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 IPR2018-01696
Patent No. 9,526,844

PETITION FOR *INTER PARTES* REVIEW

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1034	WO 01/83008 – S. Hansen & T.D. Miller., "*An Injection Device, A Preassembled Dose Setting And Injection Mechanism For An Injection Device, And A Method Of Assembling An Injection Device*" (pub'd Nov. 8, 2001)
1035	K.J. Lipska et al., *Association of Initiation of Basal Insulin Analogs vs Neutral Protamine Hagedorn Insulin With Hypoglycemia-Related Emergency Department Visits or Hospital Admissions and With Glycemic Control in Patients With Type 2 Diabetes*, 320 J. Am. Med. Ass'n 53-62 (2018).

I. INTRODUCTION

Petitioners ("Mylan") seek *inter partes* review ("IPR") of claims 21-30 of U.S. Patent 9,526,844 B2 to Veasey et al. ("the '844 patent," EX1004).

This petition shows a reasonable likelihood that claims 21-30 are unpatentable. 35 U.S.C. 314(a).

II. MANDATORY NOTICES

A. Real Parties-In-Interest

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

B. Related Matters

The '844 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 '844 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 Lily* and Co., No. 14-cv-113 (D. Del.) (consent judgment). *See* EX1030 (*Markman* opinion). The real parties-in-interest listed above are not parties to these litigations.

Mylan notes further that it is concurrently filing petitions for *inter partes*

review of U.S. Patent No. 8,603,044 (IPR2018-01675 and IPR2018-01676), U.S. Patent No.8,679,069 (IPR2018-01670), U.S. Patent No. 8,992,486 (IPR2018-001677, IPR2018-01678, and IPR2018-01679), and U.S. Patent No. 9,604,008 (IPR2018-01684) for all patent claims asserted against it in *Sanofi-Aventis U.S. LLC v. Mylan N.V.* Mylan is also filing two additional petitions against the ‘’844 patent (IPR2018-01680 and 2018-01682).

C. Identification of Counsel and Service Information

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Please direct all correspondence to lead counsel and back-up counsel at the

contact information above. Mylan consents to electronic mail service at rtorczon@wsgr.com and dcarsten@wsgr.com. A power of attorney accompanies this petition. 37 C.F.R. §42.10(b).

III. CERTIFICATIONS

Mylan certifies that the '844 patent is available for IPR, and Mylan is not barred or estopped from requesting IPR on the identified grounds.

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

Mylan requests IPR and cancellation of claims 21-30 of the '844 patent under pre-AIA 35 U.S.C. 103, as the detailed statement of the reasons for the relief requested sets forth, supported with exhibits, including the Declaration of Karl Leinsing (EX1011).

Claims 21-30 of the '844 patent were unpatentable over the prior art as follows:

Ground	Claims	Basis
1	21-29	Obviousness over US 2002/0053578 A1 (EX1015, "Møller") in combination with U.S. Patent 6,235,004 (EX1014, "Steenfeldt-Jensen")
2	30	Obvious over Møller in combination with Steenfeldt-Jensen, further combined with U.S. Patent 6,582,404 (EX1017, "Klitgaard")

V. STATEMENT OF REASONS FOR THE RELIEF REQUESTED

A. Argument Summary

The challenged claims relate to a drug-delivery device used for dispensing medicine, such as insulin and insulin analogs, from a pen-type injector. EX1004, Title, 1:25-34. As shown below, however, the drug-delivery device recited in each of claims 21-29 was disclosed, or rendered obvious, by the prior art. Moreover, 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). Claims 21-30 are therefore unpatentable over the prior art.

B. The '844 Patent[1]

1. Background

The '844 patent relates to a pen-type injector for self-administration of medicine, such as insulin and insulin analogs. *See* EX1004, Title, 1:25-34. Such injectors are appropriate for patients who do not have formal medical training, including diabetes patients. *Id.*, 1:30-34. The '844 patent states that such injectors must be easy to use, as patients using the device may have impaired vision or other

[1] For uniformity, when discussing both the '844 patent and the prior art, description of the positioning and movement of components will be relative to the "button-end" and "needle-end" of the device.

physical infirmities. *Id.*, 1:35-40.

The ’844 patent describes and claims a drug-delivery device. The ’844 patent issued with 30 claims, of which claims 21-30 are challenged by this Petition. Claim 21 is an independent claim that recites:

> 21. A drug delivery device comprising:
>
> a housing comprising a dose dispensing end and a first thread;
>
> a dose indicator comprising a second thread that engages with the first thread;
>
> a driving member comprising a third thread;
>
> a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;
>
> a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;
>
> a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing;
>
> wherein:
>
> the housing is disposed at an outermost position of the drug delivery device;
>
> the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing;
>
> the driving member is configured to rotate relative to the piston rod;

the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and

the piston rod and the driving member are configured to rotate relative to one another during dose dispensing;

and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

Id., 8:16-49.

Claim 21, therefore, recites six components that form the claimed device:

(1) "housing" (4, dark grey) disposed at an outermost position of the device that comprises a dose dispensing end and a first thread;

(2) "dose indicator" (70, green) that is threadingly engaged with the first thread on the housing, disposed between the housing and the sleeve, configured to rotate away from the needle end during dose setting and toward the needle end during dose dispensing;

(3) "piston rod" (20, yellow) comprising a fourth thread, which is driven to move a piston provided within the cartridge towards the needle end to dispense medicine;

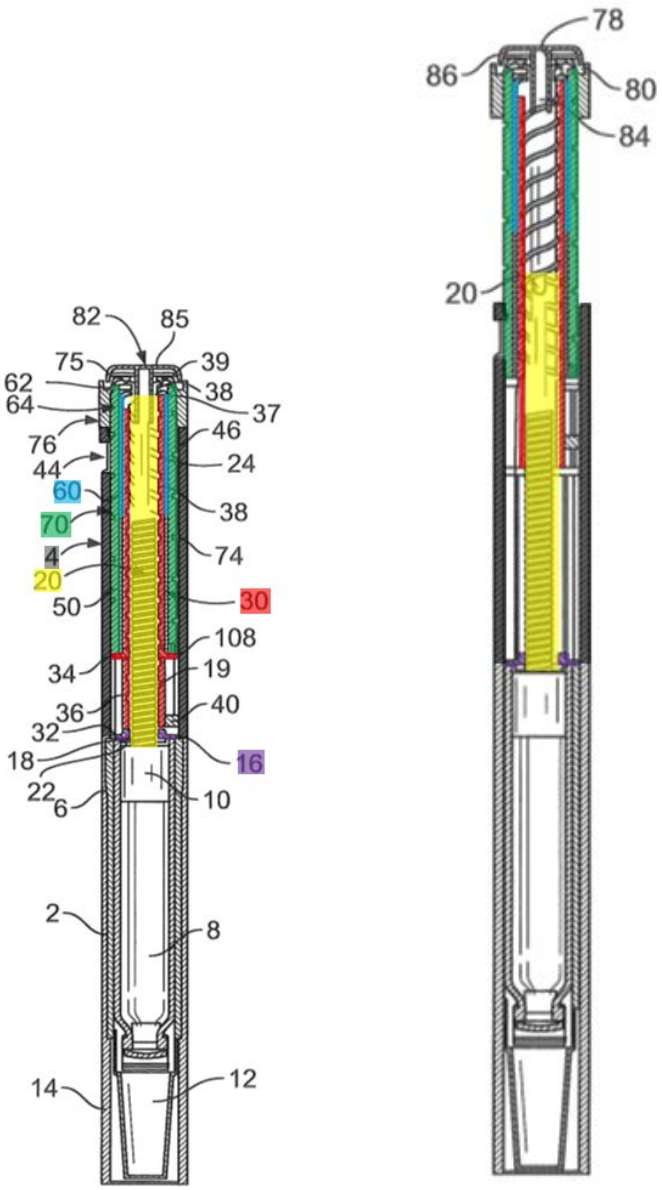
(4) "driving member" (30, red), which is threadingly engaged with the fourth thread of the piston rod, is configured to rotate relative to the piston rod, and drives the piston rod in order to move the piston when the piston rod and driving member rotate relative to one another during dose dispensing;

(5) "sleeve" (60, blue) that is disposed between the dose indicator and the

driving member and which is releasably connected to the dose indicator, rotatably fixed relative to the driving member, and configured to traverse axially with the dose indicator; and

(6) "piston rod holder" (16, purple) that is rotatably fixed relative to the house and configured to prevent the piston rod from rotating during dose setting but permit it to traverse axially towards the needle end of the device during dose dispensing.

FIGS. 1 (left) and 2 (right) of the '844 patent are reproduced below, with color-coding added to highlight the above components. *See* EX1011, ¶41.



Each of the claimed components, along with other aspects of the disclosed injector, is described below, followed by a description of the injector's operation.

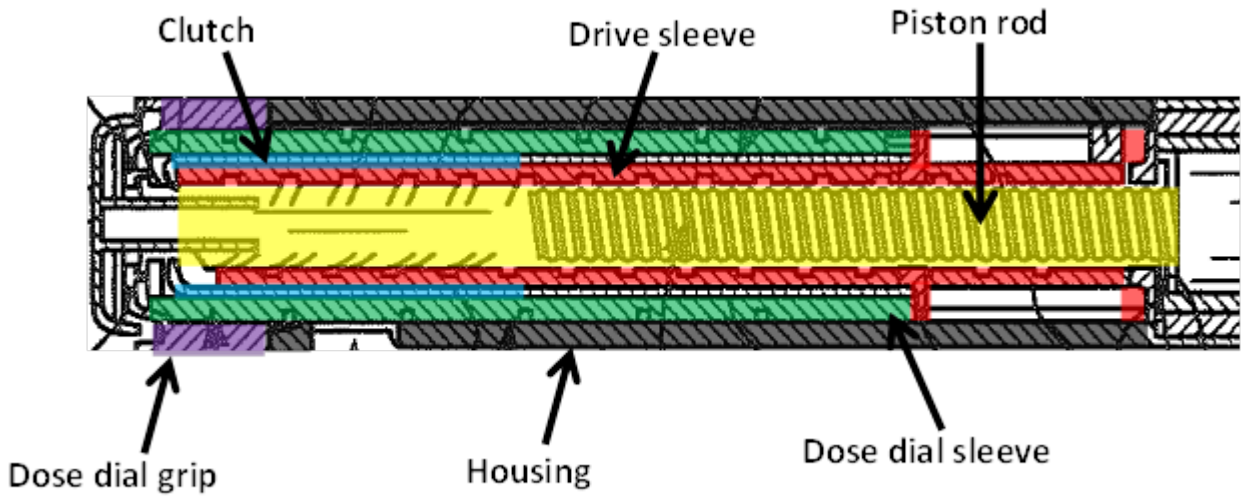
Brief Overview of the Claimed Components

The '844 patent describes an injector having a housing formed from two parts: (1) first cartridge retaining part 2 (which contains cartridge 8 from which medicine is dispensed) and (2) second main housing part 4 (gray). *See* EX1004, 3:37-47, FIG. 1.

