UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
and PFIZER INC.,
Petitioners,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2018-01678
Patent No. 8,992,486

PETITIONERS' REPLY TO PATENT OWNER RESPONSE
37 CFR §42.23

TABLE OF CONTENTS

I. INTRODUCTION

For ground 1, Sanofi separately argues claims 1, 30 and 32, leaving the remaining claims to fall with claim 1. *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc). For ground 2, Sanofi separately argues claims 1, 4, 5, 18, 20, 26, 32, 33 and 38-40, leaving the remaining claims to fall with claim 1.

II. CLAIM CONSTRUCTION

Claims have their plain meaning, consistent with the specification. 37 CFR §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). If dispositive, the broadest reasonable interpretation applies. Paper 41, 7.

Sanofi contests only ***main housing***, improperly importing limitations from a *different* patent with a *different, later-filed* disclosure. POR 8-13, citing EX1005, ("008 patent"). No authority permits retroactively acting as a lexicographer in a different, later filing, quite the opposite. *Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1375 (Fed. Cir. 2001) (changed terminology in continuation-in-part meaningful).

The petition relied on Sanofi's definition from the collateral court proceeding for a reasonable construction. Pet. 14, citing *Ex parte Schulhauser*, App. 2013-007847 (PTAB 2016) (precedential); EX1095, ¶34. Sanofi's construction for ***main housing*** was "An exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner

components." EX1019, 21. The POPR changed it to "an exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components." POPR, 23-25, from the 008 patent. Sanofi did not ask the district court to rely on the 008 patent in construing this limitation. EX1019, 21-22.

Sanofi would limit the meaning to "main housing 4" in the challenged patent (EX1003, "486 patent"). Importing embodiments into a claim is improper unless the disclosure clearly indicates that the claims and embodiments are "strictly coextensive." *Phillips*, 415 F.3d at 1323. The 486 patent does not provide lexicography or use means-plus-function claim language to tie "main housing" to any specific structure. Nor does the 486 patent indicate what Sanofi originally provided in the collateral proceeding was an unreasonable construction. *Schulhauser*, 9. Absent clear disclaimer, a narrower construction is improper. *Phillips*, 415 F.3d at 1316.

Two courts adopted two definitions: one court provisionally adopted the "ordinary meaning, and no construction is necessary", while the other court adopted Sanofi's now-proposed definition. POR 10 n.1. Courts constructions are evidence of reasonable constructions, but absent showing one court was unreasonable (which Sanofi does not do), the right construction must be at least as

broad as the broader court construction. *See* EX1095, ¶34 (considering claims as a whole).

III. GROUND 1: STEENFELDT-JENSEN

A. Steenfeldt-Jensen Suggests the Modification

Sanofi presents three arguments:

1. Steenfeldt-Jensen's suggestion of alternate embodiments "where the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver" does not suggest a threaded driver (POR, 30-32);

2. any such suggestion is for the first embodiment only, not the fifth embodiment (*id.*, 32-34); and

3. a POSA would not have followed Steenfeldt-Jensen's suggestion because the modification would have significantly increased friction losses in the drive mechanism (*id.*, 35-46).

1. Steenfeldt-Jensen Teaches an Internally-Threaded Driver Tube

Sanofi would distinguish between a "nut element" or "nut member" rotated by the driver tube, and the driver tube itself, having internal threading. POR, 30; EX2107, ¶215-22. Sanofi ignores that a driver with a nut member *is* an internally-threaded driver.

A POSA would understand Steenfeldt-Jensen describes an internally-threaded driver tube when referring to a driver rotating a nut member. EX1095,

¶¶63-64. Steenfeldt-Jensen describes two driver configurations: a driver rotating a "piston rod guide" or a "nut member" (also "nut element"). Pet. 35; EX1014, 3:41-47. These alternatives correspond to well-known screw/nut principles Sanofi's expert described. EX2107, ¶30. Embodiments with the driver rotating a piston-rod guide show the guide is not a separate component: the driver's rectangular bore prevents relative rotation between the driver and the piston rod. EX1095, ¶65; EX1014, 6:35-36 (driver tube 26 "integral with the piston rod guide"), 11:15-19 (piston rod's not round cross-section "fits through the driver tube bore which has a corresponding not round cross-section" transmitting rotation while allowing relative axial movement). Just as no meaningful distinction exists between a driver tube with an integral piston-rod guide and a driver tube with a rectangular bore, no meaningful distinction exists between a driver tube with an integral nut member and a driver tube with a threaded bore. EX1095, ¶65.

Steenfeldt-Jensen describes a "nut member" this way. Regarding an embodiment where the driver includes the piston-rod guide and the nut member is fixed, Steenfeldt-Jensen states that "end wall 4 with its threaded bore forms a nut member". EX1014, 7:41-43. A POSA would have understood a driver tube with a threaded bore similarly operates as a nut member. EX1095, ¶65. Sanofi does not offer any meaningful distinction between an internally-threaded driver tube and a driver tube with an integral nut member for a simple reason: there is none.

