

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 IPR2018-01682
Patent No. 9,526,844

PETITION FOR *INTER PARTES* REVIEW

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LIST OF EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
1001	U.S. Patent 8,679,069, <i>Pen-Type Injector</i> (issued Mar. 25, 2014)
1002	U.S. Patent 8,603,044, <i>Pen-Type Injector</i> (issued Dec. 10, 2013)
1003	U.S. Patent 8,992,486, <i>Pen-Type Injector</i> (issued Mar. 31, 2015)
1004	U.S. Patent 9,526,844, <i>Pen-Type Injector</i> (issued Dec. 27, 2016)
1005	U.S. Patent 9,604,008, <i>Drive Mechanisms Suitable for Use in Drug Delivery Devices</i> (issued Mar. 28, 2017)
1006	File History for U.S. Patent 8,679,069
1007	File History for U.S. Patent 8,603,044
1008	File History for U.S. Patent 8,992,486
1009	File History for U.S. Patent 9,526,844
1010	File History for U.S. Patent. 9,604,008
1011	Expert Declaration of Karl Leinsing MSME, PE in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent Nos. 8,679,069; 8,603,044; 8,992,486; 9,526,844 and 9,604,008
1012	<i>Curriculum Vitae</i> of Karl Leinsing MSME, PE
1013	U.S. Patent 6,221,046 - A. Burroughs et al., “Recyclable Medication Dispensing Device” (issued Apr. 24, 2001)
1014	U.S. Patent 6,235,004 – S. Steinfeldt-Jensen & S. Hansen, “Injection Syringe” (issued May 22, 2001)
1015	U.S. Patent Application US 2002/0053578 A1 – C.S. Møller, “Injection Device” (pub’d May 2, 2002)

<u>Exhibit No.</u>	<u>Description</u>
1016	U.S. Patent 6,932,794 B2 – L. Giambattista & A. Bendek, “Medication Delivery Pen” (issued Aug. 23, 2005)
1017	U.S. Patent 6,582,404 B1 – P.C. Klitgaard et al., “Dose Setting Limiter” (issued June 24, 2003)
1018	File History for U.S. Patent 6,582,404
1019	Plaintiffs’ Preliminary Claim Constructions and Preliminary Identification of Supporting Intrinsic and Extrinsic Evidence, <i>Sanofi-Aventis U.S. LLC v. Mylan GmbH</i> , No. 2:17-cv-09105 (D.N.J.)
1020	U.S. Patent 4,865,591 – B. Sams, “Measured Dose Dispensing Device” (issued Sep. 12, 1989)
1021	U.S. Patent 6,248,095 B1 – L. Giambattista et al., “Low-cost Medication Delivery Pen” (issued June 19, 2001)
1022	U.S. Patent 6,921,995 B1 – A.A. Bendek et al., “Medication Delivery Pen Having An Improved Clutch Assembly” (issued July 13, 1999)
1023	U.S. Patent 5,226,895 – D.C. Harris, “Multiple Dose Injection Pen” (issued July 13, 1993)
1024	U.S. Patent 5,851,079 – R.L. Horstman et al., “Simplified Unidirectional Twist-Up Dispensing Device With Incremental Dosing” (issued Dec. 22, 1998)
1025	Application as filed: U.S. Patent App. 14/946,203 – R.F. Veasey, “Relating to a Pen-Type Injector” (filed Nov. 19, 2015)
1026	GB 0304822.0 – “Improvements in and relating to a pen-type injector” (filed Mar. 3, 2003) (‘844 Priority Doc.)

<u>Exhibit No.</u>	<u>Description</u>
1027	WO 99/38554 – S.Steenfeldt-Jensen & S.Hansen, “An Injection Syringe” (pub’d Aug. 5, 1999) (Steenfeldt-Jensen PCT)
1028	Mylan GmbH and Biocon’s Preliminary Claim Constructions and Supporting Evidence Pursuant to L. Pat. R. 4.2, <i>Sanofi-Aventis U.S., LLC v. Mylan N.V.</i> , C.A. No. 17-cv-09105
1029	Memorandum Opinion, <i>Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.</i> , No. 16-cv-812 (filed Jan. 12, 2018)
1030	Memorandum Opinion, <i>Sanofi -Aventis U.S. LLC v. Eli Lilly and Co.</i> , No. 14-cv-113 (filed Jan. 20, 2015)
1031	N. Sclater & N.P. Chironis, Mechanisms & Mechanical Devices Sourcebook 191-95, “Twenty Screw Devices” (3d ed., July 2, 2001)
1032	EP 0 608 343 B1 – L. Petersen & N.-A. Hansen, “Large Dose Pen” (pub’d Oct. 18, 1991)
1033	A.G. Erdman & G.N. Sandor, “Mechanical Advantage”, §3.7 in 1 Mechanism Design: Analysis and Synthesis (1984)
1034	WO 01/83008 – S. Hansen & T.D. Miller., “ <i>An Injection Device, A Preassembled Dose Setting And Injection Mechanism For An Injection Device, And A Method Of Assembling An Injection Device</i> ” (pub’d Nov. 8, 2001)
1035	K.J. Lipska et al., <i>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</i> , 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 No. 9,526,844B2 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); also EX1030 (*Markman* opinion in *Sanofi -Aventis U.S. LLC v. Eli Lilly and Co.*, No. 14-cv-113 (D. Del.) (consent judgment)). 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, IPR2018-01679 and IPR2018-01696), 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 an additional petition against the ‘844 patent (IPR2018-01680).

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 §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 as follows:

Ground	Claims	Basis
1	21-29	Obvious over U.S. Patent 6,235,004 (EX1014, "Steenfeldt-Jensen")
2	30	Obvious over Steenfeldt-Jensen in combination 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 prior art rendered obvious the drug-delivery device recited in each of claims 21-29. 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.

A. The ’844 Patent¹

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, because patients using the device may have impaired vision or other 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:

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.

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;

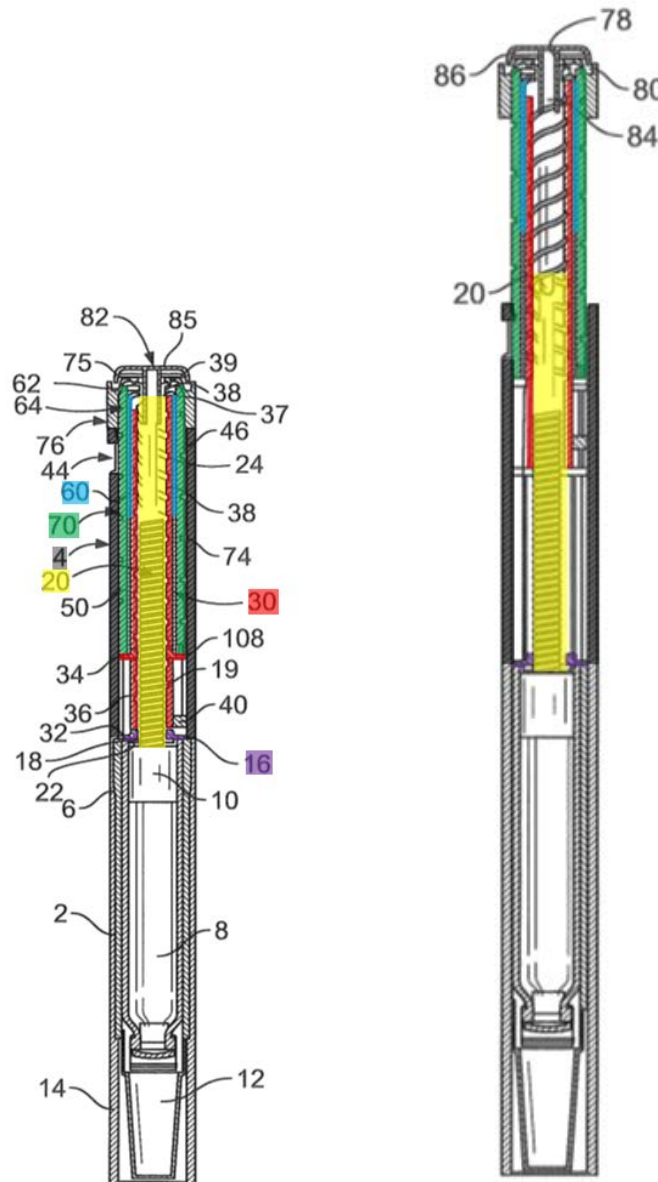
(3) “piston rod” (20, yellow) comprising a fourth thread, which is driven to move a piston provided within the cartridge towards the needle end to dispense medicine;

(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

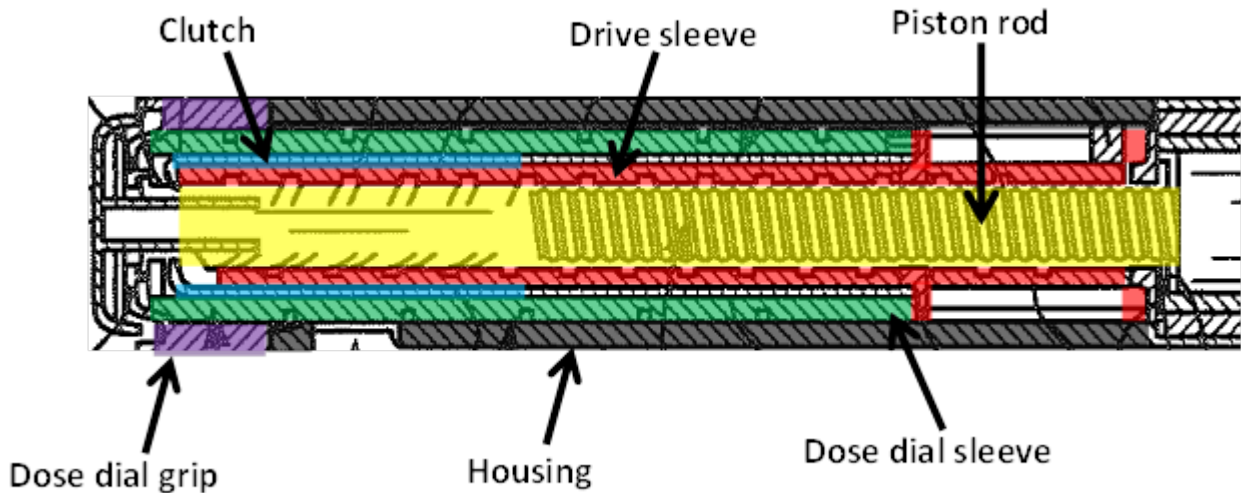
injector, is described below, followed by a description of the injector's operation.

