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Paper 79
Entered: May 29, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS, INC. and PFIZER, INC.,

Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,

Patent Owner.

IPR2018-01684
Patent 9,604,008 B2[1]

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

BROWNE, *Administrative Patent Judge*.

JUDGMENT
Final Written Decision
Determining Claims 1, 7, 8, and 17 are 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

Mylan Pharmaceuticals, Inc. ("Mylan"), on September 10, 2018, filed a Petition requesting *inter partes* review of claims 1, 3, 7, 8, 11, and 17 of U.S. Patent No. 9,604,008 B2 (Ex. 1005, "the '008 patent"). Paper 2 ("Pet."). Sanofi-Aventis Deutschland GmbH ("Patent Owner") filed a Preliminary Response (Paper 13). Applying the standard set forth in 35 U.S.C. § 314(a), we instituted an *inter partes* review of all challenged claims. Paper 19 ("Inst. Dec.").

After institution, Pfizer Inc. ("Pfizer") filed (1) a petition challenging the same claims of the '008 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*, IPR2019-00987, Papers 2 (Pfizer's Petition), 3 (Pfizer's Motion for Joinder) (May 2, 2019). For the same reasons set forth in our Institution Decision in this case, we instituted *inter partes* review on Pfizer's petition and granted Pfizer's motion for joinder. *Pfizer*, Paper 12 (Aug. 15, 2019).[2]

Patent Owner filed a Patent Owner Response (Paper 27, "PO Resp."), Petitioner[3] filed a Reply to Patent Owner's Response (Paper 42, "Pet. Reply"), and Patent Owner filed a Sur-reply (Paper 52, "PO Sur-reply"). With prior authorization, Petitioner filed a Motion to Exclude (Paper 58, "Mot."), Patent Owner filed an Opposition to Petitioner's Motion (Paper 59, "Opp."), and Petitioner filed a Reply in support of its Motion (Paper 64, "Motion Reply" or "Mot. Reply"). Additionally, Patent Owner filed

[2] This decision is entered in the record in this case as Paper 37.
[3] We refer to Mylan and Pfizer, collectively, as "Petitioner."

Observations on the Cross-Examination of Mr. Karl Leinsing (Paper 62) and Petitioner filed a Response to Patent Owner's Observations (Paper 66). Petitioner filed Observations Regarding the Testimony of Alexander Slocum, Ph.D., (Paper 63), to which Patent Owner filed a Response (Paper 65). An oral hearing was held on January 15, 2020, and a copy of the transcript was entered in the record. Paper 73 ("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 supporting evidence, we determine that Petitioner has met its burden of showing by a preponderance of the evidence that claims 1, 7, 8, and 17 are not patentable. We further determine that Petitioner has not met its burden of showing that claims 3 and 11 are unpatentable.

II. BACKGROUND

A. Related Proceedings

The parties indicate that the '008 patent has been asserted in *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105-SRC-CLW (D.N.J.); *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812-RGA-MPT (D. Del.); and *Sanofi-Aventis U.S. LLC v. Eli Lilly and*

Co., No. 1:14-cv-00113-RGA-MPT (D. Del.). Pet. 1–2; Paper 5, 2; Paper 7, 2; Paper 12, 2; Exs. 1029, 1030.

The parties also state that related patents are challenged in Cases IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01696, and IPR2019-00122. Pet. 2; Paper 5, 2–3; Paper 7, 2–3; Paper 12, 2–3.

B. The '008 Patent

The '008 patent issued March 28, 2017, from an application filed June 30, 2014, which is a continuation of four previously filed continuation applications, the earliest of which was filed on March 3, 2004. Ex. 1005,

[22], [45], [63], 1:6–11. The ’008 patent also claims priority to a foreign application filed on March 3, 2003. *Id.* at [30], 1:16–17.

The ’008 patent “relates to drive mechanisms suitable for use in drug delivery devices, in particular pen-type injectors.” *Id.* at 1:22–24. Figure 1 of the ’008 patent is reproduced below:

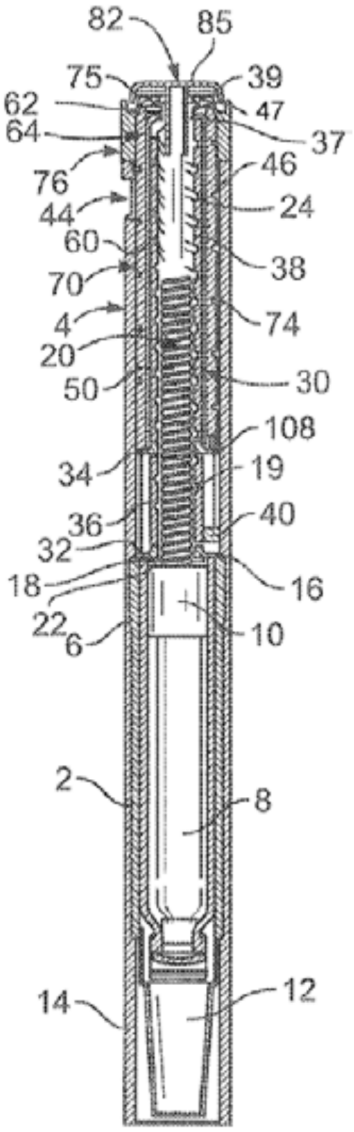

FIG. 1

Figure 1 shows a sectional view of a drug delivery device. *Id.* at 6:7–

8. The drug delivery device comprises a housing having first cartridge retaining part 2 and second main housing part 4.[4] *Id.* at 7:11–13. Main housing 4 includes helical rib 46. *Id.* at 8:61–62. The '008 patent indicates that helical rib 46 can be a thread. *See id.*

Dose dial sleeve 70 is radially inward of main housing 4. *Id.* at 8:55–56. Dose dial sleeve 70 has helical groove 74 provided about its outer surface. *Id.* at 8:56–58. Helical rib 46 of main housing 4 is adapted to be seated in helical groove 74. *Id.* at 8:61–64. The '008 patent indicates that helical groove 74 can be a thread. *See id.*

Clutch 60 is disposed between dose dial sleeve 70 and drive sleeve 30 at the second end of drive sleeve 30. *Id.* at 8:18–20, 8:34–35. Drive sleeve 30 has helical groove 38 extending along its internal surface. *Id.* at 7:62–63. The '008 patent indicates that helical groove 38 can be a thread. *See id.* Drive sleeve 30 extends about piston rod 20. *Id*. at 7:55. Piston rod 20 has first thread 19 extending from an end and second thread 24 extending from another end of piston rod 20. *Id.* at 7:40–41, 7:45–47. Second thread 24 of piston rod 20 works within helical groove 38. *Id.* at 7:63–65. Insert 16 is provided at an end of main housing part 4 near cartridge retaining part 2, and insert 16 has threaded circular opening 18. *Id.* at 7:33–36.

C. Illustrative Claim

The '008 patent has 19 claims, of which Petitioner challenges claims 1, 3, 7, 8, 11, and 17. Of those, claim 1, reproduced below, is the only independent claim.

[4] The '008 patent refers to "second main housing part 4" and "main housing 4" interchangeably. *Compare* Ex. 1003, 7:12–13 ("second main housing part 4") *with id.* at 7:15 ("main housing 4").

> 1. A drive mechanism for use in a drug delivery device comprising:
>
> a housing comprising a helical thread;
>
> a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing,
>
> an insert provided in the housing, where the insert has a threaded circular opening;
>
> a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread;
>
> a piston rod having a first thread and a second thread, wherein the first thread is engaged with the threaded circular opening of the insert and the second thread is engaged with the internal helical thread of the drive sleeve; and
>
> a clutch located between the dose dial sleeve and the drive sleeve, wherein the clutch is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve.

Ex. 1005, 17:28–45.

D. Evidence Relied Upon

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

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

(2) U.S. Patent Application Publication No. US 2002/0052578 A1 published May 2, 2002 (Ex. 1015, "Møller").[5]

In support of its challenges, Petitioner provides a declaration by Karl R. Leinsing (Ex. 1011) and a Declaration by DeForrest McDuff, Ph. D. Patent Owner supports its arguments with declarations by Alexander Slocum, Ph.D., Henry R. Grabowski, Ph.D., and Robin S. Goland, M.D.

[5] Petitioner identifies Exhibit 1015 as U.S. Patent No. 6,663,602 to Møller (Pet. 3); however, Exhibit 1015 is a patent application publication to Møller.

E. Asserted Ground

Petitioner challenges, under 35 U.S.C. § 103, claims 1, 3, 7, 8, 11, and 17 as unpatentable over Møller and Steenfeldt-Jensen. Pet. 3–4, 18–56.

III. ANALYSIS

A petition must show how the construed claims are unpatentable under the statutory ground it identifies. 37 C.F.R. § 42.104(b)(4). Petitioner bears the burden of proving unpatentability of the challenged claims, and the burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). To prevail, Petitioner must establish the facts supporting its challenge by a preponderance of the evidence. 35 U.S.C. § 316(e); 37 C.F.R. § 42.1(d).

A. Level of Ordinary Skill in the Art

Petitioner asserts that "[a] POSA[6] would include someone who had, through education or practical experience, at least the equivalent of a bachelor's degree in mechanical engineering, or a related field." Pet. 10 (citing Ex. 1011 ¶ 106). According to Petitioner, "[t]he POSA also would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g., gears, pistons) involved in drug-delivery devices." *Id.* ¶¶ 104–107. Patent Owner proposes a level of ordinary skill that "is similar to that proposed by the Petitioner." PO Resp. 17. We agree with Petitioner's definition of the level of ordinary skill in the art as it is consistent with the level of ordinary skill reflected in the '008 patent and prior art of record. Further, we agree with Patent Owner that "the slight differences between Patent Owner and Petitioner's level of ordinary skill do not affect the arguments" made by the parties such that our analysis

[6] Person of Ordinary Skill.

below would not change under either party's proposed level of ordinary skill. *Id.*

B. Claim Construction

In this *inter partes* review, claim terms are interpreted according to their broadest reasonable construction in light of the Specification of the '486 patent. 37 C.F.R. § 42.100(b) (2018); *Cuozzo Speed Techs. LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard).[7]

Petitioner states that "claim terms should be given their ordinary and customary meaning, consistent with the specification and how they would have been understood by [a person of ordinary skill in the art]" and the "ground presented below relies on the ordinary and customary meaning of the claim terms as they would be understood by a [person of ordinary skill]." Pet. 10, 12 (citing Ex. 1011 ¶¶ 108-1). Petitioner also provides interpretations of "insert," "drive sleeve," "thread," "piston rod," and "clutch" that were proffered by Patent Owner in related litigation. *Id.* at 10–11 (citing Ex. 1019, 19–21, 24–25, 27–28, 32–33). In addition, Petitioner notes that it proposed means-plus-function interpretations for "clutch" and "insert" in related litigation. Pet. 11 (citing Ex. 1028, 141–144, 150–152).

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

And, Petitioner proposes means-plus-function interpretations for these terms in this proceeding. *Id.* at 11–12 (citing Ex. 1005, 1:63–65, 2:16–18, 3:58–64, 8:48–50, 10:23–31, Figs. 1, 5–11; Ex. 1028, 135, 141–144, 152).

"Patent Owner submits no express interpretation is required for any claim term." PO Resp. 16. We agree with Patent Owner that no express claim construction of any claim term is necessary to our decision. Accordingly, we do not expressly construe any claim terms.

C. Principles of Law

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and, when presented, (4) objective evidence of nonobviousness.[8] *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966).

