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 IPR2018-01678
Patent No. 8,992,486

PETITION FOR *INTER PARTES* REVIEW

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1003	U.S. Patent 8,992,486, *Pen-Type Injector* (issued Mar. 31, 2015)
1004	U.S. Patent 9,526,844, *Pen-Type Injector* (issued Dec. 27, 2016)
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1023	U.S. Patent 5,226,895 – D.C. Harris, "Multiple Dose Injection Pen"

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1030	Memorandum Opinion, *Sanofi -Aventis U.S. LLC v. Eli Lilly and Co.*, No. 14-cv-113 (filed Jan. 20, 2015)
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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)

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

I. INTRODUCTION

Petitioner ("Mylan") seeks *inter partes* review of claims 1-6, 12-18, 20, 23, 26-30, 32, 33, 36, and 38-40 of U.S. Patent No. 8,992,486 ("the '486 patent," EX1003). 37 U.S.C. ch. 31. This petition shows a reasonable likelihood that the challenged claims are unpatentable.

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 '486 patent is asserted in *Sanofi-Aventis U.S. LLC. v. Mylan GmbH*, 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.

It also is 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 construing terms of related patents in *Sanofi -Aventis U.S. LLC v. Eli Lily and Co.*, No. 14-cv-113 (D. Del.) (terminated)). The real parties-in-interest named above are not parties to these litigations.

Mylan's IPR2018-01677 and IPR2018-01696 also challenge these claims. Mylan's IPR2018-01679 challenges other claims in this patent. Mylan has also filed IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-01680, IPR2018-01682, IPR2018-01684 and IPR2018-01696 against related patents.

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

34943.682.palib1@matters.wsgr.com and the email addresses above. A power of attorney accompanies this petition.

III. CERTIFICATIONS

Mylan certifies the '486 patent is available for IPR, and Mylan is not barred or estopped from requesting IPR on these grounds.

IV. IDENTIFICATION OF CHALLENGE; STATEMENT OF PRECISE RELIEF REQUESTED

Mylan seeks cancellation of the challenged claims for the reason stated below, supported with exhibits, including the Declaration of Karl R. Leinsing (EX1011). These claims are unpatentable under pre-AIA 35 U.S.C. 103 on these grounds:

Ground	Claims	Basis
1	1-6, 12-18, 20, 23, 26-30, 32-33, 36, 38-40	U.S. Patent 6,235,004 (EX1014, "Steenfeldt-Jensen")
2	1-6, 12-18, 20, 23, 26-30, 32-33, 36, 38-40	U.S. Patent Published Application 2002/0052578 (EX1015, "Møller") and Steenfeldt-Jensen

V. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Argument Summary

The challenged claims relate to a drive mechanism for dispensing medicine from a pen-type injector. The claims broadly recite a six-component structure that forms the mechanism. Those components include structural elements that are themselves claimed broadly. As shown below, however, each component and its structural elements were already known and commonly used in the art. What differences exist between 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). The challenged claims are therefore unpatentable.

B. The '486 Patent[1]

1. Background

The '486 patent relates to a pen-type injector for self-administering drugs. EX1003, Title, 1:20-24. Independent claim 1 recites:

> 1. A housing part for a medication dispensing apparatus, said housing part comprising:

[1] For uniformity, positioning and movement generally will be described relative to the device's "button-end" and "needle-end". *See* EX1011, ¶33.

a main housing, said main housing extending from a distal end to a proximal end;

a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing;

a dose knob disposed near a proximal end of said dose dial sleeve;

a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;

a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod; and,

a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob,

wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

Id., 6:59-7:12.

Claim 1 recites six components that form the device:

(1) "main housing" (4, gray), which houses the mechanism that dispenses medicine from a cartridge, EX1011, ¶¶24 n.4, 36;

(2) "dose dial sleeve" (70, green), which a user manipulates to set a dose for injection, *id.*, ¶36;

