

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

APTARFRANCE S.A.S.,  
Patent Owner.

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IPR2018-01055  
Patent 9,370,631 B2

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

JUNG, *Administrative Patent Judge*.

JUDGMENT  
Final Written Decision  
Determining All Challenged Claims Unpatentable  
Denying Motions to Exclude  
*35 U.S.C. § 318(a)*

## I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Petitioner has shown by a preponderance of the evidence that claims 1–4 of U.S. Patent No. 9,370,631 B2 are unpatentable.

### A. *Procedural History*

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”) filed a Preliminary Response. Paper 10. Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of the ’631 patent. Paper 11 (“Dec. to Inst.”). In particular, we instituted review of claims 1–4 on all presented challenges. Dec. to Inst. 2, 22, 28.

After institution, Patent Owner filed a Response (Paper 27, “PO Resp.”)<sup>1</sup>, to which Petitioner filed a Reply (Paper 28, “Pet. Reply”), and Patent Owner thereafter filed a Sur-Reply (Paper 31, “PO Sur-Reply”).

As described in our Order (Paper 35), Patent Owner was authorized to file a paper identifying arguments in Petitioner’s Reply that Patent Owner believed exceeded proper scope and Petitioner was authorized to file a paper

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<sup>1</sup> Patent Owner requested via email to file a corrected Response to address typographical and clerical errors and to file a corrected Exhibit 2019 that would include an errata that was not available at the time of original filing. Patent Owner represented that Petitioner did not oppose the request. We granted the request, and this Decision cites to the corrected Response and corrected Exhibit 2019.

to identify where the contention Petitioner was responding to can be found. Patent Owner filed its authorized paper (Paper 32), and Petitioner filed its authorized response (Paper 33). Both parties also filed its own motion to exclude (Papers 37, 39), oppositions to those motions (Papers 42, 43), and replies in support of those motions (Papers 46, 47).

An oral hearing in this proceeding was held on August 12, 2019; a transcript of the hearing is included in the record (Paper 51, “Tr.”).

*B. 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. Also, the ’631 patent issued from an application that is a continuation of the patent at issue in Case IPR2018-01054. Pet. 6; Paper 6, 2; PO Resp. 3.

*C. Evidence Relied Upon*

Petitioner identifies the following references as prior art in the asserted grounds of unpatentability:

- (1) U.S. Patent No. 3,205,863, issued September 14, 1965 (Ex. 1009, “Rhoades”);
- (2) EP 0 480 488 B1, published November 2, 1994 (Ex. 1008, “Marelli”);
- (3) WO 00/59806, published October 12, 2000 (Ex. 1006, “Allsop”);  
and
- (4) U.S. Patent No. 6,283,365 B1, issued September 4, 2001  
(Ex. 1007, “Bason”).

Pet. 10 (contending that the ’631 patent has “a priority date no earlier than May 15, 2003), 20 (contending that Allsop is prior art under 35 U.S.C.

§ 102(b)<sup>2</sup>), 22–23 (contending that Bason is prior art under 35 U.S.C. § 102(b)), 25 (contending that Marelli is prior art under 35 U.S.C. § 102(b)), 28 (contending that Rhoades is prior art under 35 U.S.C. § 102(b)).

In support of its proposed grounds, Petitioner relies on declarations by S. David Piper. Exs. 1002, 1058. Patent Owner filed a Declaration of Charles E. Clemens in Support of Patent Owner’s Response. Ex. 2021. Deposition transcripts for Mr. Piper and Mr. Clemens were also filed. Exs. 1057, 2019.

*D. Grounds of Unpatentability at Issue*

Petitioner challenges, and we instituted *inter partes* review of, claims 1–4 of the ’631 patent on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–4	102(b)	Allsop
1–4	102(b)	Marelli
1–4	103(a)	Bason and Rhoades
1–4	103(a)	Bason and Allsop

Dec. to Inst. 2, 22, 28.

*E. The ’631 Patent (Ex. 1001)*

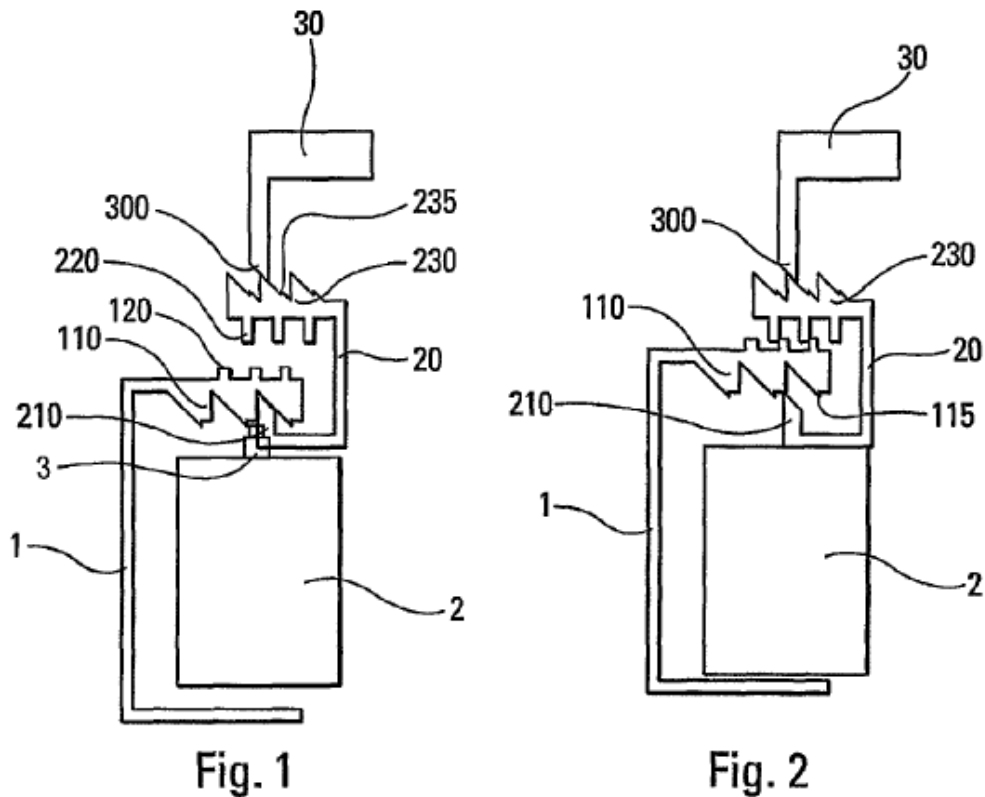
The ’631 patent issued June 21, 2016, from an application filed October 9, 2014, is a continuation of an application that issued as U.S. Patent No. 8,936,177 B2, and claims priority to a foreign application filed May 15, 2003. Ex. 1001, codes (22), (30), (45), (63), 1:6–11; *see also*

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<sup>2</sup> 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 was filed before that date, our citations to Title 35 are to its pre-AIA version.

Pet. 10 (discussing priority and contending that the '631 patent has “a priority date no earlier than May 15, 2003”); PO Resp. 3 (describing applications leading to the '631 patent and identifying a French patent application filed on May 15, 2003).

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.



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.

An important safety consideration described in the '631 patent is that the dose indicator never under-counts, in other words never “fail[] to count one or more occasions on which a dose of fluid is dispensed.” *Id.* at 5:39–40. 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 end of 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.

*F. 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<sup>3</sup> the central longitudinal axis and is displaceable rotationally around the central longitudinal axis.

