

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC. and PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

IPR2018-01676
Patent 8,603,044 B2¹

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

GERSTENBLITH, *Administrative Patent Judge*.

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

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

I. INTRODUCTION

A. Background

Mylan Pharmaceuticals Inc. (“Mylan”) filed a Petition (Paper 2, “Pet.”) requesting institution of an *inter partes* review of claims 11, 14, 15, 18, and 19 of U.S. Patent No. 8,603,044 B2 (Ex. 1002, “the ’044 patent”). Sanofi-Aventis Deutschland GmbH (“Patent Owner”) filed a Preliminary Response (Paper 10). With prior authorization, Mylan filed a Reply to Patent Owner’s Preliminary Response (Paper 13) limited to addressing whether we should exercise our discretion under 35 U.S.C. § 314(a) to deny the Petition, and Patent Owner filed a Sur-Reply in response (Paper 15). Applying the standard set forth in 35 U.S.C. § 314(a), we instituted an *inter partes* review of all challenged claims. Paper 20 (“Inst. Dec.”).

After institution, Pfizer Inc. (“Pfizer”) filed (1) a petition challenging the same claims of the ’044 patent on the same grounds asserted by Mylan and instituted in this case and (2) a motion for joinder requesting that Pfizer be joined as a petitioner in this case. *Pfizer Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-00978, Papers 2 (Pfizer’s Petition), 3 (Pfizer’s Motion for Joinder) (May 2, 2019). For the same reasons set forth in our Institution Decision in this case, we instituted *inter partes* review on Pfizer’s petition and granted Pfizer’s motion for joinder. *Id.* at Paper 12 (Aug. 15, 2019).²

Patent Owner filed a Patent Owner Response (Paper 31, “PO Resp.”), Petitioner³ filed a Reply to Patent Owner’s Response (Paper 46, “Pet. Reply”), and Patent Owner filed a Sur-reply (Paper 56, “PO Sur-reply”).

² This decision is entered in the record in this case as Paper 41.

³ We refer to Mylan and Pfizer, collectively, as “Petitioner.”

Petitioner filed a Motion to Exclude (Paper 64, “Mot.”), Patent Owner filed an Opposition to Petitioner’s Motion (Paper 65, “Opp.”), and Petitioner filed a Reply in support of its Motion (Paper 70, “Motion Reply” or “Mot. Reply”). Additionally, Patent Owner filed Observations on the Cross-Examination of Mr. Karl Leinsing (Paper 68) and Petitioner filed a Response to Patent Owner’s Observations (Paper 72). And, Petitioner filed Observations Regarding the Testimony of Alexander Slocum, Ph.D. (Paper 69), to which Patent Owner filed a Response (Paper 71). An oral hearing was held on January 15, 2020, and a copy of the transcript was entered in the record. Paper 78 (“Tr.”).

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

B. Related Proceedings

The parties indicate that the ’044 patent was asserted in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105 (D.N.J.) (“*Sanofi-9105*”);

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Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp., No. 1:16-cv-00812 (D. Del.); *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00113 (D. Del.); *Sanofi-Aventis U.S. LLC v. Eli Lilly and Co.*, No. 1:14-cv-00884 (D. Del.); and *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 1:17-cv-00181 (N.D. W.Va.). Paper 8, 2; Paper 9, 1–2; IPR2019-00978, Paper 2 at 1–2, Paper 6 at 2.

The same five claims—claims 11, 14, 15, 18, and 19—of the '044 patent also are challenged in IPR2018-01675.⁴ Paper 8, 2; Paper 9, 2. Patents related to the '044 patent are challenged in IPR2018-01670, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01684, IPR2018-01696, IPR2019-00122, and IPR2019-00979. Paper 8, 2–3; Paper 9, 1–2; *Pfizer*, IPR2019-00978, Paper 6 at 2–4.

C. Real Parties in Interest

Mylan identifies Mylan Pharmaceuticals Inc., Mylan Inc., Mylan GmbH, Biocon Research Ltd., Biocon Ltd., and Becton, Dickinson and Company as real parties in interest. Paper 8, 2.

Pfizer identifies itself and Hospira, Inc. as real parties in interest. *Pfizer*, IPR2019-00978, Paper 2 at 1.

Patent Owner identifies Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis U.S. LLC, and Sanofi Winthrop Industrie as real parties in interest. Paper 9, 1.

⁴ Pfizer also challenged the '044 patent in IPR2019-00978 and was joined subsequently as a petitioner to IPR2019-01676. *Pfizer Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-01676, Paper 41 (Aug. 15, 2019).

D. The Instituted Grounds of Unpatentability

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

| Claims Challenged | 35 U.S.C. § | Reference(s) |
|--------------------------|--------------------|---|
| 11, 14, 15, 18, 19 | 103(a) | Steenfeldt-Jensen ⁵ |
| 11, 14, 15, 18, 19 | 103(a) | Moller ⁶ and Steenfeldt-Jensen |

Petitioner supports its challenge with two declarations by Karl R. Leinsing, dated September 9, 2018 (Ex. 1011, “the Leinsing Declaration”), and September 18, 2019 (Ex. 1095, “the Leinsing Reply Declaration”).⁷

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

E. The '044 Patent

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

⁵ Exhibit 1014 (U.S. Patent No. 6,235,004 B1, issued May 22, 2001).

⁶ Exhibit 1015 (U.S. Patent Application Pub. No. 2002/0052578 A1, published May 2, 2002).

⁷ Petitioner filed a Declaration of Mr. William C. Biggs (Ex. 1049) and a Declaration of DeForest McDuff, Ph.D. (Ex. 1060), yet neither of these declarations includes this case number—IPR2018-01676—or the '044 patent on the cover sheet. Accordingly, although we reference the declarations here, it appears that they do not address the issues before us in this proceeding.

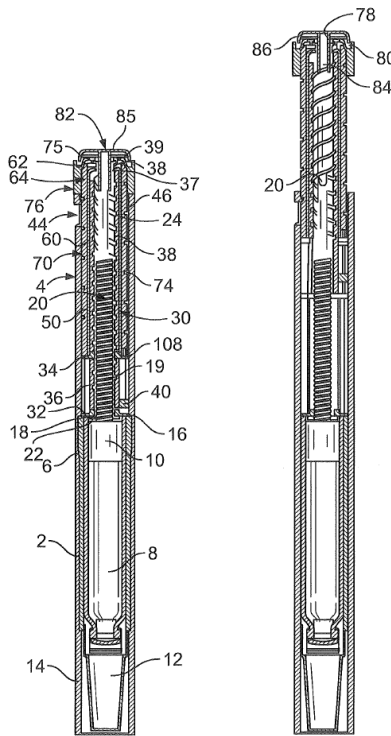


FIG. 1

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 of FIG. 1 in a second, maximum first dose dialed, position.” *Id.* at 2:53–57. The pen-type injector includes first cartridge retaining part 2 and second main housing part 4.⁸ *Id.* at 3:27–28. Insert 16 is at a first end of housing part 4 and is fixed rotationally and axially to main housing 4. *Id.* at 3:49–51. Insert 16 includes threaded circular opening 18, through which piston rod 20 extends. *Id.* at 3:51–53, 3:57–59. Piston rod 20 includes first thread 19 that engages threaded circular opening 18. *Id.* at 3:56–58.

⁸ The '044 patent refers to “second main housing part 4” and “main housing 4” interchangeably. *Compare* Ex. 1002, 3:28 (“second main housing part 4”), *with id.* at 3:30 (“main housing 4”).

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

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

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

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

F. Illustrative Claim

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

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

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

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

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

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

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

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

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

Ex. 1002, 8:7–36.

II. ANALYSIS

A. Level of Ordinary Skill in the Art

Petitioner asserts that one of ordinary skill in the art would have “had at least a bachelor’s degree in mechanical engineering, or an equivalent

degree, and three-year's experience"⁹ and would have "understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g., gears, pistons) in drug-delivery devices."¹⁰ Pet. 14 (citing Ex. 1011 ¶ 104–06). In our Institution Decision, we found that Petitioner's proposal was consistent with the level of ordinary skill in the art reflected by the prior art of record and we preliminarily adopted Petitioner's unopposed position. Inst. Dec. 13 (citing *Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978)).

In its Response, Patent Owner contends that one of ordinary skill in the art would have "a bachelor's degree in mechanical engineering or an equivalent degree." PO Resp. 12 (citing Ex. 2107 ¶ 102). Patent Owner contends that additional experience beyond the bachelor's degree is not required. *Id.* at 13. In particular, Patent Owner asserts that Petitioner proposes inconsistent levels of skill across related cases, including that one of ordinary skill "would have had 'design experience,' 'approximately three years of experience in medical-device design,' or 'three-year's experience' depending on the petition." *Id.* (citations omitted). Patent Owner further contends that "Mr. Leinsing testified that three years of experience is not

⁹ Mr. Leinsing testifies the three years of practical experience would have been "with medical device design and manufacturing." Ex. 1011 ¶ 106.

