

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 IPR2018-01679
Patent No. 8,992,486

PETITIONERS' REPLY TO PATENT OWNER RESPONSE

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I. INTRODUCTION

Of the seven claims challenged in the petition, Sanofi focuses its response on just one claim, dependent claim 56, which specifies that the clutch of claim 51 further includes “a plurality of axially extending teeth formed in an interior of a flange of said clutch.” Faced with prior art clutches that satisfy the plain and ordinary meaning of this limitation, Sanofi attempts to rewrite claim 56, insisting that teeth “formed in an interior of a flange” must be located “at the inner diameter” and cannot be formed on the proximal (button-end) or distal (needle-end) surface of the flange.

Sanofi’s justifications for this construction do not withstand scrutiny. While Sanofi and its expert, Dr. Slocum, contend that the ’486 patent’s sole embodiment shows this configuration, the disclosed embodiment is facially inconsistent with Sanofi’s proposed construction. Indeed, Sanofi’s *own* evidence, as well as Dr. Slocum’s admissions during cross-examination, confirm that Sanofi’s proposed construction is inconsistent with the specification.

Confronted with this fact during Dr. Slocum’s cross-examination, Sanofi attempted to advance a new theory during redirect. However, Sanofi’s attempt to guide Dr. Slocum to a brand-new justification for the proposed construction strays

even further from the proper claim construction inquiry, contradicts Sanofi's original position, and further undermines Dr. Slocum's credibility.

II. SANOFI DOES NOT DISPUTE THE UNPATENTABILITY OF CLAIMS 51-55 AND 57

Sanofi only addresses claim 56 as challenged in Grounds 3-4 and 6. *See* Paper 23 ("Response"), sections I, VII. For Grounds 1-3 and 5-7, Sanofi does not dispute the unpatentability of claims 51-55 and 57. Accordingly, there is no dispute that claims 51-55 and 57 are unpatentable and should be cancelled.

III. SANOFI'S PROPOSED CONSTRUCTION IS UNREASONABLY NARROW

Sanofi's first defends claim 56 by construing "an interior of a flange" to mean "at the inner diameter of the flange" and not "at the outer diameter of a flange (*i.e.*, the exterior), the side of the flange directed towards the needle-end of the device (*i.e.*, distal end or side), or the portion of the flange directed towards the button-end of the device (*i.e.*, proximal end or side)." *Id.*, 8. Sanofi urges its construction is consistent with the '486 patent specification, which allegedly describes axially-extending dog-teeth 65 formed at an inner diameter of flange 62. *Id.*, 9.

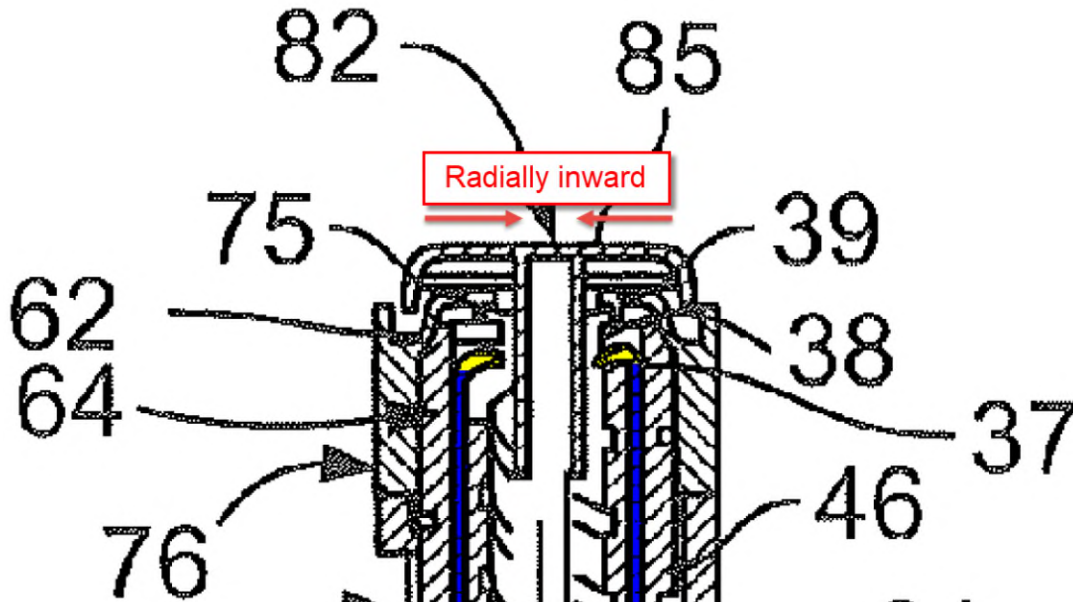
As detailed below, Sanofi's construction is unreasonably narrow and is inconsistent with the specification. Indeed, Sanofi's construction would read out

the sole embodiment disclosed in the specification. Dr. Slocum's admissions during cross-examination regarding the location of dog-teeth 65 relative to flange 62, as well Sanofi's own evidence, make clear that Sanofi's basis for its proposed construction is incorrect. *E.g.*, EX1052, 3; EX1053. Sanofi apparently recognized the problem during Dr. Slocum's cross-examination, because the questioning during redirect pivoted to a new—and equally incorrect—theory to rescue Sanofi's proposed construction. EX1054, 397:15-404:19. Guided by Sanofi counsel, Dr. Slocum contradicted his previous testimony that a protrusion in FIG. 8 was part of the drive sleeve or piston rod, alleging now that it was a "tangus" on the clutch's flange. *Id.* While this last-minute, unbriefed new theory has been waived, both Sanofi's original and new theories do not withstand scrutiny.