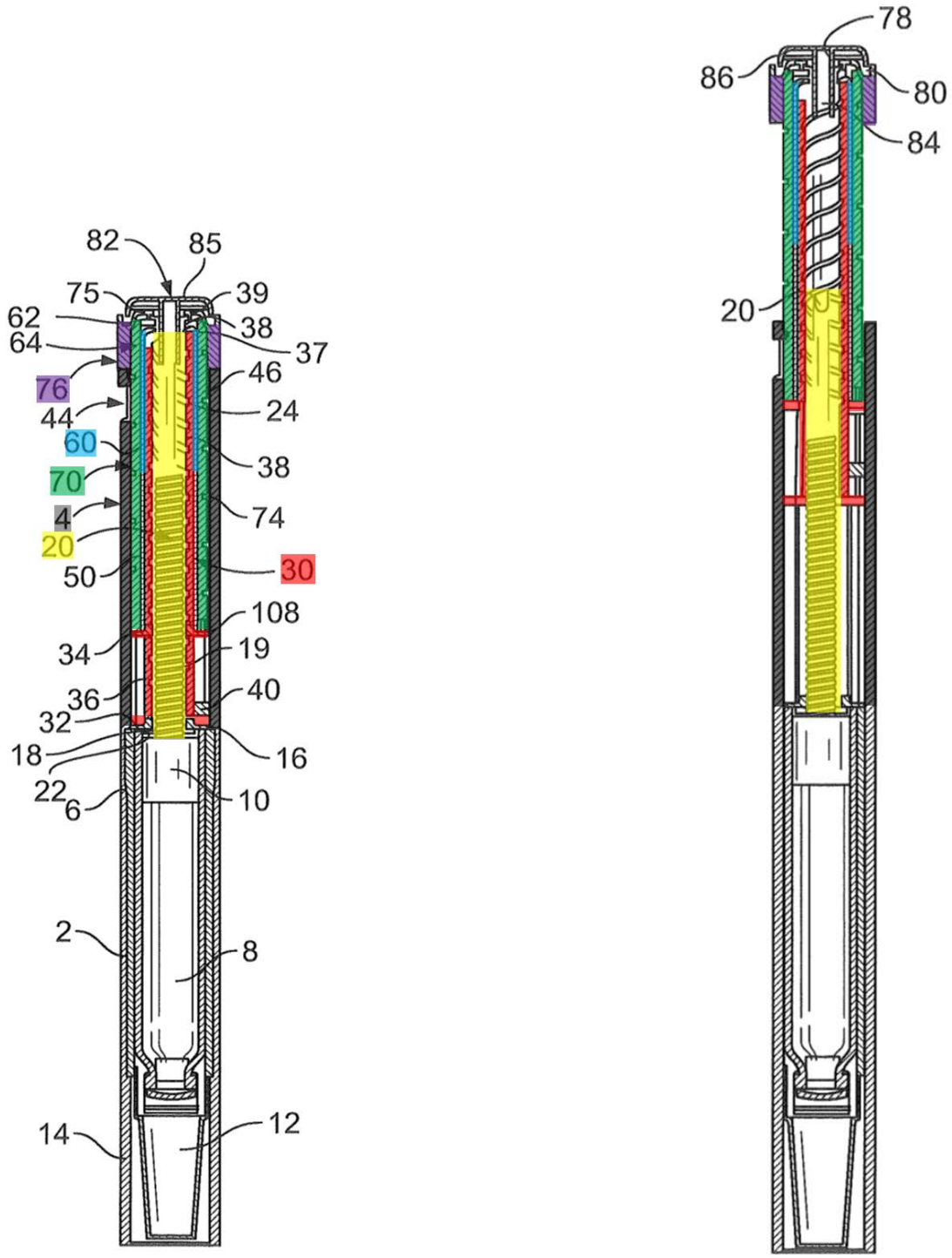
(3) “dose knob” (76, purple), which serves as a grip to manipulate the dose dial sleeve, *id.*;

(4) “piston rod” (20, yellow), which moves a piston to dispense medicine, *id.*;

(5) “driver” (30, red), which drives the piston rod to move the piston, *id.*; and

(6) “tubular clutch” (60, blue), which releasably connects components for common movement, *id.*

Below are annotated figures highlighting these components, *see* EX1011, ¶36:



Overview of the Disclosed Embodiment

The disclosed injector includes a housing formed by (1) a first cartridge retaining part 2 and (2) a main housing part 4 (gray). *See* EX1003, 3:27-38, FIG.

1; EX1011, ¶¶44-49. One embodiment includes insert 16 at housing part 4's needle-end. *Id.*, 3:49-50, FIG. 1; EX1011, ¶33. The insert is rotationally and axially fixed to the housing and includes a threaded circular opening 18. Piston rod 20's needle-end extends through the opening. *Id.*, 3:50-59, FIG. 1. Piston rod 20 includes first thread 19 that engages the insert's threaded opening 18. *Id.*, 3:56-59, FIG. 1. Piston rod 20 includes pressure foot 22 at the end that abuts piston 10 of cartridge 8. *Id.*, 3:59-61, FIG. 1.

