UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case No. IPR2019-00979
U.S. Patent No. 8,679,069 B2

PATENT OWNER SANOFI-AVENTIS DEUTSCHLAND GMBH'S NOTICE OF APPEAL UNDER 37 C.F.R. § 90.2(a)

Pursuant to 35 U.S.C. §§ 141–144, 319 and 37 C.F.R. § 90.2(a), notice is hereby given that Patent Owner Sanofi-Aventis Deutschland GmbH ("Sanofi") appeals to the United States Court of Appeals for the Federal Circuit from the Final Written Decision (Paper No. 38) (the "Final Written Decision"), in IPR2019-00979, entered on August 11, 2020, by the United States Patent and Trademark Office, Patent Trial and Appeal Board (the "Board"), and from all orders, decisions, rulings, and opinions antecedent to the Final Written Decision. This appeal is timely under 35 U.S.C. § 142 and Rule 15(a)(1) of the Federal Rules of Appellate Procedure. A copy of the Final Written Decision is attached hereto as Exhibit A.

In accordance with 37 C.F.R. § 90.2(a)(3)(ii), Sanofi further indicates that the issues on appeal may include, but are not limited to, the Board's determination that claims 1–3 of U.S. Patent Number 8,679,069 B2 has been shown to be unpatentable under 35 U.S.C. § 103 in view of the grounds of unpatentability identified in the Board's Final Written Decision, challenges to any findings supporting the determination, the Board's failure to properly consider evidence of record, the Board's legal and factual errors in undertaking the obviousness analysis, the Board's failure to consider Sanofi's arguments in support of patentability, the Board's procedural errors including its failure to strike and/or exclude certain of Petitioner's arguments and evidence and the Board's failure to

provide Sanofi an opportunity to offer rebuttal argument and evidence, the Board's findings that conflict with the evidence of record and are not supported by substantial evidence, the Board's failure to provide Sanofi with sufficient due process, the Board's failure to provide Sanofi with just compensation, the constitutionality of the Administrative Patent Judges, and other issues decided adversely to Sanofi.

Simultaneous with this submission, a copy of this Notice of Appeal is being filed through the Patent Trial and Appeal Board End to End ("PTAB E2E") System. In addition, a copy of the Notice of Appeal, along with the required docketing fee, is being filed with the Clerk of Court for the United States Court of Appeals for the Federal Circuit.

Dated: August 14, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that, in addition to being filed electronically through the PTAB E2E System, the original version of Patent Owner Sanofi-Aventis Deutschland GmbH's Notice of Appeal, has been sent via priority mail on August 14, 2020, to the Director of the United States Patent and Trademark Office, at the following address:

Director of the United States Patent and Trademark Office
c/o Office of the General Counsel
United States Patent and Trademark Office
Madison Building East, Room 10B20
600 Dulany Street
Alexandria, VA 22314-5793

The undersigned also certified that a true and correct copy of Patent Owner Sanofi-Aventis Deutschland GmbH's Notice of Appeal and the required filing fee were filed electronically via CM/ECF on August 14, 2020, with the Clerk of Court for the United States Court of Appeals for the Federal Circuit.

The undersigned also certifies that a true and correct copy of Patent Owner Sanofi-Aventis Deutschland GmbH's Notice of Appeal was served on August 14, 2020, via electronic mail, upon the following counsel of record for Petitioner Pfizer Inc.:

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Exhibit A

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Paper No. 38
Date: August 11, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

IPR2019-00979
Patent 8,679,069 B2

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

JUNG, *Administrative Patent Judge*.

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

I. INTRODUCTION

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. For the reasons that follow, we determine that Pfizer Inc. ("Petitioner") has shown by a preponderance of the evidence that claims 1–3 of U.S. Patent No. 8,679,069 B2 (Ex. 1001, "the '069 patent") are unpatentable. We also deny Petitioner's Motion to Exclude.

A. Background and Summary

Petitioner filed a Petition (Paper 2, "Pet.") requesting institution of an *inter partes* review of claims 1–3 of the '069 patent. Sanofi-Aventis Deutschland GmbH ("Patent Owner") waived filing a Preliminary Response. Paper 9. Pursuant to 35 U.S.C. § 314, we instituted an *inter partes* review of the '069 patent. Paper 12 ("Dec. to Inst."). In particular, we instituted review of claims 1–3 on all presented challenges. Dec. to Inst. 2, 13, 22.

After institution, Patent Owner filed a Response (Paper 17, "PO Resp."), to which Petitioner filed a Reply (Paper 21, "Pet. Reply"), and Patent Owner thereafter filed a Sur-reply (Paper 25, "PO Sur-reply"). Petitioner also filed a motion to exclude (Paper 33, "Mot."), and Patent Owner filed an opposition to the motion to exclude (Paper 35, "Opp."), to which Petitioner filed a Reply (Paper 37, "Mot. Reply"). No oral hearing was held in this proceeding. *See* Paper 28 (notice that Petitioner does not seek oral argument); Paper 34 (order granting Patent Owner's request to withdraw its request for oral hearing); Ex. 3001.

B. Real Parties in Interest

Petitioner indicates that Pfizer Inc. and Hospira, Inc. are real parties in interest. Pet. 1. Patent Owner indicates that Sanofi-Aventis Deutschland

GmbH, Sanofi-Aventis U.S. LLC, and Sanofi Winthrop Industrie are real parties in interest. Paper 6, 2.

C. Related Matters

The parties indicate that the '069 patent has been asserted in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105-SRC-CLW (D.N.J.) ("*Sanofi*-9105"); *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 6, 2; Ex. 1029; Ex. 1030; Ex. 2016; Ex. 2165; Ex. 2166.

Mylan Pharmaceuticals Inc. ("Mylan") challenged claim 1 of the '069 patent in IPR2018-01670, which we discuss further below. Pet. 1; Paper 6, 3. Petitioner moved for joinder with IPR2018-01670, which we denied because Petitioner additionally challenges claims 2 and 3 of the '069 patent. Paper 3; Dec. to Inst. 19–22.

Related patents are challenged in IPR2018-01675, IPR2018-01676, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01684, IPR2018-01696, IPR2019-00122, IPR2019-00977, IPR2019-00978, IPR2019-00980, IPR2019-00981, IPR2019-00982, IPR2019-00987, IPR2019-01022, and IPR2019-01023. Pet. 1–2; Paper 6, 3–4.

D. The '069 Patent (Ex. 1001)

The '069 patent issued March 25, 2014, from an application filed November 11, 2010, which is a continuation of an application filed on July 11, 2006, which, in turn, is a continuation of an application filed on March 2, 2004. Ex. 1001, codes (22), (45), (63), 1:6–12. The '069 patent also claims priority to a foreign application filed on March 3, 2003. *Id.* at code (30), 1:10–11.

The ’069 patent “relates to pen-type injectors . . . where a user may set the dose.” Ex. 1001, 1:13–17. Figures 1 and 2 of the ’069 patent are reproduced below.

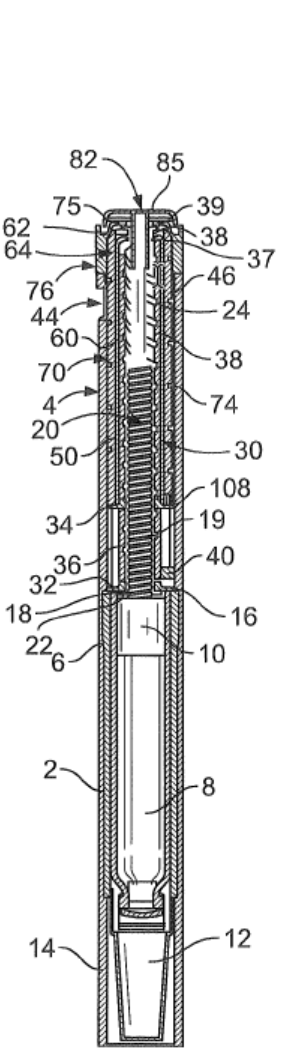

FIG. 1

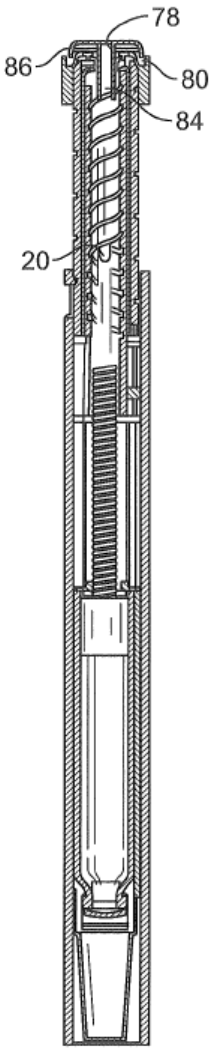

FIG. 2

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.” *Id.* at 2:38–42. The injector includes first cartridge retaining part 2 and second main

housing part 4.[1] *Id.* at 3:8–9. Insert 16 is at a first end of main housing 4 and is fixed rotationally and longitudinally to main housing 4. *Id.* at 3:29–30. Insert 16 includes threaded circular opening 18, through which piston rod 20 extends. *Id.* at 3:31–33, 3:37–39. Piston rod 20 includes first thread 19 (*id.* at 3:36) and pressure foot 22 that abuts piston 10 of cartridge 8 (*id.* at 3:39–41).

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 3:41–42, 3:51, 3:58–60. Clutch 60 is disposed about drive sleeve 30 adjacent its second end. *Id.* at 4:12–14, 4:28–29. Clutch 60 is keyed to drive sleeve 30 by splines to prevent relative rotation between clutch 60 and drive sleeve 30. *Id.* at 4:39–41.

Dose-dial sleeve 70 is outside of clutch 60 but within main housing 4. *Id.* at 4:49–51. Dose-dial sleeve 70 has helical groove 74 on its outer surface. *Id.* at 4:51–52. Dose-dial grip 76 is disposed about the second end of dose-dial sleeve 70 and secured to dose-dial sleeve 70 to prevent relative motion. *Id.* at 5:3–4, 5:6–8.

A user rotates dose-dial grip 76 to set a dose and to cause dose-dial sleeve 70 and drive sleeve 30 to rotate together out of main housing 4. *Id.* at 5:29–32, 5:42–44, Fig. 9. The dose can be reduced by turning dose-dial grip 76 in the opposite direction. *Id.* at 5:65–66, Fig. 10. The user then presses button 82, which causes clutch 60 to disengage from dose-dial sleeve 70 so that clutch 60 moves axially and dose-dial sleeve 70 rotates back into housing part 4. *Id.* at 6:6–9, 6:11–13, Fig. 11. Drive sleeve 30

[1] The ’069 patent refers to “second main housing part 4” and “main housing 4” interchangeably. *Compare* Ex. 1001, 3:9 (“second main housing part 4”), *with id.* at 3:30 (“main housing 4”).

also moves axially and causes piston rod 20 to rotate through threaded opening 18 to dispense medicine from cartridge 8. *Id.* at 6:23–25.

E. Illustrative Claim

The '069 patent has three claims, all of which Petitioner challenges. Claim 1, the only independent claim, is reproduced below:

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

Ex. 1001, 6:37–60.

F. Asserted Prior Art and Testimonial Evidence

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

U.S. Patent No. 6,221,046 B1, issued April 24, 2001 (Ex. 1013, "Burroughs");

U.S. Patent No. 6,235,004 B1, issued May 22, 2001 (Ex. 1014, "Steenfeldt-Jensen"); and

U.S. Patent Application Publication No. US 2002/0052578 A1, published May 2, 2002 (Ex. 1015, "Moller").

Petitioner provides a Declaration (Ex. 1011) and a Reply Declaration of Mr. Charles E. Clemens (Ex. 1095). Patent Owner provides a Declaration of Alexander Slocum, Ph.D. Ex. 2107. A deposition transcript for Mr. Clemens was filed. Ex. 2450. Deposition transcripts for Dr. Slocum were also filed. Exs. 1053, 1054.

Primarily in support of objective indicia of nonobviousness, Patent Owner provides declarations from Henry G. Grabowski, Ph.D. (Ex. 2109) and Dr. Robin S. Goland (Ex. 2111). *See* Ex. 2109 ¶ 7 (stating that "I have been retained by counsel for Sanofi to opine on the commercial success of Lantus® SoloSTAR®"); Ex. 2111 ¶ 14 (stating in "Summary of Opinions" that "it is my opinion that patients who require insulin or insulin analog therapy need an easy-to-use injection pen device").

In response, Petitioner provides declarations from Dr. William C. Biggs (Ex. 1048) and DeForest McDuff, Ph.D. (Ex. 1060). *See* Ex. 1048 ¶ 16 (stating that "[m]y opinions are directed principally to long-felt, unmet need arguments"); Ex. 1060 ¶ 6 (stating that the scope of work is to review and respond to the Grabowski declaration regarding commercial success).

Deposition transcripts were filed for Prof. Grabowski (Ex. 1055), Dr. Goland (Ex. 1056), Dr. Biggs (Ex. 2317), and Dr. McDuff (Ex. 2318).

G. Asserted Grounds

Petitioner asserts that claims 1–3 are unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §	Reference(s)/Basis
1–3	103(a)[2]	Burroughs
1	103(a)	Steenfeldt-Jensen
1	103(a)	Moller, Steenfeldt-Jensen

In IPR2018-01670, Mylan challenged claim 1 of the '069 patent as unpatentable over (1) Burroughs, (2) Steenfeldt-Jensen, and (3) Moller combined with Steenfeldt-Jenson. *Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2018-01670, Paper 1 (September 10, 2018) (Petition). Oral argument was held on January 15, 2020. *Mylan*, Paper 78. We determined that Mylan showed by a preponderance of the evidence that claim 1 is unpatentable over Burroughs and over Steenfeldt-Jensen. *Mylan*, Paper 81 (PTAB April 2, 2020) (Final Written Decision).

II. ANALYSIS

A. Legal Standards

In an *inter partes* review, 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.*,

[2] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the challenged claims have an effective filing date before this date, the pre-AIA version of § 103 applies.

800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail in its challenges, Petitioner must prove unpatentability by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

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

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

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

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

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

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

As described below, the parties' disputes are related to the scope and content of the asserted prior art, differences between claim 1 and the asserted prior art, and objective indicia of nonobviousness.

After reviewing the complete record, we conclude that Petitioner has shown by a preponderance of the evidence that Burroughs teaches or suggests the limitations of claims 1–3; that Steenfeldt-Jensen teaches or suggests the limitations of claim 1; that a person of ordinary skill in the art would have had a reason to modify Burroughs and Steenfeldt-Jensen with a reasonable expectation of success; and that nexus has not been demonstrated sufficiently for the asserted objective indicia of nonobviousness.

B. Level of Ordinary Skill in the Art

Petitioner asserts that one of ordinary skill in the art "would have had at least a bachelor's degree in mechanical engineering, or an equivalent degree" and "would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (*e.g.*, gears, pistons) involved in drug delivery devices." Pet. 17 (citing Ex. 1011 ¶ 106). In our Decision to Institute, we preliminarily adopted Petitioner's unopposed proposal. Dec. to Inst. 9.

According to Patent Owner, one of ordinary skill would have understood "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 . . . the basics of device design and manufacturing" and would have had "a bachelor's degree in mechanical engineering or an equivalent degree." PO Resp. 4–5 (citing Ex. 2107 ¶ 102). Patent Owner also states that its "level of ordinary skill is similar to that proposed by Petitioner" and "any slight differences do not affect the arguments made below." *Id.* at 5.

In determining the level of ordinary skill in the art, various factors may be considered, including the "type of problems encountered in the art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field." *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995) (citation and internal quotation marks omitted).

Based on the full record before us, we see no reason to disturb our preliminary finding regarding the level of ordinary skill in the art. Accordingly, we maintain and reaffirm that one of ordinary skill in the art "would have had at least a bachelor's degree in mechanical engineering, or an equivalent degree" and "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." Dec. to Inst. 9 (quoting Pet. 17). This level of skill in the art is consistent with the disclosure of the '069 patent and the prior art of record.

We agree with the parties that any differences in the parties' proposals do not affect their arguments and, thus, would not affect our analysis. PO Resp. 5.

C. Claim Construction

In an *inter partes* review based on a petition filed on or after November 13, 2018, the claims are construed

> using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. [§] 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.

Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective November 13, 2018) (codified at 37 C.F.R. § 42.100(b) (2019)); *see Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc). If the Specification "reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is "when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Uship Intellectual Props., LLC v. United States*, 714 F.3d 1311, 1313 (Fed. Cir. 2013) (quoting *Thorner v. Sony Comput. Entm't Am., LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)).

Additionally, only terms that are in controversy need to be construed, and these need be construed only to the extent necessary to resolve the controversy. *See Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (holding that "only those terms need be construed that

are in controversy, and only to the extent necessary to resolve the controversy"); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Matal*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs.* in the context of an *inter partes* review).

Petitioner states that "claim terms should be given their ordinary and customary meaning, consistent with the specification and how they would have been understood by the [person of ordinary skill in the art]." Pet. 17. Petitioner notes that Patent Owner proffered interpretations of "drive sleeve," "main housing," "piston rod," "thread/threaded/threading," and "tubular clutch" in related litigation. *Id.* at 17–18 (citing Ex. 1019, 19−24, 27–28, 30–31).

Petitioner also notes that, in related litigation, Mylan proffered a means-plus-function interpretation for "tubular clutch." *Id.* at 18 (citing Ex. 1028 (Mylan's Preliminary Claim Constructions in *Sanofi*-9105), 80–85). To the extent the proper interpretation is a means-plus-function construction, Petitioner proffers the same interpretation in this proceeding. *Id.* at 19 (citing Ex. 1001, 2:5–7, 4:42–44, 6:14–22, 11:58–12:4, Figs. 1, 5–11; Ex. 1028, 82).

In our Decision to Institute, we did not need to interpret expressly any term at that stage of the proceeding. Dec. to Inst. 9. Patent Owner "believes it is only necessary to address the construction of 'tubular clutch.'" PO Resp. 5.

1. "tubular clutch"[3]

Petitioner contends "tubular clutch" is "[a] tubular structure that couples and decouples a moveable component from another component." Pet. 18. Petitioner states that in related litigation, "Mylan proffered a preliminary means-plus-function construction for the claim term 'tubular clutch,'" where the functions are "that during dose setting, it 'clutch[es], i.e., coupling and decoupling a movable component from another component,' or, during dose setting, it 'operates to reversibly lock two components in rotation.'" *Id.* at 18–19 (citing Ex. 1028, 80–85). Petitioner identifies the structure that corresponds to those functions as "component 60" of the '069 patent. *Id.* at 19 (citing Ex. 1001, 2:5–7, 4:42–44, 6:14–22, 11:58–12:4, Figs. 1, 5–11).

Patent Owner contends that the plain and ordinary meaning of "clutch" is "a tubular component that can operate to reversibly lock two components in rotation." PO Resp. 5, 6–7. Patent Owner asserts that this is the construction adopted by the district court in *Sanofi*-9105. *Id.* at 6 (citing Ex. 2165 (Opinion and Order (D.I. 319) construing claim terms in *Sanofi*-9105, filed May 9, 2019), 13). Patent Owner contends that, in construing the term, the district court disagreed with Petitioner's proposed construction. *Id.* (citing Ex. 2165, 10–11, 13).