2. Suggestion Not Limited to the First Embodiment

Sanofi's argument that Steenfeldt-Jensen's disclosure at column 7, lines 41-47 applies only to the first embodiment fails for numerous reasons. *See* POR, 32-43. For obviousness, a POSA is capable of applying relevant teachings from one embodiment to those of another embodiment. E.g., *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1583 (Fed. Cir. 1996) (affirming suggestion to modify disclosed embodiment found elsewhere in reference).

a. Modification Suggested Outside the First Embodiment

Sanofi's attempt to limit modification to the first embodiment ignores other instances where alternative driver mechanisms are discussed. The alternative driver configurations discussion at column 7 is just one instance. Pet. 36 (citing EX1014, 2:46-53, 3:15-20). Sanofi even noted these disclosures earlier in its response. POR, 25. Sanofi's subsequent focus on column 7 ignores the broader context of Steenfeldt-Jensen's disclosure, which suggests these alternative driver mechanisms generally before turning to specific embodiments. EX1095, ¶66. A POSA is not so myopic. *Id.*

b. Threaded Drivers Applied to the Fifth Embodiment

A POSA would understand the suggestion at column 7 applied to the fifth embodiment as well. EX1095, ¶¶67-69. Steenfeldt-Jensen discussed the same drive-mechanism alternatives generally before reaching the first embodiment.

EX1014, 2:40-53, 3:10-20, 3:41-47. These sections generally explanation Steenfeldt-Jensen's invention rather than a specific embodiment. EX1095, ¶66 (citing EX1014, 2:36-3:47). A POSA would read Steenfeldt-Jensen in context and understand the described alternative was a broader discussion of drive mechanisms that can use rotating piston-rod guides or nut members. EX1095, ¶66. Not repeating of this general suggestion in the fifth embodiment did not indicate that Steenfeldt-Jensen abandoned its general suggestion: Steenfeldt-Jensen frequently avoids redundancy. EX1095, ¶67.

The relevant drive-mechanism features in the first and fifth embodiments are analogous. Both have a scale drum that rotates up and out during dose setting and rotates down and in during injection to rotate the driver tube. EX1095, ¶68 (citing EX1014, 7:3-8, 7:17-21, 11:52-55, 12:4-10). Both have driver tubes with rectangular bores (piston-rod guides) that rotate the piston rod.[1] EX1095, ¶68 (citing EX1014, 5:55-61, 6:35-37, 7:21-35, 7:41-43, 11:15-21, 12:10-13). Both have threaded piston rods that rotate through wall 4's threaded bore during

[1] The fifth embodiment does not label a piston-rod guide, but driver tube 85's equivalence is undisputed. EX1095, ¶68; EX1014, 2:48-49, 6:35-36, FIG. 2.

injection.[2] While certain surrounding components may be different, the driver tube and the nut member have analogous structures and functions for driving the piston rod. EX1095, ¶68.

Given the analogous drive mechanisms, a POSA would have appreciated that the first embodiment's alternative configuration also applies to the fifth embodiment. EX1095, ¶69. A POSA would have recognized the modifications to the driver tube (26 or 85) and wall 4 would be the same and have the same effect. *Id.* Accordingly, a POSA would not limit Steenfeldt-Jensen's express teachings to the first embodiment. *Id.*

Whether Steenfeldt-Jensen's *second* embodiment could use this modification is irrelevant because its drive mechanism is *not analogous* to that of the first and fifth embodiments. In the latter embodiments, pressing the button back-drives the scale drum, transmitting rotation to the driver tube, which then rotates the piston

---

[2] The first and fifth embodiments have different dose-setting processes (i.e. rotating ampoule holder vs. rotating the dose knob), but wall 4 operates analogously during injection, remaining fixed relative to the housing while the piston rod rides down through the threaded bore. EX1095, ¶68 (citing EX1014, 5:55-61, 7:30-40).

rod via the piston-rod guide on the driver tube. EX1095, ¶70 (citing EX1014, 7:3-6, 7:17-21, 11:52-55, 12:4-10). The second embodiment *does not have a driver tube*, so Sanofi's comparison is irrelevant. EX1014, 7:51-54 ("Different from the embodiment in FIG. 1-5 is the fact that…the driver tube 26 is omitted."), FIGS. 6-10. In the second embodiment, the button's axial movement during injection directly back-drives the piston rod via its second thread on enlargement 37. EX1095, ¶70 (citing EX1014, 7:55-67, 8:25-33, FIGS. 6-10). While the first and fifth embodiment's drive mechanisms have equivalent structure and operation for injection, the second embodiment's drive mechanism operates fundamentally differently.

Dr. Slocum acknowledged these differences between the drive mechanisms of the second embodiment and of the first and fifth embodiments. He agreed the driver tubes in the latter embodiments have "the same engagement method" with the piston rod and apply torque in the same way. EX1054, 306:23-307:19; *see also id.*, 342:3-343:18 (agreeing that transmission of force in latter embodiments was "the same fundamental type of thing" and that "driver tube 85…essentially is the same as 26"). He also agreed that the drive mechanisms' "force chain" was similar. *Id.*, 307:20-308:9. For the second embodiment, he agreed its drive mechanism did *not* share these similarities with those of the first and fifth embodiments. *Id.*, 344:7-346:25. For example, he explained (*id.*, 346:18-25):

> Well, embodiment 1, what you're doing is you're back driving a thread to rotate drive tube 26, which then rotates the piston [rod]. What embodiment 2 is doing is they are directly back driving the piston rod by the threaded connection between the button and that end 37 on the rods.
> So that's why they've eliminated the driver tube 26.

