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 IPR2018-01670
Patent No. 8,679,069

PETITIONERS' REPLY TO PATENT OWNER RESPONSE

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I. INTRODUCTION

The patent owner (Sanofi) argues that none of the three grounds render claim 1 obvious. The preponderance of evidence of record contradicts Sanofi's arguments.

II. CLAIM CONSTRUCTION

Claims have their ordinary and customary 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 will apply. Paper 19, 13.

Sanofi faults Petitioners offering an alternative means-plus-function construction for ***tubular clutch***. POR 6. Claim construction is a question of law, often determined in the decision. *Jack Guttman, Inc. v. Kopykake Enter., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002). The Board denies petitions failing to address foreseeable constructions. *Ethicon Endo-Surgery v. Covidien AG*, IPR2016-00944, Paper 8, 5-6. The Board was not confused when instituting this trial. Paper 19, 14. Anyway, Sanofi rejects means-plus-function construction for this term. POR 9. The Board provisionally adopted Sanofi's broader constructions. Sanofi has waived any argument based on a means-plus-function construction. Accordingly, Petitioners proceed with the broader plain meaning.

Sanofi construes ***tubular clutch*** as "a component that can operate to reversibly lock two components in rotation." POR 7-8. The petition—relying on Sanofi's own representations in the collateral proceeding—proposed the following construction: "A tubular structure that couples and decouples a moveable component from another component" Pet. 16, citing EX1019, 23. This construction is similar to a construction adopted in an earlier Sanofi litigation. EX1030, 12 ("A structure that couples and decouples a moveable component from another component"). The current court has construed it as "reversibly locking two components in rotation."[1] POR 12, citing EX2165, 10-11. Both courts' constructions and Sanofi's proffer are evidence of the reasonable scope of the limitation. *Ex parte Schulhauser*, App. 2013-007847, slip op. 9 (PTAB 2016) (precedential). The broadest reasonable interpretation of this limitation would at least encompass all these constructions absent a showing that one construction is unreasonable. Sanofi has not shown that any of them are unreasonable.

[1] The patent uses the term "coupled" in the abstract and claims but no variant of "lock" much less "reversibly locking", so it is unclear how this construction is more reasonable in light of the specification. *Phillips*, 415 F.3d at 1315-17.

III. GROUND 1: BURROUGHS

A. Burroughs suggests outer helical groove

Sanofi dismisses the petition as "assertions … that a POSA *could have* performed the proposed modification." POR 18-19. Sanofi misapprehends the argument. When known interchangeable solutions exist, precedent supports swapping one for another as obvious. Pet. 41-42, citing *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 417 (2007); *see also* EX1095, ¶43. The Board understood this was Petitioners' argument. Paper 19, 20-21. Sanofi posits a strawman instead and avoids addressing the actual rationale.

Sanofi argues that a POSA would have been deterred because two ribs would increase stress and wear. POR 20-21. Sanofi concedes that one could have "reduce[d] the stress on the legs 102 and 104 by changing their dimensions," but urges that the petition does not explain this and that it would disadvantageously widen the pen. POR 21-22. Precedent consistently rejects treating modifications rigidly rather than appreciating that a POSA uses routine skill in implementing changes. *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016).

Sanofi argues the further modification it requires disadvantageously makes the pen 10% wider. POR 21. Yet Dr. Biggs explains that "width is not necessarily a disadvantage because it can aid patients with grip or agility problems. For

example, the Basaglar [KwikPen] is relatively bulky to enhance gripping." EX1048, ¶50. What Dr. Slocum, a professor with no pen design experience (EX1053, 13:2-6), sees as a disadvantage, the clinician Dr. Biggs explains is an advantage seen in insulin pens currently marketed against Sanofi's insulin products.

