle. Accordingly, a POSA would have understood that either the nasal 8 (red), or the ring nut 4 (green) would be considered a stationary body and the other an axially moving piece. 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

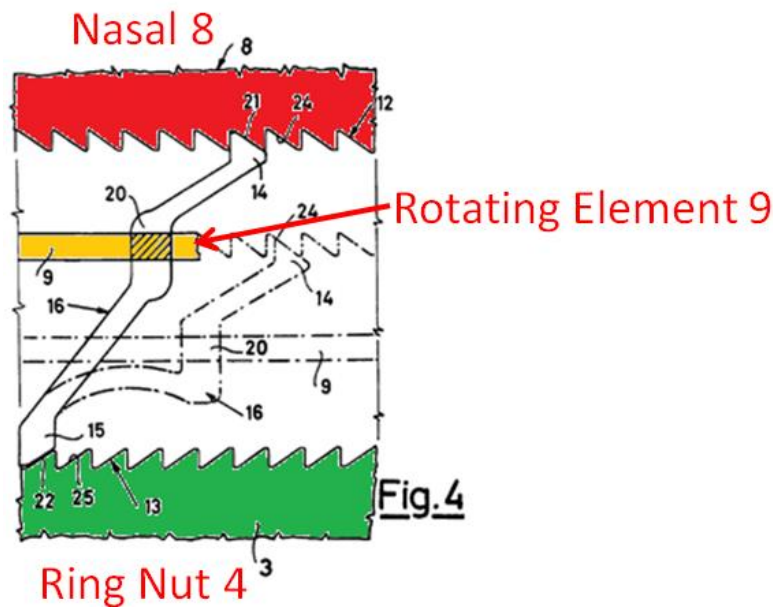
the nasal) in his or her nostril, a POSA would have understood it is really the ring nut and fluid reservoir that move, while the nasal remains stationary with respect to the user with the spout inserted in the user's nostril during use. In other words, a user does not pull the nasal down (and out of the nose) during operation, but rather moves the ring nut 4 (green) and canister towards the nasal 8 (red). Accordingly, a POSA would have understood *Marelli* to disclose a stationary body, the nasal 8 (red, below).



Ex. 1008 at Fig. 1 (annotated).

108. Inside nasal 8 there is an “internal set[] of saw-tooth shaped teeth.”

Ex. 1008 at 3:39-41.



Ex. 1008 at Fig. 4 (annotated).

109. Accordingly, nasal 8 is a stationary body that comprises at least one stationary multi-toothed gear.

- d. **“a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”**

110. *Marelli* discloses a fluid reservoir attached to the ring nut 4. As described immediately above, a POSA would have understood nasal 8 to be a stationary body. As described in ¶¶ 32-34, 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.

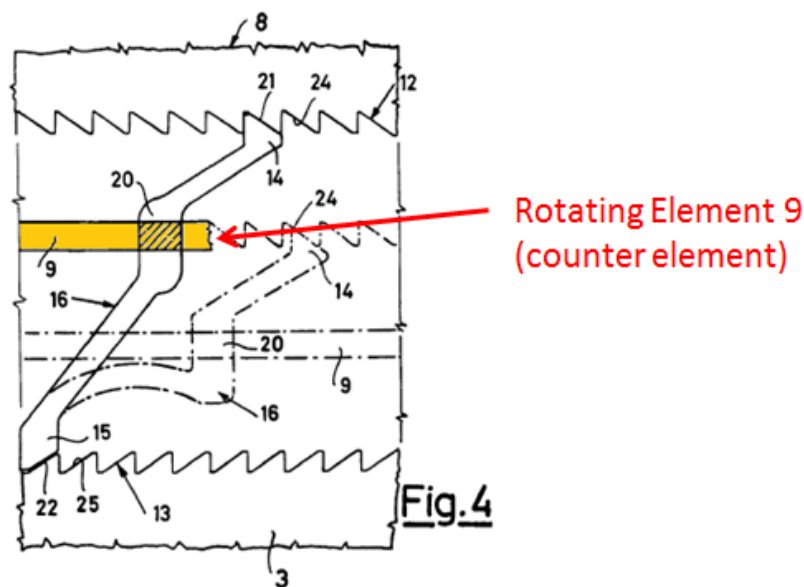
e. “a first member that is displaceable axially relative to said stationary body”

111. *Marelli* teaches ring nut 4 (first member). “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. *See* Ex. 1008 at 3:26-38.

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”

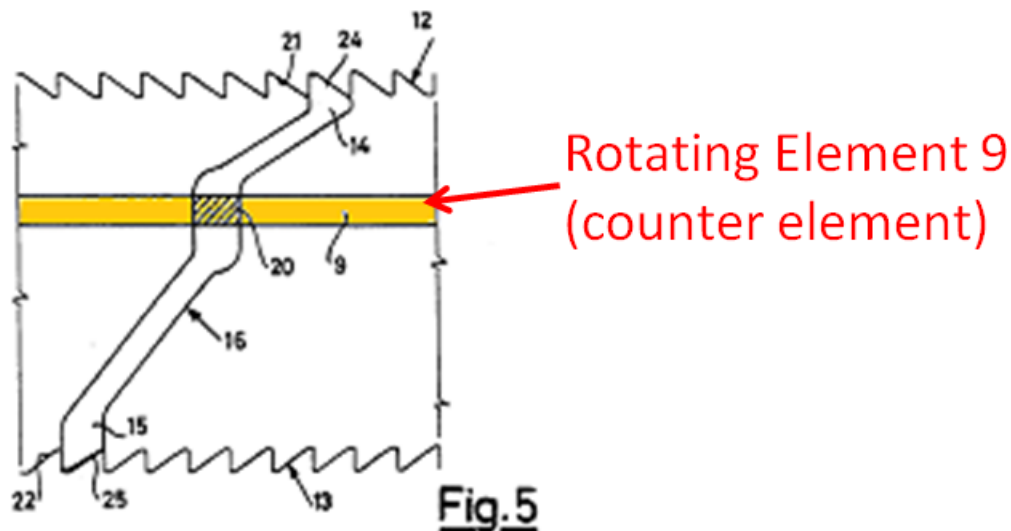
112. *Marelli* teaches a rotating element 9 (second member). Rotating element 9 is integral with small flexible legs 16. Those small flexible legs engage with the saw-tooth shaped teeth 12 of nasal 8 via their upper part 14 and engage with the saw-tooth shaped teeth 13 of ring nut 4 via their lower part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

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).

113. Upon actuation, “upper part 14 leaves the tooth 21 to position itself in a tooth 24 adjacent to it.” Ex. 1008 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.” Ex. 1008 at 4:34-36. This moves “the small leg 16 through one position.” Ex. 1008 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.” Ex. 1008 at 4:39-42.



Ex. 1008 at Fig. 5 (annotated).

