**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner

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Case No. IPR2018-01676
U.S. Patent No. 8,603,044

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# PATENT OWNER'S RESPONSE

## TABLE OF CONTENTS

**Pages**

## TABLE OF AUTHORITIES

**Page(s)**

**Cases**

**Other Authorities**

## EXHIBIT LIST

| Exhibit # | Description |
|---|---|
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| Exhibit # | Description |
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| 2025 | Excerpts from Transcript, Conference Call dated Aug. 2, 2018, *Sanofi-Aventis U.S. LLC et al. v. Mylan N.V. et al.,* Case No. 2:17- |

| Exhibit # | Description |
|---|---|
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| 2027 | Transcript, Conference Call for Case IPR2018-01675, -01676, -01678, -01680 (P.T.A.B. Feb. 5, 2019) |
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| 2102 | Leinsing Deposition Exhibit 2102: Hand drawings |
| 2103 | Leinsing Deposition Exhibit 2103: Annotations of Figures 6-15 of Burroughs |
| 2104 | Leinsing Deposition Exhibit 2104: Annotations of Figures 5-8 of the 486 Patent |
| 2105 | Leinsing Deposition Exhibit 2105: Hand drawings |
| 2106 | Leinsing Deposition exhibit 2106: Annotations of Figures 11 and 12 of Giambattista |
| 2107 | Declaration of Alexander Slocum, Ph.D. |
| 2108 | Curriculum Vitae of Alexander Slocum, Ph.D. |
| 2109 | *Reserved* |
| 2110 | *Reserved* |
| 2111 | Declaration of Dr. Robin S. Goland |
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| 2146 | Lantus COMPASS Study Report (Nov. 29, 2007), PTX-0739, Document bates stamped SANOFI3_90330807-1025 |
| 2147 | Steenfeldt-Jensen 5th Embodiment Animation |
| 2148 | Steenfeldt-Jensen 1st Embodiment Animation |
| 2149 | Steenfeldt-Jensen 2nd Embodiment Animation |
| 2150 | Steenfeldt-Jensen 5th Embodiment Thread and Slot Animation |
| 2151 | Steenfeldt-Jensen 5th Embodiment vs. Proposed Modification Animation |
| 2152 | Steenfeldt-Jensen 5th Embodiment vs. Proposed Modification Collar Friction Animation |
| 2153 | International Patent Application WO999038554A1 |
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| 2162 | Sanofi Patent Drive Sleeve and Piston Rod Animation |
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| 2164 | Deposition of Karl R. Leinsing, dated June 4, 2019 for IPR2018-01675, -01676, -01678, -01680 |
| 2165 | Opinion and Order regarding Claim Construction, *Sanofi-Aventis U.S. LLC v. Mylan, N.V.*, Civil Action No. 17-9105-SRC-SLW (D.N.J. May 9, 2019), Dkt. No. 319 |
| 2166 | Memorandum and Order regarding Claim Construction, *Sanofi-Aventis U.S. LLC v. Merck*, No. 16-812-RGA (D. Del. Jan. 12, 2018), Dkt. No. 192 |
| 2167 | Giambattista Animation (1) |
| 2168 | Giambattista Animation (2) |
| 2169 | U.S. Patent No. 4,648,872 |
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| Exhibit # | Description |
|---|---|
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| 2186 | Select Injectable Insulin Drugs Approved by the FDA in the U.S. |
| 2187 | U.S. Dollar Sales of Lantus SoloSTAR |
| 2188 | U.S. New Prescriptions of Lantus SoloSTAR |
| 2189 | U.S. Total Prescriptions of Lantus SoloSTAR |
| 2190 | U.S. Share of Sales by Drugs in the Lantus Franchise |
| 2191 | Formulary Placement of Long-Acting Insulin Pen Products: Commercial Plans |
| 2192 | Formulary Placement of Long-Acting Insulin Pen Products: Medicare Plans |
| 2193 | Formulary Placement of Long-Acting Insulin Pen Products: Medicaid Plans |

| Exhibit # | Description |
|---|---|
| 2194 | Formulary Placement of Long-Acting Insulin Pen Products in Healthcare Exchanges |
| 2195 | U.S. Share of Long-Acting Pens Among All Pens |
| 2196 | U.S. Dollar Sales of Long-Acting Pens |
| 2197 | U.S. New Prescriptions of Long-Acting Pens |
| 2198 | U.S. Total Prescriptions of Long-Acting Pens |
| 2199 | U.S. Share of Long-Acting Pen Products |
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| 2201 | 2007 Good Design Award from The Chicago Athenaeum: Museum of Architecture and Design |
| 2202 | *Reserved* |
| 2203 | U.S. Total Marketing Expenditure of Long Acting Insulin Franchises |
| 2204 | U.S. Total Marketing Expenditures of Long-Acting Insulin Pens |
| 2205 | U.S. Marketing-to-Sales Ratios of Select Injectable Insulin Drugs |
| 2206 | Møller First Embodiment Animation |
| 2207 | Møller Second Embodiment Animation |
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| 2211 | Collar Friction Model Demonstrator Animation |
| 2212 | Excerpts from Ernest Rabinowicz, Friction And Wear of Materials, 2nd Edition, 68-70 (John Wiley & Sons, Inc. 1995) |
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| Exhibit # | Description |
|---|---|
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| 2215 | Collar Friction Model Demonstration 1 |
| 2216 | Collar Friction Model Demonstration 2 |
| 2217 | Collar Friction Model Demonstration 3 |
| 2218 | SoloSTAR Dial Inject Video |

## I. INTRODUCTION

The 044 Patent concerns a novel and non-obvious pen injector that permits a user to set the appropriate dosage from a multi-dose cartridge and self-administer the injection. The unique combination of mechanisms and functionality described and claimed in the 044 Patent was the result of a successful effort by the inventors to improve upon existing, but flawed, insulin pen injectors on the market in the 2003 timeframe.

Patent Owner respectfully submits that challenged claims 11, 14-15, and 18-19 of the 044 Patent are patentable over Grounds 1-2 presented in the Petition. Petitioner concedes that Steenfeldt-Jensen does not disclose each of the limitations of the challenged claims. Thus, Ground 1 alleges that the challenged claims are obvious over Steenfeldt-Jensen alone, and Ground 2 alleges that the challenged claims are obvious over Møller and Steenfeldt-Jensen. The challenged claims are patentable for at least the following reasons.

First, to satisfy the claim limitation requiring a "drive sleeve comprising an internal threading" Petitioner argues that Steenfeldt-Jensen "expressly contemplates a modification" where the driver tube of Steenfeldt-Jensen has internal threading. Petition at 40-41. This is incorrect as Steenfeldt-Jensen contains no such disclosure. Instead, Steenfeldt-Jensen refers to a "nut member"

or "nut element" having internal threads – not the driver tube. There is no suggestion that the driver tube itself can be modified to have internal threading.

Second, even assuming Petitioner's argument were true—that Steenfeldt-Jensen has a disclosure that suggests modifying its driver tube to have internal threads—this disclosure is only applicable to Steenfeldt-Jensen's *first* embodiment, not its *fifth* embodiment as Petitioner argues. The disclosure is recited in the description of the first embodiment, refers to components in the first embodiment, and is not repeated in, or applicable to, any other embodiments.

Third, a POSITA would not have been motivated to apply Petitioner's proposed modification to Steenfeldt-Jensen's *fifth* embodiment because doing so would result in an inferior device with significantly higher injection force. Patent Owner's expert, Prof. Alexander Slocum, has created analytical and physical models demonstrating that Petitioner's modifications result in a rotating thrust surface interface that acts like a disc brake (*i.e.*, where friction is generated as one component rotates on top of another component) and requires significantly greater injection force (~50% increase) from the user. Prof. Slocum's calculations prove that Petitioner's proposed modification to Steenfeldt-Jensen's fifth embodiment severely degrades its performance and that a POSA would not have been motivated to modify Steenfeldt-Jensen in the way proposed by Petitioner.

Fourth, the combination of Møller and Steenfeldt-Jensen does not disclose an internally-threaded drive sleeve. Petitioner points to Møller's connection bars 12 and nut 13 as the claimed drive sleeve, but this component is not a sleeve. Tacitly admitting this, Petitioner argues that a POSA would have expected that connection bars 12 and nut 13 ***could*** be formed as a sleeve based on a component in Møller's second embodiment. Petitioner fails to explain what would have motivated a POSA to form connection bars 12 and nut 13 as a sleeve. Petitioner also fails to explain how to form these elements as a sleeve without impairing Møller's pen injector.

Fifth, the combination of Møller and Steenfeldt-Jensen fails to disclose an ***externally-threaded*** dose dial sleeve "configured to engage a threading provided by [a] main housing." Instead, Møller discloses an ***internally-threaded*** dose setting drum 17 that engages with a threaded tubular element 5, which is not Møller's housing. Petitioner is incorrect that a POSA would have been motivated to modify Møller's dose setting drum 17 to have exterior threads, as taught by Steenfeldt-Jensen's externally-threaded dose scale drum 80. Rather, Møller teaches away from Steenfeldt-Jensen's dose scale drum. Møller expressly references Steenfeldt-Jensen's externally-threaded dose scale drum, criticizes it, and then states that it is an objective of Møller to avoid it. Moreover, it would not have been obvious to move the dose setting drum 17's threads from its interior to

its exterior, because (a) there is no reason to do so, (b) the modification would have resulted in an undesirable increase in the amount of force required by the user to inject medicine, and (c) external threads would mechanically interfere with helical reset spring 36.

Finally, the combination of Møller and Steenfeldt-Jensen fails to teach or render obvious the limitations recited in dependent claims 15 and 17.

For these reasons, as detailed further below, Patent Owner respectfully requests that the Board find all challenged claims of the 044 Patent to be patentable over the asserted grounds of invalidity.

## II. BACKGROUND OF THE TECHNOLOGY

At the time of the inventions set forth in the 044 Patent, there were already several pen-type injectors known in the art. For example, relevant to this proceeding, 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, ¶ 28.

There were, however, problems and limitations with the prior art injection pens, including the Novo Nordisk FlexPen (*i.e.*, Steenfeldt-Jensen's commercial embodiment), which suffered from relatively high injection force resulting at least partially from having to overcome the ratchet mechanism between the driver tube

and the housing. *See* Ex. 2107, ¶ 28. A higher injection force is problematic for patients lacking dexterity and strength, particularly for certain diabetic patients suffering from hand and wrist conditions. *Id*. ¶¶ 47-53 (discussing diabetic neuropathy and other conditions that limit a diabetic's hand strength and flexibility).

Developing a new pen injector 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 some other aspect, and one must consider whether these tradeoffs will result in an overall poor or flawed design. *See id*. In the pen injector context, changes that increase the required injection force would impair the ease of use of the device; and thus, would not be worth pursuing as it would worsen the patient's experience and decrease the likelihood that the patient would remain in strict compliance with their prescribed medication regime. This in turn accelerates the progress of their disease. *See* Ex. 2107, ¶¶ 36, 44.

The FlexPen, for example, required a high injection force to dispense the medication. Ex. 2175. It took Novo Nordisk several years to introduce a modified FlexPen that addressed this particular issue. Indeed, the original Novo Nordisk FlexPen was introduced in 2001 (*see* Ex. 2137 at 53, 66, Ex. 2136 at 22), but it was not until late 2008, five years after the 044 Patent's priority date and a year after

the launch of the SoloSTAR®, that Novo Nordisk introduced the New Generation FlexPen (NGFP), which had reduced injection force requirements (*see* Ex. 2136 at 71).

The inventors of the 044 Patent successfully balanced these competing design considerations and produced a novel, non-obvious, mechanical arrangement that results in an improved pen injector.

## III. THE 044 PATENT

Pen injectors are regularly used by patients without formal medical training, such as diabetic patients who manage their condition through self-treatment. Ex. 1002, 1:25-29. The 044 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 044 Patent discloses a pen injector having a novel arrangement of mechanisms that meet these criteria. *See* Ex. 1002, Ex. 2107, ¶ 64. In particular, the 044 Patent is specifically targeted at reducing the injection force needed for dispensing medicine. *Id.,* 3:64-67 ("The illustrated embodiment . . . helps reduce the overall force required for a user to cause medicinal product to be dispensed."); *see also* Ex. 1005, 1:66-2:3 ("Surprisingly it was found that the drive mechanism according to instant invention without having a unidirectional coupling provides a

valuable technical alternative for drive mechanisms, wherein reduced force is needed to actuate the mechanism.").[1] The figures below depict an embodiment of an improved injection pen. Additionally, an animation of the embodiment's operation has been submitted as Exhibits 2117 and 2218. *See* Ex. 2107, ¶ 65 (explaining animation).

[1] This description is from the 008 Patent, which is related to the 044 Patent since both patents claim the benefit of the filing date of the same foreign application—GB 0304822.

