UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

Petitioners

v.

AptarFrance S.A.S.,

Patent Owner

Patent No. 8,936,177
Filing Date: November 9, 2005
Issue Date: January 20, 2015

Title: FLUID PRODUCT DISPENSER

Case No. To Be Assigned

PETITION FOR *INTER PARTES* REVIEW

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EXHIBITS

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1016	A.R. Clark, *Medical Aerosol Inhalers: Past, Present, and Future*, 22 AEROSOL SCI. & TECH., 374 (1995)
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1024	RESERVED
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1027	Andrew G. Weinstein, *When Should Your Asthmatic Patients Refill Their MDI Propelled with Chlorofluorocarbons?*, 70 DEL. MED. J., 293 (1998)
1028	Tina Penick Brock et al., *Accuracy of Float Testing for Metered-Dose Inhaler Canisters*, 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
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1040	Lewis, *Metered-dose inhalers: actuators old and new*, 4(3) EXPERT OPIN. DRUG. DELIV. 235 (May 2007)
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1042	Excerpts from Federal Register Vol. 66
1043	Excerpts from Federal Register Vol. 68
1044	W. Travis Cain & John J. Oppenheimer, *The misconception of using floating patterns as an accurate means of measuring the contents of metered-dose inhaler devices*, 87 ANNALS OF ALLERGY, ASTHMA, & IMMUNOLOGY, 417 (2001)
1045	RESERVED
1046	Excerpt of Douglas M. Bryce, Plastic Injection Molding, Vol. 1 (1996)
1047	R. K. Schultz, *Drug delivery characteristics of metered-dose inhalers*, 96 J. ALLERGY CLIN. IMMUNOL. 284 (1995)
1048	D. B. Price *et al.*, *Historical cohort study examining comparative effectiveness of albuterol inhalers with and without integrated dose counter for patients with asthma or chronic obstructive pulmonary disease*, 9 J. ASTHMA & ALLERGY 145 (2016)

I. INTRODUCTION

Petitioners 3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp. ("Petitioners") request *inter partes* review ("IPR") of claims 1, 2, 3, 9 and 21 (the "Challenged Claims") of U.S. Patent No. 8,936,177 (the "'177 patent") (Ex. 1001), pursuant to 35 U.S.C. §§311-319 and 37 C.F.R. §42.100 *et seq*.

The '177 patent is directed to a fluid dispenser including a dose indicator device. Ex. 1001 at 1:3-5. Dose indicator devices—sometimes referred to as dose counters—keep track of the number of doses dispensed from a fluid dispenser. *Id*. at 1:8-14; Ex. 1002 ¶23. One purported feature of the '177 patent's dose indicator is the ability to prevent undercounting of the number of doses dispensed so a user does not believe there are doses left in an empty device—a dangerous situation for patients with conditions like asthma. The dose indicator of the '177 patent purportedly prevents undercounting by: (1) counting a dose so long as the user has actuated the device a sufficient amount; and/or by (2) preventing release of a second dose of fluid until the counter has reset. Ex. 1004 at 1279:9-1280:19; Ex. 1001 at 1:66-2:12. As described below, the '177 patent claims recite features purportedly related to the prevention of undercounting, such as an incomplete actuation stroke and an incomplete return stroke. Ex. 1001 at 5:24-45; 9:28-55.

The '177 patent added nothing to what was already known in the art. "[F]luid dispensers having counting mechanisms [were] well known" by the '177

patent's priority date, a fact admitted by the patentee. Ex. 1004 at 1281:19-1282:4. As explained in Grounds 1 and 2 in this petition and its supporting documents, the Challenged Claims reflect nothing more than simple and predictable modifications to well-known metered dose inhalers ("MDIs"), including the inhalation devices disclosed in *Elliott* (Ex. 1006) and *Bason* (Ex. 1005).

The motivation to make such modifications was clear. By the early 2000s, the industry recognized that existing methods of monitoring medication in an MDI were insufficient. Ex. 1002 ¶24; Ex. 1027 at 5-6; Ex. at 1028 at 7; Ex. 1040 at 6; Ex. 1044 at 3. The U.S. Food and Drug Administration ("FDA") agreed, issuing draft guidance in 2001 and final guidance in 2003 recommending that manufacturers "integrate a dose-counting device into the development of their MDI drug product." Ex. 1002 ¶24; Ex. 1012 at 4-6; Ex. 1013 at 4-7; Ex. 1042 at 7-8; Ex. 1043 at 8; *see also* Ex. 1040 at 6; Ex. 1041 at 13. The draft and final guidance went a step further advising that, if 100% accuracy is not possible, the MDI "should be designed to specifically avoid under-counting." Ex. 1012 at 6; Ex. 1013 at 6. The FDA's guidance not only provided the motivation to include a dose counter with specific design features in an MDI, the guidance expressly acknowledged the biggest design incentive facing a person of ordinary skill in the art ("POSA") (and, in fact, the entire industry)—"it is recognized that the

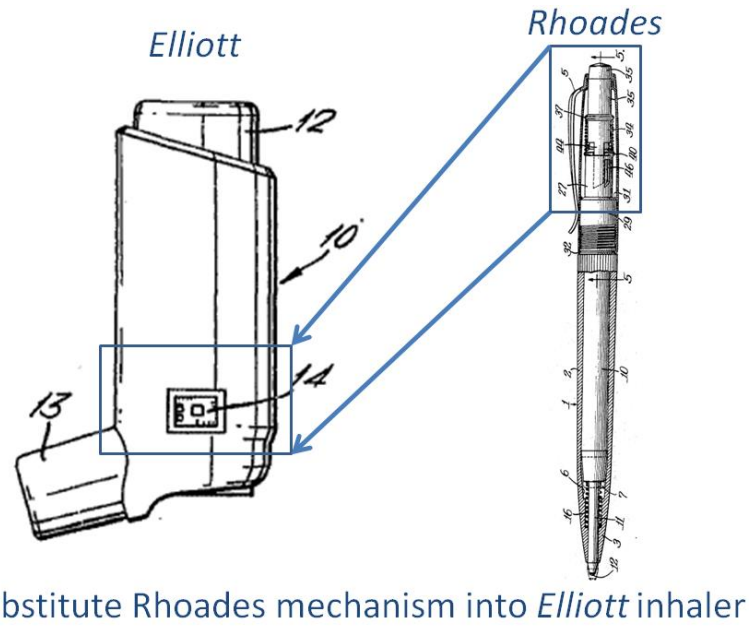
economics of [incorporating dose counters into MDIs] may be burdensome." Ex. 1012 at 6; Ex. 1013 at 6.

In light of the FDA's guidance from as early as 2001, a POSA would have understood that it would be advantageous to incorporate dose counters that err on the side of avoiding undercounting into MDIs by no later than May 15, 2003 (the '177 patent's earliest priority date), and to do so in the most cost-effective and economical way since dose counters were to be standard in MDIs coming to market. Ex. 1002 ¶¶24, 72, 135. Accordingly, a POSA would have been motivated to improve the counting mechanism of prior art MDIs that involved converting the axial movement of an actuator or canister into rotational movement of a number wheel showing the remaining doses, while keeping in mind that they would soon need to be mass produced. *See* Ex. 1010 at 4:31-5:5; Ex. 1011 at 4:9-13.

Mechanisms capable of converting axial motion into rotational motion were, of course, known prior to 2003 and had been utilized in many simple mechanical devices suitable for large-scale production. One such mechanism existed in a mass-produced pen. *Rhoades* (Ex. 1007), which was not considered by the Patent Office, discloses an inexpensive, small, easily-manufactured mechanical pen with a mechanism to convert axial movement into rotational movement. Ex. 1002 ¶25; *see generally* Ex. 1007. A POSA would have been motivated to look to analogous

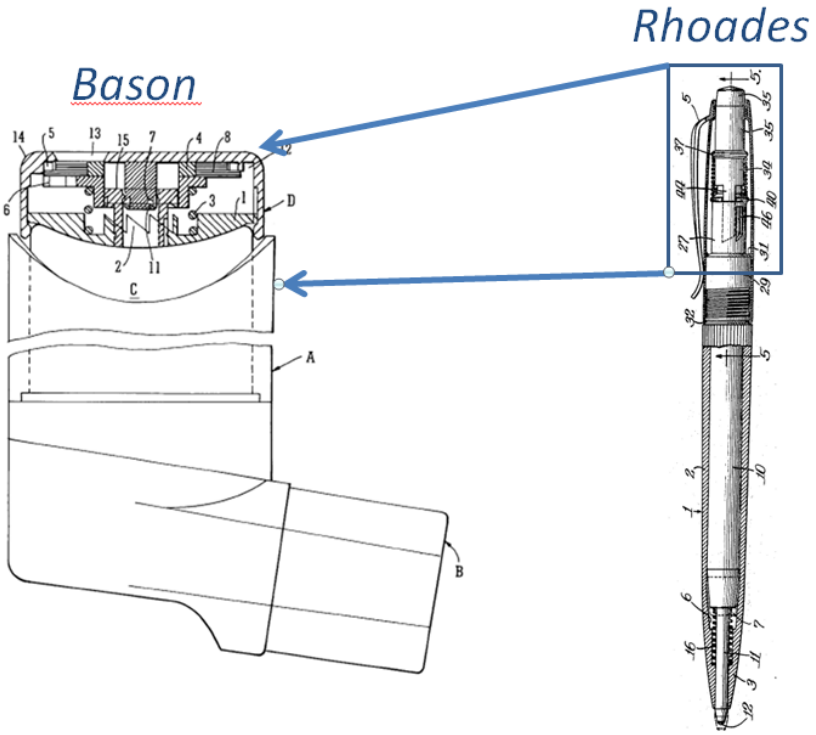
art (*e.g.*, mechanical pen art like *Rhoades*) that contained those desired features rather than designing a mechanism from scratch. Ex. 1002 ¶25. This is consistent with the experience of Petitioner's expert who, when faced with the very problem of designing and building a dose indicator prior to 2001, drew from the mechanism in a simple, plastic, inexpensive mechanical pen. *Id*. ¶¶17, 74. And others working on the design and development of counting mechanisms for use in medical devices, including MDIs, looked to simple pen technology. *Id*. ¶¶75, 137; Ex. 1031 at 2:36-47; Ex. 1032 at 1:40-48; Ex. 1033 at 15:10-25; Ex. 1034 at [56], Abstract, 3:29-39.

Accordingly, as described in Ground 1 and depicted below, a POSA would have been motivated to modify the MDI disclosed in *Elliott*—a publication from the 1970s—in light of the mechanism in *Rhoades*. Specifically, a POSA would have been motivated to make the simple and predictable substitution of the *Rhoades* mechanism for the *Elliott* counter in the *Elliott* inhaler to create an inhaler that was less expensive to manufacture, more reliable, and would incorporate the stop members of *Rhoades*, helping to avoid undercounting. Ex. 1002 ¶25.



Ex. 1006 at Fig. 3b (annotated); Ex. 1007 at Fig. 2 (annotated).

Similarly, Ground 2 explains why and how one would have made a simple and predictable modification to *Bason*, which discloses a top-mounted dose counter for use with an MDI. Ex. 1002 ¶26. A POSA would have been motivated to improve *Bason* for the same reasons he or she would have been motivated to improve *Elliott*. Substituting the *Rhoades* mechanism for the *Bason* counter, as depicted below, would result in a device that could be manufactured more cheaply and easily and would incorporate the stop members of *Rhoades*, helping to avoid undercounting. *Id*.



Ex. 1005 at Fig. 1 (annotated); Ex. 1007 at Fig. 2 (annotated).

Petitioners respectfully request institution of IPR of the Challenged Claims on Grounds 1-2.

II. MANDATORY NOTICES, STANDING, AND FEES

A. Real Party-In-Interest

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

B. Related Matters

Petitioners also filed a petition for IPR of U.S. Patent No. 9,370,631 (the "'631 patent"), purportedly owned by Aptar France S.A.S. The '177 and '631 patents were asserted against Petitioners in a patent infringement litigation

captioned *AptarGroup, Inc. et. al. v. 3M Company et al.*, No. 1:17-cv-06294-VMK (N.D. Ill. filed Aug. 30, 2017) (the "Litigation"), which is currently pending in the United States District Court for the Northern District of Illinois.

C. Lead and Backup Counsel

Petitioners provide the following designations of counsel:

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D. Service Information

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AG-3M-APTARIPR@akingump.com.

E. Certification of Grounds for Standing

Petitioners certify that the '177 patent is available for IPR, and Petitioners are not barred or estopped from requesting IPR on the asserted grounds. Specifically, Petitioners state that: (1) Petitioners are not owners of the '177 patent; (2) Petitioners have not filed a civil action challenging the validity of any claim of the '177 patent; and (3) Petitioners were served with the complaint in the Litigation on September 8, 2017, and an amended complaint on September 27, 2017.

F. Fees

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

III. OVERVIEW OF THE '177 PATENT

A. Summary of Challenged Claims

The '177 patent relates to a fluid dispenser containing a dose indicator. Ex. 1001 at 1:3-5. Claim 1, the only independent claim challenged, recites a stationary body having at least one stationary gear, an axially displaceable fluid reservoir with a dispenser member, a dose indicator device including a counter element that is displaceable axially and in rotation, and which cooperates with a stationary gear and the reservoir, so that the counter is actuated after a predetermined incomplete actuation stroke. *Id*. at 9:28-45.

Claims 2, 3, 9, and 21 are dependent claims. Claim 2 adds the requirement that during the return stroke a dose cannot be dispensed again until the counter has reset. Claim 3 adds an actuator member with an actuator gear, and defines the cooperation of gears on the counter element. Claim 9 depends from claim 3 and requires that, once the incomplete return stroke has been performed, the actuator member is positioned facing the next tooth to count again. Finally, claim 21 recites

the dispenser of claim 1 where the dispenser member is a pump or valve. *Id.* at 9:46-10:2, 10:39-44, 12:23-24.

B. Prosecution History of the '177 Patent

The '177 patent claims priority to FR 03 05858, filed on May 15, 2003. On November 9, 2005, the patentee filed the national stage entry, U.S. Application No. 10/556,432, which ultimately issued as the '177 patent having a priority date no earlier than May 15, 2003. *See* Ex. 1001 at [30].

In response to repeated rejections under 35 U.S.C. §112 (Ex. 1004 at 210-215, 1103-1111), the patentee explained "[this] technology is considered to be of the predicable arts," and "fluid dispensers having counting mechanisms [were] well known." Ex. 1004 at 1281:19-1282:4; *see also id.* at 255, 281, 1137-1139, 1149-1150, 1158-1166, 1229-1233; 1281:19-20, 1282:1-4, 1292:13-15. The named inventor of the '177 patent submitted a declaration explaining that "[o]ne of ordinary skill in the art would understand the improved portion of the fluid dispenser because the general concept of gears and actuators in a fluid dispenser is known." *Id.* at 1192. He also asserted that "one of ordinary skill in the art would understand how the various elements could be connected with each other, as evidenced in Attachment A [a listing of prior art references], which shows the level of ordinary skill in the art with respect to the use of reservoirs and counter elements in dispenser bodies and how dispensers function." *Id.* at 1192-1193.

