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 IPR2018-01684
Patent No. 9,604,008

PETITION FOR *INTER PARTES* REVIEW

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I. INTRODUCTION

Petitioner ("Mylan") seeks *Inter Partes* Review ("IPR") of claims 1, 3, 7, 8, 11, and 17 of U.S. Patent No. 9,604,008 ("the '008 patent") to Veasey, et al., titled "*Drive Mechanisms Suitable for Use in Drug Delivery Devices*" ("the '008 patent," Ex. 1001). 35 U.S.C. 311.

This Petition shows a reasonable likelihood that claims 1, 3, 7, 8, 11, and 17 of the '008 patent are unpatentable. 35 U.S.C. 314(a).

II. MANDATORY NOTICES

A. Real Parties-In-Interest (37 C.F.R. §42.8(b)(1))

Mylan's real parties-in-interest are Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan GmbH (subsidiaries of Mylan N.V.), Biocon Research Ltd. and Biocon Ltd.

A. Related Matters (37 C.F.R. §42.8(b)(2))

The '008 patent has been asserted in *Sanofi-Aventis U.S. LLC v. Mylan N.V.*, No. 2:17-cv-09105 (D.N.J.), filed October 24, 2017. Mylan and Biocon are parties in this litigation. Becton Dickinson and Company supplies pens to Mylan, but has not been named as a party.

The '008 patent also has been asserted in *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812 (D. Del.). *See* EX1029 (Markman opinion). Related patents were asserted in *Sanofi -Aventis U.S. LLC v. Eli Lilly and*

Co., No. 14-cv-113 (D. Del.) (consent judgment). EX1030 (Markman opinion). The real parties-in-interest listed above are not parties to these litigations.

Mylan has filed IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, and IPR2018-0169 against related patents.

B. Identification of Counsel (37 C.F.R. §42.8(b)(3)) and Service Information (37 C.F.R. §42.8(b)(4))

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Please direct all correspondence to lead counsel and back-up counsel. Mylan

consents to electronic mail service at 34943.682.palib1@matters.wsgr.com and the email addresses above. A power of attorney accompanies this petition.

III. CERTIFICATIONS (37 C.F.R. §42.104(a))

Mylan certifies that the '008 patent is available for IPR and Mylan is not barred or estopped from requesting IPR on the identified ground.

IV. IDENTIFICATION OF CHALLENGE AND STATEMENT OF THE PRECISE RELIEF REQUESTED

Mylan requests *inter partes* review and cancellation of claims 1, 3, 7, 8, 11, and 17 of the '008 patent under pre-AIA §103, as the detailed statement of the reasons for the relief requested sets forth, supported with exhibit copies, and the Declaration of Karl R. Leinsing, Ex. 1011. Claims 1, 3, 7, 8, 11, and 17 of the '008 patent were unpatentable on the following ground:

Ground	Claims	Basis
1	1, 3, 7, 8, 11, 17	Obvious over the combination of U.S. Patent 6,663,602 to Møller et al. (EX1015, "Møller") and U.S. Patent 6,235,004 to Steenfeldt-Jensen et al. (EX1014, "Steenfeldt-Jensen")

V. STATEMENT OF REASONS FOR THE RELIEF REQUESTED

A. Argument Summary

The challenged claims relate to a drive mechanism for dispensing medicine, such as insulin and insulin analogs, from a pen-type injector. EX1005, Title, 1:21-27. At its core, the claims broadly recites a six-component structure forming this

mechanism. Those six components include structural elements that are themselves claimed broadly. As shown in this petition, however, each of the six components claimed was known and commonly used together in the prior art. EX1011, ¶¶114-15. Where there are differences between what the prior art disclosed and what is claimed, the differences are merely "[t]he combination of familiar elements according to known methods." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007); EX1011, ¶124. The claimed invention combined familiar elements in an obvious way. Claims 1, 3, 7, 8, 11, and 17 of the '008 patent are therefore unpatentable over the prior art.

B. '008 Patent

1. Background

The '008 patent relates to a pen-type injector for self-administration of medicine, such as insulin and insulin analogs. *See* EX1005, Title, 1:31-50, 2:45-65. According to the '008 patent, such injectors are appropriate for patients who do not have formal medical training, including diabetes patients. *Id.*, 1:31-50.

While the '008 patent largely carries over the description of the embodiments presented in its parent application, it adds two additional embodiments of the piston driving mechanism. EX1005, 10:48-17:26, FIGS. 17-24; EX1011, ¶¶90-94. The first new embodiment ("Example 2") involves a piston rod with two different sets of helical threads, wherein one set of threads engages the drive sleeve. *Id.*, 4:40-46, 10:45-13:67, FIG. 17. The second new embodiment ("Example 3") makes use of a

toothed gear, wherein the teeth of said gear engage the drive sleeve. *Id*., 4:47-53, 14:1-17:26, FIGS. 18-24.

Although the engagement of the threaded drive sleeve with the piston rod involves different components in Example 3 (the drive sleeve directly engages one of the piston rod's threads in Examples 1 and 2, and the drive sleeve engages a toothed gear mounted on the end of the piston rod in Example 3), it nevertheless uses the same movement of the drive sleeve to propel the piston rod while providing a similar mechanical advantage. *Id*., 9:47-57; 11:8-29; 16:25-54; EX1011, ¶¶91-94. Indeed, the '008 patent acknowledges the many ways of configuring a piston rod, including as "a simple rod, a lead-screw, a rack and pinion system, a worm gear system, or the like." EX1005, 4:25-26. Each of these mechanical structures and systems were well-known in the art and used in numerous, different contexts to provide axial movement. *See e.g.* EX1011, ¶¶93-94, 122, 695, 794. In fact, as discussed in detail below, the use of helical threads and toothed gears as linear actuators was already established in drug-delivery pens before the earliest priority date of the '008 patent. *See e.g.*, EX1015, ¶¶6-13 (describing the use of gear wheels for driving a piston both in existing art and as part of its own disclosure); EX1014, 7:60-67, 8:45-48, FIGS. 7, 8 (describing the use of pistons with dual threads to facilitate axial movement within a drug-delivery pen). Sanofi's description of alternative embodiments using such drive mechanisms underscores the POSA's understanding that these common components

and mechanisms could be used interchangeably to provide their well-understood, predictable functions.

The ’008 patent issued with 19 claims. In this petition, Mylan challenges the patentability of claims 1, 3, 7, 8, 11, and 17. By way of example, independent claim 1 recites:

> 1. A drive mechanism for use in a drug delivery device comprising:
>
> a housing comprising a helical thread;
>
> a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing,
>
> an insert provided in the housing, where the insert has a threaded circular opening;
>
> a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread;
>
> a piston rod having a first thread and a second thread, wherein the first thread is engaged with the threaded circular opening of the insert and the second thread is engaged with the internal helical thread of the drive sleeve; and

a clutch located between the dose dial sleeve and the drive sleeve, wherein the clutch is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve.

EX1005, 17:28-45.

Independent claim 1, therefore, recites six components that form the claimed device:

(1) "housing" **(4, orange)**, which houses the internal components of the drug-delivery device. *See, e.g.*, EX1005, 2:66-3:21, 10:59-64, FIG. 17; EX1011, ¶¶44-49.

(2) "dose dial sleeve" **(70, green)**, which the user manipulates to set a specific dose for injection. *See, e.g.*, EX1005, 3:37-55, 12:5-11, FIG. 17; EX1011, ¶¶68-70.

(3) "insert" **(16, purple)**, which is disposed within the housing. *See, e.g.*, EX1005, 10:59-64, FIG. 17; EX1011, ¶¶50-51.

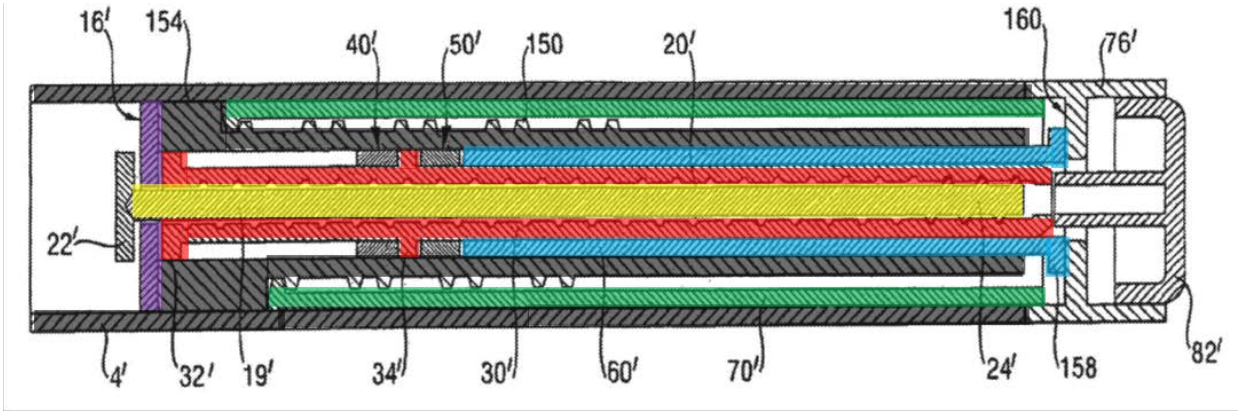
(4) "drive sleeve" **(30, red)**, which drives the piston rod in order to move the piston. *See, e.g.*, EX1005, 4:1-13; 11:18-29, FIG. 17; EX1011, ¶¶55-58.

(5) "piston rod" **(20, yellow)**, which provides translational axial movement within the drug-delivery device. *See, e.g.*, EX1005, 4:19-39, 13:1-11, FIG. 17; EX1011, ¶¶52-54.

(6) "clutch" **(60, blue)**, which is positioned between the dose-dial sleeve and the drive sleeve. *See, e.g.*, *id.*, 4:62- 5:20, 11:57-12-4, FIG. 17; EX1011, ¶¶65-57.

FIG. 17 of the '008 patent is reproduced below, with color-coding added to

highlight the above components. *See* EX1011, ¶92; EX1010, FIG. 17.



