

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

Aptar France S.A.S.,
Patent Owner

Case IPR2018-01055
Patent No. 9,370,631

**Patent Owner's Response to Petition for
Inter Partes Review of U.S. Patent No. 9,370,631**

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TABLE OF EXHIBITS

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| 2001 | Affidavit of Ryan A. Hargrave in Support of Motion for <i>Pro Hac Vice</i> Admission |
| 2002 | <i>Curriculum Vitae</i> of Ryan A. Hargrave |
| 2003 | Affidavit of Robert M. Manley in Support of Motion for <i>Pro Hac Vice</i> Admission |
| 2004 | <i>Curriculum Vitae</i> of Robert M. Manley |
| 2005 | Declaration of Charles E. Clemens in Support of Patent Owner's Preliminary Response |
| 2006 | <i>Curriculum Vitae</i> of Charles E. Clemens |
| 2007 | Petition for <i>Inter Partes</i> Review, Paper 1, IPR2018-01054 (May 10, 2018) |
| 2008 | Stein, S., <i>Advances in Metered Dose Inhaler Technology: Hardware Development</i> , 15 AAPS PHARMSCITECH 326, 330 (2014) |
| 2009 | Sander, N., et al., <i>Dose counting and the use of pressurized metered-dose inhalers: running on empty</i> , 97 ANNALS OF ALLERGY, ASTHMA & IMMUNOLOGY 34 (2006) |
| 2010 | Stuart, A., <i>More Than Just a Dose Counter</i> , 46 INNOVATIONS IN PHARMACEUTICAL TECHNOLOGY 40 |
| 2011 | Henry, A.R., <i>The Role of Statistical Tolerance Analysis Tools in Dose Counter Optimization</i> , available at http://multimedia.3m.com/mws/media/1159495O/statistical-tolerance-analysis-tools-in-dose-counters.pdf |
| 2012 | Declaration of Ryan A. Hargrave in Support of Corrected Motion for <i>Pro Hac Vice</i> Admission |
| 2013 | Declaration of Robert M. Manley in Support of Corrected Motion for <i>Pro Hac Vice</i> Admission |
| 2014 | Declaration of Benjamin G. Murray in Support of Motion for <i>Pro Hac Vice</i> Admission |
| 2015 | <i>Curriculum Vitae</i> of Benjamin G. Murray |
| 2016 | Stein, S. et al., <i>The History of Therapeutic Aerosols: A Chronical Review</i> , available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278812/ |
| 2017 | Newman, S., <i>Principles of Metered-Dose Inhaler Design</i> , 50 Respiratory Care 1177 (2005) |

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| 2018 | Malloy, R., <i>Plastic Part Design for Injection Molding</i> , , pgs. 88, 99, Hanser Pub. (1994) |
| 2019 | The Kids Should See This, available at https://thekidshouldseethis.com/post/how-does-a-retractable-ballpoint-click-pen-work |
| 2020 | Deposition Transcript of Samuel David Piper, taken January 25, 2019 |
| 2021 | Declaration of Charles E. Clemens in Support of Patent Owner's Response |

I. INTRODUCTION

On November 8, 2018, the Patent Trial and Appeal Board (“Board”) instituted *inter partes* review of claims 1-4 (the “Asserted Claims”) of U.S. Patent No. 9,370,631 (the “’631 Patent”) (Ex. 1001) at the request of Petitioners 3M Company, Merck & Co., Inc, and Merck Sharp & Dohme Corp. (collectively, “Petitioners”). Patent Owner, Aptar France S.A.S. and AptarGroup, Inc. (collectively, “Aptar” or “Patent Owner”) respectfully disagrees with Petitioners’ arguments and the Board’s decision.¹ As explained below, the claims of the ’631 Patent are not anticipated or rendered obvious by the cited references, and the patentability of these claims should be confirmed.

A. State of the Art at the Time of the Invention

Since it was first conceived of in 1955, the metered dose inhaler (“MDI”) has become one of the most commonly used forms of delivering therapeutic aerosols. Ex. 2016 at 27. As the use of MDIs has continued to grow, however, so too has the need to identify and implement ways of improving the overall safety, accuracy, and reliability of this lifesaving technology. *Id.* at 31-32

One such improvement is a reliable means of accurately indicating the number of doses of medication that have been dispensed or that have yet to be

¹ Decision Instituting *Inter Partes Review* (Nov. 8, 2018) (Paper 11) (the “Decision”).

dispensed from the inhaler. *Id.* at 32. In response to the industry’s increased adoption of MDIs, regulations eventually came to require that MDIs include more medicine than is necessary for expelling the labeled number of doses in a given canister. *See* Ex. 1013 at 5. While these prophylactic measures attempted to ensure users would not run out of medicine before the MDI reached “zero” doses, MDI users still had no reliable way of knowing how many doses remained in their inhalers. *See* Ex. 1013 at 5. After first publicly acknowledging this problem in preliminary guidance to MDI manufacturers in early 2001, in 2003 the Food and Drug Administration (“FDA”) officially recommended that going forward, accurate dose counting should be incorporated into all MDIs. Ex. 1012; Ex. 1013.

Specifically, the FDA advised manufacturers that MDIs should include mechanisms capable of providing “a clear indication of when an MDI is approaching the end of its recommended number of actuations as well as when it has reached or exceeded that number.” *Id.* at 6. The FDA expressed that “[d]ose counters should be engineered to reliably track actuations and should be designed to be as close to 100 percent reliable as possible.” Ex. 1013 at 3. Importantly, however, to the extent that error is unavoidable, the FDA cautioned that “the device should be designed to specifically avoid undercounting (i.e., the MDI sprays, but the counter does not advance).” *Id.* Namely, “[u]ndercounting could

result in patients assuming they have medication left in their MDI when they do not, a circumstance that is potentially dangerous.” *Id.*

B. Background of the Invention

Aptar set out to answer the FDA’s call. In late 2001, following the release of the FDA’s preliminary guidance, Aptar began development of a dose counter that would solve the chronic issue of MDI dosage undercounting. Two years later, Aptar came forward with just that: a “fluid dispenser including a dose indicator device that prevents any risk of under-counting, i.e. that guarantees that the indicator device is actuated each time fluid is dispensed by the fluid dispenser.” Ex. 1001 at 1:67-2:3.

Aptar filed a French patent application describing its innovative technology on May 15, 2003 as French Application No. 03/05858. A corresponding PCT application was filed on May 14, 2004 as Application No. PCT/FR2004/001189, which entered National Stage on November 9, 2005. The corresponding United States Application No. 10/556,432 issued as U.S. Patent No. 8,936,177 (“the ’177 Patent”) on Jan. 20, 2015. Aptar then filed a continuation of the ’177 Patent on October 9, 2014, which issued as the ’631 Patent on June 21, 2016.

II. LEVEL OF ORDINARY SKILL IN THE ART

Petitioners assert that a POSA 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.” Petition at 15. Aptar disagrees that Petitioners’ proposed level of skill in the art reflects the education, training, and experience required to qualify as a POSA. However, for purposes of this Response, the Board need not resolve this dispute to find that the claims are patentable over the asserted prior art.

III. RESPONSE TO CLAIM CONSTRUCTIONS OF THE ’631 PATENT CLAIM TERMS

In an inter partes review, “[a] claim in an unexpired patent shall be given its broadest reasonable construction in light of the specification of the patent in which it appears.” 37 C.F.R. § 42.100(b); see also *Cuozzo Speed Tech., LLC v. Lee*, 136 S. Ct. 2131, 2144–2145 (2016).² Claim terms are therefore presumed to have their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *In re Translogic Tech., Inc.*, 504

² The revised claim construction standard for interpreting claims in inter partes review proceedings as set forth in the final rule published October 11, 2018, does not apply to this proceeding, because the new “rule is effective on November 13, 2018 and applies to all IPR, PGR and CBM petitions filed on or after the effective date.” Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51340 (Nov. 13, 2018) (to be codified at 37 C.F.R. pt. 42).

F.3d 1249, 1257 (Fed. Cir. 2007). Here, there are no claim terms that require construction for purposes of the Board’s analysis of the patentability of the claims. *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed to the extent necessary to resolve the controversy.”).

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

Petitioners ask the Board to construe the term “stationary body comprising at least one multi-toothed gear.” Petition at 13. Aptar disagrees that Petitioners’ proposed construction for this term reflects its broadest reasonable construction. Specifically, Aptar disagrees that, in view of the file history and specification, a stationary body must include a stationary gear “as a unitary or monolithic part of the stationary body.” *Id.* However, the Board need not resolve this dispute to determine that the claims are patentable, as none of Aptar’s positions or arguments relate to whether or not the prior art references disclose a stationary gear that is unitary or monolithic to the stationary body. *Wellman*, 642 F.3d at 1361. Therefore, the Board should reject Petitioners’ proposed construction for the stationary body term.

B. “disposed on”

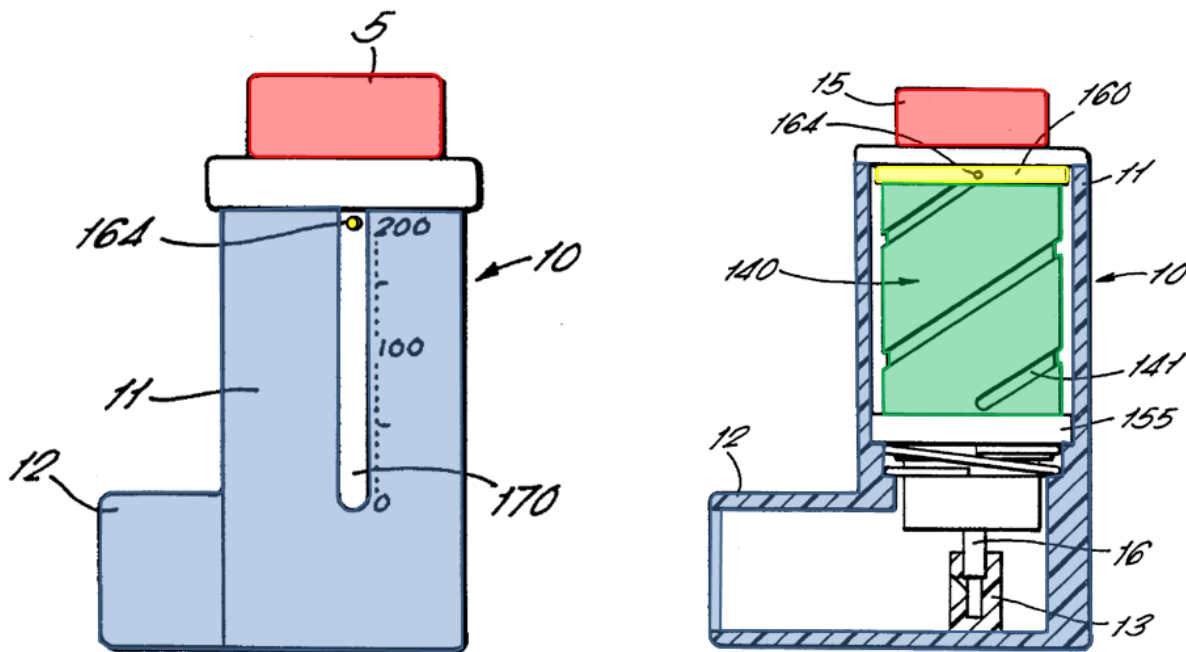
Petitioners propose that the term “disposed on” should encompass scenarios where “two components are either in direct or indirect contact with each other.”

Petition at 14. As with “stationary body,” the Board need not construe this term to find the claims of the ’631 Patent patentable because none of Aptar’s distinctions over the prior art relate to this claim element. *See Wellman*, 642 F.3d at 1361.

IV. GROUND 1: ALLSOP DOES NOT ANTICIPATE CLAIMS 1-4 OF THE ’631 PATENT

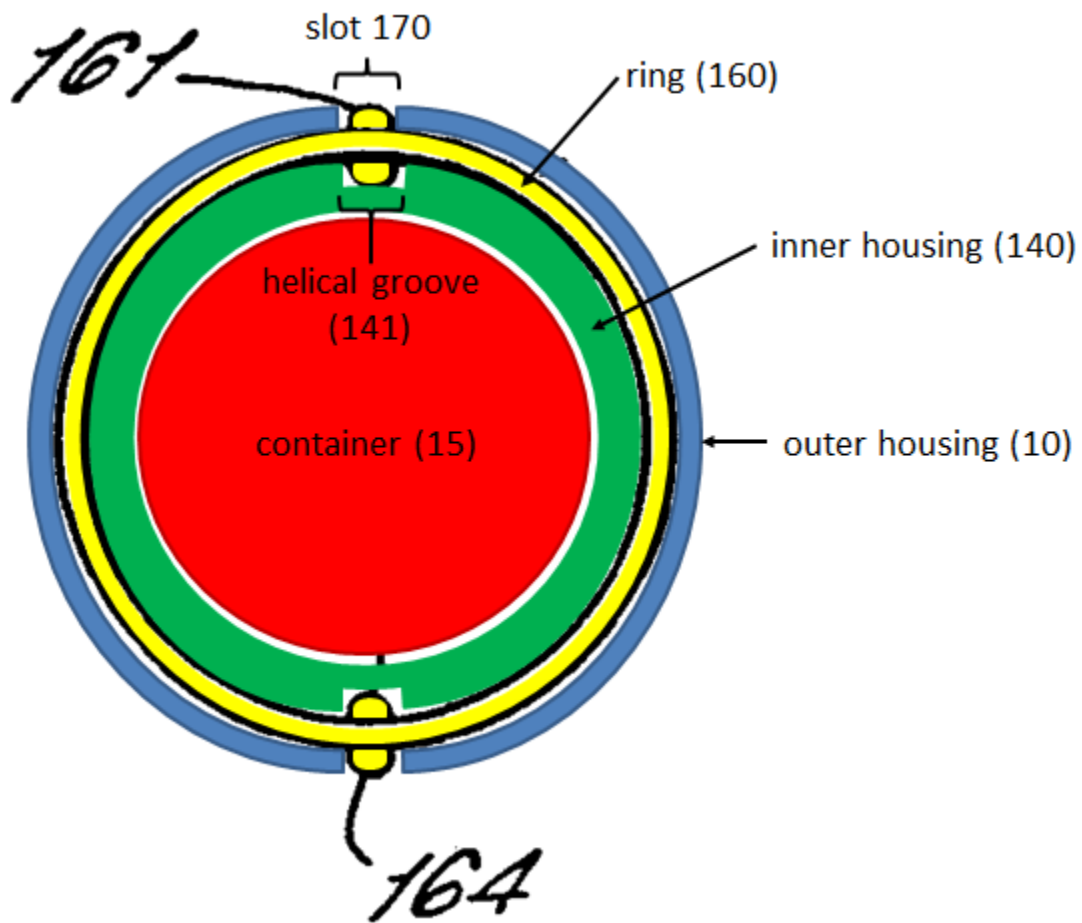
A. Introduction to Allsop, WO 00/59806 (Ex. 1006).

Allsop discloses a device, such as an inhaler, having a dose indicator. Ex. 1006, 4:20-29. As shown below, the device has several components, including an outer housing 10 (in blue), an inner housing 140 (in green), a pressurized container 15 (in red), and a ring 160 with pins 161 and 162 (in yellow).



Id. at Figs 1, 13 (annotated); Ex. 2021 at ¶16.

