UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.,

Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,

Patent Owner.

Case IPR2019-00979
Patent No. 8,679,069 B2

PETITIONER'S REPLY TO PATENT OWNER RESPONSE

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I. INTRODUCTION

Patent Owner (Sanofi) argues that none of Petitioner's three grounds render obvious claims 1-3 of U.S. Patent No. 8,679,069. But Sanofi's substantive responses are limited to claim 1—it makes no arguments defending dependent claims 2 and 3 as separately patentable. Sanofi has thus waived any separate argument for these claims. *Affinity Labs of Tex. v. DIRECTV, LLC*, 838 F.3d 1253, 1264 n.4 (Fed. Cir. 2016). For the reasons discussed in Pfizer's Petition, and below in this Reply, claims 1-3 should be cancelled as unpatentable.

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).

Sanofi faults Petitioner for offering in its Petition an alternative means-plus-function construction for "***tubular clutch***." POR 6. But this construction was first proposed in litigation involving the same claim term. EX1028, Exhibit D, 80-85. The Board denies petitions failing to address foreseeable constructions. *Ethicon Endo-Surgery* v. *Covidien AG,* IPR2016-00944, Paper 8, 5-6. Sanofi has not addressed nonobviousness under this means-plus-function construction, and any such argument is now waived. *Sony Corp. v. Collabo Innovations, Inc.*, IPR2017-

00958, Paper 31, 13-14. Accordingly, Petitioner proceeds with the broader plain meaning.

The Petition adopted Sanofi's construction proposed in related litigation: "A tubular structure that couples and decouples a moveable component from another component." Pet. 18, citing EX1019, 23-24; EX1030, 12. In this IPR, Sanofi now construes ***tubular clutch*** as "a component that can operate to reversibly lock two components in rotation."[1] POR 6-7. In a second litigation, the same term has been construed to mean "reversibly locking two components in rotation." *Id.*, citing EX2165, 10-11. These constructions are evidence of the reasonable scope of the limitation. *Ex parte Schulhauser*, App. 2013-007847, slip op. 9 (PTAB 2016). 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.

III. GROUND 1: BURROUGHS

A. Burroughs suggests an outer helical groove

Sanofi dismisses the Petition as "assertions ... that a POSA *could have*

[1] Whereas the patent uses the term "coupled," it does not discuss "lock"—much less "reversibly lock." Petitioner's construction is thus more consistent with the specification. *Phillips*, 415 F.3d at 1315-17.

performed the proposed modification." POR 19-20. Sanofi misapprehends the argument. When known interchangeable solutions exist, implementing one for another is obvious. Pet. 47-48, citing *KSR Int'l* v. *Teleflex Inc.,* 550 U.S. 398, 417 (2007); *see also* EX1095, ¶22. The Board understood this was Petitioner's argument. Paper 12, 12-13. Sanofi posits a strawman to avoid addressing that modifying Burroughs to have a helical groove would have been routine implementation of a predictable result.

Sanofi argues that increased stress and wear would have discouraged a POSA from this modification. POR 21-22. But Sanofi concedes that one could have "reduce[d] the stress on the legs 102 and 104 by changing their dimensions." *Id.*, 22-23. This is routine. EX1095, ¶¶ 20-21. Precedent consistently rejects treating modifications rigidly rather than appreciating that a POSA uses ordinary skill to implement routine changes. *Allied Erecting & Dismantling Co.* v. *Genesis Attachments, LLC*, 825 F.3d 1373, 1381 (Fed. Cir. 2016).

Sanofi argues any further modification would disadvantageously make the pen 10% wider. POR 22-23. But, as explained by Dr. Biggs, "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),[2] sees as a disadvantage, a clinician understands is an advantage of insulin pens currently marketed against Sanofi's insulin products.

Dr. Slocum contends redesigning the pen would increase injection force 15%. POR 23, citing EX2107, ¶192. He pulls this percentage out of thin air. *See* EX2107, ¶192 (no basis for percentage); EX1095, ¶24 (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). He presents mere conjecture that 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).[3]

[2] Petitioner presents the deposition of Sanofi's experts in the related action, IPR2012018-01670, involving the same patent. The Board may consider this "recent sworn testimony of the same expert addressing the same patents, references, and limitations at issue in the IPRs." *Ultratec, Inc. v. CaptionCall, LLC*, 872 F.3d 1267, 1272-73 (Fed. Cir. 2017).