2. Prosecution History

The ’008 patent issued from Application No. 14/319,388 (“the ’388 application”). Original claims 1, 3, 7-8, 10-12, 17, and 18 were rejected as anticipated by U.S. Patent No. 6,004,297 to Steenfeldt-Jensen et al. (“Steenfeldt-Jensen ’297”).[1] EX1010, 127-29, 172-73. In particular, the Examiner noted the embodiment described in FIGS. 6-10 (shown most clearly in FIG. 8) of Steenfeldt-Jensen ’297 met all limitations of those claims. *Id.* Claim 17 was also rejected as obvious over Steenfeldt-Jensen ’297, and additional claims were rejected as obvious over Steenfeldt-Jensen ’297 in combination with other references. *Id.*, 129-32, 173-76. In response, applicants attempted to traverse the rejections based on arguments alone without entering any substantive amendments. *Id*., 149-152. However, the Examiner

[1] The Steenfeldt-Jensen reference applied in Ground 1 is a continuation application of Steenfeldt-Jensen ’297.

did not find the applicants' arguments persuasive and maintained the rejections. *Id.*, 166-69.

The Examiner explained that the embodiment shown in FIGS. 6-10 of Steenfeldt-Jensen '297 disclosed housing 1 comprising a helical thread, dose scale drum 17 (the "dose dial sleeve") having a threaded surfaced that is engaged with the housing's helical thread, a wall 4 with a central bore with an internal thread 5 (the "insert"), cup-shaped cap 23 (the "drive sleeve") that is releasably connected to the dose-dial sleeve via hooks 34, and piston rod 6 with two oppositely disposed threads engaging the drive sleeve and the insert, respectively. EX1010, 166-69. To overcome the rejection, applicants amended independent claim 1 to further recite that "the clutch is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve." *Id.* 199. Although Sanofi disputed whether Steenfeldt-Jensen disclosed that the drive sleeve was "releasably connected" to the dose-dial sleeve, Sanofi never disputed Steenfeldt-Jensen's disclosure of the remaining claim limitations. *See id.*, 149-152, 203-7.

The Office thus believed Steenfeldt-Jensen's sole shortcoming was the lack of a clutch located "(i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve." *Id.* 231-33. However, as demonstrated in the asserted ground of unpatentability below, numerous references taught injector pens having a dose-dial sleeve, clutch, and drive sleeve concentrically arranged in the recited manner. *Infra*

§V.F. Applying such teachings to Steenfeldt-Jensen's sleeve-driven, dual-threaded piston rod would have been routine for a POSA and merely involved the combination of familiar, well-understood components, with each component performing its same, predictable function in the combined embodiment. EX1011, ¶¶114-15, 124, 832-37.

C. Level of Ordinary Skill

For the purposes of this petition, the relevant time is before March 3, 2003, the earliest possible priority date claimed by the '008 patent. A POSA would include someone who had, through education or practical experience, at least the equivalent of a bachelor's degree in mechanical engineering, or a related field. EX1011, ¶106. The POSA also would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g., gears, pistons) involved in drug-delivery devices. *Id*.; *see also id*., ¶¶104-05, 107.

D. Claim Construction

For this petition, claim terms should be given their ordinary and customary meaning, consistent with the specification and how they would have been understood by the POSA. 37 CFR §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc).

In the related litigation, Patent Owner Sanofi has taken positions regarding the meaning of certain claim terms, which it cannot now argue are unreasonable. *See Ex parte Schulhauser*, Appeal No. 2013-007847, slip op. at 9 (PTAB Apr. 28, 2016)

(precedential) ("A proper interpretation of claim language, under the broadest reasonable interpretation of a claim during prosecution, must construe the claim language in a way that at least encompasses the broadest interpretation of the claim language for purposes of infringement."). The relevant terms are listed below, along with Sanofi's proffered construction for those terms.

insert: a structure as defined in each of the claims in which it appears. EX1019, 32-33.

drive sleeve: "An essentially tubular component of essentially circular cross-section releasably connected to the dose dial sleeve that drives the piston during dose dispensing." *Id*., 19-20.

thread: "a rib or groove on a first structure that engages a corresponding groove or rib on a second structure." *Id*., 30-21.

piston rod: "A rod that engages with the drive sleeve/driver/driving member to advance the piston during dose dispensing." *Id*., 27-28.

clutch: "A structure that couples and decouples a moveable component from another component." *Id.*, 24-25.

In the related litigation with Sanofi, Mylan proffered a preliminary means-plus-function construction for the claim terms "clutch" and "insert." EX1028, 141-44, 150-52. The court in that litigation has not yet ruled on claim construction. To the extent that the Board concludes that the broadest reasonable interpretation of those

terms is a means-plus-function construction, Mylan provides those constructions below. 37 C.F.R. §§42.100(b); 42.104(b)(3).

As to function of the "clutch," Mylan asserts that the function is that during dose setting, it "clutch[es], i.e., coupling and decoupling a movable component from another component," or , during dose setting, it "operates to reversibly lock two components in rotation." EX1028, 143-44. Mylan points to component 60 as the corresponding structure. *Id.*, 141-43; *see also* EX1005, 2:16-18, 8:48-50; 10:23-31; FIGS. 1, 5-11.

As to the function of an insert (also piston-rod holder)[2] Mylan asserts that the function is "prevent[ing] the piston rod from rotating during dose setting and permit[ting] the piston rod to traverse axially towards the distal end during dose dispensing." EX1028, 135. Mylan points to component 16 as the corresponding structure. EX1028, 152, *see also* EX1005,1:63-65, 3:58-64, FIGS. 1, 3-5.

The ground presented below relies on the ordinary and customary meaning of the claim terms as they would be understood by a POSA. *See also* EX1011, ¶¶108-1.

[2] Even if the claim scope is indefinite, the Board still can determine whether embodiments plainly within the claim scope would have been obvious. *Ex parte McAward*, App. No. 2015-006416 at 22 n.5 (PTAB 2017) (precedential); *Ex parte Tanksley*, 26 USPQ2d 1384, 1387 (BPAI 1991) (same).

The ground also addresses the "clutch" and "insert" limitations to the extent that those terms may be construed as means-plus-function limitations.

E. Prior Art

As explained in the Leinsing declaration and addressed in further detail below in §V.F, claims 1, 3, 7, 8, 11, and 17 were obvious to a POSA at the relevant time. Numerous pen-type injectors were known before March 3, 2003, including many that used the same six-component structure claimed by the '008 patent.

1. Møller – U.S. Patent No. 6,663,602

Møller is prior art to the '044 patent under pre-AIA 35 U.S.C. 102(a) and (e). Møller described an injection device for injecting set doses of medicine that includes a similar structure as that of the '008 patent. *See generally* EX1015, ¶¶22-27; EX1011, ¶¶138-44. As shown in FIG. 1 (reproduced and color-coded below), Møller discloses an injection device comprising:

(1) "housing 1" **(gray)**, which houses the internal components of the drug-delivery device. *See e.g.* EX1015, Abstract, ¶¶22-23.

(2) "dose setting drum 17" **(green)**, which the user manipulates to set a specific dose for injection. *See e.g.* EX1015, ¶¶25-26.

(3) "wall 2" **(purple)**, which is disposed within the housing. *See e.g.* EX1015, ¶¶22-23.

(4) "piston rod 4" **(yellow)**, which provides translational axial movement

within the drug-delivery device. *See e.g.* EX1015, ¶20.

(5) "connection bars 12" having "nut 13" **(red)**, which drives the piston rod in order to move the piston. *See e.g.* EX1015, ¶¶24, 32.

(6) "bottom 19" **(blue)**, which is positioned between the dose-dial sleeve and the drive sleeve. *See e.g.* EX1015, ¶¶26, 29, 33.

A color-coded mapping of the above components is provided below with respect to FIG. 1 of Møller.

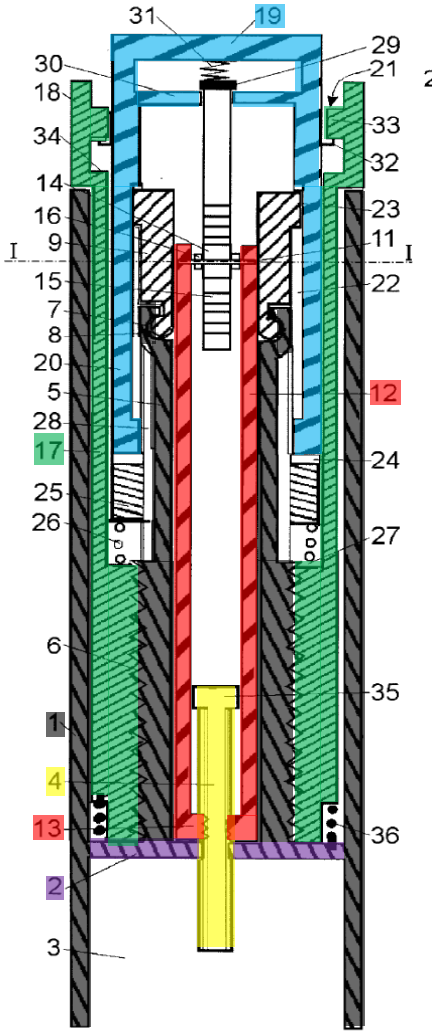


Fig. 1

EX1011, ¶139.

Møller also discloses a second embodiment with largely equivalent components and operation. EX1015, ¶¶35-40, FIGS. 3-5; *see also* EX1011, ¶80-81 n.16. Møller explains that the second embodiment, shown in FIGS. 3-5, is a preferred embodiment that uses only one gear-wheel size and notes that numbers for elements in this embodiment that correspond to elements from the first embodiment simply add 100 to the previous number (e.g., housing 1 becomes housing 101). EX1015, ¶35. A POSA therefore would have understood that, unless the second embodiment depicted or described a feature differently, the 100-series elements would operate in a manner similar to the corresponding elements of the first embodiment. *E.g.* EX1011, ¶¶139 n.16. Accordingly, while the analysis below primarily explains obviousness in terms of the first embodiment, the claims were similarly obvious from the second embodiment as well. *Id.*

2. Steenfeldt-Jensen – U.S. Patent No. 6,235,004

Steenfeldt-Jensen was issued on May 22, 2001, and is prior art to the '008 patent under pre-AIA 35 U.S.C. 102(b). Steenfeldt-Jensen also disclosed syringes for dispensing medicine. *See* EX1014, Abstract.