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

Petitioner replies that the courts' constructions and Patent Owner's proffer are "evidence of the reasonable scope of the limitation" and that the "limitation would at least encompass all these constructions absent a showing that one construction is unreasonable," which Patent Owner has not shown according to Petitioner. Pet. Reply 2 (citing Pet. 18; PO Resp. 6–7; Ex. 1019, 23–24; Ex. 1030, 12; Ex. 2165, 10–11).

Patent Owner also responds that "tubular clutch" is not a means-plus-function term, the Petition does not present "any support to overcome the presumption against applying means-plus-function," the Petition presents no analysis of whether sufficient structure is recited, and the District of New Jersey has rejected the contention that "tubular clutch" is a means-plus-function term. PO Resp. 6 (citing Ex. 2165, 12). Petitioner replies that Patent Owner "has not addressed nonobviousness under this means-plus-function construction, and any such argument is now waived." Pet. Reply 1.

We are persuaded that "tubular clutch" does not invoke § 112, ¶ 6,[4] and, for the reasons discussed below, we find that Petitioner sufficiently establishes that the asserted references disclose a "tubular clutch," under either party's 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."

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

[4] 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).

D. Scope and Content of the Asserted Prior Art

1. Burroughs (Ex. 1013)

Burroughs relates to "medical dispensing devices . . . that permit selectively measured dosages of a liquid to be dispensed." Ex. 1013, 1:13–16; *see also id.* code (57) (describing a "multi-use medication dispensing pen" that is "made of a minimal number of parts"). Figure 2 of Burroughs is reproduced below.

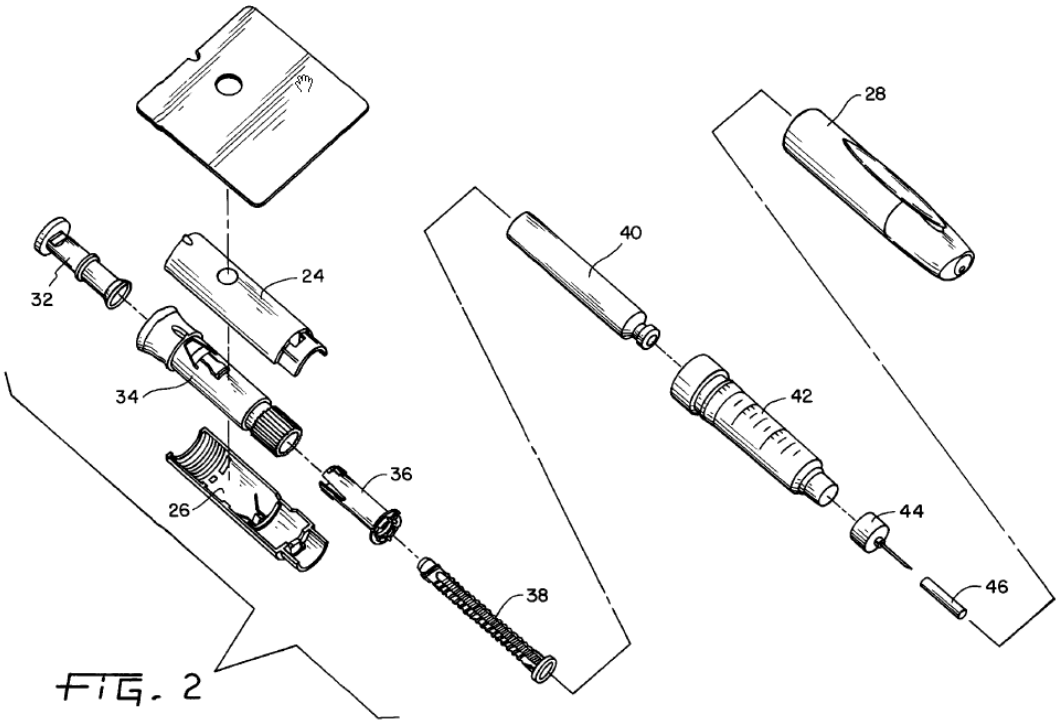

Figure 2 shows an exploded view of injection medication device 20. Ex. 1013, 6:42–43, 7:15–16. "[I]njection medication device 20 ha[s] the general appearance of a pen" and "comprises a mechanism housing 22 having a first part 24 and a second part 26." *Id.* at 7:15–20.

"Dial mechanism 34 comprises proximal portion 78, intermediate portion 80, and distal portion 82." *Id.* at 8:2–4. The "term 'proximal' shall designate a relative axial position toward the button end of the delivery pen, and the term 'distal' shall designate a relative axial position toward the

delivery needle end of the delivery pen." *Id.* at 7:9–13. "Proximal portion 78 comprises enlarged diameter portion 84, tapered portion 86, and ring 90 extending about the circumference of proximal portion 78." *Id.* at 8:4–6. "[P]roximal ends of flexible sections 92 and 95 each include fingers 94 . . . adapted for engagement with enlarged diameter portion 54 of button 32" and "[w]hen button 32 is depressed, enlarged diameter portion 54 is also depressed and . . . forces fingers 94 outward" so that "[d]ial mechanism 34 is then able to travel axially towards cartridge 40 during injection of the medical product." *Id.* at 8:11–20; *see also id.* at 8:9–11 (stating that "[g]enerally U-shaped grooves 91 and 93 (FIGS. 6, 8) are formed in intermediate portion 80 to form a flexible sections 92 and 95, respectively."). Dial mechanism 34 also includes outwardly extending threads 110, 112 that "enter helical groove 158 during commencement of the dosing process." *Id.* at 8:9–11, 8:33–36, 8:62–9:1, Figs. 3, 5.

Dial mechanism 34 engages button 32, and "button 32 comprises a hollow cylindrical portion 48 having a proximal end 50." *Id.* at 7:46–47, 8:9–14, Figs. 6, 8. "Cylindrical portion 48 . . . includes an enlarged diameter ring 54." *Id.* at 7:49–51. 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.

"Housing parts 24 and 26 include bulkhead ledges 178, 180, respectively" that include "flexible tangs 182, 184, respectively." *Id.* at 9:8–11. "[L]eadscrew 38 is shown having a ratchet teeth 204 located on two opposing sides of leadscrew 38 and axially extending along the length of leadscrew 38 from proximal end 200 to plunger engagement portion 206." *Id.* at 9:26–30. "Helical threads 208 extend along the axial length of

leadscrew 36." *Id.* at 9:30–31. "[P]lunger engagement portion 206 of leadscrew 38 is in engagement with piston 210 of cartridge 40." *Id.* at 9:32–34.

Device 20 includes nut 36 that "is generally cylindrical in shape." *Id.* at 9:12–14. "The interior surface of the distal end of nut 36 includes a helical thread 198," and "[t]hread 198 extends 350° about the inner surface of nut 36." *Id.* at 9:22–25. "Helical threads 208 extend along the axial length of leadscrew 36," and "[l]eadscrew 38 fits within the cylindrical opening of nut 36." *Id.* at 9:30–32.

Rotating dial mechanism 34 causes nut 36 to rotate and move relative to housing 20, but rotation of leadscrew 38 is prevented. *Id.* at 10:25–27. "Rotation of leadscrew 38 is prevented by a key-keyway type of engagement between the anti-backup tangs 182 and 184 and leadscrew 38," and "tangs 182, 184 form a key, and leadscrew 38 forms a keyway which comes into contact with the sides of the key." *Id.* at 10:26–30. "Upon rotation of dial 34, . . . dial mechanism 34 retracts from housing 22." *Id.* at 10:34–42. "Rotation of dial mechanism 34 causes rotation of nut 36 so that internal helical raised groove 198 of nut 36 rotates along external threads 208 of leadscrew 38 to cause nut 36 to axially retract a corresponding axial distance." *Id.* at 10:38–42.

A series of numerals are printed on dial mechanism 34 to indicate a desired dosage. *Id.* at 10:5–9. "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.

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. "Movement of leadscrew 38 is prevented in the

proximal direction due to anti-backup tangs 182, 184 being in engagement with ratchet teeth 204" so that "head 206 of leadscrew 38 remains in constant engagement with piston 210 at all times." *Id.* at 11:52–56.

2. Steenfeldt-Jensen (Ex. 1014)

Steenfeldt-Jensen "relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses" Ex. 1014, 1:12–15. Figures 15–17 of Steenfeldt-Jensen are reproduced below.

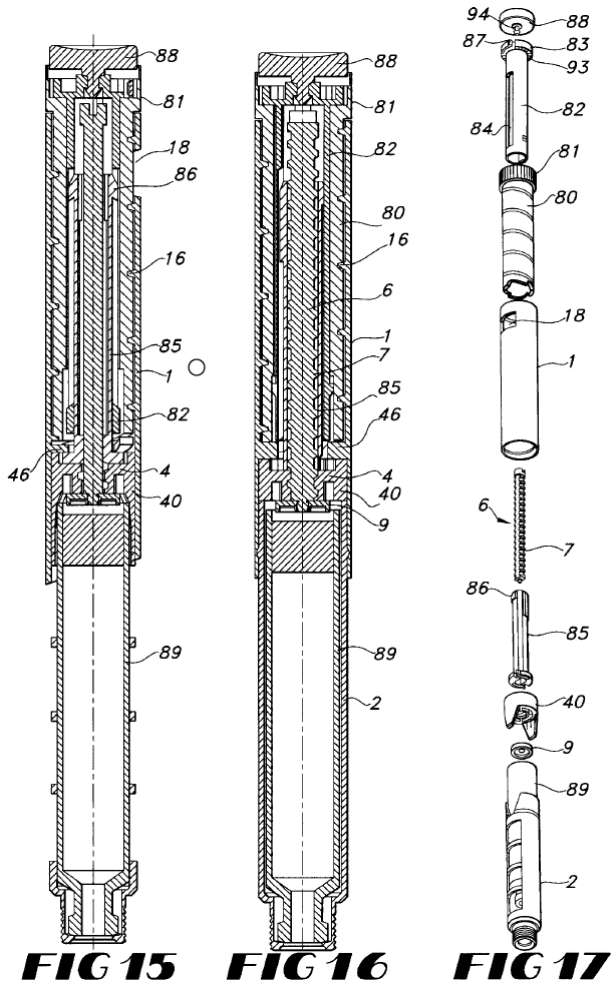

FIG 15 FIG 16 FIG 17

Figures 15 and 16 show side sectional views of a syringe, and Figure 17 shows an exploded view of the syringe of Figures 15 and 16. *Id.*

at 5:23–28. The syringe of Steenfeldt-Jensen includes tubular housing 1 that is partitioned so that a first division has ampoule holder 2. *Id.* at 5:38–40; *see also id.* at 14:11(reciting in claim 11 "a housing having proximal and distal ends").

"The end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5" and "piston rod 6 having an external thread 7 mating the thread 5 of said bore extends through said bore." *Id.* at 5:55–58. Driver tube 85 is disposed about piston rod 6. *See id.* at Figs. 15–17. "[E]nd wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing." *Id.* at 8:35–38.

"To maintain a clockwise rotation of a dose setting button for increasing the set dose the pawl mechanism working between the driver tube and the housing . . . bars clockwise rotation . . . of the driver tube." *Id.* at 11:6–11. The "thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment," and "[t]he piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section" so that "rotation is transmitted" and "the piston rod is allowed to move longitudinally through the driver tube." *Id.* at 11:11–19.

Within housing 1 is scale drum 80, and "scale drum 80 is in its outer wall provided with a helical track which is engaged by a helical rib 16 along the inner wall of the housing 1." *Id.* at 11:20–22. "At its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81 which on its cylindrical outer wall is knurled to ensure a good finger grip," *Id.* at 11:22–25.

Bushing 82 fits within scale drum 80 and over driver tube 85. Ex. 1014, 11:26–29. Bushing 82 is coupled to driver tube 85 so that both can rotate but not longitudinally move. *Id.* at 11:30–33. Injection button 88 is rotatably mounted at an end of bushing 82. *Id.* at 11:49–51.

"When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing." *Id.* at 11:52–55. "[I]f a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction the pawl mechanism working between the driver tube and the housing . . . prevent[s] the bushing 82 from following this anticlockwise rotation." *Id.* at 11:57–62.

"When the injection button 88 is pressed to inject the set dose," "the thread engagement between the helical track of the scale drum 80 and the rib 16 in the housing when the scale drum 80 is pressed back into said housing" induces "anticlockwise rotation of the dose setting button 81," and bushing 82 follows that rotation. *Id.* at 12:4–10. "The bushing will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows," and "the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2." *Id.* at 12:10–13.

3. Moller (Ex. 1015)

Moller "relates to syringes by which a dose can be set by rotating a dose setting member and by which an injection button elevates from an end of the syringe a distance proportional to the set dose." Ex. 1015 ¶ 1. Figure 1 of Moller is reproduced below.

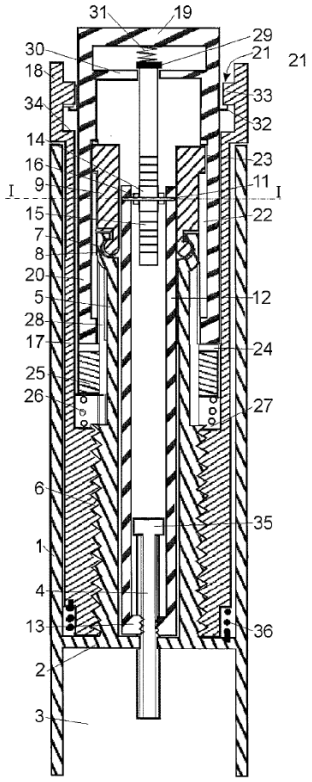

Fig. 1

Figure 1 shows a sectional view of an injection device. Ex. 1015 ¶ 17. The device includes housing 1 with partitioning wall 2 that divides housing 1 into two compartments, one with a dose setting mechanism and the other for accommodating an ampoule. *Id.* ¶ 22. Threaded piston rod 4 extends through an opening in wall 2 so that it can move longitudinally but not rotationally because threaded piston rod 4 has a non-circular cross section. *Id.* Tubular element 5 extends from the opening around threaded piston rod 4 and engages gearbox 9 so that gearbox 9 can rotate within housing 1. *Id.* ¶ 23.

Nut 13 engages the threads of the threaded piston rod 4 and connects to gearbox 9 via connection bars 12. *Id.* ¶ 24. Dose setting drum 17 engages thread 6 of tubular element 5 at one end and at the opposite end has an enlarged diameter forming dose setting button 18. *Id.* ¶ 25. Dose setting

drum 17 can be screwed into or out of housing 1 and includes a scale on its outer surface. *Id.* ¶ 25.

A cup shaped element that fits over gearbox 9 and into dose setting drum 17 forms an injection button. *Id.* ¶ 26. The cup shaped element is coupled to dose setting drum 17 so that the cup shaped element, dose setting drum 17, and gearbox 9 rotate together. *Id.*

Dose setting button 18 is rotated to set a dose, which causes dose setting drum 17 to screw out with the cup shaped element. *Id.* ¶ 29. Bottom 19 of the cup shaped element is pressed to inject the set dose. *Id.* ¶ 32.

E. Alleged Obviousness over Burroughs

Petitioner contends that Burroughs's medication dispensing pen includes the same components as recited by claim 1, except that the asserted dose dial sleeve of Burroughs has threads on its outer surface that form a helical rib to engage with a helical groove of a main housing. Pet. 27. Petitioner asserts that it would have been obvious to interchange these features to provide a dial mechanism with a helical groove on its outer surface that engages with a thread on the main housing. *Id.*

Patent Owner responds that Petitioner's proposed modification to Burroughs significantly complicates dose dispensing. PO Resp. 1. Patent Owner contends that Burroughs does not teach a "helical groove provided along an outer surface of said dose dial sleeve" and that Petitioner does not show that Burroughs would have rendered obvious such a helical sleeve. *Id.* at 16.

1. Analysis of Claim 1

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

Petitioner argues that Burroughs teaches the preamble of claim 1. Pet. 28–29 (citing Ex. 1011 ¶ 126; Ex. 1013, code (57), 7:15–19, Figs. 1, 2).

To the extent that the preamble is limiting, we find that the relied-upon portions of Burroughs teach a "multi-use medication dispensing pen" that is "made of a minimal number of parts, which include a housing" (Ex. 1013, code (57)) and "an injection medication device 20 having the general appearance of a pen" that "comprises a mechanism housing 22" (*id.* at 7:15–19). We also find that Figures 1 and 2 of Burroughs show injection medication device 20 with housing 22. We further credit Mr. Clemens's testimony because Burroughs supports it. Ex. 1011 ¶ 126 (citing Ex. 1013, 1:13–16, 7:15–20, 8:2–8, 9:12–25, 9:26–34, 10:38–42, 11:13–34, Figs. 1, 2).

Patent Owner does not present an argument regarding the preamble of claim 1. *See* PO Resp. 16–28. Because Burroughs teaches housing 22 for injection medication device 20, Petitioner persuades us that Burroughs teaches a "housing part for a medication dispensing apparatus."

b) a main housing, said main housing extending from a distal end to a proximal end;

Petitioner argues that Burroughs teaches the required main housing of claim 1. Pet. 29–30 (citing Ex. 1011 ¶¶ 158–160; Ex. 1013, 7:9–13, 7:17–20, Figs. 1–3, 5).

We find that the relied-upon portions of Burroughs state that "the term 'proximal' shall designate a relative axial position toward the button end of the delivery pen, and the term 'distal' shall designate a relative axial position toward the delivery needle end of the delivery pen" (Ex. 1013, 7:9–13) and

teach that a "device comprises a mechanism housing 22 having a first part 24 and a second part 26 (FIG. 2)" (*id.* at 7:17–20). We also find that Figures 1–3 and 5 show housing 22 with first part 24 and second part 26 that extend between ends. We further credit Mr. Clemens's testimony because Burroughs supports it. Ex. 1011 ¶¶ 158–160 (citing Ex. 1013, 7:17–20, Figs. 1–3, 5).

Patent Owner does not present an argument regarding the main housing of claim 1. *See* PO Resp. 16–28. Because Burroughs teaches a housing that extends between ends, Petitioner persuades us that Burroughs teaches "a main housing, said main housing extending from a distal end to a proximal end."

> *c) a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;*

Petitioner contends Burroughs teaches a dose dial sleeve, except that Burroughs's sleeve includes helical threads along its outer surface as opposed to a helical groove, as recited above. Pet. 30–33. In particular, Petitioner asserts dial mechanism 34 of Burroughs teaches the recited dose dial sleeve. *Id.* at 32 (citing Ex. 1011 ¶ 166; Ex. 1013, 7:31–32, Fig. 2). Petitioner argues that Burroughs's dial mechanism 34 "is positioned within housing 22, and includes on its outer surface threads 110, 112." *Id.* (citing Ex. 1011 ¶¶ 161–163; Ex. 1013, 7:65–67, 8:33–36, Figs. 1, 2, 6–9). Petitioner contends threads 110, 112 of dial mechanism 34 "are configured to releasably engage with helical spiral groove 158 provided on an inner surface of housing 22." *Id.* (citing Ex. 1011 ¶ 164; Ex. 1013, 8:62–9:1, Figs. 1, 3, 5–9).