As shown both above and in the top-down view below, ring 160 (in yellow) sits between inner housing 140 (in green) and outer housing 10 (in blue). The ring's inner pins 162 extend into the helical groove 141. Ex. 1006 at 6:6-14. Similarly, the outer pins 161 extend into slot 170 of the outer housing 10 (in blue). *Id.*



Id. at Fig. 7 (annotated); Ex. 2021 at ¶17.

The dose counter operates by a user depressing the canister 15 directly, which cause the inner housing 140 to rotate on its axis. Ex. 1006 at 9:3-11. As a

result, ring 160 is moves downwards as guided by pins 161 and 162, which sit within helical groove 141 and slot 170, respectively. *Id.* at 9:12-17. Dosage markings 172 run along slot 170 so that as pin 161 descends along slot 170, it shows the remaining doses left in the container 15. *Id.*

B. Allsop Does Not Anticipate the '631 Patent.

Allsop does not teach all of the limitations of the claims of the '631 Patent. First, Allsop does not adequately enable the push button cap alleged to be the claimed “first member.” And even if it was enabled, the push button cap is not axially displaceable as required by the claims. Second, Allsop does not disclose a second member engageable with the push button cap as claimed in the '631 Patent. Finally, Allsop does not disclose the recited changing of a displayed dose value. For each of these reasons, Allsop does not anticipate the claims of the '631 Patent.

1. Claims 1 and 3: Allsop does not anticipate a “first member that is displaceable axially relative to [a] stationary body.”

a. The push-button cap is not enabled.

Petitioners argue that Allsop anticipates this element because Allsop discloses a “push-button cap.” Petition at 37. However, Allsop’s push-button cap is not enabled, so it cannot anticipate the “first member” claim element.

“Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366

(Fed.Cir.1997). To be considered an anticipating reference, prior art “must enable that which it is asserted to anticipate.” *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003); *see also Bristol-Myers Squibb v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) (“To anticipate the reference must also enable one of skill in the art to make and use the claimed invention.”). “It is insufficient to name or describe the desired subject matter, if it cannot be produced without undue experimentation.” *Elan*, 346 F.3d at 1055. And, importantly, “when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required.” *Auto. Techs. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1283-84 (Fed. Cir. 2007).

Here, Allsop’s specification is silent as to how the push-button cap operates. There are no diagrams, images, or schematics of the push-button cap. Nor does Allsop describe the structural design of the push-button cap or explain how it interconnects and interacts with Allsop’s other components. Rather, the only information provided about the push-button cap is that it may “cover” the container to “prevent[] the ingress of dust, contaminants and moisture into the apparatus.” Ex. 1006 at 8:22-26. Such a dearth of description fails to confer the “reasonable detail” necessary to show how the push-button cap is made and used in the invention, including whether it is axially displaceable as required by the claims.

Genentech, 108 F.3d at 1366. As such, a POSA could not produce the push-button cap in Allsop without undue experimentation. *Auto. Techs.*, 501 F.3d at 1283-84.

Petitioners argue that “a POSA would have understood that the [push-button cap] could be depressed axially, moving the canister axially.” Petition at 37. The push button cap cannot work this way as described below in Section IV(B)(1)(b), But even if it did, Petitioners’ argument is nevertheless unpersuasive because “[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.” *Genentech*, 108 F.3d at 1366. The novel aspect of Allsop’s invention is using an indicator device that operates by “actuation of the pressured container” as a means of “measuring the quantity of product remaining in [the] pressurized container.” Ex. 1006 at 2:20-29. Allsop does not disclose anything about the structure or operation of the push-button cap, including how it would move axially and interact with Allsop’s other components as required to operate the indicator device. Petitioners and their expert ignore this fundamental lack of description and assume, without evidence, that “a POSA would have understood” that the push-button cap is axially depressible. Petition at 37. Because conclusory assumptions about what a POSA “would have understood” cannot fill the gap left by a patent’s insufficient

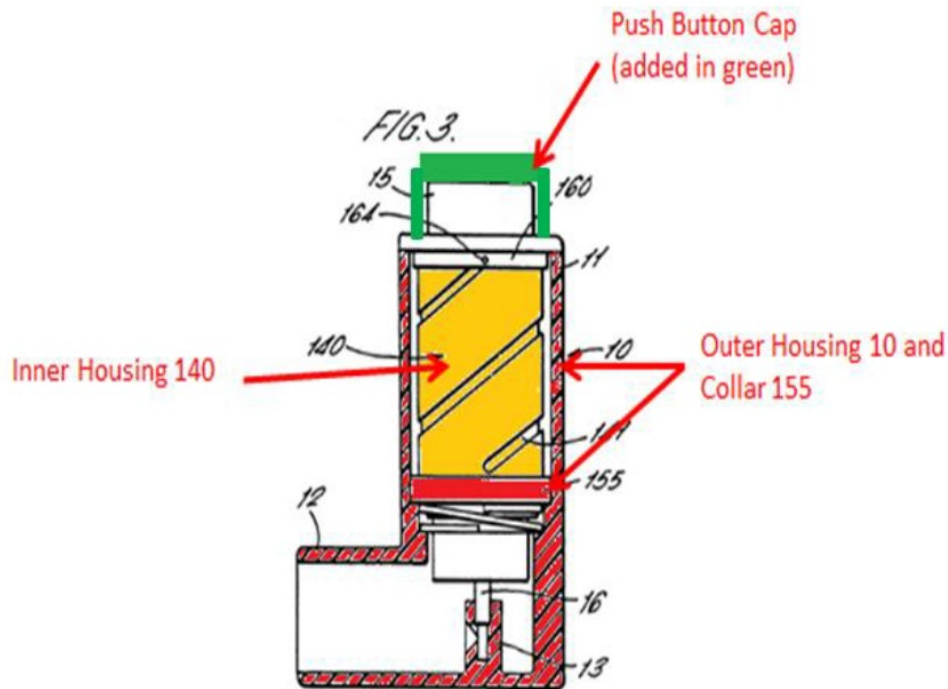
disclosure, Petitioners' arguments fail to satisfy the enablement requirement.³ *See Auto. Techs.*, 501 F.3d at 1283-84.; *Genentech*, 108 F.3d at 1366.

Accordingly, Allsop's push-button cap is not enabled, and so it cannot anticipate the "first member" claim element.

b. Allsop does not disclose axial displacement of the first member relative to a stationary body.

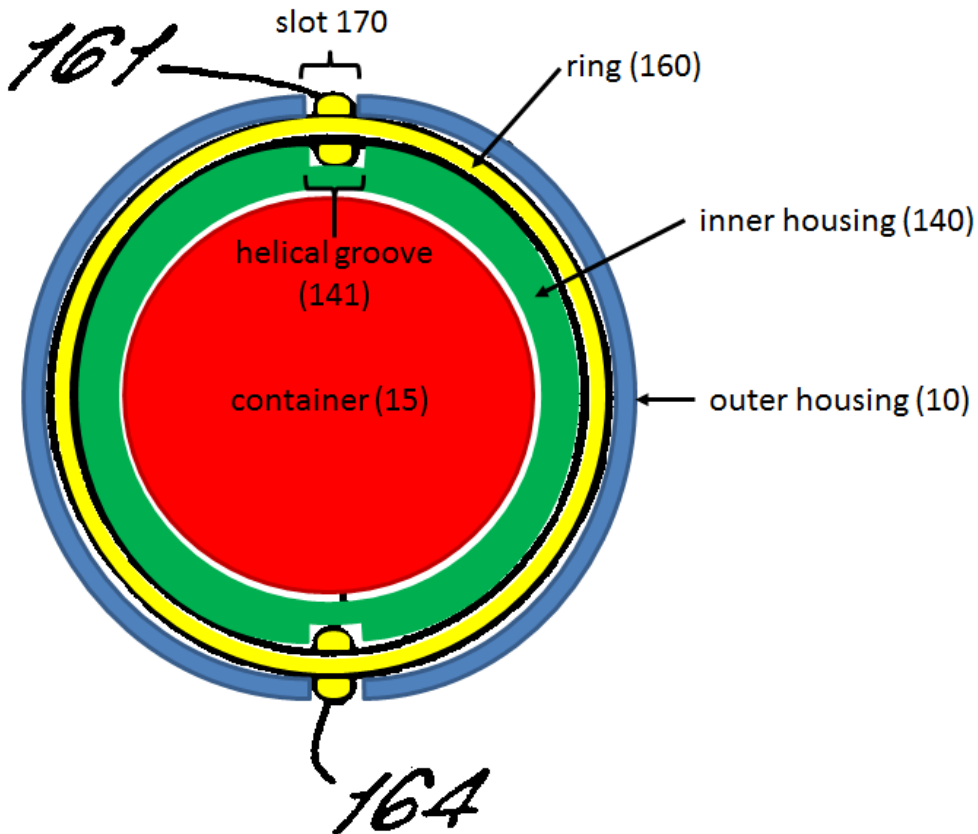
Even if Allsop's push-button cap were enabled, Allsop fails to anticipate this claim element because the push button cap is not axially displaceable relative to a stationary body as required by the claims. Petitioners suggest that Allsop's push-button cap could be designed as depicted below:

³ To the extent that Petitioners argue in their Reply that the use of push-button caps is well-known in the art, this argument still fails because "the rule that a specification need not disclose what is well known in the art is merely a rule of supplementation, not a substitute for a basic enabling disclosure." *Auto. Techs.*, 501 F.3d at 1283 (citation omitted) (internal quotation omitted).



Petition at 37.

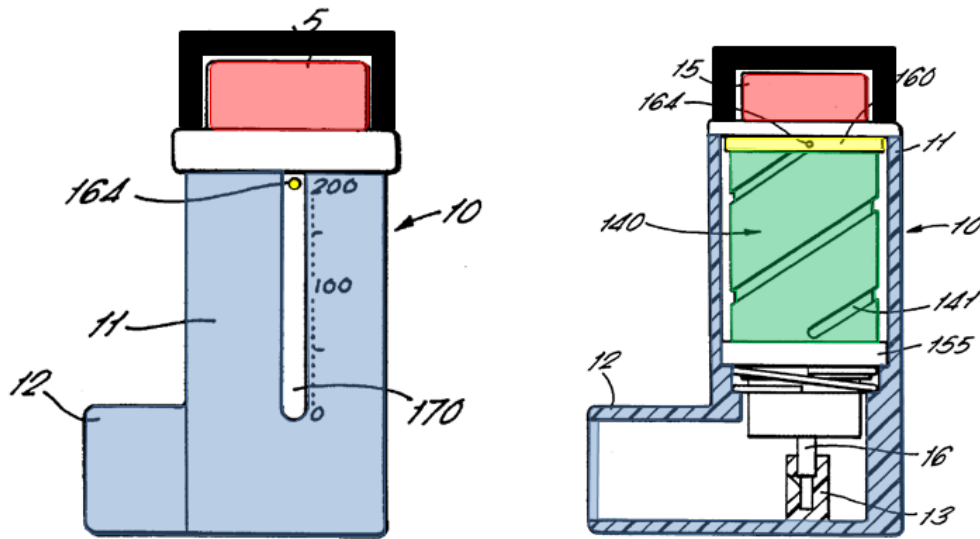
The cap (in green) has sides that appear to recess into the device between the outer housing 10 (in red) and the inner housing 141 (in yellow). As shown in the top-down view of Allsop below, the cap as described by Petitioners must be located somewhere between the inner housing (in green) and outer housing (in blue):



Ex 1006 at Fig. 7 (annotated); Ex. 2021 at ¶17.

But this is not possible. If the push-button cap were to recess into the device as shown above, then the sides of the cap would hit ring 160 and its pins 161 and 162. Ex. 2021 at ¶17-18, 32. This would either (1) prevent the cap from being depressed, or (2) cause the pins to move downward, which would result in indicating an inaccurate number of remaining doses. *Id.* Petitioners completely ignore this problem, despite the fact that proper function of the ring and pins is critical to the operability of the Allsop device. The cap as described by Petitioners will therefore interfere with the ring and the display of remaining doses, and render

Allsop inoperable. *Id.* at ¶¶31-33. This modification to Allsop cannot be correct, and therefore cannot anticipate this claim element. *See, e.g.*, MPEP 2143.01(V); *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (holding that Petitioner failed to establish obviousness because the suggested modifications rendered the prior art “inoperable for its intended purpose.”)



Ex. 1006 at Figs. 1, 3 (annotated); Clemens Decl. (Ex. 2021) at ¶34.

Allsop’s specification is, at best, silent as to Petitioners’ argument that the push button cap moves axially and, at worst, contradicts it. Allsop says nothing about the push button cap moving at all. It simply says that the cap may “cover” the container to “prevent[] the ingress of dust, contaminants and moisture into the apparatus.” *Id.* at 8:22-26. This is no different than Allsop’s “mouthpiece cover,” which “protect[s] the mouthpiece 12 from dust, dirt or other matter.” *Id.* at 4:28-

31; Ex. 2021 at ¶30. And Allsop's mouthpiece cover does not move axially. Ex. 2021 at ¶30. Thus, that a device includes a cap or cover used to prevent contamination is no guarantee that a POSA would understand the cap moves axially.

Finally, Allsop expressly teaches that the push-button cap may be added as "part of" the housing 10. Ex. 1006 at 8:22-23. But the push-button cap cannot be both "part of" the housing 10 and axially displaceable relative to that same housing 10. Ex. 2021 at ¶30. Thus, Allsop itself teaches away from Petitioners' rendering of the cap, and so the "first member" claim element is not anticipated by Allsop.

2. Claims 1 and 3: Allsop does not anticipate a "second member being engageable with said first member and said stationary body."

This claim element is not met by Allsop because the alleged second member (i.e., the inner housing) is not engageable with the first member (i.e., the push button cap) as required by these claims

As a preliminary matter, the push-button cap does not anticipate or otherwise function as the claimed first member because it is not enabled. *See, supra*, Section IV(B)(1)(a). Moreover, even if the push-button cap was enabled and a separate component from the housing 10, Allsop fails to anticipate this element as noted above in Section IV(B)(1)(b).