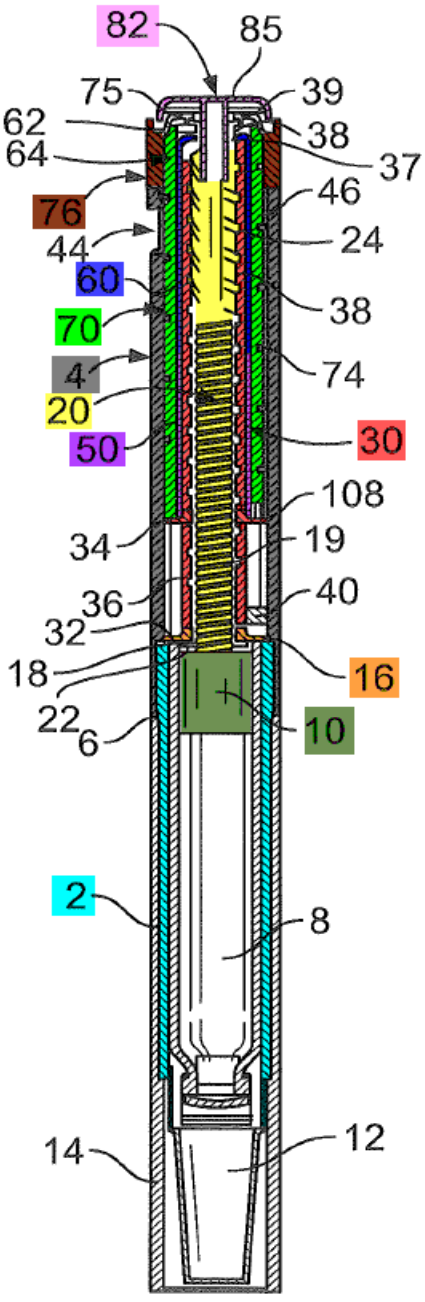



FIG. 1

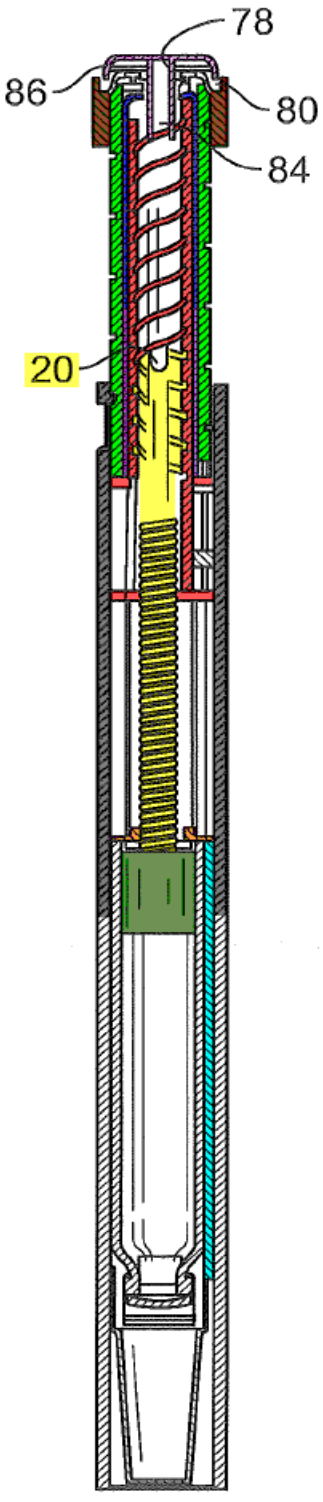



FIG. 2

**Ex. 1002, Figs. 1 and 2**

The pen injector of the shown embodiment comprises a cartridge retaining part 2 (light blue), an internally threaded main housing 4 (grey), a medicament cartridge 8 (not colored), 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).

In this embodiment, the dose value is selected by rotating the dial grip portion 76 (brown) of a dose dial sleeve 70 (light green), which winds out of the main housing 4 (grey) on a helical path defined by a threaded engagement between a helical groove on the surface of the dose dial sleeve and a helical rib 46 inside the housing. *Id.*, 5:50-6:3; Figs. 9-10.

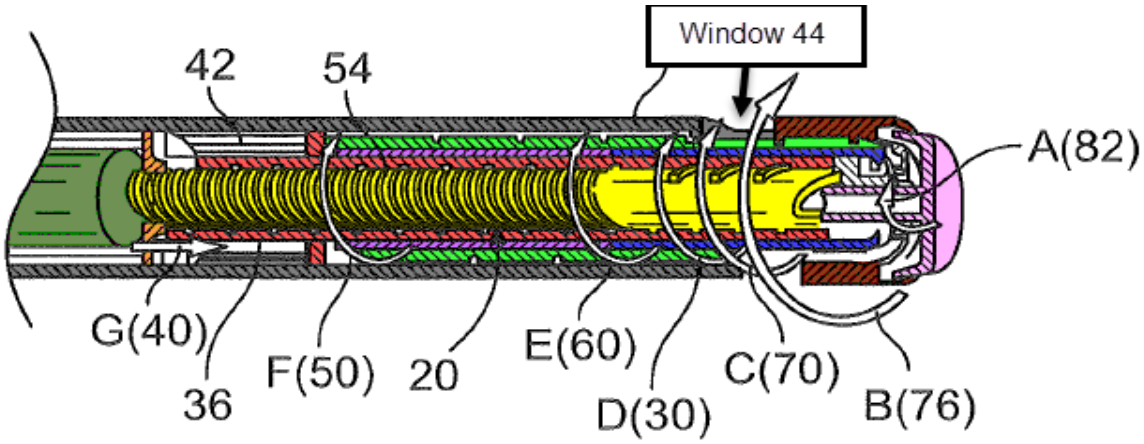



FIG. 9

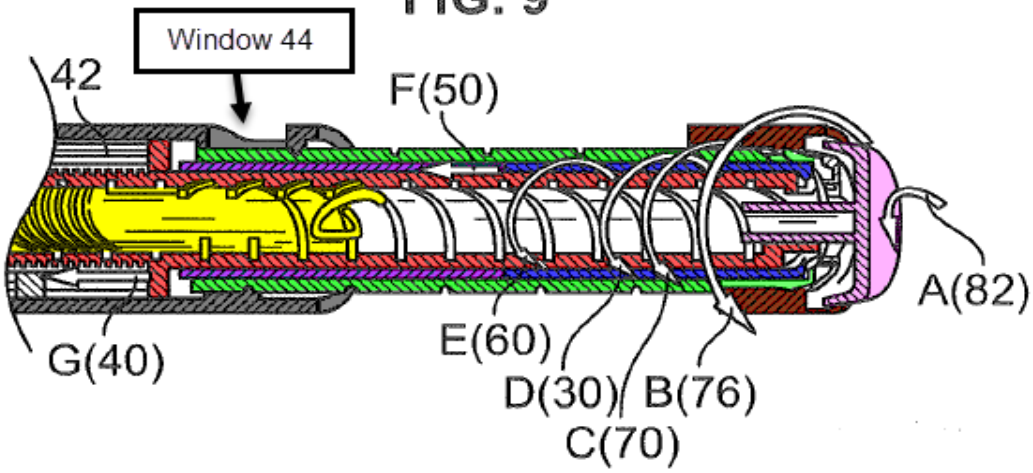



FIG. 10

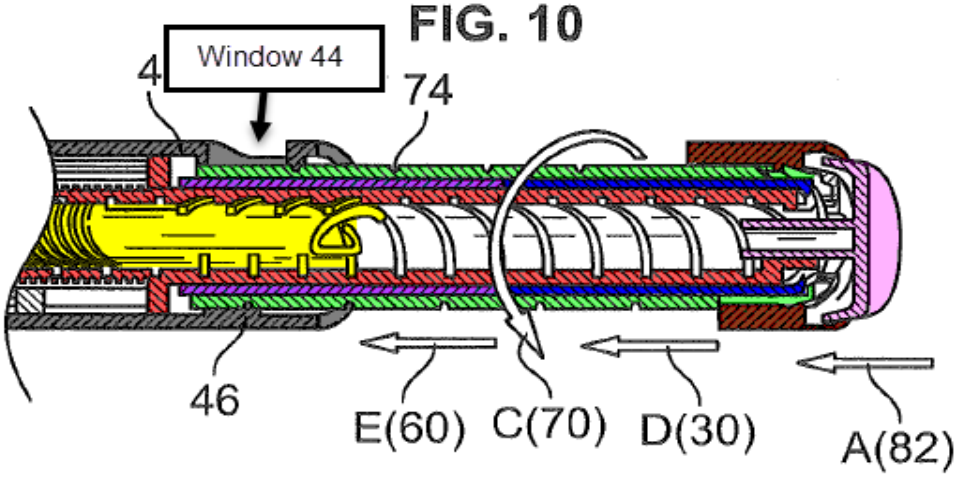



FIG. 11

**Ex. 1002, Figs. 9 – 11**

Dose markings (numbers) printed on an external surface of the dose dial sleeve 70 indicate the dosage. *Id*., 5:17-21. A clicker 50 detents the dose dial sleeve relative to the housing at each fixed dosage unit and provides audible feedback (*e.g.*, one click for every unit dialed) to assist in dose selection. *Id*., 4:33-44, 5:54-60.

The arrangement of components in this embodiment also enables the user to correct a selected dosage if it is higher than the user intended. The user can dial the dose dial grip 76 (brown) in the opposite direction without wastefully dispensing medication. *Id.*, 6:16-26. During this operation, the system essentially acts in reverse. *Id.*

Once the correct dose is selected, the user delivers a dose by pressing the dose button 82 (pink) with his or her finger or thumb, as shown in Figure 11. *Id*., 6:27-28. This user action returns the dose dial sleeve into the housing and delivers the dose by causing the drive sleeve 30 (red) to move toward the distal end of the pen, as indicated by the arrow D in Figure 11. This in turn causes a piston rod 20 (yellow) to advance a piston 10 (dark green) into the cartridge to dispense the stored medication. *Id*., 6:44-46. *See also* Ex. 2162 (animation of the depicted embodiment to show the interaction of the drive sleeve and piston rod during dose injection). During this dose-injection process the dose button and drive sleeve are not rotationally coupled to the dose dial sleeve, allowing the dose dial sleeve to

rotate back into the housing along the path defined by the helical groove (arrow C in Figure 11), while the dose button and drive sleeve travel on an axial path without rotating (arrows A and D in Figure 11). *Id*., 6:27-34; Fig. 11.

Once the dose is administered, the dose dial sleeve returns to the starting or "zero dose" position and is prevented from rotating further into the device. *Id*., 6:47-51. The user then releases the dose button, which returns the internal mechanism of the device into the dose dialing state. *Id*., 6:39-43.

## IV. CLAIM CONSTRUCTION

As stated in the Institution Decision, "only those claim terms in controversy and only to the extent necessary to resolve the controversy." Inst. Dec. at 17 (citations omitted). Patent Owner asserts that no express constructions are required to demonstrate that the challenged claims 11, 14, 15, 18, and 19 are patentable over Steenfeldt-Jensen and Møller.

## V. 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. *Id*.; *see In re GPAC*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *see also* M.P.E.P. 2141.03.

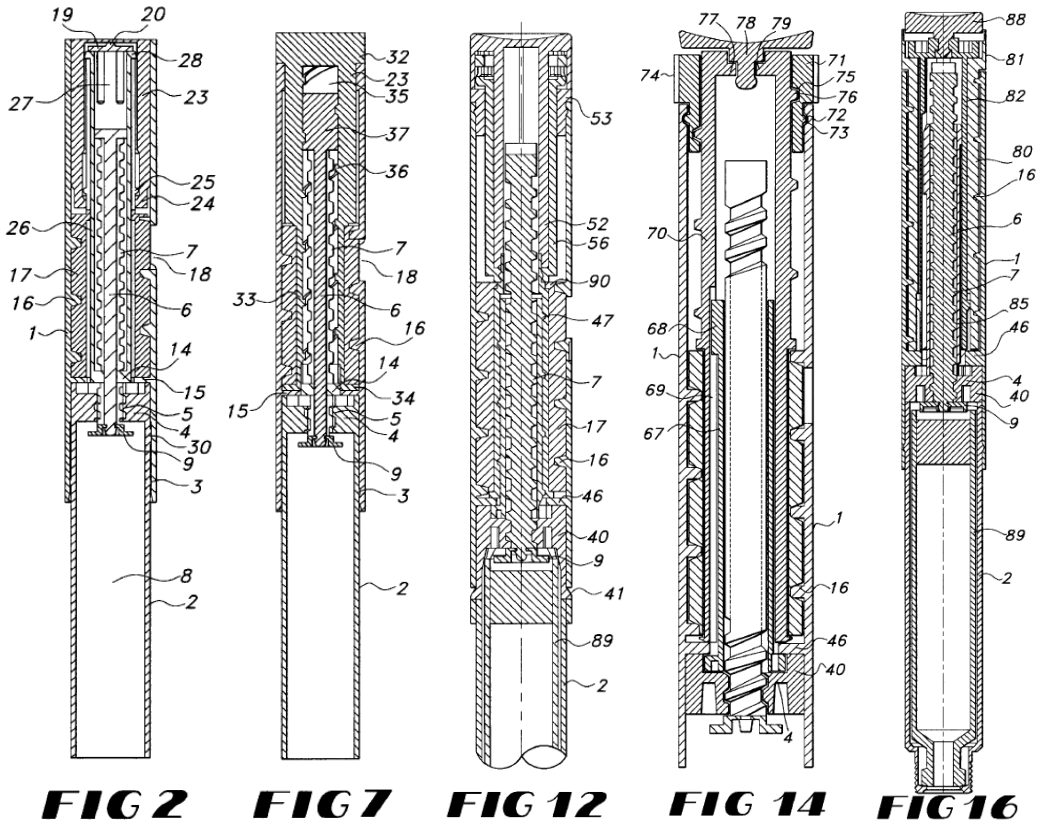
Patent Owner does not believe Petitioner's proposed level of ordinary skill should be adopted because the level of ordinary skill proposed by the Petitioner is inconsistent across the IPRs for the patents in this family. For example, in IPR2018-01684, IPR2018-01682, IPR2018-01680, and IPR2018-01670 Petitioner's 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.

## VI. THE PRIOR ART

### A. 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. 2015), was included in an IDS during prosecution of the 044 Patent and is cited on the face of the 044 Patent. *See* Ex. 1014 (claiming priority to DK 1998 00130), Ex. 2015 (same), Ex. 1007 at 0234 (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, ¶ 102 (explaining Steenfeldt-Jensen animations).




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

As discussed in greater detail in Section VII, Petitioner's arguments rely on a proposed combination of Steenfeldt-Jensen's ***fifth*** embodiment with a disclosure at column 7, lines 41-47 that is specific to Steenfeldt-Jensen's ***first*** embodiment. As summarized below, a POSA would have understood that this disclosure in Steenfeldt-Jensen's first embodiment is specific to the first embodiment and does not have general applicability to the subsequent four embodiments (including the fifth embodiment).

### 1. Steenfeldt-Jensen's Fifth Embodiment

For the grounds asserted in the Petition, Petitioner relies on the fifth embodiment (Ex. 1014 at 11:6-12:16, Figs. 15-17) to argue that Steenfeldt-Jensen discloses or renders obvious the challenged claims. *See* Petition at 21-49. The fifth embodiment, depicted in Figure 17 reproduced 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).