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

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

D. Obviousness of Claims 1, 3, 7, 8, 11, and 17 in View of the Combined Teachings of Møller and Steenfeldt-Jensen

Petitioner contends that claims 1, 3, 7, 8, 11, and 17 are unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Møller and Steenfeldt-Jensen. Pet. 18–56. Having now considered the evidence in the complete record established during trial, we are persuaded that Petitioner has demonstrated by a preponderance of the evidence that claims 1, 7, 8, and 17 would have been obvious in view of Møller and Steenfeldt-Jensen. We begin our analysis with a brief overview of the prior art. Next, we address the parties' contentions and then we discuss our reasoning.

1. Møller

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

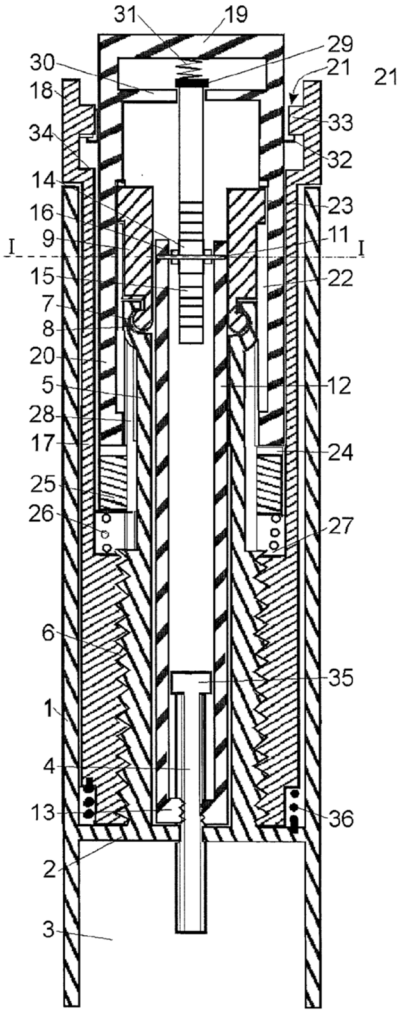

Fig. 1

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

4 and engages gearbox 9 so that gearbox 9 can rotate within housing 1. *Id.* ¶ 23.

Nut 13 engages the threads of the threaded piston rod 4 and connects to gearbox 9 via connection bars 12. *Id.* ¶ 24. Dose setting drum 17 engages thread 6 of tubular element 5 at one end and at the opposite end has an enlarged diameter forming dose setting button 18. *Id.* ¶ 25. Dose setting drum 17 can be screwed into or out of housing 1 and includes a scale on its outer surface. *Id.*

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

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

2. Steenfeldt-Jensen

Steenfeldt-Jensen "relates to injection syringes of the kind apportioning set doses of medicine from a cartridge." Ex. 1014, 1:12–13. Figures 16 and 17 of Steenfeldt-Jensen are reproduced below:

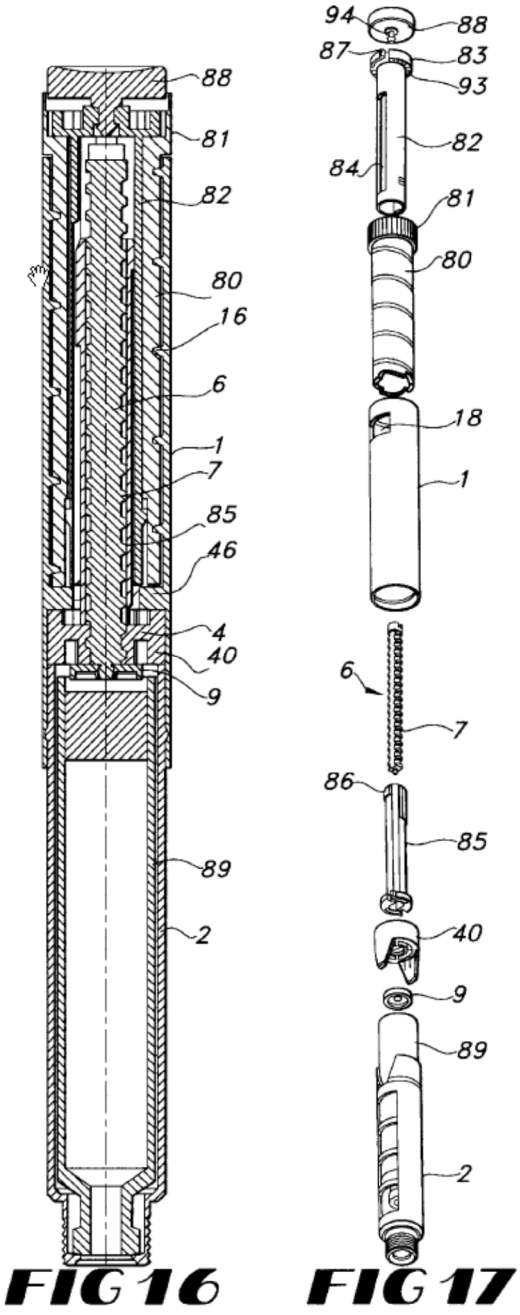

FIG 16 FIG 17

Figure 16 shows a side sectional view of a syringe, and Figure 17 shows an exploded view of that same syringe. *Id.* at 5:25–28. The syringe of Steenfeldt-Jensen includes tubular housing 1 that is partitioned so that a first division has ampoule holder 2. *Id.* at 5:38–40. Ampoule holder 2 has a central bore with thread 5 that engages external thread 7 of piston rod 6. *Id.*

at 5:55–58. Driver tube 85 is disposed about piston rod 6. *See id.* at Figs. 15–17. "The 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 11:15–19.

Within housing 1 is scale drum 80, and scale drum 80 has on its outer wall a helical track that engages a helical rib on the inner wall of housing 1. *Id.* at 11:20–22. One end of scale drum 80 has a larger diameter so as to form dose setting button 81. *Id.* at 11:22–24. 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 bushing 82 and driver tube 85 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 49–51.

A dose is set by rotating dose setting button 81, which causes scale drum 80 to rotate out of housing 1. *Id.* at 11:52–55. Injection button 88 is pressed to inject the set dose, and bushing 82 rotates with dose setting button 81 because of the engagement of the helical track of scale drum 80 with the rib of housing 1 when scale drum 80 is pressed into housing 1. *Id.* at 12:4–10. The rotation of bushing 82 rotates driver tube 85, which causes piston rod 6 to rotate and screw into ampoule 89 in ampoule holder 2. *Id.* at 12:10–13.

3. Petitioner's Challenge

Petitioner provides claim charts and arguments with citations to where Møller and Steenfeldt-Jensen teach or suggest the elements of the claims and citations to supporting declarant testimony. Pet. 19–41, 44–56. Specifically, Petitioner asserts that "[b]oth Møller and Steenfeldt-Jensen disclose drive

mechanism used in drug delivery pens." Pet. 19–20 (citing Ex. 1015 ¶¶ 1, 14, 33; Ex. 1014, 8:25–33). Petitioner asserts that "Møller teaches housing 1 with helical thread 6." *Id.* at 21–22 (citing Ex. 1015 ¶¶ 22–23, Fig. 1; Ex. 1011 ¶ 799). Petitioner asserts that "Møller teaches dose setting drum 17, which has a threaded surface engaging thread 6 of housing 1. *Id.* at 23– (citing Ex. 1015 ¶¶ 25, 29' Ex. 1015, Fig. 1; Ex. 1011 ¶ 802). Petitioner asserts that "[b]oth Møller and Steenfeldt-Jensen teach the use of an insert in the housing." *Id.* at 25 (citing Ex. 1015 ¶ 22; Fig. 1; Ex. 1014, 5:55–57, Fig. 7; Ex. 1011 ¶ 806). Petitioner asserts that "Møller and Steenfeldt-Jensen teach the use of a drive sleeve that operates in a similar manner" to the drive sleeve as claimed. *Id.* at 28 (citing Ex. 1014 ¶ 40; Figs. 3–5). Petitioner asserts that "[b]oth Møller and Steenfeldt-Jensen teach the use of a piston rod" as claimed. *Id.* at 33. Petitioner asserts that "Møller discloses a "cup shaped element" positioned between the dose dial sleeve and the drive sleeve." *Id.* at 35–36 (citing Ex. 1015, Fig. 1; Ex. 1011 ¶¶ 715, 824).

We note that the only one of these assertions contested by Patent Owner, is Petitioner's assertion that Møller discloses a housing with a thread. PO Resp. 37. We discuss Patent Owner's contentions with respect to this limitation in Section III.D.6 below.

Petitioner also asserts that one of ordinary skill in the art would have had a reason to combine Møller's and Steenfeldt-Jensen's dose-setting approaches. *Id.* at 19, 41. In particular, Petitioner starts with Møller, wherein rotating a knob on a dose indicator rotates a drive sleeve to set a dose and pressing an injection button decouples rotationally the dose indicator and the drive sleeve so that the drive sleeve moves axially without rotating. *Id.* at 41. Petitioner proposes modifying Møller so that its drive

sleeve's dose dispensing operates as taught by Steenfeldt-Jensen, wherein the drive sleeve engages a dual-threaded piston rod to drive the piston rod through a threaded piston rod holder. *Id.* (citing Ex. 1011 ¶¶ 832–833).

Petitioner contends that its proposed combination would be a simplification, a reduction of internal components, and an increase in durability that would have outweighed any concerns about an increase in friction and would have had a reasonable expectation of success. *Id.* at 18, 26 (citing Ex. 1011 ¶¶ 804–807, 832–837; Ex. 1014, 5:55–57, 7:41–43, Fig. 7), 41–44 (citing Ex. 1011 ¶¶ 114–115, 120–122, 124, 832–833, 835–854; Ex. 1014, 6:42–7:29, 11:6–19, 12:4–12, Fig. 7; Ex. 1015 ¶¶ 6–11, 24–25, 30–31).

4. Overview of Issues

As noted above, Petitioner provides claim charts and arguments with citations to where Møller and Steenfeldt-Jensen teach or suggest the elements of the claims and citations to supporting declarant testimony. Pet. 19–41, 44–56. Petitioner also argues that one of ordinary skill in the art would have had a reason to combine Møller's and Steenfeldt-Jensen's dose-setting approaches. *Id.* at 19, 41. Patent Owner submits that the proposed combination does not render the claims obvious for the reasons discussed below. PO Resp. 24–51. Patent Owner submits further that objective indicia of nonobviousness leads to a conclusion that the claimed invention would not have been obvious to one of ordinary skill in the art. *Id.* at 51–63.

Having reviewed the entire record now before us, we are persuaded that Petitioner has sufficiently demonstrated that Møller, Steenfeldt-Jensen, or both disclose or suggest each of the limitations set forth in claims 1, 7, 8, and 17 and we adopt Petitioner's findings as our own. Pet. 19–41.

Accordingly, we focus our discussion in the following two sections on the arguments raised by Patent Owner in support of its contention that the proposed combination does not render these claims obvious. We separately address claims 3 and 11 as Patent Owner presents separate arguments pertaining only to these claims. Then, we address Patent Owner's evidence of objective indicia of nonobviousness.

5. Motivation to Combine

Patent Owner asserts that a person of ordinary skill in the art would not be motivated to combine Møller and Steenfeldt-Jensen because Møller teaches away from the prosed combination and Petitioner's proffered reasoning is flawed. PO Resp. 24–37.

a. Teaching Away

In the Petition, Petitioner acknowledges that Møller "note[s] concerns with the greater friction of threaded components compared to its gear wheels and racks." Pet. 43 (citing Ex. 1011 ¶¶ 835–837). Petitioner points out, however, that the proposed combination provides the benefits of reducing the number of internal components (which allows for greater ease of assembly and reduces the likelihood of mechanical malfunction during use of the drug-delivery pen) and an increase in overall durability. *Id.* (citing Ex. 1011 ¶¶ 835–854). Given these benefits, Petitioner asserts that a person of ordinary skill in the art "would have appreciated the trade-offs of each approach and reasonably determined that the benefits of Steenfeldt-Jensen's approach outweighed any increase in friction." *Id.*

Patent Owner contends that "no motivation existed to modify Møller using Steenfeldt-Jensen's threaded gearing, because Møller expressly teaches away from using Steenfeldt-Jensen's threaded gearing." PO Resp.

