

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

3M COMPANY, MERCK & CO., INC. and
MERCK SHARP & DOHME CORP.,
Petitioner,

v.

APTARFRANCE S.A.S.,
Patent Owner.

Case IPR2018-01055
Patent 9,370,631 B2

Before HYUN J. JUNG, SCOTT A. DANIELS, and
RICHARD H. MARSCHALL, *Administrative Patent Judges*.

JUNG, *Administrative Patent Judge*.

DECISION TO INSTITUTE
35 U.S.C. § 314(a)

I. INTRODUCTION

3M Company, Merck & Co., Inc., and Merck Sharp & Dohme Corp. (collectively “Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting institution of an *inter partes* review of claims 1–4 of U.S. Patent No. 9,370,631 B2 (Ex. 1001, “the ’631 patent”). AptarFrance S.A.S. (“Patent Owner”) timely filed a Preliminary Response (Paper 10, “Prelim. Resp.”).¹ Under 35 U.S.C. § 314, an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

Upon consideration of the Petition and Preliminary Response and for the reasons explained below, we determine that Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims. As such, we institute an *inter partes* review of all challenged claims on all presented challenges, and thus, institute review of claims 1–4 of the ’631 patent.

II. BACKGROUND

A. *Related Proceedings*

The parties indicate that the ’631 patent is the subject of *AptarGroup, Inc. v. 3M Company*, Case No. 1:17-cv-06294-VMK (N.D. Ill.). Pet. 6; Paper 6, 1; Prelim. Resp. 4.

¹ Patent Owner confirmed via email that its Preliminary Response was served directly on Petitioner. Patent Owner was not able to file its Preliminary Response due to the Board’s filing system being inaccessible.

Also, the '631 patent is related to the patent at issue in Case IPR2018-01054. Pet. 6; Paper 6, 2; *see also* Prelim. Resp. 4 (stating that “Aptar filed a continuation of the '177 Patent” that “issued as the '631 Patent”).

B. The '631 Patent (Ex. 1001)

The '631 patent issued June 21, 2016, from an application filed October 9, 2014, is a continuation of an application that issued as U.S. Patent No. 8,936,177 B2, and claims priority to a foreign application filed May 15, 2003. Ex. 1001, [22], [30], [45], [63], 1:6–11; *see also* Pet. 10 (discussing priority); Prelim. Resp. 4 (describing applications leading to the '631 patent).

The '631 patent “relates to a fluid dispenser . . . including a dose indicator device for indicating . . . the number of doses that have been dispensed or that remain to be dispensed.” Ex. 1001, 1:16–19. Figures 1 and 2 of the '631 patent are reproduced below.

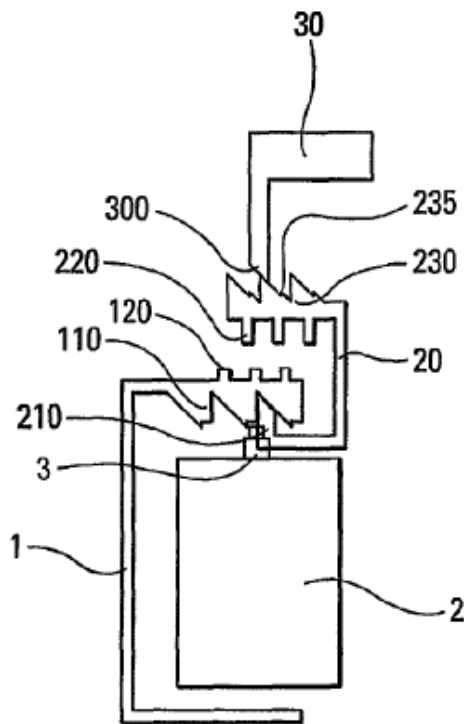


Fig. 1

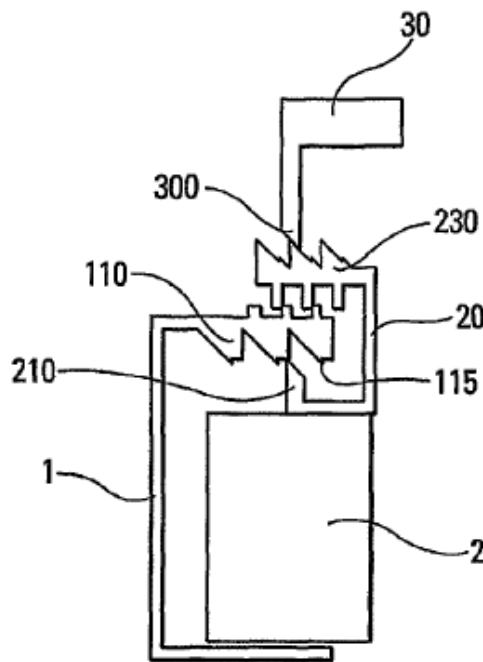


Fig. 2

Figures 1 and 2 are diagrams of a fluid dispenser showing successive positions of the dispenser during actuation. *Id.* at 4:52–55. The dispenser includes body 1, reservoir 2, dispensing member 3 mounted on reservoir 2, actuator member 30, and a dose indicator device. *Id.* at 5:19–31.

Reservoir 2 is displaceable axially with respect to body 1. *Id.* at 5:27–31.

Body 1 also includes stationary gear 110. *Id.* at 6:7. Actuator member 30 includes actuator gear 300. *Id.* at 6:15–16. The dose indicator device includes counter element 20, which can be displaced axially and rotationally relative to body 1, and counter element 20 cooperates with stationary gear 110 and actuator member 30 and/or reservoir 2. *Id.* at 6:8–12. In particular, counter element 20 includes first gear 210 that cooperates with stationary gear 110 and second gear 230 that cooperates with actuator gear 300. *Id.* at 6:13–16.

Considering Figure 1, when a user presses on actuator member 30 to displace it axially downward, the oblique profile of actuator gear 300 and second gear 230 urge counter element 20 axially downward, but the cooperation of first gear 210 and stationary gear 110 prevent counter element 20 from rotating. *Id.* at 6:20–29.

In Figure 2, the axial displacement of counter element 20 causes reservoir 2 to be also displaced axially, and first gear 210 of counter element 20 reaches a position where it no longer cooperates with stationary gear 110, thus allowing counter element 20 to rotate and actuate the dose indicator device. *Id.* at 6:33–41. The position where first gear 210 and stationary gear 110 no longer cooperate corresponds to a predetermined incomplete actuation stroke of the dispenser where the dispenser can begin to expel a dose. *Id.* at 6:43–49. By making the cooperation of first gear 210 and

stationary gear 110 correspond to the predetermined incomplete actuation stroke, the dose indicator device counts a dose as being dispensed as soon as there is any possibility of the fluid being dispensed. *Id.* at 6:51–57.

