UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner

Case No. IPR2018-01679
U.S. Patent No. 8,992,486

PATENT OWNER'S RESPONSE

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I. INTRODUCTION

The Petition asserts seven grounds, each challenging certain of claims 51-57 of U.S. Patent No. 8,992,486 ("486 Patent"). Sanofi has contemporaneously filed a motion to amend to submit substitute claims for claims 51-57. With respect to claim 56, Petitioner has not demonstrated that any of its grounds renders it obvious.[1]

The only grounds relevant to claim 56 are grounds 3, 4, and 6.[2] Steenfeldt-Jensen, the basis for grounds 3 and 4, does not disclose or render obvious a clutch having "a plurality of axially extending teeth formed in an ***interior*** of a flange of said clutch" as required by claim 56. Instead, Steenfeldt-Jensen discloses teeth formed on the ***distal side*** of a flange. Møller, the basis for ground 6, likewise does not disclose or render obvious "a plurality of axially extending teeth formed in an ***interior*** of a flange of said clutch," but instead discloses teeth formed on a ***proximal side*** of a flange (to the extent there is a flange). Accordingly, grounds 3, 4, and 6 fail to render claim 56 unpatentable.

II. BACKGROUND OF THE TECHNOLOGY

The 486 Patent relates to disposable injectors "for administration by injection of medicinal products …." Ex. 1003, 1:20-22; *see also* Ex. 2107, ¶ 64.

[1] Notwithstanding, Sanofi has filed a contingent motion to amend for claim 56.

[2] Grounds 1, 2, 5, and 7 do not address claim 56.

More specifically, the 486 Patent concerns "pen-type" injectors that permit users to set the appropriate dosage from a multi-dose cartridge and self-administer the injection. *See* Ex. 1003, 1:20-24; *see also* Ex. 2107, ¶ 64. Such pen injectors have been used by diabetic patients to self-administer insulin.

At the time of the 486 Patent, there were already several pen-type injectors known in the art. For example, the Steenfeldt-Jensen reference describes five pen injector embodiments, and its fifth embodiment closely corresponds to the Novo Nordisk FlexPen device that was commercially available at the time. *See* Ex. 1014, Figs. 1-17, Ex. 2107, ¶ 378.

The 486 Patent improves upon these prior art devices in nonobvious ways. Notably, developing a new injector pen to address prior art limitations is not as simple as substituting one component or feature for another. *See* Ex. 2107, ¶ 55. A substitution or change intended to improve one aspect of a device can negatively impact other aspects, and one must consider whether these tradeoffs result in an overall poor or flawed design. *See id*. In the pen injector context, changes that increase the size or impair the ease of use of the device are not worth pursuing if they worsen the patient's experience using the pen. *See* Ex. 2107, ¶¶ 55-61.

III. OVERVIEW OF THE 486 PATENT

The 486 Patent is directed to a pen-type injector for medications such as insulin and insulin glargine. Ex. 1003, 1:19-24. Such injectors are regularly used

by patients without formal medical training, such as diabetic patients who manage their condition through self-treatment. *Id*., 1:25-29. The 486 Patent teaches that pen injectors should meet several criteria, including being robust in construction while being easy to manipulate and understand by the user, who in many cases may be physically infirm and have impaired vision. *Id*., 1:30-35, Ex. 2107, ¶ 64.

The figures below, from the 486 Patent, depict an embodiment of an improved injection pen that meets these requirements. An animation of the embodiment's operation has been submitted as Ex. 2117. *See* Ex. 2107, ¶ 65 (explaining animation).

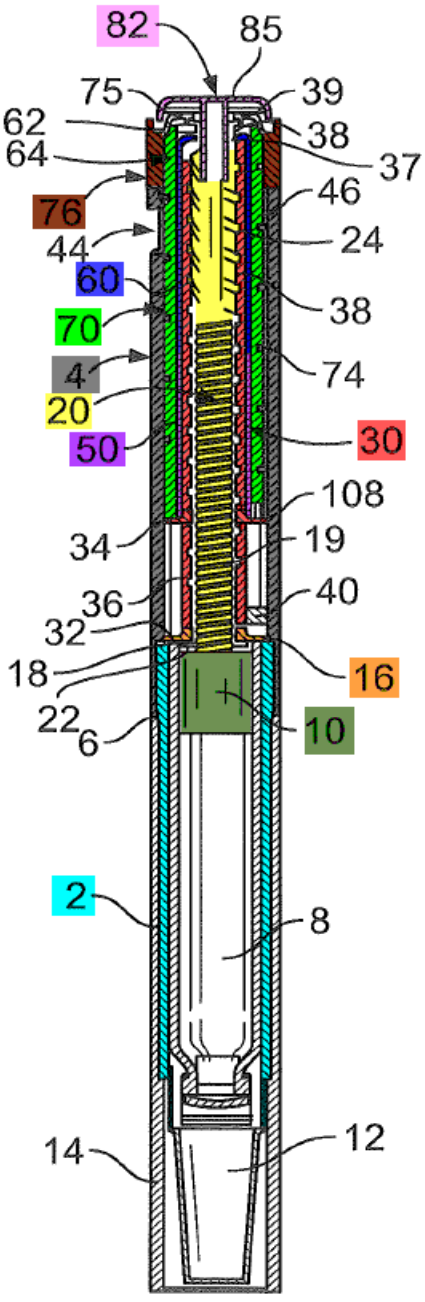


FIG. 1

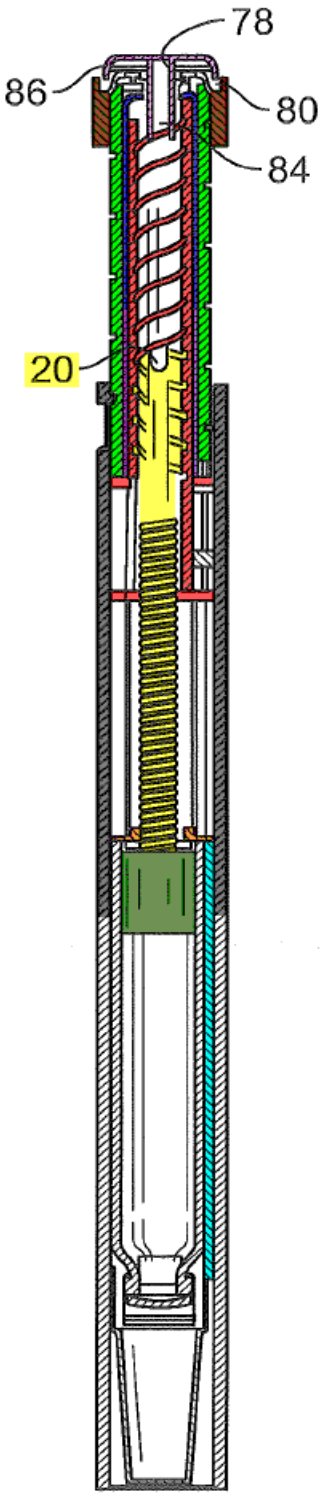
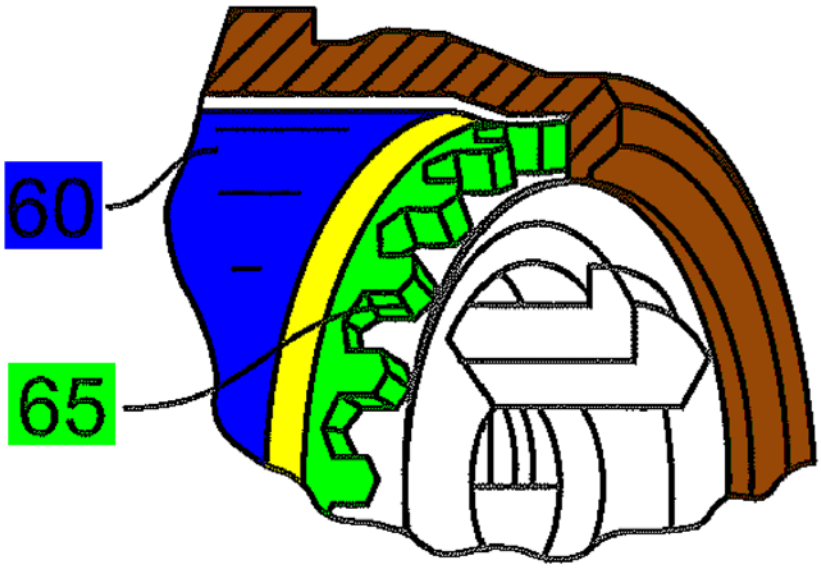