25. According to Patent Owner, "Møller states that it is an objective of his invention 'to provide an injection device, which combines the advantages of the devices according to the prior art without adopting their disadvantages" and "Møller expressly identifies the threaded gearing of WO 99/38554—i.e., Steenfeldt-Jensen's PCT counterpart" as having such disadvantages. *Id.* (quoting Ex. 1015 ¶ 11) (emphasis omitted). Specifically, Patent Owner quotes Møller's statement that

> A similar gearing is provided in WO 99/38554 [Steenfeldt-Jensen] wherein the thread with the high pitch is cut in the outer surface of a dose setting drum and is engaged by a mating thread on the inner side of the cylindrical housing. However, by this kind of gearing relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces. Therefore a traditional gearing using mutual engaging gear wheels and racks is preferred.

Id. at 25–26 (quoting Ex. 1015 ¶ 8) (emphasis omitted.

In view of these statements, Patent Owner asserts that "[t]he Board misses the import of Patent Owner's argument: Møller specifically teaches away from Steenfeldt-Jensen's threaded gearing implementation, the implementation relied upon by Petitioner, not necessarily every threaded gearing implementation." *Id.* at 26–27 (citing Petition at 41-44; Ex. 2701 ¶ 363) (emphasis omitted). According to Patent Owner, "Møller specifically notes disadvantages in Steenfeldt-Jensen's threaded gearing and particularly calls out that 'by this kind of gearing [Steenfeldt-Jensen's] relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces.'" *Id.* at 27 (citing Ex. 1014 ¶ 14). In further support, Patent Owner notes that Møller "states that it is an objective of his invention 'to provide an injection device, which combines

the advantages of the devices according to the prior art without adopting their disadvantages'" and

> that it is an objective to provide "a direct gearing," like gear wheels and racks, and to avoid a gearing between the injection button and the piston rod "by which [there are] more transformations of rotational movement to linear movement and linear movement to rotational movement," like Steenfeldt-Jensen's threaded gearing.

Id. (citing Ex. 1015 ¶ 11).

Patent Owner contends further that "even if the Board were to find that these statements are not an express teaching away, the Board should be highly skeptical, in view of Møller's disclosure, that simply swapping features in Møller and Steenfeldt-Jensen are as easy as Petitioner asserts." PO Resp. 28. According to Patent Owner, "Petitioner makes no effort to address the concerns articulated by Møller." *Id.* (quoting *Polaris Indus. v. Arctic Cat., Inc.*, 882 F.3d 1056, 1069 (Fed. Cir. 2018)) for the proposition that "even if a reference is not found to teach away, its statements regarding preferences are relevant to a finding regarding whether a skilled artisan would be motivated to combine that reference with another reference."). In its Sur-Reply, Patent Owner reiterates these arguments. PO Sur-Reply 3–5.

Petitioner disagrees asserting that Patent Owner "misapprehends what Møller is actually criticizing." Pet. Reply 1. According to Petitioner, "Møller is not criticizing all gearing that relies on screw mechanics, nor is it criticizing the particular screw mechanics of Steenfeldt-Jensen's second embodiment that were applied in the combination. Rather, Møller specifically addresses the drum-based gearing of Steenfeldt-Jensen's first and fifth embodiments." *Id.* at 2 (emphasis omitted). Petitioner explains that Møller is "concerned about friction losses caused by geared injection-

force transmission across the 'large surfaces' of the dose-setting drum—not gearing via back-driven threads generally—because the large surface area of the drum's thread generates more friction." *Id.* (citing Ex. 1095 ¶ 138). Petitioner explains further that in the embodiment relied upon (i.e. the second embodiment) "injection force is transmitted directly from button 23 to the piston rod without the force having to pass through the drum" and that "[p]ressing the button during injection back-drives the thread on enlargement 37 of the piston rod, and the resulting rotation of the piston rod pulls the piston rod down through the threaded bore that engages the rod's second thread." *Id.* at 3 (citing Ex. 1095 ¶¶ 139–140; Ex. 1014, 7:48–8:33). This, according to Petitioner, is "analogous to the way the '008 patent's drive sleeve back-drives the top thread of the piston rod." *Id.*

In support, Petitioner relies on the testimony of Patent Owner's expert, Dr. Slocum. *Id.* at 3. Specifically, Petitioner asserts that "Dr. Slocum, acknowledged the distinction between the drums in the first [and] fifth embodiments (which are part of the geared transmission of force to the piston rod) and the drum of the second embodiment (which is not)." *Id.* (citing Ex. 1054, 343:25-348:12). Petitioner asserts further that "Dr. Slocum agreed that the drum in the second embodiment just follows along with the axial movement of the button (for dose-setting purposes) and was "not involved in the gearing to drive the piston forward'." *Id.* at 4 (citing Ex. 1054, 348:8-12). Given that "the dose-setting drum in the second embodiment simply 'follows along' with the axial movement of the button . . . the drum's thread is subjected to significantly less force, meaning less friction," Petitioner contends that "Steenfeldt-Jensen's second embodiment thus transforms injection force via the small surface of element 37 rather

than via the 'large surfaces' of the dose-setting drum specifically called out in ¶8 of Møller." *Id.* at 4–5 (citing Ex. 1095 ¶¶ 140, 145). Petitioner asserts that "[t]he dose-injection mechanism applied in Petitioners' combination thus does not have the specific feature Møller criticizes" and Patent Owner "is completely wrong when it states that 'Møller specifically teaches away from Steenfeldt-Jensen's threaded gearing implementation, the implementation relied upon by Petitioner." *Id.* at 5 (quoting PO Resp. 26–27) (emphasis omitted).

Although we agree with Patent Owner, that Møller criticizes "wherein the thread with the high pitch is cut in the outer surface of a dose setting drum and is engaged by a mating thread on the inner side of the cylindrical housing," we do not agree that this criticism rises to the level of a teaching away. Ex. 1015 ¶ 8. Møller states that "[a] disadvantage [of] this construction is that the teeth of the racks and gearwheels alternating have to be brought in and out of engagement with each other with the inherit danger of clashing." *Id.* at 10. Møller states further that "[a]s only a few racks separated by intermediary untoothed recess[es] can be placed along the inner surface of the plunger only few increments can be made during a 360^{o} rotation." *Id.* Møller then states that "[i]t is an objective of the invention to provide an injection device, which combines the advantages of the devices according to the prior art without adopting their disadvantages." *Id.* at ¶ 11. Thus, Møller indicates that this system is not desirable for its purposes. Møller, however, does not indicate that this system is unsuitable for other purposes. While a prior art reference may indicate that a particular combination is undesirable for its own purposes, the reference can

nevertheless teach that combination if it remains suitable for the claimed invention. *See In re Kahn*, 441 F.3d 977, 990 (Fed. Cir. 2006).

The '008 Patent does not appear to be concerned with the disadvantages of concern in Møller. Rather, the '008 patent is concerned with providing a drug delivery device where a user may set the dose. Ex. 1005, 1:26–27. Steenfeldt-Jensen describes a mechanism which allows the user to set the dose. *See*, *e.g.*, Pet. 17-18 (citing Ex. 1014, 8:1–33; Ex. 1011 ¶¶ 794–95, 815–817). Thus, even if Møller indicates that Steendfeldt-Jensen is undesirable for its own purposes, Steenfeldt-Jensen remains suitable for the purpose of providing a device which allows the user to set the dose (*i.e.* for the claimed invention). For this reason, in this case Møller does not teach away from the proposed combination.

b. Reasons to Make the Proposed Combination

Patent Owner contends that Petitioner's articulated reasoning in support of the proposed combination is flawed. PO Resp. 29–37. Specifically, Patent Owner contends that Petitioner's statements regarding the similarities between Møller and Steenfeldt-Jensen are inaccurate and that the advantages resulting from the combination do not provide sufficient reason to combine. *Id.*

In support, Patent Owner asserts that "Møller and Steenfeldt-Jensen have substantially different gearing mechanisms." *Id.* at 29. According to Patent Owner, "Møller specifically and purposefully chose a fundamentally different gearing mechanism from the threaded gearing taught by Steenfeldt-Jensen" such that even though the "two references teach pen injectors with gearing mechanisms[, this] does not by itself suggest sufficient similarity to combine the references." *Id.* at 30 (citing Ex. 1015 ¶¶ 8, 11; Ex. 2017 ¶

368). Patent Owner asserts further that "Møller and Steenfeldt-Jensen are also materially dissimilar in that Møller includes, and its operation purportedly relies on, a cup-shaped clutch mechanism (elements 19, 20), which is missing and not needed in Steenfeldt-Jensen's second embodiment." *Id.* at 30 (comparing Ex. 1015 ¶¶ 26, 33 with Ex. 1014, 8:25–33; citing Ex. 2107 ¶ 369). Patent Owner notes that "Møller also includes a piston rod that must be driven axially without rotation during dose injection," whereas "Steenfeldt-Jensen's second embodiment is configured such that the piston rod must be screwed through a threaded opening in order to dispense a dose." *Id*. at 31 (citing Ex. 1015 ¶¶ 22, 32; Ex. 2107 ¶ 370; Ex. 1014, 8:25–33).

Turning to the sufficiency of Petitioner's reasoning, Patent Owner contends that Møller and Steenfeldt-Jensen have different objectives, with Møller being concerned with reducing friction and Steenfeldt-Jensen being concerned with minimizing the number of parts. *Id.* at 32. Given this difference in objectives, Patent Owner asserts that "a POSA would not have understood that Møller and Steenfeldt-Jensen shared compatible goals and teachings." *Id*. at 32–33 (citing Ex. 2107 ¶ 375). Acknowledging that "Møller and Steenfeldt-Jensen both provide some degree of mechanical advantage, [Patent Owner nevertheless asserts that] Møller's drive mechanism minimizes frictional losses by avoiding threaded gearing, such that the force required by the user for injection is greatly reduced." *Id.* at 33 (citing Ex. 2107 ¶ 368; Ex. 1015 ¶¶ 8, 11). According to Patent Owner, "Steenfeldt-Jensen's pen, which uses threaded gearing, does not, and cannot, provide this benefit." *Id.* (citing Ex. 2107 ¶¶ 361–362, 368).

Patent Owner contends further that Petitioner's reasoning is flawed because "[t]he Petition cites no evidence that the specific pens disclosed in Møller are prone to malfunction or are insufficiently durable." *Id.* at 34. In addition, Patent Owner contends that "Petitioner also does not substantiate that a POSA would desire a pen injector with fewer parts, particularly if a reduction in parts would eliminate advantageous features (e.g., Møller's reduced-friction driving mechanism)." *Id.* Then, Patent Owner argues that "Petitioner also fails to provide any evidence to support its assertion that the combination of Møller and Steenfeldt-Jensen would 'provide[] greater ease of use for a patient.'" *Id.* (citing Pet. 43). Patent Owner concludes this line of arguments by asserting that "Petitioner's combination diminishes the advantages possessed by the respective pen injectors in Møller and Steenfeldt-Jensen" and "stems not from the motivations of a POSA to design an improved pen, but rather from hindsight aimed solely at challenging the validity of the claim." *Id.* at 36 (citations omitted). Patent Owner reiterates these arguments in its Sur-Reply. PO Sur-Reply 5–8.

