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 IPR2018-01676
Patent No. 8,603,044

PETITIONERS' REPLY TO PATENT OWNER RESPONSE

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I. INTRODUCTION

In its response, the patent owner (Sanofi) takes an excessively narrow reading of what the references would mean to a person of ordinary skill in the art (POSA), provides a flawed and biased analysis of the proposed modification using bases deliberately shielded from review, and argues against the combination for reasons that are internally inconsistent and at odds with real-world develops already in the record. Claims 11, 14, 15, 18 and 19 should be held unpatentable for the reasons provided in the petition and further developed below.

II. GROUND 1: STEENFELDT-JENSEN SUGGESTS MODIFICATION

Sanofi presents three arguments against modifying 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 21-23.

(2) Any suggestion is for the first embodiment only. *Id.*, 24-26.

(3) A POSA would not have followed Steenfeldt-Jensen's suggestion because modification would increase friction losses in the drive mechanism. *Id.*, 26-39.

Each argument fails.

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

Sanofi sows confusion attempting to distinguish between a "nut member" (also referred to as a "nut element") rotated by the driver tube and the driver tube itself having internal threading. POR, 21; EX2107, ¶215-22. The relevant disclosures in context makes clear that a driver with a nut member *is* an internally-threaded driver.

A POSA would have understood Steenfeldt-Jensen as describing an internally-threaded driver tube when it refers to a driver rotating a nut member. EX1095, ¶¶63-64. Steenfeldt-Jensen describes two ways to configure the driver: a driver can rotate a "piston rod guide" or a "nut member" (also referred to as a "nut element"). Pet., 53-56; EX1014, 3:41-47. These alternative drivers correspond to the well-known screw/nut principles that Dr. Slocum himself described in his background section. 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….").

The depicted embodiments with the driver rotating a piston-rod guide show the guide is not a separate component but simply the driver's rectangular bore, which prevents relative rotation. EX1095, ¶65; EX1014, 6:35-36 (driver tube 26 is "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.

Indeed, this is exactly how Steenfeldt-Jensen describes a "nut member". 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 similarly operates as a nut member. EX1095, ¶65. Indeed, Sanofi does not offer a single meaningful distinction between an internally-threaded driver tube and a driver tube with an integral nut member for a simple reason: there is none.

B. A POSA Would Not Have Viewed Steenfeldt-Jensen's Suggestion as Limited to the First Embodiment

Sanofi's argument that the disclosure at column 7, lines 41-47 applies only to the first embodiment (POR, 24-26) fails for many reasons. As an initial matter, Ground 1 is an *obviousness* ground, not anticipation. For an obviousness ground, a POSA is capable of applying relevant teachings from one embodiment to those of another embodiment. *B.F. Goodrich Co. v. Aircraft Braking Sys.*, 72 F.3d 1577, 1583 (Fed. Cir. 1996) (affirming suggestion to modify found elsewhere in reference).

1. Steenfeldt-Jensen Suggests Modification Outside the First Embodiment

Sanofi attempts to limit the modification to the first embodiment but ignores other instances where the alternative driver mechanisms are discussed. Steenfeldt-Jensen's alternative driver configuration disclosure at column 7, lines 41-47 is one of many such statements the petition cited. Pet. 53-54 (citing EX1014, 2:40-53, 3:10-20, 3:41-47). Indeed, Sanofi commented on these disclosures in the previous section of its response. POR, 22. Sanofi's focus on column 7 to urge that the modification only applies to the first embodiment ignores the broader context of Steenfeldt-Jensen's disclosure, which suggests using alternative driver mechanisms generally before turning to specific embodiments. EX1095, ¶66. A POSA is not so myopic. *Id.* In any case, a POSA is not limited to the specific embodiments and can recognize and apply teachings across embodiments. *See KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 420 (2007) (explaining a POSA "will be able to fit the teachings of multiple patents together like pieces of a puzzle").

2. A POSA Would Have Recognized the Suggestion Applied to the Fifth Embodiment

A POSA would have understood the suggestion at column 7, lines 41-47 was relevant to the fifth embodiment as well. EX1095, ¶¶67-69. First, as noted above, Steenfeldt-Jensen discussed the same drive-mechanism alternatives in the general description before reaching the first embodiment. EX1014, 2:40-53, 3:10-20, 3:41-47.