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<sup>3</sup> Petitioner indicates that the claim includes an error. *See* Pet. 10.

Ex. 1001, 10:2–24.

## II. ANALYSIS

To prevail in its challenges, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

As shown below, we analyze Petitioner’s challenge of claims 1–4, under 35 U.S.C. § 103(a), as unpatentable over Bason and Rhoades and do not reach Petitioner’s other challenges. A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

The parties’ disputes are related to the scope and content of the prior art, differences between the challenged claims and the prior art, and objective evidence of nonobviousness. After reviewing the complete record, we conclude that Petitioner has shown by a preponderance of the evidence that Bason and Rhoades teach or suggest each limitation of the challenged claims; that a person of ordinary skill in the art would have had a reason to modify Bason in view of Rhoades; and that a person of ordinary skill in the



art would have had a reasonable expectation of success in combining Bason and Rhoades.

*A. Level of Ordinary Skill*

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 states that it “disagrees that Petitioners’ proposed level of skill in the art reflects the education, training, and experience required to qualify as a [person of ordinary skill in the art]“ but “the Board need not resolve this dispute to find that the claims are patentable over the asserted art.” PO Resp. 4; *see also* Tr. 17:13–19 (Petitioner’s counsel agreeing that the Board need not resolve dispute over level of skill in the art).

Based on the record before us, we find that a person “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).

*B. Claim Construction*

In the present *inter partes* review, claim terms in the ’631 patent, which is unexpired, are interpreted according to their broadest reasonable construction in light of the Specification of ’631 patent. 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).<sup>4</sup>

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 “there are no claim terms that require construction for purposes of the Board’s analysis of the patentability of the claims.” PO Resp. 5. Patent Owner also disagrees with Petitioner’s proposed interpretation of “stationary body” but states that “none of Aptar’s positions or arguments relate to whether or not the prior art references disclose a stationary gear that is unitary or monolithic to the stationary body.” *Id.* Patent Owner also states that, for “disposed on,” “the Board need not construe this term to find that the claims of the ’631 Patent

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<sup>4</sup> On October 11, 2018, the Office revised its rules to harmonize the Board’s claim construction standard with that used in civil actions under 35 U.S.C. § 282(b) in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018). This rule change does not apply here. *See* Paper 5, 1 (according filing date of May 10, 2018 to the Petition); PO Resp. 4 n.2 (agreeing that the revised claim construction standard does not apply to this proceeding).

patentable because none of Aptar’s distinctions over the prior art relate to this claim element.” *Id.* at 5–6. Petitioner’s counsel also agreed that no claim term needs to be interpreted expressly. Tr. 18:1–7.

We agree with the parties that no express interpretation is required for any claim term to resolve the parties’ disputes. *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); *see also Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

### *C. Scope and Content of the Prior Art*

#### *1. 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. Figure 1 is reproduced below.

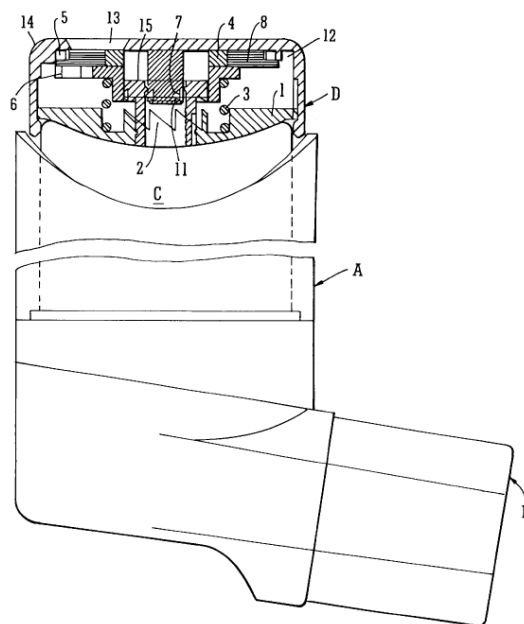


FIG. 1

Figure 1 is a part cross-sectional view of a metered dose inhaler with an indicator device. *Id.* at 1:65–67. 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. Figure 3 is reproduced below.

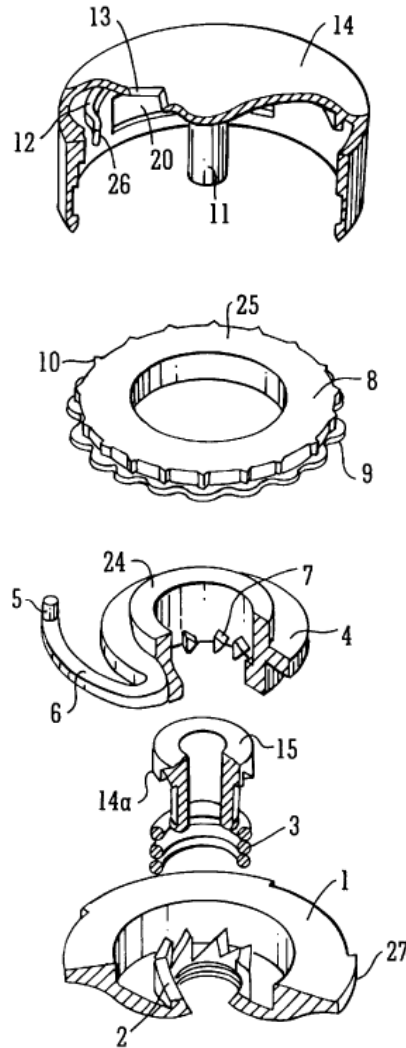


FIG. 3

Figure 3 is an “exploded perspective view of the parts of the device.” *Id.* at 2:3–4. 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 faces visible through window 13 changes by one increment for a complete depression and release of cap 14. *Id.* at 3:22–26.

## 2. 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.

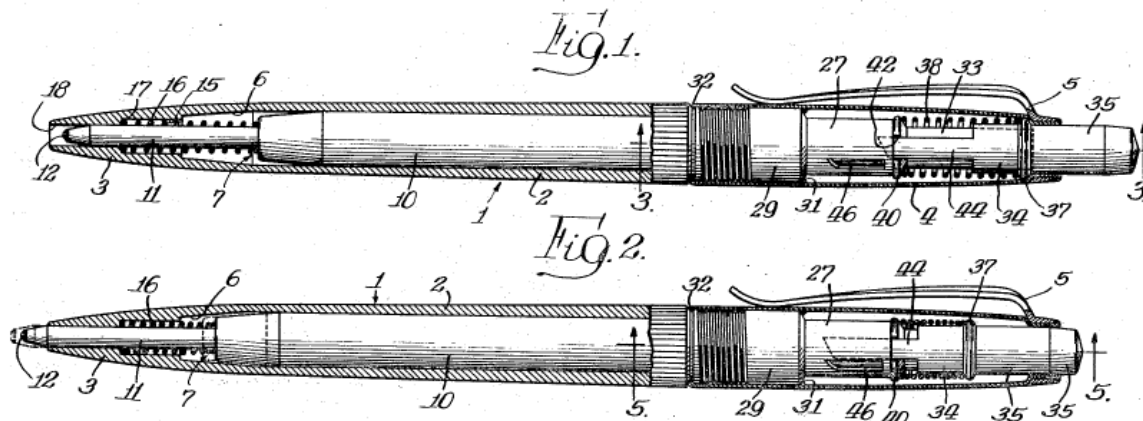


Figure 1 is a sectional view showing a point-and-cartridge unit in a retracted position, and Figure 2 is a sectional view showing the point-and-cartridge unit in a projected position. *Id.* at 2:44–51. Barrel 1 has a bore that receives point-and-cartridge unit 7. *Id.* at 3:28–32. Point-and-cartridge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

