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. IPR2018-01678
U.S. Patent No. 8,992,486

PATENT OWNER'S RESPONSE

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. BACKGROUND OF THE TECHNOLOGY 2

III. THE 486 PATENT 4

IV. CLAIM CONSTRUCTION 9

A. "Main Housing" Does Not Encompass An Interior Housing, Even If Integrally Formed With Interior Housing 9

V. LEVEL OF ORDINARY SKILL IN THE ART 14

VI. THE PRIOR ART 15

A. U.S. Patent No. 6,235,004 ("Steenfeldt-Jensen") 15

1. Steenfeldt-Jensen's Fifth Embodiment 16

2. Steenfeldt-Jensen's First Embodiment 21

3. Steenfeldt-Jensen's First Embodiment Operates Differently From the Fifth Embodiment 23

B. U.S. Patent Application Publication No. 2002/0052578 ("Møller") 26

1. Møller Does Not Disclose a "Main Housing" 27

VII. THE CITED PRIOR ART DOES NOT RENDER OBVOUS THE CHALLENGED CLAIMS 30

A. The Challenged Claims Are Patentable in View of Ground 1 30

1. Steenfeldt-Jensen Does Not Render Obvious a "driver comprising an internal threading near a distal portion of said driver" (all challenged claims) 30

a) There Is No Disclosure of Suggestion in Steenfeldt-Jensen of an Internally Threaded Driver 30

b) Steenfeldt-Jensen's Disclosure at Column 7, Lines 41-47 is for the First Embodiment, not the Fifth Embodiment 32

c) The Petitioner's Modification to Switch the Non-Circular Opening and Threaded Opening in the

Fifth Embodiment Results in an Inferior Pen Injector 35

d) Explanation For Why Petitioner's Modification Results in Higher Friction 41

e) Additional Problems Caused by Petitioner's Proposed Modification 45

2. Steenfeldt-Jensen Does Not Render Obvious a Dose Dial Sleeve That "comprises at least one radial stop, said radial stop positioned near an end of said helical groove" (claims 30 and 32) 47

B. The Challenged Claims Are Patentable in View of Ground 2 54

1. The Combination of Møller and Steenfeldt-Jensen Does Not Render Obvious "said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing" (all claims) 54

2. A POSA Would Not Have Been Motivated to Combine the Teachings of Møller and Steenfeldt-Jensen 56

a) A POSA Would Not Have Been Motivated to Combine the Teachings of Møller and Steenfeldt-Jensen 57

b) A POSA Would Not Have Been Motivated to Make the Relied-Upon Combination Due to a Purported Benefit Alleged by Petitioner 59

3. Møller Does Not Render Obvious "a helical rib provided on an inner surface of said outer housing" (claim 4) 60

a) Møller Teaches Away from Steenfeldt-Jensen's External High-Pitched Thread 61

b) A POSA Would Not Have Been Motivated to Make the Relied-Upon Combination due to a Purported Benefit Alleged by Petitioner 61

4. Møller Does Not Render Obvious a Driver Comprising "a cylindrical shape" (claim 5) 62

5. Møller Does Not Render Obvious a Clicker Comprising "at least one flexible [extending] arm" (claims 18 and 20) 63

6. Møller Does Not Render Obvious a Dose Dial Sleeve That Is "radially inward of said main housing" (claim 26) 64

7. Møller Combined With Steenfeldt-Jensen Does Not Render Obvious a "radial stop positioned near an end of [a] helical groove" or "near a distal end of said helical groove" (claims 30 and 32).....66

8. Møller Does Not Render Obvious an "Insert" (claims 38-40) 68

VIII. OBJECTIVE INDICIA OF NONOBVIOUSNESS 68

A. LANTUS® SoloSTAR® Practices Claim 1 of the 486 Patent.....70

B. The LANTUS® SoloSTAR® Satisfied Previously Unresolved Needs for Pen Injectors Due To the Inventions of the 486 Patent 70

C. The LANTUS® SoloSTAR® Received Industry Praise for its Patented Features.....74

D. The Commercial Success of the LANTUS® SoloSTAR® Is Attributable to the Inventions in the 486 Patent 76

IX. CONCLUSION.....80

TABLE OF AUTHORITIES

Page(s)

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733 F.2d 900 (Fed. Cir. 1984) 46

In re GPAC,
57 F.3d 1573 (Fed. Cir. 1995) 14

Graham v. John Deere Co. of Kan. City,
383 U.S. 1 (1966).....68, 69

KSR Int'l Co. v. Teleflex Inc.,
550 U.S. 398 (2007).....62

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No. IPR2015-01100, Paper 70 (P.T.A.B. Sep. 12, 2016).....68

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Civil Action No. 17-9105 (SRC) (D.N.J.) 10

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2105	Leinsing Deposition Exhibit 2105: Hand drawings
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2107	Declaration of Alexander Slocum, Ph.D.
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Exhibit #	Description
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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
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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
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2168	Giambattista Animation (2)
2169	U.S. Patent No. 4,648,872
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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
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

Exhibit #	Description
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2204	U.S. Total Marketing Expenditures of Long-Acting Insulin Pens
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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 486 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 486 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. The inventions are embodied in the SoloSTAR® pen that was released in 2007 and has been a significant commercial success. Patent Owner respectfully submits that the challenged claims of the 486 Patent are patentable over the Grounds presented in this Petition.

First, in Ground 1, to satisfy the claim limitation requiring a "driver comprising an internal threading" Petitioner contends that Steenfeldt-Jensen "expressly contemplates a modification" where the driver tube of Steenfeldt-Jensen is internally threaded. This is incorrect as Steenfeldt-Jensen only refers to a "nut member" or "nut element" having internal threads – not the driver tube. Even assuming that Steenfeldt-Jensen has a disclosure that suggests modifying its driver tube, this disclosure is only applicable to Steenfeldt-Jensen's *first* embodiment, not its *fifth* embodiment. And further, a POSA 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.

Second, in Ground 2, Petitioner relies on Møller combined with Steenfeldt-Jensen to provide a grooved dose dial sleeve, but Petitioner fails to show that a POSA would have been motivated to combine the prior art references. Further, Petitioner fails to show that the combination of Møller and Steenfeldt-Jensen teaches a dose dial sleeve engaged with a ***main housing*** as required by claim 1—instead, the alleged dose dial sleeve is engaged with an interior housing.

Finally, secondary indicia of non-obviousness confirm that the challenged claims of the 486 Patent are not obvious. Sanofi's SoloSTAR® pen injector, which practices claim 1 of the 486 Patent, satisfied a long-felt need in the industry for an easy-to-use, disposable pen that administered a long acting insulin or insulin analog. *See, e.g.*, Ex. 2101. The improved ease-of-use provided by the pen injector design of the 486 Patent contributed directly to the overwhelming commercial success of SoloSTAR®.

II. BACKGROUND OF THE TECHNOLOGY

At the time of the 486 Patent, there were already several pen-type injectors known in the art. For example, Steenfeldt-Jensen describes five pen injector embodiments, and its fifth embodiment closely corresponds to the Novo Nordisk FlexPen that was commercially available at the time. Ex. 1014, Figs. 1-17, Ex. 2107, ¶ 28.

Prior art injection pens, however, had limitations. The FlexPen (*i.e.*, Steenfeldt-Jensen's commercial embodiment), for example, suffered from a relatively high injection force. A higher injection force is problematic for patients lacking dexterity and strength, particularly for certain diabetic patients suffering from hand and wrist conditions. *See* Ex. 2107, ¶¶ 47-53.

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 change intended to improve one aspect of a device can negatively impact other aspects, and one must consider whether these tradeoffs result in a worse design overall. *See id*. Changes that increase the required injection force impair the device's ease-of-use, and thus, are not worth pursuing as they would worsen the patient's experience and decrease the likelihood that the patient complies with their 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 medication. Ex. 2175. It took Novo Nordisk years to modify the FlexPen to address this issue. Indeed, the original 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 486 Patent's priority date and a year after SoloSTAR® launched, that Novo Nordisk introduced the New Generation FlexPen (NGFP), with reduced injection force requirements. Ex. 2136 at 71.

The 486 Patent's inventors successfully balanced these competing design considerations and produced a novel, non-obvious, mechanical arrangement that results in an improved pen injector. Sanofi's SoloSTAR®, which practices claim 1 of the 486 Patent, has been a successful product because of these improvements. Numerous studies have touted its ease of use, particularly its low injection force. Ex. 2116, Ex. 2123, Ex. 2126.

III. THE 486 PATENT

Pen injectors are regularly used by patients without formal medical training, such as diabetics who self-administer insulin. Ex. 1003, 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 486 Patent discloses a pen injector having a novel arrangement of mechanisms that meet these criteria. *See* Ex. 2107, ¶ 64. In particular, the 486 Patent is specifically targeted at reducing the injection force needed for dispensing medicine. Ex. 1003, 3:64-67. The figures below depict an embodiment of an improved injection pen. Additionally, animations of the embodiment's operation has been submitted as Exhibits 2117 and 2162. *See* Ex. 2107, ¶ 65 (explaining animation).

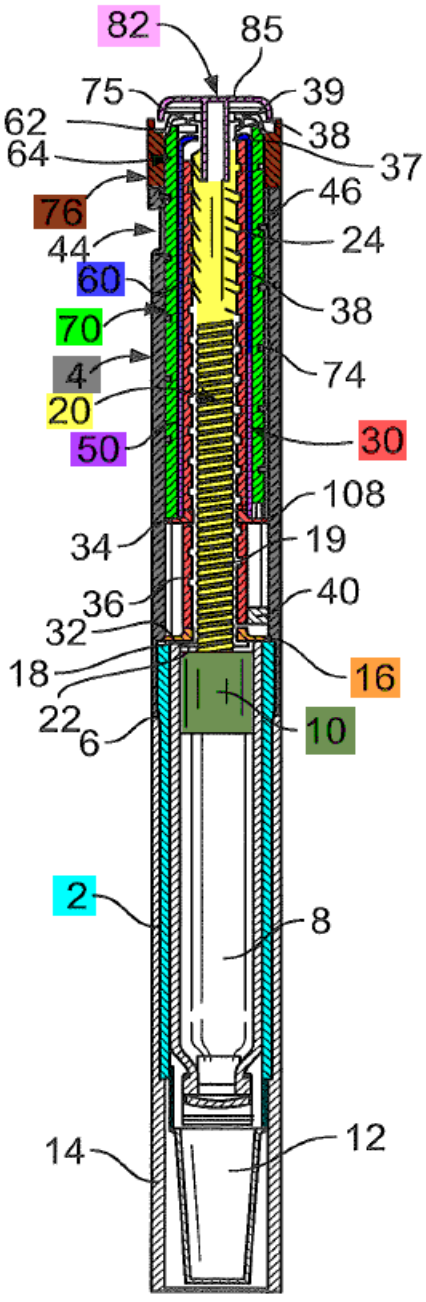

FIG. 1

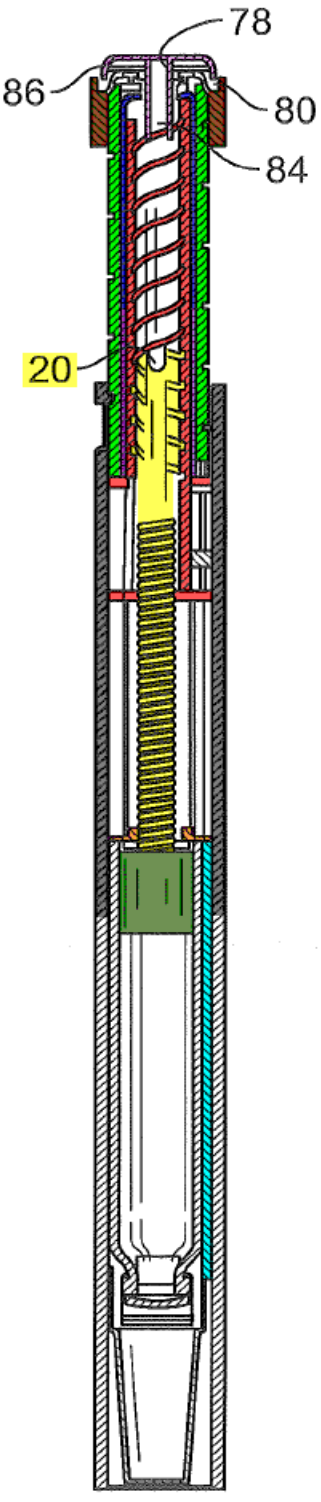

FIG. 2

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

The illustrated 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.