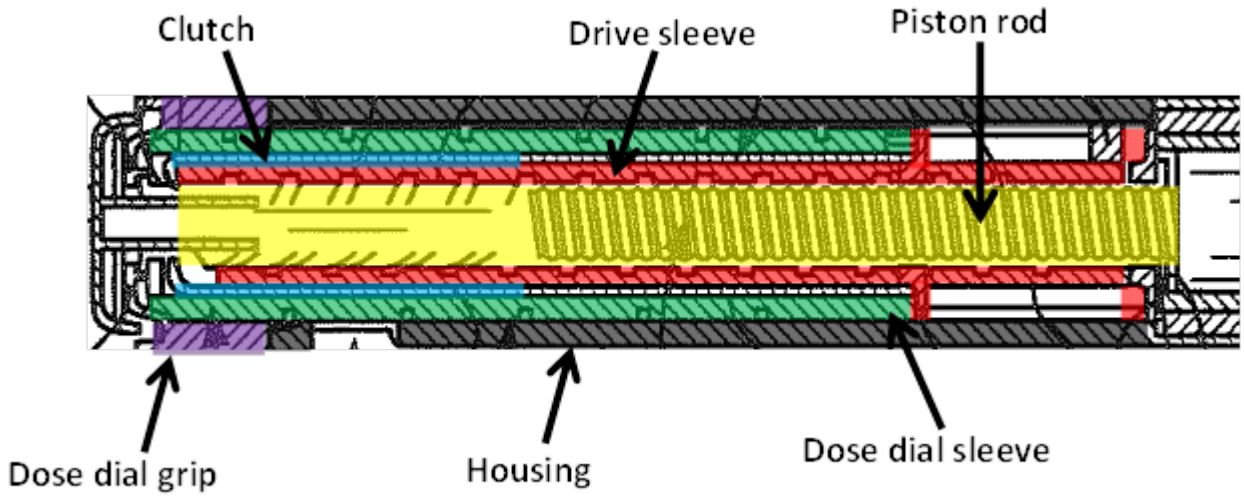


FIG. 1: Injector in a cartridge-full position, prior to dose setting

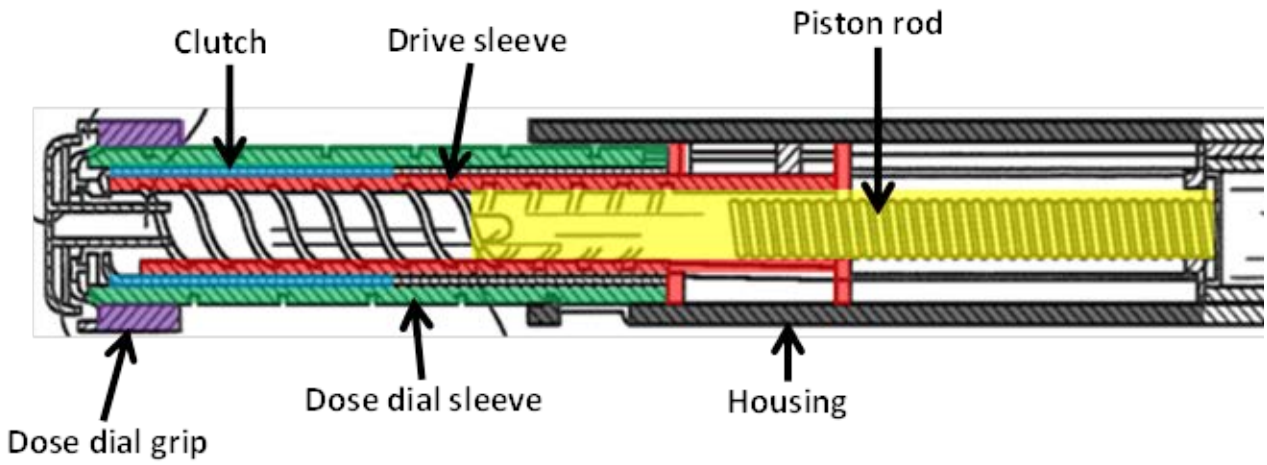


FIG. 2: Injector in a maximum dose-dialed position

EX1011, ¶42.