The embodiment of FIGS. 6-10 includes, *inter alia*:

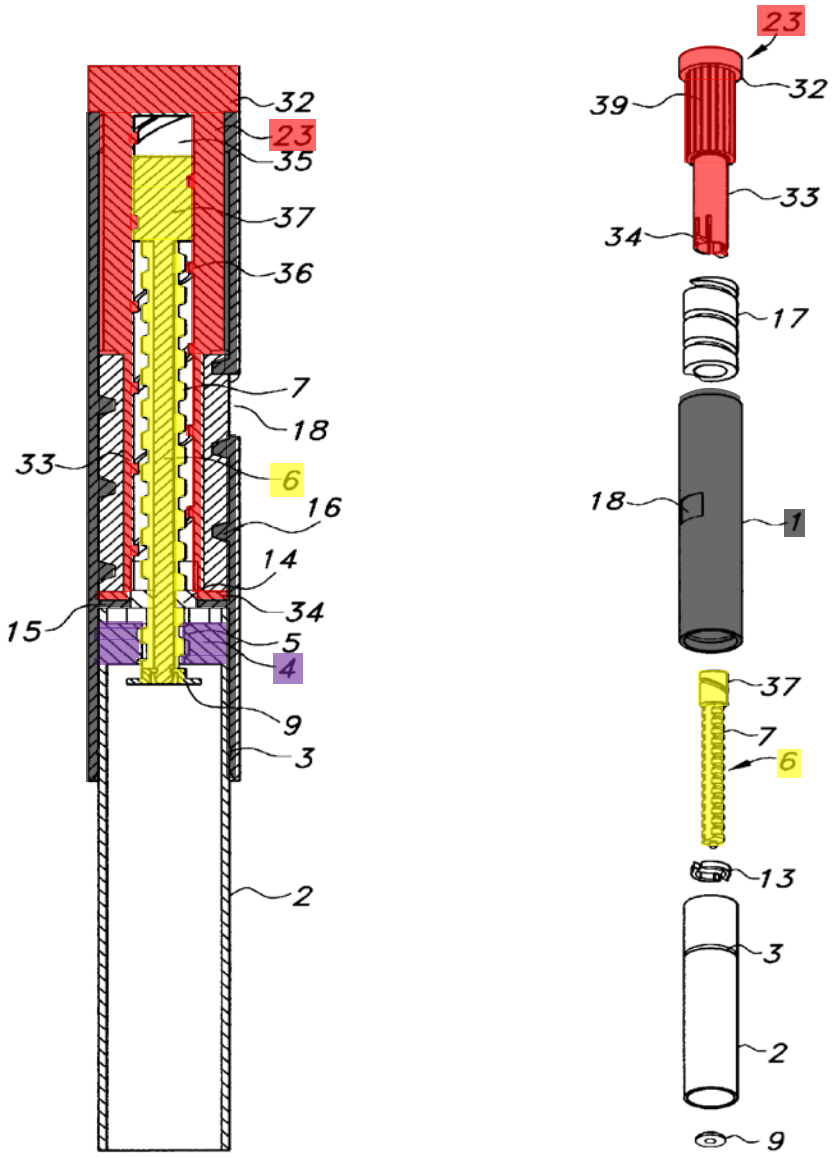
(1) "housing 1" **(gray)**, which house the internal components of the drug-delivery device. *See, e.g.*, EX1014, 7:17-29, 8:16-24.

(2) "wall 4" **(purple)**, which is disposed within the housing. *See, e.g., id.*, 6:30-47.

(3) "piston rod 6" **(yellow)**, which provides translational axial movement within the drug-delivery device. *See, e.g.*, EX1014, 7:60-8:12.

(4) "injection button 23" **(red)**, which drives the piston rod. *See, e.g.*, EX1014, 6:22-34; 7:48-8:24; *see also* EX1011, 135-37.

A color-coded mapping of the above components in FIGS. 7 (left) and 8 (right) is provided below:



EX1011, ¶135-37.

In this embodiment, the piston rod has two distinct threads (see elements 7 and 37 above). A drive sleeve (injection button 23) engages the top thread, which is a not-self-locking engagement (*i.e.* applying axial force can cause rotation), and the bottom thread engages a threaded opening in the housing. EX1014, 7:60-67, 8:25-33; EX1011, ¶136-37. Setting a dose involves rotating injection button so that it rides up the piston rod, then pressing the drive sleeve straight down, which drives rotation of the piston rod. EX1014, 8:1-33; EX1011, ¶¶136, 815-17.

The rotation of the piston rod causes it to ride back up into the drive sleeve as it rides down through the threaded opening in the housing (*i.e.* the insert). *Id.*

A POSA would have recognized that this differential-threading mechanism with opposite-handed threads would create a mechanical advantage. *Id.*, ¶136. Because of the rod's opposite linear movements relative to the sleeve/insert (riding up through the drive sleeve while riding down through the housing), the distance traveled by the piston rod is less than the distance traveled by the drive sleeve. *Id.*; *see also id.*, ¶121-22. This difference between the input and output distances creates a corresponding difference in the input and output forces, *i.e.* a mechanical advantage, based on well-understood energy-conservation principles. *Id.*, ¶121-22.

While the user sets a dose by directly rotating injection button 23, rather than an outer scale drum as in other embodiments, the principle of operation mirrors that of Møller's drive sleeve. EX1011, ¶¶794-95. That is, a drive sleeve rotates and rides up a piston rod, then pushes straight down to drive the piston rod. The mechanical benefits of Steenfeldt-Jensen's dual-threaded drive mechanism also mirror the mechanical benefits of Møller. That is, both references use the above-described operation of the drive sleeve to drive a piston-rod mechanism (a dual-threaded rod in Steenfeldt-Jensen vs. a rack-and-pinion system in Møller) to provide a mechanical advantage. *Id.*, ¶¶794, 832.

F. Ground 1: Claims 1, 3, 7, 8, 11, 17 Were Obvious over Møller in Combination with Steenfeldt-Jensen

As explained in §V.B.2, the claims of the '008 patent were allowed after an amendment specifying that the clutch is located "(i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve." EX1010, 231-33. This feature, however, was well known in the prior art.

Møller is one of many references that taught precisely this type of clutch, and its teachings were readily applicable to the drive mechanism of Steenfeldt-Jensen. *See* EX1011, ¶¶792-95. While Møller taught a different way of "dialing up" the drive sleeve (using concentrically arranged dial sleeve, clutch, and drive sleeve), the general structure and operation of the drive sleeve is the same as in the FIG. 8 embodiment of Steenfeldt-Jensen. *Id.* ¶794*; see also supra,* §V.E.2. Both have an internally threaded drive sleeve that rotates and rides up a threaded piston rod to set a dose, then drives straight down without rotating to inject a dose. *See* EX1015, ¶¶30-31, FIGS. 1, 5; EX1014, 7:48-8:24, FIG. 8; EX1011, ¶794.

Given the similar goals and principles of operation, a POSA would have had reason to combine Møller's dose-setting approach (i.e., rotating a dose-dial sleeve to rotate a drive sleeve up a piston rod) with Steenfeldt-Jensen's dose-dispensing approach (i.e. using axial movement of a drive sleeve to rotate a dual-threaded piston rod for a geared injection stroke). *See infra,* §V.F.1.b.

1. Independent Claim 1

Independent claim 1 as a whole was taught by the combination of Møller and Steenfeldt-Jensen. EX1011, ¶¶697-98.

a. Element-by-element analysis

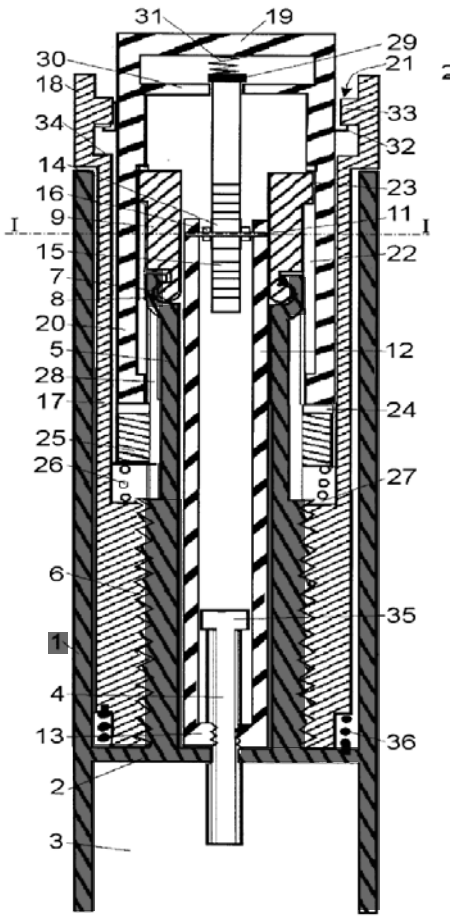
'008 Patent	Møller and Steenfeldt-Jensen
[1.Preamble] 1.	Both Møller and Steenfeldt-Jensen disclose drive mechanism used

A drive mechanism for use in a drug delivery device comprising:	in drug delivery pens. "An injection device comprising a housing ...." EX1015, claim 1. "In such a device only the forces necessary to drive the dose setting drum are transformed by a thread with a high pitch whereas the forces necessary to move the piston by injection is transmitted to said piston through a conventional gear with constantly engaging gears and racks." *Id*., ¶14. "During setting of a dose this spring may be tighter coiled so that on the dose setting drum it 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 have to exert on the injection button is only the force necessary to drive the piston rod into an ampoule to inject the set dose." *Id*., ¶33. "When the injection button is pressed to inject a set dose said button will be maintained inrotatabie [*sic*] during its axial movement as the locking between the above mentioned protrusions on the inner wall of the housing and grooves on the outer wall of the button is strong enough to absorb the torque exerted on the injection button when it drives the piston rod to rotation in a clockwise direction after having overcome the reluctance against rotation in the release direction of the unidirectional coupling." EX1014, 8:25-33.

Both Møller and Steenfeldt-Jensen are directed to drug-delivery pens that administer a user selected dosage of medication. *See* EX1015, Abstract; EX1014, Abstract. Accordingly, the combination of Møller and Steenfeldt-Jensen discloses the

preamble of claim 1. EX1011, ¶798.

’008 Patent	Møller and Steenfeldt-Jensen
[1.1] a housing comprising a helical thread;	Møller teaches housing 1 with helical thread 6. “In the device shown in FIG. 1 an elongated cylindrical housing 1 has a partitioning wall 2 which divides the housing in a compartment containing a dose setting mechanism and a compartment 3 designed for the accommodation of a not shown ampoule.” EX1015, ¶22. “Concentrically with the housing 1 the wall 2 carries on its side turning away from the compartment 3 a tubular element 5 which is at a part of it adjacent to the wall 2 provided with an outer thread 6 and which has at its free end a circumferential recess 7.” *Id*., ¶23.