These sections explain Steenfeldt-Jensen's invention generally, not a specific description limited to one embodiment. EX1095, ¶66 (citing EX1014, 2:36-3:47). A POSA would have read column 7, lines 41-47 in context and understood the described alternative as an example of Steenfeldt-Jensen's broader discussion of drive mechanisms that can use rotating piston rod guides or rotating nut members. EX1095, ¶66.

In context, not repeating this general suggestion again the fifth embodiment did not indicate Steenfeldt-Jensen had abandoned its previous suggestion. Steenfeldt-Jensen frequently avoids redundant disclosures, relying on POSAs to recognize earlier discussions apply to analogous aspects of later embodiments. EX1095, ¶67.

The relevant aspects of the drive mechanisms 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, FIGS. 3, 17). Both have driver tubes with rectangular bores (i.e. piston rod guides) that rotate the piston rod.[1] EX1095, ¶68

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[1] While the fifth embodiment does not expressly label a piston-rod guide, there is no dispute that driver tube 85 has a rectangular bore that applies torque to and rotates the piston rod while allowing the piston rod to move axially relative to the driver tube. That is precisely what a "piston rod guide" is. EX1095, ¶68; EX1014, 2:48-49

(citing EX1014, 5:55-61, 6:35-37, 7:21-35, 7:41-43, 11:15-21, 12:10-13, FIGS. 2-3, 16-17). Both have threaded piston rods that rotate through the threaded bore of wall 4 during injection.[2] In other words, while certain surrounding components may be different, the driver tube (with a rectangular bore) and the nut member (i.e., a wall with a threaded bore that does not rotate during injection) have analogous structures and functions for driving the piston rod. EX1095, ¶68.

Given the analogous drive mechanisms, a POSA would have recognized that Steenfeldt-Jensen's suggested alternative configuration in the first embodiment also applies to the fifth embodiment. EX1095, ¶69. That is, a POSA would have recognized that the modifications to the driver tube (26 or 85) and wall 4 would have

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(describing piston rod guide), 6:35-36 (driver tube 26 "integral" with piston rod guide 14), FIG. 2 (identifying piston rod guide 14 as portion of driver tube 26 with rectangular bore abutting flat surfaces of piston rod).

[2] While the first and fifth embodiments have different dose-setting processes (i.e. the rotating ampoule holder vs. rotating the dose knob), wall 4 operates in the same manner during injection (i.e. 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).

been the same and had the same impact. *Id.* Accordingly, a POSA would have seen no reason to limit Steenfeldt-Jensen's express teachings to the first embodiment. *Id.*

Sanofi's point that Steenfeldt-Jensen's *second* embodiment cannot use this modification is irrelevant: that drive mechanism is *not analogous* to the first and fifth embodiments' drive mechanism. In the latter embodiments, pressing the button back-drives the scale drum, transmitting rotation to the driver tube, which rotates the piston 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, however, *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). In other words, while the first and fifth embodiments' drive mechanisms have equivalent structure and operation for injection, the second embodiment's drive mechanism operates fundamentally differently.

Dr. Slocum himself acknowledged these differences between the second-embodiment drive mechanism and the first- and fifth-embodiment drive mechanisms. Dr. Slocum agreed that the driver tubes in the first and fifth 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 first/fifth 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. He also agreed the second embodiment's drive mechanism did *not* share these similarities with the first and fifth embodiments' drive mechanisms. *Id.*, 344:7-346:25. For example, he explained:

> 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.

Id., 346:18-25.

POSAs understand context. Given the admitted similarities between the first- and fifth-embodiment drive mechanisms, a POSA would have recognized that the first-embodiment configuration was applicable to the fifth embodiment despite the second embodiment having its own, different drive mechanism. EX1095, ¶70.

C. Sanofi's Arguments that a POSA Would Have Ignored Steenfeldt-Jensen's Suggestion Are Fundamentally Flawed

After failing to limit 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. First, Sanofi's position implies that a POSA would have disregarded Steenfeldt-Jensen's express instructions. Second, both models are premised on the incorrect assumption that POSAs would have limited themselves to designing *insulin* injector pens. Third, both models suffer from bias and numerous design flaws.