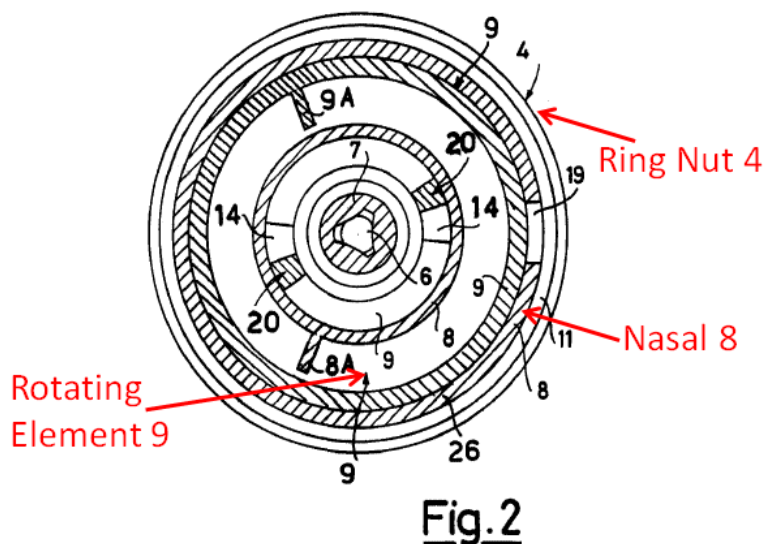
- g. **“when said first member displaces axially, said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values”**

114. This limitation is identical to a limitation of claim 1 except that this limitation does not require a fluid reservoir as part of the limitation. Accordingly, *Marelli* discloses this limitation for the same reasons described immediately above with respect to claim 1. See ¶ 101.

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

115. *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. 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 ¶¶ 111-113.



Ex. 1008 at Fig. 2 (annotated).

4. Claim 4

- a. **“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.”**

116. *Marelli* discloses a fluid reservoir attached to the ring nut 4. As described above, a POSA would have understood nasal 8 to be a stationary body. “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.” Ex. 1008 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.” Ex. 1008 at 4:22-25.

C. Ground 3: Claims 1-4 of the ’631 Patent are Obvious over Bason (Ex. 1007) in view of Rhoades (Ex. 1009)

Bason

117. *Bason* (Ex. 1007) is a U.S. Patent that issued on September 4, 2001. I have been informed by counsel that Bason is prior art to the ’631 Patent.

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

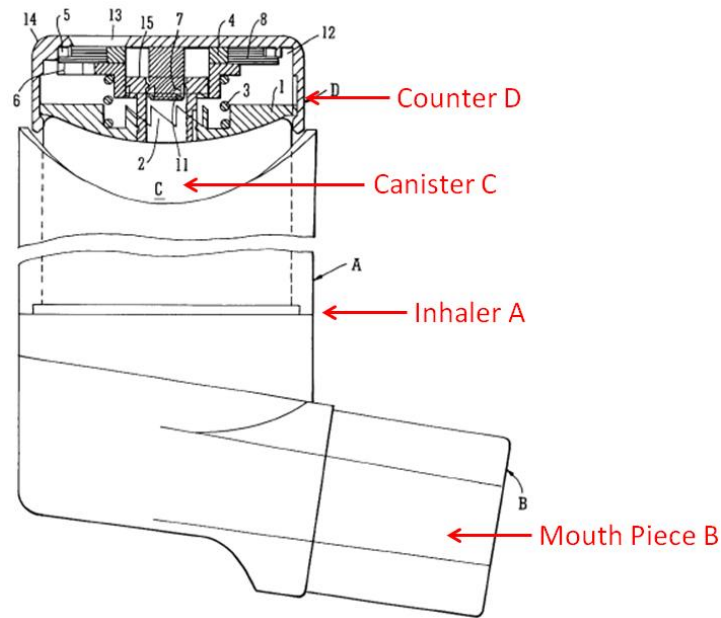
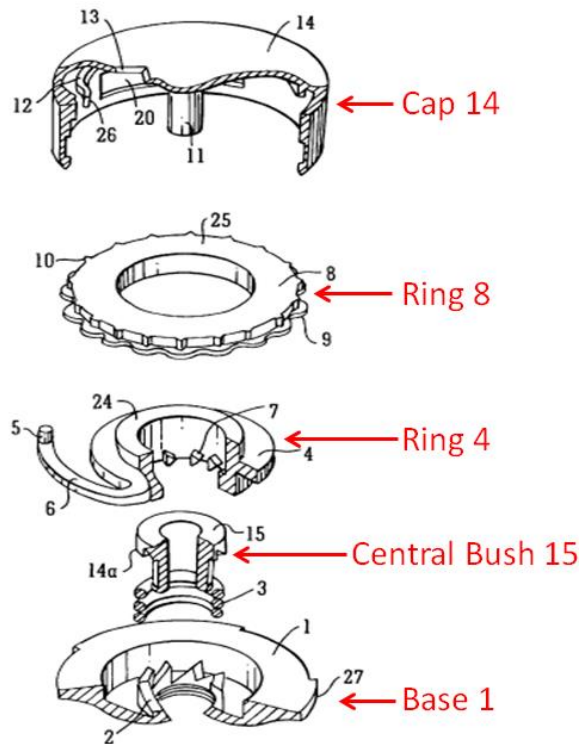


FIG. 1

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

119. *Bason* teaches a dose counter comprised of a central bush 15 that is “[d]isposed in fixed position on base 1,” (Ex. 1007 at 2:20, Figs. 1 & 3), with “downwardly directed teeth 14a,” (*id.* at 2:33-35). The 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. Ex. 1007 at 2:66-3:4. Above ring 8 is an axially movable cap. Ex. 1007 at 2:47-50.



Ex. 1007 at Fig. 3 (annotated).

120. “Upon depression of the cap 14 with respect to the base 1, the rings 4 and 8 are also depressed linearly.” Ex. 1007 at 3:15-16. After sufficient downward displacement, 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 3:17-22. 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 to rotate ring 4 further, moving it into position for the next actuation. Ex. 1007 at 3:15-26. Rotation of rings 4 and 8 changes the displayed dose value. Ex. 1007 at 3:15-24. Figure 5 shows how depression and release of the device causes teeth 7 (on ring 4) to engage teeth 2 and teeth 14a, causing rotation of ring 4 (not shown).

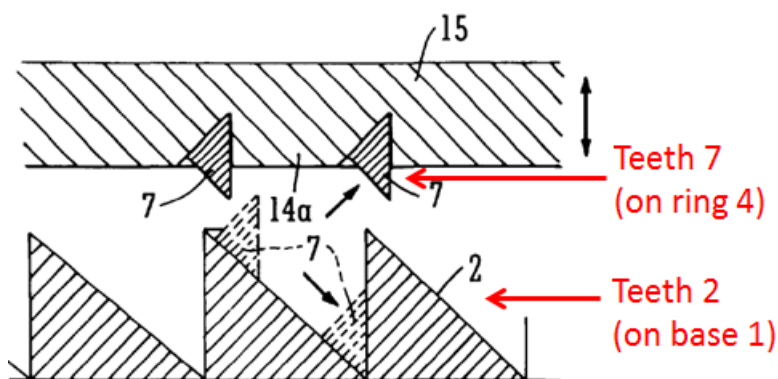


FIG. 5

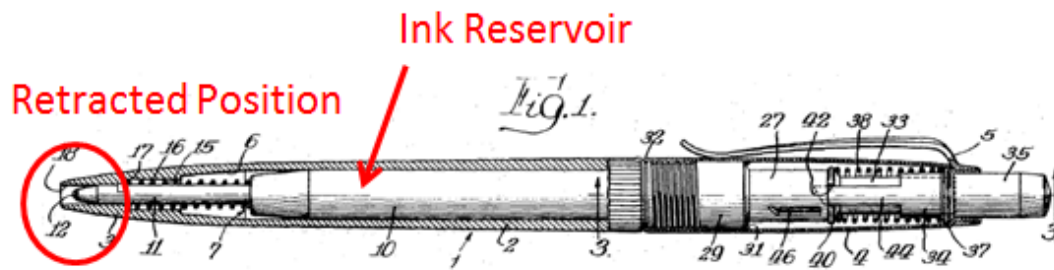
Ex. 1007 at Fig. 5 (annotated).