	 Fig. 1 EX1015, FIG. 1; EX1011, ¶799. As shown in Figure 1, housing 1 of drug delivery pen houses internal components. Housing 1 also has a series of helical threads.

The drive mechanism of Møller comprises housing 1, which houses the internal components of the drug-delivery device. *See e.g.* EX1015, FIG. 1. Housing 1 comprises thread 6. *Id*., ¶23. Based on the disclosure of Møller, a POSA would appreciate that thread 6 is a helical thread. Therefore, the combination of Møller and Steenfeldt-Jensen discloses a housing comprising a helical thread as recited in element

[1.1]. EX1011, ¶¶799-800; *see also* EX1014, 5:38-46; FIG. 7-8, 16-17.

’008 Patent	Møller and Steenfeldt-Jensen
[1.2] a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing,	Møller teaches dose setting drum 17, which has a threaded surface engaging thread 6 of housing 1. EX1015, ¶29. “A tubular dose setting drum 17 fitting into the housing 2 is at an end provided with an internal thread mating and engaging the outer thread 6 of the tubular element 5 and has at its other end a part with enlarged diameter forming a dose setting button 18. Due to the engagement with the thread 6 the dose setting drum 17 may be screwed in and out of the housing to show a number on a not shown helical scale on its outer surface in a not shown window in the housing 1.” *Id*., ¶25. “To set a dose the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 6. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will be lifted with this drum up from the end of the housing 1 …. A too high set dose can be reduced by rotating the dose setting button 18 in the opposite direction of the direction for increasing the dose.” *Id*., ¶29.

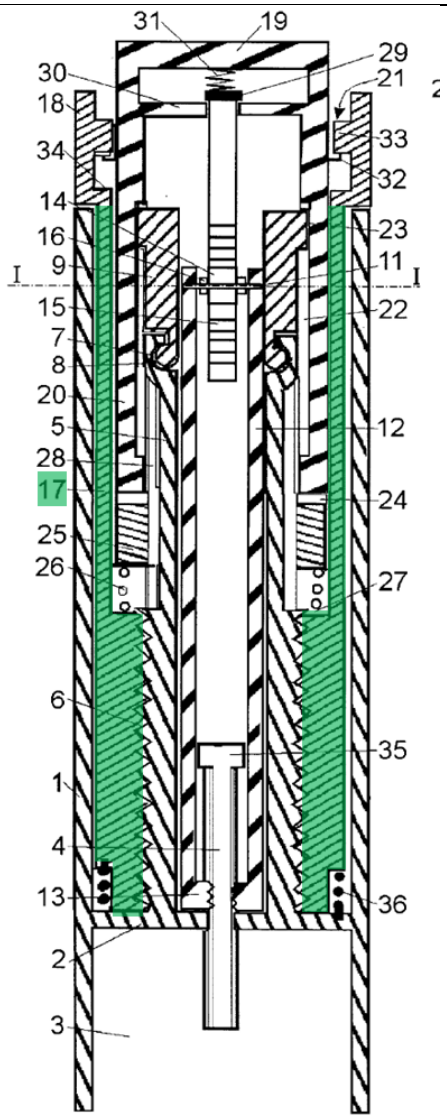
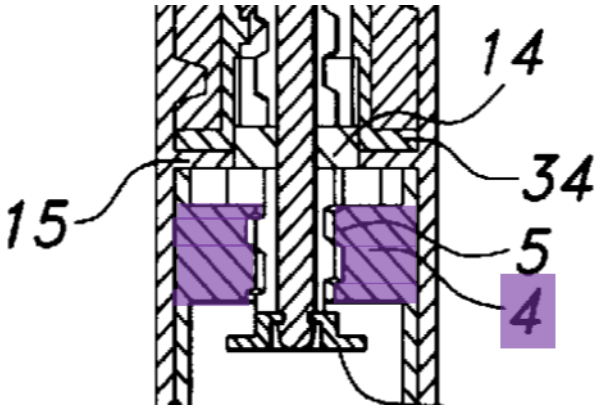


Fig. 1

EX1015, FIG. 1; EX1011, ¶802. As shown in Figure 1, dose setting drum 17 has a series of threads that engage with the threads 6 of the housing 1.

Møller teaches a dose-dial sleeve in the form of dose-setting drum 17. Dose-setting drum 17 allows for a user to dial a particular dose by rotating dose-setting button 18. EX1015, ¶29. As seen in annotated Figure 1 above, dose-setting drum 17

comprises threads that allow dose-setting drum 17 to be screwed against thread 6 of housing 1. *Id*. Therefore, the combination of Møller and Steenfeldt-Jensen discloses a dose-dial sleeve having a threaded surface that is engaged with the helical thread of the housing. *Id*.; EX1011, ¶¶801-3; *see also* EX1014, 7:51-67; FIG. 7-8, 16-17.

’008 Patent	Møller and Steenfeldt-Jensen
[1.3] an insert provided in the housing, where the insert has a threaded circular opening;	Both Møller and Steenfeldt-Jensen teach the use of an insert in the housing. Møller teaches the use of wall 2. EX1015, ¶22, FIG. 1. Steenfeldt-Jensen teaches the use of wall 4. EX1014, 5:55-57. “The end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5.” EX1014, 5:55-57. “[E]nd 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.” EX1014, 7:41-43.  EX1014, FIG. 7; EX1011, ¶806. Wall 4 is disposed in the housing 1 and has a threaded circular opening.

As explained below, a POSA would have a reason to combine the teachings of Møller and Steenfeldt-Jensen as proposed because the Steenfeldt-Jensen makes use of simpler piston-driving mechanism and the simplification and reduction of internal components is advantageous and an objective in the industry. EX1011, ¶¶832-37. The piston-driving mechanism of Steenfeldt-Jensen uses wall 4. EX1014, 5:55-57; 7:41-43; FIG. 7. Wall 4 is disposed or otherwise inserted into housing 1, and has a circular opening with internal thread 5. *Id.*; *see* EX1011, ¶¶804-7.

The combination of Møller and Steenfeldt-Jensen also meets this claim limitation to the extent that "insert" is construed as a means-plus-function limitation. The '844 patent teaches as to the "holder" or "insert" 16, that it is provided at the needle-end of housing 4, and is "secured against rotational or longitudinal motion." EX1005, 7:33-35. Insert 16 is also described as having "a threaded circular opening 18 extending therethrough." *Id.*, 7:35-37. "Alternatively, the insert may be formed integrally with the main housing 4 having the form of a radially inwardly directed flange having an internal thread." *Id.* "[P]iston rod 20 extends through the threaded opening 18 in the insert 16" by way of first thread 19. *Id.*, 7:40-43. The piston rod also has a second thread that is oppositely disposed to the first thread. *Id.*, 7:52-53. During dialing up of a dose, piston rod 20 is prevented from moving by the oppositely disposed threads. EX1014, 9:55-57. During dose dispensing, piston rod 20 rotates through the opening in the insert to advance the piston in the cartridge. *Id.*, 10:32-35.

Thus, the "holder" or "insert" 16 is secured to the housing so as to prevent rotational or longitudinal motion of the holder, and the holder has a threaded opening that it used to hold piston rod 20 so as to prevent it piston rod from rotating during dose-setting and permit it to traverse axially towards the distal end during dose dispensing. *See* EX1011, ¶808.

As taught by Steenfeldt-Jensen, the "end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5." EX1014, 5:55-57. "[P]iston rod 6 engages by its external thread 7 the internal thread of the end wall 4." *Id.*, 8:45-48. Thus, Steenfeldt-Jensen teaches a holder, end wall 4, which has a threaded opening to hold the piston rod. Based on the disclosure of Steenfeldt-Jensen, a POSA would understand that the wall 4 is rotatably fixed relative to the housing. EX1011, ¶¶805-7; EX1014, 5:55-57; 7:41-43, 8:35-42. Further, a POSA would understand that the wall 4 prevents the piston rod from rotating during dose setting. EX1011, ¶808; EX1014, 8:1-8. Still further, a POSA would understand that the wall 4 permits the piston rod to traverse axially towards the distal end during dose dispensing. EX1011, ¶808; EX1014, 8:25-33.

As discussed below, a POSA would have a reason to combine the teachings of Møller and Steenfeldt-Jensen as proposed because the Steenfeldt-Jensen makes use of simpler piston-driving mechanism and the simplification and reduction of internal components is advantageous and an objective in the industry. EX1011, ¶¶832-37.

Thus, the combination of Møller and Steenfeldt-Jensen provides the insert recited in element [1.3]. *Id.*, ¶809.

’008 Patent	Møller and Steenfeldt-Jensen
[1.4] a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread;	Møller and Steenfeldt-Jensen teach the use of a drive sleeve that operates in a similar manner. Møller teaches connection bars 12 and nut 13 in the embodiment of FIGS. 1-2, as well as analogous elements (tubular connection element 112 and nut 113) in the embodiment of FIGS. 3-5. EX1015, ¶40, FIGS. 3-5. Steenfeldt-Jensen teaches injection button 23 in the embodiment shown in FIGS. 6-10. “The rotation of the gearbox 25 is through the connection bars 12 transmitted to the nut 13, which is this way screwed up along the thread of the piston rod 4 and lifted away from its abutment with the wall 2 when a dose it set. As the dose is set by moving the nut 13 on the very piston rod which operates the piston in the not shown ampoule in the compartment 3 a dose setting limiter, which ensures that the size of the set dose does not exceed the amount of medicament left in the ampoule, can easily be established by providing the piston rod 4 with a stop 35 which limits the movement of the nut 13 up along the piston rod 4.” EX1015, ¶30. “Also the axial movement of the nut 13 relative to the housing 1 will be transmitted to the gear wheel assembly through the connection bars 12 and this movement will through the gearbox induce an outward movement of the rack 15.” *Id.*, ¶31.