Asserting that a person of ordinary skill would have recognized specific commonalities between Møller and Steenfeldt-Jensen, Petitioner contends that the references do not have differing structures and operating principles. Pet. Reply 5. Petitioner asserts further that although "Steenfeldt-Jensen may not use the word 'clutch', it nevertheless has a locking feature that allows the driver to rotate relative to the housing during dose setting but not rotate during injection" and that "because the operation of Møller's clutch causes its driver to move in the same way as Steenfeldt-Jensen's driver (i.e. button 23), the combined features maintain their same operational logic." *Id.* at 6 (citing Ex. 1014, 8:25-33). Turning to the distinction

between how Møller's piston rod and Steenfeldt-Jensen's piston rod move, Petitioner argues that this is an extraneous difference that does not matter. *Id.* According to Petitioner, "[t]he piston rods rotate differently because the drive mechanisms generate axial movement of the rod differently . . . The rotation itself is incidental to the combination." *Id.* (citing Ex. 1095 ¶ 144).

Petitioner asserts further that Patent Owner "fails to distinguish the references' goals meaningfully." *Id.* at 7 (citing PO Resp. 32–33). Specifically, Petitioner contends that Patent Owner "wrongly assumes that a POSA cannot balance competing objectives." *Id.* (citing *In re Urbanski*, 809 F.3d 1237, 1244 (Fed. Cir. 2016)). According to Petitioner, Patent Owner contradicts its own expert's statement that "[t]here will of course be tradeoffs between cost and injection force." *Id.* (quoting Ex. 2107 ¶ 36). Agreeing with this statement, Petitioner argues that "the petition explains precisely why the combination is compatible with both of these objectives, as the combination yields a pen with a mechanical advantage similar to Møller's while also requiring fewer, simpler parts." *Id.* (citing Pet. 42–44; Ex. 1011 ¶¶ 835–37).

Turning to the benefits of the proposed combination, Petitioner contends "that the SoloSTAR® pen—which Sanofi touts as providing 'greatly reduced injection force' compared to other pen injectors on the market (POR 51-63)—also uses threaded gearing." *Id.* (citing Ex. 1095 ¶ 145; Ex. 2107 ¶ 471). Petitioner asserts further that "the SoloSTAR® pen uses the same style of threaded gearing—i.e. a back-driven, dual-threaded

piston rod—as Steenfeldt-Jensen's second embodiment." *Id.* at 7–8 (citing Ex. 1095 ¶ 145).

Patent Owner's argument that Møller and Steenfeldt-Jensen have different gearing mechanisms does not convince us that the reasons proffered by Petitioner for the proposed combination are flawed. PO Resp. 29. Indeed, if Møller and Steenfeldt-Jensen shared common gearing mechanisms, there would be no need to propose their combination. Patent Owner's assertion that because Møller includes a clutch the combination is improper is similarly unconvincing. *Id.* at 30. The underlying presumption behind both arguments rests on the idea that the Møller and Steenfeldt-Jensen gearing mechanism are not physically combinable. This, however, is not the relevant inquiry. The relevant inquiry is whether the claimed subject matter would have been obvious to those of ordinary skill in the art in light of the *combined teachings* of Møller and Steenfeldt-Jensen. *See In re Keller*, 642 F.2d 413, 425 (CCPA 1981). Further, "[i]t is well-established that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of the elements." *In re Mouttet*, 686 F.3d 1322, 1332 (Fed. Cir. 2012). Moreover, in this case, Møller explicitly contemplates the proposed combination. Ex. 1015 ¶ 9. Thus, we are not convinced that Møller and Steenfeldt-Jensen are not combinable in the manner proposed by Petitioner.

Patent Owner's argument that the benefits of Steenfeldt-Jensen's mechanism do not outweigh its disadvantages is also unconvincing. PO Resp. 33–37. Patent Owner asserts that Petitioner provides no support for the enumerated advantages. Steenfeldt-Jenson, however, provides such support. *See*, *e.g.*, Ex. 1014, 1:27–30 (discussing the benefits derived from

the use of fewer parts). The testimony of Mr. Leinsing that the proposed combination provides a "simpler piston-driving mechanism and the simplification of and reduction of internal components is an advantageous and desired objective in the industry" also supports Petitioner's position. Ex. 1011 ¶ 835. Although, Patent Owner reiterates Møller's concern with reducing friction, Patent Owner does not identify where this benefit is of concern in the '008 patent. We note that friction is only mentioned once in the '008 patent in the description of the clutch. Ex. 1005, 5:5–9. In that context friction is seen as a benefit. *Id.* Thus, Patent Owner's assertion that the '008 patent is concerned with reducing friction is not supported by evidence and Patent Owner relies on attorney argument in support of its position.

A given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate any or all reasons to combine teachings. *See Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349 n. 8 (Fed. Cir. 2000) ("The fact that the motivating benefit comes at the expense of another benefit, however, should not nullify its use as a basis to modify the disclosure of one reference with the teachings of another. Instead, the benefits, both lost and gained, should be weighed against one another"). In this case, we agree with Petitioner that the benefits of the proposed combination outweigh the alleged disadvantages. Further, given the evidence in support of Petitioner's reasoning, we do not agree that the proposed modification is founded on improper hindsight. PO Resp. 36.

6. Helical Thread Limitation

Petitioner asserts that "Møller teaches housing 1 with helical thread 6," "Møller teaches dose setting drum 17, which has a threaded surface

engaging thread 6 of housing 1," and "[b]oth Møller and Steenfeldt-Jensen teach the use of an insert in the housing." Pet. 21, 23, 25. To meet the limitations at issue, Petitioner contends that "the combination of Møller and Steenfeldt-Jensen discloses a dose-dial sleeve having a threaded surface that is engaged with the helical thread of the housing." *Id.* at 25 (citing Ex. 1015 ¶ 29; Ex. 1011 ¶¶ 801–803; Ex. 1014, 7:51-67, Fig. 7–8, 16–17). As discussed in the proceeding section, Petitioner proffers reasons for making the proposed combination. *See*, *e.g.*, Pet. 26.

Patent Owner contends that "Møller's housing 1 does not have a thread, and instead, a separate internal tubular element 5 has a thread." PO Resp. 37. According to Patent Owner, "[o]nly housing 1 is a 'housing', while wall 2 and tubular element 5 are within the housing, even if integrally formed." *Id.* at 37–38 (citing Ex. 1015 ¶ 23). According to Patent Owner, "if wall 2 is the housing (it is not) then it cannot also be the claimed 'insert provided in the housing.'" *Id.* at 38 (citing Pet. 25).

Patent Owner contends further that "neither Petitioner nor its expert specify how" Steenfeldt-Jensen's wall would have been combined with Møller. *Id.* at 38. In response to this alleged lack of specificity, Patent Owner sets forth two possible ways to physically combine Steenfeldt-Jensen's wall 4 with Møller. PO Resp. 39–41. We do not reproduce these possible bodily incorporations of Steenfeldt-Jensen's wall 4 into Møller because, as discussed in the proceeding section, "[i]t is well-established that a determination of obviousness based on teachings from multiple references does not require an actual, physical substitution of the elements." *Mouttet*, 686 F.3d at 1332.

Replying to Patent Owner's contentions, Petitioner asserts that the '008 patent defines the term "housing" as "any exterior housing . . . or interior housing ('insert', 'inner body') having a helical thread." Pet. Reply 10 (quoting Ex. 1005, 2:66–3:10, 7:33–39) (emphasis omitted). Petitioner further quotes the '008 patent as stating' '"[i]n general, the housing may be unitary or a multipart component.'" *Id.* (quoting Ex. 1005, 3:9–10). According to Petitioner, "[t]he specification thus makes clear that an 'interior housing' is still a housing and that the term 'insert' can be a feature that is 'unitary' with the rest of the housing." *Id.* at 10 (citing Ex. 1095 ¶ 147). Petitioner asserts further that "[i]f any doubt remains . . . that doubt is removed by the specification's subsequent explanation that 'the insert may be formed integrally with the main housing 4 having the form of a radially inwardly directed flange having an internal thread.'" *Id.* at 10–11 (quoting Ex. 1005, 7:37–39) (emphasis omitted).

Patent Owner disagrees contending that "[t]he plain language of the claim treats the insert as distinct from the threaded housing: 'an insert provided in the housing.' The claim does not recite that the housing comprises an insert." PO Sur-Reply 13 (emphasis omitted). Patent Owner contends further that the proposed combination does not disclose claim 1 "[b]ecause Petitioners' proposed combination at most teaches an insert (*i.e.*, Møller's wall 2) provided within a non-threaded housing (*i.e.*, Møller's housing 1), and because the plain language of the claims require both 'an insert provided in the housing' and that the 'housing compris[es] a helical thread.'" *Id.* (citing PO Resp. 37–41).

We agree with Petitioner that the combined teachings of Møller and Steenfeldt-Jensen would have rendered the contested limitations obvious to

one of ordinary skill in the art at the time of the invention. Pet. 21–26; Ex. 1011 ¶¶ 799–803, 806, 832–837. We are not persuaded that the plain language of claim 1 requires an insert that is separate from the housing. Rather, the language "an insert provided in the housing" when read in light of the Specification encompasses the components of Møller identified by Petitioner as corresponding to these claimed features. Ex. 1005, 2:66–3:2, 3:9–10. Moreover, we reiterate that, as discussed above, the test for obviousness is not whether the features of one reference can be physically combined with the other reference.

7. Claim 3

Claim 3 requires an insert that is secured in the housing against rotational and longitudinal motion. Ex. 1005, 17:52–54.

Petitioner asserts that

> Both Møller and Steenfeldt-Jensen teach the use of an insert that is secured in the housing against rotational and longitudinal motion. The proposed modification would make use of wall 4 of Steenfeldt-Jensen or a comparable component that also has a circular internal thread and is secured to the housing. Wall 4 is secured in the housing against rotational and longitudinal motion.

Pet. 45–46 (citing Ex. 1014, 5:55–57, 7:41–47, Fig. 7; Ex. 1011 ¶¶ 839–841.

Patent Owner contends that "neither reference teaches an 'insert provided in said housing' where the insert is 'secured in the housing against rotational . . . motion' as claimed." PO Resp. 41 (quoting Dec. 20–21). According to Patent Owner, "Steenfeldt-Jensen's wall 4 of ampoule holder 2 . . . "is not 'secured in the housing against rotational . . . motion' as required by claim 3." *Id.* at 43–44 (quoting Pet. 44–35; citing Dec. 20).

Petitioner disagrees asserting that "Petitioners did not propose incorporating Steenfeldt-Jensen's ampoule holder 2. Rather, the petition applies Steenfeldt-Jensen's dose-dispensing mechanics to provide a pen that 'would operate in the same overall manner as . . . Møller.'" Pet. Reply 13 (quoting Ex. 1011 ¶¶ 832–834; citing Pet. 41).

Patent Owner responds that "the only argument presented in the Petition for claim 3 proposes a combination using end wall 4, which is part of the ampoule holder 2 component of Steenfeldt-Jensen, or a 'comparable component.'" PO Sur-Reply 14. Patent Owner reiterates its assertion "that wall 4 is not secured in the housing against rotational motion because it is part of the rotatable ampoule holder 2." *Id.* at 15 (citing PO Resp. 43–47). Patent Owner also argues that Petitioner's argument "that the Petition did not propose incorporating ampoule holder 2, but rather 'Steenfeldt-Jensen's *dose-dispensing* mechanics,'" is a new argument. *Id.* (citing Pet. Reply 13).

