

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.

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

PETITIONERS' REPLY TO PATENT OWNER'S RESPONSE

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PETITIONERS' EXHIBITS

Exhibit	Description
1001	U.S. Patent No. 9,370,631 (the "'631 Patent")
1002	Declaration of S. David Piper
1003	Curriculum Vitae of S. David Piper
1004	Prosecution History of Application No. 10/556,432 that led to U.S. Patent No. 8,936,177, the parent of the '631 Patent
1005	Prosecution History of Application No. 14/510,324 that led to the '631 Patent
1006	International Publication No. WO 11/59806 (" <i>Allsop</i> ")
1007	U.S. Patent No. 6,283,362 (" <i>Bason</i> ")
1008	European Patent No. EP 0480488 (" <i>Morelli</i> ")
1009	U.S. Patent No. 3,205,863 (" <i>Rhoades</i> ")
1010	U.S. Patent No. 6,747,331
1011	U.S. Patent No. 6,752,153
1012	U.S. Food and Drug Administration, Division of Pulmonary and Allergy Drug Products in the Center for Drug Evaluation and Research (DCER), <i>Draft Guidance for Industry Integration of Dose-Counting Mechanisms into MDI Drug Products</i> (November 2001)
1013	United States Food and Drug Administration, Division of Pulmonary and Allergy Drug Products in the Center for Drug Evaluation and Research (CDER), <i>Final Guidance for Industry Integration of Dose-Counting Mechanisms into MDI Drug Products</i> (March 2003)
1014	International Publication No. WO 95/26769
1015	International Publication No. WO 96/03172
1016	RESERVED
1017	European Publication No. EP 0949584 A2 (" <i>Bason Publication</i> ")
1018	A.R. Clark, <i>Medical Aerosol Inhalers: Past, Present, and Future</i> , 22 AEROSOL SCI. & TECH., 374 (1995)
1019	U.S. Patent No. 2,721,010

1020	U.S. Patent No. 5,290,539
1021	U.S. Patent No. 5,992,309
1022	U.S. Patent No. 2,126,626
1023	U.S. Patent No. 4,414,891
1024	U.S. Patent No. 7,195,134
1025	RESERVED
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1027	Andrew G. Weinstein, <i>When Should Your Asthmatic Patients Refill Their MDI Propelled with Chlorofluorocarbons?</i> , 70 DEL. MED. J., 293 (1998)
1028	Tina Penick Brock et al., <i>Accuracy of Float Testing for Metered-Dose Inhaler Canisters</i> , 42 J. OF THE PHARM. ASS'N, 582 (2002)
1029	Excerpt from Joseph Edward Shigley and Larry D. Mitchell, <i>Mechanical Engineering Design</i> , 16 (McGraw-Hill, Inc., 4 th ed., 1983)
1030	Excerpt from Robert E. Parr, <i>Principles of Mechanical Design</i> , 112-113 (McGraw-Hill, Inc., 1970)
1031	U.S. Patent No. 5,243,970
1032	U.S. Patent No. 7,090,662
1033	International Publication No. WO 2007/045904
1034	U.S. Patent No. 9,439,648
1035	RESERVED
1036	British Patent GB 1317315
1037	U.S. Patent No. 5,349,945
1038	U.S. Patent No. 6,142,339
1039	U.S. Patent No. 6,161,724
1040	International Publication No. QO 1998/56444
1041	Lewis, <i>Metered-dose inhalers: actuators old and new</i> , 4(3) EXPERT OPIN. DRUG. DELIV. 235 (May 2007)

1042	Stein and Thiel, the History of Therapeutic Aerosols: A Chronological Review 2017
1043	Excerpts from Federal Register Vol. 66
1044	Excerpts from Federal Register Vol. 68
1045	W. Travis Cain & John J. Oppenheimer, <i>The misconception of using floating patterns as an accurate means of measuring the contents of metered-dose inhaler devices</i> , 87 ANNALS OF ALLERGY, ASTHMA, & IMMUNOLOGY, 417 (2001)
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1047	Excerpt of Douglas M. Bryce, Plastic Injection Molding, Vol. 1 (1996)
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1049	D. B. Price <i>et al.</i> , <i>Historical cohort study examining comparative effectiveness of albuterol inhalers with and without integrated dose counter for patients with asthma or chronic obstructive pulmonary disease</i> , 9 J. ASTHMA & ALLERGY 145 (2016)
1050	Declaration of Ron N. Sklar in support of Motion to Appear <i>Pro Hac Vice</i>
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1054	RESERVED
1055	May 9, 2018 Declaration of Charles E. Clemens in IPR2018-01159, West Phar, Svcs., Inc. v. Sanofi-Aventis Deutschland GmbH
1056	Excerpt of Transcript of Video Deposition of Charles E. Clemens, taken October 25, 2007, in Novo NorDisk v. Sanofi-Aventis U.S. LLC, et al., No-3:07-cv-03206 (Dkt No. 233-25)
1057	Deposition Transcript of Charles E. Clemens, taken April 24, 2019
1058	Declaration of S. David Piper
1059	Declaration of Charles E. Clemens in related IPR2018-01054
1060	RESERVED

1061	Jill Matzke, <i>Chapter 16—Dfe for Engineering Managers: Making it Count—Dfe and the Bottom Line</i> , GREEN ELECTRONICS/GREEN BOTTOM LINE (2000)
1062	C. Manoharan, et. al., An Expert System for Design for Robotic Assembly, 1 J. INTELL. MANUF. 17 (1990)
1063	Reserved
1064	IEEE 100 The Authoritative Dictionary of IEEE Standards Terms (7th ed.) 2000
1065	Merriam-Webster's Collegiate Dictionary (11th ed.) 2012

I. INTRODUCTION

Aptar's challenges to the instituted grounds are based on a misreading of the prior art and the assumption that a POSA is an automaton incapable of incorporating features of one reference into another, rather than a person of ordinary creativity. The prior art, Aptar's own expert's testimony, Aptar's admissions during prosecution, and Mr. Piper's reply declaration undermine every one of Aptar's arguments.