FIG. 2

Ex. 1003, Figs. 1 and 2 (annotated)

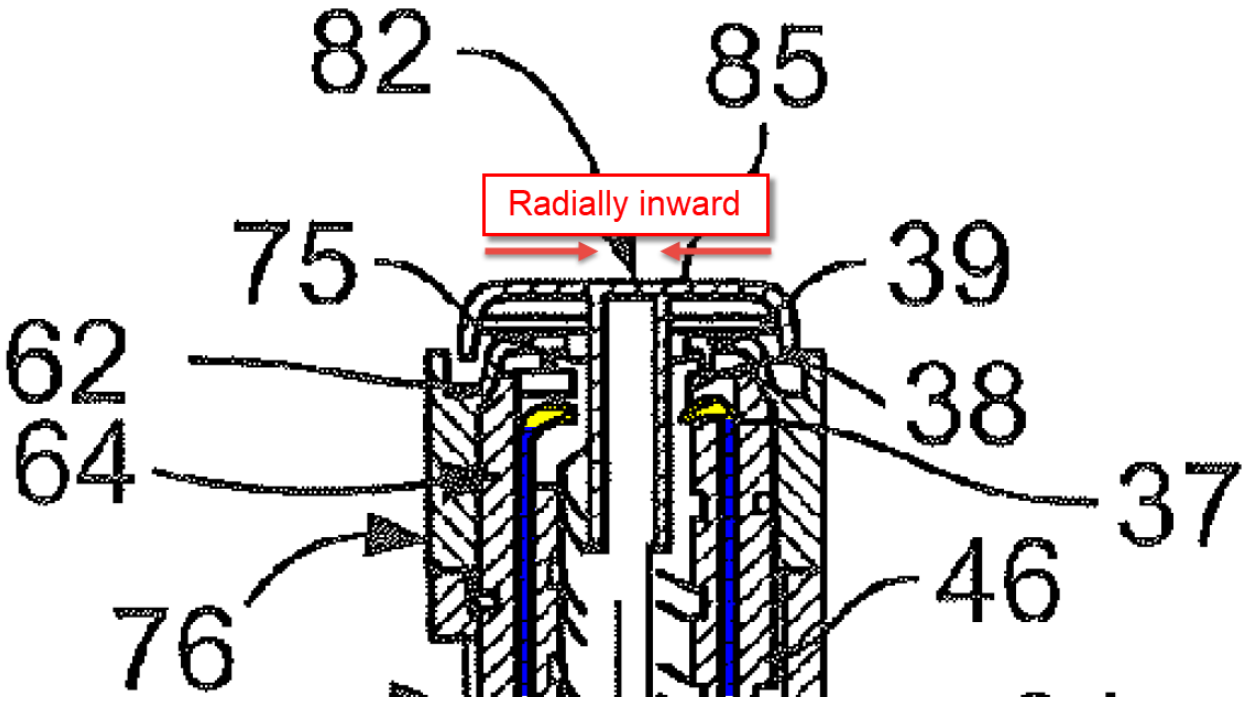
The injection pen of the shown embodiment comprises a cartridge retaining part 2 (light blue), an internally threaded main housing 4 (grey), a medicament cartridge 8, a cartridge piston 10 (dark green), an insert 16 (orange), a piston rod 20 (yellow), a drive sleeve 30 (red), a clicker 50 (purple), and clutch 60 (dark blue), an externally-grooved dose dial sleeve 70 (light green), a dose dial grip 76 (brown), and a button 82 (pink).

Relevant to this IPR, the clutch 60 (dark blue) is described as having a "radially inwardly directed flange 62" (in yellow) on its proximal, or button-side. *See* Ex. 1003, 4:54-55. This clutch is shown and described as having axially extending teeth (in light green) formed at the interior of this inwardly directed flange 62. *See* Ex. 1003, 4:58-60 ("The second end [or proximal end] of the clutch means **60** is provided with a plurality of dog teeth **65** (FIG. 8).").



Ex. 1003, Fig. 8 (annotated)

A side view of clutch 60 and radially inwardly directed flange 62 is provided in Fig. 5. Note that the dog teeth are not depicted in Fig. 5.



Ex. 1003, Fig. 5 (annotated)

IV. LEVEL OF ORDINARY SKILL IN THE ART

The correct level of ordinary skill is defined by a person who understands the mechanical elements (e.g., lead screws, clutches, gears) used in drug injection delivery devices as well as the principles governing the interactions of such mechanical elements, and further understands the basics of device design and manufacturing. That person will have a bachelor's degree in mechanical engineering or an equivalent degree. *See* Ex. 2107, ¶ 102. Patent Owner proposed level of ordinary skill reflects the educational level of workers in the field and the

sophistication of the technology. *See* Ex. 2107, ¶ 102; *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *see* MPEP 2141.03.

Patent Owner does not believe Petitioner's proposed level of ordinary skill should be adopted because the level of ordinary skill proposed by the Petitioner is inconsistent across the IPRs for the patents in this family. For example, in IPR2018-01684, IPR2018-01682, IPR2018-01680, and IPR2018-01670 Petitioner's proposed level of ordinary skill does not require any years of experience, whereas in other petitions, Petitioner states that a POSA would have had "design experience", "approximately three years of experience in medical-device design," or "three-year's experience" depending on the petition. See IPR2018-01675, Paper 2 at 14; IPR2018-01676, Paper 2 at 14, IPR2018-01679, Paper 2 at 12. Petitioner provides no reasoning for the inconsistency. Moreover, Mr. Leinsing testified that three years of experience is not required. Therefore, Patent Owner's proposed level of ordinary skill should be accepted. Regardless, the slight differences between Patent Owner and Petitioner's level of ordinary skill do not affect the arguments made below.

V. CLAIM CONSTRUCTION

The Board found that "[f]or the purposes of determining whether Petitioner demonstrates a reasonable likelihood of prevailing in its challenges, … no express interpretation is required for any claim term." Paper 14 at 9. Patent Owner

submits no express interpretation is required for any claim term with the exception of "an interior of a flange" as recited in claim 56.

A. "an interior of a flange" (Claim 56)

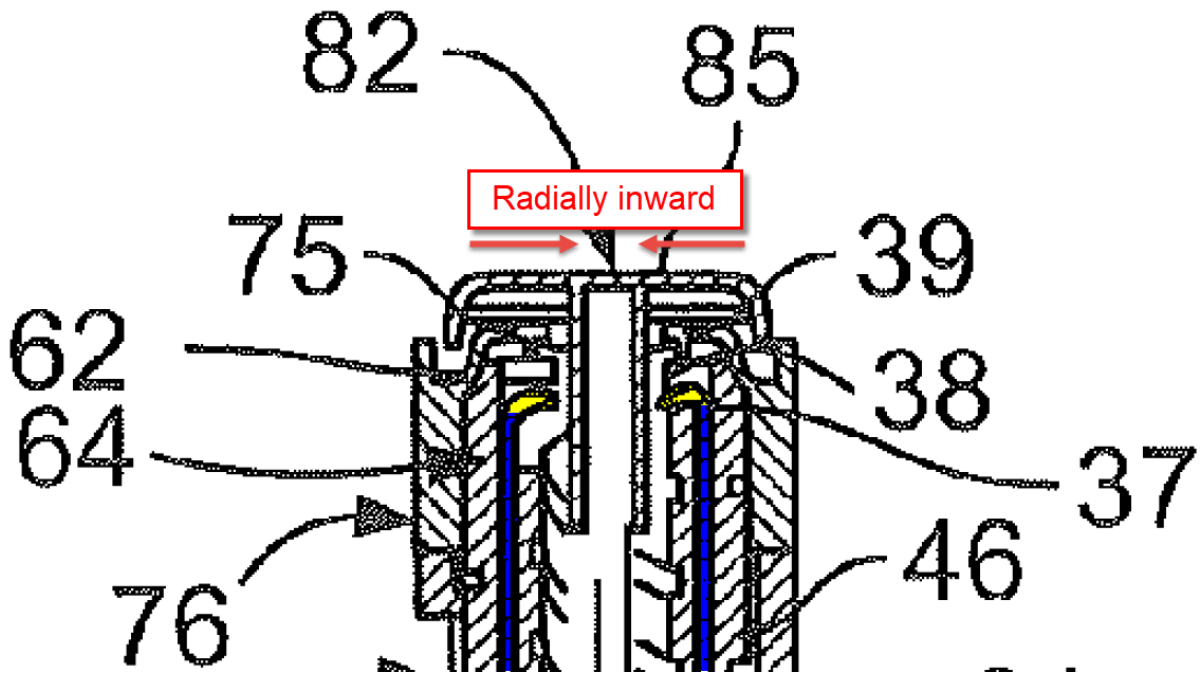
The broadest reasonable interpretation of "an interior of a flange" for a disk-shaped flange is "at the inner diameter of a flange." *See* Ex. 2107, ¶¶ 123-128. Patent Owner proffers this construction to confirm the meaning of "interior" in claim 56 and to clarify that it ***does not mean*** at the outer 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).

