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Paper 83
Entered: May 29, 2020

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.

IPR2019-00122
Patent 8,992,486 B2[1]

Before LYNNE H. BROWNE, HYUN J. JUNG, and JAMES A. TARTAL, *Administrative Patent Judges*.

BROWNE, *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 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38– 40 of U.S. Patent No. 8,992,486 B2 (Ex. 1003, "the '486 patent"). Sanofi-Aventis Deutschland GmbH ("Patent Owner") filed a Preliminary Response (Paper 9). With prior authorization, Mylan filed a Reply to Patent Owner's Preliminary Response (Paper 14) 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 16). Also with prior authorization, Mylan filed a Motion to Correct the Petition (Paper 7). We granted Mylan's Motion to Correct (Paper 11), resulting in a citation change on page 28 of the Petition. Applying the standard set forth in 35 U.S.C. § 314(a), we instituted an *inter partes* review of all challenged claims. Paper 19 ("Inst. Dec.").

After institution, Pfizer Inc. ("Pfizer") filed (1) a petition challenging the same claims of the '486 patent on the same grounds asserted by Mylan and instituted in this case and (2) a motion for joinder requesting that Pfizer be joined as a petitioner in this case. *Pfizer Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-00982, 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. *Pfizer*, Paper 12 (Aug. 15, 2019).[2]

[2] This decision is entered in the record in this case as Paper 43.

Patent Owner filed a Patent Owner Response (Paper 29, "PO Resp."), Petitioner[3] filed a Reply to Patent Owner's Response (Paper 45, "Pet. Reply"), and Patent Owner filed a Sur-reply (Paper 57, "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 55), and Petitioner filed a Response to Patent Owner's List (Paper 56). Petitioner also filed a Motion to Exclude (Paper 63, "Mot."), Patent Owner filed an Opposition to Petitioner's Motion (Paper 64, "Opp."), and Petitioner filed a Reply in support of its Motion (Paper 69, "Motion Reply" or "Mot. Reply"). Additionally, Patent Owner filed Observations on the Cross-Examination of Mr. Karl Leinsing (Paper 67) and Petitioner filed a Response to Patent Owner's Observations (Paper 70). And, Petitioner filed Observations Regarding the Testimony of Alexander Slocum, Ph.D. (Paper 68), to which Patent Owner filed a Response (Paper 70). An oral hearing was held on January 15, 2020, and a copy of the transcript was entered in the record. Paper 77 ("Tr.").

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)

[3] We refer to Mylan and Pfizer, collectively, as "Petitioner."

(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 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38– 40 of the '486 patent are unpatentable. Additionally, for the reasons explained herein, we deny Petitioner's motion to exclude.

B. Related Proceedings

The parties indicate that the '486 patent has been asserted in *Sanofi-Aventis U.S. LLC, Sanofi-Aventis Deutschland GmbH, Sanofi Winthrop Industrie v. Mylan GmbH, Biocon Ltd., Biocon Research Ltd., Biocon Sdn. Bhd. and Biocon S.A.*, Case No. 2-17-cv-09105-SRC-CLW, U.S. District Court for New Jersey; *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105-SRC-CLW (D.N.J.); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812-RGA-MPT (D. Del.); and *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00113-RGA-MPT (D. Del.). Pet. 1; Paper 5, 2; Paper 8, 2; Exs. 1029, 1030.

The parties also state that related patents are challenged in Cases IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2019-01684, and IPR2018-01696. Pet. 2; Paper 5, 3; Paper 8, 2–3.

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. Instituted Ground of Unpatentability

Petitioner asserts claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38– 40of the '486 patent are unpatentable as set forth in the chart below:

Claims Challenged	35 U.S.C. §	Reference
1–6, 12–18, 20, 23, 26–30, 32, 33, 36, 38–40	103(a)	Burroughs[4]

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. 1048).

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 '486 Patent

The '486 patent issued March 31, 2015, from an application filed June 4, 2013, which is the latest application in a series of continuation applications, the first of which was filed on March 2, 2004. Ex. 1003, [22],

[4] Exhibit 1013 (US 6,221,046 B1, iss. Apr. 24, 2001 ("Burroughs")).

[45], [63], 1:6–11. The '486 patent also claims priority to a foreign application filed on March 3, 2003. *Id.* at [30], 1:12–14.

The '486 patent "relates to pen-type injectors . . . where a user may set the dose." Ex. 1001, 1:20–24. Figures 1 and 2 of the '486 patent are reproduced below.

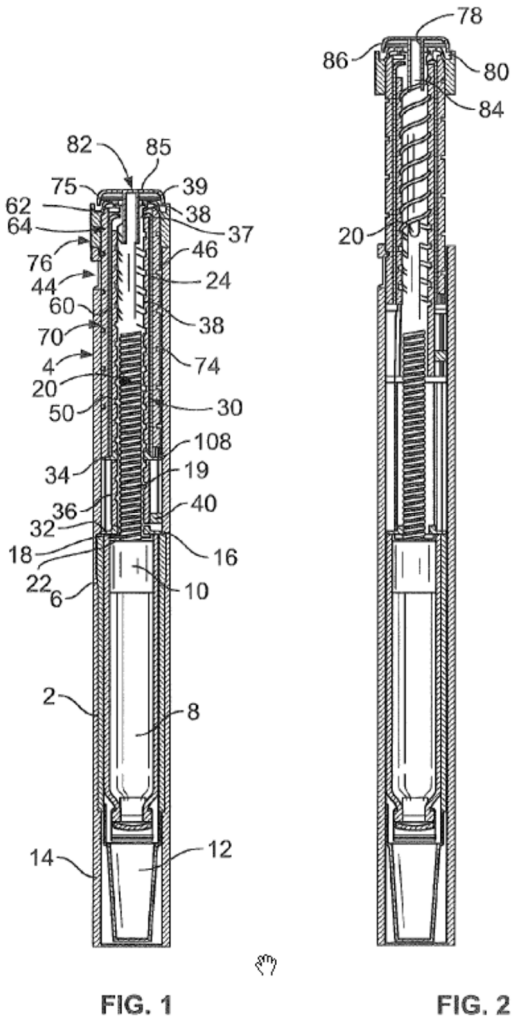

FIG. 1 FIG. 2

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 . . . in a second, maximum first dose dialed, position." Ex. 1001, 2:53– 57. The injector includes first cartridge retaining part 2 and main

housing part 4.[5] *Id.* at 3:27–28. Insert 16 is at a first end of main housing 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.

Piston rod 20 also includes pressure foot 22 that abuts piston 10 of cartridge 8. Ex. 1001, 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. Ex. 1001, 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.

A user rotates dose-dial grip 76 to set a dose and to cause dose-dial sleeve 70, clutch 60, and drive sleeve 30 to rotate together out of main housing 4. Ex. 1001, 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.

[5] The ’486 patent refers to “second main housing part 4” and “main housing 4” interchangeably. *Compare* Ex. 1003, 3:28 (“second main housing part 4”) *with id.* at 3:30 (“main housing 4”).

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 6:45–47.

F. Illustrative Claim

The '486 patent has 57 claims, of which Petitioner challenges claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38– 40. Of those, claim 1, reproduced below, is the only independent claim.

> 1. 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;
>
> a dose knob 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 driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, 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 knob, said tubular clutch operatively coupled to said dose knob,
>
> wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

Ex. 1003, 6:59–7:12.

II. ANALYSIS

A petition must show how the construed claims are unpatentable under the statutory ground it identifies. 37 C.F.R. § 42.104(b)(4). Petitioner

bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic*, 800 F.3d at 1378. To prevail, Petitioner must establish the facts supporting its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A. Level of Ordinary Skill in the Art

Petitioner asserts that "a POSA at the relevant time would have had at least a bachelor's degree in mechanical engineering, or an equivalent degree, and practical design experience." Pet. 13 (citing Ex. 1011 ¶ 106). According to Petitioner, "[t]he POSA also 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." *Id.* ¶¶ 104–107. Patent Owner proposes a level of ordinary skill that "is defined by a person 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." PO Resp. 8. Patent Owner contends that "Petitioner's proposed level of ordinary skill should [not] be adopted because the level of ordinary skill proposed by the Petitioner is inconsistent across IPR Nos. 2018-01670, -01675, -01676, -01678, -01679, -01680, -01682, -01684, and 2019-00122." *Id.* Patent Owner admits, however, that "the slight differences between Patent Owner and Petitioner's level of ordinary skill do not affect the arguments made below." *Id.* at 9. We agree with Petitioner's definition of the level of ordinary skill in the art as it is consistent with the level of ordinary skill reflected in the '486 patent and prior art of record. Further, we

agree with Patent Owner that "the slight differences between Patent Owner and Petitioner's level of ordinary skill do not affect the arguments" made by the parties such that our analysis below would not change under either party's proposed level of ordinary skill. *Id.*

B. Claim Construction

In this *inter partes* review, claim terms are interpreted according to their broadest reasonable construction in light of the Specification of the '486 patent. 37 C.F.R. § 42.100(b) (2018); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard).[6]