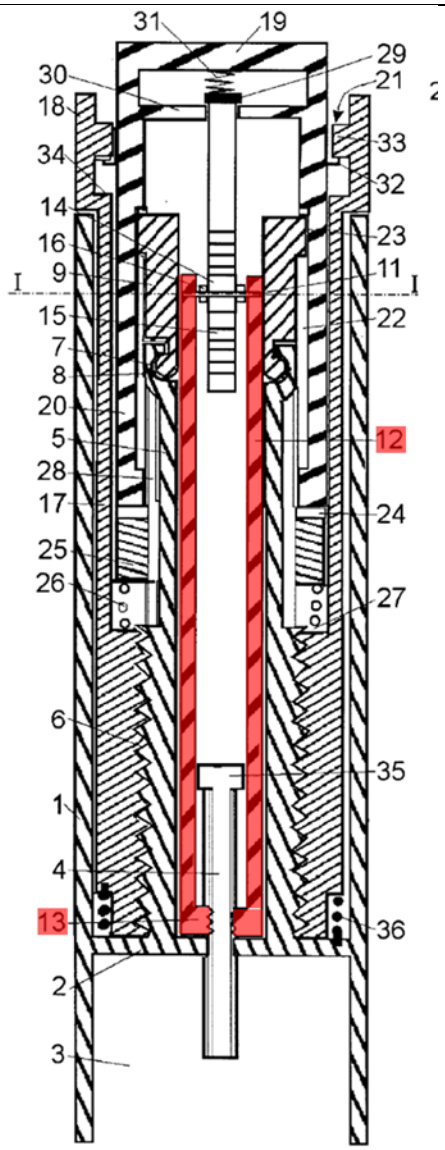
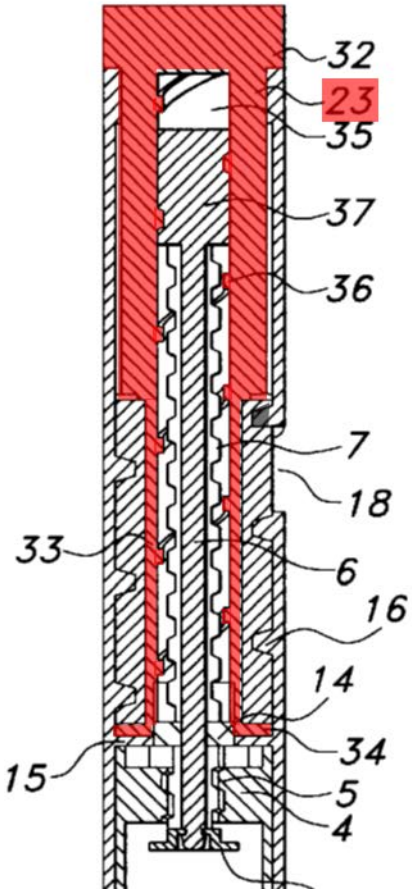


Fig. 1

EX1015, FIG. 1; EX1011, ¶811.

"To set a dose the injection button 23 is manually rotated in a clockwise direction Thereby this button is screwed outwards from the housing 1 as the piston rod 6 will through the piston rod guide 14 and the unidirectional coupling be kept inrotatable although said unidirectional coupling in influenced by a torque in its release direction, however, due to the provided initial reluctance the piston

rod guide 14 will not immediately be rotatable. In its movement outwards the injection button 23 will draw the dose scale drum 17 with it. When this drum is moved axially in the housing it will be rotated due to the not self locking thread connection between said drum 17 and the housing 1." EX1014, 6:42-53.



EX1014, FIG. 7; EX1011, ¶814.

"[T]he injection button 23 is provided with a flange 32 which abuts the end of the housing when the injection button is pressed home. The extension 33 serves as a journal for the dose scale drum 17 which is free to rotate on this journal but bound to follow axial movements of the injection button 23 due to hooks 34 at the end of the extension 33. A longitudinal bore 35 in the injection button and

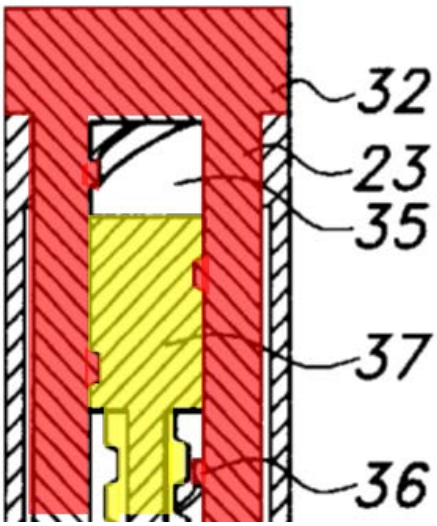
	its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6. The pitch of this thread connection is so that a not self locking thread connection is formed." EX1014, 7:55-67.

In Møller, connection bars 12 and nut 13 operate to transmit axial movement as dose-setting drum 17 is driven down during injection. EX1015, ¶32. Møller's second embodiment includes the analogous tubular connection element 112 with nut 113, which is shown as a fully enclosed, tubular component that encompasses piston rod 104. *See id*., ¶33. The tubular connection element 112 with nut 113 includes a structure that is substantially identical to that of connection bars 12 with nut 13. That is, much like connection bars 12, the tubular connection element 112 includes, at its button-end, two pins 111 that project perpendicular to the element's longitudinal axis and hold the device's gearing system. *See id*., ¶40, FIGS. 3-5. The nut 113, having an internal threading, is provided toward the tubular connection element's needle-end. *See id.*, ¶40. Tubular element 112 with nut 113 also operates in the same manner as connection bars 12 with nut 13. EX1011, ¶813.

Similarly, Steenfeldt-Jensen discloses injection button 23 which operates to transmit axial movement during injection. EX1014, 6:42-53, 7:55-67; EX1011, ¶¶814-18. Specifically, during injection, injection button 23 is "pressed to inject a set

dose." EX1014, 8:25. The downward force "drives the piston rod to rotation in a clockwise direction after having overcome the reluctance against rotation in the release direction of the unidirectional coupling." *Id.*, 8:30-34.

Further, injection button 23 is releasably connected to the other internal components, including the dose-dial sleeve (similar to dose-setting drum 17 of Møller), and it has an internal helical thread. EX1011, ¶¶816-17. As shown in FIG. 7 of Steenfeldt-Jensen, injection button 23 comprises helical rib 36 that engages with a corresponding helical groove in enlargement 37 of the piston rod. EX1014, 7:55-67, FIG. 7.

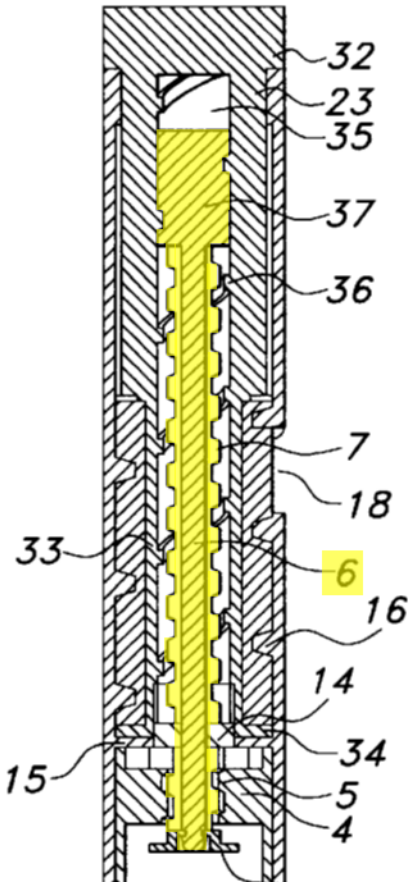


EX1014, FIG. 7; EX1011, ¶816.

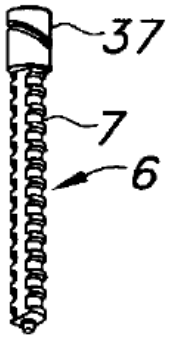
As explained below in §V.F.1.b, a POSA would have had reason to combine these references. This combination would still provide an embodiment meeting the above features of the claim. Thus, the combination of Møller and Steenfeldt-Jensen

teaches a drive sleeve releasably connected to the dose-dial sleeve and having an internal helical thread as recited in element [1.4]. EX1011, ¶¶810-18.

’008 Patent	Møller and Steenfeldt-Jensen
[1.5] a piston rod having a first thread and a second thread, wherein the first thread is engaged with the threaded circular opening of the insert and the second thread is engaged with the internal helical thread of the drive sleeve; and	Both Møller and Steenfeldt-Jensen teach the use of a piston rod. Møller teaches piston rod 4. Steenfeldt-Jensen further teaches a piston rod 6 with first and second threads. “Through the gear box 9 the force is transformed and is transmitted through the connection bars 12 to the nut 13 which will press the piston rod 4 into the compartment 3 until the dose-setting drum 17 abuts the wall 2.” EX1015, ¶32; *see also id*., FIG. 1. “The piston rod 6 engages by its external thread 7 the internal thread of the end wall 4 and is at its end in the ampoule holder terminated by a pressure foot 9 relative to which the piston rod 6 is rotatable.” EX1014, 8:45-48. “A longitudinal bore 35 in the injection button and its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6. The pitch of this thread connection is so that a not self locking thread connection is formed.” EX1014, 7:60-67.



EX1014, FIG. 7; EX1011, ¶822.



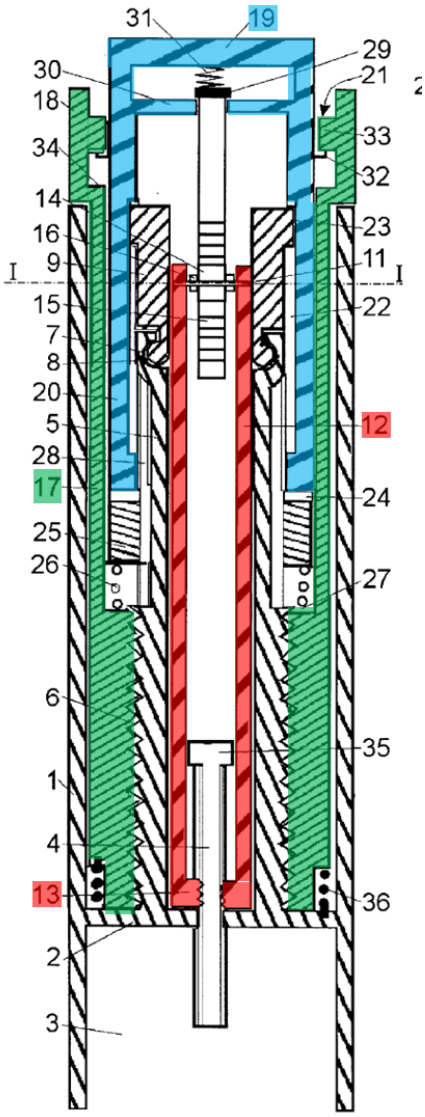
EX1014, FIG. 8; EX1011, ¶820. As shown in annotated Figures 7 and 8, Steenfeldt-Jensen teaches the use of a piston rod with a first thread and a second thread. A first thread engages with the threaded circular opening of the insert (wall 4). A second thread engages with a corresponding thread on a drive sleeve (button 23). *Id.*, 7:60-67.

