UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.

Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,

Patent Owner.

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

PATENT OWNER'S SUR-REPLY

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The Board should affirm claims 1-3.

I. CLAIM CONSTRUCTION

Petitioner urged the Board to give the claims "their ordinary and customary meaning." Reply, 1; Petition, 17. The District of New Jersey did exactly that and held, "'clutch' has its *ordinary meaning*: 'a component that can operate to reversibly lock two components in rotation.'" EX2165, 13.[1] Petitioner does not contend that the District Court's conclusion is wrong.

Under the broadest reasonable interpretation (BRI) standard, claim terms are presumed to have their *ordinary and customary meaning* as understood by one of skill in the art at the time of the invention. The Board should adopt the District Court's "ordinary meaning" construction here.

Petitioner asserts that BRI compels a different conclusion—that the ordinary meaning ascribed by the District Court is too narrow. Specifically, Petitioners argue that "tubular clutch" should include the construction Sanofi proffered in the litigation, *i.e.*, "a tubular structure that couples and decouples a moveable component from another component." Reply, 2.

Importantly, the District Court considered the construction now advanced by Petitioner and concluded that it required overcoming the "presumption of the

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[1] Emphasis added unless otherwise stated.

ordinary meaning" of tubular clutch. EX2165, 11. Thus, even if BRI mandated a broader construction, it would not encompass a construction that is outside the ordinary meaning, absent express lexicography or disavowal.

Further, Petitioner has proffered no intrinsic evidence supporting its construction, and its only extrinisic evidence is that Sanofi proffered this construction in the litigation. In contrast, Sanofi's proposed construction in this proceeding is the construction adopted by the District Court as the *ordinary meaning*.

II. GROUND 1 DOES NOT INVALIDATE CLAIMS 1-3

A. No Tubular Clutch

1. Button 32 Is Not a Tubular Clutch

Petitioner contends that Burroughs' button 32 is a "tubular clutch" under either party's construction. Under Sanofi's construction, Petitioner asserts that Burroughs' button 32 *indirectly* reversibly locks dial mechanism 34 and nut 36 in rotation by actuating splines 144 and the nut's teeth 192. Reply, 5-6. Petitioner's interpretation of "tubular clutch" unreasonably broadens the claim by permitting any structure to be a clutch as long as it directly or indirectly triggers a locking of two components. Under Petitioner's construction, a user's hand is a "clutch" because the user operates button 32 using her hand, causing splines 144 and teeth 192 to lock the

dial mechanism and nut in rotation. Petitioner's construction is clearly not reasonable.

Even accepting that a clutch need only indirectly lock two components in rotation, button 32 still is not a "tubular clutch." Burroughs teaches that splines 144 and teeth 192 lock due to axial retraction of dial mechanism 34, not button 32. EX1013, 10:15-26.

2. Splines 14 and Teeth 192 Are Not Adjacent a Distal End of a Dose Dial Grip nor a Tubular Clutch

Petitioner newly asserts that Burroughs' splines 144 and teeth 192 are a "tubular clutch." Reply, 6-7. Petitioner's new argument fails because splines 144 and teeth 192 are neither tubular nor adjacent to a distal end of a dose dial grip. Response, 27-28.

Petitioner argues that splines 144 and teeth 192 are "adjacent a distal end of said dose dial grip" because "adjacent" simply means "next to." Reply, 7. As shown below, the "distal end" of the "dose dial grip" (purple) is not "next to" splines 144 (green) or teeth 192 due to intervening structures therein:

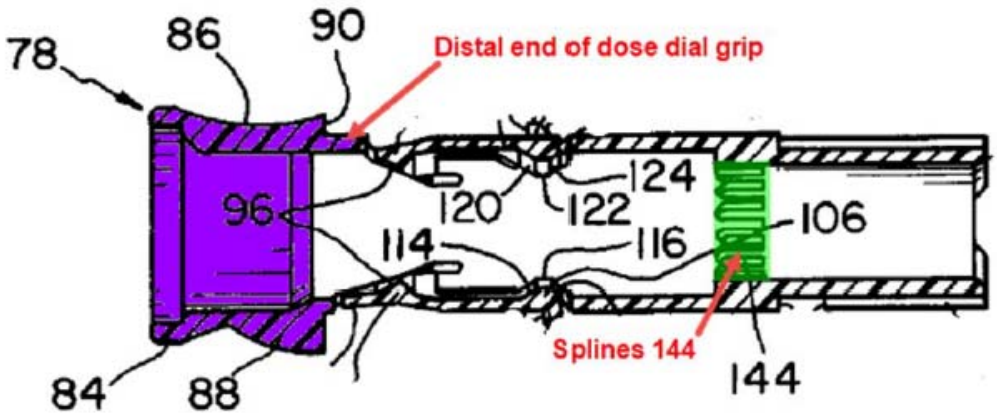


FIG. 9

EX1013, Fig. 9 (some reference numerals removed; annotated)

Petitioner also argues that dial mechanism 34 "is 'generally cylindrical in shape and is hollow throughout its axial length.'" Reply, 6. Whether dial mechanism 34 is cylindrical is irrelevant, as dial mechanism 34 is not the clutch.

