

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 No.: 2018-01055
Patent No. 9,370,631

REPLY DECLARATION OF S. DAVID PIPER

I.	REPLY TO APTAR’S ARGUMENT THAT ALLSOP DOES NOT DISCLOSE A PUSH-BUTTON CAP	2
II.	REPLY TO APTAR’S ARGUMENT THAT THE ALLSOP DEVICE DOES NOT CHANGE A DISPLAYED DOSE VALUE	3
III.	REPLY TO APTAR’S ARGUMENT THAT A POSA WOULD NOT HAVE KNOWN HOW TO CONNECT BASON’S CAP TO THE MDI.....	4
IV.	REPLY TO APTAR’S ARGUMENT THAT A POSA WOULD NOT HAVE KNOWN HOW TO SHAPE AND ALIGN THE GEARS OF THE DEVICES RESULTING FROM THE ASSERTED COMBINATIONS.....	10
V.	REPLY TO APTAR’S ARGUMENT THAT A POSA WOULD NOT HAVE KNOWN TO MODIFY THE BASON / ALLSOP COMBINATION TO INCLUDE A DISPLAYED DOSE VALUE.....	12
VI.	REPLY TO APTAR’S ARGUMENT THAT RHOADES IS NOT ANALOGOUS ART	13
VII.	CONCLUSION	14
VIII.	SIGNATURE.....	15

I, S. David Piper, declare as follows:

1. My name is S. David Piper. I have been retained by counsel for Petitioners to serve as a technical expert in this *inter partes* review proceeding.
2. My background is set forth in paragraphs 3-8 of my initial declaration (Ex. 1002) and my CV (Ex. 1003).
3. Since my initial declaration, I have reviewed Aptar's Preliminary Response (Paper 10), the Board's Institution Decision (Paper 11), Aptar's Corrected Response (Paper 27) ("Response"), the declaration of Charles Clemens (Ex. 2021), the transcript of Charles Clemens's deposition (Ex. 1057), and all of the exhibits submitted in connection with the forgoing.
4. I confirm that everything I included in my initial declaration and all of the testimony given during my deposition remain true to the best of my knowledge.
5. As I explained in my initial declaration, I was a person having more than ordinary skill in the art in the early 2003 time frame, but I worked with many engineers who fit the characterization of a POSA and I am familiar with their level of skill. Piper Decl., Ex. 1002 at ¶¶ 3-8, 13. I have been asked to provide expert testimony in this declaration in reply to issues raised by Aptar's Corrected Response (Paper 27) and the declaration (Ex. 2021) and deposition testimony (Ex. 1057) of Charles Clemens. When developing the opinions set forth below, I have

assumed the perspective of a POSA as set forth in my initial report. *See* Piper Decl., Ex. 1002 at ¶ 12.

I. REPLY TO APTAR’S ARGUMENT THAT ALLSOP DOES NOT DISCLOSE A PUSH-BUTTON CAP

6. Aptar misapprehends the Allsop reference when contending that its push-button cap cannot move axially. Response at 8-15. Aptar relies on a drawing prepared by Mr. Clemens, which depicts a cap *without* a push-button. *Id.* at 14. But a cap that cannot be pushed is not a push-button cap.

7. Mr. Clemens testified that a “push-button cap” was just “a name,” and it appears he ignored that name and accorded it no weight at all. *See* Ex. 1057, Clemens Tr. at 216:14-218:13, 219:23-220:8. Mr. Clemens is incorrect. It is clear that Allsop’s “push-button cap” includes a button that can be pushed.

8. A push-button was a common component that a POSA would have been familiar with at the time of the alleged invention. For example, another prior art reference relied on in this matter, Rhoades (Ex. 1009), includes a push-button. Rhoades, Ex. 1009, at 4:22-33. Like the push-button cap that I depicted in my initial declaration (Piper Decl., Ex. 1002 ¶ 62), Rhoades’s push-button is capable of being depressed. Rhoades, Ex. 1009, at 4:22-33 (“ . . . when the push button 35 is repeatedly depressed to thereby align alternate cam surfaces with the stationary stop members . . .”).