Dr. Slocum contends redesigning the pen would increase injection force 15%. POR 22, citing EX2107, ¶192. He pulls this percentage out of thin air. *See* EX2107, ¶192 (no basis for percentage); EX1095, ¶41 (noting analytical model based on apparent size of components and rough sketch of additional thread). Conclusory expert testimony is entitled to no weight. *Phillips*, 415 F.3d at 1318; 37 CFR §42.65(b). At most, Dr. Slocum conjectures the redesign might increase injection force enough to disadvantage some patients. *In re Kao*, 639 F.3d 1057, 1067 (Fed. Cir. 2011) ("conjecture does not supply the requisite substantial *evidence*"); cf. EX1048, ¶¶29-30 (neither Dr. Biggs nor Dr. Goland identify any real-world case where injection force actually made a difference for a patient).[2]

[2] Even if these concerns were real, Sanofi does not address routine design-arounds. EX1095, ¶¶42-43 (e.g., different rib heights, shifting of threading).

B. Burroughs suggests tubular clutch

Sanofi relies on its new claim construction to contend for this limitation. POR. 23-25. Because Sanofi has not contested unpatentability under the petition's construction, Sanofi has waived any such argument. Paper 20, 8 ("any arguments for patentability not raised in the response may be deemed waived"); *see also* EX1095, ¶¶35-36, 45-47.

Sanofi has already conceded the reasonableness of the petition's construction when it proffered the same construction adopted by the earlier court to the court in the collateral litigation. *Schulhauser*, 9. Sanofi's response does not confess to misleading the current court about the reasonableness of its then-construction; hence, there is no basis in the record to hold that the construction Sanofi proffered in district court is now unreasonable. Accordingly, the construction for this trial must be broad enough to include the petition's construction. Anyway, the different wording of the constructions does not make a practical difference in this case.

Sanofi contends that the tubular clutch must be a component that "can operate to reversibly lock two components in rotation". POR 23. Burroughs' button 32 does this. The petition explains that button 32 operates to engage and disengage dial mechanism 34 from the housing's helical groove. Pet. 32-34; EX1095, ¶48. When the user injects a dose, button 32 disengages splines connecting dial

mechanism 34 and nut 36, reversing rotational locking of those components. EX1095, ¶¶48-49; EX1013, 8:42-48, 10:21-26, 10:38-42, 11:27-30, FIGS. 9, 11; *see also* EX1011, ¶¶180, 182-83. Button 32 thus satisfies even Sanofi's new construction.

Sanofi argues under its new claim construction that Burroughs already has a "clutching device" and that the button 32 does not lock dial mechanism 34 and nut 36 because the dial mechanism's splines 144 and the nut's teeth 192 do the locking, not button 32; and the splines and teeth are not tubular. POR 26, citing EX1013, 2:59-65; EX2107, ¶209. Here, Sanofi adopts an even narrower interpretation of its new construction, requiring the clutch to act ***directly on the locked components*** to "operate to reversibly lock two components in rotation". Sanofi makes no effort to justify this even narrower construction. Moreover, Sanofi overlooks how the clutching device also meets Sanofi's new extra-narrow construction.

Sanofi characterizes the clutching device's splines and teeth as not tubular. POR 26. Dial mechanism 34 is "generally cylindrical in shape and is hollow throughout its axial length." EX1013, 7:66-67. "[A] plurality of splines 144 extend[] circumferentially about the interior surface of intermediate portion 80 of dial mechanism" and engage with teeth 192 provided on nut 36. *Id.*, 8:43-48. When engaged splines 144 and teeth 192 define a tubular ("360°") structure

(clutching device) within dial mechanism 34's intermediate portion 80. Intermediate portion 80 lies between proximal portion 78 and distal portion 82, together comprising the dial mechanism 34 (Burroughs Fig. 8, right). EX1013, 8:2-4. Sanofi does define ***adjacent***, and the patent uses the term conventionally. The term ***adjacent*** means simply "next to". *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007). Anyway, intermediate portion 80 in which the clutching device is located is on the distal end of the proximal portion 78, and thus satisfies a reasonably broad interpretation of ***adjacent*** to the distal end of the proximal portion. Thus, even Sanofi's proposed alternative reading of Burroughs satisfies Sanofi's new, extra-narrow claim construction.