Petitioner then argues that splines 144 and teeth 192 "define a tubular ('360°') structure" when engaged. Reply, 6. The parties' constructions require a tubular component or structure. A POSA would not have understood the splines and teeth to collectively define a tubular component or structure. These are discrete components and structures, not a singular component or singular structure and thus do not satisfy the construction.

B. No Helical Groove Because a POSA Would Not Have Had a Reason to Add a New Set of Threads 110, 112 to Form a Groove

Petitioner contends that adding additional threads 110, 112 to Burroughs to create a "groove" on dial mechanism 34 would have been an obvious "interchangeable solution[]." Reply, 3. Merely asserting a "design choice" does not make it obvious. *Polaris Indus., Inc. v. Arctic Cat, Inc*., 882 F.3d 1056, 1069 n.4 (Fed. Cir. 2018). Obviousness requires "a motivation to combine accompanied by a reasonable expectation of achieving what is claimed in the patent-at-issue." *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). Petitioner's alleged "interchangeability" at best goes to expectation of success, not whether a POSA would have had a *motivation* to make the change—a legally distinct concept from reasonable expectation of success. *See id.*

Moreover, Petitioner does not dispute that adding threads 110, 112 would have increased stress on the device. Reply, 3. Instead, Petitioner contends that a POSA could have *further* modified the device, and faults Sanofi for failing to "address routine design-arounds" such as using different rib heights and shifting of threading. *Id*., 3-4, n.2. The Petition, however, does not propose such changes and neither did Mr. Clemens in his opening declaration. *See also* EX2163, 195:14-21 (Mr. Leinsing, expert for Mylan in IPR2018-01670 whose opening declaration was copied for this proceeding, explaining that no other changes are required).

Further, as Mr. Clemens admits, the additional threads must engage the same groove as the existing threads 110, 112. EX1095, ¶ 22. Thus, the size and position of the added threads 110, 112 are fixed by the size and pitch of the existing threads 110, 112. EX1054, 277:19-279:2, 281:5-18. Neither Petitioner nor Mr. Clemens propose modifying the groove or threads 110, 112. Instead, Mr. Clemens states that the added threads "would not interfere with or otherwise change the nature of the rib-to-groove threaded connection between the dial mechanism and the housing." EX1095, ¶ 22. Thus, the Board should give no weight to Petitioner's assertion that a POSA could have accommodated the modification by changing the dimensions of the added thread.

Similarly, the Board should reject Petitioner's new contention that the modification could have been accommodated through application of "ordinary skill." Reply, 3. Dr. Slocum explained that Petitioner's modification would require, *e.g.*, lengthening the legs 102, 104 and increasing the thickness of the injector. Petitioner contends that making the pen thicker might aid gripping, citing the commercial Basaglar KwikPen, but makes no showing that the proposed modification would result in ease-of-grip comparable to KwikPen. *Id.*, 3-4. Moreover, making the pen thicker requires redesigning all the internal components. That Petitioner's obviousness theory requires resizing numerous internal

components under the guise of "ordinary skill" calls into question whether this is an "interchangeable solution[]."

Further, Petitioner does not dispute that the proposed modification would, in fact, increase injection force. Reply, 4. Nonetheless, Petitioner asserts that neither party identifies "any real-world case" where injection force made a difference. *Id*. Petitioner apparently ignores Dr. Goland, who testified that she has "switched a lot of people from Levemir to SoloSTAR," and that "injection force is one of the reasons." EX1056, 66:9-15.

C. Burroughs Does Not Render Obvious Claims 2-3

Burroughs does not render obvious claims 2 and 3 for the same reasons that it does not render obvious claim 1.

III. GROUND 2 DOES NOT INVALIDATE CLAIM 1

A. Steenfeldt-Jensen Does Not Suggest a Threaded Driver Tube

Steenfeldt-Jensen nowhere discloses a threaded driver tube. Response, 28-30. Accordingly, the parties' arguments about whether 7:41-47 applies to the fifth embodiment are moot. In Reply, Petitioner argues that Sanofi unduly focuses on 7:41-47 and does not consider three other cited passages. Reply, 10 (citing EX1014, 2:40-53, 3:15-20, 3:44-47). Sanofi discussed these passages in its Response at 28-30 and Petitioner does not rebut Sanofi's arguments (Reply, 10).

B. Even if Steenfeldt-Jensen Did Suggest a Threaded Driver Tube with Respect to Its First Embodiment, It Would Not Apply to the Fifth Embodiment

Even if Steenfeldt-Jensen discloses a threaded driver tube, a POSA would not have applied it to the fifth embodiment (the basis of Petitioner's challenge). Petitioner concedes that 7:41-47 (the passage that purportedly discloses a threaded driver tube) is not a blanket statement covering every embodiment in Steenfeldt-Jensen. Reply, 12. Petitioner now argues that despite no express recitation that the passage applies to the fifth embodiment, a POSA would have applied it due to the "analogous structures and functions for driving the piston rod." Reply, 11. The Reply fails to explain the lack of a statement linking the passage to the fifth embodiment.