¹⁰ The articulated level of ordinary skill in the Petition differs slightly from the level of ordinary skill proposed in the petition for IPR2018-01675, which challenges the same patent. Each petition references the same paragraph of Mr. Leinsing's Declaration, which was filed in each case.

required.” *Id.*¹¹ Patent Owner contends that what is important is that the level of skill include someone “who understands the mechanical elements (e.g., lead screws, clutches, gears) used in drug injection delivery devices as well as the principles governing the interactions of such mechanical elements, and further understands the basics of device design and manufacturing.” *Id.* at 12. Nonetheless, Patent Owner asserts that “the slight differences between Patent Owner and Petitioner’s level of ordinary skill do not affect the arguments” in this case. *Id.* at 13.

We see no reason to disturb our preliminary finding regarding the level of ordinary skill in the art. Accordingly we maintain and reaffirm that one of ordinary skill in the art “would have ‘had at least a bachelor’s degree in mechanical engineering, or an equivalent degree, and approximately three year’s experience’” and “would have ‘understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g., gears, pistons) in drug-delivery devices.’” Inst. Dec. 12–13 (quoting Pet. 14). We also find that the outcome of this case is not dependent upon whether we adopt Petitioner’s or Patent Owner’s proposed level of skill.

B. Claim Construction

In an *inter partes* review based on a petition filed prior to November 13, 2018, claim terms in an unexpired patent are construed according to their broadest reasonable interpretation in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b)

¹¹ Patent Owner does not provide a citation to where Mr. Leinsing so testified.

(2017);¹² *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). There is a presumption that claim terms are given their ordinary and customary meaning, as would be understood by a person of ordinary skill in the art in the context of the specification. *See In re Translogic Tech. Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Nonetheless, if the specification “reveal[s] a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess[,] . . . the inventor’s lexicography governs.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (en banc) (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Another exception to the general rule that claims are given their ordinary and customary meaning is “when the patentee disavows the full scope of a claim term either in the specification or during prosecution.” *Uship Intellectual Props., LLC v. United States*, 714 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.*

¹² An amendment to this rule does not apply here because the Petition was filed before November 13, 2018. *See* Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (Oct. 11, 2018) (amending 37 C.F.R. § 42.100(b) effective Nov. 13, 2018) (codified at 37 C.F.R. § 42.100(b) (2019)).

Matal, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs.* in the context of an *inter partes* review).

Petitioner provides interpretations of five terms that were proffered by Patent Owner in related litigation—“drive sleeve,” “main housing,” “piston rod,” “threading,” and “tubular clutch.” Pet. 15 (citing Ex. 1019, 19, 21, 23, 27, 30). Petitioner also explains it proffered means-plus-function interpretations for “tubular clutch” and “clicker” in related litigation and reiterates those interpretations here. *Id.* at 15–16 (citing Ex. 1028, 54–59, 62–63, 65–68; Ex. 1002, 2:16–18, 4:49–62, 4:63–65, 6:33–43). Petitioner states that the grounds presented “also address the ‘tubular clutch’ and ‘clicker’ limitations as means-plus-function limitations.” *Id.* at 16.

In our Institution Decision, we determined that none of the terms required an express construction for the purposes of determining whether Petitioner demonstrates a reasonable likelihood of prevailing in its challenged. Inst. Dec. 17.

In its Response, Patent Owner agrees with our preliminary determination from the Institution Decision, arguing that “no express constructions are required.” PO Resp. 12. Petitioner does not contend otherwise in its Reply.

Accordingly, we maintain and reiterate our preliminary determination that no claim terms require express construction to address the issues raised in this proceeding. *Vivid Techs.*, 200 F.3d at 803.

C. Legal Standards – Obviousness

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

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

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)).

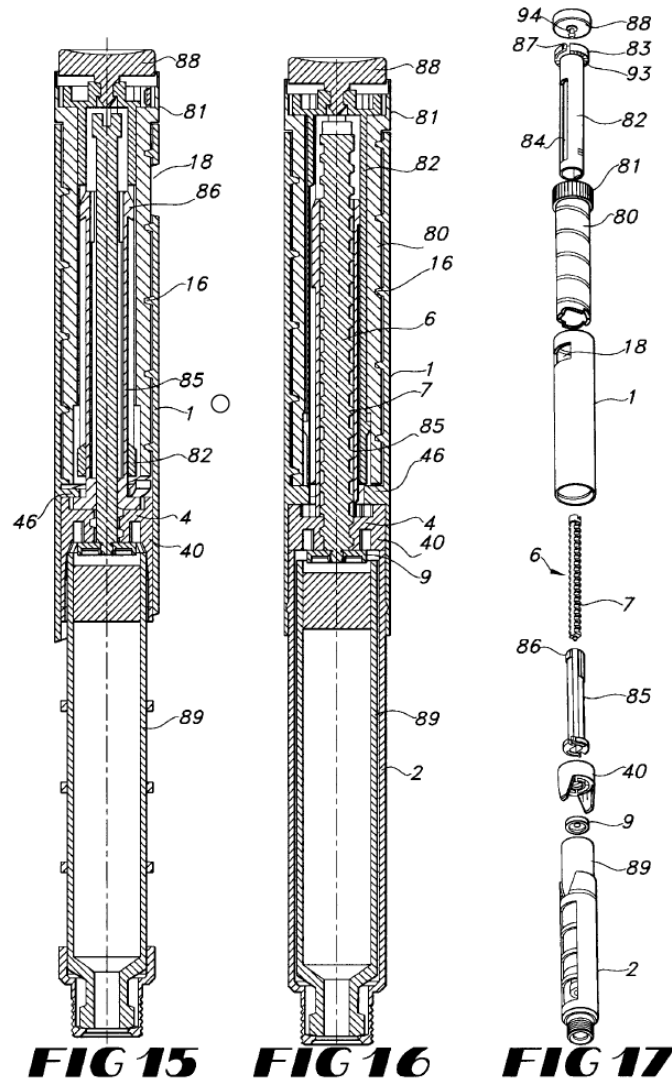
D. Obviousness over Steinfeldt-Jensen

1. Level of Ordinary Skill in the Art

As discussed above, we find that one of ordinary skill in the art at the time of the invention “would have had at least a bachelor’s degree in mechanical engineering, or an equivalent degree, and approximately three year’s experience” and “would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g., gears, pistons) in drug-delivery devices.” *See supra* § II.A.

2. Scope and Content of the Prior Art – Steinfeldt-Jensen

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 Steinfeldt-Jensen are reproduced below.



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 Steinfeldt-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 [are] 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. *Id.* at 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 11:52–54. “[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 12:4–9. “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 12:9–12.

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

Petitioner argues that “Steenfeldt-Jensen disclosed a single device comprising all claim 11 components, including the same structural limitations.” Pet. 21. Petitioner contends that “[i]f Steenfeldt-Jensen does not disclose a ‘drive sleeve[,]’ it would have been routine to modify the Steenfeldt-Jensen device to include one.” *Id.* Patent Owner disagrees.

For the reasons below, we determine that Steenfeldt-Jensen teaches or suggests the limitations of claim 11 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.

a. *Independent Claim 11*

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

Petitioner contends that “[i]f the preamble is limiting, Steinfeldt-Jensen taught it.” Pet. 21. In particular, Petitioner asserts that “Steenfeldt-Jensen describes a medicine-dispensing syringe,” which “includes tubular housing 1.” *Id.* at 22 (citing Ex. 1014, 1:12–15, 5:38–44, Figs. 15–17; Ex. 1011 ¶¶ 261–263). Pointing to Figures 15 and 16 of Steinfeldt-Jensen, Petitioner argues that “tubular housing 1 holds the drive mechanism for dispensing medicine from the syringe.” *Id.* (citing Ex. 1011 ¶ 261). Patent Owner does not contest Petitioner’s argument that Steinfeldt-Jensen teaches the preamble of claim 11.

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

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

Petitioner contends that Steinfeldt-Jensen teaches this limitation of claim 11 by disclosing “housing 1,” which “extends from button-end (proximal end) to needle-end (distal end) of the syringe.” Pet. 23 (citing Ex. 1011 ¶ 263). Patent Owner does not contest Petitioner’s argument that Steinfeldt-Jensen teaches this limitation of claim 11.

¹³ We need not determine whether the preamble of claim 11 is limiting as the parties have not raised that issue before us. Nonetheless, Patent Owner has waived any argument for patentability directed to the preamble of claim 11. *See* Paper 21 (Scheduling Order), 8 (“Patent Owner is cautioned that any arguments for patentability not raised in the response may be deemed waived.”).

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

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

Petitioner contends that Steinfeldt-Jensen’s scale drum 80 teaches the recited dose-dial sleeve of claim 11. Pet. 25 (citing Ex. 1014, 11:20–22). Pointing to Figures 15 and 16 of Steinfeldt-Jensen, Petitioner asserts that drum 80 is within housing 1. *Id.* (citing Ex. 1014, Figs. 15, 16; Ex. 1011 ¶¶ 264–265). Petitioner argues that “[t]he drum includes a ‘helical groove provided along an outer surface’ as a helical track, extending along the drum’s outer wall,” and that the “helical track is ‘configured to engage a threading provided by’ housing 1 via helical rib 16, which extends along housing 1’s inner wall.” *Id.* at 25–26 (citing Ex. 1014, 11:20–22, Figs. 16, 17; Ex. 1011 ¶¶ 264–265). Patent Owner does not contest Petitioner’s argument that Steinfeldt-Jensen teaches this limitation of claim 11.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Steinfeldt-Jensen teaches the dose dial sleeve limitation of claim 11, recited above.¹⁵

¹⁴ Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 11. *See* Paper 21, 8.