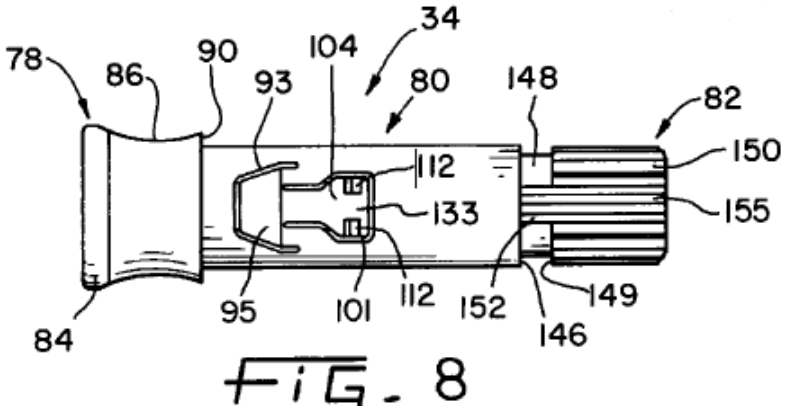

FIG. 8

Under the petition's or Sanofi's construction, whether considering the button 32 as the petition proposes or the clutching device as Sanofi proposes, Burroughs teaches a tubular clutch.

IV. GROUND 2: STEENFELDT-JENSEN SUGGESTS MODIFICATION

Sanofi presents three arguments against modification:

(1) Steenfeldt-Jensen's suggested alternate embodiments "where the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver" do not suggest a threaded driver. POR 27-29.

(2) Any suggestion is for the first embodiment only. *Id.*, 29-32.

(3) A POSA would not have followed Steenfeldt-Jensen's suggestion because modification would increase friction losses in the drive mechanism. *Id.*, 32-43.

A. Steenfeldt-Jensen Teaches 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, 28-29; 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., 60-62; EX1014, 3:41-47. These alternatives correspond to well-known screw/nut principles that Sanofi's expert described. EX2107, ¶30 ("Many pen injector designs…operate using screw and nut mechanisms…. [A]xial motion can occur by causing the screw or the nut to rotate while the other is prevented from rotating….").

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 ("integral with the piston rod guide"), 11:15-19 (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 understood a driver tube with a threaded bore operates as a nut member. EX1095, ¶65. Sanofi does not offer any meaningful distinction between them because none exists.

B. Suggestion Not Limited to First Embodiment

Sanofi's argues Steenfeldt-Jensen's disclosure at column 7, lines 41-47 applies only to the first embodiment. *See* POR, 29-32. Sanofi is wrong. For obviousness, a POSA can apply relevant teachings from one embodiment to

another. E.g., *B.F. Goodrich Co. v. Aircraft Braking Sys. Corp.*, 72 F.3d 1577, 1583 (Fed. Cir. 1996) (affirming suggestion to modify embodiment found elsewhere in reference).

1. Modification Suggested Outside 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 at column 7 is just one instance. Pet. 60-62 (citing EX1014, 2:40-53, 3:15-20, 3:44-47). Sanofi even noted these disclosures earlier in its response. POR, 28-29. Sanofi's subsequent focus on column 7 ignores the broader Steenfeldt-Jensen's context, which suggests these alternative driver mechanisms generally before turning to specific embodiments. EX1095, ¶66. A POSA is not so myopic. *Id.*; *see also KSR*, 550 U.S. at 420 (POSA able to fit different teachings together).

2. Threaded Drivers Applied to Fifth Embodiment

A POSA would know the suggestion applied to the fifth embodiment as well. EX1095, ¶¶67-69. Steenfeldt-Jensen discussed drive-mechanism alternatives generally before reaching the first embodiment. EX1014, 2:40-53, 3:10-20, 3:41-47. These sections summarize Steenfeldt-Jensen's invention rather than describe a specific embodiment. EX1095, ¶66 (citing EX1014, 2:36-3:47). A POSA would read Steenfeldt-Jensen in context and understand the alternative as a broad

discussion of drive mechanisms using rotating piston-rod guides or nut members. EX1095, ¶66. Not repeating this general suggestion later did not indicate Steenfeldt-Jensen abandoned its general suggestion: Steenfeldt-Jensen frequently avoids redundancy. EX1095, ¶67.