Petitioner and Mr. Clemens, however, acknowledge differences between the embodiments (Reply, 11; EX1095 ¶ 44) but conveniently focus their comparison on the isolated operation of the driver tubes and nut members of the first and fifth embodiments during dose dispensing without regard to the overall structure and operation of the embodiments. *Id.*

In contrast, the Response at 30-33 explains that the embodiments are not analogous and a POSA would not apply a teaching specific to the first embodiment to the fifth embodiment. The first embodiment, for example, includes a rotatable, threaded ampoule holder 2, while the fifth embodiment includes a fixed end wall 4

with a threaded bore forming a nut member. These differences mandate different dialing and dose dispensing methods. *Id.*, 9-10; *see also* EX1014, 5:38-46, 6:42-59.

Petitioner further argues that Dr. Slocum's testimony undercuts Sanofi's arguments regarding obviousness. Petitioner argues that Dr. Slocum testified that applying the disclosure to the first embodiment would impair the first embodiment's function. Reply, 13. Petitioner contends that Sanofi must be wrong about the first embodiment (*i.e.*, why would Steenfeldt-Jensen make that disclosure if it would impair the first embodiment) and therefore wrong about the fifth embodiment. Dr. Slocum opined that Petitioner's modification would impair the first embodiment. Dr. Slocum does not agree with Petitioner, however, that 7:41-47 discloses Petitioner's modification. Section III.A.

C. A POSA Would Not Be Motivated to Make Petitioner's Modification to the Fifth Embodiment

Even if Steenfeldt-Jensen at 7:41-47 disclosed a threaded driver tube, Petitioner's proposed modification to the fifth embodiment has drawbacks that would counsel against modification.

Sanofi presented analytical and physical models from Dr. Slocum demonstrating that a POSA would not modify the fifth embodiment to include a threaded driver tube because it would result in 51% higher injection force. Response, 33-44. Petitioner presents no rebuttal models or calculations. Instead, Petitioner

argued that a higher injection force would not dissuade a POSA from the modification. Reply, 13-14.

1. A High Injection Force Would Dissuade a POSA from Petitioner's Modification

Dr. Slocum concluded that Petitioner's proposed modification to the fifth embodiment would have detrimentally affected the fifth embodiment—for example, a significantly higher injection force. Response, 33-44. Petitioner, however, argues that the Board should disregard Dr. Slocum's findings because they assume "that a POSA was limited to designing insulin injector pens." Reply, 12-13. Petitioner, however, identifies no other application where higher injection force would be acceptable. Moreover, Steenfeldt-Jensen is directed to "syringes [that] are mainly made for users who have to inject themselves frequently, e.g., diabetics." EX1014, 1:16-18. A POSA, when considering whether to combine the teachings of one embodiment in Steenfeldt-Jensen with another embodiment in Steenfeldt-Jensen, would consider Steenfeldt-Jensen's context, *e.g.*, diabetic injection pens.

2. Petitioner Argues that Its Modification Is Obvious Based on Reasonable Expectation of Success

Petitioner argues that, despite Sanofi's premise that higher injection force is undesirable, "Sanofi never alleges the modification is inoperable or a POSA would not have reasonably expected success." Reply, 14. Obviousness requires "a *motivation to combine* accompanied by a reasonable expectation of achieving what

is claimed in the patent-at-issue." *Intelligent Bio-Systems,* 821 F.3d at 1367. That injection force would increase—a fact not disputed (only the magnitude)—demonstrates a POSA would be dissuaded from Petitioner's modification, even if a POSA *could* do so. *Plas-Pak Indus., Inc. v. Sulzer Mixpac AG*, 600 F. App'x 755, 758-60 (Fed. Cir. 2015).

3. Sanofi Presented Non-Obviousness Arguments Beyond the Collar Friction Model

Sanofi's Response provided evidence Petitioner's modification has additional problems. For example, the flexible arms of driver tube 85 may get stuck or pressed into the ring-shaped wall, causing the flexible arms to break. Response, 43-44. Citing Mr. Clemens's Reply declaration, Petitioner argues "a POSA would address this type of routine issue without difficulty." Reply, 17. Petitioner's assertion is incorrect. To address the problems created by Mr. Clemens' modifications to the fifth embodiment, Mr. Clemens proposes even further modifications that create their own set of problems and difficulties. For example, Mr. Clemens' further modifications call for additional material, which adds costs, require additional space in the device, and decrease usability by lengthening the pen. These new problems underscore that a POSA would not have been motivated to make Petitioner's modification in the first place.

D. Dr. Slocum's Models Are Not Flawed

Petitioner further argues that Dr. Slocum's models are flawed. Neither Petitioner nor its expert, however, inspected Sanofi's model and Mr. Clemens presented no model of his own.