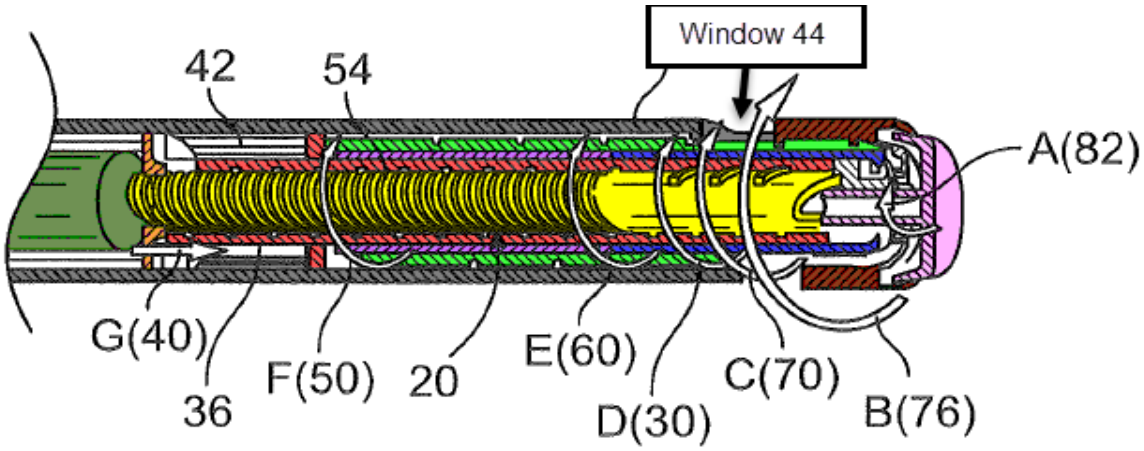

FIG. 9

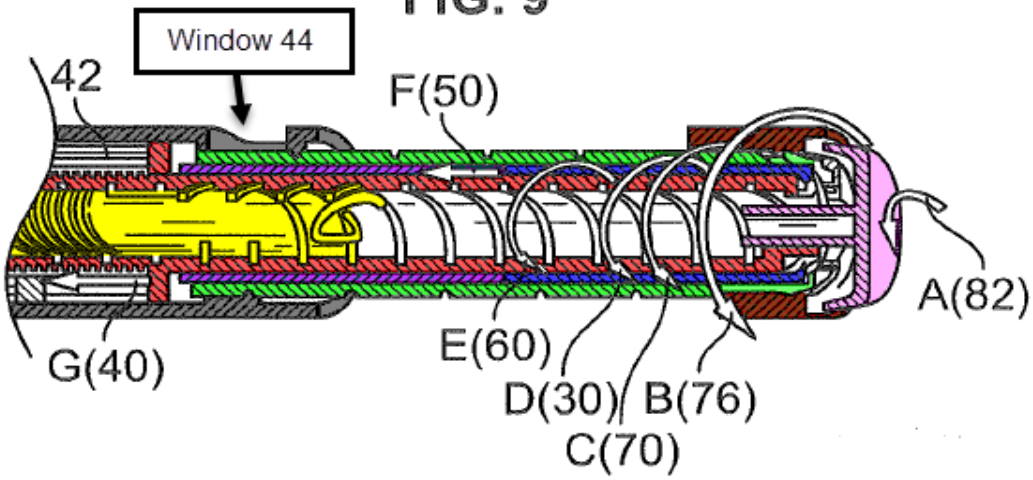

FIG. 10

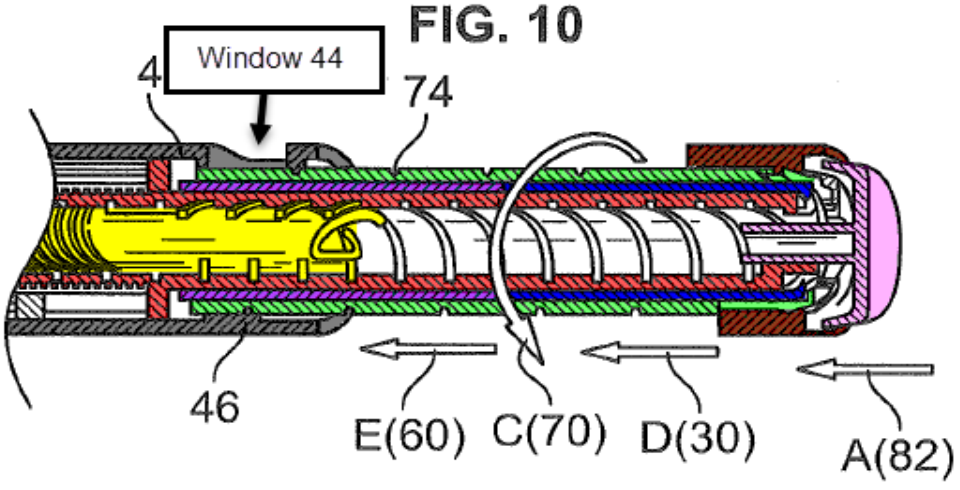

FIG. 11

Ex. 1003, 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.*, 6:28-29. 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.*, 6:45-47. *See also* Ex. 2162 (animation of embodiment). 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.*, 6:28-35; 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.*, 6:48-52. The user then releases the dose button, which returns the internal mechanism of the device into the dose dialing state. *Id.*, 6:40-44.

IV. CLAIM CONSTRUCTION

A. "Main Housing" Does Not Encompass An Interior Housing, Even If Integrally Formed With Interior Housing

In both the co-pending district court case and its Preliminary Response, Patent Owner proposed that "main housing" means "an ***exterior*** unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more

inner components."[1] This correct construction derives from lexicography in related U.S. Patent No. 9,604,008 (the "008 Patent")[2] :

> The term "housing" according to instant invention shall preferably mean any ***exterior housing ("main housing"***, "body", "shell") or interior housing ("insert", "inner body") having a helical thread. The housing may be designed to enable the safe, correct, and comfortable handling of the drug delivery device or any of its mechanism. Usually, it is ***designed to house, fix, protect, guide, and/or engage with any of the inner components*** of the drug delivery device (e.g., the drive mechanism, cartridge, plunger, piston rod) by limiting the exposure to contaminants, such as liquid, dust, dirt etc. In general, ***the housing may be unitary or a multipart component*** of tubular or non-tubular shape. Usually, the exterior housing serves to house a cartridge from which a number of doses of a medicinal product may by dispensed.

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[1] The Court in the co-pending district court case, *Sanofi-Aventis U.S. LLC et al. v. Mylan GmbH*, Civil Action No. 17-9105 (SRC) (D.N.J.), determined that "'main housing' has its ordinary meaning, and no construction is necessary." *See* Ex. 2165 at 20. However, the Court in *Sanofi-Aventis U.S. LLC, et al. v. Merck Sharp & Dohme Corp.*, Civil Action No. 16-812-RGA (D. Del.) adopted Patent Owner's construction. *See* Ex. 2166 at 7-9.

[2] The 008 Patent is related to the 486 Patent since they both claim the benefit of the filing date of the same foreign application—GB 0304822.

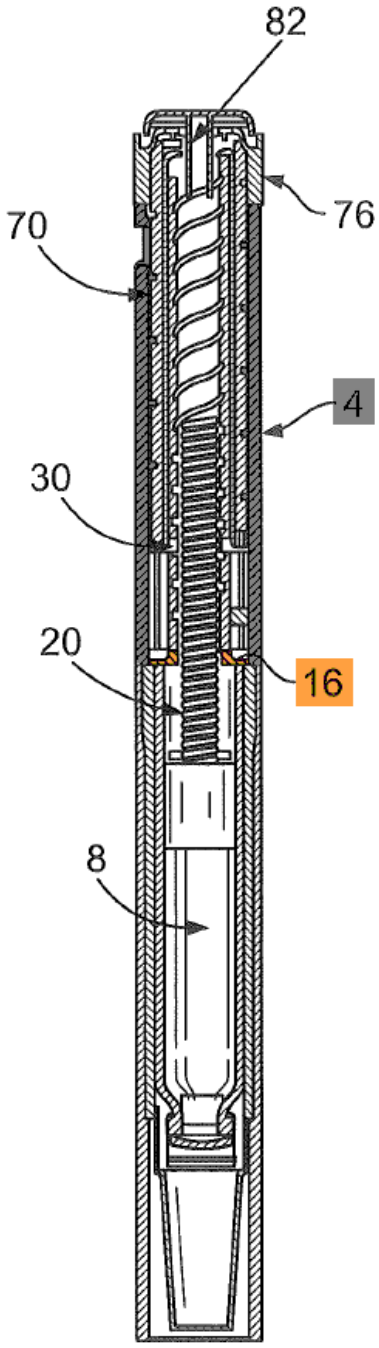
Ex. 1005, 2:66-3:12 (emphasis added). Notably, the passage above draws a clear distinction between ***exterior housing*** such as a "main housing" and ***interior housing*** such as an "insert." The former does not encompass the latter.

Even if the Board decides that this lexicography does not control, the broadest reasonable interpretation of "main housing" consistent with the 486 Patent means an exterior housing and does not encompass an interior housing even if that interior housing is integrally formed with the exterior housing.

The specifications of the 486 Patent and 008 Patent[3] further confirm that a "main housing" is an exterior housing that does not encompass interior housing, even if integrally formed with it. The embodiment depicted in the 486 Patent identifies a "main housing 4", which is an exterior housing as shown below in dark grey. Ex. 1003, 3:27-28; *see also* Ex. 1005, 7:11-13 (identifying a "main (exterior) housing part 4."). The 486 Patent separately identifies an "insert 16," which the 008

[3] The 008 Patent remains relevant because the same term in related patents is presumed to have the same construed meaning. *See Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003) ("The disputed term … is the same throughout all five patents in the genealogy …. [W]e presume, unless otherwise compelled, that the same claim term in the same patent or related patents carries the same construed meaning.").

Patent confirms is “interior housing” (orange, below) (*see* Ex. 1005, 2:66-3:2), as being formed inside the main housing 4. *See* Ex. 1003, 3:49-55.



Ex. 1003, Fig. 3 (annotated)

The 486 Patent expressly identifies the main housing and insert as separate components, and importantly the 486 Patent continues to treat the "main housing" as distinct from the "insert" even when integrally formed: "the insert may be formed integrally with the main housing 4 the form of a radially inwardly directed flange having an internal thread." Ex. 1003, 3:53-55. The specification here does not state that the insert may be *substituted* by an inwardly directed flange of the main housing (and thus the inwardly directed flange would be part of the main housing), but rather that "the insert may be formed integrally with the main housing" (and thus it is still distinct from the main housing). This disclosure supports treating an integrally-formed interior housing as distinct from a "main housing."

In contrast, Petitioner's interpretation for "main housing" reads out the word "main" from "main housing" so that it encompasses all housings—both exterior and interior. *See, e.g.*, Petition at 60-61 (identifying Møller's exterior "housing 1," interior "partitioning wall 2," and interior "tubular element 5" as the claimed "main housing"). The intrinsic record does not support this interpretation.

As discussed below in Sections VI.B.1 and VII.B.1, Patent Owner's construction of "main housing" is dispositive of Ground 2 because Møller does not disclose a "dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing," as properly construed.

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. *See id*. *In re GPAC*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *see* 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

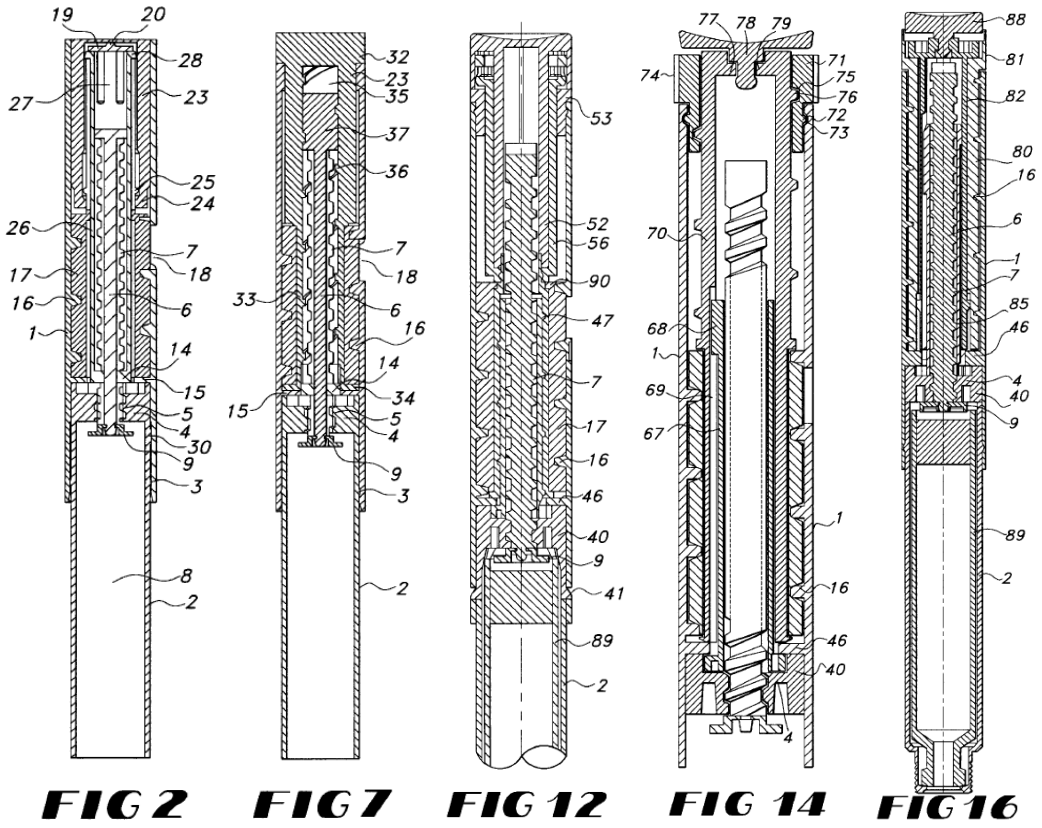
experience is not required. Therefore, Patent Owner's proposed level of ordinary skill should be accepted. Regardless, the slight differences between Patent Owner and Petitioner's level of ordinary skill do not affect the arguments made below.

VI. THE PRIOR ART

A. U.S. Patent No. 6,235,004 ("Steenfeldt-Jensen")

Steenfeldt-Jensen is a U.S. patent. Its PCT counterpart (Ex. 2014) is cited by the 486 Patent. *See* Ex. 1014 (claiming priority to DK199800130), Ex. 2014 (same), Ex. 1008 at 0118 (listing WO99/38554).

Steenfeldt-Jensen discloses five distinct pen injector embodiments. *See* Ex. 1014, Figs. 1-17. These pen injectors comprise different components and arrangements, as shown below, and are configured to operate differently. *See, e.g.*, Ex. 2148 (first embodiment animation), 2149 (second embodiment animation), 2147 (fifth embodiment animation); *see also* Ex. 2107, ¶ 137 (explaining 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 generally apply to the other embodiments.

1. Steenfeldt-Jensen's Fifth Embodiment

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. Petition at 21-49. The fifth embodiment, depicted in Figure 17 below, comprises ampoule holder 2 (turquoise), 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).