Brief Overview of Claimed Components

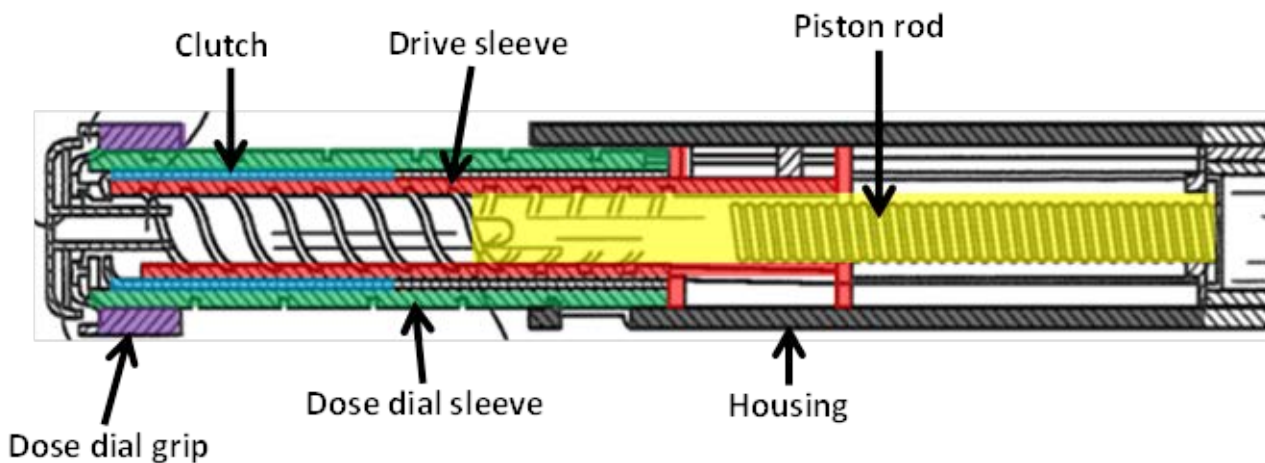
The '844 patent describes an injector having a housing that is formed from two parts: (1) first cartridge retaining part 2 (which contains cartridge 8 from which medicine is dispensed) and (2) second main-housing part 4 (orange). *See* EX1004, 3:37-47, FIG. 1. Second main-housing part 4 houses the mechanism that serves to drive piston 10 contained within cartridge 8 to dispense medicine. *Id.*, 1:44-47, FIG. 1.

In one embodiment, at the needle-end² of housing part 4, 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 insert 16'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 the teeth 65 engage with the dose dial sleeve 70. As Leinsing explains, the teeth 65 engage with “an inwardly directed flange in the form of [a] number of radially extending members 75” provided at the dose dial sleeve 70’s button-end. *See* EX1011, ¶69; *see also id.*, ¶24 n1.

Operation of the Pen Injector

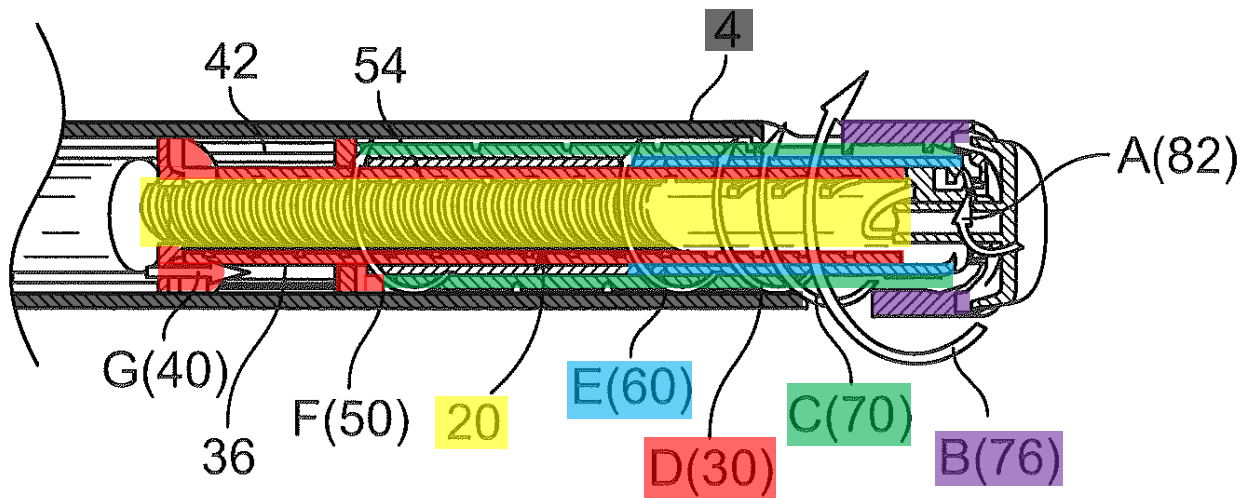


FIG. 9: Dialing up (*id.*, 2:55-56), annotated to highlight components (EX1011, ¶81)

The user also may dial down a dose, if needed. *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. As such, 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.

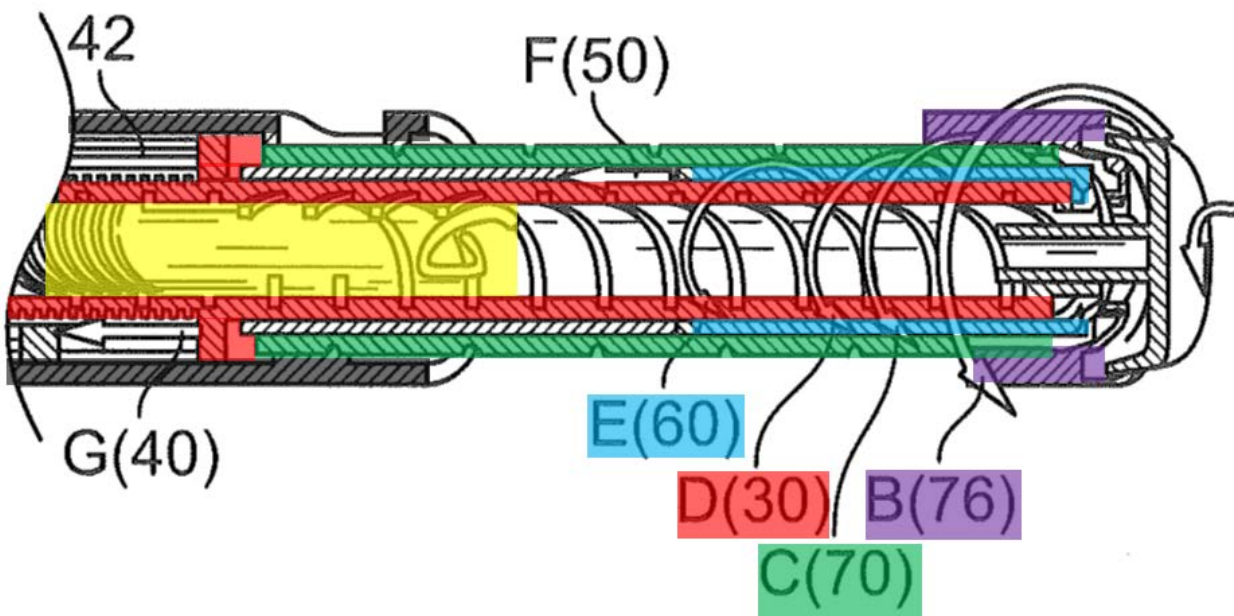


FIG. 10: Dialing down (*id.*, 57-58), annotated to highlight components (EX1011, ¶84)

Injection: Once the dose is set, the user presses button 82, applying a 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.

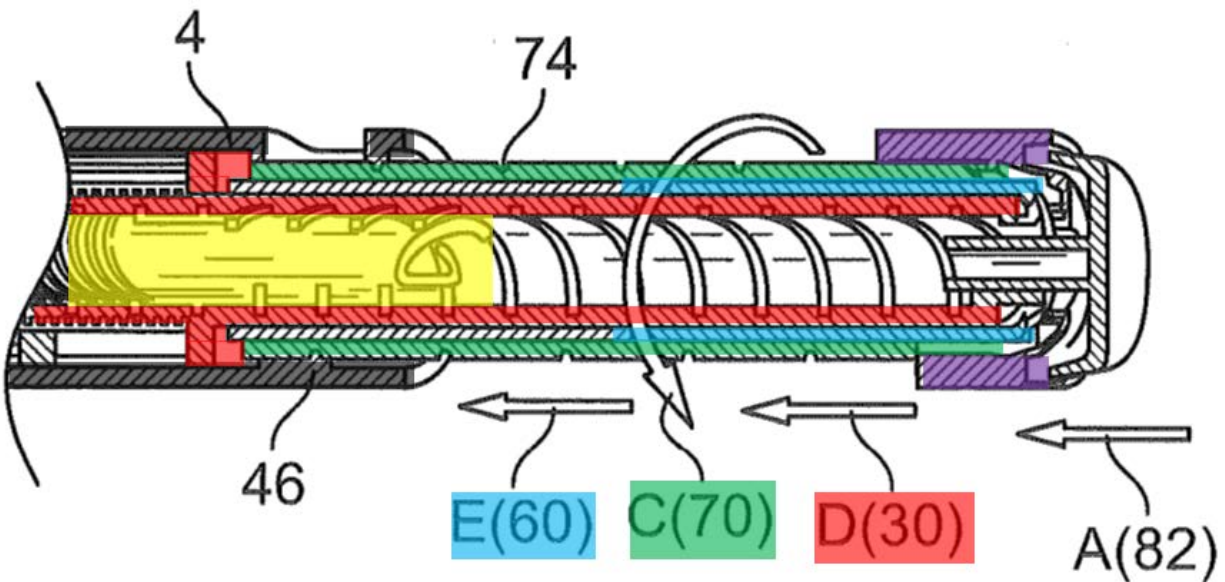


FIG. 11: Injecting dose (*id.*, 2:59-60), annotated to highlight components (EX1011, ¶88)

2. Prosecution History

The '844 patent issued from Application No. 15/156,616 ('616 application). 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. *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 Steinfeldt-Jensen (WO99/38554, EX1027) was disclosed by applicants in an Information Disclosure Statement. *Id.*, 46, 49. It was not applied substantively to the claims of the '844 patent.

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

The '616 application 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 Lilly & 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.

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 (EX1026) are difficult to view, the written description of the GB application confirms these figures are consistent with those in the ’844 patent and the other patents in the

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.

B. Level of Ordinary Skill

For the purposes of this petition, the relevant timeframes include May 17, 2016 (the filing date of the '616 application) and March 3, 2003 (the earliest priority date

priority chain (including the '203 application) in uniformly depicting external threads on the piston rod.

claimed by the '844 patent. A POSA at the relevant time would have 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.*

C. 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. 37 CFR §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*).

In the related litigation, Patent Owner Sanofi has taken positions regarding the meaning of certain claim terms, which it cannot now argue are unreasonable. *See Ex parte Schulhauser*, Appeal No. 2013-007847, slip op. at 9 (PTAB Apr. 28, 2016) (precedential) (“A proper interpretation of claim language ... at least encompasses the broadest interpretation of the claim language for purposes of infringement.”). The relevant terms are listed below, along with Sanofi's proffered construction for those terms.

“driving member”: “A component releasably connected to the dose dial sleeve that drives the piston during dose dispensing.” EX1019, 28-30.

“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.*, 21-23.

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

“the piston rod and the driving member are configured to rotate relative to one another during dose dispensing”: “Plain and Ordinary Meaning, which a POSITA would understand to be ‘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/threaded/threading”: “A rib or groove on a first structure that engages a corresponding groove or rib on a second structure.” *Id.*, 30-31.