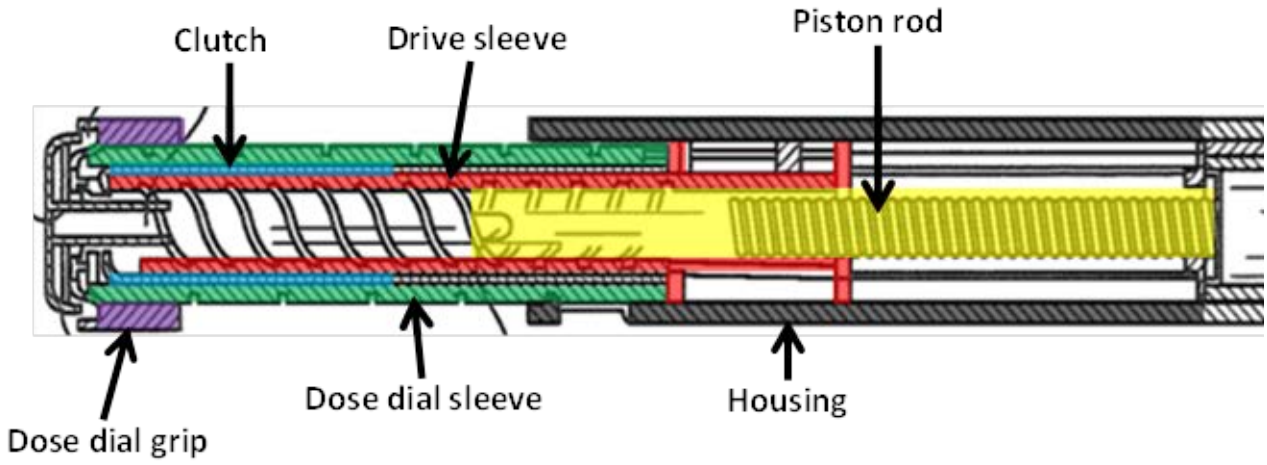
Second main housing part 4 houses the mechanism that serves to drive piston 10 contained within cartridge 8 to dispense medicine. *Id.*, 1:44-47, FIG. 1.

In an embodiment of an injector as taught by the '844 patent, at the needle-end[2] of housing part 4, an insert 16 is provided. *Id.*, 3:58-60; FIG. 1. Insert 16 is fixedly connected to the housing, both rotationally and axially, and includes threaded circular opening 18, through which the needle-end of a piston rod 20 (yellow) extends. *Id.*, 3:58-4:1; FIG. 1. Piston rod 20 includes first thread 19 that engages with insert's threaded opening 18. *Id.*, 3:65-4:1; FIG. 1. Piston rod 20 also includes pressure foot 22 at this end, which abuts piston 10 of cartridge 8. *Id.*, 4:1-3; FIG. 1.

[2] The specification refers to the needle-end of the device as its "first end," and the button-end as its "second end." *See, e.g.*, EX1004, 3:8-14. Claim 1 refers to the needle-end of the device as its "distal end," and the button-end as its "proximal end."



Partial view of FIG. 1 showing injector in a cartridge-full position, prior to dose setting (*see id.*, 2:38-40), annotated to highlight components (*see* 1011, ¶42)



Partial view of FIG. 2 showing injector in a maximum dose-dialed position (*see* EX1004, 2:41-42), annotated to highlight components (*see* EX1011, ¶42)

Piston rod 20 also includes second thread 24 that extends from its button-end. *See* EX1004, 4:3-9; FIGS. 1-2. Drive sleeve 30 (red) extends about piston rod 20. *Id.*, 4:13; FIG. 1. Drive sleeve 30 includes helical groove 38 extending along its

internal surface that engages with second thread 24. *Id.*, 4:20-23; FIG. 1.

Clutch 60 (blue) is "disposed about the drive sleeve 30, between the drive sleeve 30 and a dose dial sleeve 70" (green). *Id.*, 4:42-44; FIGS. 1, 6-7. Clutch 60 is "generally cylindrical" and located adjacent the button-end of drive sleeve 30. *See id.*, 4:58-61; FIG. 1. "[C]lutch 60 is keyed to the drive sleeve 30 by way of splines ... to prevent relative rotation between the clutch 60 and the drive sleeve 30." *Id.*, 5:2-4. At its button-end, clutch 60 includes plurality of dog teeth 65. *See id.*, 4:67-5:2; FIGS. 1-2, 8. Teeth 65 are configured to releasably engage with the button-end of dose-dial sleeve 70.[3] *See id.*, 2:39-42, 6:38-41; FIG. 1.

Dose-dial sleeve 70 is "provided outside of" clutch 60 and "radially inward of" housing 4. *Id.*, 5:12-22; FIG. 1. "[H]elical groove 74 is provided about an outer surface of the dose-dial sleeve 70." *Id.*, 5:14-15; FIGS. 1-2, 12. "[M]ain housing 4 is further provided with a helical rib 46, adapted to be seated in the helical groove 74" to allow for relative rotation. *Id.*, 4:18-20; FIGS. 15-16. Dose-dial grip 76 (purple) "is

[3] The specification does not specifically explain or show how teeth 65 engage dose-dial sleeve 70. The Leinsing declaration explains that teeth 65 engage "an inwardly directed flange in the form of [a] number of radially extending members 75" provided at dose-dial sleeve 70's button-end. *See* EX1011, ¶69; *also id.*, ¶24 n1.

disposed about an outer surface of the [button-end] of the dose dial sleeve 70." *Id.*, 5:34-35; FIGS. 1-2. "[D]ose dial grip 76 is secured to the dose dial sleeve 70 to prevent relative movement therebetween." *Id.*, 5:37-39.

Operation of the Pen Injector

Dose setting: To set a dose, the user rotates dose-dial grip 76 in one direction. *See id.*, 5:60-61; FIG. 9 (reproduced and color-coded below). At this stage, teeth 65 of clutch 60 are engaged with dose-dial sleeve 70. *See id.*, 2:5-7; 5:29-32. Such engagement causes dose-dial sleeve 70, clutch 60, and drive sleeve 30 to rotate together out of the housing. *See id.*, 5:60-63; FIG. 9. Drive sleeve 30 rotates up piston rod 20, toward its button-end, due to its engagement with piston rod 20's second thread 24. *See id.*, 5:6-13. Piston rod 20 is prevented from rotating due to its opposing, threaded engagement with insert 16. *See id.*, 4:10-11, 6:11-13.

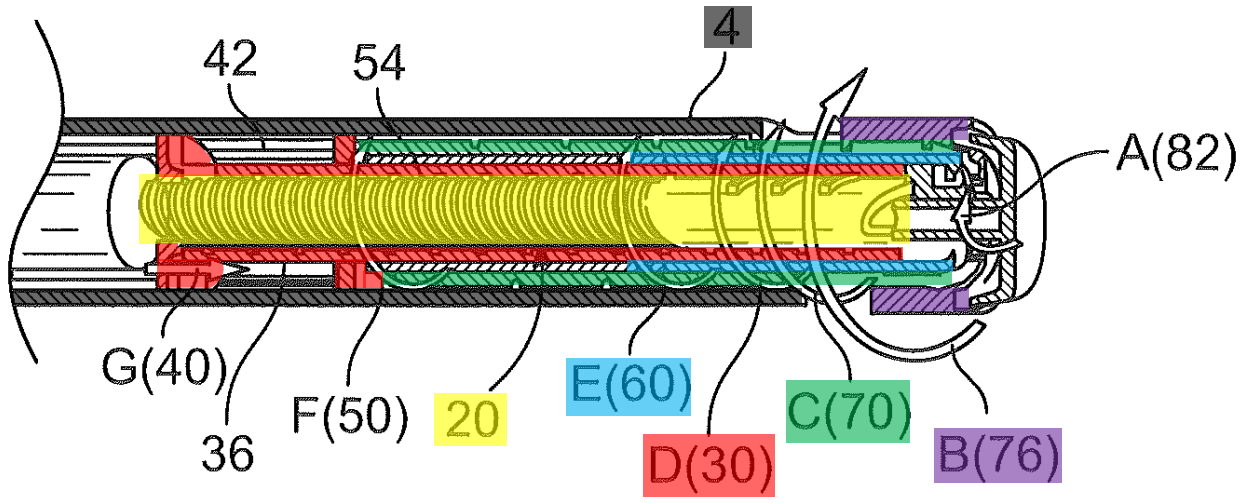


FIG. 9: Dialing up (*see id.*, 2:55-56), annotated to highlight components (*see* EX1011, ¶81)

The user also may dial down a dose. *See id.*, 6:27-30; FIG. 10 (reproduced and color-coded below). To dial-down a dose, the user rotates dose-dial grip 76 in the opposite direction (*e.g.*, clockwise direction). *See id.*, 6:30; FIG. 10. "This causes the system to act in reverse," where dose-dial sleeve 70, clutch 60, and drive sleeve 30 rotate together back into the housing. *See id.*, 5:30-31-; FIG. 10. Drive sleeve 30 rotates down piston rod 20, toward its needle-end, without corresponding rotation of piston rod 20. *See id.*, 6:4-13, FIG. 10.

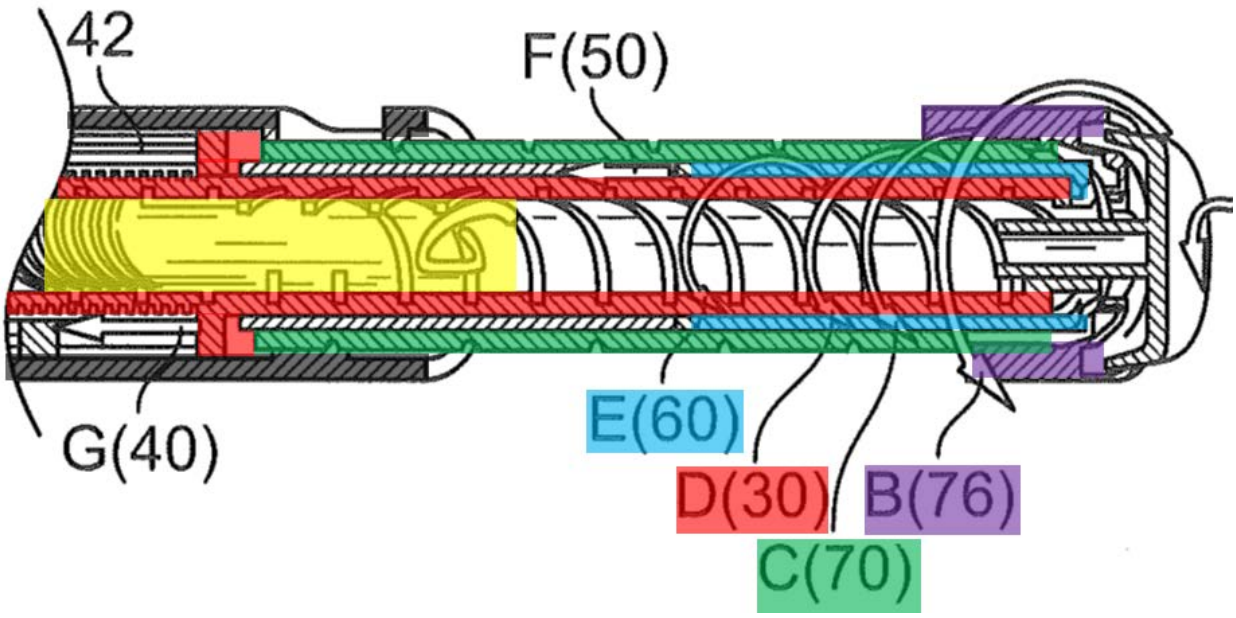


FIG. 10: Dialing down (*see id.*, 57-58), annotated to highlight components (*see* EX1011, ¶84)

Injection: Once the dose is set, the user presses button 82, applying force toward the needle-end of the device. *See id.*, 6:38-39, FIG. 11 (reproduced and

color-coded below). This displaces clutch 60 axially such that teeth 65 disengage from dose-dial sleeve 70. *Id.*, 6:40-41. Dose-dial sleeve 70 rotates back into housing 4 via its threaded connection with the housing. *Id.*, 6:43-45, FIG. 11. Now disengaged from dose-dial sleeve 70, clutch 60 does not follow this rotation, and instead, moves axially toward the needle-end of the device. *See id.*, 6:42-43, 6:48-54. Drive sleeve 30 also moves axially toward the needle-end, driving piston rod 20 to rotate through threaded opening 18, causing medicine to be dispensed from cartridge 8. *See id.*, 6:55-58, FIG. 11.