Note, it is not Patent Owner's position that every flange must be disk-shaped. However, in the present Petition, all of the prior art flanges identified by Petitioner are disk-shaped flanges.[3] Thus, to keep the focus on the issues disputed between the parties, Patent Owner restricts its construction to address what "an interior of a flange" is for a disk-shaped flange. Under the correct construction of "an interior of a flange," neither Steenfeldt-Jensen nor Møller disclose this limitation as explained below in Section VII. In the case of Steenfeldt-Jensen, what Petitioner identifies as the interior of a flange is the distal (needle end) side of

[3] A disk-shaped flange is a protrusion that extends outwardly and/or inwardly from the surface of a cylinder. *See* Ex. 2107, ¶ 123 n.7.

the flange. In the case of Møller, what Petitioner identifies as the interior of a flange is the proximal (button end) side of the flange.

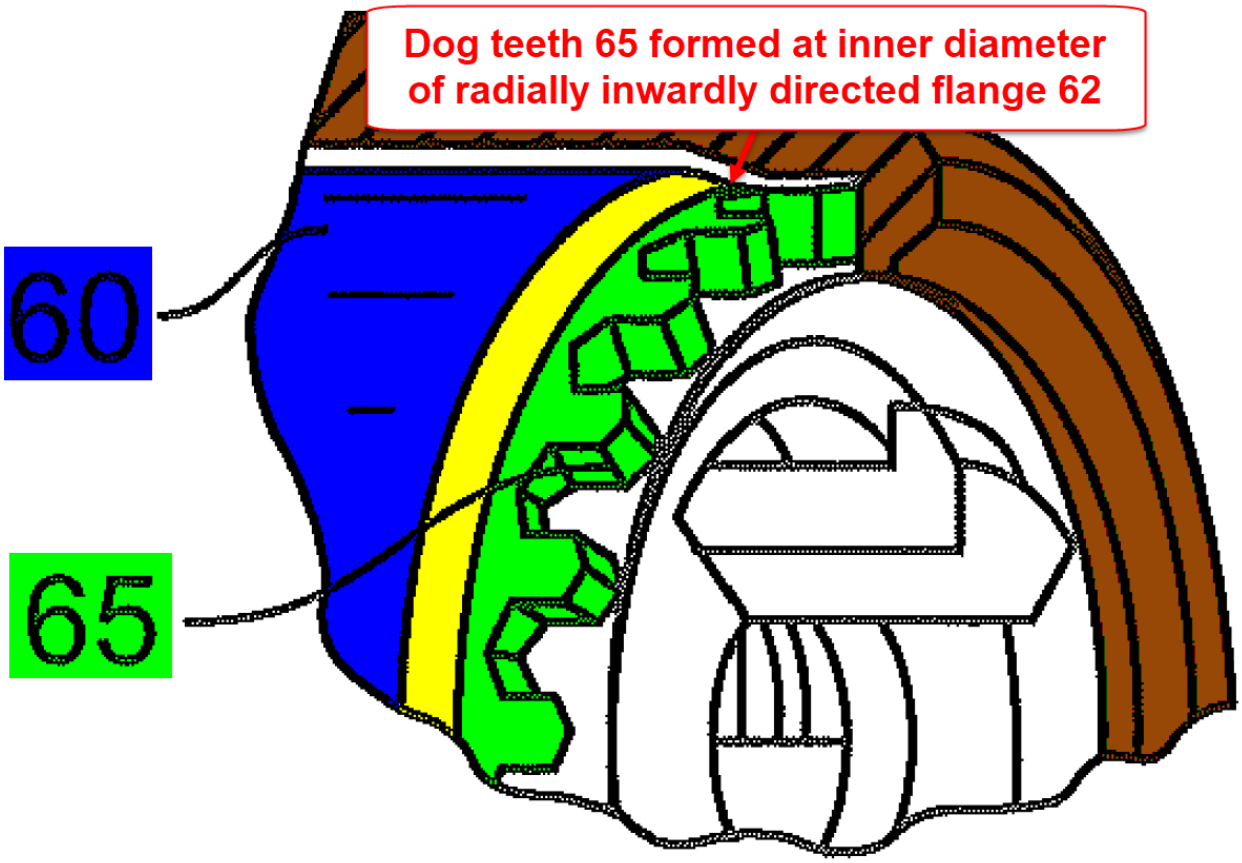
Patent Owner's construction for "an interior of a flange" is supported by the intrinsic record and confirmed by Petitioner's expert. For example, the illustrated embodiment in the 486 Patent depicts "teeth formed in an interior of a flange of said clutch," where those teeth are formed at the inner diameter of the flange. Specifically, the 486 Patent describes that the clutch means 60 comprises at its "second end 64" (or proximal end/button end) "a radially inwardly directed flange 62," which is identified below in yellow. *See* Ex. 1003, 4:54-55.



Ex. 1003, Fig. 5 (annotated)

The 486 Patent illustrates that dog teeth (light green, below) are formed at the inner diameter of flange 62 (yellow, below). *See* Ex. 1003, 4:58-60 ("The second end

[or proximal end/button end] of the clutch means **60** is provided with a plurality of dog teeth **65** (FIG. 8).").

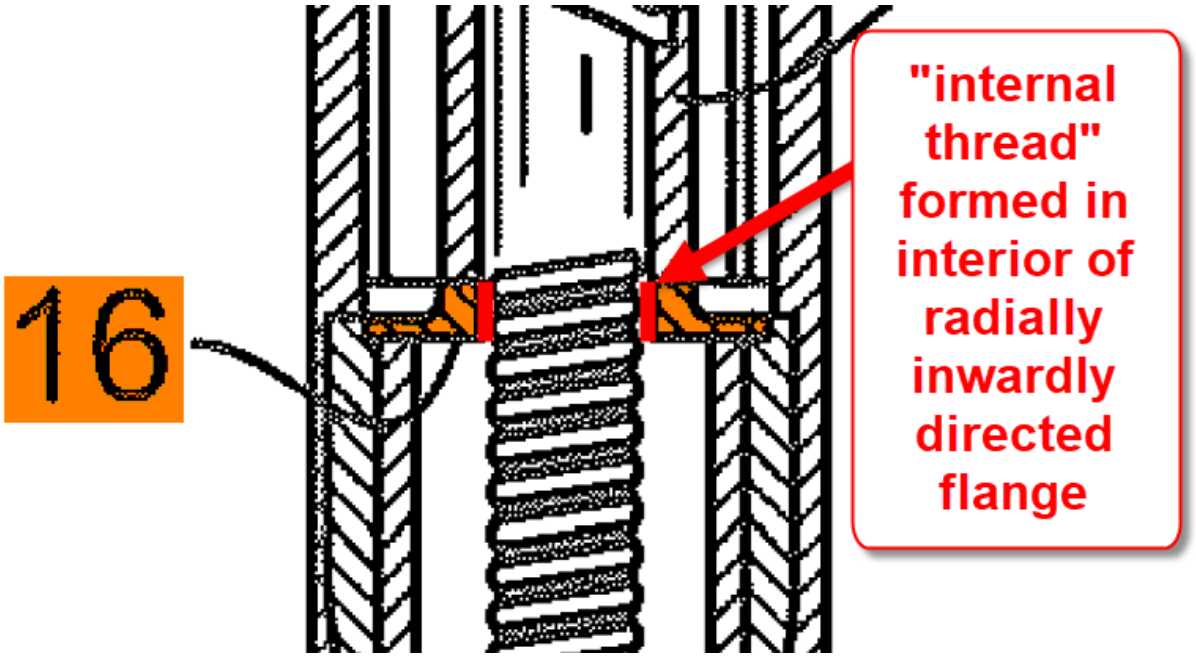


Ex. 1003, Fig. 8 (annotated)

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.