Petitioner provides interpretations of seven terms that were proffered by Patent Owner in related litigation—"driver," "main housing," "piston rod," "thread/threaded/threading," "tubular clutch," "clicker," and "insert." Pet. 14 (citing Ex. 1019, 20, 21, 24, 25, 27, 29). Petitioner also explains it proffered means-plus-function interpretations for "clutch," "clicker," and "insert" in related litigation and reiterates those interpretations here. *Id.* at 15 (citing Ex. 1028 (Mylan's Preliminary Claim Constructions in *Sanofi-Aventis U.S. LLC v. Mylan N.V.*, No. 17-cv-09105-SRC-CLW (D.N.J. Sept. 5, 2018) ("*Sanofi*")), 101–106, 112–116). Petitioner states that "[t]he

[6] On October 11, 2018, the Office revised its rules to harmonize the Board's claim construction standard with that used in federal district court. Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (now codified at 37 C.F.R. § 42.100(b) (2019)). This rule change, however, applies to petitions filed on or after November 13, 2018, so the revised claim construction standard does not apply to this proceeding. *Id.*; *see* Paper 8, 1 (according filing date of September 10, 2018 to the Petition).

ground presented below relies on the ordinary and customary meaning of the claim terms as they would be understood by a POSA." *Id.* at 16. Petitioner states further that "[t]he ground [presented] addresses also the 'clutch,' 'clicker,' and 'insert' limitations to the extent that those terms may be construed as means-plus-function limitations." *Id*. Patent Owner contends that "it is only necessary to address the construction of the term 'tubular clutch.'" PO Resp. 9. Patent Owner contends further that "clicker" and "insert" should not be construed as means-plus-function limitations. *Id.*

Petitioner contends "tubular clutch" is "[a] tubular structure that couples and decouples a moveable component from another component." Pet. 14 (citing Ex. 1019, 21). Petitioner acknowledges that in related litigation, "Mylan proffered a preliminary means-plus-function construction for '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.* at 15 (citing Ex. 1028, 106). In that case, Petitioner identified the structure in the '486 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. Patent Owner asserts that this is the construction adopted by the district court in *Sanofi*.[7] *Id.* at 10–11. Patent Owner

[7] "Tubular clutch" was construed by two different district courts. In *Sanofi*, 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

contends that, in construing the term, the district court disagreed with Mylan's proposed construction. *Id.* at 11 (citing Ex. 2165, 12).

Although we agree with the *Sanofi* district court that "tubular clutch" does not invoke § 112, ¶ 6,[8] 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, 795 (Fed. Cir. 1999).

C. Principles of Law

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406

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).

[8] 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).

(2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and, when presented, (4) objective evidence of nonobviousness.[9] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

We analyze the asserted ground of unpatentability in accordance with the above-stated principles.

D. Obviousness of Claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 in View of Burroughs

Petitioner contends that claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 are unpatentable under 35 U.S.C. § 103(a) over Burroughs. Pet. 22–67. Having now considered the evidence in the complete record established during trial, we are persuaded that Petitioner has demonstrated by a preponderance of the evidence that these claims would have been obvious in view of Burroughs. We begin our analysis with a brief overview of the prior art.

1. 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:

[9] Patent Owner provides no such evidence for our consideration. *See generally* PO Resp.

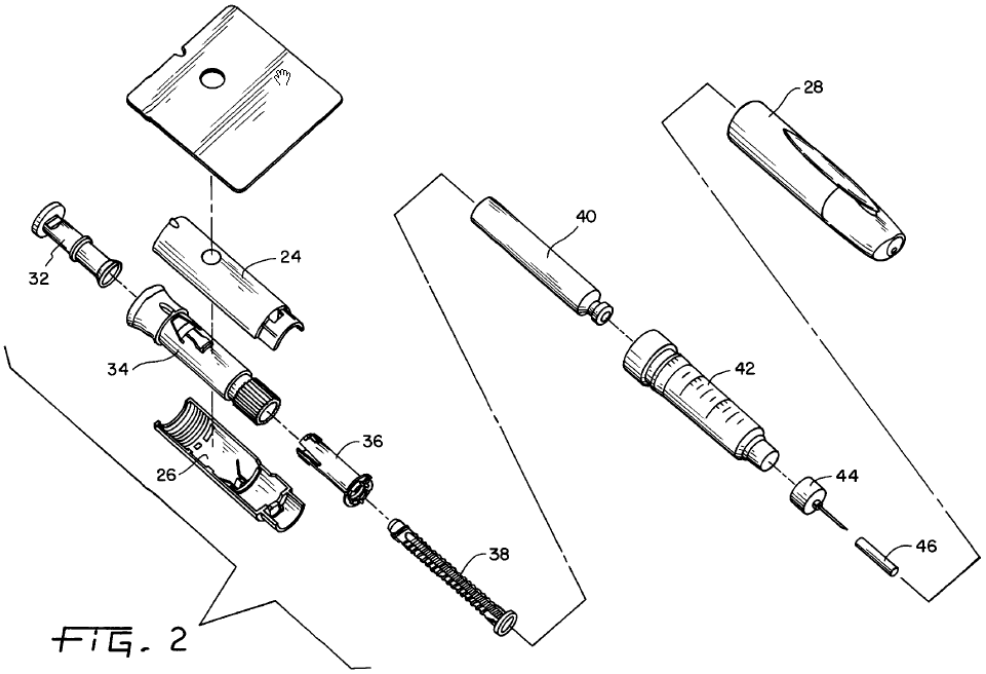

Figure 2 shows an exploded view of injection medication device 20. Ex. 1013, 6:42–43, 7:15–16. Medication device 20 includes mechanism housing 22 made from housing parts 24 and 26, button 32, dial mechanism 34, nut 36, and leadscrew 38 that forms a drive stem. *Id.* at 7:17–18, 7:32–34, 9:12–13.

In medication device 20, dial mechanism 34 engages button 32. Ex. 1013, 8:9–14, Figs. 6, 8. Dial mechanism 34 also includes outwardly extending threads 110, 112 that "enter helical groove 158 during 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. Ex. 1013, 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.

2. Differences Between the Prior Art and the Claims: Reasoning in Support of the Proposed Modifications

Petitioner provides claim charts and arguments with citations to where Burroughs teaches or suggests the elements of the claims and citations to supporting declarant testimony. Pet.22–67.

a. Independent Claim 1

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

Petitioner contends that "[t]o the extent the preamble is limiting, it is taught by Burroughs." Pet. 23. Specifically, Petitioner asserts that Burroughs teaches "an injection medication device 20 having the general appearance of a pen or mechanical pencil. The device comprises a mechanism housing 22 having a first part 24 and a second part 26 (FIG. 2)." *Id.* at 24 (citing Ex. 1013, 7:15–19, Figs. 1–2). Patent Owner does not contest Petitioner's argument that Burroughs teaches the preamble of claim 1. *See*, *generally*, PO Resp.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Burroughs teaches the preamble of claim 1.[10]

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

Petitioner contends that Burroughs teaches "a mechanism housing 22 having a first part 24 and a second part 26 (FIG. 2)." Pet. 24. According to Petitioner, "housing 22 extends from a button-end (referred to as the proximal end) to a needle-end (referred to as the distal end)." *Id.* at 25 (citing Ex. 1013, 7:9–13; Ex. 1001 ¶ 160). Patent Owner does not contest Petitioner's argument that Burroughs teaches this limitation of claim 1. *See, generally*, PO Resp.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Burroughs teaches the preamble of claim 1.[11]

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;

Petitioner contends that Burroughs teaches a "[d]ial mechanism 34 [that] is generally cylindrical in shape and is hollow throughout its axial

[10] We need not determine whether the preamble of claim 1 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 1. *See* Paper 20 (Scheduling Order), 8 ("Patent Owner is cautioned that any arguments for patentability not raised in the response may be deemed waived.").

[11] Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 1. *See* Paper 20, 8.

length." Pet. 25 (citing Ex. 1013, 7:65–67, Figs. 1–2, 6–9). Petitioner contends further that '"[d]ial mechanism 34 further includes a first U-shaped groove 100 (FIG. 6) and a second U-shaped groove 101 (FIG. 8) which form flexible legs 102, 104. Referring to FIG. 9, each leg 102, 104, respectively includes . . . an outwardly extending threads 110, 112.'" *Id.* at 26 (quoting Ex. 1013, 8:24–29, Figs. 6–9). According to Petitioner, '"Housing parts 24 and 26 further form a helical spiral groove 158 and a circumferential surface 160. Circumferential surface 160 includes opening 162 and keyed opening 163 to allow threads 110 and 112 respectively to enter helical groove 158 during the commencement of the dosing process.'" *Id.* at 26–27 (quoting Ex. 1013, 8:63–9:1, 10:31–34, Figs. 3, 5).