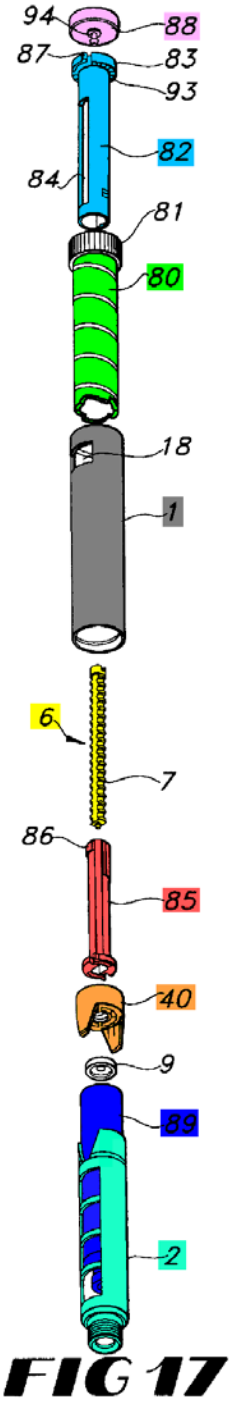
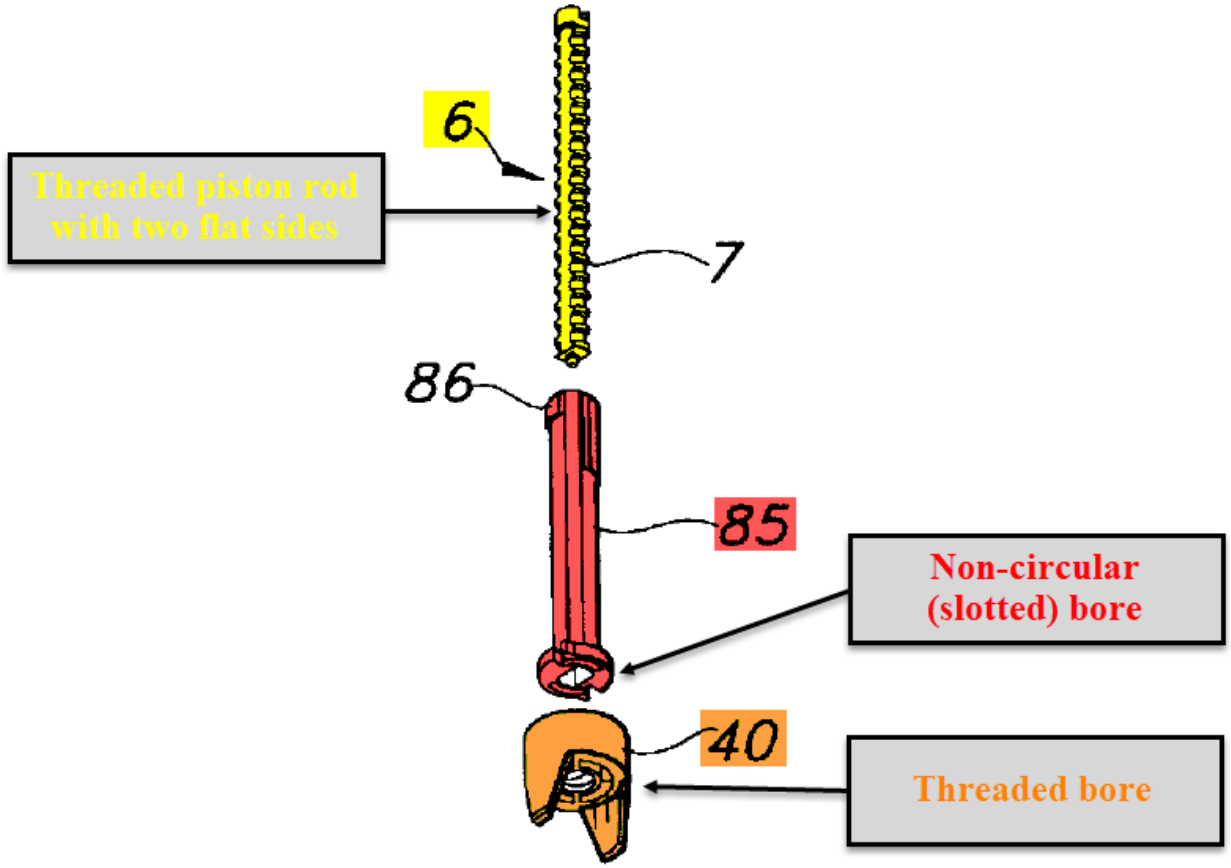


FIG 17

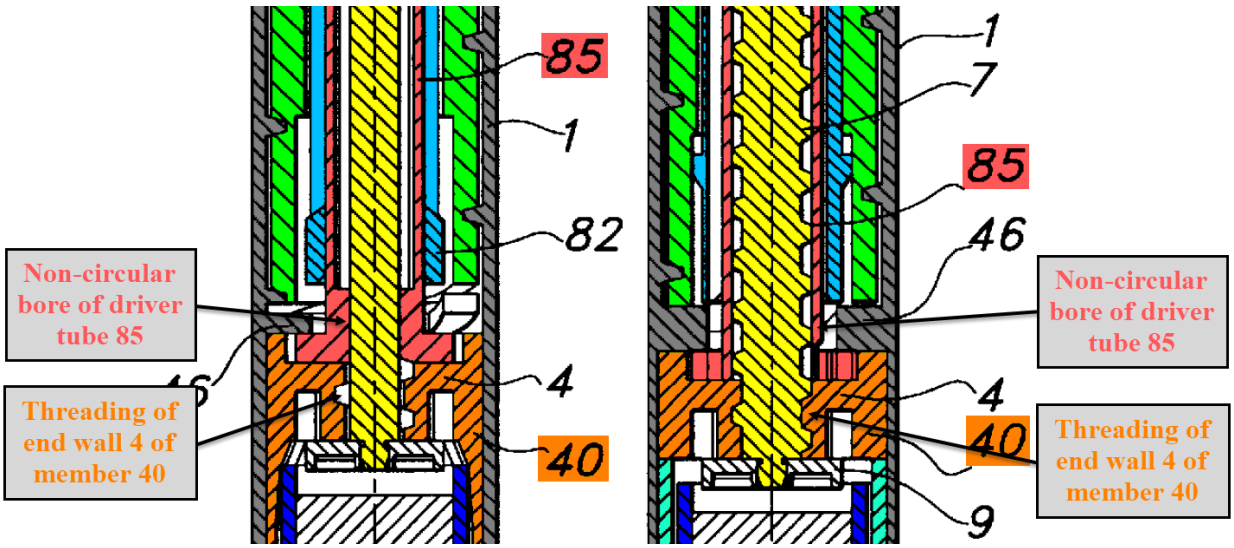
Ex. 1014, Fig. 17.

Significant to 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 because piston rod 6 (yellow) rotates with driver tube 85 (red) when driver tube 85 is rotated. The piston rod's non-circular shape fits within the driver tube's non-circular bore, thus rotationally coupling the components while allowing them to move axially relative to one another. *See* Figs. below; Ex. 2150 (animation depicting the threaded opening of member 40 and slotted opening of driver tube 85); Ex. 2107, ¶ 145.



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



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

Also significant to 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. 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 submitted as Exhibit 2147. *See* Ex. 2107, ¶ 145. 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; Ex. 2107, ¶ 137.

Due to Newton's third law, the cartridge piston applies an equal-and-opposite force to the piston rod. The reactive force is transferred through the piston rod to the internal threads of member 40, then to housing 1, and 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, 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, piston rod 6 (yellow) directly engages ampoule holder 2 (light blue). As shown below, ampoule holder 2 includes a wall 4 having a central bore with an internal thread 5, and piston rod 6 has external thread 7 that mates with 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 piston rod guide 14 (the piston rod is inserted into the piston rod guide), with torque transmitted to the driver tube 26. *Id*., 6:54-59, 7:1-3. 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.

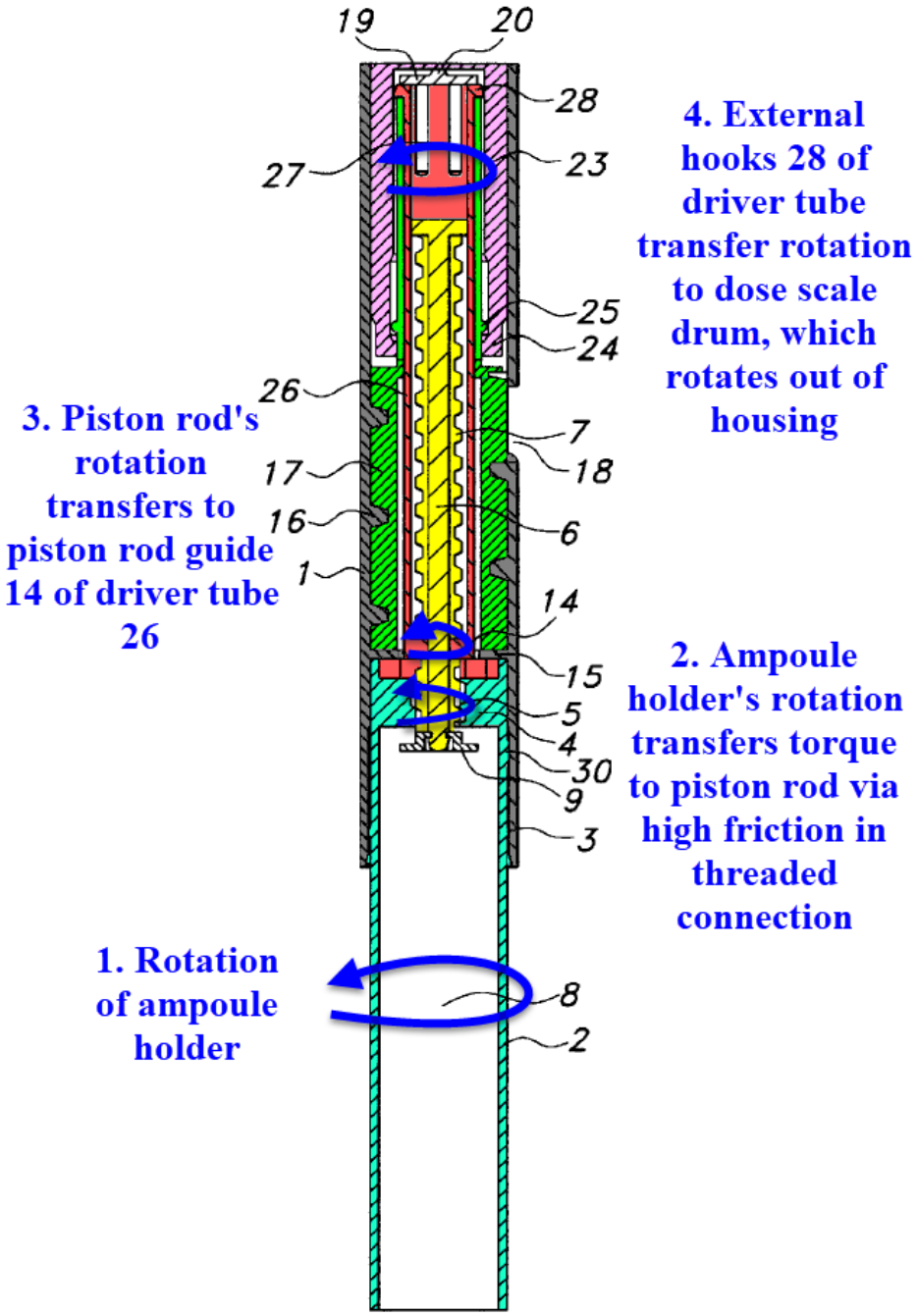


FIG 2

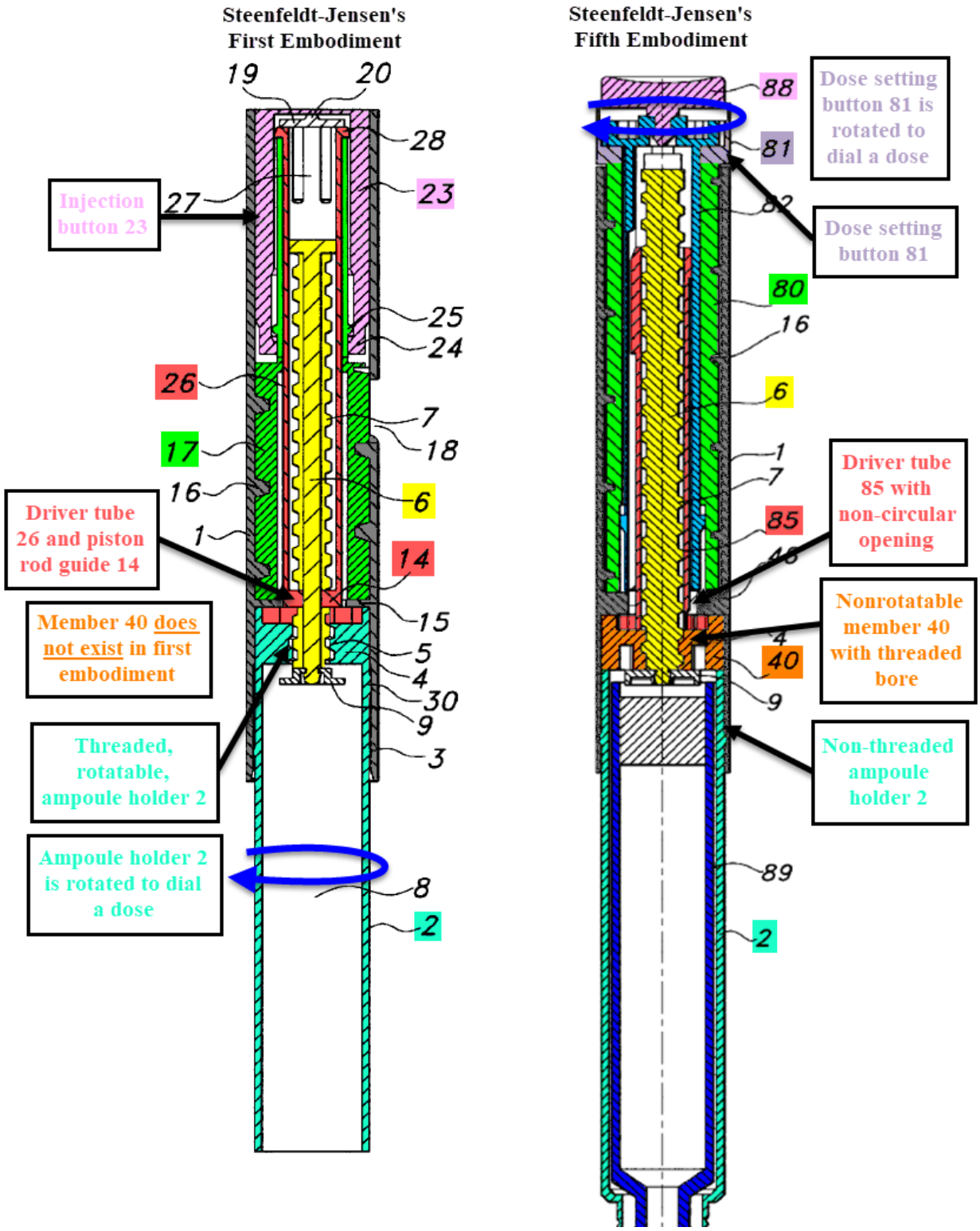
Ex. 1014, Fig. 2 (annotated).

