

Case No. IPR2018-01055

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

**DECLARATION OF CHARLES E. CLEMENS IN SUPPORT OF PATENT
OWNER'S SUR-REPLY TO PETITION FOR
INTER PARTES REVIEW OF U.S. PATENT NO. 9,370,631**

I, Charles E. Clemens, declare as follows:

I. Introduction

1. I have been asked to evaluate and assess certain information in connection with Aptar France S.A.S.'s ("Patent Owner") Sur-Reply to 3M Company, Merck & Co., Inc. and Merck Sharp & Dohme Corp.'s (collectively, "Petitioners") Reply, filed on May 13, 2019, in *inter partes* review of U.S. Patent No. 9,370,631 ("the Petition"). All of the opinions and conclusions found in this declaration are my own.

2. I make this declaration as a supplement the other declarations I have submitted in this matter. Specifically, I previously submitted the August 15, 2018 Declaration of Charles E. Clemens in Support of Patent Owner's Preliminary Response (Ex. 2005), the February 13, 2019 Declaration of Charles E. Clemens in Support of Patent Owner's Response (Ex. 2021), and the March 7, 2019 Supplemental Declaration of Charles E. Clemens in Support of Patent Owner's Response (Ex. 2022). The entirety of those declarations is incorporated herein by reference.

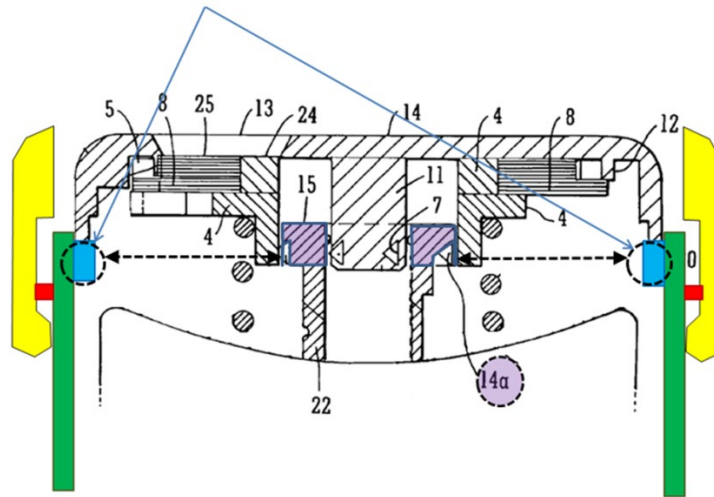
II. Petitioners' Proposed Bason/Rhoades Combination Does Not Disclose a "second member" or a "displayed dose value"

3. In my declaration dated February 13, 2019, I identified that the combination of Bason and Rhoades would be inoperable for its intended purpose because teeth 2 create a physical barrier that prevents the cap 14 from being

depressed, and because teeth 7 no longer “engage” with teeth 2 in order to rotate the ring 4. To remedy these problems, Petitioners expert, Mr. Piper, replies that Bason’s cap would be “slightly widen[ed] . . . so that its outer edge fits over the outside of the housing,” that “a rib ... would [be] added to the outside of the housing ... to prevent unintentional removal of the cap,” and that “the diameter of ring 4 [would be extended] so that teeth 7 interact with teeth 2.” Ex. 1058 ¶¶16, 23; Reply at 10-11, 15.

4. A POSA would not have combined Bason and Rhoades in the new manner described because the resulting device would be inoperable for its intended purpose. First, ring 4 would not rotate to bring a new dose value into window 13 because teeth 7 would not contact teeth 14a. Teeth 7 must press down and slide against the surface of the base’s “fixed” teeth 2, *and must return upwards to interact with teeth 14a of bush 15*, in order for ring 4 to rotate. Ex. 2021 at ¶24 (emphasis added). If the diameter of ring 4 is “extended . . . so that teeth 7 interact with teeth 2” (shown below in blue), teeth 7 no longer contact teeth 14a (shown below in purple), which remain situated on the underside of bush 15 and are separated from teeth 7 by the presence of the spring.

“ring 4 [would be extended] so that teeth 7 interact with teeth 2.”



Ex. 1007 at Fig. 2 (annotated).

5. Second, ring 4 would not rotate because central bush 15 is not mounted. Bason teaches that bush 15 is in a non-movable attachment to base 1 via a key way connection. Bonding base 1 to the canister thus allows bush 15 to stay in a “fixed position” as required for teeth 7 to correctly interact with the fixed teeth 2/14a in order to achieve ring 4’s relative rotation. Ex. 2021 at ¶¶24, 81. However, Petitioners’ combination of Bason and Rhoades removes base 1 by making teeth 2 integral with the inhaler body, so bush 15 is no longer mounted. Ex. 1002 at ¶138 (“The resulting inhaler would have been predictable, well understood by a POSA, less expensive to manufacture (no need to separately manufacture Bason base 1 and bond it to a canister), and more reliable (fewer parts that need to be manufactured and assembled).”). As a result, bush 15 is permitted to rotate freely, and there is nothing to keep it in a fixed position relative the other

components to effect relative rotation of ring 4. *See* Ex. 2021 at ¶81. Further, if unmounted, bush 15 cannot support or guide ring 4 so that pawl 5 works with radially inwardly directed kink 26 for counting. Thus, teeth 7 will not properly engage with teeth 2/14a as required to rotate ring 4 to advance the dose values.