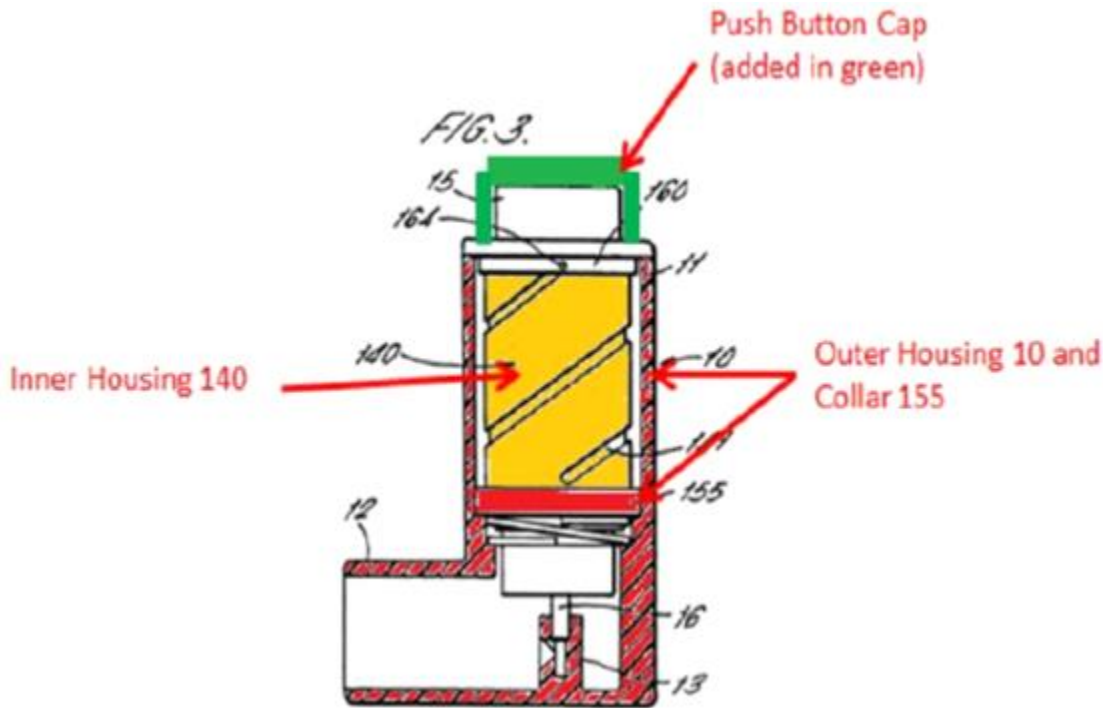
II. ALLSOP ANTICIPATES THE CHALLENGED CLAIMS

A. Allsop's Push-Button Cap

Aptar is mistaken when it argues that Allsop's push-button cap cannot move axially. Aptar's Corrected Response ("Response") at 11-15. Aptar states that the cap must sit between the Allsop device's inner and outer housings, which would allegedly result in the cap interfering with ring 160 upon depression of the push-button cap. *Id.* at 12-13. In making this argument, Aptar relies on a self-serving figure drawn by Mr. Clemens, which depicts a cap *without* a push-button.¹ *Id.* at 14.

¹ Mr. Clemens suggested that "push-button cap" was just "a name" and it appears he accorded the "name" selected by Allsop's inventor no weight at all. *See* Clemens Tr., Ex. 1057 at 216:14-218:13, 219:23-220:8. Mr. Clemens is wrong. *See* Piper Decl., Ex. 1058 ¶¶ 6-9.

But as illustrated in the Petition, the push-button cap is located on the top rim of the outer housing where it “cover[s] the upper portion of the pressurized dispensing container 15.” Allsop, Ex. 1006 at 8:22-26; Petition at 37.



A correct understanding of Allsop’s push-button cap as presented by Mr. Piper shows that the sides of the push-button cap **do not** interfere with ring 160. Piper Decl., Ex. 1058 ¶ 10. The top “push-button” portion of the cap moves axially, interacting directly with the reservoir (and therefore indirectly with the second member), and/or directly with the very top of the inner housing (second member). *Id.*; Petition at 37, 38, 39; *see also* Piper Decl., Ex. 1002 ¶ 62-63, 66, 77-78, 81.