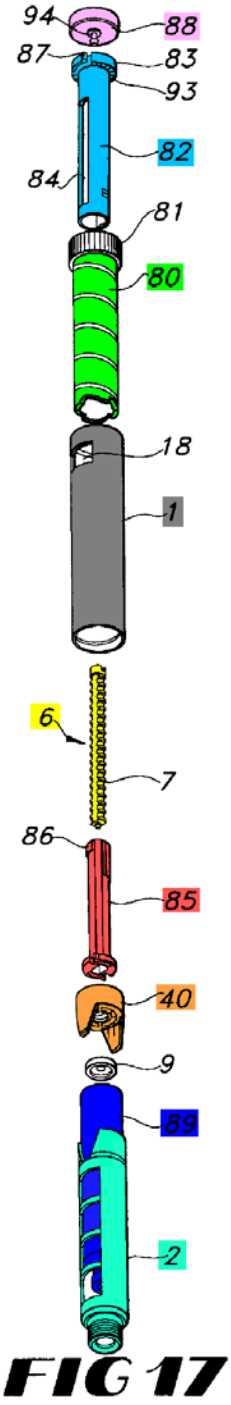
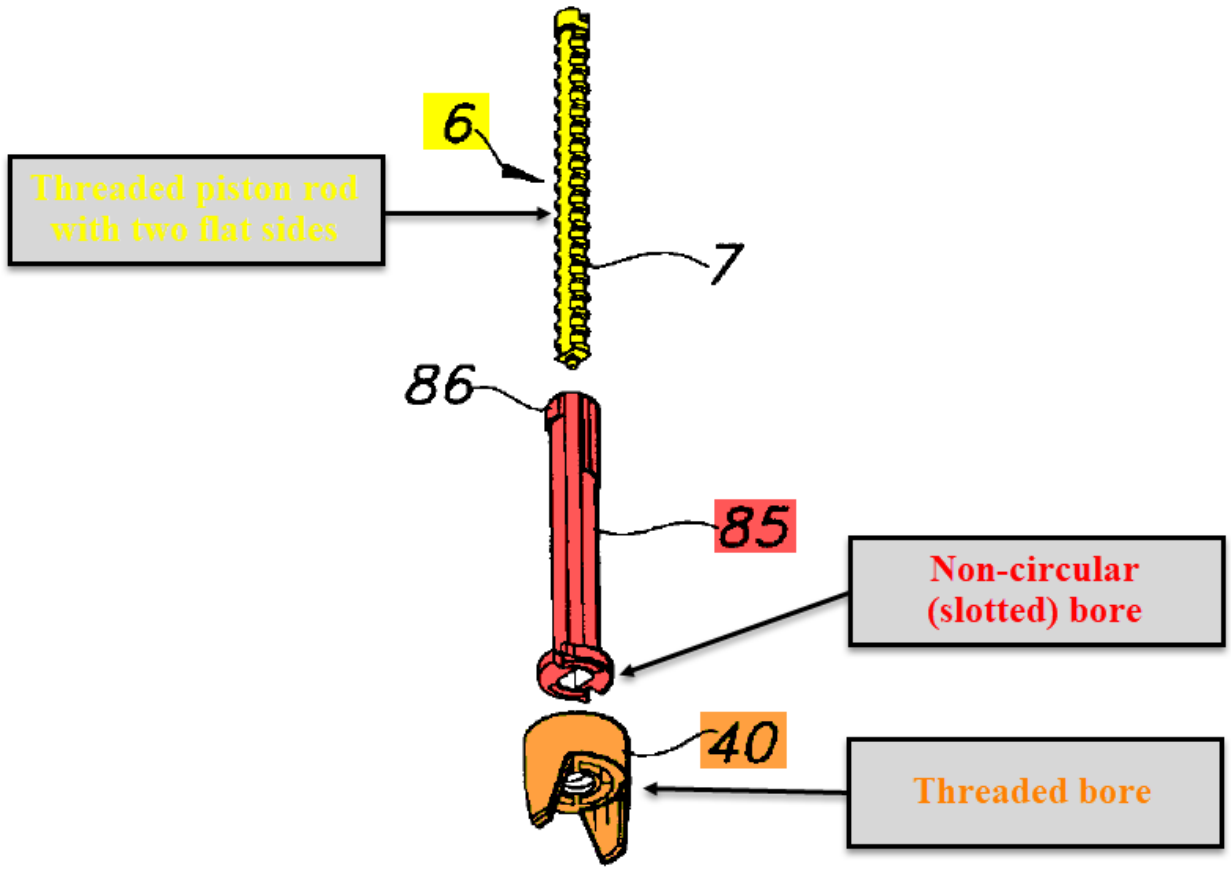


FIG 17

**Ex. 1014, Fig. 17.**

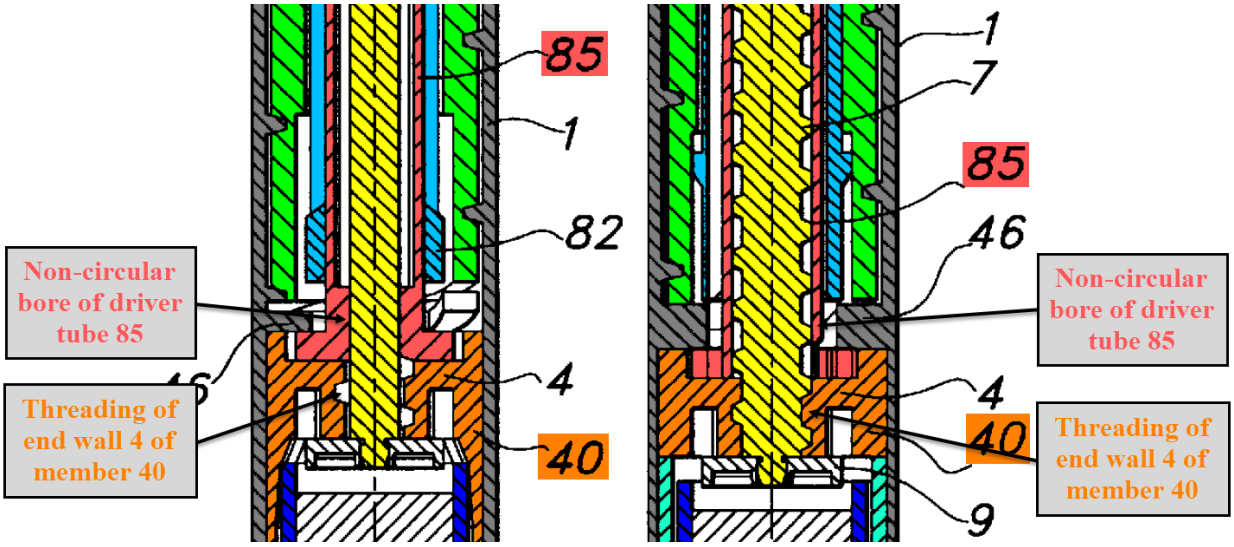
Significant to the issues raised in this Response, Steenfeldt-Jensen's fifth embodiment includes non-threaded driver tube 85 and a threaded piston rod 6

having two flat sides – *i.e.*, a non-circular threaded piston rod. This non-circular shape is necessary in the fifth embodiment because the piston rod 6 (yellow) rotates with driver tube 85 (red) when driver tube 85 is rotated. The non-circular shape of the piston rod fits within the same non-circular bore of the driver tube, thus rotationally coupling the components while allowing them to move axially relative to one another. *See* Ex. 2150 (animation depicting the threaded opening of member 40 and slotted opening of driver tube 85); *see also* Ex. 2107, ¶ 145.




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

Also significant to the issues raised in this Response is the method for dose administration in Steenfeldt-Jensen's fifth embodiment. When a dose is administered, the user applies a force to the injection button, which must be sufficient to overcome a one-way ratchet between the driver tube 85 and member 40 that otherwise prevents the driver tube 85 from rotating counter-clockwise with the bushing during dose dialing. This is illustrated below in Figures 15 and 16, which depict a close-up of driver tube 85 and member 40, as well as in an amination that has been submitted as Exhibit 2147. Ex. 2107, ¶ 145.




**Ex. 1014, Figs. 15 and 16 (cropped and annotated).**

The rotation of the driver tube 85 screws the piston rod 6 through the threaded opening in member 40 so that the piston rod 6 moves the ampoule (or cartridge) piston axially and in the distal direction to eject medicament. *See* Ex. 2147 (animation depicting dose dialing and injection); Ex. 2107, ¶ 137. Due to

Newton's third law, the cartridge piston applies an equal-and-opposite force to the piston rod. The vast majority of this reactive force is transferred through the piston rod to the internal threads of member 40, then to the housing 1, and then back to the user's hand. *See* Ex. 2107, ¶¶ 35, 233. The movement of internal mechanisms, as further described below, causes additional friction-induced resistive forces that are ultimately transferred to the user's grip. These forces, if large enough, and depending on how firmly the user is able to grasp the pen injector, can result in the pen injector slipping out of the of the user's hand during injection. *See id*.

**2. Steenfeldt-Jensen's First Embodiment**

Unlike the fifth embodiment, in Steenfeldt-Jensen's first embodiment (shown below), the piston rod 6 (yellow) directly engages the ampoule holder 2 (light blue). As shown below, the ampoule holder 2 includes a wall 4 having a central bore with an internal thread 5, and the piston rod 6 has external thread 7 that mates with the thread 5. Ex. 1014, 5:55-58. To dial a dose, the user grasps the ampoule holder and rotates it counter-clockwise relative to housing 1. *See id*., 6:42-43. When the ampoule holder is rotated, the piston rod rotates along with the ampoule holder, which in turn rotates with the piston rod guide 14 (the piston rod is inserted into the piston rod guide), with torque then transmitted to the driver tube 26. *Id*., 6:54-59, 7:1-3. As a result, due to hooks 28 at the proximal end of the

driver tube engaging slots 22 in the dose scale drum extension 21, the dose scale drum 17 will be rotated and screwed upwards. *Id*., 7:3-6.