Given the similarities between the first and fifth embodiments' drive mechanisms, a POSA would have recognized the first embodiment's alternative was applicable to the fifth embodiment, regardless of the second embodiment. EX1095, ¶70.

3. Sanofi's Arguments Are Fundamentally Flawed

After improperly limiting Steenfeldt-Jensen's suggestion to the first embodiment, Sanofi introduces an "analytical model" and a "physical model" (or "collar friction model") to argue that a POSA would have ignored Steenfeldt-Jensen's suggestion altogether. POR, 26-39. This argument has three critical flaws: Dr. Slocum mistakenly believed a POSA would ignore Steenfeldt-Jensen's suggestion because a lawyer had drafted it, not the inventor; both models are premised on the incorrect assumption that POSAs would have limited themselves to designing *insulin* injector pens; and both models have numerous inherent flaws.

a. Dr. Slocum's Justification for Ignoring Steenfeldt-Jensen's Express Teachings Are Flawed

While the response attacks the desirability of modifying the fifth embodiment, Dr. Slocum stated under cross-examination that he was against

modifying *both* the first and fifth embodiments. He acknowledged the similarities between the first and fifth embodiments' drive mechanisms (EX1054, 306:23-308:9), but insisted a POSA would not have viewed Steenfeldt-Jensen's teaching—which he admitted applied to the first embodiment—as applying to the fifth embodiment. *Id.*, 308:10-14. He further opined that a POSA would not have modified *either* embodiment. *Id.*, 308:15-313:6. He explained that he thought it was "a really stupid idea for the first one" and "a lawyer add-on" that a POSA would have ignored. *Id.*, 308:15-310:6. Dr. Slocum is about a POSA ignoring Steenfeldt-Jensen's explicit suggestion to use the alternative driver tube, but his opinion undercuts Sanofi's attempt to distinguish the first and fifth embodiments.

b. Flawed Premise

Sanofi's and Dr. Slocum's position a POSA would avoid *any* increase in friction stems from the flawed assumption that a POSA would have singularly focused on designing an *insulin* pen injector. POR at 27-28. Yet the claims and references are not limited to insulin pens. Nevertheless, Dr. Slocum based his opinion on a POSA being one who was specifically designing an insulin pen for the specific needs of a diabetic patient. EX2107, ¶¶44-61 (detailing diabetic comorbidities and corresponding design considerations); EX1053, 62:13-71:2, 63:20-24 ("a POSA would read … injector pen claims in the context of understanding that this is going to be used by a diabetic person for injecting

insulin"), 69:1-71:2 ("a POSA would understand what the context of that claim is about. This is a diabetic patient -- this is an insulin pen injector and that person will have comorbidities"); *see also id.*, 72:3-11, 75:22-76:3. He mistakenly assumed the POSA was only designing a pen for diabetic patients, leading him to incorrectly limit the design objectives to reducing injection force at all costs to accommodate the particular needs of diabetic patients.

Even if a POSA's approach were appropriately limited to concerns about diabetic patients, a restricted focus on injection force is misplaced. Injection force is *a* factor when designing pen injectors, but not the only factor. EX1095, ¶72. For example, as Dr. Biggs explains, type of insulin, cost and reliability are very important factors for many diabetic patients. EX1048, ¶¶26, 28, 32. From the patient's and the engineer's perspective, injection force is not the only thing that matters even for an insulin injector pen.

Even with its flawed premise, Sanofi never alleges the modification is inoperable or a POSA would not have reasonably expected success. This is not surprising because the modification is straightforward so its workability cannot be questioned. EX1095, ¶72.

c. Flawed Models

Even if Sanofi were correct that a POSA would have avoided any change that would increase friction, and therefore injection force, the analytical and physical models have numerous problems.

i. Bias

The models are unreliable because they were primarily designed not by Dr. Slocum, but by an inventor of the challenged patent. Dr. Slocum acknowledged at the outset of his cross-examination that he "had not done…any design work or…investigative studies of [injector pens]" (EX1053, 12:22-13:5) and "didn't have personal knowledge of the industry at the time of the invention" (*id.*, 28:18-29:2). Because he lacked expertise with injector pens, he "wanted to talk to someone who was clearly in the thick of it at the time." *Id.* This person was Robert Veasey, a named inventor of the challenged patent and not disinterested. *Id.*

Incredibly, Dr. Slocum did not simply obtain background information from Mr. Veasey, but actually allowed him to control many aspects of the analytical model. *See* EX1054, 313:10-325:12. Dr. Slocum revealed that Mr. Veasey made the crucial decisions that skewed the outcome of the tests.

