

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.

IPR2018-01054
Patent 8,936,177 B2

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 1–3, 9, and 21 of U.S. Patent No. 8,936,177 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 1–3, 9, and 21 of U.S. Patent No. 8,936,177 B2 (Ex. 1001, “the ’177 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 ’177 patent. Paper 11 (“Dec. to Inst.”). In particular, we instituted review of claims 1–3, 9, and 21 on all presented challenges. Dec. to Inst. 2, 18, 26, 27.

After institution, Patent Owner filed a Response (Paper 27, “PO Resp.”)¹, 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

¹ 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 47, 48). An oral hearing in this proceeding was held on August 12, 2019; a transcript of the hearing is included in the record (Paper 53, “Tr.”).

B. Related Proceedings

The parties indicate that the ’177 patent is the subject of *AptarGroup, Inc. v. 3M Company*, Case No. 1:17-cv-06294-VMK (N.D. Ill.). Pet. 6–7; Paper 6, 1. Also, the ’177 patent is related to the patent at issue in Case IPR2018-01055. Pet. 6; Paper 6, 2.

C. Evidence Relied Upon

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

- (1) GB 1 317 315, published May 16, 1973 (Ex. 1006, “Elliott”);
- (2) U.S. Patent No. 3,205,863, issued September 14, 1965 (Ex. 1007, “Rhoades”); and
- (3) U.S. Patent No. 6,283,365 B1, issued September 4, 2001 (Ex. 1005, “Bason”).

Pet. 10 (contending that the ’177 patent has “a priority date no earlier than May 15, 2003), 17 (contending that Elliott is prior art under 35 U.S.C. § 102(b)²), 20 (contending that Bason is prior art under 35 U.S.C. § 102(b)),

² 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,

23 (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, 1067. Patent Owner filed declarations by Charles E. Clemens. Exs. 2021, 2023. Deposition transcripts for Mr. Piper and Mr. Clemens were also filed. Exs. 1057, 1077, 2019.

D. Grounds of Unpatentability at Issue

Petitioner challenges, and we instituted *inter partes* review of, claims 1–3, 9, and 21 of the ’177 patent on the following grounds:

Claims Challenged	35 U.S.C. §	Reference(s)/Basis
1–3, 9, 21	§ 103(a)	Elliott, Rhoades
1–3, 9, 21	§ 103(a)	Bason, Rhoades

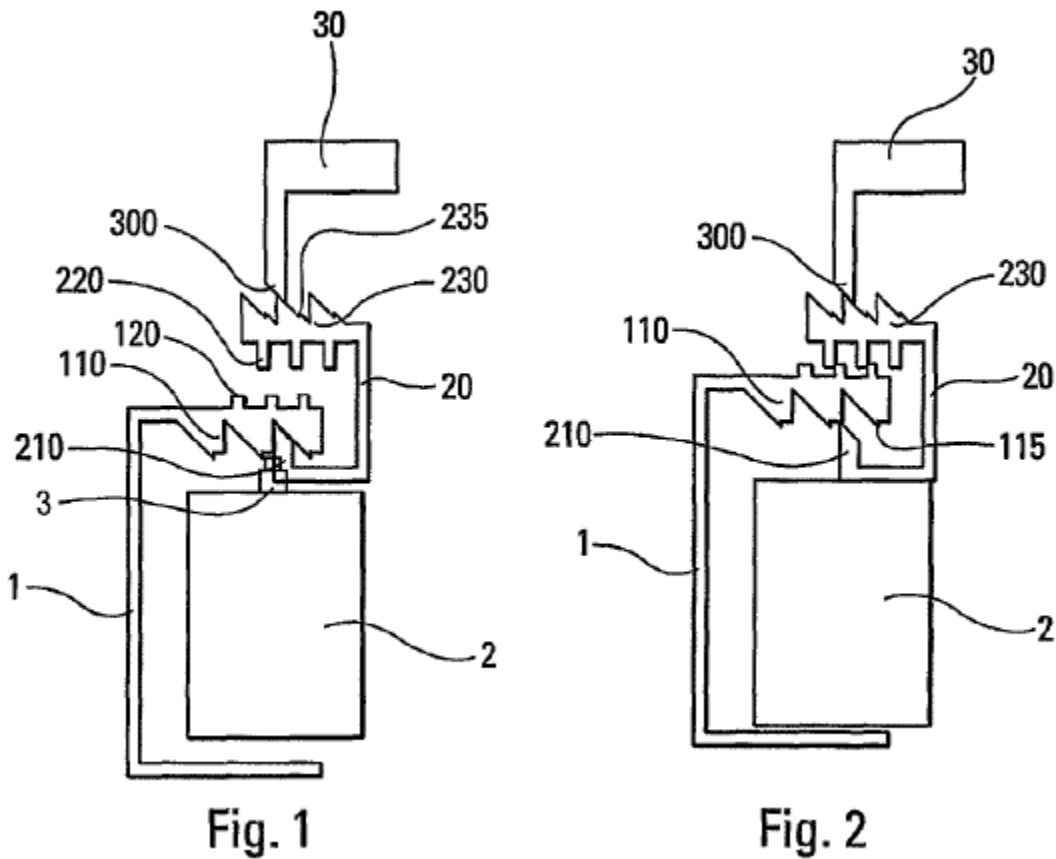
Dec. to Inst. 18, 19, 27.

E. The ’177 Patent (Ex. 1001)

The ’177 patent issued January 20, 2015, from an application filed May 14, 2004, and claims priority to a foreign application filed May 15, 2003. Ex. 1001, codes (22), (30), (45); *see also* Pet. 10 (discussing priority and contending that the ’177 patent has “a priority date no earlier than May 15, 2003); PO Resp. 3 (describing applications leading to the ’177 patent and identifying a French patent application filed on May 15, 2003).

The ’177 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, 1:3–6. Figures 1 and 2 of the ’177 patent are reproduced below.

2013. Because the application from which the ’177 patent issued was filed before that date, our citations to Title 35 are to its pre-AIA version.



Figures 1 and 2 are diagrams of a fluid dispenser showing successive positions of the dispenser during actuation. *Id.* at 4:33–36. The dispenser includes body 1, reservoir 2, dispensing member 3 mounted on reservoir 2, actuator member 30, and a dose indicator device. *Id.* at 4:64–66, 5:5–11. Reservoir 2 is displaceable axially with respect to body 1. *Id.* at 4:67.

Body 1 also includes stationary gear 110. *Id.* at 5:52. Actuator member 30 includes actuator gear 300. *Id.* at 5:60–61. 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 5:52–57. 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 5:58–61.

An important safety consideration described in the '177 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 5:17–18. 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 5:65–6:7.

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 6:11–20. 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 6:21–29. 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, reducing the risk of counter element 20 under-counting. *Id.* at 6:29–35.

The '177 patent further describes the dispenser as it reaches complete actuation and returns to its initial position. *Id.* at 6:36–7:49, Figs. 3–8.

F. Illustrative Claim

The '177 patent has 22 claims, of which Petitioner challenges claims 1–3, 9, and 21. Of those, claim 1, reproduced below, is the only independent claim.

1. A fluid dispenser comprising:
 - a stationary body (1) including at least one stationary gear (110, 122),
 - a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body,
 - a dispenser member mounted on said reservoir (2), and
 - a dose indicator device, including a counter element (20) that is displaceable axially and in rotation relative to said body (1), for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir,wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.

Ex. 1001, 9:28–45.

II. CHALLENGES UNDER 35 U.S.C. § 103

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).

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).

As discussed below, 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 Elliott 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 Elliott in view of Rhoades; and that a person of ordinary skill in the art would have had a reasonable expectation of success in combining Elliott and Rhoades.

A. Level of Ordinary Skill in the Art

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. 13 (citing Ex. 1002 ¶ 12); *see also* PO Resp. 3–4 (quoting Pet. 13).

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 any dispute over level of skill in the art).

Based on the record before us, we find 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. 13 (citing Ex. 1002 ¶ 12).

B. Claim Interpretation

In the present *inter partes* review, claim terms in the ’177 patent, which is unexpired, are interpreted according to their broadest reasonable construction in light of the Specification of ’177 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).³

Petitioner points out that the Board has interpreted already “a stationary body (1) including at least one stationary gear (110, 122)” for a Decision on Appeal during prosecution of the ’177 patent. Pet. 12 (citing Ex. 1004, 1273). Petitioner states that the same interpretation should apply to this proceeding. *Id.*

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. 4–5. Patent Owner also disagrees with Petitioner’s proposed interpretation of “stationary body” but states that its “positions and

³ 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).

arguments do not depend on whether or not the prior art references disclose a stationary gear that is unitary or monolithic to the stationary body.” *Id.* at 5. 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’ dispute. *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. Elliott (Ex. 1006)

Elliott “relates to counters for counting events and displaying the number of such events counted” that “is particularly useful in an aerosol dispenser.” Ex. 1006, 1:9–12. Figure 3b of Elliott is reproduced below.