We note that in its Reply Petitioner directs our attention to its reasoning in support of its challenge to claim 1 to bolster its challenge to claim 3. Pet. Reply 13 (citing Pet. 41). We need not decide if this is a new argument because even if we assume it is not a new argument, we determine that Petitioner has not adequately explained its reasoning in support of the proposed rejection. We agree with Patent Owner's determination that Steenfeldt-Jensen's wall 4 of ampoule holder 2 "is not rotationally fixed and thus is not 'secured in the housing against rotational . . . motion' as required by claim 3." PO Sur-Reply 15 (citing PO Resp. 43–47). With this in mind, we determine that Petitioner has not adequately explained why one of ordinary skill in the art would have been led to incorporate either Steenfeldt-Jensen's wall 4 or its dose-dispensing mechanics in Møller or how such a

modification would have resulted in the claimed invention. Thus, Petitioner has not shown that claim 3 would have been obvious to one of ordinary skill in the art at the time of the invention.

8. Claim 11

Claim 11 requires that the helical thread of the housing be an internal helical thread and that the dose dial sleeve have a threaded outer surface engaged with the internal helical thread of the housing. Ex. 1005, 18: 23–26).

Petitioner asserts that "the proposed modification makes use of Møller's outer dose-setting mechanism (a concentrically arranged dose-dial sleeve, clutch, and internally threaded drive sleeve)". Ex. 1011 ¶¶832–37. The helical thread 6 is engaged with a corresponding thread on the dose-setting drum 17." Pet. 52. Petitioner asserts further that "[t]o the extent that the thread on the dose-setting drum 17 is not considered to provide a threaded outer surface, such feature would have been obvious to POSA." *Id.* Turning to Steenfeldt-Jensen, Petitioner asserts that "Steenfeldt-Jensen describes a syringe with dose-scale drum 17, which 'in its outer wall [is] provided with a helical [groove].'" Pet. 53 (quoting Ex. 1014, 6:7-17, Fig. 3). According to Petitioner, Steenfeldt-Jensen's "housing 1 includes 'a helical protruding rib 16' that engages dose-scale drum 17's helical groove so that the dose-scale drum 17 may be rotated and axially moved in and out of the housing during use." *Id.* (citing Ex. 1014, 6:7–17, 7:17–21, Figs. 1–3). With these teachings in mind, Petitioner asserts that "[a] POSA would have recognized the benefit to placing a threaded engagement like that taught by Steenfeldt-Jensen on a drum and housing like that of Møller's device." *Id.* at 53 (citing Ex. 1011 ¶ 850). Petitioner asserts further that

> a POSA would have understood that the highpitch threaded arrangement taught by Steenfeldt-Jensen reduces the force necessary to rotate the drum back into the housing during injection (and thus reduces the overall force needed during injection), even in cases where the dose-setting drum includes an outer helical groove that engages the housing's threading. *Id.* A POSA also would have recognized that providing Møller's dose-setting drum with a helical groove on its outer surface, rather than its inner surface, would result in the same relative rotational movement between the drum and housing, and would not affect the overall operation of the device, make them essentially interchangeable. *Id.* A POSA also would have expected that such a configuration would not affect the injection force needed to drive the piston rod, given Møller's direct-gear coupling to drive the rod. *Id.* Indeed, Møller does not place any significance on the placement of that engagement. EX1011, ¶851. Thus, a POSA would have reasonably expected that an outer helical groove threading provided on the dose-setting drum would result in the same rotational function as the inner threading shown in Møller. *Id.*

Pet. 53–54.

Patent Owner contends that "[t]he Petition does not identify a thread on the outer surface of Møller's dose setting drum 17 as required by the claim, because the Møller's dose setting drum 17 has a thread on its inner surface." PO Resp. 47 (citing Pet. 50-54) (emphasis omitted). Patent Owner contends further that "[t]o the extent Petitioner argues that it would have been obvious to move the threads on the inner surface of Møller's dose setting drum to the outer surface without changing the pitch of the threads, neither Petitioner nor its expert have provided any reason for doing so." *Id.* at 49 (citing Pet. 53–54; *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017)).

We agree with Patent Owner, that Petitioner has not identified a thread on the outer surface of Møller's dose setting drum. PO Resp. 47. We

further agree that Petitioner has not adequately explained why a person of ordinary skill in the art would have modified Møller's dose setting drum to use an external thread. Without such explanation, Petitioner's reasoning is incomplete.

9. *Indicia of Nonobviousness*

a. Nexus

Objective indicia of nonobviousness are "only relevant to the obviousness inquiry 'if there is a nexus between the claimed invention and the [objective indicia of nonobviousness].'" *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006)). For objective indicia of nonobviousness to be accorded substantial weight, their proponent must establish a nexus between the evidence and the merits of the claimed invention. *ClassCo, Inc., v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016). "[T]here is no nexus unless the evidence presented is 'reasonably commensurate with the scope of the claims.'" *Id.* (quoting *Rambus Inc. v. Rea*, 731 F.3d 1248, 1257 (Fed. Cir. 2013)).

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

only a component of a commercially successful machine or process. *Id.* (reaffirming the importance of the "coextensiveness" requirement).

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

However, "[a] finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations." *Fox Factory*, 944 F.3d at 1375. "To the contrary, the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the 'direct result of the unique characteristics of the claimed invention.'" *Id.* at 1373–74 (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)). "Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention," meaning that "there must be a nexus to some aspect of the claim not already in the prior art." *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011) (emphasis in original). On the other hand, there is no requirement that "objective evidence must be tied exclusively to claim elements that are not disclosed in a particular prior art reference in order for that evidence to carry substantial

weight." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016). A patent owner may show, for example, "that it is the claimed combination as a whole that serves as a nexus for the objective evidence; proof of nexus is not limited to only when objective evidence is tied to the supposedly 'new' feature(s)." *Id.*

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

Patent Owner contends that "Sanofi's LANTUS® SoloSTAR®[9] product practices claim 1 of the 008 Patent." PO Resp. 53 (citing Ex. 2107 ¶¶ 436, 611–643). According to Patent Owner,

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

[9] As noted by Patent Owner, "LANTUS® is the commercial name for Sanofi's insulin glargine formulation, and LANTUS® SoloSTAR® is the commercial name for LANTUS® packaged in the SoloSTAR® pen injector." PO Resp. 53, n. 8. We note that "LANTUS® OptiClik®" is the commercial name for LANTUS® packaged in the OptiClik® pen injector.

Id. (citing Ex. 2107 ¶ 651) (emphasis added). Patent Owner, again relying on the testimony of Prof. Slocum, contends that "the claimed components and interfaces, such as the threaded engagements, piston rod, drive sleeve, and clutch, are reflected in the LANTUS®® SoloSTAR®" device. *Id.* (citing Ex. 2107 ¶¶ 611–643). Patent Owner does not explain sufficiently, however, how these components of the claimed invention embody the desirable features and properties. *See*, *generally*, 51–63; *see also* PO Sur-Reply 18–24.

Petitioner notes that Patent Owner "provides identical secondary consideration arguments without differentiating among claims-at-issue or patents-at-issue."[10] Pet. Reply 16 (citing Ex. 1048 ¶¶ 36–37, Attachment B-1; Ex. 1055, 53:9–12). According to Petitioner, Patent Owner's "failure to differentiate between claims and patents undermines its secondary considerations case." *Id.* at 17. Noting that Patent Owner "does not argue that [LANTUS® SoloSTAR®] practices all challenged claims,"[11] Petitioner asserts that "the claims do not require [LANTUS®] (or insulin at all), an 80-unit cartridge, a short stroke length, or a low injection force." *Id.* "Sanofi's argument ignores the claims and fails to apportion any secondary consideration to the active ingredient." *Id.* On this basis, Petitioner asserts that the claims "are not entitled to a presumption of nexus because [LANTUS® SoloSTAR®] is not 'the invention.'" *Id.*

[10] We understand Petitioner to be referring to the patents and their claims at issue in the related proceedings detailed in Section II.A above.
[11] We note that Petitioner refers to particularly claims 21 and 30; however, the '008 only has 19 claims. Accordingly, we understand this reference to be a typographical error.

In its Sur-Reply, Patent Owner asserts that it "showed how SoloSTAR® practices certain challenged claims." PO Sur-Reply 19 (citing Ex. 2107 ¶¶ 551–611). Patent Owner contends, that Petitioner "provide[s] no credible evidence rebutting these facts, or the fact that the challenged claims enable SoloSTAR®'s low injection force and other features identified in the [Patent Owner] Response." *Id.* (citing Pet. Reply 17, 23).

Patent Owner "bears the burden of showing that a nexus exists." *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999). "To determine whether the patentee has met that burden, we consider the correspondence between the objective evidence and the scope of the claim. *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (quoting *Demaco*, 851 F.2d at 1392). Patent Owner asserts the indicia of nonobviousness support a showing of long-felt need, industry praise,[12] and commercial success. We discuss Patent Owner's showing with respect to nexus and Patent Owner's showing regarding long-felt need, industry praise, and commercial success in turn below.

b. Long-felt Need

Patent Owner contends that "diabetic patients need an easy-to-use injection device with a low injection force to reduce the burden on the patient and increase the likelihood of the patient adhering to their prescribed therapy." PO Resp. 54 (citing Ex. 2111 ¶¶ 24–26). According to Patent Owner, "[p]rior to the launch of LANTUS® SoloSTAR®, there were

[12] Patent Owner includes its evidence of industry praise in with its allegations of long-felt need and commercial success. PO Resp. 55–59. As, however, these are separate secondary considerations, we consider the evidence of long-felt need, industry praise, and commercial success separately. *Mintz*, 679 F.3d at 1379.

multiple injection pens on the market for administering insulin or an insulin analog . . . These injection pens, however, had numerous shortcomings and design flaws that resulted in significant injection force." *Id.* at 54–55. In support, Patent Owner cites the testimony of Dr. Grabowski and Dr. Goland discussing these short comings. *Id.* at 55 (citing Ex. 2111 ¶¶ 23–25, 33–35; Ex. 2109 ¶¶ 52–55). Patent Owner asserts that "[t]he LANTUS® SoloSTAR® revolutionized the injection pen market, in large part because the LANTUS® SoloSTAR® was easy to use." *Id.* (citing Ex. 2142).

In an effort to show nexus to the claimed invention, Patent Owner submits that "the primary intent of the invention is to address these specific problems in the prior art – 'The illustrated embodiment . . . helps reduce the overall force required for a user to cause medicinal product to be dispensed.'" PO Resp. 56 (citing Ex. 1003, 3:64-67).[13] Patent Owner submits further that "[s]urprisingly it was found that the drive mechanism according to instant invention without having a unidirectional coupling provides a valuable technical alternative for drive mechanisms, wherein reduced force is needed to actuate the mechanism.'"[14] *Id.* (citing Ex. 1005, 1:66–2:3). Patent Owner also directs our attention to "a statement by endocrinologist Sjoberg Kho of the University of Santo Tomas Hospital that 'self-injection can be a barrier to acceptance of insulin therapy. However, the LANTUS® SoloSTAR[®] operates with a low injection force 31 percent less than other insulin pens that allows a gentle injection'" and "a statement

[13] We note that Ex. 1003 is U.S. Patent No. 8,992,486 B2, which is not the patent at issue in this proceeding. We note further that the quoted portion of the '486 patent does not appear in the '008 patent.
[14] We note that in the sentence following the quoted sentence, the '008 patent attributes this reduction in force to the clutch means. Ex. 1005, 2:3–7.

by Denis Raccah, Professor of Endocrinology, University Hospital Sainte Marguerite, France, that, 'Insulin injection with SoloSTAR® brings flexibility, satisfaction for the patients, and an opportunity for earlier initiation of insulin therapy which may contribute to better long term glycemic control.'" *Id.* at 56–57 (citing Ex. 2184, 2; Ex. 2185, 1). In addition, Patent Owner asserts that "7 out of 10 patients now prefer the lower injection force of SoloSTAR® to competitor products and in 2008 it accounted for '41% of all growth in the global injectable insulin market.'" *Id.* at 57 (citing Ex. 2121, 2, 9).