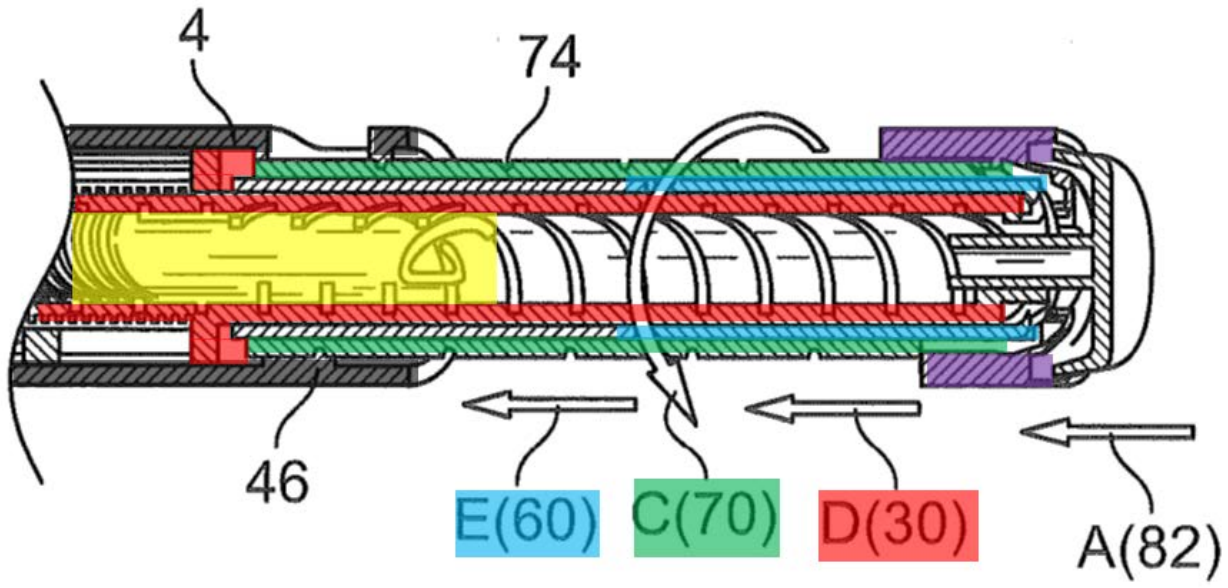


FIG. 11: Injecting dose (*see id.*, 2:59-60), annotated to highlight components (*see* EX1011, ¶88)

2. Prosecution History

The '844 patent issued from Application No. 15/156,616, which was filed on

May 17, 2016. During prosecution, pending claims 1-30 were rejected for double patenting over claims 1-14 of U.S. Patent No. 7,918,833. *See* EX1009, 79-80. Applicants submitted a terminal disclaimer over the '833 patent. *Id.*, 117. Applicants later filed an RCE and amended claim 1 to specify that "during dose delivery the drive sleeve and the piston rod are configured to rotate relative to one another." *Id.*, 141. A Notice of Allowance ensued. *Id.*, 164.

A related PCT publication of Steenfeldt-Jensen (WO99/38554, EX1027) was one of over 200 references disclosed by applicants in Information Disclosure Statements. *Id.*, 46, 49. It was not applied substantively to the claims of the '844 patent.

3. Claims 21-30 Lack Written Description Support Before May 2016

The '844 patent issued from U.S. Patent Application No. 15/156,616, which was filed on May 17, 2016. EX1004, cover. Although the '844 patent claims the benefit of the filing dates of earlier applications via U.S. Patent Application No. 14/946,203 (EX1025), filed on November 19, 2015, each of claims 21-30 lacks written description support under §112 in any of these priority documents and is not entitled to a priority date earlier than May 17, 2016. *See* Pre-AIA §§119 and 120; *In re Gosteli*, 872 F.2d 1008 (Fed. Cir. 1989).

To provide written description support, a priority document must clearly allow a POSA to recognize that the inventor invented what is claimed and must

reasonably convey that the inventor had possession of the claimed subject matter. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) ("the hallmark of written description is disclosure"). The parent application "must actually or inherently disclose the elements of the later-filed claims." *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 870 (Fed. Cir. 2010). "[A]ll the limitations must appear in the specification." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). "It is not sufficient ... that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to the modifications that the inventor might have envisioned, but failed to disclose." *Id.* "[P]roof of priority requires written disclosure in the parent application, not simply information and inferences drawn from uncited references[.]" *L.A. Biomedical Research v. Eli Lily & Co.*, 849 F.3d 1049, 1057-58 (Fed. Cir. 2017). "[A]dequate written description does not ask what is permissible, rather, it asks what is disclosed." *D Three Enterprises, LLC v. SunModo Corp.*, 890 F.3d 1042, 1052 (2018). "[T]he issue is whether a person skilled in the art would understand from the earlier application alone, without consulting the new matter ... that the inventor had possession of the claimed [element] when the [earlier] application was filed." *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1333-34 (Fed. Cir. 2008).

Each of claims 21-30 of the'844 patent lacks support in the '203 application

as well as the filings to which the ’203 application claims priority for a “piston rod” comprising an internal fourth thread that is engaged with a third thread of a “driving member.” An internally threaded piston-rod limitation first appeared in claim 21 of the ‘616 application as it was filed on May 17, 2016. EX1009, 24. Neither the ’203 application nor any of the applications to which it claims priority describes an internally threaded piston rod or engaging such internal threads with external threads of a driving member. Nor does the ’203 application or any of its priority applications contain a disclosure that external threads can be replaced with internal threads generically, much less specifically on the piston rod. EX1011, ¶¶101-02.

To the contrary, the ’203 application and each of the applications to which it claims priority repeatedly and uniformly describe the piston rod having external threads adapted to engage internal threads of two components (the drive sleeve and insert) that are “located” between the piston rod and the housing. *See, e.g.*, EX1025, 79, ¶7, 82, ¶¶38-39, 86, ¶65, FIGS. 1-7, 9-13 (first threaded portion of piston rod 20 rotates “through” threaded opening in the insert 16 during dose dispensing); EX1026, 2:1-5, 5:19-27, 11:9-11, Figs. 1-7, 9-13,[4] claim 2 (same);

[4] Although the images of the figures from the GB application in EX1026 are difficult to view, the written description of the GB application confirms these

EX1025, 79, ¶¶6-7 (drive sleeve located between dose-dial sleeve and piston rod); EX1026, 1:30-2:9 (same); EX1025, 82, ¶¶39-41 ("second thread 24" of piston rod "is adapted to work within the helical groove 38" that "extends along the internal surface of the drive sleeve 30," which drive sleeve "extends about the piston rod 20."), FIGS. 1-5, 9-11; EX1026, 5:29-30, 6:7-14, FIGS. 1-5, 9-11 (same); EX1025, 82, ¶40, 85, ¶55 (button end of piston rod 20 extends all the way to stem 84 of button 82, which stem 84 is received into receiving recess 26 of piston rod 20); EX1026, 6:4-5, 9:2-4 (same).

There is thus no written description support in the priority documents for a piston rod with internal threading that engages with external threading of the driving member. Because the '203 application does not expressly or inherently describe a piston rod with internal threading that engages with external threading of the driving member, claims 21-30 of the '844 patent are entitled to a priority date no earlier than May 17, 2016.

C. Level of Ordinary Skill

For the purposes of this petition, the relevant timeframes include May 17, 2016,

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figures are consistent with those in the '844 patent and the other patents in the priority chain (including the '203 application) in depicting external threads on the piston rod.

the filing date of the ’616 application, and March 3, 2003, the earliest priority date invoked by the ’844 patent. A POSA at the relevant time had, through education or practical experience, at least the equivalent of a bachelor’s degree in mechanical engineering, or a related field. *See* 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.*

D. Claim Construction

For this petition, claim terms should be given their ordinary and accustomed meaning, consistent with the specification and how they would have been understood by the POSA. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc); *see* EX1011, ¶108.

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). The relevant terms are listed below, along with Sanofi’s proffered construction for those terms.

driving member: “A component releasably connected to the dose dial sleeve that drives the piston during dose dispensing.” EX1019, 28.

main housing:[5] "An exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components." *Id.*, 21.

piston rod: "A rod that engages with the…driving member to advance the piston during dose dispensing." *Id.*, 27.

the piston rod and the driving member are configured to rotate relative to one another during dose dispensing: "Plain and Ordinary Meaning…'during dose dispensing, the piston rod rotates while the driving member does not rotate, the driving member rotates while the piston rod does not rotate, or both rotate at different rates and/or directions." *Id.*, 27 (citing EX1004, 6:38-67, FIG. 11; claim 21).

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

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

clicker: "A structure that provides audible and/or tactile feedback when the dose knob is rotated." *Id.*, 31.

holder: "Plain and Ordinary Meaning, which a POSITA would understand to be 'a structure that holds a referenced structure' (e.g., a piston rod holder holds a piston rod)." *Id.*, 33-34.

[5] This term was construed for the'486, '069, and '044 patents.

In the related litigation with Sanofi, Mylan proffered a means-plus-function construction for "clutch," "clicker," and "holder." EX1028, Exhibit F, 121-123, 131-135. 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, 123. Mylan points to component 60 for the corresponding structure. *Id.* 121; *see also* EX1004, 2:24-26, 4:58-5:4, 5:5-7, 6:46-54; FIGS. 1, 5-11.

As to the function of a clicker,[6] Mylan asserts is that the function is "provid[ing] audible clicks during dose setting, where each click is equal to a dose of medicament." EX1028, 134. Mylan points to component 50 for the corresponding

[6] If the scope of the claim is indefinite, the Board nevertheless can determine whether embodiments plainly within the scope of the claim 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).

structure. *Id.*, 131-134; *see also* EX1004, 2:27-29, 2:30-35, 2:36-42, 4:42-44, 4:45-57, 5:5-9, FIGS. 6-8.

As to the function of a holder,[7] 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 FIGS. 1, 3-5, component 16, as the corresponding structure for the holder. *Id.* 134-135; *see also* EX1004,1:63-65, 3:58-64.

The grounds presented below rely on the ordinary and customary meaning of the claim terms as they would be understood by a POSA. The grounds also address the "clutch," "clicker," and "holder" limitations to the extent that those terms may be construed as means-plus-function limitations.

E. Prior Art

1. Møller

Møller is prior art under pre-AIA §102(b). Møller described a device for injecting set doses of medicine that includes a similar structure to that of the '008 patent. *See generally* EX1015, ¶¶22-27. As shown in FIG. 1 (color-coded below), Møller discloses an injection device comprising (*see* EX1011, ¶139):

[7] Again, even if indefinite, the Board nevertheless can determine whether embodiments plainly within the scope of the claim would have been obvious.

(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, ¶22;

(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 for Figure 1 of Møller. *See* EX1011, ¶140.