Aptar also makes the misguided argument that Allsop fails to enable the push-button cap because it does not describe how the push-button cap interconnects with

the housing and whether the push-button cap is axially displaceable. Response at 9-10. On the contrary, Allsop describes a push-button cap that covers the container and prevents dust, contaminants, and moisture from getting into the device. Allsop, Ex. 1006 at 8:22-26. Accordingly, it is clear from the Allsop disclosure that the push-button cap covers the top of the device, otherwise it would not prevent dust, contaminants and moisture from getting into the device. Furthermore, the fact that the button of the cap is axially displaceable is clear from the type of cap that is used — a *push-button* cap. If the push-button of the cap did not move axially (i.e., if it could not be pushed), it would not be a *push-button* cap. Piper Decl., Ex. 1058 ¶¶ 7-9. Thus, the push-button cap is enabled. *See In re Gleave*, 560 F.3d 1331, 1334-36 (Fed. Cir. 2009) (explaining that a reference is enabled if it allows a POSA “to make the invention without undue experimentation”); *see also* Piper Decl., Ex. 1002 ¶¶ 62-63, 66 (demonstrating that a POSA could make the invention without undue experimentation).

B. Allsop’s Second Member Is Engageable With The Push-Button Cap

Aptar takes the erroneous position that the push-button cap does not engage with the second member. Response at 15-16. More specifically, Aptar argues that instead of engaging with the inner housing, the push-button cap interferes with it by pressing on ring 160. *Id.* at 16. But as discussed above, that is not how the push-button cap works. The push-button cap may engage with the inner housing directly,

or it may engage with it indirectly via the canister. *See* Petition at 38; Piper Decl., Ex. 1002 ¶¶ 66, 81; Piper Decl., Ex. 1058 ¶ 10.

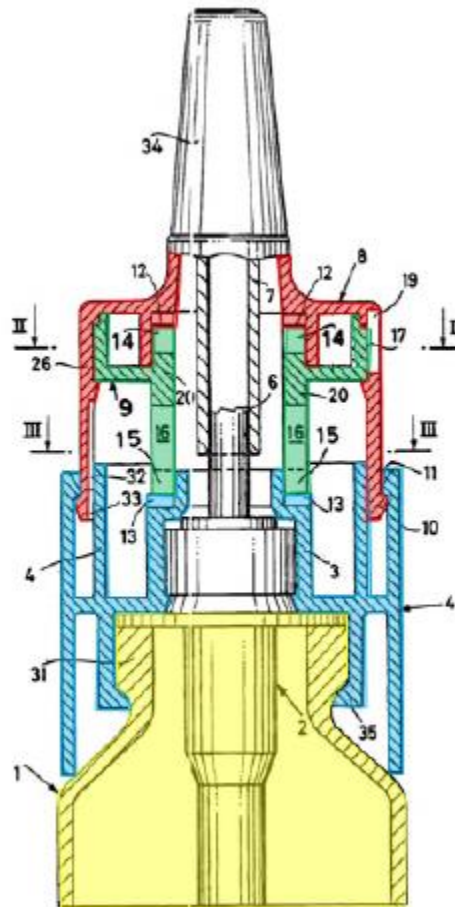
C. Allsop's Display of Dosage Values

Aptar misapprehends Allsop in making the argument that it does not include displayable dosage values from which a single dose is displayed. Response at 17-18. Aptar's argument is based on a narrow construction of "displayed" that requires the device to obscure all numbers except the current value. But Aptar has not suggested that the term "displayed" needs construction, and further, Aptar does not explain why the number indicating the remaining doses in Allsop is not "displayed" by virtue of the indicator pointing to it. The '631 Patent's specification broadly describes dose indicators and dose counters, both of which can use numbers. Ex. 1001 at 1:24-30. Mr. Clemens tried to distinguish these types of components (Clemens Tr., Ex. 1057 at 229:18-230:10), but the challenged claims are not limited to either counters or indicators — they broadly claim "dose values." *See, e.g.*, Ex. 1001 at 10:2-24. There is no basis (nor has Aptar argued one) for narrowly construing the term "displayed" simply to avoid anticipation by Allsop, particularly here where the claims are to be construed pursuant to their broadest reasonable interpretation. *See* Piper Decl., Ex. 1058 ¶¶ 11-14; *see also* Ex. 1064 at 323; Ex. 1065 at 361.

III. MARELLI ANTICIPATES THE CHALLENGED CLAIMS

A. Marelli's Second Member Is Displaceable Axially Relative To The Stationary Body

Aptar mischaracterizes Marelli when it identifies “rotating element 9” as the entire claimed “second member” and concludes that the second member does not move relative to the body. Response at 22. As the Petition explains, the “second member” limitation is met by rotating element 9, which is “integral with small flexible legs 16.” Petition at 46; Ex. 1008 at 3:39-46. In his depiction of the full Marelli device, Mr. Clemens depicted this component shaded in green.



The Petition explains that upper parts 14 and lower parts 15 of legs 16 flex axially to move over teeth 12 and 13 respectively, carrying rotating element 9 in a unitary rotation. Petition at 46-47. Aptar correctly points out that individual component 9 itself moves axially with, not relative to, nasal 8. Response at 24. But the challenged claims broadly cover a “second member.” That second member here corresponds to rotating element 9 with its *integral*, flexible legs. Those legs move axially. Piper Decl., Ex. 1002 ¶¶ 98-99; Piper Tr., Ex. 2019 at 120:19-24, 121:18-122:5.