To inject a dose, injection button 23 is pressed into the housing 1. Ex. 1014, 7:17-18. Torque on the dose scale drum 17 causes it to rotate in the clockwise and

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*., 7:18-24. 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).

Specifically, 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 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 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 40.

> "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***. This disclosure is not

repeated 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 that is cited by the 486 Patent. Ex. 1008 at 0002. Møller describes an injection pen where a rack and gear wheel provides a mechanical advantage (*i.e.*, "gearing") between an injection button and an ampoule piston. Ex. 1015, ¶¶ 0006, 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 EP608343 and WO99/38554, the latter of which is the PCT counterpart to Steenfeldt-Jensen and also cited by the 486 Patent.[4] Regarding EP608343, Møller explains that the prior art gearing is achieved from a dose setting element having a high pitch thread that rotates in unison with a driver nut having a

[4] *See* Ex. 1014 (claiming priority to DK199800130), 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.").

fine pitch thread. Ex. 1015, ¶ 0007. Møller states that WO99/38554 (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.* 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***.

Id., ¶ 0011 (emphasis added). The invention presented by Møller accounts for these advantages and disadvantages, and specifically avoids the teachings of WO99/38554. *See* Ex. 2107, ¶ 149.

1. <u>Møller Does Not Disclose a "Main Housing"</u>

In the Institution Decision, the Board made two preliminary determinations with respect to whether Møller purportedly discloses a "main housing," as properly construed: (1) "[o]n the present record, Figure 1 of Moller shows, via cross-hatching, that housing 1, wall 2, and tubular element 5 are one piece" and (2) "[m]oreover,

even if Moller's housing 1, wall 2, and tubular element 5 were distinct structural components, we are persuaded sufficiently on the present record that they appear to form 'an exterior . . . multipart component configured to . . . engage with one or more inner components,' because the proposed interpretation does not exclude a multipart component that resides on both the exterior and interior." Paper 20 at 29-30. Respectfully, the Board erred in these determinations.

As to the first preliminary determination, the Board acknowledges that Møller discloses three distinct elements: a housing 1, wall 2, and tubular element 5. Of these elements, only housing 1 meets the construction for "main housing" under Patent Owner's construction and the "plain and ordinary" meaning of main housing. Nonetheless, the Board concludes that because the cross hatching in the figure suggests that the housing, wall, and tubular element are integrally formed, the combination of these elements meets the construction for "main housing." But whether these elements are integrally formed is beside the point. Møller treats these elements discretely and the Board should too.

Relevantly, the 486 Patent ***also*** discloses that its main housing 4 may be integrally formed with its insert 16. Ex.1003, 3:53-55 ("Alternatively, the insert may be formed integrally with the main housing 4 the form of a radially inwardly directed flange having an internal thread."). The 486 Patent does <u>not</u> state that the insert may be *substituted* by an inwardly directed flange of the main housing (and thus the

inwardly directed flange would be part of the main housing). Similarly, Møller does not disclose that wall 2 is replaced by housing 1, only that wall 2 is integrally formed with housing 1. Fundamentally, the Board is engaging in a box drawing exercise that runs counter to the express disclosure of both Møller and the 486 Patent

As to the Board's second preliminary determination, the Board concludes that the proper construction does not exclude a "multipart component that resides on both the exterior and interior." Respectfully, the Board's interpretation makes the construction meaningless because it eliminates any distinction between an exterior housing (main housing) and an interior housing (insert) – the distinction specifically preserved in the related 008 Patent. Under the Board's interpretation, "main housing" swallows all the interior components (these just become parts in the multi-part housing). This cannot be what is meant by a "main housing" in the 486 Patent, particularly because the 486 Patent discloses integrally formed components yet continues to treat the main housing distinctly from the insert. *See* Ex. 1003, 3:53-55.

VII. THE CITED PRIOR ART DOES NOT RENDER OBVOUS THE CHALLENGED CLAIMS

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

1. Steenfeldt-Jensen Does Not Render Obvious a "driver comprising an internal threading near a distal portion of said driver" (all challenged claims)

a) There Is No Disclosure of Suggestion in Steenfeldt-Jensen of an Internally Threaded Driver

The challenged claims require a "driver comprising an internal threading." Petitioner concedes that Steenfeldt-Jensen's fifth embodiment does not disclose this limitation. Petition at 30. Petitioner argues, however, that a POSA would have known to modify Steenfeldt-Jensen to have this feature because the reference "expressly contemplates a modification" in which the driver tube contains an internal threading that engages the piston rod's external threading. *Id.* at 35. But, none of the four passages in Steenfeldt-Jensen cited by Petitioner discloses an internally threaded driver tube. These passages only disclose an internally threaded "nut member" or "nut element" – Steenfeldt-Jensen's driver tube itself is never threaded.

No portion of the first passage identifies a driver tube, much less an internally threaded driver tube. *See* Petition at 36 (citing Ex. 1014, 2:40-53), 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 next two passages state: (1) "rotation of the scale drum can rotate the piston rod relative to the nut member"; and (2) "rotation of the scale drum can rotate the nut member relative to the piston rod." Petition at 35 (citing Ex. 1014 at 3:15-20, 3:44-47). But these passages only recognize that for a piston rod to move axially through a nut, there must be relative rotation between the two (*i.e.*, the well-known mechanical engineering principle that either the nut 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 7:41-47, describes a driver tube rotating a "nut member." Petition at 35. Again, there is no disclosure of a threaded driver tube. 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).

Thus, none of the four passages relied on by Petitioner teaches or suggests a 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. 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. Ex. 1014, 3:41-47, 7:41-47; 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 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) (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 11:6-12:16) based on a disclosure from Steenfeldt-Jensen's first embodiment (shown in Figures 1-5 and described at 5:33-7:47):

> 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 have understood that this passage is not applicable to the fifth embodiment. *See* Ex. 2107, ¶¶ 223-226.

First, the "shown embodiment" refers to the first embodiment described with respect to Figures 1-5. *See* Ex. 1014, 5:33-7:47 (the portion of the specification describing the 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 describing Steenfeldt-Jensen's fifth embodiment). Indeed, the language from 7:41-47 originates from Steenfeldt-Jensen's provisional application, which included the first embodiment but not 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, 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 applicable to all of Steenfeldt-Jensen's embodiments. For example, applying Petitioner's modification to Steenfeldt-Jensen's second embodiment results in a ***non-functioning*** pen injector. *See* Ex. 2107, ¶ 226. As Prof. Slocum explains, placing the non-circular opening in ampoule holder 2 (turquoise) of the second embodiment, and a threaded opening in pawl 13 (red), would allow the user

to dial but not inject a dose. If the user attempts to inject a dose, the injection button would seize. *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. *Id*.

Finally, even assuming that (1) the passage was made in the context of the fifth embodiment, or (2) the passage generally applied outside the first embodiment, Petitioner's argument still fails because the passage does not teach the modification Petitioner proposes. Petitioner, as discussed in more detail in the next section, proposes 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. Ex. 2107, ¶ 227; Ex. 2164 at 219:18-220:11 (confirming modification). The passage at 7:44-47 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 is antithetical to pen injector design during the relevant time period and results in an inferior pen injector. Specifically, moving the threads to the driver tube, and moving the non-circular slot to member 40, ***introduces a major new source of friction*** to Steenfeldt-Jensen's fifth embodiment. 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 friction source 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.

Friction causes efficiency losses because some of the force going into the pen during dose injection is used overcome friction. These losses are highly undesirable as they require the user to expend greater energy to inject medicament. Ex. 1015, ¶¶ 0004-0006; *see also* Ex. 2107 ¶ 37-39, 44-45, 54, 56-57, Section II, *supra*. Injection force is regularly assessed as a benchmark for these products. *See* Ex. 2107, ¶¶ 56-57, Ex. 2163 at 80:17-81:5. A significant reason for the success of the Patent Owner's injection pen is its ease-of-use and the 486 Patent (which is

embodied in Patent Owner's pen) specifically recites that a primary purpose of its invention is to "help[] reduce the overall force required for a user to cause medicinal product to be dispensed." Ex. 1003, 3:64-67.

Prof. Slocum created an analytical model to demonstrate how friction between the pen injector elements leads to efficiency losses. 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.

Furthermore, a physical model (the "Collar Friction Model") conveys the basic principle for why Petitioner's proposed modification would not work—*i.e.*, the introduction of "collar friction" when the driver tube is adapted to have threads. *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 inject medication. *See id.*, ¶ 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 and Petitioner's proposed modification. For the model shown in Appendix A to Exhibit 2107, 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%. *Id.*, Appx. A, B.

(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 and Petitioner's proposed modification:

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.

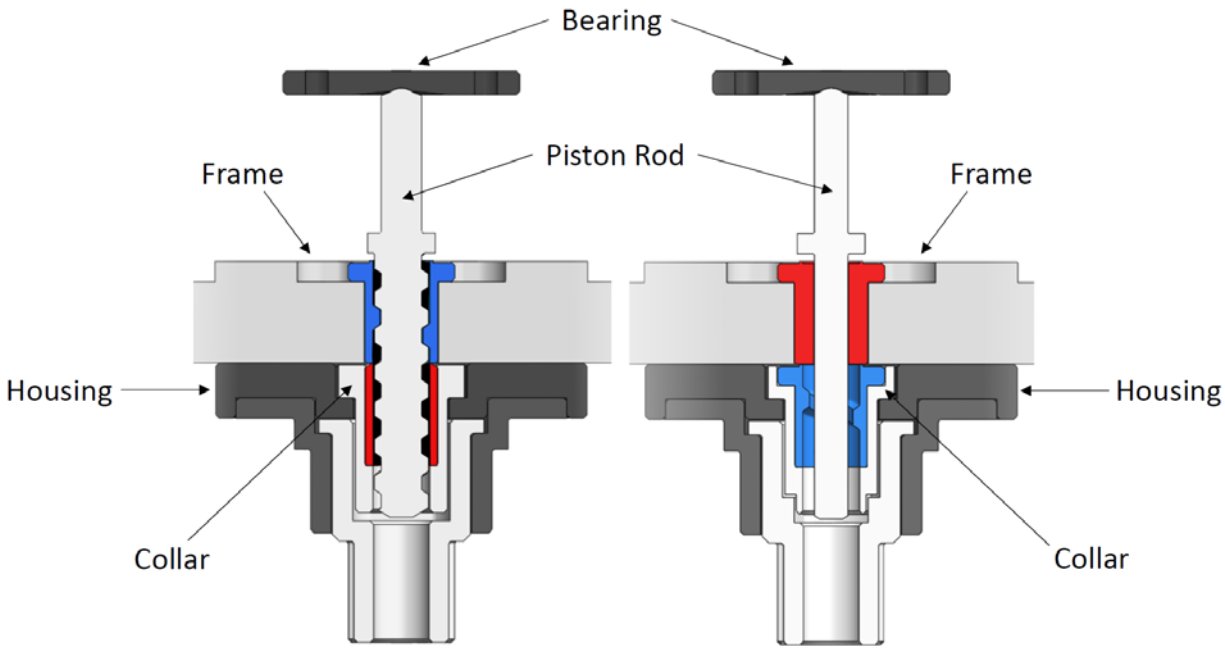
Frame plus Guide or Thread Insert: This rotationally-fixed component in combination with the Thread Insert represents threaded member 40 in Steenfeldt-Jensen's fifth embodiment. The Frame in combination with the Guide represents the slotted member in Petitioner's proposed modification.

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.

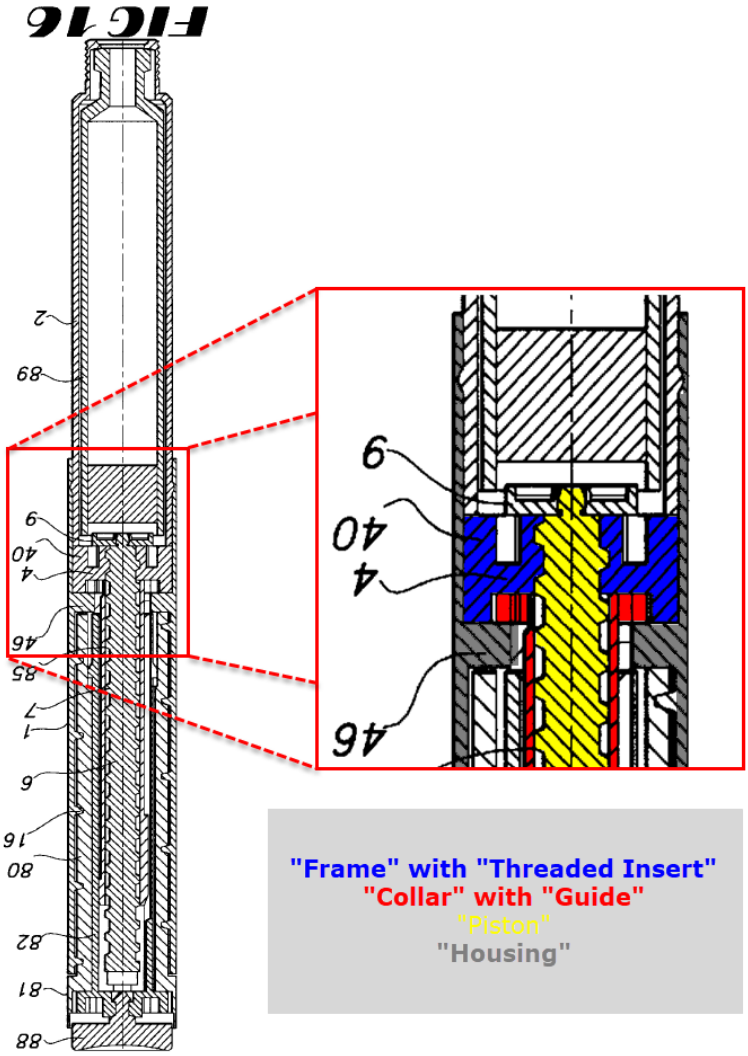
See Ex. 2107, ¶ 247. These components of the Collar Friction Model are shown in the two cross-section illustrations below.[5]

[5] 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, Exs. 2215-2217. 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.