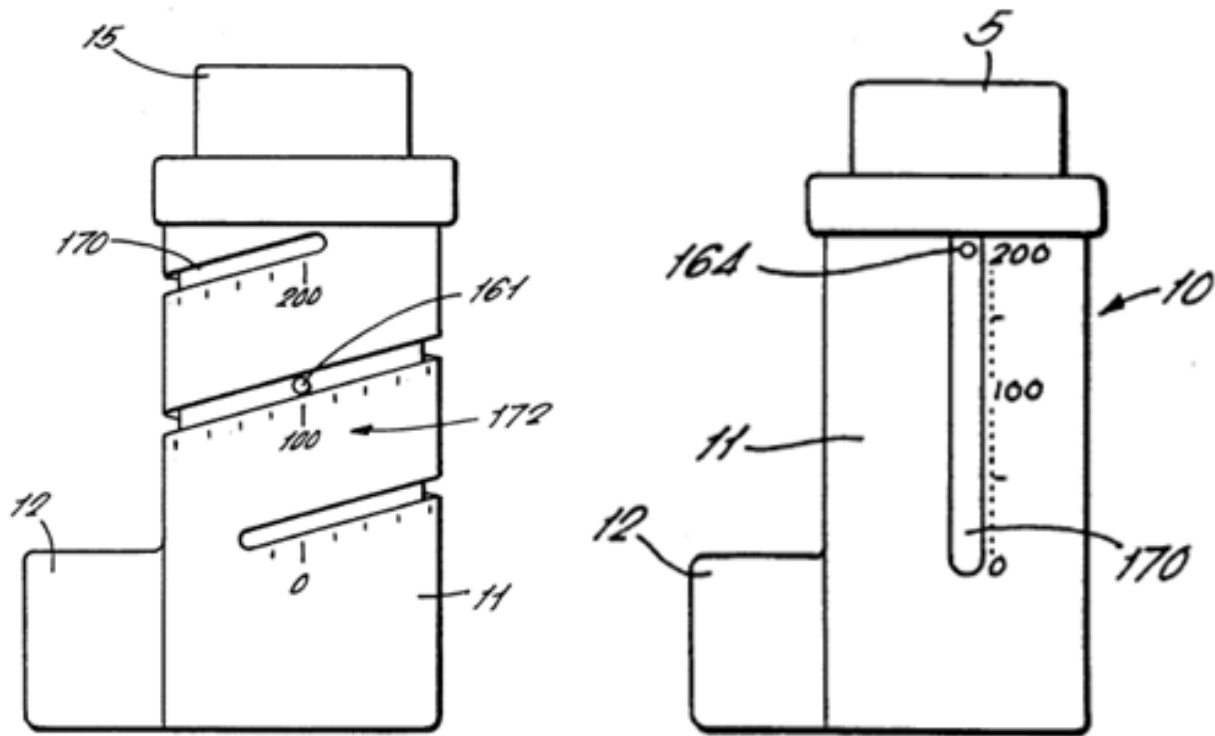
Lastly, Allsop does not disclose a first member (the alleged push button cap) that is engageable with a second member (the inner housing). Petitioners summarily state that the push-button cap engages with the inner housing, but they make no effort to explain *how* the engagement is achieved. Petition at 38. This is insufficient to prove anticipation. *See, e.g., Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315–16 (Fed. Cir. 2002) (“Typically, testimony concerning anticipation must be testimony from one skilled in the art and must identify each claim element, state the witnesses' interpretation of the claim element, and explain *in detail how* each claim element is disclosed in the prior art reference. The testimony is insufficient if it is merely conclusory.”) (emphasis added); *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1152 (Fed. Cir. 2004) (General and conclusory testimony . . . does not suffice as substantial evidence of invalidity.”). Even assuming, however, that Petitioners had provided the requisite explanation, the push-button cap does not engage with the inner housing. Rather, it interferes with it by pressing the ring 160 and pins 161, 162 such that the device no longer accurately indicates the doses remaining in the device. *See supra*, Section IV(B)(1)(b). This element is therefore not anticipated by Allsop.

3. **Claims 1 and 3: Allsop does not anticipate that when a “first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed**

dose value from among the plurality of displayable dose values.”

This claim element is not anticipated for two reasons. First, Allsop does not anticipate a “first member [that] displaces axially” for the reasons noted above in Section IV(B)(1). Second, Allsop does not anticipate the “chang[ing] a displayed dose value . . .” portion of this claim element.

The “chang[ing] a displayed dose value . . .” element requires changing a “*displayed* dose value from among the plurality of *displayable* dose values” such that only one value is visible at a time. *See* Ex. 1001 at 10: 12-17, 38-42 (emphasis added). The claim, therefore, distinguishes between doses that are displayable at all times (as in Allsop), and doses that are displayed to the patient one at a time (as in the ’631 Patent claims). *See* Ex. 2021 at ¶¶35-36. For example, Allsop discloses a means of indicating a single dose value from among a series of dose values that are *always displayed* on the exterior of the inhaler housing. *See* Ex. 1006 at 8:27-29.



Id. at Figs. 1, 13; Ex. 2021 at ¶35.

In contrast, the '631 Patent requires changing a displayed value from among a plurality of displayable dose values. Ex. 1001 at 10:15-17, 40-42. Accordingly, Allsop does not anticipate changing a “displayed” dose value from among “displayable” dose values because Allsop teaches that the entire plurality of its dose values is permanently on display. *Id.* at 8:27-29 (“Markings 172 are printed or embossed on an exterior surface of the housing 10 adjacent the slots 170.”); Ex. 2021 at ¶¶35-36. As a result, this element is not anticipated by Allsop.

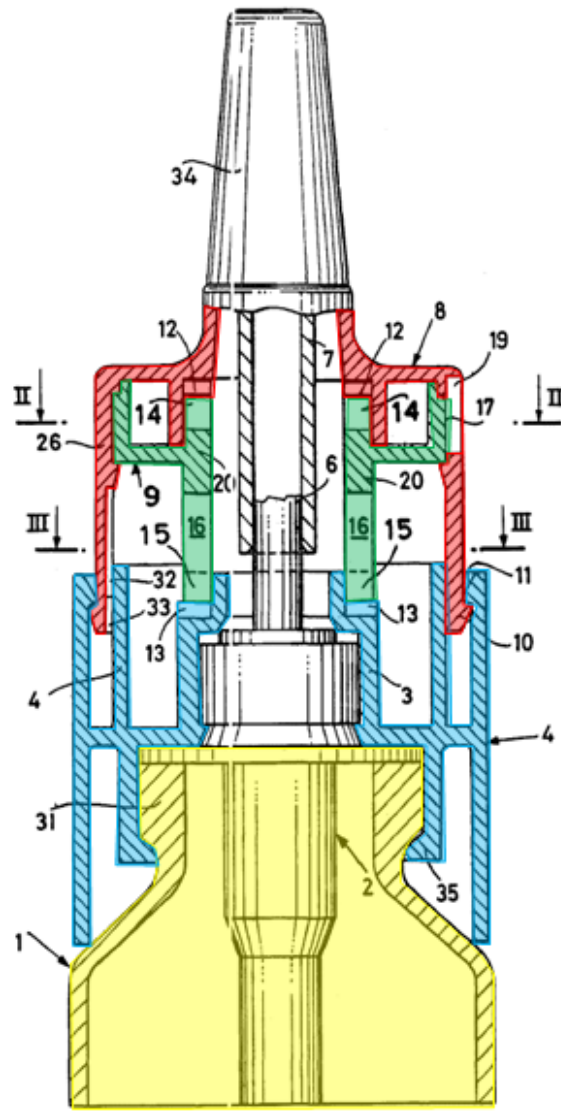
4. Claims 2 and 4: Allsop does not anticipate all elements of these dependent claims.

Because Allsop does not teach or disclose the limitations of independent claims 1 and 3, it does not anticipate dependent claims 2 and 4 for these same reasons.

V. GROUND 2: MARELLI DOES NOT ANTICIPATE CLAIMS 1-4 OF THE '631 PATENT

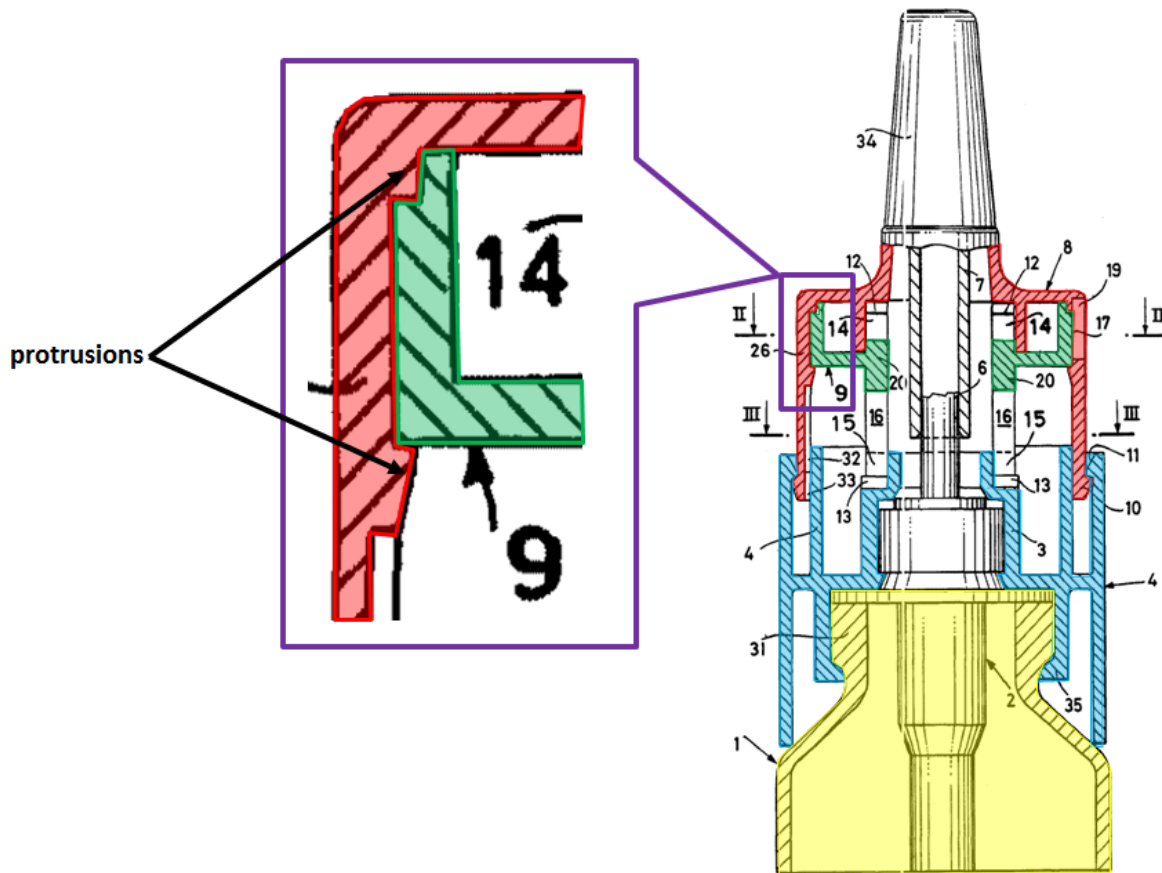
A. Introduction to Marelli, EP 0480488 (Ex. 1008).

Marelli describes a “dose counting device” for “nasal distributors.” Ex. 1008, 1:3-7. A cross-section of the invention is shown is below:



Id. at Fig. 1 (annotated); Ex. 2021 at ¶19.

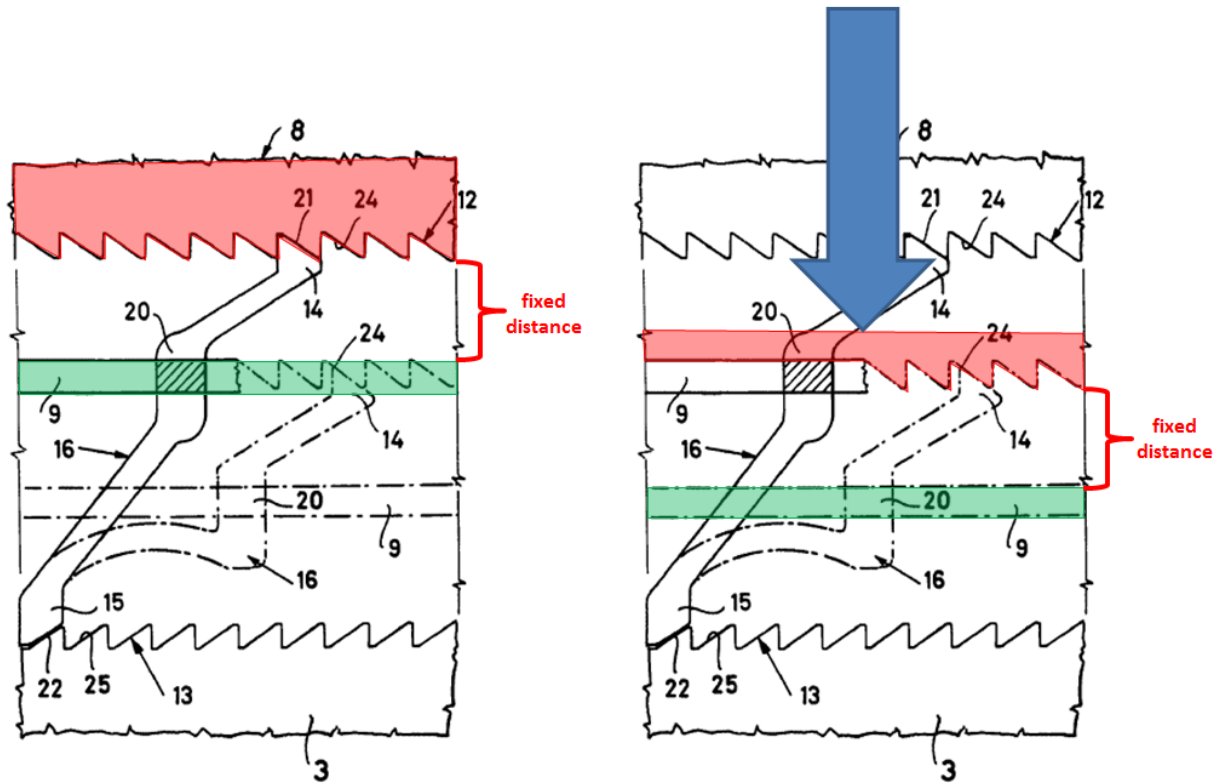
The Marelli device includes a nasal 8 (in red), a rotating element 9 (in green), a ring nut 4 (in blue), and container 1 (in yellow). A user depresses nasal 8 down inside ring nut 4. Ex. 1008 at 4:26-38. Fluid is then expelled from container 1 where it travels up to protrusion 34 and is subsequently delivered into a user's nostril. *Id.* at 3:9-25, 34-38.



Id. at Fig. 1 (annotated); Ex. 2021 at ¶40.

The device counts doses through rotating element 9. When a user depresses nasal 8, rotating element 9 is also depressed because it is retained within nasal 8 by the protrusions shown in the diagram above. *See* Ex. 2021 at ¶20. Importantly, however, the nasal 8 (shown below in red) is a fixed distance away from rotating element 9 (shown below in green). *Id.* And because of nasal 8's protrusions, when the user depresses the device (shown with the blue arrow), the nasal 8 and rotating element 9 move together such that the fixed distance between the two is always maintained. *Id.* at ¶40-41. Depression and release of the nasal 8 causes flexible

legs 16 to interact with the teeth 12 on nasal 8 and with teeth 13 on ring nut 4 to cause rotating element 9 to rotate and progress to the next dose value. Ex. 1008 at 4:22-48.



Id. at Fig 4 (annotated); Ex. 2021 at ¶41.