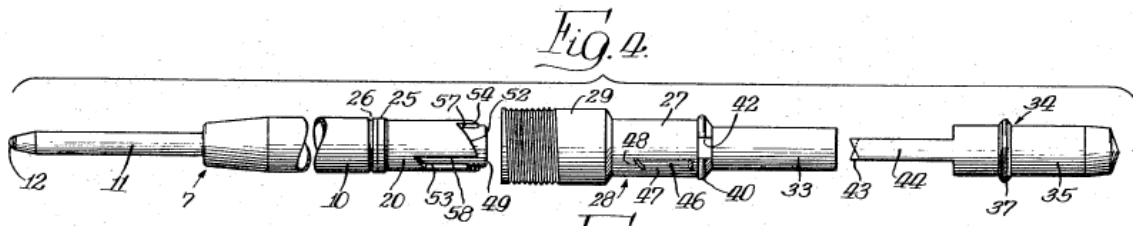
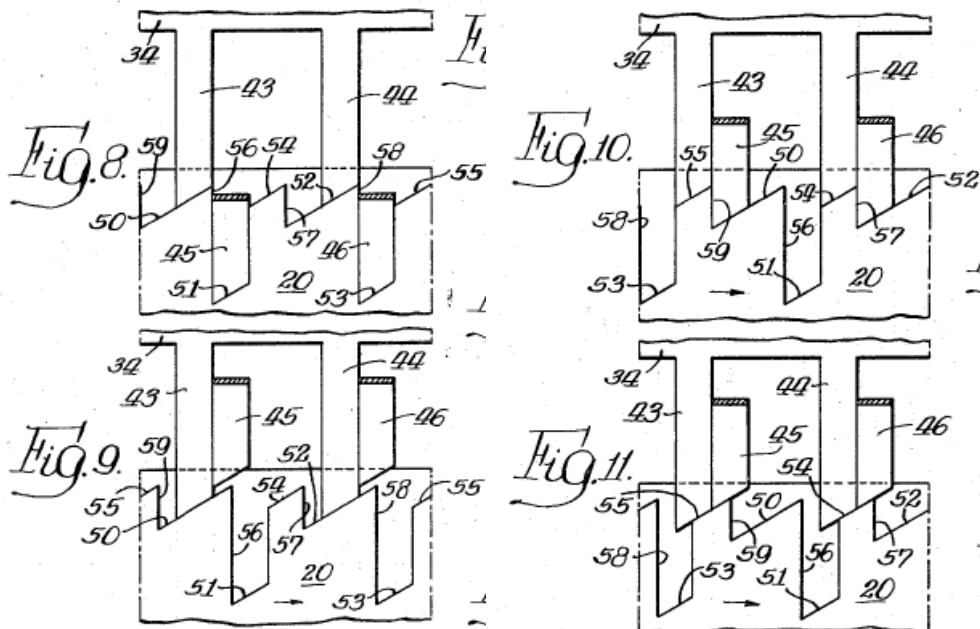


Figure 4 shows an exploded view of the point-and-cartridge unit and projecting-retracting mechanism. *Id.* at 2:57–59. Secured to the rear of ink reservoir section 10 is cam body 20 which is part of the projecting-retracting mechanism. *Id.* at 3:49–53. Cam body 20 is rotatably and slidably disposed 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.<sup>5</sup>

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

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<sup>5</sup> 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.”

*D. 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 Petitioner’s proposed combination would have rendered Bason inoperable, that the asserted references fail to teach the claimed first and second members, and that one of ordinary skill in the art would not have been motivated to combine Bason and Rhoades. PO Resp. 30–43.

*1. Claim 1*

*a. “A fluid dispenser”*

Petitioner argues that, to the extent that it is limiting, Bason and Rhoades each teach a fluid dispenser. Pet. 57–58 (citing Ex. 1002 ¶¶ 139, 153; Ex. 1007, 1:3–5; Ex. 1009, 3:34–42, 11:60–63, Figs. 1, 2); *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).

We find that the relied-upon portion of Bason teaches that Bason “concerns an indicator device, and particularly, though not exclusively, such a device adapted to serve as a dose counter for metered dose inhalers (MDI’s).” Ex. 1007, 1:3–5. We also credit Petitioner’s declarant testimony because the record supports it. Ex. 1002 ¶ 139. Patent Owner does not respond specifically to Petitioner’s arguments regarding a “fluid dispenser.” *See* PO Resp. 30–48.



Based on the full record before us, because Bason teaches an MDI, Petitioner persuades us by a preponderance of the evidence that, at least, Bason teaches a fluid dispenser.

*b. “a plurality of displayable dose values”*

Petitioner argues that Bason teaches “a plurality of displayable dose values.” Pet. 58 (citing Ex. 1007, 3:1–10); *see also id.* at 15–18 (asserting what was known in the art as of May 2003), 23–25 (asserting what Bason teaches).

We find that the relied-upon portion of Bason teaches that faces 24, 25 of rings 4, 8 “carry respectively two numeric series such that face 24 carries the series 0 to 9 while face 25 carries the series 00 to 20.” Ex. 1007, 2:67–3:4. We also find that Bason teaches that the numbers are visible through window 13 and that “[a]s the MDI is progressively used the available doses will count down eventually to zero indicating that the canister is empty” so that the “user may therefore determine at any time how many doses remain available from the canister.” *Id.* at 3:4–13. Patent Owner does not provide a response specifically for “a plurality of displayable dose values.” *See* PO Resp. 30–48.

Based on the full record before us, because Bason teaches a counter visible through window 13 that counts down available doses, Petitioner persuades us by a preponderance of the evidence that Bason teaches “a plurality of displayable dose values.”

*c. “a stationary body comprising at least one stationary multi-toothed gear”*

Petitioner argues that Bason teaches “a stationary counter component with gear teeth that is not unitary with the outer inhaler body.” Pet. 58.

According to Petitioner, Rhoades teaches stationary guide member 28 with stop members 45, 46 that are teeth. *Id.* at 58–59 (citing Ex. 1002 ¶¶ 142, 156; Ex. 1009, 4:13–21, 8:7–9); *see also id.* at 15–18 (asserting what was known in the art as of May 2003), 28–32 (asserting what Rhoades teaches).

We find that the relied-upon portion of Rhoades teaches that “[t]wo stop members 45 and 46 extend longitudinally within the central portion 27 of the guide member 28.” Ex. 1007, 4:13–15. We further credit the testimony of Petitioner’s declarant regarding Rhoades and a stationary body including at least one stationary gear because it finds support in Rhoades. Ex. 1002 ¶ 142. Patent Owner does not respond specifically to Petitioner’s arguments regarding the stationary body of claim 1. *See* PO Resp. 30–48.

Based on the full record before us, because Rhoades teaches stationary guide member 28 with stop members 45, 46, Petitioner persuades us by a preponderance of the evidence that Rhoades teaches “a stationary body comprising at least one stationary multi-toothed gear” that meets the interpretation that the stationary body contains, as a unitary or monolithic part, at least one stationary gear.