Rhoades

121. *Rhoades* (Ex. 1009) is a U.S. Patent that issued on September 14, 1965. I have been informed by counsel that *Rhoades* is prior art to the '631 Patent.

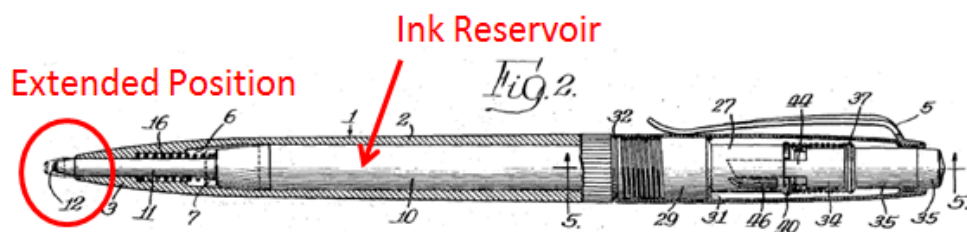
122. *Rhoades* discloses a ball point pen having a projecting and retracting mechanism that converts axial motion into rotational motion. Ex. 1009 at 1:9-12; 4:22-27. When a user pushes button 35, forwardly-directed teeth move a cam body and attached ink reservoir forward and, once the cam body has moved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

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

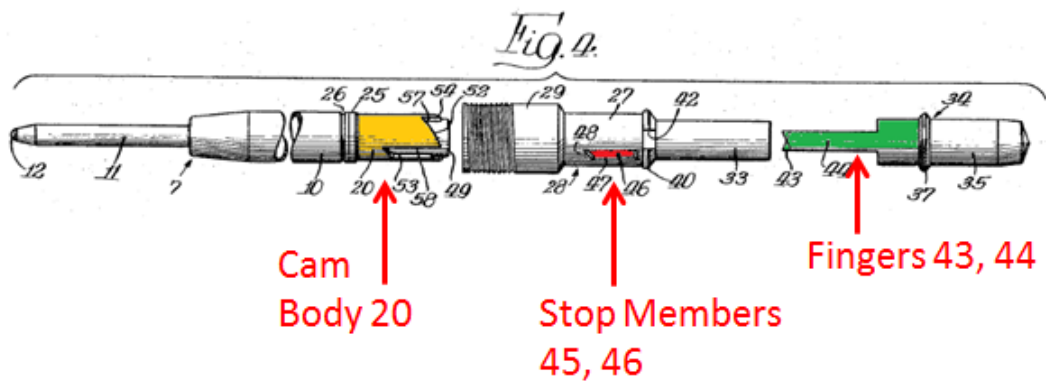


124. Figure 2 shows the pen in the extended position. See Ex. 1009 at Fig.

2 (annotated):

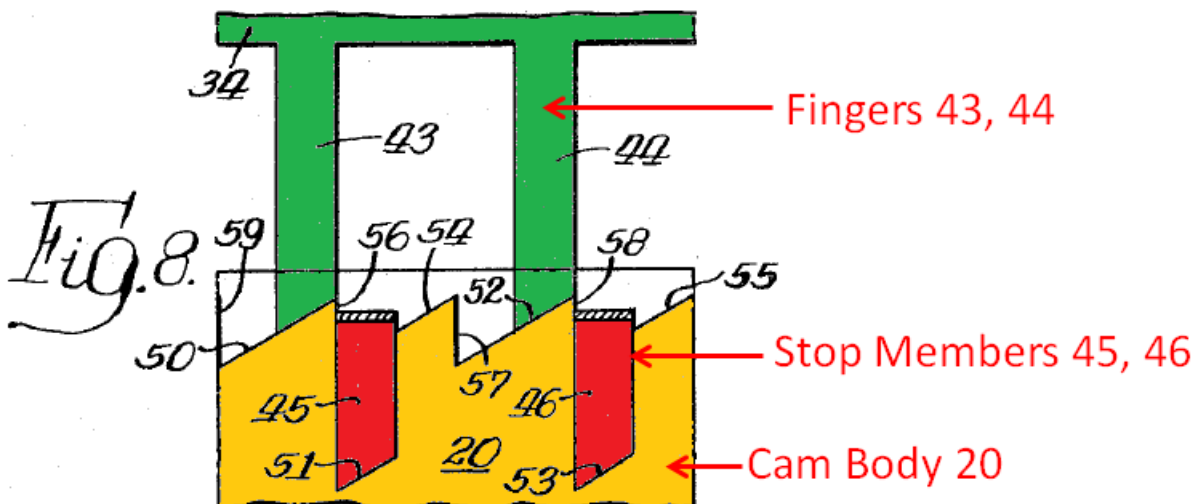


125. Specifically, *Rhoades* discloses an ink reservoir section 10 containing the fluid (ink) that will be dispensed from the ball point. Ex. 1009 at 3:36-38. The ink reservoir is connected directly to the cam body 20 (yellow, below), which is rotatably and slidably disposed within the stationary guide member 28. Ex. 1009 at 3:60-67. At the very end of the device is a 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). Ex. 1009 at 4:13-19.



Ex. 1009 at Fig. 4 (annotated).

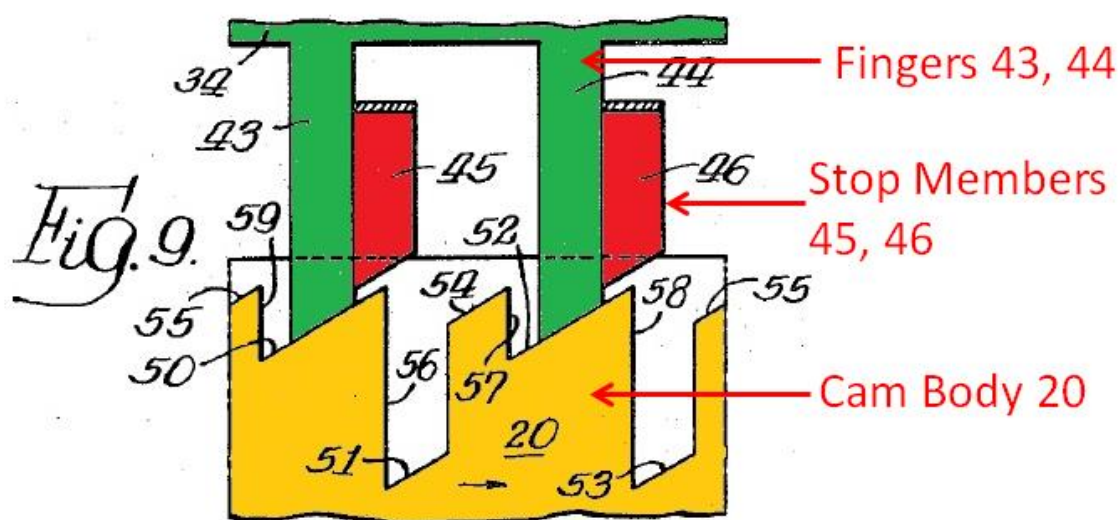
126. The cam body 20, fingers 43 and 44, and stop members 45 and 46 all have sloped faces that cooperate in causing the axial and rotational movement of cam body 20 under the force of spring 16. Ex. 1009 at 5:55-58.