The Examiner also finally rejected the pending claims as anticipated by EP 0949584A2 ("Bason Publication") (Ex. 1015), and the patentee appealed to the Patent Trial and Appeal Board ("PTAB"). Ex. 1004 at 1111-1112, 1117. At the PTAB, the patentee explained that the claim limitation "a stationary body (1) including at least one stationary gear" called for a stationary body and stationary gear having a unitary structure. *Id*. at 1285:12-20, 1286:6-14; *see also id*. at 1166-1167, 1192, 1196-1205, 1233-1234. Based on the specification, drawings, and the patentee's arguments, the PTAB expressly construed this element as "a stationary body including, ***as a unitary or monolithic part of the stationary body***, at least one stationary gear." *Id*. at 1273 (emphasis added). The PTAB explained that Bason's "teeth 2 are shown as being part of a second part 1, which ***is a separate part*** from the structure shown as corresponding to ***stationary body 'A.'***" *Id*. at 1273 (emphasis added). Accordingly, the PTAB determined the application was patentable over the Bason Publication. *Id*. at 1272-1273.

IV. CLAIM CONSTRUCTION

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

Each term of a claim in an unexpired patent subject to IPR is given its broadest reasonable interpretation ("BRI") in light of the specification of the patent in which it appears. 37 C.F.R. §42.100(b). Accordingly, to the extent these terms can be construed in light of the '177 patent's specification, Petitioners submit

constructions under the BRI standard for the following terms, and submit that all remaining terms should also be given their BRI construction.[1]

1. **"a stationary body (1) including at least one stationary gear (110, 122)"**

The '177 patent does not explicitly define the term "stationary body (1) including at least one stationary gear." The PTAB, however, already construed this term during prosecution under the BRI standard as "a stationary body including, as a unitary or monolithic part of the stationary body, at least one stationary gear." Ex. 1004 at 1273. That construction was based on the "[s]pecification and drawings, and with Appellant's contentions." *Id*. at 1273. The PTAB relied on its construction to determine that pending claims were patentable over the Bason Publication. *See supra* §III.C. The PTAB should apply that same construction here.

[1] This claim construction is not a concession by Petitioners as to the proper scope of any claim term in any litigation. The proposed construction is not a waiver of any argument that claim terms in the '177 patent fail to meet the requirements of 35 U.S.C. §112, or that a different claim scope is appropriate under the claim construction standard applied in litigation.

V. LEVEL OF ORDINARY SKILL IN THE ART

A POSA at the time of the alleged invention of the '177 patent would have had a bachelor's degree in industrial design, mechanical engineering or a related discipline and at least three to five years of industry experience in the design or manufacture of mechanical devices, or equivalent experience, education, or both. *See* Ex. 1002 ¶¶12.

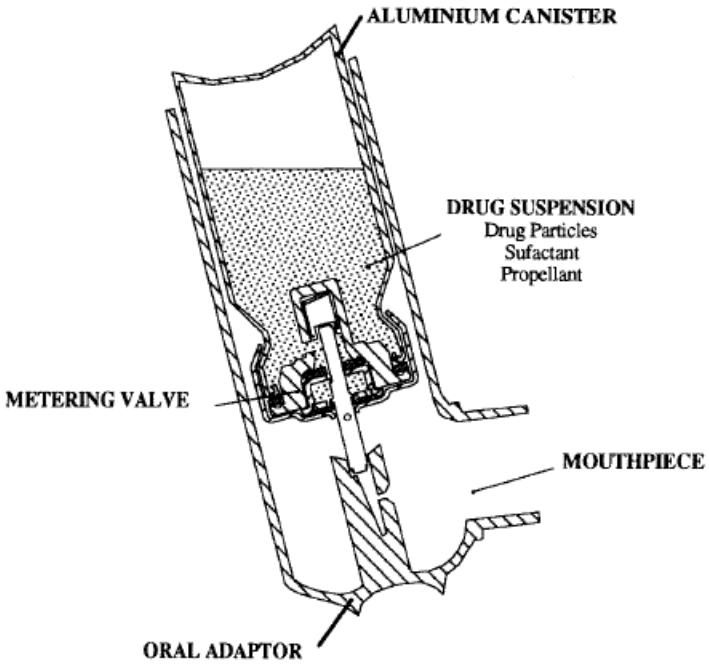
VI. SUMMARY OF THE PRIOR ART

A. The State of the Art as of May 2003

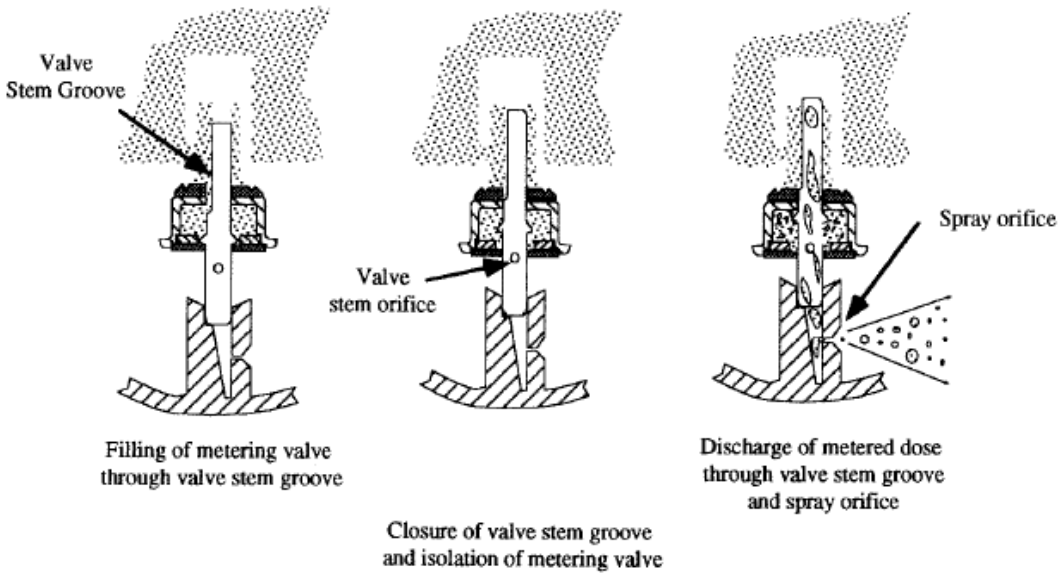
MDIs have been known and used in the art for at least 50 years. *See, e.g.*, Ex. 1012 at 4; Ex. 1002 ¶14. Dose counters for use with fluid dispensers have been designed since the early 1970s. *See, e.g.*, Ex. 1006; Ex. 1002 ¶14. During prosecution, the patentee explained that fluid dispensers and how to incorporate dose counters into fluid dispensers would have been known by a POSA. *See, e.g.*, Ex. 1004 at 255, 258-259, 281-285, 1190-1205, 1137-1139, 1149-1150, 1158-1166, 1190-1205, 1229-1233; 1281:19-20, 1282:1-4, 1292:13-15. Nonetheless, in the absence of a regulatory requirement to include a dose counter, commercial MDIs generally did not include a dose counter prior to 2003. Ex. 1002 ¶14; Ex. 1040 at 6; Ex. 1041 at 13.

MDIs have undergone little mechanical change since they were introduced in the 1950s. *See* Ex. 1002 ¶15; Ex. 1040 at 1; Ex. 1047 at 1. They were generally

known to include a canister assembly and mouthpiece (often referred to as an actuator or a boot). *See* Ex. 1002 ¶15.



Ex. 1016 at 8, Fig. 2 (excerpt). A POSA would have understood the canister assembly to have a metering valve mounted in combination with a reservoir where fluid is stored. *See* Ex. 1002 ¶16. The mouthpiece includes a valve stem receptacle which is in fluid communication with a jet, or spray orifice. *See id*. When not in use, the valve stem of the metering valve is fully engaged with the valve stem receptacle. *See id*. Upon depression of the reservoir relative to the mouthpiece, the metering valve causes a dose of fluid to be dispensed from the reservoir to the jet and out the mouthpiece where the resulting release can be inhaled by the patient. *See id.*



Ex. 1016 at 8, Fig. 2 (excerpt).

The prior art described a variety of fluid dispensers with dose counters. Ex. 1002 ¶17; *see, e.g.*, Ex. 1004 at 1190-1194; Ex. 1018; Ex. 1005; Ex. 1006; Ex. 1009; Ex. 1036; Ex. 1037; Ex. 1038; Ex. 1039. These devices, including the references in Grounds 1 and 2, typically convert axial motion from a user into rotational motion of another component, often a number wheel. Ex. 1002 ¶17; Ex. 1018 at 9:3-11; Ex. 1005 at 3:15-26; Ex. 1006 at 2:66-79. This was a common mechanism used in a variety of mechanical devices by 2003, including mechanical pens. Ex. 1002 ¶17; *see also, e.g.*, Ex. 1007 at 1:9-12, 4:22-27 (mechanical pen); Ex. 1019 (device for drying foods); Ex. 1020 (push drill); Ex. 1021 (crushing apparatus (converting rotational into axial motion)). Indeed, Petitioner's expert was asked to design and build a dose indicator prior to 2001 and, like others in the industry, looked to the mechanism of a mechanical pen. Ex. 1002 ¶17.

By 2001, the industry recognized that methods of monitoring the medication remaining in an MDI were insufficient. *Id*. ¶18; Ex. 1027 at 5-6; Ex. at 1028 at 7; Ex. 1040 at 6; Ex. 1041 at 13; Ex. 1044 at 3. That year, the FDA issued draft guidance suggesting that (1) "manufacturers with metered-dose inhalers under development for oral inhalation ***integrate a dose-counting device***," and (2) "[d]ose-counters should be engineered to reliably track actuations and . . . if some low frequency of error is unavoidable, the device should be designed to specifically avoid under-counting." Ex. 1012 at 5-6 (emphasis added); Ex. 1042 at 8. In light of the known deficiencies in then existing methods of monitoring medication level and the FDA's 2001 draft guidance, a POSA would have known by 2001 that inclusion of dose counters on future MDIs was more than a mere suggestion. Ex. 1002 ¶18. In March of 2003, the FDA issued final guidance, recommending the same. Ex. 1013 at 6-7; Ex. 1043 at 8. As a result of the FDA's draft and final guidance, manufacturers began implementing dose counters on MDIs. Ex. 1002 ¶18; Ex. 1040 at 6; Ex. 1041 at 13. Inclusion of dose counters on MDIs led to improvements for patients, including fewer emergency room visits. Ex. 1002 ¶18; Ex. 1048 at 1, 9.

It was well-understood at the time of the invention that undercounting the number of dispensed doses could lead to a patient unknowingly running out of medication. Ex. 1002 ¶19; *see, e.g.*, Ex. 1001 at 1:36-43; Ex. 1018 at 2:8-12; Ex.

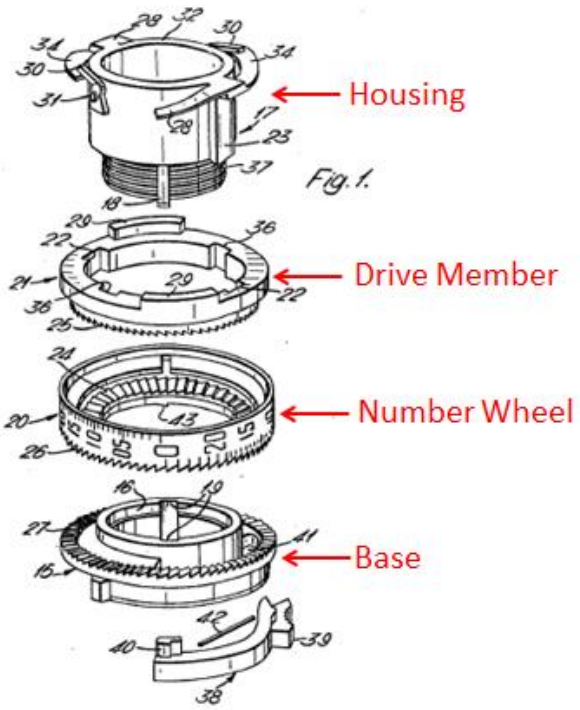
1022 at 1:12-21; Ex. 1009 at 1:39-43; Ex. 1012 at 5; Ex. 1013 at 5-6. This was particularly problematic for rescue medications that a patient might need during, for example, an asthma attack. Ex. 1002 ¶19; *see, e.g.*, Ex. 1018 at 2:1-12; Ex. 1022 at 1:12-21; Ex. 1009 at 1:39-43; Ex. 1012 at 5; Ex. 1013 at 5-6. It was also known that undercounting could be avoided by coordinating the tolerances of the counter with the tolerances of the dispenser valve to trigger counting before fluid was dispensed. Ex. 1001 at 1:41-43; *see also* Ex. 1011 at 4:9-12 ("first counting ring is actuated and rotated farther even when a dispensing stroke has been performed only incompletely"); Ex. 1010 at 4:31-5:5; Ex. 1023 at 4:22-23 ("The force required to actuate the switching device may be less than that required to actuate the dispenser."); Ex. 1002 ¶¶19-22.

B. GB 1317315 ("*Elliott*") (Ex. 1006)

Elliott published on May 16, 1973 from Application No. 59850/70, filed on October 6, 1971. *Elliott* is prior art to the '177 patent under 35 U.S.C. §102(b). Ex. 1006. *Elliott* was not considered during prosecution.

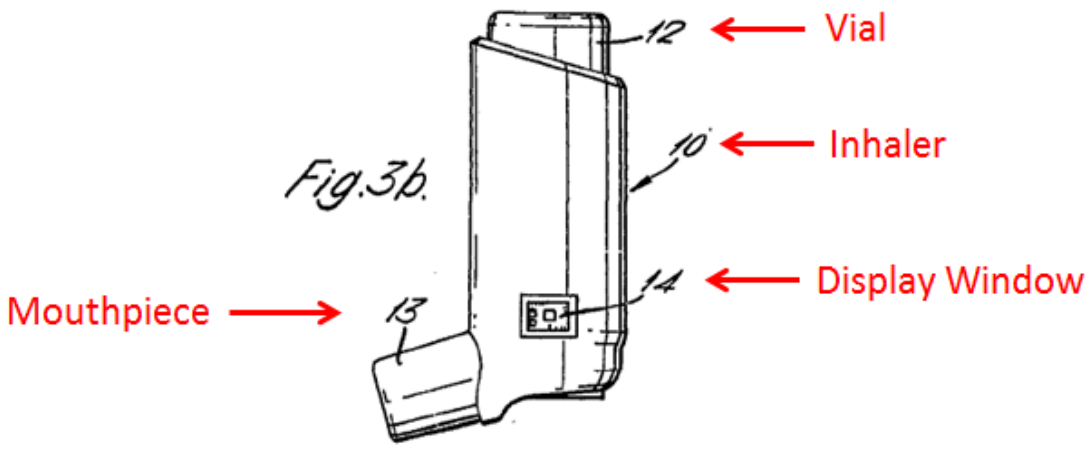
Elliott discloses a counter that can be used with an aerosol dispenser, like an inhaler. *Id.* at 1:9-13, 2:6-15; Ex. 1002 ¶54. That counter converts axial motion into rotational motion. *Id*.