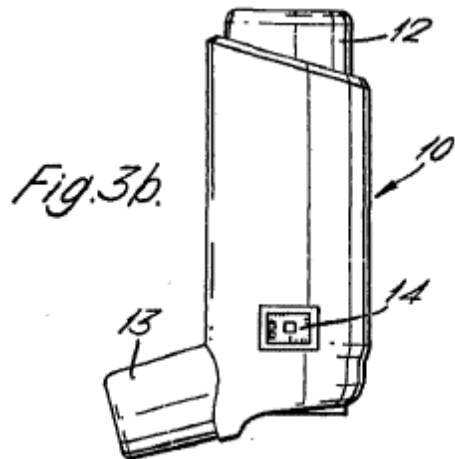


Figure 3b shows a “bronchial inhaler incorporating the counter.” *Id.* at 2:6–8. Depressing vial 12 operates inhaler 10, actuates the counter, and

causes a number displayed in window 14 of inhaler 10 to move one digit. *Id.* at 2:15–16, 2:19–22. A counter is designed to fit inside bronchial inhaler 10. *Id.* at 2:8–10. Figures 1 and 2 of Elliott are reproduced below.

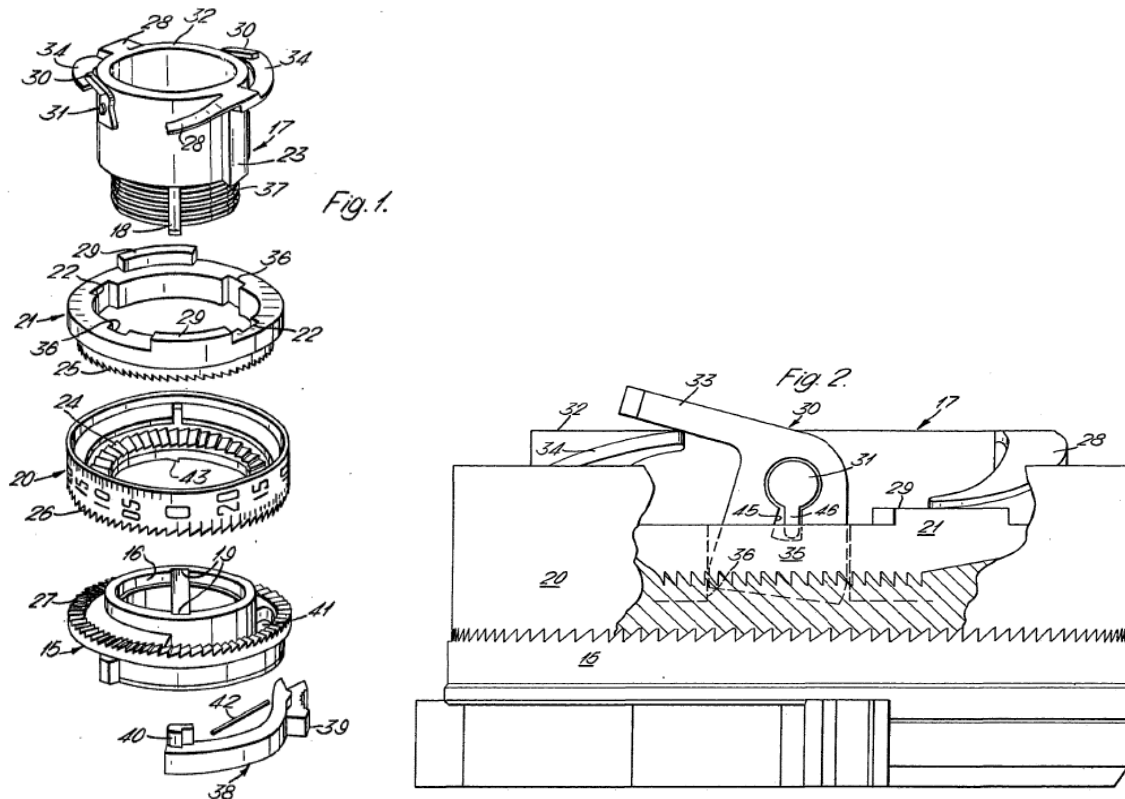


Figure 1 is an exploded, perspective view of a counter, and Figure 2 shows, partly in section, a part of the counter. *Id.* at 1:95–2:5. The counter includes circular base 15, number wheel 20 that rotates on base 15, and rotatable drive member 21 over number wheel 20. *Id.* at 2:27–28, 2:32–35. Housing 17 is received in bore 16 of base 15. *Id.* at 2:27–29. Number wheel 20 has integral ratchets 24, 26 that cooperate with ratchet 25 of drive member 21 and ratchet 27 of base 15. *Id.* at 2:41–47, Fig. 1.

Depressing vial 12 causes vial 12 to engage upper arms 33 of housing 17 to cause drive member 21 to rotate. *Id.* at 2:66–73. Rotation is

limited to one digit on number wheel 20. *Id.* at 2:79–80. Ratchet 25 of drive member 21 engages ratchet 24 of the number wheel 20, and number wheel 20 can then move over ratchet 27 of base 15 to rotate. *Id.* at 2:76–79, 2:93–97. When vial 12 is released, ratchet 25 of drive member 21 rides over ratchet 24, and ratchet 27 of base 15 maintains the position of number wheel 20. *Id.* at 2:84–93.

2. Rhoades (*Ex. 1007*)

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.

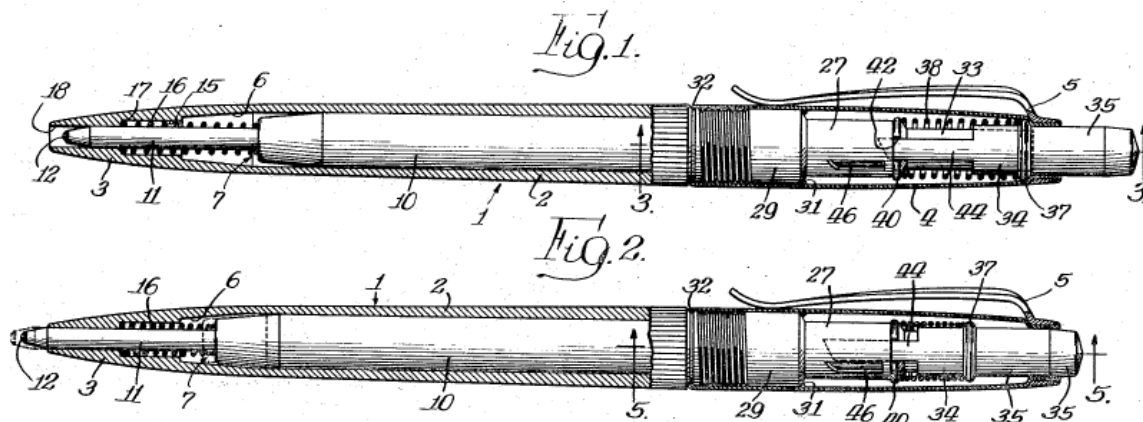


Figure 1 is a sectional view showing a point-and-cartridge unit in a retracted position, and Figure 2 is a sectional view showing the point-and-cartridge unit in a projected position. *Id.* at 2:44–51. Barrel 1 has a bore that receives point-and-cartridge unit 7. *Id.* at 3:28–32. Point-and-cartridge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

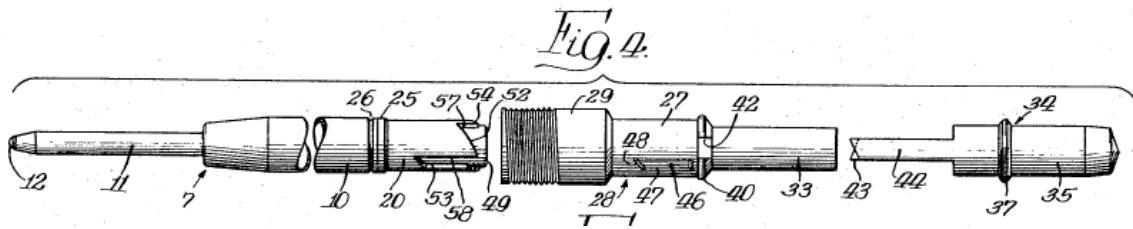
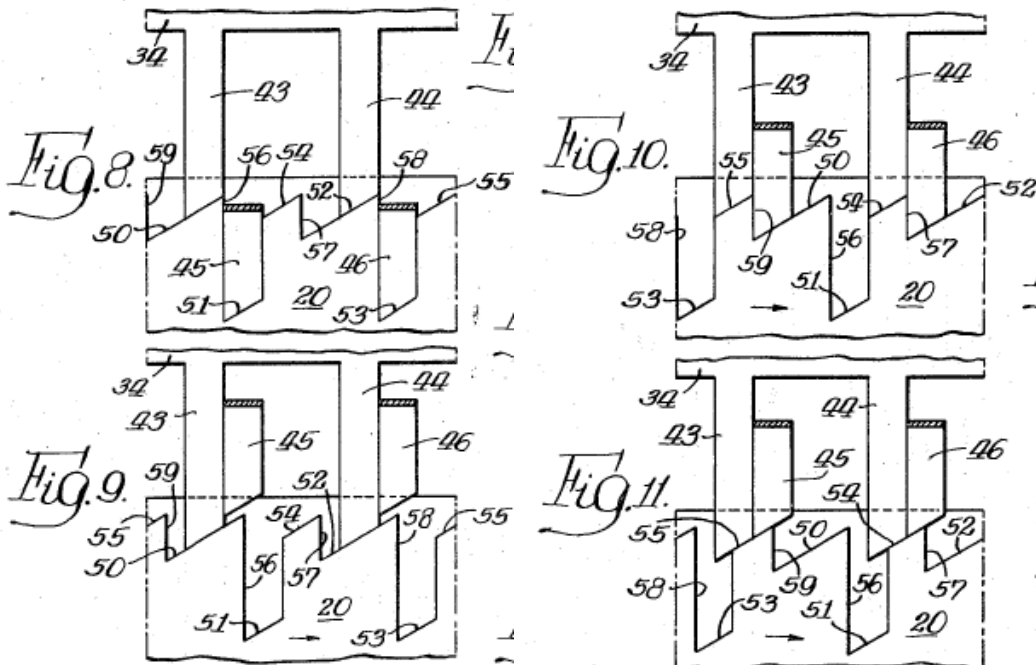


Figure 4 shows an exploded view of the point-and-cartridge unit and projecting-retracting mechanism. *Id.* at 2:57–59. Secured to the rear of ink reservoir section 10 is cam body 20 which is part of the projecting-retracting mechanism. *Id.* at 3:49–53. Cam body 20 is rotatably and slidably disposed 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 4:28–33.⁴

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

⁴ 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.