Responding to Patent Owner's submissions, Petitioner asserts that Patent Owner's "long-felt need experts didn't know what claims were at issue and provided no independent opinion about nexus to any claim." Pet. Reply 16 (citing Ex. 1055, 44:17–45:17, 47:21–25, 48:18–49:19, 50:20–51:24; Ex. 1056, 9:4–7, 18:16–20, 19:18–25, 24:22–25:5, 37:2–6). According to Petitioner, Patent Owner's "MD testified that [Patent Owner's] economist was the one who told her the [SoloSTAR®] pen was easy to use and has a low injection force. *Id.* at 16–17 (citing Ex. 1056, 11:19–14:10).

Turning specifically, to Patent Owner's allegation that there was a long-felt need for the claimed invention, Petitioner disagrees asserting that Patent Owner "concedes that existing pens were used successfully to administer insulin analogs before [SoloSTAR®]." Pet. Reply 24 (citing PO Resp. 49–51). Petitioner asserts further that "[a]s Dr. Biggs testifies, 'there was no long-felt unmet need for another insulin pen'" and "[i]n more than 30 years of practice, Dr. Goland never heard from a patient wishing they had a pen with low injection force, never saw using a syringe prevent a patient from taking [LANTUS®], and never prescribed an insulin solely based on

its pen." *Id.* (citing Ex. 1048 ¶ 39; Ex. 1056, 52:6–9, 71:4–16). Noting Patent Owner's sponsored "injection force studies, (EX2143.010; EX2144.010; EX2100.006; EX2126.004; EX2116.009; EX2123.007; EX1048, ¶58)," Petitioner directs our attention to "other studies [that] found [SoloSTAR®] did not have a lower injection force." *Id.* at 24–25 (citing Ex. 214.015; Ex 2145.020-021). According to Petitioner, "other insulin pens were already considered easy to use both generally and for patients with special challenges like age or dexterity issues." *Id.* at 25 (citing Ex. 1048 ¶¶ 45–47, 52; Ex. 1046 ¶¶ 57, 62–63).

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

Moreover, even if we assume nexus, Patent Owner fails to sufficiently demonstrate a long-felt need for a pen with a low injection force. "Long-felt need is closely related to the failure of others. Evidence is particularly probative of obviousness when it demonstrates both that a demand existed

for the patented invention, and that others tried but failed to satisfy that demand." *Eurand, Inc. v. Mylan Pharms., Inc.* (*In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*), 676 F.3d 1063, 1082 (Fed. Cir. 2012). Establishing a long-felt need requires objective evidence that the invention has provided a long-awaited, widely accepted, and promptly adopted solution to a problem existent in the art, or that others had tried but failed to solve that problem. *See In re Mixon*, 470 F.2d 1374, 1377 (CCPA 1973). Furthermore, one must demonstrate that "widespread efforts of skilled workers having knowledge of the prior art had failed to find a solution to the problem." *In re Allen*, 324 F.2d 993, 997 (CCPA 1963).

We find that Patent Owner's evidence demonstrates acceptance of the LANTUS® SoloSTAR® pen. *See*, *e.g.* Ex. 2184, 1; Ex. 2185, 1; Ex. 2121, 6. But, we also find that the evidence does not demonstrate a long awaited need for such a pen. Rather, Patent Owner's evidence demonstrates that "[p]rior to the launch of LANTUS® SoloSTAR®, there were multiple injection pens on the market for administering insulin or an insulin analog – e.g., Levemir[®] FlexPen[®] and LANTUS® OptiClik® in the long-acting category, and the Humalog[® KwikPen[®] in the rapid-and intermediate-acting categories, among many others." PO Resp. 54–55. Patent Owner's evidence does not show that others tried and failed to make such a pen. Rather, as noted above, the '008 patent attributes the reduction in force to its clutch means — a feature that was already present in other pens such as Møller's pen. *See*, *e.g.*, Ex. 1015 ¶¶ 26–27. Although, Patent Owner's evidence may demonstrate that the LANTUS® SoloSTAR® pen is an improvement over prior art pens, such evidence is insufficient to establish a long-felt need for this pen.

c. Industry Praise

In addition to the evidence of industry praised discussed in Section III.D.10.b above, Patent Owner submits evidence of awards won by its LANTUS® SoloSTAR® product. *See* PO Resp. 57–59. Specifically, Patent Owner directs our attention to evidence indicating that "SoloSTAR[®] won the Gold, International Export, and Grand Prix awards at the Design Business Association (DBA) Design Effectiveness Awards" in 2009. *Id.* at 57 (citing Ex. 2121). According to Patent Owner, "[t]he DBA is a design organization based in the UK that is interested in how a design commercially impacts a company's business." *Id.* at 57–58. Patent Owner asserts that "[t]he case study of SoloSTAR[®] for the DBA Awards describes the SoloSTAR[®]'s inventiveness as 'suitably ambitious' and explains that 'SoloSTAR[®] is the first disposable insulin pen to combine very low injection force (which provides a smooth injection experience for patients) with 80 units maximum dose capability, an important breakthrough.'" *Id.* at 58 (citing Ex. 2121, 3).

Patent Owner submits further that "SoloSTAR® [also] won the Good Design Award by the Chicago Athenaeum Museum of Architecture and Design." PO Resp. 58 (citing Ex. 2201). According to Patent Owner, "[i]n connection with this award, and as recognition of its inventiveness, the LANTUS® SoloSTAR® device was put into the permanent Design Collection of the Chicago Athenaeum Museum of Architecture and Design." *Id.* (citing Ex. 2109 ¶ 73). Patent Owner also submits that "at the Prix Galien USA 2009 Award, which "recognize[s] innovative biopharmaceutical drugs and medical technologies" and "is considered the industry's highest accolade for pharmaceutical research and development — equivalent to the

Nobel Prize," Sanofi and DCA[15] were both finalists." *Id.* at 59 (citing Ex. 2109 ¶ 74).

According to Petitioner, "[t]here is no connection between the alleged 'awards and praise' and the claims-at-issue." Pet. Reply 23 (citing Ex. 1048 ¶¶ 57–60). Petitioner asserts that the documents submitted by Patent Owner "are either made or written by Sanofi affiliates, do not praise the pen itself as being 'inventive,' or do not attribute success to the properties Sanofi relies upon." *Id.* (citing Ex. 2121 (indicating that this paper was a Sanofi/DCA authored case study); Ex. 2201 (as cited for "social good and for humanitarian concerns"); Ex. 2109 ¶¶ 73-74 (as cited for aesthetics)). Regarding the case study of SoloSTAR®, Petitioner contends that "this 'case study' was written, funded, and sponsored by Sanofi (with SoloSTAR[®] designer DCA)." *Id.* at 26 (citing Ex. 1048 ¶¶ 57–58; Ex. 1075). Thus, according to Petitioner, "[i]t is self-praise, not industry praise." *Id.* (citing Ex. 1055, 79:6–81:19). Regarding the Good Design Award, Petitioner contends that "[t]he document Sanofi cites does not attribute the award to 'inventiveness.' Nor does the statement that SoloSTAR[®] 'represents a design for social good.'" *Id.* at 27 (citing PO Resp. 53). Petitioner contends further that "[n]either the document nor the statement praises what is claimed or the features (e.g., low injection force) Sanofi argues uniquely flow from what is claimed." *Id.* (citing Ex. 1048 ¶¶ 59–60). Finally, regarding the Prix Galien USA 2009 Award, Petitioner contends that the fact that Sanofi and DCA were finalists for this award "fails to

[15] According to Patent Owner, DCA is "the design firm with whom [it] partnered in creating SoloSTAR®." PO Resp. 62.

demonstrate . . . that SoloSTAR[®] was 'inventive,' much less that the claims were inventive." *Id.* (citing Ex. 1048 ¶ 60).

Again, we agree with Petitioner. As with the proffered evidence of long-felt need discussed in Section III.D.10.b above, Patent Owner fails to demonstrate nexus between the purported evidence of industry praise and the claims at issue in this proceeding. The evidence provided indicates that LANTUS® SoloSTAR® received industry praise based on its visual design and its combination of low injection force and large maximum dose capability. *See*, *e.g.* Ex. 2121, 2–3, 5. But, these features are not coextensive with the claims of the '008 patent, because the claims do not require low injection force in combination with high maximum dose capability.

Moreover, even if we assume Patent Owner has demonstrated nexus between the alleged industry praise and the claims at issue, much of the praise was generated by Sanofi's affiliate DCA. *See*, *e.g.* Ex. 1055, 76–79. Such self-generated praise is not persuasive industry praise. Further, the evidence independent of DCA, such as consideration of LANTUS® SoloSTAR® for the Prix Galien USA 2009 award only generally specifies the criteria used to judge the nominees. Ex. 2042, 2. It does not evidence industry praise of any specific feature of the claimed invention. *Id.*

d. Commercial Success

Patent Owner submits that "[t]he tremendous commercial success of LANTUS® SoloSTAR® is further objective evidence of non-obviousness." PO Resp. 59. In support, Patent Owner asserts that "[t]he commercial success is demonstrated by the contribution of LANTUS® SoloSTAR® to the growth of the LANTUS® franchise overall, and by the strong

performance of LANTUS® SoloSTAR® when compared to other long-acting insulin and insulin analog pens." *Id.* (footnote omitted). According to Patent Owner, "[t]he commercial success of LANTUS® SoloSTAR® is also demonstrated by the overall levels and shares of dollar sales, new prescriptions, and total prescriptions, as well as the profitability and formulary placement achieved by LANTUS® SoloSTAR®." *Id.* at 60 (citing Ex. 2109 ¶ 12). Specifically, Patent Owner asserts that

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

Id.

Anticipating one of Petitioner's arguments, Patent Owner contends that "[t]o the extent Petitioner argues that Patent Owner's evidence of commercial success is not due to the claimed invention, but rather, to factors beyond the claimed invention such as, e.g., marketing, such arguments should be rejected." PO Resp. 61. Patent Owner submits that "Dr. Grabowski analyzed marketing expenditures for long-acting insulin products and determined that sales of LANTUS® SoloSTAR® exceeded sales for other well-marketed long-acting insulin products despite the fact that '[t]otal marketing expenditures for LANTUS® SoloSTAR® were in line with, or were lower than, many other long-acting insulin products.'" *Id.* at 61–62 (citing Ex. 2109 ¶¶ 16, 64–69).

Anticipating a different argument, Patent Owner contends that "to the extent Petitioner argues that Patent Owner's evidence of commercial success

is due to alleged 'blocking patents' covering the glargine molecule that is used in the production of the active ingredient in LANTUS®, any such argument would be misplaced." PO Reps. 62. According to Patent Owner, "the law does not mandate across-the-board-discounting of commercial success simply because other patents cover components of the product" and "the success of LANTUS® SoloSTAR® cannot be attributed solely to the insulin glargine molecule because LANTUS® OptiClik® used the exact same LANTUS® formulation and failed to achieve the success of SoloSTAR®." *Id.* at 62–63. In addition, Patent Owner asserts that its "earlier patents on the insulin glargine molecule did not prevent others from entering the market for non-glargine, long-acting insulin products and competing with LANTUS® SoloSTAR®. *Id.* at 63. Patent Owner identifies Levemir[®] FlexPen[®], with its long-acting insulin as an example of a disposable pen device that delivered long-acting insulin. *Id.* at 63.