Petitioner asserts "[t]hreads 110, 112 are shown to be 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. 33 (citing Ex. 1011 ¶ 167; Ex. 1013, Figs. 6–9). Relying upon Mr. Clemens's testimony, Petitioner contends "in order to properly engage with helical spiral groove 158 for rotation, threads 110, 112 also must be positioned helically relative to one another, forming a discontinuous helical rib corresponding to the housing's helical groove." *Id.* (citing Ex. 1011 ¶ 165; *cf.* Ex. 1001, 3:62–64) (also relying on Ex. 1013, Figs. 1, 7).

Thus, Petitioner argues "Burroughs discloses that dial mechanism 34 includes a 'helical rib,' in the form of threads 110, 112, along its outer surface that engages with threading on housing 22." *Id.* (citing Ex. 1011 ¶ 165). Petitioner also argues that one of ordinary skill in the art "would have considered it obvious to implement the helical rib as a helical groove corresponding to helical threading on the housing." *Id.*

Patent Owner responds that "Burroughs does not disclose a 'helical groove provided along an outer surface of said dose dial sleeve'" (PO Resp. 16); "Petitioner admits that Burroughs does not disclose a helical groove on the outer surface of the dose dial sleeve" (*id.* at 19 (citing Pet. 33)); and "there is no dispute that Burroughs fails to disclose this limitation" (*id.*).

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 below.

(1) Petitioner's Reason to Modify

Petitioner asserts one of ordinary skill in the art "would have known the alternative to reverse the features and configure threads 110, 112 as a 'helical groove.'" Pet. 46 (citing Ex. 1011 ¶¶ 166–169). In particular, Mr. Clemens testifies that one of ordinary skill in the art "would have found it obvious to add another helical rib next to the existing one, such that threads 110, 112 form a 'helical groove' that engages a threading provided by the housing." Ex. 1011 ¶ 166. Petitioner contends "[t]he use of a rib-to-groove threaded connection is a common and well-known mechanism used for the purpose of providing relative rotational movement between components." Pet. 47 (citing Ex. 1011 ¶ 168). Petitioner argues "determining whether to place a helical rib on one component and a complementary helical groove on another engaging component would have been considered a routine task," and "would have been viewed as no more than 'the predictable use of prior art elements according to their established functions.'" *Id.* (quoting *KSR*, 550 U.S. at 417). Thus, Petitioner asserts that one of ordinary skill in the art "would have considered the placement of a rib-to-groove connection to be largely interchangeable between its engaging parts." *Id.* (citing Ex. 1011 ¶ 169).

Additionally, Petitioner contends that one of ordinary skill in the art "would have understood that the rotational operability between dial mechanism 34 and housing 22 would not change if helical threads 110, 112 were provided as two, parallel ribs that formed a helical groove for engaging a helical rib on the housing." *Id.* (citing Ex. 1011 ¶ 170). Petitioner asserts one of ordinary skill in the art "would have reasonably expected that the releasable connection between dial mechanism 34 and housing 22 would remain substantially the same." *Id.* (citing Ex. 1011 ¶ 170).

Petitioner also contends that one of ordinary skill in the art "would have considered the choice as to whether the dial mechanism contained the groove and the housing contained the corresponding rib, or *vice versa*, to have been the use of well-known and familiar elements" and "would have reasonably expected that use of the elements in that configuration would have resulted in the elements performing their same, predictable functions (*e.g.*, rotational engagement)." Pet. 48 (citing Ex. 1011 ¶ 170; *KSR*, 550 U.S. at 417).

Patent Owner understands Petitioner and Mr. Clemens to be proposing "add[ing] 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. 16 (citing Pet. 48; Ex. 1011 ¶ 166; Ex. 2107 ¶ 171). Patent Owner states that Petitioner's proposal is "plac[ing] an ***additional*** thread behind Burroughs' existing threads 110, 112, such that the space ***between*** the threads forms a helical groove." *Id.* at 16–17 (citing Ex. 2107 ¶ 171).

Patent Owner argues that "[a]lthough the Petition refers to this proposed modification as 'revers[ing] the features' of Burroughs, it is plainly ***not*** a reversal" and that "[r]eversing the features would result in a spiral groove across the outer surface of dial mechanism 34 and two discrete, protruding threads 110, 112 at the inner surface of Burroughs' housing." *Id.* at 18–19 (citing Ex. 2107 ¶ 172). According to Patent Owner, Mylan's declarant in IPR2018-01670 agreed that the threads are not being swapped around. *Id.* at 19 (citing Ex. 2163, 194:15–20); *see also id.* at 17 n.2 (indicating that Mr. Clemens agreed with the cited testimony) (citing Ex. 2450, 23:15–22).

Patent Owner argues that one of ordinary skill in the art "would not have been motivated to try Petitioner's proposed modification, which increases the likelihood that the injection pen as modified would not properly function and subjects the internal components of the pen to undesirable increased stress during use." PO Resp. 19. In particular, because the Petition and Mr. Clemens argue that (1) "rib-to-groove threaded connections were known in the art," (2) "the relative placement of the ribs and grooves was 'largely interchangeable' and 'routine variations,'" and (3) a person of ordinary skill in the art "would have understood that positioning the threads 110, 112 as proposed by Petitioner to form two parallel ribs would have preserved the rotational operability of the components in Burroughs' injector pen," Patent Owner argues that Petitioner only establishes that a person of ordinary skill in the art could have made the proposed modification, not that such a person would have made the proposed modification. *Id.* at 19–20 (citing Ex. 1011 ¶¶ 168–171). 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, not that a [person of ordinary skill in the art] *would have* done so." *Id.* at 20.

In its Reply, Petitioner contends that "[w]hen known interchangeable solutions exist, [precedent supports swapping] one for another as obvious." Pet. Reply 3 (citing Pet. 47–48 (citing *KSR*, 550 U.S. at 417); PO Resp. 19–20; Ex. 1095 ¶ 22). In its Sur-reply, Patent Owner contends that "[m]erely asserting a 'design choice' does not make it obvious" and that "Petitioner's alleged 'interchangeability' at best goes to expectation of success, not whether a [person of ordinary skill in the art] would have had a *motivation* to make the change – a legally distinct concept from reasonable expectation of

success." PO Sur-reply 5 (citing *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016)).

In *KSR*, the Supreme Court stated that "when a patent 'simply arranges old elements with each performing the same function it had been known to perform' and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR*, 550 U.S. at 417 (citing *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (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) 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. Pet. 46–47; Ex. 1011 ¶¶ 166–169. 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. Ex. 1011 ¶¶ 166–170. 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.

(2) Patent Owner's Asserted Reasons Not to Make the Proposed Modification

Patent Owner also argues that a person of ordinary skill in the art would have had reasons not to make Petitioner's modification. PO Resp. 21. Patent Owner asserts that Petitioner's modification to add an additional thread to threads 110 and 112 would have (1) required that legs 102 and 104 pivot far enough inward to disengage from two threads (instead of one), (2) required an increase of 30% to 40% in force and stress during the injection process, and (3) resulted in the legs wearing out faster, thus decreasing the lifespan of Burroughs's multi-use injector. *Id.* at 21–22 (citing Ex. 2107 ¶¶ 181, 184–188).

Patent Owner also contends that although additional modifications to Burroughs's device could be made to reduce the negative consequences of Petitioner's proposed change, Petitioner does not propose any additional modifications. *Id.* at 22 (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.* According to Patent Owner, that change, however, would have also necessitated increasing the internal diameter of the injector "by at least 10 percent to accommodate the modified legs when they pivot inward during injection." *Id.* at 22–23 (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.* at 23 (citing Ex. 2107 ¶¶ 190–191). Patent Owner asserts that increasing the

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

Further, Patent Owner contends that with or without the modifications to Burroughs's legs, the injection force required for a user to dispense a dose would be increased by 15% because the legs must pivot further in order for the added threads to clear helical groove 158 during dose injection. PO Resp. 23 (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 without any benefit asserted by Petitioner or its declarant. *Id.* at 22–24 (citing Ex. 2107 ¶ 193).

In its Reply, Petitioner does not dispute Patent Owner's argument that adding threads would result in an increase in stress and wear on Burroughs's legs. *See* Pet. Reply 3–4 (citing PO Resp. 21–22). Rather, Petitioner contends that Patent Owner identifies a viable solution to such detriment—modifying the dimensions of the legs. *Id.* at 3 (citing PO Resp. 22–23). 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.[5] *Id.*

Additionally, Petitioner contends that making the device wider is not necessarily a disadvantage, relying on the testimony of Dr. Biggs that "width . . . can aid patients with grip or agility problems." *Id.* (quoting Ex. 1048

[5] Petitioner does not state expressly that modifying the dimensions of the legs is within the "routine skill" that one of ordinary skill in the art would have used when adding the additional threads, but Petitioner's Reply suggests that is what Petitioner meant. Pet. Reply 7.

¶ 50). Thus, Petitioner asserts that what Dr. Slocum considers a disadvantage (i.e., increased width), Dr. Biggs considers an advantage. *Id.* at 3–4 (citing Ex. 1053, 13:2–6). With respect to Patent Owner's argument of a 15% increase in injection force, Petitioner contends Dr. Slocum "pulls this percentage out of thin air." Pet. Reply 4 (citing PO Resp. 23; Ex. 1095 ¶ 24; Ex. 2107 ¶ 192). 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.* (citing *In re Kao*, 639 F.3d 1057, 1067 (Fed. Cir. 2011); Ex. 1048 ¶¶ 29–30).[6]

In its Sur-reply, Patent Owner contends that the Petition does not propose the further modifications Petitioner sets forth in the Reply to mitigate the additional stress resulting from the addition of threads to Burroughs's device. PO Sur-reply 5 (citing Pet. Reply 3–4 n.2; Ex. 2163, 195:14–21). 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 5–6 (citing Ex. 1054, 277:19–279:2, 281:5–18; Ex. 1095 ¶ 22). Thus, Patent Owner argues that we should "give no weight to Petitioner's assertion that a [person of ordinary

[6] 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 4 n.3 (citing Ex. 1095 ¶¶ 20–23, 26). 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.

skill in the art] could have accommodated the modification by changing the dimensions of the added thread." *Id.* at 6.

Additionally, Patent Owner encourages us to reject Petitioner's "new contention that the modification could have been accommodated through application of 'routine skill.'" PO Sur-reply 6 (quoting Pet. Reply 3). Patent Owner relies upon Dr. Slocum's testimony that Petitioner's modification would require additional substantial changes to Burroughs's device, such as lengthening legs 102, 104 and increasing the thickness of the injector. *Id.* Patent Owner also contends that Petitioner "makes no showing that the proposed modification would result in ease-of-grip." *Id.* (citing Pet. Reply 3–4). Patent Owner asserts that the additional changes required, including redesigning the internal components of the device that are sized for Burroughs's existing design, "calls into question whether this is an 'interchangeable solution[].'" *Id.* at 6–7 (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 7 (citing Pet. Reply 4). 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. Ex. 1011 ¶¶ 166–170. Patent Owner's evidence does not support the finding that Burroughs's device would be inoperable if modified as Petitioner proposes.

Ex. 2107 ¶¶ 181, 184–188, 190–193. 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. *See* Ex. 1048 ¶¶ 29, 30, 50. Specifically, the evidence discussed above reflects that increased size of the device may be an advantage to some users of the device while also a disadvantage to others. *See id.*

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[7]) 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 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

[7] 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 ordinary creativity, not an automaton").

established that modifying Burroughs's thread-groove connection to a groove-thread connection would have been obvious to one of ordinary skill in the art at the time of the invention. We weigh the evidence of record as to the full scope of claim 1 after addressing each limitation.

d) a dose dial grip disposed near a proximal end of said dose dial sleeve;

Petitioner argues that Burroughs teaches the recited dose dial grip. Pet. 33–35 (citing Ex. 1011 ¶¶ 173–175; Ex. 1013, 8:2–6, 10:34–42, Figs. 1, 2, 6–9). In particular, Petitioner argues that "Burroughs discloses a 'dose dial grip' in the form of proximal portion 78 of dial mechanism 34, located near a proximal end (*i.e.*, button-end) of the dial." *Id.* at 35 (citing Ex. 1011 ¶ 175; Ex. 1013, 8:2–6, Figs. 1, 6–9).

We find that the relied-upon portions of Burroughs teach that "[d]ial mechanism 34 comprises proximal portion 78, intermediate portion 80, and distal portion 82," "[p]roximal portion 78 comprises enlarged diameter portion 84, tapered portion 86, and ring 90 extending about the circumference of proximal portion 78," and "[u]pon rotation of dial 34, . . . dial mechanism 34 retracts from housing 22." Ex. 1013, 8:2–6, 10:34–42; *see also id.* at 7:9–13 (stating that "the term 'proximal' shall designate a relative axial position toward the button end of the delivery pen"). We also credit Mr. Clemens's testimony because Burroughs supports it. Ex. 1011 ¶¶ 173–175 (citing Ex. 1013, 8:2–6, 10:34–42, Figs. 1, 2, 6–9).

Patent Owner does not present an argument regarding the dose dial grip of claim 1. *See* PO Resp. 16–28. Because Burroughs teaches proximal portion 78 of dial mechanism 34 is towards the proximal end, Petitioner persuades us that Burroughs teaches "a dose dial grip disposed near a proximal end of said dose dial sleeve."

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

Petitioner argues that Burroughs teaches the recited piston rod. Pet. 35–39 (citing Ex. 1011 ¶¶ 176–178; Ex. 1013, 9:8–11, 9:26–34, 10:26–42, 11:52–56, Figs. 1–3, 5, 12, 13). In particular, Petitioner argues that "Burroughs further discloses a 'piston rod' in the form of leadscrew 38." *Id.* at 38.

We find that the relied-upon portions of Burroughs teach that "[h]ousing parts 24 and 26 include bulkhead ledges 178, 180, respectively" that include "flexible tangs 182, 184, respectively," "leadscrew 38 is shown having a ratchet teeth 204 located on two opposing sides of leadscrew 38 and axially extending along the length of leadscrew 38 from proximal end 200 to plunger engagement portion 206," "[h]elical threads 208 extend along the axial length of leadscrew 36," and "plunger engagement portion 206 of leadscrew 38 is in engagement with piston 210 of cartridge 40." Ex. 1013, 9:8–11, 9:26–34.

We also find that the relied-upon portions of Burroughs teach that "[r]otation of leadscrew 38 is prevented by a key-keyway type of engagement between the anti-backup tangs 182 and 184 and leadscrew 38," "tangs 182, 184 form a key, and leadscrew 38 forms a keyway which comes into contact with the sides of the key," "[r]otation of dial mechanism 34 causes rotation of nut 36 so that internal helical raised groove 198 of nut 36 rotates along external threads 208 of leadscrew 38 to cause nut 36 to axially retract a corresponding axial distance," and "[m]ovement of leadscrew 38 is prevented in the proximal direction due to anti-backup tangs 182, 184 being in engagement with ratchet teeth 204" so that "head 206 of leadscrew 38

remains in constant engagement with piston 210 at all times." *Id.* at 10:26–30, 10:38–42, 11:52–56. We further credit Mr. Clemens's testimony because Burroughs supports it. Ex. 1011 ¶¶ 176–178 (citing Ex. 1013, 9:8–11, 9:26–34, 10:26–42, 11:52–56, Figs. 1–3, 5, 12).

Patent Owner does not present an argument regarding the piston rod of claim 1. *See* PO Resp. 16–28. Because Burroughs teaches leadscrew 38 is within housing parts 24, 26 and prevented from moving during rotation of dial mechanism 34 by tangs 182, 184, Petitioner persuades us that Burroughs teaches "a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing."

> *f) a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and,*

Petitioner argues that Burroughs teaches the recited drive sleeve. Pet. 39–41 (citing Ex. 1011 ¶¶ 179–181; Ex. 1013, 9:12–25, 9:30–32, 10:38–42, Figs. 1, 2, 10, 11). In particular, Petitioner argues that "Burroughs discloses a 'drive sleeve' in the form of nut 36." *Id.* at 41 (citing Ex. 1011 ¶¶ 179–181; Ex. 1013, 9:12–13, Figs. 1, 2, 10, 11).

We find that the relied-upon portions of Burroughs teach that "[n]ut 36 is generally cylindrical in shape," "[t]he interior surface of the distal end of nut 36 includes a helical thread 198," and "[t]hread 198 extends 350° about the inner surface of nut 36." Ex. 1013, 9:12–13, 9:22–25. We also find that the relied-upon portions of Burroughs teach that "[h]elical threads 208 extend along the axial length of leadscrew 36," "[l]eadscrew 38 fits within the cylindrical opening of nut 36," and "[r]otation of dial mechanism 34 causes rotation of nut 36 so that internal helical raised groove 198 of nut 36 rotates along external threads 208 of leadscrew 38 to

cause nut 36 to axially retract a corresponding axial distance." *Id.* at 9:30–32, 10:38–42. We further credit Mr. Clemens's testimony because Burroughs supports it. Ex. 1011 ¶¶ 179–181 (citing Ex. 1013, 8:42–48, 9:12–25, 9:30–32, 10:21–26, 10:38–42, 11:27–34, Figs. 1, 2, 9–11).

Patent Owner does not present an argument regarding the drive sleeve of claim 1. *See* PO Resp. 16–28. Because Burroughs teaches that leadscrew 38 fits within nut 36 and nut 36 includes internally thread 198 that engages external thread 208 of leadscrew 38, Petitioner persuades us that Burroughs teaches "a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod."

> *g) a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,*

Petitioner argues that Burroughs teaches the recited tubular clutch. Pet. 41–45 (citing Ex. 1011 ¶¶ 182–187; Ex. 1013, 7:46–55, 8:11–20, 8:42–48, 9:16–18, 11:5–20, 11:27–30, Figs. 1, 2, 6–11, 14, 15). In particular, Petitioner argues that "Burroughs discloses a 'tubular clutch' in the form of button 32." *Id.* at 44 (citing Ex. 1011 ¶ 187).

We find that the relied-upon portions of Burroughs teach that "button 32 comprises a hollow cylindrical portion 48 having a proximal end 50" and that "[c]ylindrical portion 48 . . . includes an enlarged diameter ring 54." Ex. 1013, 7:46–51. We also find that the relied-upon portions of Burroughs teach, in relation to dial mechanism 34, that "proximal ends of flexible sections 92 and 95 each include fingers 94 . . . adapted for engagement with enlarged diameter portion 54 of button 32" and "[w]hen

button 32 is depressed, enlarged diameter portion 54 is also depressed and . . . forces fingers 94 outward" so that "[d]ial mechanism 34 is then able to travel axially towards cartridge 40 during injection of the medical product." *Id.* at 8:11–20; *see also id.* at 8:2–3 (stating that "[d]ial mechanism 34 comprises . . . intermediate portion 80"), 8:9–11 (stating that "[g]enerally U-shaped grooves 91 and 93 (FIGS. 6, 8) are formed in intermediate portion 80 to form a flexible sections 92 and 95, respectively"). We also credit Mr. Clemens's testimony because Burroughs supports it. Ex. 1011 ¶¶ 182–187 (citing Ex. 1013, 7:46–58, 8:11–20, 10:21–26, 10:34–38, 11:5–12, 11:20–23, 11:27–34, Figs. 1, 2, 9, 11, 14, 15).