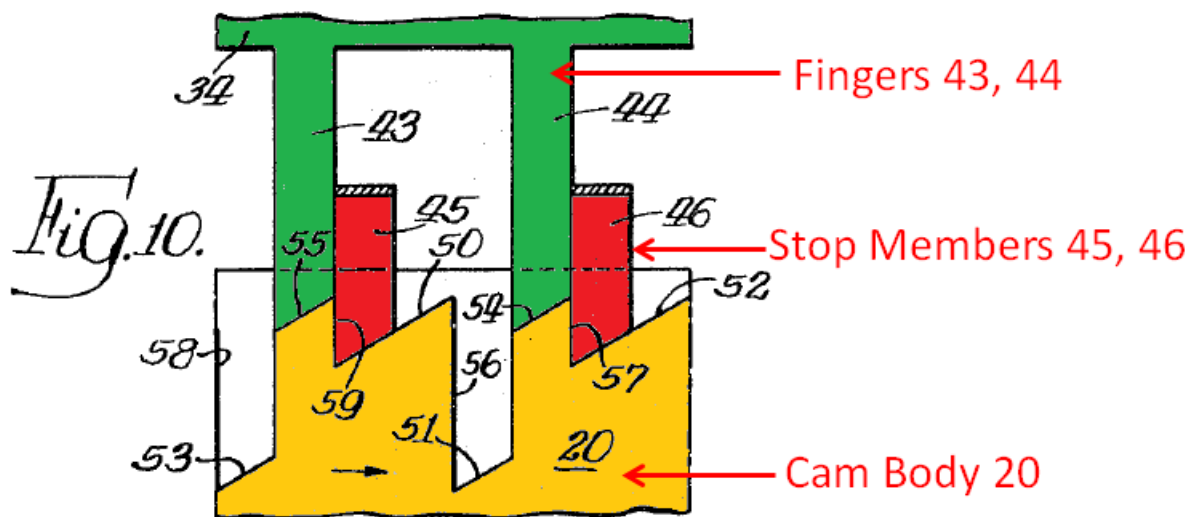
Ex. 1009 at Fig. 8 (annotated).

127. Figure 8 above shows the *Rhoades* mechanism when the device is 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

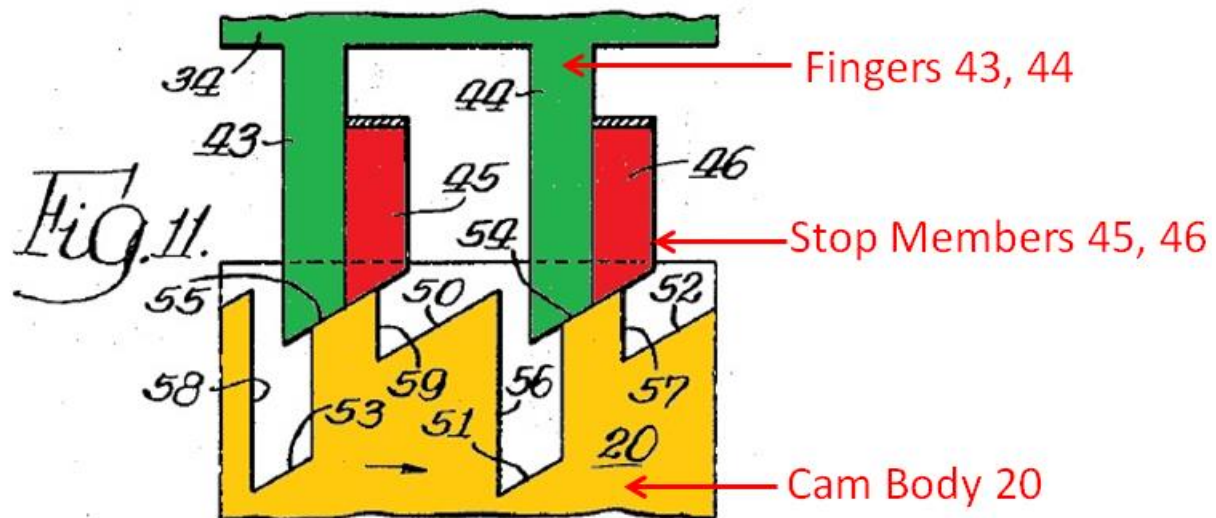
body faces 50 and 52. As fingers 43 and 44 are depressed by the plunger 34 and push button 35, they move cam body 20 axially downward. Despite the force exerted by the sloped faces of the fingers 43 and 44 and cam body 20, cam body 20 cannot rotate until it moves past stop members 45 and 46. Ex. 1009 at 5:47-50; *see* Ex. 1009 at Fig. 9 (annotated):



128. Once cam body 20 has moved axially a sufficient distance to clear the stop members 45 and 46, it begins to rotate. Ex. 1009 at 5:51-54; *see* Fig. 9, above. 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. Here, the pen is in its extended conformation. *See* Ex. 1009 at Fig. 10 (annotated):



129. 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. See Ex. 1009 at Fig. 11 (annotated):



130. 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. At that point, cam body 20 rotates until stop members 45 and 46 are aligned with deep grooves having bottoms 53 and 51. 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 *Rhoades* Figure 8.

Bason in combination with Rhoades

131. In *Bason*, the fluid reservoir is axially displaceable with respect to the inhaler body, but the stationary gear was on base 1 and was not unitary with the inhaler body. For the reasons below, a POSA would have been motivated 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*. In such a modification, the fluid reservoir would have moved axially with respect to the stationary body and gear. Each element of claims 1-4 is taught by *Bason* in view of *Rhoades*.

132. *Bason*, known before the '631 Patent's priority date, 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; ¶ 118. Such a configuration would have been useful to one designing a dose counter for use with a variety of different canisters and/or actuators. By 2001, a POSA would have known that the methods being used to

monitor the remaining doses in a metered dose inhaler were insufficient, there was a market force to improve and incorporate dose counters into commercial MDIs, and the FDA would almost certainly soon be addressing the issue. 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 metered dose inhalers. 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 metered dose inhalers did not include integrated dose counters. Ex. 1027 at 2-3, 6; Ex. 1028 at 3-5; 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 (same).

133. The FDA’s guidance not only provided the motivation to include a dose counter in an MDI with specific design features, the guidance expressly acknowledged the biggest design incentive facing a POSA (and, in fact, the entire industry) in doing so—“it is recognized that the economics of [incorporating dose counters into MDIs] may be burdensome.” Ex. 1012 at 6; Ex. 1013 at 6. In light

of the FDA's guidance from as early as 2001, a POSA not only would have been motivated to incorporate dose counters into MDIs that err on the side of avoiding undercounting by no later than May 15, 2003 (the '631 Patent's earliest priority date), but to do so in the most cost-effective and economical way since dose counters were to be standard in MDIs coming to market. These motivations would have specifically led a POSA to improve the counting mechanism of MDIs, which in many existing devices, involved converting axial movement of an actuator or canister into rotational movement of a number wheel showing the remaining doses. *See, e.g.*, Ex. 1014 at 4:31-5:5; Ex. 1011 at 4:9-13.