A. Sanofi's proposed construction

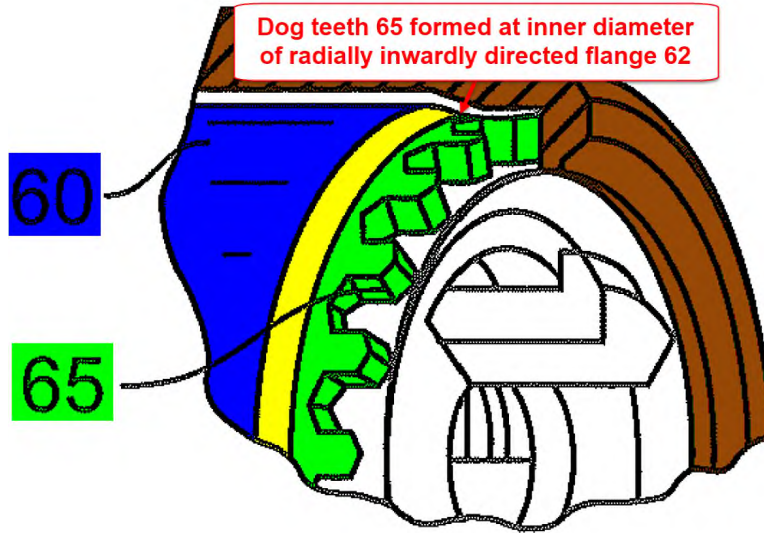
Relying on the testimony of its expert, Dr. Slocum, Sanofi contends that the '486 patent depicts, in its sole embodiment, "a plurality of axially extending teeth" formed "at the inner diameter of a flange." *See id.*, 9; EX2107, ¶124.

Sanofi specifically points to "radially inwardly directed flange 62" as corresponding to the flange of claim 56, which, as shown in Sanofi's annotated FIG. 1 (reproduced below), forms the top, or button-end, portion (yellow) of clutch 60 (blue).



Paper 23, 9; EX2107, ¶124.

Sanofi acknowledges that dog teeth 65 correspond to the plurality of axially-extending teeth recited in claim 56. Paper 23, 9-10; EX2107, ¶124; *see also* EX1053, 163:8-19 (confirming dog teeth 65 “correspond to” teeth of claim 56). Relying on its annotated FIG. 8 (reproduced below, showing a partial, cut-away view of FIG. 1), Sanofi then argues that the figure shows dog teeth 65 (light green) as being formed “at the inner diameter, or along the inner circumference,” of flange 62 (yellow). EX2107, ¶124; *see also* Paper 23, 9-10 (“Notably, these dog teeth, which are formed at the button end of the clutch 60, are formed at the inner diameter of the flange 62 and not at the outer diameter, the proximal (button end) side, or the distal (needle end) side of the flange 62.”).



Paper 23, 10; EX2107, ¶124.

During cross-examination, Dr. Slocum confirmed his understanding that flange 62 is the top portion of the clutch in FIG. 1, which he annotated yellow, and that the yellow portion of FIG. 8 is that same flange. EX1053, 158:11-19 (confirming top annotated yellow portion of annotated FIG. 1 forms flange 62); *id.*, 161:14-162:2 (confirming yellow portion of annotated FIG. 8 is the same flange identified in FIG. 1). He also resolved any ambiguity regarding his view about the location of the “inner diameter” of flange 62 (and therefore the purported location of dog teeth 65) by marking that position on his annotated version of FIG. 1. *Id.*, 164:16-165:16. Juxtaposed enlargements of Dr. Slocum’s marking of the flange’s inner diameter and the original version appear below:



EX2107, ¶124 (left); EX1050 at 4 (right); *see* EX1095, ¶20.

Thus, according to Sanofi and Dr. Slocum, the '486 patent allegedly depicts dog teeth 65 formed at the above location on flange 62, which provides the basis for limiting claim 56 to clutches having teeth formed “at the inner diameter” of a flange and not on the “needle side” or “button side” of the flange. As explained below, numerous pieces of evidence show that this characterization of dog teeth 65 is completely wrong.

B. Sanofi’s construction is inconsistent with the specification

Sanofi’s error begins with Dr. Slocum’s misidentification of flange 62 (yellow) in FIG. 8. Crucially, his coloring omits the portion of flange 62 extending