Patent Owner responds that Burroughs does not disclose or render obvious the recited tubular clutch. PO Resp. 1, 24–28. First, Patent Owner asserts that the proper construction for tubular clutch is "a tubular component that can operate to reversibly lock two components in rotation." *Id.* at 24; *see also id.* at 25 (citing Ex. 2165, 10–11). 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 24–25 (citing Pet. 18, 41–45). Thus, Patent Owner argues that "[i]n view of the construction advocated by the Petitioner in the Petition, the Petitioner should not be given a 'do-over' in its forthcoming reply." *Id.* at 25.

Second, Patent Owner contends that merely rotationally decoupling dial mechanism 34 from nut 36 and housing 22 does not establish the capability to reversibly lock those components in rotation. *Id.* at 25. Patent Owner addresses each of the functions identified by Petitioner.

With respect to the engagement between dial mechanism 34 and housing 22, Patent Owner asserts that dial mechanism 34 "is coupled to the

housing by threads 110, 112, which engage with the housing's helical groove 158." *Id.* at 25–26. 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 rotates relative to 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 invalidate the claims.

PO Resp. 26.

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." *Id.* (citing Ex. 2107 ¶ 208; Ex. 1013, 8:42–48, 10:15–26). Thus, Patent Owner asserts "button 32 does not reversibly ***lock*** two components in rotation." *Id.* at 26–27.

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." *Id.* at 27. Patent Owner quotes Burroughs's description of its "clutching device" as follows:

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

Id. (quoting Ex. 1013, 2:59–65) (citing Ex. 2107 ¶ 209) (emphasis added by Patent Owner). Patent Owner asserts that Petitioner cannot rely upon

splines 144 and teeth 192 as teaching the claimed "tubular clutch" because (1) splines 144 and teeth 192 are not tubular and (2) they are not located adjacent to a distal end of the proximal portion 78 of the dial mechanism 34, as required by claim 1. *Id.*

In its Reply, Petitioner first addresses Patent Owner's argument regarding claim construction, asserting that Patent Owner has waived any argument directed to Petitioner's non-means-plus-function construction of "tubular clutch"—"a tubular structure that couples and decouples a moveable component from another component." Pet. Reply 2 (citing Pet. 18; Ex. 1019, 23–24; Ex. 1030, 12). Petitioner also asserts that "Petitioner's proposed construction is reasonable, as [Patent Owner] conceded in proposing the same construction in litigation" and Patent Owner "offers no basis to find that the same construction it proposed in district court is now unreasonable." *Id.* at 5.

Second, 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. 41–45; PO Resp. 24–27; Ex. 1095 ¶ 31). Petitioner contends that "[w]hen the user injects a dose, button 32 disengages splines connecting dial mechanism 34 and nut 36, reversing rotational locking of those components." *Id.* at 5–6 (citing Ex. 1095 ¶¶ 31–32; 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 construction, requiring the clutch to act ***directly on the locked components*** to 'operate to reversibly lock two components in

rotation.'" *Id.* at 6. Petitioner asserts that "[w]hen engaged, splines 144 and teeth 192 define a tubular ('360°') structure (clutching device) within dial mechanism 34's intermediate portion 80" that "lies between the proximal portion 78 and distal portion 82, together comprising the dial mechanism 34." Pet. Reply 6–7 (citing Ex. 1013, 8:2–4, Fig. 8). Petitioner argues that "'***adjacent***' means simply 'next to.'" *Id.* at 7. Therefore, because "[i]ntermediate 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.* 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 2 (responding to Pet. Reply 5–6). 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.* at 2–3. Patent Owner contends that Petitioner's construction is not reasonable. *Id.* at 3. 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.* (citing Ex. 1013, 10:15–26).

Additionally, Patent Owner contends that we should disregard Petitioner's new argument[8] that splines 144 and teeth 192 teach the recited "tubular clutch." PO Sur-reply 3 (citing Pet. Reply 6–7). 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.*

Patent Owner contends the distal end of Burroughs's dose dial grip is not next to splines 144 or teeth 192 because they are separated by the intervening portion of dial 34. *Id.* at 3–4 (citing Pet. Reply 7; Ex. 1013, Fig. 9). Patent Owner also contends that 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 4 (citing Pet. Reply 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 narrower, "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

[8] To the extent Petitioner relies upon splines 144 and teeth 192 as an alternative teaching of a "tubular clutch," *see* Pet. Reply 6–7 (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. 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 6 (first full paragraph). That argument maintains Petitioner's reliance upon button 32 as teaching the "tubular clutch" and is responsive to Patent Owner's argument directed to the action of button 32 in the Patent Owner Response. Our discussion is focused on Petitioner's identification of button 32.

need not decide which construction to adopt to decide the specific issue before us.

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

Second, we do not agree with Patent Owner's more restrictive interpretation, requiring that the identified structure operate *directly* to reversibly lock two components in rotation. In particular, Patent Owner has identified no intrinsic evidence that justifies such limitation.[9] Based on the full record before us, 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

[9] 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 should identify some reason why such narrowing is appropriate. Patent Owner's hypothetical example of finding a user's hand is a clutch is inapposite as a user's hand is clearly not part of "[a] housing part for a medication dispensing apparatus" as stated in the preamble of claim 1.

mechanism 34 to move forward because threads 110, 112 are no longer in engagement with groove 158. *Id.* at 11:16–20. Burroughs explains that "[a]s dial mechanism 34 is initially moved forward, splines 144 move out of engagement with splines 192 of nut 36 to disengage the clutch by *rotationally decoupling* dial mechanism 34 from nut 36 prior to any axial movement of nut 36." *Id.* at 11:27–30 (emphasis added).

With respect to the first construction, as the above description indicates, button 32 couples and decouples a moveable component—dial mechanism 34—from another component—nut 36. With respect to the second construction, the above description also indicates that button 32 operates to *rotationally decouple* dial mechanism 34 from nut 36, which reverses the rotational locking of those two components. *See* Pet. 39 (identifying dial mechanism 34's rotational connection with nut 36); Ex. 1095 ¶ 29 (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 1 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.

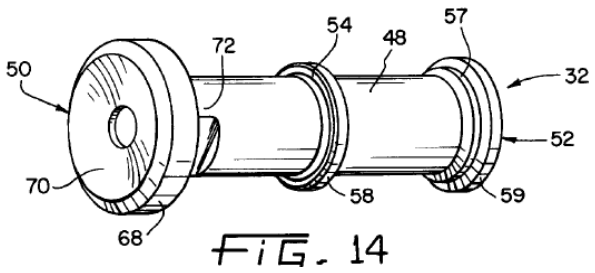

FIG. 14

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.

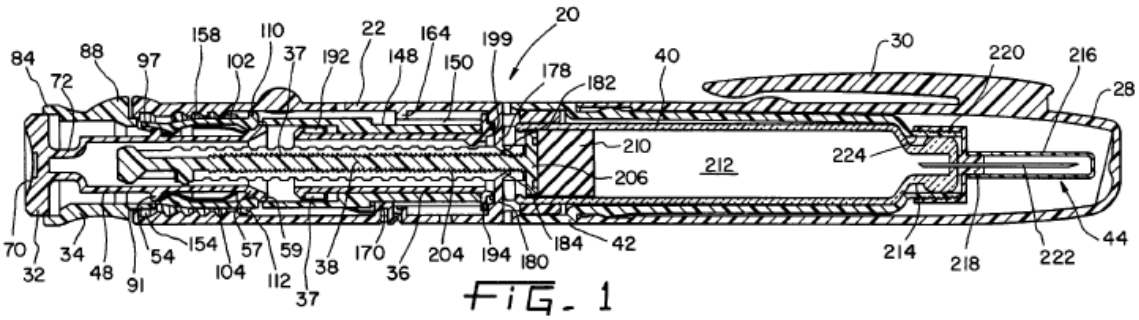

FIG. 1

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 "a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip."

h) wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

Petitioner argues that Burroughs teaches the wherein clause of claim 1. Pet. 45–46 (citing Ex. 1011 ¶ 188; Ex. 1013, Fig. 1). We find that Figure 1 of Burroughs shows that dial mechanism 34 extends circumferentially around at least a portion of button 32. We also credit

Mr. Clemens's testimony because Burroughs supports it. Ex. 1011 ¶ 188 (discussing Ex. 1013, Fig. 1).

Patent Owner does not present an argument regarding this wherein clause of claim 1. *See* PO Resp. 16–28. Because Burroughs shows dial mechanism 34 extending circumferentially around at least a portion of button 32, Petitioner persuades us that Burroughs teaches "wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch."

2. Analysis of Claim 2

Claim 2 depends from claim 1 and further requires:

> a cartridge retaining part operatively coupled to said main housing, said cartridge retaining part comprising a fluid container,
>
> wherein said fluid container defines a medicament filled reservoir with a movable plunger at a proximal end and an outlet at a distal end,
>
> said cartridge piston movable by said piston rod to be advanced toward an outlet of said fluid container when said piston rod is moved distally, wherein during a dose setting step, said dose dial grip, is rotated and moves away from said proximal end of said main housing so that a dose of a medicament contained within said medicament filled reservoir can be selected.

Ex. 1001, 6:61–7:7.

Petitioner argues that cartridge retainer part 42 secured and coupled through leadscrew 38 and piston 210 to housing 22 of Burroughs teaches the "cartridge retaining part." Pet. 48 (citing Ex. 1011 ¶¶ 858–859; Ex. 1013, 9:32–41, Fig. 1). Petitioner also argues that cartridge 40 teaches the "fluid container." *Id.* (citing Ex. 1011 ¶¶ 858–859; Ex. 1013, 9:32–41, Fig. 1).

For the wherein clause, Petitioner contends that chamber 212, piston 210, and neck 214 teach the "fluid container," "movable plunger," and "outlet," respectively. *Id.* at 48–49 (citing Ex. 1011 ¶¶ 858–859; Ex. 1013, 2:42–44, 9:32–40, Fig. 1). Petitioner also contends that piston 210, leadscrew 38, and plunger engagement portion 206 provide the required movability between the cartridge piston and piston rod. *Id.* at 49 (citing Ex. 1011 ¶ 859; Ex. 1013, 9:32–40, Fig. 1). Petitioner further contends that Burroughs teaches the rotation and movement of the dose dial grip. *Id.* (citing Ex. 1011 ¶ 860; Ex. 1013, 8:24–29, 10:34–52).

We find that the relied-upon portions of Burroughs teach that "[c]artridge 40 is housed within cartridge retainer 42, which is permanently secured to housing parts 24 and 26" (Ex. 1013, 9:34–36), "[a] liquid medication product is housed in a variable volume cartridge within the housing of the device" (*id.* at 2:42–44), and "plunger engagement portion 206 of leadscrew 38 is in engagement with piston 210 of cartridge 40" (*id.* at 9:32–34). *See also id.* Fig. 1 (showing plunger engagement portion 206 of leadscrew 38 abutting piston 210). We also find that the relied-upon portions of Burroughs teach that "[c]artridge 40 . . . comprises a tube defining an inner chamber 212 which openly terminates at its distal end in a neck 214 having a cap 216." *Id.* at 9:36–39.

We further find that the relied-upon portions of Burroughs teach that "[p]roximal portion 78 of dial 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" that respectively include "outwardly extending thread 110, 112." *Id.* at 8:24–29. We additionally find that the relied-upon portions of Burroughs teach that "[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," rotation of dial mechanism 34 causes "causes a 'click' to occur, thereby providing an audible indication of each unit of dosage dialed up," "a single numeral appears in lens 25 after each unit rotation indicating the current dose selected," and "[o]nce a dosage has been selected, that dosage may be made larger or smaller by rotating the dial assembly in either the clockwise or counterclockwise direction." *Id.* at 10:34–52. We credit the testimony of Mr. Clemens regarding claim 2 because Burroughs supports it. Ex. 1011 ¶¶ 858–860 (citing Ex. 1013, code (57), 2:42–48, 9:32–41, 9:47–49, 9:59–61, 10:15–18, 10:34–42, 10:48–49, Figs. 1, 2).

Patent Owner does not provide an argument specifically for claim 2. *See* PO Resp. 16–28; *see also* Pet. Reply 7–8 (arguing that Patent Owner "has not addressed these claims or otherwise asserted that they are independently patentable over claim 1" and "has waived any such argument").

Because Burroughs teaches (1) cartridge retainer part 42 permanently secured to housing parts 24, 26, (2) cartridge retainer part 42 houses cartridge 40, and (3) cartridge 40 houses a liquid medication product and comprises piston 210, inner chamber 212, and neck 240 with cap 216, Petitioner persuades us that Burroughs teaches "a cartridge retaining part operatively coupled to said main housing, said cartridge retaining part comprising a fluid container, wherein said fluid container defines a medicament filled reservoir with a movable plunger at a proximal end and an outlet at a distal end," as recited by claim 2.

Also, because Burroughs shows plunger engagement portion 206 of leadscrew 38 abutting piston 210 inside cartridge 40 and piston 210 is opposite neck 40, Petitioner persuades us that Burroughs teaches "said

cartridge piston movable by said piston rod to be advanced toward an outlet of said fluid container when said piston rod is moved distally."

Further, because Burroughs teaches rotating proximal portion 78 of dial mechanism 34 causes dial mechanism 34 to retract from the housing and set a dose indicated by a click and a number in lens 25, Petitioner persuades us that Burroughs teaches "wherein during a dose setting step, said dose dial grip, is rotated and moves away from said proximal end of said main housing so that a dose of a medicament contained within said medicament filled reservoir can be selected."

3. Analysis of Claim 3

Claim 3 depends from claim 2 and recites "wherein said dose dial grip is operatively configured to said tubular clutch so that, during said dose setting step, said tubular clutch, said dose dial sleeve, and said dose dial grip rotate and move in a proximal direction in relation to said main housing." Ex. 1001, 7:8–12.

Petitioner refers to its arguments regarding the recited clutch, dose dial sleeve, and dose dial grip and argues that, "[s]ince the proximal portion of the dial mechanism abuts and surrounds the end 68 of the button, turning the dial mechanism causes the button to rotate and move in a proximal direction in relation to the main housing 22." Pet. 49 (citing Ex. 1011 ¶¶ 862–863; Ex. 1013, 7:46–64, 10:34–44, Figs. 1, 6–9, 14, 15).

We find that the relied-upon portions of Burroughs teach that "button 32 comprises a hollow cylindrical portion 48" with components "to keep button 32 centered within dial mechanism 34 and also prevent button 32 from inadvertently falling or being removed from dial 34" and so that "end 68 protrudes 1.5 millimeters beyond the end of dial mechanism 34 to enable the user to easily depress the button during injection." Ex. 1013,

7:46–64, Figs. 14, 15. We also find that the relied-upon portions of Burroughs teach that "[i]n its zero-dose position, dial mechanism 34 may be axially retracted a predetermined distance, e.g. 3 to 5 mm, to engage the clutch mechanism" and "[u]pon rotation of dial 34, . . . dial mechanism 34 retracts from housing 22." *Id.* at 10:34–44, Figs. 1, 4. We further credit Mr. Clemens's testimony regarding claim 3 because Burroughs supports it. Ex. 1011 ¶¶ 862–863 (citing Ex. 1013, 7:47–58, 8:2–8, 8:63–91, 9:47–54, 10:31–42, 11:3–12, Figs. 1, 2).

Patent Owner does not provide an argument specifically for claim 3. *See* PO Resp. 16–28; *see also* Pet. Reply 7–8 (arguing that Patent Owner "has not addressed these claims or otherwise asserted that they are independently patentable over claim 1" and "has waived any such argument").

As discussed above for claim 1, because Burroughs teaches proximal portion 78 of dial mechanism 34 is towards the proximal end, Petitioner persuades us that Burroughs teaches "a dose dial grip disposed near a proximal end of said dose dial sleeve;" Petitioner persuades us that one of ordinary skill in the art would have modified dial mechanism 34 of Burroughs to arrive at the recited dose dial sleeve; and Petitioner has shown that Burroughs's button 32 teaches "a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip."

Because Burroughs teaches button 32 fixed to dial mechanism 34, and thus proximal portion 78, that is rotated out of housing 22, Petitioner persuades us that Burroughs teaches "wherein said dose dial grip is operatively configured to said tubular clutch so that, during said dose setting

step, said tubular clutch, said dose dial sleeve, and said dose dial grip rotate and move in a proximal direction in relation to said main housing."

F. Alleged Obviousness over Steenfeldt-Jensen

Petitioner argues that "Steenfeldt-Jensen disclosed a single device comprising all of the components, including the same structural limitations, recited by claim 1." Pet. 50. Petitioner also argues that "[t]o the extent that Steenfeldt-Jensen may not disclose a 'drive sleeve' as required by challenged claim 1, it would have been obvious to modify Steenfeldt-Jensen's device to include such a drive sleeve." *Id.*

Patent Owner responds that "Petitioner concedes that Steenfeldt-Jensen fails to disclose a drive sleeve that engages with a piston rod via a threaded connection" and further argues that one of ordinary skill in the art "would not have been motivated to make Petitioner's proposed modification because it renders Steenfeldt-Jensen's device inoperable for its intended purpose." PO Resp. 1.

For the reasons below, we determine that Steenfeldt-Jensen teaches or suggests the limitations of claim 1 and that one of ordinary skill in the art would have had a reason to make Petitioner's proposed modification with a reasonable expectation of success.

1. Analysis of Claim 1

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

Petitioner argues that Steenfeldt-Jensen teaches the preamble of claim 1. Pet. 50–51 (citing Ex. 1011 ¶¶ 261, 262; Ex. 1014, 1:12–15, 5:38–44, Figs. 15–17).

To the extent that the preamble is limiting, we find that the relied-upon portions of Steenfeldt-Jensen teach "injection syringes of the kind

apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses" (Ex. 1014, 1:12–15) and the "injection syringe comprises a housing" (*id.*, code (57)). *See id.* at 5:38–44 (describing that the "syringe comprise[s] a tubular housing 1"), Figs. 15–17. We also credit Mr. Clemens's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 261, 262 (citing Ex. 1014, code (57), 1:12–15, 5:38–44, Figs. 15–17).

Patent Owner does not present an argument regarding the preamble of claim 1. *See* PO Resp. 28–44. Because Steenfeldt-Jensen teaches an injection syringe with a cartridge with medicine and a housing, Petitioner persuades us that Steenfeldt-Jensen teaches a "housing part for a medication dispensing apparatus."

b) a main housing, said main housing extending from a distal end to a proximal end;

Petitioner argues that Steenfeldt-Jensen teaches the main housing recited by claim 1. Pet. 51–53 (citing Ex. 1011 ¶ 263; Ex. 1014, 5:38–44, Figs. 15–17, claim 11).

We find that the relied-upon portions of Steenfeldt-Jensen teach the syringe comprises housing 1 (Ex. 1014, 5:38–44) and has proximal and distal ends (*id.*, claim 11). *See also id.* at Figs. 15–7 (showing housing 1). We also credit Mr. Clemens's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 263 (citing Ex. 1014, 5:38–44, Figs. 15–17, claim 11).

Patent Owner does not present an argument regarding the main housing of claim 1. *See* PO Resp. 28–44. Because Steenfeldt-Jensen teaches an injection syringe with a housing having proximal and distal ends, Petitioner persuades us that Steenfeldt-Jensen teaches "a main housing, said main housing extending from a distal end to a proximal end."