For the analytical model, Dr. Slocum relied on Mr. Veasey to provide inputs for his spreadsheets that yielded the supposed 51% increase in friction. POR, 28-

29; EX2107, ¶¶242-43. Dr. Slocum allowed Mr. Veasey to set the friction coefficient to 0.1 despite admitting that lubricious plastics can have a coefficient of 0.08 or lower. EX1054, 316:10-318:5 ("He said .1. That's why I used .1."). Of the fifteen unique variables in his spreadsheet, Dr. Slocum only set *two* himself. *Id.*, 319:7-325:12. Two more were determined jointly with Mr. Veasey, while Mr. Veasey alone set 11 of 15 variables. *Id.* Mr. Leinsing explains the choices for these variables (e.g., friction coefficient, diameters of the "collar") have significant impacts on the calculation, and the choices of Mr. Veasey and Dr. Slocum differed significantly from the approach of a POSA concerned about friction. EX1095, ¶73.

The physical model was similarly designed by Mr. Veasey (or others at Mr. Veasey's company, DCA Design International Ltd. ("DCA")). Mr. Veasey designed the rig used in the "collar friction" tests. EX1053, 30:5-32:7. Mr. Veasey chose dimensions for the components tested on the rig. *Id.*, 32:8-33:4. Dr. Slocum accepted Mr. Veasey's decision to use the FlexPen as a stand-in for Steenfeldt-Jensen's fifth embodiment. *Id.*, 30:5-16 ("[Veasey] told me [that] [Steenfeldt-Jensen's] fifth embodiment closely corresponds to the disposable FlexPen. I didn't know that, but he knew that."). Moreover, Dr. Slocum accepted Mr. Veasey's choice to use components (collared sleeves) that were "much bigger, obviously than an actual injector pen" because he thought the proportions were

fair. *Id.*, 33:5-13. Mr. Leinsing explains, however, that collar size, not just proportions, significantly impacts the resulting friction. EX1095, ¶74.

Sanofi did not present Mr. Veasey as witness in this case, shielding critical aspects of the experiments from review in violation of 37 CFR §42.65(b). Dr. Slocum could not answer questions about numerous aspects of the models he did not design, meaning he could not disclose facts or data underlying his opinions during cross-examination. *Id*. Accordingly, both models are unreliable due the bias—and absence—of their ultimate designer. Given Sanofi's failure to rely on Mr. Veasey as a witness, the results reported based on the models are entitled to no weight.

ii. Not testing total change in friction

The bias noted above may explain why the Veasey-Slocum models fail to consider aspects of the modification that *reduce* friction. Despite Dr. Slocum's acknowledgement that "a careful accounting of all the forces and motions of elements in the structural loop" must be assessed (EX2107, ¶58), both models narrowly focus on friction at one point in the system without accounting for other changes. EX1095, ¶75. For example, in the unmodified embodiment, the piston rod rotates during injection, meaning pressure foot 9, which abuts the piston at the cartridge's top, rotates against the piston rod's bottom end while bearing the full force of the injection. *Id.* This drag disappears in the modified embodiment

because the piston rod does not rotate during injection. *Id.* The models only look at aspects that add friction while ignoring others that reduce friction.

iii. Designed to Fail

Even within this misleading framing, the Veasey-Slocum models are skewed to exaggerate friction losses. First, the models fail to consider that a POSA is "a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at 421. The Veasey-Slocum models *avoided* even common-sense approaches to mitigating friction. EX1095, ¶¶73, 75. Mr. Leinsing explains that Dr. Slocum failed to consider numerous friction mitigation strategies immediately apparent to a POSA. EX1095, ¶75. For example, both models assumed no lubrication despite Dr. Slocum's recognition that his assumption increased the "percent increase in friction". EX1054, 325:22-327:6 (admitting POSAs understood that lubricant would reduce total increase in friction).

The pen characteristics used in the models are also suspect. As explained above, a named inventor selected most characteristics for testing. Mr. Veasey reportedly chose FlexPen parameters, which Dr. Slocum simply assumed would accurately represent Steenfeldt-Jensen's fifth embodiment. EX1053, 41:3-42:13. Even if FlexPen dimensions were appropriate, he failed to consider *net* friction for the full device and deliberately refrained from applying the POSA's ordinary creativity. The "collar friction" model also used components (collared sleeve) that

were admittedly "much bigger, obviously, than an actual pen injector", despite the fact that this "obvious" discrepancy would increase the amount of friction in the modified embodiment. *Id.*, 33:5-13; EX1095, ¶74.

Viewed objectively, the models designed primarily by Mr. Veasey appear designed to exaggerate the impact of "collar friction". A POSA applies ordinary creativity to achieve success, not deliberate failure, so these experiments are entitled to no weight.

4. "Additional Problems" Arise Only If Trying to Fail

Sanofi's "additional problems" also show a failure to apply a POSA's perspective. Sanofi argues that if the flange on the driver tube, which includes a pawl mechanism, were subjected to additional force, it could break several ways. POR, 45-46. In particular, the pawl mechanism's "flexible arms" might break, get stuck, or push through an opening in the wall above. *Id.*; EX2107, ¶¶239-41. Sanofi approaches modification as the POSA were stumped by simple, straightforward tasks. To the extent the pawl mechanism's operation were affected at all—Sanofi offers no evidence it would be—Mr. Leinsing explains that a POSA would address this type of routine task without difficultly. EX1095, ¶76.