Moreover, the specification and claims of the 486 Patent use the synonyms "internal," "inner," "inward," and "interior" all to describe components or features disposed toward the radial center of a circular or tubular component (*i.e.*, the inner

diameter). For example, when describing the "insert 16" of the illustrated embodiment (depicted below), the 486 Patent explains that "the insert may be formed integrally with the main housing **4** [in] the form of a ***radially inwardly*** directed flange" (orange, below) "having an ***internal*** thread" (red, below). Ex. 1003, 3:53-55.

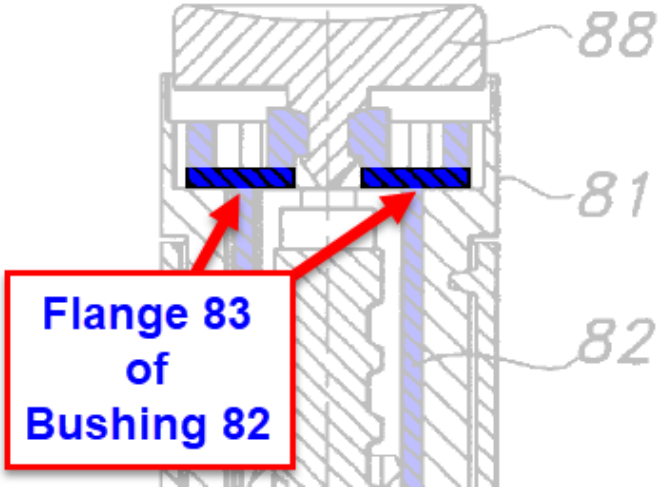


Ex. 1003, Fig. 5 (annotated)

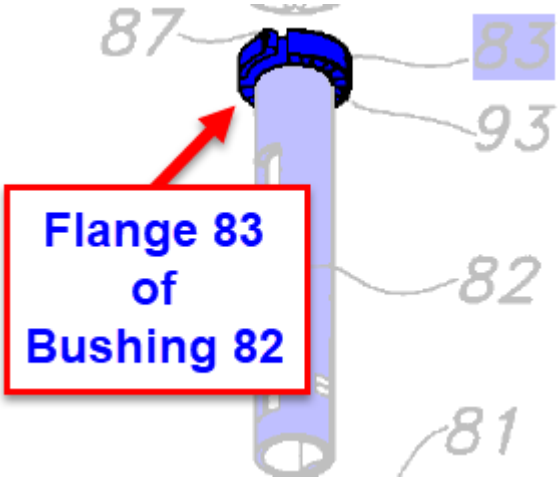
Here, and throughout the 486 Patent, "internal" means the inner diameter side of the component. Similarly, the 486 Patent describes that a "helical groove 38 extends along the ***internal*** surface of the drive sleeve 30," which is depicted in Figure 1 as the inner diameter side of the drive sleeve. Ex. 1003, 4:12-13. The 486 Patent further discloses that "[t]he nut 40 has an ***internal*** thread matching the

intermediate thread 36," which describes the nut 40 having a thread on the inner diameter of the nut. Ex. 1003, 4:20-21.

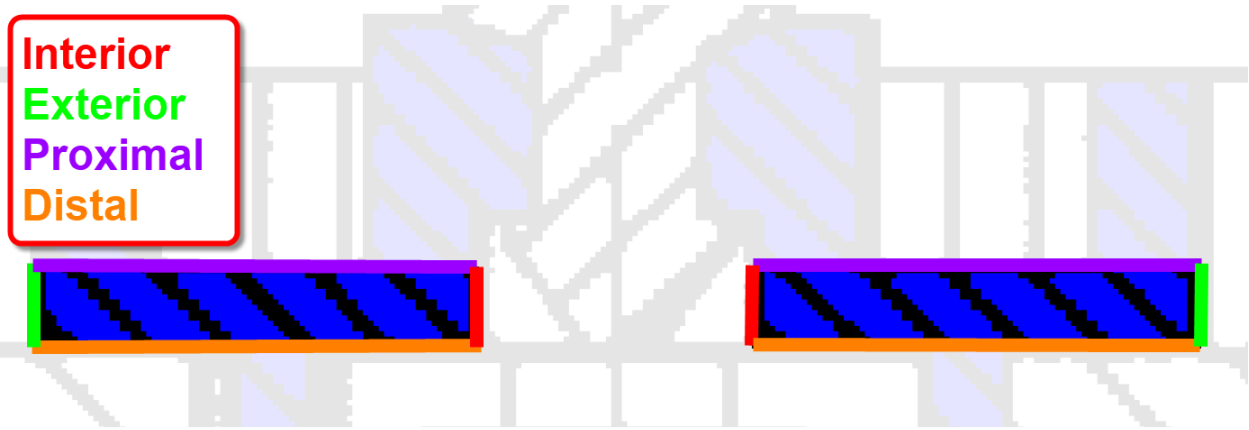
The broadest reasonable interpretation of "an interior of a flange" does not encompass the outer diameter (*i.e.*, exterior), distal side (*i.e.*, needle side), or the proximal side (*i.e.*, button side) portions of a disk-shaped flange. These portions are illustrated below on Steenfeldt-Jensen's flange 83.



Ex. 1014, Fig. 16 (annotated)



Ex. 1014, Fig. 17 (annotated)

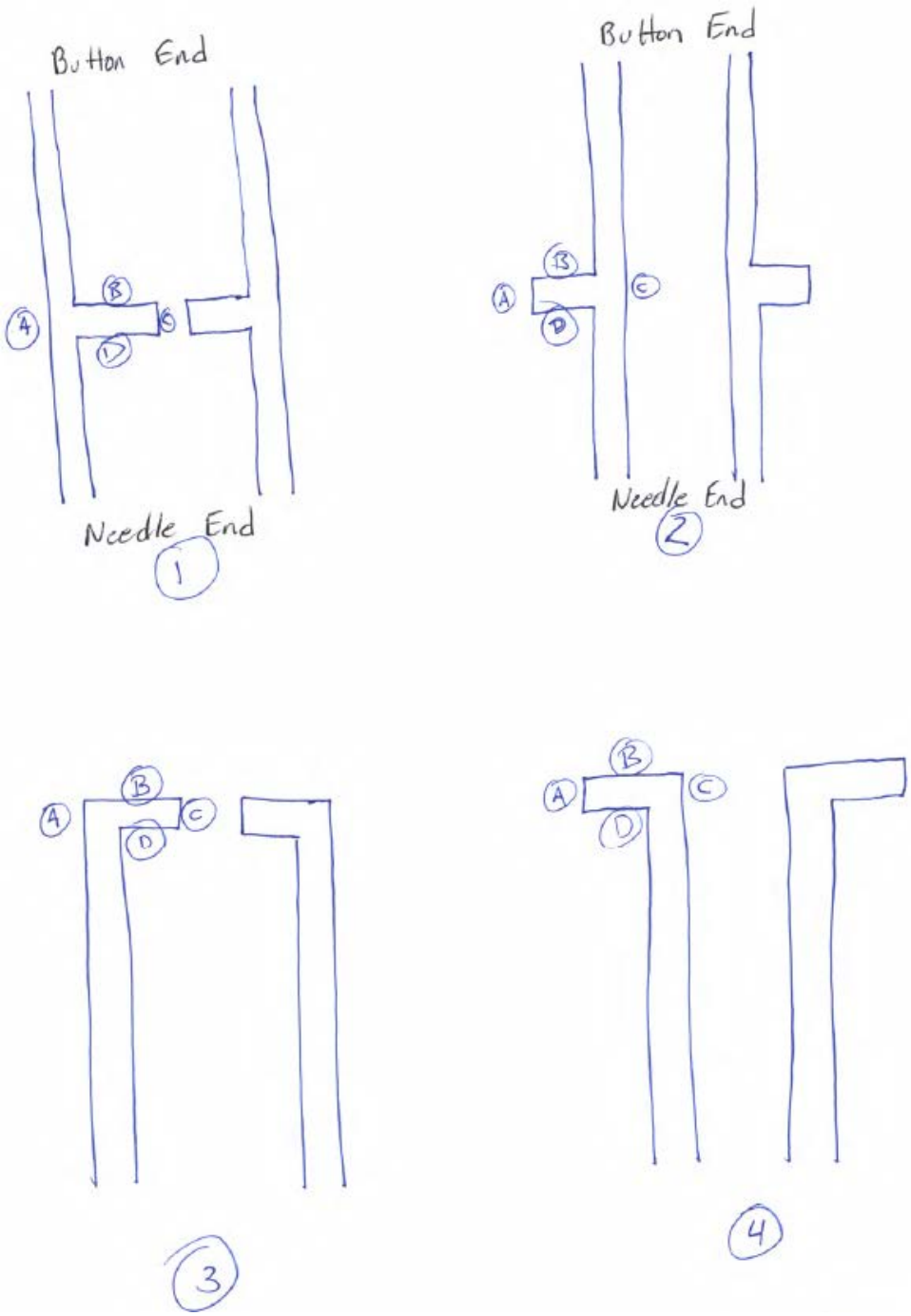


Ex. 1014, Fig. 16 (annotated)

The above three images depict Steenfeldt-Jensen's flange 83. The first image depicts the flange 83 at the proximal end (button end) of bushing 82. *See* Ex. 1014, 11:26-33 ("A bushing 82 having a flange 83 at its proximal end …."), Fig. 16. The second image provides a 3-D image of the bushing 82 and flange 83. The third image isolates the flange for better viewing. The interior, exterior, proximal, and distal sides are labeled in this isolated image.