Petitioner asserts "[t]hreads 110, 112 are rib-like structures that fit into and move within helical spiral groove 158 of 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." Pet. 27 (citing Ex. 1013, Figs. 6–9; Ex. 1011 ¶¶ 166–167). Relying on Mr. Leinsing's testimony, Petitioner contends that "[t]hreads 110, 112 are spaced apart on opposite sides of dial mechanism 34, so proper engagement of the threads with helical spiral groove 158 requires that they be positioned helically relative to one another, thereby forming a discontinuous helical rib corresponding to the housing's helical groove." *Id.*at 27–28 (citing Ex. 1011 ¶¶ 168–170); *cf.* Ex. 1003, 3:42–44. Thus, Petitioner argues "Burroughs teaches the recited 'dose dial sleeve,' except it discloses a 'helical rib' rather than a 'helical groove.'" *Id.* at 28 (citing Ex. 1011 ¶¶ 170–172).

Petitioner contends that one of ordinary skill in the art "would have considered it routine to implement the helical rib as a helical groove

corresponding to helical threading on the housing." Pet. 28. 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 asserts that one of ordinary skill in the art "would have been familiar with a limited number of interchangeable thread structures and recognized that Burroughs was merely depicting one such option." Pet. 39 (citing Ex. 1011 ¶¶ 189–190). According to Petitioner, "[p]roviding threads 110, 112 as a protruding helical groove rather than as a protruding helical rib would have been apparent to a POSA, and a POSA would have recognized that such groove-to-rib implementation of the threading would be functionally equivalent and largely interchangeable with the depicted rib-to-groove implementation." *Id.* (citing Ex. 1011 ¶¶192–193). Petitioner asserts further that "[s]electing and implementing such threading was a routine task for a POSA 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; Ex. 1011 ¶¶193–196).

In addition, Petitioner contends that one of ordinary skill in the art "would have had a reasonable expectation of success in implementing threads 110, 112 as protruding helical grooves." Pet. 39. According to Petitioner, "[g]rooved threading is a common, well-understood, predictable mechanism . . . and a POSA would have recognized that using a groove rather than a rib to engage corresponding threading on the housing would not change the function or the principle of operation of the mechanism." *Id.* (citing Ex. 1011 ¶168). In view of this assertion, Petitioner argues that a

person of ordinary skill "would have understood that a protruding u-shaped groove would operate in the same manner and provide the same function as the depicted ribs" and "would have had no difficulty implementing this minor variation of the dial mechanism's threading." *Id.* at 39–40 (citing Ex. 1011 ¶¶ 169–170). Thus, Petitioner asserts that "[i]mplementing threads 110, 112 as a groove rather than a rib therefore would have been the use of well-known, familiar elements performing their same, predictable functions." *Id.* (citing Ex. 1011 ¶ 169; *KSR*, 550 U.S. at 417).

Patent Owner raises several arguments in response. First, Patent Owner contends that "Burroughs does not disclose a dose dial sleeve that comprises a 'helical groove configured to engage a threading provided by said main housing.'" PO Resp. 21. As discussed above, Petitioner acknowledges that Burroughs does not disclose this limitation of claim 1, 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. PO Resp. 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 thread[s]' which subsequently engage with a thread on the inner surface of the housing." *Id.* at 21–22 (citing Pet. 38–40; 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. 39; Ex. 2107 ¶ 170).

Patent Owner asserts that, in contrast to cutting into the existing thread, 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. 24–25. 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.* at 25 (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 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 groove[s]" 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).[12]

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

[12] Patent Owner identifies the above portion of Petitioner's Reply in its List of Allegedly Improper Reply Arguments (Paper 55). 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.

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 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, however, does not indicate precisely how this change would be accomplished. But, 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 the specific modification 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 modification. 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.[13]

Third, turning to the merits of Petitioner's modification to Burroughs's dose dial sleeve, 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. 39–40). 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.* at 34–35 (citing *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2005)).

Petitioner replies 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 6–7 (citing Pet. 38–40; *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

[13] 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.

'interchangeability' at best goes to expectation of success." PO Sur-reply 8–9 (citing *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1069 n. 4 (Fed. Cir. 2018)). 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.* at 9 (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 [re]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 (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 a 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 ¶¶ 186–188).

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 37 (citing Ex. 2163, 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.* (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.* (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.* 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. 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.*

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. Rather, Petitioner contends that Patent Owner "sets up a strawman argument that does not represent the actual argument and avoids addressing the actual rationale." *Id.* 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.[14] *Id.*

[14] 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 explains that is what Petitioner meant. Pet. Reply 7.

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." Pet. Reply 8 (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).[15,16]

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

[15] 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.

[16] Patent Owner identifies Petitioner's footnote 3 in its List of Allegedly Improper Reply Arguments (Paper 55). 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 (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.

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.* (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 8–9). 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. "[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine." *Medichem, S.A. v. Rolabo S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006). 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 testimony[17]) 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

[17] 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.

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

Petitioner contends that "Burroughs discloses a 'dose knob' in the form of proximal portion 78 of dial mechanism 34, with this portion disposed near a proximal end (i.e., button-end) of the dial mechanism." Pet. 29 (citing Ex. 1013, 8:2–6, Figs. 1, 6–9; Ex. 1011 ¶¶ 173–175). Patent Owner does not contest Petitioner's argument that Burroughs teaches this limitation of claim 1. *See, generally*, PO Resp.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Burroughs teaches the dose knob limitation of claim 1, as recited above.[18]

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

[18] Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 1. *See* Paper 29, 8.

Petitioner contends that "Burroughs discloses a 'piston rod' in the form of leadscrew 38, which is provided within housing 22." Pet. 31 (citing Ex. 1013, 9:26–27, Figs. 1, 2, 12–13). Patent Owner does not contest Petitioner's argument that Burroughs teaches this limitation of claim 1. *See, generally*, PO Resp.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Burroughs teaches the dose knob limitation of claim 1, as recited above.[19]

vi. a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod;

Petitioner contends that "Burroughs discloses a 'driver' in the form of nut 36." Pet 34 (citing Ex. 1013, 9:12-13, Figs. 1, 2, 10–11; Ex. 1011 ¶¶ 180–181). According to Petitioner "[n]ut 36 includes helical thread 198 on its interior surface near its distal end (needle-end)." *Id.* (citing Ex. 1013, 9:13–25, Figs. 1, 2, 10–11). Petitioner contends further that "[t]his thread engages helical threads 208 on leadscrew 38." *Id.* (citing Ex. 1013, 9:30–32, Figs. 1, 2, 10–13). Patent Owner does not contest Petitioner's argument that Burroughs teaches this limitation of claim 1. *See, generally*, PO Resp.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Burroughs teaches the driver limitation of claim 1, as recited above.[20]

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[19] Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 1. *See* Paper 29, 8.
[20] Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 1. *See* Paper 29, 8.

vii. a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob,

Petitioner contends that "Burroughs discloses a 'tubular clutch' in the form of button 32." Pet. 36. According to Petitioner, "[b]utton 32 is cylindrical in shape (tubular) and includes an enlarged diameter ring 54. *Id.* (citing Ex. 1013, 7:46–51, Figs. 14, 15; Ex. 1011 ¶182). Petitioner asserts that "when button 32 is depressed for injection, ring 54 pushes onto fingers 94 provided within dial mechanism 34's internal surface." *Id.* (citing Ex. 1013, 8:11–20, Figs. 1, 9, 14, 15). Petitioner asserts further that "[t]his causes the portion of legs 102, 104 that includes threads 110, 112 to move radially inward, which causes the threads to disengage from helical groove 158 of the housing." *Id.* (citing Ex. 1013 8:15–20; Ex. 1011 ¶ 183). Petitioner explains that "[t]his disengagement then allows dial mechanism 34 to freely move toward the device's needle-end without rotating relative to the housing." *Id.* at 37 (citing Ex. 1013, 8:15–20, 11:5–20; Ex. 1011 ¶¶ 184–185). Petitioner explains further that "[b]utton 32 also causes splines 144 of dial mechanism 34 to disengage from splines 192 of nut 36, which rotationally decouples the two components." *Id.* (citing Ex. 1013, 11:27–30; Ex. 1011 ¶¶ 185–187). Thus, according to Petitioner, "button 32 serves as a clutch that allows dial mechanism 34 to disengage from (1) its rotational connection with the housing 22, and (2) its rotational connection with nut 36." *Id.* (citing Ex. 1011 ¶¶ 184–187).

Patent Owner responds that Burroughs does not disclose or render obvious the recited tubular clutch. PO Resp. 39–43. 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. Patent Owner contends that Petitioner's proposed 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.* at 40. 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.*

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 34 is coupled to the housing by threads 110 and 112, which engage with the housing's helical groove 158." *Id.* at 41. 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. 42 (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.* (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. 42. Patent Owner quotes Burroughs's description of its "clutching device" as follows:

> The clutch 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). 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.* at 42–43.

Petitioner replies by first addressing 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 9. 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.* Thus, Petitioner contends the construction of the term in this *inter partes* review "must be broad enough to include the petition's construction." *Id.* at 10.

Second, Petitioner asserts that the difference in construction "does not make a practical difference in this case." Pet. Reply 10. 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. 36–37; 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 10–11. 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 11 (citing Ex. 1013, 8:2–4, Fig. 8). Petitioner argues that "adjacent" should mean "next to." *Id.* (citing *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007). 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 12 Thus, Petitioner asserts that button 32 teaches the recited "tubular clutch" of claim 1 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, 10:15–26).