[3] Even if these concerns were real, Sanofi does not address routine design-arounds. EX1095, ¶¶20-23, 26.

B. Burroughs suggests a tubular clutch

The Petition, as supported by Mr. Clemens' declaration,[4] explained that Burroughs teaches a "tubular clutch," as construed by Petitioner. Pet. 41-45; EX1011, ¶¶182-87. Sanofi has not contested unpatentability under this construction. Sanofi has thus waived any such argument. Paper 13, 8; *see also* EX1095, ¶¶11-13, 28-31. Petitioner's proposed construction is reasonable, as Sanofi conceded in proposing the same construction in litigation. *Schulhauser*, 9. Sanofi offers no basis to find that the same construction it proposed in district court is now unreasonable.

Sanofi asserts that Burroughs lacks a "tubular clutch" under its proposed claim construction, which refers to a component that "can operate to reversibly lock two components in rotation." POR 24-27. Burroughs' button 32 does this. It operates to engage and disengage dial mechanism 34 from the housing's helical groove. Pet. 41-45; EX1095, ¶31. When the user injects a dose, button 32 disengages splines

[4] Sanofi alleges that "Mr. Clemens' declaration is entitled to little weight." POR 15-16. This argument is a mere cover for failing to ask Mr. Clemens any substantive questions of his underlying opinions regarding the '069 patent at his deposition. EX2450. As he explained, "in forming [his] own opinions for [his]declaration," he followed his normal process of reviewing the prior art, the patent, and additional documents about the IPR to "arrive[] at [his] own opinions." *Id.*, 13:8-14:2

connecting dial mechanism 34 and nut 36, reversing rotational locking of those components. EX1095, ¶¶31-32; 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 construction.

Sanofi argues 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. POR 27, citing EX1013, 2:59-65; EX2107, ¶209. Here, Sanofi adopts an even narrower interpretation of its 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, which has no support in the specification, as it does not mention any "lock" mechanism. In Burroughs, this same function is performed by the button 32. EX1095, ¶¶31-32.

Sanofi next characterizes the clutching device's splines and teeth as not tubular. POR 27. Not so. 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.

This tubular clutch is also adjacent to the corresponding dose dial grip. Intermediate portion 80 lies between proximal portion 78 and distal portion 82, together comprising the dial mechanism 34. *Id.*, 8:2-4.

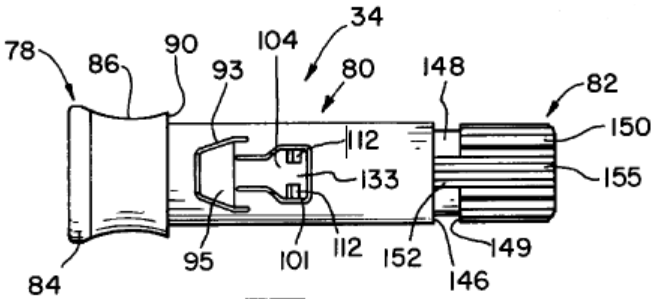

FIG. 8

Sanofi does not define ***adjacent***. 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). Intermediate portion 80 in which the clutching device is located is on the distal end of the proximal portion 78, and thus is ***adjacent*** to the distal end of the proximal portion.

Thus, 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.

C. Burroughs renders obvious claims 2 and 3

Pfizer's Petition, as supported by Mr. Clemens' declaration, detailed how Burroughs would have rendered the additional limitations of claims 2 and 3 obvious. Pet. 48-49; EX1011, ¶¶856-63. Sanofi has not addressed these claims or otherwise asserted that they are independently patentable over claim 1. Sanofi has waived any

such argument. *Zimmer Biomet Holdings, Inc. v. Four Mile Bay, LLC*, IPR2016-00012, Paper 34, 35-36. For those reasons in Pfizer's Petition and Mr. Clemens' declaration, Burroughs would render claims 2 and 3 obvious.