The first and fifth embodiments' relevant drive-mechanism features 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. Both have driver tubes with rectangular bores (piston-rod guides) that rotate the piston rod.[3] EX1095, ¶68. Both have threaded piston rods that rotate through the threaded bore of wall 4 during injection.[4] While certain surrounding components may be different, the driver tube and nut member have analogous structures and functions for driving the piston rod. EX1095, ¶68.

Given the analogous drive mechanisms, a POSA would appreciate that the first embodiment's alternative configuration also applies to the fifth embodiment.

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

[4] The first and fifth embodiments have different dose-setting processes, 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.

EX1095, ¶69. A POSA would know modifications to driver tube 26/85 and wall 4 would be the same and have the same effect. *Id.* Accordingly, a POSA would not limit Steenfeldt-Jensen's suggestion 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 relevantly require a driver tube. EX1095, ¶70 (citing EX1014, 7:3-6, 7:17-21, 11:52-67, 8:25-33, 12:4-10, FIGS. 6-10). The second embodiment *does not have a driver tube*, so Sanofi's comparison is irrelevant. EX1014, 7:51-54. Dr. Slocum 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. He also agreed that the drive mechanisms' "force chain" was similar. *Id.*, 307:20-308:9. He agreed the second embodiment's drive mechanism did *not* share these similarities with those of the first and fifth embodiments. *Id.*, 344:7-346:25. 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.

C. Flawed Premise and Models

Sanofi introduces an "analytical model" and a "physical model" ("collar friction model") to argue a POSA would have ignored Steenfeldt-Jensen's

suggestion altogether. POR 32-43. The models depend on Dr. Slocum's assumption that a POSA would ignore Steenfeldt-Jensen's suggestion, that a POSA was limited to designing *insulin* injector pens, and other dubious assumptions.

1. Dr. Slocum Ignores Express Suggestion

While the response attacks the desirability of modifying the fifth embodiment, Dr. Slocum is against modifying *both* the first and fifth embodiments. He acknowledges the similarities between these embodiments' drive mechanisms (EX1054, 306:23-308:9), but insists a POSA would dismiss the suggestion—which he admits expressly applies to the first embodiment—as applying to either embodiment. *Id.*, 308:10-313:6. In his view, it was "a really stupid idea for the first one" and "a lawyer add-on" that a POSA would ignore. *Id.* 308:15-310:6. His dismissal of Steenfeldt-Jensen's explicit suggestion to for both embodiments undercuts Sanofi's attempt to distinguish these embodiments.

2. Flawed Premise

Sanofi's argument against *any* increase in friction stems from its flawed assumption that a POSA would focus on designing only *insulin* pens. POR 32-33. Yet neither the claims nor references are limited to insulin pens. Dr. Slocum based his opinion on a POSA specifically designing an insulin pen for the specific needs of a diabetic patient. EX2107, ¶¶44-61; EX1053, 62:13-71:2, 63:20-24, 69:1-71:2; *see also id.*, 72:3-11, 75:22-76:3. This mistake leads him to limit the POSA's

design objectives to reducing injection force at all costs. Even so, a restricted focus on injection force is misplaced. Injection force is *a* factor when designing pen injectors, but not the only factor. EX1095, ¶72. Dr. Biggs explains cost and reliability are key. EX1048, ¶¶28, 32. Injection force is not even the main consideration for an insulin pen. *Id.*, ¶¶29-30. Even with its flawed premise, Sanofi never alleges the modification is inoperable or a POSA would not have reasonably expected success. Because the modification is straightforward, its workability cannot be questioned. EX1095, ¶72.

3. Flawed Models

Even if the premises were correct, Sanofi's models are badly flawed.

a. *Bias*

A named inventor (Robert Veasy), not Dr. Slocum, primarily designed the models. Dr. Slocum admits 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). Lacking relevant expertise, he "wanted to talk to someone who was clearly in the thick of it at the time." *Id.* He did not simply ask for background information, but actually allowed Mr. Veasey to control many aspects of the analytical model. *See* EX1054, 313:10-325:12. He revealed that Mr. Veasey made crucial decisions that skewed the tests' outcomes.