1. Sanofi insists that a POSA would have ignored Steenfeldt-Jensen's express instructions

First, Sanofi presents this argument as an attack on the modification's desirability in the fifth embodiment, but Dr. Slocum admitted that he was arguing against modifying *either* the first or fifth embodiment. After he acknowledged similarities between the first and fifth embodiments' drive mechanisms (EX1054, 306:23-308:9), Dr. Slocum was asked to explain why a POSA would view Steenfeldt-Jensen's teaching—which he admitted applied to the first embodiment—as not applying to the fifth embodiment. *Id.*, 308:10-14. He clarified that he was *not* suggesting modifying only the first embodiment and not the fifth; rather that a POSA would not have modify *either* embodiment. *Id.*, 308:15-313:6. He explained 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. While Dr. Slocum is incorrect that a POSA would have ignored Steenfeldt-Jensen's explicit suggestion to use the alternative driver tube—*see* the next two sections—at a minimum, his admission undercuts Sanofi's previous attempt to distinguish the first and fifth embodiments.

2. Flawed Premise

Sanofi's and Dr. Slocum's argument that a POSA would reject a modification causing *any* increase in friction stems from Sanofi's flawed assumption that a POSA would have been singularly focused on designing an *insulin* pen injector. POR 27-28.

The claims are not limited to insulin pens. The applied references are not limited to insulin pens. Nevertheless, Dr. Slocum focused a POSA 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 (discussing POSA). For example, during cross-examination he explained "a POSA would read [these]…injector pen claims in the context of understanding that this is going to be used by a diabetic person for injecting insulin." *Id.*, 63:20-24. He further explained that "in general all diabetics have, with time, decreasing manual capabilities" and that "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…." *Id.*, 69:1-71:2; *see also id.*, 72:3-11 ("[T]he POSA understands these claims are all in [the] context of an injector pen for insulin."), 75:22-76:3 (admitting lack of knowledge that injector pens were used for medications other than insulin). He thus mistakenly limited the POSA to designing a pen for diabetic patients, leading him to limit the POSA's design objectives to reducing injection force at all costs to accommodate the particular needs of diabetic patients.

Even if a POSA were appropriately limited to concerns about diabetic patients, a singular 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. From the patient's and the engineer's perspective, injection force is only thing (lesser) consideration, even for insulin pens. *Id.*, ¶¶29-30.

Even with this flawed premise, Sanofi never alleges that the petition's modification is unworkable or that a POSA would not have reasonably expected success. This is not surprising, since the modification is so straightforward that its workability was never in serious question. EX1095, ¶72.

3. 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.

a. *Bias*

First, 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). Given his admitted lack of expertise with injector pens, he "wanted to talk to someone who was clearly in the thick of it at the time." *Id.* He turned to Robert Veasey, a named inventor and therefore not a disinterested party. *Id.*; *In re Newman*, 782 F.2d 971, 974 (Fed. Cir. 1986) (*ex parte* tests entitled to little weight); *cf. Apator Miitors APS v. Kamstrup A/S*, 887 F.3d 1293, 1295 (Fed. Cir. 2018) (noting risk of inventor *testimony* being self-serving).

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. Repeatedly under questioning, Dr. Slocum revealed that Mr. Veasey, not Dr. Slocum, 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, 28-29; EX2107, ¶¶242-43. For example, Dr. Slocum admitted that 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 ("He said .1. That's why I used .1."). Of fifteen unique variables in Dr. Slocum's spreadsheet, Dr. Slocum only set *two* himself. *Id.*, 319:7-325:12. Dr. Slocum and Mr. Veasey jointly determined two more, while Mr. Veasey alone set 11 of 15 variables. *Id.* Mr.

Leinsing explains that the choices made for these variables (e.g. the coefficient of friction and the inner and outer diameters of the "collar") have a significant impact on the calculation, and the choices that were made in 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")). Dr. Slocum admitted that Mr. Veasey or DCA designed the rig that was used in the "collar friction" tests. EX1053, 30:5-32:7. He also admitted that Mr. Veasey or DCA chose the dimensions of the components tested on the rig. *Id.*, 32:8-33:4. In accepting this setup, Dr. Slocum relied on 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 or DCA's choice to use components (i.e. the 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 actual collar size, not just its proportions, significantly impacts the resulting friction. EX1095, ¶74.

