

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

IPR2018-01675
Patent 8,603,044 B2¹

Before HYUN J. JUNG, BART A. GERSTENBLITH, and
JAMES A. TARTAL, *Administrative Patent Judges*.

GERSTENBLITH, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining All Challenged Claims Unpatentable
Denying Petitioner's Motion to Exclude
35 U.S.C. § 318(a)

¹ Pfizer Inc. was joined as a petitioner in this proceeding.

I. INTRODUCTION

A. Background

Mylan Pharmaceuticals Inc. (“Mylan”) filed a Petition (Paper 2, “Pet.”) requesting institution of an *inter partes* review of claims 11, 14, 15, 18, and 19 of U.S. Patent No. 8,603,044 B2 (Ex. 1002, “the ’044 patent”). Sanofi-Aventis Deutschland GmbH (“Patent Owner”) filed a Preliminary Response (Paper 12). With prior authorization, Mylan filed a Reply to Patent Owner’s Preliminary Response (Paper 16) limited to addressing whether we should exercise our discretion under 35 U.S.C. § 314(a) to deny the Petition, and Patent Owner filed a Sur-Reply in response (Paper 19). Also with prior authorization, Mylan filed a Motion to Correct the Petition (Paper 15) and Patent Owner filed an Opposition to the Motion (Paper 18). We granted Mylan’s Motion to Correct (Paper 21), resulting in a citation change on page 25 of the Petition, which is shown in Exhibit 1037.² We also granted Patent Owner’s request to file an Amended Preliminary Response, which Patent Owner filed as Paper 23, to respond to the corrected citation in the Petition. Paper 21, 4. Applying the standard set forth in 35 U.S.C. § 314(a), we instituted an *inter partes* review of all challenged claims. Paper 28 (“Inst. Dec.”).

After institution, Pfizer Inc. (“Pfizer”) filed (1) a petition challenging the same claims of the ’044 patent on the same grounds asserted by Mylan and instituted in this case and (2) a motion for joinder requesting that Pfizer

² Because it was a very minor change, we did not require Petitioner to file a “corrected petition”; rather, we agreed that we would treat the originally filed Petition as though the correction had been made. *See* Ex. 1039, 14:17–16:4. The citation on page 25 to Exhibit 1002 was thus changed from “*cf.* EX1002, 3:42–44” to “*cf.* EX1002, 3:62–64.” Ex. 1037.

be joined as a petitioner in this case. *Pfizer Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-00977, Papers 2 (Pfizer’s Petition), 3 (Pfizer’s Motion for Joinder) (May 2, 2019). For the same reasons set forth in our Institution Decision in this case, we instituted *inter partes* review on Pfizer’s petition and granted Pfizer’s motion for joinder. *Id.* at Paper 12 (Aug. 15, 2019).³

Patent Owner filed a Patent Owner Response (Paper 38, “PO Resp.”), Petitioner⁴ filed a Reply to Patent Owner’s Response (Paper 53, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 65, “PO Sur-reply”). With prior authorization, Patent Owner filed a List of Improper Reply Arguments that Patent Owner asserts exceed the scope of a reply under 37 C.F.R. §§ 42.22 and 42.23 (Paper 63), and Petitioner filed a Response to Patent Owner’s List (Paper 64). Petitioner also filed a Motion to Exclude (Paper 71, “Mot.”), Patent Owner filed an Opposition to Petitioner’s Motion (Paper 72, “Opp.”), and Petitioner filed a Reply in support of its Motion (Paper 77, “Motion Reply” or “Mot. Reply”). Additionally, Patent Owner filed Observations on the Cross-Examination of Mr. Karl Leinsing (Paper 75) and Petitioner filed a Response to Patent Owner’s Observations (Paper 79). And, Petitioner filed Observations Regarding the Testimony of Alexander Slocum, Ph.D. (Paper 76), to which Patent Owner filed a Response (Paper 78). An oral hearing was held on January 15, 2020, and a copy of the transcript was entered in the record. Paper 85 (“Tr.”).

³ This decision is entered in the record in this case as Paper 48.

⁴ We refer to Mylan and Pfizer, collectively, as “Petitioner.”

We have jurisdiction pursuant to 35 U.S.C. § 6. This Decision is a Final Written Decision under 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 as to the patentability of the claims on which we instituted trial. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d) (2017). Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must prove unpatentability by a preponderance of the evidence. *See* 35 U.S.C. § 316(e) (2012); 37 C.F.R. § 42.1(d). Having reviewed the arguments and the supporting evidence, we determine that Petitioner has shown, by a preponderance of the evidence, that challenged claims 11, 14, 15, 18, and 19 of the '044 patent are unpatentable. Additionally, for the reasons explained herein, we deny Petitioner's motion to exclude.

B. Related Proceedings

The parties indicate that the '044 patent was asserted in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105 (D.N.J.) ("*Sanofi-9105*"); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812 (D. Del.); *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00113 (D. Del.); *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00884 (D. Del.); and *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 1:17-cv-00181 (N.D. W.Va.). Paper 10, 2; Paper 11, 2–3; IPR2019-00977, Paper 2 at 1–2, Paper 6 at 2.

The parties state that the '044 patent also is challenged in IPR2018-01676.⁵ Paper 10, 2; Paper 11, 3. The parties also state that patents related to the '044 patent are challenged in IPR2018-01670, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01684, IPR2018-01696, IPR2019-00122, and IPR2019-00979. Paper 10, 2–3; Paper 11, 2–3; *Pfizer*, IPR2019-00977, Paper 6 at 2–4.

C. Real Parties in Interest

Mylan identifies Mylan Pharmaceuticals Inc., Mylan Inc., Mylan GmbH, Biocon Research Ltd., Biocon Ltd., and Becton, Dickinson and Company as real parties in interest. Paper 10, 2.

Pfizer identifies itself and Hospira, Inc. as real parties in interest. *Pfizer*, IPR2019-00977, Paper 2 at 1.

Patent Owner identifies Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis U.S. LLC, and Sanofi Winthrop Industrie as real parties in interest. Paper 11, 2.

D. The Instituted Ground of Unpatentability

Petitioner asserts claims 11, 14, 15, 18, and 19 of the '044 patent are unpatentable as set forth in the chart below:

Claims Challenged	35 U.S.C. §	Reference
11, 14, 15, 18, 19	103(a)	Burroughs ⁶

⁵ Pfizer also challenged the '044 patent in IPR2019-00978 and was joined subsequently as a petitioner to IPR2019-01676. *Pfizer Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-01676, Paper 41 (Aug. 15, 2019).

⁶ Exhibit 1013 (US 6,221,046 B1, iss. Apr. 24, 2001 (“Burroughs”)).

Petitioner supports its challenge with two declarations by Karl R. Leinsing, dated September 9, 2018 (Ex. 1011, “the Leinsing Declaration”), and September 18, 2019 (Ex. 1095, “the Leinsing Reply Declaration”), and a declaration by Dr. William C. Biggs (Ex. 1049).

Patent Owner supports its arguments with a declaration by Alexander Slocum, Ph.D. (Ex. 2107) and a declaration by Dr. Robin S. Golan (Ex. 2111).

E. The '044 Patent

The '044 patent “relates to pen-type injectors . . . where a user may set the dose.” Ex. 1002, 1:20–24. Figures 1 and 2 of the '044 patent are reproduced below.

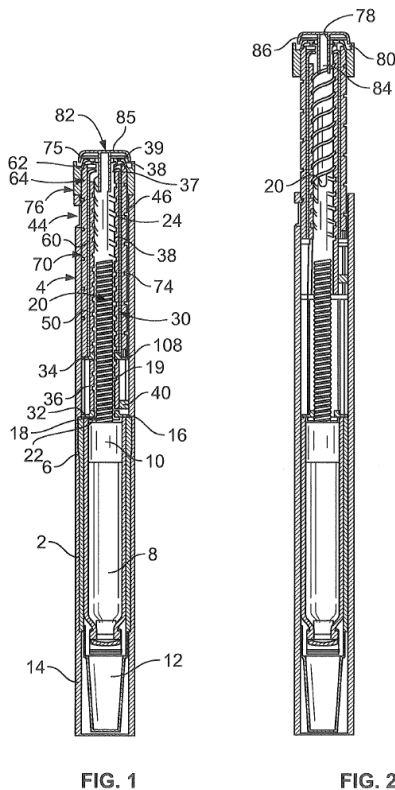


Figure 1 “shows a sectional view of a pen-type injector . . . in a first, cartridge full, position,” and Figure 2 “shows a sectional view of the pen-

type injector of FIG. 1 in a second, maximum first dose dialed, position.”
Id. at 2:53–57. The pen-type injector includes first cartridge retaining part 2 and second main housing part 4.⁷ *Id.* at 3:27–28. Insert 16 is at a first end of housing part 4 and is fixed rotationally and axially to main housing 4. *Id.* at 3:49–51. Insert 16 includes threaded circular opening 18, through which piston rod 20 extends. *Id.* at 3:51–53, 3:57–59. Piston rod 20 includes first thread 19 that engages threaded circular opening 18. *Id.* at 3:56–58.

Piston rod 20 also includes pressure foot 22 that abuts piston 10 of cartridge 8. *Id.* at 3:36–37, 3:59–60. Drive sleeve 30 extends about piston rod 20, and second thread 24 of piston rod 20 engages internal helical groove 38 of drive sleeve 30. *Id.* at 3:61–62, 4:4, 4:13–14.

Clutch or clutch means 60 is disposed about drive sleeve 30 adjacent its second end. *Id.* at 4:33–35, 4:49–50. Clutch 60 is keyed to drive sleeve 30 by splines to prevent relative rotation between clutch 60 and drive sleeve 30. *Id.* at 4:60–62. Clutch 60 also has teeth 66 that engage dose-dial sleeve 70. *Id.* at 4:50–52.

Dose dial sleeve 70 is outside of clutch 60 but within main housing 4. *Id.* at 5:3–5. Dose dial sleeve 70 has helical groove 74 on its outer surface, and helical rib 46 of housing 4 is seated in helical groove 70. *Id.* at 5:5–6, 5:9–11. Dose dial grip 76 is disposed about and secured to the second end of dose dial sleeve 70. *Id.* at 5:24–25, 5:27–28.

In operation, a user rotates dose dial grip 76 to set a dose and cause dose-dial sleeve 70, clutch 60, and drive sleeve 30 to rotate together out of

⁷ The '044 patent refers to “second main housing part 4” and “main housing 4” interchangeably. *Compare* Ex. 1002, 3:28 (“second main housing part 4”), *with id.* at 3:30 (“main housing 4”).

main housing 4. *Id.* at 5:50–53, 5:61–65, Fig. 9. The dose can be reduced by turning dose dial grip 76 in the opposite direction. *Id.* at 6:19–20, Fig. 10. The user then presses button 82, which causes clutch 60 to disengage from dose dial sleeve 70 so that clutch 60 moves axially and dose dial sleeve 70 rotates back into main housing 4. *Id.* at 6:28–35, 6:38–40, Fig. 11. Drive sleeve 30 also moves axially and causes piston rod 20 to rotate through threaded opening 18 to dispense medicine from cartridge 8. *Id.* at 6:44–46.

F. Illustrative Claim

Claim 11, the sole independent claim challenged in this proceeding, is illustrative of the claimed subject matter and reproduced below:

11. A housing part for a medication dispensing apparatus, said housing part comprising:
 - a main housing, said main housing extending from a distal end to a proximal end;
 - a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;
 - a dose dial grip disposed near a proximal end of said dose dial sleeve;
 - a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;
 - a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and,
 - a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular

clutch, and wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different.

Ex. 1002, 8:7–36.

II. ANALYSIS

A. *Level of Ordinary Skill in the Art*

Petitioner asserts that one of ordinary skill in the art “would have had at least a bachelor’s degree in mechanical engineering, or an equivalent degree, and approximately three years of experience in medical-device design” and “would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g., gears, pistons) involved in drug-delivery devices.” Pet. 14 (citing Ex. 1011 ¶ 104). In our Institution Decision, we found that Petitioner’s proposal was consistent with the level of ordinary skill in the art reflected by the prior art of record and we preliminarily adopted Petitioner’s unopposed position. Inst. Dec. 13 (citing *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978)).