> *c) a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;*

Petitioner argues that Steenfeldt-Jensen teaches the required dose dial sleeve of claim 1. Pet. 53–55 (citing Ex. 1011 ¶¶ 264, 265; Ex. 1014, 11:20–22, 11:52–54, 12:4–9, Figs. 15–17). Specifically, Petitioner argues that "Steenfeldt-Jensen discloses that the syringe includes a 'dose dial sleeve' in the form of scale drum 80." *Id.* at 54 (citing Ex. 1014, 11:20–22).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "scale drum 80 is in its outer wall provided with a helical track which is engaged by a helical rib 16 along the inner wall of the housing 1," "[w]hen a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing," and

> [w]hen the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 which is induced by the thread engagement between the helical track of the scale drum 80 and the rib 16 in the housing when the scale drum 80 is pressed back into said housing.

Ex. 1014, 11:20–22, 11:52–54, 12:4–9. We also find that Figures 15 and 16 of Steenfeldt-Jensen show scale drum 80 within housing 1. We further credit Mr. Clemens's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 264, 265 (citing Ex. 1014, 11:20–22, 11:52–54, 12:4–9, Figs. 15–17).

Patent Owner does not present an argument regarding the dose dial sleeve of claim 1. *See* PO Resp. 28–44. Because Steenfeldt-Jensen teaches that scale drum 80 is within housing 1 and has a helical track on its outer

surface that engages helical rib 16 of housing 1, Petitioner persuades us that Steenfeldt-Jensen teaches "a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve."

d) a dose dial grip disposed near a proximal end of said dose dial sleeve;

Petitioner argues that Steenfeldt-Jensen teaches the dose dial grip of claim 1. Pet. 55–56 (citing Ex. 1011 ¶¶ 266, 267; Ex. 1014, 11:22–25, 11:52–62, Figs. 15–17). In particular, Petitioner argues that "Steenfeldt-Jensen discloses a 'dose dial grip' in the form of dose setting button 81, which the user rotates to set a dose." *Id.* at 56 (citing Ex. 1011 ¶ 266; Ex. 1014, 11:22–25, Figs. 15–17).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "[a]t its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81 which on its cylindrical outer wall is knurled to ensure a good finger grip," "[w]hen a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing," and "a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction." Ex. 1014, 11:22–25, 11:52–54, 11:57–58. We also find that Figures 15–17 of Steenfeldt-Jensen show dose setting button 81 at the button-end of scale drum 80. We further credit Mr. Clemens's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 266, 267 (citing Ex. 1014, 11:22–25, 11:52–62, Figs. 15–17).

Patent Owner does not present an argument regarding the dose dial grip of claim 1. *See* PO Resp. 28–44. Because Steenfeldt-Jensen teaches dose setting button 81 at the proximal end of scale drum 80, Petitioner persuades us that Steenfeldt-Jensen teaches "a dose dial grip disposed near a proximal end of said dose dial sleeve."

> *e) a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;*

Petitioner argues that Steenfeldt-Jensen teaches the piston rod of claim 1. Pet. 56–60 (citing Ex. 1011 ¶¶ 268, 270–272; Ex. 1014, 5:55–58, 8:35–38, 11:6–19, 11:52–62, Figs. 15–17). In particular, Petitioner argues that Steenfeldt-Jensen teaches piston rod 6 that "is non-rotatable during a dose setting step relative to housing 1 due to a pawl mechanism that works between driver tube 85 and member 40" and the pawl mechanism "bars clockwise rotation of driver tube 85 relative to housing 1." *Id.* at 59–60 (citing Ex. 1011 ¶ 271; Ex. 1014, 11:6–19, 11:52–62).

We find that the relied-upon portions of Steenfeldt-Jensen teach "piston rod 6 having an external thread 7 mating the thread 5 of said bore," piston rod 6 "extends through said bore," and "end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing." Ex. 1014, 5:55–58, 8:35–38. We also find that Figure 16 of Steenfeldt-Jensen shows piston rod 6 in housing 1.

We further find that the relied-upon portions of Steenfeldt-Jensen teach that "the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment," and "[t]he piston rod has a not round cross-section and fits

through the driver tube bore which has a corresponding not round cross-section" so that "rotation is transmitted" and "the piston rod is allowed to move longitudinally through the driver tube." *Id.* at 11:11–19.

Regarding piston rod 6 being non-rotatable relative to housing 1 during dose setting, we find that Steenfeldt-Jensen teaches a pawl mechanism between the driver tube that rotates piston rod 6 and housing 1 and that the pawl mechanism prevents the driver tube from rotating during dose setting. In particular, Steenfeldt-Jensen teaches that "[t]o maintain a clockwise rotation of a dose setting button for increasing the set dose the pawl mechanism working between the driver tube and the housing . . . bars clockwise rotation . . . of the driver tube." *Id.* at 11:6–11. Steenfeldt-Jensen also teaches that "[w]hen a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing" and "[t]he bushing is kept non rotated due to its coupling to the driver tube which is locked against clockwise rotation." *Id.* at 11:52–57. "[I]f a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction," Steenfeldt-Jensen teaches that "the pawl mechanism working between the driver tube and the housing . . . prevent[s] the bushing 82 from following this anticlockwise rotation." *Id.* at 11:57–62. We additionally credit Mr. Clemens's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 268, 270–272 (citing Ex. 1014, 5:55–58, 8:34–35, 8:49–53, 11:6–15, 11:52–62, Figs. 15–17).

Patent Owner does not present an argument regarding the piston rod of claim 1. *See* PO Resp. 28–44. Because Steenfeldt-Jensen teaches piston rod 6 in housing 1 and a pawl mechanism bars rotation of the driver tube that would rotate piston rod 6 during dose setting, Petitioner persuades us that

Steenfeldt-Jensen teaches "a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing."

> *f) a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and,*

Petitioner argues that Steenfeldt-Jensen teaches the drive sleeve of claim 1. Pet. 60–64 (citing Ex. 1011 ¶¶ 273–274; Ex. 1014, 11:6–19, 11:52–62, 12:4–12, Figs. 15–17). In particular, Petitioner argues that "Steenfeldt-Jensen discloses a 'drive sleeve' in the form of driver tube 85." *Id.* at 63 (citing Ex. 1011 ¶¶ 273–274).

We find that Figure 16 of Steenfeldt-Jensen shows driver tube 85 around a portion of piston rod 6. Also, as discussed above for the recited piston rod, Steenfeldt-Jensen teaches that "the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment," and "[t]he piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section" so that "rotation is transmitted" and "the piston rod is allowed to move longitudinally through the driver tube." Ex. 1014, 11:11–19.

We also find that the relied-upon portions of Steenfeldt-Jensen teach that pressing injection button 88 injects a set dose, "the thread engagement between the helical track of the scale drum 80 and the rib 16 in the housing when the scale drum 80 is pressed back into said housing" induces "anticlockwise rotation of the dose setting button 81," bushing 82 follows that rotation, "[t]he bushing will rotate the driver tube 85 in an anticlockwise

direction which the pawl mechanism reluctantly allows," and "the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2." *Id.* at 12:4–12; *see also id.* at 11:6–11 (describing the pawl mechanism), 11:52–62 (describing dose setting). We also credit Mr. Clemens's testimony regarding what Steenfeldt-Jensen teaches in connection with this limitation because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 273–274 (citing Ex. 1014, 11:6–19, Figs. 16, 17).

Patent Owner responds that Petitioner concedes that driver tube 85 of Steenfeldt-Jensen does not engage a piston rod with an internal threading near a distal portion. PO Resp. 28 (citing Pet. 63–64). Patent Owner also responds that "[n]one of the four passages in Steenfeldt-Jensen that Petitioner relies on discloses an internally threaded driver tube," and that "[i]nstead, these passages disclose an internally threaded 'nut member' or 'nut element', which is rotated by a driver tube – the driver tube itself is not threaded." *Id.*; *see also id.* at 29–30 (arguing what the passages would teach to one of ordinary skill in the art).

We agree with Patent Owner that Petitioner argues that Steenfeldt-Jensen teaches piston rod 6 "rotationally engages with the rod through the non-circular bore, rather than 'an internal threading near a distal portion.'" Pet. 63–64 (citing Ex. 1011 ¶ 274). Petitioner, however, further argues that one of ordinary skill in the art "would have considered it obvious to modify driver tube 85 to provide the 'drive sleeve' of claim 1," which we analyze below. *Id.* at 64 (citing Ex. 1011 ¶¶ 275–279).

For the reasons above, because Steenfeldt-Jensen teaches driver tube 85 around a portion of piston rod 6, Petitioner persuades us that Steenfeldt-Jensen teaches "a drive sleeve extending along a portion of said

piston rod" that rotates the piston rod via a non-circular bore so that piston rod screws through internal threading of end wall 4.

(1) Reason to Modify

Regarding "said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod," Petitioner contends that, although Steenfeldt-Jensen teaches that driver tube 85 rotationally engages piston rod 6 via a non-circular bore, it would have been obvious to modify driver tube 85 with an internal threading near a distal portion. Pet. 69 (citing Ex. 1011 ¶ 274); *see also id.* at 64 (citing Ex. 1011 ¶¶ 275–279). Petitioner argues that "the modified device would have been understood to contain a 'drive sleeve' of claim 1 having the claimed structural elements." Pet. 69 (citing Ex. 1011 ¶ 274).

According to Petitioner, Steenfeldt-Jensen expressly states at column 7, lines 44–47, that "[e]mbodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention" and therefore, Steenfeldt-Jensen contemplates a driver tube with an internal threading to engage a piston rod's external threading. *Id.* at 69–70 (citing Ex. 1011 ¶ 275; Ex. 1014, 3:15–20, 3:44–47, 7:44–47).

Petitioner also argues that one of ordinary skill in the art would have understood driver tube 85, shown in Figures 15–17, includes a "piston rod guide" because "it allows relative axial movement of the piston rod, while preventing relative rotational movement due to its non-circular bore." *Id.* at 70 (citing Ex. 1011 ¶ 276; Ex. 1014, 2:46–53, 3:15–20). Petitioner further argues that a person of ordinary skill in the art would have understood

member 40 includes a "nut element" because member 40 has internal threading on end wall 4. *Id.* (citing Ex. 1011 ¶ 276).

Petitioner, thus, contends that Steenfeldt-Jensen suggests a "nut element" on a driver tube and a "piston rod guide" on a member and one of ordinary skill in the art "would have reason to modify (1) driver tube 85 to include an internal threading for engaging the piston rod's external threading, and (2) member 40 to include a non-circular cross-section for axially guiding the piston rod." *Id.* (citing Ex. 1011 ¶ 277). Petitioner also contends that one of ordinary skill in the art would have reasonably expected the modified parts to perform the same function as before. *Id.* at 71 (citing Ex. 1011 ¶ 278).

Patent Owner responds that one of ordinary skill in the art would have understood that column 7, lines 44–47, of Steenfeldt-Jensen does not apply to the fifth embodiment of Steenfeldt-Jensen. PO Resp. 30–31 (citing Ex. 1014, 7:41–47; Ex. 2107 ¶¶ 223–226). Patent Owner argues that the phrase "shown embodiment" in that part of Steenfeldt-Jensen refers to the first embodiment shown in Figures 1–5, the description of the fifth embodiment does not include a statement similar to "[e]mbodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube," and the provisional application included the statement at lines 41–47 of column 7 and description for the first embodiment, but not the fifth embodiment. PO Resp. 31–32 (citing Ex. 1014, 5:33–7:47, 11:6–12:16; Ex. 2127, 11:2–5).

Patent Owner also argues that one of ordinary skill in the art would not have understood that lines 41–47 of column 7 are applicable to each embodiment of Steenfeldt-Jensen because, for example, applying it to Steenfeldt-Jensen's second embodiment results in a non-functioning pen

injector. *Id.* at 32 (citing Ex. 2107 ¶ 226). Patent Owner further argues that, even if applied to the fifth embodiment, lines 41–47 of column 7 do not teach or suggest Petitioner's proposed modification. *Id.* at 32–33 (citing Pet. 69–71; Ex. 2107 ¶ 227; Ex. 2164, 219:18–220:11). According to Patent Owner, "it teaches putting a piston rod guide in end wall 4 of ampoule holder 2 (of the first embodiment), and having driver tube 26 (of the first embodiment) rotate a nut element." *Id.* at 33 (citing Ex. 2107 ¶ 215).

Petitioner replies that "a driver with a nut member *is* an internally-threaded driver" and that one of ordinary skill in the art would have understood "that when Steenfeldt-Jensen refers to a driver rotating a nut member, it describes an internally-threaded driver tube." Pet. Reply 8–9 (citing Pet. 69–71; PO Resp. 29–30; Ex. 1014, 3:41–47; Ex. 1095 ¶¶ 37–38; Ex. 2107 ¶¶ 29–30, 215–222). Petitioner contends that one of ordinary skill in the art would have understood Steenfeldt-Jensen teaches an internally-threaded driver tube when referring to a driver rotating a nut member, because Steenfeldt-Jensen describes the well-known alternative of a driver rotating a nut member or nut element, and that, because no meaningful distinction exists between an integral piston-rod guide and rectangular bore, no meaningful distinction exists between an integral nut member and threads. Pet. Reply 8–9 (citing Pet. 69–71; Ex. 1014, 3:41–47, 6:35–36, 11:15–19; Ex. 1095 ¶¶ 37–40; Ex. 2107 ¶ 30). Petitioner further contends that "Steenfeldt-Jensen states that 'end wall 4 with its threaded bore forms a nut member'" and one of ordinary skill in the art would have understood that "a driver tube with a threaded bore operates as a nut member." *Id.* at 9 (citing Ex. 1014, 7:41–43; Ex. 1095 ¶¶ 39–40).

Petitioner also replies that one of ordinary skill in the art would have been able to apply relevant teachings from one embodiment to another. *Id.*

at 9–10 (responding to PO Resp. 30–33). Petitioner argues that Steenfeldt-Jensen teaches alternative driver mechanisms before describing other embodiments and Patent Owner ignores the broader context. *Id.* at 10 (citing Pet. 69–71; PO Resp. 29–30; Ex. 1014, 2:40–53, 3:15–20, 3:44–47; Ex. 1095 ¶¶ 41–42). Because Steenfeldt-Jensen teaches alternative driver mechanisms before describing other embodiments, Petitioner contends that one of ordinary skill in the art would have known such alternatives would also apply to the fifth embodiment and "Steenfeldt-Jensen provides a broad discussion of drive mechanisms using rotating piston-rod guides or nut members." *Id.* at 10–11 (citing Ex. 1014, 2:40–53, 3:10–20, 3:41–47; Ex. 1095 ¶¶ 43–45).

Petitioner further replies that the first and fifth embodiments have analogous features so that one of ordinary skill in the art would have understood that the alternative configuration for the first embodiment applies to the fifth embodiment and the alternative would have been the same with the same effect. Pet. Reply 11–12 (citing Ex. 1095 ¶¶ 44, 45). According to Petitioner, for the first and fifth embodiments, "Dr. Slocum agreed these driver tubes have 'the same engagement method' with the piston rod and apply torque in the same way" and "agreed that the drive mechanisms' 'force chain' was similar." *Id.* at 12 (citing Ex. 1054, 306:23–308:9, 342:3–343:18). Petitioner further contends that whether the alternative configuration could be applied to the second embodiment is irrelevant because of the second embodiment's different drive mechanism. *Id.* (citing Ex. 1014, 7:51–54; Ex. 1054, 344:7–346:25).

Patent Owner replies that "Steenfeldt-Jensen nowhere discloses a threaded driver tube," and thus, "the parties' arguments about whether 7:41–47 applies to the fifth embodiment are moot." PO Sur-reply 7 (citing PO

Resp. 28–30). Patent Owner also replies that it addressed other parts of Steenfeldt-Jensen that Petitioner cites. *Id.* (citing Pet. Reply 10). Patent Owner argues that Petitioner concedes the disclosure at lines 41–47 of column 7 "is not a blanket statement," and that Mr. Clemens acknowledges the differences between embodiments but focuses on the first and fifth embodiments' driver tubes and nut members without regard to their overall structure and operation. *Id.* at 8 (citing Pet. Reply 11; Ex. 1095 ¶ 44).

Patent Owner also argues that the "embodiments are not analogous" and one of ordinary skill in the art "would not apply a teaching specific to the first embodiment to the fifth embodiment" because their differences "mandate different dialing and dose dispensing methods." *Id.* at 8–9 (citing PO Resp. 30–33; Pet. Reply 9–10; Ex. 1014, 5:38–46, 6:42–59). Patent Owner further contends that Dr. Slocum opined that Petitioner's modification "would impair the first embodiment" and lines 41–7 of column 7 does not disclose Petitioner's modification. *Id.* at 9 (citing Pet. Reply 13).

Patent Owner also replies that "the claims specifically require a threaded driver tube," Steenfeldt-Jensen's nut member is separate from the driver tube, and Petitioner misreads lines 41–47 of column 3. *Id.* at 14. Patent Owner contends that the first, third, fourth, and fifth embodiments have a nut member distinct from a driver tube and lines 41–47 of column 3 do not mention an integrally formed nut member. PO Sur-reply 15–17 (citing Ex. 1014, 3:41–47, Figs. 2, 12, 14, 16).

Patent Owner also contends that Petitioner incorrectly asserts that a driver tube with integral piston rod guide suggests a driver tube with integral nut member because Steenfeldt-Jensen does not equate the piston rod guide and the nut member. *Id.* at 17 (citing Pet. Reply 8, 9; Ex. 1014, 3:41–47).

According to Patent Owner, lines 41–47 of column 3 "at best, draw[] a parallel between a piston rod (not a piston rod guide) and nut member, but in no way suggest[] an integrally formed nut member." *Id.* at 18. Patent Owner further contends that another relied-upon portion of Steenfeldt-Jensen does not suggest a nut member integrally formed with a driver tube. *Id.* (citing Pet. Reply 9; Ex. 1014, 7:41–43).

We agree with Patent Owner that the phrase, "[i]n the shown embodiment," refers to Steenfeldt-Jensen's first embodiment because of the references to end wall 4, piston rod guide 14, and driver tube 26 that are described and shown as components of the first embodiment. Ex. 1014, 7:41–43.[10] We also find that the language that follows expressly teaches other embodiments "wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube." *Id.* at 7:44–46. Because this teaching comes after describing the first embodiment, we determine that this express teaching applies directly to the first embodiment.

Even though the teaching at column 7, lines 44–47, applies directly to the first embodiment, we agree with Petitioner that this express teaching would have, at least, suggested to one of ordinary skill in the art to consider a similar alternative for other embodiments as well, even though the same statement is not repeated after the discussion of each embodiment. *See* Pet. 69–70; Pet. Reply 8–12. We credit Mr. Clemens's testimony regarding Steenfeldt-Jensen's suggestion because, for the reasons discussed below, the full record before us supports it. Ex. 1011 ¶ 277.

[10] Steenfeldt-Jensen does not use reference numbers for the end wall, piston rod guide, and driver tube of the fifth embodiment. *See* Ex. 1001, 11:11–19.