3. *Bason (Ex. 1005)*

Bason “concerns an indicator device . . . adapted to serve as a dose counter for metered dose inhalers (MDI’s).” Ex. 1005, 1:3–5. Figures 1 and 3 are reproduced below.

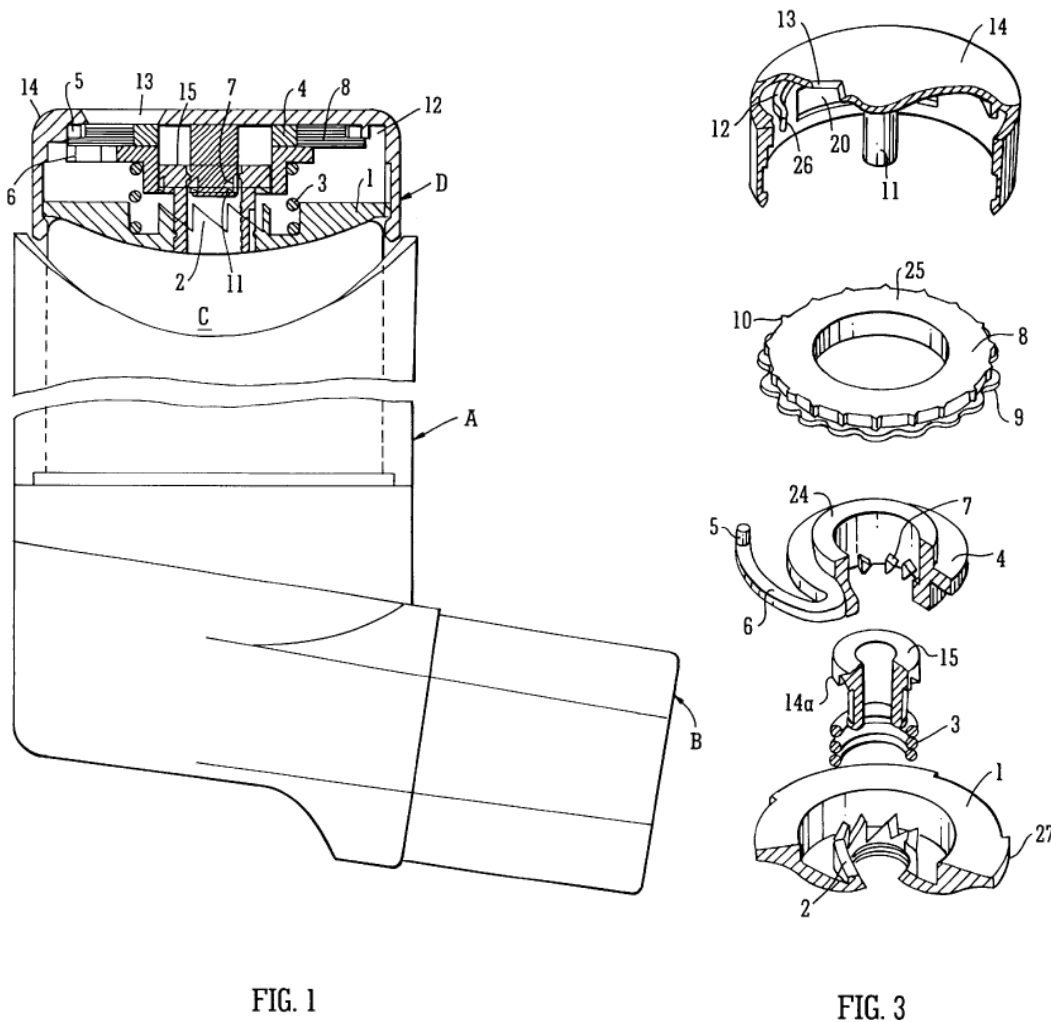


Figure 1 is a “part cross-sectional view of a meter[ed] dose inhaler having thereon an indicator device,” and Figure 3 is an “exploded perspective view of the parts of the device.” *Id.* at 1:65–67, 2:3–4. Metered dose inhaler A includes mouth-piece B for inhaling a drug from canister C,

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 to engage lower fixed teeth 2. *Id.* at 3:15–18. The triangular form of teeth 2, 7 causes 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.

D. Challenge Based on Elliott and Rhoades

Petitioner contends that the combination of Elliott and Rhoades teaches every limitation of claims 1–3, 9, and 21. Pet. 36–52. Petitioner also contends that one of ordinary skill in the art would have been motivated to substitute the counting mechanism of Elliott with the mechanism of Rhoades. *Id.* at 29–36.

Patent Owner responds that Petitioner does not explain adequately how one of ordinary skill in the art would have substituted the components of Rhoades into Elliott to ensure operability of the modified device. PO Resp. 10–13. Patent Owner also responds that Petitioner’s proposed combination of Elliott and Rhoades does not teach or suggest “a counter element (20),” as recited by claim 1. *Id.* at 13–19. Patent Owner further responds that Petitioner’s proposed combination does not teach or suggest “dose indicator device that is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke,” as recited by claim 1. *Id.* at 19–25.

Patent Owner also presents arguments specific to the limitations of dependent claims 2 and 9. *Id.* at 25–30. Additionally, according to Patent Owner, one of ordinary skill in the art would not have been motivated to combine Elliott and Rhoades. *Id.* at 30–34.

1. *Claim 1*

a. “A fluid dispenser comprising . . . ”

Petitioner argues that, to the extent that it is limiting, Elliott and Rhoades each teach a fluid dispenser. Pet. 37–38 (citing Ex. 1006, 1:11–12, 2:18–19, Fig. 3b; Ex. 1007, 3:34–42, 11:60–63, Figs. 1, 2); *see also id.* at 13–17 (asserting what was known in the art as of May 2003), 17–20 (asserting what Elliott teaches); 23–28 (asserting what Rhoades teaches).

We find that the relied upon portions teach that Elliott “relates to counters for counting event and displaying the number of such events counted” and “is particularly useful in an aerosol dispenser.” Ex. 1006, 1:9–12. We also find that the relied-upon portions also teach a valve of vial 12 that is “opened by a member connected thereto abutting a stop in the inhaler.” *Id.* at 2:16–19. We further find that Figure 3b shows “a bronchial inhaler incorporating the counter.” *Id.* at 2:6–8, Fig. 3b.

Patent Owner does not present arguments specifically for a “fluid dispenser.” *See* PO Resp. 9–34. Based on the full record before us, because Elliott teaches and shows an aerosol dispenser, particularly a bronchial inhaler, Petitioner persuades us by a preponderance of the evidence that, at least, Elliott teaches a “fluid dispenser.”

b. “a stationary body (1) including at least one stationary gear (110, 122)”

Petitioner argues that Elliott and Rhoades teach the required stationary body with at least one stationary gear. Pet. 38 (citing Ex. 1002 ¶ 87; Ex. 1006, 2:27–33, 2:46–47, Fig. 1; Ex. 1007, 4:8–21); *see also id.* at 13–17 (asserting what was known in the art as of May 2003), 17–20 (asserting what Elliott teaches); 23–28 (asserting what Rhoades teaches). In particular, Petitioner contends that Elliott teaches a stationary body, specifically “base 15 with stationary teeth 27.” *Id.* at 38 (citing Ex. 1006, 2:27–33, 2:46–47, Fig. 1).

Petitioner also contends that Rhoades teaches a stationary body, guide member 28 that includes stop members 45, 46 formed on its walls, and that stop members 45, 46 are at least one stationary gear on guide member 28. *Id.* (citing Ex. 1002 ¶ 87; Ex. 1007, 4:8–21). According to Petitioner, one of ordinary skill in the art would have incorporated the stop members of Rhoades into the inhaler body of Elliott. *Id.* (citing Ex. 1002 ¶ 86).

We find that the relied-upon portions of Elliott teach that its “counter has a circular base 15 having a bore 16 for receiving a housing 17” that is “radially located in the bore 16 by co-operating shoulders 18 and slots 19” and that the counter has an “integral ratchet 26 arranged to co-operate with a detent ratchet 27 formed in the outer circumference of the base 15.” Ex. 1006, 2:27–33, 2:44–47, Fig. 1. We also 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 ¶ 87.