IV. GROUND 2: STEENFELDT-JENSEN

Sanofi presents three arguments regarding Steenfeldt-Jensen:

(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 28-30.

(2) Any suggestion applies to the first embodiment only. *Id.,* 30-33.

(3) A POSA would not have followed Steenfeldt-Jensen's suggestion because this would increase friction losses in the drive mechanism. *Id.,* 33-44.

A. 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. *Id.*, 29-30; EX2107, ¶¶215-22. Sanofi ignores that a driver with a nut member *is* an internally-threaded driver.

Steenfeldt-Jensen describes two driver configurations rotating: a "piston rod guide" or a "nut member" (also "nut element"). Pet., 69-71; EX1014, 3:41-47. These alternatives correspond to well-known screw/nut principles. 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....”). A POSA would understand that when Steenfeldt-Jensen refers to a driver rotating a nut member, it describes an internally-threaded driver tube. EX1095, ¶¶37-38.

In the embodiments with the driver rotating a piston-rod guide, the guide is not a separate component: the driver’s rectangular bore prevents relative rotation between the driver and the piston rod. *Id.*, ¶¶39-40; 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 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. EX1095, ¶¶39-40.

Steenfeldt-Jensen describes a “nut member” in 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 that a driver tube with a threaded bore operates as a nut member. EX1095, ¶¶39-40. Sanofi does not offer any meaningful distinction between them because none exists.

B. The Suggested Modification Is Not Limited to First Embodiment

Sanofi argues Steenfeldt-Jensen's suggestion at column 7, lines 41-47 of a nut element rotated by a driver tube applies only to its first embodiment. *See* POR 30-33. 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. The Suggested Modification Goes Beyond the First Embodiment

Sanofi's attempt to limit the 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. 69-71 (citing EX1014, 2:40-53, 3:15-20, 3:44-47). Sanofi even noted these disclosures earlier in its Response. POR 29-30. Sanofi's subsequent focus on column 7 ignores Steenfeldt-Jensen's broader context, which suggests these alternative driver mechanisms generally, before turning to specific embodiments. EX1095, ¶¶41-42. A POSA is not so myopic. *Id.; see also KSR*, 550 U.S. at 420.

2. Threaded Drivers Applied to Fifth Embodiment

A POSA would know Steenfeldt-Jensen's suggestion applied to the fifth embodiment as well. EX1095, ¶¶43-45. 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, ¶42 (citing EX1014, 2:36-3:47). A POSA would understand that Steenfeldt-Jensen provides a broad discussion of drive mechanisms using rotating piston-rod guides or nut members. *Id.*, ¶¶41-43.

Dr. Slocum opines that Steenfeldt-Jensen's suggestion is made for the drive-mechanism in the first embodiment only. But the first and fifth embodiments' drive-mechanism features relevant for operation 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. *Id.*, ¶44. Both have driver tubes with rectangular bores (piston-rod guides) that rotate the piston rod.[5] *Id.* Both have threaded piston rods that rotate through the threaded bore of wall 4 during injection.[6] While surrounding components may differ, the driver tube and nut member have analogous structures and functions for driving the piston rod. *Id.*, ¶44.

[5] The fifth embodiment does not label a piston-rod guide, but its equivalent in driver tube 85 is undisputed. EX1095, ¶44; EX1014, 2:48-49, 6:35-36, FIG. 2.

[6] 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, ¶44.

Given the analogous drive mechanisms, a POSA would appreciate that the first embodiment's alternative configuration also applies to the fifth embodiment. *Id.* 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. The latter embodiments require a driver tube. *Id.*, ¶45. Dr. Slocum agreed these driver tubes 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. By contrast, the second embodiment *does not have a driver tube*, or share the above similarities with the first and fifth embodiments. EX1014, 7:51-54; EX1054, 344:7-346:25. Thus, a POSA would have recognized the first embodiment's alternative was applicable to the fifth embodiment, regardless of the second embodiment. EX1095, ¶45.