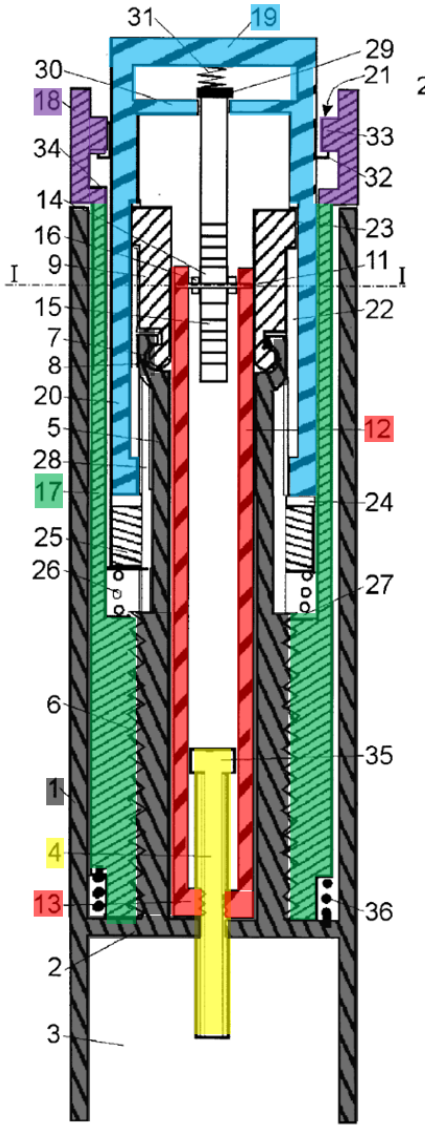


Fig. 1

Møller describes two similar embodiments: a first embodiment shown in FIGS. 1-2 and a second embodiment shown in FIGS. 3-5. The general structure and operation of these embodiments is largely the same. *Compare*, EX1015, ¶¶22-34 *with id.*, ¶¶35-40; *compare id.*, FIGS. 1-2 *with id.*, FIGS. 3-5. 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 be assumed to operate in a manner similar to the corresponding elements of the first embodiment. EX1011, ¶139 n77. Accordingly, while the analysis below primarily explains anticipation in terms of the first embodiment, the claims were similarly anticipated by the second embodiment as well. *Id.*

2. Steenfeldt-Jensen

Steenfeldt-Jensen is prior art to the '844 patent under pre-AIA §102(b).[8] Steenfeldt-Jensen disclosed injection syringes for dispensing medicine. *See* EX1014, Abstract.

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

[8] Because the effective filing date of the '844 patent is May 17, 2016, post-AIA §102 applies. Whether pre- or post-AIA §102 is applied does not make any difference to the analysis. Thus, for consistency and convenience, this petition refers to pre-AIA §102.

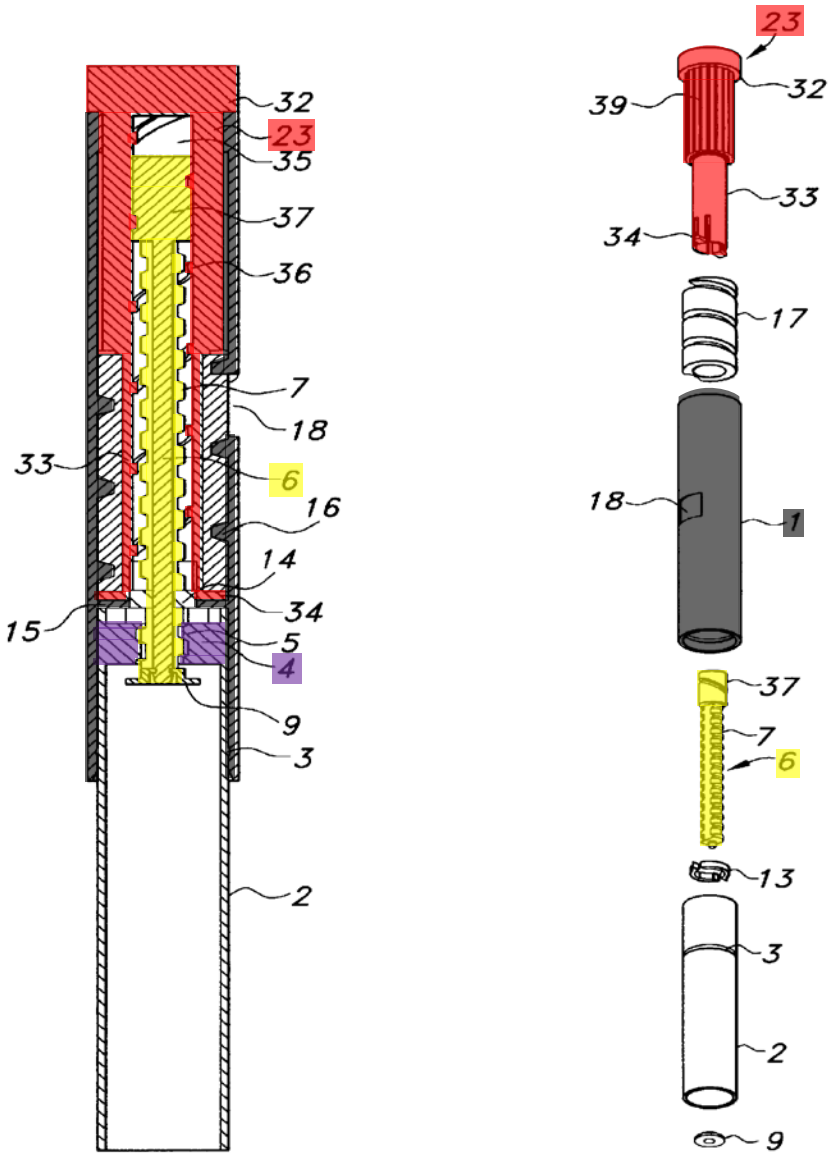
(1) “housing 1” **(gray)**, which house the internal components of the drug-delivery device. *See*, *e.g.*, EX1014, 7:17-29, 8:16-24.

(3) “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 the 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 (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, ¶¶695-96. 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.*, ¶¶695, 751.

3. Klitgaard

Klitgaard is prior art to the challenged claims of the ’844 patent under pre-AIA §102(b) and §102(e) (even under the alleged March, 3, 2003 earliest priority date). EX1017, cover (filed Sep. 6, 2000); *see also* EX1018 (prosecution history showing allowance of originally filed dependent claim amended only to make it an independent claim). Klitgaard describes a limiting mechanism to track the amount of medication administered from a drug injection device to prevent the setting of a dose in an amount that exceeds the remaining supply of medication in the cartridge. EX1017, Abstract.

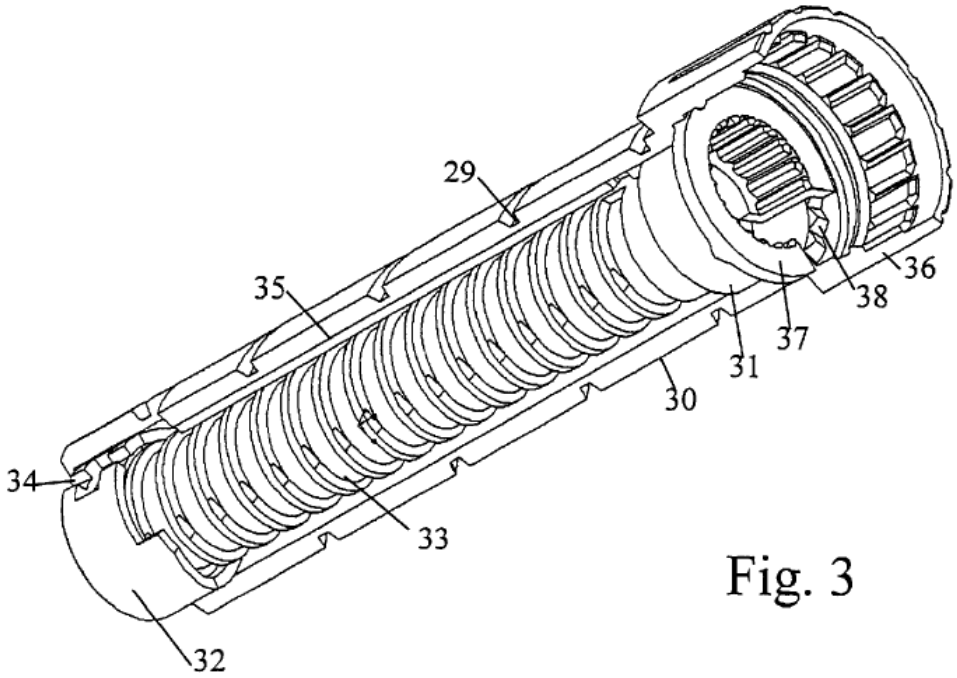


Fig. 3

FIG. 3 and its related description discloses nut member 32 that tracks each set dose of medication delivered to prevent setting a dosage that exceeds the remaining supply of medication. *Id.*, 4:16-58. EX1011, ¶149.

F. Ground 1: Møller and Steenfeldt-Jensen Rendered Claims 21- 29 Obvious

Møller and Steenfeldt-Jensen describe injector pens with drive sleeves that operate similarly. Møller's two embodiments and the FIG. 6-10 embodiment of Steenfeldt-Jensen include the same general components recited in claim 21, including the recited driving member. *Supra*, section V.E.1-2.

While Møller taught a different way of "dialing up" the drive sleeve (using concentrically arranged dial sleeve, clutch, and driving member rather than Steenfeldt-Jensen's direct manipulation of the driving member), the general structure and operation of the driving members is the same. *Id.* ¶695*; see also supra*, section 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, ¶695.

Given the similar goals and principles of operation, a POSA would have 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). *Infra*, section V.F.1.b.

1. Independent Claim 21

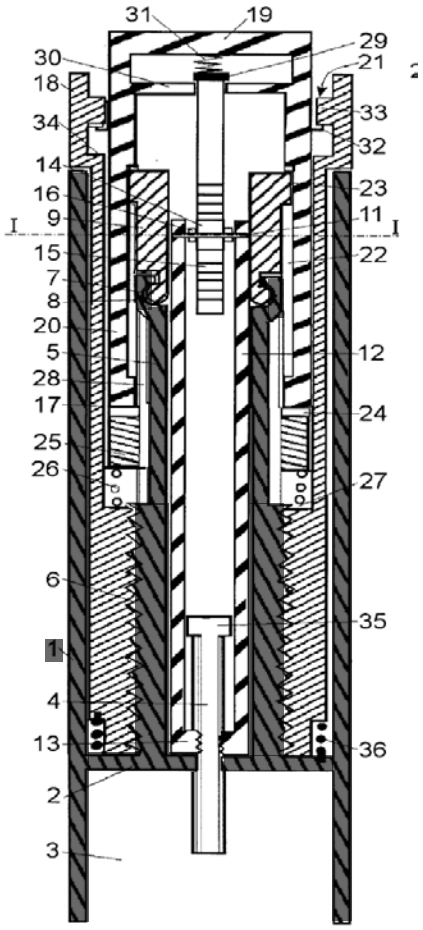
Independent claim 21 as a whole was taught by the combination of Møller and Steenfeldt-Jensen.

a. Element-by-element analysis

'844 Patent	**Møller and Steenfeldt-Jensen**
[21.Preamble] A drug delivery device comprising:	Both Møller and Steenfeldt-Jensen disclose drug-delivery devices.