9. Like the push-button in Rhoades, Allsop's push-button can be depressed, which would cause the canister to move downward. Piper Decl., Ex. 1002 ¶¶ 62-63. As discussed in my initial declaration, the push-button would have engaged with the second member either directly or indirectly. *Id.* at ¶¶ 62-63, 66.

10. Aptar takes the misguided position that if the push-button cap engaged directly with the inner housing, the push-button cap would interfere with the inner housing by "pressing the ring 160 and pins 161, 162 such that the device no longer accurately indicates the doses remaining." Response at 16. Aptar is incorrect. Allsop's push-button cap would have engaged directly with the tops of the inner housing and canister, or indirectly with the inner housing through direct contact with the canister. Piper Decl., Ex. 1002 ¶ 66. Allsop's ring 160 and pins 161, 162 do not extend above the top of the inner housing during use. Allsop, Ex. 1006 at Figs. 1-4.

II. REPLY TO APTAR'S ARGUMENT THAT THE ALLSOP DEVICE DOES NOT CHANGE A DISPLAYED DOSE VALUE

11. Aptar takes the misguided position that the device disclosed in Allsop does not "change a displayed dose value." Response at 17-18. More specifically, Aptar argues that the displayed dose value does not change because the values are always displayed. I disagree.

12. I understand that in this *inter partes* review proceeding, claim terms should be given their broadest reasonable interpretation. Piper Decl., Ex. 1002 ¶ 27.

13. Under the broadest reasonable interpretation, a POSA would understand that the term, “display,” means “to present data visually” (Ex. 1064) or “to make evident” (Ex. 1065). It is with this understanding that I analyzed and formed my opinions concerning Allsop. Piper Decl., Ex. 1002 ¶¶ 68-69.

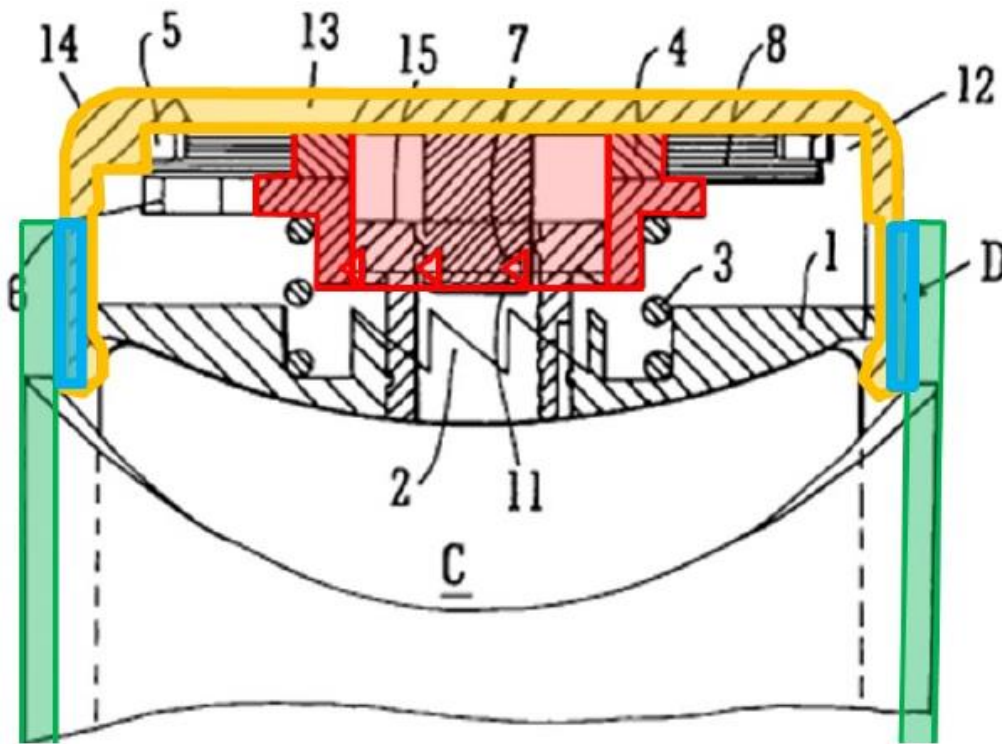
14. Allsop discloses “chang[ing] a displayed dose value from among the plurality of displayable dose values.” For example, Allsop discloses making evident how many doses remain in a canister by displaying the number of remaining doses by using a pin that points to that number. Allsop, Ex. 1006 at 9:3-25, Fig. 1. As the canister is depressed, the pin slides down, displaying a new number visually in conjunction with a pin and making evident that one fewer dose remains.