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

“clicker”: “A structure that provides audible and/or tactile feedback when the dose knob is rotated.” *Id.*, 31-32.

“holder”: “Plain and Ordinary Meaning, which a POSITA would understand

⁵ This term was construed for the ’486, ’069, and ’044 patents.

to be ‘a structure that holds a referenced structure’ (e.g., a piston rod holder holds a piston rod” *Id.*, 33-34.

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 set forth a 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 FIGS. 1, 5-11, component 60, as the corresponding structure for the clutch. *Id.* 121; *see also* EX1004, 2:24-26, 4:58-5:4, 5:5-7, 6:46-54.

As to the function of a clicker,⁶ Mylan asserts is that the function is

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).

“provid[ing] audible clicks during dose setting, where each click is equal to a dose of medicament.” EX1028, 134. Mylan points to FIGS. 6-8 for the structure of the clicker, component 50. *Id.*, 131-134; *see also* EX1004, 2:27-29, 2:30-35, 2:36-42, 4:42-44, 4:45-57, 5:5-9.

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.

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

D. Prior Art

1. Steinfeldt-Jensen

Steenfeldt-Jensen is pre-AIA §102(b) prior art to the '844 patent.⁸ Steinfeldt-Jensen disclosed syringes for dispensing medicine. *See* EX1014, Abstract. As FIGS. 16 and 17 (color-coded below) show, Steinfeldt-Jensen disclosed an embodiment⁹ of a syringe (EX1011, ¶131) comprising:

(1) “tubular housing 1” and “ampoule holder 2” (**dark grey**) disposed at an outermost position of the device that house the drug delivery components of the pen and comprise a dose dispensing end and a first thread, *see* EX1014, 5:38-54, 6:7-11, 11:20-22, claim 11, FIGS. 15-17;

(2) “scale drum 80” (**green**), that is threadingly engaged with the first thread on

⁸ Because the effective filing date of the '844 patent is May 17, 2016, post-AIA §102 applies. Whether pre- or post-AIA §102 makes no difference in this case. Thus, for consistency and convenience, this petition pre-AIA §102.

⁹ Steinfeldt-Jensen explains that analogous elements in different embodiments are provided with the same reference number. *See* EX1014, 7:49-51. Thus, while the discussion herein primarily focuses on the embodiment shown in FIGS. 15-17, a POSA would have understood that disclosures relating to other embodiments inform the structure and operation of the embodiment of FIGS. 15-17, at least for elements having identical reference numbers. *See* EX1011, ¶131 n.13.

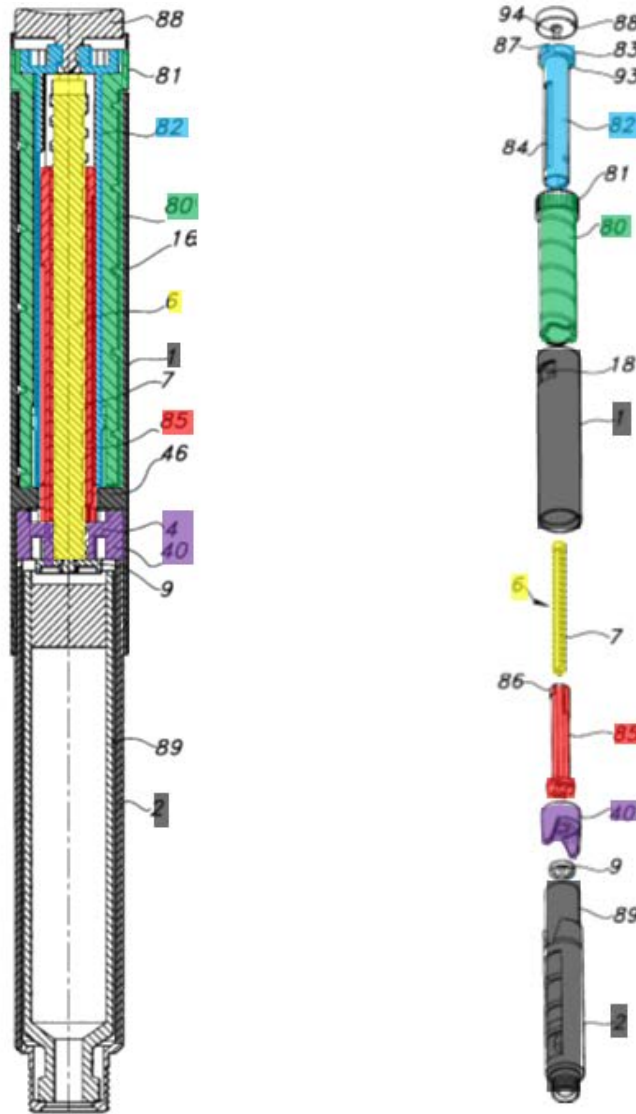
the housing, disposed between the housing and the sleeve, configured to rotate away from the needle end during dose setting and toward the needle end during dose dispensing, *see* EX1014, 11:20-22, 11:52-55, FIGS. 15-17;

(3) “piston rod 6” (**yellow**) comprising a fourth thread, which is driven to move a piston provided within the ampoule axially to dispense medicine, *see* EX1014, 5:57-65, 8:35-39; 11:6-19; FIGS. 15-17;

(4) “driver tube 85” (**red**), which rotates during injection to drive piston rod 6 downward, *see* EX1014, Abstract, .2:46-53, 2:65-3:1, 3:28-29, 8:35-39, 8:48-53, 11:6-19, 11:52-12:13; claim 11, FIGS. 15-17;

(5) “bushing 82” (**blue**), which is disposed between scale drum 80 and driving tube 85 and which is releasably connected to the scale drum and rotatably fixed relative to driver tube 85 and configured to traverse axially with scale drum 80, *see* EX1014, 11:22-56, 12:1-13, FIGS. 15-17;

(6) “member 40”, which is rotatably fixed relative to the housing and configured to prevent the piston rod from rotating during dose setting but to permit it to traverse axially towards the needle end of the device during dose dispensing, *see* EX1014, 2:46-53, 2:65-3:1, 3:28-29, 8:35-42, 9:36-42, 11:6-19, 11:52-62, 12:4-12, claim 11, FIGS. 15-17; EX1011, ¶132.



See EX1014, FIGS. 16 (left above), 17 (right above); EX1011, ¶131.

As discussed below, it would have been obvious to modify (1) driver tube 85 to include an internal threading for engaging the piston rod's external threading, and (2) member 40 to include a non-circular cross-section for axially guiding the piston rod. Indeed, a POSA would have reasonably expected that the modified

parts would be “performing the same function that [they] had been known to perform.” *See KSR*, 550 U.S. at 417.

2. Klitgaard

Klitgaard is prior art to the '844 patent under pre-AIA §102(b) and §102(e) (under the March, 3, 2003 earliest priority date). EX1017, cover (filed Sep. 6, 2000); *see also* EX1018 (prosecution history showing allowance of original dependent claim amended only to make it independent). 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.

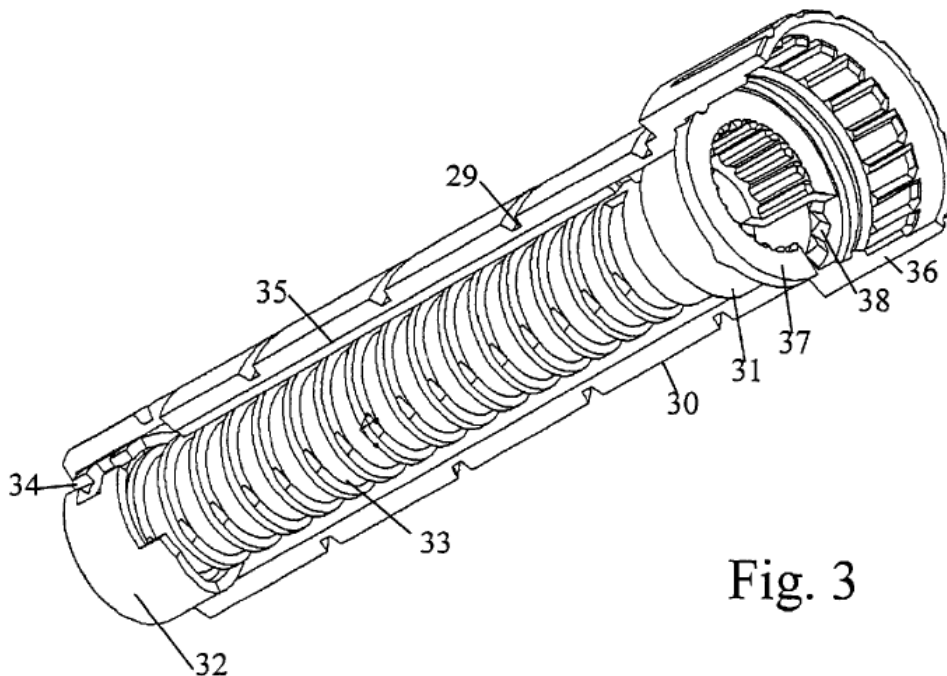


Fig. 3

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.

E. Ground 1: Claims 21-29 Are Obvious over Steenfeldt-Jensen

As demonstrated by the claim charts and analysis below, Steenfeldt-Jensen disclosed a single device comprising all of the components and structural limitations recited by claim 21 except that driving tube 85 lacks internal threads engaged to external threads of the piston rod. In Steenfeldt-Jensen, internal threads of member 40 instead engage the external threads of piston rod 6. A detailed discussion of the reasons to modify Steenfeldt-Jensen to place the internal threads in driving tube 85 follows the discussion of the individual claim elements. *See infra*, section V.E.1.b.

1. Claim 21

a. Element-by-element analysis

Steenfeldt-Jensen taught the preamble:

'844 Patent	Steenfeldt-Jensen
[21.Preamble] A drug delivery device comprising:	“The present invention provides an injection syringe” <i>Id.</i> , Abstract. “The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses.” EX1014,

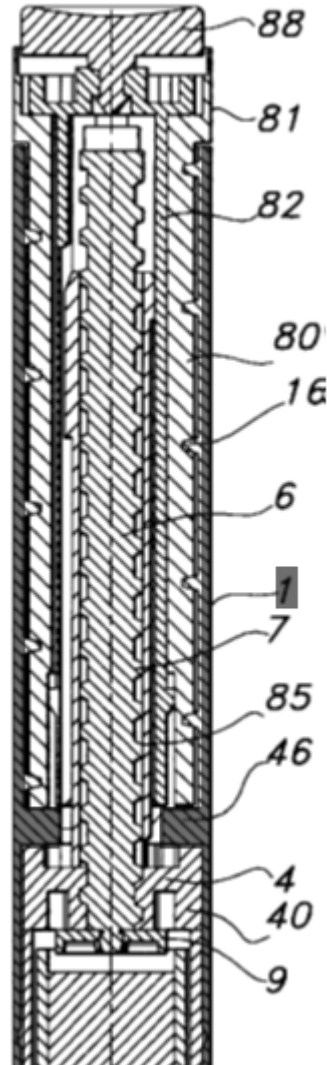
	1:12-15, FIGS. 15-17.
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Steenfeldt-Jensen describes an injection syringe for dispensing medicine.