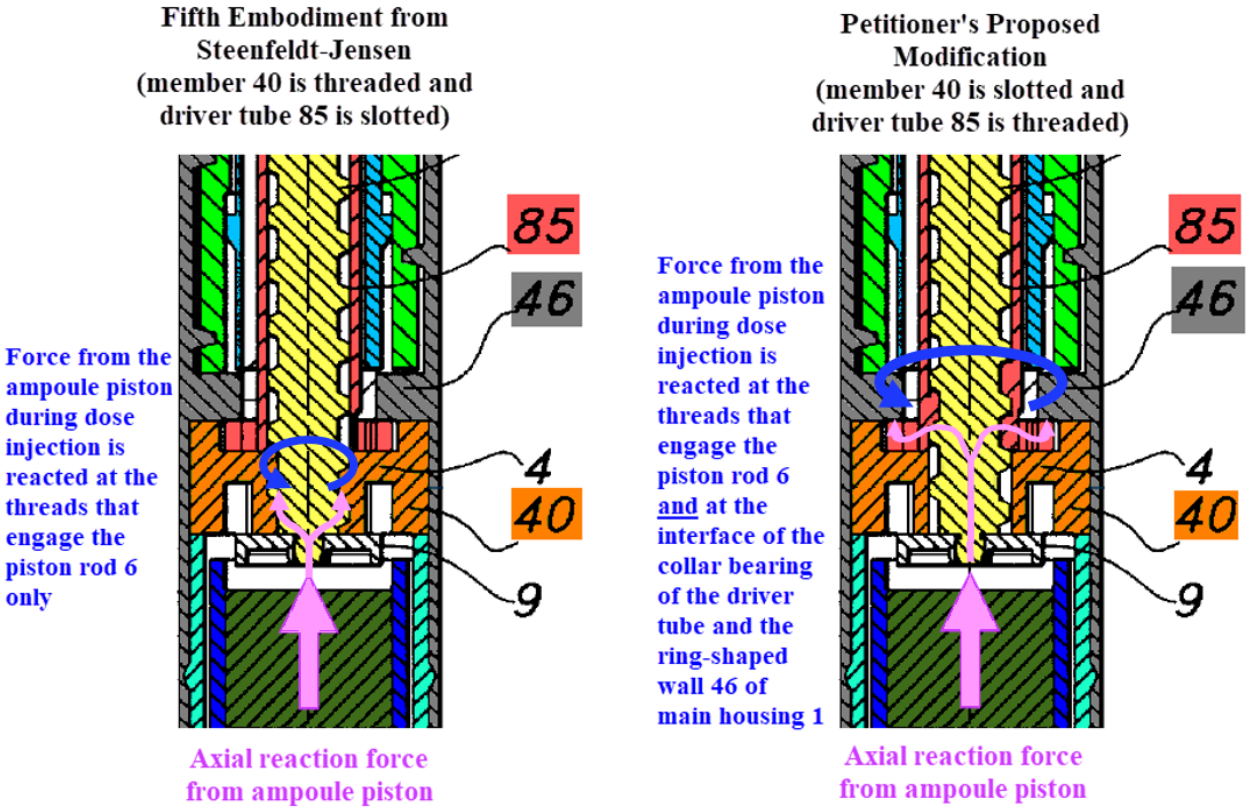
The additional friction is also apparent from what happens after the piston rod is rotated upward and then released. In the configuration representing Steenfeldt-Jensen's fifth embodiment (i.e., Collar fitted with the Guide), if the piston rod is rotated upward and then released, it rotates back down 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 due to the collar friction. *See* Ex. 2107, ¶¶ 249-251.

d) Explanation For Why Petitioner's Modification Results in Higher Friction

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 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

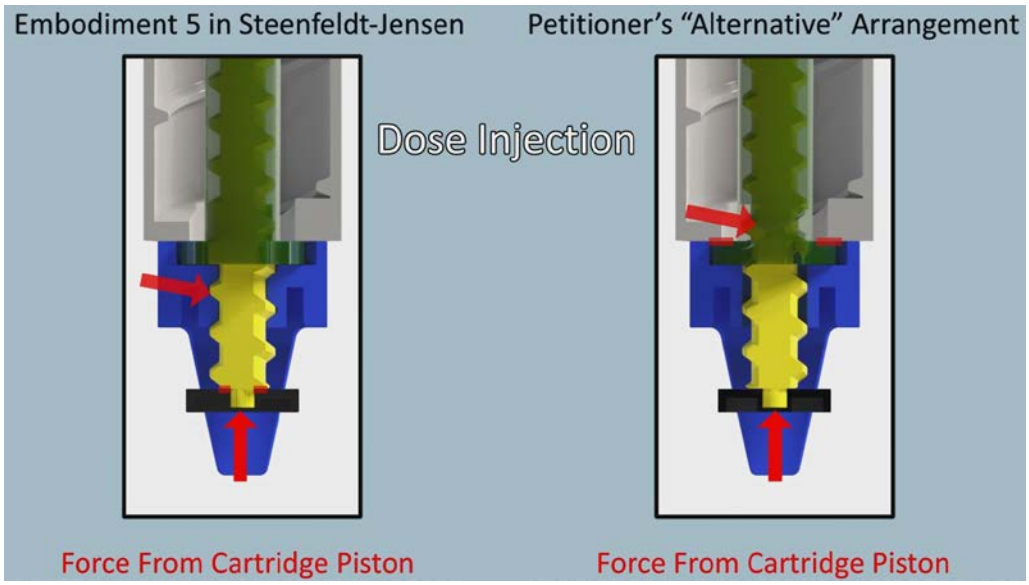
reaction. *See* Ex. 2107, ¶ 233. Accordingly, this axial force from the piston rod 6 (yellow) causes a reaction force (pink arrows) exerted by ampoule piston (dark green) against the piston rod 6 (yellow) that translates to the internal threads of non-rotatable member 40 (orange) as an upward force (also 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, the axial reaction force from ejecting the fluid is borne by member 40, which is axially and ***rotationally fixed*** within housing 1 (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 modification during injection).

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, ¶¶ 237-23. 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, a significant source of friction is introduced during injection at the rotating flange on the driver tube 85 as it is being driven upward 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 Caused by Petitioner’s Proposed Modification</u>

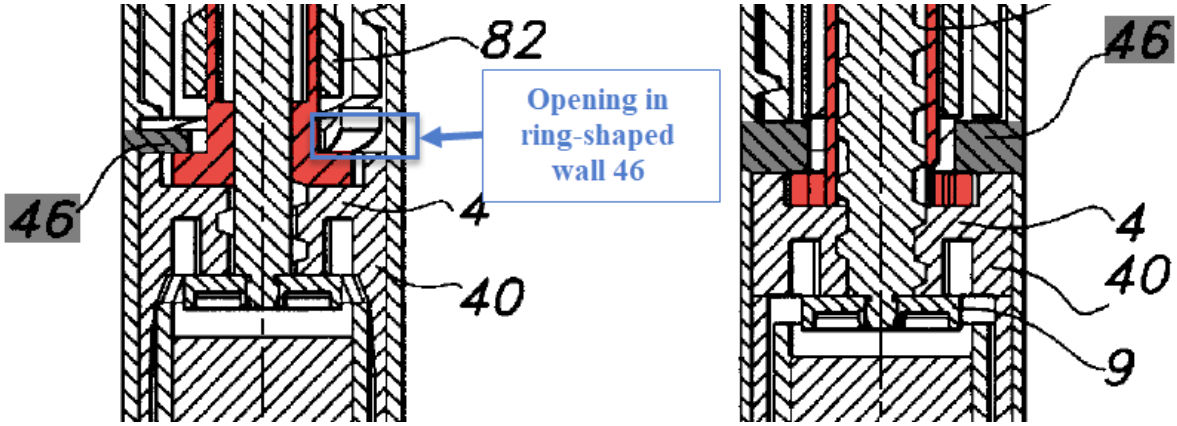
Prof. Slocum further explains that this increase in friction is one problem with Petitioner’s proposed modification. There are three other potential device failures associated with Petitioner’s modification that would discourage a POSA from making the proposed combination. *See* Ex. 2107, ¶¶ 239-241.

First, because the outer flange on 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. 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, ¶ 240.

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).

***

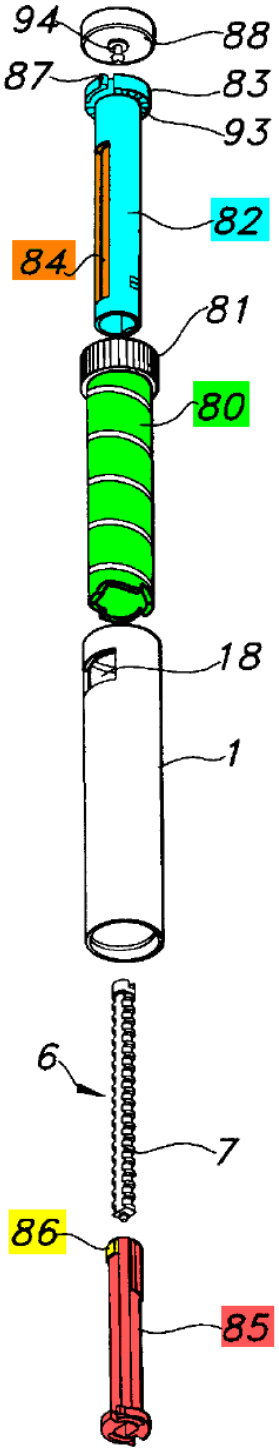
In sum, a POSA would not have been motivated to modify the fifth embodiment as proposed by Petitioner because it would have significantly increased the injection force, potentially resulted in failure, and there is no evidence of any benefit resulting from the modification. *See Plas-Pak Indus. v. Sulzer 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).

2. Steenfeldt-Jensen Does Not Render Obvious a Dose Dial Sleeve That "comprises at least one radial stop, said radial stop positioned near an end of said helical groove" (claims 30 and 32)

Petitioner acknowledges that Steenfeldt-Jensen's *fifth* embodiment—the embodiment relied upon as rendering obvious each of the challenged claims—does not teach the limitation recited in claim 30 and instead argues that it would have been obvious to modify this fifth embodiment based on a teaching in the *third* embodiment. Petition at 51-53. Petitioner argues that it would have been obvious to take the "saw tooth 91" on the *button-end* of the dose scale drum 18 in the third embodiment and modify the dose scale drum 80 in the fifth embodiment to include some unspecified radial stop at its *needle-end*. *Id.* Petitioner's argument fails as explained below.

First, a POSA would not have modified Steenfeldt-Jensen's fifth embodiment to include a radial stop on its dose scale drum 80, because Steenfeldt-Jensen already includes a mechanism on driver tube 85 that serves as a radial stop. As Petitioner's expert states, the purpose of a radial stop is "to prevent further movement of the dose scale drum during dose setting when the maximum dose for a single injection has been reached." Ex. 1011, ¶ 327. In Steenfeldt-Jensen's fifth embodiment, further movement is prevented by outer wall hooks 86 (yellow) of driver tube 85 (red) that abut against the needle-end of longitudinal slot 84 (orange) of bushing 82 (light blue) when the dose scale drum 80 (light green) is fully dialed out. *See* Ex. 2107, ¶¶ 258-

260. Petitioner's expert concedes that this mechanism serves as a radial stop. *See* Ex. 1011, ¶ 329.



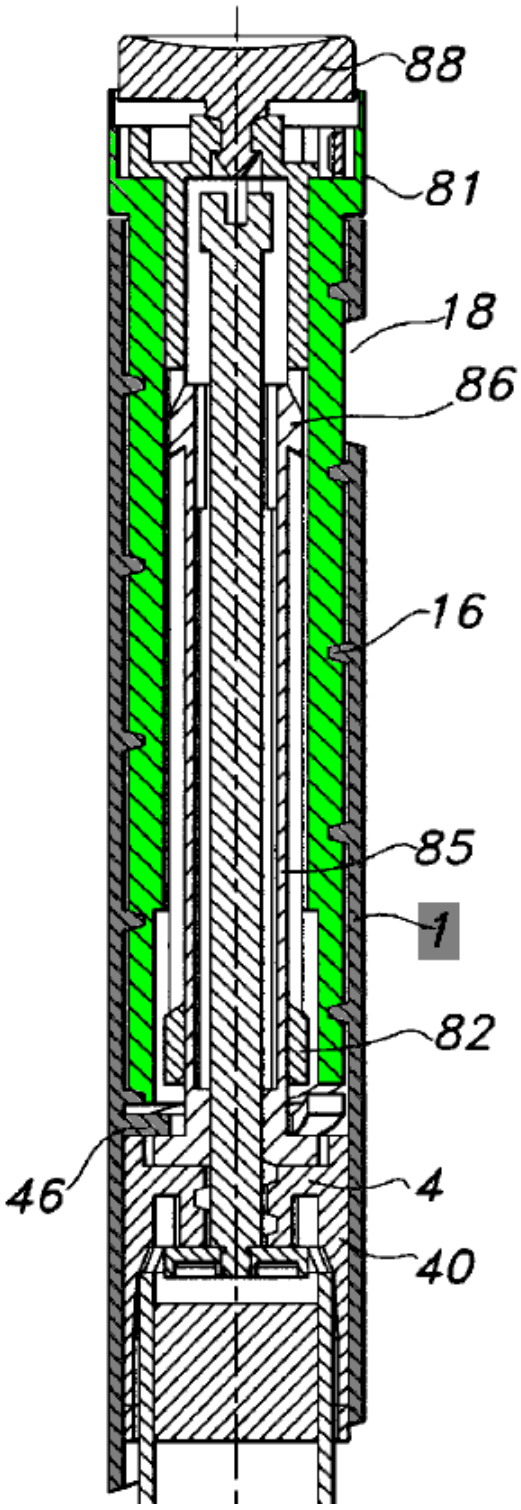
Ex. 1014, Fig. 17 (cropped and annotated)

Thus, adding a radial stop to the dose scale drum 80 of Steenfeldt-Jensen's fifth embodiment would not serve any additional purpose. *See* Ex. 2107, ¶ 259. Petitioner's expert is unable to explain why a POSA would have decided to add a radial stop, as allegedly taught by the "saw tooth 91" of Steenfeldt-Jensen's third embodiment, to dose scale drum 80. For this reason alone, Steenfeldt-Jensen fails to render obvious claims 30 and 32.