B. Marelli does not anticipate the '631 Patent.

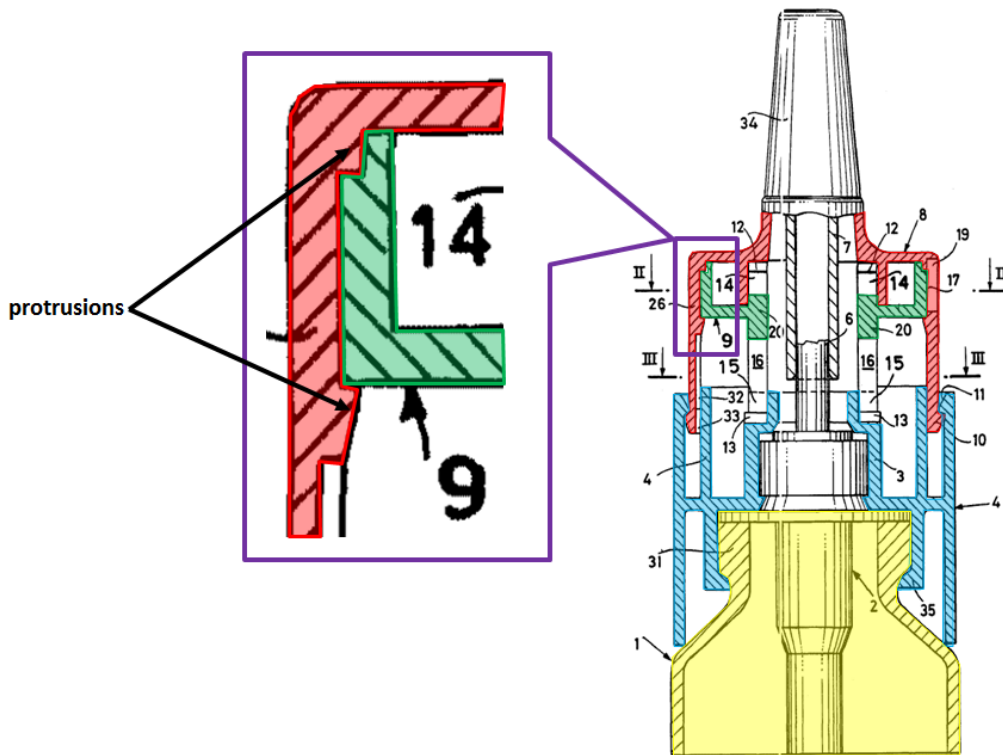
Marelli does not teach all of the limitations of the claims of the '631 Patent. Namely, the “second member” element is not present in Marelli. This is because Marelli’s rotating element 9 does not move axially “relative to” the nasal 8. Rather, the spacing between these two components is always maintained at the same fixed distance. Accordingly, because been attempted

Marelli fails to disclose the limitation of the '631 Patent of a “second member” that is axially displaceable with respect to a “stationary body”, Marelli does not anticipate the claims of the '631 Patent.

1. Claims 1 and 3: Marelli does not disclose “a second member that is displaceable axially and in rotation relative to said stationary body.”

This element is not anticipated by Marelli because Marelli’s “rotating element 9” does not move axially relative to the nasal 8 (Petitioners’ proposed stationary body). Petition at 46-47.

Petitioners identify Marelli’s nasal 8 as the claimed stationary body. Petition at 46 (“[N]asal 8 remains stationary.”). For rotating element 9 to meet the second member limitation, it must displace axially and in rotation relative to nasal 8. Ex. 1001 at 10:2-24, 26-49. This does not occur. Instead, both rotating element 9 and nasal 8 move (or stay stationary) together as one piece because of the protrusions as shown below:



Ex 1008 at Fig. 1 (annotated); Ex. 2021 at ¶40.

More specifically, rotating element 9 sits in a channel within nasal 8, affixed between two protrusions on nasal 8's interior. Ex. 1008 at 3:45-52, Fig. 1; *see also* Ex. 2019 at 122:6-125:12. If nasal 8 is stationary as Petitioners assert, then rotating element is likewise stationary due to the protrusions holding it in place. *See* Ex. 2021 at ¶40. Petitioners' expert admitted as much in his deposition. *See* Ex. 2019 at 122:6-125:12. In sum, the rotating element 9 cannot move up or down inside the nasal 8's channel. Accordingly, Marelli does not disclose a second member that is "displaceable axially" relative to a stationary body because the spacing between rotating element 9 and the nasal 8 is always maintained at the same distance.

2. Claims 1 and 3: Marelli does not disclose that when a “first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values.”

Marelli does not anticipate this element because it does not disclose a second member that “is caused to be displaced axially and permitted to rotate relative to said stationary body” for the reasons as provided in Section V(B)(1).

3. Marelli does not anticipate claims 2 and 4.

Because Marelli does not teach or disclose the limitations of independent claims 1 and 3, it does not anticipate dependent claims 2 and 4 for these same reasons. *See supra* Section V(B)(1)-(2).

VI. GROUND 3: CLAIMS 1-4 OF THE ‘631 PATENT ARE NOT OBVIOUS UNDER 35 U.S.C. § 103 OVER BASON IN VIEW OF RHOADES

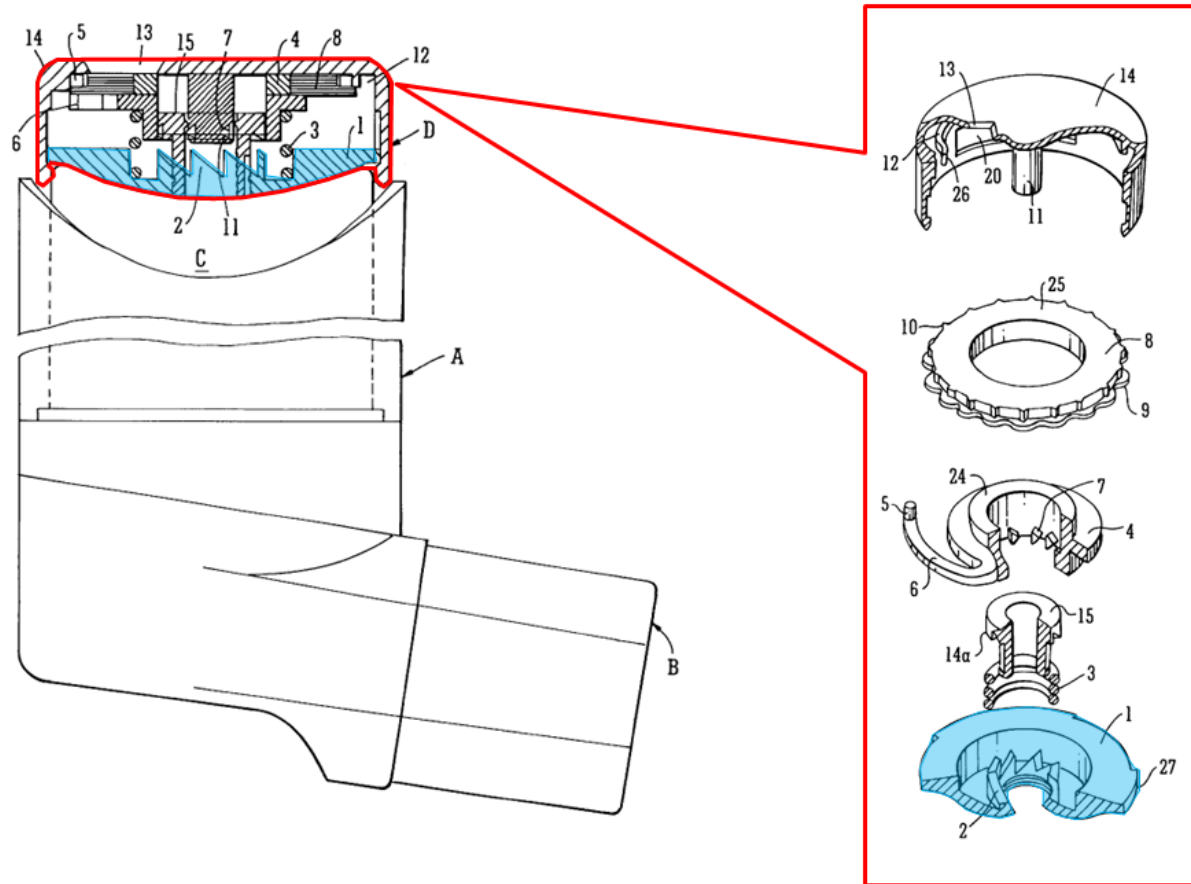
Petitioners argue that claims 1-4 of the ’631 Patent are obvious over Bason in view of Rhoades. A patent is obvious under 35 U.S.C. § 103 only if the differences between the prior art and the patented subject matter are so few that the latter would have been obvious to a POSA at the time of invention. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-407 (2007). Whether a patent is obvious is determined by (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the art, and (4) any other secondary considerations which give context to the circumstances giving rise to the patented subject matter, such as long felt but

unsolved needs, and commercial licensing success. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

It would not have been obvious for a POSA to modify Bason in view of Rhoades because (1) Petitioners' suggested modifications would render Bason inoperable for its intended purpose, (2) the combination fails to disclose each and every claim limitation of the '631 Patent, and (3) there would have been no motivation to combine Bason with Rhoades.

A. Introduction to Bason, U.S. Patent No. 6,283,365 (Ex. 1007).

Bason discloses an indicator device “adapted to serve as a dose counter for [MDIs].” Ex. 1007, 1:3-5, 2:16-19. As shown below, the Bason dose counter has five main components: base 1 (in blue), central bush 15, rings 4 and 8, and cap 14.



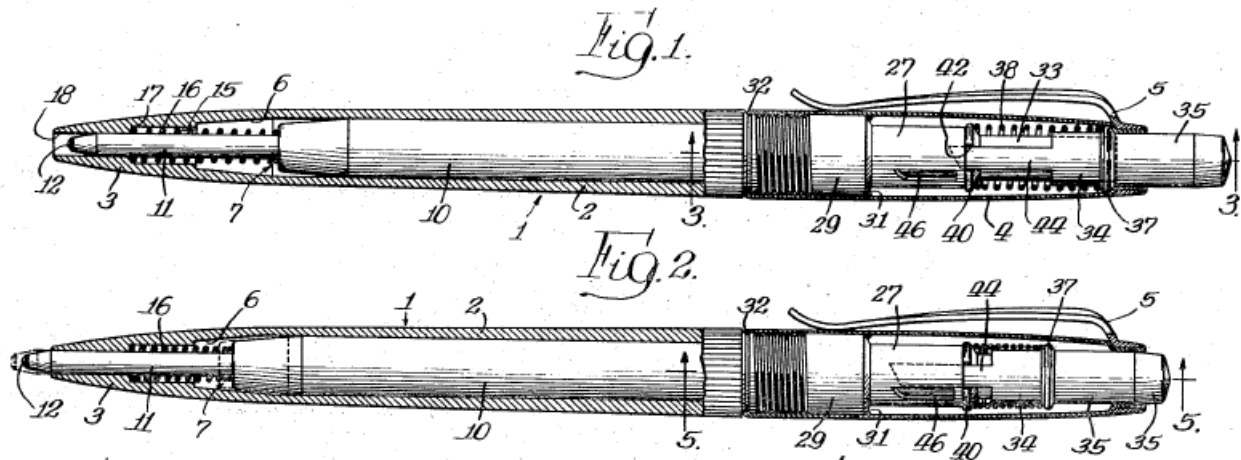
Id. at Figs. 1, 3 (annotated); Ex. 2021 at ¶22.

Depression of the cap 14 into the inhaler housing actuates the dose counter by causing rings 4 and 8 to be depressed, which causes teeth 7 of ring 4 to engage with the “fixed” teeth 2 on the base 1, urging ring 4 to rotate. Ex. 1007 at 3:15-22; Ex. 2021 at ¶23. It is critical that the base 1 of the dose counter D is “bonded” to the canister because this allows teeth 2 and teeth 14a (of base 1 and bush 15, respectively) to maintain a “fixed position” throughout the activation of the inhaler. Ex. 1007 at 2:16-23; Ex. 2021 at ¶24. The ring 4 will not begin rotation unless it is depressed so that teeth 7 slide against the surface of the “fixed” teeth 2

on the base 1. Ex. 1007 at 3:15-22. Teeth 7 of ring 4 must also subsequently engage teeth 14a for the rotation of ring 4 to be successfully completed. *Id.* at 3:18-22. If the base could rotate, or if the canister could rotate such that the base 1 could rotate, then the rings 4 and 8 would not interact with the fixed teeth correctly and the dose counter would not function. *Id.* at 1:32-44; Ex. 2021 at ¶24. Thus, a complete rotational movement of ring 4 brings a new dose value into view in window 13. Ex. 1007 at 3:22-26. Importantly, as Bason's dose values are shown on the upper surfaces of rings 4 and 8, the window 13 must be included on the top of the cap 14, rather than on the side of the cap, to permit display of Bason's dose values. *See id.* at 2:66-3:1; Ex. 2021 at ¶23.

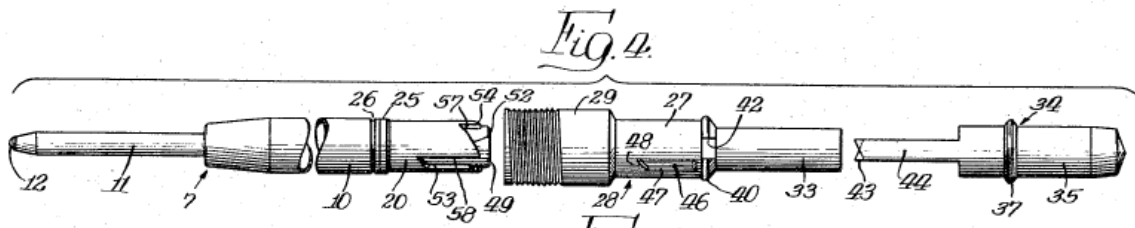
B. Introduction to Rhoades, U.S. Patent No. 3,205,836 (Ex. 1009).

Rhoades discloses a retractable ball point pen. Specifically, Rhoades relates to “ball point writing instruments . . . having a projecting and retracting mechanism operated by a push button for alternatively moving the writing point between an exposed, writing position and a concealed, non-writing position” as shown below. Ex. 1009 at 1:09-14.



Id. at Figs. 1, 2.

An exploded view of Rhoades' internal components is shown in Figure 4 below. *Id.* at 2:57-59.



Id. at Fig. 4.

The protracting and retracting mechanism operates by depressing button 35 to bring the plunger 34 into contact with cam body 20. Ex. 1009 at 3:74-4:7; Ex. 2021 at ¶26. The cam body 20 attaches to the rear end of ink reservoir and “is rotatably and slidably disposed within a tubular central portion 27 of a stationary guide member 28 so as to in effect be ‘floating’ therein.” Ex. 1009 at 3:49-67. Repeated depression of button 35 causes the plunger 34 to successively engage with the surfaces of the cam body 20. Ex. 1009 at 4:22-28. Rhoades is maintained

in a projected position when cam surfaces 50 and 52 are engaged with stop members 45 and 46, and in a retracted position when cam surfaces 54 and 55 are engaged with bottom surfaces 51 and 53. Ex. 1009 at 5:15-28; Ex. 2021 at ¶26.