Patent Owner does not present arguments contesting the asserted teachings of Elliott or Rhoades and the required stationary body with at least one stationary gear. See PO Resp. 9–34. Patent Owner, instead, responds that Petitioner’s proposed modification of Elliott in view of Rhoades would have rendered Elliott inoperable, could not have been made, and therefore would not have met the limitation. See *id.* at 11–12. We address those arguments below in our analysis of Petitioner’s reason to combine the references.

Based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Elliott teaches a stationary gear and that Rhoades teaches “a stationary body (1) including at least one stationary gear (110, 122)” or a stationary body that contains, as a unitary or monolithic part, at least one stationary gear.

c. “a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body”

Petitioner argues that Elliott and Rhoades each teach the recited fluid reservoir. Pet. 39 (citing Ex. 1002 ¶¶ 69–82; Ex. 1006, 2:19–22, Fig. 3b; Ex. 1007, 3:30–42, 3:50–53, 4:25–29, Figs. 1, 2); see also *id.* at 13–17 (asserting what was known in the art as of May 2003), 17–20 (asserting what Elliott teaches); 23–28 (asserting what Rhoades teaches).

We find that the relied-upon portions of Elliott teach that “[d]epression of the vial actuates the counter, as will be described, and causes the number displayed in a window 14 in the inhaler 10 to step one digit.” Ex. 1006, 2:19–22, Fig. 3b; see also *id.* at 2:12–14 (stating that “vial

12 containing for example a compound of the relief of asthma”). Petitioner directs us to paragraphs 69–82 of its declarant testimony for this limitation (Pet. 39); however, paragraphs 88–90 of the declaration address this limitation. We credit the testimony of Petitioner’s declarant regarding Elliott and the required axially displaceable fluid reservoir of claim 1 because it finds support in Elliott. Ex. 1002 ¶ 88.

Patent Owner does not present arguments specifically for this limitation. See PO Resp. 9–34. Based on the full record before us, because we find that Elliott teaches vial 12 in housing 10 and vial 12 can be depressed, Petitioner persuades us by a preponderance of the evidence that, at least, Elliott teaches “a fluid reservoir (2) disposed in said body so as to be axially displaceable relative to said body.”

d. “a dispenser member mounted on said reservoir (2)”

Petitioner argues that Elliott and Rhoades each teach the dispenser member of claim 1. Pet. 40 (citing Ex. 1002 ¶ 91; Ex. 1006, 1:11–12, 1:85–87, 2:6–16; Ex. 1007, 3:34–42); see also *id.* at 13–17 (asserting what was known in the art as of May 2003), 17–20 (asserting what Elliott teaches); 23–28 (asserting what Rhoades teaches). Petitioner also argues that a valve is a dispenser member. *Id.* at 40 (citing Ex. 1002 ¶ 91; Ex. 1008, 5:47–6:3; Ex. 1016, 7–9; Ex. 1047, 1–3).

We find that the relied-upon portions of Elliott teach that Elliott “is particularly useful in an aerosol dispenser,” “provides a device for fitting over the valve of an aerosol can,” and has a counter that “is designed to fit inside a bronchial inhaler 10 (Fig. 3) which comprises essentially a cylinder open at one end 11 to receive an aerosol can or vial 12 containing for example a compound of the relief of asthma, and at the other end having a

mouthpiece 13.” Ex. 1006, 1:11–12, 1:85–87, 2:6–15. We also find that Elliott teaches that “inhaler 10 is operated by depressing the vial 12.” *Id.* at 2:15–16. We further credit the testimony of Petitioner’s declarant regarding Elliott and the required dispenser member of claim 1 because it finds support in Elliott. Ex. 1002 ¶ 91.

Patent Owner does not present arguments specifically for this limitation. *See* PO Resp. 9–34. Based on the full record before us, because we find that Elliott teaches a valve for receiving a vial, Petitioner persuades us by a preponderance of the evidence that, at least, Elliott teaches “a dispenser member mounted on said reservoir (2).”

- e. *“a dose indicator device, including a counter element (20) that is displaceable axially and in rotation relative to said body (1), for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir,”*

Petitioner argues that Elliott and Rhoades each teach an element that moves axially and rotationally relative to another component, specifically number wheel 20 of Elliott and cam body 20 of Rhoades. Pet. 40 (citing Ex. 1006, 2:19–26, 2:76–79, 2:93–97; Ex. 1007, 5:22–25); *see also id.* at 13–17 (asserting what was known in the art as of May 2003), 17–20 (asserting what Elliott teaches); 23–28 (asserting what Rhoades teaches). Petitioner also argues that “mechanics of cam body 20 in *Rhoades* correspond directly to the mechanics of the claimed counter element” but “*Rhoades* does not teach that its cam body 20 is for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir.” *Id.* at 40 (citing Ex. 1002 ¶ 94). Petitioner further argues that “it would have been obvious . . . to incorporate *Rhoades*’s mechanism of

converting axial motion to rotational motion into the *Elliott* inhaler below the *Elliott* vial and to include a numbering system.” *Id.* at 41 (citing Ex. 1002 ¶ 95).

We find that the relied-upon portions of *Elliott* teach that “[d]epression of the vial actuates the counter . . . and causes the number displayed in a window 14 in the inhaler 10 to step one digit . . . in a count-down fashion,” “drive member ratchet 25 engages the upper number wheel ratchet 24 and the number wheel is thus rotated,” and “when being driven to register a count the number wheel 20, and thus also the drive member 21, moves axially against the springs 28 to move over the detent ratchet 27.” Ex. 1006, 2:19–26, 2:76–79, 2:93–97. We also find that the relied-upon portion of *Rhoades* teaches that “successive full depressions of push button 35, will, through corresponding movements of actuating fingers 43 and 44, successively depress and rotate the cam body 20.” Ex. 1007, 5:22–25. We also credit Petitioner’s declarant testimony that cam body 20 of *Rhoades* teaches an element “that is displaceable axially and in rotation relative to said body,” as recited by claim 1, because *Rhoades* teaches that cam body 20 is depressed and rotated. Ex. 1002 ¶ 94; Ex. 1007, 5:22–25.

Patent Owner responds that Petitioner relies on *Elliott*’s number wheel for teaching the counter element but that both Petitioner and its declarant admit that *Elliott*’s number wheel is not present in the proposed modification. PO Resp. 13 (citing Pet. 34, 40; Ex. 2019, 65:13–24). Petitioner replies that it “identifies *Rhoades*’s cam body as the counter element.” Pet. Reply 7–8 (citing Pet. 34, 41; PO Resp. 34; Ex. 1057, 121:11–122:12; Ex. 2021 ¶ 34).

We agree with Petitioner. As summarized above, Petitioner argues that that “mechanics of cam body 20 in *Rhoades* correspond directly to the mechanics of the claimed counter element,” but concedes that “*Rhoades* does not teach that its cam body 20 is for indicating the number of doses of fluid that have been dispensed or that remain to be dispensed from said reservoir.” Pet. 40 (citing Ex. 1002 ¶ 94). Petitioner, however, further argues that “it would have been obvious . . . to incorporate *Rhoades*’s mechanism of converting axial motion . . . to include a numbering system.” *Id.* at 41 (citing Ex. 1002 ¶ 95).

Patent Owner also argues that Petitioner has not explained its proposed combination in sufficient detail and the proposed combination is inoperable because Petitioner does not address how the components of the proposed combination would be biased so that they can engage one another. *Id.* at 13–17 (citing Ex. 1002 ¶¶ 16–17; Ex. 1006, 2:47–53, Fig. 1; Ex. 1007, 4:75–5:11, Fig. 1; Ex. 1016, Fig. 2; Ex. 2021 ¶¶ 16, 34–36). We address this argument below in our analysis of Petitioner’s reason to combine.

For the reasons above, based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Elliott teaches depressing vial 20 causes a counter to rotate to count down and that Rhoades teaches a cam body is depressed and rotated.

- f. “wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke”

Petitioner argues that Elliott and Rhoades teach the wherein clause of claim 1. Pet. 41–42 (citing Ex. 1002 ¶¶ 96, 97; Ex. 1006, 2:41–47, 2:66–79; Ex. 1007, 5:22–30, 5:39–54, Figs. 8–11); *see also id.* at 13–17 (asserting what was known in the art as of May 2003), 17–20 (asserting what Elliott teaches); 23–28 (asserting what Rhoades teaches).

We find that the relied-upon portions of Elliott teach that:

number wheel 20 is formed with an integral ratchet 24 facing the drive member 21 and co-operating with a ratchet 25 formed in the drive member 21, and also with a further integral ratchet 26 arranged to co-operate with a detent ratchet 27 formed in the outer circumference of the base 15.

Ex. 1006, 2:41–47. We also find that Elliot teaches that “[d]epression of the vial 12 causes the valve end (not shown) of the vial to engage the upper arms 33 of the bell cranks 30,” “[f]urther depression swings the upper arms 33 downwards about the pins 31, and thus the lower arms 35 move circumferentially of the housing 17 and cause the drive member 21 to rotate,” and “drive member ratchet 25 engages the upper number wheel ratchet 24 and the number wheel is thus rotated.” *Id.* at 2:66–79. Based on these teachings of Elliott, we agree with Petitioner that “the counter element cooperates directly with a stationary gear and indirectly with the reservoir” and credit Petitioner’s supporting declarant testimony, which Elliott supports. Pet. 41; Ex. 1002 ¶ 96.