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 33-44. The models depend on Dr. Slocum's opinion

that a POSA would ignore Steenfeldt-Jensen's suggestion, that a POSA was limited to designing *insulin* injector pens, and other unreasonable assumptions.

1. Dr. Slocum Ignores Express Suggestion

While Sanofi's Response attacks the desirability of modifying the fifth embodiment, Dr. Slocum is against modifying *both* the first and fifth embodiments. Despite their admittedly similar drive mechanisms (EX1054, 306:23-308:9), he insists a POSA would dismiss Steenfeldt-Jensen's suggestion 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 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 33-34. 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. Yet, neither the claims nor references are limited to insulin pens. This mistake leads him to improperly limit the POSA's design objectives to reducing injection force at all costs. Injection force is *a* factor when designing pen injectors, but not the only factor. EX1095, ¶47. 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. 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, ¶47.

3. Flawed Models

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

a. Bias

A named inventor (Robert Veasey), not Dr. Slocum, primarily designed his 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 models, which relied on crucial decisions that skewed the tests' outcomes. *See* EX1054, 313:10-325:12.

For the analytical model, Mr. Veasey provide many inputs for Dr. Slocum's spreadsheets that yielded the supposed 51% increase in friction. POR 35-36; 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. Of the fifteen unique variables, *two* were set by Dr. Slocum, two more were determined jointly with Mr. Veasey, and eleven were by Mr. Veasey alone. *Id.,* 319:7-325:12. 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, ¶48.

Mr. Veasey similarly designed the physical model used in the "collar friction" tests. EX1053, 30:5-32:7. He 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, and to use components (collared sleeves) that were "much bigger, obviously than an actual injector pen." *Id.,* 30:5-16, 33:5-13. However, collar size, not just proportions, significantly affects the resulting friction. EX1095, ¶49.

Sanofi did not present Mr. Veasey as a witness in this case, shielding critical aspects of the experiments in violation of 37 CFR §42.65(b). Dr. Slocum could not answer questions about numerous aspects of the models he did not design, so he could not disclose facts or data underlying his opinions. EX1053, 30:5-33:13; EX1054, 313:10-325:12. Accordingly, both models are unreliable due to 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 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 focus on aspects that add friction, while ignoring others that reduce friction. EX1095, ¶50. For example, one source of friction in the unmodified embodiment disappears when modified, because the piston rod does not rotate during injection. *Id.*

c. Designed to fail

The Veasey-Slocum models are skewed to exaggerate friction losses. A POSA has ordinary creativity. *KSR,* 550 U.S. at 421. The models *avoided* even common-sense approaches to mitigating friction that would be immediately apparent to a POSA. EX1095, ¶¶48, 50. For example, both models assumed no lubrication, despite this resulting in 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 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," even though this would increase friction. *Id*., 33:5-13; EX1095, ¶49.

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 43-44; EX2107, ¶¶239-41. Sanofi again assumes straightforward tasks would stump a POSA. Even if the pawl mechanism's operation were affected, a POSA would address this type of routine issue without difficultly. EX1095, ¶51.

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. For example, Giambattista (EX1016) has an internally-threaded driver tube analogous in relevant part to the modification of Steenfeldt-Jensen's driver tube. EX1095, ¶52. The driver rotates during injection and has a flange (snap ring 64) at its distal end secured against the housing:

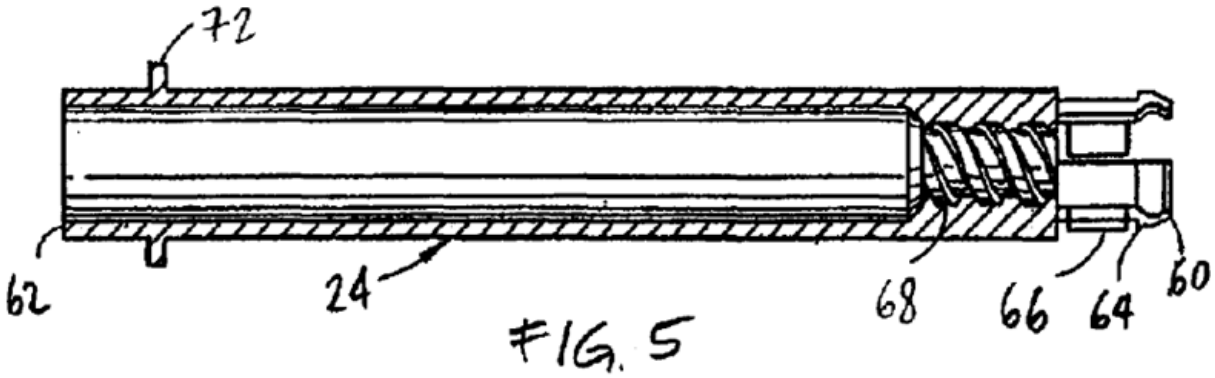

FIG. 5

EX1016, FIG. 5; *see also id.,* 3:16-26; FIGS. 2-3, 6-7. Like the Steenfeldt-Jensen's 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. Giambattista would experience "collar friction" analogous to Steenfeldt-Jensen as modified. EX1095, ¶52. 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 against Møller with two main arguments:

(1) Møller does not teach a drive "sleeve." POR 44-51.

(2) A POSA would not have modified Møller to have an externally-threaded dose-dial sleeve. *Id.,* 52-57.

A. References taught a drive sleeve

Sanofi does not dispute that Møller's second embodiment has a drive sleeve, only that the first embodiment's bar/nut implementation is not a sleeve. *Id.*, 44-51. Sanofi exaggerates the differences between the embodiments.

Møller's first and second embodiments include analogous drive mechanisms. EX1015, ¶35; EX1095, ¶55. 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, ¶56. 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, ¶56. 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, ¶56.

The main difference is that in the second embodiment, "only one gear wheel is used," meaning the mechanical advantage is 2:1. EX1015, ¶¶35, 40; EX1095, ¶57. The first embodiment adds a second gear wheel 16 with a smaller diameter so the mechanical advantage is different. 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, ¶57.

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 47-51. But the racks can engage the gear wheels whether inside or outside the driver. EX1095, ¶58. The second embodiment implements this modification 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 own evidence.

B. References taught an externally-threaded dose-scale drum

Sanofi relies on flawed teaching-away and motivation arguments.

1. Møller does not teach away

Sanofi argues that Møller criticizes Steenfeldt-Jensen's high externally-threaded dose-scale drum. POR 52-55. 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, ¶62. Møller notes a "similar

gearing" in the Steenfeldt-Jensen PCT[7] and explains that "by this kind of ***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, ¶62.

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, ¶63. Møller seeks to avoid only the embodiment's *gearing*, not its externally-threaded dose-setting drums generally. EX1095, ¶63.

Crucially, unlike Steenfeldt-Jensen's drum, Møller's dose-setting drum undisputedly is *not part of the gearing that transmits force to the piston rod*. EX1095, ¶64; EX1054, 354:19-355:24. Instead, Møller explains that "[o]nly a force

[7] Moller's reference to Steenfeldt-Jensen's "gearing" is to Steenfeldt-Jensen's first and fifth embodiments; not the second embodiment, whose dose-setting drum is not part of the gearing. EX1095, ¶62, n.4; *see also* EX1054, 346:14-348:12.

sufficient" to cause the drum "to screw itself downward ... is necessary." EX1015, ¶33. An externally-threaded dose-setting drum in Møller would not implicate gear-friction, because Møller's drum does not transmit the injection force to the piston rod like the drum of Steenfeldt-Jensen's first embodiment. EX1095, ¶64.

Sanofi warns it is not "as easy as Petitioner argues" (POR 54-61), but fails to explain why a POSA would 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 incorrectly argues that "no evidence suggest[s] that a POSA would look beyond Møller's teachings for addressing undesirable thread friction." POR 55. A POSA would look to many sources. *KSR,* 550 U.S. at 420

Sanofi argues Møller's reset spring 36 obviates any reason to reduce friction on the drum's threading. POR 55. But the spring is *optional.* EX1015, ¶33, ¶40; EX1095, ¶65. 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.