C. The Bason/Rhoades Combination as Described by Petitioners is Inoperable for Its Intended Purpose.

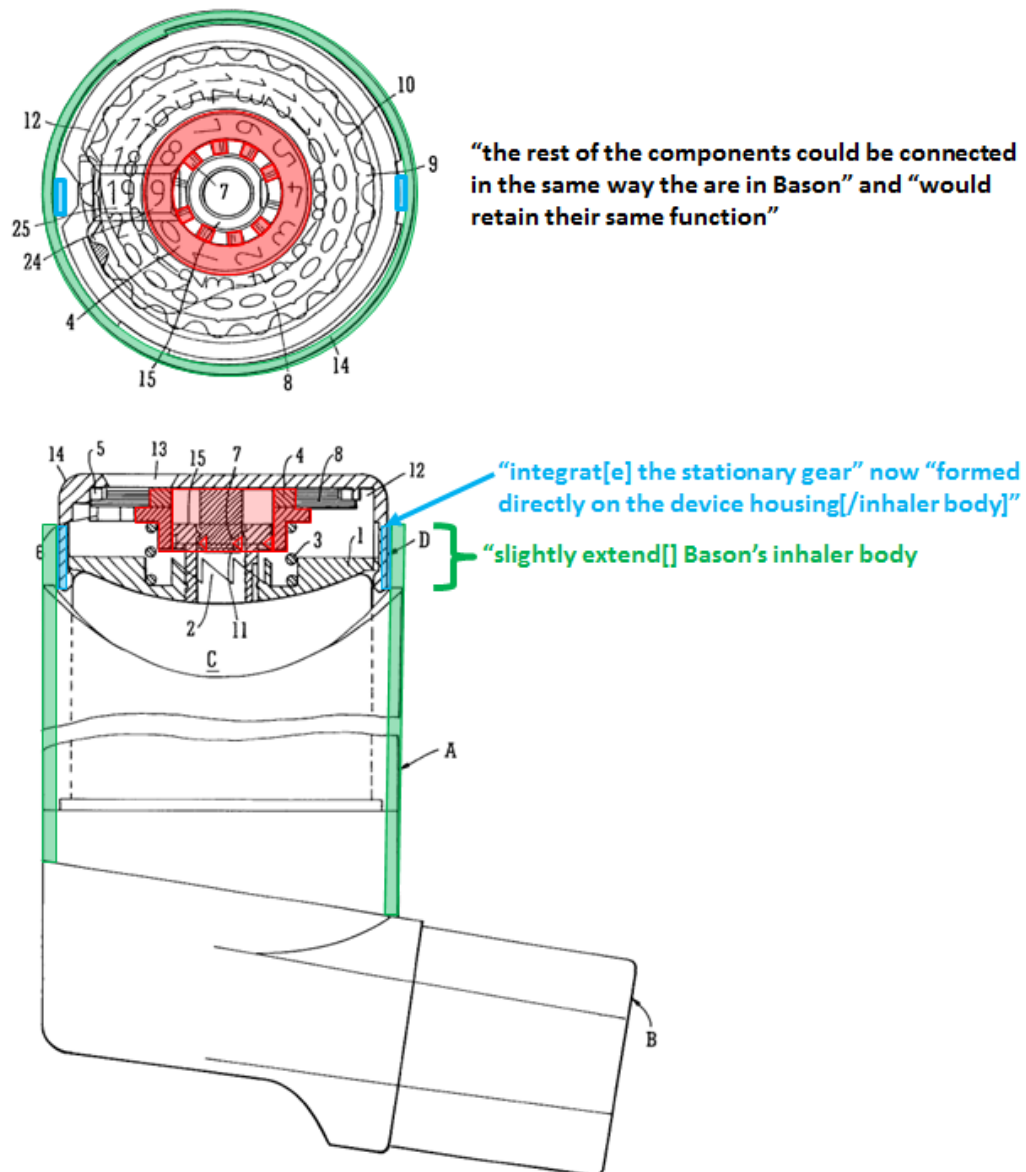
Petitioners and their expert suggest that the Bason and Rhoades would be combined as follows:

- “slightly extend[] Bason’s inhaler body;”
- “integrat[e] the stationary gear (tooth 2) of Bason into the inhaler body just as the stationary gears (stop members) of Rhoades are integrated directly on the Rhoades body;
- “the rest of the components could be connected in the same way they are connected in Bason;” and
- “all of the components would retain their same functions—depressing the Bason cap would depress rings 4 and 8; teeth 7 of ring 4 would interact with stationary teeth 2 (now formed directly on the device housing) and rotate ring 4 to change the dose value the same way they do in Bason.” (Petition at 55-56).

Petitioners provide no diagrams, schematics, or other indication/explanation of the Bason/Rhoades combination or how the components interoperate. Such a deficient explanation cannot support Petitioners’ obviousness assertion. *TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1066 (Fed. Cir. 2016) (internal citations omitted) (“An obviousness determination cannot be reached where the record lacks explanation as to *how* or *why* the references would be combined to produce the claimed invention.” (emphasis in original)); *see also. In re Nuvasive*,

Inc., 842 F.3d 1376, 1381–82 (Fed. Cir. 2016) (noting that the “factual inquiry” into the reasons for “combin[ing] references must be thorough and searching, and the need for specificity pervades”).

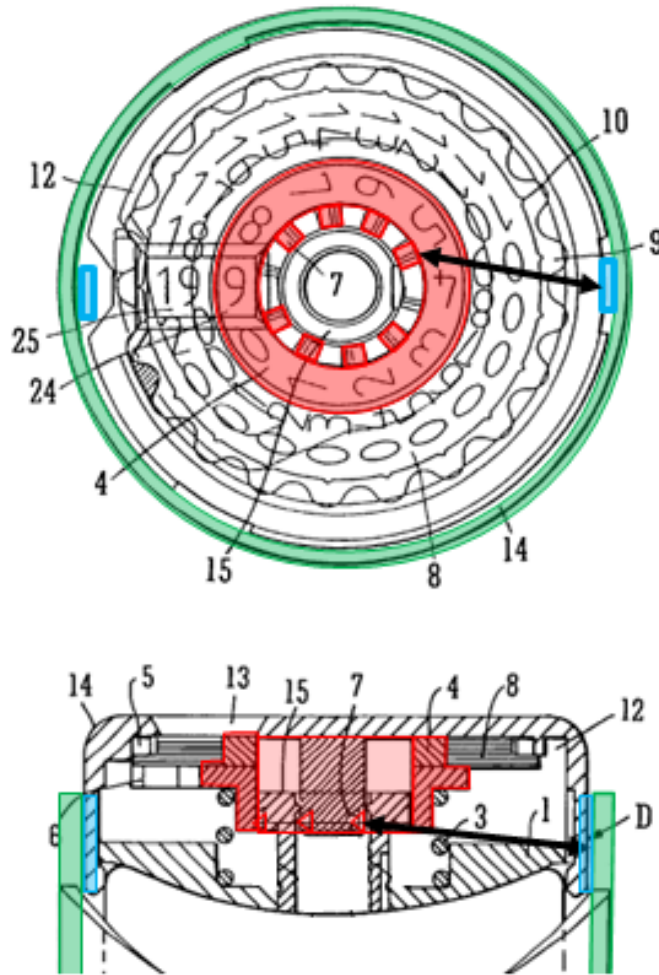
The diagrams below reflect the changes Petitioners assert a POSA would have made to Bason in view of Rhodes, with the “slightly extended” inhaler body (in green), the “integrat[ed] stationary gear” (in blue), and the ring 4 with teeth 7 (in red):



Ex. 1007 at Figs. 1, 4 (annotated); Ex. 2021 at ¶49.

As described by Petitioners, the Bason/Rhoades device would be inoperable for its intended purpose. *See* Ex. 2021 at ¶¶79-82.

In Petitioners' suggested Bason/Rhoades combination, tooth 2 (i.e., the alleged stationary gear) is moved to the inhaler body as shown in blue. Petition at 55. However, the rest of the components—including ring 4 with teeth 7 as shown in red—are “connected in the same way they are connected in Bason.”⁴ Petition at 55. And the specification of



⁴ Petitioners do not assert that any components of Rhoades are actually incorporated into the Bason inhaler, stating only that a POSA viewing Rhoades would have extended the inhaler body and moved the tooth 2 onto the inhaler body.

Bason makes clear teeth 7 must “engage the lower fixed set of teeth 2” in order to “cause[] the ring 4 to be indexed in rotation.” Ex. 1007 at 3:54-4:4.

The problem with Petitioners’ proposed combination is that teeth 7 (in red) and teeth 2 (in blue) would never come into contact as required to permit ring 4 to move in rotation, as shown above. For example, if tooth 2 is located on the inhaler body, the cap 14 and the exterior of ring 4 prevent teeth 7 and teeth 2 from touching. Ex. 2021 at ¶¶55, 60-63, 79-82. If teeth 7 and teeth 2 do not touch, they cannot “engage” to cause the rotation of ring 4. *Id.* If ring 4 does not rotate, the dose numbers will not advance, and the patient will not know how many doses of medication are in the inhaler. *Id.*

Since the Bason/Rhoades combination as explained by Petitioners does not allow ring 4 to rotate and provide an accurate indication of the number of doses remaining in the inhaler, Bason is rendered inoperable for its intended purpose. Ex. 1008 at 1:15-17 (stating its purpose as “indicat[ing] the number of times the pressurized canister is depressed to dispense a dose of the drug”). As such, the Bason/Rhoades combination fails to support a finding of obviousness here. *See, e.g.,* MPEP 2143.01(V); *Gordon*, 733 F.2d at 902.

D. The Bason/Rhoades Combination Fails to Disclose Each and Every Claim Limitation of the ’631 Patent.

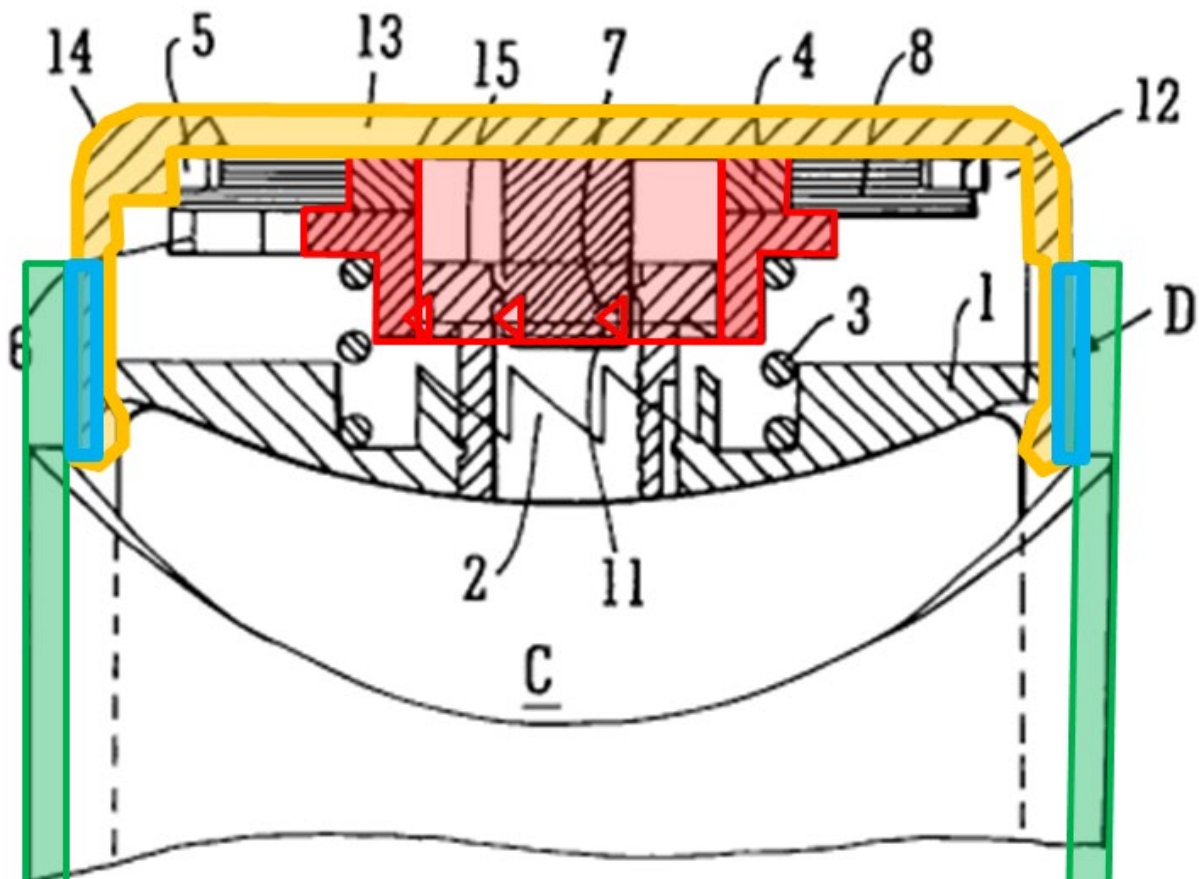
Petitioners’ proposed combination of Bason and Rhoades does not disclose each and every limitation of the claims of the ’631 Patent. First, none of the

Rhoades components are present in the proposed combination, and so they cannot render the '631 Patent obvious. Second, the Bason cap is not axially displaceable in the proposed combination and so cannot practice the "first member" limitation. Third, even if the cap could be axially depressed, the ring 4 cannot rotate as required by the "second member" element of the claims. And lastly, because the ring 4 cannot rotate, Bason's dose values cannot advance as required to disclose the recited changing of a displayed dose value in the '631 Patent. For each of these reasons, Petitioners fail to show that the '631 Patent is obvious over Bason in view of Rhoades.

1. Claims 1 and 3: Bason in view of Rhoades does not disclose a "first member that is displaceable axially relative to [a] stationary body."

The Bason/Rhoades combination does not disclose this claim element. Petitioners appear to suggest that the claimed first member is either (1) the Rhoades push button or (2) the Bason cap. Petition at 60-61. However, the Rhoades push button is not present in the Bason/Rhoades combination. *See* Petition at 55-56 (describing the modifications Petitioners propose a POSA would have made to Bason and making no mention of the Rhoades push button). Because this component is absent from the combination, it cannot form the basis for rendering this claim element obvious.

The Bason cap also does not meet this claim element because the teeth that purportedly would have been molded onto the inhaler body prevent the cap from moving axially as required by the claim. Under Petitioners' alleged combination of Bason and Rhoades, teeth 2 (in blue) are formed directly onto inhaler body (in green) and are in the same plane as cap 14 (in orange):



Ex. 1007 at Fig. 1 (annotated); Ex. 2021 at ¶55.

In this configuration, not only are teeth 2 incapable of engaging with teeth 7 because the latter remain trapped within cap 14, cap 14 is also no longer depressible relative to base 1. This is because the presence of teeth 2 on the

internal circumference of the inhaler body creates a physical barrier which blocks cap 14 from recessing inside the inhaler body so as to actuate the dose counter as shown above.⁵ Ex. 2021 at ¶ 55.

Accordingly, Petitioners’ alleged combination of Bason and Rhoades does not disclose an axially displaceable first member relative to a stationary body because if teeth 2 are molded onto the inhaler body, then cap 14 will not be able to move axially relative to the inhaler body. The Bason/Rhoades combination does not render this claim element obvious.

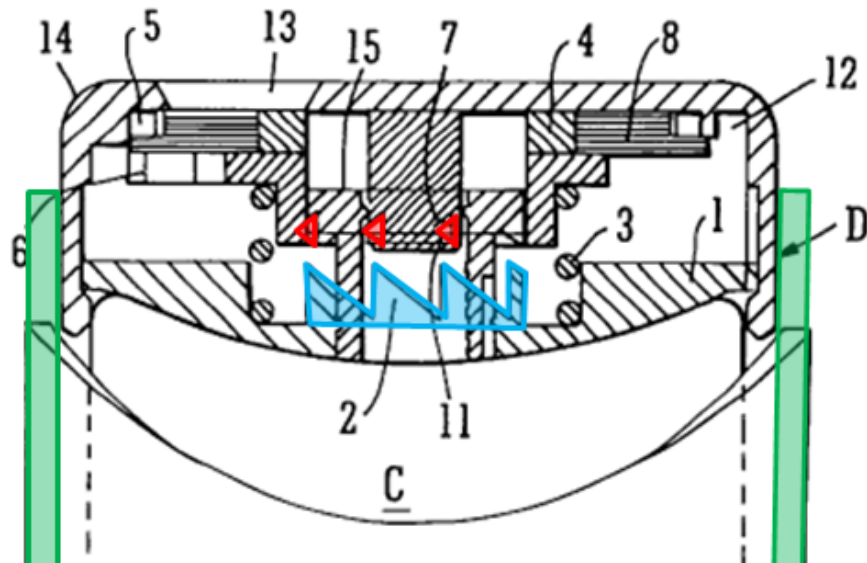
2. **Claims 1 and 3: Bason in view of Rhoades does not disclose that when a “first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate relative to said stationary body, so as to change a displayed dose value from among the plurality of displayable dose values.”⁶**

⁵ If, in the alternative, Petitioners posit that the entirety of base 1 would to be made integral with inhaler body A, then Petitioners still fail to explain how base 1 would be able to functionally cooperate with Bason’s other components and, in particular, how the inhaler would be depressed if the entire base were one piece. *See* Ex. 2021 at ¶ 81.