Turning to Rhoades, we find that the relied-upon portions of Rhoades teach that:

Successive full depressions of push button 35, will, through corresponding movements of actuating fingers 43 and 44, successively depress and rotate the cam body 20 so as to cause alternate pairs of cam surfaces 50, 52 and bottom surfaces 51, 53 to be engaged by the stationary stop members 45 and 46. This,

in turn, will cause the point-and-cartridge unit 7 to assume alternately an extended writing position and a retracted non-writing position.

Ex. 1007, 5:22–30. We also find that they teach 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 can body 20,” “[t]he interaction between the camming end portions of fingers 43 and 44 and the cam surfaces 50 and 55, respectively engaged thereby, will tend to rotate the cam body 20,” “[s]uch rotational movement of cam body 20 will, however, initially be prevented by the stop surfaces 56 and 58 which bear against the respective stop members 45 and 46,” and “[w]hen the cam body 20 has been depressed to an extent sufficient to permit the rearward edges of stop surfaces 56 and 58 to clear the forward edges of stop members 45 and 46 (FIG. 9), the cam body 20 is free to rotate.” *Id.* at 5:39–54, Figs. 8–11.

Based on these teachings of Rhoades, we agree with Petitioner’s characterization of the interaction of fingers 43, 44; cam body 20; stop members 45, 46; and cam surfaces 50, 52 to cause cam body 20 to move axially and then rotate. Pet. 41–42. We also agree with Petitioner that “cam body 20 . . . will rotate even if fingers 43, 44 are not depressed all of the way, i.e., even when a predetermined incomplete actuation stroke is performed” and credit Petitioner’s supporting declarant testimony, which is consistent with, and supported by Rhoades. Pet. 41; Ex. 1002 ¶ 97.

Patent Owner responds that Elliott’s number wheel is not present in Petitioner’s proposed combination. PO Resp. 18–19 (citing Pet. 34, 41; Ex. 2019, 65:13–24). As discussed above, Petitioner states that “*Rhoades* does not teach that its cam body 20 is for indicating the number of doses”

but argues that “it would have been obvious . . . to incorporate *Rhoades*’s mechanism of converting axial motion . . . to include a numbering system.” Pet. 40–41 (citing Ex. 1002 ¶¶ 94, 95).

Patent Owner also responds that Rhoades does not teach a “predetermined incomplete actuation stroke” as required by the claim. PO Resp. 19–20 (citing Pet. 41). According to Patent Owner, Rhoades’s plunger must be depressed fully before the cam body rotates. *Id.* at 20–24 (citing Pet. 45; Ex. 1007, 1:18–25, 5:11–28, 5:51–66, 5:72–75, 7:41–45, Fig. 8; Ex. 2021 ¶¶ 39–41).

Petitioner replies that Patent Owner’s arguments are based on a surrogate reference (Exhibit 2020), not on Rhoades, and based on a flawed assumption that Exhibit 2020 shows a complete stroke or full depression. Pet. Reply 13–14 (citing PO Resp. 19–24, 41–43; Ex. 1057, 71:5–74:6, 148:19–150:23, 166:15–23; Ex. 1058 ¶¶ 35, 36). Petitioner also argues that the cam body of Rhoades can rotate before a complete actuation stroke, specifically when fingers 43, 44 of the plunger push cam body 20 enough so that stop members 45, 46 can slide along the top inclined surface of cam body 20. *Id.* at 15–16 (citing Ex. 1057, 55:14–23, 57:15–16, 70:7–71:4, 72:13–15, 76:3–8; Ex. 1058 ¶ 39; Ex. 2020, 1:58, 2:18). Petitioner further argues that both Rhoades and Exhibit 2020 show that the plunger can be further depressed, because both show that the plunger has additional space above the stop members so that the plunger can be pushed further towards the stop members before the two structures touch. *Id.* at 16–17 (citing Ex. 1007, Fig. 9; Ex. 1057, 70:7–71:4, Ex. 1058 ¶¶ 37, 40).

Petitioner contends that Patent Owner’s declarant describes two conditions as being a full depression, but Petitioner argues that one shows an

incomplete depression when the cam body can rotate as soon as the plunger pushes the cam body clear of the stop members and the other shows a condition when the cam body has already started to rotate. *Id.* at 17–20 (citing PO Resp. 23; Ex. 1007, 5:51–56; Ex. 1054; Ex. 1057, 55:11–23, 58:5–59:19, 69:23–71:4, 72:13–15, 76:3–22; Ex. 1058 ¶¶ 41–47). Petitioner further contends that Patent Owner incorrectly argues that “Rhoades **only** operates upon full depressions.” *Id.* at 20 (citing PO Resp. 23; Ex. 1007, Fig. 9).

Based on the full record before us, Petitioner persuades us by a preponderance of the evidence that Rhoades teaches cam body 20 is free to rotate after a partial actuation stroke. As discussed above, we find that Rhoades teaches “[w]hen the cam body 20 has been depressed to an extent sufficient to permit the rearward edges of stop surfaces 56 and 58 to clear the forward edges of stop members 45 and 46 (FIG. 9), the cam body 20 is free to rotate.” Ex. 1007, 5:51–54; *see also* Ex. 1057, 72:12–15 (Patent Owner’s declarant stating that “what Rhoades is describing here and what’s happening here is that as soon as the stop member passes the relief, then cam body will rotate”); Ex. 2021 ¶ 39 (Patent Owner’s declarant stating that “the stop member prevents the cam body from rotating as the stop member still has not risen above the upper corner of the cam body’s groove”). Petitioner also persuades us by a preponderance of the evidence that Rhoades teaches that cam body 20 rotates once the plunger has performed a predetermined incomplete actuation stroke, even if the plunger does not perform a complete actuation stroke.

Patent Owner also argues that Petitioner’s proposed combination “requires one press to extend the pen tip and another to retract it.” PO Resp.

24 (citing Pet. 35). Patent Owner contends that Petitioner’s alternative modification to address these additional depressions is internally inconsistent because Petitioner proposes to modify Rhoades to be more like the purportedly inferior Elliott. *Id.* at 24–25 (citing Pet. 33–35). We address this argument below in our analysis of Petitioner’s reason to combine.

Thus, for the reasons above, because we find that (1) Elliott teaches number wheel 20, while actuating the valve that receives the vial, cooperates with circular base 15 and the vial, and (2) Rhoades teaches that cam body 20 rotates once the plunger has performed a predetermined incomplete actuation stroke, Petitioner persuades us by a preponderance of the evidence that these references, in combination, teach:

wherein said counter element (20) cooperates, while the dispenser is being actuated, firstly with said at least one stationary gear (110, 122) of said body, and secondly with said reservoir (2), so that the dose indicator device is actuated once the dispenser has performed a predetermined incomplete actuation stroke, even if the dispenser does not perform a complete actuation stroke.

g. Reason to Combine Elliott 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. 3–4 (citing Ex. 1002 ¶¶ 17, 25, 74, 75, 137; Ex. 1031, 2:36–47; Ex. 1032, 1:40–48; Ex. 1033, 15:10–25; Ex. 1034, code (56), Abstract, 3:29–39), 30–32 (citing Ex. 1002 ¶¶ 74, 75; 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 Elliott and Rhoades because Rhoades is not analogous art. PO Resp. 30. Patent Owner argues that the '177 patent and Rhoades have different purposes. *Id.* at 31 (citing Ex. 1001, 1:47–51; Ex. 1009, 1:15–17). Patent Owner also argues that Rhoades is not relevant to the problem of undercounting or MDI's. *Id.* (citing Ex. 2021 ¶¶ 61–62).

Petitioner replies that Patent Owner fails to apply the correct test for analogous art (Pet. Reply 25), that one of ordinary skill in the art would have considered Rhoades because it teaches similar structures (*id.* (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 '177 patent and Rhoades share a common purpose (*id.* at 26 (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 25–26 (citing Ex. 1056, 98–100; Ex. 1057, 186:20–189:25).

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 '177 patent or Elliott, a preponderance of the evidence persuades us that Rhoades would have been reasonably pertinent to a problem related to the '177 patent and logically would have commended itself in considering the problem. Ex. 1002 ¶¶ 74 (“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 *Elliott* as above.”), 75; Ex. 1034, code (56), Abstract, 3:29–39; Ex. 1057, 182:24–183:12. The '177 patent addresses a problem pertaining to development of simple, inexpensive, and reliable fluid dispensers, while Elliott 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 '177 patent. See Ex. 1002 ¶ 73. 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 ¶¶ 74, 75; Ex. 1034, code (56), Abstract, 3:29–39; Ex. 1057, 182:24–183:12.

ii. Motivation to Combine

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 an MDI and could be mass produced. Pet. 2–3 (citing Ex. 1002 ¶¶ 24, 72, 135; Ex. 1010, 4:31–5:5; Ex. 1011, 4:9–13; Ex. 1012, 4–6; Ex. 1013, 4–7; Ex. 1027, 5–6; Ex. 1028, 7; Ex. 1040, 6; Ex. 1041, 13; Ex. 1042, 7–8; Ex. 1043, 8; Ex. 1044, 3), 29–30 (citing Ex. 1002 ¶ 73; Ex. 1005, 3:66–4:3;

Ex. 1006, 2:8–22, Figs. 1, 3a, 3b; Ex. 1012, 5–6; Ex. 1013, 4–7; Ex. 1027, 2–3, 6; Ex. 1028, 3–5, 7; Ex. 1029, 3; Ex. 1030, 3; Ex. 1040, 6; Ex. 1041, 13; Ex. 1044, 3; Ex. 1046, 89), 33 (citing Ex. 1002 ¶ 77; Ex. 1009, 1:39–43; Ex. 1013, 6; Ex. 1018, 2:8–12; Ex. 1022, 1:12–21).