5. Pen Injector Art Shows POSAs *Pursued* Such Drive Mechanisms

POSAs actually pursued the rotating-nut approach, which contradicts Sanofi's theories that POSAs would ignore Steenfeldt-Jensen's express teachings.

A reference used in a related IPR shows POSAs *did* design pens with the type of drive mechanism suggested by Steenfeldt-Jensen. EX1095, ¶77. Giambattista (EX1016, applied in IPR2018-01680) has an internally-threaded driver tube analogous in relevant part to the modification of Steenfeldt-Jensen's driver tube. EX1095, ¶77. The driver rotates during injection and has a flange (snap ring 64) at its distal end secured against the housing:

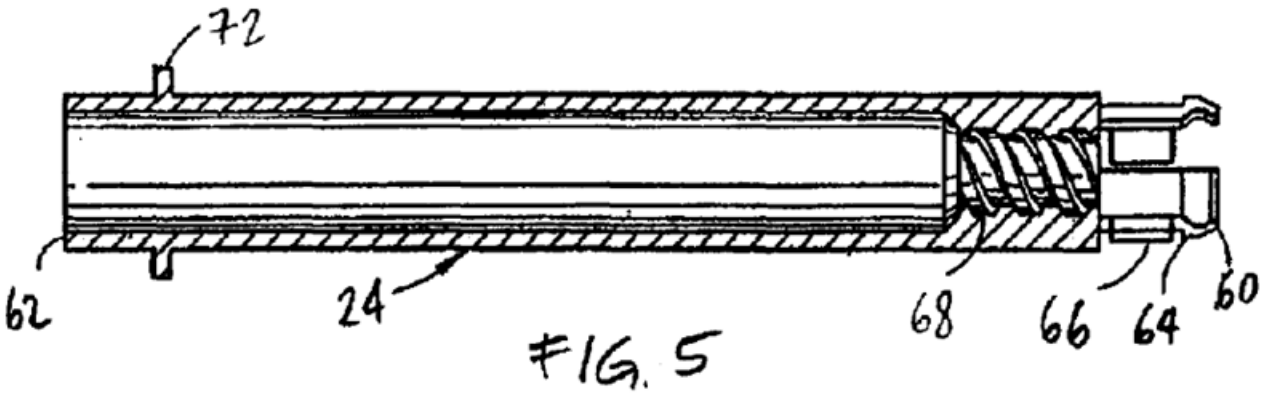

FIG. 5

EX1016, FIG. 5; *see also id.*, 3:16-26 (snap ring 64 fixes driver axially relative to housing); FIGS. 2-3, 6-7. Like the Steenfeldt-Jensen modification, Giambattista's driver 24 has an internal thread that engages the piston rod, which is prevented from rotating by its engagement with rectangular aperture 26 in bulkhead 44 (what Steenfeldt-Jensen calls a piston-rod guide). *Id.*, 3:1-26. Mr. Leinsing explains that Giambattista would experience "collar friction" analogous to Steenfeldt-Jensen as modified. EX1095, ¶77.

Despite Dr. Slocum's assertion that statements in Steenfeldt-Jensen suggesting a "rotating nut" driver tube and a non-rotating piston-rod guide were

"stupid", a type of "glib sentence[] added that makes no sense" and that a POSA "would never actually do" (EX1054, 308:10-310:22), real-world pen designers *did* pursue this approach, applying ordinary creativity.

B. Claims 30 and 32 were obvious

Sanofi contends that Steenfeldt-Jensen's fifth embodiment did not need a radial stop because it already had one and that the modification would not work. Sanofi appears to state that no modification is necessary to include a radial stop because it identifies outer wall hooks 86 that would be "near" the distal end of the dose-scale drum 80 (and its groove), when the drum is at its maximum dose setting. If so, Sanofi concedes unpatentability.

Alternatively, Steenfeldt-Jensen offering two known solutions to the same problem does not make the teaching of one solution in one embodiment unobvious to use in another embodiment. *KSR*, 550 U.S. at 421. Steenfeldt-Jensen teaches a stop to limit the travel of the dose-scale drum is desirable. The petition relies on Steenfeldt-Jensen's teaching that:

> When the dose scale drum is displaced outwardly in the housing a steep front side of a saw tooth 91 at the proximal end of the dose scale drum 18 will abut a steep front side of a similar tooth 92 on the bushing whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set.

Pet. 52-53, citing EX1014, 9:57-62. The projecting tooth would have been on the end of the drum in the direction to be limited. Pet. 53, citing EX1011, ¶328. The petition explains that the third embodiment provides a suggestion that applies equally to the fifth embodiment's drum. *Id.*; *see also* EX1095, ¶80 (reliable indication).

Sanofi urges that one would not eliminate the fifth embodiment's hook-and-slot, which is used in that embodiment to permit axial but not rotation movement. POR 49. Sanofi ignores the express teachings of Steenfeldt-Jensen as a whole, not crediting the POSA's ordinary creativity. EX1095, ¶¶80-81. The third embodiment blocks the same rotation using pawl 13's engaging member 40. EX1014, 9:36-42. Steenfeldt-Jensen provides a POSA ample guidance on modifying the fifth embodiment for a similar result. *In re Sovish*, 769 F.2d 738, 742-43 (Fed. Cir. 1985) (skill presumed). Sanofi similarly argues that a POSA when placing the stops on the housing *near* the button-end of rib and *near* the needle-end of the drum, would not account for placing the stops so that they would actually stop the drum before the maximum dose, POR 52, as if a POSA would really make that mistake. EX1095, ¶81.