In its Response, Patent Owner contends that one of ordinary skill in the art would have “a bachelor’s degree in mechanical engineering or an equivalent degree.” PO Resp. 8. Patent Owner contends that additional experience beyond the bachelor’s degree is not required. *Id.* at 9. In particular, Patent Owner asserts that Petitioner proposes inconsistent levels of skill across related cases, including that one of ordinary skill “would have had ‘design experience,’ ‘approximately three years of experience in medical-device design,’ or ‘three-year’s experience’ depending on the

petition.” *Id.* at 8–9 (citations omitted). Patent Owner further contends that “Mr. Leinsing testified that three years of experience is not required.” *Id.* at 9.⁸ Patent Owner contends that what is important is that the level of skill include someone “who understands the mechanical elements (e.g., lead screws, clutches, gears) used in drug injection delivery devices as well as the principles governing the interactions of such mechanical elements, and further understands the basics of device design and manufacturing.” *Id.* at 8. Nonetheless, Patent Owner asserts that “the slight differences between Patent Owner and Petitioner’s level of ordinary skill do not affect the arguments” in this case. *Id.* at 9.

In its Reply, Petitioner agrees with our preliminary finding from the Institution Decision that the art of record reflects the level of ordinary skill in the art. Pet. Reply 2. Petitioner also acknowledges that Patent Owner concedes that any differences in the level of ordinary skill proposed by the parties do not affect the outcome of this case. *Id.* at 1–2.

We see no reason to disturb our preliminary finding regarding the level of ordinary skill in the art. Accordingly we maintain and reaffirm that one of ordinary skill in the art “would have had at least a bachelor’s degree in mechanical engineering, or an equivalent degree, and approximately three years of experience in medical-device design” and “would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g., gears, pistons) involved in drug-delivery devices.” Inst. Dec. 12–13 (quoting Pet. 14). We also find that the outcome

⁸ Patent Owner does not provide a citation to where Mr. Leinsing so testified.

of this case is not dependent upon whether we adopt Petitioner’s or Patent Owner’s proposed level of skill.

B. Claim Construction

In an *inter partes* review based on a petition filed prior to November 13, 2018, claim terms in an unexpired patent are construed according to their broadest reasonable interpretation in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b) (2017);⁹ *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). There is a presumption that claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art in the context of the specification. *See In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Nonetheless, if the specification “reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor’s lexicography governs.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is “when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Uship Intellectual Props., LLC v. United States*, 714

⁹ An amendment to this rule does not apply here because the Petition was filed before November 13, 2018. *See* 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 Nov. 13, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)).

F.3d 1311, 1313 (Fed. Cir. 2013) (quoting *Thorner v. Sony Comput. Entm't Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)).

Additionally, only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. See *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (holding that “only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy”); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs.* in the context of an *inter partes* review).

Petitioner provides interpretations of six terms that were proffered by Patent Owner in related litigation—“drive sleeve,” “main housing,” “piston rod,” “threading,” “tubular clutch,” and “clicker.” Pet. 15–17 (citing Ex. 1019, 19, 21, 23, 27, 30). Petitioner also explains it proffered means-plus-function interpretations for “tubular clutch” and “clicker” in related litigation and reiterates those interpretations here. *Id.* (citing Ex. 1028 (Mylan’s Preliminary Claim Constructions in *Sanofi-9105*), 54–59, 62–63, 65–68; Ex. 1002, 2:16–18, 4:49–62, 4:63–65, 6:33–43). Petitioner states that the ground presented “also addresses the ‘tubular clutch’ and ‘clicker’ limitations to the extent that those terms may be construed as means-plus-function limitations.” *Id.* at 17. Patent Owner contends the only term that requires construction is “tubular clutch,” although Patent Owner also

contests Petitioner's assertion that "clicker" should be construed as a means-plus-function limitation. PO Resp. 10, 13.¹⁰

1. "tubular clutch"

Petitioner contends "tubular clutch" is "[a] tubular structure that couples and decouples a moveable component from another component." Pet. 16. Petitioner acknowledges that in related litigation, Mylan "proffered [a] preliminary means-plus-function construction[] for 'tubular clutch,'" where the functions are "that, during dose setting, it 'clutch[es], i.e., coupling and decoupling a moveable component from another component,' or it 'operates to reversibly lock two components in rotation.'" *Id.* (citing Ex. 1028, 56). In that case, Petitioner identified the structure in the '044 patent that corresponds to those functions as "component 60." *Id.* (citations omitted).

Patent Owner contends that the plain and ordinary meaning of "clutch" is "a component that can operate to reversibly lock two components in rotation." PO Resp. 12 (citing Ex. 2165 (Opinion and Order (D.I. 319) construing claim terms in *Sanofi-9105*, filed May 9, 2019), 13). Patent Owner asserts that this is the construction adopted by the district court in

¹⁰ We decline to opine on the term "clicker" because resolving the parties' apparent dispute as to whether the term invokes 35 U.S.C. § 112, ¶ 6, is not necessary to resolve any controversy presented in this case. *Vivid Techs.*, 200 F.3d at 803 (construing explicitly only those claim terms in controversy and only to the extent necessary to resolve the controversy).

Sanofi-9105.¹¹ *Id.* Patent Owner contends that, in construing the term, the district court disagreed with Mylan’s proposed construction. *Id.* (citing Ex. 2165, 10–11).

In its Reply, Petitioner asserts that the Delaware court’s construction and Patent Owner’s proposed construction in New Jersey (i.e., “a tubular structure that couples and decouples a moveable component from another component”) are evidence of the reasonable scope of the limitation. Pet. Reply 4. Thus, Petitioner contends “[t]he broadest reasonable interpretation . . . would at least encompass both of these constructions absent a showing that either construction is unreasonable.” *Id.*

In its Sur-reply, Patent Owner contends that the plain and ordinary meaning (i.e., “a component that can operate to reversibly lock two components in rotation”) should apply because there has been no express disavowal of claim scope and the Specification does not contain a lexicographic definition. PO Sur-reply 3. Patent Owner asserts that Petitioner thus lacks evidence to support any other construction. *Id.*

¹¹ “Tubular clutch” was construed by two different district courts. In *Sanofi-9105*, the U.S. District Court for the District of New Jersey, construed the term to mean “a component that can operate to reversibly lock two components in rotation.” Ex. 2165, 13. Previously, in *Sanofi-Aventis U.S. LLC v. Eli Lilly & Co.*, 14-cv-113 (RGA) (D. Del.), the U.S. District Court for the District of Delaware construed “tubular clutch” to mean “a structure that couples and decouples a moveable component from another component.” See Ex. 2165, 10 (referring to the Delaware court’s construction).

Although we are persuaded that “tubular clutch” does not invoke § 112, ¶ 6,¹² we need not decide which party’s proposed construction is the broadest reasonable construction because under either construction—“a tubular structure that couples and decouples a moveable component from another component” or “a component that can operate to reversibly lock two components in rotation”—we find that Petitioner sufficiently establishes that Burroughs discloses a “tubular clutch,” for the reasons discussed below. *See infra* § II.C.3.a.vii.

Accordingly, we determine that no claim terms require express construction beyond the discussion above. *Vivid Techs.*, 200 F.3d at 803.

C. Legal Standards – Obviousness

The U.S. Supreme Court set forth the framework for applying the statutory language of 35 U.S.C. § 103 in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966):

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

¹² Petitioner fails to present any evidence or argument to overcome the presumption that “tubular clutch,” which does not recite the word “means,” is not a means-plus-function limitation. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1349 (Fed. Cir. 2015) (when a claim limitation does not include the word “means,” there is a presumption that the term is not a means-plus-function limitation and § 112, ¶ 6 does not apply).

As explained by the Supreme Court in *KSR International Co. v. Teleflex Inc.*:

Often, it will be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.

550 U.S. 398, 418 (2007) (citing *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”)).

“Whether an ordinarily skilled artisan would have been motivated to modify the teachings of a reference is a question of fact.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1327 (Fed. Cir. 2016). “[W]here a party argues a skilled artisan would have been motivated to combine references, it must show the artisan ‘would have had a reasonable expectation of success from doing so.’” *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1360–61 (Fed. Cir. 2017) (quoting *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1068–69 (Fed. Cir. 2012)).

1. *Level of Ordinary Skill in the Art*

As discussed *supra*, we find that one of ordinary skill in the art at the time of the invention “would have had at least a bachelor’s degree in mechanical engineering, or an equivalent degree, and approximately three

years of experience in medical-device design” and “would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g., gears, pistons) involved in drug-delivery devices.” *See supra* § II.A.

2. *Scope and Content of the Prior Art – Burroughs*

Burroughs relates to “medical dispensing devices . . . that permit selectively measured dosages of a liquid to be dispensed.” Ex. 1013, 1:13–16. Figure 2 of Burroughs is reproduced below.

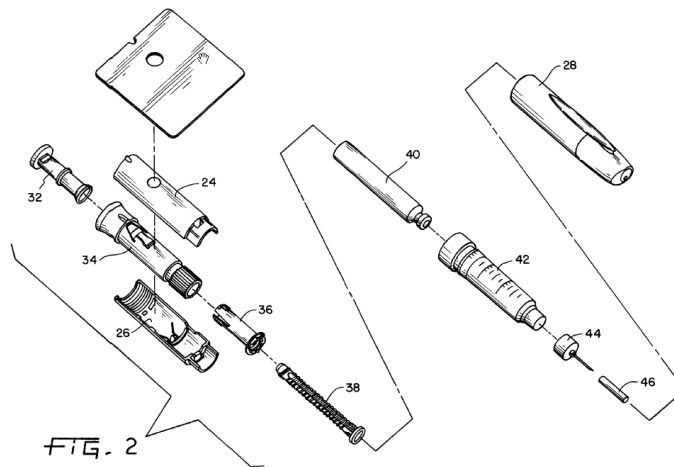


Figure 2 shows an exploded view of injection medication device 20. *Id.* at 6:42–43, 7:15–16. Medication device 20 includes mechanism housing 22 made from housing parts 24 and 26, button 32, dial mechanism 34, nut 36, and leadscrew 38 that forms a drive stem. *Id.* at 7:17–18, 7:32–34, 9:12–13.

Dial mechanism 34 engages button 32. *Id.* at 8: 9–14, Figs. 6, 8. Dial mechanism 34 also includes outwardly extending threads 110, 112 that “enter helical groove 158 during the commencement of the dosing process.” *Id.* at 8:33–36, 8:62–9:1, Figs. 3, 5. “As a dosage is being set, outwardly extending threads 110 and 112 of dial mechanism 34 ride in helical groove 158 of housing parts 24 and 26.” *Id.* at 10:60–63.

When button 32 is depressed, dial mechanism 34 travels axially towards cartridge 40. *Id.* at 8:15–20. Splines 144 on the interior of dial mechanism 34 engage teeth 192 of nut 36 when the clutch is engaged to set a dosage. *Id.* at 8:42–48, Fig. 9. A series of numerals are printed on dial mechanism 34 to indicate a desired dosage. *Id.* at 10:5–9.

Rotating dial mechanism 34 causes nut 36 to rotate and move relative to housing 20, but rotation of leadscrew 38 is prevented. *Id.* at 10:25–27. Once a desired dosage has been set, button 32 is pushed to move dial mechanism 34, nut 36, and leadscrew 38 forward to deliver the set dosage. *Id.* at 11:13–19, 11:31–34.