134. Accordingly, by the early 2000s, and certainly by 2003, the market would have forced a POSA to scale up production of a device like the *Bason* inhaler for manufacturing and use with a specific canister/actuator. A POSA, therefore, would have been motivated to improve *Bason* to increase speed and keep the cost of manufacture to a minimum, while producing consistently acceptable products and ensuring reliability of those products. Ex. 1007 at 3:66-4:3; Ex. 1022 at 1:43-45 (right column); Ex. 1029 at 3; Ex. 1030 at 3; Ex. 1047 at 89. It was well known in the art that manufacturing costs would generally have been lower, and reliability would have been greater if a device was comprised of as few separate components as possible. Ex. 1007 at 3:66-4:3; Ex. 1022 at 1:43-45 (right column); Ex. 1029 at 3; Ex. 1030 at 3. Decreasing the number of separate components

would have required fewer manufacturing and validation steps and would have resulted in fewer steps and components that could have failed. Ex. 1030 at 3. Both *Bason* and the '631 Patent recognized the economic motive behind design of such devices. Ex. 1007 at 3:66-4:3; Ex. 1001 at 2:9-11. Both *Bason* and the '631 Patent recognized the economic motive behind 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.

135. *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 ¶¶ 121-130, above. A POSA in 2003 would have been familiar with the *Rhoades* mechanism and would have looked to this type of art when seeking to improve *Bason* as above. In fact, sometime around 1998 but before 2001, in my role at Piper Medical, I was asked to look into building a dose indicator for an inhaler. It was, and still is, common engineering practice to examine related devices at the outset of a project. At the time that I was asked to look into building a dose counter for an MDI, I was aware that there were many similarities between an MDI having a dose counter and a mechanical pen. For example, both products converted an axial motion of one part

into a rotational motion of another part and contained a fluid reservoir that could be moved axially and rotationally. Furthermore, both devices had the design requirements that they be capable of being mass produced, be made primarily of plastic, be relatively inexpensive, and be portable. Therefore, upon being asked to look into building a dose counter, I took apart and examined a mechanical pen more closely to see how the mechanical components worked. I designed the dose indicator that I was asked to build by using the same type of mechanism that was disclosed inside the mechanical pen.

136. In addition to my reliance on a mechanical pen when designing a dose indicator, there are numerous examples of POSAs who relied on their knowledge of simple, plastic, mechanical devices, such as mechanical pens, when designing medical devices. For example, U.S. Patent No. 5,243,970 (“the ’970 Patent”) (Ex. 1031), is directed to a metered dose inhaler for powdered medicaments. The ’970 Patent describes in its background section a prior art MDI having a dose measuring rotatable rod. Ex. 1031 at 2:36-47. The ’970 Patent further explains that the rotatable rod is rotated by an indexing mechanism “much like that of a ball-point pen.” Ex. 1031 at 2:45-47. As another example, U.S. Patent No. 7,090,662 (“the ’662 Patent”) (Ex. 1032) describes a different type of mechanically-operated medical device, namely, a pen-type injector, and describes in its background section a prior art injector “based on the ball point pen principle.” Ex. 1032 at

1:40-48. The prior art device incorporates the ball point pen principle by incorporating a mechanism wherein “movement of the button causes a longitudinally movable tubular piston rod to engage with and move a longitudinally displaceable syringe piston located in the cartridge.” Ex. 1032 at 1:43-46. International Publication WO 2007/045904 (“the WO ‘904 Publication”), which relates specifically to a more recent design for an MDI with a dose counter, describes a drive wheel which cooperates with gears in the MDI to rotate an indicator disc (upon depression of a cap) to indicate doses dispensed or remaining. Ex. 1033 at 12:29-13:2. The WO ‘904 Publication explains that the “arrangement of protrusions [] on the drive wheel [] is similar, and operates in a similar way, to the retraction mechanism in a ball point pen.” Ex. 1033 at 15:10-25. Furthermore, U.S. Patent No. 9,439,648 (“the ‘648 Patent”) describes a suturing device with a “sheath retraction and extension mechanism [] similar to that used in retractable tip ball point pens.” Ex. 1034 at Abstract. The ‘648 Patent actually refers specifically to the mechanism in *Rhoades* as an exemplary mechanism for its sheath retraction and extension mechanism. Ex. 1034 at 3:25-39. These publications provide evidence of what I understand was common knowledge to POSAs, which is that it has been (and remains) common practice for POSAs to incorporate mechanical components from simple, mechanical devices, like a ball point pen, when designing medical devices, including MDIs. POSAs

have regularly looked to simple, mechanical devices, like a ball point pen, for structural mechanisms to achieve desired mechanical functions when designing medical devices.

137. 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 metered dose inhalers—market forces would have motivated a POSA to modify *Bason* by slightly extending *Bason*'s inhaler body (just as *Rhoades* shows guide member 28 extending beyond the reservoir), and integrating the stationary gear (tooth 2) of the *Bason* mechanism into the inhaler body, just as the stationary gears (stop members) of *Rhoades* are integrated directly on the *Rhoades* body. Such a modification was a simple variation known in the prior art and would have allowed one to injection mold the actuator with the stationary gear already included, decreasing the number of parts that would have had to have been assembled and tested. By 2003, injection molding had long been used to manufacture mechanical devices. Ex. 1047. The rest of the components could have been connected in the same way they are connected in *Bason*, or other ways well understood in the art. Indeed, these are the types of connections the patentee stressed were 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, as explained in the preceding paragraphs, a POSA would have

been motivated to make the above modification, would have had a reasonable expectation of success, and would have considered the modification predictable because the manufacturability and connectivity of the components would have been well understood by a POSA.

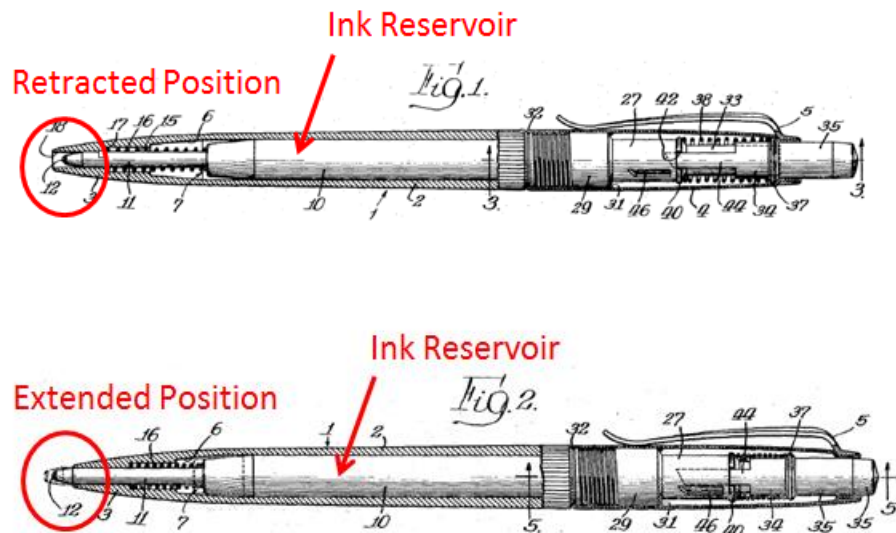
138. A POSA would further have had a reasonable expectation of success because, in such a modification all of the components would have retained their same functions—depressing the cap of *Bason* would depress rings 4 and 8; teeth 7 of ring 4 would interact with stationary teeth 2 (now formed directly on the device housing) and rotate ring 4 to change the dose value the same way they do in *Bason*. And the cap would similarly depress the canister to cause a dose to be dispensed. 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* Ex. 1001 at 1:24-59, 1:66-2:3, 2:9-11; Ex. 1022 at 1:43-45 (right column); Ex. 1029 at 3; Ex. 1030 at 3. The need to address these problems was particularly acute in the early 2000s in light of impending and ultimately issued regulatory guidance causing manufacturers to increase use of dose counters in metered dose inhalers. By May 2003, a POSA would have used well-known methods like injection molding to manufacture such a device. Ex. 1047.