The counter disclosed in *Elliott* is comprised of a housing 17, a drive member 21, a number wheel 20, and a circular base 15:



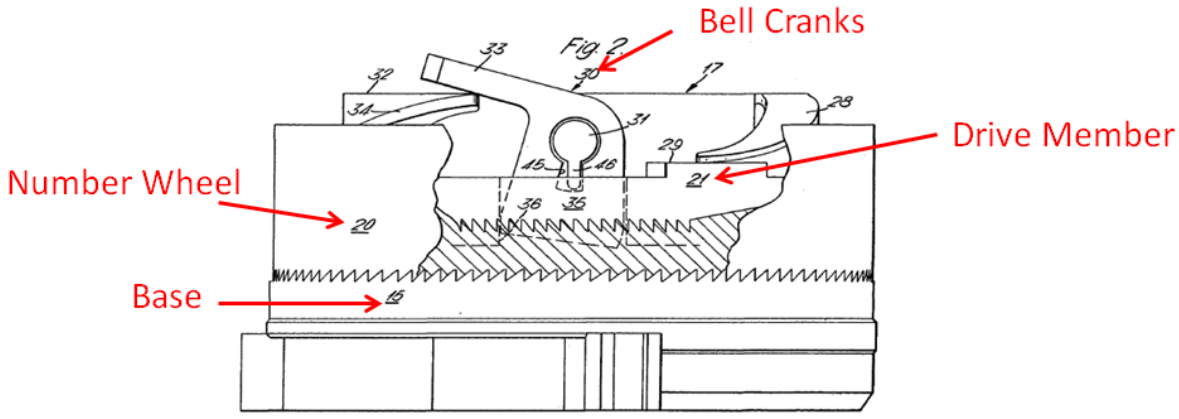
Ex. 1006 at Fig. 1 (annotated), 2:27-40.

When assembled, the counter fits near the bottom inside of an inhaler 10. Ex. 1002 ¶56. A vial 12 containing medicine is placed on top of the counter, with the valve extending through the center of the counter. Ex. 1006 at 2:8-22, 27-29. As the vial is depressed the counter is actuated, changing the value displayed in window 14. *Id*. at 2:19-26, 66-97.



Ex. 1006 at Fig. 3b (annotated).

Specifically, as the vial is depressed, it engages and depresses upper arms 33 of bell cranks 30, forcing drive member 21 to rotate (to the right in Fig. 2). *Id*. at 2:34-36, 54-76. Drive member 21 and number wheel 20 rotate up and over teeth 27 on base 15. *Id*. at 2:41-44, 76-84-97.



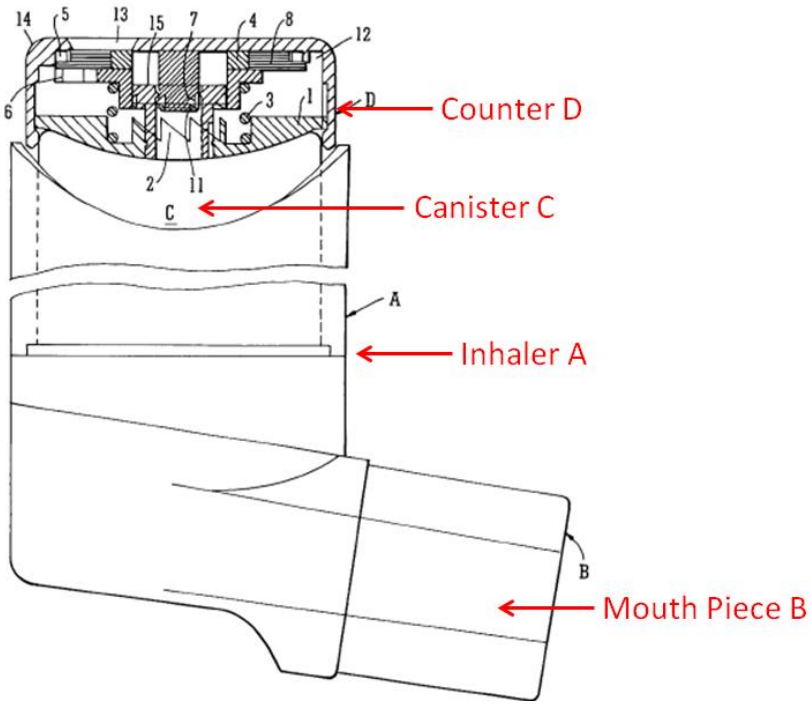
Id. at Fig. 2 (annotated).

When the vial is released, lower arms 35 move back, causing drive member 21 to rotate backwards up and over teeth 24 on the number wheel while the number wheel is held in place by teeth 27 on the base. *Id*. at 2:84-90. The net result is rotation of the number wheel one position, displaying a new dose value, with the drive member returning to its starting position. *Id*. at 2:66-97, Fig. 2.

C. U.S. Patent No. 6,283,365 ("*Bason*") (Ex. 1005)

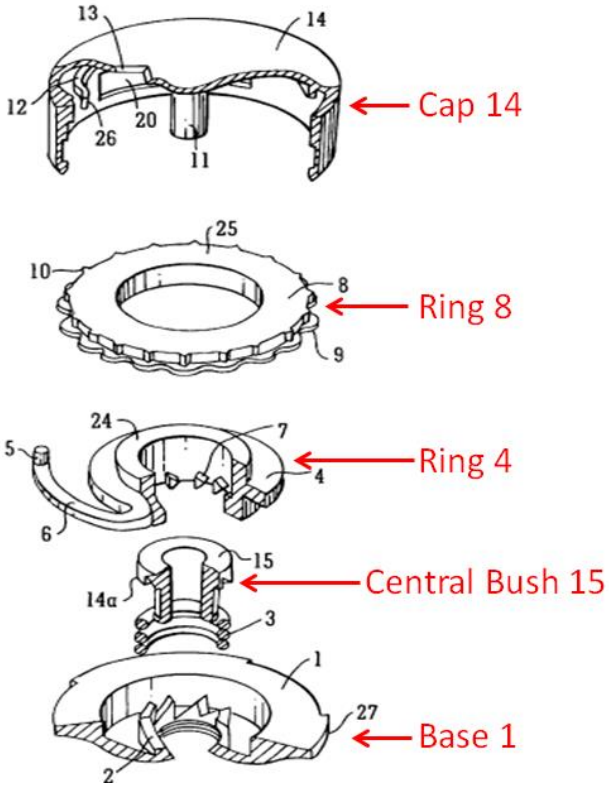
Bason issued on September 4, 2001 from Application No. 09/288,163, filed on April 8, 1999. *Bason* is prior art to the '177 patent under 35 U.S.C. §102(b). Ex. 1005. The examiner relied on the related Bason Publication in an anticipation rejection, but never cited it in an obviousness rejection.

Bason discloses a dose counter for an MDI that is attached to the base of a pressurized canister, near the top of an inhaler. *Id*. at 1:3-5, 2:16-18, Fig. 1. The *Bason* counter also converts axial motion into rotational motion. Ex. 1002 ¶128.



Ex. 1005 at Fig. 1 (annotated), 1:3-6, 2:11-15.

The *Bason* dose counter has a central bush 15 that is "[d]isposed in fixed position on the base," *id*. at 2:20-21, Figs. 1, 3, with "downwardly directed teeth 14a," *id.* at 2:33-35. Base 1 includes "upwardly directed teeth 2." *Id.* at 2:32-33, Fig. 3. Rings 4 and 8 include numerals on faces 24 and 25, and are located between teeth 2 of the base and teeth 14a of the central bush. *Id*. at 2:66-3:4; Ex. 1002 ¶129. Above ring 8 is an axially movable cap. Ex. 1005 at 2:66-3:4; Ex. 1002 ¶129.



Ex. 1005 at Fig. 3 (annotated).

"Upon depression of the cap 14 with respect to the base 1, the rings 4 and 8 are also depressed linearly," and teeth 7 of ring 4 engage the angled face of teeth 2 on the base 1, causing ring 4 to rotate (which can cause ring 8 to rotate as well). *Id*. at 3:15-22. When the user releases the cap, spring 3 causes ring 4 and the cap to move upwards, where teeth 7 (on ring 4) engage teeth 14a of the central bush, rotating ring 4 further and into position for the next actuation. *Id*. at 3:15-26; Ex. 1002 ¶130. Rotation of rings 4 and 8 changes the displayed dose value. Ex. 1005 at 3:15-24. Figure 5 shows how teeth 7 (on ring 4) sequentially engage teeth 2 and teeth 14a, causing rotation of ring 4 (not shown). Ex. 1002 ¶130.

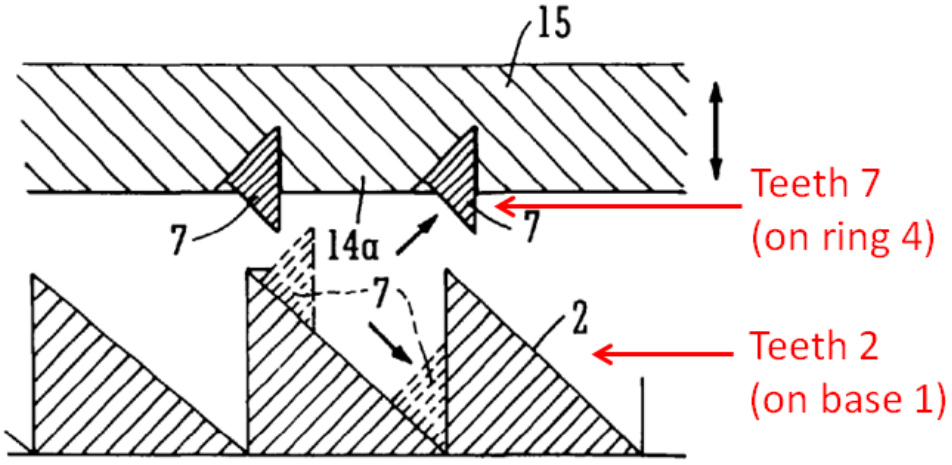


FIG. 5

Ex. 1005 at Fig. 5 (annotated).

D. U.S. Patent No. 3,205,863 ("*Rhoades*") (Ex. 1007)

Rhoades was filed on December 29, 1953 and issued on September 14, 1965, and is prior art under §102(b). Ex. 1007. *Rhoades* was not cited during prosecution of the '177 patent.

Rhoades discloses a ball point pen having a projecting and retracting mechanism that converts axial motion into rotational motion. *Id*. at 1:9-12, 4:22-27. When a user pushes button 35, forwardly-directed teeth move a cam body and attached ink reservoir forward. Ex. 1002 ¶60. Once the cam body has moved past the stop members, the cam body will rotate, and the stop members cause the reservoir to remain in its extended position. *Id*. Pushing the button again moves the cam body axially until it clears the stop members, and release of the button allows the cam body to rotate again, fully retracting the reservoir. *Id*.

Figure 1 shows the pen in the retracted position. *See* Ex. 1007 at Fig. 1 (annotated):

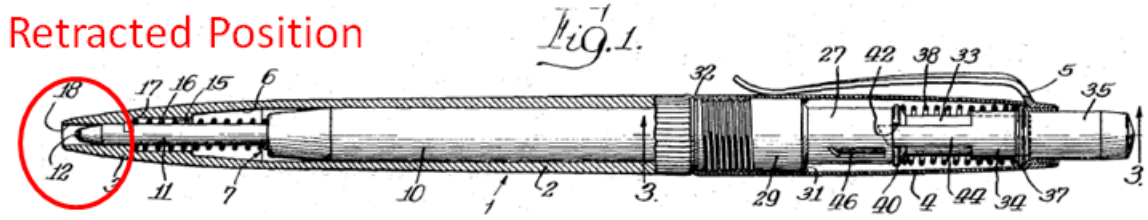
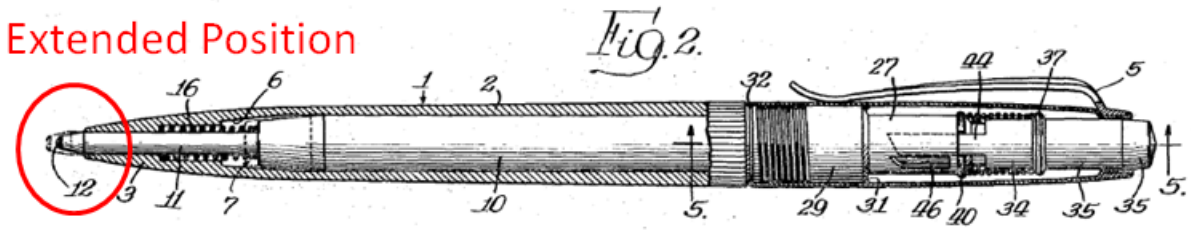
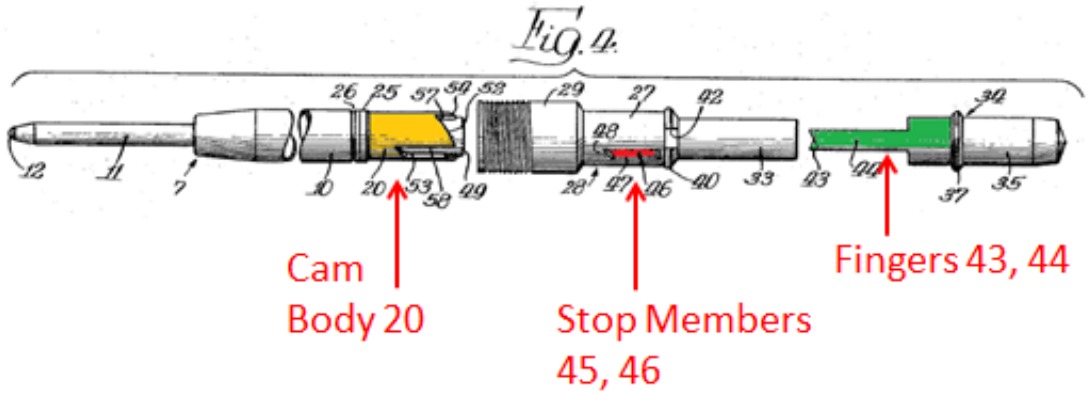


Figure 2 shows the pen in the extended position. *See id*. at Fig. 2 (annotated):

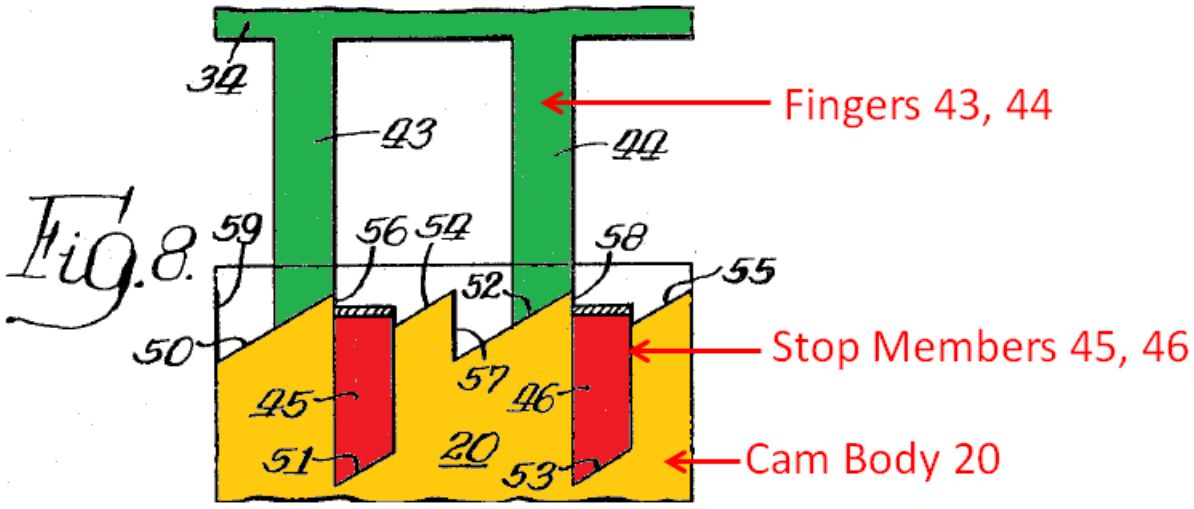


Ink reservoir section 10 containing the fluid (ink) that will be dispensed from the ball point is connected directly to the cam body 20 (yellow, below), which is rotatably and slidably disposed within the stationary guide member 28. *Id*. at 3:36-38, 60-67. At the end of the device is push button 35,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



Id. at Fig. 4 (annotated).