Despite Mr. Veasey's significant control over these models, Sanofi did not present Mr. Veasey as a witness in this case, avoiding review for pivotal aspects of the experiments. Additionally, Dr. Slocum could not answer deposition questions about numerous aspects of the models he did not design, meaning he could not disclose key facts or data underlying his opinions during cross-examination. 37 CFR §42.65(b). Accordingly, both models are unreliable due to the bias—and absence—of their ultimate designer. Because Sanofi did not offer 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 bias noted above may explain why the Veasey-Slocum models fail to consider aspects of the modification that would *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 end, rotates against the piston rod's bottom end while bearing the full injection force. *Id.* This drag disappears in the modified embodiment, however, since the piston rod does not rotate during injection. *Id.* The models thus only look at the aspect that adds friction while ignoring other aspects that reduce friction.

c. *Designed to fail*

Even within this misleading framing, the Veasey-Slocum models are skewed in multiple respects to exaggerate frictional 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. Far from applying ordinary creativity, the Veasey-Slocum models *avoided* even the most common-sense approaches to mitigating friction. EX1095, ¶¶73, 75. Mr. Leinsing explains that Dr. Slocum failed to consider numerous friction-mitigation strategies that would have occurred immediately to a POSA. EX1095, ¶75. For example, both models assumed no lubrication despite Dr. Slocum's admitted recognition that this assumption increased the "percent increase in friction" result. 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, Mr. Veasey, mostly selected those characteristics, not Dr. Slocum. *Supra,* section II.C.3.a. Mr. Veasey purportedly supplied FlexPen parameters, which Dr. Slocum simply assumed accurately represented Steenfeldt-Jensen's fifth embodiment. EX1053, 41:3-42:13. Again, even if it were somehow appropriate to use FlexPen dimensions as a stand-in, Dr. Slocum still failed to consider *net* friction for the full device and deliberately refrained from applying a POSA's ordinary creativity. The "collar friction" model also used components (i.e. the 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.

On closer inspection, the models designed primarily by Mr. Veasey apparently were deliberately designed to exaggerate the collar friction's impact in Steenfeldt-Jensen's alternate embodiment. A POSA applies ordinary creativity to achieve success, not deliberate failure, so these experiments are entitled to no weight.

D. Sanofi's "Additional Problems" Would Arise Only if a POSA Were Deliberately Trying to Fail

Sanofi's purported "additional problems" provide yet another example that Sanofi is not applying the POSA's perspective. Sanofi argues that if the drive-tube flange, which includes a pawl mechanism, were subjected to additional force in the modified embodiment, it could break in several ways. POR 38-39. In particular, the pawl mechanism's "flexible arms" allegedly might break, get stuck, or push through an opening in the wall above. *Id.*; EX2107, ¶¶239-41. Again, Sanofi approaches the modification as if straightforward tasks would stump a POSA. Even if the pawl mechanism's operation would be affected at all—and Sanofi offers no evidence that it would be—Mr. Leinsing explains that this would be the type of routine task that a POSA would have no difficultly addressing. EX1095, ¶76 (explaining, for example, use of a collar as the bearing surface).

E. Pen Injector Art Shows that POSAs *Did* Pursue Such Drive Mechanisms

The choices actual pen-injector designers made is the final blow for Sanofi's argument that a POSA would not have considered following Steenfeldt-Jensen's suggestion to implement the driver tube as a rotating nut member relative to a non-rotating piston rod guide. A reference used in a related IPR shows that POSAs *did* design pens with the type of drive mechanism suggested by Steenfeldt-Jensen. EX1095, ¶77.