IV. THE CHALLENGED CLAIMS WOULD HAVE BEEN OBVIOUS OVER BASON / RHOADES AND BASON / ALLSOP

The Petition sets forth simple combinations of known prior art references showing that the Challenged Claims would have been obvious. Unable to reasonably dispute the presence of the claimed elements in those combinations, Aptar argues that the combinations could not be assembled and/or would be inoperable. But in doing so, Aptar makes a fundamental legal error — it conducts its obviousness analysis through the lens of a POSA having no ability to overcome even the most basic technical challenges.

It is black letter law that a POSA is not an automaton. A POSA would know how to overcome routine technical challenges. A POSA would know how to adapt simple mechanical mechanisms to the problem on which that POSA is working.

And, in this case, the objective evidence confirms that a POSA could and would have easily combined the teachings of the references.²

A. Aptar's Arguments Are Undercut By Its Own Statements During Prosecution

Aptar repeatedly makes the misguided argument in its Response that a POSA would not have known how to connect or arrange the various components of the Ground 3 and Ground 4 combinations. *See, e.g.*, Response at 35-36, 50-51 (concerning the attachment of a cap to an inhaler); *id.* at 37-39, 52-53 (concerning the connection between two gears). Aptar's own statements to the Patent Office during prosecution of U.S. Patent No. 8,936,177 (the parent of the '631 Patent) undermine its arguments here.³ For example, during prosecution, the Examiner rejected Aptar's claims as indefinite, stating:

² The obviousness analysis from Aptar and its expert, Mr. Clemens, fails for additional fundamental reasons. For example, Mr Clemens could not describe the qualifications of the POSA through whose eyes he analyzed the prior art (Clemens Tr., Ex. 1057 at 37:8-41:13), nor could he describe the full obviousness analysis he performed (*id.* at 141:2-143:6, 147:16-148:15).

³ References to the prosecution history in this Reply refer to the prosecution history of U.S. Patent No. 8,936,177.

[I]t is not clear what are required structures or shapes of the elements in the claims, such as . . . an indicator device, at least one station[ary] gear, a counter element . . . and structural connections between them.

Ex. 1004 at 1222. In response to the Examiner’s rejection, Aptar argued that “[o]ne of ordinary skill in the art . . . would have understood how to shape and structure the gears and their novel interaction with each other in the claimed invention.” *Id.* at 1233. The Petition sets forth numerous additional examples where Aptar argued that a POSA would have understood how to connect or arrange the components of the claimed invention. Petition at 1-2, 10-11, 12, 16, 55, 69, n.5 (citing Ex. 1004). Yet in response to the obviousness allegations set forth in the Petition, Aptar argues that a POSA would not have known how to connect or arrange these same components. *See, e.g.*, Response at 37-39, 52-53.

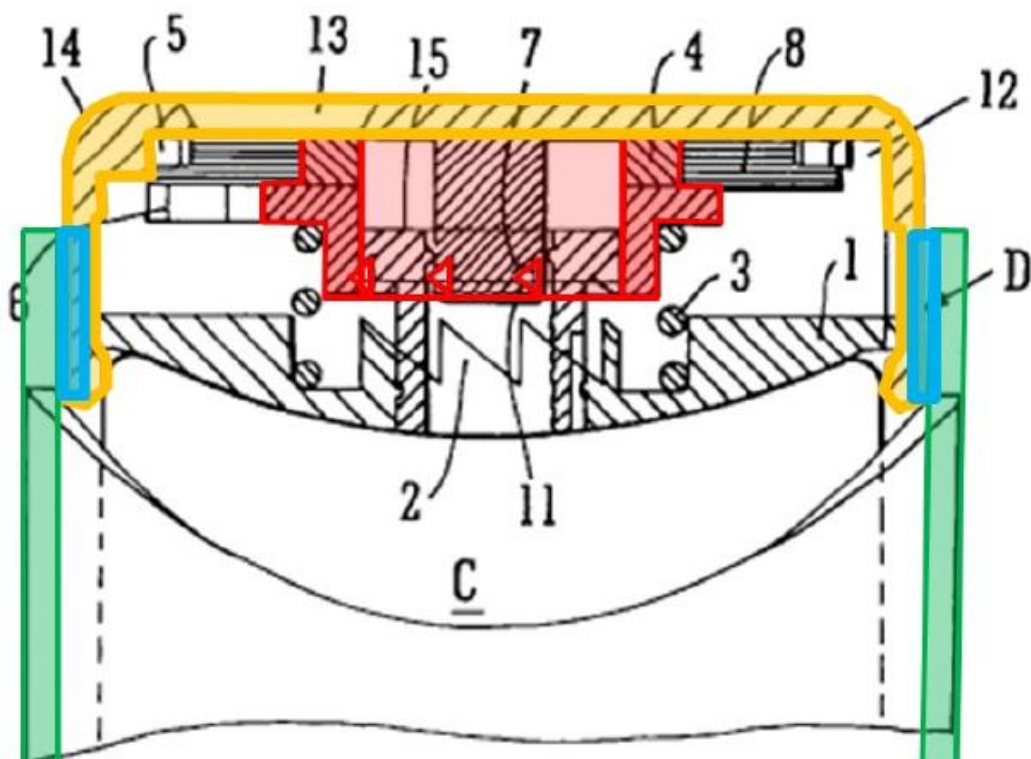
In light of Aptar’s admissions during prosecution about a POSA’s abilities, Aptar’s arguments fail. *See In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994) (when an applicant “did not provide the type of detail in his specification that he now argues is necessary in prior art references, [this] supports [a] finding that one skilled in the art would have known how to implement the features of the references.”).