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. 1044, 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 ¶ 73; Ex. 1005, 3:67–4:3, 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. Based on the full record, Petitioner persuades us by a preponderance of the evidence that one of ordinary skill in the art would have been motivated to improve counters such as the one in Elliott with the teachings of Rhoades.

iii. Operability

Petitioner argues that one of ordinary skill in the art would have substituted Elliott's counter with Rhoades's mechanism to create a less expensive, more reliable inhaler that would have avoided undercounting by way of the stop members of Rhoades. Pet. 4–5 (citing Ex. 1002 ¶ 25; Ex. 1006, Fig. 3b; Ex. 1007, Fig. 2), 32–33 (citing Ex. 1002 ¶ 76; Ex. 1029, 3; Ex. 1030, 3; Ex. 1046). Petitioner also argues that one of ordinary skill in

the art would have known that coordinating the tolerances of Rhoades's stop members with the tolerances of valve travel and refilling would minimize undercounting. *Id.* at 33–34 (citing Ex. 1002 ¶¶ 19–22, 78; Ex. 1008, 5:58–68; Ex. 1009 1:50–53; Ex. 1010, 4:31–5:5; Ex. 1011, 4:9–13).

According to Petitioner, one of ordinary skill in the art would have incorporated cam body 20 of Rhoades below the canister of Elliott, molded the stop members of Rhoades into the inhaler body of Elliott, placed the canister of Elliott on a component similar to Rhoades's plunger, and modified the cam body of Rhoades to include displayable values. *Id.* at 34 (citing Ex. 1002 ¶ 79). Petitioner contends that the proposed combination would result in an extendable and retractable inhaler that would not lose prime. *Id.* at 35 (citing Ex. 1002 ¶ 80; Ex. 1047, 1).

Alternatively, Petitioner's proposed combination would have been modified further so that the cam surfaces of cam body 20 would have used a single row of teeth of the same height and a second row of teeth of the same height to interact with the stop members. *Id.* at 35–36 (citing Ex. 1002 ¶ 81). The resulting proposed combination would not require a double action to extend and release the metering valve. *Id.*

Petitioner also contends that it would have been obvious to incorporate the unitary stop members of Rhoades into Elliott's inhaler body (*id.* at 38 (citing Ex. 1002 ¶ 86)), incorporate Rhoades into Elliott such that Elliott's aerosol can would move axially relative to inhaler body (*id.* at 39 (citing Ex. 1002 ¶¶ 69–82)), include a numbering system in the mechanism of Rhoades (*id.* at 41 (citing Ex. 1002 ¶ 95)), and combine Rhoades and Elliott so that axial movement of Elliott's canister causes axial movement of

the plunger of Rhoades to actuate the counter element (*id.* at 42–43 (citing Ex. 1002 ¶ 99)).

Patent Owner responds that Petitioner’s proposed modification would have rendered Elliott inoperable. PO Resp. 11 (citing Pet. 38). Patent Owner argues that incorporating stop members in Elliott’s inhaler body would create internal protrusions between vial 12 and a valve block mounted to vial 12. *Id.* (providing annotated Fig. 3b from Ex. 1006) (citing Ex. 2021 ¶ 29). Patent Owner also argues that “no practical tooling” can “create molded undercut features with the required angled bottom surface so as not to interfere with the inhalation flow path.” *Id.* (citing Ex. 2019, 32:4–11; Ex. 2021 ¶ 31).

Patent Owner further asserts that assembly of the device must occur through the top of the inhaler and the cam body of Rhoades could not be inserted past the stop members, as proposed by Petitioner. *Id.* at 12 (citing Pet. 34; Ex. 2021 ¶¶ 29–30). Patent Owner, thus, argues that “[b]ecause molding stop members onto the interior of Elliott’s inhaler body would make assembly of the device impossible, a [person of ordinary skill in the art] would not have modified Elliott in view of Rhoades” and the “stationary body element is not met.”

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.” Pet. Reply 1. Petitioner also argues that, during prosecution in response to an enablement rejection, Applicant argued that one of ordinary skill in the art would have understood how to connect or arrange components of the

claimed invention. *Id.* at 2–3 (citing Pet. 1–2, 10, 13, 56; PO Resp. 11–12, 26–27; Ex. 1004, 1134, 1138). Petitioner further argues that Patent Owner is arguing incorrectly that Rhoades must be bodily incorporated into Elliott. *Id.* at 4.

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. 13 (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 Elliott by incorporating Rhoades’s mechanism. *See* Pet. 4–5 (citing Ex. 1002 ¶ 25; Ex. 1006, Fig. 3b; Ex. 1007, Fig. 2), 32–33 (citing Ex. 1002 ¶ 76; Ex. 1029, 3; Ex. 1030, 3; Ex. 1046).

As for the argument that “no practical tooling” can create cheaply internal stop members in Elliott’s inhaler body (PO Resp. 11), Rhoades teaches that “[t]wo stop members 45 and 46 extend longitudinally within the central portion 27 of the guide member 28, adjacent and parallel with the fingers 43 and 44, respectively.” Ex. 1007, 4:13–16; *see also id.* at 3:65–67 (stating 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”). This teaching, taken together with Rhoades’s additional teaching that its “projecting-retracting mechanism comprises few parts, all

of which are readily manufactured by standard manufacturing methods” (*id.* at 7:59–61), persuades us that it was known in the art how to manufacture stop members 45, 46 protruding within central portion 27 of guide member 28. *See also* Pet. 34 (“The stop members of Rhoades would have been molded directly onto the Elliott inhaler body . . . just as they are formed directly on guide member 28 of Rhoades.”). Thus, based on these findings from Rhoades, we determine that it is a matter of ordinary skill, which includes knowledge of such “standard manufacturing methods,” to create internal stop members in Elliott’s inhaler body.

Regarding the argument that Petitioner’s proposed device could not be assembled through the top of the inhaler because molding stop members inside Elliott’s inhaler body would create internal protrusions (PO Resp. 11–12), Petitioner’s proposed combination does not require assembly only through the top of the inhaler (*see* Pet. 34). Rhoades does not teach a specific manner of assembling its components, and thus, such assembly would have been a matter of ordinary skill. The record does not indicate that a person with “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” could not assemble Petitioner’s proposed modification of Elliott in view of Rhoades. Thus, we determine that assembling the components of Petitioner’s proposed combination was well within the ordinary level of skill in the art.

Patent Owner also responds that Petitioner has not explained its proposed combination in sufficient detail and the proposed combination is inoperable because Petitioner does not address how the components of the

proposed combination would be biased so that they can engage one another. PO Resp. 13. According to Patent Owner, a fixed base, bell crank, and leaf spring provide bias forces to keep the components of Elliott in contact with one another, and in Rhoades, return springs 16, 38 provide bias forces to keep components in contact with each other. *Id.* at 13–14 (citing Ex. 1006, 2:47–53, Fig. 1; Ex. 1007, 4:75–5:11, Fig. 1; Ex. 2021 ¶ 16). Patent Owner argues that Petitioner does not address the fixed base, bell crank, and leaf spring of Elliott in the proposed modification and that it is not possible to bias in a predictable way or without undue experimentation using these components in the proposed modification. *Id.* at 14–15 (citing Ex. 2021 ¶¶ 34–36).

Patent Owner also argues that, if the springs of Rhoades are used, Petitioner does not describe where the springs are in the proposed modification or how the springs interact with other components. *Id.* at 15. Patent Owner contends that, if Petitioner is arguing that one of ordinary skill in the art would have known how and where to incorporate the springs, then Petitioner’s obviousness arguments would be based on conclusory allegations about what one of ordinary skill in the art would have known. *Id.* Patent Owner further contends that placing springs in Elliott would have interfered with Elliott’s valve when dispensing a dose of medicine, and, thus, would have rendered Elliott inoperable for its intended purpose. *Id.* at 15–18 (citing Ex. 1002 ¶¶ 16–17; Ex. 1016, Fig. 2; Ex. 2021 ¶¶ 16, 36; Ex. 2029, 28:11–29:7, 138:23–140:12).

Petitioner replies that the Petition argues using spring 16 of Rhoades in the proposed combination of Elliott and Rhoades. Pet. Reply 8–9 (citing Pet. 25, 32). Petitioner also argues that artisans of ordinary skill would have

known how to bias the components. *Id.* at 10 (citing PO Resp. 16; Ex. 1006, 2:47–53; Ex. 1057, 199:16–19). Patent Owner replies that Petitioner does not overcome the flaws in its proposed combination that Patent Owner has asserted. PO Sur-Reply 10–11 (citing PO Resp. 13–18; Pet. Reply 7–10).