1. Claim 1

a. “A fluid dispenser”

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

140. *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. Ex. 1009 at 11:60-63.



Ex. 1009 at Figs. 1-2 (annotated).

b. “a plurality of displayable dose values”

141. *Bason* discloses rotational rings 4 and 8, which have upper faces 24 and 25, respectively. “These faces carry respectively two numeric series such that

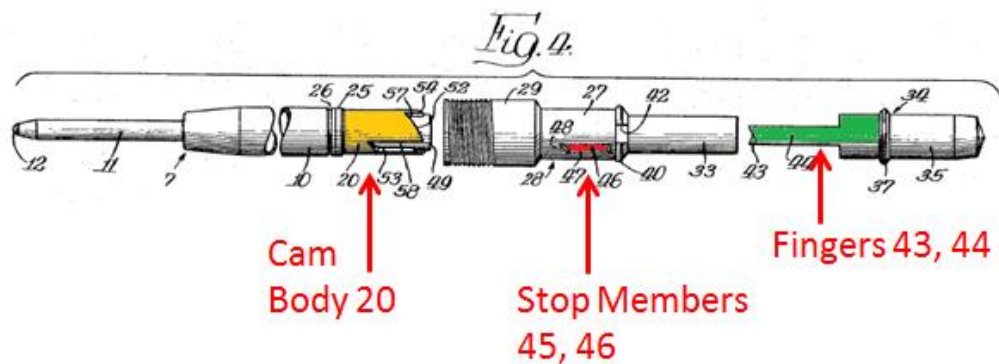
face 24 carries the series 0 to 9 while face 25 carries the series 00 to 20. Thus, through the window 13 there may be visible progressively the numbers 000 to 200. . . . As the MDI is progressively used the available doses will count down eventually to zero” Ex. 1007 at 3:1-10.

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

142. As described in ¶ 29, the claimed stationary body must be unitary and monolithic with at least one stationary multi-toothed gear. As described in ¶ 29, *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. “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” Ex. 1009 at 8:7-9. The stop members 43 and 44 are teeth on the stationary gear of guide member 28. Accordingly, guide member 28 is a stationary body with at least one stationary multi-toothed gear.

d. “a first member that is displaceable axially relative to said stationary body”

143. *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.” Ex. 1009 at 5:39-43. See Ex. 1009 at Fig. 4 (annotated):



144. *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. In light of *Rhoades* and its integrated stop members, a POSA would have incorporated *Bason*’s teeth 2 directly on the inhaler body, and the inhaler body would be the claimed stationary body. In such a configuration, the cap 14 would move axially relative to the stationary body.

e. “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”

145. As explained above in ¶¶ 121-130, *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.” Ex. 1009 at 3:66-68. Cam body 20 can engage with stop members 45 and 46. *See, e.g.*, Ex. 1009 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.” Ex. 1009 at 4:22-28. *See also* ¶¶ 121-130.

146. *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 (base 1 in *Bason*, which, in the above described combination is incorporated into the inhaler body) and rotational ring 4 begins to rotate.

- f. **“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**

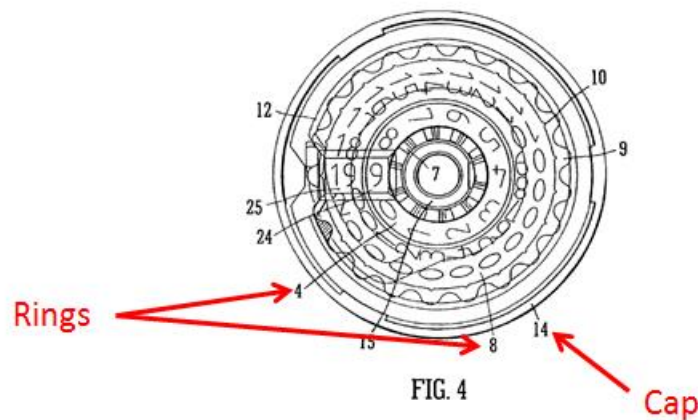
said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values”

147. The cooperation of the first and second members resulting in axial and rotational movement of the cam body 20 in *Rhoades* is described in ¶¶ 126-130. “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.

148. 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 ¶¶ 117-120, 144, 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. *Bason* discloses rings that carry with them numeric series—“[a]s the MDI is progressively used the available doses will count down eventually to zero,” which a POSA would have included on cam body 20. Ex. 1007 at 3:1-10.

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

149. *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). 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 ¶¶144, 146.



Ex. 1007 at Fig. 4 (annotated).

150. 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. Incorporating teeth 2 directly in the *Bason* inhaler body would not alter the common axis.

2. Claim 2

- a. **“The fluid dispenser according to claim 1, wherein the second member comprises at least one multi-toothed gear.”**

151. *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.

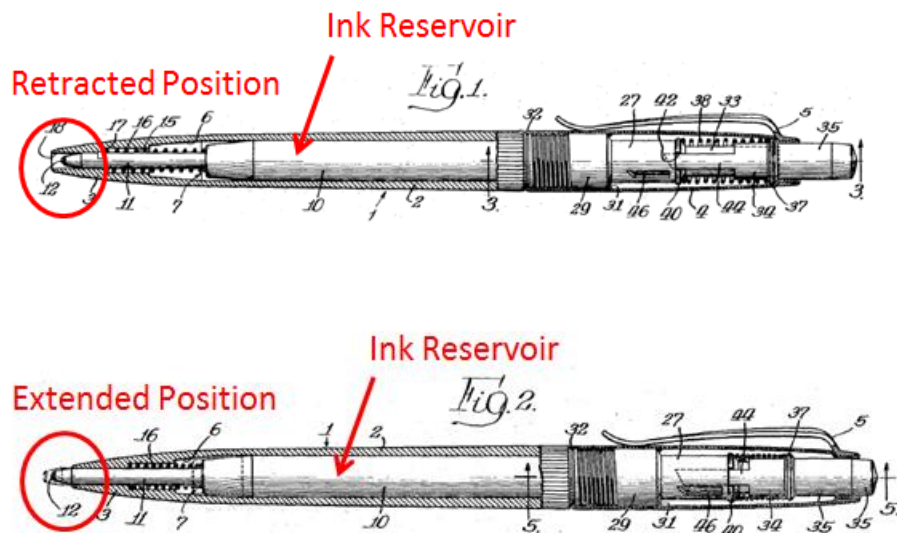
152. *Rhoades* teaches a cam body “with a plurality of cam surfaces 50, 52, 54, 55 diametrically opposite pairs of which are successively engageable by the fingers 43 and 44 to impart unidirectional rotational movement” to the cam body. Ex. 1009 at 4:23-26.