*d. “a first member that is displaceable axially relative to said stationary body”*

Petitioner argues that Bason teaches “cap 14, which is depressed by the user to depress the canister and rings 4 and 8.” Pet. 61 (citing Ex. 1002 ¶ 144; Ex. 1007, Abstract, 3:15–16, Fig. 1); *see also id.* at 15–18 (asserting what was known in the art as of May 2003), 23–25 (asserting what Bason teaches). Petitioner also argues that Rhoades teaches push button 35 formed with plunger 34 that has fingers 43, 44, and that, when push button 35 is depressed, fingers 43, 44 move with respect to stop members 45, 46 and

move cam body 20. Pet. 60–61 (citing Ex. 1009, 4:10–13, 5:39–43, Fig. 4); *see also id.* at 15–18 (asserting what was known in the art as of May 2003), 28–32 (asserting what Rhoades teaches).

According to Petitioner, “[i]n light of *Rhoades* and its integrated stop members, one would have incorporated *Bason*’s teeth 2 directly on the inhaler body, and the inhaler body would be the claimed stationary body” and thus, “cap 14 would move axially relative to the stationary body.” *Id.* at 61 (citing Ex. 1002 ¶¶ 144, 161).

Patent Owner responds that the push button of Rhoades is not a part of Petitioner’s proposed combination. PO Resp. 34 (citing Pet. 55–56, 60–61). Patent Owner also argues that cap 14 of Bason does not meet the first body limitation “because the teeth that purportedly would have been molded onto the inhaler body prevent the cap from moving axially as required by the claim.” *Id.* at 35–36 (citing Ex. 1007, Fig. 1; Ex. 2021 ¶¶ 55, 81). We address these arguments below in our analysis of Petitioner’s reason to combine the references.

We find that the relied-upon portion of Bason teaches “a spring-loaded cap (14) which may be depressed in relation to a second part (1) mounted on the domed base of the canister (C)” and that “[u]pon depression of the cap 14 with respect to the base 1, the rings 4 and 8 are also depressed linearly.” Ex. 1007, Abstract, 3:15–16, Fig. 1. We also find that Rhoades teaches “fingers 43 and 44 formed integrally with and extending forwardly from the plunger 34 inside the central, tubular portion 27 of the guide member 28” and that “[w]hen the push button 35 is depressed, the actuating fingers 43 and 44 will be moved downwardly (as viewed in FIG. 8) with respect to stationary stop members 45 and 46 and will carry with them the

cylindrical cam body 20.” Ex. 1009, 4:10–13, 5:39–43. We further credit the testimony of Petitioner’s declarant because the record supports it. Ex. 1002 ¶ 144.

Based on the full record before us, Petitioner persuades us by a preponderance of the evidence that (1) Bason teaches cap 14 that can be depressed axially and (2) Rhoades teaches push button 35 that, when depressed, axially moves fingers 43, 44 with respect to stop members 45, 46. As discussed above, Petitioner persuades us that Rhoades’s stationary guide member 28 with stop members 45, 46, teaches the recited stationary body. Petitioner, thus, persuades us by a preponderance of the evidence that these references, in combination, teach “a first member that is displaceable axially relative to said stationary body.”

*e. “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”*

Petitioner argues that ring 4 of Bason and cam body 20 of Rhoades each teach the second member of claim 1. Pet. 61–62 (citing Ex. 1002 ¶¶ 146, 163; Ex. 1009, 3:66–68, 4:22–28, 5:11–28, 5:51–54); *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).

We find that Bason teaches that “[u]pon depression of the cap 14 with respect to the base 1, the rings 4 and 8 are also depressed linearly” causing “teeth 7 to engage the lower fixed set of teeth 2” and “caus[ing] the ring 4 to be indexed in rotation.” Ex. 1007, 3:15–19; *see also* Pet. 24 (citing Ex. 1007, 3:15–22). We also find that the relied-upon portions of Rhoades teach that “cam body 20 is rotatably and slidably disposed within a tubular

central portion 27 of a stationary guide member 28 so as to in effect be ‘floating’ therein” and “cam body 20 is . . . provided with a plurality of cam surfaces 50, 52, 54, 55 diametrically opposite pairs of which are successively engageable by the fingers 43 and 44 to impart unidirectional rotational movement as well as longitudinal reciprocating movement to the cam body . . . when the push button 35 is repeatedly depressed.” Ex. 1009, 3:66–68, 4:22–28.

Patent Owner responds that the cam body of Rhoades is not present in Petitioner’s proposed combination. PO Resp. 36–37 (citing Pet. 55–56, 61–62). Patent Owner also argues that ring 4 of Bason cannot rotate as required by the claim. *Id.* at 37–38 (citing Ex. 1007, 2:28–38, Fig. 1; Ex. 2021 ¶ 60). We address these arguments below in our analysis of Petitioner’s reason to combine.

Based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Bason teaches ring 4 that moves axially and rotates and Rhoades teaches cam body 20 that is rotatably and slidably disposed in stationary guide member 20. As discussed above, Petitioner persuades us that Rhoades’s stationary guide member 28 with stop members 45, 46, teaches the recited stationary body. Petitioner, thus, persuades us by a preponderance of the evidence that these references, in combination, teach “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.”

- f. “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”*

Petitioner argues that Rhoades teaches that reservoir section 10, a fluid reservoir, moves axially relative to cam body 20, a stationary body. Pet. 62 (citing Ex. 1009, 3:59–60); *see also id.* at 15–18 (asserting what was known in the art as of May 2003), 28–32 (asserting what Rhoades teaches). Petitioner also refers to its previous arguments that Bason teaches first and second members cooperating to result in axial and rotational movement of ring 4 and that the canister of Bason moves axially relative to the inhaler housing. *See id.* at 15–18 (asserting what was known in the art as of May 2003), 23–25 (asserting what Bason teaches).

Petitioner, thus, argues that “[i]f the teeth of base 1 are molded into the inhaler body such that the inhaler body is the stationary body, the canister moves axially relative to the stationary body.” *Id.* at 62–63 (citing Ex. 1002 ¶ 148). Petitioner further argues that “*Bason* discloses rings that carry with them numeric series, which a [person of ordinary skill in the art] would have included on cam body 20.” *Id.* at 63 (citing Ex. 1007, 3:1–10)

We find that the relied-upon portion of Rhoades teaches that “cam body 20 is secured to the rear end of reservoir section 10.” Ex. 1009, 3:59–60. As discussed above, we find that Rhoades teaches that cam body 20 moves axially relative to stationary guide member 28. *Id.* at 3:66–68, 4:22–28. We, therefore, agree with Petitioner that reservoir section 10 secured to

cam body 20 would also move axially relative to stationary guide member 28. Pet. 62.

We also find that Bason teaches that the “counter consists of a first part or base 1 which, in manufacture of the canister C is bonded to the domed base thereof.” Ex. 1007, 2:16–18; *see also* Pet. 23 (citing Ex. 1007, 1:3–5, 2:16–18, Fig. 1). As determined above, we find that Bason teaches that “[u]pon depression of the cap 14 with respect to the base 1, the rings 4 and 8 are also depressed linearly” and “[o]wing to the triangular formation of teeth 7 and 2 this causes the ring 4 to be indexed in rotation, (see Fig. 5) and upon return or release of the cap, . . . further rotational movement of the ring 4.” Ex. 1007, 3:15–22. Because ring 4 of Bason’s counter moves downwardly and rotationally and because the counter is bonded to Bason’s canister, we agree with Petitioner that Bason’s canister moves axially and rotates.