In so doing, however, we recognize, as Patent Owner points out, that one of ordinary skill in the art may not have applied the taught or suggested alternative arrangement to the second embodiment because of differences in the structure of the second embodiment as compared to the first. *See* PO Resp. 32. That the alternative arrangement may not have applied to the second embodiment, however, does not lead to the conclusion that one of ordinary skill in the art would not have or could not have applied the suggestion to Steenfeldt-Jensen's other embodiments. *See* Ex. 1095 ¶ 45.

We agree with Petitioner that (1) the various embodiments of Steenfeldt-Jensen have either analogous or the same components, and (2) Steenfeldt-Jensen does not repeat descriptions for those components in the discussion of each latter embodiment. *See* Pet. Reply 10–12. For example, the first embodiment includes "wall 4 having a central bore with an internal thread 5" and "piston rod 6 having an external thread 7 mating the thread 5 of said bore" (Ex. 1014, 5:56–58); the second embodiment has a piston rod (*id.* at 7:64); the third embodiment includes "piston rod 6 [that] engages by its external thread 7 the internal thread of the end wall 4" (*id.* at 8:45–46); the fourth embodiment also has an internally threaded wall 4 that is not described but shown in Figure 14; and for the fifth embodiment, "the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall" (*id.* at 11:11–14). *See also id.* at Figs. 2 (showing, for the first embodiment, externally threaded piston rod 6 engaging internally threaded wall 4), 7 (showing, for the second embodiment, externally threaded piston rod 6 engaging internally threaded wall 4), 11–12 (showing, for the third embodiment, externally threaded piston rod 6 engaging internally threaded wall 4), 14 (showing, for the fourth

embodiment, internally threaded wall 4), 15–16 (showing, for the fifth embodiment, externally threaded piston rod 6 engaging internally threaded wall 4).

Based on the portions of Steenfeldt-Jensen discussed above, we find that Steenfeldt-Jensen does not repeat certain descriptions for components that are analogous or the same in each embodiment, including end wall 4. *See* Ex. 1014, 8:45–46, 11:11–14, Fig. 14. We find that one of ordinary skill in the art would have understood that Steenfeldt-Jensen employed this method of description and would have applied lines 44–47 of column 7 to embodiments with the same or analogous components—the first, third, fourth, and fifth embodiments—because lines 44–47 of column 7 relate to, at least, end wall 4, which is included in each of those embodiments. Ex. 1011 ¶ 277; Ex. 1095 ¶ 44. We also find that the first and fifth embodiments have substantially similar arrangements of piston rods, piston rod guides, and nut members. *Compare id.* at Fig. 3, *with id.* at Fig. 17; *see also* Ex. 1054, 306:23–308:9 (Dr. Slocum testifying that driver tubes and piston rods shown in Figs. 3 and 17 work similarly), 342:3–343:19 (Dr. Slocum testifying that driver tubes of the first and fifth embodiments work similarly). Additionally, we find that the fact that Steenfeldt-Jensen does not repeat the description of the piston rod guide or nut element, also discussed at lines 44–47 of column 7, means that these components are not so different from the first embodiment that further description of those components is warranted for the other embodiments.

Regarding whether Steenfeldt-Jensen would have taught or suggested a driver tube with an integral nut element, Petitioner provides evidence that one of ordinary skill would have understood lines 41–47 of column 3 to suggest such a driver tube. *See* Pet. Reply 8–9 (citing Pet. 69–71; PO

Resp. 29–30; Ex. 1014, 3:41–47, 6:35–36, 11:15–19; Ex. 1095 ¶¶ 37–40; Ex. 2107 ¶¶ 30, 215–222). Patent Owner provides a refuting argument with support from what Steenfeldt-Jensen expressly teaches. *See* PO Sur-reply 14–18 (citing Pet. Reply 8–9; Ex. 1014, 3:41–47, 7:41–43, Figs. 2, 12, 14, 16). Patent Owner points to portions of the record that do not indicate that one of ordinary skill in the art would have been limited to only the express teachings in the manner argued by Patent Owner. Petitioner, on the other hand, sufficiently shows with support from Steenfeldt-Jensen's teachings and declarant testimony that, even if Steenfeldt-Jensen does not teach expressly a driver tube with an integral nut element, Steenfeldt-Jensen, at lines 41–47 of column 3, suggests such a driver tube, and the understanding of one of ordinary skill in the art would not have been limited to only the express teachings. *See* Pet. 69–71; Pet. Reply 8–9; Ex. 1011 ¶¶ 275–277; Ex. 1014, 2:46–53, 3:15–20, 3:41–47, 7:41–47, 6:35–36, 11:15–19; Ex. 1095 ¶¶ 37–40; Ex. 2107 ¶ 30.

For the reasons above, Petitioner persuades us that one of ordinary skill in the art, reading that an alternative arrangement can include a "piston rod guide [that] is provided in the wall 4 and a nut element [that] is rotated by the driver tube" (Ex. 1014, 7:44–46), "would have reason to modify (1) driver tube 85 to include an internal threading for engaging the piston rod's external threading, and (2) member 40 to include a non-circular cross-section for axially guiding the piston rod" in Steenfeldt-Jensen's fifth embodiment. Pet. 69–70; Ex. 1011 ¶¶ 275–277; Ex. 1095 ¶¶ 37–40. We also agree with Petitioner that one of ordinary skill in the art would have reasonably expected the modified parts to perform the same function as before, and thus, one of ordinary skill in the art would have had a reasonable expectation of success in making Petitioner's proposed modification. *See*

Pet. 71 (citing Ex. 1011 ¶ 278). We further credit Mr. Clemens's testimony regarding Petitioner's proposed modification because it finds support in Steenfeldt-Jensen. Ex. 1011 ¶¶ 275–278 (citing Ex. 1014, 2:46–53, 3:15–20, 3:44–47, 7:44–47, 8:48–53, Figs. 15–17).

For the reasons above, we determine that Petitioner's modified driver tube 85 rotating a nut member with internal threading engaging externally threaded piston rod 6 would result in "said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod," as required by claim 1.

(a) Patent Owner's Models and Asserted Higher Friction

Patent Owner also responds that Petitioner's proposed modification to switch the non-circular opening and threaded opening of Steenfeldt-Jensen's fifth embodiment would result in an inferior pen and thus, one of ordinary skill in the art would not have been motivated to make Petitioner's proposed modification. PO Resp. 33–44; *see also id.* at 1 (arguing that Petitioner's proposed modification would have rendered Steenfeldt-Jensen inoperable for its intended purpose). In particular, Patent Owner argues that moving threads to the driver tube and moving the non-circular bore to member 40 would cause "a major new source of friction to Steenfeldt-Jensen's fifth embodiment." *Id.* at 33 (citing Ex. 2107 ¶¶ 232–238).

Patent Owner contends that higher friction would increase injection force, which is a benchmark. *Id.* at 34 (citing Ex. 1015 ¶¶ 4–6; Ex. 2107 ¶¶ 37–39, 44–45, 54, 56–57; Ex. 2163, 80:17–81:5). In support of its argument, Patent Owner points us to "an analytical model presented in a spreadsheet" and a "Collar Friction Model." *Id.* at 34–35 (citing Ex. 2107 ¶¶ 242–255; Ex. 2211; Ex. 2215; Ex. 2216; Ex. 2217); *see also id.* at 35–36

(explaining the analytical model and contending that it shows "Petitioner's proposed modification increases the amount of force required from the user to inject a dose by 51%") (citing Ex. 2107, App'x A ¶¶ 242–244), 36–39 (explaining the Collar Friction Model and contending that "manually rotating the Collar with the Threaded Insert requires 50% more force on average to advance the piston rod than rotating the Collar with Guide") (citing Ex. 2107 ¶¶ 245–255; Ex. 2215; Ex. 2216; Ex. 2217), 39–42 (explaining why Petitioner's modification results in higher friction) (citing Ex. 1004, 1:36–40; Ex. 1014, 12:10–13, Fig. 16; Ex. 1015 ¶¶ 4–6; Ex. 2107 ¶¶ 54–57, 229–231, 233–238, 242–244; Ex. 2152).

Petitioner replies that Patent Owner's models are based on Patent Owner's declarant ignoring Steenfeldt-Jensen's suggested alternative for the fifth embodiment but that Patent Owner's declarant agreed that the suggestion expressly applied to the first embodiment. Pet. Reply 12–13 (citing PO Resp. 33–44; Ex. 1054, 306:23–313:6). Petitioner also argues that Patent Owner assumes incorrectly that one of ordinary skill in the art would focus on designing only insulin pens. *Id.* at 13 (citing PO Resp. 33–34). According to Petitioner, the claim and asserted references are not limited to such pens. *Id.* (citing Ex. 1053, 62:13–71:2, 72:3–11, 75:22–76:3; Ex. 2107 ¶¶ 44–61). Petitioner agrees that injection force is a factor, but argues that it is not the only factor one of ordinary skill in the art would consider when designing pen injectors. *Id.* at 13–14 (citing Ex. 1048 ¶¶ 28–30, 32; Ex. 1095 ¶ 47).

Petitioner also replies that Patent Owner's models are flawed because (1) a named inventor provided most of the inputs for the analytical model spreadsheet (*id.* at 14–16 (citing PO Resp. 35–36; Ex. 1053, 12:22–13:5, 28:18–29:2, 30:5–33:13; Ex. 1054, 313:10–325:12; Ex. 1095 ¶¶ 48,

49; Ex. 2107 ¶¶ 242–243)), (2) the models focus on friction at one point but ignore reductions in friction at other points (*id.* at 16 (citing Ex. 1095 ¶ 50; Ex. 2107 ¶ 58)), and (3) the models exaggerate friction losses by not considering the changes, within the ordinary level of creativity, that one of ordinary skill in the art could also make to minimize friction (*id.* at 16–17 (citing Ex. 1053, 33:5–13, 41:3–42:13; Ex. 1054, 325:22–327:6; Ex. 1095 ¶¶ 48–50)).

Patent Owner replies that Dr. Slocum's analytical and physical models show a 51% higher injection force that would dissuade one of ordinary skill in the art from making Petitioner's modification. PO Sur-reply 9 (citing PO Resp. 33–44). According to Patent Owner, "Petitioner presents no rebuttal models or calculations," only argument, and "identifies no other application where higher injection force would be acceptable." *Id.* at 9–10 (citing Pet. Reply 12–14; Ex. 1014, 1:16–18); *see also id.* at 11 (arguing that "injection force would increase—a fact not disputed (only the magnitude)"). According to Patent Owner, when considering whether to combine teachings of embodiments, one of ordinary skill in the art "would consider Steenfeldt-Jensen's context, *e.g.*, diabetic injection pens." *Id.* at 10 (citing Ex. 1014, 1:16–18). Patent Owner argues that Dr. Slocum "verified the models, conducted his own experiments, and gathered his own data" and the named inventor is not an employee and has no financial stake in the outcome of this proceeding. *Id.* at 12 (citing Pet. Reply 14–16; Ex. 2107 ¶¶ 242–255). Patent Owner also argues that the "51% increase in injection force is derived from a comparison between the fifth embodiment and the modified fifth embodiment." *Id.* at 13 (citing Pet. Reply 16). Patent Owner further argues that any friction mitigation applied to the modified fifth embodiment would also be "applied to the unmodified fifth embodiment and thus would be a

wash." *Id.* (citing Pet. Reply 16). Patent Owner lastly replies that Petitioner did not inspect Patent Owner's models and presents no refuting evidence. *Id.* at 12, 13, 14.

We find that the first and fifth embodiments have substantially similar arrangements of piston rods, piston rod guides, and nut members. *Compare* Ex. 1014, Fig. 3, *with id.* at Fig. 17. Patent Owner presents persuasive evidence that Petitioner's proposed modification would increase friction to some extent. Nonetheless, Steenfeldt-Jensen expressly teaches an alternative configuration wherein a piston rod guide is in wall 4 and a driver tube rotates a nut element instead of a piston rod guide. *See id.* at 7:41–47. Petitioner provides persuasive evidence that at least some of the friction increase could be offset by making routine changes well within the level of ordinary skill in the art and that the increase would not have dissuaded one of ordinary skill in the art from applying the alternative disclosed in Steenfeldt-Jensen to the fifth embodiment. Ex. 1095 ¶¶ 48–50.

Additionally, even if we assume, as Patent Owner contends, that Steenfeldt-Jensen's alternative arrangement were limited to the first embodiment, Patent Owner's models indicate that, by implementing that alternative in the first embodiment, friction would also increase. Despite this result, Steenfeldt-Jensen does not indicate that the alternative configuration for the first embodiment has higher friction or that any resulting increase in friction is a cause for concern. *See* Ex. 1014, 7:41–47. Therefore, Steenfeld-Jensen's disclosure further supports our finding that an increase in friction would not have dissuaded one of ordinary skill in the art from making Petitioner's proposed modification to Steenfeldt-Jensen's fifth embodiment.

(b) Issues with the Flexible Arms

Patent Owner also contends that there are other potential failures in Petitioner's proposed modification. PO Resp. 43–44. Specifically, Patent Owner argues that flexible arms of driver tube 85, which act as a ratchet with member 40, can break, get stuck, or become jammed in an opening in a ring-shaped wall. *Id.* (citing Ex. 1014, 11:55–62, Figs. 15, 16; Ex. 2107 ¶¶ 239–241).

Petitioner replies that Patent Owner offers no evidence that the flexible arms would be affected and that one of ordinary skill in the art could address the asserted potential failures as a "routine issue without difficulty." Pet. Reply 17–18 (citing PO Resp. 43–44; Ex. 1095 ¶ 51; Ex. 2107 ¶¶ 239–241). Patent Owner replies that Petitioner proposes further modifications that would lead to other problems and difficulties. PO Sur-reply 11 (citing PO Resp. 43–44; Pet. Reply 17).

As discussed above, Steenfeldt-Jensen expressly describes an alternative configuration wherein a piston rod guide is in wall 4 and a driver tube rotates a nut element instead of a piston rod guide. *See* Ex. 1014, 7:41–47. Steenfeldt-Jensen does not address whether the alternative configuration results in potential failures in the flexible arms of the alternative driver tube. *See id.* Patent Owner's declarant opines that there may be potential issues with these flexible arms in Petitioner's proposed modification, but that testimony does not cite sufficient supporting evidence. *See* Ex. 2107 ¶¶ 239–241. Thus, because Steenfeldt-Jensen proposes a similar modification and does not address potential failures in the flexible arms of the alternative driver tube, and because Patent Owner's declarant, as one of ordinary skill in the art, recognizes these potential failures, the full record persuades us that such potential failures are matters that would have been

recognized by ordinarily skilled artisans and would have been addressed by those artisans. Ex. 1095 ¶ 51. Therefore, based on the full record before us, Patent Owner's asserted potential failures in the flexible arms of the alternative driver tube do not show that one of ordinary skill in the art would have been dissuaded from making Petitioner's proposed modification.

(c) Determination as to the Reason to Modify

For the reasons above, based on the full record before us, Petitioner persuades us that Steenfeldt-Jensen suggests Petitioner's proposed modifications. Petitioner persuades us that the expressly taught modification for Steenfeldt-Jensen's first embodiment would have suggested to one of ordinary skill in the art to modify Steenfeldt-Jensen's fifth embodiment.

Petitioner also presents arguments based on Exhibit 1016.[11] Pet. Reply 17–18 (citing Ex. 1016, 3:1–26, Figs. 2, 3, 5–7; Ex. 1054, 308:10–310:22; Ex. 1095 ¶ 52). Patent Owner argues that Petitioner presents a new argument based on Exhibit 1016. PO Sur-reply 18–19 (citing Pet. Reply 17–18). We do not need to address Exhibit 1016 because, for the reasons above, Petitioner persuades us that one of ordinary skill in the art would have made Petitioner's proposed modification based on arguments made in the Petition.

g) a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,

Petitioner argues that Steenfeldt-Jensen teaches the required tubular clutch of claim 1. Pet. 64–67 (citing Ex. 1011 ¶¶ 280–283; Ex. 1014, 11:26–42, 11:52–62, 12:1–13, Figs. 15–17). Specifically, Petitioner argues that bushing 82 teaches the tubular clutch because rosette 93 of teeth engage teeth on dose setting button 81 during injection and disengage during dose

[11] Giambattista, U.S. Patent No. 6,932,794 B2, issued August 23, 2005.

setting. *Id.* at 66–67 (citing Ex. 1011 ¶¶ 280–281, 283; Ex. 1014, 11:26–42, 11:52–62, 12:1–12, Figs. 15–16).

We find that the relied-upon portions of Steenfeldt-Jensen teach that "bushing 82 ha[s] a flange 83 at its proximal end" (Ex. 1014, 11:26), "[i]n the dose setting button a compartment is . . . provided with . . . a bottom with a rosette of teeth having a triangular cross-section" (*id.* at 11:34–37), "flange 83 of the bushing 82 is adopted in said compartment" (*id.* at 11:37–38), and "[a]t its distal side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment" (*id.* at 11:40–42).

We also find that the relied-upon portions of Steenfeldt-Jensen teach that "[d]uring the setting the rosette in the dose setting button forces the rosette 93 on the flange 83 of the bushing 82 out of engagement" (*id.* at 12:1–3) and "[w]hen the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81" (*id.* at 12:4–7). As discussed above for the recited "dose dial grip," Petitioner argues that "Steenfeldt-Jensen discloses a 'dose dial grip' in the form of dose setting button 81, which the user rotates to set a dose." Pet. 56 (citing Ex. 1011 ¶ 266; Ex. 1014, 11:22–25, Figs. 15–17). We additionally find that Figures 15–17 show bushing 82 is tubular and located near dose setting button 81. We further credit Mr. Clemens's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶¶ 280–283 (citing Ex. 1014, 11:26–49, 11:52–62, 12:1–13, Figs. 15–17).

Patent Owner does not present an argument regarding the tubular clutch of claim 1. *See* PO Resp. 28–44. Because Steenfeldt-Jensen teaches bushing 82 is tubular, located near dose setting button 81, and can engage or

disengage with dose setting button 81, Petitioner persuades us that Steenfeldt-Jensen teaches "a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip."

h) wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

Petitioner argues that Steenfeldt-Jensen teaches this wherein clause of claim 1. Pet. 68–69 (citing Ex. 1011 ¶ 285; Ex. 1014, 11:26–28, Figs. 15–16). As discussed above for the recited dose dial sleeve, Petitioner contends that "Steenfeldt-Jensen discloses that the syringe includes a 'dose dial sleeve' in the form of scale drum 80." *Id.* at 54 (citing Ex. 1014, 11:20–22).

We find that the relied-upon portion of Steenfeldt-Jensen teaches that "bushing 82 . . . fits into the scale drum 80." Ex. 1014, 11:26–28. We also find that Figures 15 and 16 of Steenfeldt-Jensen show scale drum 80 circumferentially around a portion of bushing 82. We further credit Mr. Clemens's testimony because Steenfeldt-Jensen supports it. Ex. 1011 ¶ 285 (citing Ex. 1014, 11:28–30, Figs. 15–16).

Patent Owner does not present an argument regarding this wherein clause of claim 1. *See* PO Resp. 28–44. Because Steenfeldt-Jensen teaches scale drum 80 circumferentially around a portion of bushing 82, Petitioner persuades us that Steenfeldt-Jensen teaches "wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch."