Sanofi's next assumes, based on drawings, that the fifth embodiment lacks space for a projecting tooth such as the third embodiment's without widening the pen. POR 49-50. First, Sanofi concedes the modification can be done albeit with a

wider pen. Yet Dr. Biggs explains that wider pens exist and, for some patients, facilitate gripping. EX1048, ¶50. Second, precedent warns against placing too much reliance on dimensions shown in drawings. *E.g.*, *In re Andersen*, 743 F.2d 1578, 1581 (Fed. Cir. 1984). Here, Sanofi does not explain how teeth 91, 92 of the third embodiment would fit between the drum 17 and the bushing 53 shown Steenfeldt-Jensen Figures 11-13 either, yet they do. EX1095, ¶81.

IV. GROUND 2: MØLLER AND STEENFELDT-JENSEN

A. Claim 1

Sanofi's principal argument turns on its construction for "main housing" (POR 54-56). As explained above (**Error! Reference source not found.**.II), Sanofi is construction is wrong. *See also* EX1095, ¶¶33-34, 108. Sanofi also contends that Møller teaches away. POR 57. Sanofi acknowledges Møller prefers gears rather than saying threads do not work, as the Board provisionally found. POR 57-58. Sanofi disagrees, but the facts show that the Board is correct. Sanofi argues Steenfeldt-Jensen's "fifth embodiment closely corresponds to the Novo Nordisk FlexPen that was commercially available at the time." POR 2. Yet the FlexPen continues to be used today, almost two decades later. EX1048, ¶48, citing EX1057, 5. The art did not consider Møller's preference a teaching away. *See* EX1095, ¶¶101-04 (explaining POSA's understanding of Møller's preference).

Sanofi next argues against modifying Møller's threading to be a groove on Steenfeldt-Jensen's dose-scale drum. POR 59-60. The petition explained that Møller's threading would have been understood to contain a groove and, even if not, grooves and threads were predictably "interchangeable" and expected to function equivalently. Pet., 65-66, citing EX1011, ¶¶349-53; EX1095, ¶99. Interchangeability of known solutions is a well-established reason to modify. *KSR*, 550 U.S. at 421.

B. Claim 4

Sanofi makes the same teaching away argument, which fails for the same reason it failed for claim 1. POR 61; EX1095, ¶¶101-04, 109. Sanofi also contends that Møller fails to suggest an advantage that the petition ascribes to Steenfeldt-Jensen. POR 61-62, citing Pet. 80; *see* EX1095, ¶¶105-106, 109 (addressing helical spring "solution" of Møller). Precedent rejects arguments that ignore the combination and focus instead on purported deficiencies of references individually. *Nat'l Steel Car v. Canadian Pac. Ry.*, 357 F.3d 1319, 1336-37 (Fed. Cir. 2004). If the references are considered as a whole as a POSA understood them, claim 4 remains obvious.

C. Claim 5

Sanofi argues that nut 13 is not cylindrical but provides no evidence apart from Møller's silence about its shape. *See* EX1095, ¶110 (noting Dr. Slocum does

not dispute nut is cylindrical). The petition, relying on expert testimony, explains why a POSA would have understood the nut to "comprise a cylindrical shape." Pet., citing EX1011, ¶394, see also annotated Fig 1 (below):

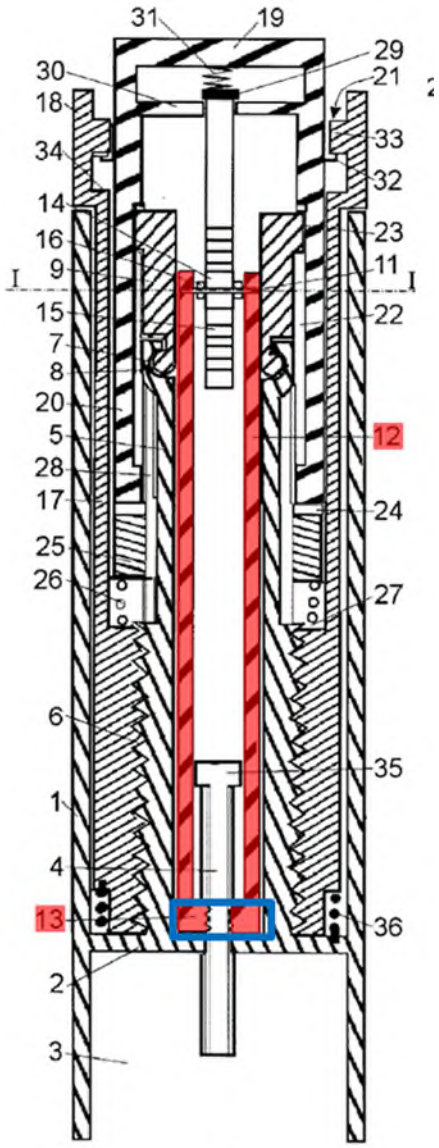

Fig. 1

In the context of a cylindrical pen, a POSA would understand the nut's inner and outer faces each define "a cylindrical shape". Sanofi's attorney argument is no

match for actual evidence. *Johnston v. IVAC Corp.*, 885 F.2d 1574, 1581 (Fed.Cir.1989) ("Attorneys' argument is no substitute for evidence.").