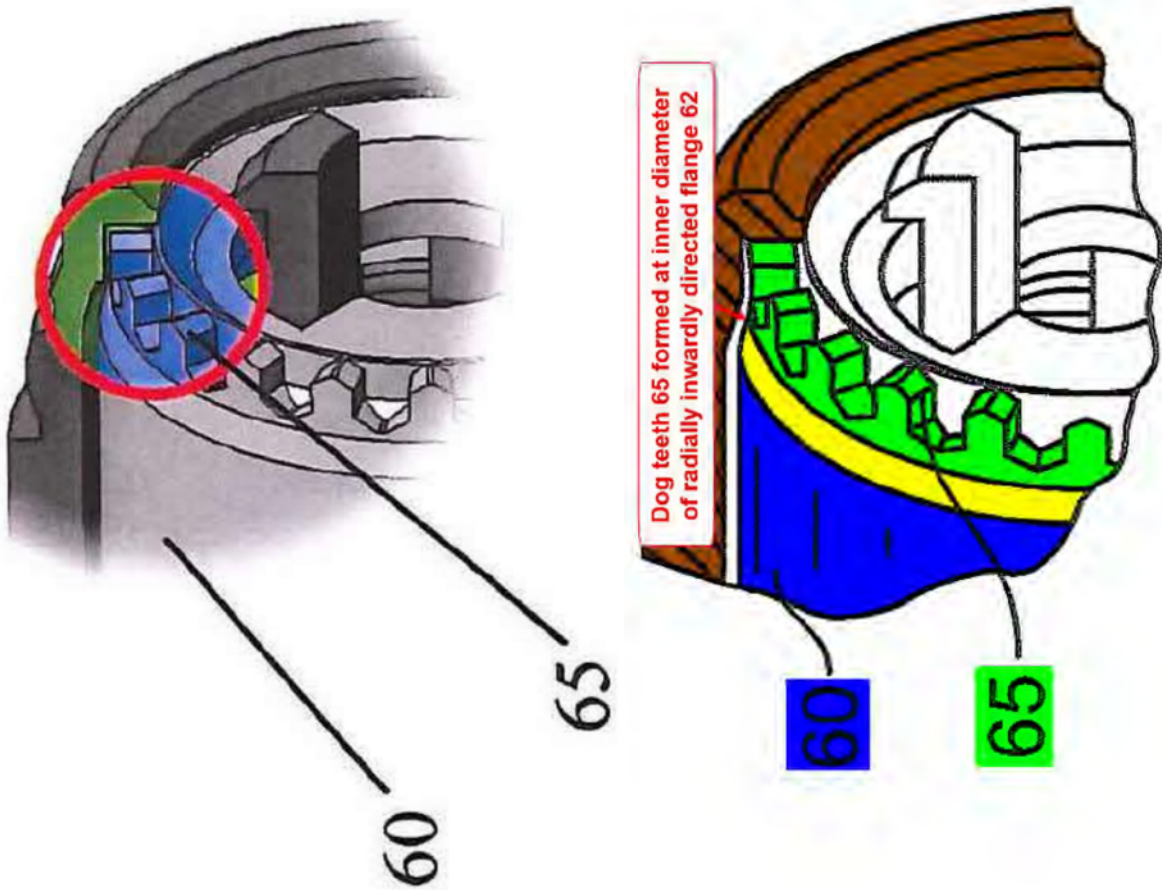
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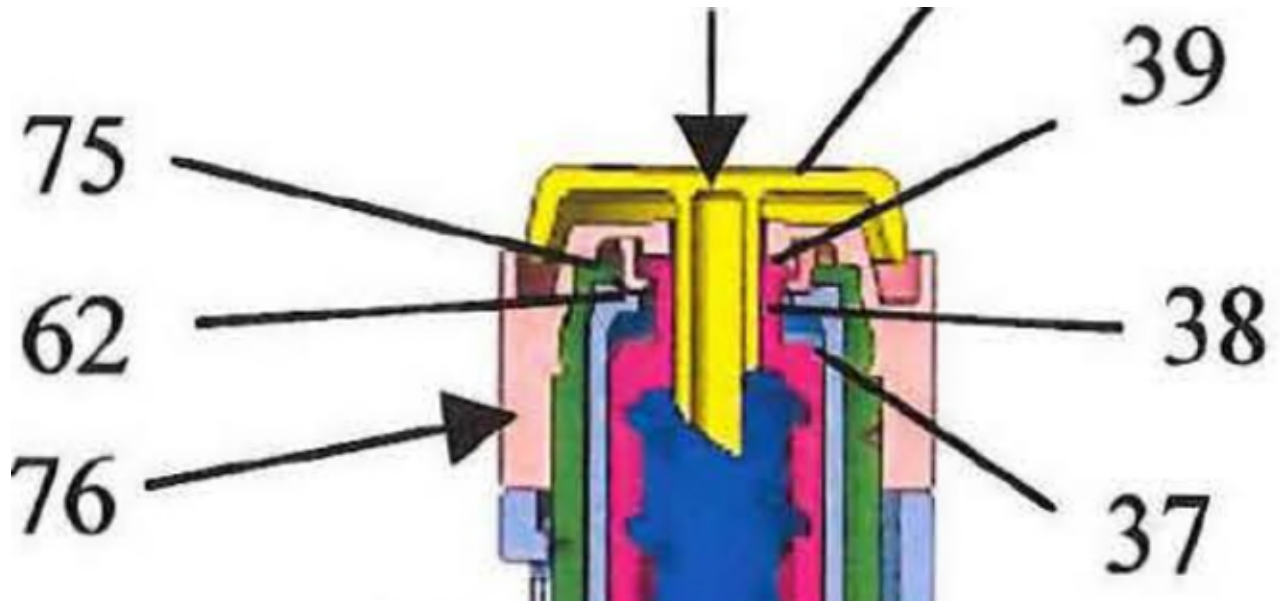
radially inward beyond dog teeth 65, which leads him to incorrectly characterize the position of the teeth on the flange. EX1095, ¶¶18-24.

This error can be seen in the juxtaposition below comparing Dr. Slocum's coloring of FIG. 8 to the original coloring of FIG. 8 of EX2157¹ (rotated for clarity):

¹ Sanofi represents that EX2157 is a copy of the GB application as submitted to the UK patent office. EX2157.002; EX1053, 106:13-107:15. While photocopying appears to have removed the coloring from in the published version of the GB application (EX1026), Dr. Slocum acknowledged that EX2157's disclosure has the same content as the challenged patents. *Id.*, 138:18-23.

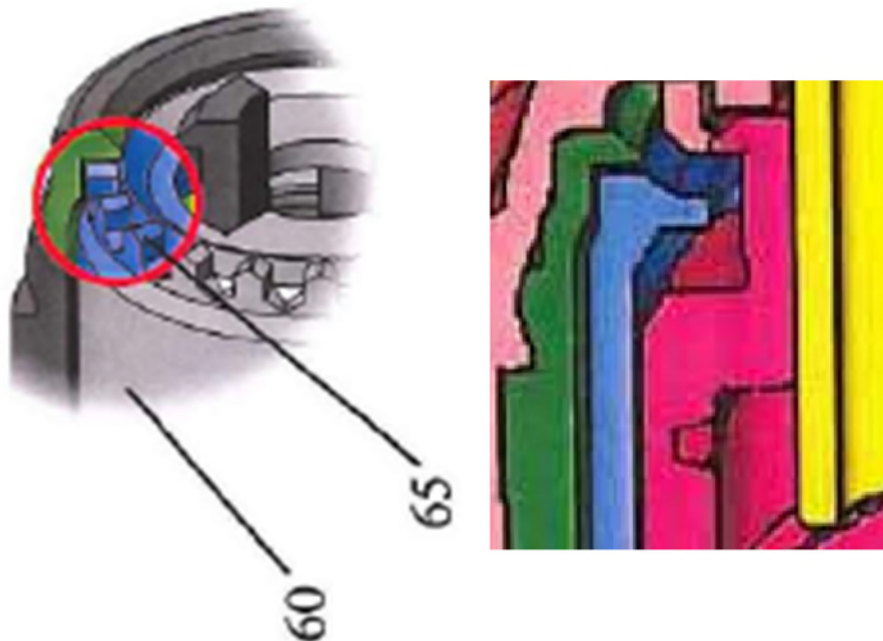


EX2157, FIG. 8 (left); EX2107, ¶124 (right) (rotated). EX2157 depicts the clutch as blue in all figures (EX2157, FIGS. 1-5, 7-11), making clear that the blue inner ring in FIG. 8 is part of the clutch. That this inner ring is in fact part of flange 62 is unmistakable in view of FIG. 1:



EX2157, FIG. 1 (partial view); *see also* EX1026, FIG. 1.