Both Møller and Steenfeldt-Jensen use a piston rod that is driven forward during injection to adminster a dosage of medication. *See* EX1015, ¶¶22, 30, 32; EX1014, 7:17-29, 7:60-67, 8:45-48, FIGS. 7-8. A POSA would have a reason to combine the teachings of Møller and Steenfeldt-Jensen to make use of Steenfeldt-Jensen's simpler piston-driving mechanism while achieving the same mechanical advantage. EX1011, ¶¶832-37. The piston-driving mechanism of Steenfeldt-Jensen makes use of a piston with first and second threads.

External threads 7 provide for a first thread. EX1014, 8:45-46 ("The piston rod 6 engages by its external thread 7 the internal thread of the end wall 4."). And, as depicted in Figure 8, enlargement 37 provides a second thread. EX1014, 9:60-65 ("A longitudinal bore 35 in the injection button and its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6."). Thus, the combination of Møller and Steenfeldt-Jensen provides for element [1.5].[3] EX1011, ¶¶819-23.

'008 Patent	Møller and Steenfeldt-Jensen
[1.6] a clutch	Møller discloses a "cup shaped element" positioned between the

[3] As discussed in §V.B.2, Steenfeldt Jensen's teaching of limitation was not disputed during prosecution.

located between the dose dial sleeve and the drive sleeve, wherein the clutch is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve.	dose dial sleeve and the drive sleeve.  Fig. 1 EX1015, FIG. 1; EX1011, ¶¶715, 824. “To inject a set dose the injection button is pressed by pressing on the bottom 19. In the initial phase of the pressing the spring 31 is compressed where after the pressing force is directly transmitted to the head 29 of the rack 15 and this way to the rack 15 itself. Through the gear box 9 the force is transformed and is transmitted

	through the connection bars 12 to the nut 13 which will press the piston rod 4 into the compartment 3 until the dose-setting drum 17 abuts the wall 2." EX1015, ¶32. "A head 29 on the projecting end of the rack 15 is with a play fixed at the bottom of the cup shaped element between the bottom 19 forming the injection button and an inner wall 30 near this bottom. The rack is fixed in a position with its head pressed against the wall 30 by a spring 31 between the bottom 19 and the head 29." EX1015, ¶28. "To set a dose the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 6. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will be lifted with this drum up from the end of the housing 1. By the rotation of the cup shaped element the V-shaped teeth 24 at the edge of its open end will ride over the V-shaped teeth of the non rotatable ring 25 to make a click sound for each unit the dose is changed. A too high set dose can be reduced by rotating the dose setting button 18 in the opposite direction of the direction for increasing the dose. When the dose setting drum is screwed up along the thread 6 on the tubular element 5 the ring 25 will follow the dose setting drum in its axial movement as the spring 26 is supported on the shoulder 27. The spring will keep the V-shaped teeth of the ring 25 and the cup shaped element in engagement and maintain in engagement the coupling 21, which may comprise Δ-shaped protrusions 32 on the cup shaped element engaging Λ-shaped recesses in an inner ring 33 in the dose setting button 18." *Id.*, ¶29.

Møller teaches a "cup shaped element", which act as a clutch. Møller's first embodiment includes a "cup shaped element" (the clutch) that includes bottom 19 (the surface pressed by the user to inject a dose) and tubular part 20. EX1015, ¶26, FIG. 1; EX1011, ¶¶824. As shown in FIG. 1, the cup-shaped element is seated within dose-setting button 18 (the dose knob) and passes through its entire length. The cup-shaped element is thus located adjacent the needle-end (distal end) of dose-setting button 18. EX1011, ¶824-25. The cup-shaped element is operatively coupled to dose-setting button 18 via the engagement of Δ-shaped protrusions 32 with corresponding recesses 33 in dose-setting button 18. *See* EX1015, ¶29, FIG. 1; EX1011, ¶¶826-29. The cup-shaped element serves as a clutch by rotationally coupling dose-setting button 18 and drum 17 (the dose-dial sleeve) to connection bars 12 and nut 13 (the driver) during dose setting, then rotationally decoupling those components during injection. *See* EX1015, ¶¶29-30, 32-33, FIG. 1; EX1011, ¶¶826-29.

Møller's second embodiment includes a similar clutch: tubular element 120, which carries button 119. *See* EX1015, ¶¶38-40, FIGS. 3-5; EX1011, ¶¶829-830. Tubular element 120 is seated within dose-setting button 118 and is operatively coupled to button 118 via teeth 132, which releasably engage corresponding teeth 133 in button 118. EX1015, ¶¶36, 38-39, FIGS. 3-5; EX1011, ¶829-30. As with the first embodiment, this releasable engagement rotationally couples dose-setting button 118 and drum 117 (the dose-dial sleeve) to tubular element 112 and nut 113

(the driver) during dose setting, then rotationally decouples those components during dose setting. *See* EX1015, ¶36, FIG. 1; EX1011, ¶829-30.

To the extent that "clutch" is construed as being a means-plus-function limitation, the combination of Møller and Steenfeldt-Jensen renders it obvious. The '008 patent discloses clutch 60. According to the '008 patent:

> The clutch means 60 is generally cylindrical and is provided at a first end with a series of circumferentially directed saw teeth 66 (see FIG. 7) [and is normally engaged with clicker 50]. Each saw tooth comprises a longitudinally directed surface and an inclined surface. Towards the second end 64 of the clutch means 60 there is located a radially inwardly directed flange 62. The flange 62 of the clutch means 60 is disposed between the shoulder 37 of the drive sleeve 30 and the radially outwardly directed flange 39 of the extension 38. The second end of the clutch means 60 is provided with a plurality of dog teeth 65 (FIG. 8) [that are adapted to engage with the dose-dial sleeve]. The clutch 60 is keyed to the drive sleeve 30 by way of splines (not shown) to prevent relative rotation between the clutch 60 and the drive sleeve 30.

EX1005, 8:35-47, 8:53-54, 5:10-13.

The tubular clutch as described by the '008 patent, therefore, is "generally

cylindrical," having a series of "circumferentially directed ... teeth" at its first (needle) end, and also a plurality of teeth at a second (button) end. EX1005, 8:35-47. The teeth on the needle-end engage the clicker, and the teeth on the button-end engage the dose-dial sleeve. *Id.*, 8:53-54, 9:36-39. As taught by the '008 patent, the clutch is also keyed to the drive sleeve, through the use of splines, to prevent relative rotation between the clutch and drive sleeve. *Id.*, 8:44-47.

The cup-shaped element (with tubular part 20) and tubular element 120 of Møller operate in a similar manner using a similar structure. *Compare* EX1015, FIGS. 1, 5 *with* EX1005, FIGS. 6-8. For example, like clutch 60, tubular element 120 includes a set of axially extending teeth 132 at its button-end that releasably engage corresponding teeth 133 in dose-setting button 118. *See* EX1015, ¶¶36, 39, FIGS. 3-5; EX1011, ¶¶824-31; *see also* EX1015, ¶¶29-30 (discussing similar structure of the cup-shaped element), FIG. 1. Both embodiments also include a biasing element (spring 26/126) that exerts upward force to keep the clutch engaged during dose setting. *See* EX1015, ¶¶27, 29, 39, FIGS. 3-5; EX1011, ¶829. The user then applies force to the button (bottom 19 or button 119), which pushes the teeth out of engagement to rotationally decouple the components during injection. *See* EX1015, ¶¶27, 29, 39, FIGS. 3-5; EX1011, ¶829. Thus, bottom 19 and tubular element 120 not only have the structure of clutch 60 of the '844 patent, they also serve as a clutch because they releasably decouple the components during injection. *See* EX1011,

¶¶824-831.

Thus, the combination of Møller and Steenfeldt-Jensen teaches element [1.6]. *Id*.

b. Reason to combine and expectation of success

As explained below, a POSA had reason to combine Møller's dose-setting approach (rotating a dose-dial sleeve to rotate a drive sleeve up a piston rod) with Steenfeldt-Jensen's dose-dispensing approach (using axial movement of a drive sleeve to rotate a dual-threaded piston rod for a geared injection stroke). In the resulting combination, the user would interact with a pen as in Møller. The user would rotate a knob on the dose indicator that would, in turn, rotate the drive sleeve to set a dose. Pressing the injection button would then rotationally decouple the dose indicator and the drive, and the drive sleeve would then move axially without rotating, just as in Møller. The drive sleeve's dose-dispensing, however, would operate as taught by Steenfeldt-Jensen. Rather than using Møller's complicated rack-and-pinion system to provide the mechanical advantage during injection, the drive sleeve would engage a dual-threaded piston rod as taught by Steenfeldt-Jensen. The resulting rotation of the piston rod would drive the piston rod down through the threaded piston rod holder to dispense the dose, again as taught by Steenfeldt-Jensen. EX1011, ¶¶832-33.

The usefulness and practicability of this combination would have been apparent

to a POSA due to the similar structures, operational principles, and objectives of the references. Notably, their drive sleeves have similar piston-rod engagements and similar movement principles: a cylindrical, internally threaded drive sleeve rotates up a threaded piston rod during dose-setting and moves axially downward during injection to drive the piston rod. *See* EX1015, ¶¶30-31 (describing the movement of connection bars 12 and nut 13 during dose dialing and injection); EX1014, 6:42-7:29 (describing the movement of injection button 23 during dose dialing and injection); EX1011, ¶832.

The drive mechanisms also provide the same benefit. Each involves a gearing mechanism that produces a mechanical advantage. *Id.*, ¶835. Møller teaches the benefit of providing gearing between the driver and the piston rod "so that the button has a larger stroke than has the piston." EX1015, ¶6. "By such a gearing the movement of the injection button is made larger and the force, which has to be exerted on the injection button, is correspondingly reduced." *Id*. Møller also appreciated that gearing of piston rod could be achieved in different ways. *See* EX1015, ¶¶7-11. A POSA would have been familiar with these approaches and found implementing them in an injector pin to be a routine task. EX1011, ¶¶121-22.