The '631 patent further describes the dispenser as it reaches complete actuation and returns to its initial position. *Id.* at 6:58–8:7, Figs. 3–8.

C. Illustrative Claim

The '631 patent has 4 claims, all of which Petitioner challenges. Of those, claims 1 and 3 are independent. Claim 1 is reproduced below.

1. A fluid dispenser comprising:
 - a plurality of displayable dose values;
 - a stationary body comprising at least one stationary multi-toothed gear;
 - a first member that is displaceable axially relative to said stationary body;
 - a second member that is displaceable axially and in rotation relative to said stationary body, said second member being engageable with said first member and said stationary body; and
 - when said first member displaces axially, the stationary body is configured to allow a fluid reservoir to be axially displaceable relative to said stationary body and 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,
 - wherein the stationary body, the first member, and the second member are arranged to have a common central longitudinal axis, and the first member is displaceable axially along the central longitudinal axis, and the second member is displaceable axially along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis.

Ex. 1001, 10:2–24.

² Petitioner indicates that the claim includes an error. *See* Pet. 10.

D. Asserted Grounds

Petitioner challenges claims 1–4, under 35 U.S.C. § 102(b),³ as anticipated by (1) Allsop⁴ or (2) Marelli.⁵ Petitioner also challenges claims 1–4, under 35 U.S.C. § 103(a), as unpatentable over (1) Bason⁶ and Rhoades⁷ or (2) Bason and Allsop. In support of its proposed grounds, Petitioner relies on a Declaration of S. David Piper (Ex. 1002).

Petitioner states that a person of ordinary skill in the art “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.” Pet. 15 (citing Ex. 1002 ¶ 12). Patent Owner disagrees with Petitioner’s asserted level of ordinary skill but does not propose a level of ordinary skill at this stage of the proceeding. Prelim. Resp. 5. Patent Owner also states that “the Board need not resolve this dispute to find that institution should be denied.” *Id.*

We preliminarily adopt Petitioner’s asserted level of ordinary skill solely to determine whether there is a reasonable likelihood that Petitioner would prevail with respect to at least 1 of the claims challenged in the Petition.

³ The relevant sections of the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (Sept. 16, 2011), took effect on March 16, 2013. Because the application from which the ’631 patent issued is a continuation of an application that was filed before that date, our citations to Title 35 are to its pre-AIA version.

⁴ WO 00/59806, published Oct. 12, 2000 (Ex. 1006).

⁵ EP 0 480 488 B1, published Nov. 2, 1994 (Ex. 1008).

⁶ US 6,283,365 B1, issued Sept. 4, 2001 (Ex. 1007).

⁷ US 3,205,863, issued Sept. 14, 1965 (Ex. 1009).

III. ANALYSIS

A. Claim Construction

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard).

Petitioner proposes interpreting “a stationary body comprising at least one multi-toothed gear” to mean “a stationary body including, as a unitary or monolithic part of the stationary body, at least one stationary gear.” Pet. 13. Petitioner notes that the Board already interpreted a similar term in the related patent. *Id.* (citing Ex. 1004, 1273). Petitioner contends that the same interpretation should apply to this proceeding. *Id.* at 14. Petitioner also proposes interpreting “disposed on” so as “to allow indirect contact—two pieces that are connected via an intermediary are disposed on each other.” *Id.* at 14–15 (citing Ex. 1001, 7:23–26, Figs. 1–8).

Patent Owner responds that Petitioner’s proposed interpretations do not reflect their broadest reasonable constructions. Prelim. Resp. 6. Patent Owner, however, states that “there are no claim terms that require construction for purposes of the Board’s decision on institution.” *Id.* at 5.

We agree with Patent Owner that, for the purposes of determining whether Petitioner demonstrates a reasonable likelihood of prevailing in its challenges, no express interpretation is required for any claim term. *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (construing explicitly only those claim terms in controversy and only to the extent necessary to resolve the controversy).

B. Challenges Under 35 U.S.C. § 102(b)

1. Challenge Based on Allsop

Petitioner contends that Allsop discloses all the limitations of claims 1–4. Pet. 2, 33–41. Patent Owner responds that Allsop was considered during the prosecution of the '631 patent. Prelim. Resp. 2, 6–9.

a. Allsop (Ex. 1006)

Allsop relates particularly to “improvements in apparatus providing means for measuring the quantity of product remaining in a pressurised dispensing container.” Ex. 1006, 1:4–8. Figures 3–6 of Allsop are reproduced below.

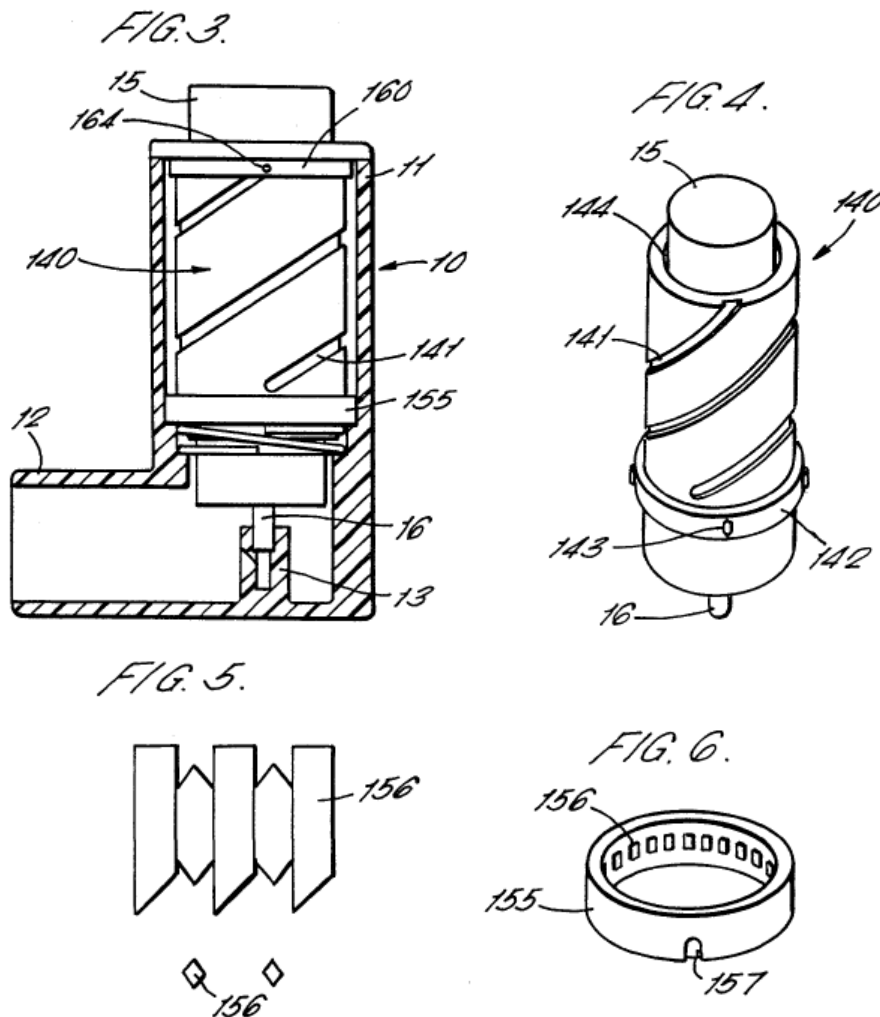


Figure 3 is a sectional side view of the apparatus; Figure 4 is a perspective view of an inner housing of the apparatus; and Figures 5 and 6 show the lugs and collar of the apparatus. *Id.* at 3:7–15.