¹⁵ Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 11. *See* Paper 21, 8.

- iv. *“a dose dial grip disposed near a proximal end of said dose dial sleeve;”*

Petitioner contends that Steinfeldt-Jensen’s dose-setting button 81, which a user rotates to set a dose, teaches the recited dose dial grip of claim 11. Pet. 26 (citing Ex. 1014, 11:22–25, Figs. 15–17; Ex. 1011 ¶ 266). Petitioner asserts that “[d]ose-setting button 81 is at the button-end of scale drum 80.” *Id.* at 26–27 (citing Ex. 1014, Figs. 15–17; Ex. 1011 ¶ 266). Patent Owner does not contest Petitioner’s argument that Steinfeldt-Jensen teaches this limitation of claim 11.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Steinfeldt-Jensen teaches the dose dial grip limitation of claim 11, recited above.¹⁶

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

Petitioner contends that Steinfeldt-Jensen teaches piston rod 6, which “is non-rotatable during a dose-setting step relative to housing 1 due to a pawl mechanism between driver tube 85 and member 40.” Pet. 29 (citing Ex. 1014, 5:55–58, 11:6–19, 11:52–62, Figs. 15–17; Ex. 1011 ¶¶ 268, 271). Petitioner asserts the following with respect to Steinfeldt-Jensen’s dose setting:

The pawl mechanism bars clockwise rotation of driver tube 85 relative to housing 1. When dose-setting button 81 rotates clockwise to dial-up a dose, corresponding rotation of scale drum 80 is not transmitted to driver tube 85. To dial-down a dose, dose-setting button 81 rotates anticlockwise, but corresponding rotation of scale drum 80 is still not transmitted

¹⁶ Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 11. *See* Paper 21, 8.

to driver tube 85 due to the pawl mechanism's "sufficient reluctan[ce]" against anticlockwise rotation. Because piston rod 6 is coupled to driver tube 85 in such a way that "rotation is transmitted," and driver tube 85 does not rotate during dose setting, piston rod 6 also cannot rotate during a dose-setting step.

Id. (citing Ex. 1014, 11:6–19, 11:52–62; Ex. 1011 ¶ 271). Patent Owner does not contest Petitioner's argument that Steinfeldt-Jensen teaches this limitation of claim 11.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Steinfeldt-Jensen teaches the piston rod limitation of claim 11, recited above.¹⁷

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

Petitioner contends that Steinfeldt-Jensen teaches a "drive sleeve" "in the form of driver tube 85." Pet. 31 (citing Ex. 1011 ¶¶ 273–274).

Petitioner explains the operation of driver tube 85 as follows:

Driver tube 85 "extend[s] along a portion of" the piston rod 6 by having a bore with a non-circular cross-section through which piston rod 6, also having a non-circular cross-section, extends. Ex. 1014, 11:15–17, Figs. 15, 16; Ex. 1011 ¶¶ 273–274. Drive tube 85 couples to scale drum 80's rotational movement only during the injection process, which causes piston rod 6 to rotate through an internal threading provided in the member 40 and into the cartridge holder compartment. *See* Ex. 1014, 11:6–19; Ex. 1011 ¶ 273. To drive piston rod 6, driver tube 85 rotationally

¹⁷ Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 11. *See* Paper 21, 8.

engages with the rod through the non-circular bore, rather than “an internal threading near a distal portion.” Ex. 1011 ¶ 274.

Pet. 31. Petitioner asserts that it would have been obvious to one of ordinary skill in the art “to modify the piston rod drive to provide claim 11’s ‘drive sleeve.’” *Id.* at 32 (referring to Pet. § V.F.2).

In particular, Petitioner contends that, although Steinfeldt-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 its distal portion, which “would have been understood to contain a ‘drive sleeve’ having the structural elements of claim 11.” *Id.* at 40 (citing Ex. 1011 ¶ 274).

Petitioner asserts “Steenfeldt-Jensen states 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.’” Pet. 40 (quoting Ex. 1014, 7:44–47) (citing *id.* at 3:15–20, 3:44–47; Ex. 1011 ¶ 275). Therefore, Petitioner argues that Steinfeldt-Jensen “expressly contemplates a modification in which the driver tube contains internal threading that engages the piston rod’s external threading.” *Id.* (citing Ex. 1011 ¶ 275).

Additionally, Petitioner contends that Steinfeldt-Jensen “explains the piston-rod guide allows the piston rod to move axially (but not rotatably) relative to it, whereas the nut allows relative rotation of the piston rod.” Pet. 41 (citing Ex. 1014, 2:46–53, 3:15–20; Ex. 1011 ¶ 276). Petitioner asserts one of ordinary skill in the art would have understood that driver tube 85, in the context of Figures 15–17, includes a “piston rod guide” because “it allows relative axial piston-rod movement, while preventing

relative rotational movement due to its non-circular cross-section.” *Id.* (citing Ex. 1011 ¶ 276). Petitioner further argues that one of ordinary skill in the art would have understood that “member 40 includes a ‘nut element’ due to its internal threading.” *Id.* (citing Ex. 1011 ¶ 276).

Petitioner, thus, contends that Steinfeldt-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.” Pet. 41 (citing Ex. 1011 ¶ 277). Petitioner asserts that, in this circumstance, one of ordinary skill in the art “would have considered the driver tube to be a component for driving the piston rod having internal threading near its distal portion for engaging external threading of the piston rod.” *Id.* (citing Ex. 1011 ¶ 277).

Petitioner argues that one of ordinary skill in the art “would have reasonably expected such modification would have resulted in the device operating in the same manner”—“that when the driver tube rotates during injection, the threaded engagement between the driver tube and the piston rod cause the piston rod to be axially displaced through the member’s non-circular opening and into the ampoule.” *Id.* at 41–42 (citing Ex. 1011 ¶ 278). Thus, Petitioner asserts that the modified parts would perform the same function that they were known to perform. *Id.* at 62 (citing Ex. 1011 ¶ 278; *KSR*, 550 U.S. at 417).

In its Response, Patent Owner observes that Petitioner “concedes that Steinfeldt-Jensen’s fifth embodiment does not disclose” a “drive sleeve comprising an internal threading” as recited by claim 11. PO Resp. 29.

Therefore, Patent Owner's argument, discussed below, is directed to refuting Petitioner's contention that one of ordinary skill in the art would have modified Steinfeldt-Jensen as proposed.

Patent Owner raises four primary arguments in its Response. We discuss each.

a) *Steenfeldt-Jensen Would Have Suggested an Internally Threaded Driver Tube to One of Ordinary Skill in the Art*

As discussed above, Petitioner contends Steinfeldt-Jensen would have suggested an internally threaded driver tube to one of ordinary skill in the art. *See, e.g.*, Pet. 40 (citing Ex. 1011 ¶ 275). Patent Owner contends that Steinfeldt-Jensen does not disclose or suggest an internally threaded driver tube; instead, the passages cited by Petitioner disclose “an internally threaded ‘nut member’ or ‘nut element,’ which is rotated by a driver tube – the driver tube itself is not threaded.” PO Resp. 29. In particular, Patent Owner asserts that “[a]t best, the passages teach an internally threaded nut member and a piston rod with relative movement between the two components.” *Id.* at 31. But, Patent Owner contends, “the nut member is not the driver tube, and Steinfeldt-Jensen makes clear throughout its disclosure that the nut member and the driver tube are different components.” *Id.* (citing Ex. 1014, 3:41–47, 7:41–47, 10:2–10, Fig. 13).

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 “Steenfeldt-Jensen as describing an internally-threaded driver tube when it refers to a driver rotating a nut member.” Pet. Reply 2 (citing PO Resp. 21; Ex. 1095 ¶¶ 63–64; Ex. 2107 ¶¶ 215–222). Petitioner

contends Steinfeldt-Jensen “describes two ways to configure the driver: a driver can rotate a ‘piston rod guide’ or a ‘nut member’ (also referred to as a ‘nut element’),” and that “[t]hese alternative drivers correspond to . . . well-known screw/nut principles” that even Dr. Slocum describes in the background section of his declaration. *Id.* (citing Pet. 53–56; Ex. 1014, 3:41–47; Ex. 2107 ¶ 30). Petitioner asserts that “[j]ust as no meaningful distinction exists between a driver tube with an integral piston-rod guide and a driver tube with a rectangular bore, no meaningful distinction exists between a driver tube with an integral nut member and a driver tube with a threaded bore.” *Id.* at 2–3 (citing Ex. 1095 ¶ 65); *see id.* at 2 (citing Ex. 1014, 6:35–36 (describing the driver tube as “integral with the piston rod guide”), 11:15–19 (describing the piston rod and driver tube bore as having “not round cross-section[s],” which allows for transmission of rotation but also permits relative axial movement)). Petitioner contends that Steinfeldt-Jensen describes a “nut member” in similar terms when it “states that ‘end wall 4 with its threaded bore forms a nut member.’” *Id.* at 3 (quoting Ex. 1014, 7:41–43). Thus, Petitioner argues that one of ordinary skill in the art would have understood that “a driver tube with a threaded bore similarly operates as a nut member.” *Id.* (citing Ex. 1095 ¶ 65).