Alternatively, the petition explains why a POSA would have considered Møller's tubular connection element 112 structurally and functionally equivalent to connection bars 12, suggesting that the driver may be formed as a cylindrical sleeve. Pet. 82, citing EX1011, ¶395; *see also* EX1095, ¶¶93-97, 110.

D. Claims 18 and 20

Sanofi argues the petition failed to provide reason to combine Steenfeldt-Jensen's clicker arm with Møller. POR 63. The petition explained the clickers in both references were "interchangeable" with predictable function. Pet. 88, citing EX1011, ¶¶413-415; *see also* EX1095, ¶111. Known interchangeability is sufficient for obviousness. *KSR*, 550 U.S. at 421.

E. Claim 26

Sanofi contends Møller does not show the dose-dial sleeve (Møller drum 17) "radially inward of said main housing." Møller Figure 1 (annotated, below) shows drum 17 (green) radially inside of the housing 1 (gray). If some housing portion is also within the drum, Sanofi provides no argument or evidence that this limitation should be construed narrowly to exclude this possibility. *See* EX1095, ¶112.

F. Claims 32-33

Sanofi makes the same argument for these claims that it made under ground 1 (III.B). POR 66-68. Sanofi is wrong for the same reasons. EX1095, ¶¶79-81, 113.

G. Claims 38-40

Sanofi argues that wall 2 cannot be both the claimed insert and the main housing 1. Sanofi again relies on its unsupportable claim construction argument. Sanofi is wrong for the reasons provided on claim construction above (**Error! Reference source not found.**.II).

V. SECONDARY CONSIDERATIONS

Sanofi bears the burden of production for secondary considerations. *Prometheus Labs. v. Roxane Labs.*, 805 F.3d 1092, 1101-02 (Fed. Cir. 2015). Sanofi's secondary considerations fail for lack of nexus. Lantus SoloStar is not "the invention" because the claims do not require Lantus, an 80-unit cartridge, a particular stroke length or injection force.[3] The "overwhelming consideration" in

[3] Aside from Lantus, these unclaimed properties do not drive Lantus SoloStar performance. EX1048, ¶¶52-56; *see also* EX1048, ¶¶25, 27-29. Nor are the claims essential for these properties. EX1095, ¶¶154-56.

insulin-prescription decisions is "the insulin itself." EX1048, ¶25; EX2145.008, .015, 022; EX2146 at 13, 77-78 36; *see also* EX1055, 28:14-29:22, 30:2-6. The patents simply are not important. EX1048, ¶¶37-39 (discussing EX2146 at 13, 36, 43, 75, 77-78; EX2145.020-022; EX1045, EX1067, EX1072. Insulin pens are "largely fungible." EX1048, ¶¶27-28.

Sanofi leveraged its Lantus franchise and years of Lantus marketing to drive SoloStar sales. EX1048, ¶¶48-51; EX1056, 69:9-70:10. Sanofi pushed consumers to use SoloStar instead of OptiClik. EX1048, ¶¶46-47; EX2145.008 ("conversion strategy"), EX2145.0099 (OptiClik samples discontinued), EX2145.0099 ("limit competition between portfolio entities"), EX2145.010; EX1055, 125:16-127:6. Economic evidence confirms that Lantus, not SoloStar, drove commercial performance, and that Sanofi converted Lantus users onto SoloStar. EX1048, ¶¶20-21, 25-27, 30-35, 40-41, 64; Attachments B-2—B-9; EX1055, 96:13-20 (changed trajectory); EX1055, 86:20-87:6, 88:14-19, 103:18-104:6, 104:14-105:3-5 (KwikPen and FlexTouch don't practice claims). Lantus blocking patents thus support finding a lack of nexus. EX1048, ¶¶30-35, 63-67. There is no connection between any alleged awards or industry praise and the claims-at-issue. EX1048, ¶¶57-60. Without nexus, secondary considerations cannot be attributed to the claims.

A. No Long-Felt, Unmet Need

Dr. Biggs testifies "there was no long-felt unmet need for another insulin pen." EX1048, ¶39. Other available pens were easy to use and "largely fungible" with SoloStar from the perspective of the patient and the prescriber. EX1048, ¶¶27, 29, 32-44, 52. In over 30 years of practice, Dr. Goland never heard a patient wish they had a pen with lower injection force, never saw syringe use prevent a patient from taking Lantus, and never prescribed an insulin solely based on its pen. EX1056, 52:6-9, 71:4-16. Other insulin pens were considered easy to use both generally and for patients with challenges like age or infirmity. EX1048, ¶¶45-47, 52; EX1046.009, .0037, .0039, .0057, .0062-.0063, .0075; EX2145.026; EX1048, ¶¶51-53, 56; EX2143.001, EX2143.010, EX2143.070; EX2126.001, EX2126.003; EX2143.005, EX2143.009. Sanofi's SoloStar was not an unusually good pen. EX1048, ¶¶43. 49.