Giambattista (applied in IPR2018-01680) has an internally-threaded driver tube that is, in relevant part, analogous to Steenfeldt-Jensen's modified driver tube. EX1095, ¶77. As in Steenfeldt-Jensen, the driver rotates during injection and has a flange (snap ring 64) at its distal end that is secured against the housing:

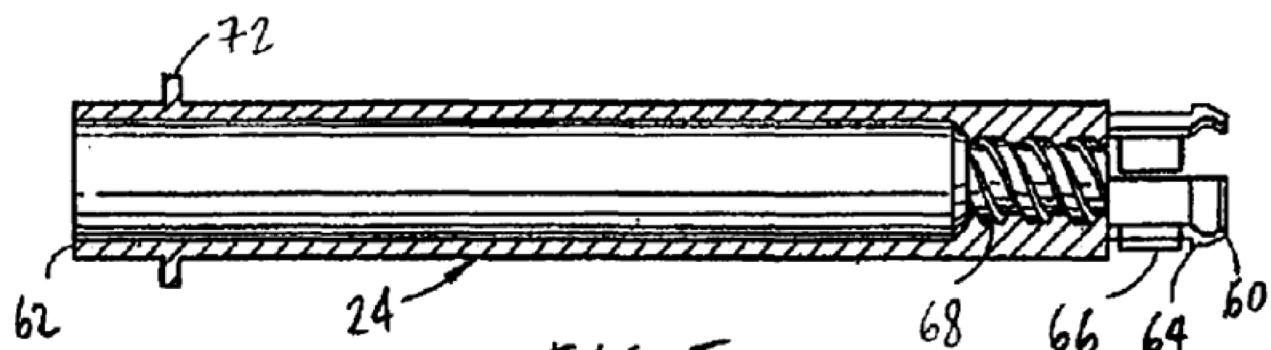

FIG. 5

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

Sanofi's argument betrays Dr. Slocum's lack of qualifications. He asserts that Steenfeldt-Jensen's suggestion of 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), actual pen designers, yet a reference on which he opines in another IPR actually *did* pursue this approach. The record shows that, unlike the approach evident in Sanofi's models, those of ordinary skill in the art apply routine creativity with success.

III. GROUND 2: MØLLER IN VIEW OF STEENFELDT-JENSEN

Sanofi defends the independent claims with two main arguments:

(1) Møller does not teach a drive "sleeve" because the driver's top portion in the first embodiment includes "bars" that are not tubular, and the driver of the second embodiment—which Sanofi does not dispute is a sleeve—is structurally and functionally different from the first driver. POR, 47-56.

(2) A POSA would not have modified Møller to have an externally-threaded dose-dial sleeve. *Id.*, 56-63.

Sanofi also argues that a POSA would not have reason to provide a clicker with a flexible arm and a spline as dependent claim 15 recites. *Id.*, 64-65.

Each of these arguments lacks merit.

A. The references teach a drive sleeve

Sanofi does not dispute that Møller's second embodiment discloses a drive sleeve, arguing only that the first embodiment's bar/nut implementation is not a sleeve and that the second embodiment's sleeve would interfere with the device's operation. POR 47-56. This argument ignores the first driver's actual structure and exaggerates the differences between the embodiments.

Møller's first and second embodiments include analogous drive mechanisms, with "corresponding … elements … given the same reference … with a prefixed '1'." EX1015, ¶35; EX1095, ¶94. In both embodiments, the driver (connection bars 12 and nut 13, tubular connection element 112 and nut 113) is connected to a gear-wheel assembly (gear wheels 14/16, 114) engaging two racks: the first rack (rack 15, 115) indirectly attached to the button, the second (rack 10, 110) attached to the gearbox (gearbox 9, 109). EX1015, ¶¶24, 39-40; EX1095, ¶95. In both embodiments, the driver rotates and rides up the piston rod during dose-setting and pushes straight down during injection (carrying the piston rod with it). EX1015, ¶¶24, 30-32, 40; EX1095, ¶95. In both embodiments, axial movement of the button, and therefore 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 embodiments, the gear wheels carry the driver/piston rod with them during injection, and 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.

Contrary to Sanofi's argument, the differences between these two implementations are minimal: mainly that in the second embodiment "only one gear wheel is used", meaning the mechanical advantage is necessarily 2:1 (i.e., the gear-wheel assembly, and thus the driver and piston rod, move "a distance which is half the distance which the rack 115 is moved"). EX1015, ¶¶35, 40; EX1095, ¶96. The first embodiment simply adds second gear wheel 16 with a smaller diameter on the sides of gear wheel 14 so the mechanical advantage can be something other than 2:1 (depending on the relative sizes of gear wheels 14 and 16). EX1015, ¶24. Even this difference is optional, however, because Møller explains that the first embodiment could *instead* have a single gear size (as in the second embodiment) to provide a 2:1 mechanical advantage. EX1015, ¶34; EX1095, ¶96.