III. REPLY TO APTAR’S ARGUMENT THAT A POSA WOULD NOT HAVE KNOWN HOW TO CONNECT BASON’S CAP TO THE MDI

15. Aptar takes the unreasonable position 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.

16. 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

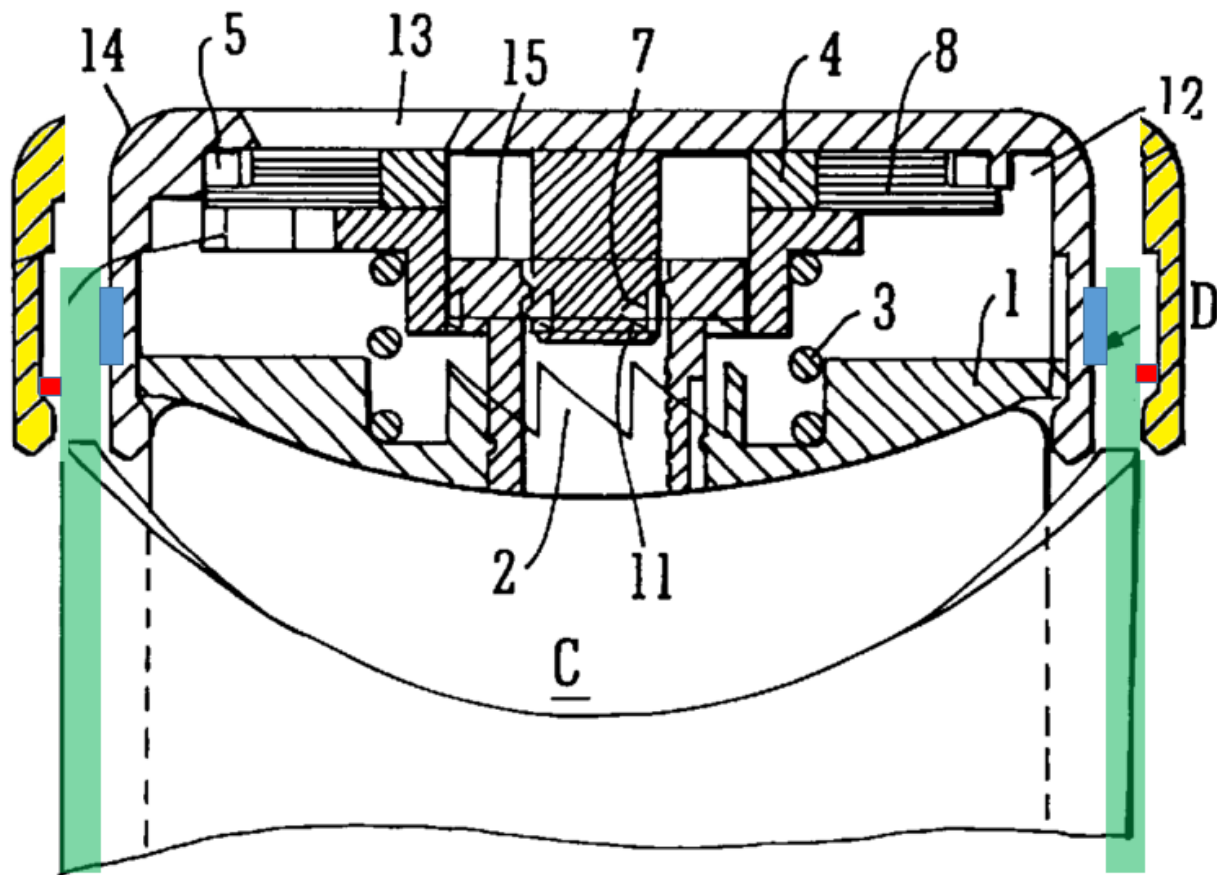
inhaler body and connected the remaining components as disclosed in Bason *or* using “*other ways well-understood in the art.*” Petition at 55-56; Piper Decl., Ex. 1002 at ¶ 137. Aptar and Mr. Clemens ignore that a POSA could have used well-understood ways to connect the components. Response at 30, 32; Clemens Tr., Ex. 1057 at 231:6-22. Aptar annotated Figure 1 of Bason, arguing that it illustrates how a POSA would have combined these references.