Additionally, Patent Owner contends that we should disregard Petitioner's new argument[21] that splines 144 and teeth 192 teach the recited

[21] 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

"tubular clutch." PO Sur-reply 5 (citing 37 C.F.R. § 42.23(b); August 2018 Trial Practice Guide Update 15). 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. 42–43). Patent Owner contends the distal end of Burroughs's dose knob 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.

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 reversibly lock two components in rotation"—we find that Burroughs's button 32 teaches the recited "tubular clutch" of claim 1. 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.

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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.

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 flaw in Petitioner's position that justifies such limitation.[22] 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 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

[22] 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 and basis 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 1.

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.

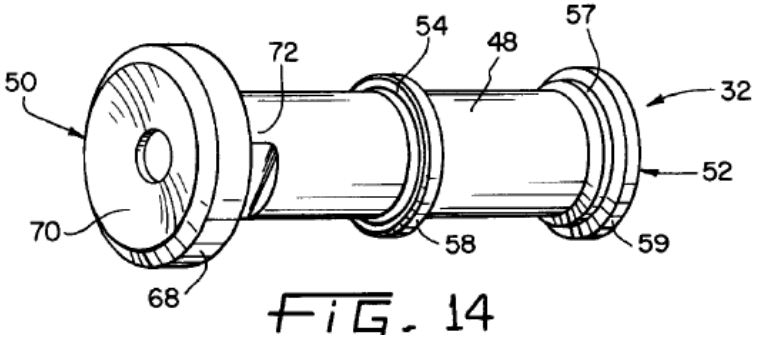

FIG. 14

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.

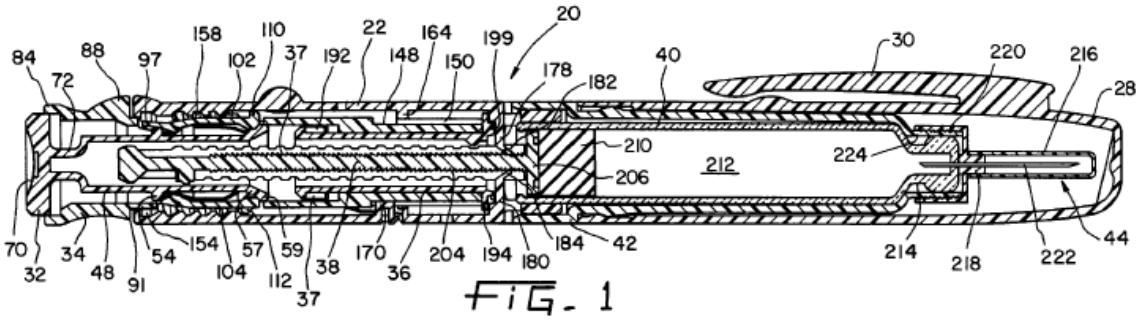

Figure 1 "is a sectional assembly view" of Burroughs's device. *Id.* at 6:40–41.

Accordingly, for the reasons discussed above, we find that Petitioner has shown that Burroughs's button 32 teaches the tubular clutch limitation of claim 1.

> *viii. wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.*

Petitioner contends that "[f]igure 1 shows that dial mechanism 34 (the dose-dial sleeve) extends circumferentially around at least a portion of button 32 (the clutch)." Pet. 38 (citing *See* Ex. 1013, Fig. 1; Ex. 1011 ¶ 188). Patent Owner does not contest Petitioner's argument that Burroughs teaches this limitation of claim 1. *See, generally*, PO Resp.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Burroughs teaches the dose knob limitation of claim 1, as recited above.[23]

3. Dependent Claims 2–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40

Claims 2–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40 ultimately depend from claim 1. Ex. 1003, 7:14–9:31. Petitioner contends that

[23] Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 1. *See* Paper 29, 8.

Burroughs teaches or renders obvious the additional limitations recited in these claims. Pet. 40–67. 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 1. *See generally* PO Resp.; *see also* Pet. Reply 1 (noting that Patent Owner only argues claim 1 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. 40–67. 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 2–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38–40.

4. Indicia of Nonobviousness

a. Nexus

Objective indicia of nonobviousness are "only relevant to the obviousness inquiry 'if there is a nexus between the claimed invention and the [objective indicia of nonobviousness].'" *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006)). For objective indicia of nonobviousness to be accorded substantial weight, their proponent must establish a nexus between the evidence and the merits of the claimed invention. *ClassCo, Inc., v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016). "[T]here is no nexus unless the evidence presented is 'reasonably

commensurate with the scope of the claims.'" *Id.* (quoting *Rambus Inc. v. Rea*, 731 F.3d 1248, 1257 (Fed. Cir. 2013)).

A patentee is entitled to a presumption of nexus "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'embodies the claimed features, and is coextensive with them.'" *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000))). On the other hand, the patentee is not entitled to a presumption of nexus if the patented invention is only a component of a commercially successful machine or process. *Id.* (reaffirming the importance of the "coextensiveness" requirement).

"[T]he purpose of the coextensiveness requirement is to ensure that nexus is only presumed when the product tied to the evidence of secondary considerations 'is the invention disclosed and claimed.'" *Id.* at 1374 (quoting *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1392 (Fed. Cir. 1988)). "[T]he degree of correspondence between a product and a patent claim falls along a spectrum. At one end of the spectrum lies perfect or near perfect correspondence. At the other end lies no or very little correspondence." *Id.* "A patent claim is not coextensive with a product that includes a 'critical' unclaimed feature that is claimed by a different patent and that materially impacts the product's functionality." *Id.* at 1375.

However, "[a] finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations." *Fox Factory*, 944 F.3d at 1373. "To the contrary, the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary

considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Id.* at 1373–74 (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)). "Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention," meaning that "there must be a nexus to some aspect of the claim not already in the prior art." *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011) (emphasis in original). On the other hand, there is no requirement that "objective evidence must be tied exclusively to claim elements that are not disclosed in a particular prior art reference in order for that evidence to carry substantial weight." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016). A patent owner may show, for example, "that it is the claimed combination as a whole that serves as a nexus for the objective evidence; proof of nexus is not limited to only when objective evidence is tied to the supposedly 'new' feature(s)." *Id.* at 1330.

Ultimately, the fact finder must weigh the secondary considerations evidence presented in the context of whether the claimed invention as a whole would have been obvious to a skilled artisan. *Id.* at 1331–32. Once the patentee has presented a prima facie case of nexus, the burden of coming forward with evidence in rebuttal shifts to the challenger "to adduce evidence to show that the commercial success was due to extraneous factors other than the patented invention." *Demaco*, 851 F.2d at 1393.

Patent Owner contends that "Sanofi's LANTUS® SoloSTAR®[24] product practices claim 1" of the '486 Patent. PO Resp. 45 (citing Ex. 2107 ¶¶ 513–550). According to Patent Owner,

> As explained by Prof. Slocum, the inventions in the challenged claims describe a set of components that elegantly work together to provide the user a mechanical device that is easy to use and includes a combination of desirable features and properties, such as (i) *low injection force*, (ii) *short injection stroke length or higher maximum dose per injection*, and (iii) *a relatively small number of components that decrease the complexity of the device*.

Id. (citing Ex. 2107 ¶ 650) (emphasis added). Patent Owner, again relying on the testimony of Prof. Slocum, contends that "the claimed components and interfaces, such as the threaded engagements, piston rod, driver, and tubular clutch, are reflected in the LANTUS® SoloSTAR®" device. *Id.* (citing Ex. 2107 ¶¶ 513–550). Patent Owner does not explain sufficiently, however, how these components of the claimed invention embody the desirable features and properties. *See*, *generally*, 45–55; *see also* PO Sur-Reply 12–20.

Petitioner notes that Patent Owner "provides identical secondary consideration arguments without differentiating among claims-at-issue or patents-at-issue."[25] Pet. Reply 13 (citing Ex. 1060 ¶¶ 36–37, Attachment B-1; Ex. 1055, 53:9–12). According to Petitioner, Patent Owner's "failure to differentiate between claims and patents undermines its secondary

[24] As noted by Patent Owner, "LANTUS® is the commercial name for Sanofi's insulin glargine formulation, and LANTUS® SoloSTAR® is the commercial name for LANTUS® packaged in the SoloSTAR® pen injector. PO Resp. 45, n. 4.

[25] We understand Petitioner to be referring to the patents and their claims at issue in the related proceedings detailed in Section II.A above.

considerations case." *Id.* Noting that Patent Owner "does not argue that [LANTUS® SoloSTAR®] practices all challenged claims, just claim 1," Petitioner asserts that "the claim does not require [LANTUS®] (or insulin at all), an 80-unit cartridge, a short stroke length, or a low injection force. *Id.* "Sanofi's argument ignores the claims and fails to apportion any secondary consideration to the active ingredient." *Id.* On this basis, Petitioner asserts that the claims "are not entitled to a presumption of nexus because LANTUS® SoloSTAR® is not 'the invention.'" *Id.*

In its Sur-Reply, Patent Owner asserts that it "showed how SoloSTAR® practices certain challenged claims." PO Sur-Reply 14 (citing Ex. 2107 ¶¶ 551–611). Patent Owner contends, that Petitioner "provide[s] no credible evidence rebutting these facts, or the fact that the challenged claims enable SoloSTAR®'s low injection force and other features identified in the [Patent Owner] Response." *Id.* (citing Pet. Reply 20).