3. *Differences Between the Prior Art and the Claims;
Motivation to Modify*

Petitioner contends claims 11, 14, 15, 18, and 19 would have been obvious over Burroughs. Pet. 19–48. Petitioner provides claim charts and arguments with citations to where Burroughs allegedly teaches the limitations of the claims and citations to supporting declarant testimony. *Id.*

a. *Independent Claim 11*

i. *“A housing part for a medication dispensing apparatus, said housing part comprising:”*

Petitioner contends that, “[t]o the extent the preamble of claim 11 is limiting, Burroughs” teaches “injection medication device 20 for dispensing medicine,” including “mechanical housing 22 containing the device’s drive mechanism.” Pet. 20–21 (citing Ex. 1013, Abs., 7:15–19, Fig. 1; Ex. 1011 ¶ 156). Patent Owner does not contest Petitioner’s argument that Burroughs teaches the preamble of claim 11.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Burroughs teaches the preamble of claim 11.¹³

ii. *“a main housing, said main housing extending from a distal end to a proximal end;”*

Petitioner contends that Burroughs teaches this limitation of claim 11 by disclosing “mechanism housing 22,” which “includes a first part 24 and a second part 26 that are secured together to house the drive mechanism.” Pet. 23 (citing Ex. 1013, 7:18–20, Figs. 1, 2, 3, 5; Ex. 1011 ¶ 158). Petitioner asserts that “the mechanism housing 22 extends from a button-end (referred to as the proximal end) to a needle-end (referred to as the distal end),” as shown in Figure 1 of Burroughs. *Id.* (citing Ex. 1013, 7:9–13; Ex. 1011 ¶ 160). Patent Owner does not contest Petitioner’s argument that Burroughs teaches this limitation of claim 11.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Burroughs teaches the main housing limitation of claim 11, as recited above.¹⁴

¹³ We need not determine whether the preamble of claim 11 is limiting as the parties have not raised that issue before us. Nonetheless, Patent Owner has waived any argument for patentability directed to the preamble of claim 11. *See* Paper 29 (Scheduling Order), 8 (“Patent Owner is cautioned that any arguments for patentability not raised in the response may be deemed waived.”).

¹⁴ Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 11. *See* Paper 29, 8.

- iii. *“a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;”*

Petitioner contends Burroughs teaches a dose dial sleeve, except that Burroughs’s sleeve includes helical threads along its outer surface as opposed to a helical groove, as recited above. Pet. 25–26. In particular, Petitioner asserts dial mechanism 34 of Burroughs teaches the recited dose dial sleeve. Pet. 25 (citing Ex. 1013, 7:31–32, Fig. 2; Ex. 1011 ¶¶ 162–165). Petitioner argues that Burroughs’s dial mechanism 34 “is positioned within housing 22, and includes, on its outer surface, threads 110, 112.” *Id.* (citing Ex. 1013, 7:65–67, 8:33–36, Figs. 1, 2, 6–9; Ex. 1011 ¶ 166). Petitioner contends threads 110, 112 of dial mechanism 34 “are configured to releasably engage a helical spiral groove 158 provided on an inner surface of the housing 22.” *Id.* (citing Ex. 1013, 8:62–9:1, Figs. 1–3, 5–9; Ex. 1011 ¶ 167).

Petitioner asserts “[t]hreads 110, 112 are rib-like structures that fit into and move within helical spiral groove 158 of the housing parts 24, 26 to allow the dial mechanism to rotate and move axially away from the needle-end of the housing during the dose-setting phase.” *Id.* (citing Ex. 1013, Figs. 6–9; Ex. 1011 ¶ 164). Relying upon Mr. Leinsing’s testimony, Petitioner contends “in order to properly engage with the helical spiral groove 158 for rotation, the threads 110, 112 also must be positioned helically relative to one another, forming a discontinuous helical rib corresponding to the housing’s helical groove.” *Id.* (citing Ex. 1011 ¶ 165; *cf.* Ex. 1002, 3:62–64) (also relying on Ex. 1013, Figs. 1, 7). Thus,

Petitioner argues Burroughs “discloses that the dial mechanism 34 includes a ‘helical rib,’ in the form of threads 110, 112, along its outer surface that engages with a threading on the housing 22.” *Id.* (citing Ex. 1011 ¶ 166).

Petitioner asserts one of ordinary skill in the art “would have considered reversing the features and configuring threads 110, 112 as a ‘helical groove’ to be an obvious alternative.” *Id.* at 40 (citing Ex. 1011 ¶ 170). In particular, Mr. Leinsing testifies that one of ordinary skill in the art “would have found it obvious to add another helical rib next to the existing one, such that threads 110, 112 form a ‘helical groove’ that engages a threading provided by the housing.” Ex. 1011 ¶ 166. Petitioner contends “[t]he use of a rib-to-groove threaded connection is a common and well-known mechanism used to provide relative rotational movement between components.” Pet. 41 (citing Ex. 1011 ¶ 168). Petitioner argues “determining whether to place a helical rib on one component and a complementary helical groove on another engaging component . . . [would have been] a routine task, and would have been viewed . . . as no more than ‘the predictable use of prior art elements according to their established functions.’” *Id.* (quoting *KSR*, 550 U.S. at 417) (citing Ex. 1011 ¶ 171). Thus, Petitioner asserts one of ordinary skill in the art “would have considered the placement of a rib-to-groove connection to be largely interchangeable between its engaging parts.” *Id.* (citing Ex. 1011 ¶ 169).

Additionally, Petitioner contends one of ordinary skill in the art “would have understood that the rotational operability between dial mechanism 34 and housing 22 would not change if helical threads 110, 112 were provided as u-shaped, protruding grooves for engaging a helical rib on the housing.” Pet. 40 (citing Ex. 1011 ¶ 170). Petitioner asserts one of

ordinary skill in the art “would have reasonably expected that the use of the elements in that configuration would have resulted in the elements performing their same, predictable functions (*e.g.*, rotatable engagement). *Id.* at 42 (citing Ex. 1011 ¶ 170; *KSR*, 550 U.S. at 417).

Patent Owner raises several arguments in response. First, Patent Owner contends “Burroughs does not disclose a ‘helical groove provided along an outer surface of said dose dial sleeve.’” PO Resp. 21. As discussed above, Petitioner acknowledges that Burroughs does not disclose this limitation of claim 11, and we agree with the parties that Burroughs does not. Our determination that Burroughs fails to teach this limitation does not end our inquiry because Petitioner proposes modifying Burroughs as set forth above.

Second, Patent Owner contends that Petitioner and Mr. Leinsing propose two different, conflicting modifications to Burroughs. *Id.* at 21–27. Patent Owner explains that it understood Petitioner to propose “a convoluted modification to Burroughs in which a groove would be cut *into the existing threads 110 and 112*, creating ‘grooved threads’ which subsequently engage with a thread on the inner surface of the housing.” *Id.* at 21 (citing Pet. 41–42; Ex. 2107 ¶ 170). Patent Owner asserts that this is what it understood when Petitioner asserted the helical threads 110, 112 would be provided as “u-shaped.” *Id.* at 22 (citing Pet. 41).

Patent Owner contends that, in contrast to cutting into the existing threads, Mr. Leinsing proposes adding another helical rib next to the existing one such that threads 110, 112, along with the added thread, form a helical groove that engages with a threading provided by the housing. PO Resp. 25. Thus, Patent Owner describes Mr. Leinsing’s proposal as “plac[ing] an

additional thread behind Burroughs’ existing threads 110 and 112, such that the space *between* the threads forms a helical groove.” *Id.* (citing Ex. 2107 ¶ 171). Patent Owner asserts “[n]owhere does the Petition suggest duplicating threads 110, 112 and then offsetting those new threads to create a helical grove that mates with the ‘wall’ of the groove on the housing 22.” *Id.* at 26.

In its Reply, Petitioner contends that the Petition and Mr. Leinsing’s declaration are consistent. Pet. Reply 5–6. In particular, Petitioner asserts that the Petition “says nothing about cutting into the threads to make this modification.” *Id.* at 5. Rather, Petitioner explains that the Petition proposes changing helical threads 110, 112 into “u-shaped protruding grooves” and Mr. Leinsing’s declaration explains that this is accomplished by forming the threads as “two, parallel ribs.” *Id.* at 5–6 (quoting Ex. 1011 ¶ 170).¹⁵

In its Sur-reply, Patent Owner maintains that the Petition “did not assert an obviousness theory based on adding another set of threads 110, 112 to Burroughs’ dial mechanism to form a ‘groove’ between two sets of threads.” PO Sur-reply 7 (citing PO Resp. 21–24). Patent Owner contends that Petitioner’s Reply does not dispute that the Petition “proposed ‘chang[ing] the helical threads 110, 112 into ‘u-shaped protruding grooves’” and that Petitioner’s position that this language indicates duplication of the

¹⁵ Patent Owner identifies the above portion of Petitioner’s Reply in its List of Improper Reply Arguments (Paper 63). We find that this discussion in Petitioner’s reply is not an improper reply argument because it responds to Patent Owner’s argument (raised in its Response) that the Petition and Mr. Leinsing proposed different modifications to Burroughs. As discussed *infra*, the modifications are consistent.

thread rather than forming a groove in the existing threads is improbable. *Id.* (quoting Pet. Reply 5).

We disagree with Patent Owner that Petitioner and Mr. Leinsing propose different theories of modification. The Petition proposes changing the helical threads 110, 112 to u-shaped protruding grooves, as discussed above. The Petition does not state that one would “cut” a groove into the thread, as Patent Owner contends. The Petition expressly relies on the declaration of Mr. Leinsing, and Mr. Leinsing provides detail on how to implement the modification proposed in the Petition when he testifies that “a person of ordinary skill would have found it obvious *to add another helical rib next to the existing one*, such that the threads 110, 112 form a ‘helical groove’ that engages a threading provided by the housing.” Ex. 1011 ¶ 166 (emphasis added). This testimony is the clearest explanation of precisely how the existing threads 110, 112 would be modified to form u-shaped protruding grooves. This paragraph of Mr. Leinsing’s declaration begins his discussion of how one of ordinary skill in the art would modify Burroughs. *See generally id.* ¶¶ 160–172. The discussion that follows, including his testimony quoted above from paragraph 170, is premised upon that manner of implementation. Although we agree to some extent with Patent Owner that the Petition could have been written to identify more clearly how the u-shaped protruding grooves would be formed, we do not find the Petition deficient in this regard or that it proposes a theory of obviousness that conflicts with Mr. Leinsing’s testimony.¹⁶

¹⁶ In light of our finding above, Patent Owner’s assertion that one of ordinary skill in the art would not have cut a groove into threads 110, 112 (*see* PO Resp. 29–33) is inapposite.

Third, turning to the merits of Petitioner’s modification to Burroughs’s dose dial sleeve, Patent Owner contends Petitioner provides no rationale for the proposed modification. PO Resp. 34. Rather, Patent Owner asserts that the Petition and Mr. Leinsing state only that

rib-to-groove threaded connections were known in the art, that the relative placement of the ribs and grooves was “largely interchangeable” and “routine variations,” and that a [person of ordinary skill in the art] would have understood that positioning the threads 110, 112 as proposed by Mr. Leinsing to form two parallel ribs would have preserved the rotational operability of the components in Burroughs’ injector pen.

Id. (citing Ex. 1011 ¶¶ 168–171; Pet. 40–42). Patent Owner contends that “these assertions do no more than establish that a [person of ordinary skill in the art] could have performed the proposed modification,” and do not provide a “reason or rationale to do so.” *Id.* (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2005)).

In its Reply, Petitioner contends that “[w]hen known interchangeable solutions to a problem exist, the case law fully supports that swapping one solution for the other is well within the realm of the obvious.” Pet. Reply 6 (citing Pet. 41–42 (citing *KSR*, 550 U.S. at 417); Ex. 1095 ¶ 43).

In its Sur-reply, Patent Owner contends that “[m]erely asserting a ‘design choice’ does not make it obvious” and that “Petitioners’ alleged ‘interchangeability’ at best goes to expectation of success.” PO Sur-reply 9. Patent Owner asserts that “Petitioners never address what *motivation* a [person of ordinary skill in the art] would have to make the change – a legally distinct concept from reasonable expectation of success.” *Id.* (citing *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016)).

In *KSR*, the Supreme Court stated that “when a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR*, 550 U.S. at 417 (citing *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 282 (1976)). The Court stated that applying the principles from its previous cases “may be more difficult in other cases than it is here because the claimed subject matter may involve more than the simple substitution of one known element for another or the mere application of a known technique to a piece of prior art ready for the improvement.” *Id.*

In the circumstances presented here, Petitioner establishes sufficiently that the addition of a thread to form a groove (where there was a thread) and the addition of a thread (where there was a groove) is the type of simple substitution envisioned by *KSR* where the artisan simply rearranges old elements (a thread-groove connection) with each performing the same function, yielding no more than one of ordinary skill in the art would have expected. As Petitioner explains, this is a question of known interchangeability. In such circumstance, and on the facts presented here, we find that Petitioner sufficiently sets forth a basis as to why one of ordinary skill in the art would have modified Burroughs—because thread-groove arrangements and groove-thread arrangements were known to be interchangeable—and one of ordinary skill in the art would have had a reasonable expectation of success in producing the same predictable result. That finding does not end our inquiry, however, because Patent Owner additionally contends that one of ordinary skill in the art would have been

deterred from making the modifications proposed by Petitioner, which we now address.