A comparison of FIG. 8 with the other figures also makes Sanofi's mistake apparent. To illustrate, FIG. 8 (rotated, left) is shown next to the corresponding portion of FIG. 11:



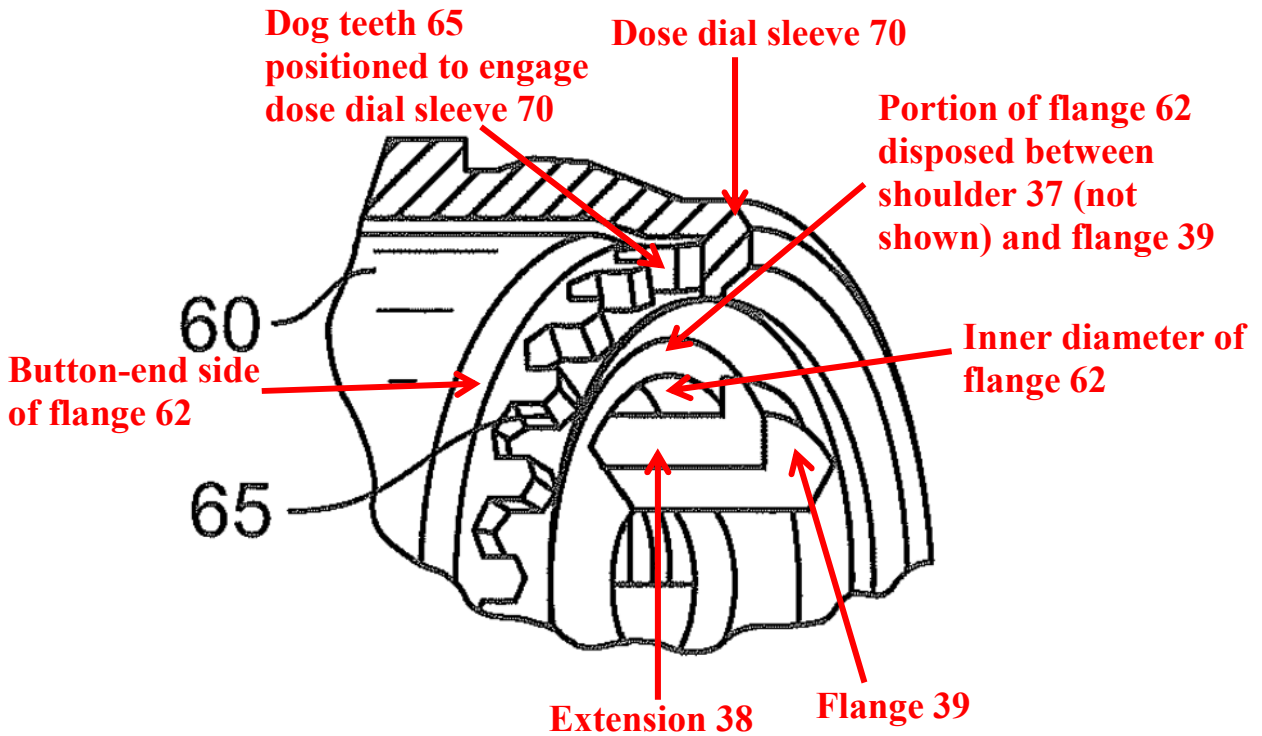
See EX1095, ¶27. As seen above, the top portion of the dose-dial sleeve (green) curls over the top of the clutch (blue) to engage the dog teeth from above.

EX1095, ¶27. These figures show that if, as Sanofi argues, dog teeth 65 are formed at the inner diameter of flange 62, the teeth *would not engage* dose dial sleeve 70. EX1095, ¶27; EX1050, ¶124 (annotating inner diameter of flange 62). Such a configuration would negate the entire purpose of dog teeth 65.

The '486 patent's description of flange 62 confirms that, contrary to Sanofi's position, dog teeth 65 are formed on the *button side* of flange 62, which extends radially inward beyond the teeth, *not* at the inner diameter of the flange. EX1095, ¶28. The specification explains that drive sleeve 30 includes a shoulder 37 "formed between a second end [*i.e.*, button-end] of the drive sleeve 30 and an extension 38 provided at the second end of the drive sleeve 30." EX1003, 4:27-29; *see also id.*, FIG. 1. "[E]xtension 38 has reduced inner and outer diameters in comparison to the remainder of the drive sleeve 30," and at its button-end, "a radially outwardly directed flange 39" is provided. *Id.*, 4:29-32. Flange 62 "is disposed between the shoulder 37 ... and the radially outwardly directed flange 39 of the extension 38." *Id.*, 4:55-58. In addition, dog teeth 65 are configured to "to engage with a second end [*i.e.*, button-end] of" dose dial sleeve 70, which, as shown in the figures, is positioned radially outward relative to clutch 60, which

itself is, in turn, positioned radially outward relative to the drive sleeve 30. *See id.*, 2:17-19, 4:33-35, 6:29-31, 5:3-5, FIGS. 1, 9-11; *see also* EX1011, ¶¶38-39 (annotating components shown in FIGS. 1-2).

Mr. Leinsing explains that the description above would have informed the POSA of two aspects regarding the relative positions of dog teeth 65 and flange 62: (1) dog teeth 65 must be positioned sufficiently outward so that they can engage the radially-outward dose dial sleeve 70; and (2) flange 62 must extend sufficiently inward so that it can be disposed between the radially-inward shoulder 37 and flange 39 of drive sleeve 30. EX1095, ¶23. In view of this, when considering FIG. 8 of the '486 patent, a POSA would have understood that, contrary to Sanofi's annotations, flange 62 extends radially inward beyond dog teeth 65, as shown in the annotated figure below, such that dog teeth 65 are formed on the flange's *button-end side* rather than at its inner diameter:



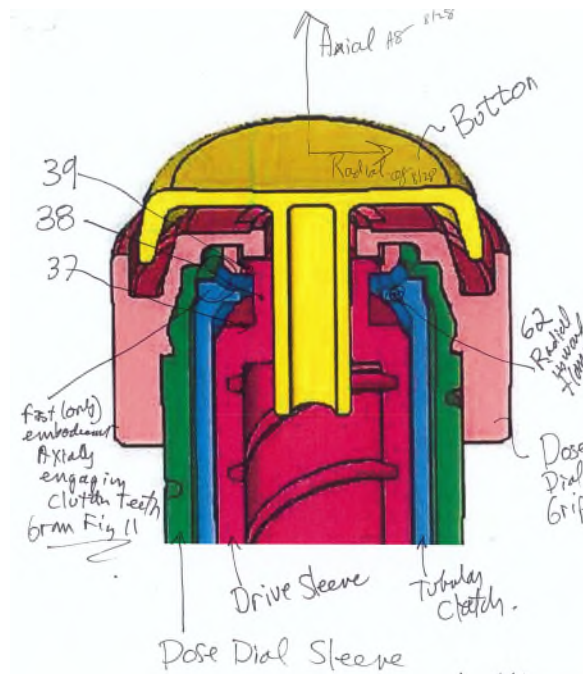
EX1095, ¶23. Indeed, while Dr. Slocum subsequently changed his testimony on this issue, he initially agreed that flange 62 is “disposed between” shoulder 37 and flange 39 of drive sleeve 30 and that the “projection” shown in FIG. 8 is part of the drive sleeve. EX1053, 147:20-149:20; *see also id.*, 169:13-170:11 (“...So essentially between 39 and 37 you are capturing flange 62”).

The evidence thus shows that Sanofi’s narrow construction not only lacks support in the specification but is flatly contradicted by it.

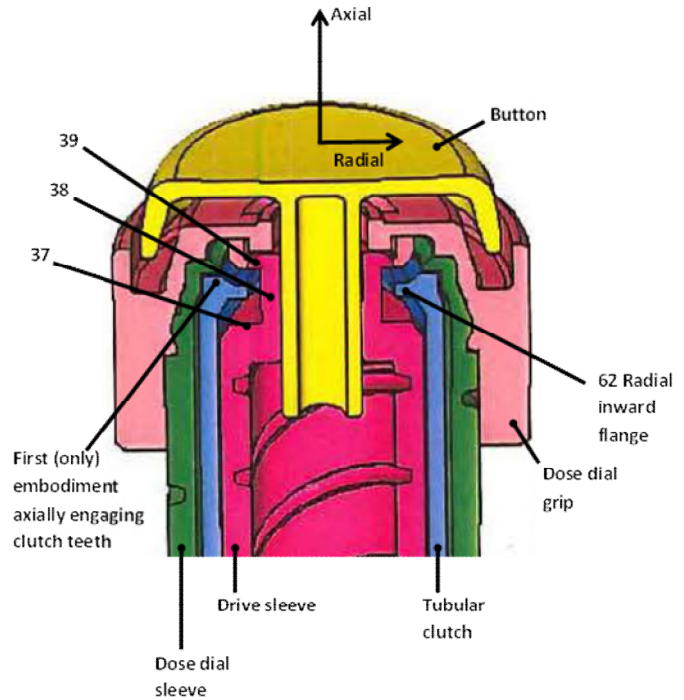
C. Dr. Slocum’s testimony and Sanofi’s evidence confirms that dog teeth 65 are not formed at the inner diameter of flange 62

Sanofi’s position is further undermined by Dr. Slocum’s admissions, not to mention the evidence *Sanofi itself* submitted with its response.

During cross-examination, Dr. Slocum identified locations of dog teeth 65 and flange 62 that contradicted his declaration testimony. He initially maintained that his coloring of flange 62 in FIG. 8, shown at paragraph 124 of his declaration, was accurate and that the inner lip shown in blue in EX2157, FIG. 8 was not part of flange 62. EX1053, 166:22-168:20 and 173:3-20 (flange located radially inward of dog teeth 65 in FIG. 8 is blue because it is “smeared”). However, when asked to label flange 62 and dog teeth 65 on an enlarged image of FIG. 11 as shown in EX2157—a document Dr. Slocum identified as showing the *same embodiment* as the ’486 patent (*id.*, 228:9-15)—Dr. Slocum correctly identified dog teeth 65 as being formed on the *button* side of the flange, *not* at the inner diameter of flange 62. *Id.*, 181:4-182:17, 186:21-189:23, 191:21-193:4. Dr. Slocum’s original annotations are shown below (left) along with a clearer reproduction of those annotations (right).



EX1052, 3



EX1095, ¶28

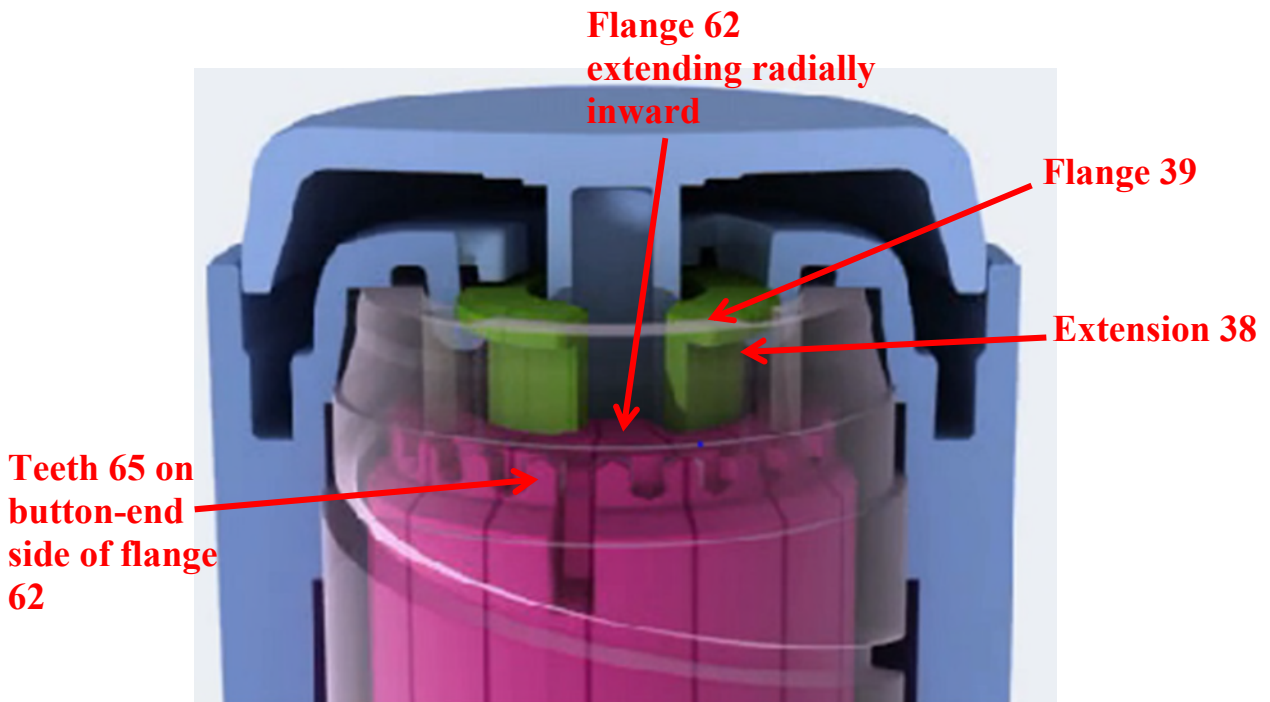
These annotations contradict Sanofi's position, as well as Dr. Slocum's previous testimony, that dog teeth 65 are formed at the inner diameter of flange 62 and not on the button side or needle side of flange 62. These admissions confirm that Dr. Slocum's claim-construction testimony (EX2107, ¶¶123-28) and his corresponding analysis of the applied references (*id.*, ¶¶334-54) should be given little to no weight.