We further find that the relied-upon portion of Bason teaches that faces 24, 25 of rings 4, 8 “carry respectively two numeric series such that face 24 carries the series 0 to 9 while face 25 carries the series 00 to 20,” “through the window 13, there may be visible progressively the numbers 000 to 200,” and “the device counts down so that when the MDI is new and unused the number 200 will be visible thus indicating that there are 200 doses available within the canister to which the device is attached.” Ex. 1007, 2:67–3:8. We credit the testimony of Petitioner’s declarant regarding Bason because the record supports it. Ex. 1002 ¶ 148.

Patent Owner responds that Petitioner relies on ring 4 of Bason or cam body 20 of Rhoades for teaching the second member but that the cam body of Rhoades is not part of Petitioner’s proposed combination. PO Resp. 37

(citing Pet. 55–56, 61–62). Patent Owner also argues that ring 4 of Bason fails to teach the second member because, in the proposed combination, it cannot rotate. *Id.* at 37–39 (citing Ex. 1007, 2:20–38, 2:43–58, 3:15–22, Fig. 1; Ex. 2021 ¶¶ 60–62). Patent Owner, thus, contends that Bason and Rhoades would not have rendered obvious the second element of the claims. We address this argument below in our analysis of Petitioner’s reason to combine.

Based on the full record before us, Petitioner persuades us by a preponderance of the evidence that, when cap 14 of Bason (the first member) is depressed, the canister of Bason is allowed to be displaced axially and rotationally relative to the housing of Bason. Petitioner also persuades us by a preponderance of the evidence that ring 4 of Bason (the second member) displaces axially and rotates relative to the housing so that the counter of Bason counts down. Petitioner, thus, persuades us by a preponderance of the evidence that these references, in combination, teach

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.

- g. *“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”*



Petitioner argues that Bason teaches circular base 1 (stationary body), cylindrical cap 14 (first member), and circular rotational ring 4 (second member) sharing the same axis and the claimed movement of the first and second members. Pet. 63–64 (citing Ex. 1002 ¶¶ 149, 165; Ex. 1007, 2:5–6, Fig. 4). Petitioner also argues that Rhoades teaches cylindrical guide member 28 (stationary body), plunger with fingers 43, 44 (first member), and cylindrical cam body 28 (second member) sharing the same axis. *Id.* at 64 (citing Ex. 1002 ¶¶ 150, 166). Petitioner further argues that incorporating teeth 2 of Bason in Bason’s inhaler would not alter the common axis. *Id.* (citing Ex. 1002 ¶¶ 149, 165).

We find that Figure 4 of Bason shows base 1, cap 14, and ring 4 sharing the same axis. Ex. 1007, Fig. 4. As discussed above, we find that Bason teaches that cap 14 is displaceable axially along the central longitudinal axis and that ring 4 moves downwardly and rotates around the same central longitudinal axis. We also credit the testimony of Petitioner’s declarant regarding the wherein clause because the record supports it. Ex. 1002 ¶¶ 149, 150, 165, 166. Patent Owner does not respond specifically to Petitioner’s arguments for the wherein clause. *See* PO Resp. 30–48.

Based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Bason and Rhoades each teach the wherein clause of claim 1.

*h. Reason to Combine Bason and Rhoades*

*i. Analogous Art*

To determine if a prior art reference is analogous, one must consider “(1) whether the art is from the same field of endeavor, regardless of the

problem addressed, and (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved." *In re Clay*, 966 F.2d 656, 658 (Fed. Cir. 1992). "A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *Id.* at 659.

Petitioner contends that one of ordinary skill in the art would have looked to Rhoades. Pet. 53–54 (citing Ex. 1002 ¶¶ 134–136; Ex. 1031, 2:36–47; Ex. 1032, 1:40–48; Ex. 1033, 15:10–25; Ex. 1034, code (56), Abstract, 3:29–39). Patent Owner responds that a person of ordinary skill in the art would not have been motivated to combine Bason and Rhoades because Rhoades is not analogous art. PO Resp. 39. Patent Owner argues that the '631 patent and Rhoades have different purposes. *Id.* at 39–40 (citing Ex. 1001, 1:67–2:3; Ex. 1009, 1:15–17). Patent Owner also argues that Rhoades is not relevant to the problem of undercounting or MDI's. *Id.* at 40 (citing Ex. 2021 ¶¶ 68–69).

Petitioner replies that Patent Owner fails to apply the correct test for analogous art (Pet. Reply 15), that one of ordinary skill in the art would have considered Rhoades because it teaches similar structures (*id.* at 16 (citing Ex. 1057, 180:22–182:4)), that Patent Owner's declarant considered pens and medical devices together (*id.* (citing Ex. 1055 ¶ 47; Ex. 1057, 182:24–183:12)), and that the parent patent and Rhoades share a common purpose (*id.* at 16–17 (citing Ex. 1057, 160:15–163:17)). According to Petitioner, Patent Owner's declarant "agreed that engineers take basic known

mechanisms and apply them to other products” and “that 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.” *Id.* at 16 (citing Ex. 1056, 98–100; Ex. 1057, 187:25–189:25). Petitioner also argues that the Petition identified examples of medical device components that are analogous to pens. *Id.* at 17–18 (citing Pet. 32; Ex. 1031; Ex. 1032, 1:7–9).

Based on the full record before us, we determine that Rhoades is analogous art. Although Rhoades may not be in the same field as the ’631 patent or Bason, a preponderance of the evidence persuades us that Rhoades would have been reasonably pertinent to a problem related to the ’631 patent and logically would have commended itself in considering the problem. Ex. 1002 ¶ 135 (“A [person of ordinary skill in the art] would have been familiar with the *Rhoades* mechanism and would have looked to this type of art when seeking to improve *Bason* as above.”); Ex. 1034, code (56), Abstract, 3:29–39; Ex. 1057, 182:24–183:12. The ’631 patent addresses a problem pertaining to development of simple, inexpensive, and reliable fluid dispensers, while Bason and Rhoades also supply simple structures that convert linear to rotational motion, and Rhoades seeks to provide a reliable and easy to manufacture mechanism, thus addressing some of the same problems addressed by the ’631 patent. *See* Ex. 1002 ¶ 134. A preponderance of the evidence also persuades us that one of ordinary skill in the art would have looked to pens such as the pen disclosed by Rhoades, as indicated by the testimony of both parties’ declarants. Ex. 1002 ¶¶ 134, 135; Ex. 1034, code (56), Abstract, 3:29–39; Ex. 1057, 182:24–183:12.

*ii. Motivation to Combine*

Petitioner 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. Pet. 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).

We determine that, in view of the recognized insufficiency of monitoring remaining medication in MDI's (Ex. 1027, 2–3, 6; Ex. 1028, 3–5, 7; Ex. 1045, 3) and FDA guidance (Ex. 1012, 5–6; Ex. 1013, 4–7), one of ordinary skill in the art would have been motivated to include a counter that avoids undercounting doses in an MDI and can be mass produced. We also credit the testimony of Petitioner's declarant that one of ordinary skill in the art would have looked to other small, mechanical devices that could be mass produced because the record supports the testimony. Ex. 1002 ¶ 134; Ex. 1007, 3:66–4:3, Ex. 1029, 3; Ex. 1030, 3. Patent Owner does not present arguments that industry recognition of insufficient counters and guidance from the FDA would fail to motivate one of ordinary skill in the art. *See generally* PO Resp. Thus, based on the full record, Petitioner

persuades us that one of ordinary skill in the art would have been motivated to improve Bason with the teachings of Rhoades.