Although not presented in the Petition, Mr. Leinsing implies that a POSA would have recognized that hooks 86 and a radial stop on a dose dial sleeve are interchangeable. Ex. 1011, ¶ 330. Mr. Leinsing asserts, without any supporting reasoning, that a POSA would have viewed hooks 86 on driver tube 85 and an imagined radial stop on the dose scale drum 80 as being structurally and functionally equivalent—this is not true. *See* Ex. 2107, ¶ 260 (explaining differences between hooks 86 and radial stop on a dose dial sleeve). Hooks 85 are necessary to the fifth embodiment to allow relative axial movement, but not relative rotational movement, between bushing 82 and driver tube 85. Thus, a POSA would not have removed hooks 85 in favor of an unspecified radial stop on the dose dial sleeve. *See id.*

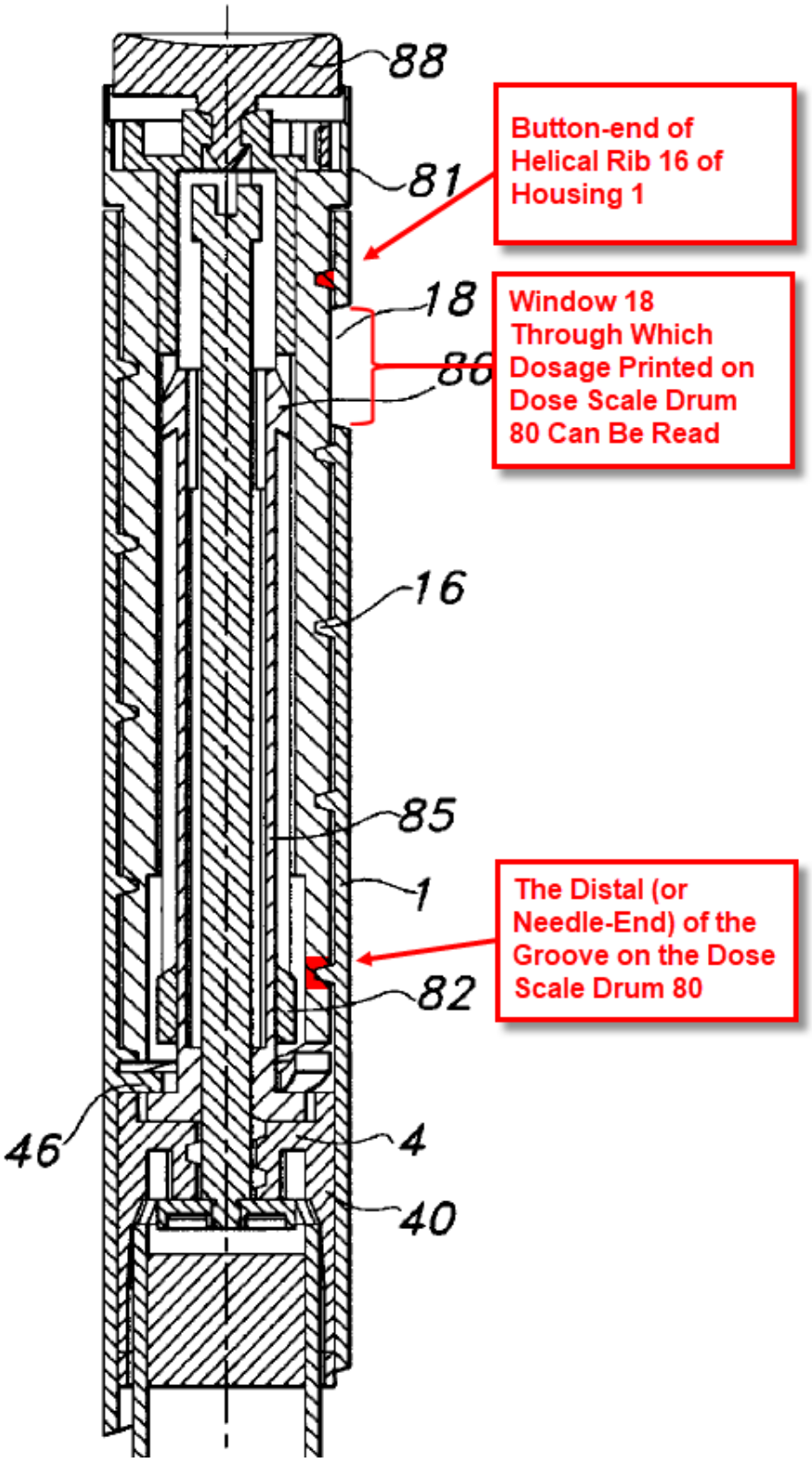
Second, Mr. Leinsing has not explained how it would have been practical to implement a radial stop, as taught by the ***button-end*** saw tooth 91 in Steenfeldt-Jensen's third embodiment, on the ***needle-end*** of the dose scale drum 80 in Steenfeldt-Jensen's fifth embodiment. At most, Petitioner and its expert state that a

POSA "would have understood" to put a "radial stop, such as a protruding tooth," near the needle-end of the dose scale drum 80, and Mr. Leinsing adds that this "protruding tooth" would abut a corresponding stop on housing 1 near the button-end of its helical rib 16. *See* Petition at 53, Ex. 1011, ¶ 329. Steenfeldt-Jensen's fifth embodiment, however, does not have any space for a pair of protruding teeth, or other stops, between the dose scale drum 80 (light green) and housing 1 (grey) without widening the pen, which runs counter to pen injector design principles. *See* Ex. 2163 at 169:12-170:20, Ex. 2107, ¶ 261.



Ex. 1014, Fig. 15 (cropped and annotated)

Moreover, a POSA would not add "a corresponding stop provided on the housing 1 near the button-end of its helical rib 16" to engage a radial stop near the needle-end of the dose scale drum 80, as Mr. Leinsing alleges (Ex. 1011, ¶ 329), because doing so means that the dose scale drum 80 (and all of the dosage indications printed thereon) would screw out past window 18 of the housing—*i.e.*, well past its maximum dosage. *See* Ex. 2107, ¶ 262.



Ex. 1014, Fig. 15 (cropped and annotated).

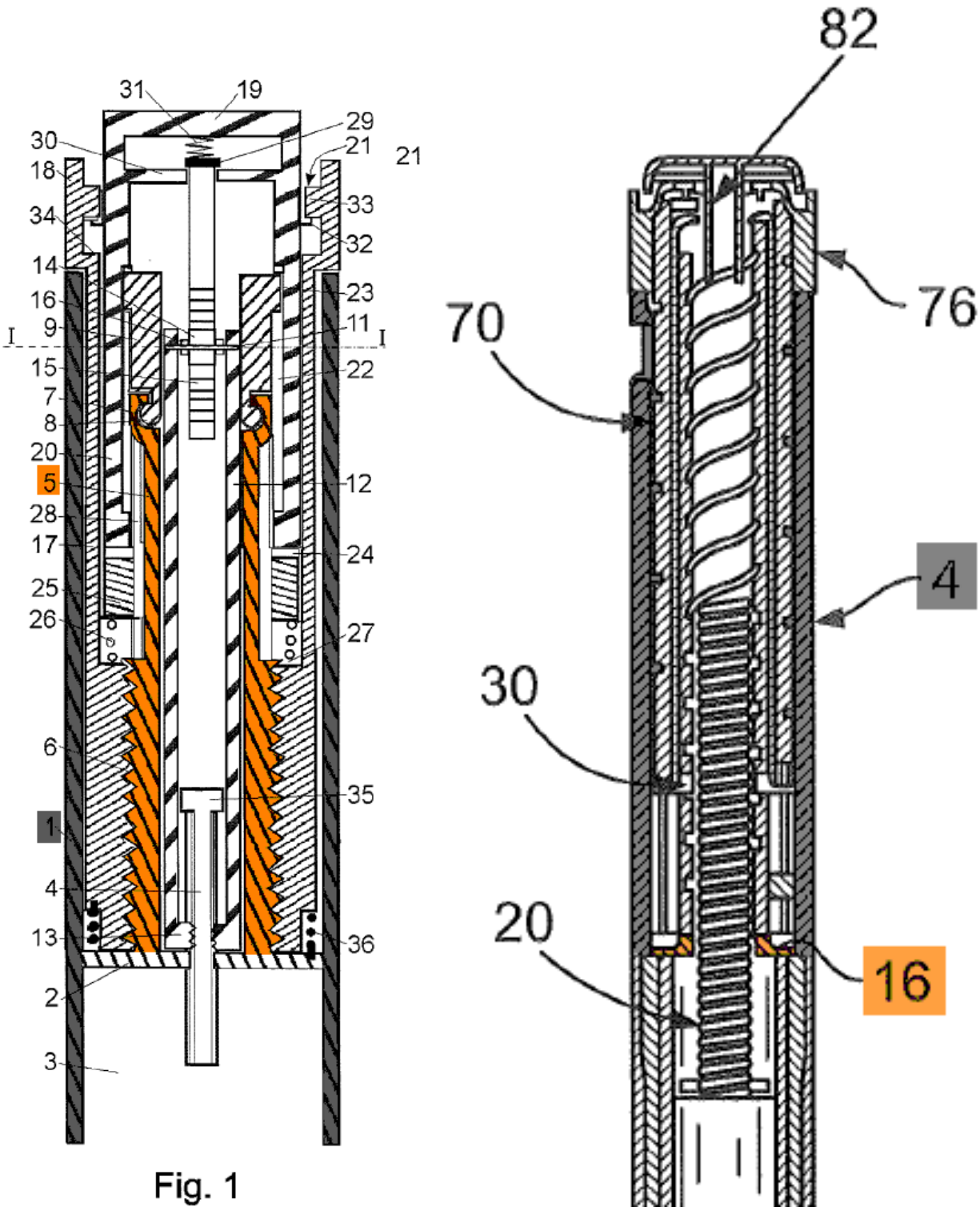
Because the Petition fails to show that a POSA would have been motivated to modify the fifth embodiment to include a radial stop on a dose dial sleeve, as required by claim 30, or to include such a stop near the distal end (*i.e.*, needle end) of a groove on a dose dial sleeve, as required by claim 32, the Petition fails show that claims 30 and 32 are obvious.

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

1. The Combination of Møller and Steenfeldt-Jensen Does Not Render Obvious "said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing" (all claims)

Møller does not disclose that dose-setting drum 17 is configured to engage a threading provided by said ***main housing*** as claim 1 requires. Instead, the threads of Møller's dose setting drum 17 engage those of tubular element 5, which is not the "main housing." Ex. 2107, ¶¶ 286, 298-302 .

Whether under Patent Owner's construction or the plain and ordinary meaning, a "main housing" does not encompass interior housing. Sections V, VI.B.1. Møller's tubular element 5 (orange) is not the "main housing", because it is an interior housing. *See* Ex. 2107, ¶ 300. Nor can Møller's tubular element 5 be understood as an exterior housing as it is identified in Figure 1 and in the written description as separate and distinct from the exterior housing – housing 1 (grey). Ex. 1015, ¶ 0023 (emphasis added).



Ex. 1015, Fig. 1 (annotated) (left), Ex. 1002, Fig. 3 (annotated) (right).

Møller's tubular element 5 (orange) is akin to the 486 Patent's "insert" (orange). *See* Ex. 2107, ¶¶ 300-301. "Insert" in the 486 Patent is described as a separate, distinct interior component that can be integrally formed with the main housing. *See* Ex. 1003, 3:49-55; *see also* Sections V, VI.B.1. Like the 486 Patent's "insert", Møller's tubular element 5 is distinct from housing 1, even though it may be formed integrally with it. *See* Ex. 1003 at 3:53-55; *see also* Ex. 2107, ¶ 301, Ex. 2164 at 304:6-11 (acknowledging Møller's wall 2, which separates housing 1 from tubular element 5, as the insert).

Because Møller's dose-setting drum does not comprise threads that engage a main housing, Petitioner fails to show that the combination of Møller and Steenfeldt-Jensen teaches or renders obvious claim 1.

2. A POSA Would Not Have Been Motivated to Combine the Teachings of Møller and Steenfeldt-Jensen

Petitioner fails to demonstrate that a POSA would have been motivated to combine Møller and Steenfeldt-Jensen. Petitioner asserts that to the extent that Møller does not disclose a "helical groove," a POSA would have modified Møller such that inner threads of Møller's tubular dose setting drum become the "groove from Steenfeldt-Jensen's teaching of a similar dose-dial sleeve having a 'helical track.'" Petition at 65. A POSA would not have been motivated to modify Møller as proposed for the reasons set forth below.

a) A POSA Would Not Have Been Motivated to Combine the Teachings of Møller and Steenfeldt-Jensen

Møller expressly teaches away from combining its invention with Steenfeldt-Jensen. Ex. 2107, ¶¶ 288-292, 304. Specifically, Møller disparages the threaded gearing of WO99/38554, which is the related Steenfeldt-Jensen PCT publication (*See* Ex. 2015):

> 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). Møller's embodiments pointedly avoid Steenfeldt-Jensen's grooved dose scale drum and Petitioner's expert has not explained why a POSA would disregard Møller's criticism. *See* Ex. 2107, ¶¶ 289-290, 294. *See also 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 preliminarily notes "that 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 of Moller." Paper 20 at 31. 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 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, 304; *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 argues. *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 it would have been obvious to modify the internal threading on Møller's tubular dose setting drum 17 to be a groove from Steenfeldt-Jensen's dose scale drum 80. Petition at 65-66. This argument fails for two reasons.

First, Møller's inventors expressly considered Steendfeldt-Jensen's externally-grooved dose scale drum 80 and rejected it. Ex.1015, ¶ 0008 (". . . most of the transformed force is ***lost due to friction*** between the sliding surfaces."), ¶ 0011 ("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*** ….”), Fig. 1; *see also* Ex. 2107, ¶ 294.

Second, Petitioner haas not pointed to any reason why Møller would be modified in this way. *See* Ex. 2107, ¶ 294. Petitioner did not point to evidence suggesting that a POSA would look beyond Møller’s teachings to support such a modification. *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 ….”).

In sum, Møller expressly considered Steenfeldt-Jensen’s teachings and rejected them, and Petitioner has not established a reason to modify Møller as proposed. Petitioner is incorrect that “a POSA would have known to implement thread 6 as a groove from Steenfeldt-Jensen’s teaching of a similar dose-dial sleeve ….”