EX1014, abstract, 1:12-15, FIGS. 15-17; EX1011, ¶612. Accordingly, to the extent it is limiting, Steenfeldt-Jensen taught the preamble of claim 21.

Steenfeldt-Jensen taught element [21.1].

'844 Patent	Steenfeldt-Jensen
[21.1] a housing comprising a dose dispensing end and a first thread;	<p>“The syringe comprise[s] a tubular housing 1 ... [into] which an ampoule holder 2 is snapped[.]” EX1014, 5:38-44, FIGS. 15-17.</p> <p>“A medication delivery pen comprising ... a housing having proximal and distal ends[.]” <i>Id.</i>, claim 11.</p>



Id., FIG. 16 (detail; housing 1 annotated gray); EX1011, ¶613.

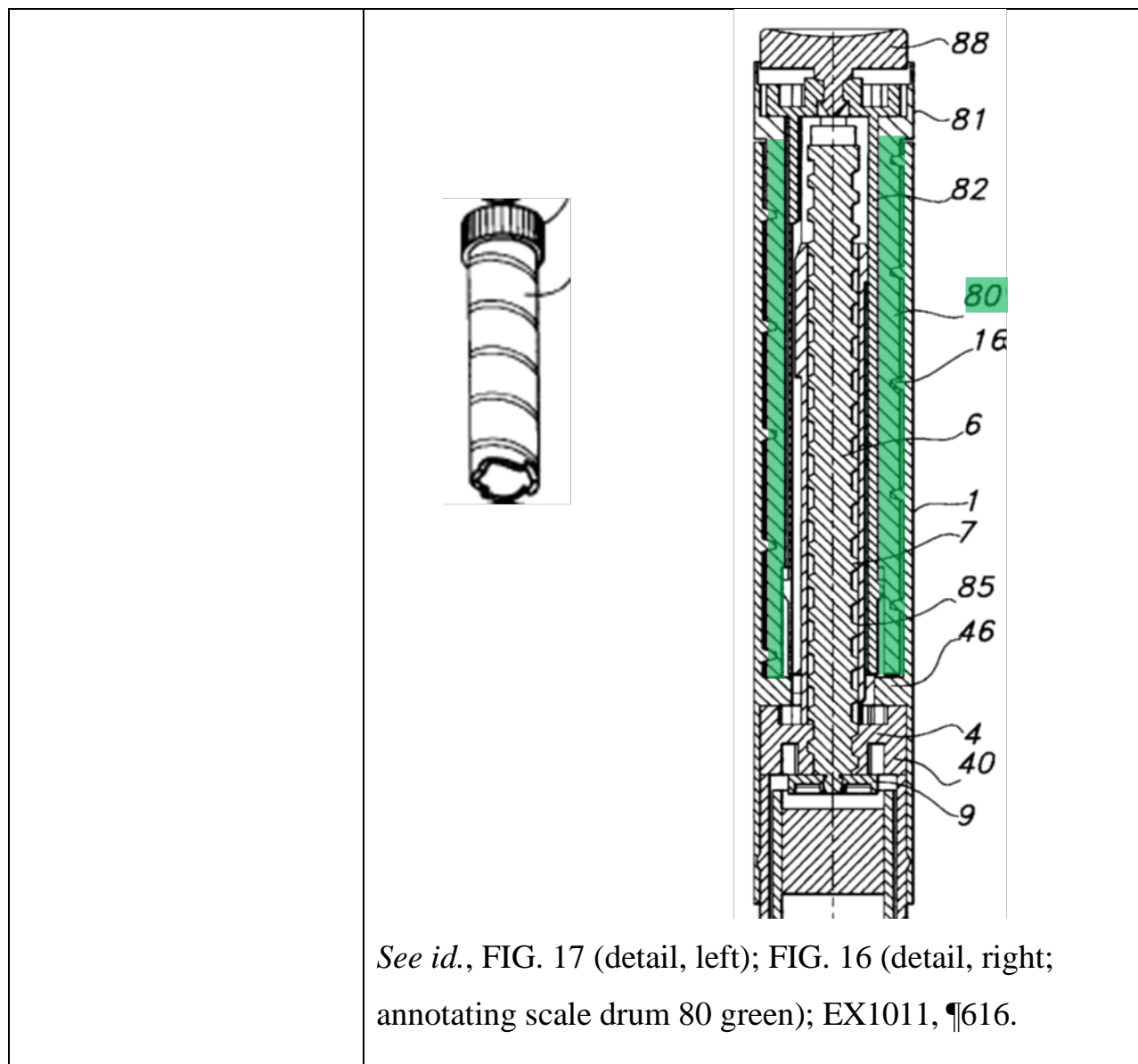
“On the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. EX1014, 6:7-11; *see also id.*, 3:34-44, 11:20-22.

As shown in FIGS. 15-17, housing 1 and ampoule holder 2 extend from a button-end (referenced as the proximal end) to a needle- or dose dispensing-end of

the syringe. EX1011, ¶614. Housing 1 comprises an inner thread on its inner wall. EX1014, 3:34-44, 6:7-11, 11:20-22. Steenfeldt-Jensen thus taught the elements of the claimed “housing” recited in element [21.1].

Steenfeldt-Jensen taught element [21.2].

'844 Patent	Steenfeldt-Jensen
[21.2] a dose indicator comprising a second thread that engages with the first thread;	<p>“On the inner wall of ... the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. A dose scale drum 17 is in its outer wall provided with a helical groove defining a corresponding external thread mating the inner thread[.]” EX1014, 6:7-11.</p> <p>“Number indicating set doses are printed on the outer wall of the dose drum 17 and the number corresponding to a set dose is shown in window 18 provided in the side wall of the housing 1.” <i>Id.</i>, 6:18-21.</p> <p>“The size of the set dose can ... be seen on the part of the dose scale drum which is presented in the window 18.” <i>Id.</i>, 11-13.</p> <p>“A scale drum 80 is in its outer wall provided with a helical track which is engaged by a helical rib 16 along the inner wall of the housing 1.” EX1014, 11:20-22, FIGS. 15-17.</p>

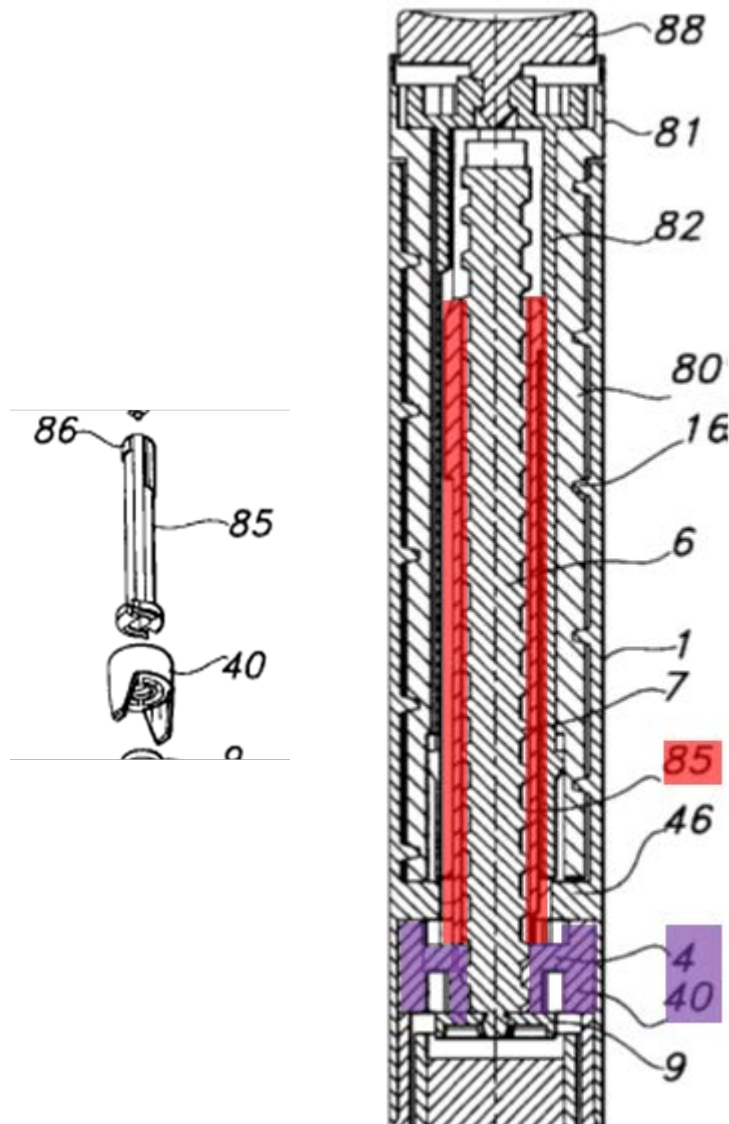


Steenfeldt-Jensen disclosed that the syringe includes a “dose indicator” in the form of dose scale drum 17 or scale drum 80. EX1014, 11:20-22; EX1011, ¶615. The drum includes a “helical groove provided along an outer surface” in the form a helical track, which extends along the drum’s outer wall. EX1014, 3:34-44, 6:7-11, 11:20-22, FIGS. 16-17; EX1011, ¶615. The helical track is “configured to engage a threading provided by” housing 1 via helical rib 16, which extends along

housing 1's inner wall. *Id.* A dose is set by screwing the scale drum out of the housing and scale drum 80 is pressed back into the housing during dose dispensing. EX1014, 11:52-54, 12:4-9. Numbers indicating set doses are printed on an outer wall of the dose drum and viewable outside the housing via a window. EX1014, 6:18-21, 7:11-16, 9:52-56, 10:40-45; EX1011, ¶617. Steinfeldt-Jensen explains that analogous elements in different embodiments are provided with the same reference number. *See id.*, 7:49-51. As can be seen in FIG. 17 of Steinfeldt-Jensen, the embodiment shown in that figure has window 18, thus scale drum 80 also serves as a dose indicator. Steinfeldt-Jensen thus taught the claimed “dose indicator.”

Steenfeldt-Jensen suggested element [21.3].

'844 Patent	Steenfeldt-Jensen
[21.3] a driving member comprising a third thread;	“The present invention provides an injection syringe compris[ing] ...a piston rod drive[.]” EX1014, Abstract.



See id., FIGS. 17 (detail, left), 16 (detail, right; annotating driver tube 85 red and member 49 purple); EX1011, ¶618.