In its Sur-reply, Patent Owner argues that “the claims specifically require a threaded driver tube, not a nut member rotated by a driver tube” and that this is a distinction. PO Sur-reply 9. Patent Owner contends that the first, third, fourth, and fifth embodiments of Steinfeldt-Jensen teach a nut member distinct from a driver tube and the disclosure at lines 41–47 of column 3 do not mention an *integrally formed* nut member. *Id.* at 10–11 (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 an integral nut member because Steinfeldt-Jensen does not equate the piston rod guide and the nut member. PO Sur-reply 11 (citing Pet. Reply 2–3; 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 12. Patent Owner further contends that lines 41–43 of column 7 do not suggest a nut member integrally formed with a driver tube. *Id.* at 12 (citing Pet. Reply 3; Ex. 1014, 7:41–43).

We find that Petitioner establishes Steinfeldt-Jensen would have suggested a driver tube with an integral nut element to one of ordinary skill in the art at the time of the invention. In particular, 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 2–3 (citing Pet. 21; Ex. 1014, 3:41–47, 6:35–36, 11:15–19; Ex. 1095 ¶¶ 63–65; Ex. 2107 ¶ 30). On this record, we find persuasive, and thus credit, Mr. Leinsing’s testimony that “a driver tube with a nut member is equivalent to a driver tube with an internally-threaded bore.” Ex. 1095 ¶ 65. Patent Owner’s argument—that an internally threaded driver tube is not disclosed expressly—does not detract from Petitioner’s contention and Mr. Leinsing’s testimony that one of ordinary skill in art would have understood that Steinfeldt-Jensen *suggests* a driver tube with an internally-threaded bore. *See* PO Sur-reply 9–13 (citing Pet. Reply 2–3, 17–18; Ex. 1014, 3:41–47, 7:41–43, Figs. 2, 12, 14, 16). On the full record before us, we find that Petitioner sufficiently shows that, even though Steinfeldt-Jensen does not *disclose* a driver tube with internal

threading, one of ordinary skill in the art would have understood Steinfeldt-Jensen, at lines 41–47 of column 3, to *suggest* such a driver tube. *See* Pet. 21, 30–32, 40–42; Pet. Reply 2–3; Ex. 1011 ¶ 277; Ex. 1095 ¶ 69.

*b) One of Ordinary Skill in the Art
Would Have Modified Steinfeldt-
Jensen’s Fifth Embodiment*

Patent Owner contends that one of ordinary skill in the art would have understood that the alternative described in column 7, lines 44–47, relates only to the structure of the first embodiment (shown in Figures 1–5) of Steinfeldt-Jensen, not the fifth embodiment (shown in Figures 15–17). PO Resp. 32–33 (citing Ex. 1014, 5:33–7:47, 11:6–12:16; Ex. 2107 ¶¶ 223–226). Patent Owner argues that (1) the phrase “shown embodiment” (recited at column 7, line 41) refers to the embodiment shown in Figures 1–5 (i.e., the first embodiment), (2) the description of the fifth embodiment does not include a statement similar to the statement relied upon in column 7— “[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 (3) the provisional application (for Steinfeldt-Jensen) includes the alternative for the first embodiment, but, like the reference itself, does not include a similar alternative for the fifth embodiment. PO Resp. 30–31 (citing Ex. 1014, 5:33–7:47, 11:6–12:16; Ex. 2127, 11:2–5).

Additionally, Patent Owner contends that one of ordinary skill in the art would not have understood that the alternative was applicable to each embodiment of Steinfeldt-Jensen because, for example, applying that alternative to Steinfeldt-Jensen’s second embodiment would result in a non-functioning pen injector. *Id.* at 33 (citing Ex. 2107 ¶ 226). Patent Owner asserts that, even if applied to the fifth embodiment, the alternative

would not teach or suggest Petitioner's proposed modification. *Id.* at 33–34 (citing Pet. 36; 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 34 (citing Ex. 2107 ¶ 215).

In its Reply, Petitioner contends that one of ordinary skill in the art would have applied relevant teachings from one Steinfeldt-Jensen embodiment to another. Pet. Reply 3–8. Petitioner argues that Steinfeldt-Jensen teaches alternative driver mechanisms before describing other embodiments and Patent Owner ignores the broader context. *Id.* at 4 (citing Pet. 53–54; PO Resp. 22; Ex. 1014, 2:40–53, 3:10–20, 3:41–47; Ex. 1095 ¶ 66). Thus, Petitioner contends that one of ordinary skill in the art would have known such alternatives would also apply to the fifth embodiment and such a general suggestion does not have to be repeated. *Id.* at 5 (citing, e.g., Ex. 1095 ¶¶ 66–69).

Additionally, Petitioner asserts that the first and fifth embodiments each include a driver tube and nut member with analogous structures and functions for driving the piston rod, even though other structures in the embodiments are different. Pet. Reply 5–6 (citing, e.g., Ex. 1095 ¶ 68). Petitioner contends that because the drive mechanisms are analogous, 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 “modifications to the driver tube (26 or 85) and wall 4 would have been the same and had the same impact.” *Id.* at 6–7 (citing Ex. 1095 ¶ 69).

Further, Petitioner argues that it is irrelevant whether the alternative configuration could be applied to the second embodiment because the second embodiment has a different drive mechanism. *Id.* at 7 (citing Ex. 1014, 7:3–6, 7:17–21, 7:51–54, 7:55–67, 8:25–33, 11:52–55, 12:4–10, Figs. 6–10; Ex. 1095 ¶ 70). Petitioner asserts that Dr. Slocum agreed that the first and fifth embodiments have essentially the same transmission of force and that the second embodiment is different. *Id.* at 7–8 (citing Ex. 1054, 306:23–307:19, 307:20–308:9, 342:3–343:18, 344:7–346:25). Accordingly, Petitioner contends that “[g]iven the admitted similarities between the first- and fifth-embodiment drive mechanisms, a [person of ordinary skill in the art] would have recognized that the first-embodiment configuration was applicable to the fifth embodiment despite the second embodiment having its own, different drive mechanism.” *Id.* (citing Ex. 1095 ¶ 70).

In its Sur-reply, Patent Owner contends that Petitioner concedes the disclosure at lines 41–47 of column 7 “is not a blanket statement covering every embodiment in Steinfeldt-Jensen.” PO Sur-reply 1. Patent Owner argues that Mr. Leinsing acknowledges that there are differences between the embodiments, but conveniently dismisses those differences. *Id.* at 2 (citing Pet. Reply 5–7; Ex. 1095 ¶¶ 68; Ex. 1106 ¶ 69). Rather, Patent Owner asserts 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.” *Id.* (citing PO Resp. 22–25). Patent Owner further contends that Dr. Slocum’s testimony undercuts Petitioner’s argument and that Dr. Slocum does not agree that one of ordinary skill in the art would have undertaken such modification. *Id.* at 2–3.

We find that the phrase, “[i]n the shown embodiment,” specifically refers to Steinfeldt-Jensen’s first embodiment because (1) the language comes at the end of the written description of the first embodiment and refers to *the shown* embodiment (i.e., the embodiment that was shown previously in the written description of Steinfeldt-Jensen, meaning in Figures 1–5), (2) the only embodiment previously *shown* is that of the first embodiment, and (3) the phrase “piston rod guide 14” is not used in the written description of the other embodiments. Ex. 1014, 7:41–43.¹⁸ Thus, we find that Steinfeldt-Jensen discloses this alternative in the express context of the first embodiment.

Nonetheless, we find, as argued by Petitioner, that one of ordinary skill in the art would have, at a minimum, considered whether the alternative described therein also would apply to other embodiments, even though the alternative is not repeated after the discussion of each embodiment.¹⁹ In this regard, we credit Mr. Leinsing’s testimony regarding Steinfeldt-Jensen’s suggestion because, for the reasons discussed below, the full record before us supports it. Ex. 1011 ¶ 277.

¹⁸ The “shown embodiment” specifically refers to “end wall 4,” “piston rod guide 14,” and “driver tube 26.” Ex. 1014, 7:41–43.

¹⁹ In so finding, however, we recognize, as Patent Owner points out, that one of ordinary skill in the art may not have applied the alternative to the second embodiment in Steinfeldt-Jensen because of differences in the structure of the second embodiment as compared to the first. *See* PO Resp. 33. 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 alternative to Steinfeldt-Jensen’s other embodiments, particularly the fifth embodiment. *See* Ex. 1095 ¶ 70.