Allsop's dispensing apparatus comprises housing 10 that includes collar 155 with inwardly directed lugs 156 that have angled upper and lower surfaces. *Id.* at 4:5–9, 6:30–33, Figs. 5, 6. The apparatus also comprises inner cylindrical housing 140. *Id.* at 5:14–15. Container 15 can be inserted and removed from inner cylindrical housing 140. *Id.* at 5:23–25. Inner cylindrical housing 140 has annular flange 142 with spaced-apart protrusions 143 on an exterior surface of flange 142. *Id.* at 5:27–29. A spring between housing 10 and inner cylindrical housing 140 biases inner cylindrical housing 140 upwardly. *Id.* at 7:20–23.

Depressing container 15 causes inner cylindrical housing 140 to move downwardly and protrusions 143 contact lugs 156 of collar 155. *Id.* at 9:3–9. Inner cylindrical housing 140 is urged to rotate incrementally when protrusions 143 contact the angled surfaces of lugs 156. *Id.* at 9:7–11. When container 15 is released, the spring urges inner cylindrical housing 140 upwardly, and protrusions 143 cause it to rotate. *Id.* at 9:18–22.

When inner cylindrical housing 140 rotates, ring 160 with pins 161 that are received in groove 141 of inner cylindrical housing 140 and in longitudinally oriented slot 170 of the housing moves vertically in slot 170. *Id.* at 5:33–6:9, 6:15–17, 9:11–17. Markings 172 adjacent slot 170 indicate doses remaining. *Id.* at 6:23–27, 8:27–32, 9:16–17.

b. Claims 1–4

Petitioner argues that Allsop discloses all the elements of claims 1–4. Pet. 2, 34–41 (citing Ex. 1002 ¶¶ 59–66, 68–81, 83–85; Ex. 1006, 2:20–29,

4:5–20, 5:14–32, 6:30–7:6, 7:9–10, 8:22–26, 9:3–11, 9:13–25, 10:4–9, Figs. 1, 3, 4, 6; Ex. 1018, 6–8; Ex. 1019 2:34–59, Figs. 1, 2; Ex. 1020, 5:47–6:8, Figs. 1, 2); *see also id.* at 15–18 (asserting what was known in the art as of May 2003), 20–22 (asserting what Allsop discloses).

Patent Owner responds that the Board should exercise its discretion under 35 U.S.C. § 325(d) to deny the Petition because Allsop was considered during the prosecution of the '631 patent. Prelim. Resp. 2, 6–9. As discussed below in greater detail, we decline to exercise our discretion under 35 U.S.C. § 325(d) because of the particular circumstances of this case.

2. Challenge Based on Marelli

Petitioner contends that Marelli discloses all the limitations of claims 1–4. Pet. 2, 42–51. Patent Owner responds that Marelli was considered during the prosecution of the '631 patent. Prelim. Resp. 2, 6–9.

a. Marelli (Ex. 1008)

Marelli “relates to a dose counting device for a distributor of doses of fluid products, especially for pharmaceutical use.” Ex. 1008, 1:3–5. Figure 1 of Marelli is reproduced below.

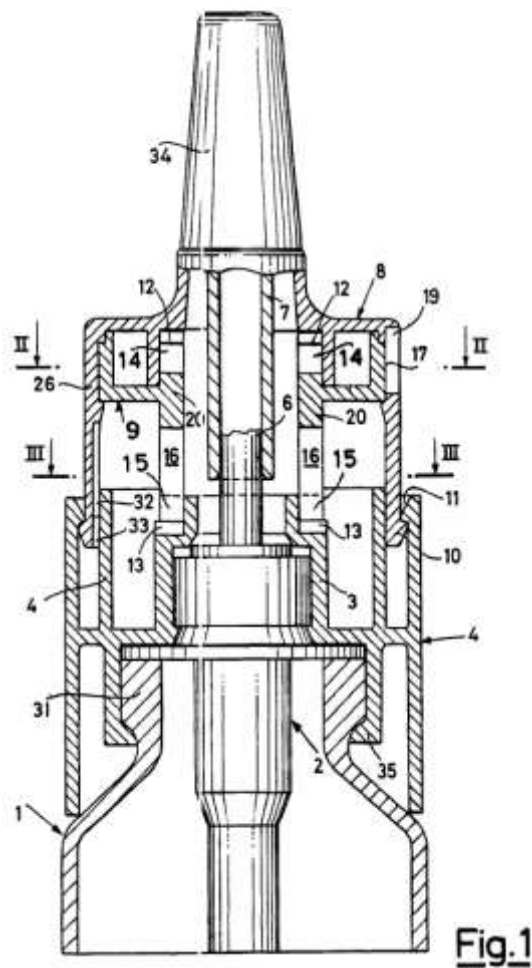


Figure 1 shows a sectional view of a dose counting device. *Id.* at 2:49–51. Marelli's device comprises container 1 with distribution valve 2. *Id.* at 3:9–13. Distribution valve 2 is associated with container 1 through flange 3 forming ring nut 4 fastened to container 1. *Id.* at 3:14–19. The operating member of valve 2 is translatable nasal 8. *Id.* at 3:24–25. Figure 4 of Marelli is reproduced below.

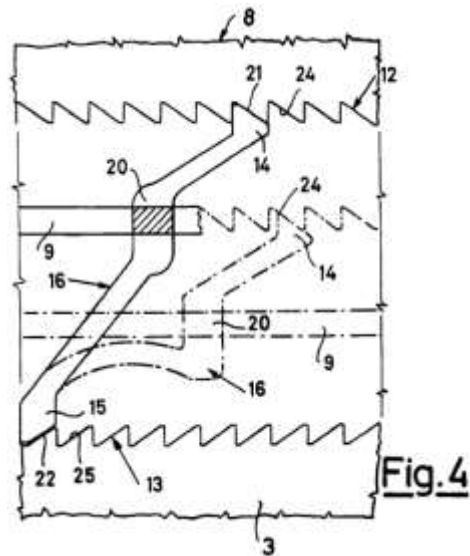


Figure 4 shows a flexible leg 16 and two sets of teeth 12, 13. *Id.* at 2:56–3:3. Inside nasal 8 and ring nut 4 are internal teeth 12, 13 that engage circumferentially spaced legs 16 via corresponding upper parts 14 and lower parts 15 of legs 16. *Id.* at 3:39–44. Legs 16 are integral with rotating element 9 that has numerical indices 17. *Id.* at 3:44–46.