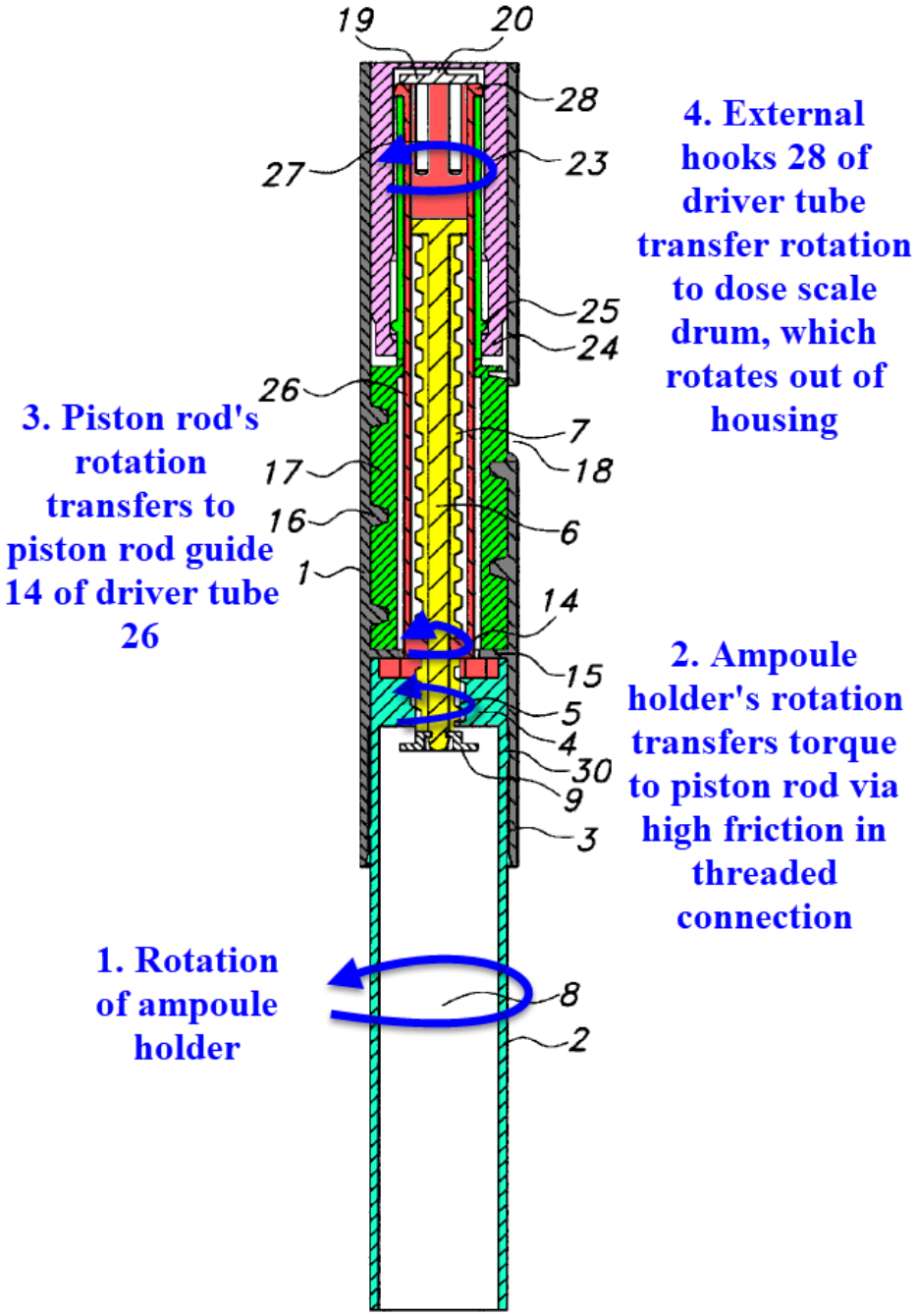


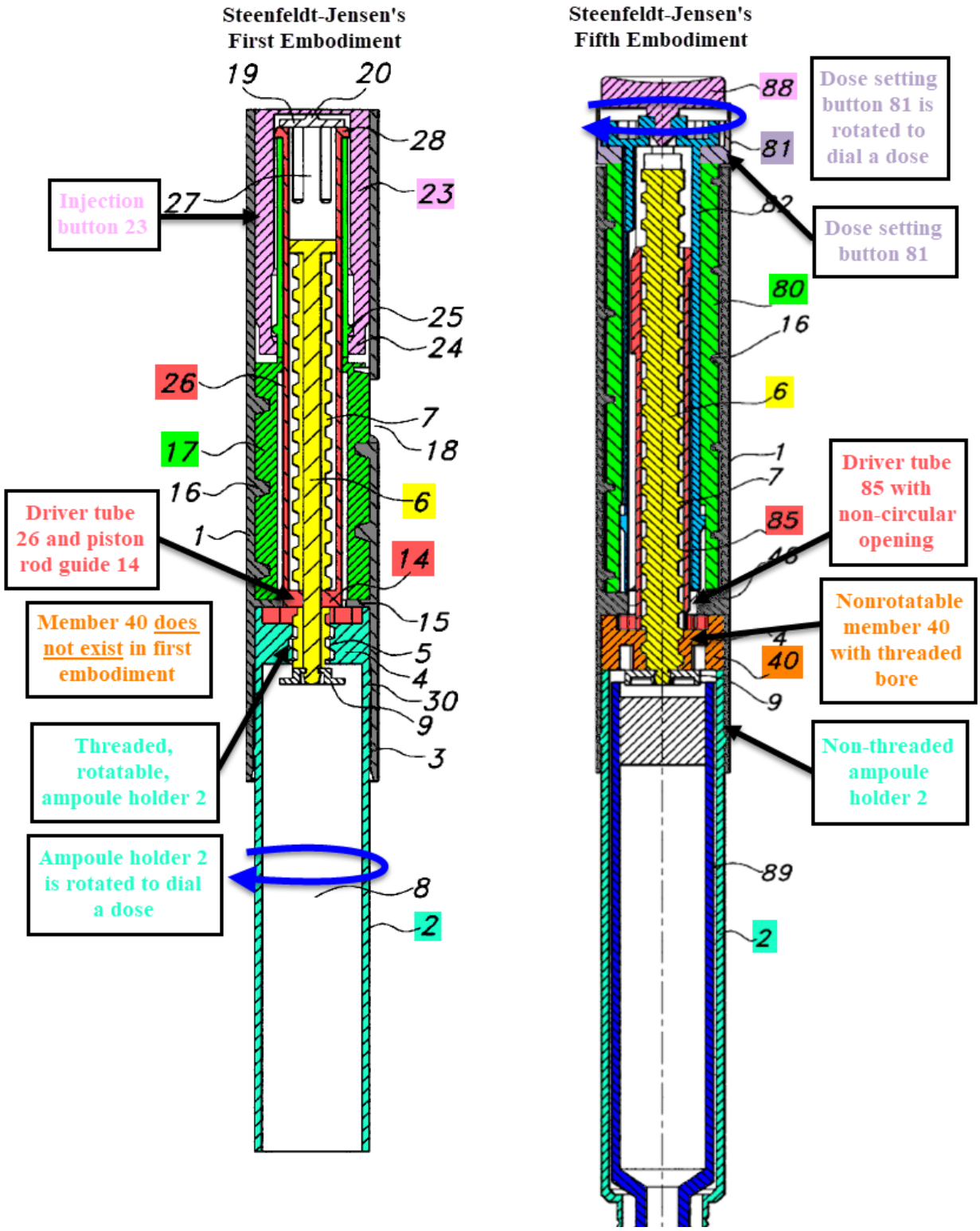

FIG 2

**Ex. 1014, Fig. 2 (annotated).**

To inject a dose, injection button 23 is pressed into the housing 1. Ex. 1014, 7:17-18. This applies a torque on the dose scale drum 17 causing it to rotate in the clockwise direction due to the threaded connection between the dose scale drum and the housing. *Id*., 7:18-21. The torque is transmitted via the slots 22 in the drum extension 21 and the hooks 28 at the end of the driver tube 26. *Id*., 7:21-24. The torque is then transmitted to the piston rod guide 14. *Id*.

### 3. Steenfeldt-Jensen's First Embodiment Operates Differently From the Fifth Embodiment

As described above, Steenfeldt-Jensen's first and fifth embodiments (below left and right, respectively), are different pen injector embodiments, and a POSA would understand that the teachings from one do not necessarily apply to the other. *See* Ex. 2107, ¶¶ 223-226.




**Ex. 1014, Figs. 2 and 16 (annotated).**

In particular, Steenfeldt-Jensen's first embodiment comprises components that are not part of the fifth embodiment and *vice versa*. The first embodiment includes an ampoule holder 2 (turquoise) that is rotatable with respect to the housing 1 (dark grey) and includes an end wall 4 with a threaded opening 5 that mates with the threads on piston rod 6 (yellow). The first embodiment also identifies a piston rod guide 14 (red) and a driver tube 26 (red). The fifth embodiment, however, does not have an ampoule holder 2 with a threaded end wall 4. Instead, the fifth embodiment includes member 40 (orange) with a threaded end wall 4.

The first embodiment is described in Steenfeldt-Jensen at column 5, line 33, through column 7, line 47, and the fifth embodiment is separately described at column 11, line 6, through column 12 line 16. The disclosure that Petitioner relies on to argue that a POSA would modify the fifth embodiment is recited at the end of the description for Steenfeldt-Jensen's first embodiment and is reproduced below. *See* Petition at 35.

> "In the ***shown embodiment*** [embodiment 1] the end wall 4 with its threaded bore forms a nut member relative to which the piston rod is rotated by the piston rod guide 14 and the driver tube 26. Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention."

Ex. 1014, 7:41-47 (emphasis added). This disclosure refers to the piston rod guide 14, end wall 4, and driver tube 26 of the first embodiment, thus confirming that the disclosure is directed to the first embodiment. Moreover, this disclosure is not repeated or otherwise referenced for any other embodiment, including for the fifth embodiment. *See* Ex. 2107, ¶¶ 223-226.

**B. 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 044 Patent. Ex. 1007 at 0038. Møller was filed on June 14, 2001. Møller is directed to providing an injection pen where the mechanism providing a mechanical advantage (*i.e.*, "gearing") between an injection button and an ampoule piston comprises gear racks and gear wheels. *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. Møller explains that this gearing reduces the force necessary to deliver an injection—*i.e.*, injection force—to assist users who have reduced finger strength. *Id.*; *see also* Ex. 2107, ¶ 148.

In discussing the types of gearing that can be used to achieve a mechanical advantage in an injection pen, Møller considers the prior art teachings. Specifically, Møller references and describes EP 608 343 and WO 99/38554, the

latter of which is the PCT counterpart to Steenfeldt-Jensen and also cited on the face of the 044 Patent.[2] Møller explains that the prior art gearing of EP 608 343 is achieved from a dose setting element having a high pitch thread that rotates in unison with a driver nut having a fine pitch thread. Ex. 1015, ¶ 0007. Then Møller states that WO 99/38554 (Steenfeldt-Jensen) discloses a "similar gearing" that relies on a dose setting drum having a high-pitch thread. *See* Ex. 1015, ¶ 0008. Møller notes that "by this [*i.e.*, Steenfeldt-Jensen's] kind of gearing relative large surfaces are sliding over each other so that ***most of the transformed force is lost due to friction between the sliding surfaces***." *Id.* (emphasis added). As a result, "a traditional gearing using mutual engaging gear wheels and racks is preferred." *Id.* Significantly, Møller then explains that:

> It is an objective of the invention to provide an injection device, which combines the advantages of the devices according to the prior art ***without adopting their disadvantages*** and to provide a device wherein is established a direct gearing, ***i.e., a gearing by which more transformations of rotational movement to linear movement and linear movement to rotational movement <u>are avoided</u>, between the injection button and the piston rod***.

[2] *See* Ex. 1014 (claiming priority to DK 1998 00130), Ex. 2003 (same); *see also* Ex. 1011, ¶ 356 ("In discussing the background for this invention, I note that Møller discusses the device disclosed in Steenfeldt-Jensen.").

*Id.*, ¶ 0011 (emphasis added). The invention presented by Møller accounts for these advantages and disadvantages, and notably does not implement the teachings of WO 99/38554—*i.e.*, Steenfeldt-Jensen's teachings—(of which Møller is fully aware) because Steenfeldt-Jensen achieves a gearing between the injection button and the piston rod through "transformations of rotational movement to linear movement and linear movement to rotational movement" (*i.e.*, by using two helical threads with different pitches to achieve a mechanical advantage), which Møller says should be avoided. *See* Ex. 2107, ¶ 149.

Møller's first embodiment, the embodiment relied upon by Petitioner, is configured and described as follows. *See also* Ex. 2017 (animation depicting Møller's first embodiment). To set a dose, "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.*

"The rotation of the dose setting button 18 and the cup shaped element is further transmitted to the gearbox 9 through the protrusions 23 on this gearbox engaging the longitudinal recesses 22 in the inner wall of the tubular part 20 of said cup shaped element." *Id.*, ¶ 0030. "The rotation of the gearbox 25 is through the connection bars 12 transmitted to the nut 13, which is this way screwed up along the thread of the piston rod 4 and lifted away from its abutment with the wall 2 when a dose it set." *Id.*

To dispense a dose, "the injection button is pressed by pressing on the bottom 19." *Id.*, ¶ 0032. The protrusions 32 are drawn out of engagement with recesses in the ring 33, such that the "dose-setting drum 17 can now rotate relative to the injection button and will do so when the Δ-shaped protrusions 32 press against a shoulder 34 at the bottom of the dose setting button 18." *Id.*, ¶ 0033. "Only a force sufficient to make the dose setting drum rotate to screw itself downward along the thread 6 is necessary as the force necessary to make the injection is transmitted to the piston rod 4 through the gearbox 9." *Id.*

## VII. THE CITED PRIOR ART DOES NOT TEACH OR RENDER OBVIOUS THE CHALLENGED CLAIMS

### A. The Challenged Claims Are Patentable in View of Ground 1

#### 1. Steenfeldt-Jensen Does Not Teach or Render Obvious a "drive sleeve comprising an internal threading … adapted to engage an external thread of said piston rod" (all challenged claims)

##### a) There Is No Disclosure of Suggestion in Steenfeldt-Jensen of an Internally Threaded Drive Sleeve

Challenged claims 11, 14-15, 18-19, which depend from claim 11, require a "drive sleeve comprising an internal threading." Petitioner concedes that Steenfeldt-Jensen's fifth embodiment does not disclose this limitation. Petition at 31. Petitioner argues, however, that a POSA would have known to modify Steenfeldt-Jensen "to provide driver tube 85 with internal threading." *Id.* at 40. None of the four passages in Steenfeldt-Jensen that Petitioner relies on discloses or suggests an internally threaded driver tube. Instead, these passages disclose an internally threaded "nut member" or "nut element", which is rotated by a driver tube – the driver tube itself is not threaded.

The first passage is at column 2, lines 40-53. Petition at 41. No portion of this passage identifies a driver tube, much less an internally threaded driver tube. *See* Ex. 2107, ¶¶ 215-216. Instead, this passage identifies (i) an axially moveable, but non-rotatable "piston rod guide", and (ii) a rotatable "nut member" having an internal thread. Ex. 1014, 2:40-53. Petitioner does not explain how this passage,

which does not mention a driver tube, suggests a threaded driver tube. The only threaded component described is the "nut element."

The next two passages are from column 3 at lines 15-20 and at lines 41-47. Petition at 40-41. These passages state: (1) "rotation of the scale drum can rotate the piston rod relative to the nut member"; or (2) "rotation of the scale drum can rotate the nut member relative to the piston rod." *See* Petition at 40-41 (citing Ex. 1014 at 3:15-20, 3:44-47). These passages only recognize that for a piston rod to move axially through a nut member, there must be relative rotation between the piston rod and the nut member (*i.e.*, the well-known mechanical engineering principle that either the nut member rotates, or the piston rod rotates as a threaded rod moves through a threaded nut). *See* Ex. 2107, ¶¶ 216-217. These disclosures do not disclose or suggest modifying a driver tube to have threads. *See* Ex. 2107, ¶¶ 215-217.

The final passage, at column 7, lines 41-47, describes a driver tube rotating a threaded "nut member." Petition at 40. Again, there is no disclosure that a driver tube is threaded. Ex. 1014, 7:44-47 ("Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a ***nut element is rotated by the driver tube*** and such embodiment will not be beyond the scope of the invention.") (emphasis added); *see also* Ex. 2017, ¶¶ 218-220.

Thus, none of the four passages relied on by the Petitioner teaches or suggests the driver tube having internal threads. At best, the passages teach an internally threaded nut member and a piston rod with relative movement between the two components. But the nut member is not the driver tube, and Steenfeldt-Jensen makes clear throughout its disclosure that the nut member and the driver tube are different components. *See, e.g.*, Ex. 1014, 3:41-47, 7:41-47; *see also* FIG. 13, 10:2-10 (identifying a "nut member 48," also referred to as a "nut element" and a discrete "driver tube 45"). Accordingly, the passages relied on by Petitioner ***do not*** support the modification suggested by the Petitioner, and thus Petitioner cannot show obviousness as a matter of law. *See Eurand, Inc. v. Mylan Pharms., Inc. (In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.)*, 676 F.3d 1063, 1069 (Fed. Cir. 2012) (a party asserting obvious must support its reason to modify the prior art with evidence) (citing *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009)).

**b) Steenfeldt-Jensen's Disclosure at Column 7, Lines 41-47 is for the First Embodiment, not the Fifth Embodiment**

Petitioner argues that a POSA would have known to modify Steenfeldt-Jensen's fifth embodiment (shown in Figures 15-17 and described at col. 11, ln. 6 through col. 12, ln. 16) based on a passage from Steenfeldt-Jensen's discussion of

its first embodiment (shown in Figures 1-5 and described at col. 5, ln. 33 through col. 7, ln. 47):

> In the ***shown embodiment*** [embodiment 1] the end wall 4 with its threaded bore forms a nut member relative to which the piston rod is rotated by the piston rod guide 14 and the driver tube 26. Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention.