Sanofi's claim-construction arguments are further undermined by the animations Sanofi submitted to demonstrate the structure and operation of the disclosed pen. The animation in EX2117 shows that the clutch's teeth

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are not formed at the inner diameter of flange 62. As shown in the annotated screenshot below, Sanofi's depiction of the clutch shows that the dog teeth are formed on the button side of the flange, with the flange extending radially inward so that it is disposed between the drive sleeve's shoulder and flange. See EX2117 (animating solid components shown in FIG. 9 of challenged patents; showing drive sleeve in green and clutch in red); EX2107, ¶65 (Dr. Slocum stating that animation "fairly and accurate[ly] shows" the pen embodiment described in the challenged patents).



EX1095, ¶29 (annotated screenshot of EX2117 captured at 2:30). Sanofi's proposed construction is thus inconsistent with the specification, the

admissions of Sanofi's expert during cross-examination, and the evidence that Sanofi itself submitted with its response.

D. Sanofi incorrectly characterizes Mr. Leinsing's testimony

Contrary to Sanofi's claim, Mr. Leinsing did not "agree[] that the inner diameter of a circular flange would be the interior of the flange...." POR, 13-15; *See also* EX2107, ¶127. During his deposition, Mr. Leinsing answered questions about which of four pre-labeled "sides" or "surfaces" would be proximal, distal, interior, and exterior. EX2163, 151:18-159:6; EX2107, ¶127 ("Mr. Leinsing was asked to identify the **sides** of the disk-shaped flanges drawn in Exhibit 2102...." (emphasis added)). Claim 56, however, refers to teeth formed "in an interior of a flange", not teeth formed "on an interior side" or "on an interior surface" of a flange. Dr. Slocum characterizes Mr. Leinsing as testifying that "side (C) is the interior of the disk-shaped flange" in figures 1 and 3 of EX2102 and that "side (C) could be considered the interior of the flange" for figures 2 and 4. EX2107, ¶127. Sanofi's sleight of hand attempts to equate interior "sides" or "surfaces" of a flange (which Mr. Leinsing addressed in his answers) with "an interior" of a flange. These are not equivalent. EX1095, ¶30. Mr. Leinsing's comments on EX2102 are thus irrelevant to the construction of claim 56.

E. Sanofi's new theory is untimely and incorrect

As explained above, Dr. Slocum's annotation of flange 62 and dog teeth 65 (see EX1052) flatly contradicted his declaration testimony that dog teeth 65 are located at the inner diameter of flange 62 and not on the flange's button end. During redirect, Sanofi's counsel appeared to guide Dr. Slocum toward a new (though also incorrect) theory to support Sanofi's proposed construction. EX1054, 397:15-404:19.

First, Dr. Slocum's shifting testimony regarding the identity of this so-called "tangus" further undermines his credibility on this subject matter. Dr. Slocum initially acknowledged during cross-examination that the central projection (later called a tangus) shown in FIG. 8 extending beyond the top of clutch 60 was extension 38 and flange 39 of the drive sleeve. *Id.*, 147:20-149:18. He later claimed to have misspoken, now thinking that it was a protrusion of the piston rod, though he was "not really sure now what that little tangus looking thing is." *Id.*, 170:22-171:10. He then changed his testimony again, claiming that he was "not sure what that hook is now" before returning to his previous position that it was "pretty clearly...an extension of the piston rod." *Id.*, 177:25-179:10. Finally, after prompting from Sanofi's counsel during redirect, he changed his testimony yet again to state that this component was not part the drive sleeve, not part of the

piston rod, but actually part of the clutch itself. *Id.*, 392:19-398:18. His new opinion is that the gray projection is a “tangus” of the clutch that interacts with the button during disengagement, despite the fact that no such component is ever described or even mentioned in the ’486 patent. *See id.*, 397:15-398:18.

Sanofi’s counsel then prompted Dr. Slocum to develop his understanding of the supposed “tangus” by having him reference images of *SoloSTAR components*. *Id.*, 398:19-404:19 (referencing images of SoloSTAR components in EX2107, ¶¶450-51). Those images are not part of the ’486 specification, nor has Sanofi shown that the images were publicly available at the relevant time period. The numerous structural differences between the depicted SoloSTAR clutch and the clutch of the ’486 patent further demonstrate the inappropriateness of using this image to interpret what is disclosed in the ’486 patent. EX1095, ¶31. Sanofi’s counsel then led Dr. Slocum to develop his understanding of this “tangus” as corresponding to the teeth recited in claim 56 by referencing his “physical examination of the SoloSTAR”. EX1054, 401:4-404:19. The POSA interprets claim 56 in view of *the specification*, not in view of a later commercial product (SoloSTAR documents and SoloSTAR devices).