1. There Is No Bias

Petitioner argues that the models are unreliable due to bias because they were "primarily designed" by Mr. Veasey, an inventor of the 069 Patent. Reply, 14-16. First, Dr. Slocum independently verified the models, conducted his own experiments, and gathered his own data. EX2107, ¶¶ 242-255. Second, Petitioner fails to show how Mr. Veasey is biased because he is an inventor. Mr. Veasey is not a Sanofi employee, nor does he have a stake in this IPR. Third, even assuming that Mr. Veasey is an interested party, it is well established that a party's interest alone cannot affect the credibility of scientific evidence when Petitioner has presented no opposing evidence (*e.g.*, no models). *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1346 (Fed. Cir. 2007).

Furthermore, while Petitioner argues that Mr. Veasey selected eleven variables for the analytical model, Petitioner complains about only the coefficient of friction and collar diameter. Reply, 14-15. Dr. Slocum, however, explained that the coefficient of friction and collar diameter measurements correspond to FlexPen, the commercial embodiment of Steenfeldt-Jensen's fifth embodiment. Response, 35.

Petitioner also complains that Mr. Veasey "…designed the physical model…." Reply, 15. But aside from a conclusory argument that the collar was too big (Reply, 15), Petitioners do not deny the principles underlying the model. Response, 36.

Finally, Petitioner argues that while Mr. Veasey played a role in the development of the models, "Sanofi did not present Mr. Veasey as a witness in this case." Reply, 15. Petitioner could have, but chose not to, seek Mr. Veasey's testimony under 35 U.S.C. § 24 or 37 C.F.R. 42.51. *See also* EX2451, 12:10-13:10, 21:18-25 (transcript of a call between Sanofi, the Board, Pfizer, and Mylan regarding additional discovery of Mr. Veasey).

2. The Analytical Model Tests Total Change in Friction

Petitioner next argues that the models do not test the total change in friction. Reply, 16. The 51% increase in injection force is derived from a comparison between the fifth embodiment and the modified fifth embodiment. In contrast, Petitioner presents no evidence as to what the difference in injection force would be.

3. The Models Are Not Designed to Fail

Petitioner argues that the models do not use a "POSA's ordinary creativity," like adding lubrication. Reply, 16. Any "common-sense approaches to mitigating friction" applied to the modified fifth embodiment could be applied to the unmodified fifth embodiment and thus would be a wash.

Additionally, Petitioner repeats its criticism that the variables in the analytical model came from the commercial embodiment of Steenfeldt-Jensen's fifth embodiment—and that the collar in the physical model was too big. Reply, 16-17. Yet neither Petitioner nor Mr. Clemens present models of their own. Moreover, neither Petitioner nor Mr. Clemens inspected the physical model.

E. No Internally Threaded Driver Tube in the Form of an Integrated Nut Member at 3:41-47

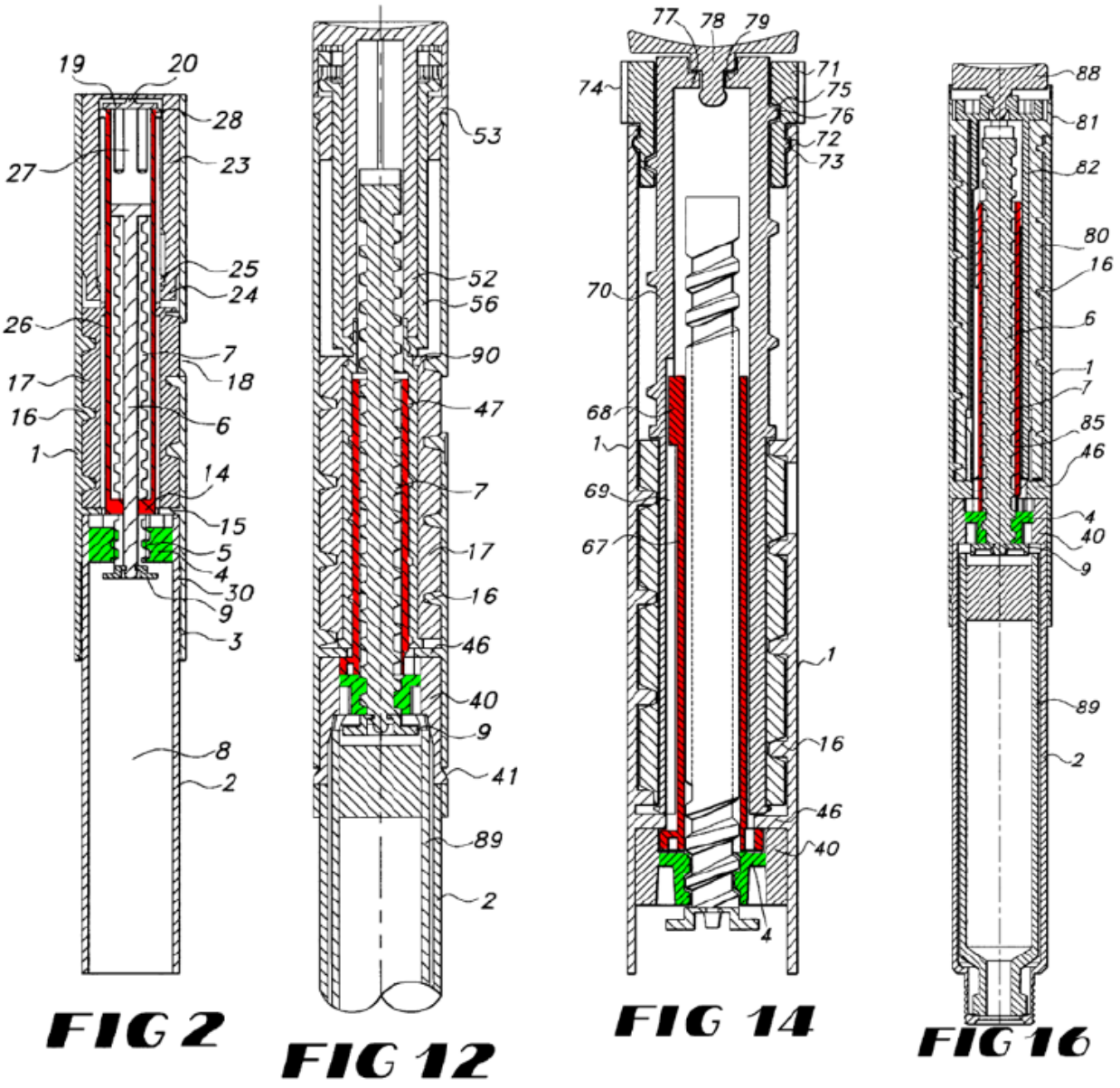
In Reply, Petitioner now argues that a driver tube with an integral nut member is indistinguishable from a threaded driver tube and thus should invalidate. Reply, 8-9.