Ex. 1014, 7:41-47 (emphasis added). This argument fails because a POSA would understand that this passage is not applicable to the fifth embodiment. *See* Ex. 2107, ¶¶ 223-226.

First, the "shown embodiment" in the passage is referring to the first embodiment described with respect to Figures 1-5. *Id.*, 5:33-7:47 (the portion of the specification describing first embodiment). The discussion of the fifth embodiment in Steenfeldt-Jensen does not include a similar passage. *See* Ex. 1014, 11:6-12:16 (the portion of the Steenfeldt-Jensen describing the fifth embodiment). And indeed, the language from column 7, lines 41-47 originates from Steenfeldt-Jensen's provisional application, which included the first embodiment, but did not include the fifth embodiment. *See* Ex. 2127, 11:2-5; *see generally id*. (lacking any description of the fifth embodiment). When the fifth embodiment was added to the specification, similar language was not included to

cover the fifth embodiment, thus further indicating that the passage is not applicable to the fifth embodiment.

Second, a POSA would have understood that the passage is not a general teaching having applicability to all of Steenfeldt-Jensen's embodiments. For example, modifying Steenfeldt-Jensen's second embodiment would result in a ***non-functioning*** pen injector. *See* Ex. 2107, ¶ 226. As Prof. Slocum explains in his declaration, placing the non-circular opening in the ampoule holder 2 (turquoise) of the second embodiment and putting a threaded opening in the pawl 13 (red) would allow the user to dial the dose but not inject the dose. *See id*. If the user attempts to inject a dose, the injection button would not move. *See id*. Accordingly, a POSA would have understood that the passage that Petitioner relies on for their alleged modification is made specifically and only for the first embodiment. *See id*.

Finally, even assuming that (1) the passage was made in the context of the fifth embodiment, or (2) the passage had some general applicability outside the first embodiment, Petitioner's argument still fails because the passage does not teach the modification that Petitioner proposes. Petitioner is proposing the following modification to the fifth embodiment:

> **Steenfeldt-Jensen Actual Fifth Embodiment:** member 40 has threads that engage with the threads on the piston rod, and the driver tube has a non-circular bore that the piston rod slots into.

> **Petitioner's Modified Fifth Embodiment:** member 40 has a non-circular slot that the piston rod slots into, and the driver tube has threads that engage with threads on the piston rod.

Petition at 36. *See also* Ex. 2107, ¶ 227; Ex. 2164 at 219:18-220:11 (Petitioner's expert confirming the nature of the proposed modification to Steenfeldt-Jensen's fifth embodiment). The passage at column 7, lines 41-47 does not suggest this modification. Instead, it teaches putting a piston rod guide in end wall 4 of ampoule holder 2 (of the first embodiment), and having driver tube 26 (of the first embodiment) rotate a nut element. *See* Ex. 2107, ¶ 215.

#### c) The Petitioner's Modification to Switch the Non-Circular Opening and Threaded Opening in the Fifth Embodiment Results in an Inferior Pen Injector

Further, Petitioner's proposed modification to the fifth embodiment of Steenfeldt-Jensen (as detailed in the previous paragraph) is antithetical to pen injector design during the relevant time period and results in an inferior pen injector. Specifically, moving the threads on member 40 to the driver tube, and moving the non-circular slot on the driver tube to member 40, ***introduces a major new source of friction*** to Steenfeldt-Jensen's fifth embodiment. As detailed below, in Petitioner's modified embodiment the outward flange (which includes flexible arms) of the threaded driver tube is forced up against an inner flange of the housing during dose injection, thus creating a disk brake. *See* Ex. 2107, ¶¶ 232-238. This new source of friction results in an inferior device with higher injection

force, which is a critical design consideration for a pen injector. Accordingly, a POSA would not have been motivated to make this modification. *See* Ex. 2107, ¶¶ 212-255.

As background, friction results in efficiency losses because some of the force going into the pen during dose injection must overcome friction. These losses are highly undesirable as they require the user to expend greater energy to inject medicament. *See, e.g.*, Ex. 1015, ¶¶ 0004-0006 (discussing the need for pen injectors to require only low injection forces); *see also* Ex. 2107 ¶ 37-39, 44-45, 54, 56-57 (explaining the design that for the diabetic population, pen injectors having higher injection forces (the force necessary to overcome the internal friction of the device) can dissuade users from following prescribed injection plans and thus impair self-management of their disease), Section II, *supra*. Injection force is regularly assessed as a benchmark for these products. *See* Ex. 2107, ¶¶ 56-57 (describing various studies focused on the injection forces of commercially available pens), *see also* Ex. 2163 at 80:17-81:5 ("… diabetic patients typically don't have the strength to inject the medicine like a patient without diabetes. So there's a lot of focus in pen injectors to reduce the force of injection.").

Prof. Slocum created analytical models presented in the form of a spreadsheet that show how friction between the different pen injector elements leads to efficiency losses with a resultant increase in the net injection force.

Specifically, Prof. Slocum calculated the injection force of Steenfeldt-Jensen's fifth embodiment and then, controlling for all variables, calculated it again for Petitioner's proposed modification to demonstrate the difference in injection force.

Furthermore, a physical model, referred to as the "Collar Friction Model," conveys the basic principle for why Petitioner's proposed modification would result in an inferior device—i.e., the introduction of "collar friction" when the driver tube is modified to have threads to interface with the piston rod. See Ex. 2107, ¶¶ 245-255. Prof. Slocum explains that this Collar Friction Model directly compares Steenfeldt-Jensen's fifth embodiment with Petitioner's proposed modification to the fifth embodiment. *See id*. Videos and animations demonstrating the Collar Friction Model have been provided to the Board as Exhibit Nos. 2211, 2215-2217.

*(1) Analytical Model*

To quantitatively compare the impact of Petitioner's proposed modification to Steenfeldt-Jensen's fifth embodiment, Prof. Slocum used an analytical model that determines the efficiency of a pen injector for a given set of parameters. *See* Ex. 2107, ¶¶ 242-244; *id.*, Appx. A,. A more efficient pen injector requires less force by the user to move the ampoule piston to inject medication. *See* Ex. 2107, ¶ 243; *id.*, Appx. A. Friction plays a large role in efficiency because the user must exert sufficient force to overcome the internal friction of the pen injector (*i.e.*,

increased friction reduces the efficiency of the force applied by the user). The model calculates this force for both Steenfeldt-Jensen's fifth embodiment (where a rotating driver tube is not internally threaded) and Petitioner's proposed modification to the fifth embodiment (where a rotating driver tube is internally threaded). For the model shown in Appendix A to Prof. Slocum's declaration, Prof. Slocum used physical parameters of the FlexPen, which is the commercial embodiment of Steenfeldt-Jensen's fifth embodiment. The difference in force delivered to the ampoule piston is 4.5N, which means that mathematically, and by holding all variables other than Petitioner's proposed modification constant, Petitioner's proposed modification increases the amount of force required from the user to inject a dose by 51%.

*(2) Collar Friction Model*

The Collar Friction Model physically demonstrates the principle underlying why Petitioner's proposed modification significantly degrades performance. *See* Ex. 2017, ¶¶ 245-255. Videos demonstrating the Collar Friction Model have been submitted as Exhibits 2215-2217. The model includes the following components that can be arranged to demonstrate both Steenfeldt-Jensen's fifth embodiment (*i.e.*, a piston rod threadedly engaged with member 40 and slotted to the driver tube) and Petitioner's proposed modified embodiment (*i.e.*, a piston rod slotted to a member 40 and threadedly engaged with the driver tube):

**Housing:** This component represents housing 1 of Steenfeldt-Jensen's fifth embodiment.

**Collar plus Guide or Thread Insert:** This rotating component in combination with the slotted red piece ("Guide") represents the unthreaded driver tube 85 of Steenfeldt-Jensen's fifth embodiment. The Collar in combination with the threaded blue piece ("Thread Insert") represents a threaded driver tube according to Petitioner's proposed modification.

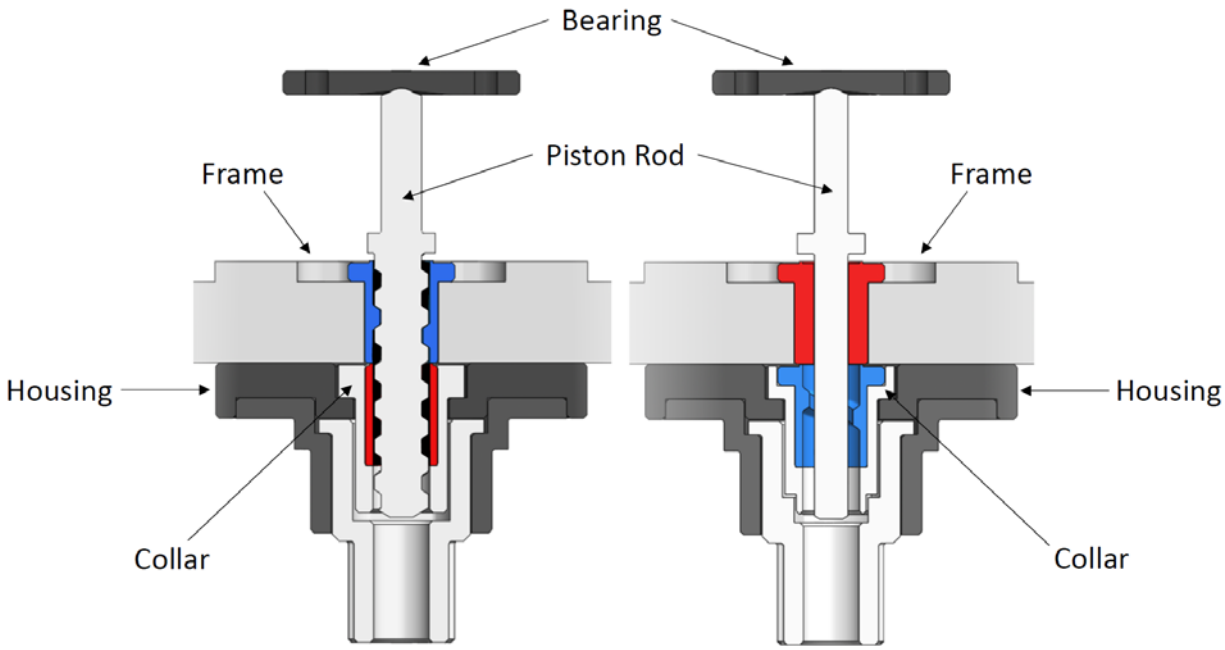
**Frame plus Guide or Thread Insert:** This rotationally-fixed component in combination with the Thread Insert represents threaded member 40 in Steenfeldt-Jensen's fifth embodiment. The Frame in combination with the Guide represents the slotted member in Petitioner's proposed modification.

**Piston Rod:** This component represents the piston rod 6 in Steenfeldt-Jensen's fifth embodiment.

**Bearing:** This component carries a 2 kg weight that is used to represent the resistive force experienced by Steenfeldt-Jensen's piston rod 6 when it presses the ampoule piston during dose injection.

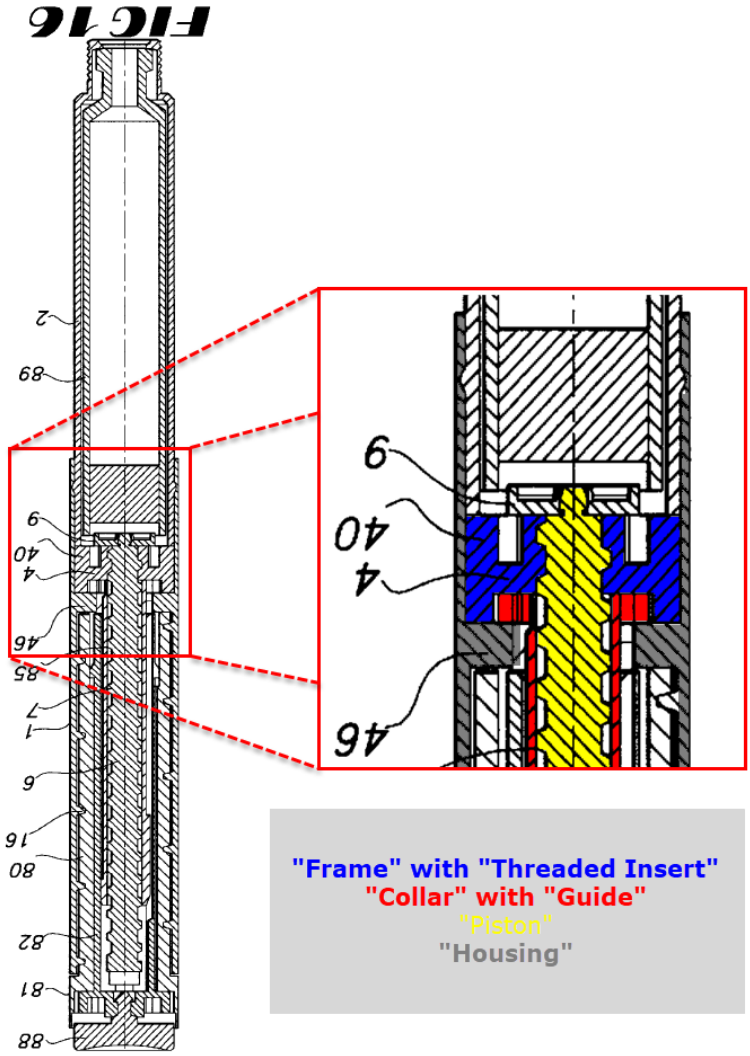
*See* Ex. 2107, ¶ 247. These components of the Collar Friction Model are shown in the two cross-section illustrations below.[3]

[3] In the arrangement on the right below, the perspective of the Guide and the Piston Rod are offset by 90° to provide additional visual details.