B. The Bason / Rhoades and Bason / Allsop Devices Disclose A “First Member That Is Displaceable Axially Relative To [A] Stationary Body”

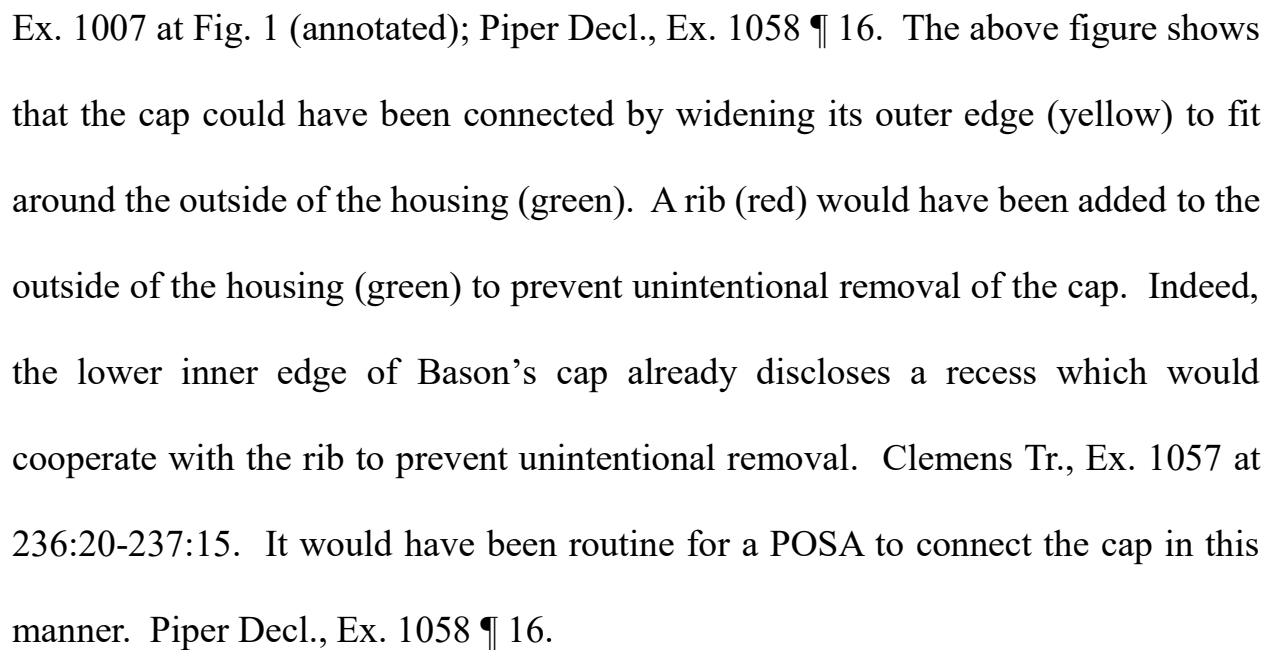
Aptar makes the misguided argument that a POSA would not have known how to connect Bason’s cap to the MDI so that the cap could move axially. Response at

35-36. But connecting the cap to ensure that it could move axially involves routine pre-production steps within the skillset of a POSA. Piper Decl., Ex. 1058 ¶¶ 16-20. A POSA is not an automaton that would be incapable of making routine modifications to the device. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420–21 (2007).

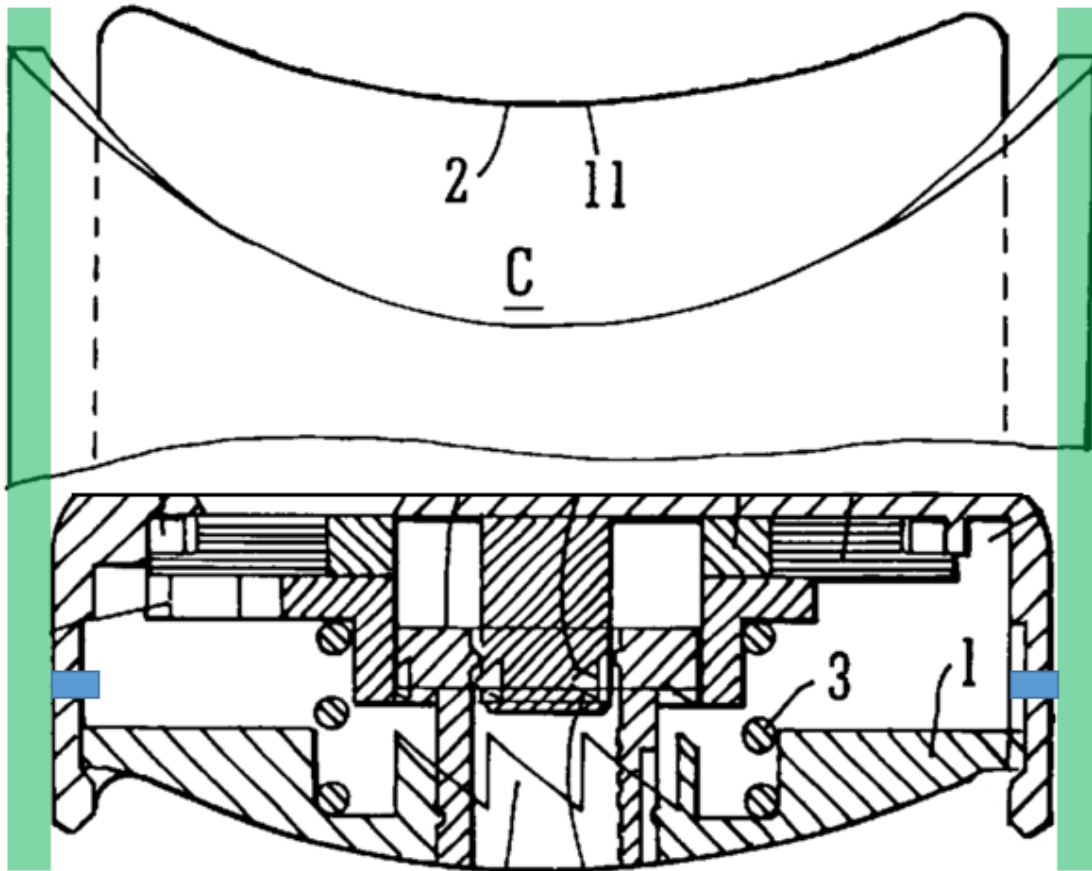
As explained in the Petition with respect to Ground 3, A POSA would have extended Bason's body, integrated the stationary gear of Bason into the inhaler body, and connected the remaining components as disclosed in Bason *or other ways well-understood in the art*. Petition at 55-56. Both Aptar and Mr. Clemens ignore that a POSA could have used well-understood ways to connect the components. Response at 30; Clemens Tr., Ex. 1057 at 231:6-22. And during prosecution, Aptar stated that these connections were well-known to a POSA. Ex. 1004 at 1138 (“[O]ne of ordinary skill would understand the structure and connection of a body, reservoir, actuator, counter, and dispenser member.”). Aptar annotated Figure 1 of Bason, arguing that it illustrates how a POSA would have combined these references.



