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 IPR2019-00122
Patent No. 8,992,486

PETITIONERS' REPLY TO PATENT OWNER RESPONSE
37 CFR §42.23

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I. INTRODUCTION

The patent owner (Sanofi) reads Burroughs (EX1013), not as a whole, but as disjoint teachings in a manner inconsistent with precedent and the understanding of a person of ordinary skill in the art (POSA). The preponderance of evidence of record—including testimony from pen designer Karl Leinsing (EX1011, EX1095) and cross examination testimony from Sanofi's Professor Slocum (EX1053, EX1054)—contradicts Sanofi's arguments. Sanofi urges commercial success, praise and long-felt need, but its bases and analysis are woefully deficient. Far more credible testimony from petitioner's Drs. McDuff (EX1060) and Biggs (EX1048) illuminate the flawed assumptions in the testimony of Sanofi's Drs. Grabowski and Goland.

Claims not argued separately stand or fall together. *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc). Sanofi only separately argues claim 1,[1] leaving the remaining claims to stand or fall with claim 1 from which they depend. For the reasons given in the petition alone and in light of the arguments below, all challenged claims are unpatentable.

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[1] Sanofi only discusses claims 14 and 38 to deny a means-plus-function reading for ***clicker*** and ***insert***, respectively. POR 13.

II. LEVEL OF SKILL

Sanofi disputes the level of skill in the art and whether it requires any years of experience but concedes that any differences between the parties do not affect this trial. POR 8-9. Petitioners agree with the Board that the art of record amply reflects the level of skill. Paper 19, 16-17.

III. 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 it would make a difference, the Board will adopt the broadest reasonable interpretation in this trial. Paper 19, 13-14.

Sanofi asserts that Petitioners have not settled on a meaning for ***tubular clutch***, ***clicker***, and ***insert***, which the petition explained could be subject to a means-plus-function interpretation. POR 9. Claim construction is a question of law, and the tribunals regularly arrive at a final construction in their final decisions. *Jack Guttman, Inc. v. Kopykake Enter., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002) ("District courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves."). In fact, the Board will deny petitions for failing to address a foreseeable alternate construction. *Ethicon Endo-Surgery, Inc. v. Covidien AG*, IPR2016-00944, Paper 8, 5-6 (denying follow-on institution for claim construction

not addressed in earlier petition). The Board was not confused when instituting this trial. Paper 19, 15-16.

In any case, Sanofi rejects means-plus-function constructions for these terms. POR 10-13. Similarly, the institution decision provisionally adopted Sanofi's broader constructions. Sanofi has waived any argument resting on a means-plus-function construction, including any separate argument that the art would not teach the invention with a means-plus-function construction. Accordingly, Petitioners will proceed with the broader plain and ordinary meaning for these terms.

Other than contending ***clicker*** and ***insert*** are not means-plus-function limitations, Sanofi's response only addresses the construction of ***tubular clutch***, which Sanofi would construe as "a component that can operate to reversibly lock two components in rotation." POR 10-12. While Sanofi challenges Petitioners' means-plus-function construction for its use of the phrase "during dose setting", Sanofi does not address the plain-meaning construction that the petition offered. The petition—relying on Sanofi's own representations to the district court 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 does not restrict the claims to dose setting, rendering Sanofi's argument moot.

In an earlier proceeding, Sanofi proffered a similar construction of the term ("A first component that couples and decouples at least a second component to a third component."), which the court construed as "[a] structure that couples and decouples a moveable component from another component." EX1030, 12. Sanofi proffered this construction in the collateral litigation, but the court rejected, "as inconsistent with the ordinary meaning, claim construction proposals that would have required a structure that 'couples and decouples' two components rather than reversibly locking two components in rotation."[2] POR 12, citing EX2165, 10-11. While the current court's construction is evidence of the reasonable scope of the limitation, the earlier court's construction and Sanofi's subsequent proffer in the current court is evidence—an admission—about the reasonable scope of the limitation. *Ex parte Schulhauser*, Appeal No. 2013-007847, slip op. 9 (PTAB 2016) (precedential). The broadest reasonable interpretation of this limitation would at least encompass both of these constructions absent a showing that either

[2] Given that the contested patent uses the term "coupled" in the abstract and claims but does not use any variant of "lock" much less "reversibly locking", it is not clear how Sanofi's new construction is more reasonable in light of the specification. *Phillips*, 415 F.3d at 1315-17.

construction is unreasonable. Sanofi has made no such showing beyond noting the current court's construction, and certainly has not stated that its construction proffered to the current court, and adopted by an earlier court, was unreasonable.

IV. GROUND 1: BURROUGHS

A. Burroughs suggests a "helical groove provided along an outer surface of said dose dial sleeve"

1. Sanofi's "inconsistent" modification argument is a canard

Sanofi argues that the petition presents a "convoluted" modification, while Petitioners' expert, Karl Leinsing, provides an inconsistent modification. POR 21. Sanofi misapprehends the petition's rationale and Mr. Leinsing's testimony.

The petition notes that Burroughs describes flexible legs 102, 104 with outwardly extending threads 110, 112. Pet. 26, citing EX1013, 8:24-29. These threads fit into a helical groove 158 on the housing. Pet. 27. The petition with supporting testimony explains that the placement of threads and grooves are known to be interchangeable, and proposes to change the helical threads 110, 112 into a "protruding u-shaped groove". Pet. 39. Contrary to Sanofi's assertions, the petition says nothing about cutting into the threads to make this modification. In context, turning a single thread into a "protruding groove" indicates duplication of the thread. There is nothing convoluted about treating two threads as forming the groove for an engaging thread. The Board understood the proposed modification in

its institution decision. Paper 19, 22-23. To the extent Sanofi was truly confused, it needed only consult the cited paragraph in the Leinsing declaration, which explains (EX1011, ¶170):

> [T]he rotational operability between the components would be retained if the threads 110, 112 of the dial mechanism were configured as two, parallel ribs that form a discontinuous, helical groove for engaging the housing's threading.