Petitioner disagrees contending that Patent Owner "provides no benchmarks for evaluating success, applies a faulty 'pens only' market definition, and formulary status does not separately demonstrate commercial success." Pet. Reply 27 (citing Ex. 1048 ¶¶ 17–22, 25–28). As an example, Petitioner contends that "Dr. Grabowski relies on a misleading 8,000% growth rate for SoloSTAR[®] when, as Dr. McDuff points out, the failed OptiClik[®] pen similarly enjoyed an 8,000% growth rate in its first three years." *Id.* at 28 (citing Ex. 1048 ¶ 20). According to Petitioner, "Dr. Grabowski argues [LANTUS® SoloSTAR®]'s commercial success is supported by the 'strong performance' of Apidra[®] SoloSTAR[®], Toujeo

[®] SoloSTAR[®], and Admelog[®] SoloSTAR[®],[16] even though peak annual sales of Apidra[®] SoloSTAR[®] and Admelog[®] SoloSTAR[®] fall below the sales of [LANTUS® OptiClik®] that he describes as 'deficient.'" *Id.* (citing Ex. 1048 ¶ 70–71). Petitioner contends further that Patent Owner "inappropriately excluded insulin injectable products from its market share analyses to inflate [LANTUS® SoloSTAR®]'s market share 2–3 times." *Id.* (citing Ex. 1048 ¶ 25–27). In response, Petitioner asserts that Patent Owner's "commercial success arguments thus improperly take [LANTUS® SoloSTAR®]'s commercial performance out of context." *Id.*

Responding to Patent Owner's contention that "LANTUS® SoloSTAR® sales and prescriptions remained strong despite the entry of several competing long-acting insulin pen products beginning in 2015," Petitioner asserts that "introduction of competing Basaglar[®] and Tresiba [®] long-acting insulin products completely changed the trajectory of both the [LANTUS®] and [Toujeo® SoloSTAR®] products without practicing the claims-at-issue." Pet. Reply 28 (citing PO Resp. 54; Ex. 1048 ¶¶ 30–35, 64). According to Petitioner, "Dr. Grabowski himself previously explained that generic entry of a biologic is expected to have less and a slower impact on the sales of the existing biologic than it would have for a small molecule because of biologics' increased manufacturing costs" and "Dr. Goland confirmed that existing diabetes patients are particularly reluctant to switch to a different insulin product." *Id.* at 28–29 (citing Ex. 1055, 143:10–144:10; Ex. 1056, 71:17–22). As a result, Petitioner asserts that "[t]he

[16] According to Petitioner, Apidra® SoloSTAR®, Toujeo ® SoloSTAR®, and Admelog® SoloSTAR® are insulin delivery pens that utilize a competitor's insulin product in a SoloSTAR® pen. Pet. Reply 28.

change in trajectory for [LANTUS® and Toujeo SoloSTAR®] product performance upon introduction of competing long-acting insulins provides strong evidence that [SoloSTAR®] itself is not a commercial success." *Id.* at 29.

Petitioner also contends that LANTUS® SoloSTAR® "overtook Levemir[®] FlexPen[®] not because of any unique [SoloSTAR®] attributes, but because of what it shared in common with OptiClik[®]: [Patent Owner] selected it as the exclusive [LANTUS®] pen in the United States." Pet. Reply 29 (citing Ex. 1048 ¶¶ 20–22, 30–35). According to Petitioner, "Levemir[®] launched almost five years after [LANTUS®], and the first Levemir[®] pen (FlexPen[®]) launched more than a year after the first [LANTUS®] pen (OptiClik[®])." *Id.* (citing Ex. 2186). Consequently, LANTUS® OptiClik® "had twice as many prescriptions in 2007 as Levemir[®] FlexPen[®]" which, Petitioner asserts, accounts for LANTUS® SoloSTAR®'s alleged commercial success. *Id.* (citing Ex. 2198).

Patent Owner replies that "Petitioners' own data demonstrates that LANTUS® SoloSTAR® has been the number one prescribed insulin or insulin analog product with the greatest market share in every year since 2014, and is overall the third most-prescribed insulin product of the last twenty years." PO Sur-Reply 18 (citing Ex. 1060, Attachment B-10; Ex. 2318, 31:14–17, 31:25–32:8). Patent Owner contends that "Petitioners' own economist Dr. McDuff acknowledged the billions of dollars in sales of SoloSTAR® and admitted that a separate profitability analysis was not required to prove its commercial success." *Id.* (citing Ex. 2318, 15:10–13, 28:7–19, 29:20–30:18; *In re Sernaker*, 702 F.2d 989, 996 (Fed. Cir. 1983)). Patent Owner asserts further that "even considering the much broader

market that Petitioners identify, SoloSTAR® still has the largest market share of any insulin product." *Id.* (citing Ex. 1060, Attachment B-10; Ex. 2318, 31:14–17, 31:25–32:8). Patent Owner also asserts that "while SoloSTAR® and OptiClik® enjoyed similar growth rates in their first four years on the market, even though OptiClik® was an inferior pen, the number of SoloSTAR® prescriptions more than quadrupled that of OptiClik® in the first four years of each product's respective launch." *Id.* at 19 (citing Ex. 1060, Attachment B-10; Ex. 2318, 18:23–19:20).

Turning to Petitioner's argument that formulary placement does not demonstrate commercial success, Patent Owner contends that "Petitioners do not deny that SoloSTAR® enjoys favorable placement in health plans, and its economist Dr. McDuff admitted that SoloSTAR®'s mechanical features and attributes would have contributed to that favorable placement." PO Sur-Reply 19 (citing Ex. 2318, 33:7–36:3); Pet. Reply 27.

Central to Patent Owner's allegations regarding commercial success is its assertion that the LANTUS® SoloSTAR® pen embodies the claimed invention. PO Resp. 53.[17] We, however, for reasons similar to those discussed in Sections III.D.10.b–c above, are not convinced that this is the case. Patent Owner contends that "[t]he tremendous success of LANTUS® SoloSTAR®, as compared to pens with long-acting insulins that failed to address the long-felt but unfilled need for a low injection force device" demonstrates "a strong nexus with the claimed invention." PO Resp. 63. Patent Owner, however, has not sufficiently demonstrated that this "tremendous success" can fairly be attributed to the claimed invention which

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

does not require low injection force or insulin, let alone LANTUS®' long-acting insulin formulation. Accordingly, we find that Patent Owner fails to sufficiently demonstrate nexus between the proffered evidence of commercial success and the claims.

Even if we assume nexus, Patent Owner has not sufficiently demonstrated commercial success. Both Patent Owner and Petitioner rely on the evidence in Attachment B-10 to the Declaration of Deforest McDuff, Ph.D. submitted by Petitioner. *See*, *e.g.* Pet. Reply 28; *see also* PO Sur-Reply 18. Attachment B-10 presents total prescription data by year for 40 insulin delivery products for the 20 year period 1999–2019. Ex. 1060, Attachment B-10. It also provides corresponding market share data for that same time period. *Id.* The data presented in this table is the most pertinent evidence regarding commercial success provided in this proceeding. Patent Owner submits that it demonstrates commercial success of the LANTUS® SoloSTAR® pen, and thus, the claimed invention. PO Sur-Reply 18. Petitioner contends that this evidence demonstrates the opposite. Pet. Reply 28. We find the evidence, at best, to be inconclusive.

Attachment B-10 shows that from the introduction of LANTUS® Vial in 2002, until 2019, LANTUS® delivery products (i.e. LANTUS® Vial, LANTUS® OptiClik®, and LANTUS® SoloSTAR®) were by far the most proscribed insulin delivery devices. Ex. 1060, Attachment B-10. As shown, from 2002 to 2011 prescriptions of LANTUS® Vial grew from approximately 1.3 to 11 million prescriptions, while the most successful competing LANTUS® products (Humulin[®] and Novolog[®]) each grew to prescription levels of about 5 million prescriptions. *Id.* Thus, Attachment B-10 clearly demonstrates the commercial success of LANTUS® Vial

during that time period. Attachment B-10 also demonstrates that once LANTUS® OptiClik® was introduced, prescriptions of LANTUS® Vial decreased as prescriptions of LANTUS® OptiClik® increased, with the overall number of LANTUS® OptiClik® prescriptions slowly, but steadily climbing. *Id.* We note that during the time period that LANTUS® OptiClik® was the only alternative to LANTUS® Vial, the number of LANTUS® Vial prescriptions essentially stayed the same.

In 2008, LANTUS® SoloSTAR® was introduced. Ex. 1060, Attachment B-10. From 2008–2011, prescriptions of LANTUS® SoloSTAR® steadily rose while prescriptions of LANTUS® OptiClik® declined. *Id.* During this time period, prescriptions of LANTUS® Vial continued to remain steady. *Id.* Then in 2012, things changed. *Id.* First, prescriptions of LANTUS® OptiClik® dropped off significantly. *Id.* By 2014, prescriptions of LANTUS® OptiClik® dropped to a mere 382 prescriptions. *Id.* During the time period from 2011–2016 (when prescriptions of LANTUS® SoloSTAR® hit their peak), prescriptions of LANTUS® Vial began to decrease at a rate of about 500,000 prescriptions per year. It is unknown why prescriptions of LANTUS® Vial began to decline starting in 2012, but it appears that they declined as the prescriptions of LANTUS® SoloSTAR® increased. Patent Owner submits that this is because of the superior features of the LANTUS® SoloSTAR® pen. *See* PO Sur-Reply 19. Whereas, Petitioner suggests that it was because of the introduction of competing products. Pet. Reply 28 (citing Ex 1048 ¶¶ 30–35, 64). Regardless, the evidence clearly shows that the number of LANTUS® SoloSTAR®'s prescriptions peaked in 2016 and that most of the increase in prescriptions for LANTUS® SoloSTAR® merely offset the

decline in prescriptions for LANTUS® Vial. Thus, the evidence does not support a showing of commercial success for LANTUS® SoloSTAR®. Rather, it appears to show a fairly stable number of prescriptions for LANTUS® products from 2009–2016, with a decline in those prescriptions from 2017–2019.

e. Conclusion re Indicia of Nonobviousness

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

E. Weighing the Graham Factors

"Once all relevant facts are found, the ultimate legal determination [of obviousness] involves the weighing of the fact findings to conclude whether the claimed combination would have been obvious to an ordinary artisan." *Arctic Cat*, 876 F.3d at 1361. On balance, considering the record presently before us, we determine that Petitioner has shown, by a preponderance of the evidence, that Møller and Steenfeldt-Jensen would have rendered the subject matter of claims 1, 7, 8, and 17 obvious to one of ordinary skill in the art at the time of the invention.

In particular, we find that Møller and Steenfeldt-Jensen teach or suggest each of the limitations of claims 1, 7, 8, and 17. We further find that one of ordinary skill in the art would have had a reason to combine the teachings of Møller and Steenfeldt-Jensen with a reasonable expectation of success. Weighing these findings with our determinations of the level of ordinary skill and the objective indicia of nonobviousness in the record, a preponderance of the evidence persuades us that claims 1, 7, 8, and 11 of the '008 patent is unpatentable over Møller and Steenfeldt-Jensen. Further,

even if nexus to the objective indicia of nonobviousness were assumed, we do not find the proffered evidence of long-felt need, industry praise, or commercial success to outweigh the case of obviousness in this proceeding.

F. Petitioner's Motion to Exclude

Petitioner filed a motion to exclude Exhibits 2001, 2004, 2005, 2100–2107, 2109, 2113–2153, 2158–2162, 2164–2183, 2185–2200, 2203–2212, 2214–2218, 2223–2225, and the redirect testimony in Exhibit 1054. Paper 58 ("Mot."), 1. Petitioner, as the "moving party," "has the burden of proof to establish that it is entitled to the requested relief." 37 C.F.R. § 42.20 (2017).