Sanofi stresses the gear assembly sits inside connection bars 12 in the first embodiment but outside the tubular connection element 112 in the second embodiment, arguing that switching from an internal to an external gear wheel assembly "would require a significant reconstruction and redesign…." POR 52-55.

Sanofi is wrong. EX1095, ¶97. The racks can easily engage the gear wheels whether inside or outside the driver. *Id.* Curiously, Sanofi argues that the device "would need to be redesigned to make additional space" to allow the racks to engage external gear wheels. POR 54-55. But FIG. 2 shows *ample* space for such racks, and the second embodiment *already does this* without requiring the pen "to be widened" as Sanofi alleges. *Compare* EX1015, FIG. 1 *with id.*, FIGS. 3-5. Indeed, Sanofi's own representation of the first and second embodiments shows comparable widths. *See* EX2206 and EX2207.

Sanofi's drive-sleeve arguments misapprehend the petition, and conflict with Møller and even Sanofi's own evidence.

B. The references teach an externally-threaded dose-scale drum

Sanofi relies on flawed teaching-away and motivation arguments.

1. Møller does not teach away from externally-threaded drive sleeves

Sanofi urges Møller teaches away from the modification, purportedly criticizing Steenfeldt-Jensen's high externally-threaded dose-scale drum. POR 57-59. Sanofi misinterprets Møller's comments.

Møller's comment on WO 99/38554 (a Steenfeldt-Jensen PCT) specifically addresses using an externally-threaded dose-setting drum in *gearing*, not externally-threaded dose-setting drums generally. Møller references "gearing" in which the piston rod is rotated during injection by back-driving an externally-threaded dose-setting element, whose rotation is then transmitted to the driver mechanism with a "fine pitch." EX1015, ¶7. The "gearing" in such a system comes from the rotational coupling of a high-pitch drum and a fine-pitch piston rod, because the drum's rotation (upon being back-driven during injection) causes axial displacement of the piston rod that is less than the drum's axial displacement (due to their different pitches). EX1095, ¶101-02. Møller notes a "similar gearing" in the Steenfeldt-Jensen PCT[3] 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

[3] Møller's reference to Steenfeldt-Jensen's "gearing" involving the dose-setting drum makes clear that Møller refers to the gearing of Steenfeldt-Jensen's first and fifth embodiments, which have such gearing, not the second embodiment, whose dose-setting drum 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 Steenfeldt-Jensen's second embodiment).

added). Møller thus specifically focuses on friction losses *in the gearing system* because those components are subjected to the full injection force. EX1095, ¶102.

Møller's specific focus on gearing friction is even clearer when stating its objective to "provide a device wherein is established a direct gearing, i.e. a gearing by which ***more transformations of rotational movement to linear movement and linear movement to rotational movement are avoided, between the injection button and the piston rod***." EX1015, ¶11 (emphasis added). The disfavored aspect of Steenfeldt-Jensen's PCT is the first embodiment transmitting injection force to the piston rod by back-driving the "large surfaces" of the dose-setting drum's threading (i.e. a "transformation[] of…linear movement to rotational movement…between the injection button and the piston rod."). *Id.*; EX1095, ¶103. Accordingly, Møller seeks to avoid only the *gearing* of Steenfeldt-Jensen's first embodiment, not its externally-threaded dose-setting drums generally. EX1095, ¶103.

Crucially, Møller's dose-setting drum is *not part of the gearing that transmits force to the piston rod* (EX1095, ¶104), which Sanofi's expert acknowledged during cross examination (EX1054, 354:19-355:24). Møller does not transmit injection force to the piston rod by back-driving the dose-setting drum's threads as Steenfeldt-Jensen does. *Id.* Instead Møller explains:

> Only a force sufficient to make the dose setting drum rotate to screw itself downward along the thread 6 is necessary as the force necessary to

make the injection is transmitted to the piston rod 4 through the gearbox 9.