“[P]en comprising ... a piston rod drive for driving said piston rod in a distal direction inside the cartridge, said piston rod drive including a first part having an internal thread mating the thread of said piston rod..., [and] a second part mating with the not circular cross-section of

	<p>said piston rod, wherein said first and second parts are rotatable relative to one another to drive the piston rod in an axial direction" <i>Id.</i>, claim 11; <i>see also id.</i>, 2:46-53 (describing parts as "a nut member" and a "piston rod guide," respectively).</p> <p>"[A] unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction" <i>Id.</i>, 2:65-3:1; <i>see also id.</i>, claim 11 ("one-way coupling"), 3:28-29.</p> <p>"The end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing" <i>Id.</i>, 8:35-37, FIGS. 15-17.</p> <p>"A driver tube 45 is at one end provided with the pawl 13 which engages pawl wheel teeth in the member 40 and is held between a ring shaped wall 46 in the housing and the end wall 4 in the member 40 to keep the driver tube 45 from axial movement but allowing it to rotate." <i>Id.</i>, 8:48-53; <i>see also id.</i>, FIGS. 13, 15-17.</p>
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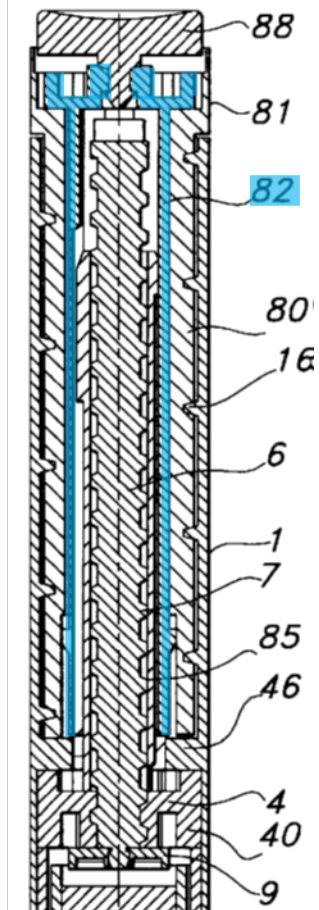
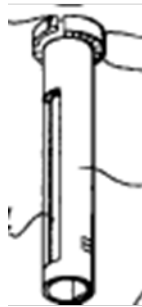
In several places, Steinfeldt-Jensen states that its syringes include a "piston rod drive" that includes driver tube 85 (a sleeve rotationally coupled to the piston rod due to its unthreaded, non-circular cross-section) and member 40 (an element that has a threaded circular opening and that is fixed to the housing). *See, e.g.*, EX1014, Abstract, 2:46-53, claims 1, 6, 11; EX1011, ¶618. Driver tube 85

constitutes a drive sleeve that extends along a portion of piston rod 6 and is releasably connected to scale drum 80. EX1011, ¶619. Driver tube 85 couples to scale drum 80’s rotational movement only during the injection process. *Id.* To drive piston rod 6, driver tube 85 rotationally engages with the rod through a bore having a non-circular cross-section, rather than an internal threading near a distal portion. *Id.*, ¶620. As explained more in section V.E.2, a POSA would have considered it obvious to modify the piston rod drive to provide the “driving member” of claim 21.

Steenfeldt-Jensen taught element [21.4].

'844 Patent	Steenfeldt-Jensen
<p>[21.4] a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;</p>	<div data-bbox="906 1056 1112 1690" data-label="Image"> </div> <p>EX1014, FIG. 16 (detail; annotating bushing 82 blue); EX1011, ¶627.</p> <p>“A bushing 82 having a flange 83 at its proximal end ...</p>

fits into the scale drum 80 and over the driver tube 85[.]” EX1014, 11:26-33 (emphasis added), FIG. 17.



See id., FIGS. 17 (detail, left; bushing 82), 16 (detail, right; annotating bushing 82 blue); EX1011, ¶627.

“At its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81 which on its cylindrical outer wall is knurled to ensure a good finger grip.” EX1014, 11:22-25.

“In the dose setting button [81] a compartment is provided having ... a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the

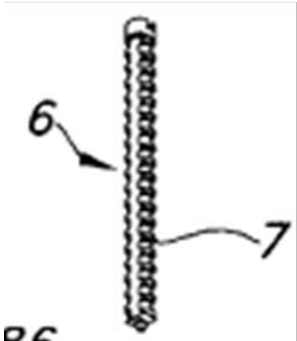
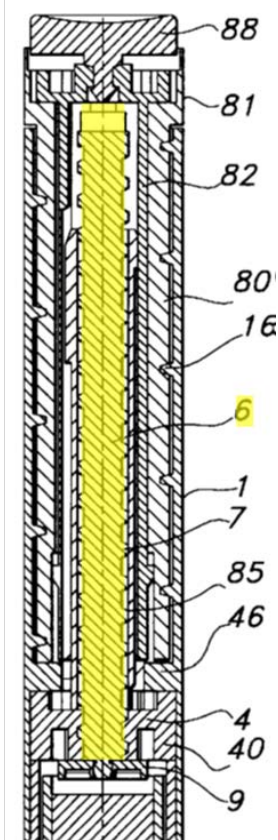
	<p>bushing 82 is adopted in said compartment At its distal side [<i>i.e.</i>, needle-end side] the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment.” EX1014, 11:34-42, FIG. 17.</p> <p>“During the [dose] setting the rosette in the dose setting button [81] forces the rosette 93 on the flange 83 of the bushing 82 out of engagement.” <i>Id.</i>, 12:1-3.</p> <p>“When the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81.” <i>Id.</i>, 12:4-13.</p>
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Steenfeldt-Jensen disclosed the claimed “sleeve” in the form of bushing 82. As shown in FIG. 17, bushing 82 is a tubular structure that is disposed between dose indicator 80 and drive member 85. *See* EX1014, 11:26-27, 12:4-13; FIGS. 15-17; EX1011, ¶628.

Bushing 82 also is a clutch due to rosette of teeth 93, which are configured to releasably engage with corresponding teeth on dose-setting button 81. *See* EX1014, 12:4-12; EX1011, ¶629. This likewise makes bushing 82 releasably connected to scale drum 80 because dose-setting button 81 is integrally formed with scale drum 80. *See* EX1014, 11:22-25; EX1011, ¶629. When engaged, rotation of dose-setting button 81 is transmitted to driver tube 85 during dose

dispensing via bushing 82. *See* EX1014, 12:4-12; EX1011, ¶630. Thus, bushing 82 also serves as a clutch because it releasably couples movement of moveable dose-setting button 81 of scale drum 80 to moveable driver tube 85. *See* EX1011, ¶630. Accordingly, Steenfeldt-Jensen taught the “sleeve” recited in element [21.4].

Steenfeldt-Jensen taught element [21.5].

'844 Patent	Steenfeldt-Jensen
<p>[21.5] a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;</p>	<p>“ [P]iston rod 6 having an external thread 7 mating the [internal] thread 5 of [a central bore of end wall 4] extends through said bore.” EX1014, 5:57-58; <i>see also id.</i>, FIGS. 15-17.</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div>

	<p><i>See id.</i>, FIGS. 17 (detail, left), 16 (detail, right; annotating piston rod 6 yellow)); EX1011, ¶631.</p> <p>“The end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing[.]” EX1014, 8:35-38; <i>see also id.</i>, FIGS. 15-17.</p> <p>“[T]hread of the piston rod and the thread in the end wall [4] of the housing [are] so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment.” <i>Id.</i>, 11:11-19.</p>
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Steenfeldt-Jensen disclosed a “piston rod” in the form of piston rod 6. *Id.*, 5:55-58, FIGS. 15-17; EX1011, ¶631. “A piston rod 6 having an external thread 7 mating the [internal] thread 5 of [a central bore of end wall 4] extends through said bore.” EX1014, 5:57-58; *see also id.*, FIGS. 15-17. End wall 4 with internal thread 5 is provided in separate member 40. *Id.*, 8:35-38. As discussed above with respect to the driving member element, it would have been obvious for external thread 7 of the piston rod to mate with internal threads of driver tube 85. EX1011, ¶632. This modification is discussed in detail in Section V.I.1.b.

Steenfeldt-Jensen taught element [21.6].

'844 Patent	Steenfeldt-Jensen
[21.6] a piston rod	“[P]iston rod drive including a first part having an

<p>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;</p>	<p>internal thread mating the thread of said piston rod..., [and] a second part mating with the not circular cross-section of said piston rod, wherein said first and second parts are rotatable relative to one another to drive the piston rod in an axial direction” <i>Id.</i>, 14:9-40 (claim 11); <i>see also id.</i>, 2:46-53 (describing parts as “a nut member” and a “piston rod guide,” respectively). “[A] unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not in the opposite direction” <i>Id.</i>, 2:65-3:1; <i>see also id.</i>, 14:26 (claim 11, “one-way coupling”). “The unidirectional coupling may be a coupling comprising a pawl sliding over a pawl wheel” <i>Id.</i>, 3:28-29. “The end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing, the member 40 having protrusions 41 engaging slots 42 in the housing to lock the member 40 to the housing 1. Further the member 40 has at its periphery longitudinal recesses 43 which are engaged by not shown internal ribs in the housing to lock the member 40 against rotation relative to the housing.” <i>Id.</i>, 8:35-42, FIGS. 15-17. “To set a dose the button 23 is rotated in a clockwise direction. This rotation is due to the coupling between</p>
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the ribs 61 and the slots 62 transmitted to the nut member 48 which is then screwed in distal direction along the driver tube 45 which is held inrotatably in the housing due to the reluctan[ce] of the pawl 13 to move along the pawl teeth in the member 40.” *Id.*, 9:36-42.

“To maintain a clockwise rotation of a dose setting button [81] for increasing the set dose the pawl mechanism working between the driver tube [85] and the housing is turned so that it bars clockwise rotation and reluctantly allows anticlockwise rotation of the driver tube. Further the thread of the piston rod and the thread in the end wall [4] of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube.” *Id.*, 11:6-19.

“When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end [*i.e.*, button-end] of the housing. The bushing [82] is kept non-rotated due to its coupling to the driver tube which is locked against

	<p>clockwise rotation and if a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction the pawl mechanism working between the driver tube and the housing is sufficient[ly] reluctant to rotate in its not blocking direction to prevent the bushing 82 from following this anticlockwise rotation.” <i>Id.</i>, 11:52-62.</p> <p>“When the injection button 88 is pressed to inject the set dose ... [t]he bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed further into an ampoule 89 in the ampoule holder 2.” <i>Id.</i>, 12:4-12.</p>
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Steenfeldt-Jensen disclosed a “piston rod holder” in the form of member 40. Member 40 is rotatably fixed relative to the housing. EX1014, 8:35-42 (longitudinal recesses 43 of member 40 with internal ribs of housing 1 “lock the member 40 against rotation relative to the housing”); EX1011, ¶633.

By virtue of being rotatably fixed relative to the housing, member 40 is configured to prevent the piston rod from rotating relative to the housing during dose setting via the interaction of its pawl wheel teeth with the pawl wheel of driver tube 85. *Id.*, 8:48-53, 11:6-19, 11:52-62; EX1011, ¶634. The pawl mechanism is designed to bar clockwise rotation of driver tube 85 relative to housing 1. *See* EX1014, 11:6-19; EX1011, ¶634. Thus, when dose-setting button

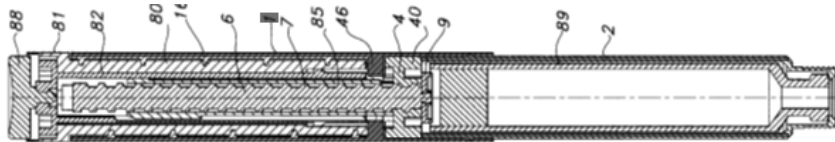
81 is rotated clockwise to dial-up a dose, the corresponding rotation of scale drum 80 is not transmitted to driver tube 85 (or thereby to the piston rod) due to the pawl mechanism. *See* EX1014, 11:52-62; EX1011, ¶634. Moreover, if a user needs to dial-down a dose, dose-setting button 81 is rotated anticlockwise, but the corresponding rotation of the scale drum 80 is still not transmitted to driver tube 85 (or thereby to the piston rod) due to the pawl mechanism's "sufficient reluctan[ce]" against anticlockwise rotation. *See* EX1014, 11:52-62; EX1011, ¶635. Thus, because piston rod 6 is coupled to driver tube 85 in such a way that "rotation is transmitted," EX1014, 11:15-19, and because driver tube 85 does not rotate during dose setting, piston rod 6 also does not rotate during dose setting. *See* EX1011, ¶635.