A POSA would have appreciated several advantages of Steenfeldt-Jensen's approach. For example, a POSA would have recognized that Steenfeldt-Jensen's dual-threaded piston-rod mechanism provided a mechanical advantage similar to

Møller's with fewer, more stress-tolerant components. EX1011, ¶¶835-36. For example, Steenfeldt-Jensen's piston-driving mechanism is accomplished with only a drive sleeve, a dual-threaded piston rod, and an insert, whereas Møller's system requires a more intricate arrangement of multiple moving, interconnected structures. *See e.g.* EX1014, FIG. 7; EX1015, ¶¶24-25; EX1011, ¶835. Reducing the number of internal components in a drug-delivery pen is an objective in the industry. EX1011, ¶¶835-54. For example, having fewer internal components creates greater ease of assembly and reduces the likelihood of mechanical malfunctioning of the drug-delivery pen. *Id*. Similarly, a POSA would also appreciate that using less-fragile components is advantageous because it increases overall durability of the drug-delivery pen and provides greater ease of use for a patient. *Id.* While Møller does note concerns with the greater friction of threaded components compared to its gear wheels and racks, a POSA would have appreciated the trade-offs of each approach and reasonably determined that the benefits of Steenfeldt-Jensen's approach outweighed any increase in friction. *Id.*, ¶¶835-37.

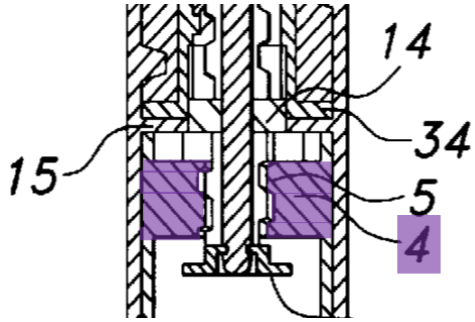
The mechanical advantages provided by the piston-driving mechanism of Steenfeldt-Jensen, along with the increase in durability and reduction in components would have provided ample reason to combine Møller and Steenfeldt-Jensen as proposed. EX1011, ¶835-37. Further, as noted above, both Møller and Steenfeldt-Jensen have the same overall operation wherein a drive sleeve rotates upwards during

dose-setting and drives straight down during injection to administer the drug. *See* EX1015, ¶¶30-31; EX1014, 11:6-19, 12:4-12. The proposed combination of their teachings thus would not change the principle of operation and would merely involve the arrangement of familiar elements performing the same function as before. EX1011, ¶837; *KSR*, 550 U.S. at 416 (2007). POSAs were familiar with the design and implementation of these common mechanisms and would have found the combination to be a routine application of their knowledge and abilities. *See* EX1011, ¶¶114-15, 120-22, 124. Accordingly, a POSA would have had a reasonable expectation of success.

2. Dependent Claims 3, 7, 8, 11, and 17

Dependent claims 3, 7, 8, 11, and 17 were also obvious over Møller and Steenfeldt-Jensen. *Id.*, ¶838.

'008 Patent	Møller and Steenfeldt-Jensen
3. The drive mechanism of claim 1, wherein the insert is secured in the housing against rotational and	Both Møller and Steenfeldt-Jensen teach the use of an insert that is secured in the housing against rotational and longitudinal motion. Møller teaches the use of wall 2. Steenfeldt-Jensen teaches the use of wall 4. "[A] partitioning wall 2 … divides the housing in a compartment containing a dose setting mechanism and a compartment 3 designed for the accommodation of a not shown ampoule. A threaded piston rod 4 has a not round cross section by which it fits through a central opening in the wall 2 so that the piston rod 4 can be displaced

longitudinal motion.	longitudinally through the central opening in the wall 2 but not rotated relative to this wall." EX1015, ¶22; *see also* EX1015, FIG. 1. "The end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5." EX1014, 5:55-57. "In the shown embodiment 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." EX1014, 7:41-47.  EX1014, FIG. 7; EX1011, ¶¶839. Wall 4 is secured in the housing against rotational and longitudinal motion.

Both Møller and Steenfeldt-Jensen teach the use of an insert that is secured in the housing against rotational and longitudinal motion. The proposed modification would make use of wall 4 of Steenfeldt-Jensen or a comparable component that also has a circular internal thread and is secured to the housing. Wall 4 is secured in the housing against rotational and longitudinal motion. EX1014, 5:55-57, 7:41-47, FIG. 7;

EX1011, ¶¶ 839-41. Thus, the combination of Møller and Steenfeldt-Jensen rendered obvious claim 3.

’008 Patent	Møller and Steenfeldt-Jensen
7. The drive mechanism of claim 1, wherein the threaded surface of the dose dial sleeve has a first lead.	“A tubular dose setting drum 17 fitting into the housing 2 is at an end provided with an internal thread mating and engaging the outer thread 6 of the tubular element 5 and has at its other end a part with enlarged diameter forming a dose setting button 18. Due to the engagement with the thread 6 the dose setting drum 17 may be screwed in and out of the housing to show a number on a not shown helical scale on its outer surface in a not shown window in the housing 1.” *Id*., ¶25. “To set a dose the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 6. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will be lifted with this drum up from the end of the housing 1 … A too high set dose can be reduced by rotating the dose setting button 18 in the opposite direction of the direction for increasing the dose.” *Id*., ¶29.

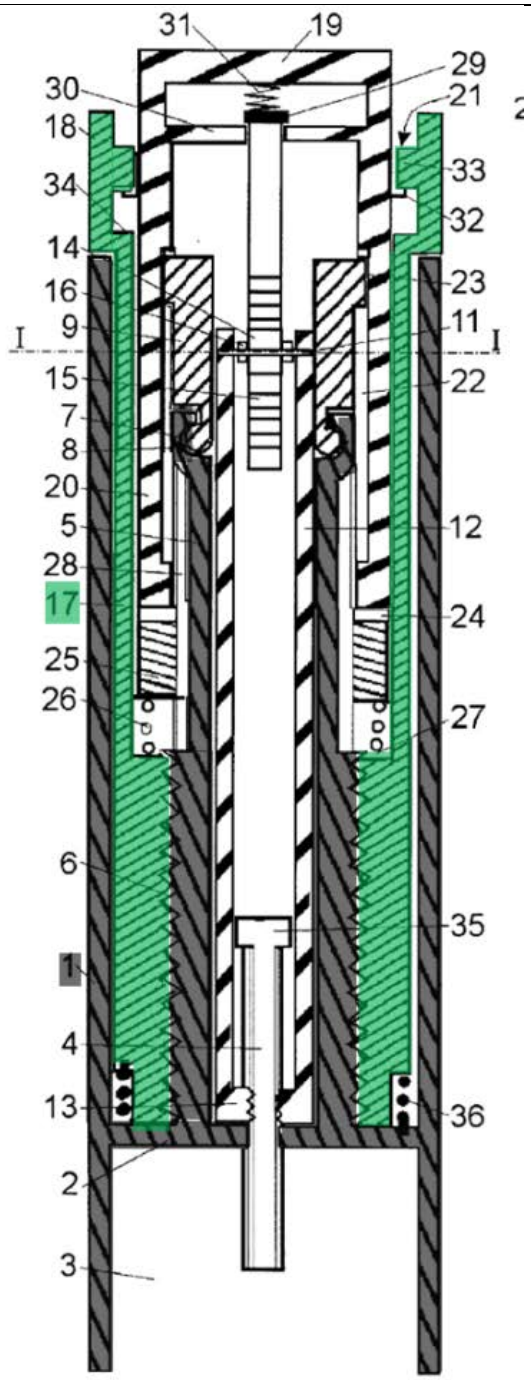
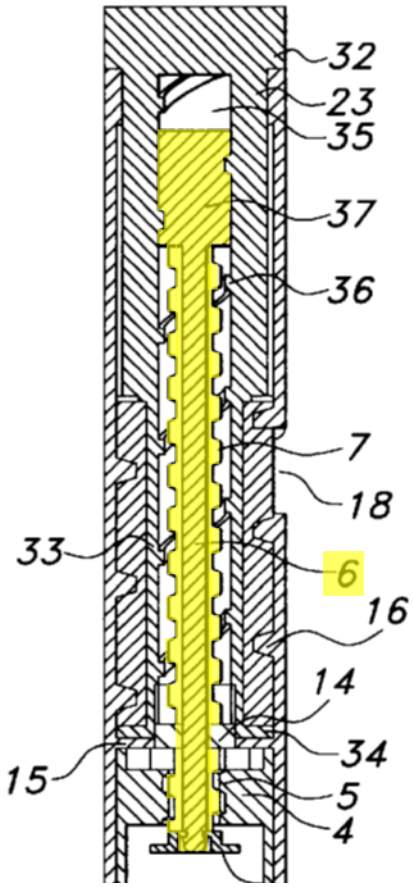


Fig. 1

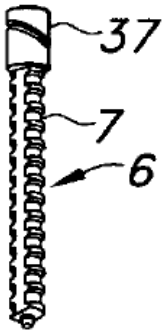
EX1015, FIG. 1; EX1011, ¶847. As shown in Figure 1, dose-setting drum 17 has a series of threads that engage with the threads 6 of the housing 1.

As discussed above, Møller's dose-setting drum has a threaded surface, which facilitates rotation of the drum along the housing thread. EX1015, ¶29, 40. A POSA would have understood that a lead is simply the linear distance traveled during one full rotation of the threaded component. EX1011, ¶842. The threaded surface of drum 17/117 thus has a first lead. *Id.* Thus, the combination of Møller and Steenfeldt-Jensen rendered obvious claim 7.

'008 Patent	Møller and Steenfeldt-Jensen
8. The drive mechanism of claim 7, wherein the first thread of the piston rod has a second lead.	"The piston rod 6 engages by its external thread 7 the internal thread of the end wall 4 and is at its end in the ampoule holder terminated by a pressure foot 9 relative to which the piston rod 6 is rotatable." EX1014, 8:45-48.



EX1014, FIG. 7; EX1011, ¶822.



EX1014, FIG. 8.