In the graphic above on the left, the model is arranged to demonstrate Steenfeldt-Jensen's fifth embodiment, and therefore, the Thread Insert (blue) is fitted to the Frame and the Guide (red) is fitted to the Collar. On the right, the

model is arranged to demonstrate Petitioner's proposed modification, and therefore, the Guide (red) is fitted to the Frame, and the Thread Insert (blue) is fitted to the Collar. Figure 16 of Steenfeldt-Jensen is also reproduced below with annotations to show the orientation of the Collar Friction Model:




As Prof. Slocum explains in his declaration and the videos submitted as Exhibits 2215-2217, simply swapping the location of the threaded opening and the slotted opening (*i.e.*, by swapping the Guide and Threaded Insert) creates a

significant difference. *See* Ex. 2107, ¶¶ 249-254, Ex. 2215, Ex. 2216, Ex. 2217. That is, rotating the Collar with the Threaded Insert (Petitioner's proposed modification) is more difficult than rotating the Collar with the Guide (Steenfeldt-Jensen's fifth embodiment). Specifically, manually rotating the Collar with the Threaded Insert requires approximately 50% more force on average to advance the piston rod than rotating the Collar with Guide. *See* Ex. 2107, ¶¶ 252-254.

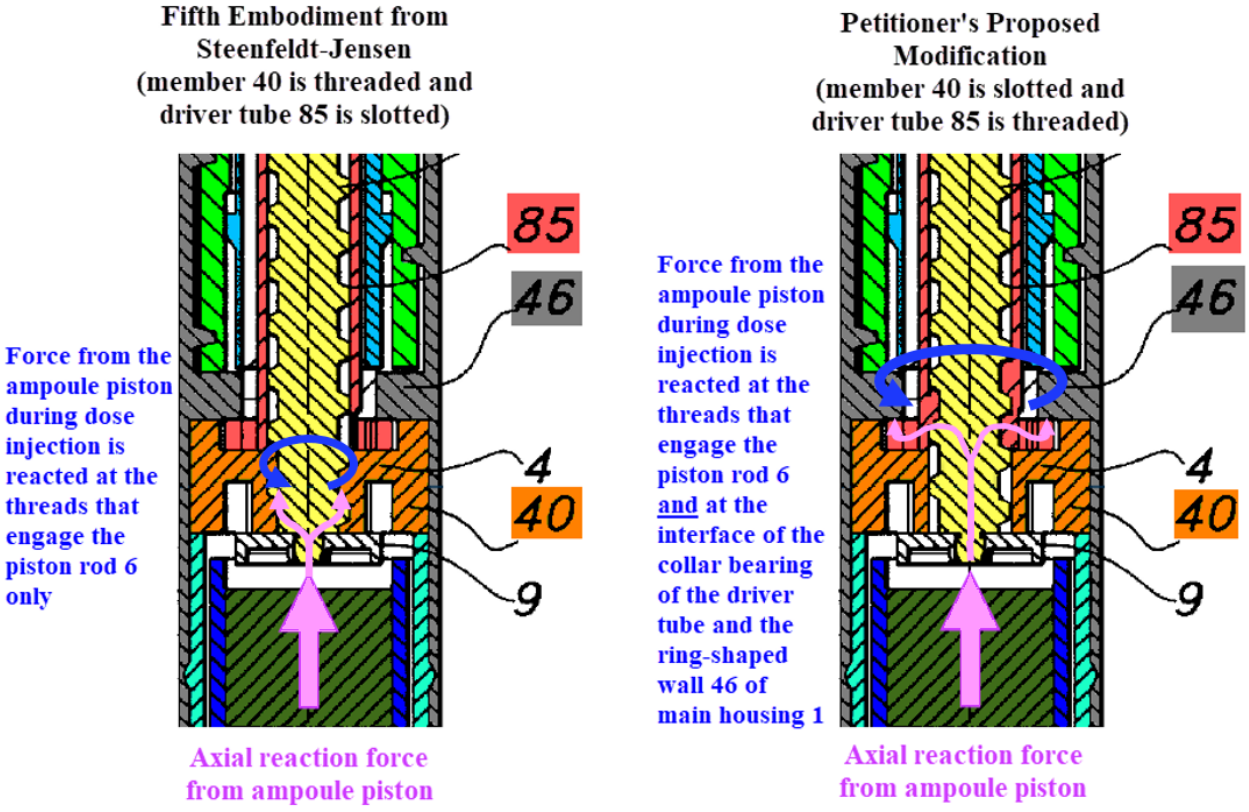
The additional friction is also apparent from what happens after the piston rod is rotated upward and then released. In the configuration representing Steenfeldt-Jensen's fifth embodiment (i.e., Collar fitted with the Guide), if the piston rod is rotated upward and then released, it rotates back down to its original position because of the 2 kg weight on the bearing. In contrast, in the configuration representing Petitioner's proposed modification (i.e., Collar fitted with the Thread Insert), if the piston rod is rotated upward and then released, it remains stuck in place because the 2 kg weight is insufficient to overcome the additional friction (i.e., the collar friction). *See* Ex. Ex. 2107, ¶¶ 249-251.

**d) <u>Explanation For Why Petitioner's Modification Results in Higher Friction</u>**

The reason that Petitioner's modification introduces more friction to Steenfeldt-Jensen's fifth embodiment is explained below.

Steenfeldt-Jensen's unmodified fifth embodiment is reproduced in the figure below, at left. During dose injection, an axial force is delivered from the piston

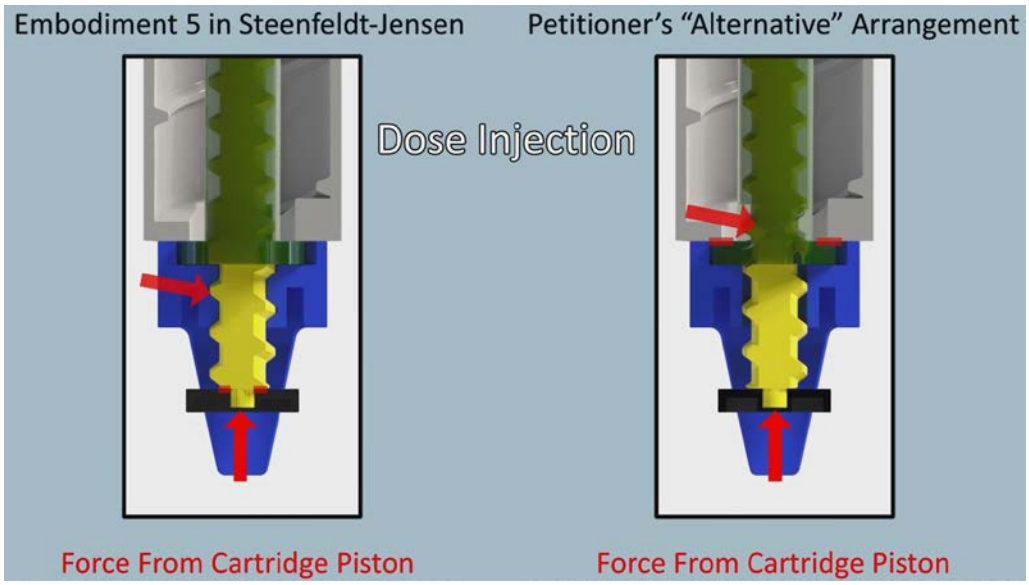
rod 6 (yellow) to the ampoule piston (dark green). For every action, there is an equal and opposite reaction. *See* Ex. 2107, ¶ 233. Accordingly, this axial force from the piston rod 6 (yellow) causes a reaction force (pink arrows) exerted by ampoule piston (dark green) against the piston rod 6 (yellow) that translates to the internal threads of non-rotatable member 40 (orange) as an upward force (also pink lines with arrows) which in turn flows to the housing of the injector held by the palm and fingers of the user's hand gripping the housing. *See* Ex. 2107, ¶¶ 233-238. Thus, in the fifth embodiment, all of the axial reaction force from ejecting the fluid from the ampoule is borne by member 40, which is axially and ***rotationally fixed*** within housing 1 (denoted in grey). *See* Ex. 2107, ¶ 233.



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

Importantly, in the unmodified fifth embodiment, the force at member 40 acts at a small radius and thus introduces only minor frictional torque ($\tau = r \times F$) (blue arrow) at the threaded interface between the piston rod 6 and member 40. *See* Ex. 2017, ¶ 234; *see also* Ex. 2152 (animation comparing Steenfeldt-Jensen's fifth embodiment to Petitioner's proposed modified embodiment during the dose injection phase of operation).

In contrast, in the Petitioner's modified device (rightmost figure, above), essentially all of the reaction force is borne by now-threaded driver tube 85 (red), instead of by member 40. *See* Ex. 2107, ¶¶ 235-236. But, unlike member 40, driver tube 85 ***is not rotationally fixed*** with respect to housing 1 (and the housing's ring-shaped wall 46) because the driver tube 85 must also rotate as the piston rod 6 is driven axially during dose injection. *See* Ex. 1014, 12:10-13, Ex. 2107, ¶¶ 237-238. Accordingly, driver tube 85 in the modified device must resist the reaction thrust force ***at the same time that it is rotating***, and this force is increased by rotating contact between the flange on the driver tube that extends radially outward to contact a surface on the housing 1. *See* Ex. 2107, ¶¶ 237-238; *see also* Ex. 2152.




**Ex. 2152 (screenshot from animation)**

Thus, in addition to the friction between the threads of piston rod 6 and those of driver tube 85, a significant source of friction is introduced during dose injection at the flange on the driver tube 85 as it is being driven upward as it rotates by thread reaction forces into the ring-shaped wall 46 of housing 1 (grey). *See* Ex. 2107, ¶¶ 237-238. This driver tube flange now acts as a disk brake and is what Prof. Slocum refers to as the drag torque or collar friction. *See* Ex. 2107, ¶ 238. Because this new friction interface is at a greater radius than the friction interface between piston rod 6 and member 40 in the fifth embodiment, the resulting frictional torque (blue arrows) is much greater ($\tau = r \times F$), ***approximately 50% greater.*** *See* Ex. 2107, ¶¶ 242-244 (describing calculations to show increase in frictional torque).

As a result, Petitioner's modified device needs considerably more injection force to overcome these larger friction losses, which is contrary to the critical design objectives in this art. *See* Ex. 1004, 1:36-40 ("The injector must be … easy to use … in terms of the manipulation of the parts …. In the case of those with diabetes, many users will be physically infirm …."), Ex. 1015, ¶¶ 0004-0006 (discussing the need for pen injectors to require only low injection forces); *see also* Ex. 2107, ¶¶ 54-57, Section II, *supra*. Modifying the fifth embodiment as Petitioner proposes ***increases friction*** and impairs the device. *See* Ex. 2107, ¶¶ 229-231.

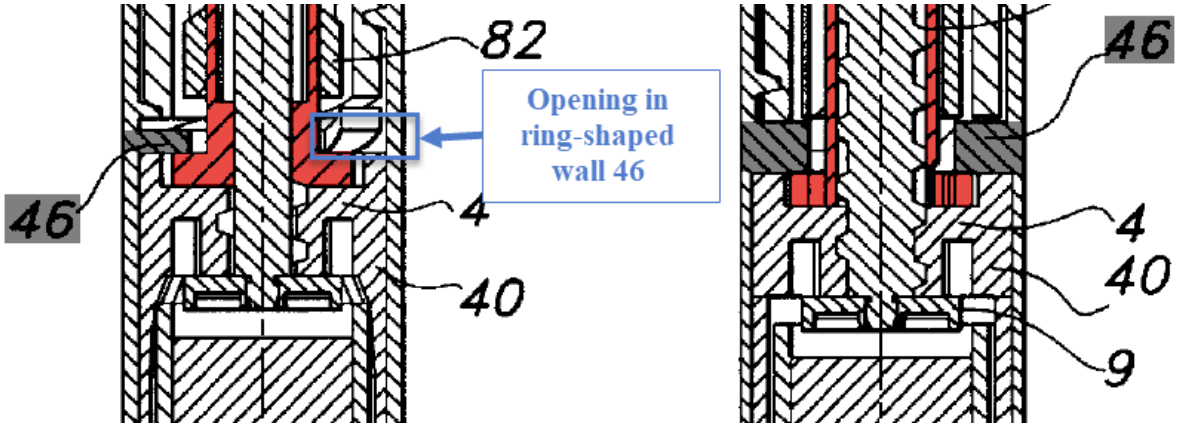
**e) <u>Additional Problems Cause by Petitioner's Proposed Modification</u>**

Prof. Slocum further explains that this increase in friction is only one of the problems with Petitioner's proposed modification. There are three other potential device failures associated with Petitioner's modification that would discourage a POSA from making the proposed combination. *See* Ex. 2107, ¶¶ 239-241.

First, because the outer flange on the driver tube 85 is comprised of flexible arms that act as a ratchet with member 40, the flexible arms can break, rendering the device inoperable, when subjected to the frictional stresses from being pressed up against ring-shaped wall 46 of housing 1. Indeed, this happened when Prof. Slocum attempted to build and test Petitioner's modification. *See* Ex. 2107, ¶ 240.

Second, the flexible arms, which serve as ratchet arms to prevent rotation in one direction (*see, e.g.*, Ex. 1014, 11:55-62), may get stuck and prevent the rotation necessary for injection. See Ex. 2107, ¶ 239.

Third, because there is an opening in the ring-shaped wall (identified below with a blue box), the arms could be pressed into the opening, thereby causing the device to fail by jamming the driver tube 85 or causing the flexible arms to pass above the ring-shaped wall such that the driver tube 85 moved proximally into the housing. *See* Ex. 2107, ¶ 239.




**Ex. 1014, Figs. 15 and 16 (cropped and annotated).**

***

In sum, a POSA would not have been motivated to modify the fifth embodiment in the manner suggested by Petitioner because it would have made the device significantly increased the injection force, potentially resulted in several types of failures, and there is no evidence of any benefit resulting from the modification. *See Plas-Pak Indus. v. Sulzer Mixpac AG*, 600 F. App'x 755, 758-60

(Fed. Cir. 2015) ("However, combinations that change the 'basic principles under which the [prior art] was designed to operate,' or that render the prior art 'inoperable for its intended purpose,' may fail to support a conclusion of obviousness.") (internal citations omitted); *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) ("The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.").