For the analytical model, Dr. Slocum relied on Mr. Veasey to provide many inputs for his spreadsheets that yielded the supposed 51% increase in friction. POR, 34-35; EX2107, ¶¶242-43. He 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. Of fifteen unique variables, Dr. Slocum only set *two* himself, two more were determined jointly with Mr. Veasey, while Mr. Veasey alone set 11 of 15 variables. *Id.*, 319:7-325:12. Mr. Leinsing explains these variables (e.g., friction coefficient, diameters of the "collar") significantly affect the calculation, and the choices of Mr. Veasey and Dr. Slocum differed significantly from the approach of a POSA concerned about friction. EX1095, ¶73.

Mr. Veasey similarly designed the physical model (or others at Mr. Veasey's company, DCA Design International Ltd. ("DCA") did). 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. 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 affects 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. *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.

b. *Not testing total change in friction*

The Veasey-Slocum models fail to consider aspects of the modification that *reduce* friction. Dr. Slocum's states "a careful accounting of all the forces and motions of elements in the structural loop" must be assessed (EX2107, ¶58), yet both models narrowly focus on friction at one point without accounting for other changes. EX1095, ¶75. For example, one source of friction in the unmodified embodiment 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.

c. *Designed to fail*

The Veasey-Slocum models are skewed to exaggerate friction losses. First, the models fail to consider that a POSA's ordinary creativity. *KSR*, 550 U.S. at 421. The models *avoided* even common-sense approaches to mitigating friction.

EX1095, ¶¶73, 75. Mr. Leinsing explains the models 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.

The pen characteristics used in the models are also suspect. 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 appropriate, he failed to consider *net* friction for the full device and deliberately refrained from exercising ordinary creativity. The "collar friction" model used components admittedly "much bigger, obviously, than an actual pen injector", despite even though this would increase friction. *Id.*, 33:5-13; EX1095, ¶74.

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.

D. Additional Problems Arise Only If Trying to Fail

Sanofi argues that if the flange on the driver tube, were subjected to additional force, the pawl mechanism's "flexible arms" might break, get stuck, or

push through an opening in the wall above. POR 42-43; EX2107, ¶¶239-41. Sanofi again assumes straightforward tasks would stump a POSA. Even if the pawl mechanism's operation were affected—Sanofi offers no evidence it would be—Mr. Leinsing explains that a POSA would address this type of routine issue without difficultly. EX1095, ¶76.

E. Pen Art Shows Such Drive Mechanisms are Used

Other pens use the rotating-nut approach, which contradicts Sanofi's theories that POSAs would ignore Steenfeldt-Jensen's express suggestion. A reference in related IPR2018-01680 shows design pens with the type of drive mechanism Steenfeldt-Jensen suggested. EX1095, ¶77. Giambattista (EX1016) 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:

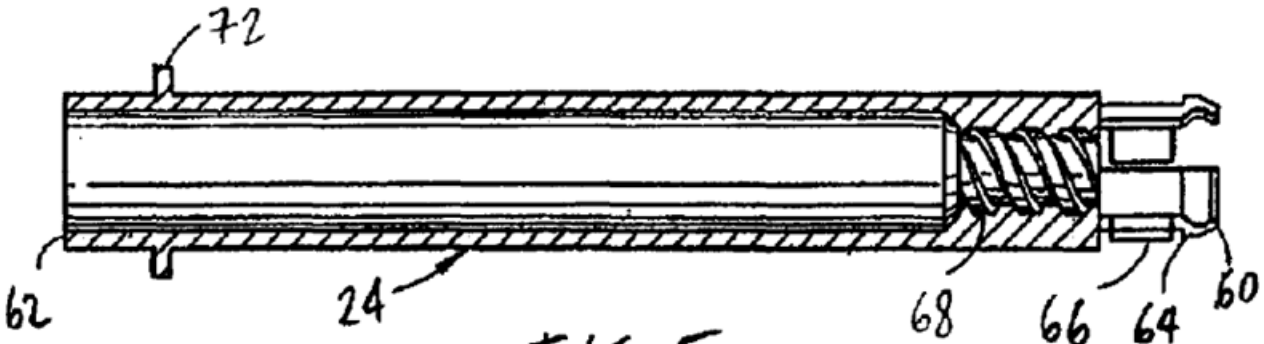

FIG. 5

EX1016, FIG. 5; *see also id.*, 3:16-26; FIGS. 2-3, 6-7. Like the Steenfeldt-Jensen modification, Giambattista's driver 24 has an internal thread engaging the piston rod, which engages 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 Steenfeldt-Jensen's suggestion was "stupid" (EX1054, 308:10-310:22), real-world pen designers *did* pursue this approach, applying ordinary creativity.

V. GROUND 3: MØLLER IN VIEW OF STEENFELDT-JENSEN

Sanofi defends claim 1with two main arguments:

(1) Møller does not teach a drive "sleeve." POR, 43-50.

(2) A POSA would not have modified Møller to have an externally-threaded dose-dial sleeve. *Id.*, 51-57.

A. References taught drive sleeve

Sanofi does not dispute Møller's second embodiment is a drive sleeve, only that the first embodiment's bar/nut implementation is not a sleeve, which would interfere with the device's operation. POR 43-50. Sanofi exaggerates the differences between the embodiments.

Møller's first and second embodiments include analogous drive mechanisms, EX1015, ¶35; EX1095, ¶94. In both, the driver is connected to a gear-wheel assembly engaging two racks: the first attached to the button, the second attached to the gearbox; and in both, the driver rotates and rides up the piston rod during dose-setting and pushes straight down during injection. EX1015, ¶¶24, 30-32, 39-40; EX1095, ¶95. In both, axial movement of the button and the first rack causes the gear-wheel assembly to ride along the racks, moving a shorter axial distance than the button/first rack. EX1015, ¶¶12-13, 31, 40; EX1095, ¶95. In both, the different axial distances traveled by the button and the gears/driver/piston rod results in a mechanical advantage. EX1015, ¶¶32, 34, 40; EX1095, ¶95.

The main difference is that in the second embodiment "only one gear wheel is used", meaning the mechanical advantage is necessarily 2:1. EX1015, ¶¶35, 40; EX1095, ¶96. The first embodiment adds second gear wheel 16 with a smaller diameter so the mechanical advantage is no longer 2:1. EX1015, ¶24. Even this difference is optional, because Møller explains the first embodiment could also have a single gear size for a 2:1 mechanical advantage. EX1015, ¶34; EX1095, ¶96.

Sanofi stresses the gear assembly sits inside connection bars 12 but outside the tubular connection element 112, arguing that switching "would require a significant redesign…." POR 46-50. But the racks can engage the gear wheels

whether inside or outside the driver. EX1095, ¶97. Sanofi argues the device "would need to be redesigned to make additional space." POR 50. But the second embodiment *already does this* without requiring the pen "to be widened". *Compare* EX1015, FIG. 1 *with id.*, FIGS. 3-5. Indeed, Sanofi's representation of the embodiments shows comparable widths. *See* EX2206 and EX2207.

Sanofi's drive-sleeve arguments conflict with Møller and Sanofi's evidence.

B. References taught externally-threaded dose-scale drum

Sanofi relies on flawed teaching-away and motivation arguments.

1. Møller does not teach away

Sanofi argues that Møller criticizing Steenfeldt-Jensen's high externally-threaded dose-scale drum. POR 51-54. But Møller specifically addresses using an externally-threaded drum in *gearing*, not externally-threaded drums generally. EX1015, ¶7. The "gearing" comes from the rotational coupling of a high-pitch drum and a fine-pitch piston rod, which causes axial displacement of the piston rod that is less than the drum's axial displacement. EX1095, ¶101-02. Møller notes a "similar gearing" in the Steenfeldt-Jensen PCT[5] and explains that "by this kind of

[5] Møller's reference to Steenfeldt-Jensen's "gearing" is to Steenfeldt-Jensen's first and fifth embodiments; not the second embodiment, whose dose-setting drum

gearing relative[ly] large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces." EX1015, ¶8 (emphasis added). Møller then states its preference for "traditional ***gearing*** using mutual engaging gear wheels and racks…." *Id*. (emphasis added). Møller focuses on friction losses *in the gearing system* because those components are subjected to the full injection force. EX1095, ¶102.