Patent Owner asserts the indicia of nonobviousness support a showing of long-felt need, industry praise, and commercial success. We discuss Patent Owner's showing with respect to nexus and each of these alleged secondary considerations in turn below.

b. Long-felt Need

Patent Owner contends that "diabetic patients need an easy-to-use injection device with a low injection force to reduce the burden on the patient and increase the likelihood of the patient adhering to their prescribed therapy." PO Resp. 46 (citing Ex. 2111 ¶¶ 24–26). According to Patent Owner, "[p]rior to the launch of LANTUS® SoloSTAR®, there were multiple injection pens on the market for administering insulin or an insulin analog . . . These injection pens, however, had numerous shortcomings and

design flaws that resulted in significant injection force." *Id.* at 46–47. In support, Patent Owner cites the testimony of Dr. Goland discussing these shortcomings. *Id.* at 47 (citing Ex. 2111 ¶¶ 33–35. Patent Owner asserts that "[t]he LANTUS® SoloSTAR® revolutionized the injection pen market, in large part because the LANTUS® SoloSTAR® was easy to use." *Id.* (citing Ex. 2142).

In an effort to show nexus to the claimed invention, Patent Owner submits that "the primary intent of the invention is to address these specific problems in the prior art – 'The illustrated embodiment . . . helps reduce the overall force required for a user to cause medicinal product to be dispensed.'" PO Resp. 48 (citing Ex. 1003, 3:64–67). Patent Owner submits further that "[s]urprisingly it was found that the drive mechanism according to instant invention without having a unidirectional coupling provides a valuable technical alternative for drive mechanisms, wherein reduced force is needed to actuate the mechanism.'"[26] *Id.* (citing Ex. 1003, 1:66–2:3). Patent Owner also directs our attention to "a statement by endocrinologist Sjoberg Kho of the University of Santo Tomas Hospital that 'self-injection can be a barrier to acceptance of insulin therapy. However, the LANTUS® SoloSTAR[®] operates with a low injection force 31 percent less than other insulin pens that allows a gentle injection'" and "a statement by Denis Raccah, Professor of Endocrinology, University Hospital Sainte Marguerite, France, that, 'Insulin injection with SoloSTAR® brings

[26] We note that this language does not appear in the '486 patent. Rather, it appears in the '008 patent at issue in related IPR2018-01684. We note that in the sentence following the quoted sentence, the '008 patent attributes this reduction in force to the clutch means. Ex. 1005, 2:3–7.

flexibility, satisfaction for the patients, and an opportunity for earlier initiation of insulin therapy which may contribute to better long term glycemic control.'" *Id.* at 48–49 (citing Ex. 2184, 2; Ex. 2185, 1). In addition, Patent Owner asserts that "7 out of 10 patients now prefer the lower injection force of SoloSTAR® to competitor products and in 2008 it accounted for "41% of all growth in the global injectable insulin market.'" *Id.* at 49 (citing Ex. 2121, 2, 9).

Petitioner replies that, according to the testimony of Dr. Biggs, '"there was no long-felt unmet need for another insulin pen.'" Pet. Reply. 21 (quoting Ex. 1048 ¶ 39). Petitioner also argues that "[i]n more than 30 years of practice, Dr. Goland never heard from a patient wishing they had a pen with low injection force, never saw using a syringe prevent a patient from taking LANTUS®, and never prescribed an insulin solely based on its pen." *Id.* (citing Ex. 1056, 52:6–9, 71:4–16). According to Petitioner, "[i]n contrast to Sanofi-sponsored injection force studies, (EX2143.010; EX2144.010; EX2100.006; EX2126.004; EX2116.009; EX2123.007; EX1048, ¶58), other studies found [SoloSTAR®] did not have a lower injection force." *Id.* at 21–22 (citing omitted). Petitioner asserts further that Patent Owner's self-funded, self-authored, or self-edited publications "do not demonstrate industry recognition of an unmet need." *Id.* at 23 (citing Ex. 2128.009; Ex. 2123.007; Ex. 2185).

Patent Owner asserts that, according to Dr. Goland, SoloSTAR® was preferred over OptiClik®, earlier FlexPen[®]s were hard to push, and some patients did not take their insulin because prior art devices were problematic." PO Sur-reply 18–19 (citing Ex. 1056, 34:3–17, 35:16–12). Patent Owner also replies that Dr. Goland transitioned patients to

SoloSTAR® because of its lower injection force. *Id.* at 19 (citing Ex. 1056, 66:9–15).

According to Patent Owner, Mr. Leinsing acknowledges a focus on reducing injection force. PO Sur-Reply 19 (citing Ex. 2316, 80:24–81:1). Patent Owner also argues that Dr. Biggs suggests "any long-felt need was satisfied by the L[ANTUS]® vial and syringe, that patients complaining of injection force could have caregivers . . . administer their treatments . . ., and that patients could carry around . . . preloaded syringes," but Dr. Goland disagrees, opining that those suggestions would be disliked by patients. *Id.* (citing Ex. 1048 ¶¶ 31–32; Ex. 1056, 52:23–53:25, 58:18–59:24; Ex. 2317, 70:10–19, 84:24–85:14). Patent Owner further argues that Dr. Biggs's testimony is undermined by his admission that his suggestions may not be covered under Medicare or insurance and that the majority of his patients switched from [LANTUS®] vial to [LANTUS® SoloSTAR®], which most patients preferred. *Id.* (citing Ex. 2317, 115:23–116:6, 118:19–22).

We agree with Petitioner that Patent Owner fails to establish nexus between evidence of the alleged long-felt need for a pen with a reduced force requirement and the claims at issue in this proceeding. Although, Patent Owner has provided evidence supporting its position that the asserted objective evidence of long-felt need is tied to a specific product (i.e. LANTUS® SoloSTAR[®]), Patent Owner has not demonstrated that this product "embodies the claimed features, and is coextensive with them." *Fox Factory*, 944 F.3d at 1373. Specifically, Patent Owner has not sufficiently explained how the limitations set forth in the claims at issue satisfy the alleged long-felt need by identifying where these claims require low injection force as compared to other pens. For this reason, Patent Owner is

not entitled to the presumption of nexus. For the same reasons, Patent Owner has not demonstrated nexus for this secondary consideration.

Moreover, even if we assume nexus, Patent Owner fails to sufficiently demonstrate a long-felt need for a pen with a low injection force. "Long-felt need is closely related to the failure of others. Evidence is particularly probative of obviousness when it demonstrates both that a demand existed for the patented invention, and that others tried but failed to satisfy that demand." *Eurand, Inc. v. Mylan Pharms., Inc.* (*In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*), 676 F.3d 1063, 1082 (Fed. Cir. 2012). Establishing a long-felt need requires objective evidence that the invention has provided a long-awaited, widely accepted, and promptly adopted solution to a problem existent in the art, or that others had tried but failed to solve that problem. *See In re Mixon*, 470 F.2d 1374, 1377 (CCPA 1973). Furthermore, one must demonstrate that "widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem." *In re Allen*, 324 F.2d 993, 997 (CCPA 1963).

Patent Owner's evidence demonstrates acceptance of the LANTUS® SoloSTAR® pen. *See*, *e.g.* Ex. 2184, 1; Ex. 2185, 1; Ex. 2121, 6. It does not, however, demonstrate a long awaited need for such a pen. Rather, Patent Owner's evidence demonstrates that "[p]rior to the launch of LANTUS® SoloSTAR®, there were multiple injection pens on the market for administering insulin or an insulin analog – e.g., Levemir® FlexPen® and LANTUS® OptiClik® in the long-acting category, and the Humalog® KwikPen® in the rapid-and intermediate-acting categories, among many others." PO Resp. 54. Patent Owner's evidence does not show that others tried and failed to make such a pen. While, Patent Owner's evidence may

demonstrate that the LANTUS® SoloSTAR® pen is an improvement over prior art pens, such evidence is insufficient to establish a long-felt need for this pen.

c. *Industry Praise*

Patent Owner submits evidence of awards won by its LANTUS® SoloSTAR® product. *See* PO Resp. 49–51. Specifically, Patent Owner directs our attention to evidence indicating that "SoloSTAR[®] won the Gold, International Export, and Grand Prix awards at the Design Business Association (DBA) Design Effectiveness Awards" in 2009. *Id.* at 49–50 (citing Ex. 2121). According to Patent Owner, "[t]he DBA is a design organization based in the UK that is interested in how a design commercially impacts a company's business." *Id.* at 50. Patent Owner asserts that "[t]he case study of [SoloSTAR®] for the DBA Awards describes the [SoloSTAR®]'s inventiveness as 'suitably ambitious' and explains that 'SoloSTAR® is the first disposable insulin pen to combine very low injection force (which provides a smooth injection experience for patients) with 80 units maximum dose capability, an important breakthrough.'" *Id.* (citing Ex. 2121, 3).