Fourth, Patent Owner contends that one of ordinary skill in the art would have been deterred from making the modifications Petitioner proposes. PO Resp. 35–38. Patent Owner asserts that Petitioner’s modification to add an additional thread to threads 110 and 112 would have (1) required that legs 102 and 104 pivot far enough inward to disengage from two threads (instead of one), (2) required an increase of 30% to 40% in force and stress during the injection process, and (3) resulted in the legs wearing out faster, thus decreasing the lifespan of Burroughs’s multi-use injector. PO Resp. 35–36 (citing Ex. 2107 ¶¶ 184–188).

Patent Owner also contends that although additional modifications to Burroughs’s device could be made to reduce the negative consequences of Petitioner’s proposed change, Petitioner does not propose any additional modifications. *Id.* at 36–37 (citing Ex. 2163 (Mr. Leinsing’s deposition testimony), 195:14–25). As an example of an additional modification, Patent Owner asserts that the stress exerted on the legs could be reduced by changing their dimensions. *Id.* at 36 (citing Ex. 2107 ¶ 189). According to Patent Owner, that change, however, would have also necessitated increasing the internal diameter of the injector “by at least 10 percent in order to accommodate the modified legs when they pivot inward during injection.” *Id.* at 37 (citing Ex. 2107 ¶¶ 190–191). Patent Owner argues that increasing the diameter is undesirable because it is more difficult to grasp and manipulate, especially for diabetic patients who may suffer from hand and wrist conditions that decrease their grip strength and dexterity. *Id.* (citing Ex. 2107 ¶¶ 190–191). Patent Owner asserts that increasing the

diameter of the device would also require more material for manufacturing and would make the device heavier and less portable. *Id.*

Further, Patent Owner contends that with or without the modifications to Burroughs's legs, the injection force required for a user to dispense a dose would be increased by 15% because the legs must pivot further in order for the added threads to clear helical groove 158 during dose injection. PO Resp. 37–38 (citing Ex. 2107 ¶ 192). Increasing injection force also is considered a detriment because of the device's use by diabetic patients who have decreased hand and wrist strength as discussed above. *Id.* (citing Ex. 2107 ¶ 192).

In its Reply, Petitioner does not dispute Patent Owner's argument that adding threads would result in an increase in stress and wear on Burroughs's legs. Pet. Reply 7 (citing PO Resp. 35–36). Rather, Petitioner contends that Patent Owner identifies a viable solution to such detriment—modifying the dimensions of the legs. *Id.* (citing PO Resp. 36–37). Petitioner asserts that one of ordinary skill in the art would have used routine skill to implement the proposed change (i.e., adding threads) presumably contending that one of ordinary skill would have also considered modifying the dimensions of the legs.¹⁷ *Id.*

¹⁷ Petitioner does not state expressly that modifying the dimensions of the legs is within the “routine skill” that one of ordinary skill in the art would have used when adding the additional threads, but Petitioner's Reply suggests that is what Petitioner meant. Pet. Reply 7 (stating that “[c]ase law . . . consistently rejects treating modifications rigidly rather than appreciating that a [person of ordinary skill in the art] would use routine skill in implementing the change”).

Additionally, Petitioner contends that making the device wider is not necessarily a disadvantage, relying on Dr. Biggs’s testimony that “width . . . can aid patients with grip or agility problems.” *Id.* (quoting Ex. 1048 ¶ 50). Thus, Petitioner asserts that what Dr. Slocum considers a disadvantage (i.e., increased width), Dr. Biggs considers an advantage. *Id.* at 8. With respect to Patent Owner’s argument of a 15% increase in injection force, Petitioner contends Dr. Slocum “pulls this ‘significant’ percentage out of thin air.” *Id.* (citing Ex. 2107 ¶ 192; Ex. 1095 ¶ 41). Petitioner asserts that Dr. Slocum’s testimony is conclusory and entitled to no weight, but that, even if injection force were increased, that may only disadvantage some, not all, patients. *Id.* at 8–9 (citing *In re Kao*, 639 F.3d 1057, 1067 (Fed. Cir. 2011); Ex. 1048 ¶¶ 29–30).^{18,19}

In its Sur-reply, Patent Owner contends that the Petition does not propose the “routine options” Petitioner sets forth in the Reply to mitigate the additional stress resulting from the addition of threads to Burroughs’s

¹⁸ Petitioner further contends, in a footnote, that Patent Owner does not address routine options one of ordinary skill in the art would employ to counter an increase in injection force, such as employing different thread heights and shifting the threading. Pet. Reply 9 n.3 (citing Ex. 1095 ¶¶ 42–43). We do not fault Patent Owner for its lack of prescience or ability to predict Petitioner’s argument. Thus, we disagree with Petitioner’s suggestion that Patent Owner should have addressed these issues in its Response.

¹⁹ Patent Owner identifies Petitioner’s footnote 3 in its List of Allegedly Improper Reply Arguments (Paper 63). We find that the position stated in Petitioner’s footnote is not an improper reply argument because it responds to Patent Owner’s argument (raised in its Response) regarding potential negative consequences of making the modification proposed by Petitioner. Nonetheless, Petitioner is cautioned that a substantive argument generally should not be placed only in a footnote for full consideration.

device. PO Sur-reply 9–10 (citing Pet. Reply 9 n.3). Patent Owner also asserts that the size and position of the additional threads are necessarily fixed by the size of the existing threads 110, 112 and the pitch of the existing helical groove, neither of which Petitioner originally proposed to modify. *Id.* at 10 (citing Ex. 1054, 277:19–279:2, 281:5–18). Thus, Patent Owner argues that we should “give no weight to Petitioners’ assertion that a [person of ordinary skill in the art] could have accommodated the modification through ‘different rib heights’ or ‘shifting of threading.’” *Id.* at 10–11.

Additionally, Patent Owner encourages us to reject Petitioner’s “new contention that the modification could have been accommodated through other unspecified applications of ‘routine skill.’” PO Sur-reply 11 (quoting Pet. Reply 7). Patent Owner relies upon Dr. Slocum’s testimony that Petitioner’s modification would require additional substantive changes to Burroughs’s device, such as lengthening legs 102, 104 and increasing the thickness of the injector, and Patent Owner contends that Petitioner provides no evidence that these are “routine” modifications. *Id.* Patent Owner asserts that given the additional changes required, including redesigning the internal components of the device that are sized for Burroughs’s existing design, Petitioner’s modification is “hardly an ‘interchangeable solution[.]’” *Id.* at 11–12 (alteration by Patent Owner).

Further, Patent Owner argues that Petitioner does not contest that injection force would increase even if Petitioner disputes the precise amount of that increase. *Id.* at 12 (citing Pet. Reply 8). Patent Owner also points to the testimony of Dr. Goland, that injection force is one of the reasons she has switched patients to certain devices over others. *Id.* (citing Ex. 1056, 66:9–15).

We find the evidence weighs in Petitioner’s favor as to the question of whether it would have been obvious to modify Burroughs’s dose dial sleeve. The evidence reflects, on the facts presented here, that a groove-thread connection and a thread-groove connection are interchangeable. Patent Owner’s evidence does not support the finding that Burroughs’s device would be inoperable if modified as Petitioner proposes. And, we expressly find, and agree with Petitioner, that Burroughs would be operable. Patent Owner’s evidence, at best, suggests that Burroughs’s device might not operate as well for every user. Petitioner’s evidence, however, suggests that is not necessarily the case for everyone. Specifically, the evidence discussed above reflects that increased size of the device may be an advantage to some users of the device while also a disadvantage to others. *See Medichem, S.A. v. Rolabo S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine.”). Further, we find that Patent Owner establishes that additional stress and force would likely be experienced by the addition of threads, but Petitioner (and Dr. Slocum’s testimony²⁰) establishes that one of ordinary skill in the art would understand how to accommodate that stress and that additional modifications could be made to alleviate that stress if desired. We do not, however, find that additional modifications are required because, although added stress is a

²⁰ Even though Dr. Slocum proposes modifications not originally presented by Petitioner, the modifications proposed are well within the level of ordinary skill in the art and we find that one of ordinary skill in the art would have understood them and undertaken them if increased stress were a concern. *See KSR*, 550 U.S. at 421 (one of ordinary skill in the art “is also a person of creativity, not an automaton”).

potential detriment of the modification, we do not find that it would deter one of ordinary skill in the art from adding the additional threads and do not find that it would render Burroughs inoperable for its intended purpose. Finally, even though we find that injection force may increase, we again are not persuaded that it is of the order that would render Burroughs inoperable for all users such that one of ordinary skill in the art would not undertake the modification. In short, we determine that Petitioner has established that modifying Burroughs's thread-groove connection to a groove-thread connection would have been obvious to one of ordinary skill in the art at the time of the invention. We weigh the evidence of record as to the full scope of claim 11 after addressing each limitation. *See infra* § II.C.5.

iv. "a dose dial grip disposed near a proximal end of said dose dial sleeve;"

Petitioner contends Burroughs teaches a dose dial grip "in the form of a proximal portion 78 of the dial mechanism 34, located near a proximal end (*i.e.*, button-end) of the dial." Pet. 27 (citing Ex. 1013, 8:2–6, Figs. 1, 6–9; Ex. 1011 ¶ 173). Petitioner asserts that "the proximal portion 78 is externally positioned at housing 22's proximal end, and thus constitutes a grip for the user to grasp in order to rotate the dial mechanism 34 during dose setting." *Id.* (citing Ex. 1013, 10:34–42; Ex. 1011 ¶ 175). Patent Owner does not contest Petitioner's argument that Burroughs teaches this limitation of claim 11.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Burroughs teaches the dose dial grip limitation of claim 11, as recited above.²¹

- v. *“a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;”*

Petitioner contends Burroughs teaches a piston rod in the form of “leadscrew 38,” which is “provided within the housing 22.” Pet. 29 (citing Ex. 1013, 9:26–27, Figs. 1, 2, 12, 13; Ex. 1011 ¶ 176). Petitioner asserts that “[d]uring dose setting, rotation of dial mechanism 34 causes corresponding rotation of a nut 36, which engages external threads 208 of the leadscrew.” *Id.* at 29–30 (citing Ex. 1013, 10:26–42, Fig. 1; Ex. 1011 ¶ 177). Petitioner argues that “anti-backup tangs 182, 184 provided on the housing 22” prevent the transmission of rotation to leadscrew 38. *Id.* at 30 (citing Ex. 1013, 10:26–42, Fig. 1; Ex. 1011 ¶ 177). Further, Petitioner contends “[l]eadscrew 38 does not rotate relative to the housing 22 during dose setting.” *Id.* (citing Ex. 1011 ¶ 177). Patent Owner does not contest Petitioner’s argument that Burroughs teaches this limitation of claim 11.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Burroughs teaches the piston rod limitation of claim 11, as recited above.²²

²¹ Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 11. *See* Paper 29, 8.

²² Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 11. *See* Paper 29, 8.