Sanofi contends that "injection force was a primary concern." It was not. EX1048, ¶¶29-30; *see also* EX1048, ¶53 (discussing EX2146.037-040). Contrary to Sanofi-sponsored injection-force studies, other studies found SoloStar did not have lower injection force. EX1048, ¶58; EX214.015, EX2145.020-021.

Sanofi relies on Sanofi-funded, -authored, or -edited publications that do not demonstrate industry recognition of an unmet need. EX2128.009; EX2123.007; EX2185 (Sanofi press release). Sanofi also proffers an infomercial under the url

"showbizandstyle". EX2184.001; EX2184.003 ("Buy Content"). Quotes in the article appear to be from Sanofi's press release. *Compare* POR, 51 (citing EX2184.0001) *with* EX2185.001. These exhibits do not constitute "industry recognition"; they are Sanofi marketing.

B. No Industry Praise

Sanofi's exhibits fail to establish industry praise for the claimed invention. The SoloStar "case study" for DBA was written, funded, and sponsored by Sanofi. EX1048, ¶¶57-58; EX1075. Self-praise is not industry praise. EX1055, 79:6-81:19. The exhibits regarding the Architecture & Design award (EX2201) and the Prix Galien award do not attribute the awards to "inventiveness." Nor do they praise what is claimed or features (*e.g.*, low injection force) Sanofi argues are claimed. EX1048, ¶¶57-58.

C. No Commercial Success

Sanofi argues that Lantus SoloStar enjoyed fast, long-sustained growth, profitability, and good formulary placement. But Dr. Grabowski never evaluated profitability. EX1048, ¶¶23-24. Furthermore, Sanofi provides no benchmarks for evaluating success, applies a faulty pens-only market definition, and formulary status does not separately demonstrate commercial success. EX1048, ¶¶17-22, 25-28. OptiClik also enjoyed an 8,000% growth rate in its first three years. EX1048, ¶20. Peak annual sales of Apidra SoloStar and Admelog SoloStar fall below the

sales of Lantus OptiClik that Sanofi's expert describes as "deficient." EX1048, ¶¶70-71. Sanofi's exclusion of insulin injectable products from its market share analyses improperly inflates Lantus SoloStar's market share. EX1048, ¶¶25-27. Sanofi's commercial-success arguments thus present Lantus SoloStar 's commercial performance out of context.

Lantus SoloStar lost market share after 2015 does not demonstrate commercial success. Basaglar and Tresiba long-acting insulin products completely changed trajectory for both Lantus and Toujeo SoloStar products without practicing the claims. EX1048, ¶¶30-35, 64; EX1055, 96:13-20. Generic entry of biologics is not expected to replace existing biologic as much or as fast as for small molecules. EX1055, 143:10-144:10. Diabetes patients are particularly reluctant to switch to a different insulin product. EX1056, 71:17-22. The downturn for Lantus and Toujeo SoloStar after 2015 provides strong evidence that SoloStar itself is not a commercial success.

Lantus SoloStar benefited from a Lantus franchise that predated the Levemir franchise by five years and inherited the foundation of earlier Lantus pen (OptiClik). EX2186.002. OptiClik had twice as many prescriptions in 2007 as Levemir FlexPen. EX2198. Lantus SoloStar overtook Levemir FlexPen not because of any unique SoloStar attributes but because, like OptiClik, Sanofi selected it as the exclusive U.S. Lantus pen. EX1048, ¶¶20-22, 30-35.

Sanofi's alleged secondary considerations do not diminish the strong obviousness case.

VI. CONCLUSION

The challenged claims are unpatentable and should be canceled.

Respectfully submitted,

Date: 18 September 2019

/Richard Torczon/
Richard Torczon, Reg. No. 34,448

CERTIFICATION UNDER 37 CFR §42.24(d)

I certify that the word count for this reply totals 5562, which is less than the 5,600 words allowed under 37 CFR §42.24(a)(i).

Respectfully submitted,

Date: 18 September 2019

/Richard Torczon/
Richard Torczon, Reg. No. 34,448

CERTIFICATE OF SERVICE

I certify that this reply was served today on the Patent Owner at the email correspondence address of the Patent Owner as follows:

Elizabeth Stotland Weiswasser	**elizabeth.weiswasser@weil.com**
Anish R. Desai	**anish.desai@weil.com**
Sundip K. Kundu	**sundip.kundu@weil.com**
Kathryn M. Kantha	**kathryn.kantha@weil.com**
William S. Ansley	**sutton.ansley@weil.com**
Matthew D. Sieger	**matthew.sieger@weil.com**
Adrian C. Percer	**adrian.percer@weil.com**
Brian C. Chang	**brian.chang@weil.com**
WEIL, GOTSHAL & MANGES LLP	**Sanofi.IPR.Service@weil.com**
John S. Goetz, Joshua A. Griswold, Matthew S. Colvin, Kenneth W. Darby and W. Karl Renner	**PTABInbound@fr.com**

Respectfully submitted,

Date: 18 September 2019

/Richard Torczon/
Richard Torczon, Reg. No. 34,448