What the petition expressly intends is two protruding ribs that form a groove. Sanofi adopts a strawman reading of the petition and declaration to create confusion where none exists. Sanofi's arguments built on its misapprehension (POR 27-33) should be disregarded.

Sanofi notes that Mr. Leinsing rejected its mischaracterization of the modification during his deposition. POR 27-28, citing EX2163, 193:22-194:11. Far from supporting Sanofi's argument, Mr. Leinsing's answer should have alerted Sanofi to its misapprehension of the proposed modification.

2. The petition established a reason to modify

Sanofi addresses the petition's rationale as "Mr. Leinsing's proposed modification" but dismisses it as "assertions [that] do no more than establish that a POSA *could have* performed the proposed modification." POR 34-35 (original emphasis). Again, Sanofi misapprehends the argument. When known

interchangeable solutions to a problem exist, the case law fully supports that swapping one solution for the other is well within the realm of the obvious. Pet. 38-40, citing *KSR*, 550 U.S. at 417; *see also* EX1095, ¶43. The Board understood this to be Petitioners' argument. Paper 19, 23. Again, Sanofi sets up a strawman argument that does not represent the actual argument and avoids addressing the actual rationale.

Sanofi further argues that a POSA would have been deterred from making the proposed modification because two ribs would increase the stress and wear on Burroughs' flexible legs 102, 104. POR 35-37. 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 a POSA would not have wanted to do it because it would increase the width of the pen. POR 37. Case law, however, consistently rejects treating modifications rigidly rather than appreciating that a POSA would use routine skill in implementing the change. For example, in *Allied Erecting & Dismantling Co. v. Genesis Attachments, LLC*, the court affirmed a modification that might have disadvantages because (1) the possibility of disadvantages does not obviate the reason to change and (2) the further modification to mitigate the disadvantage was readily apparent. 825 F.3d 1373, 1381 (Fed. Cir. 2016).

Sanofi argues the further modification it suggests has the disadvantage of making the pen 10% wider. POR 37. 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, Dr. Biggs explains is an advantage seen in insulin pens currently marketed against Sanofi's insulin products.

Sanofi relies on Dr. Slocum's testimony to contend that redesigning the pen as proposed would "significantly" increase injection force 15%. POR 38, citing EX2107, ¶192. Dr. Slocum pulls this "significant" percentage out of thin air. *See* EX2107, ¶192 (providing no basis for percentage); EX1095, ¶41 (noting analytical model "is based entirely on dimensions determined from the apparent relative size of components in Burroughs's patent drawings and a rough sketch of the location of the additional thread" provided by Mr. Leinsing during deposition). Conclusory expert testimony is entitled to no weight. See, e.g., *Phillips*, 415 F.3d at 1318; 37 CFR §42.65(b). At most, Dr. Slocum asserts 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*") (original emphasis); 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]

B. Burroughs suggests a tubular clutch located adjacent a distal end of, and operatively coupled to, the dose-dial grip

Sanofi relies on its claim construction (see section III, above) to contend that the petition fails to address this limitation. POR. 39-42. 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.

As explained above, Sanofi has already conceded the reasonableness of the construction the petition employed 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 the construction; hence, there is no basis in the record to hold that the construction Sanofi proffered in district court is now unreasonable.

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[3] Even if these unsupported concerns were real, Sanofi does not address any of the routine options at the POSA's disposal. EX1095, ¶¶42-43 (e.g., different rib heights, shifting of threading).

Accordingly, the construction of the limitation for this trial must be broad enough to include the petition's construction. In any case, 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 39-42. 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. 36-37; EX1095, ¶48 (citing EX1013 7:49-55). Moreover, when the user injects a dose, button 32 operates to disengage the splined connection between dial mechanism 34 and nut 36, thus reversing the rotational locking of those two 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, based on its new claim construction, that Burroughs already has a "clutching device" and that the button 32 does not reversibly lock dial mechanism 34 and nut 36 because splines 144 on the dial mechanism and teeth 192 on the nut do the locking, not button 32; and the splines and teeth are not tubular. POR 42-43, 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 misapprehends how the clutching device also meets Sanofi's new extra-narrow construction.

Sanofi characterizes the clutching device as splines and teeth as not tubular. POR 42-43. The dial mechanism 34 is "generally cylindrical in shape and is hollow throughout its axial length." EX1013, 7:66-67. Burroughs teaches (8:43-48) that:

> a plurality of splines 144 extend[] circumferentially about the interior surface of intermediate portion 80 of dial mechanism 34. Splines 144 extend 360° about the inner circumference of intermediate portion 80 and engage with teeth 192 (FIGS. 10, 11) provided on nut 36 when the clutch is engaged to set a dosage.