- vi. *“a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and,”*

Petitioner contends Burroughs teaches a drive sleeve in the form of nut 36. Pet. 32 (citing Ex. 1013, 9:12–13, Figs. 1, 2, 10, 11; Ex. 1011 ¶¶ 179–181). Petitioner asserts “[n]ut 36 includes, on its interior surface and near its distal end (*i.e.*, needle-end), a helical thread 198.” *Id.* (citing Ex. 1013, 9:13–25, Figs. 1, 2, 10, 11; Ex. 1011 ¶ 179). Petitioner contends that thread 198 “engages the helical threads 208 of the leadscrew 38” and that nut 36 extends along a portion of leadscrew 38. *Id.* (citing Ex. 1013, 9:30–32, Figs. 1, 2, 10–13; Ex. 1011 ¶ 179). Patent Owner does not contest Petitioner’s argument that Burroughs teaches this limitation of claim 11.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Burroughs teaches the drive sleeve limitation of claim 11, as recited above.²³

- vii. *“a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,”*

Petitioner contends Burroughs teaches “a ‘tubular clutch’ in the form of button 32.” Pet. 34 (citing Ex. 1011 ¶¶ 182–187). Petitioner explains the design and operation of Burroughs’s button 32 as follows:

Button 32 is cylindrical in shape (*i.e.*, tubular) and includes an enlarged diameter ring 54. EX1013, 7:46–51, FIGS. 14, 15; EX1011, ¶182. Burroughs discloses that, when button 32 is

²³ Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 11. *See* Paper 29, 8.

depressed for injection, ring 54 pushes onto fingers 94 provided within dial mechanism 34's internal surface. EX1013, 8:11–20, FIGS. 1, 9, 14, 15; EX1011, ¶183. This causes legs 102, 104 of dial 34, which includes threads 110, 112, to collapse inward, causing the threads' disengagement from the housing's helical groove 158. EX1013, 8:15–20; EX1011, ¶183. Dial mechanism 34 is then free to move axially toward the device's needle-end, without rotating relative to the housing. EX1013, 8:18–20, 11:5–20; EX1011, ¶183. Moreover, button 32 also causes splines 144 of dial mechanism 34 to disengage from splines 192 of nut 36, which rotationally decouples the two components. EX1013, 11:27–30; EX1011, ¶183.

Id. at 34–35. Petitioner asserts that “button 32 serves as a clutch that allows dial mechanism 34 to disengage from (1) its rotational connection with housing 22, and (2) its rotational connection with nut 36.” *Id.* at 35 (citing Ex. 1011 ¶ 183).

Petitioner contends that Figure 1 of Burroughs illustrates button 32 “adjacent a distal end of the proximal portion 78 of dial mechanism 34.” *Id.* (citing Ex. 1013, Fig. 1; Ex. 1011 ¶ 184). Petitioner argues that button 32 “is operatively coupled to this grip portion by virtue of its engagement with fingers 94 of dial mechanism 34.” *Id.* (citing Ex. 1013, Figs. 1, 6–9, 14, 15; Ex. 1011 ¶¶ 185–187).²⁴

In its Response, Patent Owner contends that Burroughs does not disclose or render obvious the recited tubular clutch. PO Resp. 43–48. First, Patent Owner asserts that the proper construction for tubular clutch is “a tubular component that can operate to reversibly lock two components in rotation.” *Id.* at 44. Patent Owner contends that Petitioner's proposed

²⁴ Petitioner also cites to the '044 patent's description of the operation of the clutch with respect to the dose dial sleeve. Pet. 35 (citing Ex. 1002, 2:5–7, 6:6–9).

construction of the term as a means-plus-function limitation included this operation as one of the functions, yet Petitioner fails to address this function in the Petition. *Id.* Thus, Patent Owner argues that “[i]n view of the construction advocated by the Petitioner in the Petition and at the District Court, the Petitioner should not be given a ‘do-over’ in its forthcoming reply.” *Id.* at 45.

Second, Patent Owner contends that the “mere[] . . . capability to ‘rotationally decouple’” two components does not establish the capability to reversibly lock those components in rotation. PO Resp. 45. Patent Owner addresses each of the functions identified by Petitioner.

With respect to the engagement between dial mechanism 34 and housing 22, Patent Owner asserts that dial mechanism 34 “is coupled to the housing by threads 110 and 112, which engage with the housing’s helical groove 158.” *Id.* at 46. Patent Owner provides the following:

As Burroughs explains, “[u]pon rotation of dial 34, threads 110, 112 move within housing groove 158 in the proximal direction ***as dial mechanism 34 retracts from housing 22 . . .***”

Ex. 1013, 10:34–37. As Professor Slocum explains, this means that the dial mechanism 34 is rotating relative to the housing 22, and therefore dial mechanism 34 and housing 22 are not “reversibly locked in rotation.” Ex. 2107 ¶ 207. Thus, Petitioner’s first theory does not render the claims invalid because the dial mechanism is never locked rotationally to the housing.

Id.

With respect to the engagement between dial mechanism 34 and nut 36, Patent Owner contends button 32 “never locks the dial to the nut;” rather, “splines 144 and 192 engage to couple the dial to the nut when the user retracts the *dial mechanism* from the zero-dose position during dose

setting.” PO Resp. 46–47 (citing Ex. 2107 ¶ 208; Ex. 1013, 8:42–48, 10:15–26). Thus, Patent Owner asserts “button 32 does not reversibly *lock* two components in rotation.” *Id.* at 47 (citing Ex. 2107 ¶ 208).

Third, Patent Owner contends that Burroughs discloses a “clutch” consisting of splines 144 and teeth 192, which “reversibly lock two components in rotation – dial mechanism 34 and nut 36.” PO Resp. 47. Patent Owner quotes Burroughs’s description of its “clutching device” as follows:

The clutching device comprises *a series of splines on the inner cylindrical surface of the dial mechanism which axially engage corresponding splines on the outer surface of the nut.* The splines are engaged with one another by retracting the dial mechanism with respect to the nut after the dial mechanism has been rotated to its zero-dose position.

Id. (quoting Ex. 1013, 2:59–65) (citing Ex. 2107 ¶ 209) (emphasis added by Patent Owner). Patent Owner asserts that Petitioner cannot rely upon splines 144 and teeth 192 as teaching the claimed “tubular clutch” because (1) splines 144 and teeth 192 are not tubular and (2) they are not located adjacent to a distal end of the proximal portion 78 of the dial mechanism 34, as required by claim 11. *Id.*

In its Reply, Petitioner first addresses Patent Owner’s argument regarding claim construction, asserting that Patent Owner has waived any argument directed to Petitioner’s non-means-plus-function construction of “tubular clutch”—“a tubular structure that couples and decouples a moveable component from another component.” Pet. Reply 11. Petitioner also asserts that Patent Owner “conceded the reasonableness of the construction the petition employed when it proffered the same construction adopted by the earlier court [i.e., the Delaware District Court] to the court in

the collateral litigation [i.e., the New Jersey District Court].” *Id.* at 12. Thus, Petitioner contends the construction of the term in this *inter partes* review “must be broad enough to include the petition’s construction.” *Id.*

Second, Petitioner asserts that the difference in construction “does not make a practical difference in this case.” *Id.* In particular, Petitioner asserts that button 32 operates to reversibly lock two components in rotation because it operates to engage and disengage dial mechanism 34 from the housing’s helical groove. *Id.* (citing Pet. 32–34; Ex. 1095 ¶ 48). Petitioner contends that “when the user injects a dose, button 32 operates to disengage the splined connection between dial mechanism 34 and nut 36, thus reversing the rotational locking of those two components.” *Id.* (citing Ex. 1095 ¶¶ 48–49; Ex. 1013, 8:42–48, 10:21–26, 10:38–42, 11:27–30, Figs. 9, 11; Ex. 1011 ¶¶ 180, 182–183). Thus, Petitioner contends button 32 teaches a tubular clutch under Patent Owner’s new construction. *Id.*

Third, Petitioner contends that Patent Owner “adopts an even narrower interpretation of its new construction, requiring the clutch to act ***directly on the locked components*** to ‘operate to reversibly lock two components in rotation.’” Pet. Reply 13. Petitioner asserts that “[w]hen engaged[,] the splines 144 and teeth 192 define a tubular (‘360°’) structure (clutching device) within the intermediate portion 80 of the dial mechanism 34. The intermediate portion 80 lies between the proximal portion 78 and distal portion 82, together comprising the dial mechanism 34” *Id.* at 13–14 (citing Ex. 1013, 8:2–4, Fig. 8). Petitioner argues that “adjacent” should mean “next to.” *Id.* Therefore, because “intermediate portion 80 in which the clutching device is located is on the distal end of the proximal portion 78,” Petitioner contends it is next to the

distal end of the proximal portion. *Id.* at 14. Thus, Petitioner asserts that button 32 teaches the recited “tubular clutch” of claim 11 under either construction. *Id.*

In its Sur-reply, Patent Owner contends Petitioner’s interpretation of “tubular clutch” “unreasonably broadens the claim by permitting *any* structure to be a clutch as long as it directly *or indirectly* triggers a locking of two components.” PO Sur-reply 4. Patent Owner asserts that such interpretation would permit a “user’s hand” to be a “clutch” because “the user operates button 32 using her hand, causing splines 144 and teeth 192 to lock the dial mechanism and nut in rotation.” *Id.* Patent Owner contends that whatever scope is given to a claim term, it must be reasonable and Petitioner’s construction is not. *Id.* Even if considering an indirect action, Patent Owner asserts splines 144 and teeth 192 lock due to axial retraction of dial mechanism 34, not button 32, and, therefore, button 32 still is not a tubular clutch. *Id.* at 4–5 (citing Ex. 1013, 10:15–17).

Additionally, Patent Owner contends that we should disregard Petitioner's new argument²⁵ that splines 144 and teeth 192 teach the recited "tubular clutch." PO Sur-reply 5 (citing 37 C.F.R. § 42.23(b); Trial Practice Guide Update 15 (August 2018)). Even if considered, however, Patent Owner asserts these structures do not teach the "tubular clutch" because (1) they are not tubular and (2) they are not adjacent to a distal end of a dose dial grip. *Id.* (citing PO Resp. 47). Patent Owner contends the distal end of Burroughs's dose dial grip is not next to splines 144 or teeth 192 because they are separated by the intervening portion of dial 34. *Id.* And, splines 144 and teeth 192 are not tubular because the parties' construction requires a singular component or structure, which the splines and teeth are not. *Id.* at 6–7.

To begin, we reiterate that under either construction—the broader, "a tubular structure that couples and decouples a moveable component from another component" or, the more narrow, "a component that can operate to

²⁵ Patent Owner identifies Petitioner's argument that splines 144 and teeth 192 teach a "tubular clutch" in its List of Improper Reply Arguments (Paper 63). To the extent Petitioner relies upon splines 144 and teeth 192 as an alternative teaching of a "tubular clutch," *see* Pet. Reply 13–14 (discussing the shape and location of splines 144 and teeth 192), we agree with Patent Owner that the identification of a different structure in Burroughs (i.e., splines 144 and teeth 192 as opposed to button 32) would be an improper new argument impermissibly raised in Petitioner's Reply. However, we do not find improper Petitioner's argument that the tubular clutch is not required to act *directly* to operate to reversibly lock two components in rotation. *See id.* at 13 (first paragraph). That argument maintains Petitioner's reliance upon button 32 as teaching the "tubular clutch" and is responsive to Patent Owner's argument directed to the action of button 32 in the Patent Owner Response. Our discussion is focused on Petitioner's identification of button 32.

reversibly lock two components in rotation”—we find that Burroughs’s button 32 teaches the recited “tubular clutch” of claim 11, as explained below. Therefore, we need not decide which construction is the broadest reasonable construction to decide the specific issue before us.

First, Patent Owner does not dispute that button 32 satisfies the first construction of tubular clutch. Patent Owner’s arguments are instead directed to the second construction. For the reasons explained by Petitioner and detailed below, we find that Burroughs’s button 32 is a tubular structure that couples and decouples a moveable component from another component.

Second, we do not agree with Patent Owner’s restrictive interpretation of the second construction, requiring that the identified structure operate *directly* to reversibly lock two components in rotation. In particular, Patent Owner has identified no intrinsic evidence or flaw in Petitioner’s position that justifies such limitation.²⁶ In the context of applying the broadest reasonable construction in light of the specification, we determine that an identified structure may teach a tubular clutch even if it operates to *indirectly* reversibly lock two components in rotation. In particular, the phrase “a component that can operate to” does not limit how that component

²⁶ By this statement we do not imply that Patent Owner has any specific burden in this context; rather our statement is directed to the unremarkable concept that a party seeking to read a construction more narrowly, in the context of applying the broadest reasonable construction in light of the specification, should identify some reason why such narrowing is appropriate. Patent Owner’s hypothetical example of finding a user’s hand is a clutch is inapposite as a user’s hand is clearly not part of “[a] housing part for a medication dispensing apparatus” as stated in the preamble of claim 11.

operates to accomplish the remainder of the construction—“reversibly lock two components in rotation.”