Both parties agree that Rhoades teaches biasing with springs 16, 38. Pet. 25; PO Resp. 13–14. 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 substitute Rhoades’s mechanism into Elliott. Ex. 1002 ¶ 12. Also, as discussed above, Rhoades does not teach a specific manner of assembling its components, and thus, such assembly would have been a matter of ordinary skill. Further, Rhoades does not describe in detail how to bias its components, other than describing the presence of springs 16, 38, and thus, indicates that such biasing is a matter of ordinary skill. In view of these determinations, Petitioner persuades us that one of ordinary skill in the art would have been able to incorporate spring 16 of Rhoades into the proposed combination of Elliott and Rhoades so that the components of Rhoades are biased and so that Elliott’s valve can perform as Elliott teaches. The record does not present a reason that the proposed combination would have been beyond ordinary skill.

Patent Owner also argues that Petitioner’s proposed combination “requires one press to extend the pen tip and another to retract it.” PO Resp. 24 (citing Pet. 35). Patent Owner contends that Petitioner’s alternative modification of two sets of teeth of same height to interact with the stop members to avoid these additional depressions is internally inconsistent because Petitioner proposes to modify Rhoades to be more like the purportedly inferior Elliott. *Id.* at 24–25 (citing Pet. 33–35). Patent Owner

also argues that Petitioner’s declarant does not offer an explanation of how to effectuate this modification. *Id.* at 25 (Ex. 1002 ¶ 81). Patent Owner, thus, contends that Petitioner is employing mere conclusory statements. *Id.*

For the reasons discussed above, Petitioner persuades us that one of ordinary skill in the art would have made the proposed combination of Elliott and Rhoades. Also, 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. We need not analyze Petitioner’s alternative, further modification of Elliott and Rhoades to determine whether the challenged claims are patentable.

iv. Teaching Away

Patent Owner also responds that “Rhoades expressly teaches away from the strict physical design tolerances applicable to MDIs such as Elliott,” and that both parties’ declarant agree that designing an MDI requires attention to strict physical tolerances. PO Resp. 32–33 (citing Ex. 2021 ¶¶ 59–62; Ex. 2029, 135:10–17). Patent Owner argues that Rhoades teaches away from such strict tolerances and that one of ordinary skill in the art would have understood Rhoades was not designed for the accuracy required of MDIs. *Id.* at 33 (citing Pet. 53–54; Ex. 1009, 8:6–16; Ex. 2021 ¶ 61). Patent Owner, thus, argues that one of ordinary skill in the art would not have been motivated to combine Elliott and Rhoades. *Id.* at 33–34.

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. 1007, 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 in the art 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). Patent Owner contends that Petitioner is introducing improperly new arguments for obviousness. PO Sur-Reply 1–4 (citing Pet. Reply 4–8, 10–11, 15, 21). Patent Owner also responds to those asserted new arguments. *Id.* at 4–9 (citing Pet. 34, 58; PO Resp. 11–12; Pet. Reply 4–7; Ex. 2018, 99; Ex. 2019, 28:11–29:7, 116:22–119:6, 138:23–140:12, Ex. 2021 ¶¶ 5–7, 81).

Because of our analysis of 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 directly from claim 1 and recites

wherein, during the return stroke of the dispenser after dispensing a dose, said dose indicator device prevents the fluid from being expelled again until said dispenser has completed a predetermined incomplete return stroke, said dispenser and said dose indicator device being capable of being actuated once again, once the predetermined incomplete return stroke has been performed, even if the dispenser does not perform the complete return stroke and said dispenser is actuated once again before returning to its rest position.

According to Petitioner, Rhoades teaches that cam body 20 is displaced by fingers 43, 44 of plunger 34 and once fingers 43, 44 are aligned with grooves with faces 51, 53, plunger 34 is released under force of spring 38. Pet. 43 (citing Ex. 1002 ¶ 102; Ex. 1007, 5:39–50, Fig. 11). Petitioner contends that “[c]am body 20 cannot be rotated again *until* the plunger is released a sufficient distance to allow fingers 43 and 44 to clear the vertical faces 56 and 58 of cam body 20.” *Id.* at 43–44 (citing Ex. 1002 ¶ 102; Ex. 1007, 5:72–6:11, Fig. 11). Petitioner also contends that “the point of the predetermined incomplete return stroke” is “where, *e.g.*, the fingers 43 and 44 have passed the tip of the next sloped faces 50 and 52.” *Id.* at 45. For the reasons discussed above for claim 1, we agree with Petitioner’s characterization of Rhoades’s teachings regarding cam body 20, and we find that the relied-upon portions of Rhoades support Petitioner’s position.

Petitioner argues that one of ordinary skill in the art “would have understood that, to prevent a second dispensing of fluid before the counter was reset, that point needed only be further from rest position than the axial distance from the rest position required to refill the metering valve chamber.” *Id.* at 44–45 (citing Ex. 1002 ¶ 103; Ex. 1007, Fig. 11). Petitioner also argues that, before this point, “device cannot be actuated again because additional release and depression of the canister will simply cause fingers 43 and 44 to just slide up and down the deep groove of the cam body” and after passing the point, “the cam body can rotate and align the stop member in the groove with bottom 53, and the counter mechanism can be actuated again whether the metering valve chamber has been refilled or not.” *Id.* at 45 (citing Ex. 1002 ¶ 104).

Petitioner further argues that one of ordinary skill in the art “would have known that the height of the cam faces, stop members, and teeth could be designed to correlate the point of the incomplete return stroke with the point of chamber refilling” and “would have designed the height of the teeth to cause chamber refilling to occur after the valve has been released enough so that fingers 43 and 44 have cleared the vertical faces 56 and 58.” *Id.* at 45–46 (citing Ex. 1002 ¶ 105; Ex. 1008, 5:58–68; Ex. 1009, 1:50–53).

Patent Owner responds for claim 2 that Petitioner’s proposed combination of Elliott and Rhoades fails to teach or suggest its limitations because Rhoades teaches a complete actuation stroke. PO Resp. 26, 28–29. Patent Owner also argues that Petitioner concedes that the asserted references do not teach this limitation because Petitioner asserts that one of ordinary skill in the art would have understood that the limitation is required, but that such an argument requires “too many leaps between the disclosures of Elliott and Rhoades and the requirements of claim 2.” *Id.* at 26 (citing Pet. 44), 29 (citing Pet. 46). Patent Owner faults Petitioner for not describing how the cam faces, stop members, and teeth are modified so that the point of the incomplete return stroke correlates to the point of chamber refilling while maintaining “(1) maintaining interoperability of all of the device’s components, (2) ensuring that the medication is dispensed properly, or (3) achieving these goals within the small tolerance stack of an MDI.” *Id.* at 27 (citing Pet. 45–46; Ex. 2021 ¶ 43). Patent Owner also contends that Petitioner does not argue why such modifications would have been made. *Id.* at 27–28 (citing Ex. 2021 ¶ 43).

Based on the relied upon evidence, we determine that one of ordinary skill in the art would have known how to design the cam faces, stop

members, and teeth of Rhoades to correlate with a point of incomplete return stroke with the point of chamber refilling. *See* Pet. 45–46 (citing Ex. 1002 ¶ 105; Ex. 1008, 5:58–68; Ex. 1009 1:50–53). Exhibit 1009 is a patent that issued before the priority date of the ’177 patent, and it states that “[t]ypically, the dose indicating device has an indexing (i.e. counting) mechanism actuated by movement of the container relative to the housing, wherein a preset amount of relative movement results in a count being indexed.” Ex. 1009, 1:50–53. Exhibit 1009 provides evidence that it is a matter of ordinary skill to relate movement of a container to movement in a counter. *See id.* Petitioner also provides a reason for the modification, “to prevent a second dispensing of fluid before the counter was reset.” Pet. 44 (citing Ex. 1002 ¶ 103). We credit the supporting testimony of Petitioner’s declarant because the record supports it. Ex. 1002 ¶ 103; Ex. 1007, 5:72–6:11, Fig. 11; Ex. 1009, 1:50–53.

Thus, for the reasons above, Petitioner persuades us by a preponderance of the evidence that Elliott and Rhoades teach or suggest the limitations of claim 2 and that one of ordinary skill in the art would have had a reason to modify Elliott in view of Rhoades.

3. *Claim 3*

Claim 3 depends directly from claim 1 and recites

in which said body (1) includes a stationary gear (110) co-operating with a first gear (210) of said counter element (20), said counter element (20) including a second gear (230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser, the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation, the stationary gear (110) preventing said counter element (20) from turning until said

counter element (20) no longer co-operates with said stationary gear (110), after a predetermined axial displacement of said counter element (20) corresponding to said predetermined incomplete actuation stroke of the dispenser.