⁶ The Bason/Rhoades combination also fails to disclose the “first member” element of this claim limitation because it does not disclose a first member that “displaces axially” for the reasons as provided in Section VI(D)(1).

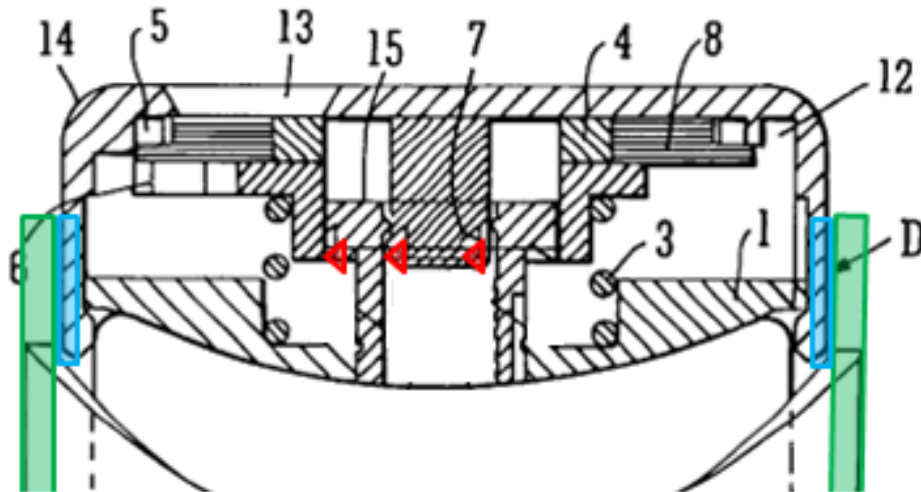
Petitioners appear to suggest that the claimed second member is either (1) the Rhoades cam body or (2) the Bason ring 4. Petition at 61-62. However, the Rhoades cam body is not present in the Bason/Rhoades combination. *See* Petition at 55-56 (describing the modifications Petitioners propose a POSA would have made to Bason and making no mention of the Rhoades cam body). Because this component is absent from the combination, it cannot form the basis for rendering this claim element obvious.

In addition, Bason ring 4 fails to disclose the “second member” element of this claim limitation because it cannot rotate as required by the claim. Bason discloses teeth 2 that are “upwardly directed teeth” (shown in blue below) located near the center of base 1, as well as teeth 7 that are “inwardly directed triangular teeth” located on the inner surface of ring 4 (shown in red below). Ex. 1007 at 2:28-38.



Id. at Fig. 1 (annotated); Ex. 2021 at ¶¶60.

Importantly, Bason teaches that teeth 7 (in red) are located directly above teeth 2 (in blue) such that the former will come into contact with the latter when the cap 14 and ring 4 are displaced axially downwards. Ex. 1007 at 2:28-38, 3:15-22. However, if Bason is modified as suggested by Petitioners (to move teeth 2 of base 1 to the inhaler body), then teeth 7 (in red) cannot engage teeth 2 (in blue) as shown below. Ex. 2021 at ¶¶61-62. Rather, they are separated by various components of Bason, including the cavity 1a of base 1, the radially outwardly directed flange of ring 4, spring 3, and cap 14. See Ex. 1007 at 2:20-38, 43-58, 3:15-22; Ex. 2021 at ¶¶61-62.



Id. at Fig. 1 (annotated); Ex. 2021 at ¶ 62.

The only way that ring 4 rotates is by its teeth 7 engaging with teeth 2. *Id.* at 3:15-22. If they cannot engage, then the ring 4 will not rotate as required by this claim element. Ex. 2021 at ¶62. If the ring 4 cannot rotate, then the displayed dose value will not change as also required by this claim element. *Id.* at ¶63. Therefore, the Bason/Rhoades combination does not render this claim element obvious.

3. Claims 2 and 4: Bason/Rhoades does not render these claims obvious.

Because independent claims 1 and 3 are not obvious over Bason in view of Rhoades, dependent claims 2 and 4 are not obvious for these same reasons.

E. A POSA Would Not Have Been Motivated to Combine Bason with Rhoades.

Petitioners' argument that the '631 Patent is obvious over Bason in view of Rhoades must also be rejected because a POSA would not have been motivated to combine Bason with Rhoades.

As an initial matter, Rhoades is not analogous art and a POSA would therefore not have looked to combine Bason with Rhoades. To determine if prior art is analogous, the Federal Circuit has stated that "if a reference disclosure and the claimed invention have a same purpose, the reference relates to the same problem, which supports an obviousness rejection." *Unwired Planet, LLC v. Google Inc.*, 841 F.3d 995, 1001 (Fed. Cir. 2016). Here, the purpose of the '631

Patent is to “provide a fluid dispenser including a dose indicator device that prevents any risk of under-counting, i.e., that guarantees that the indicator device is actuated each time fluid is dispensed by the fluid dispenser.” Ex. 1001 at 1:67-2:3. In contrast, Rhoades does not count or indicate anything; its purpose is simply to “provide a ball point writing instrument having an improved push button operated projecting and retracting mechanism.” Ex. 1009 at 1:15-17. Nor does the mechanism of action taught by Rhoades—the extension and retraction of a ball-point tip—cause anything to dispense or suggest a need to prevent undercounting. Ex. 2021 at ¶¶68-69. As such, Rhoades is neither specifically relevant to the problem of undercounting nor generally relevant to MDIs, and so cannot “be considered within the prior art for purposes of the obviousness analysis.”⁷ *Circuit Check Inc. v. QXQ Inc.*, 795 F.3d 1331, 1335-36 (Fed. Cir. 2015).⁸

⁷ None of Petitioners’ references establish that Rhoades is analogous. For example, U.S. Patent No. 5,234,970 (“Ambrosio”) discusses prior art U.K. Patent No. 2,165,159 (“Auvinent”) disclosing a device for rotating an indexing mechanism much like that of a ball-point pen. Ex. 1031 at 2:36-51. Ambrosio then expressly teaches away from Auvinent: “However, because of the cup-like arrangement of this patent, adhesion can occur along the walls of each depression, *which is disadvantageous from a delivery viewpoint.*” *Id.* at 2:47-51 (emphasis added). Similarly, while U.S. Patent No. 7,090,662 (“Wimpenny”) discusses the

Furthermore, Rhoades expressly teaches away from the strict physical design tolerances applicable to MDIs such as Bason. A metered dose inhaler must reliably execute upon every single actuation, with every individual function effectuated in a space of just a few millimeters. Ex. 2021 at ¶¶ 75-76. Both parties' experts agree that careful attention to these strict physical tolerances would have been essential to a POSA designing an MDI because failing to take such into

“ball point pen principle” of patent DE 3,814,023, Wimpenny clarifies that such “does not address the problem of incorrect dose setting by the user.” Ex. 1032 at 1:40-48. Moreover, Wimpenny and other references were filed *after* the '631 Patent. *See* Exs. 1032 (filed in 2004); 1033 (filed in 2005); 1034 (filed in 2016); *see also* Ex. 2021 at ¶72.

⁸ Moreover, that Petitioners propose two very different ways of combining Bason and Rhoades in this Petition and in their Petition regarding the '177 Patent makes clear that the modifications they propose are not predictable as Petitioners suggest. *See* Petition at 56 (“Accordingly, a POSA would have been motivated to make the above modification and would have had a reasonable expectation of success in doing so; the modification was predictable because the manufacturability and connectivity of such components was well-understood by a POSA.”); *see also* Ex. 2007 (Petition for Inter Partes Review at 52-71, IPR2018-01054 (May 10, 2018)) (describing that a POSA would have incorporated Rhoades's cam body 20 into Bason, bonding it to the base of Bason's canister, and that the outer housing of Bason would correspond to Rhoades's guide member 28).

account would risk creating a device whose efficacy is undermined by components that do not operate as designed due to minor geometrical variations between parts.⁹ Ex. 2021 at ¶¶74-78; *see also* Ex. 2019 at 135:10-17 (“I would say that a meter dose inhaler product with gears that work together, there will be certain level of tolerances that are required for the gears to work together. And if those tolerances aren’t met, the gears may not actually work together.”). Indeed, in the case of an MDI user suffering from asthma, such inefficacy could be life-threatening.

And although Petitioners assert that a POSA would have looked to Rhoades as “a small, plastic, inexpensive mechanical device that converts axial motion . . . into rotational motion,” (Petition at 53-54), Rhoades expressly teaches *away* from “close manufacturing tolerances.” Ex. 1009 at 8:6-16 (“None of the operating parts of the projecting-retracting mechanism in accordance with my invention requires close manufacturing tolerances for dependable operation.”). Thus, regardless of whether or not Rhoades’s cam mechanism is less expensive to

⁹ For example, the distance traveled by the components in Rhoades is substantially greater than the distance traveled by the canister of an MDI. Ex. 2021 at ¶77. Notwithstanding that smaller range of motion, the travel distance of actuation of the inhaler must enable (1) delivery of the dose of medication; (2) refill of the valve’s metering chamber; and (3) engagement of an accurate counting mechanism to allow the count to progress. *Id.* at ¶76. None of those purposes are taught or suggested by Rhoades.

manufacture, a POSA would have understood that it simply was not designed for the precision required of MDIs.¹⁰ Ex. 2021 at ¶¶74-78. The consequence of these differences is that a POSA would have no motivation to combine Bason with Rhoades. *WMS Gaming, Inc. v. Int’l Game Tech.*, 184 F.3d 1339, 1355 (Fed.Cir.1999) (“When an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references.”); *see also Dome Patent L.P. v. Lee*, 799 F.3d 1372, 1380 (Fed. Cir. 2015).¹¹

¹⁰ Petitioners also fail to explain why a POSA would have any reasonable chance of success of incorporating Rhoades’ non-precision components into an MDI absent evidence that such a combination had ever even been attempted. Ex. 2021 at ¶78. Petitioners’ expert testifies that he looked to the mechanism of a pen when asked to design a dose indicator prior to 2001. Ex. 1002 at ¶¶ 17, 135. But he cites no evidence or proof, and he fails to provide enough detail regarding the technology and design at issue to evaluate whether his experience at the time is relevant to the Board’s task here. Indeed, Piper provides no sketches, notes, diagrams, drawings, lab books to support his claim. His bare testimony cannot support Petitioners’ obviousness assertions.

¹¹ It is also worth noting that a video describing the operation of the pen disclosed in Rhoades (and identifying Rhoades by patent number) indicated that the pen was designed by a team of sixty-six people. *See* Ex. 2020, The Kids Should See This,

VII. GROUND 4: CLAIMS 1-4 OF THE ‘631 PATENT ARE NOT OBVIOUS UNDER 35 U.S.C. § 103 OVER BASON IN VIEW OF ALLSOP

It would not have been obvious for a POSA to modify Bason in view of Allsop because Petitioners’ suggested modifications would render Bason inoperable for its intended purpose, the combination fails to disclose each and every claim limitation of the ’631 Patent, and because there would have been no motivation to combine Bason with Allsop.

A. The Bason/Allsop Combination as Described by Petitioners Would be Inoperable for Its Intended Purpose.

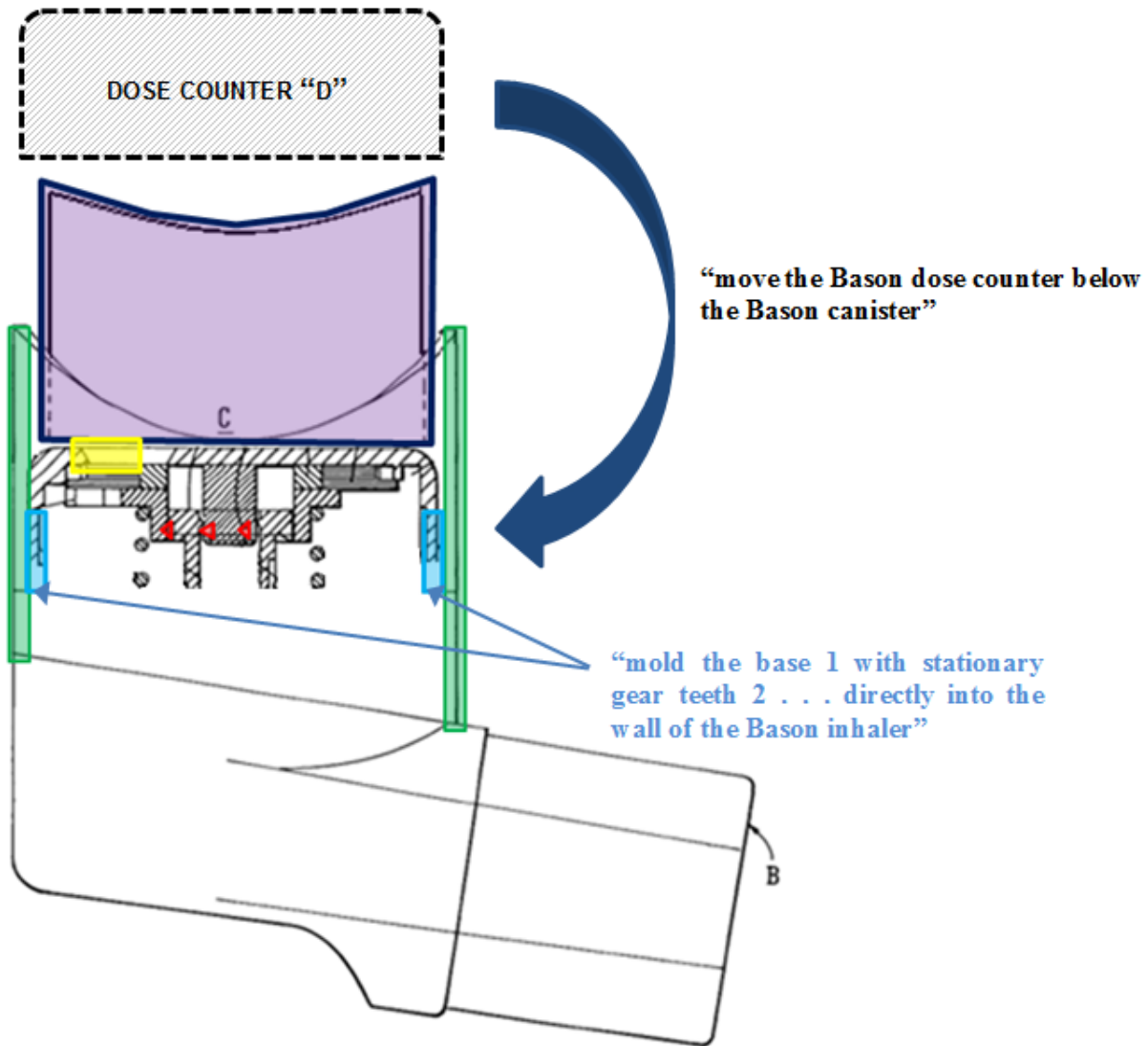
Petitioners and their expert propose that Bason and Allsop would be combined as follows:

- “move the Bason dose counter below the Bason canister;”
- “mold the base 1 with stationary gear teeth 2 . . . directly into the wall of the Bason inhaler”
- “all of the components would retain their same functions—depressing the canister of Bason would depress the cap it would now be sitting on top of. The cap would depress rings 4 and 8, causing teeth 7 of ring 4 to interact with stationary teeth 2 and rotate ring 4 to change the dose value the same way they do in

available at <https://thekidshouldseethis.com/post/how-does-a-retractable-ballpoint-click-pen-work> at 3:44. These highly optimized mechanisms are extremely unique for their purpose (requiring 60 people to create) and are not easily modified or interchanged for other purposes *See id*; Ex. 2021 at ¶69.