There are three problems with this argument. First, the claims specifically require a threaded driver tube, not a nut member rotated by a driver tube. Second, as explained below, nowhere does Steenfeldt-Jensen teach an integrally formed nut member. Steenfeldt-Jensen describes its nut member as a separate component. Third, as also explained below, the leap Petitioner uses to demonstrate its integrally formed nut member misreads Steenfeldt-Jensen at 3:41-47.

1. Steenfeldt-Jensen Does Not Teach a Nut Member Integrally with a Driver Tube

Nowhere does Steenfeldt-Jensen teach a nut member integrally formed with the driver tube. As depicted below in the first, third, fourth, and fifth embodiments,[2] the nut member (green) is distinct from the driver tube (red):

[2] The second embodiment does not include a driver tube.



EX1014, Figs. 2, 12, 14, 16 (annotated)

Similarly, the passage relied on by Petitioner, 3:41-47, makes no mention of an *integrally formed* nut member:

> The thread connection by which the injection button is screwed out from the housing by setting a dose may be the thread connection between the dose scale drum and the

> housing. In this case the dose scale drum must be coupled to a driver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed.

EX1014, 3:41-47. Steenfeldt-Jensen does not teach an integrally formed nut member, much less a threaded driver tube.

2. Steenfeldt-Jensen Does Not Suggest a Nut Member Integrally Formed with a Driver Tube

Petitioner's apparent argument that Steenfeldt-Jensen discloses an integral nut member is based on 3:41-47, from which Petitioner seemingly draws a parallel between the piston rod guide and the nut member; and, because the piston rod guide is elsewhere described as integrally formed, concludes the nut member may therefore be integrally formed. *See, e.g.*, Reply, 8 ("Steenfeldt-Jensen describes two driver configurations rotating: a 'piston rod guide' or a 'nut member.'"); *id.*, 9 ("In the embodiments with the driver rotating a piston-guide, the guide is not a separate component"); *id.* ("Just as there is no meaningful distinction between a driver tube with an integral piston-rod guide and one with a rectangular bore, there is no meaningful distinction between a driver tube with an integral nut member and one with a threaded bore.").

These logical gymnastics are predicated on Steenfeldt-Jenson purportedly equating the piston rod guide and nut member. Reply, 8 ("Steenfeldt-Jensen

describes two driver configurations rotation: a 'piston rod guide' or a 'nut member.'"); EX1014, 3:41-47. But, Steenfeldt-Jensen does not equate the piston rod driver and nut member. Steenfeldt-Jenson, 3:41-47 recites:

> The thread connection by which the injection button is screwed out from the housing by setting a dose may be the thread connection between the dose scale drum and the housing. In this case the dose scale drum must be coupled to a driver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed.

EX1014, 3:41-47. The passage, at best, draws a parallel between a piston rod (not a piston rod guide) and nut member, but in no way suggests an integrally formed nut member just as it does not suggest an integrally formed piston rod.

Petitioner also points to Steenfeldt-Jensen, 7:41-47, for support. Reply, 9. Nothing in this passage suggests that the nut member is integrally formed with the driver tube. The passage teaches that "end wall 4 with its threaded bore forms a nut member". EX1014, 7:41-43. End wall 4 is not the driver tube.

F. The Board Should Reject Petitioner's New Argument that Steenfeldt-Jensen Suggests a Threaded Driver Tube Because of Disclosures in Giambattista

Petitioner newly argues in Reply that Steenfeldt-Jensen suggests a threaded driver tube because a separate non-prior art patent, Giambattista includes a threaded

driver tube. Reply, 17-18. To the extent Petitioner relies on Giambattista as part of the combination, it cannot because this argument was not in the Petition. Similarly, to the extent Petitioner relies on Giambattista to demonstrate a motivation, it cannot because Petitioner did not rely on Giambattista in the Petition to support obviousness.