### B. The Challenged Claims Are Patentable in View of Ground 2

#### 1. The Combination of Møller and Steenfeldt-Jensen Does Not Teach or Render Obvious "a drive sleeve extending along a portion of said piston rod" (all challenged claims)

Petitioner argues that Møller's connection bars 12 having a nut 13 teach the claimed "drive sleeve." Petition at 60-63. In the co-pending district court litigation, the Petitioner, Patent Owner, and Court all agree that a drive ***sleeve*** is at least "an essentially tubular component." Ex. 2016 at .002, Ex. 2165 at 18. As shown with red shading in both the side and top-down cross-sectional views below, the connection bars 12 and the nut 13 do not form a sleeve, or an essentially tubular component:

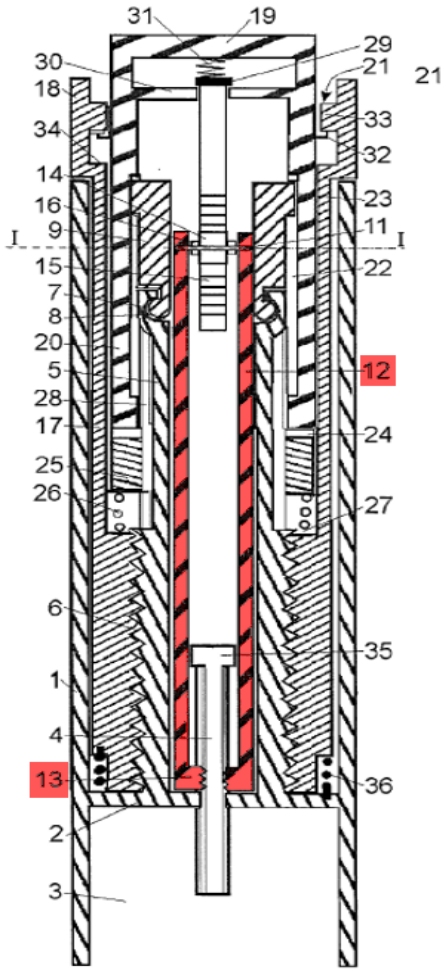



Fig. 1

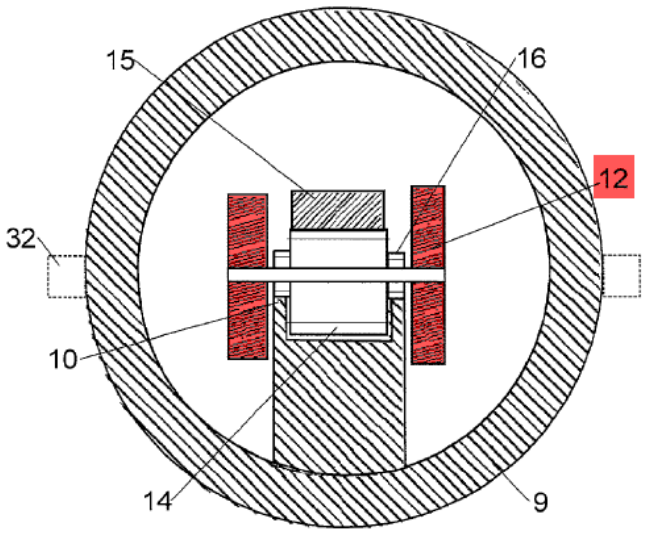



Fig. 2

**Ex. 1015, Figs. 1 and 2 (red shading added).**

Rather, the connection bars constitute two parallel bars, which are not a sleeve. *See* Ex. 2107, ¶¶ 273-275 (explaining that Møller's two parallel bars and nut are not essentially tubular, nor do they form a long cylindrical shape).

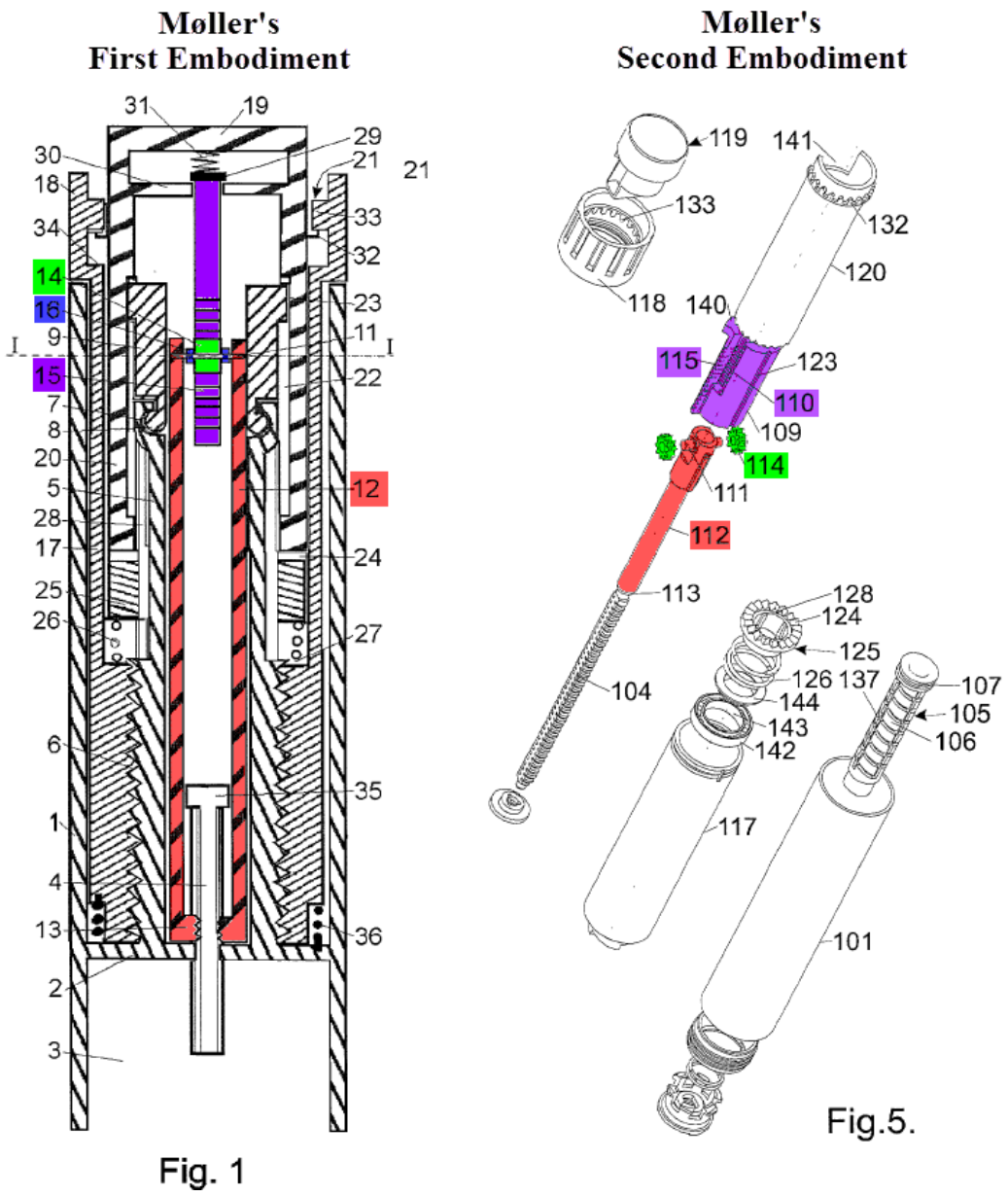
Tacitly admitting that connection bars 12 and nut 13 do not comprise the claimed "drive sleeve," Petitioner points to tubular connection element 112 and nut 113 in Møller's ***second embodiment*** to try to overcome this deficiency. Petition at 63. The Petition is devoid of any argument, however, that a POSA would have

been motivated to modify the connection bars 12 to form a sleeve according to the teachings of Møller's second embodiment, or that a POSA would have been motivated to combine connection element 112 into Møller's first embodiment. *See, e.g.*, M.P.E.P. 2143 (listing exemplary rationales supporting a motivation to combine, none of which is addressed in the Petition). Instead, Petitioner merely contends that "a POSA would have understood [connection bars 12 and nut 13 in the first embodiment and connection element 112 and nut 113 in the second embodiment] to be structurally and functionally equivalent." *Id.* at 63. Based on this purported structural and functional equivalency, Petitioner concludes that a POSA "would have expected connection bars 12 with nut 13 could readily be formed as a tubular structure that encompasses piston rod 4, without affecting the device's operation." *Id.* Again, the Petition does not allege that a POSA would have been motivated to form connection bars 12 and nut 13 as a tubular structure, and indeed there does not appear to be any reason to do so. *See Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017) (vacating a finding of obviousness made in an IPR proceeding in part because the Board's finding "seems to say no more than that a skilled artisan, once presented with two references, would have understood that they ***could*** be combined. And that is not enough ….") (emphasis added).

Nonetheless, as explained below, it is not correct that the connection bars 12 and nut 13 in Møller's first embodiment are structurally and functionally equivalent to connection element 112 and nut 113 in the second embodiment. Nor is it correct that a POSA would have expected that the connection bars 12 and nut 13 in Møller's first embodiment could be formed as a tubular structure without affecting the device's operation. *See* Ex. 2107, ¶¶ 276-275.

**a) A POSA Would Not Have Considered Connection Bars 12 and Nut 13 Functionally and Structurally Equivalent to Connection Element 112 and Nut 113**

Petitioner contends that connection bars 12 and nut 13 in Møller's first embodiment are structurally and functionally equivalent to connection element 112 and nut 113 in Møller's second embodiment and thus it would have been obvious to form connection bars 12 and nut 13 as a tubular structure. Petition at 63. The figure below, at a minimum, makes clear that connection bars 12 in the first embodiment are not structurally equivalent to the connection element 112 in the second embodiment:




**Ex. 1015, Figs. 1 and 5 (annotated).**

The connection bars 12 and connection element 112 are differently shaped, engage with components in different ways, and operate in different manners. *See* Ex. 2206 (animation depicting Møller's first embodiment), Ex. 2207 (animation depicting Møller's second embodiment), Ex. 2107, ¶ 150 (explaining animations

depicting Møller's first and second embodiments). As shown below, in Møller's first embodiment, connection bars 12 have an open shape that ***internally*** accommodates both gear wheel 14 (green), gear wheel 16 (blue), and rack 15 (purple); and more importantly, allow gear wheel 16 (blue) to engage rack 10 (yellow), which is connected to the gearbox 9 as shown below. *See* Ex. 1015, ¶ 0024, Ex. 2107, ¶¶ 278-279.

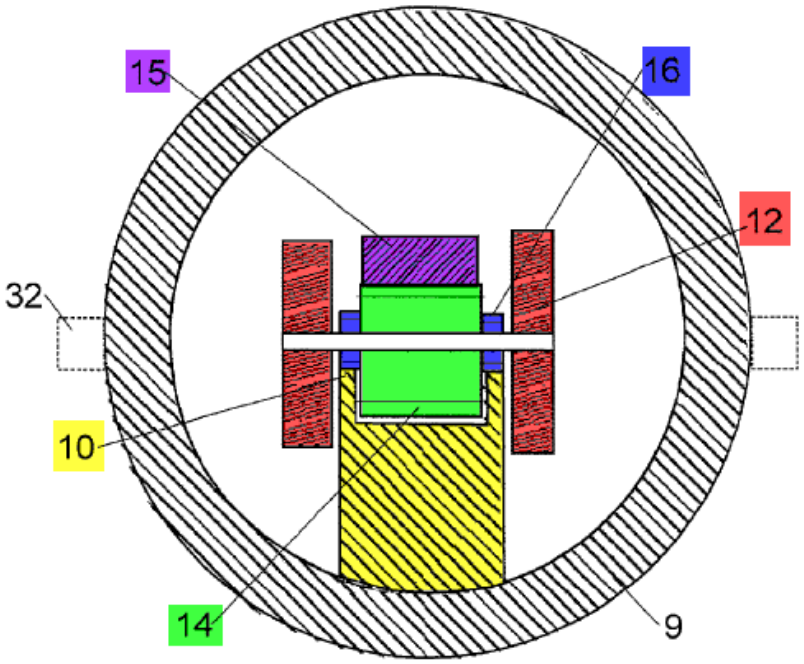



Fig. 2

**Ex. 1015, Fig. 2 (annotated).**

In contrast, in Møller's second embodiment, connection element 112 (see Fig. 5, above) has a closed tubular shape with gear wheel 114 (green) ***mounted on its exterior*** and is engaged with racks 110 and 115 (both purple), which are also

***exterior*** to connection element 112. *See* Ex.1015, ¶¶ 0039-0040, Ex. 2107, ¶¶ 279-280. Thus, the tubular structure of connection element 112 is not configured for internal gears and racks, or to have internal gears (*e.g.*, gear wheels 16 in blue) which mate with an external rack (*e.g.*, rack 10 in yellow).

In sum, a POSA would not have considered the connection bars 12 and nut 13 in Møller's first embodiment functionally and structurally equivalent to connection element 112 and nut 113 in Møller's second embodiment. Petitioner's contention otherwise is conclusory, without any meaningful analysis or comparison of the differences between the components. *See* Ex. 2107, ¶ 281. Thus, because Petitioner's obviousness argument is predicated on this purported equivalency, the argument fails. Accordingly, Møller does not teach or render obvious claim limitation [11.5], and thus does not render obvious claims 11, 14, 15, 18, and 19.

**b) A POSA Would Not Have Expected Connection Bars 12 With Nut 13 Could Be Formed as a Tubular Structure That Encompasses Piston Rod 4 Without Affecting the Device's Operation**

Even if the Petitioner were correct that the components are equivalent, neither Petitioner nor its expert explains how to implement the tubular shape of connection element 112 in the first embodiment without interfering with the internally mounted gear wheels 14 and 16, and racks 10 and 15 and thus the device's operation. Petitioner simply concludes:

> Given Møller's teaching that the tubular connection element 112 with nut 113 corresponds to connection bars 12 with nut 13, a POSA would have understood the components to be structurally and functionally equivalent. EX1011, ¶¶370-71. A POSA thus would have expected connection bars 12 with nut 13 could readily be formed as a tubular structure that encompasses piston rod 4, without affecting the device's operation. *Id.* Møller thus taught the claimed "drive sleeve."

Petition at 63.