Turning to Burroughs, Burroughs teaches that after a desired dosage is set, a user inserts the needle of the device and pushes button 32 to inject the dosage. Ex. 1013, 11:13–16. This is accomplished by the button moving out of engagement with legs 102 and 104, which then allows dial mechanism 34 to move forward because threads 110, 112 are no longer in engagement with groove 158. *Id.* at 11:16–20. Burroughs explains that “[a]s dial mechanism 34 is initially moved forward, splines 144 move out of engagement with splines 192 of nut 36 to disengage the clutch by *rotationally decoupling* dial mechanism 34 from nut 36 prior to any axial movement of nut 36.” *Id.* at 11:27–30 (emphasis added).

With respect to the first construction, as the above description indicates, button 32 couples and decouples a moveable component—dial mechanism 34—from another component—nut 36. With respect to the second construction, the above description also indicates that button 32 operates to *rotationally decouple* dial mechanism 34 from nut 36, which reverses the rotational locking of those two components. *See* Pet. 35 (identifying dial mechanism 34’s rotational connection with nut 36); Ex. 1095 ¶ 48 (discussing, *inter alia*, the releasable engagement between dial mechanism 34 and nut 36).

Additionally, with respect to the remaining limitations of the tubular clutch clause of claim 11 recited in the heading above, Patent Owner does not dispute that button 32 is tubular and located adjacent a distal end of said dose dial grip (i.e., Burroughs’s proximal portion 78 of dial mechanism 34).

Figure 14 of Burroughs, reproduced below, illustrates the tubular structure of button 32.

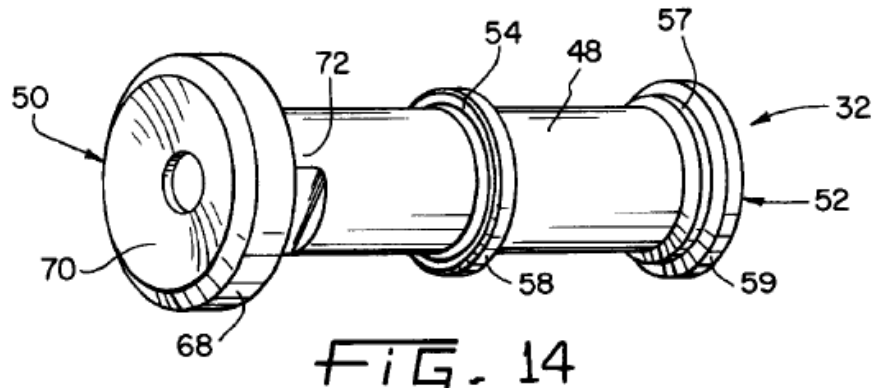


Figure 14 “is a perspective view of the button.” Ex. 1013, 6:66.

Figure 1 of Burroughs, reproduced below, illustrates that button 32 is adjacent (i.e., next to) proximal portion 78 (unlabeled, but it is located at the leftmost area identified by numeral 34) of dial mechanism 34.

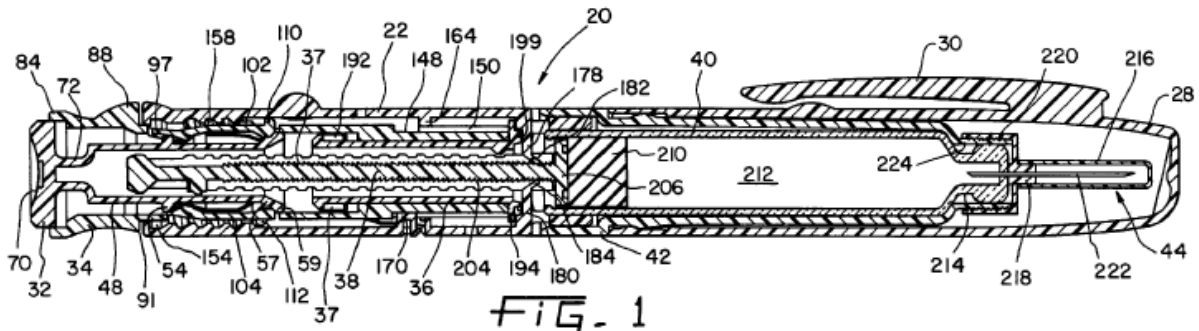


Figure 1 “is a sectional assembly view” of Burroughs’s device. *Id.* at 6:40–41.

Accordingly, for the reasons discussed above, we find that Petitioner has shown that Burroughs’s button 32 teaches the tubular clutch limitation of claim 11.

- viii. *“wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, and wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different.”*

As discussed *supra*, Petitioner points to Burroughs’s dial mechanism 34 as teaching the recited “dose dial sleeve,” and contends threads 110 and 112 have a first lead. Pet. 36. Petitioner also points to Burroughs’s nut 36 as teaching the recited “drive sleeve,” contending nut 36 includes helical thread 198 with a second lead. *Id.* at 37, 39.

Petitioner provides the following argument regarding the use of different leads:

Burroughs does not specifically address the lead on threads 110 and 112, nor for helical thread 198. The [person of ordinary skill in the art] would understand that, to the extent that the lead on threads 110 and 112 is the same as the lead on helical thread 198, they would rotate at the same rate, and when the leads are different, the dose-dial sleeve and drive sleeve can be made to rotate at different rates. EX1011, ¶¶189-94, *cf.* EX1002, 5:61-65.

It would have been well within the level of skill of the ordinary artisan to determine the appropriate lead on threads 110 and 112 as well as for helical thread 198 to achieve the required relative rate of rotation of the dose-dial sleeve to the drive sleeve. EX1011, ¶195. As Burroughs is silent on the leads on threads 110 and 112 and helical thread 198, and, thus, does not expressly state that they have to be the same, a [person of ordinary skill in the art] would understand that Burroughs may have contemplated both the same and different. EX1011, ¶194.

Pet. 39–40. Additionally, Petitioner asserts:

Because the '044 patent does not expressly discuss making the leads of the helical groove of the dose-dial sleeve and the lead of the internal threading of the drive sleeve different, the specification of the '044 patent concedes that a [person of ordinary skill in the art] had the skill to make the leads different, as well as the same.

Id. at 40 (citing Ex. 1011 ¶¶ 196–199).

As indicated above, Petitioner relies upon Mr. Leinsing's testimony. In particular, Mr. Leinsing testifies that "a person of ordinary skill would have understood that leads of threaded, moveable components in injection devices dictated the rate of axial travel of the components as they are rotated." Ex. 1011 ¶ 193. Thus, Mr. Leinsing explains that those of ordinary skill in the art design leads "to achieve a desired rate of axial travel when [a] component is rotated." *Id.* In the context of Burroughs, Mr. Leinsing opines that

a person of ordinary skill in the art would have understood that the lead of the dial mechanism's threading would dictate how much the dial mechanism 34 would retract out of the housing 22 during dose dialing. With regard to the nut 36, a person of ordinary skill would have understood that the lead of the nut's threading would dictate how much the nut 36 would travel up the leadscrew 38 during dose dialing, which, in turn, would ultimately dictate the amount the leadscrew 38 would travel axially into the cartridge during dispensing. And, because the dial mechanism 34 and the nut 36 are rotationally engaged during dose dialing, a person of ordinary skill would have understood that the number of rotations a user dialed the dial mechanism 34 would determine not only the length of axial travel of the dial 34, but also the length of travel of the nut 36, and thus the amount of dose dispensed by the leadscrew 38.

Given this, if it was desired that the dial mechanism 34 retract from the housing 22 at a rate equal to the rate at which the nut 36 climbed up the leadscrew 38, then a person of

ordinary skill would have understood that the leads of those components should be the same. Similarly, if it was desired that the dial mechanism 34 retract from the housing 22 at a faster or slower rate than the rate at which the nut 36 climbed up the leadscrew 38, then a person of ordinary skill would have understood that the leads of those components should be different.

A person of ordinary skill would have also known that, by setting the lead of an external, helical thread of a “dose dial sleeve” larger than the lead of an internal, helical thread of a “drive sleeve,” usability of the device during the dose setting process may be improved. For instance, in cases where only small doses of medicine are needed during an injection, a person of ordinary skill would have understood that such a configuration would allow the user to retract the dose dial sleeve [a] larger distance than the distance needed for the drive sleeve to drive the piston rod to deliver the small dose. Thus, due to larger travel of the dose dial sleeve, the user may better perceive smaller changes in the dose during the dose setting process. *See* EX1015, 1:33–57

Ex. 1011 ¶¶ 193–195.

Patent Owner raises three arguments regarding the above-recited limitation of claim 11. First, Patent Owner reiterates the argument discussed above—Burroughs purportedly fails to disclose or render obvious a dose dial sleeve with a helical groove. PO Resp. 39. Thus, Patent Owner contends Burroughs cannot disclose or render obvious a first lead of said helical groove. We address this argument above and determine that Petitioner’s position was persuasive on the complete record before us. *See supra* § II.C.3.a.vi.

Second, Patent Owner contends that “[e]ven if Burroughs did disclose or render obvious a helical groove of the dose dial sleeve, which it does not, Burroughs does not disclose that the lead of such a groove is different from

the second lead of the drive sleeve.” PO Resp. 39. Patent Owner asserts that “Petitioner admits Burroughs is silent as to the leads of the dose dial sleeve and drive sleeve. . . . Thus, there is no dispute that Burroughs does not disclose this limitation.” *Id.* (citing Pet. 39; Ex. 1011 ¶ 192; Ex. 2107 ¶ 196).

Third, Patent Owner contends Burroughs does not render obvious the different lead recitation of claim 11. PO Resp. 40–43. Patent Owner asserts “Petitioner fails to establish a credible reason to make the lead of the dose dial sleeve threads 110 and 112 different from the lead of the helical thread 198 on the nut 36.” *Id.* at 40. In particular, Patent Owner contends that Mr. Leinsing’s reliance upon Exhibit 1015²⁷ is “inapposite, as it describes difficulties in perceiving small movements of the *injector button* on a pen injector during the *injection process*, not movements of a dosage dial during the process of setting a dose.” *Id.* (citing Moller ¶ 5). Patent Owner asserts that Dr. Slocum testifies that one of ordinary skill would not look to such teaching because it would not be applicable to a dose dialing mechanism that operates in a substantially different way. *Id.* at 41 (citing Ex. 2107 ¶ 200). Additionally, Patent Owner contends that Burroughs “already provides a means for users to perceive small changes in the dose during the dose setting process” because, when the dial mechanism is rotated, an audible “click” sound is generated indicating that an additional unit of dosage has been dialed. PO Resp. 41–42 (citing Ex. 1013, 10:38–47; Ex. 2107 ¶ 201). And, Patent Owner also points to lens 25, which allows a

²⁷ U.S. Patent Application Pub. No. US 2002/0052578 A1, published May 2, 2002 (“Moller”).

numeral to be seen by the user that indicates the selected dose. *Id.* at 42 (citing Ex. 1013, 10:5–14, 10:48–49; Ex. 2107 ¶ 201).

Further, Patent Owner asserts that “there is no evidence that the mechanism provided by Burroughs was ineffective or suffered from problems,” such that one of ordinary skill would seek to make modifications to perceive small changes in the dose-setting process. *Id.* at 42 (citing Ex. 2107 ¶ 201). Thus, Patent Owner contends Petitioner fails to identify any motivation to make the modifications proposed. *Id.* at 42–43. Lastly, to the extent Petitioner relies upon design choice, Patent Owner contends “[t]he mere fact that threads with different leads were a design choice that was known to a [person of ordinary skill] does not establish obviousness.” *Id.* at 43 (citing *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 n.4 (Fed. Cir. 2018)).

In its Reply, Petitioner contends that Burroughs is silent as to whether the leads are the same or different. Pet. Reply 9. Thus, Petitioner asserts that one of ordinary skill would have understood that either choice—using the same lead or different leads—was available. *Id.* (citing Pet. 39–40 (citing Ex. 1011 ¶ 194)). Additionally, Petitioner argues that Patent Owner has not identified any criticality for choosing different leads. *Id.* (citing *In re Dillon*, 919 F.2d 688, 695 (Fed. Cir. 1990) (en banc); *Sud-Chemie Inc. v. Multisorb Techs. Inc.*, 554 F.3d 1001, 1004–05 (Fed. Cir. 2009)).