At a minimum, Dr. Slocum’s pivot to an entirely new theory implies that Sanofi’s proffered claim construction was originally based on an incorrect reading

of the '486 patent. The mistake became apparent when, addressing Sanofi's new theory, Dr. Slocum agreed with Sanofi's counsel that the newly-dubbed "tangus" in FIG. 8 was located on the clutch's flange—i.e. *the very same flange he previously denied was part of the clutch* when focusing on dog teeth 65. EX1054, 404:10-19. Dr. Slocum's opinions regarding claim 56 should thus be given little or no weight in view of the contradictory, shifting nature of his testimony on these issues. Dr. Slocum's express use of SoloSTAR materials as the basis for his latest interpretation of FIG. 8 further demonstrates that his redirect testimony should be given little or no weight.

Regardless, Sanofi's new position is not supported by the '486 patent or any other relevant evidence. Neither the '486 patent nor the as-filed GB priority application describes clutch 60 as having a "tangus" or similar structure for interacting with button 82. EX1095, ¶31. Sanofi's animation of the pen embodiment shown in the patents similarly shows no tangus axially extending from the clutch. *See* EX2117. As made clear by Sanofi's redirect, Sanofi's "tangus" theory comes from the ***SoloSTAR product***, not the specification. EX1054, 397:15-404:19, 409:9-410:3. Sanofi's last-minute attempt to rescue its proposed construction exposes its construction for what it is: an unsupported, unreasonably narrow construction based not on the plain language of the claim or

on the specification, but on the desire to evade prior art that closely resembles the sole embodiment disclosed in the '486 specification.

IV. DR. SLOCUM'S TESTIMONY IN SUPPORT OF SANOFI'S PROPOSED CONSTRUCTION SHOULD BE ACCORDED LITTLE OR NO WEIGHT

As explained above, Dr. Slocum's testimony regarding claim 56 is inconsistent with the relevant evidence, has repeatedly and meaningfully changed, and is improperly based on references to a commercial product that would not have been publicly available at the relevant time, let alone part of the specification. As explained above, and as shown in Dr. Slocum's subsequent admissions during cross-examination, his original declaration testimony relies on an incorrect assessment of the '486 patent's disclosure. *Supra*, section III.B.

Dr. Slocum's repeatedly changing testimony regarding the very figures he presented in support of his original opinion further undermines his credibility on these issues. *Supra*, sections III.B-C, E. Lastly, Dr. Slocum's "tangus" testimony is based on leading questions and reference to a SoloSTAR document and a physical SoloSTAR pen, neither of which is part of the specification. *Supra*, section III.E. These serious problems fatally undermine the reliability of Dr. Slocum's testimony regarding the proper construction of claim 56. Accordingly, his testimony should be accorded little to no weight.

V. THE PRIOR ART TAUGHT A CLUTCH AS RECITED IN CLAIM 56

As explained below, under the correct interpretation of the phrase “an interior of a flange,” a POSA would have understood both Steinfeldt-Jensen and Møller as disclosing a clutch that includes “a plurality of axially extending teeth formed in an interior of a flange” of the clutch as recited in claim 56.

A. Grounds 3-4: Steinfeldt-Jensen

Sanofi does not dispute that Steinfeldt-Jensen discloses or suggests a clutch having axially-extending teeth formed on a flange. *See* Paper 23, 23-27. Sanofi argues only that those teeth are not formed “at the inner diameter” of that flange, only on its distal (or needle-end) side. *See* EX2107, ¶344 (acknowledging POSA “would have understood that the rosette of teeth 93 are formed on the distal-side of the flange 83”). As explained above, this argument is based on a flawed interpretation of claim 56. *Supra*, section III.

Under the appropriate construction, Steinfeldt-Jensen anticipated and rendered claim 56 obvious. *Pet.*, 42-43 (anticipation), 46 (obviousness); *In re Paulsen*, 30 F.3d 1475, 1481 (Fed. Cir. 1994) (anticipation can subsume obviousness). Steinfeldt-Jensen discloses forming axially-extending teeth on a flange in a position that is substantially similar to what is described by the ’486 patent (i.e. radially inward of the flange’s outermost diameter). EX1095, ¶90.

Even in Sanofi's annotated figures, flange 83 extends inwardly past teeth 93, with teeth 93 being formed on the flange's needle-end side radially inward of its outer diameter. *See* Paper 23, 24-25. Mr. Leinsing explains that this location of the teeth satisfies the plain and ordinary meaning of teeth "formed in an interior of a flange". EX1095, ¶90.

Claim 56 is thus unpatentable in view of Steinfeldt-Jensen.

B. Ground 6: Møller

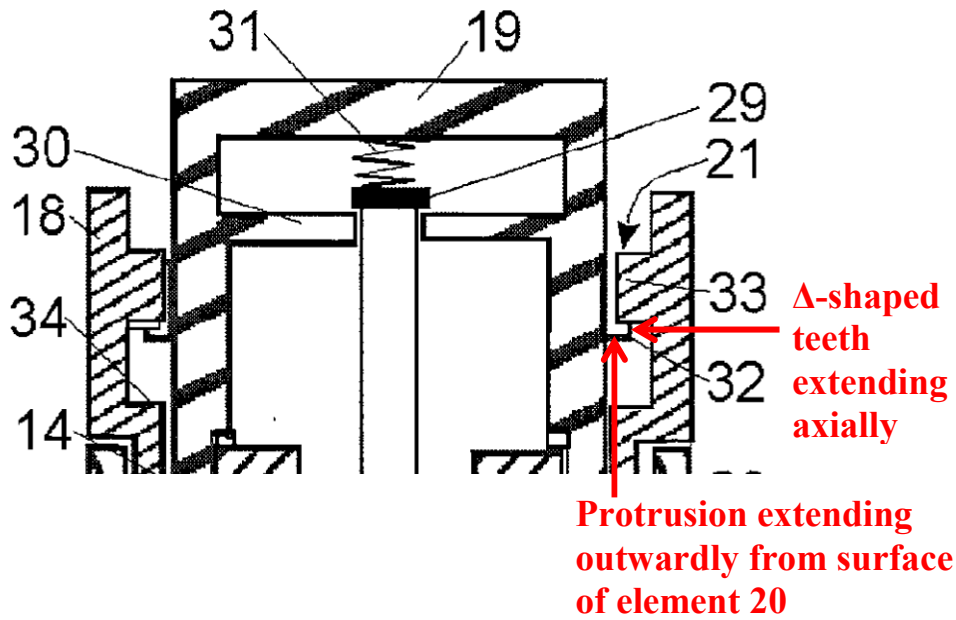
For Ground 6, Sanofi argues that Møller's first embodiment fails to disclose a flange from which Δ -shaped protrusions 32 axially extend. Paper 23, 27 (citing EX2107, ¶351). For the second embodiment, Sanofi contends that what Petitioners identify as a flange "is nothing more than the end of elongated tubular element 120," and, even accepting that tubular element 120 contains such a flange, teeth 132 are formed on its button-end side. Paper 23, 28-29 (citing EX2107, ¶¶352-53).