When engaged the splines 144 and teeth 192 define a tubular ("360°") structure (clutching device) within the intermediate portion 80 of the dial mechanism 34. The intermediate portion 80 lies between the proximal portion 78 and distal portion 82, together comprising the dial mechanism 34 (see Burroughs Fig. 8, right). EX1013, 8:2-4. Sanofi does point to any special definition for ***adjacent***, and the contested patent does not appear to use the term in an

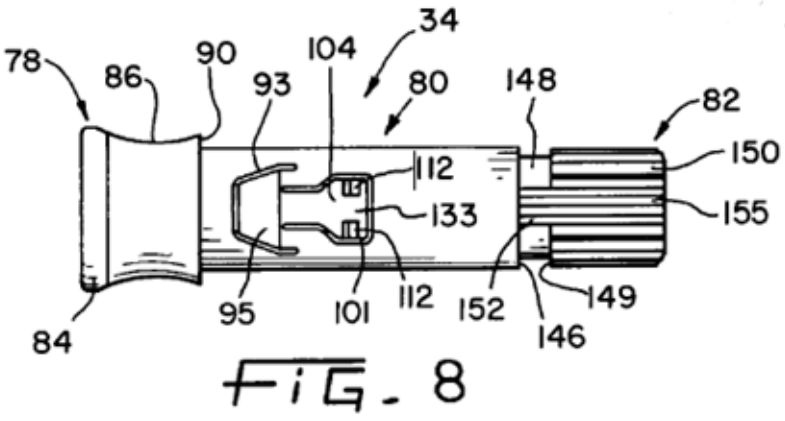


FIG. 8

unconventional way. Case law indicates that ***adjacent*** should not be given an unduly complicated meaning but should be understood to mean simply "next to". *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1333 (Fed. Cir. 2007) (reversing construction as too narrow). In any case, the 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.

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

V. NO NEXUS FOR ALLEGED SECONDARY CONSIDERATIONS

Sanofi bears the burden of production for secondary considerations. *Prometheus Labs., Inc. v. Roxane Labs., Inc.*, 805 F.3d 1092, 1101-02 (Fed. Cir. 2015). Secondary considerations require "a nexus to establish that the evidence relied upon traces its basis to a novel element in the claim and not to something in the prior art." *Biomarin Pharmaceutical Inc. v. Genzyme Therapeutic Products Ltd. P'ship*, IPR2013-00537, Paper 79, 22; *see also Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1311-12, n.14 (Fed. Cir. 2006). Each of Sanofi's arguments fails for lack of nexus.

Sanofi provides identical secondary consideration arguments without differentiating among claims-at-issue or patents-at-issue. EX1060, ¶¶36-37, Attachment B-1; EX1055, 53:9-12. Sanofi's commercial success and long-felt need experts didn't know what claims were at issue and provided no independent opinion about nexus to any claim. EX1055, 44:17-45:17, 47:21-25, 48:18-49:19, 50:20-51:24; EX1056, 9:4-7, 18:16-20, 19:18-25, 24:22-25:5, 37:2-6. Sanofi's MD testified that Sanofi's economist was the one who told her the SoloStar pen was easy to use and has a low injection force. EX1056, 11:19-14:10. Sanofi's failure to differentiate between claims and patents undermines its secondary considerations case.

Sanofi does not argue that Lantus SoloStar practices all challenged claims, just claim 1. POR 45. But even claim 1 is not entitled to a presumption of nexus because Lantus SoloStar is not "the invention." For example, the claim does not require Lantus (or insulin at all), an 80-unit cartridge, a short stroke length, or a low injection force. Sanofi's argument ignores the claim and fails to apportion any secondary consideration to the active ingredient.

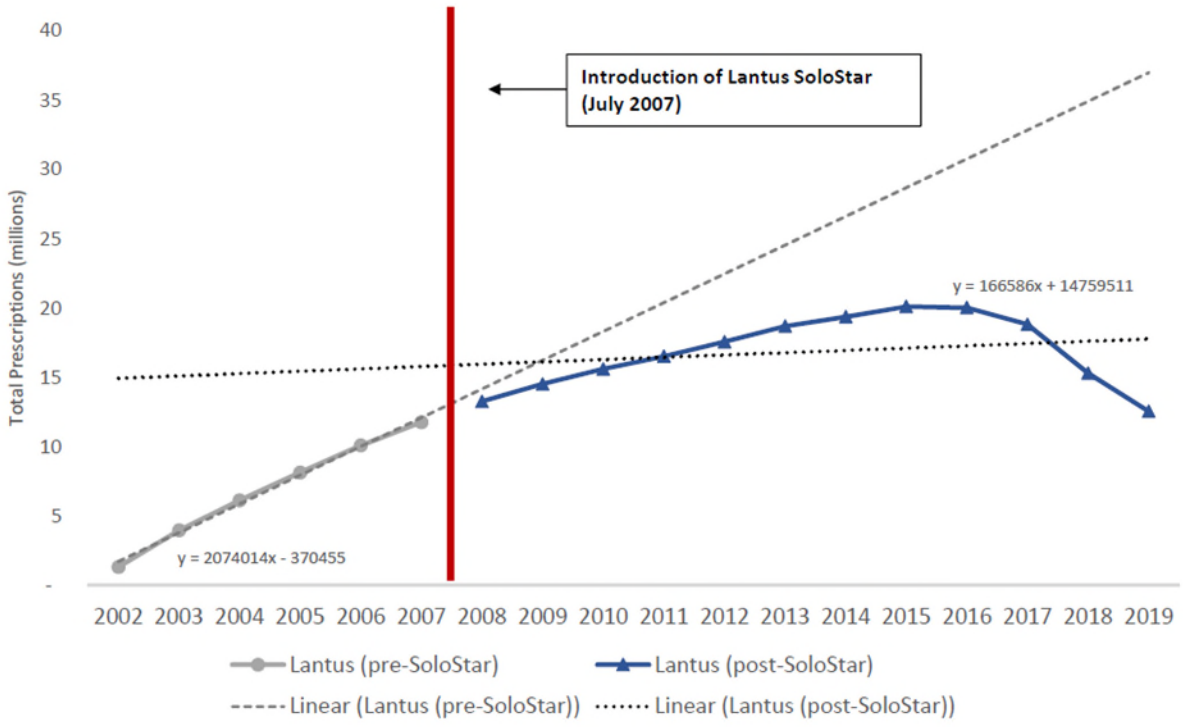
By arguing that SoloStar drove Lantus sales and recognition, Sanofi gets the facts exactly backwards. The "overwhelming consideration" in insulin-prescription decisions is "the insulin itself." EX1048, ¶25. Insulin pens are "largely fungible from the perspective of the patient and prescriber." EX1048, ¶¶27-28. Thus, Lantus