Specifically, we find, as argued by Petitioner, that several embodiments of Steinfeldt-Jensen have either the same or analogous components, particularly end wall 4. *See* Pet. Reply 3–8. 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 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* Ex. 1014, Fig. 2 (showing, for the first embodiment, externally threaded piston rod 6 engaging internally threaded wall 4), Figs. 11–12 (showing, for the third embodiment, externally threaded piston rod 6 engaging internally threaded wall 4), Fig. 14 (showing, for the fourth embodiment, internally threaded wall 4), Figs. 15–16 (showing, for the fifth embodiment, externally threaded piston rod 6 engaging internally threaded wall 4).

As reflected above, there are common elements, particularly end wall 4, across at least the first, third, fourth, and fifth embodiments disclosed in Steinfeldt-Jensen. 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 Figures 3 and 17 work similarly), 342:3–343:19 (Dr. Slocum testifying that driver tubes of the first and fifth embodiments work similarly). Also as

discussed above, lines 44 through 47 of column 7 describe an alternative wherein wall 4 is modified. Because each of these embodiments has the same “wall 4,” as well as other structural similarities, we find that this disclosure would have at least suggested that the alternative could be applied to other similarly structured embodiments, particularly, the fifth embodiment. In this regard, we find Mr. Leinsing’s testimony more persuasive for the same reason and, thus, credit his testimony over that of Dr. Slocum’s. *See, e.g.*, Ex. 1011 ¶ 277; Ex. 1095 ¶¶ 66–69.

For the reasons discussed 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 Steinfeldt-Jensen’s fifth embodiment. Pet. 41; Ex. 1011 ¶ 277; Ex. 1095 ¶ 69; *see* Pet. 41–43 (Petitioner’s full discussion of the modifications). 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. 41–42 (citing Ex. 1011 ¶ 278). We further credit Mr. Leinsing’s testimony regarding Petitioner’s proposed modification because it finds support in Steinfeldt-Jensen, as discussed above. 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).

Accordingly, we determine that Petitioner's modified driver tube 85 rotating a nut member with internal threading engaging externally threaded piston rod 6 meets the language "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 recited by claim 11.

c) *One of Ordinary Skill in the Art
Would Not Have Been Dissuaded
from Modifying Steinfeldt-Jensen
Because It Would Have Resulted in an
Inferior Pen*

Patent Owner asserts that Petitioner's proposed modifications to switch the non-circular opening and threaded opening of Steinfeldt-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. 34–45. In particular, Patent Owner argues that moving threads to the driver tube and moving the non-circular bore to member 40 would introduce "***a major new source of friction*** to Steinfeldt-Jensen's fifth embodiment." *Id.* at 34 (citing Ex. 2107 ¶¶ 232–238).

Patent Owner contends that higher friction would increase injection force, which is regularly assessed as a benchmark for these products. *Id.* at 34–35 (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 the form of a spreadsheet" and a physical model, referred to as the "Collar Friction Model." *Id.* at 35–36 (citing Ex. 2107 ¶¶ 245–255; Exs. 2211, 2215–2217). Patent Owner asserts that the analytical models demonstrate that "Petitioner's proposed

modification increases the amount of force required from the user to inject a dose by 51%.” *Id.* at 36–37 (citing Ex. 2107, ¶¶ 242–244, Appx. A). Patent Owner contends that the Collar Friction Model demonstrates 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.” *Id.* at 41 (citing Ex. 2107 ¶¶ 252–254); *see id.* at 41–45 (explaining why Petitioner’s modification results in higher friction). Thus, Patent Owner asserts that “[m]odifying the fifth embodiment as Petitioner proposes **increases friction** and impairs the device.” *Id.* at 45 (citing Ex. 2107 ¶¶ 229–231).

In Reply, Petitioner raises three main arguments. Pet. Reply 8–16. First, Petitioner contends that Dr. Slocum’s opinion is based on ignoring Steinfeldt-Jensen’s expressly stated alternative for the first embodiment, which, as discussed above, we find one of ordinary skill in the art would have applied to the fifth embodiment. Pet. Reply 9–10 (citing Ex. 1054, 306:23–313:6 (Dr. Slocum explaining that one of ordinary skill in the art would not have applied Steinfeldt-Jensen’s modification to either the first or fifth embodiment)).

Second, Petitioner asserts that Patent Owner’s position is based on a flawed premise—that modifications to Steinfeldt-Jensen are only relevant to insulin pen injectors, whereas Steinfeldt-Jensen and the ’044 patent claims are not limited to *insulin* pen injectors. *Id.* at 10–11 (citing PO Resp. 27–28; Ex. 2107 ¶¶ 44–61; Ex. 1053, 62:13–71:2, 75:22–76:3). Petitioner asserts that Dr. Slocum’s focus on insulin pen injectors led him to limit one of ordinary skill in the art’s “design objectives to reducing injection force at all costs.” *Id.* Although injection force is a factor, Petitioner contends it is only

one factor one of ordinary skill in the art would consider when designing pen injectors. *Id.* at 11 (citing Ex. 1048 ¶¶ 28–30, 32 (Dr. Biggs’ testimony discussing cost and reliability as important factors); Ex. 1095 ¶ 72).

Third, Petitioner argues that Patent Owner’s models are flawed because (1) the models are unreliable because the physical model was designed by Mr. Veasey, a named inventor on the ’044 patent, not by Dr. Slocum and Dr. Slocum relied upon Mr. Veasey for many inputs in the analytical model spreadsheet (*id.* at 11–14 (citing Ex. 1053, 12:22–13:5, 28:18–29:2, 30:5–33:13; Ex. 1054, 313:10–325:12; Ex. 1095 ¶¶ 73, 74; Ex. 2107 ¶¶ 242–243)), (2) the models do not assess total change in friction because they focus on friction at one point in the system, but ignore the possibility of reducing friction at other points (*id.* at 14 (citing Ex. 1095 ¶ 75; Ex. 2107 ¶ 58)), and (3) the models were designed to fail because they exaggerate friction losses by not considering changes, within the ordinary level of creativity, that one of ordinary skill in the art could also make to minimize friction (*id.* at 14–16 (citing Ex. 1053, 33:5–13, 41:3–42:13; Ex. 1054, 325:22–327:6; Ex. 1095 ¶¶ 73–75)).

In its Sur-reply, Patent Owner argues first that the models are not unreliable or biased because “Dr. Slocum independently verified the models, conducted his own experiments, and gathered his own data.” PO Sur-reply 6 (citing Ex. 2017 ¶¶ 242–255, App’x B, E). Patent Owner asserts that Mr. Veasey is not an employee of Patent Owner and does not have a financial stake in this proceeding. *Id.* Even assuming Mr. Veasey is an interested party, Patent Owner notes that Petitioner has not presented any opposing evidence regarding increased friction and injection force. *Id.* at 6–7. Second, Patent Owner contends that the analytical model does test the

total change in friction because the 51% increase in injection force is “derived from a comparison between the fifth embodiment and modified fifth embodiment.” *Id.* Third, Patent Owner argues that Petitioner’s critique of the models as not employing common-sense approaches to reducing friction is inapposite because (1) Petitioner did not inspect the physical model and (2) those common-sense approaches could be used to mitigate friction in both the unmodified fifth embodiment as well as the modified fifth embodiment, thus resulting in no offset of total friction. *Id.* at 8.

Patent Owner presents persuasive evidence that Petitioner’s proposed modifications would increase friction to some extent. Nonetheless, Steinfeldt-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) and 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 Steinfeldt-Jensen to the fifth embodiment (*see, e.g.*, Ex. 1095 ¶¶ 73–75).

On the full record before us, we find that Petitioner has established that despite an increase in friction, one of ordinary skill in the art would not have been dissuaded from modifying Steinfeldt-Jensen’s fifth embodiment as Petitioner proposes. In particular, we credit Petitioner’s evidence that Steinfeldt-Jensen is not limited to insulin injection syringes (*see, e.g.*, Ex. 1014, 1:16–17 (discussing diabetics as a non-limiting example of users who inject themselves frequently and to whom the disclosed injection syringe is directed); Pet. Reply 10–11 (discussing Dr. Slocum’s testimony

focusing on diabetic patients), and that, even if the focus were solely on diabetic patients and insulin injection syringes, “[i]njection force is *a* factor when designing pen injectors, but not the only factor” (*id.* (citing Ex. 1095 ¶ 72)).

*d) One of Ordinary Skill in the Art
Would Not Have Been Dissuaded
from Modifying Steinfeldt-Jensen
Because of Potential Failures in the
Flexible Arms of the Driver Tube*

Patent Owner contends that there are three other potential failures associated with Petitioner’s proposed modification that would have discouraged one of ordinary skill in the art from making the changes. PO Resp. 45–47. First, Patent Owner asserts the flexible arms on driver tube 85 could break when subjected to additional frictional. *Id.* at 45. Patent Owner contends that this occurred when Dr. Slocum “attempted to build and test Petitioner’s modification.” *Id.* (citing Ex. 2107 ¶ 240). Second, Patent Owner argues that the flexible arms “may get stuck and prevent the rotation necessary for injection.” *Id.* at 46 (citing Ex. 2107 ¶ 239). Third, Patent Owner asserts that the flexible arms “could be pressed into [an opening in the ring-shaped wall], thereby causing the device to fail by jamming the driver tube 85 or causing the flexible arms to pass above the ring-shaped wall such that the driver tube 85 moved proximally into the housing.” *Id.* (citing Ex. 2107 ¶ 239; Ex. 1014, Figs. 14, 15).