As discussed in Section V.E.1.b, it would have been obvious to a POSA to modify the piston rod drive so that the internal threads of the piston rod drive are located on driver tube 85 instead of on member 40 and so that member 40 (instead of driver tube 85) mates with the not circular cross section of the piston rod. With this modification, member 40 would still be rotatably fixed to the housing and would still prevent the piston rod from rotating relative to the housing during dose setting. EX1011, ¶636-638.

Both with and without the modification, member 40 permits the piston rod to traverse axially towards the dose dispensing end during dose dispensing. EX1011,

¶638. Prior to modification, the “thread of the piston rod and the thread in the end wall [4] of the housing [are] so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment.” *Id.*, 11:11-15. “When the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 ... [and t]he bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed further into an ampoule 89 in the ampoule holder 2.” *Id.*, 12:4-12. Swapping the location of the threads and the non-circular cross section between driver tube 85 and member 40 would result in member 40 being configured to (i) prevent the piston rod from rotating relative to the housing during dose setting; and (ii) permit the piston rod to traverse axially towards the dose dispensing end during dose dispensing, as recited in element [21.6]. EX1011, ¶639.

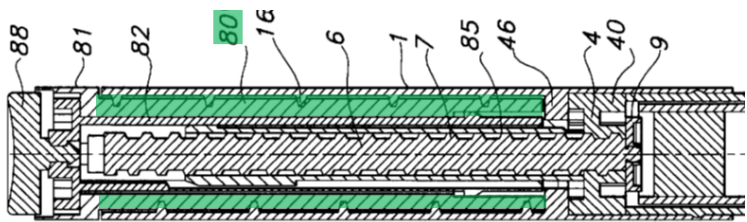
Steenfeldt-Jensen taught element [21.7].

'844 Patent	Steenfeldt-Jensen
[21.7] wherein: the housing is disposed at an outermost position of the drug delivery device;	<p data-bbox="578 1566 1430 1730">“The syringe comprise[s] a tubular housing 1 ... [into] which an ampoule holder 2 is snapped[.]” EX1014, 5:38-44, FIGS. 15-17.</p> 

	<i>Id.</i> , FIG. 16 (annotating housing 1 gray); EX1011, ¶640.
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As shown in FIGS. 15-17, housing 1 and ampoule holder 2 are disposed at an outermost position of the drug-delivery device. EX1011, ¶641. Accordingly, Steinfeldt-Jensen satisfies element [21.7].

Steenfeldt-Jensen taught element [21.8].

'844 Patent	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;	<p>“[S]cale drum 80 is in its outer wall provided with a helical track which is engaged by a helical rib 16 along the inner wall of the housing 1.” EX1014, 11:20-22, FIGS. 15-17.</p>  <p><i>Id.</i>, FIG. 16 (detail; annotating scale drum 80 green); EX1011, ¶642.</p> <p>“[B]ushing 82 ... fits into the scale drum 80[.]” EX1014, 11:26-28, FIG. 17.</p> <p>“When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing[.]” <i>Id.</i>, 11:52-54.</p> <p>“When the injection button 88 is pressed to inject the set dose ... the anticlockwise rotation of the dose setting</p>

	button 81 ... is induced by the thread engagement between the helical track of the scale drum 80 and the rib 16 in the housing when the scale drum 80 is pressed back into said housing.” <i>Id.</i> , 12:4-10.
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As shown in FIGS. 15-17, scale drum 80 is disposed between housing 1 and bushing 82. *See also* EX1014, 11:20-28; EX1011, ¶642. Scale drum 80 is configured to (i) rotate clockwise and traverse axially away from the dose dispensing end during dose setting and (ii) rotate counterclockwise and traverse axially towards the dose dispensing end during dose dispensing. *Id.*, 11:52-54, 12:4-9; EX1011, ¶644. Accordingly, Steenfeldt-Jensen taught the “the dose indicator is disposed between the housing and the sleeve and is configured to rotate and traverse” as recited in element [21.8].

Steenfeldt-Jensen suggests element [21.9]:

'844 Patent	Steenfeldt-Jensen
[21.9] the driving member is configured to rotate relative to the piston rod;	<i>See</i> element 21.3 above. “[T]he thread of the piston rod and the thread in the end wall [4] of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way

	<p>rotation is transmitted[.]” <i>Id.</i>, 11:11-18.</p> <p>“When the injection button 88 is pressed to inject the set dose ... [t]he bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed further into an ampoule 89 in the ampoule holder 2.” <i>Id.</i>, 12:4-12.</p>
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Steenfeldt-Jensen disclosed that member 40 rotates relative to piston rod 6. As Leinsing explains, pawl 13 engages pawl teeth provided in the member 40 to allow for rotation between member 40 and driver tube 85 during dose dispensing. EX1011, ¶646; *see also* EX1014, 8:48-53, 11:6-19, 11:52-62, 12:4-12. Member 40 thus rotates relative to the piston rod because the piston rod 6 is coupled to the driver tube 85 in such a way that “rotation is transmitted.” EX1014, 11:15-19. As discussed further in Section V.I.1.b, it would have been obvious to modify the piston rod drive so that the internal threads of the piston rod drive are located on driver tube 85 instead of member 40 and so that member 40 (instead of driver tube 85) mates with the not circular cross section of the piston rod. *See, e.g.*, EX1011, ¶647. In such an embodiment, driver tube 85 rotates relative to piston rod 6 during dose dispensing, as recited in element [21.9].

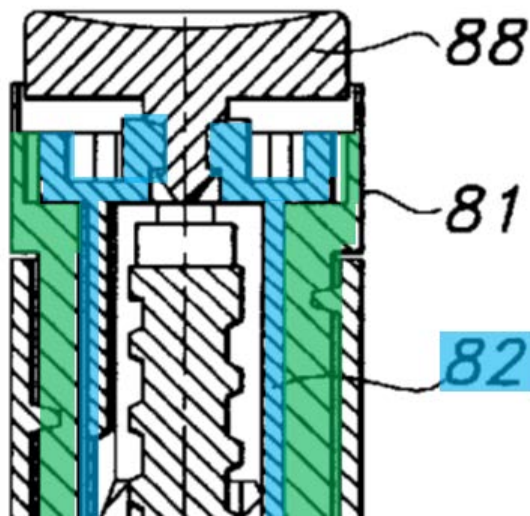
Steenfeldt-Jensen taught element [21.10]:

'844 Patent	Steenfeldt-Jensen
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[21.10] the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and

“A bushing 82 having a flange 83 at its proximal end and having a pair of opposite longitudinal slots 84 through its side walls fits into the scale drum 80 and over the driver tube 85 which tube has on its outer wall hooks 86 engaging the slots 84 of the bushing 82 whereby the bushing 82 and the 30 driver tube 85 is coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements.” EX1014, 11:26-33.

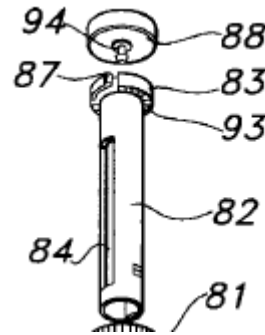
“The bushing [82] is kept non-rotated due to its coupling to the driver tube[.]” *Id.*, 11:55-56.



Id., FIG. 16 (detail; annotating bushing 82 blue and drum 80 green); EX1011, ¶650.

“The bushing 82 is mounted in the scale drum 80 with protrusion on the outer wall of the bushing 82 engaging recesses in the inner wall of the scale drum 80 so that limited movement of the bushing in the scale drum is

allowed so that the bushing can be moved axially relative to the scale drum to make or not make the teeth of said rosettes engage each other.” EX1014, 11:43-49.



Id., FIG. 17; 1011, ¶650.

“When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing [.]” EX1014., 11:52-54.

“When the injection button 88 is pressed to inject the set dose ... the scale drum 80 is pressed back into said housing.” *Id.*, 12:4-9.

Bushing 82 is rotatably fixed relative to driver tube 85. EX1011, ¶649.

Driver tube 85 “has on its outer wall hooks 86 engaging the slots 84 of the bushing 82 whereby the bushing 82 and the 30 driver tube 85 is coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements.” *Id.*, 11:26-33; *see also id.*, 11:55-56 (“bushing [82] is kept non-rotated due to its coupling to the driver tube”).

Bushing 82 is also configured to traverse axially with the dose indicator. As disclosed in FIGS. 15-17, flange 83 of bushing 82 protrudes over scale drum 80 at

the button end of the device. EX1011, ¶650. “When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing [.]” EX1014, 11:52-54. Bushing 82 is configured to axially traverse out of the housing with scale drum 80 to permit scale drum 80 to traverses axially out of the housing because flange 83 of bushing 82 protrudes over the proximal end of scale drum 80.¹⁰ EX1011, ¶650. Longitudinal slots 84 through side walls of bushing 82 permit bushing 82 to translate axially without transmitting longitudinal (*i.e.*, axial) displacement to the driver tube 85. EX1014, 11:26-33. Bushing 82 is thus configured to traverse axially with scale drum 80 during dose setting. EX1011, ¶651.

Bushing 82 is also configured to traverse axially with scale drum 80 during dose dispensing. EX1011, ¶652. “When the injection button 88 is pressed to inject the set dose said rosettes [on upper surface of dose-setting button 81 and distal surface of flange 83 of bushing 82] are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 ...

¹⁰ This embodiment in FIG. 16 is distinguishable from that shown in FIGS. 11-13 in which “a bushing 53 is secured to be non rotatable an[d] non displaceable to said housing” via engagement of housing lugs 54 and bushing recesses. EX1014, 8:63-67.

when the scale drum 80 is pressed back into said housing.” *Id.*, 12:4-9. As shown in FIGS. 15-16, injection button 88 pushes scale drum 80 back into the housing via bushing 82. Bushing 82 thus is configured to traverse axially towards the dose dispensing end with scale drum 80 during dose dispensing.

Accordingly, Steinfeldt-Jensen taught the “the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator” as recited in element [21.10].