3. Møller Does Not Render Obvious “a helical rib provided on an inner surface of said outer housing” (claim 4)

Petitioner concedes that Møller “does not depict a helical groove on the inner surface of the housing” as required by Claim 4. Petition at 78. Nonetheless, 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 to

have "a high-pitch rib-to-groove connection taught by Steenfeldt-Jensen between the inner surface of housing 1 and the outer surface of drum 17 of Møller's drum …." Petition at 80. Petitioner is wrong for at least the reasons below.

a) Møller Teaches Away from Steenfeldt-Jensen's External High-Pitched Thread

As explained in Section VII.B.2, a POSA would not have been motivated to combine Møller with the specific reference that Møller's teaches away from. Møller expressly disparages the high-pitch thread taught by Steenfeldt-Jensen, which is the same thread that Petitioner argues a POSA would have used to modify Møller. *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: "Because the threaded engagement in Steenfeldt-Jensen is configured to reduce sliding friction between the drum and housing, a POSA would have understood this configuration would reduce the force needed to rotate the drum back into the housing during injection." Petition at 80.

Petitioner points to no evidence suggesting that a POSA would look beyond Møller's teachings for addressing undesirable thread friction. And nor would a POSA, as 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, ¶ 317. Petitioner does not address why a POSA would ignore the helical reset spring in favor of a different solution.

In sum, Møller expressly considered Steenfeldt-Jensen's teachings and rejected them as disadvantageous, and Møller proposes a different solution to the purported "problem." There is also no apparent reason to modify Møller as Petitioner proposes. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Accordingly, claim 4 of the 486 Patent is valid.

4. Møller Does Not Render Obvious a Driver Comprising "a cylindrical shape" (claim 5)

Petitioner contends that Møller teaches this claim limitation by arguing that a POSA would have understood that Møller's nut 13 is cylindrical. Møller, however, does not describe nut 13 as having a cylindrical shape. Additionally, Petitioner asserts no reason to modify connection bars 12 and nut 13 to be a sleeve, and a POSA would not have found it obvious to form these components as a sleeve. Moreover,

connection bars 12 and nut 13 are not structurally and functionally equivalent to the tubular connection element 112 with nut 13. *See* Ex. 2107, ¶¶ 319-323. Thus, Møller fails to render obvious claim 5.

5. Møller Does Not Render Obvious a Clicker Comprising "at least one flexible [extending] arm" (claims 18 and 20)

Both claims 18 and 20 require a clicker having a "flexible [extending] arm," and Petitioner fails to articulate a *prima facie* showing that a POSA would have been motivated to combine the alleged flexible arm from Steenfeldt-Jensen with Møller's teachings. *See* Petition at 84-88 (relying entirely on Steenfeldt-Jensen for the disclosure of a clicker that comprises a flexible arm). 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 into 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"). Petitioner has only argued that a POSA would be motivated to combine Steenfeldt-Jensen and Møller to add Steenfeldt-Jensen's "high-pitch helical groove." Petition at 62-66, 77-80. Merely alleging, as Petitioner does, that a POSA would have understood that Steenfeldt-Jensen discloses the limitations recited claims 18 and 20 is not factually or legally sufficient to conclude

that the combination of Møller and Steenfeldt-Jensen renders this claim obvious. *See* Petition at 84-88; *see also* Ex. 2107, ¶¶ 324-326.

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 [extending] arm" as required by claims 18 and 20.

6. Møller Does Not Render Obvious a Dose Dial Sleeve That Is "radially inward of said main housing" (claim 26)

Claim 26 requires that the dose dial sleeve is "radially inward of said main housing." Møller's dose-setting drum 17, however, is not "radially inward of said main housing". As shown below, while the piston rod 4 (yellow) is radially inward of the combination of housing 1, insert 2, and tubular element 5 (Petitioner's "main housing"), dose-setting drum 17 (light green) is not – specifically it is not radially inward of tubular element 5. *See* Ex. 2107, ¶¶ 327-331. Thus, Møller does not render obvious claim 26.

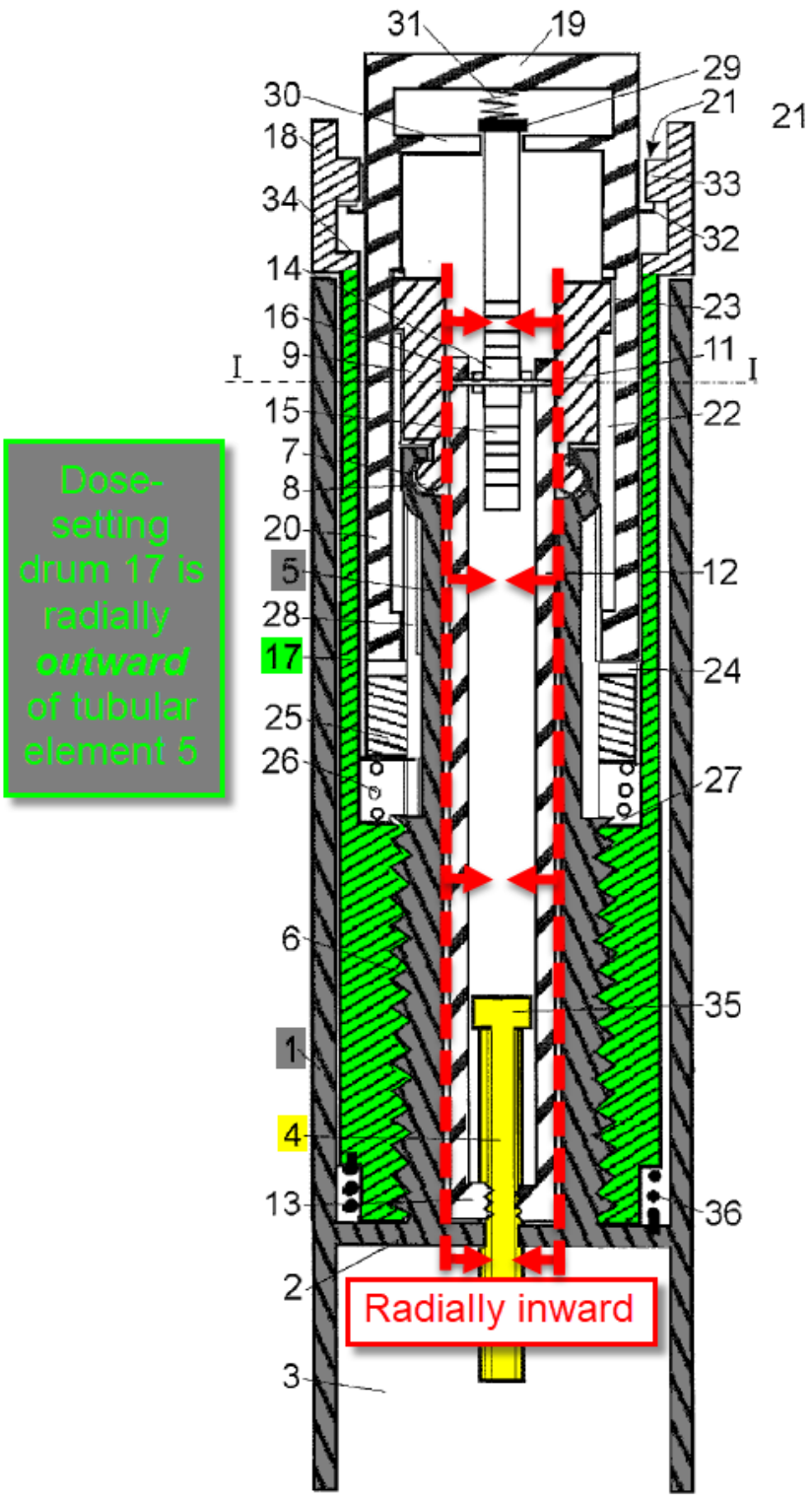


Fig. 1

Ex. 1015, Fig. 1 (annotated)

7. Møller Combined With Steenfeldt-Jensen Does Not Render Obvious a "radial stop positioned near an end of [a] helical groove" or "near a distal end of said helical groove" (claims 30 and 32)

Petitioner argues that it would have been obvious to take the "saw tooth 91", which Petitioner alleges is a "radial stop", on the *button-end* of a dose scale drum 18 in Steenfeldt-Jensen and modify the dose-setting drum 17 of Møller to include some unspecified type of radial stop at its *needle-end*. *Id.* Petitioner's argument fails as explained below.

Petitioner has not explained how it would have been possible or practical to implement a radial stop, as taught by the ***button-end*** saw tooth 91 in Steenfeldt-Jensen's third embodiment, on the ***needle-end*** of the Møller's dose-setting drum 17. Petition at 95. Møller does not have any space for a pair of protruding teeth, or other stops, between the dose-setting drum 17 (light green) and housing 1 (grey) without widening the pen, which runs counter to pen injector design principles. *See* Ex. 2163 at 169:12-170:20; Ex. 2107, ¶¶ 332-333.

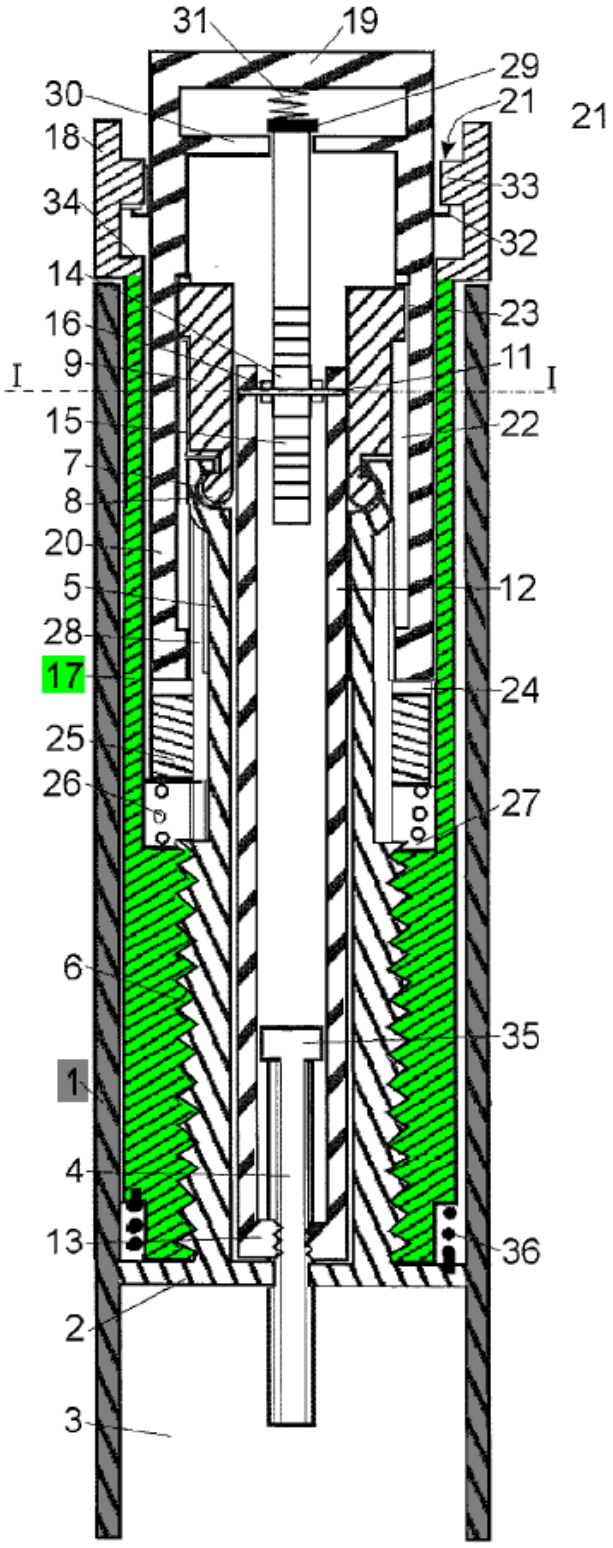


Fig. 1

Ex. 1014, Fig. 15 (cropped and annotated)

Because the Petition fails to show that a POSA would have been motivated to modify Møller's embodiment to include a radial stop on a dose dial sleeve, as required by claim 30, or to include such a stop near the distal end (*i.e.*, needle end) of a groove on a dose dial sleeve, as required by claim 32, the Petition fails show that claims 30 and 32 are obvious.

8. Møller Does Not Render Obvious an "Insert" (claims 38-40)

Claims 38-40 each require an "insert provided at a distal end of the main housing ." Petitioner relies solely on Møller's "wall 2" as the insert (Petition at 97-98), but Petitioner also relies on wall 2 as "main housing." Section VII.B.1 If wall 2 is part of the "main housing" for claim 1, it cannot be the "insert" for claims 38-40. Conversely, if wall 2 is the "insert" for claims 38-40, it cannot be part of the "main housing" for claim 1. Petitioner fails to show claims 38-40 are rendered obvious by Møller.

VIII. OBJECTIVE INDICIA OF NONOBVIOUSNESS

The PTAB has recognized that "objective evidence of nonobviousness[] may lead to a conclusion that the claimed invention would not have been obvious to one with ordinary skill in the art." *Lupin Ltd. v. Senju Pharm. Co*., No. IPR2015-01100, Paper 70 at 20 (P.T.A.B. Sep. 12, 2016). Objective indicia help "guard against slipping into use of hindsight, and to resist the temptation to read into the prior art the teachings of the invention in issue." *Graham v. John Deere Co. of Kan. City*, 383

U.S. 1, 36 (1966). Objective indicia of nonobviousness may include long-felt but unresolved need for the invention, commercial success of embodying products, and industry praise, among other factors, which the PTAB must evaluate before reaching an obviousness determination. *Id*. at 35-36; *see also Transocean Offshore Deepwater Drilling Inc. v. Maersk Drilling USA, Inc*., 699 F.3d 1340, 1349-50 (Fed. Cir. 2012). The Federal Circuit has held that evidence of objective indicia "may often be the most probative and cogent evidence in the record." *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1328 (Fed. Cir. 2016).

A nexus must exist between the objective indicia and the claimed invention. *WBIP*, 829 F.3d at 1331. The nexus inquiry is directed to the invention as a whole and not to individual limitations. *Id*. at 1330. A nexus is presumed to exist "when the patentee shows that the asserted objective evidence is tied to a specific product and that product 'is the invention disclosed and claimed in the patent.'" *Id*. at 1329. Here, the objective indicia and nexus to the claimed invention confirm the non-obviousness of the 486 Patent.