SoloStar commercial performance derives from demand for Lantus, which Sanofi tied to the SoloStar for its own business reasons. EX1048, ¶¶27-28.

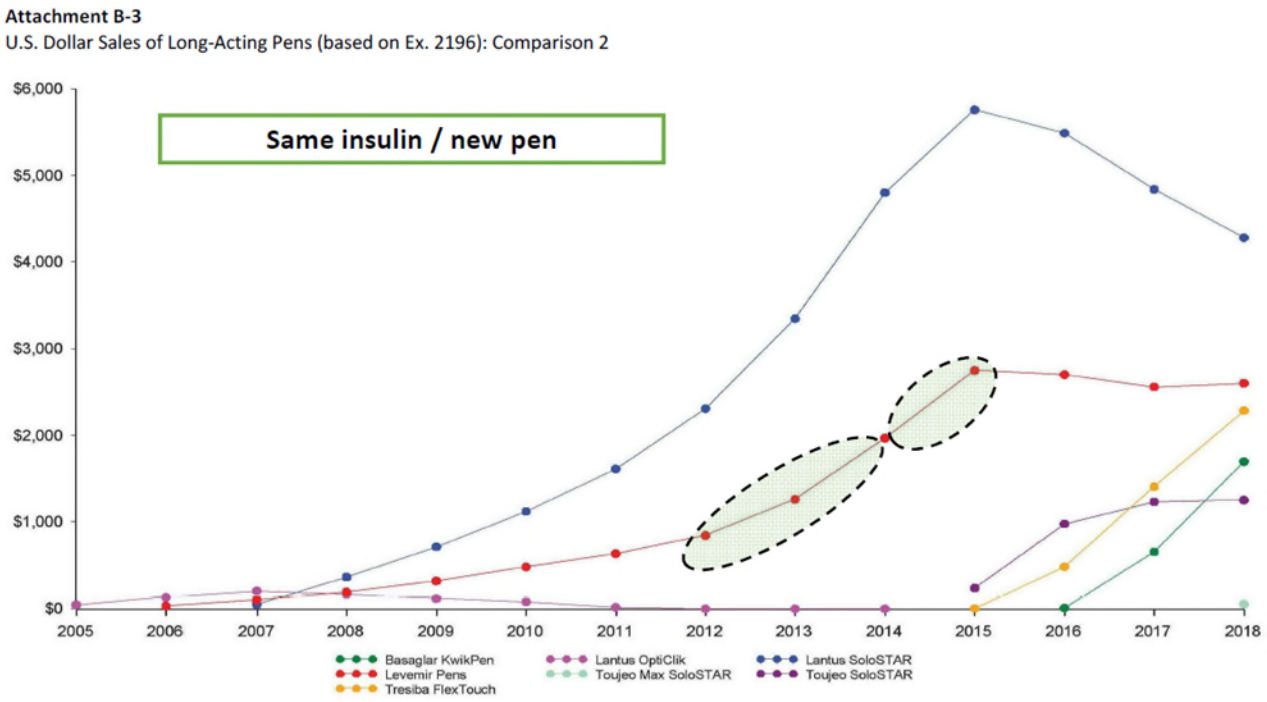
Sanofi's own documents confirm that prescription decisions are driven by Lantus characteristics (e.g., once-daily dosing and 24-hour control), not the SoloSTAR pen. EX2146 at 13, 77-78 36; EX2145.008, .015 ("real value…is Lantus itself."), EX2145.022 ("our long term advantage comes from the insulin properties"); *see also* EX1055, 28:14-29:22, 30:2-6. The patents-at-issue simply are not important to injectable-pen Lantus. EX1060, ¶¶38-39 (discussing EX2146 at 13, 36, 43, 75, 77-78; EX2145.020-022; EX1045, EX1067, EX1072. Sanofi used its Lantus franchise and years of marketing to drive SoloStar sales. EX1060, ¶¶48-51; EX1056, 69:9-70:10.

The economic evidence confirms that Lantus SoloStar's commercial performance is not driven by any feature unique to the SoloStar pen. EX1060, ¶¶30-35. The Lantus franchise growth rate had already stabilized before SoloStar's introduction. EX1060, ¶21. Attachment B-7:

Attachment B-7
Chart of Lantus Franchise Total Prescriptions by Year

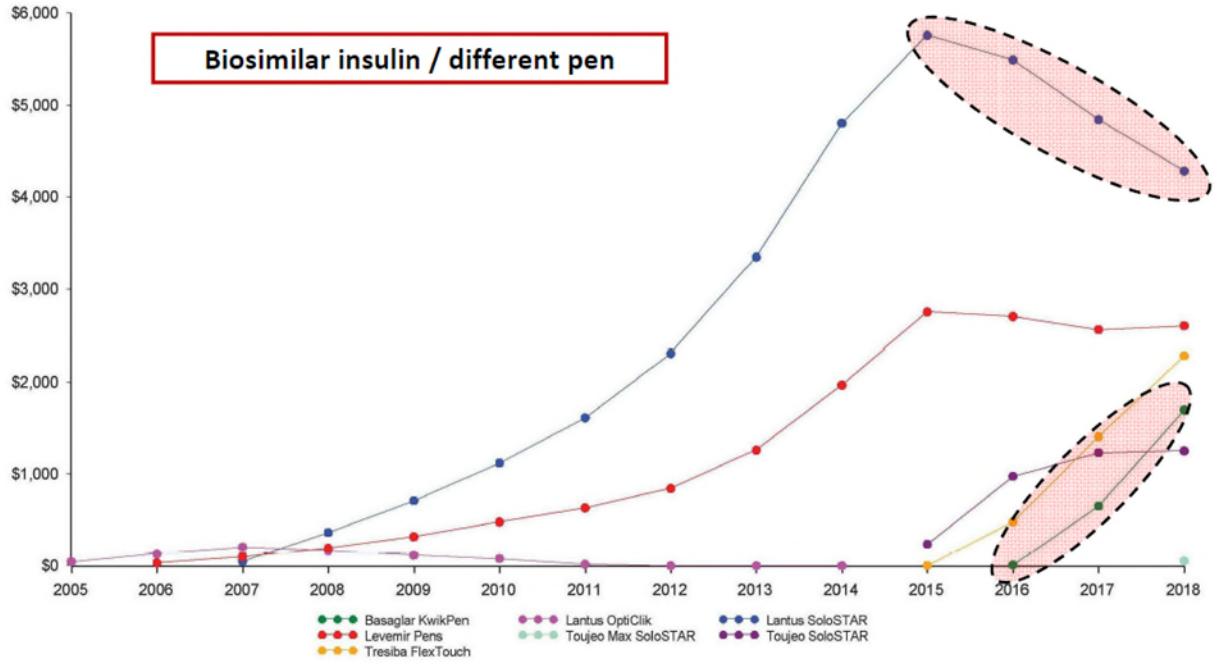


Changes in injector pens (FlexPen to FlexTouch) did not improve performance of Levemir, an existing long-acting insulin competitor to Lantus SoloStar. EX1060, ¶¶30-35, 64, Attachments B-3:

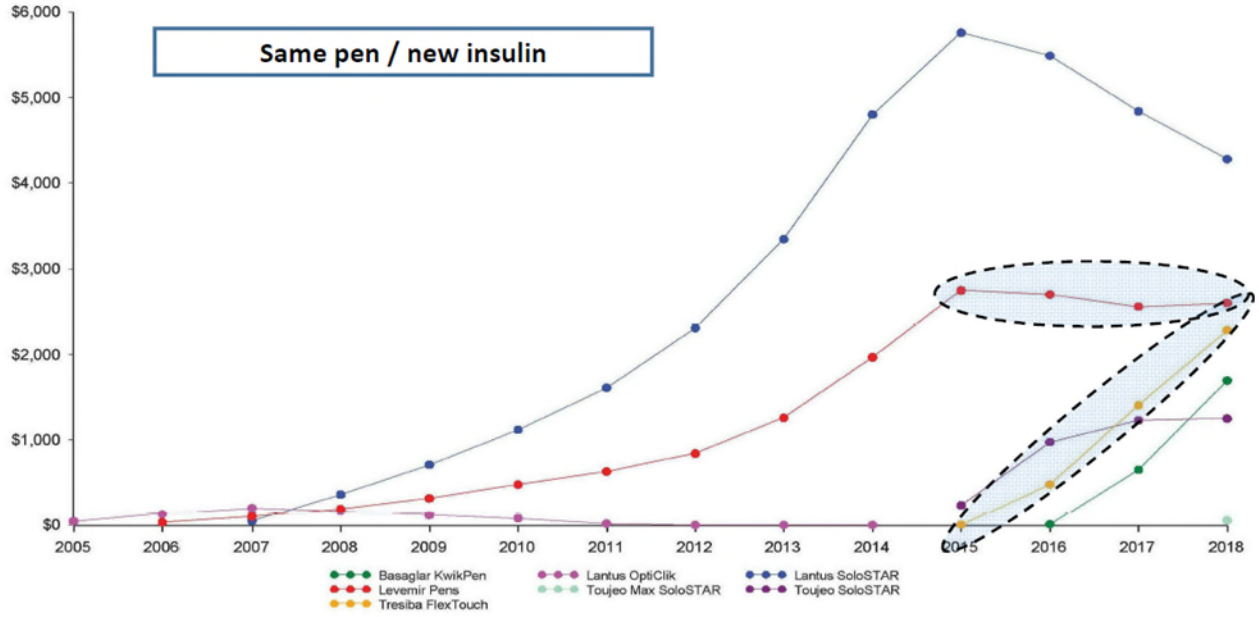


But introducing a competing long-acting insulin (Basaglar or Tresiba) in an existing pen (KwikPen or FlexTouch) had a dramatic impact. EX1060, ¶¶30-35, 64; EX1055, 96:13-20. Attachments B-2, B-4, B-6:

Attachment B-2
U.S. Dollar Sales of Long-Acting Pens (based on Ex. 2196): Comparison 1