When nasal 8 is depressed to move relative to ring nut 4, legs 16 are urged elastically by teeth 12 moving towards teeth 13. *Id.* at 4:22–28, Fig. 4 (illustrated by dotted lines). During the urging, upper part 14 moves from tooth 21 to adjacent tooth 24 of teeth 12. *Id.* at 4:28–30. When nasal 8 is released, teeth 12 move away from teeth 13, and lower part 15 moves from tooth 22 to an adjacent tooth, thereby moving leg 16 through one position. *Id.* at 4:30–39, Fig. 5. When leg 16 moves, numerical index 17 attached to rotating element 9 is rotated one position, thus, updating number of doses that have been distributed. *Id.* at 4:42–46.

b. Claims 1–4

Petitioner contends that Marelli discloses all the elements of claims 1–4. Pet. 42–51 (citing Ex. 1002 ¶¶ 90, 93, 94, 96–98, 100, 101, 106, 107,

109–112, 115, 116; Ex. 1008, 1:3–5, 1:26–27, 2:52–53, 3:9–52, 4:9–11, 4:13–30, 4:34–36, 4:39–48, Figs. 1, 2, 4, 5); *see also id.* at 15–18 (asserting what was known in the art as of May 2003), 25–27 (asserting what Marelli discloses).

Patent Owner responds that the Board should exercise its discretion under 35 U.S.C. § 325(d) to deny the Petition because Marelli was considered during the prosecution of the '631 patent. Prelim. Resp. 2, 6–9. We decline for the reasons discussed below to exercise our discretion under 35 U.S.C. § 325(d) because of the particular circumstances of this case.

C. Challenges Under 35 U.S.C. § 103(a)

1. Challenge Based on Bason and Rhoades

Petitioner contends that the combination of Bason and Rhoades teaches the limitations of claims 1–4. Pet. 57–65. Petitioner also contends that one of ordinary skill in the art would have been motivated to combine Bason and Rhoades. *Id.* at 52–57.

Patent Owner responds that Bason was considered during the prosecution of the '631 patent and a related patent. Prelim. Resp. 2, 7–8, 10–12. Patent Owner also responds that Petitioner fails to explain sufficiently its proposed modification of Bason in view of Rhoades, that Rhoades is not analogous art, and that one of ordinary skill in the art would have had no motivation to combine Bason and Rhoades. *Id.* at 2, 12–26.

For the reason explained below, based on the present record, Petitioner shows a reasonable likelihood that it would prevail with respect to at least one claim.

a. Bason (Ex. 1007)

Bason “concerns an indicator device . . . adapted to serve as a dose counter for metered dose inhalers (MDI’s).” Ex. 1007, 1:3–5. Figures 1 and 3 are reproduced below.

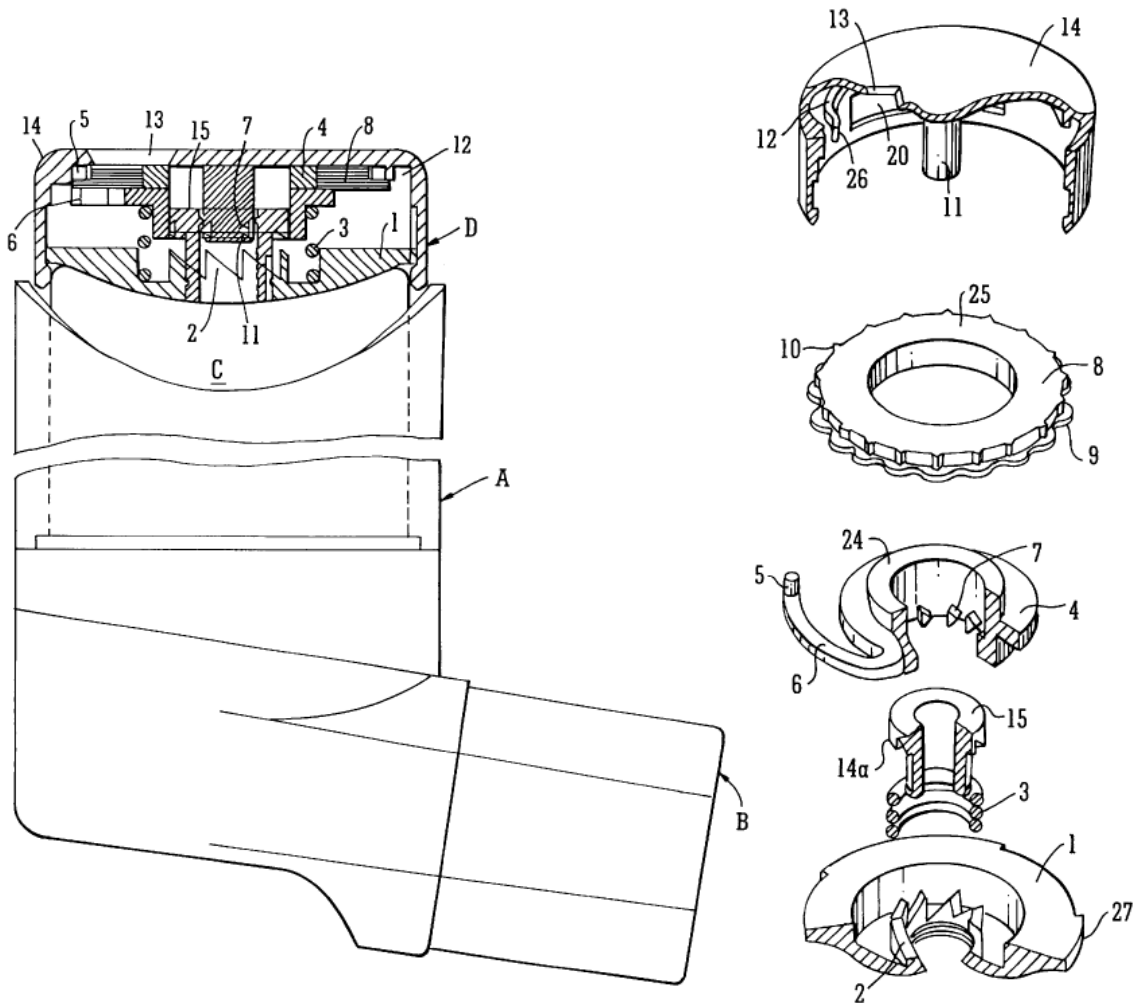


FIG. 1

FIG. 3

Figure 1 is a part cross-sectional view of a metered dose inhaler with an indicator device, and Figure 3 is an “exploded perspective view of the parts of the device.” *Id.* at 1:65–67, 2:3–4. Metered dose inhaler A includes

mouth-piece B for inhaling a drug from canister C, and counter D is bonded to or removably attached to canister C. *Id.* at 2:11–16, 3:66–4:3.