In its Reply, Petitioner asserts that Patent Owner offers no evidence that the flexible arms would be affected necessarily, but, even if they were, Mr. Leinsing explains that “this would be the type of routine task that a [person of ordinary skill in the art] would have no difficulty addressing.”

Pet. Reply 16 (citing Ex. 1095 ¶ 76 (referring to Mr. Leinsing's testimony to use a collar as the bearing surface)).²⁰

In its Sur-reply, Patent Owner asserts that Mr. Leinsing presents no evidence that addressing these potential failures would be routine. PO Sur-reply 5 (citing Pet. Reply 16 (citing Ex. 1095 ¶ 76)).

As discussed above, Steinfeldt-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. Steinfeldt-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 evidence does not support the finding that Petitioner's modifications inevitably result in failure or even that failure is necessarily likely to occur more often. Additionally, we find that Petitioner sufficiently establishes that if failure were to occur one of ordinary skill in the art would have the means to cure the failure or to modify the mechanism further to mitigate the potential increased frictional force resulting in said failure. *See, e.g.,* Ex. 1095 ¶ 76. For these reasons, we find that even if we accept Patent Owner's arguments that additional potential failures may be likely post-modification, we do not find that those potentials would dissuade

²⁰ Petitioner also presents arguments based on Exhibit 1016 (U.S. Patent No. 6,932,794 B2, issued August 23, 2005). Pet. Reply 17–18. Patent Owner asserts that Petitioner presents a new argument based on Exhibit 1016, which we should reject. PO Sur-reply 12–13 (citing Pet. Reply 18–19). We do not need to address Exhibit 1016 because, for the reasons discussed herein, other arguments and supporting evidence presented by Petitioner persuade us that one of ordinary skill in the art would have been prompted to make Petitioner's proposed modifications.

one of ordinary skill in the art from modifying Steinfeldt-Jensen's fifth embodiment as Petitioner proposes.

For the reasons above, based on the full record before us, Petitioner persuades us that Steinfeldt-Jensen suggests a "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 recited by claim 11.

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

Petitioner contends Steinfeldt-Jensen's bushing 82 teaches the tubular clutch of claim 11. Pet. 34. Petitioner asserts that bushing 82 is "a tubular structure," which has a "rosette of teeth 93" that releasably engage corresponding teeth on dose-setting button 81. *Id.* (citing Ex. 1014, 11:26–27, 12:4–13, Figs. 15–17; Ex. 1011 ¶ 283). Petitioner argues that "[w]hen engaged, dose-setting button 81's rotation transmits to driver tube 85 during injection." *Id.* (citing Ex. 1014, 12:4–12; Ex. 1011 ¶ 283). Thus, Petitioner asserts "bushing 82 is a clutch because it releasably couples movement of dose-setting button 81 to driver tube 85." *Id.* (citing Ex. 1011 ¶ 283).

Additionally, Petitioner contends "[b]ushing 82 also operatively couples to dose-setting button 81 by releasable engagement of teeth 93 with corresponding teeth on the bottom," and that bushing 82 is adjacent button 81's needle-end. *Id.* 34–35 (citing Ex. 1014, 11:34–42, Figs. 15, 16; Ex. 1011 ¶ 283).

Patent Owner does not contest Petitioner's argument that Steinfeldt-Jensen teaches this limitation of claim 11.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Steinfeldt-Jensen teaches the tubular clutch limitation of claim 11, recited above.²¹

viii. “wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, and”

Petitioner contends Steinfeldt-Jensen teaches the above-recited relative positioning of the dose-dial sleeve and tubular clutch by “show[ing] that scale drum 80 ‘extends circumferentially around at least a portion of bushing 82.’” Pet. 35–36 (citing Ex. 1014, 11:26–28, Figs. 15, 16; Ex. 1011 ¶ 285). Patent Owner does not contest Petitioner’s argument that Steinfeldt-Jensen teaches this limitation of claim 11.

For the reasons explained by Petitioner above, which we expressly adopt, we find that Petitioner has shown that Steinfeldt-Jensen teaches the above-recited wherein clause of claim 11.²²

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

Petitioner contends that Steinfeldt-Jensen teaches a threaded “dose dial sleeve” in scale drum 80 and an internally-threaded drive sleeve in driver tube 85 and member 40, for the reasons discussed above. Pet. 39 (citing Ex. 1014, Abstr., 2:46–53, 8:35–37, 11:20–22, 14:9–40, Figs. 15–17;

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

²² Additionally, we find that Patent Owner has waived any argument for patentability directed to this limitation of claim 11. See Paper 21, 8.

Ex. 1011 ¶ 286) (relying upon Petitioner’s arguments directed to the dose dial sleeve and drive sleeve limitations of claim 11 discussed above in §§ II.C.3.a.iii., vi). Additionally, Petitioner asserts “[t]he spacing of drum 80’s groove and of the internal thread mating the piston-rod’s thread are different, indicating that the first and second leads are different.” *Id.* (citing Ex. 1011 ¶ 287).

Patent Owner does not contest Petitioner’s argument that Steinfeldt-Jensen teaches this limitation of claim 11 aside from the arguments directed to the drive sleeve limitation discussed above.

For the reasons explained by Petitioner above, which we expressly adopt, and the reasons we discussed in our consideration of Petitioner’s argument directed to the drive sleeve limitation of claim 11, we find that Petitioner has shown that Steinfeldt-Jensen teaches the above-recited wherein clause of claim 11.

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

Claims 14, 15, 18, and 19 ultimately depend from claim 11. Petitioner contends that Steinfeldt-Jensen teaches or renders obvious the additional limitations recited in these claims. Pet. 42–43 (claim 14), 43–46 (claim 15), 46–47 (claim 18), 48–49 (claim 19). Petitioner relies upon Mr. Leinsing’s declaration testimony in support of its contentions regarding these claims. *See id.*

Patent Owner does not raise an argument directed to the additional limitations recited expressly by these dependent claims, relying instead on its arguments directed to independent claim 11. *See generally* PO Resp.

We have reviewed Petitioner’s argument and evidence cited in support thereof, which we expressly adopt. *See* Pet. 42–49. Based on the

reasons set forth by Petitioner and the evidence in support thereof, *see id.*, we find that Petitioner has shown that Steinfeldt-Jensen teaches the additional limitations recited in claims 14, 15, 18, and 19.²³

4. *Objective Indicia of Nonobviousness*

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

5. *Weighing the Graham Factors*

“Once all relevant facts are found, the ultimate legal determination [of obviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan.” *Arctic Cat*, 876 F.3d at 1361. As discussed above, Petitioner persuades us Steinfeldt-Jensen teaches or suggests each of the limitations of the claims, that one of ordinary skill in the art would have reasonably expected the structures (as modified by Petitioner) to perform the same function as they did before modification, 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. 41–42 (citing Ex. 1011 ¶ 278) *see also* Ex. 1011 ¶¶ 275–278 (citing Ex. 1014, 2:46–53, 3:15–20, 3:44–47, 7:44–47, 8:48–53,

²³ Claims 14 and 15 recite a “clicker.” As we stated *supra*, we decline to opine on whether the term “clicker” invokes 35 U.S.C. § 112, ¶ 6. Claim 19 recites that the main housing further comprises a helical rib adapted to be seated in the helical groove on the outer surface of the dose dial sleeve. Petitioner relies upon the same modification discussed in the context of Petitioner’s analysis of the dose dial sleeve and helical groove limitation of claim 11. Pet. 47–48.

Figs. 15–17). Further, as also addressed above, despite Patent Owner’s arguments and evidence to the contrary, we do not find that one of ordinary skill in the art would have been dissuaded from modifying Steinfeldt-Jensen’s fifth embodiment as Petitioner proposes. On balance, considering the record presently before us, we determine that Petitioner has shown, by a preponderance of the evidence, that Steinfeldt-Jensen would have rendered the subject matter of claims 11, 14, 15, 18, and 19 obvious to one of ordinary skill in the art at the time of the invention.

E. Obviousness over Moller and Steinfeldt-Jensen

Petitioner also challenges claims 11, 14, 15, 18, and 19 as unpatentable over Moller and Steinfeldt-Jensen. Pet. 49–90. Because we determine that the claims are unpatentable over Steinfeldt-Jensen alone, we do not reach this additional challenge to the same claims. *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”); *see also Boston Scientific Scimed, Inc. v. Cook Gr. Inc.*, No. 19-1594, -1604, -1605, slip op. at 11 (CAFC Apr. 30, 2020) (nonprecedential) (agreeing, in the same context, “that the Board need not address issues that are not necessary to the resolution of the proceeding”).