C. References taught an externally-threaded dose-dial sleeve

Sanofi argues that the modified dose-setting drum would interfere with Møller's spring. POR 56-57. If so, a POSA would not place the threads "precisely where" the reset spring exists, but in a place to maintain operability. A POSA would have had no difficulty using routine skill to provide an externally-threaded dose-setting drum. EX 1095, ¶65. Further, Sanofi ignores Møller's teaching that the reset spring is optional. EX1015, ¶¶33, 40.

Sanofi argues that a POSA would have avoided added friction but ignores the very reset spring Sanofi previously addressed. POR 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, ¶66. 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, which all rely on Lantus SoloStar, lack nexus to the claimed invention. Lantus SoloStar is not "the invention." Yet, Sanofi relies on unclaimed features of Lantus SoloStar, including the Lantus drug product, its 80-unit cartridge, its stroke length, or its injection force to assert that the claimed

invention is nonobvious.[8] EX1095, ¶¶68-70. But 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. As compared to the insulin itself, the claimed injection pen for delivering the insulin is not an important factor driving the market. EX1060, ¶¶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 to drive SoloStar sales. EX1060, ¶48-51; EX1056, 69:9-70:10. Sanofi pushed Lantus consumers to convert to SoloStar from OptiClik. *Id.*, ¶¶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. EX1060, ¶¶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

[8] Aside from Lantus, these unclaimed properties do not drive Lantus SoloStar performance. EX1060, ¶¶52-56; *see also id.*, ¶¶25, 27-29. Nor are the claim elements essential for these properties. EX1095, ¶¶68-70.

practice claims). Lantus' blocking patents thus support finding a lack of nexus. EX1060, ¶¶30-35, 63-67. There is no connection between any alleged awards or industry praise and the claims-at-issue. *Id.*, ¶¶57-60. Without nexus, secondary considerations cannot be attributed to the claims.

A. No Long-Felt, Unmet Need

Dr. Biggs explains "there was no long-felt unmet need for yet 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. *Id.*, ¶¶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. *Id.*, ¶¶29-30; *see also* EX1060, ¶53 (discussing EX2146.037-040). Contrary to Sanofi-

sponsored injection-force studies, other studies found SoloStar did not have lower injection force. EX1048, ¶58; EX2145.015, EX2145.020-021.

Sanofi relies on its own 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 62 (citing EX2184.0001) with EX2185.001. These exhibits do not constitute "industry recognition." They are Sanofi marketing.

B. No Industry Praise

Sanofi fails to establish industry praise for the claimed invention. The SoloStar "case study" for DBA was written, funded, and sponsored by Sanofi. EX1060, ¶¶57-58; EX1075. Self-praise is not industry praise. EX1055, 79:6-81:19. The exhibits regarding the Architecture & Design award (EX2201, EX2223) 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. EX1060, ¶¶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. EX1060, ¶¶23-24. Sanofi provides no benchmarks for evaluating success, applies a faulty pens-only market definition, and overstates the importance of formulary status to demonstrate commercial success. *Id.*, ¶¶17-22, 25-28. OptiClik also enjoyed an 8,000% growth rate in its first three years. *Id.*, ¶20. Peak annual sales of Apidra SoloStar and Admelog SoloStar fall below the sales of Lantus OptiClik that Sanofi's expert describes as "deficient." *Id.*, ¶¶70-71. Sanofi improperly inflates Lantus SoloStar's market share by arbitrarily excluding insulin injectable products. *Id.*, ¶¶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. *Id.*, ¶¶30-35, 64; EX1055, 96:13-20. Generic entry of biologics is not expected to replace existing biologics 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. EX 1056, 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 attributes but because, like OptiClik, Sanofi selected it as the exclusive U.S. Lantus pen. EX1060, ¶¶20-22, 30-35.

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

VII. CONCLUSION

Claims 1-3 should be held unpatentable.

Dated: January 31, 2020

Respectfully submitted,

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CERTIFICATION UNDER 37 CFR §42.24(d)

I certify that the word count for this reply totals 5,581, which is less than the 5,600 words allowed under 37 CFR §42.24(c)(1).

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