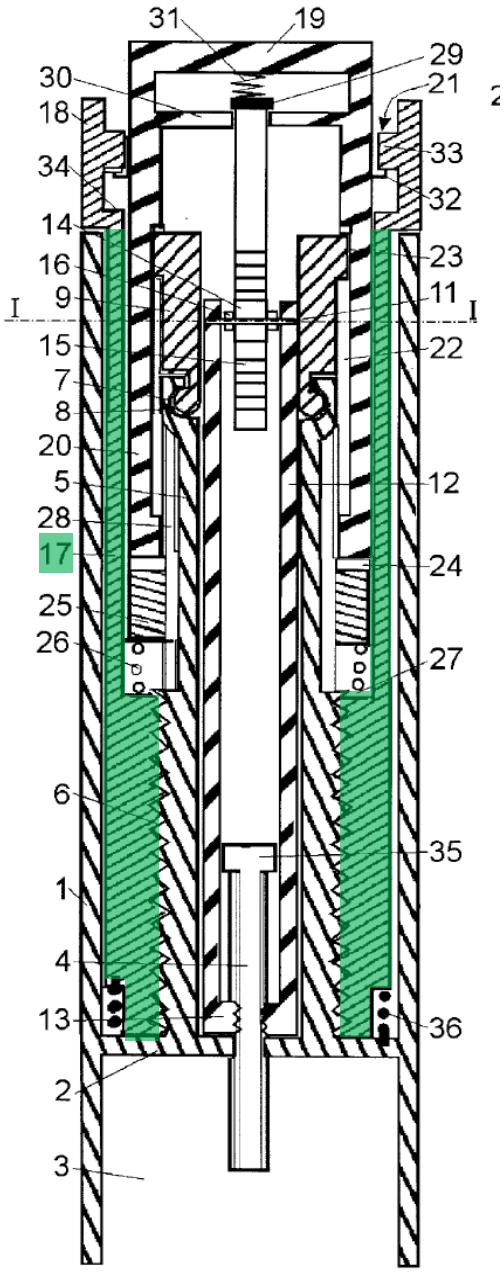
Both Møller and Steenfeldt-Jensen are directed to drug-delivery pens that administer a user selected dosage of medication. EX1015, Abstract; EX1014, Abstract. Accordingly, to the extent it is limiting, the combination of Møller and Steenfeldt-Jensen disclosed the preamble. EX1011, ¶699.

'844 Patent	**Møller and Steenfeldt-Jensen**
[21.1] a housing comprising a dose dispensing end and a first thread;	Møller teaches housing 1 with a dispending end and a first thread 6. "[T]he force exerted on the button is directly transmitted to ... a piston closing one end of an ampoule in the syringe which ampoule contains the medicament to be injected. When the

	piston is pressed into the ampoule the medicament is pressed out through a needle mounted through a closure at the other end of the ampoule." *Id.*, ¶3; *see also id.* ¶5. "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[n] ... ampoule." EX1015, ¶22.  Fig. 1 EX1015, FIG. 1; EX1011, ¶701. As shown in Figure 1, the housing 1 of drug delivery pen houses internal components. The housing 1 also has a series of helical threads.

The drive mechanism of Møller comprises housing 1 that houses the internal components of the drug-delivery device. *See e.g.* EX1015, Figure 1. Housing 1 has "a proximal end and a distal end." EX1015, claim 1; *see also id*., claims 5, 11, 15. Based on the disclosure of Møller, a POSA would appreciate that the distal end provides a dose dispensing end. EX1011, ¶700; *see also* EX1015, claim 5, Figure 1, ¶¶32-33. Further, housing 1 comprises a first thread 6. *Id*., ¶23. Therefore, the combination of Møller and Steenfeldt-Jensen disclosed a housing comprising a dose dispensing end and a first thread as recited in element [1.1]. EX1011, ¶700; *see also* EX1014, 5:38-46; FIG. 7-8, 16-17.

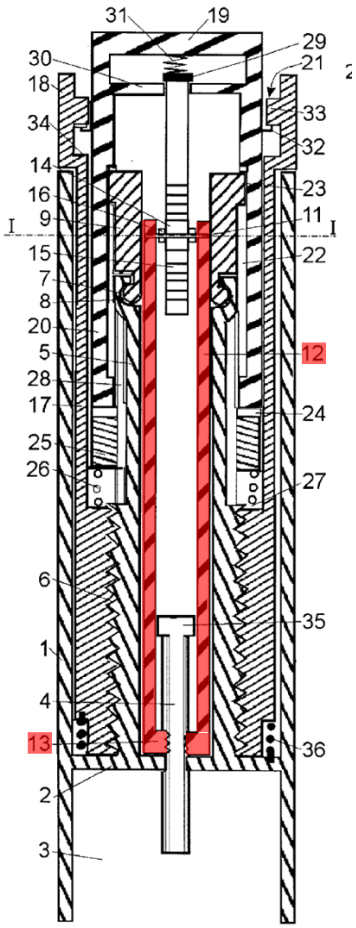
'844 Patent	**Møller and Steenfeldt-Jensen**
[21.2] a dose indicator comprising a second thread that engages with the first thread;	Møller teaches dose setting drum 17, which provides a second thread that engages thread 6 of housing 1. EX1015, ¶29. "A tubular dose setting drum 17 fitting into the housing 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

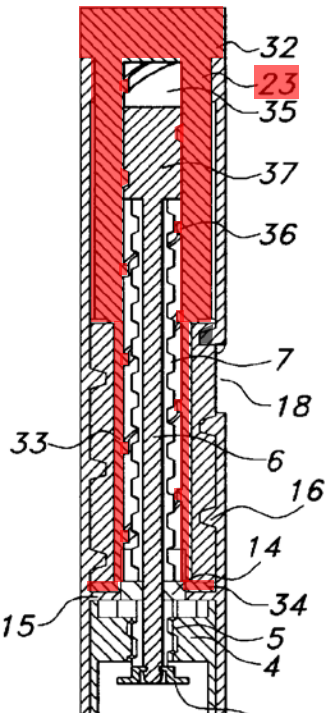
	screw the dose-setting drum 17 up along the thread 6. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will be lifted with this drum up from the end of the housing 1." *Id.*, ¶29.  Fig. 1

	EX1015, FIG. 1; EX1011, ¶705. As shown in FIG. 1, dose setting drum 17 has a series of threads that engage with the threads 6 of the housing 1.

Møller teaches dose indicator in the form of dose setting drum 17. Dose setting drum 17 allows for a user to set 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 disclosed a dose indicator comprising a second thread that engages with the first thread. *Id*.; EX1011, ¶703; *see also* EX1014, 7:51-67; FIG. 7-8, 16-17.

'844 Patent	**Møller and Steenfeldt-Jensen**
[21.3] a driving member comprising a third thread;	Møller and Steenfeldt-Jensen teach the use of drive members 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... 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; *see also id.* ¶31.  Fig. 1 EX1015, Figure 1; EX1011, ¶707. The piston-driving mechanism of Møller makes use of the connection bars

	12 and nut 13, which has an internal helical thread thereon. "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 unid[i]rectional coupling be kept inrotatable although said unidirectional coupling i[s] 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." EX1014, 8:1-8; *see also id.* 7:55-67.  EX1014, FIG. 7; EX1011, ¶710.

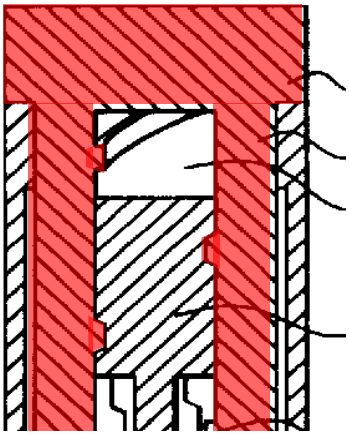
For the reasons set forth below in section V.F.1.b, a POSA would have had a reason to combine the teachings of Møller and Steenfeldt-Jensen to make use of Steenfeldt-Jensen's piston-driving mechanism, which accomplishes similar gearing (provides a similar mechanical advantage) with fewer, more durable components. EX1011, ¶754. The resulting combination would be a drug-delivery pen that is more durable overall, less prone to malfunction, and provides greater ease of use for a patient. *Id.* A POSA would appreciate that making use of Steenfeldt-Jensen's piston-driving mechanism achieves these advantages while still accomplishing the same gearing mechanism between the drive sleeve and the piston rod "so that the button has a larger stroke than has the piston." EX1015, 1:52-58.

In Møller, connection bars 12 and nut 13 operate to transmit axial movement as dose setting drum 17 is driven down during injection. EX1015, 5:36-44. Thus, connection bars 12 and nut 13 form a driving member comprising a third thread, as provided by nut 13. EX1011, ¶707. In an alternative embodiment, Møller incorporates the use of a tubular connection element 112 with a nut 113, which, as shown in FIGS. 3-5, is a fully enclosed, tubular component that encompasses the piston rod 104. *See* EX1015, 6:45-48. 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

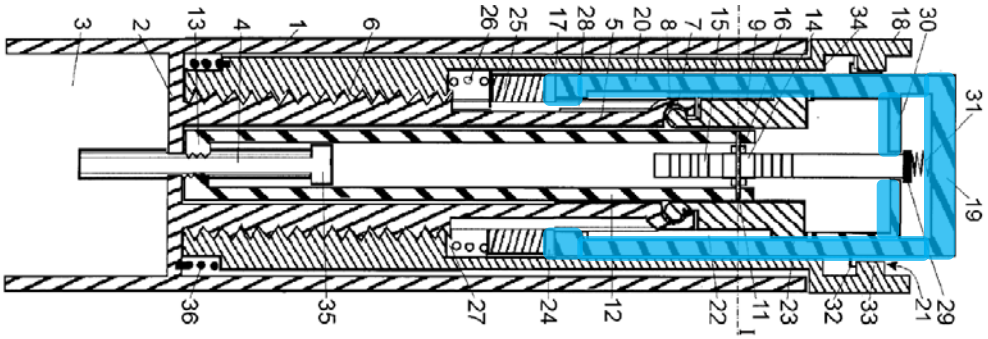
element 112 includes, at its button-end, two pins 111 that project perpendicular to the element's longitudinal axis and hold the device's gearing system. *See id.*, 6:49-53, FIGS. 3-5. The nut 13, having an internal threading, is provided toward the tubular connection element's needle-end. *See id.*, 6:45-48. Moreover, the tubular element 112 with nut 113 operates in the same manner as connection bars 12 with nut 13 and thus also teaches a driving member as recited in [21.3]. EX1011, ¶709.

Similarly, Steenfeldt-Jensen discloses cup shaped cap 23 or injection button 23 which operates to transmit axial movement during injection and serves as a driving member. EX1014, 6:42-53, 7:55-67. EX1011, ¶711. 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." EX1014, 8:30-34.

Further, the cup shaped cap 23 or injection button 23of Steenfeldt-Jensen is releasably connected to the other internal components, including the dose-dial sleeve (dose setting drum 17 of Møller) and has an internal helical thread. EX1011, ¶711-712. As shown in Figure 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, Figure 7.