F. Petitioner’s Motion to Exclude

Petitioner filed a motion to exclude Exhibits 2001–2014, 2017–2026, 2100–2102, 2104–2107, 2111–2153, 2158–2201, 2203–2212, 2214–2218, 2223–2225, and the redirect testimony in Exhibit 1054. Petitioner, as the “moving party,” “has the burden of proof to establish that it is entitled to the requested relief.” 37 C.F.R. § 42.20 (2017).

1. *Exhibits 2001–2011 and 2019–2026*

Petitioner moves to exclude Exhibits 2001–2011 and 2019–2026 pursuant to Federal Rules of Evidence (“FRE”) 402 and 403 because purportedly they are not relevant to any contested issue in this proceeding and risk confusing the issues. Mot. 1–2, 4–5. Patent Owner responds that these exhibits “were offered to show information that was relevant to § 325(d) issues raised during the preliminary stage of this proceeding.” Opp. 1. Patent Owner asserts that these exhibits do not lack relevance, have no risk of confusing the issues, and should therefore remain in the record. *Id.* at 2. In its Motion Reply, Petitioner contends that Patent Owner acknowledges that these exhibits no longer have relevance to the issues in this proceeding and should therefore be excluded. Mot. Reply 1. Petitioner asserts that, if not excluded, “their admissibility should be limited to the purpose for which they were submitted” pursuant to FRE 105. *Id.*

Petitioner’s only basis to exclude these exhibits is because they were offered during the pre-institution phase of this proceeding concerning only our discretion to deny institution, not the merits of the asserted grounds of unpatentability, and are therefore no longer relevant. Petitioner does not direct our attention to any prior Board decision that granted a motion to exclude exhibits that were relevant only to the pre-institution phase of an *inter partes* review. And, we do not agree that we should do so here. In an *inter partes* review, which is akin to a bench trial, there is little risk of confusion. Additionally, simply because an exhibit is relevant to the pre-institution stage and not necessarily the post-institution stage of an *inter partes* review proceeding, does not justify excluding it from the record. To the contrary, the record contains other documents that may similarly be

characterized as such, e.g., a patent owner’s preliminary response. Therefore, we are not persuaded to exclude the exhibits or expressly limit their purpose pursuant to FRE 105 and Petitioner’s Motion is denied with respect to these exhibits.

2. *Exhibit 2012*

Exhibit 2012 is an animation purportedly showing the operation of an embodiment of the injection pen described in the ’044 patent. Mot. 3. Petitioner contends that Exhibit 2012 should be excluded under FRE 801–804 as hearsay because it is offered for the truth of its content without satisfying any of the hearsay exceptions. *Id.* Patent Owner contends that FRE 703 permits experts to rely upon hearsay if reasonable to do so in the expert’s field. Opp. 2. Patent Owner asserts that Exhibit 2012 is identical to Exhibit 2117, which Dr. Slocum relies upon in his declaration. *Id.* (citing Ex. 2107 ¶ 65). Patent Owner asserts that “[c]omputer models such as shown in EX201[2]^[24] are used and relied upon in mechanical engineering” and because it was reasonable for Dr. Slocum to rely upon it for his analysis, it should not be excluded. *Id.* (citations omitted). In its Motion Reply, Petitioner contends that although an expert may rely upon hearsay in forming an opinion, pursuant to FRE 703, that does not make the evidence admissible in trial. Mot. Reply 1–2. Petitioner asserts that if the exhibit is not excluded, it should be limited to the purpose for which it was submitted—showing the basis for Dr. Slocum’s expert testimony—and should not be used for any other purpose. *Id.* at 2 (citing FRE 105).

²⁴ Patent Owner incorrectly states “EX2011” in this one instance of discussing Exhibit 2012. *See* Opp. 2.

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

3. *Exhibits 2013 and 2014*

Exhibit 2013 is Mylan's claim construction brief in the related district court proceeding. Petitioner contends that language quoted from the brief is "taken out of context." Mot. 3. Thus, Petitioner contends the exhibit should be excluded pursuant to FRE 402 and 403.²⁵

Exhibit 2014 is a "Memorandum Opinion" of the U.S. District Court for the District of Delaware construing claim terms from several related patents, including the '044 patent. Ex. 2014. In particular, the district court construed the term "main housing," which is recited in several claims of the

²⁵ Petitioner states "FRE 402-402," but we understand Petitioner to refer to FRE 402 and 403. See Mot. 3.

'044 patent. Ex. 2014, 8–10.²⁶ Petitioner contends that the district court's claim construction is not relevant to any contested issue in this proceeding, "lacks relevance, risks confusing the issues, and is prejudicial to Mylan." Mot. 3.

Patent Owner responds, contending that Exhibits 2013 and 2014 are relevant to claim construction. Opp. 2–3. In particular, Patent Owner asserts that Exhibit 2013 shows the construction to which Mylan agreed in district court and Exhibit 2014 shows how a district court construed the same term in the '044 patent, each of which is relevant to how that term should be construed here. *Id.* Petitioner does not address these exhibits in its Motion Reply.

Petitioner has not shown that these exhibits are not relevant, risk confusion, or are prejudicial such that they should be excluded. To the contrary, we agree with Patent Owner that (1) positions taken on claim terms at issue in this proceeding by parties to this proceeding and (2) district court claim construction of terms at issue in this proceeding is relevant to our consideration of the terms. Further, any risk of confusion or prejudice is extremely minimal because we understand that those constructions are not binding upon us, but, rather, are informative as to how others have considered the terms. Accordingly, Petitioner's Motion is denied with respect to Exhibits 2013 and 2014.

²⁶ The page numbers cited are those of the exhibit, not the Memorandum Opinion.

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

Petitioner contends the above-listed exhibits should be excluded pursuant to FRE 402 and 403 “because they were not discussed in the response, cannot be relevant to it, and consequently serve only to confuse and create prejudice through belated surprise.” Mot. 7. Patent Owner asserts that Exhibits 2117, 2118, 2127, 2136, 2147–2150, 2152, 2162–2165, 2175, 2206, 2207, 2211, and 2215–2217 are cited in the Patent Owner Response. Opp. 5 (citing PO Resp. 5–7, 11, 14, 18–19, 32, 34–37, 40–41, 43–44, 47, 51, 55). Patent Owner contends that Exhibits 2100–2102 and 2104–2106 are exhibits to the deposition of Mr. Leinsing and are relevant because they “provide necessary context for Mr. Leinsing’s cross-examination, which Petitioner has not sought to exclude.” *Id.* Additionally, Patent Owner asserts that Dr. Slocum “considered and reasonably relied upon [each of these exhibits] in forming his opinions regarding the validity of the challenged patent and thus should be admitted under FRE 703.” *Id.* Petitioner does not address these exhibits in its Motion Reply.

Several of these exhibits pertain exclusively to Patent Owner’s arguments regarding objective indicia of nonobviousness. *See, e.g.*, Ex. 2196 (described by Patent Owner as “U.S. Dollar Sales of Long-Acting Pens Among All Pens”). Patent Owner does not rely upon objective indicia of nonobviousness in its Patent Owner Response in this case, but does rely upon such evidence in its responses in several related cases. *See* Tr. 83:20–23 (counsel for Patent Owner confirming during the oral hearing that Patent Owner does not rely upon objective indicia of nonobviousness in this *inter partes* review). Patent Owner filed the same declaration by Dr. Slocum in nine related *inter partes* reviews, including this proceeding. *See* Ex. 2107,

caption. Thus, it is likely many of these exhibits are not relevant to *this proceeding*. Nonetheless, it is not an efficient use of resources to parse through Dr. Slocum’s reliance upon each of these exhibits to determine whether they apply solely to the issue of objective indicia or have a broader applicability. Additionally, Patent Owner has shown that the sole basis argued in Petitioner’s Motion for exclusion—that the exhibits were not cited in Patent Owner’s Response—is not correct for each of these exhibits, as many were cited. Nonetheless, with respect to the exhibits that were not cited, the lack of citation is not, in and of itself, dispositive as to whether an exhibit should be excluded. Accordingly, Petitioner has not satisfied its burden to show that these exhibits should be excluded.

5. *Exhibits 2117, 2147–2152, 2162, 2167, 2168, 2206, 2207, 2211, 2215–2218*²⁷

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

²⁷ 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. 7 (addressing FRE 402 and 403), *with id.* at 8 (addressing FRE 801–804).

purpose for which they were submitted—showing the basis for Dr. Slocum’s expert testimony—and not used for any other purpose pursuant to FRE 105. Mot. Reply 1–2.

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

6. *Exhibits 2136, 2137, and 2175*

Petitioner contends that Exhibits 2136, 2137, and 2175 should be excluded pursuant to FRE 402 and 403 because they “relate to commercial pens and their properties, such as injection force, are irrelevant to the extent they rely on an improper standard of obviousness and unclaimed features,” and “are also prejudicial and confuse the issues as a result.” Mot. 8–9.