Response at 35. Using this construct, Aptar asserts that placing teeth 2 (blue) on the inhaler body would prevent the cap from being depressed. *Id.* But as Aptar admitted during prosecution of the application that resulted in the '177 Patent, the elements can be connected using *various* techniques well understood in the art. Ex. 1004 at 281. The existence of caps used in inhalers was well-known at the time of the invention and was discussed in many references cited during prosecution of the '177 Patent's application. *See* Ex. 1004 at 403, 409, 617, 650. For example, as Mr. Piper explained, this cap could have been connected by slightly widening it so that its outer edge fits over the outside of the housing. Piper Decl., Ex. 1058 ¶ 16. This is illustrated in the following figure:



Aptar presents this same misguided argument with respect to Ground 4, Bason in view of Allsop. Response at 49-51. In this combination, a POSA would have placed the Bason dose counter below the canister, rather than above the canister. Thus, a POSA would have implemented another of the various, routine, and obvious connections for this combination. For example, as depicted in the figure below, the cap would have been designed with slots through which teeth 2 (blue) would protrude:



Piper Decl., Ex. 1058 ¶¶ 17-18. As illustrated above, teeth 2 would have projected through slots in the cap.⁴ Those slots would have been slightly taller than the height of the teeth, allowing the cap to move up and down upon operation of the MDI.⁵ This is another of the various, routine, and obvious manners in which a POSA would have connected the components. Ex. 1004 at 281; Piper Decl., Ex. 1058 ¶¶ 17-18. A POSA was fully capable of making these design choices. *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1382 (Fed. Cir. 2007) (“[W]e do not ignore the modifications that one skilled in the art would make to a device borrowed from the prior art.”); *Arctic Cat v. Polaris Indus.*, IPR2014-01427, Paper 58, 22-23 (“Petitioner is not required to account for every technical challenge in order to show obviousness”).

⁴ Teeth 2 would also have been designed to facilitate assembly of the dose counter below the canister. For example, a POSA would have known to taper teeth 2 (narrower at the top, wider at the bottom), to allow the cap to slide into position. Piper Decl., Ex. 1058 ¶¶ 19-20; *see also* Ex. 1061 at 190; Ex. 1062 at 19.

⁵ This would have been equally applicable to the combination of Bason and Rhoades described immediately above. Piper Decl., Ex. 1058 ¶ 18.

C. The Bason / Rhoades and Bason / Allsop Devices Disclose “When Said First Member Displaces Axially . . . Said Second Member Is Caused To Be Displaced Axially And Permitted To Rotate Relative To Said Stationary Body, So As To Change A Displayed Dose Value From Among The Plurality Of Displayable Dose Values”

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

⁶ Despite the Petition’s explanation, Aptar and Mr. Clemens created self-serving figures allegedly depicting their understanding of a potential device resulting from the combinations described in the Petition. Not only do those figures ignore any level of skill on the part of the POSA, but Mr. Clemens admits his figures do not depict devices where the teeth interact or where the components retain their same functions, as described in the Petition. *See* Clemens Tr. at 234:19-236:15.

the diameter of ring 4 so that teeth 7 interact with teeth 2, just as they do in Bason.

See Piper Decl., Ex. 1058 ¶¶ 21-23.