Møller seeks to avoid transformations between linear and rotational motion between the injection button and piston rod. EX1015, ¶11. Steenfeldt-Jensen PCT's first embodiment transmits injection force to the piston rod by back-driving the "large surfaces" of the dose-setting drum's threading. *Id.*; EX1095, ¶103. Møller seeks to avoid only the embodiment's *gearing*, not its externally-threaded dose-setting drums generally. EX1095, ¶103.

Crucially, unlike Steenfeldt-Jensen's drum, Møller's dose-setting drum is *not part of the gearing that transmits force to the piston rod* (EX1095, ¶104), as Dr. Slocum acknowledged (EX1054, 354:19-355:24). Instead Møller explains that "[o]nly a force sufficient" to cause the drum "to screw itself downward . . . is necessary." EX1015, ¶33. An externally-threaded dose-setting drum in Møller

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is not part of the gearing. EX1095, ¶102, n.3; *see also* EX1054, 346:14-348:12 (acknowledging drum is not part of gearing in second embodiment).

would not implicate Møller's gear-friction concern, because Møller's drum does not transmit the injection force to the piston rod like the drum of Steenfeldt-Jensen's first embodiment. EX1095, ¶104. Sanofi's teaching-away argument is based on a misapprehension.

Sanofi warns is not "as easy as Petitioner argues" (POR 53-60), but fails to explain why a POSA be stumped implementing an externally-threaded dose-scale drum—a feature Steenfeldt-Jensen and *numerous* other pens possess. Moreover, this warning contradicts Dr. Slocum's insistence (addressing IPR2018-01680) that a POSA viewing Sanofi's specification would immediately envision vastly more complicated modifications to the drive sleeve. *See* EX1051; EX1053, 126:4-21.

2. Sanofi misapprehends Møller and is internally inconsistent

Sanofi argues that "no evidence suggest[s] that a POSA would look beyond Møller's teachings for addressing undesirable thread friction." POR, 54-55. *KSR*, 550 U.S. at 420 (POSA looks to many sources).

Sanofi argues Møller's reset spring 36 obviates any reason to reduce friction on the drum's threading. POR 54-55. The spring as *optional*. Møller, ¶33, ¶40; EX1095, ¶105. Even for embodiments using a reset spring, Sanofi does not explain why an externally-threaded dose-setting drum would not be equally or more effective. *KSR*, 550 U.S. at 421 (obvious to pursue known options).

C. References taught externally-threaded dose-dial sleeve

Sanofi first argues that the modified dose-setting drum would interfere with Møller's spring. POR 56. Petitioners did not suggest that a POSA would place the threads "precisely where" the reset spring exists. POR 56. Anyway, Sanofi ignores Møller's teaching that the reset spring is optional. EX1015, ¶¶33, 40. Sanofi's suggestion of unavoidable interference between the drum and the spring presumes POSA incapability, but a POSA would have had no difficulty providing an externally-threaded dose-setting drum. EX1095, ¶105.

Sanofi argues that a POSA would have avoided added friction but ignores the very reset spring Sanofi previously addressed. POR, 56-57. Møller already teaches an optional configuration using a reset spring to counteract friction losses from the dose-setting drum during injection. EX1015, ¶33; EX1095, ¶106. Sanofi's argument is internally inconsistent and wrong.

VI. 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.[6] EX1095, ¶¶154-56. The "overwhelming consideration" in 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

[6] 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.

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.

VII. CONCLUSION

Claim 1 should be held unpatentable.

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 5424, which is less than the 5,600 words allowed under 37 CFR §42.24(a)(i).

Respectfully submitted,

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CERTIFICATE OF SERVICE

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