Depressing cap 14 causes rings 4, 8 to depress, and teeth 7 engage lower fixed teeth 2. *Id.* at 3:15–18. The triangular form of teeth 2, 7 cause ring 4 to rotate. *Id.* at 3:18–19. Releasing cap 14 causes teeth 7 to engage upper teeth 14a which causes further rotation of ring 4. *Id.* at 3:20–22. Each rotation causes movement of ring 4 so a number on face 24 visible through window 13 changes by one increment for a complete depression and release of cap 14. *Id.* at 3:22–26.

b. Rhoades (Ex. 1009)

Rhoades “relates generally to ball point writing instruments . . . having a projecting and retracting mechanism operated by a push button.” Ex. 1007, 1:9–12. Figures 1 and 2 of Rhoades are reproduced below.

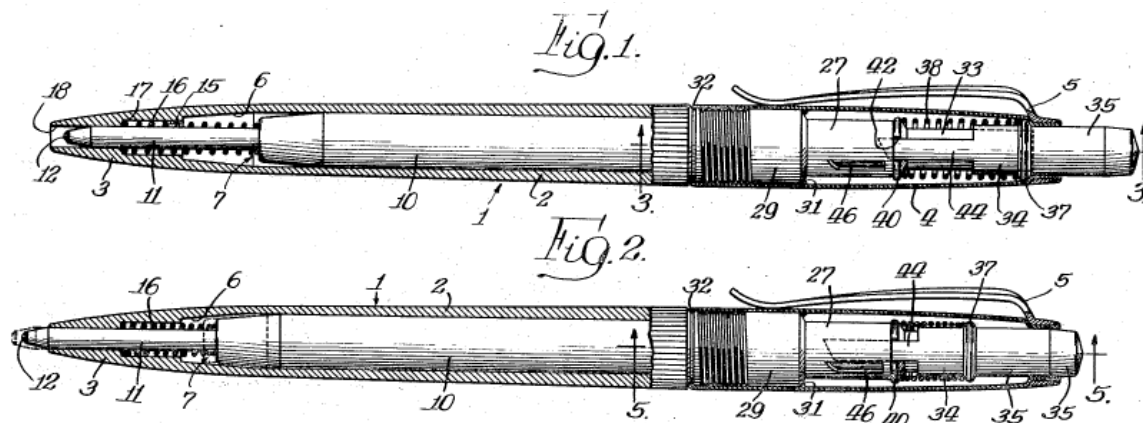


Figure 1 is a sectional view showing a point-and-cartridge unit in a retracted position, and Figure 2 is a sectional view showing the point-and-cartridge unit in a projected position. *Id.* at 2:44–51. Barrel 1 has a bore that receives point-and-cartridge unit 7. *Id.* at 3:28–32. Point-and-cartridge unit 7 is connected to a projecting-retracting mechanism and includes ink

reservoir section 10, ink feed section 11, and ball writing point 12. *Id.* at 3:31–39. Figure 4 of Rhoades is reproduced below.

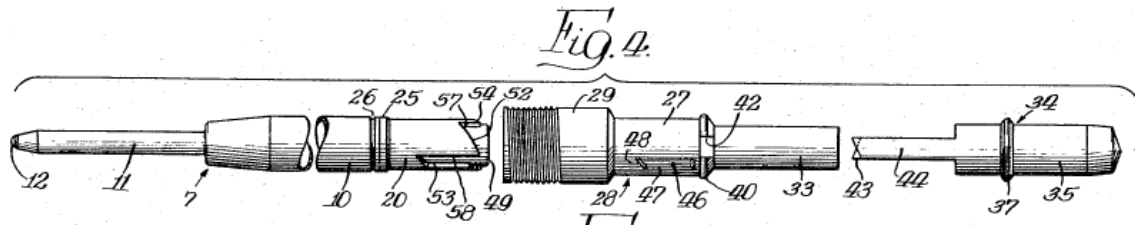
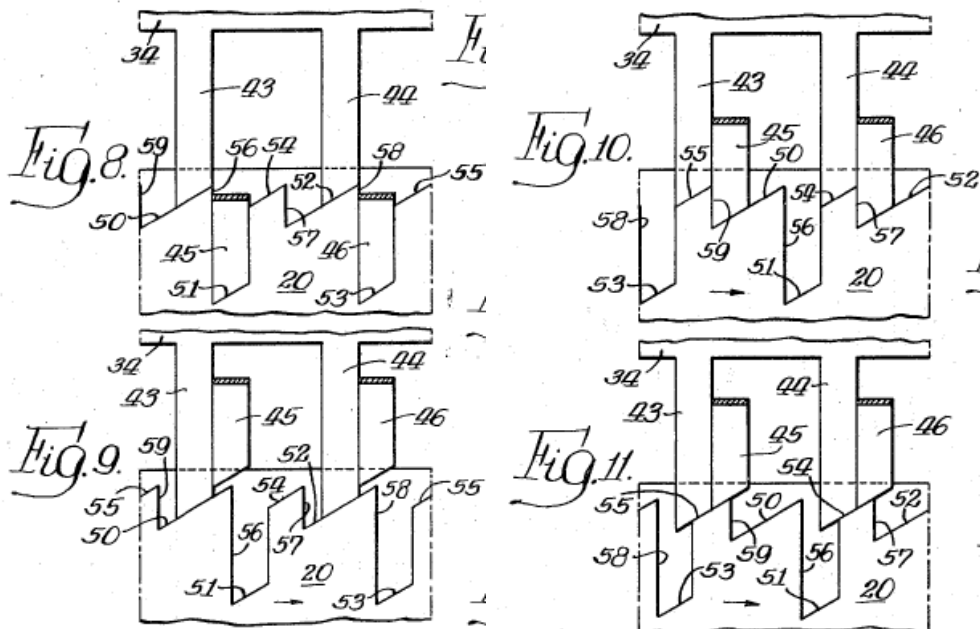


Figure 4 shows an exploded view of the point-and-cartridge unit and projecting-retracting mechanism. *Id.* at 2:57–59. Secured to the rear of ink reservoir section 10 is cam body 20 which is part of the projecting-retracting mechanism. *Id.* at 3:49–53. Cam body 20 is rotatably and slidably disposed within stationary guide member 28. *Id.* at 3:65–67. Tubular plunger 34 is formed with push button 35, which is biased rearwardly by spring 38. *Id.* at 4:1–2, 4:75–5:1. Fingers 43, 44 are formed integrally with plunger 34 and extend forwardly. *Id.* at 4:10–12. Figures 8–11 of Rhoades are reproduced below.