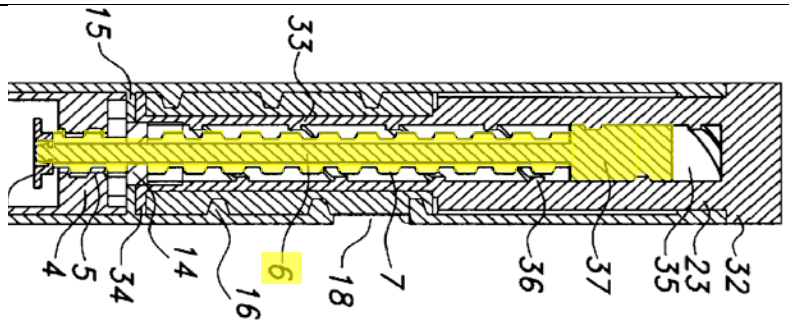
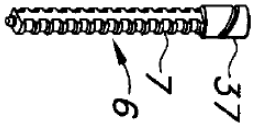


EX1014, Figure 7; EX1011, ¶712. Thus, the combination of Møller and Steenfeldt-Jensen taught a drug-delivery device comprises a driving member having a third thread. EX1011, ¶712.

'844 Patent	**Møller and Steenfeldt-Jensen**
[21.4] a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;	Møller discloses a "cup shaped element" disposed between the dose indicator and the driving member, and releasably connected to the dose indicator.  EX1015, FIG. 1.

The cup-shaped element (sleeve) is disposed between the connection bars 12 and nut 13 of Møller (or, upon modification, the injection button 23 of Steenfeldt-Jensen), and dose setting drum 17. EX1011, ¶715. Thus, the cup shaped element is located between the dose indicator and the driving member. *Id*. Further, the cup-shaped element (sleeve) is as separate component that is releasably connected to the other internal components of the drug-delivery pen, including the dose setting drum 17 (dose indicator). *See* EX1015, Figure 1. Thus, the combination of Møller and Steenfeldt-Jensen taught element [21.4]. EX1011, ¶717.

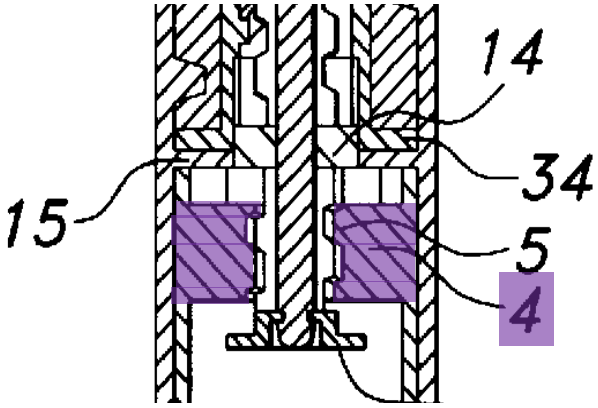
'844 Patent	**Møller and Steenfeldt-Jensen**
[21.5] a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;	Both Møller and Steenfeldt-Jensen teach the use of a piston rod. Møller teaches piston rod 4. Steenfeldt-Jensen teaches piston rod 6. "Through 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, 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.

	 EX 1014, FIG. 7; EX 1011, ¶720.  EX1014, FIG.8; EX1011, ¶719. 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, 27, 30; EX1014, 7:17-29, 7:60-67, 8:45-48, Figures 7-8; EX1011, ¶718. 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 achieveing the same mechanical advantage. EX1011, ¶718. The piston-driving mechanism of

Steenfeldt-Jensen uses a piston with an internal thread that engages with a corresponding thread on the driving member (injection button 23). And, as depicted in Figure 8, the enlargement 37 provides for an internal 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 a piston rod comprising an internal fourth thread that is engaged with the third thread. EX1011, ¶¶721-722.

'844 Patent	**Møller and Steenfeldt-Jensen**
[21.6] a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse	Both Møller and Steenfeldt-Jensen teach the use of a piston rod holder that is rotatbly fixed 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. "In the proximal side of the end wall 4 the bore is enlarged and the internal side of the enlargement is provided with pawl wheel teeth 10 having a steep front edge 11 facing the clockwise direction and a ramp shaped rear edge 12 facing the anticlockwise direction. At least one pawl 13 mounted on a

axially towards the distal end during dose dispensing;	piston rod guide 14 co-operates with the pawl teeth 10 so that said piston rod guide can only be rotated clockwise in the ampoule holder 2." EX1014, 5:66-6:6; *see also id.* 8:35-42.  EX1014, FIG. 7; EX1011, ¶724. "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 unid[i]rectional coupling be kept inrotatable although said unidirectional coupling i[s] 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." EX1014, 8:1-8. "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." *Id*., 8:25-33.

The piston-driving mechanism of Steenfeldt-Jensen uses wall 4 as a piston rod holder. EX1014, 5:55-57; 7:41-43; Figure 7. Based on the disclosure of Steenfeldt-Jensen, a POSA would understand that the wall 4 is rotatably fixed relative to the housing. EX1011, 725; 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, 726; 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, 727; EX1014, 8:25-33. Thus, the combination of Møller and Steenfeldt-Jensen provides the insert recited in element [21.6].

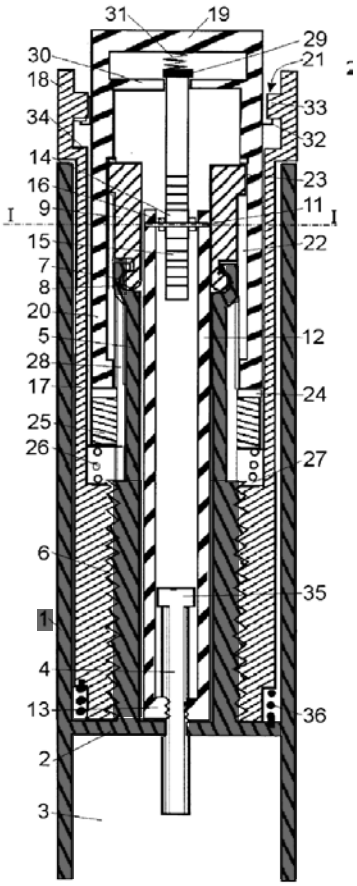
The combination of Møller and Steenfeldt-Jensen also meets this claim limitation to the extent that "holder" is construed as a means-plus-function limitation. The '844 patent teaches as to the "holder" or "insert" 16, that it is provided at the needle-end of housing 4, and it is "secured against rotational or longitudinal motion." EX1004, 3:58-60. Insert 16 is also described as having "a threaded circular opening 18 extending therethrough." *Id.*, 3:60-62. "Alternatively, the insert may be formed integrally with the main housing 4 [in] the form of a radially inwardly directed flange having an internal thread." *Id.*, 3:62-64.

"[P]iston rod 20 extends through the threaded opening 18 in the insert 16" by way of first thread 19. *Id.*, 3:65-67-4:1. The piston rod also has a second thread that is oppositely disposed to the first thread. *Id.*, 4:10-11. During dialing up of a dose, piston rod 20 is prevented from moving by the oppositely disposed threads. *Id.*, 6:11-13. During dose dispensing, piston rod 20 rotates through the opening in the insert to advance the piston in the cartridge. *Id.*6:55-58. Thus, the "holder" or "insert" 16 is secured to the housing such 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..

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) that has a threaded opening to hold the piston rod.

Element [21.6] expressly requires the remaining structure and function defined by the specification of the '844 patent. That is, element [21.6] requires "a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing." Thus, as set

forth in the analysis above, Steenfeldt-Jensen teaches this element to the extent it is construed as means-plus-function. And 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 of and reduction of internal components is advantageous and a desired objective in the industry. EX1011, 728.

’844 Patent	Møller and Steenfeldt-Jensen
[21.7] wherein: the housing is disposed at an outermost position of the drug delivery device;	Møller teaches housing 1, which is the outermost component of the drug-delivery device.  Fig. 1

	EX1015, FIG. 1, EX1011, ¶730. As shown in FIG. 1, the housing 1 is in the outermost position relative to the other components of the drug-delivery pen.

Based on the disclosure of Møller, a POSA would understand that the housing 1 of the drug-delivery device is disposed at the outermost position. EX1011, ¶730; EX1015, ¶22; *see also* EX1014, 5:38-46; FIG. 7-8, 16-17. Thus, the combination of Møller and Steenfeldt-Jensen discloses the subject matter recited in element [21.7].

’844 Patent	Møller and Steenfeldt-Jensen
[21.8] the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing;	Møller teaches a dose setting drum 17 which is positioned between the housing 1 and the cup-shaped element.

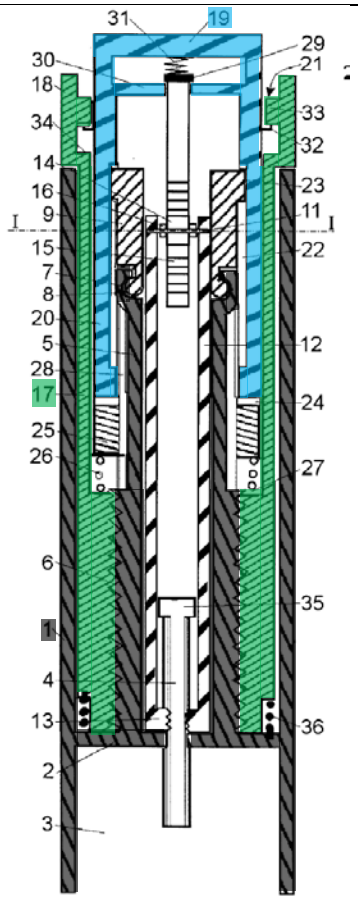


Fig. 1

EX1015, FIG. 1; *see also id.*, FIG. 3-5; EX1011, ¶733. As shown in FIG. 1, dose setting drum 17 is disposed between the housing 1 and the cup shaped element.

"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 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." *Id*., ¶32; *see also id.* ¶29.

Based on the disclosure of Møller, a POSA would understand that the dose setting drum 17 (dose indicator) is positioned between the housing 1 (housing) and the cup-shaped element (sleeve). EX1011, ¶¶733-734; EX1015, FIG. 1; *see also id*., FIG. 3-5. Further, a POSA would understand that during dose setting, the dose setting drum 17 is rotated upwards towards the proximal end of the drug-delivery pen. EX1011, ¶735-736; EX1015, ¶29. Thus, the dose-setting drum is configured to rotate and traverse axially away from the dose-dispensing end during dose setting. *Id*. Still further, a POSA would understand that during injection, the dose-setting drum 17 is rotated downward towards the distal end of the drug-delivery pen. EX1011, ¶736; EX1015, ¶32. Thus, the dose-setting drum is configured to rotate and traverse axially towards the dose-dispensing end during dose dispensing.

Id. Thus, the combination of Møller and Steenfeldt-Jensen discloses the subject matter recited in element [21.8].

'844 Patent	**Møller and Steenfeldt-Jensen**
[21.9] the driving member is configured to rotate relative to the piston rod;	The combination of Møller and Steenfeldt-Jensen teaches a driving member. See element [21.3] above. "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 i[s] 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." EX1014, 7:55-67, 8:1-8, FIG. 7.

As discussed above for element [21.3], the combination of Møller and Steenfeldt-Jensen teaches a driving member in the form of injection button 23 of Steenfeldt-Jensen. EX1011, ¶738; EX1014, 6:42-53,7:55-67, FIG. 7. Steenfeldt-Jensen explains that the injection button 23 of rotates during the dose-setting phase while the piston is not rotated. EX1014, 6:42-53; 7:55-67. Thus, a POSA would understand that the injection button 23 is a driving member that is configured to rotate relative to the piston rod. EX1011, ¶¶740-741.