G. Objective Indicia of Nonobviousness

Patent Owner argues that "the ['069 Patent addressed a long-felt, but unmet need in the insulin pen injector industry – the need for an injection pen with reduced injection force" and the "commercial embodiment of the ['069 Patent, Sanofi's LANTUS® SoloSTAR®[1], achieved critical acclaim

and overwhelming commercial success that is directly attributable to the [']069 Patent." PO Resp. 2; *see also* Ex. 2109 ¶ 6 (stating that Patent Owner "sells Lantus®, insulin glargine (of rDNA origin), both in vial form ('Lantus® vial') and in pen form ('Lantus® SoloSTAR®')").

1. 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))); *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33, 32 (PTAB January 24, 2020) (precedential, designated April 14, 2020). 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 1375. "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.*

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 argues that "Sanofi's LANTUS® SoloSTAR® product practices the challenged claim" and Dr. Slocum "confirms that the claimed components and interfaces, such as the threaded engagements, piston rod, drive sleeve, and tubular clutch, are reflected in the LANTUS® SoloSTAR®." PO Resp. 59 (internal footnote omitted) (citing Ex. 2107 ¶¶ 472–512). According to Patent Owner,

> As explained by Prof. Slocum, the inventions in the challenged claim 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 ¶¶ 472–512) (emphasis added).

Petitioner replies that "Lantus[®] SoloStar[®] is not 'the invention'" because Patent Owner "relies on unclaimed features . . . , including the Lantus[®] drug product, its 80-unit cartridge, its stroke length or its injection

force." Pet. Reply 23–24 (citing Ex. 1095 ¶¶ 68–70). Petitioner also argues that the "'overwhelming consideration' in insulin-prescription decisions is 'the insulin itself,'" that the "the claimed injection pen for delivering the insulin is not an important factor driving the market," and "[i]nsulin pens are 'largely fungible.'" *Id.* at 24 (citing Ex. 1048 ¶¶ 25, 27–28; Ex. 1055, 28:14–29:22, 30:2–6; Ex. 1060 ¶¶ 37–39; Ex. 2145, 8, 15, 22; Ex. 2146, 13, 36, 77–78). According to Petitioner, Lantus® drove SoloStar® sales, and Patent Owner pushed SoloStar® over OptiClik®, another pen with long-acting insulin from Sanofi. *Id.* at 24–25 (citing Ex. 1055, 86:20–87:6, 88:14–19, 96:13–20, 103:18–104:6, 104:14–105:5, 125:16–127:6; Ex. 1056, 69:9–70:10; Ex. 1060 ¶¶ 20–21, 25–27, 30–35, 40–41, 46–51, 64, Attachments B-2–B-9; Ex. 2145, 8, 10, 99). Petitioner contends that "Lantus[®]' blocking patents" show no nexus and "[t]here is no connection between any alleged awards or industry praise and the claims-at-issue." *Id.* at 25 (citing Ex. 1060 ¶¶ 30–35, 57–60, 63–67).

Patent Owner replies that Petitioner provides no rebuttal evidence and does not analyze the challenged claim to determine whether SoloSTAR® embodies the claim. PO Sur-reply 25 (citing Pet. Reply 23–24; Ex. 1060 ¶¶ 25, 27–30, 52–56; Ex. 2107 ¶¶ 472–512). Patent Owner also argues that Mr. Leinsing opines that the claim covers prior art pens instead of analyzing whether unclaimed features are responsible for low injection force and other attributes. *Id.* (citing Ex. 1095 ¶ 70; Ex. 2107 ¶ 650).

Patent Owner also replies that "Petitioner provides 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 Response" and "provides no analysis of the challenged claims, whether they enable commercially-successful features, or whether SoloSTAR® embodies

them." PO Sur-Reply 25 (citing Pet. Reply 23–24; Ex. 1060 ¶¶ 25, 27–30, 52–56). Patent Owner also replies that Mr. Leinsing "argues against nexus because he believes the claims cover the prior art pens" and "provides no analysis of any unclaimed features of SoloSTAR® purportedly responsible for its low injection force and other attributes." *Id.* (citing Ex. 1095 ¶ 70; Ex. 2107 ¶ 650).

The challenged claims do not require expressly any particular injection force, injection stroke, or dose per injection. *See* Ex. 1001, 6:37–7:12. The challenged claims also recite a housing part comprising a main housing, dose dial sleeve, dose dial grip, piston rod, and drive sleeve, but it does not require any particular number of parts for the medication dispensing apparatus, much less a relatively small number of components. *See id.* The word "comprising" also indicates that additional components could be added to the ones expressly recited. *See id.* at 6:38. The challenged claim further requires the recited components to be in particular relative positions, such as "positioned within said housing," "disposed near," "provided within said housing," "extending along a portion of said piston rod," and "located adjacent a distal end of said does dial grip," but, other than threaded engagements between certain components, the challenged claim does not recite expressly how the components work together during injection. *See id.* at 6:37–60. As discussed above, the required threaded engagements were known in the art.

Patent Owner's declarant opines that the challenged claim describes components that provide desirable features and properties, such as low injection force, short injection stroke or higher dose per injection, and a relatively small number of components. Ex. 2107 ¶¶ 472–512. Patent Owner, however, does not explain sufficiently how the recitation of

limitations in the claims corresponding to those components necessarily result in the asserted desirable features and properties. *See* PO Resp. 58–68; *see also* PO Sur-reply 23–29. With this understanding of the scope of the challenged claims, we analyze Patent Owner's proffered evidence of objection indicia of nonobviousness.

Patent Owner "bears the burden of showing that a nexus exists." *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999). "To determine whether the patentee has met that burden, we consider the correspondence between the objective evidence and the scope of the claim." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (quoting *Demaco*, 851 F.2d at 1392). 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 the asserted long-felt need, industry praise, and commercial success in turn below.

2. Long-Felt, Unmet Need

Patent Owner contends that, according to Dr. Goland's testimony, there was a "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. 59–60 (citing Ex. 2111 ¶¶ 22–26). Patent Owner also contends that available injection pens "had numerous shortcomings and design flaws that resulted in significant injection force" higher than SoloSTAR®, and that "made the devices difficult to use and thus increased the risk of patients not adhering to their insulin and insulin-analog therapy." *Id.* at 60–61 (citing Ex. 2107 ¶ 646; Ex. 2109 ¶¶ 52–55; Ex. 2111 ¶¶ 23–25, 33–35; Ex. 2143; Ex. 2144). According to Patent Owner, SoloSTAR® "revolutionized the injection pen

market" because it was easier to use, as confirmed by literature at the time. *Id.* at 61 (citing Ex. 2111 ¶ 33; Ex. 2116, 7; Ex. 2142). Patent Owner asserts that the '069 patent addressed reducing overall force required for use, as reflected in a related patent; that industry recognized SoloSTAR® solved the "problem of needing to deliver high doses with a short dial extension and with low injection force"; and that patients preferred SoloSTAR®. *Id.* at 61–62 (citing Ex. 1001, 3:44–47; Ex. 1005, 1:66–2:3; Ex. 2117; Ex. 2121, 2, 9; Ex. 2123, 6; Ex. 2128; Ex. 2143; Ex. 2144; Ex. 2184, 2; Ex. 2185, 1). Patent Owner, thus, asserts that SoloSTAR® "satisfied a long-felt but unmet need for an easy-to-use pen that was particularly well suited to administer medication with a low injection force." *Id.* at 62.

Petitioner replies that, according to the testimony of Dr. Biggs, other insulin pens were available, fungible with SoloSTAR®, and easy to use. Pet. Reply 25 (citing Ex. 1048 ¶¶ 27, 29, 32–44, 52). Petitioner also argues that "SoloStar[®] was not an unusually good pen." *Id.* (citing Ex. 1048 ¶¶ 43, 49). Petitioner additionally argues that "Dr. Goland never heard a patient wish they had a pen with lower injection force, never saw syringe use prevent a patient from taking Lantus[®], and never prescribed an insulin solely based on its pen." *Id.* at 25 (citing Ex. 1056, 52:6–9, 71:4–16). According to Petitioner, injection force was not a concern, and SoloSTAR® does not have a lower injection force. *Id.* at 25–26 (citing Ex. 1048 ¶¶ 29–30, 58; Ex. 1060 ¶ 53; Ex. 2145, 15, 20–21). Petitioner further replies that Patent Owner presents marketing that does not show industry recognition of an unmet need. *Id.* at 26 (citing PO Resp. 62; Ex. 2123, 7; Ex. 2128, 9; Ex. 2184, 1, 3; Ex. 2185).

Patent Owner replies that, according to Dr. Goland, SoloSTAR® was preferred over OptiClik®, earlier FlexPens® were hard to push, and some

patients did not take their insulin because prior art devices were problematic. PO Sur-reply 27–28 (citing Pet. Reply 25; Ex. 1056, 34:3–17, 35:7–36:12; Ex. 2100; Ex. 2111 ¶¶ 31–43; Ex. 2113; Ex. 2116; Ex. 2121; Ex. 2123; Ex. 2126; Ex. 2128; Ex. 2140; Ex. 2143; Ex. 2144; Ex. 2184; Ex. 2185). Patent Owner also replies that Dr. Goland transitioned patients to SoloSTAR® because of its lower injection force. *Id.* at 28 (citing Ex. 1056, 66:9–15).

According to Patent Owner, Mylan's declarant in IPR2018-01670 acknowledges a focus on reducing injection force. *Id.* (citing Ex. 2316, 80:24–81:1). Patent Owner also argues that Dr. Biggs suggests "any long-felt need was satisfied by the Lantus® 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.* at 28–29 (citing Ex. 2317, 38:7–39:3, 115:23–116:6, 118:19–22).

We agree with Petitioner that Patent Owner fails to establish a nexus between the purported evidence of alleged long-felt need for a pen with a reduced injection force 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 (citing *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018)). Specifically, Patent Owner has not explained sufficiently how the limitations set forth in the claims at issue satisfy the alleged long-felt need by identifying where the claim requires low injection force as compared to other pens. As discussed above, the challenged claims do not require expressly any particular injection force, injection stroke, or dose per injection, and does not expressly recite how the claimed components work together during injection. *See* Ex. 1003, 6:37–7:12. For this reason, Patent Owner is not entitled to the presumption of nexus, and Patent Owner has not otherwise demonstrated nexus for the asserted long-felt need.

Moreover, even if we assume nexus, Patent Owner fails to sufficiently demonstrate a long-felt need for a pen with a low injection force. The Federal Circuit has explained that "[l]ong-felt need is closely related to the failure of others," and that "[e]vidence] 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).

We find that Patent Owner's evidence demonstrates acceptance of the Lantus® SoloStar® pen. *See*, *e.g.*, Ex. 2184, 1; Ex. 2185, 1; Ex. 2121, 6. But, we also find that the evidence does not 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. 60. Patent Owner's evidence does not show that others tried and failed to make such a pen. Rather, as noted above, the '069 patent attributes the reduction in force to its clutch means — a feature that was already present in other pens such as Moller's pen. *See, e.g.*, Ex. 1015 ¶¶ 26–27. Although 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 particular pen.

3. Industry Praise

Patent Owner contends that it received a "high level of praise and industry recognition" for designs in the SoloSTAR® device. PO Resp. 62–63. 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 63 (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.* 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.* at (citing Ex. 2121, 3).

Patent Owner submits further that "SoloSTAR® won the Good Design Award by the Chicago Athenaeum Museum of Architecture and Design." PO Resp. 63 (citing Ex. 2109 ¶ 73; Ex. 2201; Ex. 2223). According to Patent Owner, "[i]n connection with this award, the LANTUS® and Apidra® SoloSTAR® devices were put into the permanent Design Collection of the Chicago Athenaeum Museum of Architecture and Design." *Id.* (citing Ex. 2223, 2); *see also* Ex. 2109 ¶ 56 (testifying that Apidra® SoloSTAR® is another product practicing the patent at issue). 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." PO Resp. 64 (citing Ex. 2109 ¶ 74); *see also id.* at 62 (identifying DCA as "the design firm with whom Sanofi partnered in creating SoloSTAR®").

Petitioner replies that Patent Owner's evidence is either self-praise or is praise directed to features, such as low injection force, that are not required by the challenged claim. Pet. Reply 26 (citing Ex. 1055, 79:6–81:19; Ex. 1060 ¶¶ 57–58; Ex. 1075; Ex. 2201; Ex. 2223). Patent Owner replies that it did not make up or give itself industry praise. PO Sur-reply 29. Patent Owner argues that the awards cannot be denied. *Id.* (citing Ex. 1060 ¶¶ 57–60). Patent Owner also argues that articles concerning SoloSTAR® were peer reviewed, are not diminished by Patent Owner's involvement, and refer to low injection force. *Id.* (citing Ex. 2116; Ex. 2224; Ex. 2318, 72:11–73:18, 76:2–77:4; Ex. 2223).

Again, we agree with Petitioner. As with the proffered evidence of long-felt need discussed above, Patent Owner fails to demonstrate nexus between the purported 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 challenged claim because the claim does 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 claim at issue, much of the praise was generated by DCA, Sanofi's affiliate. *See, e.g.*, Ex. 1055 ¶¶ 57–60. Such self-generated praise is not persuasive industry praise. Further, 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. 2042, 2. It does not evidence industry praise of any specific feature of the claimed invention. *Id.*

4. Commercial Success

Patent Owner contends that SoloSTAR® contributed to "the growth of the LANTUS® franchise overall" and performed well "compared to other long-acting insulin and insulin analog pens." PO Resp. 64. Relying on the testimony of Dr. Grabowski, Patent Owner argues that (1) "LANTUS® SoloSTAR® has enjoyed fast and long-sustained growth in terms of dollar sales, new prescriptions, and total prescriptions"; (2) "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®" demonstrate commercial success; (3) "sales and prescriptions

for LANTUS® SoloSTAR® remained strong despite the entry of several competing long-acting insulin and insulin analog drugs (all in pen form) starting in 2015"; and (4) "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.* at 64–65 (citing Ex. 2109 ¶ 12).

Patent Owner also contends that LANTUS® SoloSTAR® grew faster than LANTUS® OptiClik®, specifically in number of new prescriptions. *Id.* at 65 (citing Ex. 2109 ¶¶ 12, 37). Patent Owner further contends that "the features of the device disclosed and claimed in the 069 Patent and used in LANTUS® SoloSTAR® contributed to its commercial success." *Id.* at 65–66 (citing Ex. 2107 ¶¶ 472–512; Ex. 2109 ¶ 53). According to Patent Owner, factors beyond claimed features, such as marketing, did not drive SoloSTAR®'s commercial success because "total marketing expenditures for LANTUS® SoloSTAR® were in line with, or were lower than, many other long-acting insulin products." *Id.* at 66 (citing Ex. 2109 ¶¶ 16, 64–69).

Regarding "alleged 'blocking patents' covering the glargine molecule that is used in the production of the active ingredient in LANTUS®," Patent Owner argues that "the law does not mandate across-the-board-discounting of commercial success simply because other patents cover components of the product," and that the Board should "weigh the evidence on a case-by-case basis, in light of the specific commercial success argument being made." *Id.* at 67. Patent Owner also argues that "the success of LANTUS® SoloSTAR® cannot be attributed solely to the insulin glargine molecule because LANTUS® OptiClik® used the exact same LANTUS® formulation"

and did not achieve SoloSTAR®'s success, thus the design of SoloSTAR® must have attributed at least in part to the success. *Id.* Patent Owner further argues that "Sanofi's 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®." *Id.* Patent Owner identifies Levemir® FlexPen® with its long-acting insulin as an example of a disposable pen device with long-acting insulin. *Id.*

Petitioner replies that Dr. Grabowski did not evaluate profitability and Patent Owner "provides no benchmarks for evaluating success, applies a faulty pens-only market definition, and overstates the importance of formulary status to demonstrate commercial success." Pet. Reply 26–27 (citing Ex. 1060 ¶¶ 23–24). Petitioner argues that OptiClik® did as well in its first three years and certain versions of SoloSTAR® fell below Lantus® OptiClik® sales. *Id.* (citing Ex. 1060 ¶¶ 20, 70–71). Petitioner also argues that Patent Owner excludes other insulin injectable products from its market share analysis and thus, presents commercial success "out of context." *Id.* (citing Ex. 1060 ¶¶ 25–27).

Responding to Patent Owner's contention that "Lantus[®] SoloStar[®] lost market share after 2015," Petitioner asserts that "Basaglar and Tresiba long-acting insulin products completely changed trajectory for both Lantus[®] and Toujeo SoloStar[®] products without practicing the claims." Pet. Reply 27 (citing Ex. 1055, 96:13–20; Ex. 1060 ¶¶ 30–35, 64). According to Petitioner, "[g]eneric entry of biologics is not expected to replace existing biologics as much or as fast as for small molecules" and "[d]iabetes patients are particularly reluctant to switch to a different insulin product." *Id.* (citing Ex. 1055, 143:10–144:10; Ex. 1056, 71:17–22). As a result, Petitioner asserts that "[t]he downturn for Lantus[®] and Toujeo

SoloStar[®] after 2015 provides strong evidence that SoloStar[®] itself is not a commercial success." *Id.*

Petitioner also replies that "Lantus[®] SoloStar[®] benefited from a Lantus[®] franchise that predated the Levemir[®] franchise by five years and inherited the foundation of earlier Lantus[®] pen (OptiClik[®])" and "OptiClik[®] had twice as many prescriptions in 2007 as Levemir[®] FlexPen[®]." Pet. Reply 27–28 (citing Ex. 2186, 2; Ex. 2198). Petitioner contends that "Lantus[®] SoloStar[®] overtook Levemir[®] FlexPen[®] not because of any unique SoloStar[®] attributes but because, like OptiClik[®], [Patent Owner] selected it as the exclusive U.S. Lantus[®] pen." *Id.* at 28 (citing Ex. 1060 ¶¶ 20–22, 30–35).

Patent Owner replies that Petitioner's data shows SoloSTAR® has been commercially successful. PO Sur-reply 23 (citing Ex. 2318, Attachment B-10, 31:14–17, 31:25–32:8). Patent Owner argues that the diabetes community has widely adopted SoloSTAR®. *Id.* at 23–24 (citing Pet. Reply 26–28). Patent Owner contends that Dr. McDuff acknowledged the large SoloSTAR® sales and admitted that profitability analysis is not required. *Id.* at 24 (citing Ex. 2318, 15:10–13, 28:7–19, 29:20–30). Patent Owner also contends that SoloSTAR® has the largest market share in Petitioner's asserted broader market. *Id.* (citing Ex. 1060, Attachment B-10; Ex. 2318, 31:14–17, 31:25–32:8). Patent Owner further contends that SoloSTAR® prescriptions more than quadrupled OptiClik®'s in the first four years of launch and that SoloSTAR® grew the Lantus® market and remains number one. *Id.* (citing Ex. 1060, Attachment B-10; Ex. 2318, 18:23–19:20, 21:22–22:8). Patent Owner asserts that "SoloSTAR® enjoys favorable placement in health," due, in part as admitted by Dr. McDuff, to its

"mechanical features and attributes." *Id.* at 24–25 (citing Pet. Reply 27; Ex. 2318, 33:7–36:3).