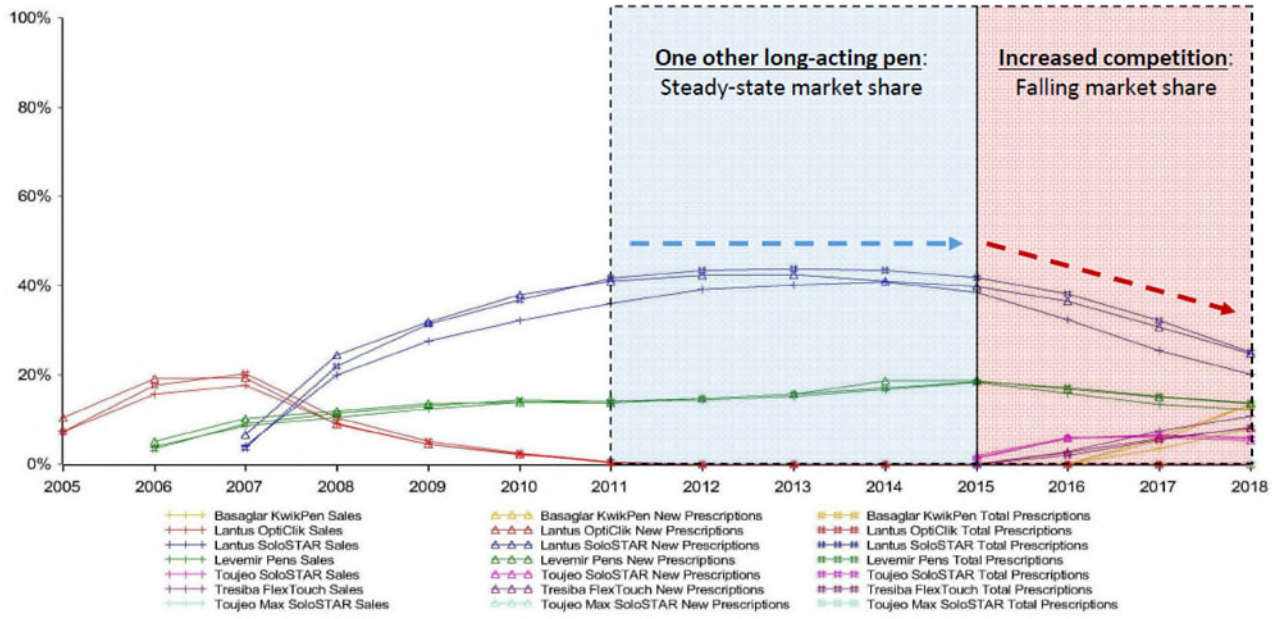


Attachment B-4
U.S. Dollar Sales of Long-Acting Pens (based on Ex. 2196): Comparison 3



Attachment B-6

U.S. Share of Long-Acting Pens Among All Pens (based on Ex. 2195)

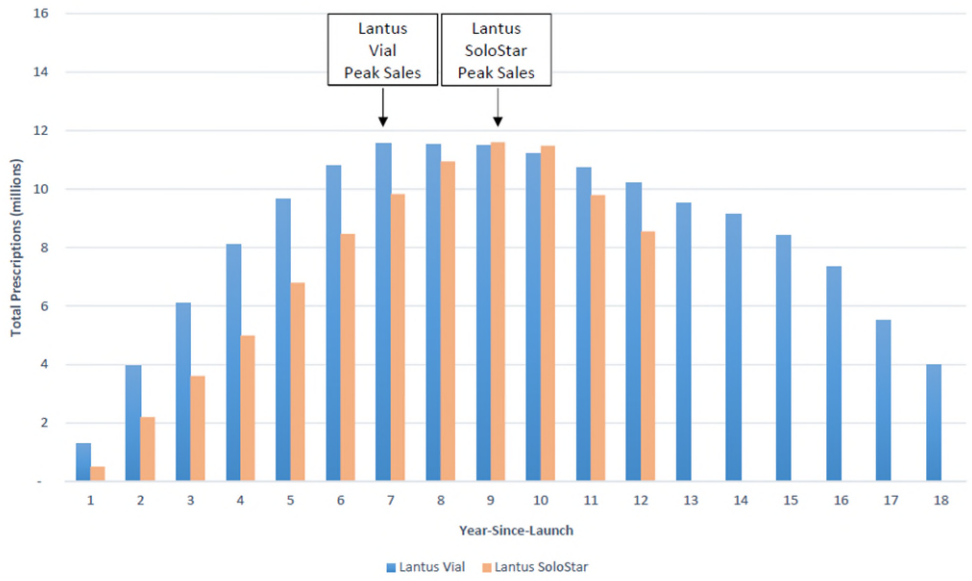


Neither the FlexTouch nor the KwikPen practice the challenged claims. EX1055, 86:20-87:6, 88:14-19, 103:18-104:6, 104:14-105:3-5. This economic evidence confirms Lantus SoloStar's commercial performance does not reflect demand for the SoloStar pen or for the challenged claims. EX1060, ¶35. That Lantus SoloStar's commercial performance is tied to the active ingredient covered by several blocking patents supports finding a lack of nexus to the alleged secondary considerations. EX1060, ¶¶30-35, 61-65.