A. LANTUS® SoloSTAR® Practices Claim 1 of the 486 Patent

As an initial matter, Sanofi's LANTUS® SoloSTAR®[6] product practices claim 1 of the 486 Patent. Ex. 2107, ¶¶ 513-550. As explained by Prof. Slocum, the inventions in the challenged claims describe a set of components that elegantly work together to provide the user a mechanical device that is easy to use and includes a combination of desirable features and properties, such as (i) low injection force, (ii) short injection stroke length or higher maximum dose per injection, and (iii) a relatively small number of components that decrease the complexity of the device. Ex. 2107, ¶ 650. For example, Prof. Slocum confirms that the claimed components and interfaces, such as the threaded engagements, piston rod, driver, and tubular clutch, are reflected in the LANTUS® SoloSTAR®. Ex. 2107, ¶¶ 513-550.

B. The LANTUS® SoloSTAR® Satisfied Previously Unresolved Needs for Pen Injectors Due To the Inventions of the 486 Patent

As set forth below, due to the contributions of the above features described by Prof. Slocum, the LANTUS® SoloSTAR® satisfied long-felt, but unresolved needs existing in commercially available pen injectors.

[6] LANTUS® is the commercial name for Sanofi's insulin glargine formulation, and LANTUS® SoloSTAR® is the commercial name for LANTUS® packaged in the SoloSTAR® pen injector.

Dr. Robin Goland, a leading endocrinologist and co-director of the Naomi Berrie Diabetes Center at Columbia University, explains that for patients dealing with a lifelong condition that requires daily medication/care, as with diabetes, anything that can be done to reduce the burden of living with such a condition is a huge benefit. Ex. 2111, ¶ 22. For example, people suffering from diabetes experience higher rates of deterioration of fine motor skills that impact hand–eye coordination, balance, and dexterity, among other basic skills. Ex. 2111, ¶ 23. These problems can be especially pronounced with the elderly. *Id.* Moreover, people with diabetes suffer from higher rates of carpal tunnel syndrome (diabetic hand), stiff hand syndrome, shoulder-hand syndrome (reflex dystrophy), and limited joint mobility, the latter of which is especially common with younger patients. Ex. 2111, ¶ 24. Each of these conditions interferes with the patient's basic life activities, in particular, with the ability to administer diabetic medications. Ex. 2111, ¶ 25. Accordingly, diabetic patients need an easy-to-use injection device with a low injection force to reduce the burden on the patient and increase the likelihood of the patient adhering to their prescribed therapy. Ex. 2111, ¶¶ 24-26.

Prior to the launch of LANTUS® SoloSTAR®, there were multiple injection pens on the market for administering insulin or an insulin analog – *e.g.*, Levemir FlexPen and Lantus OptiClik in the long-acting category, and the Humalog KwikPen in the rapid-and intermediate-acting categories, among many others. These injection

pens, however, had numerous shortcomings and design flaws that resulted in significant injection force. A 2007 study, for example, found that FlexPen ranked far below SoloSTAR in injection force. Ex. 2143; *see also* Ex. 2144. The OptiClik likewise had many deficiencies, including a direct drive system that resulted in a high injection force. Ex. 2107, ¶ 646. Numerous other studies confirmed the relatively high injection force of each of the pens on the market at the time of and prior to the launch of SoloSTAR. Ex. 2111, ¶¶ 23-25 (discussing studies); Ex. 2109, at ¶¶ 52-55 (discussing studies). As Dr. Goland explains, the high injection force of these prior art pens made the devices difficult to use and thus increased the risk of patients not adhering to their insulin and insulin-analog therapy. Ex. 2111, ¶¶ 33-35.

The LANTUS® SoloSTAR® revolutionized the injection pen market, in large part because the LANTUS® SoloSTAR® was easy to use. *See, e.g.*, Ex. 2142, Press Release, Prix Galien, 2009 (naming DCA as a candidate for the prestigious Best Medical Device for SolosTAR®). As Dr. Goland explains, "the pen is so easy-to-use because of the low injection force, or the amount of pressure a patient needs to apply to the injection button in order to inject the dose." Ex. 2111 ¶ 33. This is reflected in literature at the time that demonstrates that the LANTUS® SoloSTAR® required a greatly reduced injection force. *See e.g.*, Ex. 2116 at 7 (explaining the challenge of combining low injection force with the need for a short dial extension

and large dose injections). Moreover, these papers confirm that injection force was a primary concern.

And, as recited in the 486 Patent, the primary intent of the invention is to address these specific problems in the prior art – "The illustrated embodiment . . . helps reduce the overall force required for a user to cause medicinal product to be dispensed.", Ex. 1003, 3:64-67. Indeed, as reflected in a related patent, "[s]urprisingly 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.".[7] Ex. 1005, 1:66-2:3.

The industry extensively recognized SoloSTAR for solving the problem of needing to deliver high doses with a short dial extension and with low injection force. Ex. 2128; Ex. 2117; Ex. 2123 at 6; Ex. 2184 at 2 (containing a statement by endocrinologist Sjoberg Kho of the University of Santo Tomas Hospital that "self-injection can be a barrier to acceptance of insulin therapy. However, the Lantus® SoloSTAR operates with a low injection force 31 percent less than other insulin pens that allows a gentle injection."); Ex. 2185 at 1.

[7] This description is from the 008 Patent, which is related to the 486 Patent. *See* footnote 2, *infra*.

Patients likewise expressed a preference for SoloSTAR for its low injection force. *See e.g.*, Ex. 2143; Ex. 2121 at 2, 9 (finding that 7 out of 10 patients now prefer the lower injection force of SoloSTAR® to competitor products and in 2008 it accounted for "41% of all growth in the global injectable insulin market"); Ex. 2144.

The product has thus satisfied a long-felt but unmet need for an easy-to-use pen that was particularly well suited to administer medication with a low injection force.

C. The LANTUS® SoloSTAR® Received Industry Praise for its Patented Features

The nonobviousness of the 486 patent is further demonstrated by the high level of praise and industry recognition that Sanofi and DCA, the design firm with whom Sanofi partnered in creating SoloSTAR®, received for the designs embodied in the SoloSTAR® device. In 2009, for example, SoloSTAR won the Gold, International Export, and Grand Prix awards at the Design Business Association (DBA) Design Effectiveness Awards. *See* Ex. 2121. The DBA is a design organization based in the UK that is interested in how a design commercially impacts a company's business. The case study of SoloSTAR for the DBA Awards describes the SoloSTAR's inventiveness as "suitably ambitious" and explains that "SoloSTAR® is the first disposable insulin pen to combine very low injection force (which provides a smooth injection experience for patients) with 80 units maximum

dose capability, an important breakthrough." *Id*. at 3. SoloSTAR also won the Good Design Award by the Chicago Athenaeum Museum of Architecture and Design. Ex. 2201. In connection with this award, and as recognition of its inventiveness, the Lantus® SoloSTAR® device was put into the permanent Design Collection of the Chicago Athenaeum Museum of Architecture and Design. Ex. 2109, ¶ 73.

Additionally, in 2007, SoloSTAR® won the Good Design Award by the Chicago Athenaeum Museum of Architecture and Design. *Id*. The criteria for this award are "quality design of the highest form, function, and aesthetics a standard beyond ordinary consumer products and graphics." *Id*. Christian K. Narkiewicz-Laine, President of the Chicago Athenaeum Museum of Architecture and Design noted that "SoloSTAR represents a design for social good and for humanitarian concerns." *Id*. In connection with this award, the Lantus® and Apidra® SoloSTAR® devices were put into the permanent Design Collection of the Chicago Athenaeum Museum of Architecture and Design, as recognition of its inventiveness. *Id*.

Finally, at the Prix Galien USA 2009 Award, which "recognize[s] innovative biopharmaceutical drugs and medical technologies" and "is considered the industry's highest accolade for pharmaceutical research and development — equivalent to the Nobel Prize," Sanofi and DCA were both finalists. *Id*. ¶ 74.

In sum, Sanofi and DCA received a high level of acclaim for the design of the SoloSTAR® device.

D. The Commercial Success of the LANTUS® SoloSTAR® Is Attributable to the Inventions in the 486 Patent

The tremendous commercial success of LANTUS® SoloSTAR® is further objective evidence of non-obviousness. The commercial success is demonstrated by the contribution of LANTUS® SoloSTAR® to the growth of the LANTUS® franchise overall, and by the strong performance of LANTUS® SoloSTAR® when compared to other long-acting insulin and insulin analog pens.[8]

As explained by Dr. Grabowski, LANTUS® SoloSTAR® has enjoyed fast and long-sustained growth in terms of dollar sales, new prescriptions, and total prescriptions. *Id.*, ¶ 12. The commercial success of LANTUS® SoloSTAR® is also demonstrated by the overall levels and shares of dollar sales, new prescriptions, and total prescriptions, as well as the profitability and formulary placement achieved by LANTUS® SoloSTAR®. *Id.* This success is notable because sales and prescriptions

[8] Although Patent Owner's commercial success evidence focuses on the long-acting insulin and insulin-analog market in which LANTUS® SoloSTAR® competes, the device satisfied long-felt needs left unresolved by inferior injection pen devices in other markets, such as the rapid-acting and intermediate acting markets.

for LANTUS® SoloSTAR® remained strong despite the entry of several competing long-acting insulin and insulin analog drugs (all in pen form) starting in 2015. *Id.* Furthermore, the LANTUS® SoloSTAR® achieved the highest level of sales among long-acting insulin and insulin analog pens even though it launched after several other long-acting insulin and insulin analog pens, including the Levemir® FlexPen® (the commercial embodiment of Steenfeldt-Jensen), which was the first long-acting insulin or insulin analog product available in a disposable pen. *Id.*

The success of LANTUS® SoloSTAR® is further evidenced by its substantial growth relative to LANTUS® OptiClik®, which is an older pen injector product that included the same insulin glargine formulation as LANTUS® SoloSTAR®. *Id.*, ¶ 12. For example, new prescriptions of LANTUS® OptiClik® totaled 461 thousand in the third year after its launch, and total prescriptions amounted to 1.2 million by this time. By comparison, new prescriptions of LANTUS® SoloSTAR® (using the exact same insulin formula) totaled 1.6 million in the third year after its launch, and total prescriptions amounted to 3.9 million by this time. *Id.*, ¶ 37.

As explained by Prof. Slocum and Dr. Grabowski, each of the features of the device disclosed and claimed in the 486 Patent and used in LANTUS® SoloSTAR® contributed to its commercial success. Ex. 2109, ¶ 53; Ex. 2107, ¶¶ 513-550, 650. For example, there was a long-felt but unfulfilled need for an easy-to-use pen device with low injection force. As explained in the supporting declaration of Dr. Goland,

the SoloSTAR® device satisfied that need and drove patient adoption. Additionally, as explained in the supporting declaration of Dr. Grabowski, the SoloSTAR® device won numerous design awards, and achieved significant industry praise. Finally, as explained above and in the supporting declaration of Prof. Slocum, the SoloSTAR® device embodies the challenged claims of the 486 patent. Thus, there is a nexus between the claimed invention in the 486 patent and the commercial success of LANTUS® SoloSTAR®.

As explained by Prof. Slocum and Dr. Grabowski, each of the features of the device disclosed and claimed in the 486 Patent and used in LANTUS® SoloSTAR® contributed to its commercial success. Ex. 2109 ¶ 53; Ex. 2107, ¶¶ 513-550, 650. For example, there was a long-felt but unfulfilled need for an easy-to-use pen device with low injection force. As explained in the supporting declaration of Dr. Goland, the SoloSTAR® device satisfied that need and drove patient adoption. Additionally, as explained in the supporting declaration of Dr. Grabowski, the SoloSTAR® device won numerous design awards, and achieved significant industry praise. Finally, as explained above and in the supporting declaration of Prof. Slocum, the SoloSTAR® device embodies the challenged claims of the 486 patent. Thus, there is a nexus between the claimed invention in the 486 patent and the commercial success of LANTUS® SoloSTAR®.

To the extent Petitioner argues that Patent Owner's evidence of commercial success is not due to the claimed invention, but rather, to factors beyond the claimed invention such as, e.g., marketing, such arguments should be rejected. In particular, Dr. Grabowski analyzed marketing expenditures for long-acting insulin products and determined that sales of LANTUS® SoloSTAR® exceeded sales for other well-marketed long-acting insulin products despite the fact that total marketing expenditures for LANTUS® SoloSTAR® were in line with, or were lower than, many other long-acting insulin products. Ex. 2109, ¶¶ 16, 64-69. Patent Owner's marketing of LANTUS® SoloSTAR® therefore does not explain the commercial success of LANTUS® SoloSTAR®.

Moreover, to the extent Petitioner argues that Patent Owner's evidence of commercial success is due to alleged "blocking patents" covering the glargine molecule that is used in the production of the active ingredient in Lantus®, any such argument would be misplaced. First, the law does not mandate across-the-board-discounting of commercial success simply because other patents cover components of the product. Rather, the PTAB is directed to weigh the evidence on a case-by-case basis, in light of the specific commercial success argument being made. *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1339 (Fed. Cir. 2018), *pet. for cert filed*, No. 18-1280 (U.S. Apr. 8, 2019).

Second, as described above, the success of Lantus® SoloSTAR® cannot be attributed solely to the insulin glargine molecule because Lantus® OptiClik® used the exact same Lantus® formulation and failed to achieve the success of SoloSTAR®. Thus, the success of SoloSTAR® is attributable at least in part to its unique design covered by the 486 patent.

Third, Sanofi's earlier patents on the insulin glargine molecule did not prevent others from entering the market for non-glargine, long-acting insulin products and competing with Lantus® SoloSTAR®. Indeed, as explained above, numerous other competitive pen devices existed prior to Lantus SoloSTAR®. The Levemir FlexPen, for example, was a disposable pen device that delivered long-acting insulin. Sanofi's patents on the insulin glargine molecule do not cover the Levemir formulation and did not prevent competition between those devices. The tremendous success of Lantus® SoloSTAR®, as compared to pens with long-acting insulins that failed to address the long-felt but unfilled need for a low injection force device, therefore shares a strong nexus with the claimed invention.

Thus, the commercial success of LANTUS® SoloSTAR®, which practices claim 1 of the 486 Patent, confirms the nonobviousness of the 486 Patent.

IX. CONCLUSION

Patent Owner 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 13,874 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.

Dated: June 25, 2019

Respectfully submitted,

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The undersigned hereby certifies that on June 25, 2019, the foregoing Patent Owner's Response and accompanying exhibits were served via electronic mail upon the following:

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