Patent Owner submits further that SoloSTAR® "also won the Good Design Award by the Chicago Athenaeum Museum of Architecture and Design." PO Resp. 50 (citing Ex. 2201). According to Patent Owner, "[i]n connection with this award, and as recognition of its inventiveness, the [LANTUS]® SoloSTAR® . . . device[] was put into the permanent Design Collection of the Chicago Athenaeum Museum of Architecture and Design." *Id.* at 50–51(citing Ex. 2109 ¶ 73). Patent Owner also submits that "at the Prix Galien USA 2009 Award, which "recognize[s] innovative

biopharmaceutical drugs and medical technologies" and "is considered the industry's highest accolade for pharmaceutical research and development — equivalent to the Nobel Prize," Sanofi and DCA were both finalists." *Id.* at 51 (citing Ex. 2109 ¶ 74).

Petitioner contends that "[n]one of the cited documents establish industry praise for the claimed invention. Pet. Reply 23. Noting that Patent Owner "relies on a 'case study of SoloSTAR[®] submitted to the DBA, implying the DBA awards recognized SoloStar[®]'s 'inventiveness,'" Petitioner asserts that "this 'case study' was written, funded, and sponsored by [Patent Owner] (with [SoloSTAR®] designer DCA[27])." *Id.* (citing Ex. 1060 ¶¶ 57–58; Ex. 1075). Thus, according to Petitioner, "[i]t is self-praise, not industry praise. *Id.* (citing Ex. 1055, 79:6–81:19).

Regarding the Good Design Award, Petitioner contends that "[t]he document Sanofi cites does not attribute the award to 'inventiveness.' Nor does the statement that SoloSTAR[®] 'represents a design for social good.'" Pet. Reply at 24 (citing PO Resp. 50). Petitioner contends further that "[n]either the document nor the statement praises what is claimed or the features (e.g., low injection force) Sanofi argues uniquely flow from what is claimed." *Id.* (citing Ex. 1060 ¶¶ 59–60). Finally, regarding the Prix Galien USA 2009 Award, Petitioner contends that the fact that Sanofi and DCA were finalists for this award "fails to demonstrate . . . that [SoloSTAR®] was 'inventive,' much less that the claims were inventive." *Id.* (citing Ex. 1060 ¶ 60).

[27] According to Patent Owner, DCA is "the design firm with whom [it] partnered in creating SoloSTAR®." PO Resp. 49.

Again, we agree with Petitioner. Patent Owner fails to demonstrate nexus between the evidence of industry praise and the claims at issue in this proceeding. The evidence provided indicates that LANTUS® SoloSTAR® received industry praise based on its visual design and its combination of low injection force and large maximum dose capability. *See*, *e.g.* Ex. 2121, 2–3, 5. But, these features are not coextensive with the claims of the '486 patent, because the claims do not require low injection force in combination with high maximum dose capability.

Moreover, even if we assume Patent Owner has demonstrated nexus between the alleged industry praise and the claims at issue, much of the praise was generated by Sanofi's affiliate DCA. *See*, *e.g.* Ex. 1055, 76–79. Such self-generated praise is not persuasive of industry praise. Further, the evidence independent of DCA, such as consideration of LANTUS® SoloSTAR® for the Prix Galien USA 2009 award only generally specifies the criteria used to judge the nominees. Ex. 2142, 2. It does not evidence industry praise of any specific feature of the claimed invention. *Id.*

d. Commercial Success

Patent Owner submits that "[t]he tremendous commercial success of LANTUS® SoloSTAR® is further objective evidence of non-obviousness." PO Resp. 51. In support, Patent Owner asserts that "[t]he commercial success is demonstrated by the contribution of LANTUS® SoloSTAR® to the growth of the LANTUS® franchise overall, and by the strong performance of LANTUS® SoloSTAR® when compared to other long-acting insulin and insulin analog pens." *Id.* (footnote omitted). According to Patent Owner, [t]he commercial success of LANTUS® SoloSTAR® is also demonstrated by the overall levels and shares of dollar sales, new

prescriptions, and total prescriptions, as well as the profitability and formulary placement achieved by LANTUS® SoloSTAR®." *Id.* at 52 (citing Ex. 2109 ¶ 12). Specifically, Patent Owner asserts that

> the LANTUS® SoloSTAR® achieved the highest level of sales among long-acting insulin and insulin analog pens even though it launched after several other long-acting insulin and insulin analog pens, including the Levemir® FlexPen® (the commercial embodiment of Steenfeldt-Jensen), which was the first long-acting insulin or insulin analog product available in a disposable pen.

Id.

Anticipating one of Petitioner's arguments, Patent Owner contends that "[t]o the extent Petitioner argues that Patent Owner's evidence of commercial success is not due to the claimed invention, but rather, to factors beyond the claimed invention such as, e.g., marketing, such arguments should be rejected." PO Resp. 53. Patent Owner submits that "Dr. Grabowski analyzed marketing expenditures for long-acting insulin products and determined that sales of LANTUS® SoloSTAR® exceeded sales for other well-marketed long-acting insulin products despite the fact that '[t]otal marketing expenditures for LANTUS® SoloSTAR® were in line with, or were lower than, many other long-acting insulin products.'" *Id.* at 53–54 (citing Ex. 2109 ¶¶ 16, 64–69).

Anticipating a different argument, Patent Owner contends that "to the extent Petitioner argues that Patent Owner's evidence of commercial success is due to alleged 'blocking patents' covering the glargine molecule that is used in the production of the active ingredient in [LANTUS]®, any such argument would be misplaced." *Id.* at 54. According to Patent Owner, "the law does not mandate across-the-board-discounting of commercial success

simply because other patents cover components of the product" and "the success of LANTUS® SoloSTAR® cannot be attributed solely to the insulin glargine molecule because LANTUS® OptiClik® used the exact same LANTUS® formulation and failed to achieve the success of SoloSTAR®." *Id.* at 53–54. In addition, Patent Owner asserts that its "earlier patents on the insulin glargine molecule did not prevent others from entering the market for non-glargine, long-acting insulin products and competing with LANTUS® SoloSTAR® . . . numerous other competitive pen devices existed prior to LANTUS® SoloSTAR®. The Levemir[®] FlexPen[®], for example, was a disposable pen device that delivered long-acting insulin." *Id.* at 55.

Petitioner disagrees, contending that Patent Owner "provides no benchmarks for evaluating success, applies a faulty 'pens only' market definition, and formulary status does not separately demonstrate commercial success." Pet. Reply 24 (citing Ex. 1060 ¶¶ 17–22, 25–28). As an example, Petitioner contends that "Dr. Grabowski relies on a misleading 8,000% growth rate for [SoloSTAR®] when, as Dr. McDuff points out, the failed OptiClik[®] pen similarly enjoyed an 8,000% growth rate in its first three years." *Id.* at 25 (citing Ex. 1060 ¶ 20). According to Petitioner, "Dr. Grabowski argues LANTUS® [SoloSTAR®]'s commercial success is supported by the 'strong performance' of Apidra[®] [SoloSTAR®], Toujeo[®] [SoloSTAR®], and Admelog[®] [SoloSTAR®], even though peak annual sales of Apidra[® [SoloSTAR®] and Admelog[® [SoloSTAR®] fall below the sales of LANTUS® OptiClik[®] that he describes as 'deficient.'" *Id.* (citing Ex. 1060 ¶ 70–71). Petitioner contends further that Patent Owner "inappropriately excluded insulin injectable products from its market share analyses to inflate LANTUS®

[SoloSTAR®]'s market share 2–3 times." *Id.* (citing Ex. 1060 ¶ 25–27). In response, Petitioner asserts that Patent Owner's "commercial success arguments thus improperly take LANTUS® [SoloSTAR®]'s commercial performance out of context." *Id.*

Responding to Patent Owner's contention that "[LANTUS® SoloSTAR®] sales and prescriptions remained strong despite the entry of several competing long-acting insulin pen products beginning in 2015," Petitioner asserts that "introduction of competing Basaglar[®] and Tresiba[®] long-acting insulin products completely changed the trajectory of both the [LANTUS®] and Toujeo[® SoloSTAR®] products without practicing the claims-at-issue." Pet. Reply 25 (citing Ex. 1060 ¶¶ 30–35, 64; Ex. 1055, 96:13–20). According to Petitioner, "Dr. Grabowski himself previously explained that generic entry of a biologic is expected to have less and a slower impact on the sales of the existing biologic than it would have for a small molecule because of biologics' increased manufacturing costs" and "Dr. Goland confirmed that existing diabetes patients are particularly reluctant to switch to a different insulin product." *Id.* at 25–26 (citing Ex. 1055, 143:10–144:10; Ex. 1056, 71:17–22). As a result, Petitioner asserts that "[t]he change in trajectory for [LANTUS®] and Toujeo[® SoloSTAR®] product performance upon introduction of competing long-acting insulins provides strong evidence that [SoloSTAR®] itself is not a commercial success. *Id.* at 26.