Figures 8–11 are diagrams illustrating how cam surfaces of the cam body cause the point-and-cartridge unit to retract and project. *Id.* at 2:69–3:3. Stop members 45, 46 extend longitudinally within guide member 28 adjacent and parallel with fingers 43, 44 of plunger 34. *Id.* at 4:13–16. Cam body 20 has cam surfaces 50, 52, 54, 55 engageable by fingers 43, 44 to impart rotational and longitudinal reciprocating movements to cam body 20. *Id.* at 4:22–27.

Stop surface 56 extends parallel with the axis of cam body 20 and is between the trailing edge of cam surface 51 and leading edge of cam surface 50. *Id.* at 4:48–51. Similarly, stop surfaces 57, 58, 59 extend between cam surfaces 52, 54, cam surfaces 52, 53, and cam surfaces 50, 55, respectively. *Id.* at 4:51–58. When push button 35 is depressed repeatedly, alternate cam surfaces are aligned with stop members 45, 46 to maintain point-and-cartridge unit 7 in projected and retracted positions. *Id.* at 4:28–33.⁸

Two contiguous sets of cam and stop surfaces are thus provided, each set comprising bottom surface 51, 53 flanked by cam surfaces 50, 54 and 52, 55, respectively. *Id.* at 4:65–67. When cam body 20 is oriented so that stop members 45, 46 engage cam surfaces 50, 52, point-and-cartridge unit 7 will be in its projected position. *Id.* at 5:11–15. If stop members 45, 46 engage bottom surfaces 51, 53, point-and-cartridge unit 7 will be in its retracted position. *Id.* at 5:15–22. Successive depressions of push button 35 move fingers 43, 44 and thus, depress and rotate cam body 20 to cause alternate

⁸ In lines 28–33 of column 4, Rhoades describes “connected unit 7” and “point-and-cartridge unit 27,” which appears to be an error because, in previous portions of the specification, Rhoades refers to “point-and-cartridge unit 7” and “tubular central portion 27.”

pairs of cam surfaces 50, 52 and bottom surfaces 51, 53 to engage stationary stop members 45, 46. *Id.* at 5:22–28.

c. Claims 1–4

Petitioner argues that the combination of Bason and Rhoades teaches the limitations of claims 1–4. Pet. 52 (citing Ex. 1002 ¶ 131), 57–65 (citing Ex. 1002 ¶¶ 139, 142, 144, 148–150, 153, 156–159, 161, 165–168; Ex. 1007, Abstract, 1:3–8, 2:5–6, 2:28–30, 3:1–10, 3:15–16, Figs. 1, 4; Ex. 1009, 3:34–42, 3:49–52, 3:59–60, 3:66–68, 4:10–33, 5:11–28, 5:39–43, 5:51–58, 8:7–9, 11:60–63, Figs. 1, 2, 4); *see also id.* at 15–18 (asserting what was known in the art as of May 2003), 23–25 (asserting what Bason teaches); 28–32 (asserting what Rhoades teaches).

Petitioner also argues that market forces would have motivated one of ordinary skill in the art to modify Bason to incorporate a stationary gear directly into the inhaler body as taught by Rhoades. *Id.* at 51–52 (citing Ex. 1002 ¶¶ 134–137). Petitioner contends that industry recognition of insufficient dose counters and FDA guidance would have motivated one of ordinary skill in the art to include a counter that would avoid undercounting doses in a metered dose inhaler and could be mass produced. *Id.* at 52–53 (Ex. 1002 ¶¶ 132, 134; Ex. 1007, 3:66–4:3; Ex. 1012, 5–6; Ex. 1013, 5–7; Ex. 1022, 1:43–45; Ex. 1027, 2–3, 6; Ex. 1028, 3–5; Ex. 1029, 3; Ex. 1030, 3; Ex. 1041, 6; Ex. 1042, 13; Ex. 1045, 3; Ex. 1047, 89), 55 (citing Ex. 1002 ¶ 138). Petitioner also contends that one of ordinary skill in the art would have looked to Rhoades. *Id.* at 53–54 (citing Ex. 1002 ¶¶ 134–136; Ex. 1031, 2:36–47; Ex. 1032, 1:40–48; Ex. 1033, 15:10–25; Ex. 1034, [56], Abstract, 3:29–39).

Petitioner proposes to substitute Bason's counter with Rhoades's mechanism to create a less expensive, more reliable inhaler and to avoid undercounting by way of the stop members of Rhoades. *Id.* at 55–56 (citing Ex. 1002 ¶ 138). According to Petitioner, one of ordinary skill in the art would have extended Bason's inhaler body and integrated tooth 2 of Bason into the inhaler body in the same manner that the stop members of Rhoades are integrated into Rhoades's body. *Id.* (citing Ex. 1002 ¶ 137); *see also id.* at 60 (citing Ex. 1002 ¶ 159), 61 (citing Ex. 1002 ¶¶ 144, 161). Petitioner argues the remaining components would be connected as taught in Bason “or other ways well-understood in the art.” *Id.* at 55–56 (citing Ex. 1002 ¶¶ 137, 138; Ex. 1004, 255, 281, 1137–1139, 1149–1150, 1158–1166, 1190–1205, 1229–1233, 1281, 1282, 1292; Ex. 1022, 1:43–45; Ex. 1029, 3; Ex. 1030, 3). Petitioner contends that the proposed modification is a variation known in the art and would simplify manufacturing. *Id.* at 55 (citing Ex. 1002 ¶ 137; Ex. 1047).

Patent Owner responds that the Board should exercise its discretion under 35 U.S.C. § 325(d) to deny the Petition because Bason was considered during the prosecution of the '631 patent and its parent. Prelim. Resp. 2, 6–8, 10–12. For the reasons explained below, the circumstances of this particular case do not persuade us to exercise our discretion to deny institution under 35 U.S.C. § 325(d).

Patent Owner also responds that Petitioner's combination is not described in sufficient detail. Prelim. Resp. 12. Patent Owner faults Petitioner for failing to include any figures, describe how teeth 2 would be integrated into the inhaler, explain how the modification would affect dose counting, and explain how to use features in Bason or Rhoades that are not

part of the proposed modification. *Id.* at 13–14 (citing Pet. 55, 56, 61–62; Ex. 2005 ¶ 22). Patent Owner also argues that Bason’s ring 4 does not teach the rotatable second element of independent claims 1 and 3 because ring 4 would not rotate. *Id.* at 15–16 (citing Pet. 62; Ex. 2005 ¶ 29).