Petitioner contends that Rhoades's faces 50, 51, 52, 53, and 54–59 of cam body 20 teach “a first gear (210) of said counter element (20).” Pet. 46–47 (citing Ex. 1002 ¶¶ 110–112; Ex. 1007, 4:10–12, Fig. 8). Petitioner also contends that cam surfaces 50, 52, 54–59 of cam body 20 teach “said counter element (20) including a second gear (230) co-operating with an actuator gear (300) of an actuator member (30) of the dispenser.” *Id.* at 47–48 (citing Ex. 1002 ¶¶ 110, 112; Ex. 1007, 4:10–12). Petitioner argues that one of ordinary skill in the art would have understood that “gear” as used in the '177 patent refers to surfaces that restrict or cause movement and that there are two gears on each of cam body 20 of Rhoades and number wheel 20 of Elliott. *Id.* at 48–49 (citing Ex. 1002 ¶¶ 110, 113, 114).

Petitioner further argues that Rhoades teaches cam surfaces 50, 52, 54, 55 are engaged by fingers 43, 44 “to impart unidirectional rotational movement as well as longitudinal reciprocating movement to the cam body,” thereby teaching “the teeth of said second gear (230) and/or of said actuator gear (300) being made so that axial displacement of the actuator member causes said counter element (20) to be displaced axially and in rotation,” as recited by claim 3. *Id.* at 49 (citing Ex. 1007, 4:22–27).

Petitioner finally argues that Rhoades teaches push button 35 connected to plunger 34 with fingers 43, 44 that move through guide member 28, the asserted stationary member. *Id.* at 49–50 (citing Ex. 1007, 3:68–72, 4:1–13, Figs. 8–12). Petitioner contends that fingers 43, 44 successively engaging the faces and cam surface of cam body 20 to move

cam body 20 axially and rotationally, but stop members 45, 46 prevent the cam body moving rotationally until cam body 20 has been moved axially a predetermined distance corresponding to a predetermined incomplete actuation stroke. *Id.* at 50 (citing Ex. 1002 ¶¶ 116, 117; Ex. 1007, 4:22–33, 5:39–63, Figs. 8, 9).

Based on our review of the relied-upon portions of Rhoades, we agree with Petitioner that Rhoades teaches the limitations of claim 3 for the reasons asserted by Petitioner.

Petitioner also contends that one of ordinary skill in the art “would have understood how to connect a canister to, and how to set the dimensions and tolerances of the cam surfaces and stop members to ensure that medicine would be dispensed after the point of the incomplete actuation stroke.” *Id.* (citing Ex. 1002 ¶ 117). Petitioner further refers to its arguments that one of ordinary skill in the art would have incorporated Rhoades into Elliott with or without modification to the teeth of cam body 20. *Id.* at 51. As determined above, we determine that it is a matter of ordinary skill to adjust the cam faces, stop members, and teeth of Rhoades to correlate with a point of incomplete return stroke with the point of chamber refilling. Ex. 1002 ¶ 105; Ex. 1008, 5:58–68; Ex. 1009 1:50–53.

Patent Owner responds for claim 3 that Petitioner’s proposed combination of Elliott and Rhoades fails to teach or suggest its limitations for the same reasons asserted for claim 1. PO Resp. 29. For the reasons stated above for claim 1, a preponderance of the evidence persuades us that Elliott and Rhoades teach or suggest the limitations of claim 1 and that one of ordinary skill in the art would have incorporated the Rhoades’s mechanism for converting axial into rotational motion into Elliott.

Thus, in view of the full record before us, a preponderance of the evidence persuades us that Rhoades teaches the limitations of claim 3.

4. Claim 9

Claim 9 depends from claim 3 and recites “in which, once the predetermined incomplete return stroke has been performed, the actuator member (30) is positioned facing the following tooth of the second gear (230) of the counter element (20), enabling the dispenser and the dose indicator device to be actuated once again.”

Petitioner argues that Rhoades teaches, after passing the point of an incomplete actuation stroke, cam body 20 rotates and fingers 43, 44 are positioned to engage with faces 50, 52, the following teeth of cam body 20, thereby allowing fluid reservoir section 10 and cam body 20 to be actuated again. Pet. 51–52 (citing Ex. 1002 ¶¶ 121–122; Ex. 1007, Fig. 2). Based on our findings and determinations above regarding the mechanism of Rhoades and the asserted incomplete actuation stroke, we agree with Petitioner that Rhoades teaches the limitations of claim 9 for the reasons asserted by Petitioner.

Patent Owner responds for claim 9 that Petitioner’s proposed combination of Elliott and Rhoades fails to teach or suggest its limitations for the same reasons asserted for claim 1 and because Rhoades fails to teach or suggest a predetermined incomplete return stroke or a device capable of actuating after a predetermined incomplete return stroke is performed. PO Resp. 29–30 (citing Pet. 51–52). As determined above for claim 1, a preponderance of the evidence persuades us that Elliott and Rhoades teach or suggest the limitations of claim 1 and that one of ordinary skill in the art

would have incorporated the Rhoades's mechanism for converting axial into rotational motion into Elliott.

Thus, in view of the full record before us, a preponderance of the evidence persuades us that Rhoades teaches the limitations of claim 9.

5. *Claim 21*

Claim 21 depends directly from claim 1 and recites "wherein the dispenser member is a pump or a valve."

Petitioner argues that Elliott teaches a valve for vial 12. Pet. 52 (citing Ex. 1002 ¶ 125; Ex. 1006, 1:85–86). Petitioner also argues that one of ordinary skill in the art "would have incorporated the *Rhoades* mechanism into the *Elliott* inhaler, retaining the inhaler medicine in a vial or aerosol can with a valve." *Id.* (citing Ex. 1002 ¶ 126). We find that the relied upon portion of Elliott teaches a valve. Ex. 1006, 1:85–86 ("The invention further provides a device for fitting over the valve of an aerosol can.").

Patent Owner responds for claim 21 that Petitioner's proposed combination fails to teach or suggest its limitations for the same reasons asserted for claim 1. PO Resp. 30. For the reasons stated above for claim 1, a preponderance of the evidence persuades us that Elliott and Rhoades teach or suggest the limitations of claim 1 and that one of ordinary skill in the art would have incorporated the Rhoades's mechanism for converting axial into rotational motion into Elliott.

Thus, in view of the full record before us, a preponderance of the evidence persuades us that Rhoades teaches the limitations of claim 21.

6. *Objective Evidence of Nonobviousness*

Patent Owner contends that the '177 patent "met a long felt, but unresolved need for an accurate dose counter that avoided undercounting."

PO Resp. 50. 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 ’177 patent “addressed the long-felt need in the industry for an accurate dose counter that avoided undercounting.” *Id.* at 50–51 (citing Ex. 1013, 2).

Petitioner replies that Patent Owner admits that the claimed invention of the ’177 patent responds to FDA’s guidance calling for MDI’s that minimized undercounting. Pet. Reply 28 (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 29 (citing Ex. 1013, 2, 3; Ex. 1057, 209:3–212:10; Ex. 2021 ¶ 91). Petitioner also contends that, before the FDA guidance, suitable counters were known and manufacturers could sell fluid dispensers without dose counters. *Id.* (citing Ex. 1057, 213:2–6). 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 29–30.

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.* at 30 (citing Ex. 1057, 212:16–25). Petitioner also argues that fluid dispensers with dose counters were admitted to be known during prosecution 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 (Bason stating that it “concerns an indicator device . . . adapted to serve as a dose counter for metered dose inhalers (MDI’s)”; Ex. 2021 ¶ 91 (Patent Owner’s declarant stating that the “Bason design already reflected the FDA’s recommendation for dose counting, therefore a POSA would not have been motivated to improve it in view of Rhoades”).

The full record before us does not persuade us that the ’177 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.

7. *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) Elliott and Rhoades teach all the limitations of claims 1–3, 9, and 21; (3) one of ordinary skill in the art would have had a reason to modify Elliott 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 1–3, 9, and 21 of the '177 patent are unpatentable over Elliott and Rhoades.

E. Challenge Based on Bason and Rhoades

Petitioner also challenges claims 1–3, 9, and 21 as unpatentable over Bason and Rhoades. As discussed above, we determine that Petitioner has shown by a preponderance of the evidence that the same claims are unpatentable over Elliott and Rhoades. Therefore, we do not reach the challenge based on Bason and Rhoades.

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, 74, 78, 86, 103, 122, and 136 of Exhibit 1002 and paragraphs 8, 21–29, 36, 48–52, and 54 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, 3–6.

We cite to paragraphs 74 and 103 in our analysis of analogous art and dependent claim 9. 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, paragraph 74 finds adequate factual basis in the declarant's personal experience, and paragraph 103 finds adequate factual basis in Figure 11 of Rhoades. We cite the other listed paragraphs only to indicate where Petitioner believes support is found for its arguments.

Patent Owner also argues that paragraphs 8, 21–29, 36, 48–52, and 54 of Exhibit 1058 raise new arguments or lack sufficient factual basis. *Id.* at 7–12. 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, 1056, and 1060. 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, 1056, or 1060 in our analysis.

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

IV. CONCLUSION⁵

In summary:

Claims	35 U.S.C. §	Reference(s)/ Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–3, 9, 21	103(a)	Elliott, Rhoades	1–3, 9, 21	
1–3, 9, 21	103(a)	Bason, Rhoades		
Overall Outcome			1–3, 9, 21	

V. ORDER

Accordingly, it is:

ORDERED that claims 1–3, 9, and 21 of U.S. Patent No. 8,936,177 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;

⁵ 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).

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.

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