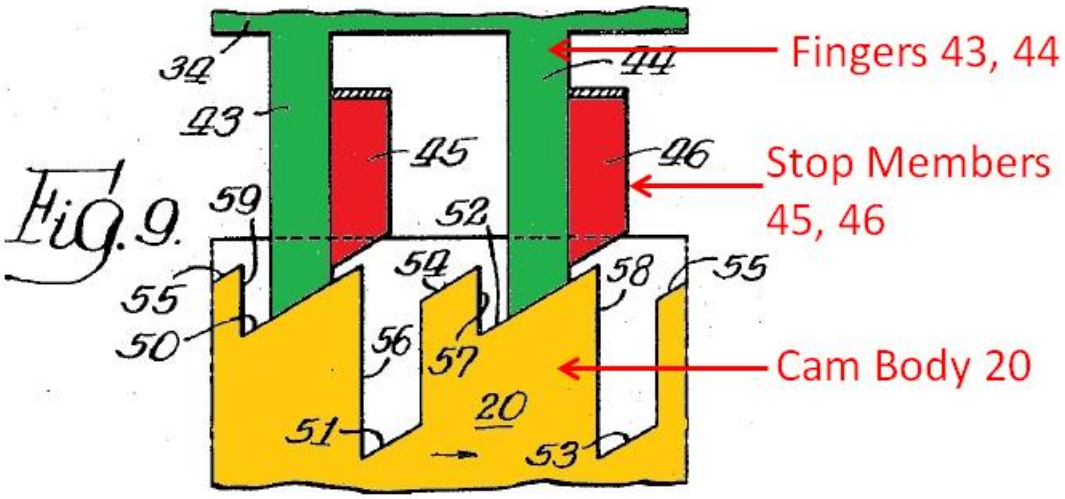
The cam body 20, fingers 43 and 44, and stop members 45 and 46 all have sloped faces that cooperate in causing the axial and rotational movement of cam body 20 under the force of spring 16. *Id*. at 5:55-58; Ex. 1002 ¶64.



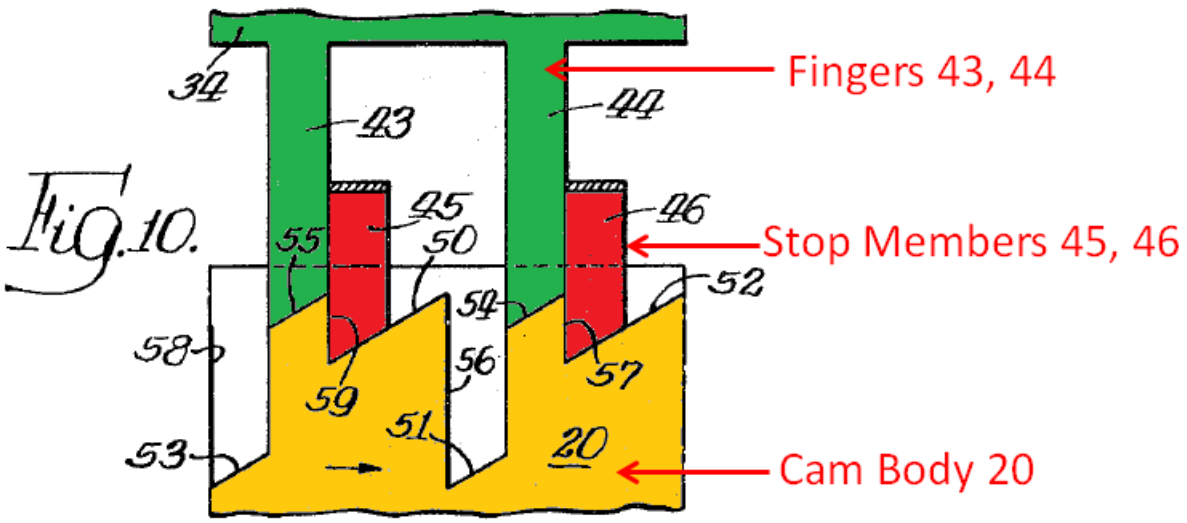
Ex. 1007 at Fig. 8 (annotated).

Figure 8 above shows the *Rhoades* mechanism fully retracted. *Id*. at 5:15-22. Stop members 45 and 46 reside in the deep grooves with bottom surfaces 51 and 53, while fingers 43 and 44 rest against cam body faces 50 and 52. Ex. 1002

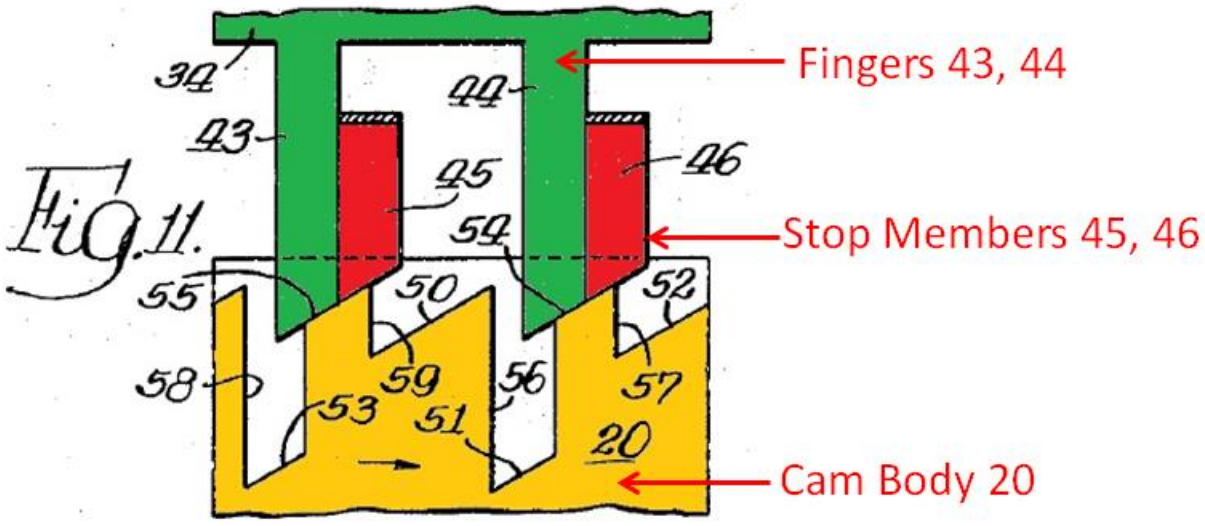
¶65. As fingers 43 and 44 are depressed by the plunger 34 and push button 35, they move cam body 20 axially downward. Despite the force exerted by the sloped faces of the fingers 43 and 44, cam body 20 cannot rotate until it moves past stop members 45 and 46. *Id.*; Ex. 1007 at 5:47-50, Fig. 9 (annotated):



Once cam body 20 has moved axially a sufficient distance to clear the stop members 45 and 46, it begins to rotate. Ex. 1002 ¶66; Ex. 1007 at 5:51-54, Fig. 9. When plunger 35 is released, the cam body continues to rotate until the stop members abut faces 57 and 59, and the fingers rest on faces 54 and 55. Ex. 1002 ¶66. Here, the pen is in its extended conformation. *See* Ex. 1007 at Fig. 10 (annotated):



Finally, when the plunger 35 is depressed again, it causes vertical faces 59 and 57 to slide along stop members 45 and 46. Once cam body 20 has moved a sufficient distance axially so that faces 59 and 57 clear the stop members, cam body 20 again rotates. Ex. 1002 ¶67; *see* Ex. 1007 at Fig. 11 (annotated):



Once cam body 20 rotates enough for fingers 43 and 44 to align with the deep grooves containing bottoms 51 and 53, fingers 43 and 44 will move freely up and down as plunger 35 is released and depressed unless and until the plunger is

released a sufficient distance to allow the tips of fingers 43 and 44 to clear the tips of sloped faces 50 and 52. Ex. 1002 ¶68. 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 Figure 8. *Id*.

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

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

Ground	Proposed Statutory Rejections for the '177 Patent
1	Claims 1, 2, 3, 9 and 21 are rendered obvious under §103(a) by *Elliott* in view of *Rhoades*
2	Claims 1, 2, 3, 9 and 21 are rendered obvious under §103(a) by *Bason* in view of *Rhoades*

VIII. EACH CHALLENGED CLAIM OF THE '177 PATENT IS UNPATENTABLE

Pursuant to 37 C.F.R. §42.104(b)(4)-(5), the Challenged Claims are unpatentable for the reasons set forth in detail below.

A. GROUND 1: Claims 1, 2, 3, 9 and 21 of the '177 Patent are Obvious under 35 U.S.C. §103 over *Elliott* in view of *Rhoades*

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

By the early 2000s, the industry recognized that existing methods of monitoring the amount of medication remaining in an MDI were insufficient. Ex. 1027 at 2-3, 6 (noting in 1998 the "float test" is a poorly validated method, but could be superior to manual counting); Ex. 1044 at 3 (concluding in November 2001 that the float test is unreliable and "[m]anufacture[rs] must develop more reliable means to allow patients to evaluate . . . the number of actuations that remain"); Ex. 1028 at 3-5, 7 (noting in 2002 that "clinicians and asthma educators should not recommend [the float test]").

The FDA issued draft guidance in 2001 and final guidance in 2003 recommending the inclusions of integrated dose counters in commercial MDIs. *See* Ex. 1012 at 5-6; Ex. 1013 at 4-7; Ex. 1040 at 6 (explaining that patient difficulty in determining whether an MDI was empty led to the 2003 guidance). Despite the well-known need for inhalers with dose counters, commercial MDIs were not required to, and did not, include integrated dose counters until after the FDA's guidance. Ex. 1040 at 6 ("[L]aunch of Seretide Evohaler™ (GlaxoSmithKline) introduced the first MDI with a built-in dose counter in 2004."); Ex. 1041 at 13.

A POSA would have understood at the time of the alleged invention in the '177 patent that future MDIs would ***have to*** include dose counters. Ex. 1002 ¶73. *Elliott*, known since the 1970s, teaches a dose counter located below a pressurized canister. Ex. 1006 at 2:8-22, Figs. 1, 3a, and 3b, *supra* §VI.B. A POSA would have understood that he or she would have to improve prior art like *Elliott* to scale up production, maximizing efficiency of manufacture and product reliability and increasing commercially viability. Ex. 1002 ¶73; Ex. 1005 at 3:66-4:3; Ex. 1029 at 3; Ex. 1030 at 3; Ex. 1046 at 89. It was well-known that manufacturing costs would generally be lower and reliability would be greater if a device was comprised of fewer separate components, requiring fewer manufacturing and validation steps. Ex. 1002 ¶73; *see, e.g.*, Ex. 1005 at 3:67 to 4:3; Ex. 1029 at 3; Ex. 1030 at 3. Indeed, decreasing manufacturing and assembly costs is one of the goals identified in the '177 patent's specification. Ex. 1001 at 1:57-59; Ex. 1002 ¶73. Faced with the need to mass produce MDIs with integrated dose counters, a POSA would have looked to other small, inexpensive mechanical devices that could be mass produced when seeking to improve devices like *Elliott*. Ex. 1002 ¶73.

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) and

teaches a device suitable for mass production. *See* Ex. 1002 ¶74, *supra* §VI.D. A POSA working in the design and development of counting mechanisms in medical devices (including MDIs) would have looked and did look to such analogous art (*i.e.*, mechanical pen technology) both before and after the '177 patent's priority date. *See, e.g.*, *id*. ¶75; Ex. 1031 at 2:36-47 (disclosing a dosing device with a rod rotated by an indexing mechanism "much like that of a ball-point pen"); Ex. 1032 at 1:40-48 (describing a pen-type injector, and including in the background a prior art reference "based on the ball point pen principle"); Ex. 1033 at 15:10-25 (disclosing an MDI with a dose counter having a drive wheel and explaining that an "arrangement of protrusions [] on the drive wheel [] is similar, and operates in a similar way, to the retraction mechanism on a ball point pen"); Ex. 1034 at [56], Abstract, 3:29-39 (disclosing a suturing device with a "sheath retraction and extension mechanism [] similar to that used in retractable tip ball point pens" and referring specifically to *Rhoades*). Moreover, Petitioner's own expert was asked to design and build a dose indicator prior to 2001, and like other skilled artisans in the field, he looked to the mechanism in a simple, plastic, and inexpensive mechanical pen that converted axial motion into rotational motion. Ex. 1002 ¶74. *Rhoades* is analogous art to the claimed invention. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007); *Sci. Plastic Prods. v. Biotage AB*, 766 F.3d 1355, 1357-60 (Fed. Cir. 2014) (references related to sealing carbonated beverage bottles relevant to

claims directed to low pressure liquid chromatographic cartridges). A POSA would have been familiar with the *Rhoades* mechanism and would have looked to *Rhoades* when seeking to improve *Elliott* as described above. Ex. 1002 ¶74.

Rhoades uses different components to rotate the cam body than *Elliott* uses to rotate its counter wheel, but both mechanisms existed in the art for decades. *Id*. ¶76. In light of the industry's understanding leading up to and after the FDA's guidance—that companies would need to start incorporating integrated dose counters into their MDIs—a POSA would have made the simple substitution of the known *Rhoades* mechanism into the *Elliot* inhaler to reach the claimed invention. *See Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337, 1343-44 (Fed. Cir. 2008) (swapping the type of switch used to complete a circuit in a device was a combination of familiar elements using known methods). This substitution would have resulted in an inhaler where the individual components retained their same functions. Ex. 1002 ¶76. The resulting inhaler would have been predictable, well-understood by a POSA, more reliable, have had fewer components, have been less expensive to manufacture, and would have addressed the very safety concerns that the '177 patent allegedly solved. *See* Ex. 1001 at 1:8-43, 47-51, 57-59; Ex. 1002 ¶76; 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. *See KSR*, 550 U.S. at 424; *Purdue Pharma L.P. v. Epic*

Pharma, LLC, 811 F.3d 1345, 1354-55 (Fed. Cir. 2016); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1377 (Fed. Cir. 2000) (patented process was developed in response to a regulatory requirement). By May 2003, a POSA could have used well-known methods like injection molding to make such a device. Ex. 1046. Accordingly, a POSA had a reasonable expectation of success and the substitution was predictable because the manufacturability would have been well-understood by a POSA. Ex. 1002 ¶76.

The FDA guidance also suggested that, if counters were to err, they should avoid undercounting, something a POSA would already have known. Ex. 1013 at 6; Ex. 1002 ¶77; *see, e.g.*, Ex. 1001 at 1:36-43; Ex. 1018 at 2:8-12; Ex. 1022 at 1:12-21; Ex. 1009 at 1:39-43. There are only two design options—err on the side of undercounting, or err on the side of overcounting. Ex. 1002 ¶77. Because preventing undercounting would lead to a safer product, a POSA would have designed dose counters to err on the side of avoiding undercounting. *Id*.