Based on our review of the Petition, Petitioner sufficiently describes its proposed modification of Bason in view of Rhoades. *See* Pet. 55–56, 60, 61. As summarized above, Petitioner proposes modifying Bason by extending its inhaler body and integrating its tooth 2 into the inhaler body in the same manner that the stop members of Rhoades are integrated into Rhoades’s body. *See id.* Regarding whether the proposed modification would cause ring 4 to rotate, the parties’ Declarants present conflicting testimony (*see, e.g.*, Ex. 1002 ¶ 138; Ex. 2005 ¶ 29), and “such testimonial evidence will be viewed in the light most favorable to the petitioner solely for purposes of deciding whether to institute an *inter partes* review.” 37 C.F.R. § 42.108(c).⁹ At this stage, Petitioner presents sufficient argument and evidence regarding its proposed modification.

Patent Owner also responds that Rhoades is not analogous art because it is not directed to the same purpose as the ’631 patent. Prelim. Resp. 16–17. Patent Owner additionally contends that Petitioner’s cited references and declarant testimony do not establish that Rhoades is analogous art. *Id.* at 18–19 (citing Pet. 53–54; Ex. 1031, 2:36–51; Ex. 1032, 1:40–48; Ex. 1033; Ex. 1034; Ex. 2005 ¶¶ 18, 19).

⁹ We follow the same approach on other issues where the Patent Owner’s conflicting expert testimony creates a genuine issue of material fact with Petitioner’s expert testimony.

At this stage of the proceeding, Petitioner provides sufficient argument that Rhoades is reasonably pertinent because the subject matter of Rhoades would have commended itself to an inventor's attention in considering problems related to small, inexpensive mechanical devices. *See* Pet. 3–4 (citing Ex. 1002 ¶¶ 17, 25, 135; Ex. 1031 2:36–47; Ex. 1032, 1:40–48; Ex. 1033, 15:10–25; Ex. 1034, [56], Abstract, 3:29–39), 18 (citing Ex. 1002 ¶ 17; Ex. 1006, 9:3–11; Ex. 1007, 3:15–16; Ex. 1008, 4:9–48; Ex. 1009, 1:9–12, 4:22–27; Ex. 1021; Ex. 1022; Ex. 1023), 30 (citing Ex. 1002). Petitioner, in particular, sufficiently contends that a skilled artisan would have looked to Rhoades because it relates to a simple and inexpensive device that converts axial motion into rotational motion. *Id.* at 53–54 (citing Ex. 1002 ¶¶ 134–136; Ex. 1031 2:36–47; Ex. 1032, 1:40–48; Ex. 1033, 15:10–25; Ex. 1034, [56], Abstract, 3:29–39).

Patent Owner further responds that one of ordinary skill in the art would not have been motivated to combine Bason and Rhoades. Prelim. Resp. 19 (citing Pet. 53–54). Patent Owner argues that the proposed combination does not relate to Rhoades's mechanism of action and Petitioner does not argue sufficiently why one of ordinary skill in the art would have been motivated to modify Bason as asserted by Petitioner. *Id.* at 19–20 (citing Pet. 53–55). Patent Owner also argues that Petitioner incorrectly asserts that one of ordinary skill in the art would have looked to any small, mass-produced device, such as Rhoades. *Id.* at 20–21. Patent Owner further argues that (1) Rhoades is not a precision device, (2) Rhoades teaches away from close manufacturing tolerances, (3) the proposed combination is inoperable for its intended purpose because ring 4 would not rotate, and (4) the proposed combination does not yield predictable results

because Petitioner proposes a different combination based on the same references in the related proceeding IPR2018-01054. *Id.* at 21–26 (citing Pet. 55; Ex. 1007, 1:15–17; Ex. 1009, 8:6–16; Ex. 2005 ¶¶ 23, 25–27, 29, 30; Ex. 2007, 52–71).

At this stage, because the competing declarant testimonies create genuine issues of material fact, we view testimonial evidence in the light most favorable to the Petitioner solely for purposes of deciding whether to institute an *inter partes* review. 37 C.F.R. § 42.108(c). Petitioner’s Declarant testifies that one of ordinary skill in the art would have looked to Rhoades and that ring 4 would rotate in the proposed combination. *See* Ex. 1002 ¶¶ 134–136, 138. Also, the challenged claims do not require expressly “close manufacturing tolerances,” and even if they were to include such a requirement, the issue would be better decided on a record developed at trial to determine whether Rhoades criticizes, discourages, or disparages having parts with close manufacturing tolerances. Further, at this stage, the record does not indicate that the teachings of Bason and Rhoades can only be combined in a single manner and that one of ordinary skill in the art could not have combined these references to arrive at another combination.

For the reasons above, after considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that Petitioner shows a reasonable likelihood that it would prevail with respect to at least 1 of the claims challenged in the petition. As such, we institute *inter partes* review of all the challenged claims on all presented challenges. *See* 35 U.S.C. § 314(a).

2. Challenge Based on Bason and Allsop

Petitioner contends that the combination of Bason and Allsop teaches the limitations of claims 1–4. Pet. 69–74. Petitioner also argues that one of ordinary skill in the art would have been motivated to combine Bason and Allsop. *Id.* at 65–69.

Patent Owner responds that Petitioner does not explain sufficiently its modification of Bason in view of Allsop and fails to show how the references teach or suggest the recited “first member” and “second member.” Prelim. Resp. 26–28. Patent Owner also responds that one of ordinary skill in the art would not have been motivated to combine Bason and Allsop. *Id.* at 28–31.

a. Claims 1–4

Petitioner contends that Bason and Allsop each teach the limitations of claims 1–4 with references to previous arguments regarding anticipation by Allsop and obviousness in view of Bason and Rhoades. Pet. 69–74 (citing Ex. 1002 ¶¶ 180, 184, 186, 191, 192, 194, 199, 201; Ex. 1006, 7:8–10). Petitioner also argues that market forces would have motivated one of ordinary skill in the art to modify Bason to fix its dose counter below the canister and integrally mold teeth 2 into its inhaler body in view of Allsop with a reasonable expectation of success. *Id.* at 65–67 (citing Ex. 1002 ¶¶ 169, 172–175; Ex. 1004, 255, 281, 1137–1139, 1149–1150, 1158–1166, 1190–1205, 1229–1233, 1281, 1282, 1285, 1292; Ex. 1006, 7:8–10, Figs. 3, 4; Ex. 1007, Fig. 1; Ex. 1022, 1:43–45; Ex. 1028, 3; Ex. 1029, 3; Ex. 1030, 3; Ex. 1047), 70 (citing Ex. 1002 ¶¶ 180, 191; Ex. 1006, 7:8–10), 71 (citing Ex. 1002 ¶ 194), 72 (citing Ex. 1002 ¶ 184), 73 (citing Ex. 1002 ¶¶ 186,

199). Petitioner also contends that one of ordinary skill in the art would have looked to Allsop. *Id.* at 66 (citing Ex. 1002 ¶ 171).