Steenfeldt-Jensen suggests element [21.11]:

'844 Patent	Steenfeldt-Jensen
[21.11] the piston rod and the driving member are configured to rotate relative to one another during dose dispensing;	<p><i>See</i> element 21.3 above.</p> <p>“[T]he thread of the piston rod and the thread in the end wall [4] of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way rotation is transmitted[.]” <i>Id.</i>, 11:11-18.</p> <p>“When the injection button 88 is pressed to inject the set dose ... [t]he bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed further into an ampoule 89 in the ampoule</p>

	holder 2.” <i>Id.</i> , 12:4-12.
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Steenfeldt-Jensen disclosed that piston rod 6 and member 40 are configured to rotate relative to one another during dose dispensing. Pawl 13 engages pawl teeth provided in member 40 to allow for rotation between member 40 and driver tube 85 during dose dispensing. EX1011, ¶654; *see also* EX1014, 8:48-53, 11:6-19, 11:52-62, 12:4-12. Member 40 and piston rod 6 thus rotate relative to one another because the piston rod 6 is coupled to driver tube 85 in such a way that “rotation is transmitted.” EX1014, 11:15-19; EX1011, ¶654. As discussed further in §V.E.1.b, it would have been obvious to modify the piston rod drive so the internal threads of the piston rod drive are located on driver tube 85 instead of member 40 and so member 40 (instead of the driver tube 85) mates with the not circular cross section of the piston rod. EX1011, ¶655. In such an embodiment, driver tube 85 and piston rod 6 rotate relative to one another during dose dispensing as recited in element [21.11].

Steenfeldt-Jensen taught element [21.12]:

'844 Patent	Steenfeldt-Jensen
[21.12] and the piston rod is configured to traverse axially towards the dose dispensing end	“[T]he thread of the piston rod and the thread in the end wall [4] of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder

during dose dispensing.	<p>compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube.” <i>Id.</i>, 11:11-19.</p> <p>“When the injection button 88 is pressed to inject the set dose ... [t]he bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed further into an ampoule 89 in the ampoule holder 2.” <i>Id.</i>, 12:4-12.</p>
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Both with and without the modification, piston rod 16 is configured to traverse axially towards the dose-dispensing end during dose dispensing. EX1011, ¶656. Prior to modification, the “thread of the piston rod and the thread in the end wall [4] of the housing [are] so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment.” EX1014, 11:11-15. “When the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 ... [and t]he bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed

further into an ampoule 89 in the ampoule holder 2.” *Id.*, 12:4-12. Swapping the location of the threads and the non-circular cross section as between driver tube 85 and member 40 still would result in piston rod 6 configured to traverse axially towards the dose dispensing end during dose dispensing, as recited in element [21.12]. EX1011, ¶657.

b. Reason to modify and reasonable expectation of success

As described above, Steenfeldt-Jensen disclosed a piston-rod drive comprising driver tube 85. While driver tube 85 (the driver) does not show internal threading in the FIGS. 15-17 embodiment, Steenfeldt-Jensen suggests an alternative embodiment in which (1) driver tube 85 does have such threading and rotates relative to piston rod 6 during injection to drive the piston rod through member 40 and (2) member 40 operates as a non-threaded piston-rod guide, preventing rotation of piston rod 6 relative to the housing but allowing axial displacement. In such an embodiment, a POSA would have considered driver tube 85 to meet all limitation of the recited “driving member” and member 40 to meet all limitations of the recited “piston rod holder.” *See* EX1011, ¶¶620-621.

Steenfeldt-Jensen expressly contemplates a modification in which the driver tube contains an internal threading that engages the piston rod’s external threading. EX1011, ¶622. Steenfeldt-Jensen initially teaches this type of embodiment in general terms, describing a driving mechanism that includes two elements: (1) a

“piston rod guide” relative to which the piston rod is “axially displaceable but not rotatable” and (2) a “nut member” that is “rotatable but not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod[.]” EX1014, 2:40-53. Steinfeldt-Jensen then describes alternative ways to drive the piston rod: rotation of the scale drum can rotate the piston rod relative to the nut member, or rotation of the scale drum can rotate the nut member relative to the piston rod. *Id.*, 3:15-20, 3:41-47; EX1011, ¶622. In the latter approach, the piston rod would be prevented from rotating relative to a piston rod guide, such that the rotating nut would drive the piston rod through the piston rod guide. EX1011, ¶622.

The former approach reflects the operation of the embodiment shown in FIGS. 15-17, as driver tube 85 is rotationally coupled to piston rod 6, and rotation of scale drum 80 during injection rotates driver tube 85 and piston rod 6 relative to member 40, which is essentially a fixed “nut member.” *See* EX1014, 11:6-19; 12:4-12; EX1011, ¶623. Steinfeldt-Jensen expressly suggests that embodiments using the former (fixed-nut) approach can be implemented using the latter (rotating-nut) approach. EX1014, 7:44-47 (“Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the

invention.”); *see also id.*, 3:15-20, 3:44-47 (suggesting interchangeability of fixed and rotating drive nuts); EX1011, ¶623.

Given Steinfeldt-Jensen’s suggestion that fixed-nut and rotating-nut approaches are interchangeable, and given its express contemplation of such alternative configurations of the piston rod drive (*see id.* 7:41-47), a POSA would have interpreted Steinfeldt-Jensen as suggesting that driver tube 85 could be implemented with internal threading (*i.e.* as a rotating nut element), while member 40 could be implemented as a fixed piston rod guide (*i.e.* preventing rotation of piston rod 6 relative to the housing). *See* EX1011, ¶624. A POSA thus would have had reason to modify (1) driver tube 85 to include an internal threading for engaging the external threading of piston rod 6, and (2) member 40 to include a non-circular cross-section for preventing rotation of piston rod 6 relative to the housing while permitting axial displacement. *See id.*

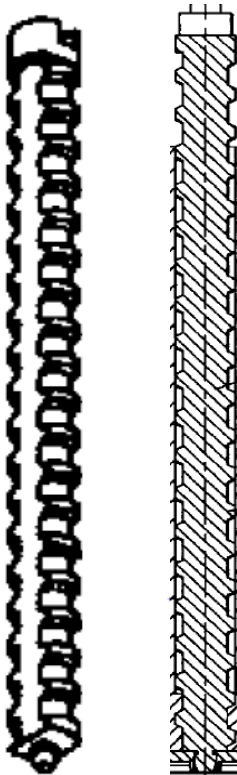
A POSA would have reasonably expected success with the suggested embodiment. A POSA would have been familiar with the structure and operation of drive nuts that rotate to push a non-rotating piston rod forward. *See* EX1011, ¶625. Steinfeldt-Jensen’s repeated indication of the interchangeability of fixed-nut and rotating-nut embodiments further demonstrates that POSAs expected such modifications to involve the use of familiar elements operating in a predictable manner. *Id.* A POSA would have recognized that all other aspects of the device

could operate in the same manner as before, so the modification would not change the device's principle of operation. *Id.* Moreover, the design and operation of the rotating-nut version of driver tube 85 would have been routine and predictable. *See* EX1011, ¶626. The above modification thus would have involved the use of well-known, familiar elements performing their same, predictable functions. *See KSR*, 550 U.S. at 417.

Accordingly, claim 21 as a whole was obvious over Steenfeldt-Jensen.

2. Claim 22

Steenfeldt-Jensen disclosed claim 22:

'844 Patent	Steenfeldt-Jensen
<p>[22] The drug delivery device of claim 21 where the piston rod has a circular cross-section.</p>	<p><i>See</i> claim 21 above.</p> 

	EX1014, FIGS. 16-17 (details); EX1011, ¶658.
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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, ¶658. Further, as Leinsing explains, piston rod 6 has a “circular cross-section” with flat sides. *Id.*, ¶658. Steenfeldt-Jensen 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.

3. Claim 23

Steenfeldt-Jensen disclosed claim 23:

'844 Patent	Steenfeldt-Jensen
[23] The drug delivery device of claim 21 further comprising a clutch.	<p>“In the dose setting button [81] a compartment is provided having ... a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment At its distal side [<i>i.e.</i>, needle-end side] the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment.” EX1014, 11:34-42, FIG. 17.</p> <p>“During the [dose] setting the rosette in the dose setting</p>

	<p>button [81] forces the rosette 93 on the flange 83 of the bushing 82 out of engagement.” <i>Id.</i>, 12:1-3.</p> <p>“When the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81.” <i>Id.</i>, 12:4-13.</p>
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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. This Petition relies on bushing 82 of Steinfeldt-Jensen to meet the sleeve limitation of element [21.4], as well as the clutch limitation of claim 23. EX1011, ¶659-660. In particular, flange 83 with rosette 93 of teeth engages corresponding teeth in a compartment of dose-setting button 81 to releasably couple the components. EX1014, 11:34-42.

The '844 patent does not specifically discuss a “sleeve” that is disposed between the “dose indicator” and the “driving member,” and is also releasably connected to the “dose indicator.” The '844 patent discloses “clutch 60” that is “disposed about the drive sleeve 30, between the drive sleeve 30 and a dose dial sleeve 70.” EX1004. 4:42-44. Clutch 60 is “generally cylindrical.” *Id.*, 4:59-60. “Dose dial sleeve 70” serves as the dose indicator of claim 21, as a visual indication of the dose that may be dialed “is provided on the outer surface of the dose sleeve 70.” “Drive sleeve 30” serves as the driving member.

As taught by the '844 patent, when a dose is dialed, clicker 50 and clutch 60 are engaged, and drive sleeve 30, clicker 50, clutch means 60, and dose dial sleeve 70 rotate with the dose dial grip 76. *Id.*, 5:60-63. EX1011, ¶661. The dose is dispensed by depressing button 82, which displaces clutch 60 axially with respect to dose dial sleeve 70. Thus, clutch 60 is disposed between the dose indicator (dose dial sleeve 70) and the driving member (drive sleeve 30) and is (ii) releasably connected to the dose indicator (dose dial sleeve 70) as the clutch 60 is displaced with respect to dose dial sleeve 70 upon dosing. Thus, 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.

4. Claims 24-25 and 29

Steenfeldt-Jensen satisfied claims 24-25 and 29:

'844 Patent	Steenfeldt-Jensen
[24] The drug delivery device of claim 23 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.	<i>See</i> claims 21 and 23 and element [21.4] above. “The flange 83 of the bushing 82 is adopted in said compartment and has at its periphery a radial protrusion 87 which is biased toward the side wall of the compartment.” EX1014, 11:37-40. “Therefore by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 to the next
[25] The drug delivery	

<p>device of claim 24 where the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.</p> <p>[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.</p>	<p>one, the recesses being so spaced that one click corresponds to a chosen change of the set dose, e. g. one unit or a half unit.” <i>Id.</i>, 11:62-67</p> <p>“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.” <i>Id.</i>, 6:48-53.</p>
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Steenfeldt-Jensen taught a clicking system that operates by having protrusion 87 extend from bushing 82 into a number of depressions or recesses such that the spacing of the depressions or recesses causes tactile and audible feedback as the protrusions snap into the depressions when dose-setting button 81 is rotated “in any direction.” EX1014, 6:48-54, 11:37-40, 11:62-67; *see also* EX1011, ¶¶662-663. Clicker means were well known elsewhere in the art. *See, e.g.*, EX1013, 10:42-52.

Steenfeldt-Jensen expressly taught that “[t]he 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.” EX1014, 6:48-53 (emphasis added); EX1011, ¶¶664, 679-680. It thus taught that the clutch provides both audible and tactile feedback indicative of unit doses of medicament.