’844 Patent	Møller and Steenfeldt-Jensen
[21.10] the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and	“A bottom 19 in a deep cup shaped element, which has a tubular part 20 fitting into the dose setting drum 17 and encompassing the gearbox 9, forms an injection button. Coupling means between the dose setting drum 17 and the cup shaped element ensures that rotation of the dose setting drum 17 is transmitted to the cup shaped element. Further the inner wall of the tubular part 20 has longitudinal recesses 22 engaged by protrusions 23 on the gearbox 9 so that rotation of the dose setting drum 17 via the cup shaped element is transmitted to the gearbox 9.” EX1015, ¶¶25-26; *see also id.*, ¶29. “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 unid[i]rectional coupling be kept inrotatable although said unidirectional coupling i[s] 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.” EX1014, 8:1-8.

As discussed above for element [21.4], the combination of Møller and Steenfeldt-Jensen teaches a sleeve in the form of a “cup shaped element” as described in Møller. The disclosure of Møller makes clear that the cup-shaped element is configured to rotate and move axially with dose-setting drum 17.

EX1015, ¶¶26, 29. Thus, the sleeve of Møller is configured to traverse axially with the dose indicator. EX1011, ¶¶746-748.

The piston-driving mechanism of Steenfeldt-Jensen makes use of injection button 23 as a driving member (see above for element [21.3]). EX1014, 7:55-67, FIG. 7. A POSA would have understood, based on the combination of Møller and Steenfeldt-Jensen, that the "cup shaped element" would be rotatably fixed relative to injection button 23. *Id*. Thus, the combination of Møller and Steenfeldt-Jensen teaches a sleeve that is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator as recited in element [21.10].

'844 Patent	**Møller and Steenfeldt-Jensen**
[21.11] the piston rod and the driving member are configured to rotate relative to one another during dose dispensing;	"A longitudinal 60 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 65 this thread connection is so that a not self locking thread connection is formed." EX1014, 7:60-67; *see also id.* 8:25-33.

The piston-driving mechanism of Steenfeldt-Jensen makes use of piston rod 7 and injection button 23 (driving member). EX1014, FIG. 7. Steenfeldt-Jensen explains that piston rod 7 rotates relative to injection button 23 (driving

member) during dose dispensing. EX1014, 7:17-40. Thus, a POSA would have appreciated that the combination of Møller and Steenfeldt-Jensen teaches a piston rod and a driving member that are configured to rotate relative to one another during dose dispensing. as recited in element [21.11]. EX1011, ¶749.

'844 Patent	**Møller and Steenfeldt-Jensen**
[21.12] and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.	Both Møller and Steenfeldt-Jensen teach the use of piston rods that traverse axially towards the dose dispensing end during dose dispensing. Møller teaches piston rod 4. Steenfeldt-Jensen further teaches a piston rod 6. "To inject the set dose the injection button 23 is pressed home into the housing 1. Thereby the dose scale drum 17 is pressed in the distal direction and due to the thread connection between said drum and the housing 1 a torque is exerted on the drum rotating this drum in a clockwise direction.... The pawls 13 on the piston rod guide are allowed to rotate in the clockwise direction when the torque is strong enough to overcome the reluctance provided by the protrusions 29 on the pawls engaging the depressions 32 in the ramp shaped edges of the pawl wheel teeth." EX1014, 7:17-29; *see also id.* 7:30-40.

Based on the disclosure of Steenfeldt-Jensen, a POSA would have appreciated that, during dose injection, the piston rod moves axially towards a

distal end. EX1011, ¶750; EX1014, 7:17-40. Thus, a POSA would have understood that the combination of Møller and Steenfeldt-Jensen teaches a piston rod that is configured to traverse axially towards the dose dispensing end during dose dispensing as recited in element [21.12].

For the reasons discussed above, each and every element of claim 21 and the subject matter of claim 21 as a whole was taught by the combination of Møller and Steenfeldt-Jensen.

b. Reason to combine; reasonable expectation of success

As explained below, 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). In the resulting combination, the user would interact with the 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, ¶¶752-53.

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, e.g.*, 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, ¶751.

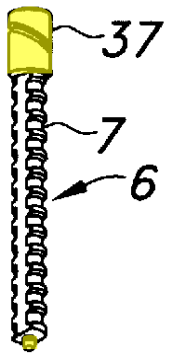
The drive mechanisms also provide the same benefit. Each involves a gearing mechanism that produces a mechanical advantage. *Id.*, ¶754. Møller teaches the benefit of providing gearing between the driver and the piston rod "so that the button has a larger stroke than has the piston." EX1015, ¶6. "By 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 recognized that Steenfeldt-Jensen's dual-threaded piston-rod mechanism provided a mechanical advantage similar to Møller's with fewer and more stress-tolerant components. EX1011, ¶¶754-55. 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, ¶754. Reducing the number of internal components in a drug-delivery pen is an objective in the industry. EX1011, ¶¶754-55. 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 as 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*., ¶¶754-56.

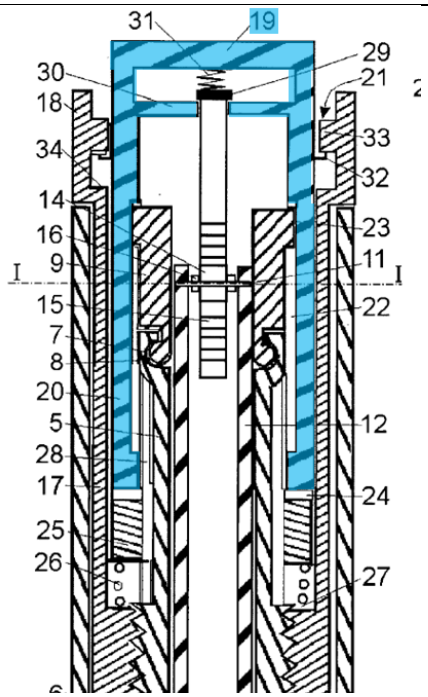
The mechanical advantages provided by the piston-driving mechanism of Steenfeldt-Jensen, along with the increase in durability and reduction in components would have provided ample reason to combine Møller and Steenfeldt-Jensen as proposed. EX1011, ¶754-56. Further, as noted above, both Møller and Steenfeldt-Jensen 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, ¶756; *KSR*, 550 U.S. at 416 (2007). Accordingly, a POSA would have had a reasonable expectation of success.

2. Dependent Claims 22-29

'844 Patent	**Møller and Steenfeldt-Jensen**
[22] The drug delivery device of claim 21 where the piston rod has a circular cross-section.	 EX1014, FIG. 8; EX1011, ¶758.

As an initial matter, claim 22 refers to *a* circular cross-section rather than reciting that the piston rod has a uniformly circular cross section along its entire length. FIGS. 15-17 of Steenfeldt-Jensen disclose that piston rod 6 has a circular cross-section at each of its proximal and distal ends. EX1011, ¶758. Even if "a" circular cross-section were interpreted to require a circular cross-section through the rod's entire length, a POSA would have recognized that the '844 patent's own piston rod does not have a perfectly circular cross-section along its threaded portion, as the thread itself results in a cross-section that is not entirely circular. *Id.*, ¶759. In this context, a POSA would have viewed Steenfeldt-Jensen as teaching a circular cross-section despite depicting a straight edge along a portion of the otherwise circular rod. *Id.* The references thus taught the "drug delivery device of claim 21 where the piston rod has a circular cross-section," as recited in claim 22. Claim 22 as a whole was thus obvious over Steenfeldt-Jensen.

'844 Patent	**Møller and Steenfeldt-Jensen**
23. The drug delivery device of claim 21 further comprising a clutch.	Møller discloses a "cup shaped element" that serves as a clutch.



EX1015, FIG 1; EX1011; ¶762.

"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; *see also id.* ¶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.... 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.

Clutch 60 of the '844 patent serves both as the "sleeve" as recited in element [21.4] as well as the clutch of claim 23. EX1011, ¶ 763. Møller teaches a "cup shaped element", which act as a clutch. Møller's first embodiment includes a "cup shaped element" (clutch) that includes bottom 19 (the surface pressed by the user to inject a dose) and tubular part 20. EX1015, ¶26, FIG. 1; EX1011, ¶761. As shown in FIG. 1, the cup shaped element is seated within dose-setting button 18 (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. 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, ¶761. The cup-shaped element serves as a clutch by rotationally coupling dose-setting button 18 and drum 17 (dose-dial sleeve) to connection bars 12 and nut 13 (driver) during dose

setting, then rotationally decoupling those components during injection. *See* EX1015, ¶¶29-30, 32-33, FIG. 1; EX1011, ¶761.

To the extent that "tubular clutch" is construed as being a means-plus-function limitation, the combination of Møller and Steenfeldt-Jensen rendered it obvious. The '844 patent discloses clutch 60. EX1004, 4:58-5:4, 5:10-11, 2:24-26. The tubular clutch described by the '844 patent is "generally cylindrical," having a series of "circumferentially directed ... teeth" at is first, i.e., needle, end, and also has a plurality of teeth at a second, i.e., button end. *Id.*, 4:58-5:4. The teeth on the needle end engage with the clicker, and the teeth on the button end engage with the dose-dial sleeve. *Id.*, 5:10-11, 5:60-63, 6:38-45. As taught by the '844 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.*, 5:2-4.

The cup-shaped element (having tubular part 120) and tubular element 120 of Møller operate in a similar manner using a similar structure. *Compare* EX1015, FIGS. 1, 5 *with* EX1004, 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; *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. 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, ¶761. 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. *Id*.

Accordingly, Møller taught a "tubular clutch" as claimed in claim 23.

Dependent claims 24, 25, and 29 were obvious over the combination of Møller and Steenfeldt-Jensen:

'844 Patent	**Møller and Steenfeldt-Jensen**
[24] The drug delivery device of claim 23 where the clutch provides audible and tactile feedback indicative of unit doses of medicament. [25] The drug delivery device of claim 24 where the clutch provides audible clicks	*See* claim 23 above regarding "clutch" limitation. Møller and Steenfeldt-Jensen both teach that the clutch may provide audible and tactile feedback for various functions. "Thereby a click coupling is established which makes a click noise when the V-shaped teeth at the edge of the cup shaped element by rotation of this element rides over the V-shaped teeth of the ring 25." EX1015, ¶27. "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

during dose cancelling, where each click is equal to a unit dose of medicament. [29] The drug delivery device of claim 21 further comprising a clicker that provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.	18 in the opposite direction of the direction for increasing the dose." *Id*., ¶29. "The clicks may be taken as an audible signal indicating the size of the set dose." EX1014, 3:21-27. "The angular spacing of the depressions are appropriately made so that a dose of one unit is set when the protrusion is moved from one depression to the neighbouring depression so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose." *Id*., 6:48-53.

The combination of Møller and Steenfeldt-Jensen discloses the use of audible and tactile feedback, such as clicks, to serve various functions. EX1015, ¶¶27, 29; EX1014, 3:21-27, 6:48-53. For example, the clutch of the drug-delivery pen can "make a click sound for each unit the dose is changed." EX1015, 55-59; *see also* EX1014, 3:21-27. A POSA would appreciate that such clicks are "audible and tactile feedback indicative of unit doses of medicament" as recited in dependent claim 24. EX1011, ¶767. A POSA would also appreciate that such clicks are provided when the dosage is too high, and the user resets or cancels the dosage. EX1011, ¶767; EX1015, ¶29. Thus, the combination of Møller and

Steenfeldt-Jensen renders obvious the subject matter recited in dependent claims 25 and 29. To the extent that Møller and Steenfeldt-Jensen to not expressly discuss audible clicks during dose cancelling, such usage of clicks would certainly have been obvious to POSA given the other teachings and suggestions in Møller and Steenfeldt-Jensen regarding using clicks and audible signals. EX1011, ¶767; EX1015, 39-44,. 55-59; EX1014, 3:21-27, 6:48-53.