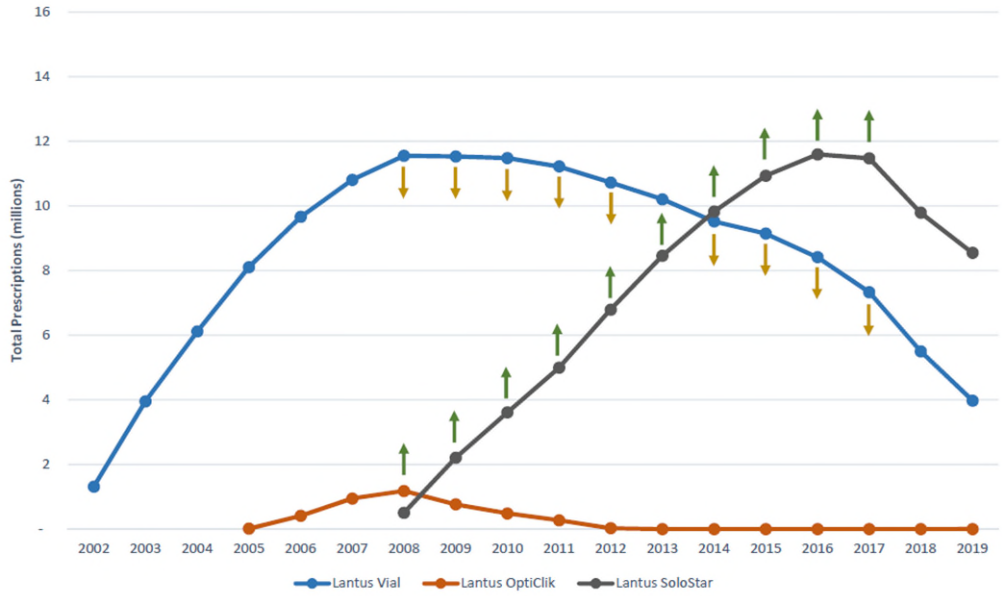
Sanofi contends that SoloSTAR replaced OptiClik because the claimed invention was superior. As explained above, however, SoloSTAR did not enhance Lantus sales, and Dr. Grabowski's testimony misrepresents the market and the data.

EX1060, ¶¶20, 25-27, 40-41. Attachments B-8, B-9 demonstrate that Sanofi merely shifted Lantus vial prescription to Lantus SoloStar prescriptions:

Attachment B-8
Chart of Lantus Vial and Lantus SoloStar Total Prescriptions by Year-Since-Launch



Attachment B-9
Chart of Lantus Product Total Prescriptions by Year



Sanofi's own documents confirm Sanofi pushed consumers of Lantus to use SoloSTAR instead of OptiClik, not any market preference for the claimed invention. EX1060, ¶¶46-47; EX2145.008 ("conversion strategy"), EX2145.0099 (OptiClik samples discontinued), EX2145.0099 ("limit competition between portfolio entities"), EX2145.010. Sanofi switched patients from OptiClik to SoloStar "in support of its business considerations." EX1055, 125:16-127:6. Sanofi's business decision to convert Lantus customers to SoloStar does not establish nexus, it undermines it.

Sanofi argues unclaimed properties provide nexus between SoloStar and the claims-at-issue. But as Mr. Leinsing testifies, the challenged claims are not essential for these unclaimed properties. EX1095, ¶¶154-56. Furthermore, these unclaimed properties do not drive Lantus SoloStar performance. EX1060, ¶¶52-56; *see also* EX1048, ¶¶25, 27-30.

Sanofi argues industry praise and recognition to support nexus, but these documents are either made or written by Sanofi affiliates, do not praise the pen itself as being "inventive," or do not attribute success to the properties Sanofi relies upon. EX2121 (Sanofi/DCA authored case study); EX2201 ("social good and for humanitarian concerns"); EX2109, ¶¶73-74; (aesthetics). There is no connection between the alleged "awards and praise" and the claims-at-issue. EX1060, ¶¶57-60.

Because of lack of nexus, none of the alleged secondary considerations can be attributed to the challenged claims.

A. No Long-Felt, Unmet Need for the Claimed Invention

Sanofi concedes that existing pens were used successfully to administer insulin analogs before SoloStar, but argues they were difficult to use because of a "relatively high injection force," that Lantus SoloStar "revolutionized the injection pen market, in large part because [it] was easy to use," and that patients preferred SoloStar for its low injection force. POR, 49-51. Although Sanofi's OptiClik was a uniquely bad pen, Sanofi's replacement SoloStar was not an unusually good pen. EX1048, ¶¶43. 49. Indeed, 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.

As Dr. Biggs testifies, "there was no long-felt unmet need for another insulin pen." EX1048, ¶39. In more than 30 years of practice, Dr. Goland never heard from a patient wishing they had a pen with low injection force, never saw using a syringe prevent a patient from taking Lantus, and never prescribed an insulin solely based on its pen. EX1056, 52:6-9, 71:4-16. In contrast to Sanofi-sponsored injection force studies, (EX2143.010; EX2144.010; EX2100.006; EX2126.004; EX2116.009; EX2123.007; EX1048, ¶58), other studies found SoloStar did not

have a lower injection force. *See, e.g.*, EX214.015 (versus FlexPen and Lillypen), EX2145.020-021 (NovoPen 4; Innlet).

Contrary to Sanofi's arguments, other insulin pens were already considered easy to use both generally and for patients with special challenges like age or dexterity issues. EX1048, ¶¶45-47, 52; EX1046.0057, .0062-.0063. Sanofi's studies confirm that both SoloStar and FlexPen were "very easy to use." EX2145.026; EX1060, ¶53; EX2143.001, EX2143.010, EX2143.070; EX2126.001. Sanofi's studies concluded both the SoloStar and FlexPen were suitable in both elderly and younger patients and those with visual and dexterity impairments, and "were associated with ***comparable usability***." EX2126.003 (emphasis added); EX1060, ¶56; EX2143.005, EX2143.009. SoloStar was a "best-performing pen device ***in a statistical tie with FlexPen***." EX2146.009; *see also id.* at .0037, .0039, .0075; EX1060, ¶52. SoloStar may have addressed Sanofi's business needs, but not any unmet patient needs. EX1048, ¶51.