Bason [t]he valve would extend through the counting mechanism just as it does in Allsop.” (Petition at 66-68.)

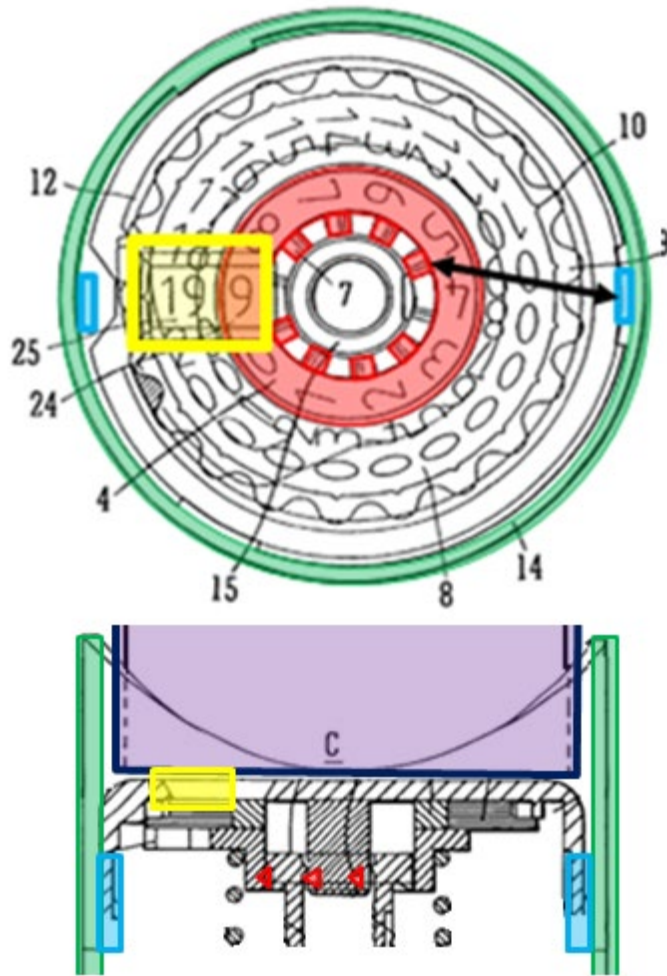
As with the Bason/Rhoades combination, Petitioners do not include diagrams, schematics, or any other indication/explanation of how the Bason/Allsop combination functions or how the components interoperate. The figure below reflects Petitioners’ proposed modifications, including Bason’s dose counter moved below the canister (in purple), base 1 with teeth 2 (in blue) integrally molded directly onto the inhaler body (in green), and teeth 7 (in red) remaining integral to ring 4:



Ex. 1007 at Fig. 1; Ex. 2021 at ¶87.

Petitioners’ suggested modifications to Bason in view of Allsop would render the device inoperable for its intended purpose because the dose values cannot advance, and the numeric indicia are also not visible to the user.

Bason explains that when a user depresses the inhaler, “teeth 7 [] engage with the teeth 2” which “causes the ring 4 to be indexed in rotation.” *Id.* at 3:15-

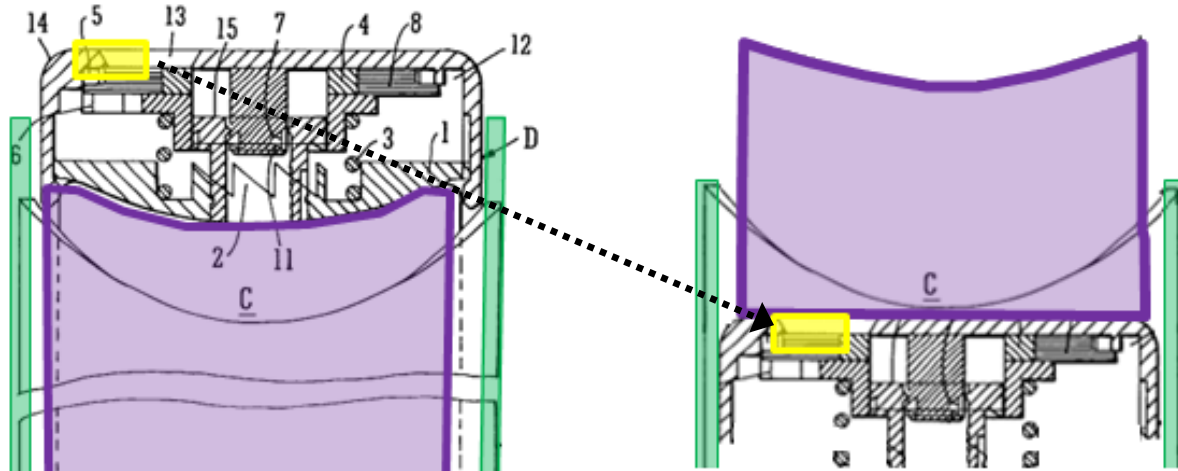


22, 52-57. However, as shown to the left, if teeth 2 (in blue) are “integrally molded” to the inhaler body (in green), teeth 7 (in red) will not come into contact with teeth 2 upon depression of the device. Ex. 2021 at ¶91. Critically, if the ring 4 cannot rotate, then each actuation of the inhaler will not bring a new dose value into view in window 13 (in yellow) to indicate the doses

remaining in the canister. Ex. 2021 at ¶92.

Petitioners’ modifications also result in the numeric dose values in window 13 being completely obscured from view. Ex. 2021 at ¶93. Bason instructs that the “upper circular part of the cap 14 includes a window 13” through which is “visible progressively the numbers 000 to 200.” See Ex. 1008 at 2: 56-3:6. As shown below, however, moving the dose counter disclosed in Bason “to a position immediately below the canister” causes the display window 13 (in yellow) to be

completely covered by the bottom of the canister (in purple). Ex. 1002 at 98; Ex. 2021 at ¶93.



Ex. 1007 at Fig. 1; Ex. 2021 at ¶93.

Because the window 13 is covered by the canister, there is no way for a user to read the numeric dose values on the upper surface of the ring 4. Ex. 2021 at ¶93. Petitioners offer no explanation as to how new dose values could rotate into window 13 if teeth 7 do not come into contact with teeth 2, or how window 13 could be visible if the dose counter is repositioned beneath the canister. As described, the Bason/Allsop combination therefore does not indicate the number of doses remaining in the inhaler. Ex. 2021 at ¶92-93. Given that Bason's express purpose is to "indicate the number of times the pressurized canister is depressed to dispense a dose of the drug," (Ex. 1007 at 1:15-17), Petitioners' proposed modifications render Bason inoperable for its intended purpose and fail to support a finding of obviousness. *See, e.g.*, MPEP 2143.01(V); *Gordon*, 733 F.2d at 902.

B. The Bason/Allsop Combination Fails to Disclose Each and Every Claim Limitation of the '631 Patent.

Petitioners' proposed combination of Bason and Allsop does not disclose each and every limitation of the claims of the '631 Patent. First, none of the Allsop components are present in the proposed combination, so they cannot render the '631 Patent obvious. Second, the proposed Bason/Allsop combination does not disclose either the "first member" or the "second member" claim elements of the '631 Patent because Bason's cap 14 does not displace axially and Bason's ring 4 does not rotate as required by the claims. Third, the proposed combination does not disclose the recited changing of a displayed dose value in the '631 Patent because Bason's dose values are neither "displayed" nor "displayable." For each of these reasons, Petitioners fail to show that the '631 Patent is obvious over Bason in view of Allsop.

1. Claims 1 and 3: Bason in view of Allsop does not disclose a "first member that is displaceable axially relative to [a] stationary body."

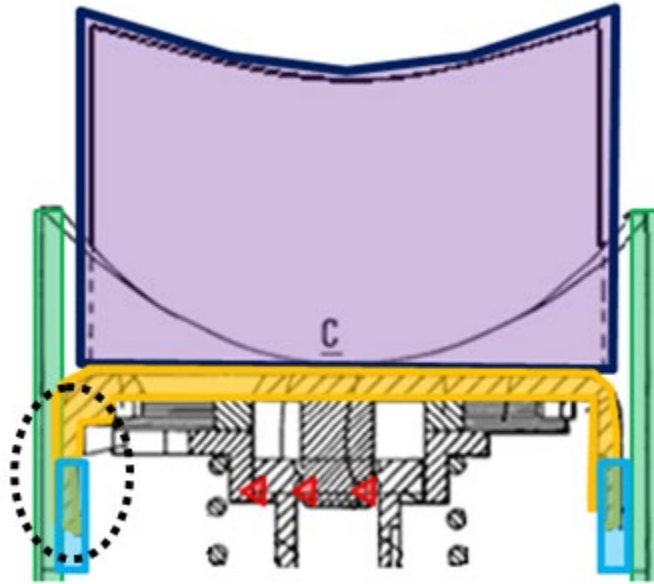
Petitioners spend all of one sentence describing how the Bason/Rhoades combination renders this claim element obvious. Petition at 71. This one sentence simply refers the reader to their analysis of the Bason/Rhoades combination, which

is fundamentally different than the Bason/Allsop combination.¹² *Id.* (citing to Sections VIII.C.2.e and VIII.A.1.e.). Petitioners cannot support their Bason/Allsop combination with evidence relating to a completely different combination that operates in a different way. *Intellectual Ventures II LLC v. Ericsson Inc.*, 685 F. App'x 913, 920 (Fed. Cir. 2017) (citing *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1379 (Fed. Cir. 2016) (reversing a finding of obviousness where the Petitioner “merely attempted to incorporate its arguments based on [one combination of prior art] to its obviousness analysis based on [another combination of prior art with the same reference]”)). This alone defeats a finding of obviousness.

In addition, the Bason/Allsop combination fails to disclose this claim element because, as shown below, if teeth 2 (in blue) are molded onto the Bason inhaler body (in green), then the cap 14 (in orange) cannot move axially relative to the inhaler body. Ex. 2021 at ¶89. Teeth 2 (in blue) occupy the same plane as cap 14 (in orange), and there is no way for cap 14 to axially depress downwards. *Id.* This is because the presence of teeth 2 on the internal circumference of the inhaler body creates a physical barrier that blocks cap 14 from recessing inside the inhaler

¹² As just one example, the Bason/Rhoades combination requires the dose counter to be **above** the canister, while the Bason/Allsop combination requires the dose counter to be **below** the canister. See Petition at 55-56, 66-68.

body so as to actuate the dose counter, as shown below. In short, the alleged first member (cap 14) cannot move axially as claimed.



Ex. 1007 at Fig. 1; Ex. 2021 at ¶89.

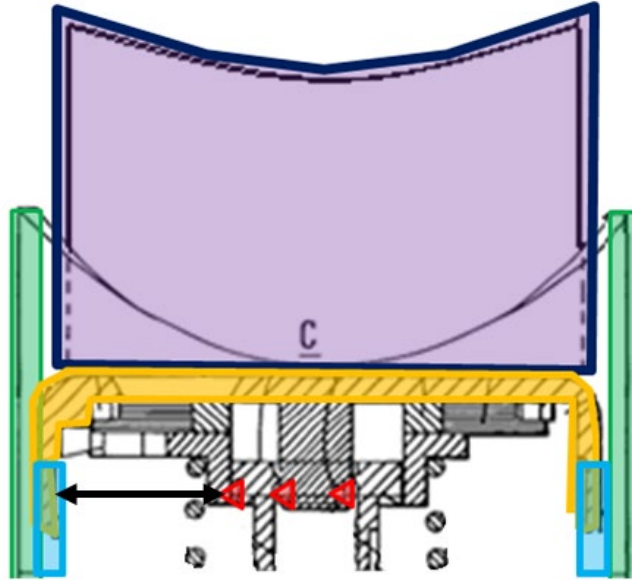
This element is therefore not rendered obvious by the combination of Bason and Allsop.

2. Claims 1 and 3: Bason in view of Allsop does not disclose that when a “first member displaces axially . . . said second member is caused to be displaced axially and permitted to rotate relative to said stationary body.”

As with the previous claim element, Petitioners simply to refer to earlier sections of the Bason/Rhoades combination to argue this claim element is obvious. Petition at 72 (citing to Sections VIII.C.2.h. and VII.A.1.h.). Yet the Bason/Rhoades combination is fundamentally different than the Bason/Allsop combination alleged here because it requires the dose counter to be **above** the

canister rather than **below** the canister. *See* Petition at 55-56, 66-68. Moreover, while Petitioners appear to claim that Allsop's inner housing 140 could be the claimed "second member," Petitioners' expert admits that this component is absent from the proposed combination. Ex. 2019 at 143:18-21 ("[P]art number 140 would not . . . be included."). Again, Petitioners cannot point to components which are not even disclosed in the combination as the basis for rendering this claim element obvious. Nor can Petitioners support their Bason/Allsop combination with analysis of a completely different combination that operates in a fundamentally different way. *Magnum Oil*, 829 F.3d at 1379.

Moreover, Petitioners' proposed combination of Bason in view of Allsop fails to disclose both the "first member" and "second member" elements of this claim limitation because, if Bason's teeth 2 are formed directly on Bason's inhaler body, then Bason's cap 14 will not be able to move axially relative to Bason's inhaler body and Bason's ring 4 will not be permitted to rotate. Ex. 2021 at ¶¶89-92.



Ex. 1007 at Fig. 1; Ex. 2021 at ¶91.

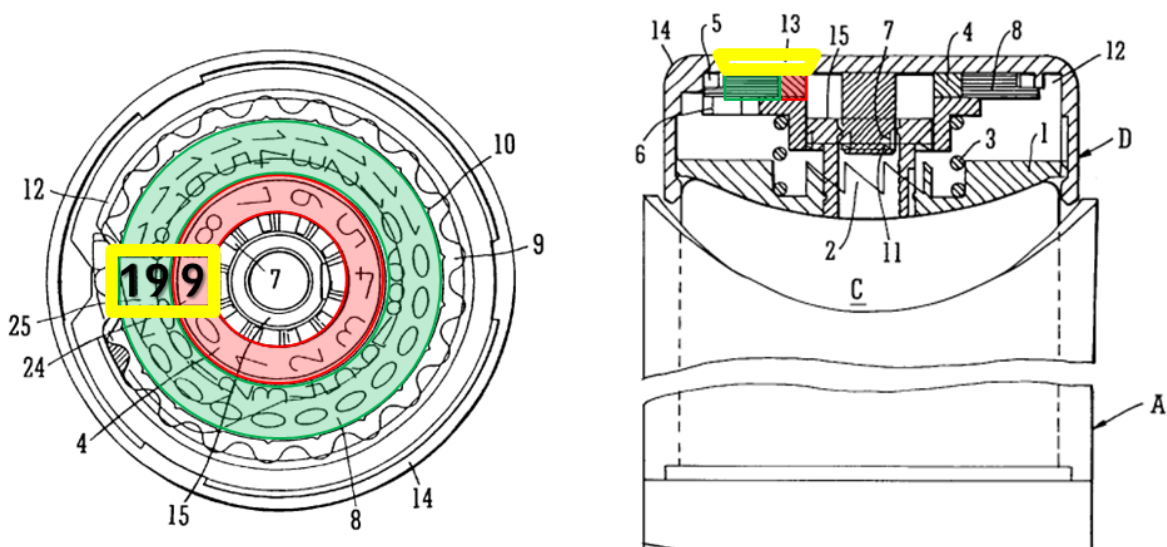
As shown above, integrally molding teeth 2 (in blue) onto the internal circumference of the inhaler body (in green) prevents cap 14 (in orange) from recessing inside the inhaler body so as to displace axially downwards. *Id.* at ¶89. As a result, there is no way for teeth 2 to come into contact with teeth 7 as required to bring the ring 4 in rotation. *Id.* And even if cap 14 could be depressed, ring 4 cannot rotate because there is no way for teeth 7 to contact teeth 2. This is because teeth 7 and teeth 2 are separated by various components of Bason, including the radially outwardly directed flange of ring 4, spring 3, and cap 14. *See id.* at 2:20-38, 43-58, 3:15-22. Ex. 2021 at ¶91. As a result, the alleged first member (cap 14) does not displace axially, and the alleged second member (ring 4) does not rotate as required by this claim element.