Moreover, this argument cannot save Petitioner. There is no evidence that Giambattista would motivate a POSA to modify Steenfeldt-Jensen's fifth embodiment to have a threaded driver tube.

IV. GROUND 3 DOES NOT INVALIDATE CLAIM 1

A. No "Drive Sleeve"

The claims require "a drive sleeve," which the parties agree is at least "an essentially tubular component." Petitioner pointed to connection bars 12 with nut 13 in Møller's first embodiment (the basis for the challenge) and argued that these components "***could*** readily be formed as a tubular structure." Petition, 85-86. Petitioner alternatively argued that Møller's first embodiment could be modified based on Møller's second embodiment because the embodiments are allegedly "structurally and functionally equivalent." Petition, 85. In Reply, Petitioner foregoes its first argument and pushes its second argument. Petitioner, however, has not adequately addressed Sanofi's criticism of its combination.

1. A POSA Would Not Be Motivated to Combine Møller's First and Second Embodiments

Obviousness requires "*a motivation to combine* accompanied by a reasonable expectation of achieving what is claimed in the patent-at-issue." *Intelligent Bio-Systems*, 821 F.3d at 1367. Motivation to combine and reasonable expectation of success are two different legal concepts. *Id.*; *Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017). Petitioner has not articulated *why* a POSA would make Petitioner's combination—particularly when Petitioner is wholesale modifying Møller's first embodiment.

Not only is there no reason that a POSA would have made Petitioner's modification, a POSA would have been dissuaded from it. As explained in the Response, the open arrangement of connection bars 12 with nut 13 in Møller's first embodiment supports internal gears. Extending bars 12 to make a tubular structure in Møller's first embodiment, *i.e.*, to reflect the closed arrangement in Møller's second embodiment, requires a wholesale redesign to address the internal gears. Response, 49-51.

Mr. Clemens characterizes these differences as "minimal." EX1095, ¶ 57. Mr. Clemens opines that, "The racks can easily engage the gear wheels whether they are inside the driver or outside the driver." *Id.*, ¶ 58. Mr. Clemens opines that if the gears are outside the driver, "Møller's second embodiment shows how such an

arrangement can be accomplished."[3] *Id.* First, there should be no dispute that such a "combination" is a substantial redesign of the first embodiment. *Compare* EX2206, EX2207. Second, at this point, Mr. Clemens is not modifying Møller's first embodiment (the basis of the challenge), but is simply using the second embodiment.

Mr. Clemens further opines that if the gear wheels are inside the driver, "the sleeve could be readily formed with a slot cutout to accommodate the gears." EX1095, ¶ 58[4]. First, Møller's second embodiment does not teach using cut-outs to accommodate internal gears, *i.e.*, Petitioner's modification is no longer taught by the second embodiment. Second, this begs the question: *why* would a POSA make the modification if cut-outs are needed? Why not continue using the open design of the first embodiment? Mr. Clemens never explains what benefit a POSA would gain by adding material to the first embodiment that would increase cost, weight, and the complexity of the device.

2. Møller's First and Second Embodiments Are Not Structurally or Functionally Equivalent

Møller states that connection bars 12 and nut 13 *correspond* to connection element 112 and nut 113, but the two sets of structures are not equivalent because

[3] Note, neither Petitioner nor Mr. Clemens asserts this in the Petition.

[4] This argument does not appear in the Petition.

the latter support external gears, while the former support internal gears. Response, 47-49; EX2107, ¶¶ 279-281.

Petitioner ignores these structural differences, only noting certain high-level structural similarities and instead pointing to the operational commonalities between connection bars 12 with nut 13 and connection element 112 with nut 113. Reply, 19. Operational equivalence is not structural equivalence. Mounting the gear wheels internally requires a significantly different structural arrangement than mounting the gear wheels externally. Compare EX2206, EX2207.

B. No Dose Dial Sleeve with Grooves on Its Outer Surface

Claim 1 requires a dose dial sleeve having a groove on its outer surface. The Petition argued that a POSA would have been motivated to implement Steenfeldt-Jensen's externally-grooved dose dial sleeve in Møller because the high-pitch threads on the dose dial sleeve would have reduced friction in Møller's device. Petition, 94-96. As the Response explained, Møller discloses its own solution to friction: a helical reset spring 36. Response, 54-55; EX2107, ¶ 294.

Petitioner asserts that Sanofi "misapprehends" Møller's teachings because the reset spring is optional. Reply, 22. That is exactly Sanofi's point – *if* friction is a problem, the helical reset spring addresses it. A POSA therefore had no reason to look beyond Moller's teachings. EX2107, ¶ 294.