Sanofi incorrectly contends that "injection force was a primary concern." POR 48. As Dr. Biggs explains, "injection force was never the reason patients were unwilling or unable to inject themselves," and patients who could not self-inject "would not have been aided by the marginal differences in injection force between FDA-approved injector pens." EX1048, ¶¶29-30; *see also* EX1060, ¶53 (discussing EX2146.037-040). The ease-of-use evidence discussed above confirms

any alleged difference in injection force was not material and there was no unmet need.

Sanofi cites post-SoloStar, Sanofi-funded, -authored, or -edited publications that do not demonstrate industry recognition of an unmet need. EX2128.009; EX2123.007; EX2185 (PR Newswire distribution of Sanofi press release). It also cites an article placed in the "Lifestyle" section of the "Philippine Daily Inquirer" under the url of "showbizandstyle" alongside stories like "Mesmerized by Harry Connick's blue eyes." EX2184.001; *see also* EX2184.003 ("Buy Content"). Moreover, statements in the article Sanofi misattributed to Sjoberg Kho appear to be from Sanofi's press release. *Compare* POR, 48 (citing EX2184.0001) *with* EX2185.001 ("self-injection can be a barrier"). These exhibits do not constitute "industry recognition"; they are Sanofi marketing.

B. No Industry Praise for the Claimed Invention

None of the cited documents establish industry praise for the claimed invention. For example, Sanofi relies on a "case study of SoloSTAR" submitted to the DBA, implying the DBA awards recognized SoloStar's "inventiveness" for allegedly combining "very low injection force" with "80 units maximum dose capability." POR, 50 (citing EX2121.003). But this "case study" was written, funded, and sponsored by Sanofi (with SoloStar designer DCA). EX1060, ¶¶57-58; EX1075. It is self-praise, not industry praise. EX1055, 79:6-81:19.

Sanofi relies on an Architecture and Design award as "recognition of [SoloStar's] inventiveness." POR, 50-51 (citing EX2201). The document Sanofi cites does not attribute the award to "inventiveness." Nor does the statement that SoloSTAR "represents a design for social good". POR, 50. Neither the document nor the statement praises what is claimed or the features (*e.g.*, low injection force) Sanofi argues uniquely flow from what is claimed. EX1060, ¶¶59-60.

Sanofi argues that Sanofi and DCA were finalists for the Prix Galien USA 2009 Award but again fails to demonstrate this is evidence that SoloStar was "inventive," much less that the claims were inventive. EX1060, ¶60. Sanofi's proffered evidence fails to establish that industry praise supports the challenged claims.

C. No Commercial Success for the Claimed Invention

Sanofi argues that Lantus SoloSTAR enjoyed fast and long-sustained growth in terms of overall levels and shares of dollar sales, new prescriptions, total prescriptions, as well as profitability and formulary placement. POR, 51-52 (citing EX2109, ¶12). But Dr. Grabowski never evaluated profitability. EX1060, ¶¶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. EX1060, ¶¶17-22, 25-28.

For example, Dr. Grabowski relies on a misleading 8,000% growth rate for SoloStar when, as Dr. McDuff points out, the failed OptiClik pen similarly enjoyed an 8,000% growth rate in its first three years. EX1060, ¶20. Similarly, Dr. Grabowski argues Lantus SoloStar's commercial success is supported by the "strong performance" of Apidra SoloStar, Toujeo SoloStar, and Admelog SoloStar, even though peak annual sales of Apidra SoloStar and Admelog SoloStar fall below the sales of Lantus OptiClik that he describes as "deficient." EX1060, ¶¶70-71. Sanofi also inappropriately excluded insulin injectable products from its market share analyses to inflate Lantus SoloStar's market share 2-3 times. EX1060, ¶¶25-27. Sanofi's commercial success arguments thus improperly take Lantus SoloStar's commercial performance out of context.

Sanofi argues that Lantus SoloStar sales and prescriptions remained strong despite the entry of several competing long-acting insulin pen products beginning in 2015. POR, 52. However, introduction of competing Basaglar and Tresiba long-acting insulin products completely changed the trajectory of both the Lantus and Toujeo SoloStar products without practicing the claims-at-issue. EX1060, ¶¶30-35, 64; EX1055, 96:13-20. Dr. Grabowski himself previously explained that generic entry of a biologic is expected to have less and a slower impact on the sales of the existing biologic than it would have for a small molecule because of biologics' increased manufacturing costs. EX1055, 143:10-144:10. Dr. Goland confirmed

that existing diabetes patients are particularly reluctant to switch to a different insulin product. EX1056, 71:17-22. The change in trajectory for Lantus and Toujeo SoloStar product performance upon introduction of competing long-acting insulins provides strong evidence that SoloStar itself is not a commercial success.

Sanofi argues Lantus SoloStar overtook Levemir FlexPen and Lantus OptiClik despite launching later. POR, 52-53. But Levemir launched almost five years after Lantus, and the first Levemir pen (FlexPen) launched more than a year after the first Lantus pen (OptiClik). EX2186.002. Lantus 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 of what it shared in common with OptiClik: Sanofi selected it as the exclusive Lantus pen in the United States. EX1060, ¶¶20-22, 30-35.

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

VI. CONCLUSION

The challenged claims are unpatentable and should be canceled.

Date: 18 September 2019

Respectfully submitted,

/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 4438, which is less than the 5,600 words allowed under 37 CFR §42.24(a)(i).

Date: 18 September 2019

Respectfully submitted,

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

CERTIFICATE OF SERVICE

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

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

Date: 18 September 2019

Respectfully submitted,

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