This had routinely been accomplished by coordinating the valve travel length to the tolerances of the mechanical components of the dose counter so that the dose counter would actuate (*i.e.*, count) before the fluid was dispensed. *Id*. ¶¶19-22, 78; Ex. 1001 at 1:25-27; Ex. 1008 at 5:58-68 (release of dose after axial depression of valve); Ex. 1009 at 1:50-53 (preset amount of relative movement results in a count); Ex. 1010 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). A POSA would have known that coordinating the tolerances of the *Rhoades* stop members with the tolerances of valve travel and refilling could further decrease the possibility of undercounting, and would have thus been motivated to incorporate the entire *Rhoades* mechanism into *Elliott* to take advantage of this feature in a predictable way. Ex. 1002 ¶¶19-22, 78.

To make the above substitution, a POSA would have incorporated cam body 20 of Rhoades immediately below the canister (where the counting mechanism of *Elliott* resides). *Id*. ¶79. The stop members of *Rhoades* would have been molded directly onto the *Elliott* inhaler body (increasing manufacturing efficiency and device reliability while decreasing manufacturing and assembly costs) just as they are formed directly on guide member 28 of *Rhoades*. *Id.* The canister would sit on a component analogous to the *Rhoades* plunger having fingers 43 and 44 of *Rhoades*. *Id*. Instead of the *Elliott* number wheel, the rotating *Rhoades* cam body could have been easily modified to include displayable values. *Id*. This is the type of substitution that one of skill in the art could easily have made, and the results would have been predictable. *Id*.; *supra* §III.B. Indeed, all of the components incorporated from *Rhoades* would have retained their original function and cam body 20 would have also displayed numerals (which does not change its mechanical function in any way). Ex. 1002 ¶79.

Inclusion of the *Rhoades* mechanism in the *Elliott* inhaler would have resulted in an inhaler that is extendable and retractable like the *Rhoades* pen. Depressing the cap once would have caused a dose of fluid to be dispensed, and the metering chamber would have remained in the extended position. *Id*. ¶80. Then when the user was ready to take another dose, he or she would have depressed the cap to return the canister to its rest position, allowing the metering chamber to refill with fresh fluid. *Id*. The user would then have expelled the fluid by depressing the cap and returning the chamber to the extended configuration. *Id*. This mechanism would have had the added benefit of allowing the metering chamber to refill immediately prior to dispensing fluid, preventing medication in the metering chamber from settling. *Id*. This would also have motivated a POSA. Because the metering chamber would refill immediately before inhalation, a POSA would have understood this mechanism would also have avoided the problem of "loss of prime," a problem identified well before the invention claimed in the '177 patent. *Id*.; Ex. 1047 at 1.

Alternatively, if a POSA wanted to incorporate the *Rhoades* mechanism into a simple depress-and-release inhaler like the one depicted in *Elliott*, he or she would have made a simple and predictable modification to the cam surfaces of cam body 20. Ex. 1002 ¶81. Rather than using two gears with separate heights, a POSA would have simply used a single row of teeth, all of the same height, and

separately incorporated a second row of teeth of the same height to interact with the stop members. *Id*. Such a device would not have required the "double" clicking like a pen to extend and release the metering valve. *Id*. Either configuration of the cam body surfaces would have resulted in a device with the elements of the Challenged Claims.

Rhoades teaches a simple, inexpensive, mechanism to convert axial motion into rotational motion. A POSA designing an inhaler with a dose counter would have recognized the above economic, design, and safety benefits of using elements from the *Rhoades* mechanism in an MDI. *Id*. The industry's understanding of the insufficient methods of monitoring drug level, the impending FDA guidance, and the issuance of that guidance would have motivated the combination of these well-known pieces.

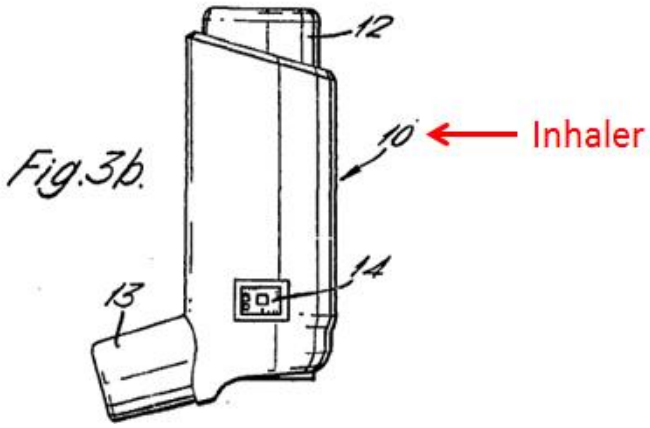
2. *Elliott* and *Rhoades* Disclose Each and Every Limitation of Claims 1, 2, 3, 9 and 21 of the '177 Patent

Each element of claims 1, 2, 3, 9 and 21 is taught by *Elliott* in view of *Rhoades*. *See* Ex. 1002 ¶69. For the reasons above, a POSA would have been motivated to substitute the *Rhoades* mechanism for the counting mechanism in *Elliott*. *See* Ex. 1002 ¶¶69-82.

i. Claim 1

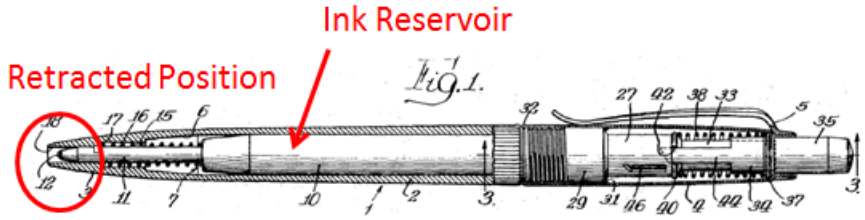
(a) **Claim 1 Preamble**: "A fluid dispenser comprising:"

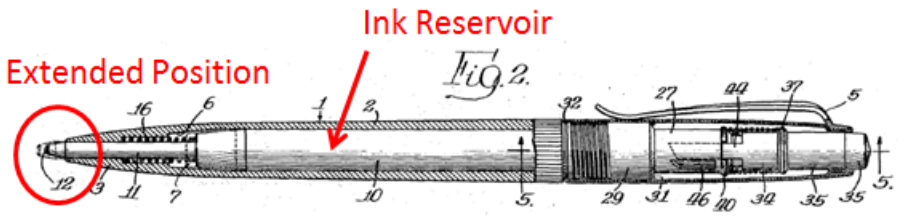
To the extent the preamble is deemed limiting, *Elliott* discloses that its counter may be used with an aerosol dispenser, *e.g.*, an inhaler 10. Ex. 1006 at 1:11-12; 2:18-19.



Id. at Fig. 3b (annotated).

Rhoades describes a ball point pen having an ink reservoir section 10 connected to the ball writing point 12. Ex. 1007 at 3:34-42. Ink (*i.e.*, fluid) is dispensed from the ink reservoir to the ball writing point. *Id*. at 11:60-63; *see id.* at Figs. 1 and 2 (annotated):





(b) **Claim 1**: "a stationary body (1) including at least one stationary gear (110, 122),"

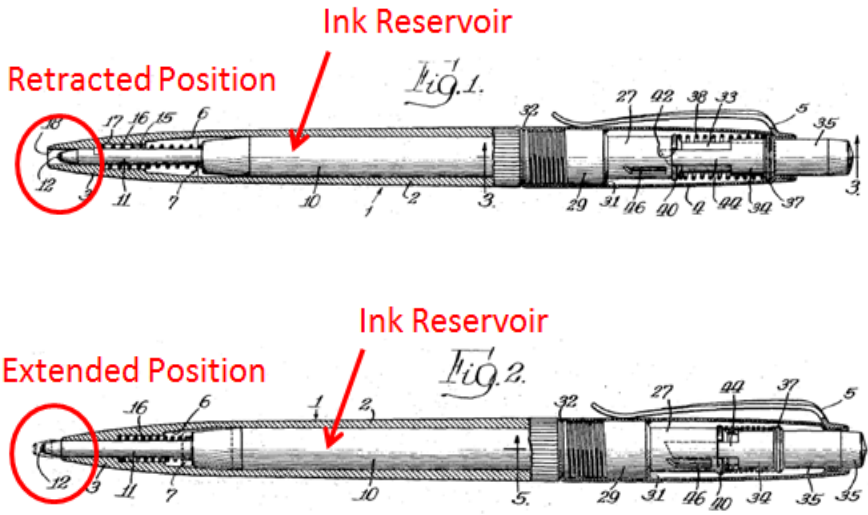
As explained in §IV.A.1, the '177 patent requires the stationary body include, as a unitary or monolithic part, at least one stationary gear. The housing depicted in *Elliott* does not contain, as a unitary or monolithic part, at least one unitary stationary gear. *Elliott* includes a stationary component, base 15 with stationary teeth 27. Ex. 1006 at 2:27-33, 46-47, Fig. 1. For the reasons in §VIII.A.1, however, it would have been obvious to a POSA to incorporate the unitary stop members of the *Rhoades* stationary body into the *Elliott* inhaler body when substituting the *Rhoades* mechanism into *Elliott*. Ex. 1002 ¶86.

Rhoades discloses a guide member 28, which is a stationary body. *Id*. ¶87; Ex. 1007 at 4:8-21. The guide member includes two stop members 45 and 46 formed on its walls (*i.e.*, stop members are unitary with the guide member). Ex. 1007 at 4:8-21. Those stop members 45 and 46 are at least one stationary gear included on the *Rhoades* stationary body (guide member 28). Ex. 1002 ¶87.

(c) **Claim 1**: "a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body,"

Elliott discloses a vial 12 (*i.e.*, fluid reservoir) that is inside of the inhaler body and moves axially within and relative to that stationary body upon depression of the reservoir. Ex. 1006 at 2:19-22, Fig. 3b.

Rhoades discloses an ink reservoir section 10 (*i.e.*, a fluid reservoir) that is connected to cam body 20, which is slidably disposed entirely within stationary guide member 28. Ex. 1007 at 3:30-42; 3:50-53; 4:25-29. The ink reservoir section (*i.e.*, fluid reservoir) moves axially relative to the stationary guide member 28 (*i.e.*, stationary body). *See id.* at Figs. 1 and 2 (annotated):



As discussed above, it would have been obvious to incorporate the *Rhoades* mechanism into the *Elliott* inhaler such that the aerosol can of *Elliott* would move axially relative to the inhaler body containing the stationary gear. Ex. 1002 ¶¶69-82; §VIII.A.1.

(d) **Claim 1**: "a dispenser member mounted on said reservoir (2), and"

Elliott discloses an aerosol can or vial 12 (*i.e.*, reservoir) with a valve mounted thereto. Ex. 1006 at 1:11-12; 1:85-87, 2:6-16. The valve is a dispenser member. Ex. 1002 ¶91; Ex. 1008 at 5:47-6:3; Ex. 1016 at 7-9; Ex. 1047 at 1-3.

Rhoades discloses an ink reservoir section 10 containing ink that is fluidly connected to the ball writing point 12. Ex. 1007 at 3:34-42. The ball writing point 12 is a dispenser member of the *Rhoades* pen. *Id.*; *see also id*. at Fig. 1; Ex. 1002 ¶92.

(e) **Claim 1**: "a dose indicator device, including a counter element (20) that is displaceable axially and in rotation relative to said body (1), for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir,"

Elliott discloses a number wheel 20 (counter element) that moves axially and in rotation over the teeth 27 of base 15, *see* Ex. 1006 at 2:93-97 (axially), 2:76-79 (rotation), which causes the displayed number to step one digit. *Id*. 2:19-26.

Rhoades discloses an element, the cam body 20, which is displaceable axially and in rotation relative to said body. Ex. 1007 at 5:22-25. *See also* §VI.D. Thus, the mechanics of cam body 20 in *Rhoades* correspond directly to the mechanics of the claimed counter element. Ex. 1002 ¶94. However, *Rhoades* does not teach that its cam body 20 is for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir.

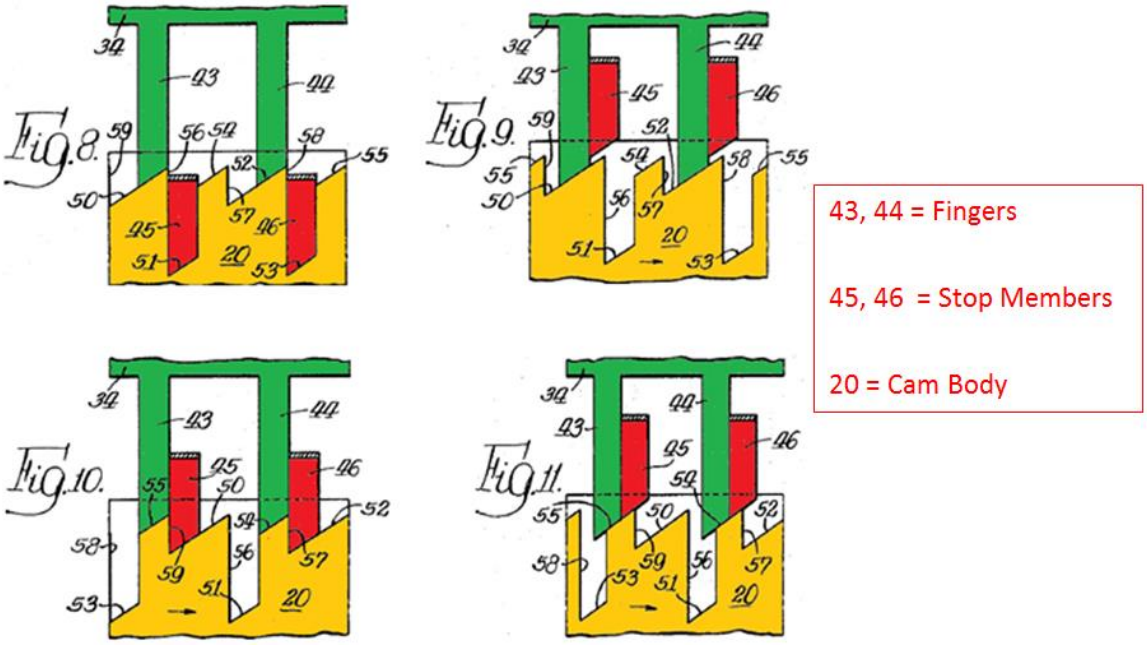
For the reasons in §VIIIA.1, it would have been obvious to a POSA to incorporate *Rhoades's* mechanism of converting axial motion to rotational motion into the *Elliott* inhaler below the *Elliott* vial and to include a numbering system. *Id*. ¶95.

(f) **Claim 1:** "wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke."

Elliott discloses that number wheel 20 (*i.e.*, counter element) moves axially and in rotation over teeth 27 of base 15 when vial 12 (*i.e.*, reservoir) is displaced axially. *See* Ex. 1006 at 2:41-47, 2:66-79. Accordingly, the counter element cooperates directly with a stationary gear and indirectly with the reservoir. Ex. 1002 ¶96.

Rhoades discloses that fingers 43 and 44 directly interact with surfaces of cam body 20 to move it axially and then in rotation. Ex. 1007 at 5:22-30, 39:47. In *Rhoades*, cam body 20 (corresponding to the claimed counter element) will rotate even if fingers 43, 44 are not depressed all of the way, *i.e.*, even when a predetermined incomplete actuation stroke is performed. Ex. 1002 ¶97. Specifically, fingers 43, 44 exert axial and rotational force on cam body 20 causing cam body 20 to be displaced axially—but initially cam body 20 is not rotated due

to cooperation with stationary stop members 45 and 46 (*i.e.*, stationary gears). Ex. 1007 at 5:39-50, Figs. 8-11. Once cam body 20 has displaced axially a sufficient distance, the cam surfaces 50, 52 clear the bottom surface of the stop members 45 and 46 and the cam body 20 rotates. *Id*. at 5:51-54, Fig. 9. For example, once finger 43 is depressed just far enough to allow the sloped face of cam surface 50 to slide along the sloped face of stationary stop member 45, then finger 43 can be released to return axially upward and sloped face 45 will slide along sloped face 50 completing the rotation of cam body 20. Ex. 1002 ¶97; Ex. 1007 at 5:51-54.