But as noted above, the non-tubular, open shape of connection bars 12 in the first embodiment provides sufficient space for the ***internal*** gear wheels and racks, and importantly permits gear wheels 16 (blue) to engage rack 10 (yellow). The first embodiment at minimum would require a significant reconstruction and redesign of elements to accommodate a tubular structure because a tubular structure would interfere with the engagement of rack 10 (yellow) and gear wheel 16 (blue), which is only possible due to the open shape of connection bars 12. For example, the gear wheels (14 and 16) and racks (10 and 15) would need to be mounted on the exterior if connection bars 12 were formed as a tubular structure. If one were to follow the teachings of the second embodiment, gear wheels and racks would be positioned on both sides of the tubular structure. *See* Ex. 1015, Fig. 5 (depicting a pair of identical gear wheels 114 on either side of the tubular connection element 112). Therefore, each side of the tubular structure would have gear wheels 14 and 16 and corresponding racks 15 and 10. Because the four racks

(two of rack 10 and two of rack 15) and the four gear wheels (two of gear wheel 14 and two of gear wheel 16) would be mounted externally in this modified embodiment, the interior of the pen injector would need to be redesigned to make additional space. *See* Ex. 2107, ¶ 283. Otherwise, the pen injector would need to be widened to accommodate these extra components, which would run counter to a well-understood design objective of reducing the size of a pen injector for hand-held use. *See, e.g.*, Ex. 2107, ¶ 59 (explaining that pen injectors, particularly those intended for infirm patients such as a many diabetics, need to be easy to hold to facilitate use); *see also* Ex. 2163 at 169:12-170:20 (stating that only very small increases in pen width might be acceptable). Petitioner has not explained how this significant redesign could be accomplished without increasing its size and thus affecting the device's operation by a user.

Given the significant differences and the advantage provided by the open (not tubular) shape of connection bars 12, a POSA would not have been motivated to implement a sleeve shaped connection element in Møller's first embodiment. *See* Ex. 2107, ¶¶ 282-283. Petitioner therefore has not articulated a sufficient reason motivating a POSA to modify Møller's first embodiment by substituting the parallel connection bars 12 with a tubular structure, like that of tubular connection element 112. *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) ("Obviousness requires more than a mere showing that the prior art includes

separate references covering each separate limitation in a claim under examination.... Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.") (citing *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418, 421, (2007)).

Accordingly, Møller does not teach or render obvious claim limitation [11.5], and thus does not render obvious claims 11, 14, 15, 18, and 19.

### 2. A POSA Would Not Have Been Motivated to Modify Møller to Include Steenfeldt-Jensen's Externally-Threaded Dose Scale Drum and Internally-Threaded Housing (all challenged claims)

Claim [11.2] requires a "dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve." Ex. 1002, claim 11. Thus, the claim explicitly requires a threaded engagement between the exterior of a dose dial sleeve and the main housing. The Petition concedes that Møller "does not disclose 'a helical groove' 'provided along an outer surface of' [Møller's dose-setting] drum 17." Petition at 57.

Petitioner asserts that a POSA would be motivated to modify the inner threads of the tubular dose setting drum 17 and the outer thread 6 of tubular

element 5 in Møller such that the tubular dose setting drum 17 instead comprised "a high-pitched helical groove as taught by Steenfeldt-Jensen on the outer surface" that engaged with a helical rib on the inner surface of the housing 1. Petition at 78-79; *see also id.* at 56-57, 76-79. A POSA, however, would not have been motivated to modify Møller as proposed for at least the reasons set forth below.

**a) A POSA Would Not Have Been Motivated to Combine Moller With Steenfeldt-Jensen's Externally-Grooved Dose Scale Drum 80**

Møller explains that it is an objective of his invention "to provide an injection device, which combines the advantages of the devices according to the prior art ***without adopting their disadvantages*** …." Ex. 1015, ¶ 0011 (emphasis added). As an example of a disadvantageous prior art teaching, Møller identifies the threaded gearing of WO 99/38554—*i.e.*, Steenfeldt-Jensen's PCT counterpart—due to its undesirable friction losses. Møller specifically, criticizes Steenfeldt-Jensen as follows:

> A similar gearing is provided in WO 99/38554 [Steenfeldt-Jensen's PCT counterpart] wherein the thread with the high pitch is cut in the outer surface of a dose setting drum and is engaged by a mating thread on the inner side of the cylindrical housing. ***However, by this kind of gearing relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces***. Therefore a traditional gearing using mutual engaging gear wheels and racks is preferred.

Ex. 1015, ¶ 0008 (emphasis added).[4] The Møller injection device pointedly, and purposefully, avoids Steenfeldt-Jensen's disadvantageous high-pitched and externally-grooved dose scale drum, and neither Petitioner nor its expert, have explained why a POSA would disregard Møller's teaching against using Steenfeldt-Jensen. *See* Ex. 2107, ¶¶ 289-290. *See Polaris Indus., Inc. v. Arctic Cat, Inc*., 882 F.3d 1056, 1069 (Fed. Cir. 2018) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant."); *see also General Elec. Co. v. United Techs. Corp*., IPR2017-00428, Paper No. 38 at p. 24 (P.T.A.B. June 22, 2018) ("[Prior Art A] expressly considered at least some of the one-stage versus two-stage tradeoffs and specifically chose the one-stage option. By expressly weighing the tradeoffs and choosing the one-stage option, [Prior Art A] teaches away from modifying the Wendus ADP engine to include the two-stage option.").

In its Institution Decision, the Board provisionally notes "that Moller's paragraph 8 states that 'traditional gearing using mutual engaging gear wheels and racks is preferred' (Ex. 1015 ¶ 8 (emphasis added)), which may indicate sliding surfaces may not be one of the disadvantages discussed in paragraph 11." Paper 20

[4] WO 99/38554 is the related PCT publication to Steenfeldt-Jensen. *See* Ex. 2015.

at 32 n.10. The Board misses the import of Patent Owner's argument: Møller teaches away from ***Steenfeldt-Jensen's*** high-pitch threading, not necessarily ***every*** type of threaded engagement. Møller states that it is an objective of his invention "to provide an injection device, which combines the advantages of the devices according to the prior art ***without adopting their disadvantages*** …." Ex. 1015, ¶ 0011 (emphasis added). A POSA would thus have not read Møller's disclosures criticizing Steenfeldt-Jensen's high-pitch threads and conclude that it would have been obvious to combine Møller with the very reference it disparages and seeks to improve upon. *See* Ex. 2107, ¶¶ 288-292; *see also Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) ("When a piece of prior art 'suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant' the piece of prior art is said to 'teach away' from the claimed invention.") (*quoting In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)).

Further, even if the Board were to find that these statements are not an express teaching away, the Board should be highly skeptical, in view of Møller's disclosure, that simply swapping features in Møller and Steenfeldt-Jensen are as easy as Petitioner asserts. *See Polaris Indus.*, 882 F.3d at 1069 ("But even if a reference is not found to teach away, its statements regarding preferences are

relevant to a finding regarding whether a skilled artisan would be motivated to combine that reference with another reference.").

**b) A POSA Would Not Have Been Motivated to Make the Relied-Upon Combination Due to a Purported Benefit Alleged by Petitioner**

Despite Møller's teaching-away, Petitioner argues that a POSA would have been motivated to modify the internal threading on Møller's tubular dose setting drum 17 due to a purported advantage. Specifically, the Petition states: "Because Steenfeldt-Jensen's threaded engagement is configured to reduce the friction between the sliding surfaces of the drum and housing, a POSA would have understood that this configuration would reduce the force needed to rotate the drum back into the housing during injection." Petition at 78. This argument fails.

Petitioner and its expert point to no evidence suggesting that a POSA would look beyond Møller's teachings for addressing undesirable thread friction. And nor would a POSA because Møller teaches its own solution. Specifically, Møller teaches a "helical reset spring 36" that "exerts a torque approximately corresponding to the torque necessary to overcome the friction in the movement of the dose setting drum along the thread 6 so that the force which the user has to exert on the injection button is only the force necessary to drive the piston rod into the ampoule to inject the set dose." Ex. 1015, ¶ 0033; *see also* Ex. 2107, ¶ 294.

The Petition does not address why a POSA would need to look outside of Møller to solve a "problem" already addressed by Møller.

In sum, Møller expressly considered Steenfeldt-Jensen's teachings and rejected them as not advantageous, and Møller proposes a different solution to the purported "problem." Petitioner is incorrect that "[a] POSA would have had reason to incorporate a high-pitch helical groove as taught by Steenfeldt-Jensen," let alone one that is "on the outer surface of Møller's drum." Because there is no apparent reason to modify Møller as Petitioner proposes, Petitioner has failed to show that it would have been obvious to combine Møller and Steenfeldt-Jensen as proposed. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

**3. The Combination of Møller and Steenfeldt-Jensen Does Not Teach or Render Obvious "said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve" (all challenged claims)**

Petitioner identifies Møller's dose-setting drum 17 as the claimed dose dial sleeve. Petitioner concedes, however, that dose-setting drum does not disclose a helical groove provided along its outer surface as required by claim 1. Nonetheless, Petitioner argues that it would have been "obvious to modify internal threading of drum 17 as an external threading that engaged the housing for the same rotational movement relative to the housing as disclosed in Steenfeldt-Jensen." Petition at 57, 76-79. Petitioner's argument does not withstand scrutiny.

As explained above in Section V.B.3, a POSA would not have been motivated to combine the teachings of Steenfeldt-Jensen's dose scale drum with Møller's pen injector. *See* Ex. 2107, ¶¶ 303-304. Further, neither Petitioner nor its expert have put forth any reasoning for why a POSA would have switched the threading of Møller's dose setting drum from internal to external as described in Steenfeldt-Jensen.

Indeed, configuring Møller's housing 1 to have an internal rib that engaged with an external groove of the dose setting drum 17 would be problematic. First, a threaded engagement between housing 1 and dose setting drum 17 would interfere with helical reset spring 36. *See* Ex. 1015, Fig. 1 (element 36); *see also* Ex. 2107, ¶ 305. This helical reset spring 36 exists between the housing 1 and dose setting drum 17, precisely where Petitioner proposes to place a threaded connection. Neither Petitioner nor its expert has explained how their proposed modification would avert interference between the threads and the spring, which could cause the device to malfunction. *See id*.

Second, moving the threads from the inside of dose setting drum 17 to the outside would increase the friction losses during dose dispensing, which would be antithetical to Møller's teachings. *See* Ex. 2107, ¶¶ 54-57, 306 (explaining that Møller's aim to reduce friction losses to the extent possible while achieving pen injector having a mechanical advantage). As with any thread engagement,

frictional forces arise from the surfaces of the threads sliding past each other. *See* Ex. 2107, ¶¶ 37-39, 306. So when the dose setting drum's threads, and the resulting frictional forces from rotation during dose dispensing, are placed further from the axis of rotation, the counter-torque increases. *See* Ex. 2107, ¶ 306 (noting that torque is the product of a force applied at a distance from the axis of rotation). The user will have to overcome this greater counter-torque (*i.e.*, friction losses) to inject a dosage of medication, which means that the user will have to exert a greater injection force. *See* Ex. 2107, ¶¶ 37-39, 306. Therefore, a POSA would not have been motivated to modify Møller to have threads between the housing 1 and dose scale drum 17, and a POSA would not have had a reasonable expectation of success in making this modification. *See* Ex. 2107, ¶ 308.

Thus, the Petition fails to show that the combination of Møller and Steenfeldt-Jensen teaches or renders obvious "said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve" as required by claim limitation [11.2]. Thus, the Petition fails to show that claim 11 and its dependent claims are anticipated or obvious.

#### 4. The Combination of Møller and Steenfeldt-Jensen Does Not Teach or Render Obvious "a least one flexible arm … and at least one spline … to provide said audible feedback" (claim 15)

Petitioner fails to articulate a *prima facie* showing that a POSA would have been motivated to combine the alleged flexible arm, tooth member, and spline from Steenfeldt-Jensen with Møller's teachings. *See* Petition at 82-84 (relying entirely on Steenfeldt-Jensen for the disclosure of a clicker that comprises a flexible arm, tooth member, and spline). Specifically, Petitioner has not explained whether, why, and how a POSA would have been motivated to substitute the alleged clicker in Møller (*i.e.*, interacting "V-shaped teeth") with a flexible arm and splines, or whether, why, and how a POSA would have incorporated an additional clicker in Møller that comprises Steenfeldt-Jensen's alleged flexible arm and splines. *See Personal Web Techs., LLC*, 848 F.3d at 993-94 (stating that it "is not enough" to base a conclusion of obviousness on a finding that a POSA would have understood two references "could be combined"); *see also* Ex. 2107, ¶ 310. Instead, Petitioner has only argued that a POSA would be motivated to combine Steenfeldt-Jensen and Møller with respect to Steenfeldt-Jensen's "high-pitch helical groove." Petition at 76-79. Therefore, merely alleging, as Petitioner does, that a POSA would have understood that Steenfeldt-Jensen discloses the limitation recited claim 15 is not factually or legally sufficient to conclude that the

combination of Møller and Steenfeldt-Jensen renders this claim obvious. *See* Petition at 82-84.

Accordingly, the Petition fails to show that the combination of Møller and Steenfeldt-Jensen teaches or renders obvious "wherein said clicker comprises: at least one flexible arm, said flexible arm comprising at least one tooth member, and at least one spline, wherein when said dose dial grip is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback" as required by claim 15.

#### 5. The Combination of Møller and Steenfeldt-Jensen Does Not Teach or Render Obvious "wherein said main housing further comprises a helical rib … adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve" (claim 19)

The combination of Møller and Steenfeldt-Jensen does not reach or render obvious this claim limitation for the same reasons as explained in Section VI.B.3 and VI.B.4., *supra* (explaining that Møller does not teach a threading between the inner surface of the main housing and the outer surface of the dose dial sleeve, and explaining that it would not have been obvious to adapt Møller in this way using Steenfeldt-Jensen's teaching).

## VIII. CONCLUSION

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

Dated: June 25, 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 11,991 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.

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.

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## CERTIFICATE OF SERVICE

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