Petitioner also contends that "[LANTUS®] [SoloSTAR®] overtook Levemir[®] FlexPen[®] not because of any unique [SoloSTAR®] attributes, but because of what it shared in common with OptiClik[®]: [Patent Owner] selected it as the exclusive [LANTUS®] pen in the United States." Pet.

Reply 26 (citing Ex. 1048 ¶¶ 20–22, 30–35). According to Petitioner, "Levemir[®] launched almost five years after [LANTUS®], and the first Levemir[®] pen (FlexPen[®]) launched more than a year after the first [LANTUS®] pen (OptiClik[®])." *Id.* (citing Ex. 2186). Consequently, "[LANTUS®] OptiClik[®]® had twice as many prescriptions in 2007 as Levemir[®] FlexPen[®]" which, Petitioner asserts, accounts for [LANTUS® SoloSTAR®]'s alleged commercial success. *Id.* (citing Ex. 2198).

Patent Owner replies that "Petitioner's own data demonstrates that L[ANTUS]® SoloSTAR® has been the number one prescribed insulin or insulin analog product with the greatest market share in every year since 2014, and is overall the third most-prescribed insulin product of the last twenty years." PO Sur-Reply 12 (citing Ex. 1060, Attachment B-10; Ex. 2318, 33:7–36:3). Patent Owner contends that "Petitioners' own economist Dr. McDuff acknowledged the billions of dollars in sales of SoloSTAR® and admitted that a separate profitability analysis was not required to prove its commercial success." *Id.* at 13 (citing Ex. 2318, 15:10–13, 28:7–19, 29:20–30:18; *In re Sernaker*, 702 F.2d 989, 996 (Fed. Cir. 1983)). Patent Owner asserts further that even considering the much broader market that Petitioners identify, "SoloSTAR® still has the largest market share of any insulin product." *Id.* (citing Ex. 1060, Attachment B-10; Ex. 2318, 31:14–17, 31:25–32:8). Patent Owner also asserts that "while SoloSTAR® and OptiClik® enjoyed similar growth rates in their first four years on the market, even though OptiClik® was an inferior pen, . . . the number of SoloSTAR® prescriptions more than quadrupled that of OptiClik® in the

first four years of each product's respective launch." *Id.* (citing Ex. 1060, Attachment B-10; Ex. 2318, 18:23–19:20).

Turning to Petitioner's argument that formulary placement does not demonstrate commercial success, Patent Owner contends that "Petitioners do not deny that SoloSTAR® enjoys favorable placement in health plans, and its economist Dr. McDuff admitted that SoloSTAR®'s mechanical features and attributes would have contributed to that favorable placement. PO Sur-Reply 14 (citing Ex. 2318, 33:7–36:3).

Central to Patent Owner's allegations regarding commercial success is its assertion that the LANTUS® SoloSTAR® pen embodies the claimed invention.[28] PO Resp. 45. We, however, for reasons similar to those discussed in Sections III.D.10.b–c above, are not convinced that this is the case. Patent Owner contends that "[t]he tremendous success of [LANTUS]® SoloSTAR®, as compared to pens with long-acting insulins that failed to address the long-felt but unfilled need for a low injection force device" demonstrates "a strong nexus with the claimed invention." PO Resp. 55. Patent Owner, however, has not sufficiently demonstrated that this "tremendous success" can fairly be attributed to claimed invention which does not require low injection force or insulin, let alone LANTUS®'s long-acting insulin formulation.

Even if we assume nexus, Patent Owner has not sufficiently demonstrated commercial success. Both Patent Owner and Petitioner rely on the evidence in Attachment B-10 to the Declaration of Deforest McDuff, Ph.D. (Ex. 1060) submitted by Petitioner. *See*, *e.g.* Pet. Reply 28; *see also*

[28] We note that the claims do not require "LANTUS®."

PO Sur-Reply 18. Attachment B-10 presents total prescription data by year for 40 insulin delivery products for the 20 year period 1999–2019. Ex. 1060, Attachment B-10. It also provides corresponding market share data for that same time period. *Id.* The data presented in this table is the most pertinent evidence regarding commercial success provided in this proceeding. Patent Owner submits that it demonstrates commercial success of the LANTUS® [SoloSTAR®] pen, and thus, the claimed invention. PO Sur-Reply 13. We find the evidence, at best, to be inconclusive.

Attachment B-10 shows that from the introduction of LANTUS® Vial in 2002, until 2019, LANTUS® delivery products (i.e. LANTUS® Vial, LANTUS® OptiClik®, and LANTUS® SoloSTAR®) were by far the most proscribed insulin delivery devices. Ex. 1060, Attachment B-10. As shown, from 2002 to 2011 prescriptions of LANTUS® Vial grew from roughly 1.3 to roughly 11 million prescriptions, while the most successful competing products (Humulin and Novolog) each grew to prescription levels of roughly 5 million prescriptions. *Id.* Thus, Attachment B-10 clearly demonstrates the commercial success of LANTUS® Vial during that time period. Attachment B-10 also demonstrates that once LANTUS® OptiClik® was introduced, prescriptions of LANTUS® Vial decreased as prescriptions of LANTUS® OptiClik® increased, with the overall number of LANTUS® OptiClik® prescriptions slowly, but steadily climbing. *Id.* We note that during the time period that LANTUS® OptiClik® was the only alternative to LANTUS® Vial, the number of LANTUS® Vial prescriptions essentially stayed the same.

In 2008, LANTUS® SoloStar was introduced. Ex. 1060, Attachment B-10. From 2008–2011, prescriptions of LANTUS® SoloSTAR® steadily

rose while prescriptions of LANTUS® OptiClik® declined. *Id.* During this time period, prescriptions of LANTUS® Vial continued to remain steady. *Id.* Then in 2012, things changed. *Id.* First, prescriptions of LANTUS® OptiClik® dropped off significantly. *Id.* By 2014, prescriptions of LANTUS® OptiClik® dropped to a mere 382 prescriptions. *Id.* During the time period from 2011–2016 (when prescriptions of LANTUS® SoloSTAR® hit their peak), prescriptions of LANTUS® Vial began to decrease at a rate of about 500,000 prescriptions per year. It is unknown why prescriptions of LANTUS® Vial began to decline starting in 2012, but it appears that they declined as the prescriptions of LANTUS SoloSTAR® increased. Patent Owner submits that this is because of the superior features of the LANTUS® SoloSTAR® pen. *See* PO Sur-Reply 19. Whereas, Petitioner suggests that it was because of the introduction of competing products. Pet. Reply 28 (citing Ex 1048 ¶¶ 30–35, 64). Regardless, the evidence clearly shows that the number of LANTUS® SoloSTAR®'s prescriptions peaked in 2016 and that most of the increase in prescriptions for LANTUS® SoloSTAR® merely offset the decline in prescriptions for LANTUS® Vial. Thus, the evidence does not support a showing of commercial success for LANTUS® SoloSTAR®. Rather, it appears to show a fairly stable number of prescriptions for LANTUS® products from 2009–2016, with a decline in those prescriptions from 2017–2019.

5. Conclusion re Indicia of Nonobviousness

Having considered all the indicia of nonobviousness submitted by Patent Owner, we find that the evidence does not show nexus between the claimed invention and long-felt need, industry praise, or commercial success. *In re Affinity Labs* at 901.

E. 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 1350, 1361 (Fed. Cir. 2017). 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 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38– 40 obvious to one of ordinary skill in the art at the time of the invention.

In particular, we find that Burroughs teaches or suggests each of the limitations of claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38– 40. We further find that one of ordinary skill in the art would have had a reason to modify Burroughs in the manner suggested by Petitioner. Weighing these findings with our determinations of the level of ordinary skill and the objective indicia of nonobviousness in the record, a preponderance of the evidence persuades us that claims 1–6, 12–18, 20, 23, 26–30, 32, 33, 36, and 38– 40 of the '486 patent is unpatentable over Burroughs. Further, even if nexus to the objective indicia of nonobviousness were assumed, we do not find the proffered evidence of long-felt need, industry praise, or commercial success to outweigh the case of obviousness in this proceeding.

F. Petitioner's Motion to Exclude

Petitioner filed a motion to exclude Exhibits 2001–2015, 2017–202[4][29], 2026, 2100–2107, 2109, 2113–2115, 2117–2153,

[29] In listing the Exhibits to which Petitioner objects, the Motion recites exhibits "201–2023" after "2017. Mot. 1. All exhibit numbers, however, are 4 digits. It appears that "201" should be deleted such that the Motion recited 2017–2013. Further, although it is not included in the listing of the

2158–2162, 2164, 2166–2183, 2185–2201, 2203–2212, 2214–2218, and 2223–2225, and the redirect testimony in Exhibit 1054. Paper 63 ("Mot."), 1. 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).

a. Exhibits 2001–2011, 2017–2024, 2026

Petitioner contends that the above-listed exhibits should be excluded pursuant to FRE 402 and 403 because they are "not relevant to any contested issue in this proceeding." Mot. 1–4. Patent Owner responds that "[t]hese exhibits were offered to show information that was relevant to § 325(d) issues raised during the preliminary stage of this proceeding." Opp. 1. As such, according to Patent Owner, "these exhibits do not lack relevance and should remain in the record." *Id.* Petitioner does not dispute that these exhibits were relevant to the § 325(d) issues raised during the preliminary stage of this proceeding. Mot. Reply 1. Instead, Petitioner argues that "the exhibits are no longer relevant for any legitimate purpose." *Id.* (citing 35 U.S.C. § 314(d)). Petitioner asserts that "[t]he papers should be excluded under FRE 402–403 as irrelevant and likely to cause confusion." *Id.* Alternatively, Petitioner contends that "their admissibility should be limited to the purpose for which they were submitted." *Id.* (citing FRE 105).