Ex. 1007 at Figs. 8-11 (annotated).

For the reasons explained in §VIII.A.1, it would have been obvious for a POSA to combine the *Rhoades* mechanism with the *Elliott* inhaler. In such a configuration, axial movement of the *Elliott* canister during actuation of the device

would have caused the necessary axial movement of the plunger with fingers 43 and 44 to actuate the counter element. Ex. 1002 ¶99. As explained in §VIII.A.1, a POSA could have designed the device to not require additional depressions to extend and retract the canister.

ii. Claim 2

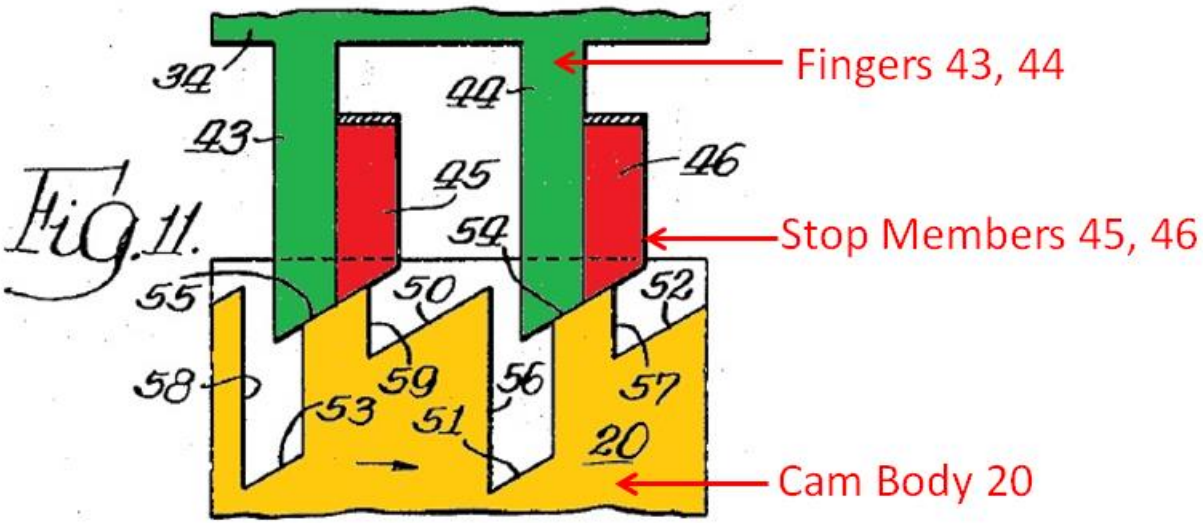
(a) **Claim 2 Preamble**: "A dispenser according to claim 1,"

Elliott in combination with *Rhoades* discloses a dispenser according to claim 1 as discussed above. Ex. 1002 ¶101.

(a) **Claim 2**: "wherein, during the return stroke of the dispenser after dispensing a dose, said dose indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke,"

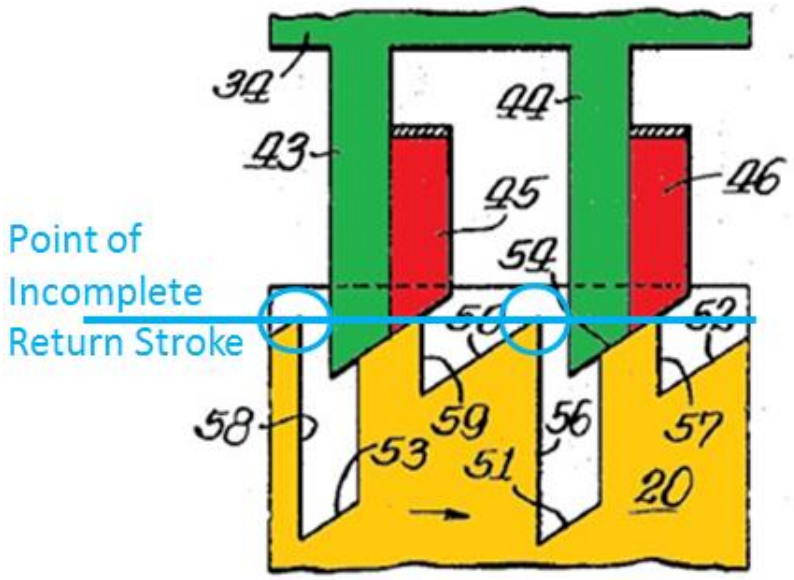
As described in §VI.D, *Rhoades* discloses a cam body 20 that is displaced axially by fingers 43 and 44 of plunger 34 to extend the ink reservoir, and pressed and released a second time to retract the ink reservoir. Ex. 1007 at 5:39-50. *Rhoades* Figure 11 depicts the mechanism just before the return stroke of the retracting step. In Figure 11, the plunger is being depressed and teeth 43 and 44 are about to align with the deep grooves that have faces 51 and 53. Ex. 1002 ¶102. Once teeth 43 and 44 align with those grooves, the plunger can be released under the force of spring 38. *Id*. Cam body 20 cannot be rotated again ***until*** the plunger

is released a sufficient distance to allow fingers 43 and 44 to clear the vertical faces 56 and 58 of cam body 20. *Id*.



Ex. 1007 at Fig. 11 (annotated); *see also id.* at 5:72 to 6:11.

That point—where, *e.g.*, the fingers 43 and 44 have passed the tip of the next sloped faces 50 and 52—is the point of the predetermined incomplete return stroke. A POSA would have understood that, to prevent a second dispensing of fluid before the counter was reset, that point needed only be further from rest position than the axial distance from the rest position required to refill the metering valve chamber. Ex. 1002 ¶103.



Ex. 1007 at Fig. 11 (annotated).

Prior to passing that point, the device cannot be actuated again because additional release and depression of the canister will simply cause fingers 43 and 44 to just slide up and down the deep groove of the cam body. Ex. 1002 ¶104. After passing that point, the cam body can rotate and align the stop member in the groove with bottom 53, and the counter mechanism can be actuated again whether the metering valve chamber has been refilled or not. *Id*. Thus, the indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke. *Id*.

A POSA would have known that the height of the cam faces, stop members, and teeth could be designed to correlate the point of the incomplete return stroke with the point of chamber refilling. *Id*. ¶105; *see* Ex. 1008 at 5:58-68; Ex. 1009 at 1:50-53; Ex. 1010 at 4:31-5:5; Ex. 1011 at 4:9-13. A POSA would have designed

the height of the teeth to cause chamber refilling to occur after the valve has been released enough so that fingers 43 and 44 have cleared the vertical faces 56 and 58. Ex. 1002 ¶105; *see* Ex. 1008 at 5:58-68; Ex. 1009 at 1:50-53.

(b) **Claim 2**: "said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to it rest position."

After passing the point of the incomplete return stroke described above, cam body 20 begins to rotate again due to the sloped interaction between the stop members and the cam body, under the axial force of spring 16. Ex. 1002 ¶106. At that point, depression of the canister and corresponding depression of fingers 43 and 44 will cause the cam body to rotate again indicating an additional dose. *Id*.

iii. Claim 3

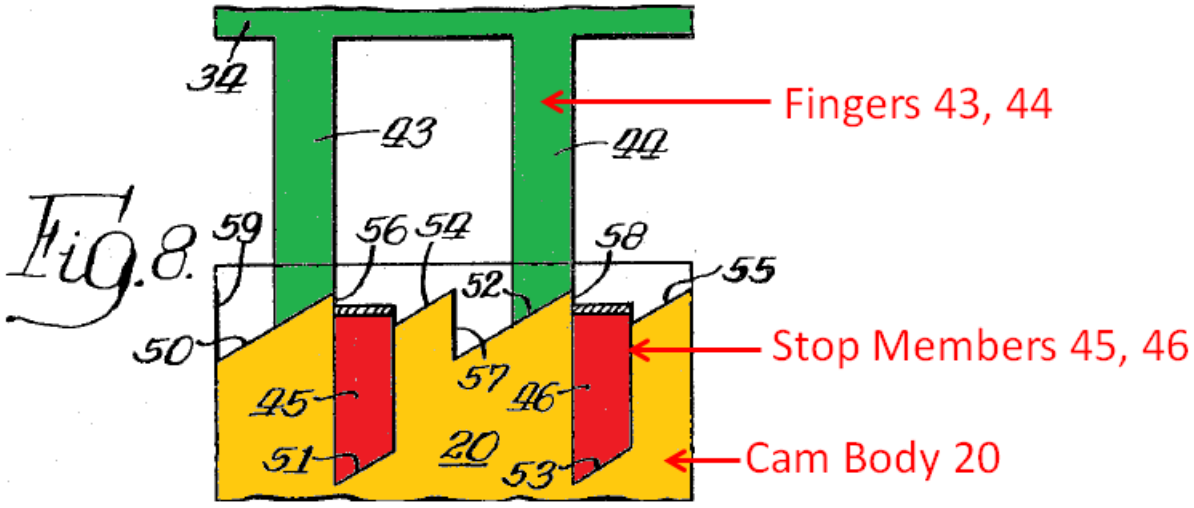
(a) **Claim 3 Preamble**: "A dispenser according to claim 1,"

Elliott in combination with *Rhoades* discloses a dispenser according to claim 1 as discussed above. Ex. 1002 ¶108.

(b) **Claim 3**: "in which said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20),"

Rhoades discloses cam body 20 with a plurality of cam surfaces. Cam surfaces 51 and 53 correspond to part of a first gear that cooperates with stop

members 45 and 46. The stop members 45 and 46 can also interact with faces 50, 52, and 54-59.



Ex. 1007 at Fig. 8 (annotated).

Accordingly, cam surfaces 51 and 53 cooperate with the stationary body (guide member 28) via stop members 45 and 46 exclusively, and cam surfaces 50, 52, and 54-59 interact with stop members 45 and 46 nonexclusively. *See* Ex. 1002 ¶¶110, 111. A POSA would have understood that all faces 50, 51, 52, 53, and 54-59 correspond to the first gear of the counter element.

(c) **Claim 3**: "said counter element (20) including a second gear (230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser,"

Rhoades discloses a push button 35 connected to plunger 34 (actuator member) with integrally formed fingers 43 and 44 (teeth of actuator gear) extending forward from the plunger 34. Ex. 1007 at 4:10-12. The fingers 43 and

44 cooperate with cam surfaces 50, 52, and 54-59 of the cam body 20. A POSA would understand *Rhoades* to teach that cam surfaces 50, 52, and 54-59 make up the second gear of the cam body. Ex. 1002 ¶110, 112.

A POSA would have understood "gear" as it was used in the '177 patent to refer to a set of surfaces or teeth that either restrict or cause movement of another part. *Id*. ¶110. A POSA would have understood that a single component could include two gears and that any one gear is defined by a "set" of teeth or surfaces that interact with another component to impart or restrict movement of that component. *Id*. ¶113. If cam body 20 interacts with one component (fingers 43 and 44) by one set of teeth (cam surfaces 50, 52, and 54-59), but interacts with a different component (stop members 45 and 46) by a different set of teeth (cam surfaces 50-59) a POSA would have understood that cam body 20 contains two different gears because the interacting sets of teeth are different. *Id*. Although the two sets contain common teeth, a POSA would know that two sets are different because both sets do not contain all the same elements (*e.g.*, a unitary single gear regardless of how many other gears it is interacting with). *Id*. In *Rhoades*, stop members 45 and 46 must interact with surfaces 51 and 53 when the device is in the retracted position. Fingers 43 and 44 do not need to ever interact with surfaces 51 and 53. Fingers 43 and 44 (as well as stop members 45 and 46) must interact with surfaces 50, 52, and 54-59. *Id*.

Elliott teaches a number wheel 20 with a row of teeth 24 on the upper surface, and a row of teeth 26 on the lower surface. *Id*. ¶114. A POSA would have understood that two such gears could be included on the same component, and the teeth could be facing the same direction. *Id*. To the extent the cam body 20 does not already teach two gears, in light of *Elliott*, a POSA would have understood that the first gear, the surfaces interacting with the stationary body, could be formed as a gear completely separate from the second gear, but also on the cam body.

(d) **Claim 3**: "the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation,"

Rhoades discloses that "[t]he cylindrical cam body 20 is, in accordance with the invention, provided 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 as well as longitudinal reciprocating movement to the cam body***." Ex. 1007 at 4:22-27 (emphasis added).

(e) **Claim 3**: "the stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser."

Rhoades discloses a push button 35 connected to tubular plunger 34 (actuator member) that is integral with fingers 43 and 44 (teeth of actuator gear),

which extend axially from the plunger. Ex. 1007 at 4:1-13. The fingers move axially through guide member 28 (stationary body). *Id*. at 3:68-72, 4:10-13, Figs. 8-12. As described above, *Rhoades* discloses that cam body 20 has several faces created by four teeth arranged around the circumference of the cam body. *See* §VI.D. These teeth are successively engageable by fingers 43, 44 to move the cam body axially and rotationally upon successive depressions of push button 35. Ex. 1007 at 4:22-33. At the retracted position, stop members 45 and 46 are engaged with first gear faces 51, 53, 56 and 58. *See id.* at Fig. 8. As cam body 20 is displaced axially by the force of fingers 43 and 44, cam body 20 continues to cooperate with stop members 45 and 46, which prevent the cam body from rotating. *Id*. at 5:39-50; Ex. 1002 ¶116.

Once cam body 20 has been axially displaced a predetermined distance (*i.e.*, it no longer cooperates with stationary gear), cam surfaces 56 and 58 clear the surface of the stop members 45 and 46 and cam body 20 rotates, which corresponds to a predetermined incomplete actuation stroke of the dispenser. Ex. 1007 at 5:51-63, Figs. 8-9; Ex. 1002 ¶117. As explained in §§VI.A and VIII.A.1, a POSA would have understood how to connect a canister to, and how to set the dimensions and tolerances of the cam surfaces and stop members to ensure that medicine would be dispensed after the point of the incomplete actuation stroke. Ex. 1002 ¶117.

As described in §VIII.A.1 above, a POSA would have incorporated the *Rhoades* mechanism into the *Elliott* inhaler, with or without modification to the cam body 20 teeth.