*iii. Operability*

Petitioner proposes to modify Bason's counter with Rhoades's teachings to create a less expensive, more reliable inhaler and to avoid undercounting by way of the stop members of Rhoades. Pet. 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 Petitioner's proposed modification is not sufficiently explained and would have been inoperable for its intended purpose. PO Resp. 30–32 (citing Pet. 38; Ex. 1007, Figs. 1, 2; Ex. 2021 ¶¶ 49, 79–82). Patent Owner argues that moving Bason's teeth 2 to its inhaler body would result in teeth 7 and teeth 2 failing to come into contact and thus, ring 4 would not rotate. *Id.* at 32–33 (citing Pet. 55; Ex. 1008, 1:15–17; Ex. 2021 ¶¶ 55, 60–63, 79–82).

Petitioner replies that Patent Owner is unable to dispute that Bason and Rhoades teach the claimed elements and that Patent Owner “conducts its obviousness analysis through the lens of a [person of ordinary skill in the art] having no ability to overcome even the most basic technical challenges.” Pet. Reply 6. Petitioner replies that a person of ordinary skill in the art “is not an automaton,” “would know how to overcome routine technical challenges,” and “would know how to adapt simple mechanical mechanisms to the problem on which that [person of ordinary skill in the art] is working.” *Id.* at 6–7. Petitioner also argues that, during prosecution of the parent patent in response to an indefiniteness rejection, Applicant argued that one of ordinary skill in the art would have understood how to shape and structure the gears of the claimed invention and how to connect and arrange the claimed components. *Id.* at 7–8 (citing Pet. 1–2, 10–12, 16, 55, 69, n.5; PO Resp. 37–39, 52–53, ; Ex. 1004, 1222, 1233).

As determined above, we agree with the parties 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); PO Resp. 4 (stating that “Board need not resolve this dispute [over level of ordinary skill in the art] to find that the claims are patentable over the asserted art”); Tr. 17:13–19 (Petitioner’s counsel agreeing that the Board need not resolve any dispute over level of skill in the art). We determine that such a level of ordinary skill in the art would have been sufficient to modify Bason in view of Rhoades as proposed by Petitioner. *See* Pet. 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; Ex. 1047); *see also id.* at 60 (citing Ex. 1002 ¶ 159), 61 (citing Ex. 1002 ¶¶ 144, 161).

Patent Owner also responds that the push button of Rhoades is not a part of Petitioner’s proposed combination. PO Resp. 34 (citing Pet. 55–56, 60–61). Patent Owner argues that the cap of Bason does not meet first body limitation “because the teeth that purportedly would have been molded onto the inhaler body prevent the cap from moving axially as required by the claim.” *Id.* at 35–36 (citing Ex. 1007, Fig. 1; Ex. 2021 ¶¶ 55, 81).

Petitioner replies that “connecting the cap to ensure that it could move axially involves routine pre-production steps within the skillset of a [person of ordinary skill in the art].” Pet. Reply 8–9 (citing PO Resp. 35–36; Ex. 1058 ¶¶ 16–20). Petitioner argues that the Petition explains that one of ordinary skill in the art “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*,” which are ignored by Patent Owner and its declarant. *Id.* at 9 (citing Pet. 55–56; PO Resp. 30; Ex. 1057, 231:6–22). Petitioner also argues that, during prosecution of the parent application, such connections were admitted to be well understood in the art using various techniques. *Id.* at 9–10 (citing PO Resp. 35; Ex. 1004, 281, 403, 409, 617, 650, 1138).

Patent Owner further responds that Petitioner relies on ring 4 of Bason or cam body 20 of Rhoades for teaching the second member but that the cam body of Rhoades is not part of Petitioner’s proposed combination. PO Resp. 37 (citing Pet. 55–56, 61–62). Patent Owner also argues that ring 4 of Bason fails to teach the second member because, in the proposed combination, it

cannot rotate. *Id.* at 37–39 (citing Ex. 1007, 2:20–38, 2:43–58, 3:15–22, Fig. 1; Ex. 2021 ¶¶ 60–62). Patent Owner, thus, contends that Bason and Rhoades would not have rendered obvious the second element of the claims.

Petitioner replies that the Petition argues that teeth 7 would interact with teeth 2 and that the components would retain their functions. Pet. Reply 14 (citing Pet. 56, 68). According to Petitioner, the Petition argued that a person of ordinary skill in the art would have connected the components so that they would interact. *Id.* at 14–15 (citing Ex. 1004, 1233; Ex. 1058 ¶¶ 21–23).

As discussed above, based on the level of ordinary skill in the art that we apply to our analysis, such a level of ordinary skill would have been sufficient to apply the teachings of Rhoades to Bason. Also, as discussed above, Petitioner contends that arranging the parts so that, in the proposed combination of Bason and Rhoades, teeth 7 and 2 can engage to rotate ring 4 would have been a matter of ordinary skill. In view of our determination regarding the level of ordinary skill in the art and Petitioner’s evidence of skill in the art (Ex. 1002 ¶ 137; Ex. 1004, 255, 281, 1137–1139, 1149–1150, 1158–1166, 1190–1205, 1229–1233, 1281, 1282, 1292; Ex. 1022, 1:43–45; Ex. 1047), Petitioner persuades us that one of ordinary skill in the art would have been able to apply the teachings of Rhoades to Bason so that the components of the proposed combination can perform as Bason teaches. The record does not present a reason that the proposed combination would have been beyond ordinary skill.

Patent Owner argues that Petitioner fails to explain why one of ordinary skill in the art would have had a reasonable chance of success in incorporating Rhoades’s components into an MDI. PO Resp. 43 n.10 (citing



Ex. 1002 ¶¶ 17, 135; Ex. 2021 ¶ 78). Petitioner, however, argues that one of ordinary skill in the art “would have had a reasonable expectation of success” because “the modification was predictable because the manufacturability and connectivity of such components was well-understood.” Pet. 56 (citing Ex. 1002 ¶ 137).

For the reasons discussed above, Petitioner persuades us that one of ordinary skill in the art would have made the proposed combination of Bason and Rhoades. Pet. 56. Because the proposed combination is a matter of ordinary skill in the art, we determine that one of ordinary skill in the art would have had a reasonable expectation of success in making Petitioner’s proposed combination.

*iv. Teaching Away*

Patent Owner also responds that “Rhoades expressly teaches *away* from ‘close manufacturing tolerances’” and thus, one of ordinary skill “would have understood that it simply was not designed for the precision required of MDIs,” thereby providing no motivation to combine with Bason. PO Resp. 42–43 (citing Ex. 1009, 8:6–16; Ex. 2020; Ex. 2021 ¶¶ 69, 74–78). Petitioner replies that “Rhoades says only that close manufacturing tolerances are not ‘require[d],’ not that they could not or should not be used. Pet. Reply 18 (citing Ex. 1009, 8:14–16).

Rhoades states that “[n]one of the operating parts of the projecting-retracting mechanism in accordance with my invention requires close manufacturing tolerances for dependable operation.” Ex. 1009, 8:14–16. We determine that this statement, when read by a person of ordinary skill in the art, would not have led in a direction divergent from stricter tolerances. The statement merely states that close manufacturing tolerances are not

required, but it does not criticize, discredit, or otherwise discourage seeking close manufacturing tolerances.