As these exhibits were cited during this proceeding and we do not wish to disturb the record by excluding them, Petitioner's Motion is denied. We do, however, agree with Petitioner that their use shall be limited to the purpose for which they were submitted.

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challenged exhibits, Petitioner argues that Exhibit 2024 should be excluded. *Id.* 1, 3. Thus, "2017, 201–2023" should be read as 2017–2024.

b. Exhibit 2012, 2117, 2124–2152, 2162, 2167, 2168, 2206, 2207, 2211, 2215–2218

Petitioner moves to exclude Exhibit 2012 under FRE 801–804 because it is offered "to show an animated operation of an embodiment of the injection pen described in the '486 patent." Mot. 3 (citing Prelim. Resp. 32). According to Petitioner, "[t]he animation is hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions." *Id.* Petitioner makes similar allegations regarding Exhibits 2117, 2124–2152, 2162, 2167, 2168, 2206, 2207, 2211, and 2215–2218. Mot. 9. Patent Owner contends that FRE 703 permits experts to rely upon hearsay if reasonable to do so in the expert's field. Opp. 1, 13. Petitioner does not address this exhibit in its Motion Reply. *See generally*, Mot. Reply.

Petitioner does not explain why it was not reasonable for Patent Owner's expert to rely on the animations. Thus, Petitioner has not satisfied its burden to shown that these exhibits should be excluded.

c. Exhibits 2013–2015

Petitioner asserts that Exhibits 2013–2015 should be excluded under FRE 801–804 because they are offered to define a claim term. Mot. 3 (citing Prelim. Reps. 39–40). Patent Owner agrees that these exhibits were offered to show how a person of ordinary skill in the art would have understood a claim term, but argues that the exhibits "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. 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 1303, 1318 (Fed. Cir. 2005) ("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.

d. 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 '486 patent, for certain data and a model used for various calculations in Dr. Slocum's declaration. *Id.* at 4–5. 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. 6–7 (citations omitted). 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 7 (citing Ex. 2107 ¶¶ 25–61). Patent Owner also contends Dr. Slocum documented his opinions with facts and data. *Id.* at 8.

Second, Patent Owner asserts that Petitioner's criticism of Dr. Slocum's reliance upon the information and model obtained from Mr. Veasey are unfounded. Opp. 8. 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. 11 (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 3. 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 '486 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.

e. Exhibits 2100–2102, 2104–2106, 2113–2115, 2118–2120, 2122, 2124–2127, 2129–2141, 2145–2153, 2158–2162, 2164, 2166–2183, 2185–2200, 2203–2212, 2214–2218, 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. 7. 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." Opp. 3. 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 does not address these exhibits in its Motion Reply. *See generally*, Mot. Reply.

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.

f. Ex. 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. 7; Opp. 5. Petitioner contends that Patent Owner's use of Exhibit 2103 "lacks relevance, risks confusing the issues, is misleading, and is prejudicial." Mot. 7. Petitioner complains that the exhibit "is offered to establish an actual modification purported to be embodied by the annotations." *Id.* 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.

g. Ex. 2109

Petitioner moves to exclude paragraphs 19, 20, 31, 35, 45, 49, 50, 52, 53, 56, 71, and 72 of Dr. Grabowski's declaration (Ex. 2109) "under FRE 801–804 because they constitute hearsay to the extent they repeat and rely on statements made in an interview." Mot. 8. Petitioner asserts further that they should also be excluded under FRE 702, 703, and 705 because these paragraphs do 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.* Petitioner also asserts that these paragraphs "do not disclose the underlying facts and data, and do not set forth the bases of their opinions. For example, Dr. Grabowski uses IMS Health data to form his opinions, which data are not provided." *Id.*

Patent Owner responds that "FRE 703 permits experts to rely upon hearsay if reasonable to do so in the expert's field. As Dr. Grabowski is a pharmaceutical economist offering opinions on the commercial success of the devices at issue, it was reasonable for him to rely upon a device expert (Dr. Slocum) and an endocrinologist (Dr. Goland), both of whom are reliable sources and were subject to cross-examination." Opp. 12.

Patent Owner responds further that "Petitioners' remaining objections under FRE 702, 703, and 705 do not argue anything specific for Sanofi to rebut, other than to state that Dr. Grabowski did not provide IMS Health data with his declaration." Opp. 13. Patent Owner notes that "Petitioners cite no authority that a party must file every single document that an expert considers in forming his opinions" and that "37 C.F.R. § 42.65(a) only

requires that expert testimony disclose the underlying facts or data." *Id.* Patent Owner asserts that it complied with that rule. *Id.* Petitioner replies that Patent Owner's "position is contrary to the Board's rules, which require the expert's testimony be given little or no weight" when the data underlying that opinion is not available. Mot. Reply.4.

Petitioner has not shown that it was unreasonable for Dr. Grabowski to rely on hearsay in this instance. Further, Petitioner's argument that the data underlying Dr. Grabowski's testimony is not available goes to the weight that testimony should be given, not to its admissibility. Accordingly, Petitioner has not satisfied its burden to show that this exhibit should be excluded.

h. Exhibits 2116, 2117, 2121, 2123, 2128, 2142–2144, 2175, 2184, 2185, 2201

Petitioner contends that the above-listed exhibits should be excluded pursuant to FRE 402 and 403 because they "are irrelevant to the extent they rely on an improper standard of obviousness and unclaimed features." Mot. 9. Petitioner contends further that "[t]hese exhibits are also prejudicial and confuse the issues as a result." *Id.* Noting that Petitioner moves "to exclude these exhibits as irrelevant because injection force and ease of use are allegedly not required by the challenged claims," Patent Owner asserts further that "Petitioners' contention that the challenged claims do not enable low injection force is no basis to exclude these exhibits on relevancy grounds" and that "as Dr. Grabowski is permitted to rely upon these exhibits under FRE703, there is no basis to exclude them." Opp. 14.

Petitioner responds that "case law holds that secondary considerations cannot be based on unclaimed features." Mot. Reply 5 (citing *Fox Factory* at

6). According to Petitioner, "there is no claim construction issue to be decided because Sanofi has never proffered the construction necessary to make these exhibits relevant." *Id.* Alternatively, Petitioner contends that "exhibits should be limited to the purpose for which they were submitted (showing the benefits of unclaimed features)." *Id.* (citing FRE 105).

Petitioner's response does not address Patent Owner's arguments. Further, Petitioner has not shown that it was unreasonable for Dr. Grabowski to rely on these exhibits. Thus, Petitioner has not satisfied its burden to show that these exhibits should be excluded.

i. Exhibits 2223, 2224

Petitioner moves to exclude Exhibits 2223 and 2224 because they are "offered to show secondary considerations." Mot. 9. According to Petitioner "[t] They are hearsay without exception, lack authentication, and are unreasonably prejudicial because they are cited for a new purpose." *Id.* at 9–10. Patent Owner responds that Exhibit 2223 was cited in Dr. Grabowski's declaration and that Exhibit 2224 was presented to Dr. McDuff during his deposition. Opp. 15. Patent Owner asserts further that "Dr. Grabowski is permitted to rely upon E[xhibit] 2223 under FRE[]703, there is no basis to exclude it" and there is no basis to exclude Exhibit 2224. *Id.* Petitioner does not address these exhibits in its Motion Reply. *See*, *generally* Mot. Reply.

Petitioner has not shown that it was unreasonable for Dr. Grabowski to rely on Exhibit 2223 or adequately explained why Exhibit 2224 should be excluded. Thus, Petitioner has not satisfied its burden to show that these exhibits should be excluded.

III. SUMMARY[30]

For the reasons discussed above, Petitioner has demonstrated, by a preponderance of the evidence that claims 1–6, 12–18, 20, 23, 26–30, 32–33, 36, and 38–40 would have been obvious in view of Burroughs. Additionally, although we deny Petitioner's Motion to Exclude, we limit the use of Exhibits 2001–2011, 2017–2024, and 2026 as described above.

The chart below summarizes our conclusions regarding the challenged claims.

Claim(s)	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–6, 12–18, 20, 23, 26–30, 32–33, 36, 38–40	103(a)	Burroughs	1–6, 12–18, 20, 23, 26–30, 32–33, 36, 38–40	
Overall Outcome			1–6, 12–18, 20, 23, 26–30, 32–33, 36, 38–40	

IV. ORDER

[30] 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).

After due consideration of the record before us, and for the foregoing reasons, it is:

ORDERED that claims 1–6, 12–18, 20, 23, 26–30, 32–33, 36, 38–40 of the '486 patent are held unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 63) is denied; and

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

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