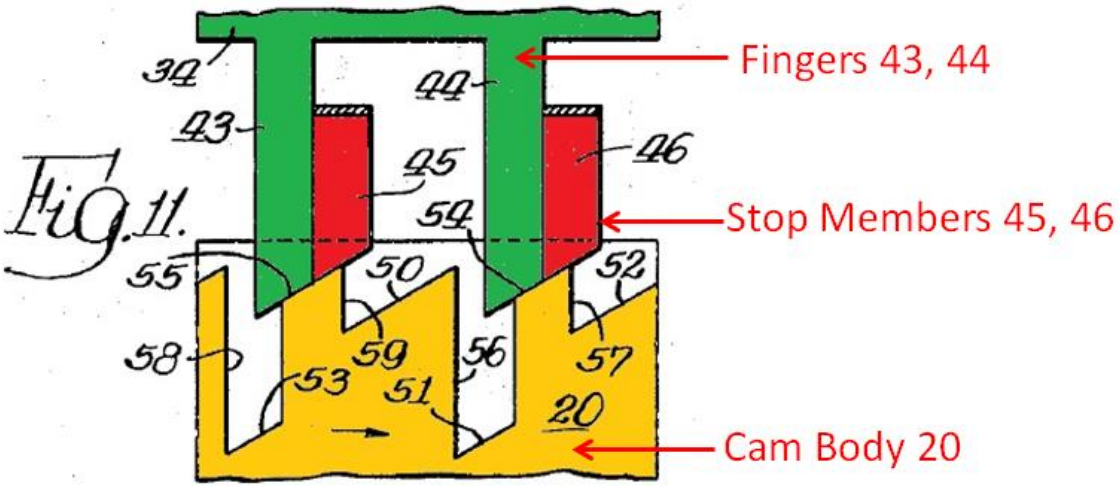
iv. Claim 9

(a) **Claim 9 Preamble**: "A dispenser according to claim 3,"

Elliott in combination with *Rhoades* discloses a dispenser according to claim 3 as discussed above. Ex. 1002 ¶120.

(b) **Claim 9**: "in which, once the predetermined incomplete return stroke has been performed, the actuator member (30) is positioned facing the following tooth of the second gear (230) of the counter element (20), enabling the dispenser and the dose indicator device to be actuated once again."

As described in §VIII.A.2(ii) above, *Rhoades* teaches that the plunger completes an incomplete return stroke once fingers 43 and 44 clear the vertical faces 56 and 58 of the teeth of the second gear of the cam body 20. And as described in that section, after passing that point of the incomplete return stroke, cam body 20 will rotate and fingers 43 and 44 of plunger 34 (*i.e.*, actuator member) will be positioned to cooperate with the next tooth (faces 50 and 52) of cam body 20 (counter element), allowing the fluid reservoir section 10 (dispenser) and cam body 20 (counter element) to be actuated one again. Ex. 1002 ¶¶121-122.



Ex. 1007 at Fig. 11 (annotated).

v. Claim 21

(a) **Claim 21 Preamble**: "A dispenser according to claim 1,"

Elliott in combination with *Rhoades* discloses a dispenser according to claim 1 as discussed above. Ex. 1002 ¶124.

(b) **Claim 21**: "wherein the dispenser member is a pump or a valve."

Elliott discloses that vial 12 (aerosol can) contains a valve. Ex. 1006 at 1:85-86 ("[t]he invention further provides a device for fitting over the valve of an aerosol can."). Therefore, *Elliott* discloses that the dispenser member is a valve. Ex. 1002 ¶125. As explained in §VIII.A.1, a POSA would have incorporated the *Rhoades* mechanism into the *Elliott* inhaler, retaining the inhaler medicine in a vial or aerosol can with a valve. *Id*. ¶126.

B. GROUND 2: Claims 1, 2, 3, 9 and 21 of the '177 Patent are Obvious under 35 U.S.C. §103 over *Bason* in view of *Rhoades*

Each element of claims 1, 2, 3, 9 and 21 is taught by *Bason* in view of *Rhoades*. *See* Ex. 1002 ¶132. For the reasons below, a POSA would have been motivated to modify *Bason* by incorporating the mechanism described in *Rhoades* into the *Bason* inhaler on top of the canister, in the same location as the *Rhoades* counter. *See id*. ¶132.

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

As discussed above, by the early 2000s, the industry had recognized that existing methods of monitoring medication level in an MDI were insufficient. Ex. 1027 at 2-3, 6; Ex. 1028 at 3-5; Ex. 1044 at 3; *supra* §VIII.A.1. That problem led the FDA to issue draft guidance in 2001, and final guidance in 2003, recommending the inclusions of integrated dose counters in MDIs. Ex. 1012; Ex. 1013; Ex. 1040 at 6. Despite the known deficiencies in prior methods of monitoring drug level and the longstanding interest in dose counter development, commercial MDIs did not include integrated dose counters until after that regulatory guidance. Ex. 1027 at 2-3, 6; Ex. 1028 at 3-5; Ex. 1040 at 6; Ex. 1041.

A POSA would have understood at the time of the alleged invention in the '177 patent that future MDIs would ***have to*** include dose counters. Ex. 1002 ¶136. *Bason*, known before the '177 patent's priority date, teaches a dose counter located at the top of an inhaler (bonded to the base of the canister). Ex. 1005 at 2:16-18, Fig. 1; *supra* §VI.C. A POSA would have understood that he or she would have to

improve on the prior art inhalers and dose counters, like *Bason*, to increase their commercially viability. For example, that POSA would have been faced with the problem of scaling up production of a device like the *Bason* counter for manufacturing and use with a specific canister/actuator, and needing to maximize efficiency of manufacture and product reliability. Ex. 1002 ¶136; Ex. 1005 at 3:66-4:3; Ex. 1029 at 3; Ex. 1030 at 3; Ex. 1046 at 89. It was well-known in the art that manufacturing costs would be lower, and reliability would be greater if a device was comprised of as few separate components as possible. Ex. 1002 ¶136; Ex. 1005 at 3:67-4:3; Ex. 1020 at 1:43-45; Ex. 1029 at 3; Ex. 1030 at 3. This would have required fewer manufacturing and validation steps and would require fewer steps and components that could fail. Ex. 1002 ¶136; Ex. 1030 at 3. Indeed, decreasing the cost of manufacturing and assembly is one of the goals expressly listed in the '177 patent's specification. Ex. 1001 at 1:57-59. A POSA would have routinely looked to other known small, inexpensive, mechanical devices when seeking to improve devices like *Bason* in such ways. Ex. 1002 ¶136.

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). *See* Ex. 1002 ¶137, *supra* §VI.D. A POSA would have been familiar with the *Rhoades* mechanism and would have looked to this type of art when seeking to improve

Bason as above. Ex. 1002 ¶137. Indeed, skilled artisans working in the design and development of counting mechanisms in medical devices (including MDIs) would have looked to such analogous art (*i.e.*, mechanical pen technology) and did look to such analogous art both before and after the '177 patent's priority date. *See, e.g.*, Ex. 1002 ¶137; Ex. 1031 at 2:36-47 (disclosing a dosing device with a rod rotated by an indexing mechanism "much like that of a ball-point pen"); Ex. 1032 at 1:40-48 (describing a pen-type injector, and including in the background a prior art reference "based on the ball point pen principle"); Ex. 1033 at 15:10-25 (disclosing an MDI with a dose counter having a drive wheel and explaining that an "arrangement of protrusions [] on the drive wheel [] is similar, and operates in a similar way, to the retraction mechanism on a ball point pen"); Ex. 1034 at [56], Abstract, 3:29-39 (disclosing a suturing device with a "sheath retraction and extension mechanism [] similar to that used in retractable tip ball point pens" and referring specifically to Rhoades). Moreover, Petitioner's own expert was asked to design and build a dose indicator prior to 2001 and, like other skilled artisans in the field, he looked to the mechanism in a simple, plastic, and inexpensive mechanical pen that converted axial motion into rotational motion. Ex. 1002 ¶137. Accordingly, *Rhoades* is analogous art to the claimed invention. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007); *Sci. Plastic Prods. v. Biotage AB*, 766 F.3d 1355, 1357-60 (Fed. Cir. 2014) (references related to sealing carbonated beverage

bottles relevant to claims directed to low pressure liquid chromatographic cartridges).

Rhoades uses different components to rotate the cam body than *Bason* uses to rotate ring 4, but both mechanisms were known in the art. Ex. 1002 ¶138. In light of the industry's understanding leading up to the FDA's guidance—that companies would need to start incorporating integrated dose counters into their MDIs—a POSA would have made the simple substitution of the known *Rhoades* mechanism into the *Bason* device to reach the claimed invention. *See Agrizap*, 520 F.3d at 1343-44. The technology here "is considered to be of the predictable arts." Ex. 1004 at 1281:19-20. Substituting the *Rhoades* mechanism into the *Bason* inhaler would result in an inhaler where the majority of components retained their same functions, and the resulting inhaler would have been predictable, well-understood by the POSA, less expensive to manufacture, more reliable, and would have addressed the very safety concerns that the '177 patent sought to solve. *See* Ex. 1001 at 1:8-43, 47-51, 57-59; Ex. 1002 ¶138. The need to address these problems was particularly acute in the early 2000s in light of impending and ultimately issued regulatory guidance. *See KSR*, 550 U.S. at 424; *Purdue Pharma*, 811 F.3d at 1354-55; *Ecolochem*, 227 F.3d at. By May 2003, a POSA could have used well-known methods like injection molding to manufacture such a device. Ex. 1046. Accordingly, a POSA had a reasonable expectation of success and the

substitution was predictable because the manufacturability was well-understood by a POSA. Ex. 1002 ¶138.

The FDA guidance also suggested that if counters were to err, they should avoid undercounting, something that a POSA would already have known. Ex. 1013 at 6; Ex. 1002 ¶139; *see, e.g.*, Ex. 1001 at 1:36-43; Ex. 1018 at 2:8-12; Ex. 1022 at 1:12-21; Ex. 1009 at 1:39-43. Notably, there are only two design options—attempt to err on the side of undercounting, or attempt to err on the side of overcounting. Ex. 1002 ¶139. Because preventing undercounting would lead to a safer product, a POSA would have opted to design dose counters that erred on the side of avoiding undercounting. *Id*.

This had routinely been accomplished by coordinating the valve travel length to the tolerances of the mechanical components of the dose counter so that the dose counter would actuate (*i.e.*, count) before fluid was dispensed. *Id*. ¶¶19-22, 140; Ex. 1001 at 1:25-27; Ex. 1008 at 5:58-68 (release of dose after axial depression of valve); Ex. 1009 at 1:50-53 (preset amount of relative movement results in a count); Ex. 1010 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). A POSA would have known that coordinating the tolerances of the *Rhoades* stop members with the tolerances of valve travel and refilling could further decrease the possibility of undercounting, and one would

have been motivated to incorporate the entire *Rhoades* mechanism into *Bason* to take advantage of this feature in a predictable way. Ex. 1002 ¶140.

To make the above substitution, a POSA would have incorporated cam body 20 facing upward and bonded to the base of the canister, at the top of the inhaler where the counting mechanism of *Bason* resides. *Id*. ¶141. The outer housing of *Bason* would correspond to the guide member 28 of *Rhoades* and would have been extended slightly to reach above the canister (as the guide member 28 in *Rhoades* extends beyond the rotating element). *Id*. And, as in *Rhoades*, the stop members would be molded directly onto the *Bason* inhaler body (increasing manufacturing efficiency and device reliability while decreasing manufacturing and assembly costs). *Id*. Accordingly, the resulting inhaler body would have served the same function as guide member 28. The *Bason* cap would have included fingers 43 and 44 of *Rhoades* pointing downwards towards the cam body 20. *Id*. In other words, if the pen was held pointed downwards, as if to write on paper, the mechanism would have had the same configuration it would have when incorporated into the *Bason* inhaler. *Id*. The *Rhoades* cam body could have been easily modified to include displayable values and would rotate. *Id*. This is the type of substitution that one of skill in the art could easily have made, and the results would have been predictable. *Id*.; *supra* §III.B. Indeed, all of the components incorporated from

Rhoades would retain their original function and cam body 20 would also display numerals (which does not change its mechanical function in any way).

Inclusion of the *Rhoades* mechanism in the *Bason* inhaler would have resulted in an inhaler that was extendable and retractable like the *Rhoades* pen. Depressing the cap once would have caused a dose of fluid to be dispensed, and the metering chamber would have remained in the extended position. *Id*. ¶142. Then when the user was ready to take another dose, he or she would have depressed the cap to return the canister to its rest position, allowing the metering chamber to refill with fresh fluid. *Id*. The user would then have expelled the fluid by depressing the cap and returning the chamber to the extended configuration. *Id*. This mechanism would have had the added benefit of allowing the metering chamber to refill immediately prior to dispensing the fluid, preventing medication in the metering chamber from settling. *Id*. This would also have motivated a POSA. Because the metering chamber would refill immediately before inhalation, a POSA would have understood this mechanism would also have avoided the problem of "loss of prime," a problem identified well before the invention claimed in the '177 patent. *Id*.; Ex. 1047 at 1.

Alternatively, if a POSA wanted to incorporate the *Rhoades* mechanism into a simple depress and release inhaler like the one depicted in *Bason*, he or she would have made a simple and predictable modification to the cam surfaces of cam

body 20. Ex. 1002 ¶143. Rather than two gears with separate heights, a POSA would have used a single row of teeth, all of the same height, and separately incorporate a second row of teeth of the same height to interact with the stop members. *Id*. Such a device would not have required the "double" clicking like a pen to extend and release the metering valve. *Id*. Either configuration of the cam body surfaces would have resulted in a device where the elements of the Challenged Claims. *Id*.

Rhoades teaches a simple, inexpensive, mechanism to convert axial motion into rotational motion. A POSA designing an inhaler with a dose counter would have recognized the above economic, design, and safety benefits of using elements from the *Rhoades* mechanism in an MDI. *Id*. ¶144. The industry's understanding of the insufficient methods of monitoring drug level, the impending FDA guidance and the issuance of that guidance would have motivated the combination of these well-known pieces. *Id*.

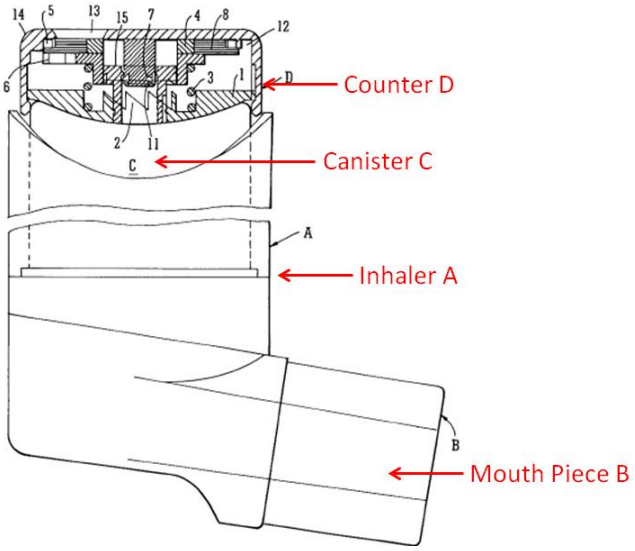
2. ***Bason*** **and** ***Rhoades*** **Disclose Each and Every Limitation of Claims 1, 2, 3, 9 and 21 of the '177 Patent**

Each element of claims 1, 2, 3, 9 and 21 is taught by *Bason* in view of *Rhoades*. *See* Ex. 1002 ¶132. For the reasons above, a POSA would have been motivated to substitute the *Rhoades* mechanism for the counting mechanism in the inhaler disclosed by *Bason*. *See* Ex. 1002 ¶¶134-144.

i. Claim 1

(a) **Claim 1 Preamble**: "A fluid dispenser comprising:"

To the extent the preamble is deemed limiting, *Bason* discloses a fluid dispenser. Ex. 1002 ¶146. *Bason* discloses a device for use with MDIs, which include a dispenser member for dispensing fluid. Ex. 1005 at 1:3-8; 2:11-14; Fig. 1. Figure 1 of *Bason* shows such a product with Canister "C."



Ex. 1005 at Fig. 1 (annotated); *see also* Ex. 1005 at 1:3-6, 2:11-15.

Rhoades also discloses a fluid dispenser. *See* §VIII.A.2.i.a.