*v. Asserted New Arguments*

Petitioner also presents arguments as to how one of ordinary skill could have made the proposed modification. Pet. Reply 4–7 (citing PO Resp. 12; Ex. 1057, 116:11–21, 119:7–120:17, 137:16–139:20; Ex. 1058 ¶ 8; Ex. 2018, 99), 10–11 (citing Ex. 1007, Fig. 1; Ex. 1057, 236:20–237:15; Ex. 1058 ¶ 16). Patent Owner contends that Petitioner is introducing improperly new arguments. PO Sur-Reply 1–4 (citing Pet. 26–27, 46–47; Pet. Reply 5–6, 10–13, 15, 21), 6–7 (citing Pet. Reply 10–11, 15). Patent Owner also responds to those asserted new arguments. *Id.* at 7–10 (citing Pet. 55–56, 60–61; PO Resp. 37–39; Pet. Reply 4–7, 13; Ex. 1007, 1:15–17, 2:16–25, 2:35–37, 2:43–48, 2:66–3:5, 3:18–22, Fig. 2; Ex. 2021 ¶¶ 23, 24, 81; Ex. 2023 ¶¶ 4–6).

Because our analysis relies on the arguments presented in the Petition, we do not need to address Petitioner’s arguments in its reply or whether those arguments are improper new arguments.

*2. Claim 2*

Claim 2 depends from claim 1 and recites “wherein the second member comprises at least one multi-toothed gear.” Ex. 1001, 10:25–26.

Petitioner argues that Bason and Rhoades each teach the limitations of claim 2. Pet. 64–65 (citing Ex. 1007, 2:28–30; Ex. 1009, 4:23–26); *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).

We find that the relied-upon portion of Bason teaches that “ring 4 defines an inner cylindrical space within the lower end of which there is

located an annular series of projections formed as inwardly directed triangular teeth 7.” Ex. 1007, 2:28–30. We also find that the relied-upon portion of Rhoades teaches “cylindrical cam body 20 is, in accordance with the invention, provided with a plurality of cam surfaces 50, 52, 54, 55.” Ex. 1009, 4:23–26. Patent Owner responds that “[b]ecause independent claims 1 and 3 are not obvious over Bason in view of Rhoades, dependent claims 2 and 4 are not obvious for these same reasons.” PO Resp. 39.

Based on the full record before us, Petitioner persuades us that, because Bason and Rhoades each teach a member with teeth, these references each teach “wherein the second member comprises at least one multi-toothed gear,” as recited by claim 2. Also, for the reasons discussed above, Petitioner persuades us that one of ordinary skill in the art would have combined Bason and Rhoades with a reasonable expectation of success.

### *3. Claim 3*

Claim 3 recites:

- A fluid dispenser comprising:
  - a plurality of displayable dose values;
  - a stationary body comprising at least one stationary multi-toothed gear;
  - a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body;
  - 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, 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 along the central longitudinal axis and is displaceable rotationally around the central longitudinal axis.

Ex. 1001, 10:27–49.

Claims 1 and 3 both recite a “fluid dispenser, “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,” and “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.”

*Compare* Ex. 1001, 10:1–11 *with id.* at 10:27–30, 10:33–38.

Petitioner presents the same arguments and relies upon the same evidence for these recitations of claim 3 as it does for claim 1. *See* Pet. 57–59, 60–62. For the reasons above, we find that the relied-upon portions of Bason and Rhoades teach the same recitations in claim 3.

Petitioner argues that both Bason and Rhoades teach “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” for the same reasons presented for claim 1’s recitation

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.

Pet. 63; *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). Patent Owner responds that Bason and Rhoades fail to teach the claimed first and second members of claims 1 and 3. PO Resp. 34–39.

For the reasons discussed for claim 1’s similar limitation and based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Bason and Rhoades teach “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.”

Petitioner argues that Bason and Rhoades each teach “a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body,” as recited by claim 3. Pet. 59–60 (citing Ex. 1002 ¶¶ 157, 158; Ex. 1009, 3:35–37, 3:49–52; 4:13–19, 4:29–33, 5:13–19, 5:39–43, 5:51–58); *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 one of ordinary skill in the art would have molded Bason’s stationary gear teeth 2 directly on Bason’s inhaler body, thereby teaching a stationary body with at least one stationary multi-toothed gear and a fluid reservoir axially displaceable relative to the stationary body. *Id.* at 60 (citing Ex. 1002 ¶ 159).

As discussed above, we find that Bason teaches “an indicator device, and particularly, though not exclusively, such a device adapted to serve as a

dose counter for metered dose inhalers (MDI's)." Ex. 1007, 1:3–5. We also find that the relied-upon portions of Rhoades teach that ink reservoir section 10 contains ink; cam body 20 is secured to reservoir section 10; plunger 34 is formed with fingers 43, 44 that extend through guide member 28; stop members 45, 46 are formed within guide member 28; and stop members 45, 46 engage surfaces of the cam body to maintain cam body position or allow it to rotate. Ex. 1009, 3:35–37, 3:49–52; 4:13–19, 4:29–33, 5:13–19, 5:39–43, 5:51–58.

Based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Bason and Rhoades teach "a fluid reservoir disposed on said stationary body so as to be axially displaceable relative to said stationary body," as recited by claim 3.

The final wherein clause of both claims 1 and 3 are identical. *Compare id.* at 10:19–25 *with id.* at 10:44–50. Petitioner presents the same arguments and relies upon the same evidence for the wherein clause of claim 3 as it does for the wherein clause of claim 1. *See* Pet. 63–64. For the reasons stated above for claim 1, we find that the relied-upon portions of Bason and Rhoades teach the wherein clause of claim 3.

Based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Bason and Rhoades teach the limitations of claim 3. Also, for the reasons discussed above, Petitioner persuades us that one of ordinary skill in the art would have combined Bason and Rhoades with a reasonable expectation of success.

#### 4. Claim 4

Claim 4 depends from claim 3 and recites “wherein the fluid reservoir is configured to be axially displaced relative to said stationary body during actuation of the fluid dispenser.” Ex. 1001, 10:50–52.

Petitioner argues that Bason teaches the limitations of claim 4. Pet. 65 (citing Ex. 1002 ¶ 167; Ex. 1007, Abstract, Fig. 1); *see also id.* at 15–18 (asserting what was known in the art as of May 2003), 23–25 (asserting what Bason teaches). Petitioner also argues that one of ordinary skill in the art “would have been motivated to combine Bason with *Rhoades* such that the *Bason* inhaler housing includes *Bason* teeth 2 and operates as the stationary body” and thus, “the *Bason* fluid reservoir moves axially relative to that stationary body, and it is that same axial motion that causes actuation of the fluid dispenser.” *Id.* (citing Ex. 1002 ¶ 168).

We find that the relied-upon portion of Bason teaches and shows a “dose counter attached or attachable to the base of a pressurised canister for a metered dose inhaler and comprising a spring-loaded cap (14) which may be depressed in relation to a second part (1) mounted on the domed base of the canister (C).” Ex. 1007, Abstract, Fig. 1. We also credit Petitioner’s declarant testimony regarding claim 4 because the record supports it. Ex. 1002 ¶ 167. Patent Owner responds that “[b]ecause independent claims 1 and 3 are not obvious over Bason in view of Rhoades, dependent claims 2 and 4 are not obvious for these same reasons.” PO Resp. 39.