3. Claim 3

- a. **“A fluid dispenser”**

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

154. *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. Ex. 1009 at 11:60-63.



Ex. 1009 at Figs. 1-2 (annotated).

b. “a plurality of displayable dose values”

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

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

156. As described in ¶ 29, the claimed stationary body must be unitary and monolithic with at least one stationary multi-toothed gear. As described in ¶ 299, *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. “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” Ex. 1009 at 8:7-9. The stop members 43 and 44 are teeth on the stationary gear of guide member 28. Accordingly, guide member 28 is a stationary body with at least one stationary multi-toothed gear.

d. “a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”

157. *Bason* teaches the use of a pressurized canister for use with a metered dose inhaler. 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.

158. *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. Ex. 1009 at 3:49-52.

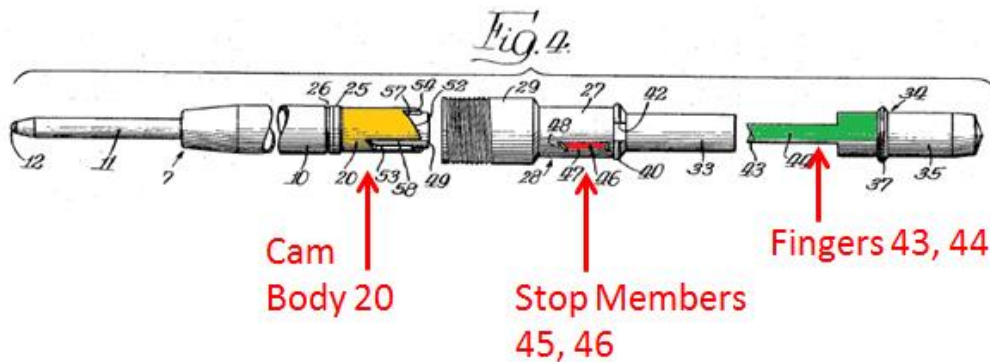
The cam body is located within stationary body guide member 28 (which contains stationary stop members 45 and 46), and is moved axially by fingers 43 and 44 of plunger 34. Ex. 1009 at 4:13-19, 5:13-19, 5:39-43, 5:51-58. When the cam body 20 displaces axially, the connected ink reservoir section also displaces axially. Ex. 1009 at 5:39-43. Accordingly, the fluid reservoir (ink reservoir section) moves axially relative to the stationary body (guide member 28). Cam body 20 and the directly connected ink reservoir also interact directly with stop members 45 and 46. Ex. 1009 at 4:29-33, 5:51-58. Accordingly, the *Rhoades* ink reservoir is disposed on the guide member 28 through interactions between its directly connected cam body 20 and the stop members formed integrally on guide member 28.

159. As described in ¶¶ 131-138, in view of *Rhoades*, which teaches 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. In such a device, the inhaler body would be the claimed stationary body with at least one stationary multi-toothed gear. The canister, moving axially relative to the inhaler body, as it always does, would therefore move axially relative to that stationary body. 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.

e. **“a first member that is displaceable axially relative to said stationary body”**

160. *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.” Ex. 1009 at 5:39-43. See Ex. 1009 at Fig. 4 (annotated):



161. *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. In light of *Rhoades*, one would have incorporated *Bason*’s teeth 2 directly on the inhaler body, and the inhaler body would be the claimed stationary body. In such a configuration, the cap 14 would move axially relative to the stationary body.

- 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”**

162. As explained above in ¶¶ 121-130, *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.” Ex. 1009 at 3:66-68. Cam body 20 can engage with stop members 45 and 46. *See, e.g.*, Ex. 1009 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.” Ex. 1009 at 4:22-28. *See also* ¶ 145.

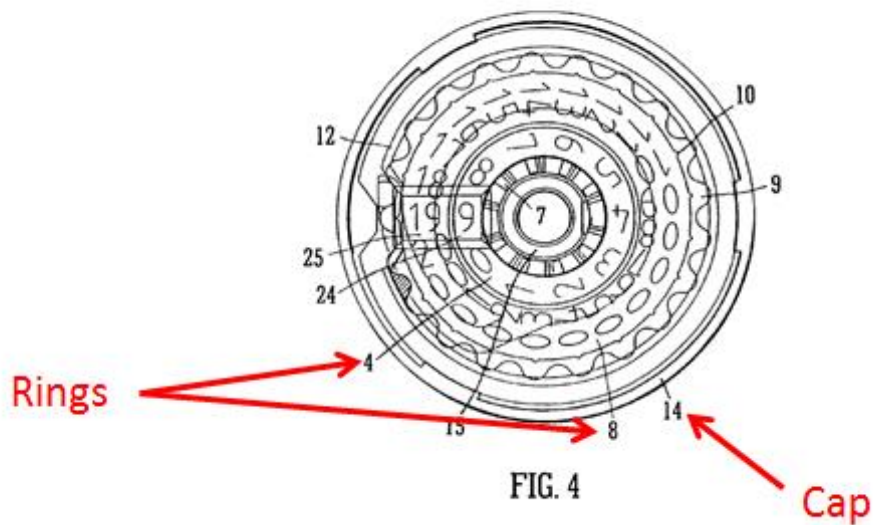
163. *Bason* teaches rotational ring 4 (second member) that is moved axially by direct contact with the cap 14 (first member). Upon sufficient axial depression, teeth 7 of rotational ring 4 contact teeth 2 of the stationary body (base 1 in *Bason*, which, in the above described combination is incorporated into the inhaler body) and rotational ring 4 begins to rotate.

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

164. This limitation is identical to a limitation of claim 1 except that this limitation 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 with respect to claim 1. *See* ¶¶ 147-148.

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

165. *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). 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* ¶¶ 161, 163.



Ex. 1007 at Fig. 4 (annotated).

166. 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. Incorporating teeth 2 directly in the *Bason* inhaler body would not alter the common axis.

4. Claim 4

- a. **“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.”**

167. *Bason* discloses that the pressurized canister is moved axially relative to the inhaler body A when the canister is depressed by the user. Ex. 1007 at Abstract, Fig. 1. It is that axial depression that causes the dispenser to actuate.

168. *Rhoades* discloses that the stop members (stationary gear teeth) could have been 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 ¶¶ 131-138. 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.

D. Ground 4: Claims 1-4 of the '631 Patent are Obvious over Bason (Ex. 1007) in view of Allsop (Ex. 1006)

169. 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*. Moreover, a POSA would have had a reasonable expectation of success and the modification would have been predictable because the manufacturability and connectivity of components of MDIs with a dose counter were well understood by a POSA. In such a modification, the fluid reservoir would have moved axially with respect to the stationary body and would have addressed the same element raised by the patentee during prosecution, as explained above in ¶ 29. Each element of claims 1-4 is taught by *Bason* in view of *Allsop*.

170. A POSA would have been motivated to improve *Bason* because of the same market forces and for the same reasons described in ¶¶ 131-138.