Finally, with respect to Ground 4 only, Aptar takes the misguided position that the Bason / Allsop combination would not include a displayed dose value. More specifically, Aptar argues that Bason’s window, which is on top of the counter, will not be visible if the counter sits below the canister. Response at 54-55. Again, Aptar’s argument assumes that a POSA is an automaton, and it also ignores Mr. Piper’s testimony and the prior art fluid dispensers known to a POSA that disclose a window below the canister for displaying dose values. *See* Ex. 1036 at Fig. 3b; Piper Tr., Ex. 2019 at 129:9-14 (“there’s a window 13 in Bason that indicates a count of the doses, and obviously that arrangement would have to be made on the side of the device that a patient would see the number of actuations”); Clemens Tr., Ex. 1057 at 243:11-244:18, 246:12-247:21; *see also* Piper Decl., Ex. 1058 ¶ 25.

D. Rhoades Is Pertinent Art

Aptar takes the unwarranted position that because the device described in Rhoades does not have the same “purpose” as the device described in Bason, Rhoades is not analogous art. Response at 39-40. But Aptar failed to consider the correct test for analogous art. *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992) (A reference is analogous if it is “reasonably pertinent to the particular problem with

which the inventor is involved,” and “logically would have commended itself to an inventor’s attention in considering his problem.”).

A POSA would have considered the mechanisms disclosed in Rhoades. Piper Decl., Ex. 1002 ¶¶ 135-136. Rhoades’s structure is very similar to that of an MDI like Bason, including that it possesses a body, a fluid reservoir, a gear, and a means for converting linear motion to rotational motion. Clemens Tr., Ex. 1057 at 180:22-182:4. Even Aptar’s expert, Mr. Clemens, has considered the components of mechanical pens and medical devices together when previously testifying on behalf of a different Petitioner. Ex. 1055 ¶ 47 (explaining that a *pen*-type injector medical device “has simple mechanical structures . . . [which] can be found in an age-old mechanism[] of a retractable ball point pen”); Clemens Tr., Ex. 1057 at 182:24-183:12. A POSA would have been familiar with the mechanism found in mechanical pens. *Id.* at 175:16-176:19. Mr. Clemens also agreed that engineers take basic known mechanisms and apply them to other products (Ex. 1056 at 98-100; Clemens Tr., Ex. 1057 at 186:20-187:24), and at a high level, anybody skilled in the art that knew Rhoades’s device converted linear to rotational motion could consider using that mechanism in an inhaler to operate a dose counter. Clemens Tr., Ex. 1057 at 187:25-189:25.

Mr. Clemens also admitted that Rhoades and the ’177 Patent share a stated purpose. For example, one of the stated purposes of the ’177 Patent is “to provide

such a fluid dispenser that [is] simple and inexpensive to manufacture and to assemble and that it is reliable in use,” and a stated purpose of Rhoades is to provide a reliable mechanism that is readily manufactured and assembled and that will operate satisfactorily for a long period of time. Clemens Tr., Ex. 1057 at 160:15-163:17.

The Petition also identifies numerous examples of medical device components that are analogous to pens. Petition at 54. Aptar argues that two of those references, Ambrosio (Ex. 1031) and Wimpenny (Ex. 1032) “teach away” by distinguishing prior art disclosures.⁷ Response at 40 n.7. But none of the references cast doubt that

⁷ Aptar’s “teaching away” arguments related to Ambrosio and Wimpenny are misplaced. In their specifications, Ambrosio and Wimpenny attempt to distinguish their inventions from certain prior art references. For example, Ambrosio criticizes cup-like features disclosed in the prior art to which powder medicament may stick. Clemens Tr., Ex. 1057 at 193:11-13; Ex. 1031 at 2:47-50. Wimpenny criticizes a prior art pen-like device because it does not address incorrect dose setting by the user. Ex. 1032 at 1:47-48. Mr. Clemens could not explain why these statements allegedly taught away. Clemens Tr., Ex. 1057 at 192:24-193:21, 197:21-198:16. Regardless, neither reference teaches away from using components from a mechanical pen in the context of developing a medical device.

components of a pen may be used in conjunction with a medical device. Indeed, the invention of Wimpenny “relates to . . . pen-type injectors.” Ex. 1032 at 1:7-9.

E. Rhoades Does Not Teach Away

Aptar also takes the misguided position that Rhoades teaches away from the use of strict physical tolerances. Response at 41-42. It does not. *Meiresonne v. Google, Inc.*, 849 F.3d 1379, 1382 (Fed. Cir. 2017) (“A reference that merely expresses a general preference for an alternative invention but does not criticize, discredit, or otherwise discourage investigation into the claimed invention does not teach away.” (internal quotation marks omitted)). Rhoades says only that close manufacturing tolerances are not “require[d],” not that they could not or should not be used. Ex. 1009 at 8:14-16. Regardless, “the challenged claims do not require expressly ‘close manufacturing tolerances.’” Institution Decision at 22.

V. A POSA WOULD HAVE BEEN MOTIVATED TO COMBINE BASON / ALLSOP

In addition to the arguments addressed in Section IV.B-C, Aptar makes the misguided argument that it would not have been obvious to combine Bason in view of Allsop for two reasons: (1) it is not clear how the valve stem would travel through the cap; and (2) it would not have been obvious to combine the references because one discloses components below the canister and the other discloses components above. Again, Aptar’s analysis seeks to improperly impose an obviousness analysis

from the perspective of a POSA that is an automaton, rather than a POSA having ordinary creativity.