Patent Owner responds that Petitioner does not explain how Bason would be modified while maintaining its operability. Prelim. Resp. 26. Specifically, Patent Owner argues that Petitioner fails to explain how the dose counter of Bason can be disengaged from the base, moved to below the canister, engaged with stationary components so as to be axially movable, and still function as described in Bason. *Id.* (citing Ex. 2005 ¶ 34). Patent Owner also argues that Petitioner does not explain adequately how Bason's valve would clear the dose counter and how teeth 2 can be integrally formed in the housing. *Id.* at 26–27 (citing Ex. 2005 ¶ 34).

The record at this stage does not indicate that disengaging the dose counter of Bason and moving it to below Bason's canister would fail to maintain Bason's operability. The present record also does not indicate that adjusting Bason's dose counter and valve was beyond ordinary skill. Petitioner provides declarant testimony indicating that its proposed modification of Bason in view Allsop would have been within ordinary skill. *See* Ex. 1002 ¶¶ 172–173; *see also* Pet. 15 (asserting that the level of ordinary skill in the art would include “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”). Petitioner also relies on Allsop to provide evidence that integrating teeth was known in addition to declarant testimony. Pet. 66–67 (citing Ex. 1002 ¶ 172; Ex. 1006, 7:8–10, Figs. 3, 4), 68 (citing Ex. 1002 ¶ 174; Ex. 1029, 3; Ex. 1030, 3).

Patent Owner also responds that Petitioner does not identify where Bason and Allsop teach the required “first member” and “second member” of the proposed combination because Petitioner refers to its arguments that Allsop anticipates the claims and to its arguments that Bason and Rhoades would have rendered obvious the claims. Prelim. Resp. 27–28 (citing Pet. 72). Petitioner sufficiently shows by reference to these arguments where either Bason or Allsop teaches the first and second members of the claims. *See* Pet. 36–38 (citing Ex. 1002 ¶¶ 62–66, 77–81; Ex. 1006, 8:22–24, 9:3–11, 9:17–25, Fig. 3), 61 (citing Ex. 1002 ¶¶ 144, 161; Ex. 1007, Abstract, 3:15–16, 5:14–32, Fig. 1), 62 (citing Ex. 1002 ¶¶ 146, 163).

Patent Owner further responds that one of ordinary skill in the art would not have been motivated to combine Bason with Allsop because Bason teaches away from fewer parts and because the combination would have rendered Bason inoperable for its intended purpose as the number of doses remaining would not be visible. Prelim. Resp. 28–31 (citing Pet. 67, 69; Ex. 1007, 1:15–20, 3:58–60; Ex. 2005 ¶¶ 35, 36). We agree that Petitioner does not address expressly modifying Bason further so that the number of doses remaining would be visible by also moving the window of Bason. At this stage, however, the record indicates such a modification was known and well within ordinary skill. *See* Pet. 15 (asserted level of ordinary skill in the art); Ex. 1006, 9:13–17, 10:4–9 (Allsop describing single number is visible); Ex. 1007, 3:1–10 (Bason describing window 13 showing available doses); Ex. 1008, 3:45–52, 4:42–46 (Marelli describing progressive numerical indices 17 visible through observation window 19).

For the reasons above, after considering the evidence and arguments presented in the Petition and Preliminary Response, we determine that

Petitioner shows a reasonable likelihood that it would prevail with respect to its challenge based on Bason and Allsop.

3. Long-Felt Need

Patent Owner contends that the '631 patent “met a long felt, but unresolved need.” Prelim. Resp. 33. Patent Owner argues that “there was no method by which a patient could accurately determine how many doses remained,” “drug makers (including Petitioners) failed to create an accurate MDI dose counter,” and the '631 patent “addressed the long-felt need in the industry for an accurate dose counter that avoided undercounting.” *Id.* at 33–34 (citing Ex. 1013, 2).

Whether the '631 patent addressed a long-felt, but unresolved, need presents an issue that would be better decided on a record developed at trial. Establishing long-felt need requires objective evidence of a problem that was recognized in the art and existed for a long period of time in the art without solution. The record at this stage insufficiently shows, for example, that the need was a persistent one recognized by those of ordinary skill in the art and that the need was not satisfied by another before the '631 patent.

D. 35 U.S.C. § 325(d)

Patent Owner responds that the Board should exercise its discretion under 35 U.S.C. § 325(d) to deny the Petition because Allsop, Marelli, and Bason were considered during the prosecution of the '631 patent. Prelim. Resp. 2, 6–8, 10, 12. In particular, Patent Owner argues that the Examiner considered Allsop and Marelli as indicated by a signed Information Disclosure Statement that includes both of these references. *Id.* at 8–9 (citing Ex. 1005, 5–6, 74–75). Regarding Bason, Patent Owner points to an Information Disclosure Statement that contains Bason, an Office Action that

cited Bason for a rejection under § 102(b), and a responsive Amendment that led to allowance in the prosecution of the '631 patent. *Id.* at 10–11 (citing Ex. 1005, 70–71, 85). Patent Owner also points us to an Information Disclosure Statement, an Office Action, and a Decision on Appeal for a related patent. *Id.* at 10 (citing Ex. 1004, 400, 1111–1112, 1272–1273).

Because Petitioner proposes to combine Bason with Rhoades, which the record indicates has not been previously considered, the circumstances of this particular case do not persuade us to exercise our discretion to deny institution under 35 U.S.C. § 325(d). Also, because Petitioner shows a reasonable likelihood of prevailing in its challenge based on Bason and Rhoades, we are not persuaded to deny institution for the anticipation challenges based on Allsop and Marelli. *See PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (stating “[e]qual treatment of claims and grounds for institution purposes has pervasive support in *SAS [Institute Inc. v. Iancu]*, 138 S. Ct. 1348 (2018)”]; *see also Adidas AG v. Nike, Inc.*, 894 F.3d 1256, 1258 (Fed. Cir. 2018) (remanding for the Board to consider non-instituted ground).

IV. CONCLUSION

The Supreme Court held that a final written decision under 35 U.S.C. § 318(a) must decide the patentability of all claims challenged in the petition. *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018). After considering the evidence and arguments presented in the Petition and the Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood of success in proving that at least one of claims 1–4 of the '631 patent is unpatentable.

Because Petitioner has shown that there is a reasonable likelihood that it would prevail with respect to at least one of the challenged claims, we institute an *inter partes* review of all challenged claims on all presented challenges.

At this stage of the proceeding, the Board has not made a final determination as to the patentability of any challenged claim or any underlying factual and legal issues.

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–4 of U.S. Patent No. 9,370,631 B2 is instituted with respect to all grounds set forth in the Petition; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), *inter partes* review of U.S. Patent No. 9,370,631 B2 shall commence on the entry date of this Order, and notice is hereby given of the institution of a trial.

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Patent 9,370,631 B2

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