Petitioner contends that Sanofi has not explained why using an externally threaded dose-setting drum would not have been more effective than Møller's reset spring. But Sanofi explained that Møller's reset spring avoids the torsional friction losses inherent to a dose-setting drum (Response, 56-57; EX2107, ¶ 306) and Møller emphatically teaches ***avoiding*** added frictional losses (Response, 52-55; EX2107, ¶¶288-290.) Moreover, Petitioner attempts to shift its burden to Sanofi. Petitioner has to show ***why*** a POSA would have chosen Petitioner's proposed change. 35 U.S.C. § 316(e). Petitioner has never explained why a POSA would have looked beyond Møller to address a problem already solved by Møller.

V. OBJECTIVE INDICIA OF NONOBVIOUSNESS SUPPORT THE PATENTABILITY OF CLAIM 1

A. SoloSTAR® Is Commercially Successful

Petitioner's own data demonstrates that Lantus® SoloSTAR® has been the number one prescribed insulin or insulin analog product with the greatest market share every year since 2014, and is overall the third most-prescribed insulin product of the last twenty years. EX1060, Attachment B-10; EX2318, 31:14-17, 31:25-32:8. Notwithstanding, Petitioner questions its own data, alleging that (i) Sanofi did not set forth evidence of profitability, (ii) Sanofi overstates SoloSTAR®'s market share, (iii) SoloSTAR® had the same growth rate as the inferior OptiClik®, and (iv) SoloSTAR®'s formulary placement does not show commercial success. Reply 26-

28. None of this diminishes the vast and longstanding adoption of SoloSTAR® within the diabetes community.

First, Petitioner's economist Dr. McDuff acknowledged the billions of dollars in sales of SoloSTAR® and admitted that a profitability analysis was not required to prove its commercial success. EX2318, 15:10-13, 28:7-19, 29:20-30; *see also In re Sernaker*, 702 F.2d 989, 996 (Fed. Cir. 1983).

Second, even considering the broader market that Petitioner identifies, SoloSTAR® *still* has the largest market share of any insulin product. EX1060, Attachment B-10; EX2318, 31:14-17, 31:25-32:8.

Third, while SoloSTAR® and OptiClik® enjoyed similar growth rates in their first four years on the market, the number of SoloSTAR® prescriptions more than quadrupled that of OptiClik® in the first four years of each product's launch. EX1060, Attachment B-10; EX2318, 18:23-19:20. SoloSTAR® prescriptions and market share greatly overshadow that of OptiClik® and provide further evidence of commercial success. Petitioner cannot deny that SoloSTAR® substantially grew the Lantus® market and remains the number one product. EX2318, 21:22-22:8.

Finally, Petitioner argues that Sanofi "overstates the importance of formulary status to demonstrate commercial success." Reply, 27. But Petitioner does not deny that SoloSTAR® enjoys favorable placement in health plans, and Dr. McDuff

admitted that SoloSTAR®'s mechanical features and attributes would have contributed to that favorable placement. EX2318, 33:7-36:3.

B. Sanofi Demonstrated a Nexus Between the Commercial Success and Challenged Claims

1. SoloSTAR® Is the Commercial Embodiment of the Challenged Claims

While Sanofi showed how SoloSTAR® practices certain challenged claims (EX2107, ¶¶ 472-512), Petitioner provides no credible evidence rebutting these facts, or the fact that the challenged claims enable SoloSTAR®'s low injection force and other features identified in the Response. Reply, 23-24. Petitioner's footnote citation to the declaration of Mr. DeForest McDuff provides no analysis of the challenged claims, whether they enable commercially-successful features, or whether SoloSTAR® embodies them. *See* EX1060, ¶¶ 25, 27-30, 52-56. Petitioner also cites Mr. Clemens's declaration, but he argues against nexus because he believes the claims cover the prior art pens disclosed in Burroughs and Møller. EX1095, ¶ 70. The argument fails for the reasons set forth in Sections II-IV. Mr. Clemens also provides no analysis of any unclaimed features of SoloSTAR® purportedly responsible for its low injection force and other attributes. *See* EX2107, ¶ 650. Thus, Mr. Clemens's sole paragraph on nexus fails to rebut Sanofi's considerable evidence.

2. Lantus®, Blocking Patents, and Sanofi's Marketing Do Not Explain SoloSTAR®'s Commercial Success

Petitioner claims that the features of SoloSTAR® enabled by the challenged claims do not drive commercial success, and asserts that any commercial success is attributable to the Lantus® drug, so-called blocking patents thereon, and Sanofi's marketing efforts.

Sanofi set forth extensive evidence that SoloSTAR®'s commercial success is due at least in part to the features that the challenged claims enable, such as low injection force. EX2109, ¶ 53; EX2107, ¶¶ 472-512. Dr. Goland, an endocrinologist and Co-Director of the Columbia University Diabetes Center, which treats 14,000 patients annually, testified that she has transitioned numerous patients to SoloSTAR®, "[a]nd injection force is one of the reasons." EX1056, 16:3-14, 66:9-15. The nexus between SoloSTAR®'s lower injection force and its commercial success is further confirmed by comparison to OptiClik®, which had a higher injection force, delivered the same Lantus® drug, but performed significantly worse than SoloSTAR® and was discontinued. EX2109, ¶¶ 19, 35-39; EX2111, ¶ 28. Petitioner's economist did not even consider the benefits of SoloSTAR® over OptiClik® in forming his opinions. EX2318, 26:11-23. He also agreed that Lantus® is not solely responsible, and the technical features of SoloSTAR® helped drive its commercial success. EX2318, 26:11-23.