Petitioner also contends that the written description portion of the ’044 patent Specification does not indicate any criticality to the different leads limitation and that the requirement of different leads is only recited in the claim. Pet. Reply 10. Further, Petitioner explains that Mr. Leinsing did not cite Moller “as another reason to modify: he was just offering a simple

illustration that a larger travel (from the larger lead) in the dose-dial sleeve is one way to improve user perception of small dialing changes.” *Id.* at 10–11 (citing Ex. 1095 ¶¶ 53–56). And, Petitioner asserts that Dr. Slocum does not dispute Mr. Leinsing’s testimony regarding differences in axial travel during dose-dial setting. *Id.* at 11 (citing Ex. 1095 ¶¶ 56–59).

In its Sur-reply, Patent Owner reiterates that Petitioner does not provide a reason to implement Burroughs using different leads. PO Sur-reply 12. Additionally, Patent Owner points to Petitioner’s statement, in its Reply, that Petitioner does not rely on Moller as a reason to modify Burroughs, which “undercut[s] [Petitioner’s] obviousness theory.” *Id.* at 13. And, Patent Owner repeats that one of ordinary skill would not have been motivated to modify Burroughs because Burroughs “provide[s] features that solved any problems with perceiving movements of the dose dial.” *Id.* (citing Ex. 2107 ¶ 201; PO Resp. 41–43).

First, it is undisputed that Burroughs does not state that the leads are the same or different. It is also undisputed that the ’044 patent Specification provides no evidence of criticality directed toward the claimed different leads limitation.²⁸ Rather, the evidence set forth above provides support for finding that Burroughs renders obvious leads that are the same as well as leads that are different. In particular, there is no evidence or argument that

²⁸ Patent Owner does not argue that different leads are critical to the invention recited in claim 11.

Burroughs's device would only work or work as intended (i.e., as described) if the leads are the same.²⁹

Second, Petitioner, via Mr. Leinsing's testimony, provides a reason, with rational underpinning, as to why one of ordinary skill in the art would have formed Burroughs's device with different leads (to alter the distance of travel thereby enabling users to better perceive smaller changes in the dose during dose setting). That Burroughs includes other means of enabling users to perceive changes in the dose during dose setting (as identified by Patent Owner and Dr. Slocum) does not detract from the reason provided by Petitioner and Mr. Leinsing. Further, we need not rely upon Moller to support Mr. Leinsing's testimony because (a) it is grounded in logic well within the knowledge of one of ordinary skill in the art and (b) Patent Owner does not dispute Petitioner's argument that employing different leads would alter the distance traveled.³⁰ We also find that Petitioner establishes sufficiently that one of ordinary skill in the art would have had a reasonable expectation of success that employing threads with different leads would lead to the predictable result of altering the distance traveled. We weigh the evidence of record as to the full scope of claim 11 below. *See infra* § II.C.5.

b. Dependent Claims 14, 15, 18, and 19

Claims 14, 15, 18, and 19 ultimately depend from claim 11. Petitioner contends that Burroughs teaches or renders obvious the additional

²⁹ In light of the facts presented here, we find that it is not accurate to characterize Petitioner's argument as proposing a *modification* to Burroughs. Rather, in the specific context presented, Burroughs equally supports employing threads with the same as well as different leads.

³⁰ Because we do not rely upon Moller, we need not determine whether Moller's explicit teaching would apply directly to Burroughs.

limitations recited in these claims. Pet. 42–44 (claims 14 and 15), 44–47 (claim 18), 47–48 (claim 19). Petitioner relies upon Mr. Leinsing’s declaration testimony in support of its contentions regarding these claims. *See id.*

Patent Owner does not raise an argument directed to the additional limitations recited expressly by these dependent claims, relying instead on its arguments directed to independent claim 11. *See generally* PO Resp.; *see also* Pet. Reply 1 (noting that Patent Owner only argues claim 11 leaving the remaining claims to stand or fall therewith).

We have reviewed Petitioner’s argument and evidence cited in support thereof, which we expressly adopt. *See* Pet. 42–48. Based on the reasons set forth by Petitioner and the evidence in support thereof, *see id.*, we find that Petitioner has shown that Burroughs teaches the additional limitations recited in claims 14, 15, 18, and 19.³¹

4. *Objective Indicia of Nonobviousness*

Neither party presents evidence of objective indicia of nonobviousness. *See* Tr. 83:20–23 (counsel for Patent Owner confirming during the oral hearing that Patent Owner does not rely upon objective indicia of nonobviousness in this *inter partes* review).

³¹ Claims 14 and 15 recite a “clicker.” As we stated *supra*, we decline to opine on whether the term “clicker” invokes 35 U.S.C. § 112, ¶ 6. Claim 19 recites that the main housing further comprises a helical rib adapted to be seated in the helical groove on the outer surface of the dose dial sleeve. Petitioner relies upon the same modification discussed in the context of Petitioner’s analysis of the dose dial sleeve and helical groove limitation of claim 11. Pet. 47–48.

5. *Weighing the Graham Factors*

“Once all relevant facts are found, the ultimate legal determination [of obviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan.” *Arctic Cat*, 876 F.3d at 1361. On balance, considering the record presently before us, we determine that Petitioner has shown, by a preponderance of the evidence, that Burroughs would have rendered the subject matter of claims 11, 14, 15, 18, and 19 obvious to one of ordinary skill in the art at the time of the invention.

D. *Petitioner’s Motion to Exclude*

Petitioner filed a motion to exclude Exhibits 2001–2023, 2100–2107, 2111–2153, 2158–2201, 2203–2212, 2214–2218, 2223–2225, and the redirect testimony in Exhibit 1054. Petitioner, as the “moving party,” “has the burden of proof to establish that it is entitled to the requested relief.” 37 C.F.R. § 42.20 (2017).

1. *Exhibits 2001–2011 and 2016–2023*

Petitioner moves to exclude Exhibits 2001–2011 and 2016–2023 pursuant to Federal Rules of Evidence (“FRE”) 402 and 403 because purportedly they are not relevant to any contested issue in this proceeding and risk confusing the issues. Mot. 1–4. Patent Owner responds that these exhibits “were offered to show information that was relevant to § 325(d) issues raised during the preliminary stage of this proceeding.” Opp. 1. Patent Owner asserts that these exhibits do not lack relevance, have no risk of confusing the issues, and should therefore remain in the record. *Id.* at 2. In its Motion Reply, Petitioner contends that Patent Owner acknowledges that these exhibits no longer have relevance to the issues in this proceeding

and should therefore be excluded. Mot. Reply 1. Petitioner asserts that, if not excluded, “their admissibility should be limited to the purpose for which they were submitted” pursuant to FRE 105. *Id.*

Petitioner’s only basis to exclude these exhibits is because they were offered during the pre-institution phase of this proceeding concerning only our discretion to deny institution, not the merits of the asserted grounds of unpatentability, and are therefore no longer relevant. Petitioner does not direct our attention to any prior Board decision that granted a motion to exclude exhibits that were relevant only to the pre-institution phase of an *inter partes* review. And, we do not agree that we should do so here. In an *inter partes* review, which is akin to a bench trial, there is little risk of confusion. Additionally, simply because an exhibit is relevant to the pre-institution stage and not necessarily the post-institution stage of an *inter partes* review proceeding, does not justify excluding it from the record. To the contrary, the record contains other documents that may similarly be characterized as such, e.g., a patent owner’s preliminary response. Therefore, we are not persuaded to exclude the exhibits or expressly limit their purpose pursuant to FRE 105 and Petitioner’s Motion is denied with respect to these exhibits.

2. *Exhibit 2012*

Exhibit 2012 is an animation purportedly showing the operation of an embodiment of the injection pen described in the ’044 patent. Mot. 3. Petitioner contends that Exhibit 2012 should be excluded under FRE 801–804 as hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions. *Id.* Patent Owner contends that FRE 703 permits experts to rely upon hearsay if reasonable to do so in the

expert's field. Opp. 2. Patent Owner asserts that Exhibit 2012 is identical to Exhibit 2117, which Dr. Slocum relies upon in his declaration. *Id.* (citing Ex. 2107 ¶ 65). Patent Owner asserts that “[c]omputer models such as shown in EX2012 are used and relied upon in mechanical engineering” and because it was reasonable for Dr. Slocum to rely upon it for his analysis, it should not be excluded. *Id.* In its Motion Reply, Petitioner contends that although an expert may rely upon hearsay in forming an opinion, pursuant to FRE 703, that does not make the evidence admissible in trial. Mot. Reply 1–2. Petitioner asserts that if the exhibit is not excluded, it should be limited to the purpose for which it was submitted—showing the basis for Dr. Slocum's expert testimony—and should not be used for any other purpose. *Id.* at 2 (citing FRE 105).

Patent Owner does not dispute that Exhibit 2012 constitutes hearsay. Petitioner does not dispute that Dr. Slocum was permitted to rely upon it in formulating his opinions. Patent Owner does not contend that Dr. Slocum relied upon Exhibit 2012; rather, Patent Owner asserts Dr. Slocum relied upon Exhibit 2117, which Patent Owner asserts is identical to Exhibit 2012. Patent Owner does not explain why it submitted two identical animations as exhibits or why it needs both Exhibit 2012 and Exhibit 2117 in the record when Dr. Slocum opined regarding Exhibit 2117. Nonetheless, to the extent Exhibit 2012 was cited during this proceeding, we do not wish to disturb the record by excluding it as a duplicate. Accordingly, although Petitioner's Motion is denied, we agree that the use of Exhibit 2012 should be, and hereby is, limited to the purpose of showing the basis for Dr. Slocum's testimony.

3. *Exhibits 2013–2015*

Exhibits 2013–2015 are excerpts from three dictionaries offered by Patent Owner to support its definition of “helical” in its Preliminary Response. Paper 23, 26–28. Petitioner seeks to exclude Exhibits 2013–2015 pursuant to FRE 801–804 because Petitioner contends the definitions are offered for the truth of their content without satisfying any of the hearsay exceptions. Mot. 3. Patent Owner contends that “[t]hese exhibits were offered to show how a person of ordinary skill in the art would have understood the term ‘helical,’ and thus are not hearsay because they were offered to show the effect on the reader and/or the belief of the author, not for the truth of the matter asserted.” Opp. 2–3. Petitioner does not address these exhibits in its Motion Reply.

As anyone who practices patent law understands, dictionary definitions are routinely considered extrinsic evidence that may shed light on the plain and ordinary meaning of a claim term. *See, e.g., Phillips*, 415 F.3d at 1318 (“Within the class of extrinsic evidence, the court has observed that dictionaries . . . can be useful in claim construction.”) (citation omitted). Additionally, for the reasons explained by Patent Owner, notably that the definitions were not offered for the truth of the matter asserted, we do not consider Exhibits 2013–2015 hearsay. Accordingly, Petitioner’s Motion is denied with respect to Exhibits 2013–2015.

4. *Exhibits 2100–2102, 2104–2106, 2111–2153,
2158–2201, 2203–2212, 2214–2218, and 2225*

Petitioner contends the above-listed exhibits should be excluded pursuant to FRE 402 and 403 “because they were not discussed in the response, cannot be relevant to it, and consequently serve only to confuse and create prejudice through belated surprise.” Mot. 6. Patent Owner

asserts that Exhibits 2163 and 2165 were cited in the Patent Owner Response. Opp. 4 (citing PO Resp. 11–13, 23, 28, 33, 37, 45). Patent Owner contends that Exhibits 2100–2102 and 2104–2106 are exhibits to the deposition of Mr. Leinsing and are relevant because they “provide the necessary context for Mr. Leinsing’s cross-examination, which Petitioner has not sought to exclude.” *Id.* Additionally, Patent Owner asserts that Dr. Slocum “considered and reasonably relied upon [each of these exhibits] in forming his opinions regarding the validity of the challenged patent and thus should be admitted under FRE 703.” *Id.* Petitioner points to several of these exhibits³² in responding to Patent Owner’s argument, contending that they do not relate to any claimed feature and are directed to Patent Owner’s argument regarding objective indicia of nonobviousness. Mot. Reply 4–5.