To the extent that "clicker" is construed as a means-plus-function limitation, Møller and Steenfeldt-Jensen still rendered the claims obvious at least for the reasons provided above when applying Steenfeldt-Jensen to claims 24, 25, and 29. Moreover, Møller discloses the use of a rosette of V-shaped teeth at the edge of the open end of a cup-shaped element and V-shaped teeth 24, which provides an audible click to a user upon rotation of the dose-dial grip. *See* EX1015, ¶¶27-29, 40; FIG. 1. One of the structures that is taught by the '844 patent for use as a clicker is saw teeth that ride over one another to produce a click. EX1004, 6:33-35. Thus, Møller also teaches a clicker having the same function and structure as that of the '844 patent.

Dependent claim 26 was obvious over the combination of Møller and Steenfeldt-Jensen:

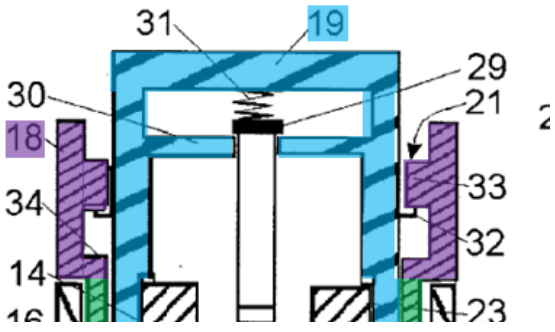
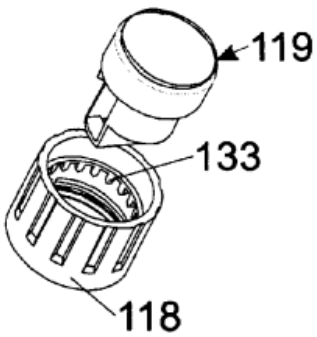
'844 Patent	**Møller and Steenfeldt-Jensen**
[26] The drug	*See* claim 24 above.

delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament.	Møller teaches a "cup shaped element" that acts as a clutch, which allows dose cancelling without dispending medication. "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." EX1015, ¶29.

A POSA would have appreciated that the Møller's "cup shaped element" allows for dose canceling where "[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." EX1015, ¶29; EX1011, ¶769. The described dose canceling is made possible by the "cup shaped element." Specifically, "[d]ue 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." EX1015, ¶29. The combination of Møller and Steenfeldt-Jensen thus taught the "drug delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament," as recited in claim 26.

Dependent claim 27 was obvious under the combination of Møller and Steenfeldt-Jensen:

'844 Patent	**Møller and Steenfeldt-Jensen**
[27] The drug delivery	*See* claim 24 above. Møller teaches a "bottom 19" (or alternatively "button 119") that is

device of claim 24 further comprising a button seated in an annular recess of a dose dial grip on a proximal end of the dose indicator, where the button is rotatable relative to the dose indicator.	disposed in an annular recess of the dose setting button 18, which is on a proximal end of the dose setting drum 17. "To inject a set dose the injection button is pressed by pressing on the bottom 19." *Id.*, ¶32. "A tubular element 120 having ridges 122 which engages recesses 123 on the gearbox is at its upper end closed by a button 119 from which a force provided by pressing this button is transmitted to the tubular element 120." *Id.*, ¶38; *see also id.*, ¶¶28, 29, 31. "At its outer end projecting from the gearbox the shell carrying the rack 115 is provided with a flange 140 which is positioned in a cut out 141 in the end of the tubular element 120 carrying the button 119 so that this button and the tubular element 120 can be moved so far inward in the device that the engagement of the teeth 132 and 133 can be released before the button 119 abuts the flange 140." *Id.*, ¶39. "The rotation of the dose setting button 18 and the cup shaped element is further transmitted to the gearbox 9 through the protrusions 23 on this gearbox engaging the longitudinal recesses 22 in the inner wall of the tubular part 20 of said cup shaped element." EX1015, ¶30.   *Id.*, FIGS. 1, 5; EX1011, ¶774.

Møller teaches the use of a "bottom 19," which acts as a button. EX1015, ¶32. Bottom 19 is disposed within the dose setting drum 17. *See* EX1015, FIG. 1. Dose setting drum 17 comprises a dose setting button 18. *Id*., ¶29. As shown in FIG. 1 of Møller, dose setting button 18 is an annular portion at the proximal end of the dose setting drum 17. Rotation of the dose setting button 18 facilitates setting of the desire dosage. *Id*., ¶29. Based on the disclosure of Møller, a POSA would understand that the dose setting button 18 serves as a dose-dial grip. EX1011, ¶774. Accordingly, bottom 19 is a button that is seated in an annular recess of the dose setting drum 17. More specifically, bottom 19 is seated in an annular recess of a dose-dial grip (dose setting button 18) on a proximal end of the dose indicator (dose setting drum 17). *Id.*; *see also* EX1015, ¶¶28, 32, 38-39. Furthermore, a POSA would appreciate that the bottom 19 is rotatable relative to the dose indicator (dose setting drum 17). EX1011, ¶775. Additionally, Møller also discloses another embodiment that teaches the use of "a button 119", which is provided as a physically distinct component but seats and moves similarly to bottom 19. EX1015, ¶38, FIG. 5. Thus, the combination of Møller and Steenfeldt-Jensen renders obvious a button seated in an annular recess of a dose-dial grip on a proximal end of the dose indicator, where the button is rotatable relative to the dose indicator as recited in claim 27.

Dependent claim 28 was obvious under the combination of Møller and Steenfeldt-Jensen:

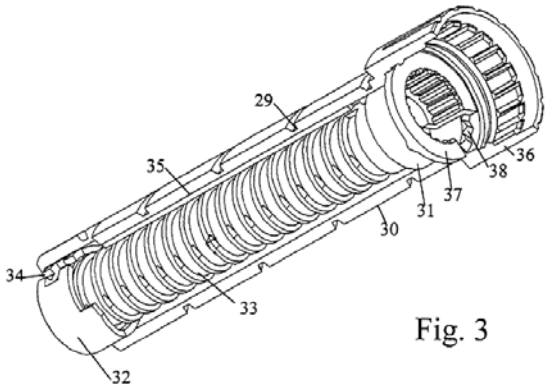
'844 Patent	**Møller and Steenfeldt-Jensen**
[28] The drug delivery device of claim 27 where axial movement of the button caused by distally applied pressure to the button initiates dose delivery by displacing the clutch axially with respect to the dose indicator and driving member.	*See* claim 27 above. Møller discloses a button in the form of bottom 19 (or alternatively button 119). *See* EX1015, ¶¶28, 32, 38-39, FIG. 1, 5. "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." *Id*., ¶32.

Møller teaches the use of a bottom 19 (or alternatively button 119). *See* EX1015, ¶¶28, 32, 38-39, FIG. 1, 5. As Møller explains, to initiate an injection, the bottom 19 is pressed. *Id*., ¶32. A POSA would appreciate that pressing down on the bottom 19 as described by Møller means that distally applying pressure to the button (bottom 19) results in axial movement of said button (bottom 19). EX1011, ¶777; *see also* EX1015, ¶32. A POSA would further appreciate that, as

bottom 19 is pressed, the clutch (cup-shaped element) is axially displaced relative to the dose indicator (dose-setting drum 17) and the driving member (injection button 23 of Steenfeldt-Jensen). EX1011, ¶777; *see also* EX1015, ¶¶31-33. Thus, the combination of Møller and Steenfeldt-Jensen renders obvious a drug-delivery pen where axial movement of the button caused by distally applied pressure to the button initiates dose delivery by displacing the clutch axially with respect to the dose indicator and driving member as recited in claim 28.

G. Ground 2: Møller, Steenfeldt-Jensen and Klitgaard Rendered Claims 30 Obvious

As discussed above in Ground 6, the combination of Møller and Steenfeldt-Jensen rendered claim 21 obvious. Employing a nut in the drug-delivery pen of Steenfeldt-Jensen to track each set dose of medicament would have been obvious in view of Klitgaard.

'844 Patent	**Møller and Steenfeldt-Jensen**
[28] The drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered.	 Fig. 3 EX1017, FIG. 3; EX1011, ¶783.

	"During the setting of a dose the nut member 32 is ... rotated with the dose setting member 30 relative to the driver 31 so that the position of the nut member 32 on this driver is dependent on the dose set. When the dose is injected ... the dose setting member 30 is ... forced to rotate relative to the housing [and] the rotation will be transmitted to the driver 31 ... and during this rotation the nut member 32 will maintain its position on the driver 31 . This way the position of the nut member 32 on the driver 31 will always indicate the total sum of set and injected doses. When the length of the helical track 33 in the driver 31 is adapted to the amount of medicine in a cartridge the nut member 32 will reach the end of the track 33 and stop for setting a dose larger than the amount remaining in the cartridge." EX1017, 4:33-58.

Klitgaard disclosed an injection device for dispensing medicine. *See* EX1017, Abstract. In Klitgaard, the "driver is provided with a track having a length which is related to the total amount of liquid in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of this dose setting member. " EX1017, Abstract. Because the track follower moves further into the track "[e]ach time a dose is set and injected," it tracks each dose of medication that is delivered and prevents setting of a dose larger than the remaining liquid in the cartridge. *Id.*

For example, FIG. 3 and its related description disclose nut member 32 that tracks each set dose of medication delivered to prevent setting a dosage that exceeds the remaining supply of medication in the cartridge. EX1017, 4:16-58. During dose setting, dose-setting member 30 is threaded out from internal threads on a housing. *Id.*, 4:16-25. At the same time, nut member 32 screws up along a helical track on the outer surface of driver 31 due to engagement between a ridge on the inner side of dose-setting element 30 and a recess 34 in the outer wall of nut member 32. *Id.*, 4:26-37. During dose dispensing, dose-setting member 30 is forced to rotate relative to the housing and transmits rotational force to driver 31, but nut member 32 maintains its position on driver 31 to "always indicate the total sum of set and injected doses." *Id.*, 4:37-58; EX1011, ¶¶782-84.

Klitgaard expressly disclosed a reason a POSA would have had to employ a nut that tracks each set dose of medicament delivered in order to "always indicate the total sum of set and injected doses" and prevent setting a dose that exceeds the remaining available supply of medication in the cartridge. EX1017, 4:52-58, Abstract. Klitgaard further explains that "it is convenient if a limiting device is provided which makes it impossible to set a dose that exceeds the amount of medicament which is left in the cartridge." EX1017, 1:34-37. These same benefits would be desirable in the Steenfeldt-Jensen drug-delivery device discussed above regarding claim 21. EX1011, ¶785.

A POSA would have had a reasonable expectation of success in incorporating such a nut into the drug-delivery pen based on the combination of Møller and Steenfeldt-Jensen . EX1011, ¶786. For example, nut member 32 could be readily adapted and disposed between tubular connection element 112 and tubular part 105 to track each set dose of medicament delivered. *Id.*, ¶¶786-90. These components have the concentric arrangement and relative movement identified by Klitgaard as the foundation for applying its nut. *Id.*, ¶787.

Accordingly, claim 30 was obvious over the combination of the teachings of Møller, Steenfeldt-Jensen, and Klitgaard.

VI. CONCLUSION

For the reasons set forth above, claims 21-30 are unpatentable. The unpatentability of these claims patent 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 that an IPR of the challenged claims 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 13,770, 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.

Dated: 10 September 2018

/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. 8,679,844 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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