At deposition, Petitioner's expert confirmed the construction proffered by the Patent Owner: "A. So the thread is on the inside or inner diameter" (discussing a radially inwardly directed flange of the 486 Patent); "Q. And -- all right. So the thread here isn't -- it's not exposed on the surface of the flange facing the proximal end of the pen injector. Is that fair? A. No. It's on the inner hole or diameter portion of that insert." (Discussing the same). Ex. 2163 at 148:18-19, 149:20-25.

Petitioner's expert was also asked to label the sides of different flanges using the drawing depicted below, which is from Ex. 2102. *See* Ex. 2163 at 151:18-159:6.



Ex. 2102

With respect to figures 1-4, Mr. Leinsing confirmed that side (B) is the proximal (button end) surface of the circular flange and side (D) is the distal (needle end) surface of the circular flange. *See* Ex. 2163 at 153:4-14, 154:24-155:9, 158:4-21. Mr. Leinsing testified that side (C) is the interior surface of the circular flange in figures 1 and 3 and that side (C) could be considered the interior surface in figures 2 and 4. *See* Ex. 2163 at 151:18-153:19 ("Yeah. C would be the interior surface in Figure 1 of Exhibit 2102."), 155:13-18, 158:4-21. Mr. Leinsing further testified that he did not think figures 1 and 3 showed an exterior of a circular flange, but confirmed that figures 2 and 4 did at side (A). *See* Ex. 2163 at 153:20-154:23, 155:10-11, 158:4-21. Thus, Mr. Leinsing agrees that the inner diameter of a circular flange would be the interior of the flange, and that the proximal, distal, and exterior sides of the flange are different.

Accordingly, Patent Owner submits that the broadest reasonable interpretation of "an interior of a flange" consistent with the specification of the 486 Patent is "at the inner diameter of a flange" for a disk-shaped flange. It does not encompass the proximal end (button end), distal end (needle end), or exterior end of the flange.

VI. THE PRIOR ART

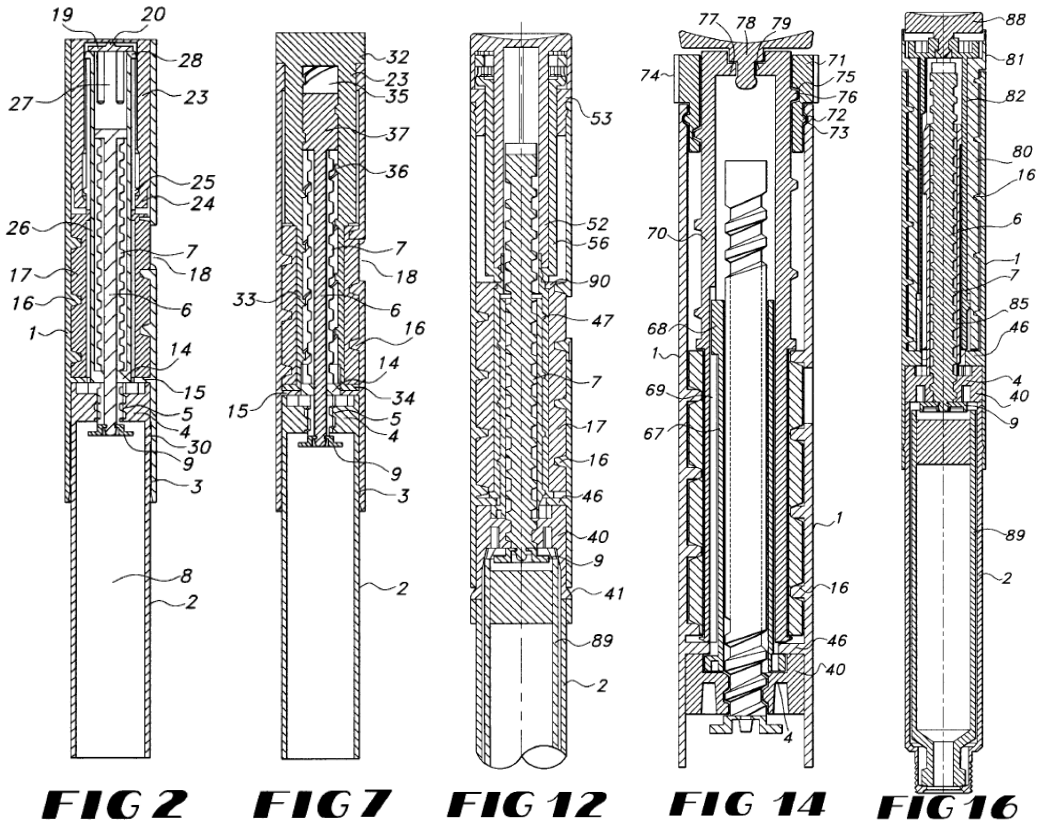
A. Burroughs (Ex. 1013)

Petitioner relies on the Burroughs reference for grounds 1 and 2. In this Response, Patent Owner addresses only grounds 3, 4, and 6. Thus, the Burroughs reference is not pertinent to the issues addressed herein.

B. U.S. Patent No. 6,235,004 ("Steenfeldt-Jensen") (Ex. 1014)

Steenfeldt-Jensen is a U.S. patent. Its PCT counterpart application, WO 99/38554 (Ex. 2153), was included in an IDS during prosecution of the 486 Patent and is cited on the face of the 486 Patent. *See* Ex. 1014 (claiming priority to DK 1998 00130), Ex. 2014 (same), Ex. 1008 at 0118 (listing WO 99/38554).

Steenfeldt-Jensen discloses five distinct pen injector embodiments. *See* Ex. 1014, Figs. 1-17. The first, second, third, fourth, and fifth embodiments are depicted in figures 1-5, figures 6-10, figures 11-13, figure 14, and figures 15-17, respectively. *See* Ex. 1014, 5:33-37, 7:48-49, 8:34-35, 10:14-15, 11:6. These pen injectors comprise different components and arrangements, as shown below, and are configured to operate differently. *See, e.g.*, Ex. 2148 (animation of the first embodiment), 2149 (animation of the second embodiment), 2147 (animation of the fifth embodiment); *see also* Ex. 2107, ¶ 137 (explaining Steenfeldt-Jensen animations).



Ex. 1014, Figs. 2, 7, 12, 14, and 16.

1. Steenfeldt-Jensen's Fifth Embodiment

For the relevant grounds, grounds 3, 4, and 6, Petitioner primarily relies on the fifth embodiment (Ex. 1014, 11:6-12:16, Figs. 15-17) to argue that Steenfeldt-Jensen discloses or renders obvious the challenged claims. *See* Petition at 34-47, 63-66. The fifth embodiment, depicted in an exploded view, below, comprises an ampoule holder 2 (turquoise), an ampoule (or cartridge) 89 (dark blue), pressure foot 9, member 40 (orange), driver tube 85 (red), piston rod 6 (yellow), housing 1 (grey), scale drum 80 (light green), bushing 82 (light blue), and injection button 88 (purple).