Patent Owner filed the same declaration by Dr. Slocum in nine related *inter partes* reviews, including this proceeding. *See* Ex. 2107, caption. Patent Owner does not rely upon objective indicia of nonobviousness in its Patent Owner Response in this case, but does rely upon such evidence in its responses in several of the other cases. *See* Tr. 83:20–23 (counsel for Patent Owner confirming during the oral hearing that Patent Owner does not rely upon objective indicia of nonobviousness in this *inter partes* review). Thus, it is likely many of these exhibits are not relevant to *this proceeding*. Nonetheless, it is not an efficient use of resources to parse through Dr. Slocum’s reliance upon each of these exhibits to determine whether they apply solely to the issue of objective indicia or have a broader applicability.

³² Specifically, Petitioner points to Exhibits 2116, 2117, 2121, 2123, 2126, 2128, 2136, 2137, 2142–2144, 2175, 2184, 2185, and 2201. Mot. Reply 4–5.

Additionally, the sole basis argued in Petitioner’s Motion for exclusion—that the exhibits were not cited in Patent Owner’s Response—is not, in and of itself, dispositive as to whether an exhibit should be excluded.

Accordingly, Petitioner has not satisfied its burden to show that these exhibits should be excluded.

5. *Exhibit 2103*

Exhibit 2103 consists of hand-drawn annotations made by Mr. Leinsing during his deposition in response to questions pertaining to Petitioner’s proposed modifications to Burroughs’s device. Mot. 6; Opp. 7. Petitioner contends that Patent Owner’s use of Exhibit 2103 “lacks relevance, risks confusing the issues, is misleading, and is prejudicial.” Mot. 6–7. Petitioner complains that the exhibit “is offered to establish an actual modification purported to be embodied by the annotations.” *Id.* at 6. Patent Owner contends that the exhibit is relevant to Mr. Leinsing’s opinions regarding modifying Burroughs, which is one of the central issues in this proceeding. Opp. 5 (citing Ex. 2163, 189:3–15). Petitioner does not address Patent Owner’s arguments in its Motion Reply.

We agree with Patent Owner that Exhibit 2103 is relevant to the proceeding for the reason explained by Patent Owner. Additionally, Petitioner’s argument does not provide any explanation as to why the exhibit risks confusing the issues, is misleading, or is prejudicial. Accordingly, Petitioner’s Motion is denied with respect to Exhibit 2103.

6. *Exhibits 2117, 2147–2152, 2162, 2167, 2168, 2206, 2207, 2211, 2215–2218*³³

Petitioner contends the above-listed exhibits are animations “offered to show animated operations of prior art and non-prior art injection pens” and should be excluded pursuant to FRE 801–804 “because they are offered for the truth of their contents without satisfying any of the hearsay exceptions.” Mot. 8. Patent Owner provides the same response here as it did with respect to Petitioner’s challenge to Exhibit 2012. Opp. 13. Namely, Dr. Slocum relied upon each in formulating his opinions. *Id.* Petitioner addresses these exhibits along with Exhibit 2012 in its Motion Reply, contending that if they are not excluded, they should be limited to the purpose for which they were submitted—showing the basis for Dr. Slocum’s expert testimony—and not used for any other purpose pursuant to FRE 105. Mot. Reply 1–2.

For the reasons explained in our discussion of Exhibit 2012, we do not exclude these exhibits, but we do agree with Petitioner that their use shall be limited to showing the basis for Dr. Slocum’s testimony.

7. *Exhibits 2223 and 2224*

Petitioner contends that Exhibits 2223 and 2224 are offered to show objective indicia of nonobviousness, but “[t]hey are hearsay without exception, lack authentication, and are unreasonably prejudicial because they are cited for a new purpose.” Mot. 8. Patent Owner contends that these

³³ Petitioner’s challenge to the admissibility of these exhibits pursuant to FRE 402 and 403 is discussed above. This section is directed to Petitioner’s challenge based on FRE 801–804, which Petitioner discusses separately. *Compare* Mot. 6 (addressing FRE 402 and 403), *with id.* at 8 (addressing FRE 801–804).

exhibits are relevant to objective indicia of nonobviousness and that Exhibit 2224 pertains to an exhibit cited in two declarations directed to the same issue. Opp. 13–14.

Aside from the obvious burden of determining which exhibits are applicable to which of the specific *inter partes* reviews involving the parties and related patents, it is not clear to us why the parties filed documents and exhibits pertaining to objective indicia of nonobviousness *in this proceeding* when Patent Owner does not rely upon objective indicia of nonobviousness, as discussed above. Thus, these exhibits have no relevance to the matters before us. Nonetheless, we are not inclined to exclude exhibits in a piecemeal fashion because that would undoubtedly leave other exhibits similarly situated in the record. *See, e.g.*, Ex. 1060 (Declaration of DeForest McDuff, Ph.D., which was filed by Petitioner in this proceeding even though this proceeding is not identified in the caption of the exhibit and the declaration is directed solely to responding to Patent Owner’s contentions regarding objective indicia of nonobviousness in other related proceedings). Accordingly, Petitioner’s Motion is denied as to Exhibits 2223 and 2224.

8. *Exhibits 1054 and 2107*

Petitioner seeks to exclude Dr. Slocum’s entire declaration (Ex. 2107) and the deposition redirect examination of Dr. Slocum (Ex. 1054, 391–406) pursuant to FRE 702, 703, and 705. Mot. 4–6, 7–8. Petitioner raises three primary reasons. First, that Dr. Slocum did not have personal knowledge of injection pens or the industry during the relevant time period. *Id.* at 4. Second, that Dr. Slocum relied upon Mr. Veasey, one of the named inventors of the ’044 patent, for certain data and a model used for various calculations in Dr. Slocum’s declaration. *Id.* at 4–6. And, third, that

Exhibit 2017 should be excluded for the additional reason that it “does not provide sufficient facts or data, is not the product of reliable principles and methods, and has not applied the proper principles to the facts of this proceeding.” *Id.* at 7. As an example, Petitioner contends that Appendices A through F “do not set forth the principles used nor do they demonstrate the calculations used in generating the spreadsheets” and, thus, “should be excluded for failing to disclose the underlying facts and data, and failing to set forth the bases of Dr. Slocum’s opinions.” *Id.* at 7–8.

Patent Owner responds to each of Petitioner’s challenges. First, with respect to Dr. Slocum’s personal knowledge, Patent Owner correctly observes that neither party’s proposed definition of the ordinary level of skill in the art requires specific knowledge of, or experience with, pen injectors. Opp. 6 (citing Ex. 1011 ¶ 106; Ex. 2107 ¶ 102). Additionally, Patent Owner contends that there is no requirement that an expert have personal knowledge of the subject matter upon which the expert’s opinion is based at the time of the invention. Opp. 7. Further, Patent Owner asserts that Dr. Slocum acquired the relevant knowledge by “(i) research[ing] the prior art, (ii) canvass[ing] literature on pre-critical date pen injectors, design considerations, and design standards, and (iii) convers[ing] with those in the industry (*i.e.*, Mr. Veasey and Dr. Goland).” *Id.* at 8 (citing Ex. 2107 ¶¶ 25–61). Patent Owner also contends Dr. Slocum documented his opinions with facts and data. *Id.*

Second, Patent Owner asserts that Petitioner’s criticism of Dr. Slocum’s reliance upon the information and model obtained from Mr. Veasey are unfounded. In particular, Patent Owner asserts that Dr. Slocum performed his own investigation and research into design

considerations and the state of the art, as documented in his declaration. *Id.* at 9 (citing Ex. 2107 ¶¶ 25–61). Patent Owner notes that Petitioner does not assert that any of the design considerations noted by Dr. Slocum are incorrect. Patent Owner raises additional arguments regarding the specific discussions between Dr. Slocum and Mr. Veasey, but those arguments appear directed to a model and data regarding issues raised in several of the related *inter partes* reviews, not this specific proceeding. *See id.* at 9–11 (discussing measurements of the FlexPen and embodiments in another reference not at issue in this proceeding).

Third, Patent Owner contends that Petitioner ignores that Patent Owner “served as supplemental evidence the native spreadsheets that specify [the] principles and calculations” set forth in Appendices A through F. Opp. 12 (citing Ex. 2226). Patent Owner further asserts that “the measurements provided by Mr. Veasey are corroborated, unrebutted, and reliable.” *Id.*

Petitioner’s Motion Reply reiterates Petitioner’s contentions regarding Dr. Slocum, including that even if he could be an expert, he “objectively failed to act as an expert in this case.” Mot. Reply 2. Petitioner also challenges Dr. Slocum’s acceptance of Mr. Veasey’s data “without question,” contending that Dr. Slocum only did so because “he had no relevant knowledge or experience.” *Id.* at 4. Petitioner also asserts that Patent Owner hid Mr. Veasey’s involvement in Dr. Slocum’s testimony precluding Petitioner from cross-examining Mr. Veasey. *Id.*

To begin, Dr. Slocum is undisputedly an expert in mechanical engineering with knowledge and experience *beyond* the level of ordinary skill in the art as the parties have proposed and we have adopted. *See*

Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1363 (Fed. Cir. 2008) (noting that “[a] witness possessing merely ordinary skill will often be qualified to present expert testimony both in patent trials and more generally”) (citations omitted). Additionally, as both parties acknowledge, there is no requirement that an expert have personal knowledge of the technology during the specific relevant time period in order to qualify as an expert. In this regard, we find that Patent Owner and Dr. Slocum have established sufficient support, as detailed above, as to how he acquired knowledge of the specific technology at issue—the mechanical operation and design of injection pens. Further, Dr. Slocum’s reliance upon other individuals, including Mr. Veasey, to provide information upon which he based his opinions does not render him unqualified to offer an expert opinion. To the extent the credibility of any of the individuals upon which Dr. Slocum relied may be in doubt, e.g., Mr. Veasey’s potential bias as a named inventor on the ’044 patent, those issues are the proper subject of cross-examination, go to the weight accorded the evidence, and do not justify excluding Dr. Slocum’s testimony on the facts presented here. And, to the extent Petitioner questions the data or model provided by Mr. Veasey, the proper recourse is to probe the bases for such during cross-examination, as discussed further below. Therefore, Petitioner has not shown that Dr. Slocum should be disqualified as an expert in this proceeding. Accordingly, Petitioner’s Motion as directed to the redirect examination testimony of Exhibit 1054 and Dr. Slocum’s declaration (Ex. 2107) is denied.

Additionally, it is not clear that the parties’ arguments regarding Dr. Slocum’s reliance upon Mr. Veasey are applicable to this proceeding. In

particular, much of the discussion regards data and a model that are not relied upon here. Mr. Veasey's involvement was discussed extensively during a conference call applicable to several related cases, but the parties did not deem that discussion relevant to this proceeding and the transcript of that call is not of record in this case even though it is of record in several of the related cases. *See, e.g., Mylan Pharm. Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2018-01676, Ex. 1108 (Nov. 22, 2019) (Transcript of Nov. 18, 2019, Telephonic Conference). Nonetheless, for completeness, we find that Petitioner's assertions that Patent Owner hid Mr. Veasey's involvement are unfounded. In particular, Dr. Slocum acknowledged in Appendix B of his declaration that the "[i]nput values were provided by Mr. Robert Veasey of DCA Engineering." Ex. 2107, App. B at 2. Thus, we find that Petitioner could have, but did not, seek to depose Mr. Veasey and therefore Petitioner's arguments regarding Mr. Veasey's involvement do not justify excluding Dr. Slocum's declaration (Ex. 2107) or redirect testimony (Ex. 1054).

III. SUMMARY³⁴

For the reasons discussed above, Petitioner has demonstrated, by a preponderance of the evidence, that claims 11, 14, 15, 18, and 19 would

³⁴ 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. 16,654 (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).

have been obvious over Burroughs. Additionally, although we deny Petitioner's Motion to Exclude, we limit the use of Exhibits 2012, 2117, 2147–2152, 2162, 2167, 2168, 2206, 2207, 2211, and 2215–2218 as described above.

The chart below summarizes our conclusions regarding the challenged claims.

Claims Challenged	35 U.S.C. §	Reference	Claims Shown Unpatentable	Claims Not Shown Unpatentable
11, 14, 15, 18, 19	103(a)	Burroughs	11, 14, 15, 18, 19	
Overall Outcome			11, 14, 15, 18, 19	

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 11, 14, 15, 18, and 19 of U.S. Patent No. 8,603,044 B2 are determined to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 71) is denied; and

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

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