As to the first argument, Aptar doesn't dispute that in the claimed combination the valve stem would travel through the dose counter. Rather, Aptar implies that a POSA would not have known how to create an opening through the middle of the components. Of course, just as a POSA would have known to use injection molding to mold stop members to the inhaler body, a POSA also would have known to injection mold the dose counter components to include an aperture through their center. Piper Decl., Ex. 1058 ¶ 19. Moreover, inserting the valve stem through a dose counter in an MDI in exactly this fashion had been well-known in the prior art for decades. *See* Elliott, Ex. 1036 at Figs. 1-3; Clemens Tr., Ex. 1057 at 49:13-51:21, 244:8-18.

As to the second argument, the fact that one reference positions components on top and the other on the bottom would not have dissuaded a POSA from combining these references. Both references are in the same field of endeavor. Both disclose MDIs with dose counters for tracking the number of doses of medication used or remaining. Both devices do so by converting linear motion to rotational motion. Both devices are similar in structure and function, and the configuration of an inhaler with a dose counter below the canister was well-known in the art. *See, e.g.,* Elliott, Ex. 1036; Clemens Tr., Ex. 1057 at 244:8-15. It would have been

obvious for a POSA to combine these devices and a POSA would have been motivated to do so to create an inexpensive, reliable and integrated dose counter that could be mass-produced in light of the FDA's guidance. Piper Decl., Ex. 1002 ¶¶ 169-176.

VI. SECONDARY CONSIDERATIONS

A. Long-Felt Need

Aptar makes the unsupported argument that there was a long-felt but unresolved need for its invention. Aptar's argument is premised on its suggestion that the claimed invention satisfies a particular safety need. But the challenged claims do not include any safety features. Clemens Tr., Ex. 1057 at 214:9-215:3.

Regardless, Aptar admits that it developed its alleged invention *in response to* the FDA's guidance. Aptar states:

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.

Response at 3. In other words, immediately after the FDA issued its draft guidance on December 11, 2001, Aptar began developing its dose counter. Less than seventeen months later, Aptar filed its French patent application. Aptar developed its dose counter in response to a shortly-felt regulatory directive, not in response to a long-felt but unresolved need. *See Ecolchem, Inc. v. S. Cal. Edison Co.*, 227 F.3d

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1361, 1377 (Fed. Cir. 2000) (“Ecolchem’s process was developed not in response to a long-felt need in the power industry, but in response to a shortly-felt requirement imposed by EPRI’s guidelines.”); *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1354-55 (Fed. Cir. 2016) (“[T]here was no pressing need for companies to create a [new] product before the FDA’s mandate, as they were able to continue to sell their [original] products.”).

Aptar’s argument to the contrary appears to be based on a fundamental misreading of the FDA’s guidance. *See* Response at 63. The FDA did not suggest there was an absence of sufficiently accurate dose counters. Rather, it simply recognized that commercial products did not incorporate dose counters at all. *See* 2003 FDA Guidance, Ex. 1013 at 2 (“Currently available MDIs offer no practical way for patients to track the remaining numbers of doses”). Aptar’s expert agrees. Clemens Tr., Ex. 1057 at 209:3-211:4, 211:5-212:10 (referring to ¶ 91 of Mr. Clemens’s declaration in IPR2018-01054 (Ex. 1059), which argues that Bason “already reflected the FDA’s recommendation for dose counting”); Ex. 1059 ¶ 91. The guidance ultimately recommended that “manufacturers with metered-dose inhalers under development for oral inhalation integrate a dose-counting device.” Ex. 1013 at 3. There was no pressing need to develop new dose counters before the FDA’s guidance because (1) suitable counters were known (Ex. 1059 ¶ 91; Clemens Tr., Ex. 1057 at 209:3-211:4, 211:5-212:10) and (2) like in *Purdue*, manufacturers

were free to sell their fluid dispensers without dose counters (Clemens Tr., Ex. 1057 at 213:2-6).

The FDA's guidance does not evidence a long-felt need for Aptar's alleged invention. It shows why a POSA would have been motivated to combine known references by 2003 to decrease device costs in preparation for mass production. *Ecolochem*, 227 F.3d at 1377.

B. Failure Of Others

Finally, Aptar makes the unsupported argument that “drug makers (including Petitioners) failed to create an accurate MDI dose counter.” Response at 63. But the mere absence of a certain product in the marketplace is not evidence of long-felt need or failure of others. *See Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1324-25 (Fed. Cir. 2004). Aptar cites no evidence to support its suggestion that anyone, let alone Petitioners, tried and failed to create an accurate MDI dose counter, and Mr. Clemens considered none. Clemens Tr., Ex. 1057 at 212:16-25. Finally, Aptar ignores admissions made during prosecution of the '177 Patent that fluid dispensers having dose counters were well-known. Ex. 1004 at 1282:2-4. There is no evidence that prior art dose counters would have been insufficient to satisfy the FDA's recommendation if they were integrated into commercial products.

VII. CONCLUSION

Cancellation of the challenged claims is respectfully requested.

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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 Petitioners' Reply to Patent Owner's Response totals 4,517, which is less than the 5,600 allowed under 37 C.F.R. § 42.24(c)(1).

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petitioners' Reply to Patent Owner's Response was served on counsel of record on May 13, 2019, by filing this document through the End-to-End System, as well as delivering a copy via electronic mail to the counsel of record for the Patent Owner at the following address:

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