Response at 35. More specifically, Aptar argues that placing teeth 2 (blue) on the inhaler body would prevent the cap from being depressed. *Id.* But as Aptar admitted during prosecution, the elements can be connected using *various* techniques that were well-understood in the art. '177 Patent Prosecution History, Ex. 1004 at 281. For example, it would have been obvious to a POSA to connect

the housing. This is illustrated in the following figure:

REPLY FIG. 1

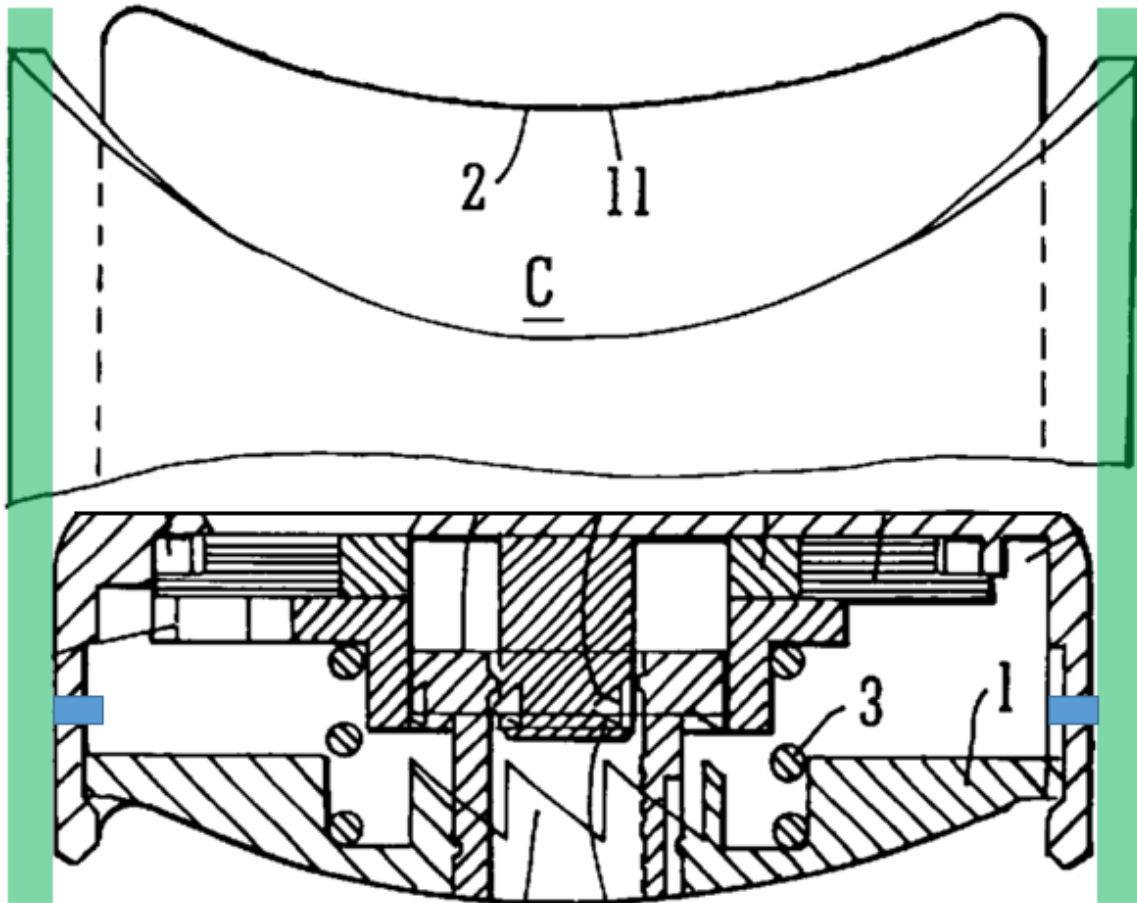


The above figure shows that the cap would have been connected by widening its outer edge (yellow) to fit around the outside of the housing (green). A rib (red) would have been added to the outside of the housing (green) to prevent unintentional removal of the cap. Indeed, the lower inner edge of Bason's cap already discloses a recess which would cooperate with the rib to prevent unintentional removal. Bason, Ex. 1007 at Fig. 2. It would have been routine for a

POSA to connect the cap in this manner if the POSA encountered a minor technical challenge like the presence of teeth on the inhaler's body. Indeed, the use of caps in many different ways was well-known at the time of invention. *See, e.g.,* Bason, Ex. 1007; Allsop, Ex. 1006; '177 Patent Prosecution History, Ex. 1004 at 403-410, 617, 650 (references cited during prosecution of the related '177 Patent that disclose and use various different caps).

17. Aptar presents this same argument with respect to Ground 4, Bason in view of Allsop. Response at 49-51. In this combination, the Bason dose counter is placed below the canister, rather than above the canister. Piper Decl, Ex. 1002 at ¶¶ 169, 175. Thus, a POSA would have implemented another of the various, routine, and obvious connections for this combination. '177 Patent Prosecution History, Ex. 1004 at 281. For example, as depicted in the figure below, the cap would have been designed with slots through which teeth 2 (blue) would protrude:

REPLY FIG. 2



18. As illustrated above, teeth 2 would have projected through slots in the cap. 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. This approach also would have been applicable to the combination of Bason and Rhoades described immediately above.