Central to Patent Owner's allegations regarding commercial success is its assertion that the Lantus® SoloStar® pen is coextensive with, and thus, embodies the claimed invention. *See* PO Resp. 64–68. We, however, for reasons similar to those discussed 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. 68. Patent Owner, however, has not sufficiently demonstrated that this "tremendous success" can fairly be attributed to the claimed invention, which does not require low injection force or insulin, let alone Lantus®'s long-acting insulin formulation. For the reasons above, we determine that there is no nexus to the asserted commercial success.

Even if we assume nexus, Patent Owner has not sufficiently demonstrated commercial success. Attachment B-10 to the Declaration of Deforest McDuff, Ph.D. 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. 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 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 24. Whereas, Petitioner suggests that it was because of the introduction of competing products. Pet. Reply 27 (citing Ex 1048 ¶¶ 30–35, 64). Regardless, the evidence clearly shows that the number of Lantus®

SoloStar® 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. Determination as to Indicia of Nonobviousness

Having considered all the indicia of nonobviousness submitted by Patent Owner, we do not find sufficient evidence of nexus to long-felt need, industry praise, or commercial success.

H. Weighing the Graham *Factors*

"Once all relevant facts are found, the ultimate legal determination [of obviousness] involves weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan." *Arctic Cat*, 876 F.3d at 1361. Above, based on full record before us, we provide our factual findings regarding (1) the level of ordinary skill in the art, (2) the scope and content of the prior art, (3) any differences between the claimed subject matter and the prior art, and (4) objective evidence of nonobviousness.

In particular, we find that (1) Petitioner's proposed level of ordinary skill in the art is consistent with the prior art of record, (2) Burroughs teaches or suggests each of the limitations of claims 1–3, (3) one of ordinary skill in the art would have had a reason to modify Burroughs with a reasonable expectation of success, and (4) there is insufficient demonstration of nexus to objective evidence of nonobviousness in the record. Also, we find that Steenfeldt-Jensen teaches or suggests each of the limitations of

claim 1 and one of ordinary skill in the art would have had a reason to modify Steenfeldt-Jensen with a reasonable expectation of success.

Weighing these findings with our determinations of level of ordinary skill and objective evidence of nonobviousness in the record, a preponderance of the evidence persuades us that (1) claims 1–3 of the '069 patent are unpatentable over Burroughs, and (2) claim 1 is unpatentable over Steenfeldt-Jensen. Further, even if nexus to objective evidence of nonobviousness were established and we reweighed the evidence presented by the parties, including Patent Owner's evidence directed to alleged long-felt need, industry praise, and commercial success, we would come to the same determination for the reasons provided above—that claims 1–3 of the '069 patent would have been obvious to one of ordinary skill in the art at the time of the invention over the asserted prior art in this proceeding.

I. Alleged Obviousness Over Moller and Steenfeldt-Jensen

Petitioner also challenges claim 1 as unpatentable over Moller and Steenfeldt-Jensen. Pet. 71–96. Because we determine that claim 1 is unpatentable over Burroughs alone and over Steenfeldt-Jensen alone, we do not reach this additional challenge to claim 1. *See SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018) (holding a petitioner "is entitled to a final written decision addressing all of the claims it has challenged").

III. PETITIONER'S MOTION TO EXCLUDE

Petitioner moves to exclude Exhibits 2100–2107, 2109, 2113–2126, 2128–2153, 2158–2164, 2166–2201, 2203–2212, 2214–2218, 2223, and 2224. Mot. 1. Petitioner notes that objections were filed. *Id.* (citing Papers 18, 26). Petitioner also requests that "[t]o the extent that any exhibit or portion of an exhibit is not excluded, use of the exhibit should be

restricted to the use for which it was originally submitted." *Id.* at 5. 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(c).

A. Exhibits 2100–2102, 2104–2106, 2113–2115, 2118–2120, 2122, 2124, 2125, 2129–2135, 2138–2141, 2145, 2146, 2151, 2153, 2158–2162, 2166–2174, 2176–2183, 2186–2200, 2203–2210, 2212, 2214, and 2218

Petitioner contends the above-listed exhibits should be excluded pursuant to Federal Rules of Evidence ("FRE") 402 and 403 "because they were not discussed in Sanofi's Response, cannot be relevant to it, and consequently serve only to confuse and create prejudice through belated surprise." Mot. 1.

Patent Owner contends that Exhibits 2100–2102 and 2104–2106 are exhibits to the deposition of Mr. Leinsing, declarant for Mylan in IPR2018-01670, and are relevant because they "provide necessary context for Mr. Leinsing's cross-examination." Opp. 1. Patent Owner also contends that Mr. Leinsing's cross-examination is relevant to the present proceeding. Additionally, Patent Owner asserts that "each of these exhibits was among the materials that Dr. Slocum considered and reasonably relied upon in forming his opinions regarding the validity of the challenged patent and thus should be admitted under FRE703." *Id.* Patent Owner contends that "at least EX2100-2102, 2113, 2120, 2131, 2134-2135, 2138, 2153, 2158-2161, 2166-2171, 2173-2174, 2176-2183, 2206-2207, 2214, and 2218 were expressly cited by Dr. Slocum in his declaration testimony." *Id.* (citing Ex. 2107 ¶¶ 26, 27, 29, 33, 36, 41, 44–46, 48–53, 56, 95–97, 114, 127, 149, 150, 428, 432, 462, 474). Patent Owner also contends that "EX2124, 2145, 2146, 2186–2199, 2203–2205, and 2208–2210 were also considered and expressly cited by Dr. Grabowski in forming his opinions" and "EX2125,

2140-2141, and 2200 were also considered and expressly cited by Dr. Goland in forming her opinions." *Id.* at 2 (citing Ex. 2109 ¶¶ 32–34, 39–45, 51, 53–55, 66–68; Ex. 2111 ¶¶ 23, 25, 43).

Petitioner replies that the facts and data relied upon by an expert must still be relevant to be admissible, and Patent Owner has not shown relevance. Mot. Reply 1. Petitioner also replies that Dr. Slocum's declaration responds to five *inter partes* reviews, and thus, significant portions are not relevant to this proceeding. *Id.* (citing Ex. 2107 ¶ 1). *Id.* Petitioner contends that the portions cited by Patent Owner are not in the part of Dr. Slocum's declaration that addresses the '069 patent. *Id.* Petitioner also argues that the Board has found in a related proceeding that the '069 patent lacks sufficient nexus to the alleged benefits supported by testimonies of Drs. Grabowski and Goland, and thus, the exhibits relied upon by them are irrelevant. *Id.* at 1–2.

We cite these exhibits to indicate where Patent Owner believes support can be found for its asserted objective indicia of nonobviousness. We do not, however, rely on these exhibits in our analysis. Additionally, the sole basis argued in Petitioner's Motion for Exclusion—that the exhibits were not cited in Patent Owner's Response—is not, in and of itself, dispositive as to whether an exhibit should be excluded. Accordingly, Petitioner has not satisfied its burden to show that these exhibits should be excluded.

B. Exhibit 2103

Exhibit 2103 consists of hand-drawn annotations made by Mylan's declarant, Mr. Leinsing, during his deposition in IPR2018-01670 and in response to questions pertaining to Petitioner's proposed modifications to Burroughs's device. Mot. 1; Opp. 3. Petitioner contends that Patent

Owner's use of Exhibit 2103 "lacks relevance, risks confusing the issues, is misleading, and is prejudicial." Mot. 2. Petitioner complains that the exhibit "is offered to establish an actual modification purported to be embodied by the annotations." *Id.* at 1–2. Patent Owner contends that the exhibit is relevant to Mr. Leinsing's opinions regarding modifying Burroughs, which was adopted by Mr. Clemens and is one of the central issues in this proceeding. Opp. 3 (citing Paper 3, 5; Ex. 2163, 189:3–15).

Petitioner replies that Mr. Clemens submitted his declaration before Mr. Leinsing's deposition and thus, could not have adopted Mr. Leinsing's testimony. Mot. Reply 2. Petitioner also argues that Patent Owner had the opportunity to depose Mr. Clemens about this exhibit but did not. *Id.* (citing Ex. 2450).

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.

C. Exhibits 2100–2106, 2163, and 2164

Petitioner moves to exclude Exhibits 2100–2106, 2163, and 2164 (deposition exhibits and transcripts of Mylan's declarant in IPR2018-01670) under FRE 402 and 403 because they "lack relevance, risk confusing the issues, are misleading, and are prejudicial" and under FRE 801–804 "as hearsay offered for the truth of their contents without satisfying any hearsay exception." Mot. 2. Patent Owner argues that Mr. Clemens adopted the opinions of Mylan's declarant and are therefore relevant to this proceeding. Opp. 4 (citing Paper 3, 5; Paper 17, 15–16). Patent Owner also argues that the parties have not misrepresented the exhibits so there can be no risk of

confusing the issues and Petitioner offered to be bound by Mylan's declarant testimony so there can be no prejudice to Petitioner. *Id.* at 4–5 (citing Paper 10, 2).

Regarding hearsay, Patent Owner argues that experts can "rely upon hearsay if reasonable to do so in the expert's field," and Dr. Slocum relied on Exhibits 2100, 2101, 2103, 2163, and 2164 to understand the state of the art and to understand Petitioner's declarant testimony. *Id.* at 5 (citing Ex. 2017 ¶¶ 29, 36, 44–61, 171, 172, 179, 227, 230, 377). Petitioner provides the same reply arguments we summarize above for Exhibit 2103. Mot. Reply 2.

For Exhibits 2100–2102, 2104–2106, 2163, and 2164, we cite these exhibits only to indicate where Patent Owner believes support can be found for its arguments. For the reasons above, we deny Petitioner's Motion with respect to Exhibit 2103. We also do not rely on these exhibits in our analysis. Thus, Petitioner's Motion is denied with respect to Exhibits 2100–2106, 2163, and 2164.

D. Exhibit 2107

Petitioner seeks to exclude Dr. Slocum's entire declaration (Ex. 2107) pursuant to FRE 702, 703, and 705. Mot. 2–3. Petitioner argues that certain portions of the declaration refer to Appendices A through F which were not submitted with the declaration in this proceeding and thus, "Dr. Slocum's declaration does not set forth the principles used in forming his opinion." *Id.* at 2. Petitioner also argues that Dr. Slocum without justification relied upon Mr. Veasey, one of the named inventors of the '069 patent, for certain data about a third-party pen and a model used for various calculations in the declaration. *Id.* at 3 (citing Ex. 1053, 12:22–13:5, 28:18–29:2, 30:5–33:13; Ex. 1054, 313:10–325:12).

Patent Owner responds that Petitioner's criticism of Dr. Slocum's reliance upon the information and model obtained from Mr. Veasey are unfounded. Opp. 6–9. 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 6–7 (citing Ex. 2107 ¶¶ 25–61), 9 (citing Ex. 1053, 30:5–33:13). Patent Owner raises additional arguments regarding the specific discussions between Dr. Slocum and Mr. Veasey. *Id.* at 7–8 (discussing measurements of the FlexPen® and embodiments in Steenfeldt-Jensen). Patent Owner notes that Petitioner does not assert that any of the design considerations noted by Dr. Slocum are incorrect. *Id.* at 8–9.

Patent Owner further 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. *Id.* at 10 (citing Ex. 2453). Patent Owner further asserts that "the measurements provided by Mr. Veasey are corroborated, unrebutted, and reliable." *Id.* Patent Owner lastly compares Dr. Slocum's declaration with Mr. Clemens's declaration. *Id.* at 10–11.

Petitioner replies that the record does not support Patent Owner's contentions because it shows Dr. Slocum accepted data and a test rig from Mr. Veasey and an opinion from Dr. Goland to make up for an absence of relevant experience in the field. Mot. Reply 3 (citing Ex. 1053, 7:23–8:4, 28:9–29:20, 30:23–33:13, 37:21–38:3, 40:20–42:13, 46:23–47:2, 47:25–51:13, 54:2–22, 75:8–21, 203:2–5, 209:13–213:5; Ex. 1054, 316:22–323:18, 329:13–331:11, 332:23–333:25; Ex. 1056, 52:6–9, 71:4–16). Petitioner argues that Dr. Slocum's testimony cannot be a product of reliable principles and methods or has reliably applied those principles and methods. *Id.* at 3–

4. Petitioner also reiterates that Appendices A through F were not submitted with Dr. Slocum's declaration. *Id.* at 4. Petitioner lastly argues that Patent Owner's comparison to Mr. Clemens's declaration should be disregarded. *Id.*

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"). Additionally, 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 by Patent Owner, as to how he acquired knowledge of the specific technology at issue—the mechanical operation and design of injection pens. Opp. 6–9.

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, 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.

Therefore, Petitioner has not shown that Dr. Slocum should be disqualified as an expert in this proceeding. Accordingly, Petitioner's Motion with respect to Dr. Slocum's declaration (Ex. 2107) is denied.

E. Exhibit 2109

Petitioner contends that paragraphs 19, 20, 31, 35, 45, 49, 50, 52, 53, 56, 71, and 72 of Exhibit 2109, the Declaration of Henry G. Grabowski, Ph.D., should be excluded under FRE 801–804 "because they constitute hearsay to the extent they repeat and rely on statements made in an interview." Mot. 3. Petitioner also contends that Exhibit 2109 should be excluded under FRE 702, 703, and 705 "because 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.*

Patent Owner argues that "FRE703 permits experts to rely upon hearsay if reasonable to do so in the expert's field" and Dr. Grabowski, a pharmaceutical economist, reasonably relied on "a device expert (Dr. Slocum) and an endocrinologist (Dr. Goland), both of whom are reliable sources and were subject to cross-examination." Opp. 11. Patent Owner also argues that "Dr. Grabowski does not introduce the hearsay statements of the two experts; instead, he provides his own opinions of the facts based on his interviews." *Id.* Patent Owner further argues that "Petitioner cites no authority that a party must file every single document that an expert considers in forming his opinions" and that Patent Owner has disclosed "Dr. Grabowski's reliance on IMS Health data," and "the underlying IMS Health data is voluminous." *Id.* at 11–12. Petitioner replies that Patent Owner's position is contrary to 37 C.F.R. § 42.65(a). Mot. Reply 4.

Whether every supporting document for Exhibit 2109 has been filed in addition to being identified in Dr. Grabowski's declaration, goes to the weight we should give to that testimony. As for the paragraphs at issue from Exhibit 2019, Petitioner deposed Dr. Grabowski (Ex. 1055), Dr. Slocum (Exs. 1053, 1054), and Dr. Goland (Ex. 1056), and we agree with Patent Owner that Dr. Grabowski "provides his own opinions . . . based on his interviews," which we can appropriately weigh. Opp. 11.

Thus, Petitioner's motion with respect to Exhibit 2109 is denied.

F. Exhibits 2117, 2147–2152, 2162, 2167, 2168, 2206, 2207, 2211, and 2215–2218[12]

Petitioner contends the above-listed exhibits are animations "offered to show animated operations of prior art and non-prior art and non-prior art injection pens" and should be excluded pursuant to FRE 801–804 "because they are offered for the truth of their contents without satisfying any of the hearsay exceptions." Mot. 4. Patent Owner provides the same response here as it did with respect to Petitioner's challenge to Exhibit 2109. Opp. 12–13. Namely, Dr. Slocum relied upon each in formulating his opinions. *Id.* Petitioner does not provide a reply argument. Mot. Reply 4.

For the reasons explained in our discussion of Exhibit 2109, we do not exclude these exhibits. We, however, agree with Petitioner that the use of these exhibits should be limited. Mot. 5.

[12] Petitioner's challenge to the admissibility of these exhibits pursuant to FRE 402 and 403 is discussed above. This section is directed to Petitioner's challenge based on FRE 801–804, which Petitioner discusses separately. *Compare* Mot. 1 (addressing FRE 402 and 403), *with id.* at 4 (addressing FRE 801–804).

G. Exhibits 2116, 2117, 2121, 2123, 2126, 2128, 2136, 2137, 2142–2144, 2175, 2184, 2185, 2201, and 2223

Petitioner moves to exclude the above-listed exhibits under FRE 402 and 403 "because the properties for which they are cited (e.g., injection force and ease of use) are not required by the challenged claims so these exhibits serve only to confuse the issues and create prejudice through needless multiplication of issues" and under FRE 801–804 "as hearsay offered for the truth of their contents without satisfying any hearsay exception." Mot. 4. Petitioner also argues that Exhibits 2121, 2142, 2184, 2185, and 2201 "should be excluded under FRE 901 for lack of support to show that they are what Sanofi purports them to be" and that Exhibit 2223 "is just self-serving advertisement by an interested entity." *Id.* at 4–5.

Patent Owner responds that Dr. Slocum relied upon each of these exhibits in formulating his opinions. Opp. 13–14. Petitioner replies that the asserted low injection force and ease of use are not claimed features and thus, do not show sufficient nexus to the challenged claims. Mot. Reply 5. Petitioner also argues that "the exhibits should be limited to the purpose for which they were submitted (showing the benefits of unclaimed features)." *Id.*

For the reasons explained in our discussion of Exhibit 2109, we do not exclude these exhibits. We, however, agree with Petitioner that the use of these exhibits should be limited. Mot. 5; Mot. Reply 5.

H. Exhibit 2224

Petitioner contends that Exhibit 2224 are offered to show objective indicia of nonobviousness, but "[i]t is hearsay without exception, lack authentication, and are unreasonably prejudicial because they are cited for a new purpose." Mot. 5. Patent Owner responds that the exhibit was

presented without objection during deposition of Dr. McDuff and confirms that Exhibit 2116, which is cited in Dr. McDuff's and Dr. Grabowski's declarations, was peer-reviewed and a reliable source of information. Opp. 15 (citing Ex. 1060 n.127; Ex. 2109 n.53; Ex. 2318, 73:3–18, 88:7–89:20. Petitioner replies that Patent Owner does not contest the Exhibit 2224 is hearsay and an expert's reliance on Exhibit 2224 does not make it admissible. Mot. Reply 5.

We agree that Patent Owner does not dispute that Exhibit 2224 constitutes hearsay, and Petitioner does not dispute that Dr. McDuff and Dr. Grabowski were permitted to rely upon an exhibit that pertains to Exhibit 2116 in formulating their opinions. Accordingly, Petitioner's Motion is denied as to Exhibit 2224, but its use is limited to showing the basis for Dr. McDuff's and Dr. Grabowski's testimonies.

IV. PETITIONER'S SUBMISSION OF CORRECTED EXHIBIT

With the Board's permission and Patent Owner's agreement, Petitioner submitted a corrected copy of Exhibit 1088. Paper 22, 1. Petitioner requested that the originally filed Exhibit 1088 be expunged. *Id.* The request is granted.

V. CONCLUSION[13]

In summary:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
1–3	103	Burroughs	1–3	
1	103	Steenfeldt-Jensen	1	
1	103	Moller, Steenfeldt-Jensen[14]		
Overall Outcome			1–3	

VI. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 1–3 of U.S. Patent No. 8,679,069 B2 have been shown, by a preponderance of the evidence, to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is denied;

FURTHER ORDERED that Exhibit 1088 is expunged; and

[13] Should Patent Owner wish to pursue amendment of the challenged claim 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).

[14] As explained above in Section II.I., we do not reach the challenge to claim 1 based on Moller and Steenfeldt-Jensen because the same claim is determined to be unpatentable over Burroughs and unpatentable over Steenfeldt-Jensen.

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

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