As the petition explained, Møller discloses, in a first embodiment, a cup-shaped element 20 (*i.e.*, a clutch) having a plurality of axially-extending teeth in the form of Δ -shaped protrusions 32. Paper 2, 58-60 (citing EX1015, ¶29; EX1011, ¶¶527-29). While the figures depicting the first embodiment are merely schematics showing the general structure of the device, Mr. Leinsing explained that Møller's second embodiment further informs the structure of the Δ -shaped

protrusions of the first embodiment. *See* EX1011, ¶527 (citing EX1015, ¶¶35-36).

Mr. Leinsing further noted that Møller's second embodiment illustrates protrusions 132 as being formed in an interior of a flange, which a POSA would have understood as Møller disclosing corresponding protrusion 32 being similarly formed. *See* EX1011, ¶¶528-29 (citing EX1015, FIG. 5).

This understanding is further supported by a comparison of Møller's first and second embodiments, which both show a protrusion that extends outwardly from the surface of element 20/120 (*i.e.*, a "flange" per Sanofi's definition, *see* Paper 23, 27 (citing EX2107, ¶¶123, n.7, 351)); EX1095, ¶119. For example, as shown in the annotated, partial view of FIG. 1 below, a POSA would have understood FIG. 1 as illustrating element 20 having an outwardly-extending protrusion from which teeth 32 extend from the protrusion's button-end side.



Id., ¶119.

In FIG. 5 of the informative second embodiment, Møller presents an even clearer illustration of the flange and its teeth. *Id.*, ¶120 . That figure shows a protrusion extending outwardly from the outer surface of element 120 (annotated yellow below), with teeth 132 (annotated green below) axially extending from the protrusion's button-end side in an area that is radially inward of the flange's outer diameter. *See id.*, ¶121 (flange provides base for teeth 132, which mesh with corresponding Λ -shaped recesses within inner ring 133 of the dose-setting button).

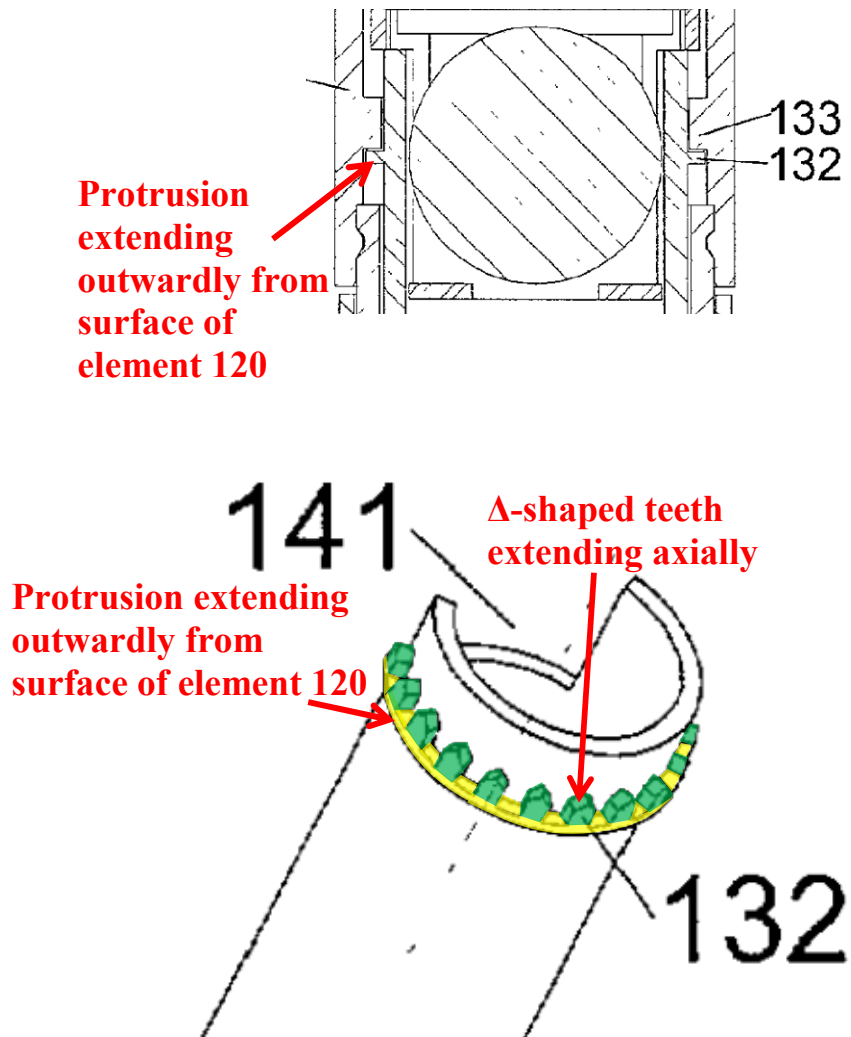


FIG. 3 (top; partial, annotated); FIG. 5 (bottom; partial, annotated); EX1095, ¶120.

Mr. Leinsing explains that the configuration disclosed in Møller satisfies the plain and ordinary meaning of claim 56. *Id.*, ¶121. Indeed, Møller’s clutch teeth have essentially the same structure (axially extending teeth), location (button side of a flange radially inward of the flange’s outer diameter), and operation