6. Third, Bason's dose values would not be visible out of window 13 due to the new extended diameter of ring 4. The dose values are visible out of window 13 on the upper faces 24 and 25 of the rotational rings 4 and 8, with ring 8 "concentrically disposed above and around" ring 4. Ex. 2021 at ¶23. If ring 4 were "extended" to the outer circumference of the cap "so that teeth 7 interact with teeth 2," then the diameter of ring 4 would be greater than or equal to the diameter of ring 8 and have the effect of disrupting the concentric organization of top surfaces 24 and 25 and displacing the dose values from window 13. Further, if ring 8 is moved to the inside diameter of ring 4, the sequencing of counting and displaying numbers during rotation becomes inoperable. Additionally, the dose values would no longer be visible to a user, and the combination of Bason and Rhoades would be inoperable for its intended purpose.

III. Petitioners' Proposed Bason/Allsop Combination Does Not Disclose a "second member" or a "displayed dose value"

7. In my declaration dated February 13, 2019, I also identified that the combination of Bason and Allsop would be inoperable for its intended purpose because teeth 2 create a physical barrier that prevents the cap 14 from being

depressed, because teeth 7 no longer “engage” with teeth 2 in order to rotate the ring 4, and because the dose values are not “displayed” or “displayable” out of window 13 if the Bason dose counter is moved below the canister. To remedy these problems, Petitioners expert, Mr. Piper, replies that the “cap would [be] designed with slots through which teeth 2 [] would protrude” which would be “slightly taller than the height of the teeth, allowing the cap to move up and down upon operation of the MDI,” that “a POSA would have . . . taper[ed] teeth 2 (narrower at the top, wider at the bottom), to allow the cap to slide into position,” that “the diameter of ring 4 [would be extended] so that teeth 7 interact with teeth 2,” and that window 13 would “be made on the side of the device.” Ex. 1058 ¶¶17-19, 23, 25; Reply at 12-13, 15.

8. A POSA would not have combined Bason and Allsop in the new manner described by Mr. Piper because the resulting device would be inoperable for its intended purpose. First, ring 4 would not rotate to bring a new dose value into window 13 because teeth 7 would not contact teeth 14a on bush 15. As previously explained, for ring 4 to rotate, teeth 7 must return upwards to interact with teeth 14a of bush 15. Ex. 2021 at ¶24. Thus, if the diameter of ring 4 is “extended . . . so that teeth 7 interact with teeth 2” then teeth 7 do not contact teeth 14a because they are prevented from interacting by the presence of the spring.

9. Second, ring 4 would not rotate because central bush 15 is not mounted. As previously explained, the fixed attachment of bush 15 to base 1, which Bason teaches is “bonded to the domed base” of the canister, is essential to permit teeth 7 to engage with teeth 2/14a to cause relative rotation of ring 4. Ex. 1007 at 2:16-19. However, “the base 1 with stationary gear 2 would have been molded directly into the wall of the *Bason* inhaler” in the new Bason and Allsop combination, so bush 15 cannot mount. Ex. 1002 at ¶174. Because bush 15 cannot mount, it is not “non-moveable.” The resulting free rotation of bush 15 prevents teeth 7 from interfacing with teeth 2/14a to effect the relative rotation of ring 4, and bush 15 cannot support or guide ring 4 so that pawl 5 works with radially inwardly directed kink 26 for counting.

10. Third, the new combination of Bason and Allsop would not display a dose value because window 13 cannot be moved to the side of the device as Mr. Piper asserts. As explained in my declaration dated February 13, 2019, relocating window 13 to the side of the device would also necessitate “redesigning the structure of the rings 4 and 8, central bush 15, curved arm 6, pawl 5, downwardly directed wall 12, and radially inwardly directed kink 26.” Ex. 2021 at ¶99. Rings 4 and 8 would need to be rotated ninety degrees in orientation and stacked on top of one another so that the dose values appearing on the top surfaces of rings 4 and 8 could be viewed out of window 13, as displayed from a horizontal perspective

rather than a vertical perspective. Additionally, curved arm 6 and upwardly directed pawl 5, which act to rotate ring 8, would need to be redesigned as they currently are placed on the outer extremity of the cap (where window 13 would apparently be moved, and where teeth 7 and teeth 2 would purportedly interact). Redesign would also be required for central bush 15, which is loose and unmounted in the Petitioners combination, and would require at least a new bonding process step contradicting the motivation for fewer manufacturing steps. Lastly, downwardly directed wall 12 with kink 26 would physically interfere with newly re-located rings 4 and 8 and be required to be operationally moved and reconfigured to interact with pawl 5. However, even if a POSA redesigned all of these components and their functional interactions, it would still not be possible to relocate window 13 to the “side of the device” because the outer extremity of the cap is consumed by the alleged interaction between teeth 7 on the newly extended diameter of ring 4, with teeth 2 which have been re-located to the inner diameter of the inhaler body.

I declare under penalty of perjury under the laws of the United States of America and the State of California that the foregoing is true and correct.

Dated: February 13, 2019

A handwritten signature in black ink, appearing to read "C. E. Clemens", is written over a horizontal line.

Charles E. Clemens