Based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Bason teaches the limitations of claim 4. Also, for the reasons discussed above, Petitioner persuades us that one of

ordinary skill in the art would have combined Bason and Rhoades with a reasonable expectation of success.

*5. Objective Evidence of Nonobviousness*

Patent Owner contends that the '631 patent “met a long felt, but unresolved need for an accurate dose counter that avoided undercounting.” PO Resp. 62. Patent Owner argues that “there was no method by which a patient could accurately determine how many doses remained,” the '631 patent responded “to remedy this long-felt industry need for an accurate dose counter that avoided undercounting,” and “drug makers (including Petitioners) failed to create an accurate MDI dose counter,” and *Id.* at 62–63 (citing Ex. 1013, 2).

Petitioner replies that the claims of the '631 patent do not include any safety features. Pet. Reply 20 (citing Ex. 1057, 214:9–215:3). Petitioner also argues that Patent Owner admits that the claimed invention of the '631 patent responds to the FDA's guidance calling for MDI's that minimized undercounting. *Id.* (citing PO Resp. 3). Petitioner contends that the FDA guidance noted that commercial products did not incorporate dose counters and recommended that MDI manufacturers integrate a dose-counting device. *Id.* at 21 (citing PO Resp. 63; Ex. 1013, 2, 3; Ex. 1057, 209:3–212:10; Ex. 1059 ¶ 91). Petitioner also contends that, before the FDA guidance, suitable counters were known and manufacturers could sell fluid dispensers without dose counters. *Id.* at 21–22 (citing Ex. 1057, 209:3–212:10, 213:2–6; Ex. 1059 ¶ 91). Petitioner, thus, contends that the FDA guidance shows a



motivation to combine references, but does not show a long-felt need as asserted by Patent Owner. *Id.* at 22.

Regarding failure of others, Petitioner replies that Patent Owner relies on mere absence but provides insufficient evidence that anyone tried and failed to develop an accurate MDI dose counter. *Id.* (citing PO Resp. 63; Ex. 1057, 212:16–25). Petitioner also argues that fluid dispensers with dose counters were admitted to be known during prosecution of a parent application and that no evidence shows that known dose counters could not satisfy the FDA’s recommendations. *Id.* (citing Ex. 1004, 1282).

We find that the relied upon portions of the FDA guidance do not make clear that existing counters were inadequate, even though it does recommend that MDI’s under development include a dose-counting device. Ex. 1013, 2, 3. The full record indicates that counters for MDI’s were known and may have been sufficiently accurate to meet the FDA recommendation. Ex. 1005, 1:3–5 (stating that it “concerns an indicator device . . . adapted to serve as a dose counter for metered dose inhalers (MDI’s)”); Ex. 1057, 211:6–212:10 (Patent Owner’s declarant agreeing that “the Bason design already reflected the FDA’s recommendation for dose counting,” that “it is a design that included a counter which was what the FDA was recommending,” and that “designs like the Bason design [were] already known”).

The full record before us does not persuade us that the ’631 patent met a long felt, but unresolved need for an accurate dose counter that avoided undercounting or that others tried but failed to create an accurate MDI dose counter.

### 6. *Weighing the Graham Factors*

“Once all relevant facts are found, the ultimate legal determination [of obviousness] involves weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan.”

*Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1361 (Fed. Cir. 2017) (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

Above, based on full record before us, we provide our factual findings regarding (1) the level of ordinary skill in the art, (2) the scope and content of the prior art, (3) any differences between the claimed subject matter and the prior art, and (4) objective evidence of nonobviousness.

In particular, we find that (1) Petitioner’s proposed level of ordinary skill in the art is consistent with the prior art of record; (2) Bason and Rhoades teach all the limitations of claims 1–4; (3) one of ordinary skill in the art would have had a reason to modify Bason in view of Rhoades with a reasonable expectation of success, and (4) the asserted objective evidence of nonobviousness insufficiently shows a long-felt, but unmet, need or failure by others. Weighing these underlying factual determinations, a preponderance of the evidence persuades us that claims 1–4 of the ’631 patent are unpatentable over Bason and Rhoades.

### *E. Remaining Challenges*

Petitioner also challenges claims 1–4 as anticipated by Allsop or Marelli and as unpatentable over Bason and Allsop. As discussed above, we determine that Petitioner has shown by a preponderance of the evidence that the same claims are unpatentable over Bason and Rhoades. Therefore, we do not reach the other challenges.

### III. MOTIONS TO EXCLUDE

#### *A. Petitioner's Motion to Exclude*

Petitioner filed a motion to exclude Exhibit 2020. Paper 37. Exhibit 2020 is only cited to indicate where Patent Owner believes support can be found for its arguments.

Because we do not rely on Exhibit 2020 in our analysis, we deny Petitioner's motion to exclude as moot.

#### *B. Patent Owner's Motion to Exclude*

Patent Owner filed a motion to exclude paragraphs 17, 134, and 135 of Exhibit 1002 and paragraphs 16–19, 23, 25, and 28 of Exhibit 1058. Paper 39, 1; *see also* Papers 16, 30 (objecting to evidence served with Petition and Petitioner's Reply). These exhibits are the Expert Declaration of S. David Piper and Reply Declaration of S. David Piper. Patent Owner argues that the above-listed paragraphs of Exhibit 1002 lack factual basis under Federal Rules of Evidence 702. Paper 39, 3–5.

We cite to paragraphs 134 and 135 in our analysis of analogous art. As indicated above, the record supports the testimony in these paragraphs. We do not cite these paragraphs alone but also cite supporting evidence, which supports the proposition in question without the need to rely on only these paragraphs. Further, paragraphs 134 and 135 find adequate factual basis in the declarant's personal experience. We cite paragraph 17 only to indicate where support is believed to be found for an argument.

Patent Owner also argues that paragraphs 6–10, 16–19, 23, 25, and 28 of Exhibit 1058 raise new arguments or lack sufficient factual basis. *Id.* at 6–11. We cite some of these paragraphs only to indicate where Petitioner believes support can be found for its arguments, but we do not rely on any of

the above-listed paragraphs in our analysis. Patent Owner also moves to exclude Exhibits 1032, 1033, 1055, and 1056. Paper 39, 1. We cite these exhibits only to indicate where Petitioner believes support can be found for its arguments. We do not rely on Exhibits 1032, 1033, 1055, or 1056 in our analysis.

For the reasons above, we deny Patent Owner's motion to exclude.

#### IV. CONCLUSION<sup>6</sup>

In summary:

<b>Claims</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/ Basis</b>	<b>Claims Shown Unpatentable</b>	<b>Claims Not Shown Unpatentable</b>
1–4	§ 102(b)	Allsop		
1–4	§ 102(b)	Marelli		
1–4	§ 103(a)	Bason, Rhoades	1–4	
1–4	§ 103(a)	Bason, Allsop		
<b>Overall Outcome</b>			1–4	

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<sup>6</sup> Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner's attention to the April 2019 Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. *See* 84 Fed. Reg. 16654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. § 42.8(a)(3), (b)(2).

V. ORDER

Accordingly, it is:

ORDERED claims 1–4 of U.S. Patent No. 9,370,631 B2 have been shown, by a preponderance of the evidence, to be unpatentable;

FURTHER ORDERED that Petitioner’s motion to exclude is denied as moot;

FURTHER ORDERED that Patent Owner’s motion to exclude is denied; and

FURTHER ORDERED that, because this is a Final Written Decision, the parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2018-01055  
Patent 9,370,631 B2

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