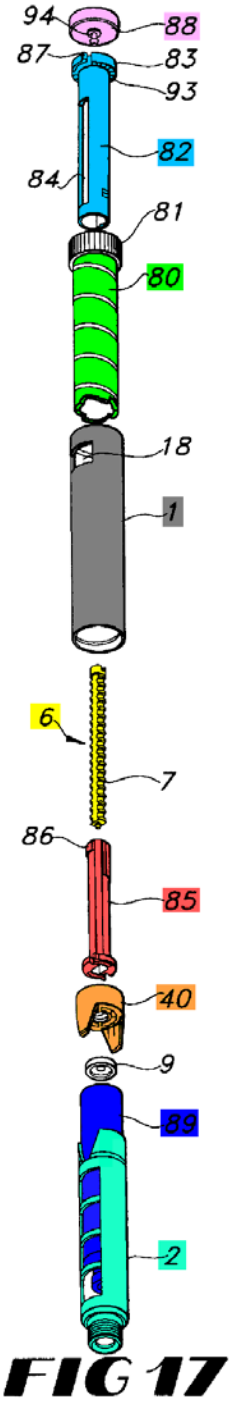
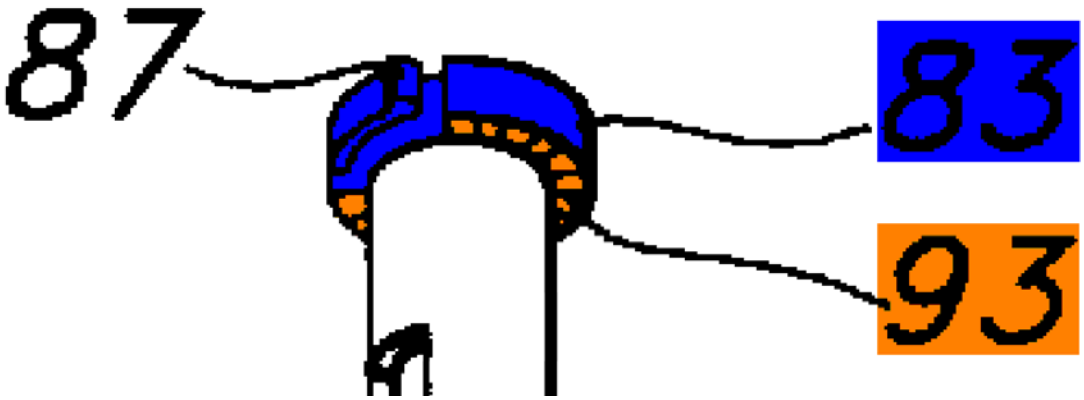


FIG 17

Ex. 1014, Fig. 17

Significant to the issues in this IPR proceeding, Steenfeldt-Jensen's rosette of teeth 93 (orange) is formed on the distal side (*i.e.*, needle end) of flange 83 (blue) of bushing 82, as depicted below.



Ex. 1014, Fig. 17 (cropped and annotated)

C. U.S. Patent Application Publication No. 2002/0052578 ("Møller")

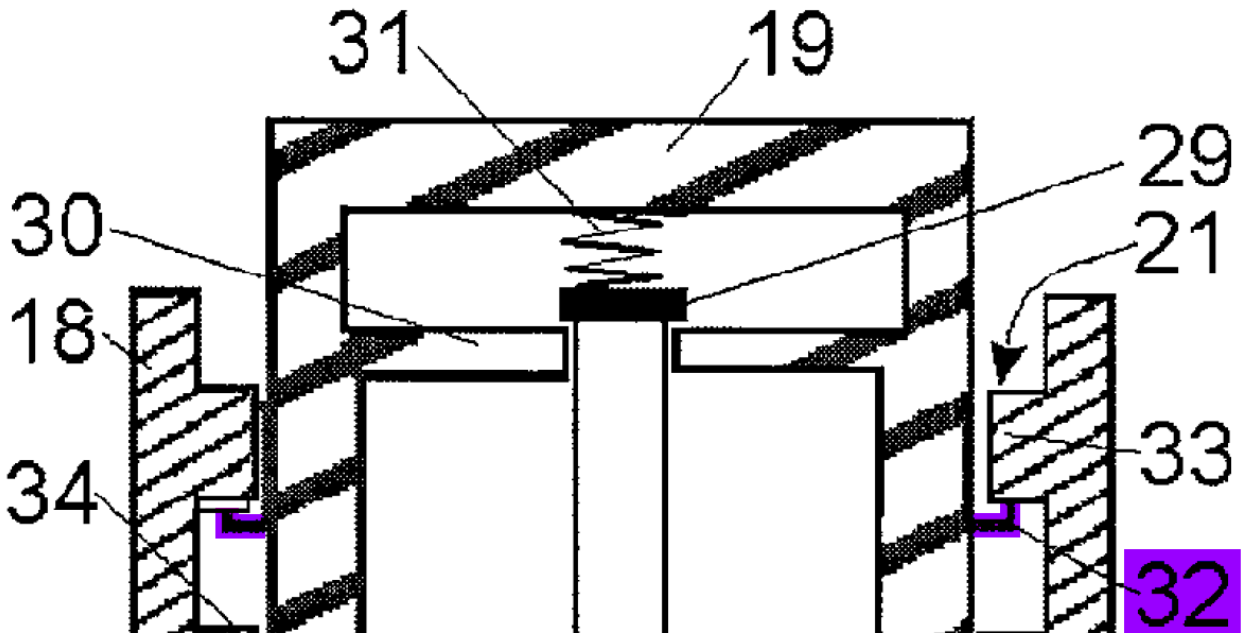
Møller is a U.S. patent application publication dated May 2, 2002. Møller was submitted in an IDS and is cited on the face of the 486 Patent. Ex. 1008 at 0118. Møller was filed on June 14, 2001. Møller is aimed at providing an injection pen where the mechanism providing a mechanical advantage (*i.e.*, "gearing") between an injection button and an ampoule piston comprises a rack and gear wheel. *See* Ex. 1015, ¶¶ 0006 ("Consequently a wish for a gearing between the injection button and the piston has occurred so that the button has a larger stroke than has the piston."), 0011, 0013; *see also* Ex. 2107, ¶¶ 148-149. Møller explains that this gearing reduces the force necessary to deliver an

injection—*i.e.*, injection force—to help users who have reduced finger strength. *Id.*; *see also* Ex. 2107, ¶ 148.

The embodiment primarily relied upon by Petitioner in grounds 3, 4 and 6 is Møller's first embodiment, but Petitioner also cites to Møller's second embodiment. *See* Ex. 2206 (animation depicting Møller's first embodiment), Ex. 2207 (animation depicting Møller's second embodiment); *see also* Ex. 2107, ¶ 150 (describing animations). To set a dose according to the first embodiment, "the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 6. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will be lifted with this drum up from the end of the housing 1." Ex. 1015, ¶ 0029. "When the dose setting drum is screwed up along the thread 6 on the tubular element 5 the ring 25 will follow the dose setting drum in its axial movement as the spring 26 is supported on the shoulder 27." *Id.* "The spring will keep the V-shaped teeth of the ring 25 and the cup shaped element in engagement and maintain in engagement the coupling 21, which may comprise Δ-shaped protrusions 32 on the cup shaped element engaging Δ-shaped recesses in an inner ring 33 in the dose setting button 18." *Id.*

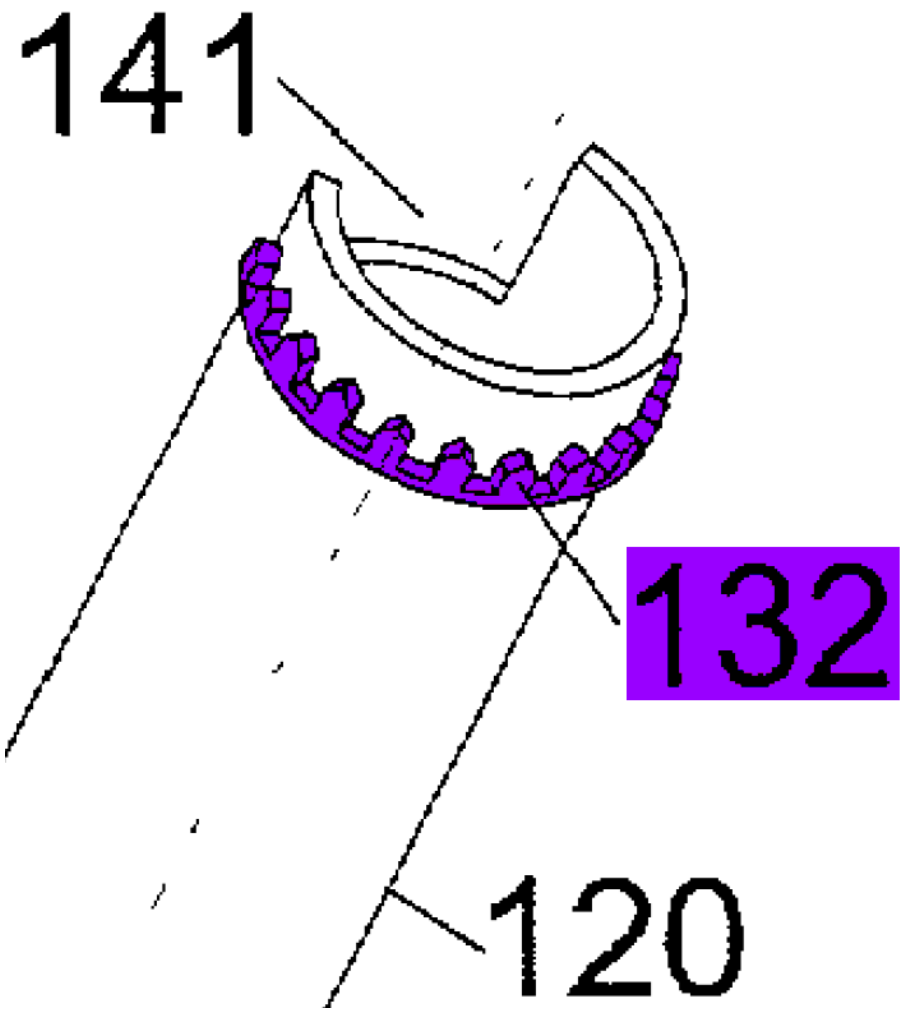
Importantly for the issues in this IPR proceeding, the "Δ-shaped protrusions 32" (purple) are depicted as being formed on a cup-shaped element, as depicted below. Møller does not depict or describe whether Δ-shaped protrusions 32 are