EX1015, ¶33. An externally-threaded dose-setting drum in Møller 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's passing warning that the modification is not "as easy as Petitioner asserts" (POR 59-60) is baseless. Sanofi fails to explain why a POSA would find it difficult to implement an externally-threaded dose-scale drum—a feature possessed by Steenfeldt-Jensen and *numerous* other pen injectors. Moreover, this warning conflicts with Dr. Slocum's insistence (addressing a written-description issue from IPR2018-01680) that a POSA viewing Sanofi's specification would have immediately envisioned the implementation of a vastly more complicated modification to the drive sleeve. *See* EX1051 (Dr. Slocum's drawing of supposedly easy modification); EX1053, 126:4-21 (as POSA, embodiment shown in EX1051 would "pop into your head right away").

2. Sanofi's motivation argument misapprehends Møller and is internally inconsistent

Sanofi argues that a POSA lacked motivation because "no evidence suggest[s] that a POSA would look beyond Møller's teachings for addressing undesirable thread friction." POR, 60-61. Precedent bars assuming a POSA's perspective is limited to solutions from a single reference. *KSR*, 550 U.S. at 420.

Sanofi further argues that Møller's reset spring 36, which aids drawing the dose-setting drum back during injection, obviates any desire to reduce friction on the drum's threading. POR 60-61. Yet Møller describes that reset spring as *optional*. Møller, ¶33 (spring "can" be mounted on drum), ¶40 (replacing reset spring 36); EX1095, ¶105. Moreover, even for embodiments using a reset spring, Sanofi offers no explanation of why an externally-threaded dose-setting drum would not be equally effective, if not more so. *KSR*, 550 U.S. at 421 (obvious to pursue known options).

C. The references teach an externally-threaded dose-dial sleeve engaging a main housing's internal threading

Sanofi's additional arguments against the proposed combination also fail. Sanofi first argues that the modified dose-setting drum would interfere with Møller's spring (POR 61-62), misapprehending the petition, Møller, and the POSA's abilities. Petitioners did not suggest that a POSA would place the threads "precisely where" the reset spring exists, as Sanofi asserts. POR 62. Even if Sanofi's blinkered view of the modification were accurate, Sanofi ignores Møller's teaching that the reset is optional. EX1015, ¶¶33, 40. Regardless, Sanofi's suggestion that a POSA would not have been able to avoid interference between the dose-setting drum and the reset spring incorrectly presumes a POSA is incapable of completing straightforward tasks. A

POSA would have had no difficulty whatsoever providing an externally-threaded dose-setting drum. EX1095, ¶105.

Sanofi's second argument that a POSA would have avoided added friction from the external threading ignores the very reset spring Sanofi addressed in the previous paragraph. POR, 62-63. As Sanofi emphasizes elsewhere in its response, Møller already teaches an optional configuration using a reset spring to counteract friction losses from the dose-setting drum during injection. POR, 60-61; EX1015, ¶33; EX1095, ¶106. Sanofi's argument is thus internally inconsistent and wrong.

D. The references teach a clicker with a flexible arm and splines (claim 15)

Sanofi does not dispute that the references' combined teachings disclose a clicker with a flexible arm and splines, disputing only Petitioners' discussion of the combination. POR, 64-65. However, the petition demonstrated it was obvious to provide the recited clicker between analogous rotating components in Steenfeldt-Jensen. Pet. 43-46; EX1095, ¶111. A POSA would find this arm/spline implementation—which was well known and commonly used in pen injectors—equally applicable to Møller's analogous clicker. *See, e.g.,* EX1011, ¶¶413-15.

E. The references teach a main housing with a helical rib seated in the dose-dial sleeve's external groove (claim 19)

Sanofi offers no defense for claim 19 beyond its arguments for claim 1, which Petitioners addressed above. POR, 65; *supra,* sections III.A-D.

IV. CONCLUSION

For all the reasons stated above, as well as those in the petition, the challenged claims are unpatentable.

Respectfully submitted,

Date: 18 September 2019

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

<u>CERTIFICATION UNDER 37 CFR §42.24(d)</u>

I certify that the word count for this reply totals 5468, 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

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

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