(b) **Claim 1**: "a stationary body (1) including at least one stationary gear (110, 122),"

Bason depicts a metered dose inhaler A with a canister C inside of an outer inhaler housing. Ex. 1005 at Fig. 1; 2:11-15. *Bason* also discloses a stationary component (base 1) of the dose counting mechanism, which includes teeth 2. *See id.* at 2:16-27. As noted in §III.C, the PTAB previously determined that the *Bason*

Publication did not expressly disclose "a stationary body (1) including at least one stationary gear (110, 122)" because the outer housing did not have a unitary monolithic gear—the teeth were on separate component, base 1. Ex. 1002 ¶148.

Rhoades discloses the claimed stationary body (1) including at least one stationary gear. *See* §VIII.A.2.i.b.

(c) **Claim 1**: "a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body,**"**

Bason discloses a fluid reservoir (canister C) that is disposed in the inhaler body, and that fluid reservoir is axially displaceable relative to the outer device housing. Ex. 1005 at 6:20, Fig. 1; Ex. 1002 ¶150.

Rhoades discloses "a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body." *See* §VIII.A.2.i.c.

(d) **Claim 1**: "a dispenser member mounted on said reservoir (2), and"

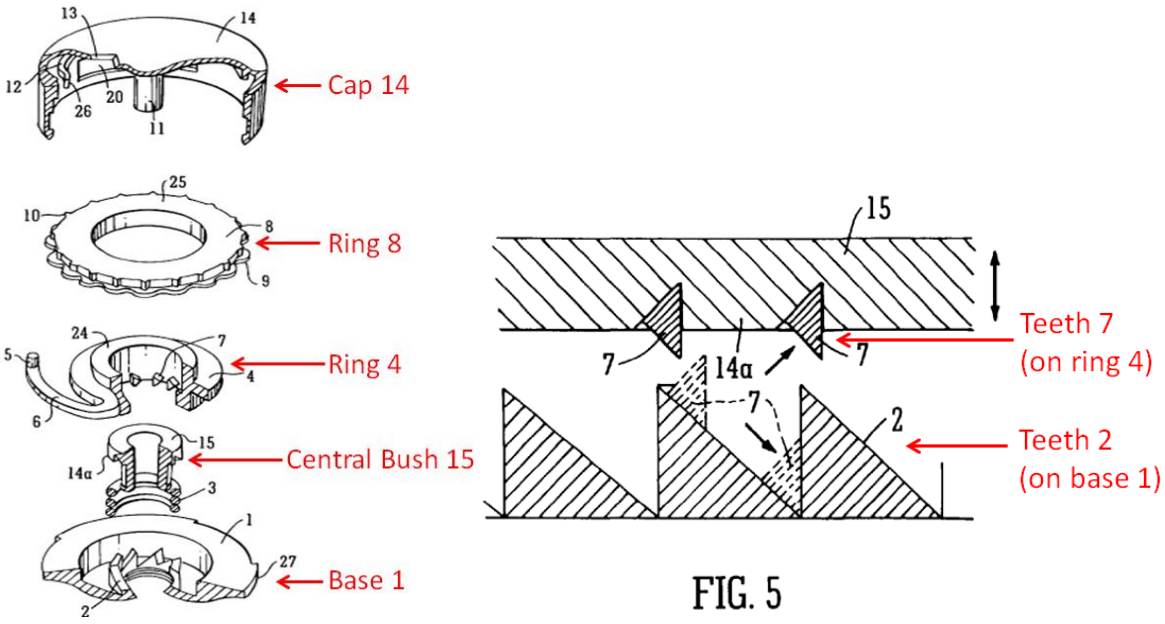
As shown above in Figure 1, *Bason* discloses a metered dose inhaler A holding a canister C and having a mouth-piece B. A POSA would have understood that an MDI like the one shown in *Bason*, with a canister C, inherently teaches a dispenser member mounted on the canister C (reservoir)—if the canister did not have a dispenser member it could not expel medication. Ex. 1002 ¶152. The inclusion of a valve on a canister for use in an MDI was well-known by a POSA.

See Ex. 1004 at 1191, 1194; Ex. 1016 at 6-8; Ex. 1008 at 5:47-6:8, Figs. 1, 2; Ex. 1017 at 1:5-24, Figs. 1, 2; Ex. 1025 at 1:45-58; Ex. 1047 at 1; Ex. 1002 ¶152.

Rhoades discloses "a dispenser member mounted on said reservoir 2." *See* §VIII.A.2.i.d.

(e) **Claim 1**: "a dose indicator device, including a counter element (20) that is displaceable axially and in rotation relative to said body (1), for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir,"

Bason discloses a counter element (ring 4) that is displaceable axially and in rotation relative to the device housing body to effect the dose-indicating count down. "Upon depression of the cap 14 with respect to the base 1, the ***rings 4 and 8 are also depressed linearly*** causing, upon each depression, the teeth 7 to engage the lower fixed set of teeth 2. Owing to the triangular formation of the teeth 7 and 2 this ***causes the ring 4 to be indexed in rotation***, (*see* Fig. 5) and upon return or release of the cap, the teeth 7 then engage the upper teeth 14a causing a further rotational movement of the ring 4." Ex. 1005 at 3:15-22 (emphasis added). The axial and rotational movement of the counter element (*i.e.*, ring 4) results in a change in the displayed number of remaining doses. "[T]he device counts down . . . [a]s the MDI is progressively used the available doses will count down eventually to zero indicating that the canister is empty." *Id*. at 3:6-11; Ex. 1002 ¶154.



See Ex. 1005 at Figs. 3 and 5 (annotated).

As described in §VIII.A.2.i.e, *Rhoades* discloses an element, cam body 20, which is displaceable axially and in rotation relative to said body. Ex. 1007 at 5:22-25. Thus, the mechanics of cam body 20 in *Rhoades* correspond directly to the mechanics of the claimed counter element. However, *Rhoades* does not teach that its cam body 20 is for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir. Ex. 1002 ¶155.

A POSA would have incorporated the *Rhoades* cam body above the *Bason* canister—the same location cam body 20 is located relative to the reservoir in *Rhoades* itself, and the same location that the *Bason* counter is currently located. He or she would also have included the numbers from the *Bason* rings on the *Rhoades* cam body to keep track of the dispensed doses. Ex. 1002 ¶156. The

inhaler body would have been the stationary body with stop members like guide member 28 in *Rhoades*. Finally, in such a combination, the *Rhoades* plunger with fingers 43 would have been depressed axially as it is in *Rhoades*, and as the cap is in *Bason*.

(f) **Claim 1: "**wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke."

Before actuation of the MDI in *Bason*, tooth 7 of ring 4 (counter element) is in cooperation with a first downwardly facing notch 14a of the central bush 15 (a stationary component of the counter). *See* Ex. 1005 at Figs. 3 and 5. When the cap is depressed axially (*i.e.*, an actuation stroke), canister C (fluid reservoir) is depressed. *Id*. at 1:50-52, 2:11-14; Ex. 1002 ¶157. Depression of the cap also causes ring 4 to be depressed axially, causing tooth 7 of ring 4 to contact the sloped face of tooth 2 to rotate ring 4. When the cap is released (*i.e.*, a return stroke), tooth 7 of ring 4 moves upward and engages the sloped face of a second, adjacent downwardly directed tooth 14a on the central bush 15 to further rotate ring 4. Ex. 1002 ¶157; Ex. 1005 at 3:20-26, Fig. 5.

In the event of an incomplete actuation stroke, tooth 7 of ring 4 will not slide all the way to the bottom right of tooth 2. Ex. 1002 ¶158. However, when tooth 7

slides most of the way to the bottom of tooth 2 (*i.e.*, an incomplete actuation stroke), to the point where the upper corner of tooth 7 is directly below the left edge of notch 14a, then tooth 7 will still catch in notch 14a upon release of the canister and will complete its rotation by nesting in notch 14a. Ex. 1002 ¶158. As such, the counter element will still complete a rotation after a predetermined incomplete actuation stroke has been performed and the number displayed in window 13 will change. *Id*. Thus, the dose indicator device (*i.e.*, ring 4 and corresponding indicia) is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke. *Id*.

Rhoades teaches this element. *See* §VIII.A.2.i.f.

For the reasons explained in §VIII.B.1, it would have been obvious for a POSA to combine the *Rhoades* mechanism with the *Bason* inhaler. A POSA would have understood that, in such a configuration, depression of the *Bason* cap would cause the necessary axial movement of the plunger with fingers 43 and 44 to actuate the counter element (just as depression of the *Rhoades* push button actuates the *Rhoades* mechanism). Ex. 1002 ¶160. Moreover, as explained in §VIII.B.1 above, a POSA could modify the teeth of the *Rhoades* cam body 20 to design an inhaler that did not require addition depressions to extend and retract the canister.

ii. Claim 2

(a) **Claim 2 Preamble**: "A dispenser according to claim 1,"

Bason in combination with *Rhoades* discloses a dispenser according to claim 1 as discussed above. Ex. 1002 ¶162.

(b) **Claim 2**: "wherein, during the return stroke of the dispenser after dispensing a dose, said dose indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke,"

Rhoades discloses that "during the return stroke of the dispenser after dispensing a dose, said dose indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke." *See* §VIII.A.2.ii.b.

(c) **Claim 2**: "said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to it rest position."

Rhoades discloses this element. *See* §VIII.A.2.ii.c.

As described in §VIII.B.1, a POSA would have combined *Bason* with *Rhoades* by incorporating the *Rhoades* mechanism into the *Bason* inhaler, with or without modifying the *Rhoades* cam faces. Ex. 1002 ¶165.

iii. Claim 3

(a) **Claim 3 Preamble**: "A dispenser according to claim 1,"

Bason in combination with *Rhoades* discloses a dispenser according to claim 1 as discussed above. Ex. 1002 ¶167.

(b) **Claim 3**: "in which said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20),"

Rhoades discloses that "said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20)." *See* §VIII.A.2.iii.b.

(c) **Claim 3**: "said counter element (20) including a second gear (230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser,"

Rhoades discloses that "said counter element (20) including a second gear (230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser." *See* §VIII.A.2.iii.c.

Just as *Elliott* expressly taught two separate gears, *see* §VIII.A.2.iii.c, *Bason* provides that same teaching here. *Bason's* ring 4 (counter element) includes teeth 7. Teeth 7 have a triangular portion projecting upward, and a triangular section projecting downward. Ex. 1002 ¶170. Teeth 7 are nothing more than two separate gears, directly on top of each other, pointing in opposite directions. *Id*. The upward facing portion of tooth 7 interacts with teeth 14a on the central bush; the downward facing portion of tooth 7 interacts with stationary tooth 2. *Id*.

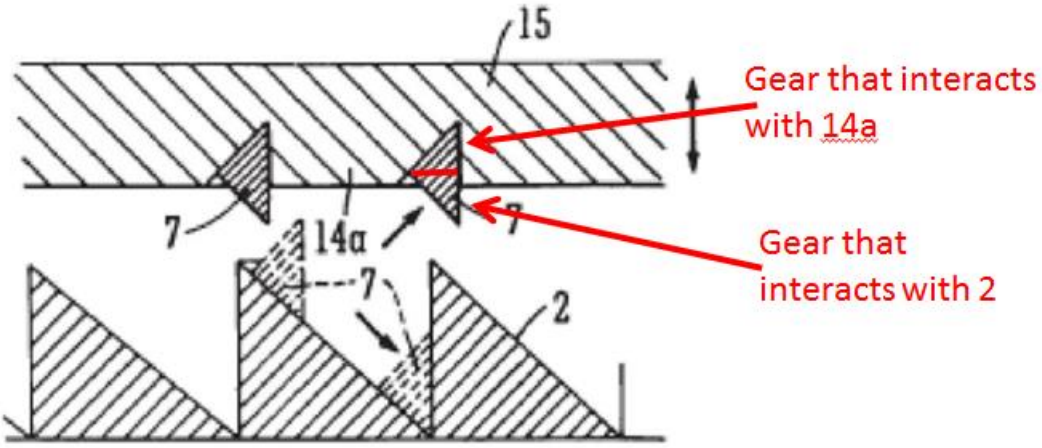


FIG. 5

Ex. 1005 at Fig. 5 (annotated). Although neither portion of tooth 7 in *Bason* interacts with an actuator gear, *Bason* would have taught a POSA, to the extent it is necessary, that a single component (rotational ring 4) can have two gears that interact with separate other components. Ex. 1002 ¶171.

(d) **Claim 3**: "the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation,"

Rhoades discloses that "the teeth of said second gear (230) and/or of said actuator gear (300) [are] made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation." *See* §VIII.A.2.iii.d.

(e) **Claim 3**: "the stationary gear (110) preventing said counter element (20) from turning until said counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser."

Rhoades discloses this element. *See* §VIII.A.2.iii.e.

As described in §VIII.B.1 above, a POSA would have combined *Bason* and *Rhoades* by wholly incorporating the *Rhoades* mechanism into the *Bason* inhaler with or without modifying the teeth. Ex. 1002 ¶174.

iv. Claim 9

(a) **Claim 9 Preamble**: "A dispenser according to claim 3,"

Bason in combination with *Rhoades* discloses a dispenser according to claim 1 as discussed above. Ex. 1002 ¶176.

(b) **Claim 9**: "in which, once the predetermined incomplete return stroke has been performed, the actuator member (30) is positioned facing the following tooth of the second gear (230) of the counter element (20), enabling the dispenser and the dose indicator device to be actuated once again."

Rhoades discloses that "once the predetermined incomplete return stroke has been performed, the actuator member (30) is positioned facing the following tooth of the second gear (230) of the counter element (20), enabling the dispenser and the dose indicator device to be actuated once again." *See* §VIII.A.2.iv.b.

As described in §VIII.B.1 above, a POSA would have combined *Bason* and *Rhoades* by wholly incorporating the *Rhoades* mechanism into the *Bason* inhaler. Ex. 1002 ¶178.

v. Claim 21

(a) **Claim 21 Preamble**: "A dispenser according to claim 1,"

Bason in combination with *Rhoades* discloses a dispenser according to claim 1 as discussed above. Ex. 1002 ¶180.

(b) **Claim 21**: "wherein the dispenser member is a pump or a valve."

Bason discloses a metered dose inhaler A including "a mouth piece B through which a user may inhale a drug dispensed from a canister C removably contained within the inhaler." Ex. 1005 at 2:12-14. A POSA would have understood that the canister used in the MDI described in *Bason* included a dispenser member that is a valve. Ex. 1004 at 1191, 1194; Ex. 1005 at 1:2-5, 2:11-15, Fig. 1; Ex. 1008 at 5:47-6:8, Figs. 1, 2; Ex. 1016 at 6-8; Ex. 1017 at 1:5-24, Figs. 1, 2; Ex. 1025 at 1:45-58; Ex. 1002 ¶181. A POSA would have wholly incorporated the *Rhoades* mechanism into the *Bason* inhaler. *See* §VIII.B.1.

IX. CONCLUSION

Petitioners respectfully request that IPR of the '177 patent be instituted and that the Challenged Claims be cancelled as unpatentable under 35 U.S.C. §318(b).

Respectfully submitted,

Date: May 10, 2018

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

Under the provisions of 37 C.F.R. §42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for *Inter Partes* Review totals 13,979, which is less than the 14,000 allowed under 37 C.F.R. §42.24(a)(i).

Respectfully submitted,

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CERTIFICATE OF SERVICE

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

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