Piston rod 20 includes second thread 24, extending from its button-end. *See* EX1003, 3:61-62, FIGS. 1-2. Drive sleeve 30—elsewhere referred to as "driver"—extends about piston rod 20 and includes internal helical groove 38 that engages second thread 24. *Id.*, 4:4-13, FIG. 1.

Clutch 60 is "disposed about the drive sleeve, between the drive sleeve 30 and a dose dial sleeve 70." *Id.*, 4:33-35, FIGS. 1, 6-7. Clutch 60 is "generally cylindrical" and located adjacent driver 30's button-end. *Id.*, 4:50-52, FIG. 7. "The clutch 60 is keyed to the drive sleeve 30 by way of splines ... to prevent relative rotation between the clutch 60 and the driver 30." *Id.*, 4:60-62. Clutch 60's button-end includes dog teeth 65. *See* EX1003, 4:58-60, FIGS. 1-2, 8. Teeth 65 releasably engage dose-dial sleeve 70's button-end. *Id.*, 6:29-31, FIG. 1. The specification does not explain how teeth 65 engage dose-dial sleeve 70, though

they presumably engage "an inwardly directed flange in the form of [a] number of radially extending members 75" at dose-dial sleeve 70's button-end. *See* EX1011, ¶69 (citing EX1003, 5:22-24).

Dose-dial sleeve 70 is "provided outside of" the clutch 60 and "radially inward of" the housing 4. *Id.*, 5:6-5, FIG. 1. "A helical groove 74 is provided about an outer surface of the dose-dial sleeve 70." *Id.*, 5:5-6, FIGS. 1-2, 12. "The main 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.*, 5:9-11, FIGS. 15-16. Dose knob 76 (purple) "is disposed about an outer surface of the [button-end] of the dose dial sleeve 70." *Id.*, 5:24-25, FIGS. 1-2. "The dose knob 76 is secured to the dose dial sleeve 70 to prevent relative movement therebetween." *Id.*, 5:27-29.

Operation of the Pen Injector

Dose setting: To set a dose, the user rotates dose knob 76 one direction. *Id.*, 5:50-51, FIG. 9 (annotated below). Now clutch 60's teeth 66 engage dose-dial sleeve 70 (*id.*, 5:50-59) causing dose-dial sleeve 70, clutch 60, and driver 30 to rotate together out of the housing. *Id.*, FIG. 9. Driver 30 rotates up piston rod 20, toward its button-end, due to its engagement with piston rod 20's second thread 24. *Id.*, 5:61-65. Piston rod 20 cannot rotate due to its opposing, threaded engagement with the insert 16. *Id.*, 4:4-13, 6:1-3.

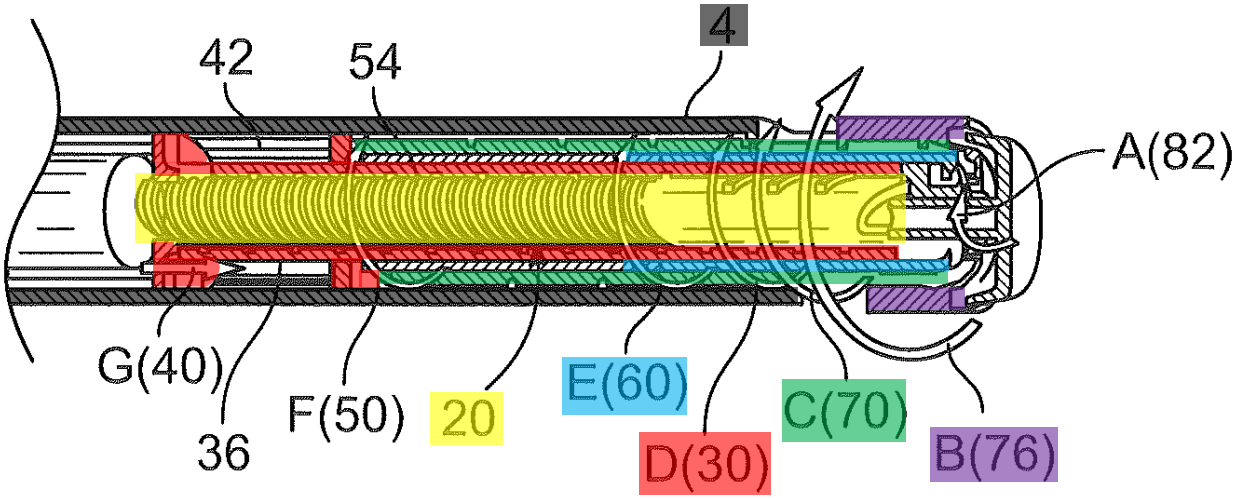


FIG. 9: Dialing up

EX1011, ¶81.