As noted above with respect to claim 1, thread 7 on Steenfeldt-Jensen's piston rod 6 corresponds to the recited first thread. This thread engages with the threaded opening in the housing. EX1014, 8:45-48. The lead of this thread is the linear

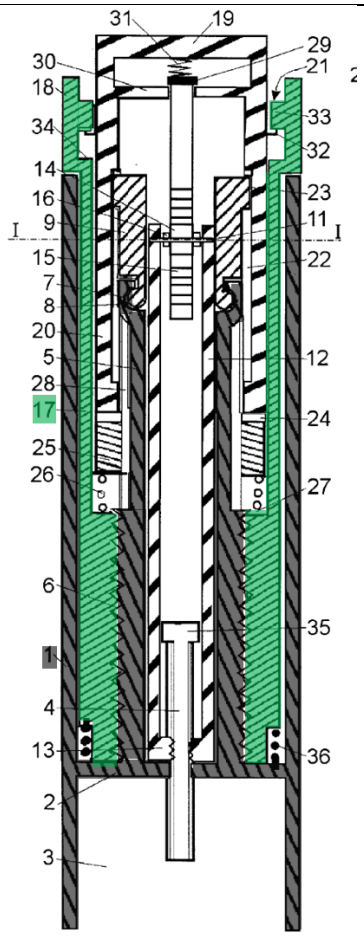
distance that it travels during one rotation. EX1011, ¶842.

As an initial matter, claim 8 does not state that the first and second leads must be different. *Id.*, ¶844. In any event, providing different leads on the recited threads would have been apparent to a POSA. *Id.*, ¶¶845-46. First, Steenfeldt-Jensen depicts various embodiments in which the lead of the piston rod's thread is different from that of the corresponding dose-scale drum. *See, e.g.*, EX1014, FIGS 2, 7, 12, 16 (showing different leads on drum threading and piston rod threading). Steenfeldt notes that the drum has a "high pitch", which is important for the operation of the dose-scale drum, since it requires a not-self-locking engagement between it and the housing. *Id.*, 6:7-17; EX1011, ¶845 (large pitch implies large lead). A POSA would have appreciated that this type of threading was also used in Møller. EX1011, ¶846. Indeed, Møller expressly notes the "high pitch" threading on a dose-setting drum compared to the "fine pitch" on the piston-rod thread in another injector-pen reference. EX1015, ¶¶6-7. Accordingly, Møller and Steenfeldt suggest the desirability of having a higher lead on the "first thread" of the piston rod compared to the lead of the dose-dial sleeve.

Claim 8 was thus obvious over Møller and Steenfeldt-Jensen.

'008 Patent	Møller and Steenfeldt-Jensen
11. The drive mechanism of	"A tubular dose setting drum 17 fitting into the housing 2 is at an end provided with an internal thread mating and engaging the outer

claim 1, wherein the helical thread of the housing is an internal helical thread and the dose dial sleeve has a threaded outer surface that is engaged with the internal helical thread of the housing.	thread 6 of the tubular element 5 and has at its other end a part with enlarged diameter forming a dose setting button 18. Due to the engagement with the thread 6 the dose setting drum 17 may be screwed in and out of the housing to show a number on a not shown helical scale on its outer surface in a not shown window in the housing 1." EX1015, ¶25. "To set a dose the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 6. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will be lifted with this drum up from the end of the housing 1 … A too high set dose can be reduced by rotating the dose setting button 18 in the opposite direction of the direction for increasing the dose." *Id*., ¶29.

	 Fig. 1 EX1015, FIG. 1; EX1011, ¶847; *see also* EX1015, FIGS. 3-5.

As described above, the proposed modification makes use of Møller's outer dose-setting mechanism (a concentrically arranged dose-dial sleeve, clutch, and internally threaded drive sleeve). EX1011, ¶¶832-37. The helical thread 6 is engaged with a corresponding thread on the dose-setting drum 17.

To the extent that the thread on the dose-setting drum 17 is not considered to provide a threaded outer surface, such feature would have been obvious to POSA.

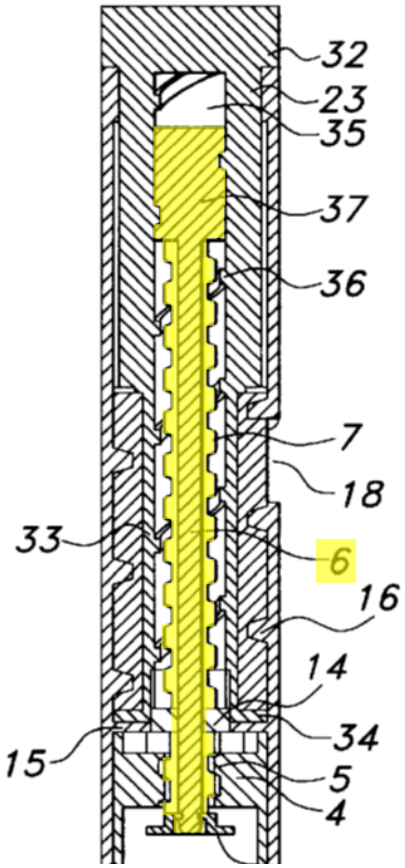
EX1011, ¶849. Steenfeldt-Jensen describes a number of syringes for dispensing medicine. *See, e.g.*, EX1014, Abstract, 1:12-15. The syringes include a "dose dial sleeve," in the form of a dose scale drum, which contains a helical groove formed along its outer surface for engagement with threading on the syringe's housing. *See, e.g.*, EX1014, 6:7-17, FIGS. 2-3. For instance, Steenfeldt-Jensen describes a syringe with dose-scale drum 17, which "in its outer wall [is] provided with a helical [groove]." *Id.*, 6:7-17, FIG. 3. A housing 1 includes "a helical protruding rib 16" that engages dose-scale drum 17's helical groove so that the dose-scale drum 17 may be rotated and axially moved in and out of the housing during use. *See id*., 6:7-17, 7:17-21, FIGS. 1-3. Steenfeldt-Jensen further describes other embodiments having a dose-scale drum with an outer helical groove for threaded engagement with the syringe's housing. *See, e.g., id*., 8:8-12, 9:52-56, 10:40-45, 11:20-22, FIGS. 8, 13, 17.

A POSA would have recognized the benefit to placing a threaded engagement like that taught by Steenfeldt-Jensen on a drum and housing like that of Møller's device. EX1011, ¶850. Specifically, a POSA would have understood that the high-pitch threaded arrangement taught by Steenfeldt-Jensen reduces the force necessary to rotate the drum back into the housing during injection (and thus reduces the overall force needed during injection), even in cases where the dose-setting drum includes an outer helical groove that engages the housing's threading. *Id.* A POSA also would have recognized that providing Møller's dose-setting drum with a helical groove on

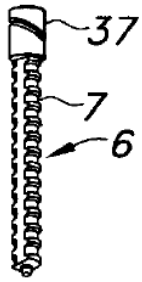
its outer surface, rather than its inner surface, would result in the same relative rotational movement between the drum and housing, and would not affect the overall operation of the device, make them essentially interchangeable. *Id.* A POSA also would have expected that such a configuration would not affect the injection force needed to drive the piston rod, given Møller's direct-gear coupling to drive the rod. *Id.* Indeed, Møller does not place any significance on the placement of that engagement. EX1011, ¶851. Thus, a POSA would have reasonably expected that an outer helical groove threading provided on the dose-setting drum would result in the same rotational function as the inner threading shown in Møller. *Id*.

Accordingly, Møller and Steenfeldt-Jensen rendered obvious claim 11. *Id*., ¶852.

'008 Patent	Møller and Steenfeldt-Jensen
17. The drive mechanism of claim 1 where the first and second threads of the piston rod are oppositely disposed	"The piston rod 6 engages by its external thread 7 the internal thread of the end wall 4 and is at its end in the ampoule holder terminated by a pressure foot 9 relative to which the piston rod 6 is rotatable." EX1014, 8:45-48. "A longitudinal bore 35 in the injection button and its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6. The pitch of this thread connection is so that a not self locking thread connection is formed." EX1014, 7:60-67.



EX1014, FIG. 7; EX1011, ¶822. As shown in annotated Figure 7, Steenfeldt-Jensen teaches the use of a piston rod with a first thread and a second thread. A first thread engages with the threaded circular opening of the insert (wall 4). A second thread engages with a corresponding thread on a drive sleeve (button 23). EX1014, 7:60-67.



EX1014, FIG. 8; EX1011, ¶854. As shown in Figure 8, the first

	thread 6 along the piston rod 6 has an opposite orientation relative to that of the thread on the enlargement 37. EX1011, ¶855.

As described above, the proposed modification makes use of Steenfeldt-Jensen's inner piston-driving mechanism (a piston rod with a first thread engaging an insert and a second thread engaging a drive sleeve). *See infra,* §V.F.1.b; EX1011, ¶¶832-37. As best seen in FIG. 8 of Steenfeldt-Jensen, the first and second threads of the piston rod are oppositely disposed. EX1014, FIG. 8; EX1011, ¶853-55. Indeed, a POSA would have recognized that such configuration was necessary for the driving mechanism to function. *Id.*, ¶855. That is, for the movement of the drive sleeve to drive the piston rod through the threaded insert, the rotation of the piston rod must pull it down through the insert while it is also riding back up through the drive sleeve. *Id.* Thus, the combination of Møller and Steenfeldt-Jensen rendered obvious claim 17.

VI. CONCLUSION

For the reasons set forth above, claims 1, 3, 7, 8, 11, and 17 are unpatentable. The unpatentability of these claims is not an abstract concern. The high cost of insulin products reduces patient compliance, with adverse effects for American diabetics. *See* EX1035, 2, 8. Mylan respectfully requests, therefore, that an IPR of this claim be instituted.

/Richard Torczon/
Reg. No. 34,448

CERTIFICATION UNDER 37 C.F.R. §42.24(d)

Under the provisions of 37 C.F.R. §42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for Inter Partes Review totals 10,182, which is less than the 14,000 allowed under 37 C.F.R. 42.24(a)(i). In accordance with 37 C.F.R. 42.24(a), this word count does not include table of contents, table of authorities, mandatory notices under §42.8, certificate of service or word count, or appendix of exhibits or claim listing.

/Richard Torczon/
Reg. No. 34,448

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, I certify that I caused to be served a true and correct copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,604,008 and Exhibits 1001-1035** by *Federal Express Next Business Day Delivery* on 10 September 2018 on the Patent Owner's correspondence address of record for the subject patent as follows:

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Respectfully submitted,

Dated: 10 September 2018

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