formed on a flange. *See* Ex. 2107, ¶ 123 n.7 (noting that a POSA understands a flange as a protrusion that extends outwardly and/or inwardly from the surface of a cylinder).



Ex. 1015, Fig. 1 (cropped and annotated)

Also significant to the issues in this IPR proceeding, from Møller's second embodiment, the Petition references a tubular element 120 having teeth 132 formed around its exterior surface, which are shown in purple, below.



Ex. 1015, Fig. 5 (cropped and annotated)

VII. THE CITED PRIOR ART DOES NOT TEACH OR RENDER OBVIOUS CLAIM 56

A. Ground 1 Does Not Challenge Claim 56

Ground 1 challenges claims 51-55 and 57 as being anticipated by Burroughs. Petition at 22-32. Substitute claims for claims 51-55 and 57 are addressed in the motion to amend submitted concurrently with this Response.

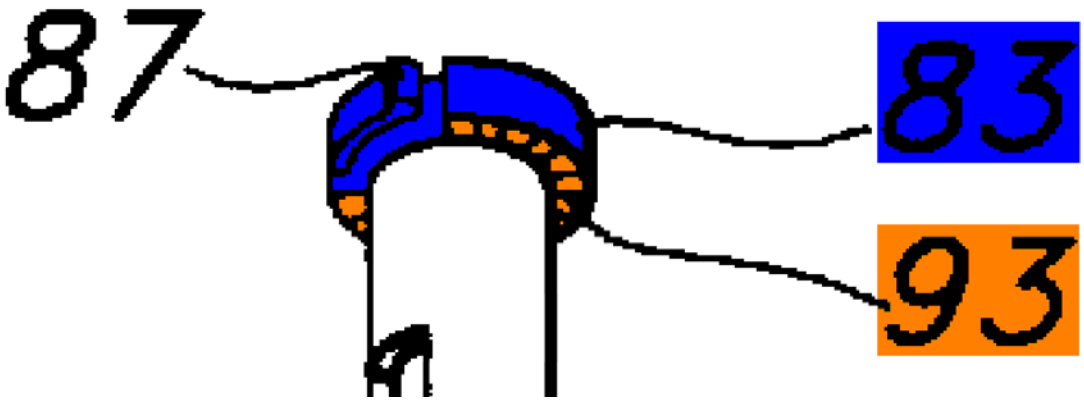
B. Ground 2 Does Not Challenge Claim 56

Ground 2 only challenges claims 54-55 as being anticipated by Burroughs. Petition at 32-34. Substitute claims for claims 54-55 are addressed in the motion to amend submitted concurrently with this Response.

C. Claim 56 Is Patentable in View of Ground 3

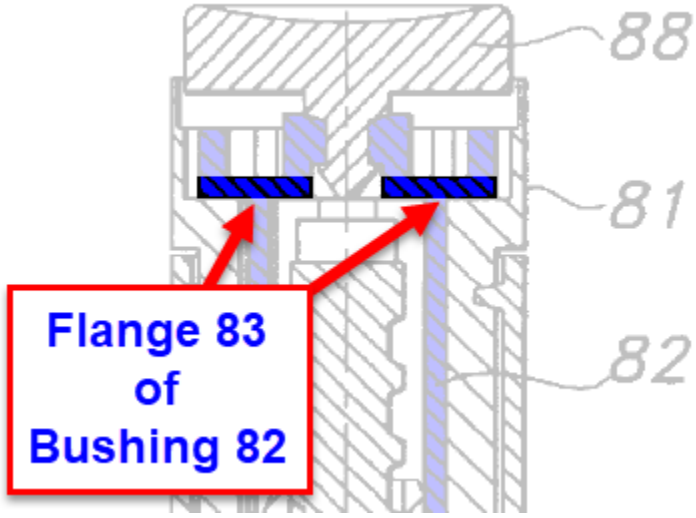
Ground 3 challenges claims 51-53 and 56-57 as being anticipated by Steenfeldt-Jensen's fifth embodiment. Petition at 34-46. Substitute claims for claims 51-53 and 56-57 are addressed in the motion to amend submitted concurrently with this Response. With regards to claim 56, the Petition fails to show that Steenfeldt-Jensen teaches a clutch "comprising a plurality of axially extending teeth formed in an interior of a flange" as required by claim 56.

Petitioner identifies the rosette of teeth 93 (orange) on the flange 83 (blue) of the bushing 82 in Steenfeldt-Jensen's fifth embodiment as satisfying this limitation. Petition at 42-43. Specifically, Petitioner argues that, "Figure 17 also shows that teeth 93 extend axially and are formed in an interior of flange 83." Petition at 43. Figure 17 is depicted below.

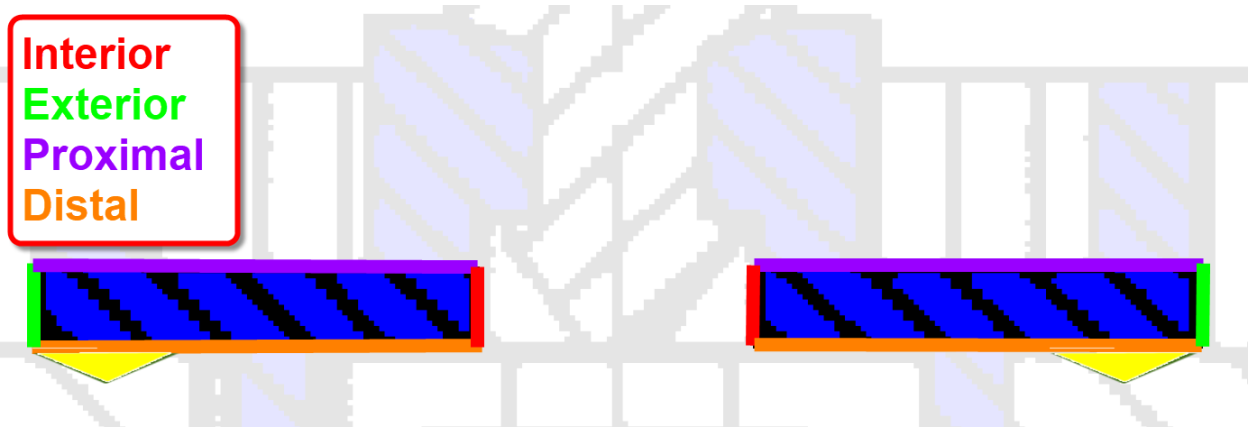


Ex. 1014, Fig. 17 (cropped and annotated).