19. 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

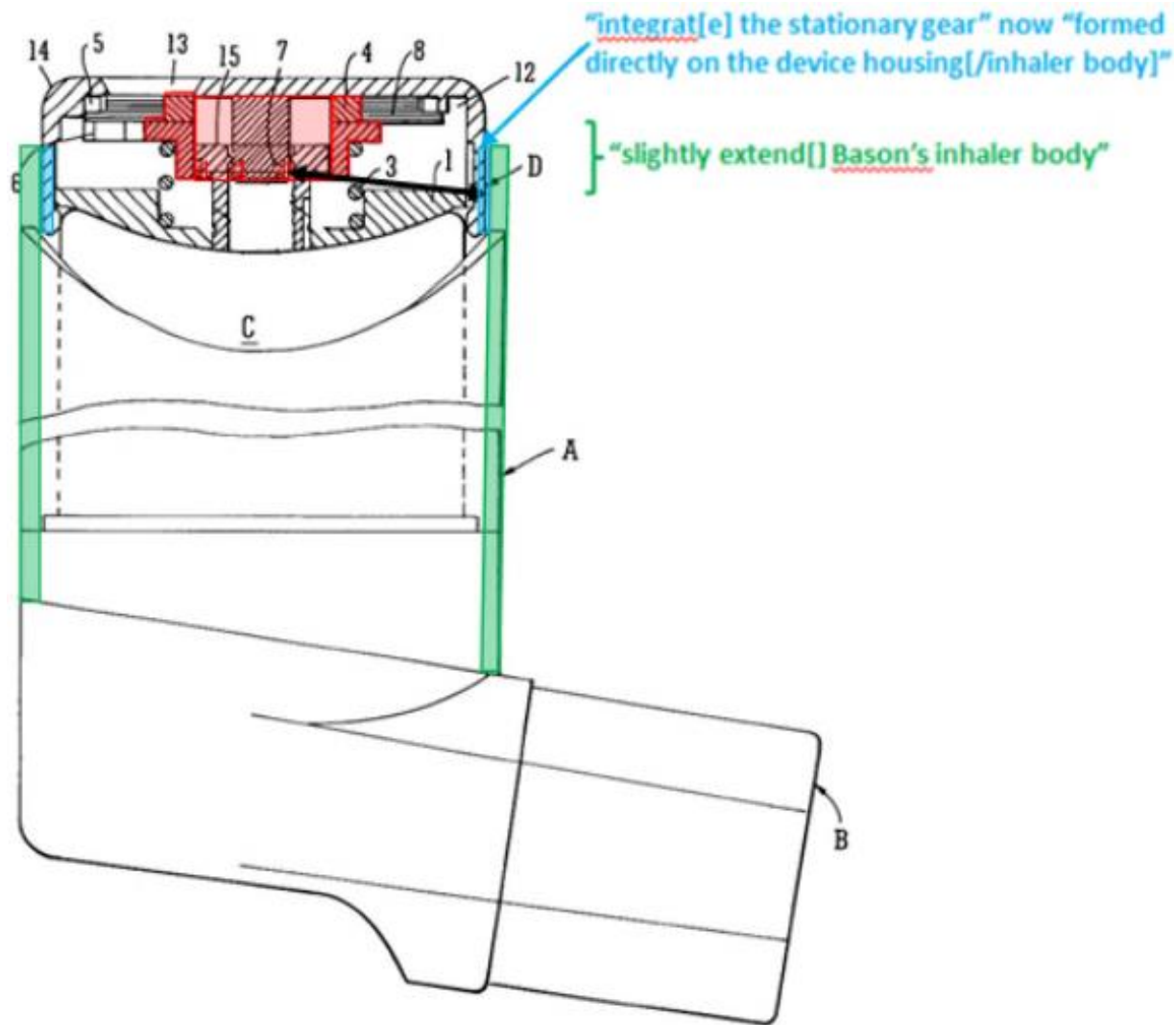
position. And it would have been routine for one of skill in the art to injection mold an aperture through the cap for the stem of the canister to pass through. Indeed, that same conformation was used in the prior art. *See* Elliott, Ex. 1036 at Figs. 1, 3a, 3b.

20. This approach would have resulted in a snap-fit between the cap and the inhaler body. A snap fit was a known and desirable means for connecting components and was commonly used as it requires fewer parts, no adhesives, no ultrasonic welding, minimizes cost and eases manufacture. Ex. 1061, Jill Matzke, *Chapter 16 – Dfe for Engineering Managers: Making it Count—Dfe and the Bottom Line*, in GREEN ELECTRONICS/GREEN BOTTOM LINE 185, 189-190, (Lee H. Goldberg & Wendy Middleton eds., 2000) (“ . . . snap-fit parts require fewer fasteners and are quicker to assemble, reducing manufacturing costs.”); Ex. 1062, C. Manoharan *et al.