Regarding the "blocking patents", Petitioner's economist confirmed that the blocking patents are directed to insulin glargine rather than delivery devices, and would not have discouraged developing a device for use with non-glargine insulin. EX2318, 80:2-81:15. Second, even if the blocking patents did serve as some barrier, they expired by 2015, and could not account for SoloSTAR®'s success beyond that date. *See, e.g.*, EX2318, 79:7-11.

Finally, Petitioner states that Sanofi's marketing drove commercial success, not product features. But it is hardly surprising that Sanofi would highlight SoloSTAR®'s features in marketing materials and encourage patients to switch to SoloSTAR®. Such marketing efforts followed the design of a pen with the needed features that prior pens lacked. EX1048, ¶ 43; EX2318, 64:11-22. Dr. McDuff agreed that marketing alone does not account for commercial success (EX2318, 64:23-65:6), and that the same marketing strategy with a poorly designed pen could have resulted in lower market share for SoloSTAR®. EX2318, 65:7-15, 69:3-8. Moreover, Prof. Grabowski explained that Sanofi's marketing efforts and expenditures were on par with or lower than its competitors, and would not solely be responsible for commercial success. EX2109, ¶¶ 64-68.

C. SoloSTAR® Satisfied the Long-Felt Need for an Easy-to-Use Injection Device with Low Injection Force

Petitioner claims that SoloSTAR® did not satisfy any long-felt need because other pens were "fungible" and met patient needs. *See* Reply, 25. But in Dr. Goland's

experience running a facility with 14,000 diabetes patients, not a single patient preferred the earlier OptiClik® device to SoloSTAR®, and the earlier FlexPen was "very hard to push." EX1056, 34:3-17, 35:16-36:12. The prior devices were so problematic that patients did not want to take their insulin. *Id.*, 35:7-15; *see also* EX2111, ¶¶ 31-43; EXS2100, 2113, 2116, 2121, 2123, 2126, 2128, 2140, 2143, 2144, 2184, 2185. SoloSTAR® addressed these problems, and Dr. Goland transitioned her patients to SoloSTAR® in part due to its lower injection force. EX1056, 66:9-15.

Mr. Karl Leinsing, who Mylan Pharmaceuticals, Inc. suggests is an expert witness on pen injectors in a related matter, acknowledged that "there's a lot of focus in pen injectors to reduce the force of injection." EX2163, 80:24-81:1.

Remarkably, Dr. Biggs suggested that any long-felt need was satisfied by the Lantus® vial and syringe, that patients complaining of injection force could have caregivers come into their homes to administer their treatments, and that patients could carry around mini-refrigerated cases with preloaded syringes. EX1048, ¶¶ 31-32; EX2317, 70:10-19, 84:24-85:14, EX1048, ¶¶ 31-32. Dr. Goland responds that such suggestion are "horrific" and "frighten[ing]"; patients overwhelmingly dislike using a vial and syringe for diabetes treatments. EX1056, 52:23-53:25; *see also id.*, 58:18-59:24. Dr. Biggs also admitted that such solutions may not be covered under Medicare or insurance. EX2317, 38:7-39:3. His opinion is further undermined by

his testimony that the majority of his Lantus® patients have switched from the Lantus® vial to Lantus® SoloSTAR®, and most patients prefer the SoloSTAR® after switching. EX2317, 115:23-116:6, 118:19-22.

D. Industry Praise and Awards Provide Further Objective Indicia

Sanofi did not make up the SoloSTAR® awards or bestow upon itself industry praise. Nor does Dr. McDuff deny that SoloSTAR® won the awards. EX1060, ¶¶ 57-60. As for industry articles, although many articles were sponsored by Sanofi or authored by Sanofi employees, they still appear in academic journals that, in some cases, were double-blind peer reviewed by anonymous experts. *See, e.g.*, EX2116; EX2224; EX2318, 72:11-73:18. Sanofi's involvement thus does not diminish their relevance. The articles also reference the low injection force of SoloSTAR® and thus support nexus. *See, e.g.*, EX2318, 76:2-77:4; EX2223.

VI. CONCLUSION

The patentability of claims 1-3 should be affirmed.

Dated: March 13, 2020

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CERTIFICATE OF COMPLIANCE

1. The undersigned certifies that this brief complies with the type volume limitations of 37 CFR § 42.24(a)(1)(i). This brief contains 5,535 words (excluding the table of contents, the table of authorities, mandatory notices under 37 CFR § 42.8, the certificate of service, certificate of compliance, and appendix of exhibits), as calculated by the "Word Count" feature of Microsoft Word 2016, the word processing program used to create it.

2. The undersigned further certifies that this brief complies with the typeface requirements of 37 CFR § 42.6(a)(2)(ii) and typestyle requirements of 37 CFR § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14 point font.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 13, 2020, the foregoing Patent Owner's Response and accompanying exhibits were served via electronic mail upon the following:

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