As is clear from Figure 17, teeth 93 (orange) are not "formed in an ***interior*** of a flange." As properly construed, the interior of flange is along the inner diameter of the flange. *See* Section V, *supra*. Rather, teeth 93 (orange) are formed on the distal end (*i.e.*, needle-end side) of flange 83 (blue). *See* Ex. 2107, ¶¶ 340-346. The cross-sectional view provided in Figure 16 confirms that the teeth (added in yellow to correspond with location in Figure 17) are provided on a distal side of the flange, not an interior of the flange:



Ex. 1014, Fig. 16 (cropped and annotated)



Ex. 1014, Fig. 16 (cropped and annotated)

Petitioner's expert, at deposition, confirmed that the underside of a flange is the distal side of the flange, not the interior of the flange. *See* Ex. 2163 at 155:7-9, 158:10-21 (testifying that side (D) in figure 4 of Exhibit 2102, which corresponds to the location of Steenfeldt-Jensen's rosette of teeth 93, is the distal side of the flange); Ex. 2012, Fig. 4. He further confirmed that the interior of a flange is the inner diameter of the flange. *See* Ex. 2163 at 148:9-20 (identifying internal threads of a flange in the 486 Patent as being "the thread … on the inside or inner diameter"), 155:13-18, 155:10-21 (saying that the inner diameter of a flange similar to Steenfeldt-Jensen's flange 83 "could be the interior"); Ex. 2012, Fig. 4. In Steenfeldt-Jensen's fifth embodiment, the rosette of teeth 93 are not formed on the inner diameter (*i.e.*, interior) of flange 83.

Thus, Steenfeldt-Jensen does not disclose this limitation and cannot render claim 56 anticipated.

D. Claim 56 Is Patentable in View of Ground 4

Ground 4 challenges claim 56 as being obvious over Steenfeldt-Jensen's fifth embodiment. Similar to Ground 3, Petitioner does not point to any new disclosures in Steenfeldt-Jensen for rendering obvious claim 56. Instead, Petitioner argues that "[t]o the extent it is not immediately apparent from FIG. 17 and the corresponding description … that the teeth of rosette 93 extend axially …, a POSA would have found it obvious to implement the teeth in this manner." Petition at 47. Petitioner's sole obviousness argument is that it would have been obvious to extend the teeth axially. But in making this argument, Petitioner does not address the entire claim limitation required by claim 56: "comprising a plurality of axially extending teeth ***formed in an interior of a flange***."

Regardless of whether the teeth extend axially or it would have been obvious to extend the teeth axially, Petitioner does not address that Steenfeldt-Jensen's teeth 93 are formed on the distal side (*i.e.*, needle-end side) of flange 83, and not on "an interior of a flange" as required by claim 56. Nor does Petitioner suggest that it would have been obvious to relocate teeth that are on the distal side of the flange to the interior of the flange. All Petitioner is suggesting is that the teeth would extend axially. *See* Ex. 2107, ¶¶ 347-349. Failure to address the entire claim limitation is fatal to Petitioner's obviousness challenge. *See In re Gulack*,

703 F.2d 1381, 1385 (Fed. Cir. 1983) (all limitations must be considered when determining patentability over the prior art).

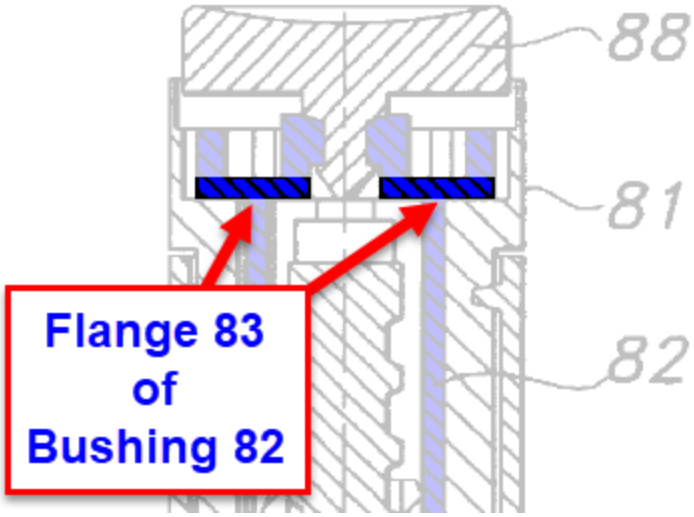
Thus, Steenfeldt-Jensen does not render claim 56 obvious for the same reasons addressed above.

E. Claim 56 Is Patentable in View of Ground 6

Ground 6 challenges claims 51-53 and 56-57 as being anticipated by Møller. Petition at 47-63. Substitute claims for claims 51-53 and 56-57 are addressed in the motion to amend submitted concurrently with this Response. With regards to claim 56, the Petition fails to show that Steenfeldt-Jensen teaches a clutch "comprising a plurality of axially extending teeth formed in an interior of a flange" as required by claim 56.

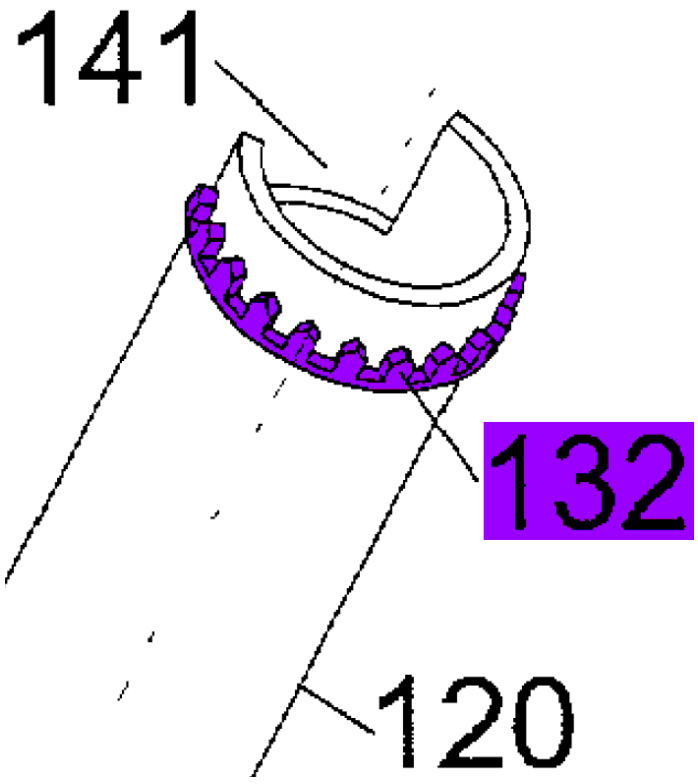
Petitioner argues that Møller discloses "Δ-shaped protrusions 32 on the cup shaped element" and that "those protrusions (teeth 32 in FIG.1 and teeth 132 in FIG. 5) extend axially from an interior of a flange of the clutch." Petition at 59-60.

Petitioner's argument fails for two reasons. First, the teeth identified by Petitioner (purple) are not formed in an interior of a ***flange*** – there is no flange. As explained by Prof. Slocum, the ordinary meaning of flange is a protrusion that extends outwardly and/or inwardly from the surface of a cylinder. *See* Ex. 2107, ¶¶ 123 n.7, 351. For example, Steenfeldt-Jensen discloses a flange 83 that extends outwardly and inwardly of bushing 82:



Ex. 1014, Fig. 16

In contrast, what Petitioner Møller as a "flange" is nothing more than the end of an elongated tubular element 120: This is best seen in Møller at Figure 5:



Ex. 1015, Fig. 5 (annotated)

According to Petitioner's argument, teeth 132 extend axially from elongated tubular element 120. Tubular element 120 is not a flange. *See* Ex. 2107, ¶ 352. Thus, Møller cannot anticipate claim 56.

Second, even accepting that elongated tubular element 120 is a flange (it is not), teeth 132 are not formed in an ***interior*** of elongated tubular element 120. Clear from Figure 5, teeth 132 extend from the proximal side of elongated tubular element 120, not from the interior of the elongated tubular element 120. *See* Ex. 2107, ¶ 353. Thus, Møller cannot anticipate claim 56.

F. Grounds 5 and 7 Do Not Challenge Claim 56

Grounds 5 and 7 only challenge claims 54-55 as being obvious over each of Steenfeldt-Jensen and Møller combined with Burroughs. Petition at 63-66. Substitute claims for claims 54-55 are addressed in the motion to amend submitted concurrently with this Response.

VIII. CONCLUSION

For the reasons set forth above, Patent Owner respectfully requests that the Board rejects Petitioner's grounds and uphold claim 56 as patentable.

Dated: June 24, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. The undersigned certifies that this brief complies with the type volume limitations of 37 CFR § 42.24(a)(1)(i). This brief contains 4,195 words (excluding the table of contents, the table of authorities, mandatory notices under 37 CFR § 42.8, the certificate of service, certificate of compliance, and appendix of exhibits), as calculated by the "Word Count" feature of Microsoft Word 2016, the word processing program used to create it.

2. The undersigned further certifies that this brief complies with the typeface requirements of 37 CFR § 42.6(a)(2)(ii) and typestyle requirements of 37 CFR § 42.6(a)(2)(iii). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14 point font.

Dated: June 24, 2019

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CERTIFICATE OF SERVICE

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