*, *An expert system for design for robotic assembly*, 1 J INTELL MANUF 17, 19 (1990) (“It is desirable to design parts that are self-fastening (e.g. compliant tabs or snap-fit parts) and do not require additional fastening elements.”). Indeed, I note that Mr. Clemens agrees that designers would have been motivated to design these devices with as few components as possible. Clemens Tr., Ex. 1057 at 26:23-27:3.

IV. REPLY TO APTAR’S ARGUMENT THAT A POSA WOULD NOT HAVE KNOWN HOW TO SHAPE AND ALIGN THE GEARS OF THE DEVICES RESULTING FROM THE ASSERTED COMBINATIONS

21. Aptar takes the misguided position 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 33, 38. Aptar is incorrect. As I explained in my initial declaration, in the devices resulting from the Bason / Rhoades and Bason / Allsop combinations, “teeth 7 of ring 4 would *interact with* stationary teeth 2” and they would have “retained their same function.” Piper Declaration at ¶¶ 138, 175 (emphasis added.)

22. Aptar and Mr. Clemens included figures purporting to show the devices of the asserted combinations that I described in my initial declaration. Response at 35, 38. These figures do not reflect the combinations that I described. For example, Mr. Clemens included the below figure in his declaration, wherein teeth 7 and teeth 4 do *not* interact.