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

172. To improve the *Bason* device as described in ¶¶ 1178-120, 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. *See also* Ex. 1006 at 7:8-10, Figs. 3, 4.³

³ 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. For example, fixing the *Bason* dose counter in place below the canister allows the fluid reservoir to move relative to a stationary body with an

173. A POSA 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 have been. Ex. 1030 at 3. Here, *Bason* teaches a dose counter located in the cap. 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. This requires coordination between a spring in the dose counter and a spring in the valve of the canister. A POSA would have been motivated to improve *Bason* by moving the counter below the canister, as in *Allsop*, where the entire axial force would have been directed at moving the canister, requiring coordination of *only* the spring in the valve, and where the displacement of the canister would have caused the dose counter to actuate.

174. Furthermore, the base 1 with stationary gear teeth 2 would have been molded directly into the wall of the *Bason* inhaler, as taught in *Allsop*, decreasing costs even further. Ex. 1029 at 3; Ex. 1030 at 3. This modification would not have required any extension of the inhaler body; the counting device would have been

integral gear, negating the patentee's arguments traversing the anticipation rejection during prosecution. *See* Ex. 1005 at 70-71, 85-86.

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

175. A POSA would further have had a reasonable expectation of success because, in such a modification, all of the components would have retained their same functions—depressing the canister of *Bason* would depress the cap that 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*. The valve would extend through the counting mechanism just as it does in *Allsop*. The resulting inhaler would have been predictable, 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 Ex. 1001 at 1:24-59, 1:66-2:3, 2:9-11; Ex. 1022 at 1:43-45 (right column); Ex. 1029 at 3; Ex. 1030 at 3. Indeed, this modification is a simple variation known in the prior art and 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, would have had a reasonable expectation success, and would have considered the

modification predictable because the manufacturability and connectivity of such components would have been well understood by a POSA.

176. The need to address these problems was particularly acute in the early 2000s in light of impending and ultimately issued regulatory guidance causing manufacturers to increase use of dose counters in metered dose inhalers. By May 2003, a POSA would have used well-known methods like injection molding to manufacture such a device. Ex. 1047.

1. Claim 1

a. “A fluid dispenser”

177. To the extent the preamble is deemed limiting, both *Bason* and *Allsop* discloses a fluid dispenser. See ¶ 139 (*Bason*); ¶ 60 (*Allsop*).

b. “a plurality of displayable dose values”

178. Both *Bason* and *Allsop* disclose a plurality of displayable dose values for the reasons above. See ¶ 141 (*Bason*); ¶ 61 (*Allsop*).

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

179. *Bason* discloses an inhaler body and a dose counter with a stationary component base 1, which contains stationary teeth 2. ¶ 142 (*Bason*). *Allsop* discloses “a stationary body comprising at least one stationary multi-toothed gear” for the reasons above. See ¶ 62 (*Allsop*).

180. For the reasons in ¶¶ 169-176 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. *Allsop* expressly discloses this as an alternate conformation. Ex. 1006 at 7:8-10. Alternatively, a POSA 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*.⁴

d. “a first member that is displaceable axially relative to said stationary body”

181. Both *Bason* and *Allsop* disclose “a first member that is displaceable axially relative to said stationary body” for the reasons above. ¶ 144 (*Bason*); ¶¶ 62-63 (*Allsop*).

⁴ 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. This is a configuration the applicant cited numerous times as present in the prior art during prosecution. See Ex. 1004 at 1190-1205 (referring to Attachment A); see, e.g., Ex. 1037; Ex. 1038; Ex. 1039; Ex. 1040.

- e. **“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”**

182. 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 ¶ 146 (*Bason*); ¶¶ 64-66 (*Allsop*).

- f. **“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”**

183. Both *Bason* and *Allsop* disclose the fluid reservoir/displacement limitation for the reasons above. See ¶ 148 (*Bason*); ¶¶ 678-70 (*Allsop*).

184. For the reasons described in ¶¶ 169-176, a POSA would have been motivated to move, and easily could have moved, 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*. The resulting device would include a fluid reservoir that moves axially relative to the stationary body.

- g. **“wherein the stationary body, the first member, and the second member are arranged to have a common**

central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis”

185. Both *Bason* and *Allsop* disclose the common central axis limitation for the reasons above. See ¶ 1499 (*Bason*); ¶¶ 71-72 (*Allsop*).

186. 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 ¶¶ 1699-1766. Either modification would retain the shared axis of the stationary body and stationary gear as shown in both *Bason* and *Allsop*.

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

187. 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 ¶ 151 (*Bason*); ¶ 72 (*Allsop*).

3. Claim 3

a. “A fluid dispenser”

188. To the extent the preamble is deemed limiting, both *Bason* and *Allsop* discloses a fluid dispenser. See ¶ 153 (*Bason*); ¶ 73 (*Allsop*).

b. “a plurality of displayable dose values”

189. Both *Bason* and *Allsop* disclose a plurality of displayable dose values for the reasons above. See ¶ 155 (*Bason*); ¶ 74 (*Allsop*).

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

190. *Bason* discloses an inhaler body and a dose counter with a stationary component base 1, which contains stationary teeth 2. See ¶ 156 (*Bason*). *Allsop* discloses “a stationary body comprising at least one stationary multi-toothed gear” for the reasons above. See ¶ 75 (*Allsop*).

191. For the reasons in ¶¶ 1699-1766 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. *Allsop* expressly discloses this as an alternate conformation. Ex. 1006 at 7:8-10. Alternatively, a POSA 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

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

d. “a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body”

192. 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. See ¶ 157 (*Bason*).

193. *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 ¶ 76 (*Allsop*).

194. As described in ¶¶ 169-176, 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.

e. “a first member that is displaceable axially relative to said stationary body”

195. Both *Bason* and *Allsop* disclose “a first member that is displaceable axially relative to said stationary body” for the reasons above. See ¶ 161 (*Bason*); ¶¶ 77-789 (*Allsop*).

canister—a configuration the applicant cited numerous times as present in the prior 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. “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”**

196. 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 ¶ 163 (*Bason*); ¶¶ 80-82 (*Allsop*).

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

197. Both *Bason* and *Allsop* disclose the displacement limitation for the reasons above. See ¶ 164 (*Bason*); ¶ 82 (*Allsop*).

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

198. Both *Bason* and *Allsop* disclose the common central axis limitation for the reasons above. See ¶ 165 (*Bason*); ¶¶ 83-845 (*Allsop*).

199. 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 ¶¶ 1699-1766. Either modification would have

retained the shared axis of the stationary body and stationary gear as shown in both *Bason* and *Allsop*.

4. Claim 4

- a. **“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.”**

200. *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* ¶ 85 (*Allsop*).

201. 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* ¶¶ 169-176. 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.

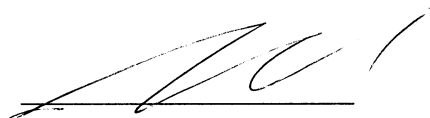
VIII. CONCLUSION

202. For the foregoing reasons, a POSA would have concluded that each of claims 1-4 of the '631 Patent would have been (1) anticipated by *Allsop*, (2) anticipated by *Marelli*, (3) obvious over *Bason* in view of *Rhoades*, and (4) obvious over *Bason* in view of *Allsop*.

IX. SIGNATURE

203. I hereby declare that all statements made in this Declaration of my own personal knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine, imprisonment, or both, under Section 1001 of Title 18 of the U.S. Code.

Dated: MAY 9, 2018

A handwritten signature in dark ink, consisting of stylized, overlapping loops and strokes, positioned above a horizontal line.

S. David Piper