Accordingly, this element is not rendered obvious by the combination of Bason and Allsop.

3. Claims 1 and 3: Bason in view of Allsop does not disclose “chang[ing] a displayed dose value from among the plurality of displayable dose values.”

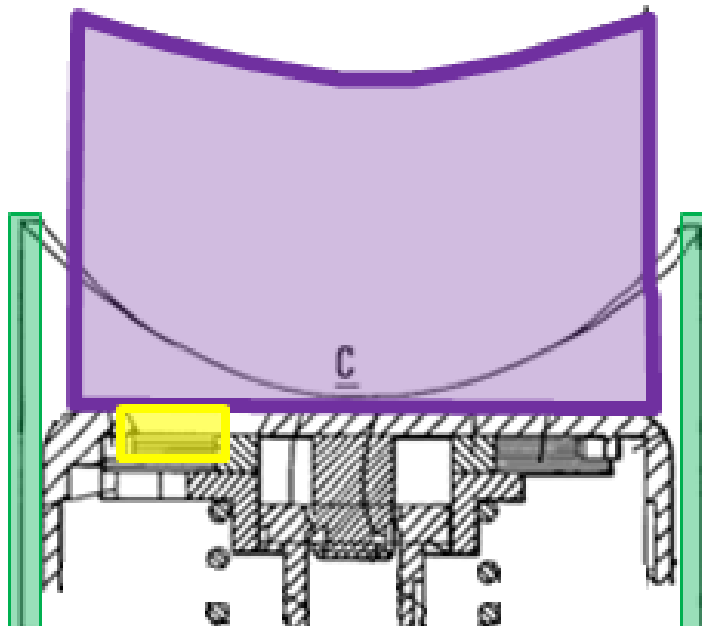
As above, Petitioners refer to earlier sections of a different combination (Bason/Rhoades) to argue this claim element is obvious. Petition at 69 (citing to Sections VIII.C.2.b and VIII.A.1.b). Because Petitioners’ cite to a fundamentally different combination, as described above, Petitioners’ proof is deficient.

The difference between the two combinations is critical to analysis of this claim element. If the Bason dose counter is placed below the canister, then Bason’s dose values are neither “displayed” nor a “plurality of displayable dose values” as required by the claim. Bason teaches that the dose values are displayed through a window (in yellow) on the top of the cap 14 as shown below:



Ex. 1007 at Figs. 1, 4; Ex. 2021 at ¶23.

Bason discloses that ring 4 (in red) and ring 8 (in green) “each carry[] on its **upper surface** indicia visible through a window (13) in the cap.” Ex. 1007 at Abstract (emphasis added); *see also id.* at 2:66-3:1 (explaining that “the upper faces of 24 and 25 [] of the rotational rings 4 and 8” are viewed “through window 13.”). However, Petitioners’ proposed modification of Bason in view of Allsop, moves the entire dose counter underneath the canister as shown below. Petition at 66. When this modification is made, the display window 13 is longer visible because it is covered by the canister.



Ex. 1007 at Fig. 1; Ex. 2021 at ¶93.

Petitioners offer no explanation to account for the newly obscured position of window 13. Nor could they. The window 13 cannot be moved to the side of the

inhaler body and still display the dose values. Ex. 2021 at ¶99. This is because the dose values are located on the top surfaces 24 and 25 of rings 4 and 8, respectively, and thus would not be visible from a window located on the side of the inhaler body. Ex. 1007 at Abstract, 2:66-3:1; Ex. 2021 at ¶¶ 99. The rings 4 and 8, as well as the central bush 15, would need to be completely redesigned. Ex. 2021 at ¶¶98-99. Petitioners and their expert fail to even mention this problem, much less explain how to modify Bason's rings to overcome it. As a result, this claim element cannot be found obvious in view of the Bason/Allsop combination.

4. Claims 2 and 4: Bason/Rhoades does not render these claims obvious.

Because independent claims 1 and 3 are not obvious over Bason in view of Rhoades, dependent claims 2 and 4 are not obvious for these same reasons.

C. A POSA Would Not Have Been Motivated to Combine Bason with Allsop

Petitioners' argument that a POSA would have been motivated to combine Bason with Allsop is unpersuasive given that Petitioners' combination has not been fully described.

"An obviousness determination cannot be reached where the record lacks explanation as to how or why the references would be combined to produce the claimed invention." *TriVascular, Inc. v. Samuels*, 812 F.3d 1056, 1066 (Fed. Cir. 2016) (internal citations omitted) (emphasis in original); *In re Nuvasive, Inc.*, 842

F.3d at 1381–82. The Federal Circuit thus instructs that a petitioner arguing that a patent is invalid for obviousness “cannot employ mere conclusory statements” but “must instead articulate specific reasoning, based on evidence of record.” *In re Magnum Oil*, 829 F.3d at 1380.

Petitioners here explain only that a POSA would have been motivated to “move the Bason dose counter below the Bason canister” and/or “integrally mold[] the teeth 2 into the inhaler housing.” Petition at 66-67. But such modifications would inevitably require fundamental redesign of Bason well beyond what is obvious or possible, particularly considering the divergent ways in which the devices in Bason and Allsop are respectively organized around the medicinal canister. Ex. 2021 at ¶98. For example, Allsop teaches a device whose various components are organized both concentrically around and beneath the canister, where Bason teaches a device that is wholly confined within a cap attached to the base of the canister. *Id.* The structural modifications Petitioners propose would require significant reworking of the systems disclosed in Bason and Allsop and improperly rely on impermissible hindsight reconstruction that the Board has rejected in the past. *Apple Inc. v. ContentGuard Holdings, Inc.*, IPR2015-00447, 2015 WL 4264954, at *14 (Patent Tr. & App. Bd. July 10, 2015) (“The various proposed modifications lead to the conclusion that the Petition improperly relies upon *ex post* reasoning and impermissible hindsight to piece

together the hypothetical Kahn-Linn system in a manner meant to resemble the '956 patent claims.”) (internal quotations omitted).

Moreover, Petitioners do not even acknowledge the numerous fundamental problems with their proposed modification, including: (1) how to modify the cap and other dose counter components to account for the valve stem needing to travel through the middle of the dose counter; (2) how to redesign the window 13 now that the dose counter is located below the canister; (3) how to redesign rings 4 and 8 to contain dose values viewable through a window in the side of the inhaler; (4) how to make teeth 2 engage with teeth 7 now that they are no longer able to touch; and (5) how to modify the cap to be depressible when new teeth 2 are on the interior surface of the inhaler body. Ex. 2021 at ¶98. All of these questions remain unanswered and leave fundamental holes in Petitioners' proof.

In short, the '631 Patent cannot be deemed invalid over a combination that Petitioners have not sufficiently described. Because Petitioners fail to describe the Bason/Allsop combination in anything more than conclusory terms, “merely surmising that one would have understood” that Bason could be combined with Allsop is “too thin a reed to support a conclusion of obviousness here.” *Acclarent, Inc. v. Ford Albritton, IV*, Case IPR2018–00268, 2018 WL 2553983, at *6 (Patent Tr. & App. Bd. May 31, 2018); *Purdue Pharma L.P. v. Depomed, Inc.*, 643 Fed. App'x 960, 966 (Fed. Cir. 2016) (“Its expert opined generally on the interrelated

teachings of those references, but did not explain in sufficient detail how or why a skilled artisan would have been motivated to combine the ‘swelling’ and ‘substantially intact’ features of the Shell formulation with the Baveja formulation to attain the claimed dosage form.”).

D. The U.S. Patent & Trademark Office has Already Considered Bason at Length.

The Patent Office has already considered and rejected Bason. During prosecution of the ’631 Patent, the Examiner rejected the claims over related EP 0949584A2 (“Bason EP Application”) under § 102(b) in an August 27, 2015 Office Action.¹³ *See* Ex. 1005 (Office Action, Aug. 27, 2015) at 70-71. In response, Aptar noted that Bason discloses that the canister C is bonded to the base 1 and, thus, does not teach the claimed stationary body because the canister C cannot be axially displaced with respect to the stationary body. Ex. 1005 (Amendment Under 37 C.F.R. § 1.111, Jan. 27, 2016) at 85. The claims were subsequently allowed. The Patent Office has already considered whether Bason

¹³ The Bason EP Application was also cited in an Information Disclosure Statement, and the Examiner expressly indicated that it had been considered; *see* Ex. 1004 (Office Action, Aug. 27, 2015) at Information Disclosure Statement (annotated by Examiner to indicate that all references were considered except where lined through).

discloses the elements of the claims of the '631 Patent and found that it does not. *See* Ex. 1004 (Decision on Appeal, July 2, 2014) at 1272-73.

In addition, Bason was cited and considered at length by the Examiner and the Board during the prosecution of the '177 Patent. Petition, Ex. 1017. Aptar cited the Bason EP Application in an information disclosure statement on December 6, 2010. Ex. 1004 (Information Disclosure Statement, Dec. 6, 2010) at 400. In an Office Action dated February 18, 2011, the Examiner rejected the claims of the '177 Patent over the Bason EP Application. Ex. 1004 (Office Action, Feb. 14, 2011) at 1111-12; *see also id.* at Information Disclosure Statement (annotated by Examiner to indicate that all references were considered except where lined through). On appeal, the Board ultimately found that the Examiner did not establish by a preponderance of the evidence that the Bason EP Application disclosed each and every limitation of the claims, and so it did not sustain the anticipation rejections over the Bason EP Application. Ex. 1004 (Decision on Appeal, July 20, 2014) at 1272-73. The claims were allowed, and the '177 Patent issued on January 20, 2015.

As a result, considering these arguments again here would waste the Board's resources. *See* 37 C.F.R. § 42.1(b) (stating the Board's policy of securing the "just, speedy, and inexpensive resolution of every proceeding"); *Becton Dickinson & Co. v. B. Braun Melsungen AG*, Case IPR2017-01586, 2017 WL 6405100, at *6

(*Patent Tr.& App. Bd. Dec. 15, 2017*) at *8 (“Based on the Petitioner’s explanation as to how and why a person of skill in the art would have combined the references, and here, considering the same and similar references as applied during examination, we find little if any, different argument then that considered previously by the Office.”). The Board should therefore reject Petitioners’ request to spend even more resources devoted to yet another analysis of Bason.

VIII. GROUNDS 3 & 4: PETITIONER IGNORES OBJECTIVE INDICIA OF NONOBVIOUSNESS OF THE CLAIMED INVENTIONS

Objective indicia of nonobviousness are often “the most probative evidence of nonobviousness in the record, and enable[] the . . . court to avert the trap of hindsight.” *Crocs, Inc. v. Int’l Trade Comm’n*, 598 F.3d 1294, 1310 (Fed. Cir. 2010); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (objective evidence of nonobviousness “may often be the most probative and cogent evidence in the record”). For this reason, consideration of objective indicia is part of the overall obviousness analysis, not just an afterthought. *In re Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation*, 676 F.3d 1063, 1075-76 (Fed. Cir. 2012) (noting that a fact finder “may not defer examination of the objective considerations until after the fact finder makes an obviousness finding”); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008) (noting that objective indicia are “not just a

cumulative or confirmatory part of the obviousness calculus but constitute[] independent evidence of nonobviousness.”).

“The existence of an enduring, unmet need is strong evidence that the invention is novel, not obvious, and not anticipated. If people are clamoring for a solution, and the best minds do not find it for years, that is practical evidence—the kind that can’t be bought from a hired expert, the kind that does not depend on fallible memories or doubtful inferences—of the state of knowledge.” *In re Mahurkar Patent Litigation*, 831 F. Supp. 1354, 1378 (N.D. Ill. 1993), *aff’d*, 71 F.3d 1573 (7th Cir. 1995). Here, objective indicia point to a conclusion of nonobviousness because the ’631 Patent met a long felt, but unresolved need for an accurate dose counter that avoided undercounting.¹⁴

For nearly fifty years before the invention of the ’631 Patent, there was no method by which a patient could accurately determine how many doses remained in his or her MDI. Ex. 1013 at 2. As a result, patients were left to guess how

¹⁴ Objective evidence of nonobviousness can include copying, long felt but unsolved need, failure of others, commercial success, unexpected results created by the claimed invention, unexpected properties of the claimed invention, licenses showing industry respect for the invention, and skepticism of skilled artisans before the invention. *Power Integrations, Inc. v. Fairchild Semiconductor Intern., Inc.*, 711 F.3d 1348, 1368 (Fed. Cir. 2013).

many doses were left in their MDIs and had only two practical options: (1) throw away an MDI that still contained medicine or (2) use an MDI that may be empty of medicine and risk not receiving the correct drug dose. As the FDA ultimately recognized, “[t]he former is wasteful, and the latter is potentially dangerous.” Ex. 1013 at 2.

In 2001, the FDA issued draft guidance calling for a more accurate dose counters, and final guidance on the same in March 2003—just two months before Aptar filed its French application disclosing the groundbreaking technology of the ’631 Patent.¹⁵ The ’631 Patent was thus the result of Aptar’s efforts to respond to remedy this long-felt industry need for an accurate dose counter that avoided undercounting. At the time of the invention of the ’631 Patent, competitors in the industry were aware of this problem, but had been unable to create a satisfactory solution. Ex. 1013 at 2. However, despite the proliferation of inferior MDIs for many years, drug makers (including Petitioners) failed to create an accurate MDI dose counter.¹⁶ This powerful evidence, in conjunction with the conclusory

¹⁵ Aptar filed its French Application for the ’177 Patent, the ’631 Patent’s parent, in May 2003.

¹⁶ This is the case even though some of the prior art alleged has been in the public domain since 1965. *See* Ex. 1009 at 5.

reasoning provided in the Petition, shows that Aptar's challenged claims are not obvious. Accordingly, the Board should deny Grounds III and IV in the Petition.

IX. CONCLUSION

The Patent Owner respectfully requests that the Board find claims 1-4 of the '631 Patent to be patentable over the cited prior art, as each of the grounds in the Petition fail for the reasons noted above.

Respectfully submitted,

Dated: February 13, 2019

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CERTIFICATE OF COMPLIANCE WITH WORD COUNT

Pursuant to 37 C.F.R. § 42.24(a), (b), (d), I hereby certify that the attached **Patent Owner's Response to Petition for *Inter Partes* Review of U.S. Patent No. 9,370,631** contains 11,721 words, excluding the parts exempted by 37 C.F.R. § 42.24(a)(1).

Respectfully submitted,

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CERTIFICATE OF SERVICE

A copy of the **Patent Owner's Response to Petition for *Inter Partes* Review of U.S. Patent No. 9,370,631** has been served on Petitioner via electronic mail at the following correspondence address:

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