Patent Owner asserts that these exhibits “were offered to demonstrate the importance of injection force as a design consideration and how the commercial embodiment of Steinfeldt-Jensen—*i.e.*, the FlexPen—already had a problem with high injection force.” Opp. 14 (citing Ex. 2107 ¶ 29). Patent Owner contends that this information is relevant to its argument that one of ordinary skill in the art would not have modified Steinfeldt-Jensen if such modification increased injection force and that the relevance of these exhibits outweighs any risk of confusion or prejudice. *Id.* In its Motion Reply, Petitioner contends that “[a]ll three of these exhibits post-date [Patent Owner’s] claimed priority date” and therefore “remain irrelevant to any pending issue” because “motivation is determined at the time of filing.” Mot. Reply 5.

To the extent, as Patent Owner contends, these exhibits are offered to demonstrate the importance of injection force as a design consideration, that

point is noted in our consideration of the parties' arguments above. It is not clear that Patent Owner needs these three exhibits to convey that point.

Nonetheless, we reach the findings discussed herein, determining that one of ordinary skill in the art would have been prompted to modify Steinfeldt-Jensen as proposed by Petitioner. Accordingly, although we do not exclude these exhibits, we are cognizant of the time period to which they pertain as well as the limited purpose for which they were submitted and, in that regard, do not find that their presence is prejudicial or misleading.

7. *Exhibits 2223 and 2224*

Petitioner contends that Exhibits 2223 and 2224 are offered to show objective indicia of nonobviousness, but “[t]hey are hearsay without exception, lack authentication, and are unreasonably prejudicial because they are cited for a new purpose.” Mot. 9. Patent Owner contends that these exhibits are relevant to objective indicia of nonobviousness and that Exhibit 2224 pertains to an exhibit cited in two declarations directed to the same issue. Opp. 14–15.

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

this proceeding is not identified in the caption of the exhibit and the declaration is directed solely to responding to Patent Owner's contentions regarding objective indicia of nonobviousness in other related proceedings). Accordingly, Petitioner's Motion is denied as to Exhibits 2223 and 2224.

8. *Exhibits 1054 and 2107*

Petitioner seeks to exclude Dr. Slocum's entire declaration (Ex. 2107) and the deposition redirect examination of Dr. Slocum (Ex. 1054, 391–406) pursuant to FRE 702, 703, and 705. Mot. 5–8. Petitioner raises three primary reasons. First, that Dr. Slocum did not have personal knowledge of injection pens or the industry during the relevant time period. *Id.* at 5. Second, that Dr. Slocum relied upon Mr. Veasey, one of the named inventors of the '044 patent, for certain data and a model used for various calculations in Dr. Slocum's declaration. *Id.* at 4–6. And, third, that Exhibit 2017 should be excluded for the additional reason that it “does not provide sufficient facts or data, is not the product of reliable principles and methods, and has not applied the proper principles to the facts of this proceeding.” *Id.* at 7. As an example, Petitioner contends that Appendices A through F “do not set forth the principles used nor do they demonstrate the calculations used in generating the spreadsheets” and, thus, “should be excluded for failing to disclose the underlying facts and data, and failing to set forth the bases of Dr. Slocum's opinions.” *Id.* at 7–8.

Patent Owner responds to each of Petitioner's challenges. First, with respect to Dr. Slocum's personal knowledge, Patent Owner correctly observes that neither party's proposed definition of the ordinary level of skill in the art requires specific knowledge of, or experience with, pen injectors. Opp. 7 (citing Ex. 1011 ¶ 106; Ex. 2107 ¶ 102). Additionally, Patent Owner

contends that there is no requirement that an expert have personal knowledge of the subject matter upon which the expert's opinion is based at the time of the invention. *Id.* at 7–8. Further, Patent Owner asserts that Dr. Slocum acquired the relevant knowledge by “(i) research[ing] the prior art, (ii) canvass[ing] literature on pre-critical date pen injectors, design considerations, and design standards, and (iii) convers[ing] with those in the industry (*i.e.*, Mr. Veasey and Dr. Goland).” *Id.* at 8 (citing Ex. 2107 ¶¶ 25–61). Patent Owner also contends Dr. Slocum documented his opinions with facts and data. *Id.*

Second, Patent Owner asserts that Petitioner's criticism of Dr. Slocum's reliance upon the information and model obtained from Mr. Veasey are unfounded. In particular, Patent Owner asserts that Dr. Slocum performed his own investigation and research into design considerations and the state of the art, as documented in his declaration. *Id.* at 9–10 (citing Ex. 2107 ¶¶ 25–61). Patent Owner notes that Petitioner does not assert that any of the design considerations noted by Dr. Slocum are incorrect. *Id.* at 10. Additionally, Patent Owner raises additional arguments regarding Dr. Slocum's reliance upon Mr. Veasey's measurements of a FlexPen, “to quantify the impact of Mr. Leinsing's proposed modification to Steinfeldt-Jensen's fifth embodiment” and argues that Petitioner failed to rebut the accuracy of the data provided. *Id.* at 10–11.

Third, Patent Owner contends that Petitioner ignores that Patent Owner “served as supplemental evidence the native spreadsheets that specify [the] principles and calculations” set forth in Appendices A through F. Opp. 12 (citing Ex. 2226). Patent Owner further asserts that “the

measurements provided by Mr. Veasey are corroborated, un rebutted, and reliable.” *Id.*

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

To begin, Dr. Slocum is undisputedly an expert in mechanical engineering with knowledge and experience *beyond* the level of ordinary skill in the art as the parties have proposed and we have adopted. *See Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1363 (Fed. Cir. 2008) (noting that “[a] witness possessing merely ordinary skill will often be qualified to present expert testimony both in patent trials and more generally”) (citations omitted). Additionally, as both parties acknowledge, there is no requirement that an expert have personal knowledge of the technology during the specific relevant time period in order to qualify as an expert. In this regard, we find that Patent Owner and Dr. Slocum have established sufficient support, as detailed above, as to how he acquired knowledge of the specific technology at issue—the mechanical operation and design of injection pens. Further, Dr. Slocum’s reliance upon other individuals, including Mr. Veasey, to provide information upon which he based his opinions does not render him unqualified to offer an expert opinion. To the extent the credibility of any of the individuals upon which

Dr. Slocum relied may be in doubt, e.g., Mr. Veasey's potential bias as a named inventor on the '044 patent, those issues are the proper subject of cross-examination, go to the weight accorded the evidence, and do not justify excluding Dr. Slocum's testimony on the facts presented here. And, to the extent Petitioner questions the data or model provided by Mr. Veasey, the proper recourse is to probe the bases for such during cross-examination, as discussed below. Therefore, Petitioner has not shown that Dr. Slocum should be disqualified as an expert in this proceeding. Accordingly, Petitioner's Motion as directed to the redirect examination testimony of Exhibit 1054 and Dr. Slocum's declaration (Ex. 2107) is denied.

Additionally, Mr. Veasey's involvement was discussed extensively during a conference call. *See* Ex. 1108 (Transcript of Nov. 18, 2019, Telephonic Conference). We find that Petitioner's assertions that Patent Owner hid Mr. Veasey's involvement are unfounded. In particular, Dr. Slocum acknowledged in Appendix B of his declaration that the "[i]nput values were provided by Mr. Robert Veasey of DCA Engineering." Ex. 2107, App. B at 2. Thus, we find that Petitioner could have, but did not, seek to depose Mr. Veasey and therefore Petitioner's arguments regarding Mr. Veasey's involvement do not justify excluding Dr. Slocum's declaration (Ex. 2107) or redirect testimony (Ex. 1054).

III. SUMMARY²⁸

Petitioner has demonstrated, by a preponderance of the evidence, that claims 11, 14, 15, 18, and 19 would have been obvious over Steinfeldt-Jensen. Additionally, although we deny Petitioner’s Motion to Exclude, we limit the use of Exhibits 2012, 2117, 2147–2152, 2162, 2167, 2168, 2206, 2207, 2211, and 2215–2218 as described above.

The chart below summarizes our conclusions regarding the challenged claims.

| Claims Challenged | 35 U.S.C. § | Reference(s) | Claims Shown Unpatentable | Claims Not Shown Unpatentable |
|--------------------------|--------------------|---|----------------------------------|--------------------------------------|
| 11, 14, 15, 18, 19 | 103(a) | Steenfeldt-Jensen | 11, 14, 15, 18, 19 | |
| 11, 14, 15, 18, 19 | 103(a) | Moller, Steinfeldt-Jensen ²⁹ | | |
| Overall Outcome | | | 11, 14, 15, 18, 19 | |

²⁸ Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this decision, we draw Patent Owner’s attention to the April 2019 *Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding*. See 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. See 37 C.F.R. § 42.8(a)(3), (b)(2).

²⁹ As explained above in Section II.E, we do not reach the challenge to claims 11, 14, 15, 18, and 19 based on Moller and Steinfeldt-Jensen because the same claims are determined to be unpatentable over Steinfeldt-Jensen.

IV. ORDER

In consideration of the foregoing, it is hereby:

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

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 64) is denied; and

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

IPR2018-01676
Patent 8,603,044 B2

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