1. Exhibits 2001, 2004, 2005, 2117, 2147–2152, 2162, 2168, 2206, 2207, 2211, 2215–2218

Exhibits 2001, 2004, 2005, 2117, 2147–2152, 2162, 2168, 2206, 2207, 2211, 2215–2218 are animations. Mot. 1, 6. The objections raised for these exhibits are essentially the same. *Id.* Specifically, Petitioner contends that each exhibit 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. 1, 12. Patent Owner asserts that Exhibit 2012 is identical to Exhibit 2117, which Dr. Slocum relies upon in his declaration. *Id.* (citing Ex. 2107 ¶ 65).

Addressing Exhibit 2001, Patent Owner asserts that "[c]omputer models such as shown in EX2001 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. Opp. 1. Patent Owner makes

similar assertions regarding Exhibits 2004, 2005, 2117, 2147–2152, 2162, 2168, 2206, 2207, 2211, 2215–2218. *Id.* at 1, 13.

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. Petitioner asserts that if the exhibits are not excluded, they should be limited to the purpose for which they were submitted—showing the basis for Dr. Slocum's expert testimony—and should not be used for any other purpose. *Id.* (citing FRE 105). Patent Owner does not dispute that these Exhibits constitute hearsay. Opp. 1, 12. Petitioner does not dispute that Dr. Slocum was permitted to rely upon them in formulating his opinions. Mot. 1.

Patent Owner, however, does not contend that Dr. Slocum relied upon Exhibit 2001; rather, Patent Owner asserts Dr. Slocum relied upon Exhibit 2117, which Patent Owner asserts is identical to Exhibit 2001. Opp. 1. Patent Owner does not explain why it submitted two identical animations as exhibits or why it needs both Exhibit 2001 and Exhibit 2117 in the record when Dr. Slocum opined regarding Exhibit 2117. Nonetheless, to the extent Exhibit 2001 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 2001 should be, and hereby is, limited to the purpose of showing the basis for Dr. Slocum's testimony. Further, we do not exclude Exhibits 2004, 2005, 2117, 2147–2152, 2162, 2168, 2206, 2207, 2211, 2215–2218, but we do agree with Petitioner that their use shall be limited to showing the basis for Dr. Slocum's testimony.

2. 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. 1–5. 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 2. Second, that Dr. Slocum relied upon Mr. Veasey, one of the named inventors of the '008 patent, for certain data and a model used for various calculations in Dr. Slocum's declaration. *Id.* at 2–3. 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 4. 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 4–5.

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. 5 (citing Ex. 1011 ¶ 106; Ex. 2107 ¶ 102). Additionally, Patent Owner contends that there is no requirement that an expert have personal knowledge of the subject matter upon which the expert's opinion is based at the time of the invention. Opp. 6. 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 6 (citing Ex. 2107 ¶¶ 25–61). Patent Owner also contends Dr. Slocum documented his opinions with facts and data. *Id.* at 7.

Second, Patent Owner asserts that Petitioner's criticism of Dr. Slocum's reliance upon the information and model obtained from Mr. Veasey are unfounded. Opp. 7. 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 8 (citing Ex. 2107 ¶¶ 25–61). Patent Owner notes that Petitioner does not assert that any of the design considerations noted by Dr. Slocum are incorrect. Patent Owner raises additional arguments regarding the specific discussions between Dr. Slocum and Mr. Veasey, but those arguments appear directed to a model and data regarding issues raised in several of the related *inter partes* reviews, not this specific proceeding. *See id.* at 8–10 (discussing measurements of the FlexPen and embodiments in another reference not at issue in this proceeding).

Third, Patent Owner contends that Petitioner ignores that Patent Owner "served as supplemental evidence the native spreadsheets that specify [the] principles and calculations" set forth in Appendices A through F." Opp. 10 (citing Ex. 2226). Patent Owner further asserts that "the measurements provided by Mr. Veasey are corroborated, unrebutted, and reliable." *Id.* at 11.

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 '008 patent, those issues are the proper subject of cross-examination, go to the weight accorded the evidence, and do not justify excluding Dr. Slocum's testimony on the facts presented here. And,

to the extent Petitioner questions the data or model provided by Mr. Veasey, the proper recourse is to probe the bases for such during cross-examination, as discussed further below. Therefore, Petitioner has not shown that Dr. Slocum should be disqualified as an expert in this proceeding. Accordingly, Petitioner's Motion as directed to the redirect examination testimony of Exhibit 1054 and Dr. Slocum's declaration (Ex. 2107) is denied.

Additionally, it is not clear that the parties' arguments regarding Dr. Slocum's reliance upon Mr. Veasey are applicable to this proceeding. In particular, much of the discussion regards data and a model that are not relied upon here. Mr. Veasey's involvement was discussed extensively during a conference call applicable to several related cases, but the parties did not deem that discussion relevant to this proceeding and the transcript of that call is not of record in this case even though it is of record in several of the related cases. *See, e.g.*, *Mylan Pharm. Inc. v. Sanofi-Aventis Deutschland GmbH*, IPR2019-01676, Ex. 1108 (Nov. 22, 2019) (Transcript of Nov. 18, 2019, Telephonic Conference). Nonetheless, for completeness, we find that Petitioner's assertions that Patent Owner hid Mr. Veasey's involvement are unfounded. In particular, Dr. Slocum acknowledged in Appendix B of his declaration that the "[i]nput values were provided by Mr. Robert Veasey of DCA Engineering." Ex. 2107, App. B at 2. Thus, we find that Petitioner could have, but did not, seek to depose Mr. Veasey and therefore Petitioner's arguments regarding Mr. Veasey's involvement do not justify excluding Dr. Slocum's declaration (Ex. 2107) or redirect testimony (Ex. 1054).

3. Exhibits 2100, 2102–2106, 2113–2115, 2118–2120, 2122, 2124, 2125, 2127, 2129–2135, 2138–2141, 2145–2148, 2150–2153, 2158–2162, 2164–2174, 2176–2181, 2186–2200, 2203–2205, 2208–2212, 2214–2117, 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. 4. Patent Owner contends that Exhibits 2100 and 2102–2106 are exhibits to the deposition of Mr. Leinsing and are relevant because they "provide the necessary context for Mr. Leinsing's cross-examination, which Petitioner has not sought to exclude." Opp. 3. Additionally, Patent Owner asserts that Dr. Slocum "considered and reasonably relied upon [each of these exhibits] in forming his opinions regarding the validity of the challenged patent and thus should be admitted under FRE 703." *Id.* Petitioner does not address these exhibits in its Motion Reply. *See generally*, Mot. Reply.

The sole basis argued in Petitioner's Motion for exclusion—that the exhibits were not cited in Patent Owner's Response—is not, in and of itself, dispositive as to whether an exhibit should be excluded. Accordingly, Petitioner has not satisfied its burden to show that these exhibits should be excluded.

4. Ex. 2109

Petitioner moves to exclude paragraphs 19, 20, 31, 35, 45, 49, 50, 52, 53, 56, 71, and 72 of Dr. Grabowski's declaration (Ex. 2109) "under FRE 801–804 because they constitute hearsay to the extent they repeat and rely on statements made in an interview." Mot. 5. Petitioner asserts further that they should also be excluded under FRE 702, 703 and 705 because these

paragraphs do not "provide sufficient facts or data, is not the product of reliable principles and methods, and has not applied the proper principles to the facts of this proceeding." *Id.* Petitioner also asserts that these paragraphs "do not disclose the underlying facts and data, and do not set forth the bases of their opinions. For example, Dr. Grabowski uses IMS Health data to form his opinions, which data are not provided." *Id.*

Patent Owner responds that FRE 703 permits experts to rely upon hearsay if reasonable to do so in the expert's field. As Dr. Grabowski is a pharmaceutical economist offering opinions on the commercial success of the devices at issue, it was reasonable for him to rely upon a device expert (Dr. Slocum) and an endocrinologist (Dr. Goland), both of whom are reliable sources and were subject to cross-examination." Opp. 11.

Patent Owner responds further that "Petitioners' remaining objections under FRE 702, 703, and 705 do not argue anything specific for Sanofi to rebut, other than to state that Dr. Grabowski did not provide IMS Health data with his declaration." Opp. 12. Patent Owner notes that "Petitioners cite no authority that a party must file every single document that an expert considers in forming his opinions" and that "37 C.F.R. § 42.65(a) only requires that expert testimony disclose the underlying facts or data." *Id.* Patent Owner asserts that it complied with that rule. *Id.* Petitioner does not address this exhibit in its Motion Reply. *See generally*, Mot. Reply.

Petitioner has not shown that it was unreasonable for Dr. Grabowski to rely on hearsay in this instance. Accordingly, Petitioner has not satisfied its burden to show that these exhibits should be excluded.

5. Exhibits 2101, 2116, 2121, 2123, 2126, 2128, 2136, 2137, 2142–2144, 2175, 2184, 2185, 2201

Petitioner contends that the above-listed exhibits should be excluded pursuant to FRE 402 and 403 because they "are irrelevant to the extent they rely on an improper standard of obviousness and unclaimed features." Mot. 6. Petitioner contends further that "[t]hese exhibits are also prejudicial and confuse the issues as a result." *Id.* Patent Owner asserts that Petitioner moves "to exclude these exhibits as irrelevant because injection force and ease of use are allegedly not required by the challenged claims." Opp. 13. Patent Owner asserts further that "Petitioners' contention that the challenged claims do not enable low injection force is no basis to exclude these exhibits on relevancy grounds" and that "as Dr. Grabowski is permitted to rely upon these exhibits under FRE703, there is no basis to exclude them." *Id.* at 13–14.

Petitioner responds that "[a]ll three[18] of these exhibits post-date Sanofi's claimed priority date. Hence, unless Sanofi concedes that it is not entitled to its benefit and priority dates, these exhibits remain irrelevant to any pending issue." Mot. Reply 4–5. According to Petitioner, Patent Owner's "effort to use these exhibits for an issue to which they are not pertinent underscores the potential for misuse and prejudice to Mylan. These exhibits should be excluded as irrelevant, misleading, and prejudicial." *Id.* at 5 (citing FRE 402- 403). Alternatively, Petitioner contends that "exhibits should be limited to the purpose for which they were submitted (showing the benefits of unclaimed features)." *Id.* (citing FRE 105).

[18] We note that more than three exhibits are discussed. Accordingly, we understand Petitioner's reference to three exhibits to be a typographical error.

Petitioner has not shown that it was unreasonable for Dr. Grabowski to rely on these exhibits. Thus, Petitioner has not satisfied its burden to show that these exhibits should be excluded.

IV. SUMMARY[19]

For the reasons discussed above, Petitioner has demonstrated, by a preponderance of the evidence that claims 1, 7, 8, and 17 would have been obvious over Møller and Steenfeldt-Jensen. Additionally, although we deny Petitioner's Motion to Exclude, we limit the use of Exhibits 2001, 2004, 2005, 2117, 2147–2152, 2162, 2168, 2206, 2207, 2211, and 2215–2218 as described above.

The chart below summarizes our conclusions regarding the challenged claims.

Claim(s)	35 U.S.C. §	References	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1, 3, 7, 8, 11, 17	103(a)	Møller, Steenfeldt-Jensen	1, 7, 8, 17	3, 11
Overall Outcome			1, 7, 8, 17	3, 11

[19] 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).

V. ORDER

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

ORDERED that claims 1, 7, 8, and 17 of the '008 patent are held unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude (Paper 58) is denied; and

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

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