Steenfeldt-Jensen also taught that the clicking occurs when dose-setting button 81 is rotated “in any direction,” which includes the dose cancelling direction. EX1014, 11:62-67. EX1011, ¶665. It also taught that each click is equal to a unit dose of medicament: “the recesses being so spaced that one click corresponds to a chosen change of the set dose, e. g. *one unit* or a half unit.” *Id.*, 11:62-67 (emphasis added); EX1011, ¶666.

Steenfeldt-Jensen thus taught the drug-delivery device of claims 21 and 23 where the clutch provides audible and tactile feedback indicative of unit doses of medicament, where the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament, and where the pen comprises a clicker that provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament, as recited respectively in claims 24, 25,

and 29. Each of claims 24, 25, and 29 as a whole was thus obvious over Steenfeldt-Jensen.

Moreover, to the extent that “clicker” is a means-plus-function limitation, Steenfeldt-Jensen teaches it as well. EX1011, ¶684. The ’844 patent teaches that in dialing a dose, “flexible arm 52” with “toothed member 54” is dragged over “splines 42” to produce a click. EX1004, 5:64-6:3. Thus, a structure taught by the ’844 patent that is used to provide an audible click is a flexible arm being dragged over splines.

Steenfeldt-Jensen teaches identifies radial protrusion 87 as providing the clicking in the embodiment as shown in FIG. 15-17. Radial protrusion 87 sits in a compartment of dose setting button 81 that includes “axial recesses” (*i.e.* splines) and is “biased toward the side wall of the compartment.” EX1014, 11:34-42; 11:52-67. When dose-setting button 81 rotates, “radial protrusion 87...will click from one of the axial recess[es] in the inner wall of the dose-setting button 81 to the next one....” *Id.*, 11:52-67. Thus, Steenfeldt-Jensen teaches the use of a flexible arm being dragged over splines to create an audible click, and thus, teaches the same structure performing the same function.

5. Claim 26

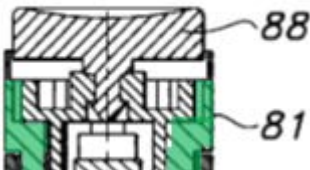

Steenfeldt-Jensen disclosed the “drug delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament,” as recited in

claim 26. Claim 24 is obvious over Steinfeldt-Jensen for the reasons discussed above.

Steenfeldt-Jensen taught the clutch allows dose cancelling without dispensing medicament. EX1011, ¶668. “It must be possible with a minimum of trouble to cancel or change a wrongly set dose” and a dose may be cancelled by preventing the button rotation from being “transmitted to the driver.” EX1014, 1:20-22, 2:24-28. In discussing FIGS. 15-17, Steinfeldt-Jensen describes how the bushing permits a dose-cancelling mechanism without rotating the bushing 82 and driving tube 85 to dispense the dose. “When a dose is set ... bushing is kept non rotated due to its coupling to the drive tube which is locked against clockwise rotation *and if a set dose is reduced by* rotating the dose setting button 81 in an anticlockwise direction the pawl mechanism ... is sufficient[ly] reluctant to rotate in its not blocking direction to prevent the bushing 82 from following this anticlockwise rotation.” *Id.*, 11:52-62 (emphasis added). Only when injection button 88 is pressed “so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81” will the bushing “rotate the driver tube 85” so that “the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2.” *Id.*, 12:1-13; EX1011, ¶669. Steinfeldt-Jensen thus taught a clutch that “allows the dose cancelling without dispensing medicament,” as recited in claim 26. EX1011, ¶669. Claim 26 as a whole was thus obvious over Steinfeldt-Jensen.

6. Claim 27

Steenfeldt-Jensen disclosed claim 27:

'844 Patent	Steenfeldt-Jensen
<p>[27] The drug delivery 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.</p>	<p>See claim 24 above.</p> <p>“At its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81, which on its cylindrical outer wall is knurled to ensure a good finger grip.” EX1014, 11:22-25; FIGS. 15-17.</p>  <p><i>Id.</i>, FIG. 16 (detail; annotating dose-setting button 81 green); EX1011, ¶671.</p>  <p>EX1014, FIG. 17 (detail; injection button 88); EX1011, ¶671.</p> <p>“An injection button 88 is rotatably mounted with a pivot pin 94 journaled in an end wall of the bushing 82.” <i>Id.</i>, 11:49-51.</p>

Steenfeldt-Jensen disclosed a “dose dial grip” in the form of dose-setting button 81, which the user rotates to set a dose. See EX1014, 11:22-25, 11:52-62,

FIGS. 15-17; EX1011, ¶670. Dose-setting button 81 is provided at the proximal (button-end) of scale drum 80. *Id.* FIGS. 15-17 demonstrate that injection button 88 is seated in an annular recess of dose-setting button 81 of scale drum 80 on a proximal end of scale drum 80. EX1011, ¶670. Injection button 88 fits within the cylindrical outer wall of dose-setting button 81. EX1014, 11:22-25, 12:4-9 (injection button 88 presses bushing 82 into engagement with scale drum 80); FIGS. 15-17.

Steenfeldt-Jensen also disclosed that injection button 88 is rotatable relative to scale drum 80. EX1011, ¶672. As shown in FIGS. 15-17, “injection button 88 is rotatably mounted with a pivot pin 94 journaled in an end wall of the bushing 82.” *Id.*, 11:49-51. During dose setting, bushing 82 is rotatable with respect to scale drum 80. *Id.*, 11:52-62 (“When a dose is set by rotating the dose-setting button 81 in a clockwise direction, the scale drum is screwed out of the housing ... [but t]he bushing [82] is kept non-rotated”). The rotatable mounting of injection button 88 on bushing 82 means that injection button 88 is rotatable relative to scale drum 80 during dose dispensing as well. EX1011, ¶672. Steenfeldt-Jensen thus renders obvious the “drug delivery 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,” as recited in claim 27. EX1011, ¶673.

7. Claim 28

Steenfeldt-Jensen disclosed the additional limitations of claim 28:

'844 Patent	Steenfeldt-Jensen
<p>[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.</p>	<p>See claim 27 above.</p> <p>“In the dose setting button [81] a compartment is provided having ... a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment At its distal [needle-end] side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment.” EX1014, 11:34-42, FIG. 17.</p> <p>“The bushing 82 is mounted in the scale drum 80 with protrusion on the outer wall of the bushing 82 engaging recesses in the inner wall of the scale drum 80 so that a limited movement of the bushing in the scale drum is allowed so that the <i>bushing can be moved axially relative to the scale drum to make or not make the teeth of said rosettes engage each other.</i>” <i>Id.</i>, 11:43-49 (emphasis added).</p> <p>“During the [dose] setting the rosette in the dose setting button [81] forces the rosette 93 on the flange 83 of the bushing 82 out of engagement.” <i>Id.</i>, 12:1-3.</p> <p>“When the injection button 88 is pressed to inject the set dose said rosettes are pressed into engagement so that</p>

	the ... bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed further into an ampoule 89 in the ampoule holder 2.” <i>Id.</i> , 12:4-12.
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Steenfeldt-Jensen disclosed that depression of injection button 88 initiates dose delivery by displacing bushing 82 axially with respect to scale drum 80 (and thereby driver tube 85). In a rest state, rosettes on the distal surface of flange 83 of bushing 82 are spaced apart from rosettes on the bottom of the compartment formed in dose-setting button 81. EX1014, 11:34-42, 12:1-3, FIG. 17. Dose-setting button 81 is part of scale drum 80, and rotation of the scale drum thus does not rotate the bushing (and thereby driving tube 85 or piston rod 6) when the rosettes between dose-setting button 81 and bushing 82 are spaced apart. EX1011, ¶674.

A “protrusion on the outer wall of the bushing 82” that engages “recesses in the inner wall of the scale drum 80” permits “limited movement of the bushing in the scale drum so ... that the bushing can be moved axially relative to the scale drum to make or not make the teeth of said rosettes engage each other.” EX1014, 11:43-49. Dose delivery is initiated by depressing injection button 88, which is mounted into bushing 82 “with a pivot pin 94 journaled in an end wall of the bushing 82.” *Id.*, 11:49-51. Depression of injection button 88 thus depresses

bushing 82 relative to scale drum 80 until the rosettes of bushing 82 and scale drum 80 come into contact with one another. *Id.*, 12:4-12. This same distally-applied pressure presses the scale drum 80 “back into said housing,” and rotates the driver tube 85 and piston rod in an anticlockwise direction such that “the piston rod is thereby screwed further into an ampoule 89” to dispense the dose. *Id.* This constitutes axial movement of the injection button 88 caused by distally applied pressure to the injection button 88 initiating dose delivery by displacing the bushing axially with respect to scale drum 80. EX1011, ¶675.

As injection button 88 and bushing 82 move axially in concert towards the dose dispensing end, driving tube 85 cannot move axially with them because driving tube 85 is fixed axially relative to the housing due to the disposition of its distal flange (i.e., pawl) between ring shaped wall 46 and the end wall 4 in the member 40. *See id.*, 8:48-53, FIGS. 15-17; EX1011, ¶676. In other words, depression of injection button 88 also causes axial displacement of bushing 82 with respect to driving tube 85. Steinfeldt-Jensen thus taught 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,” as recited in claim 28. EX1011, ¶677.

F. Ground 2: Claim 30 Is Obvious over Steinfeldt-Jensen In Further View of Klitgaard

As discussed above in Ground 1, Steinfeldt-Jensen renders claim 21 obvious. Employing a nut in the drug-delivery pen of Steinfeldt-Jensen to track each set dose of medicament would have been obvious in view of Klitgaard:

'844 Patent	Steinfeldt-Jensen & Klitgaard
<p>[30] The drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered.</p>	<div data-bbox="474 739 1253 1291"> <p>Fig. 3</p> </div> <p>EX1017, FIG. 3; EX1011, ¶687.</p> <p>“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</p>

	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, 4:16-58.
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Klitgaard disclosed an injection device for dispensing medicine. 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 set and prevents setting of a dose larger than the remaining liquid in the cartridge. *Id.*; EX1011, ¶686.

For example, FIG. 3 and its related description disclose nut member 32, which 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, ¶687.

Klitgaard expressly disclosed reasons a POSA would have had to employ a nut that tracks each set dose of medicament delivered 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 Steenfheldt-Jensen drug-delivery device discussed above regarding claim 21. EX1011, ¶¶688-689.

A POSA would have had a reasonable expectation of successfully incorporated such a nut into the drug delivery pen of Steenfheldt-Jensen . EX1011, ¶690. Nut member 32 as described in Klitgaard could be readily adapted and disposed between the bushing 82 and scale drum 80 to track each set dose of medicament delivered. *Id.*, ¶692.

Accordingly, claim 30 was obvious over the combination of the teachings of Steenfheldt-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 13,544, which is less than the 14,000 allowed under 37 C.F.R. 42.24(a)(i). In accordance with 37 C.F.R. 42.24(a), this word count does not include table of contents, table of authorities, mandatory notices under §42.8, certificate of service or word count, or appendix of exhibits or claim listing.

/Richard Torczon/
Reg. No. 34,448

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, I certify that I caused to be served a true and correct copy of the foregoing: **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 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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