Clemens Declaration at ¶ 49.

23. As I explained in my initial declaration, and as Aptar admitted during prosecution, a POSA of ordinary creativity would have known how to connect teeth 7 and teeth 2 so that they interact. Piper Decl., Ex. 1002 at ¶¶ 138, 175; Prosecution History, 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.”). For example, a POSA would have extended the diameter of

ring 4 so that teeth 7 interact with teeth 2, just as they do in Bason. At the time of the invention, POSAs knew how to adjust the size of gears and gear teeth, and to take into account the other components of the device when making these connections. The prosecution history of the '177 Patent and Mr. Clemens's testimony confirm that these modifications were well within the level of those skilled in the art. Prosecution History, Ex. 1004 at 255, 1138, 1191-1192, 1230-1233, 1281:18-20, 1292:8-17; Clemens Tr., Ex. 1057 at 131:4-7, 131:22-132:13.

V. REPLY TO APTAR'S ARGUMENT THAT A POSA WOULD NOT HAVE KNOWN TO MODIFY THE BASON / ALLSOP COMBINATION TO INCLUDE A DISPLAYED DOSE VALUE

24. Aptar takes the unwarranted 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, would not be visible if the counter sits below the canister. Response at 54-55.

25. As I explained at my deposition, a POSA would have known to modify the device resulting from the Bason / Allsop combination to ensure that the numbers are visible to a user. For example, "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 [so] that a patient would see the number of actuations." Piper Dep. Tr., Ex. 2019 at 129:9-14. Indeed, references I've reviewed in this matter show such a configuration. *E.g.*, Elliott, Ex. 1036 at Fig.

3b. Likewise, a POSA would have known to arrange the numbers on the number wheel so that they would have been visible through that window. This would have been a simple modification for a POSA to make.

VI. REPLY TO APTAR’S ARGUMENT THAT RHOADES IS NOT ANALOGOUS ART

26. Aptar takes the erroneous position that Ambrosio (Ex. 1031) and Wimpenny (Ex. 1032) do not establish that a prior art pen would have commended itself to a POSA’s attention in considering how to design an MDI that satisfied the requirements of the FDA’s 2001 Draft Guidance (Ex. 1012) and 2003 Final Guidance (Ex. 1013).

27. Ambrosio and Wimpenny make clear that a POSA would have relied on knowledge of mechanical pens when designing medical devices. Piper Decl., Ex. 1002 ¶ 136; Ambrosio, Ex. 1031 at 2:36-47; Wimpenny, Ex. 1032 at 1:40-48. In fact, Ambrosio’s disclosure of “an indexing mechanism much like that of a ball-point pen” was made with reference to a powder MDI. Piper Decl., Ex. 1002 ¶ 136; Ambrosio, Ex. 1031 at 2:36-47 (discussing U.K. Patent No. 2,165,159, which is directed to a powder MDI).

28. Aptar argues that Ambrosio and Wimpenny discuss pen-like features of prior art references, which Ambrosio and Wimpenny then distinguish from their inventions. Response at 40 n.7. That is irrelevant. The fact remains that Ambrosio and Wimpenny show that a POSA would have equated pen components

with medical device components having similar features, such as a rotatable rod. Ambrosio, Ex. 1031 at 2:36-47. This is consistent with my own experience of analyzing the components of a mechanical pen when called on to build a dose counter around 1998. Piper Decl., Ex. 1002 ¶ 135.

VII. CONCLUSION

29. For the foregoing reasons and for the reasons set forth in my initial declaration, a POSA would have concluded that each of claims 1-4 of the '631 Patent are anticipated by the Allsop reference and the Marelli reference, and would have been obvious over (1) Bason in view of Rhoades and (2) Bason in view of Allsop.

VIII. SIGNATURE

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

Dated: MAY 13, 2019

A handwritten signature in dark ink, consisting of stylized, overlapping loops and a long horizontal stroke at the end, positioned above a thin horizontal line.

S. David Piper