The user also may dial down a dose. *Id.*, 6:16-19, FIG. 10 (annotated below). To dial-down, the user rotates dose knob 76 in the opposite direction. *Id.*, 6:19, FIG. 10. "This causes the system to act in reverse," where dose-dial sleeve 70, clutch 60, and driver 30 rotate together back into the housing. *Id.*, 6:19-20, FIG. 10. Driver 30 rotates down piston rod 20, toward its needle-end, without corresponding piston-rod 20 rotation. *Id.*, 6:1-3, FIG. 10.

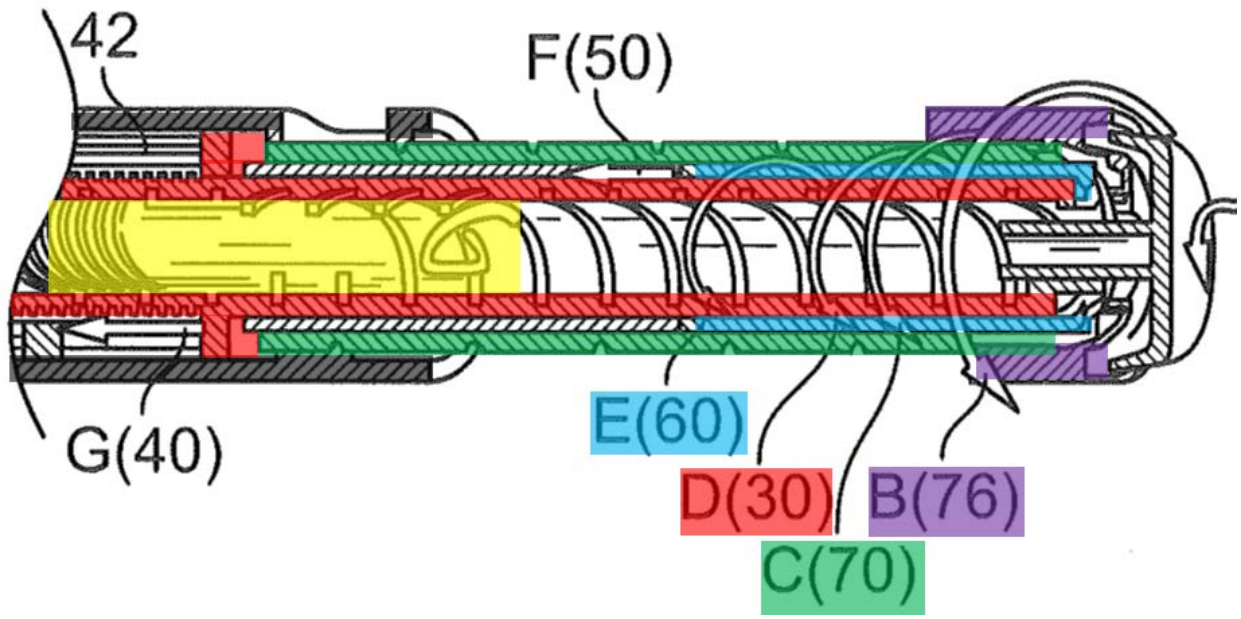


FIG. 10: Dialing down

EX1011, ¶84.

Injection: Once set, the user presses button 82, applying force toward the device's needle-end (*id.*, 6:28-29, FIG. 11), displacing clutch 60 axially so teeth 65 disengage from dose-dial sleeve 70 (*id.*, 6:29-31), which rotates back via its threaded connection into the housing 4. *Id.*, 6:33-35, FIG. 11. Now disengaged from dose-dial sleeve 70, clutch 60 does not rotate but instead moves axially toward the needle-end. *Id.*, 6:31-33, 6:38-40. Driver 30 also moves axially toward the needle-end, driving piston rod 20 to rotate through threaded opening 18, causing medicine dispense from cartridge 8. *Id.*, 6:45-47.

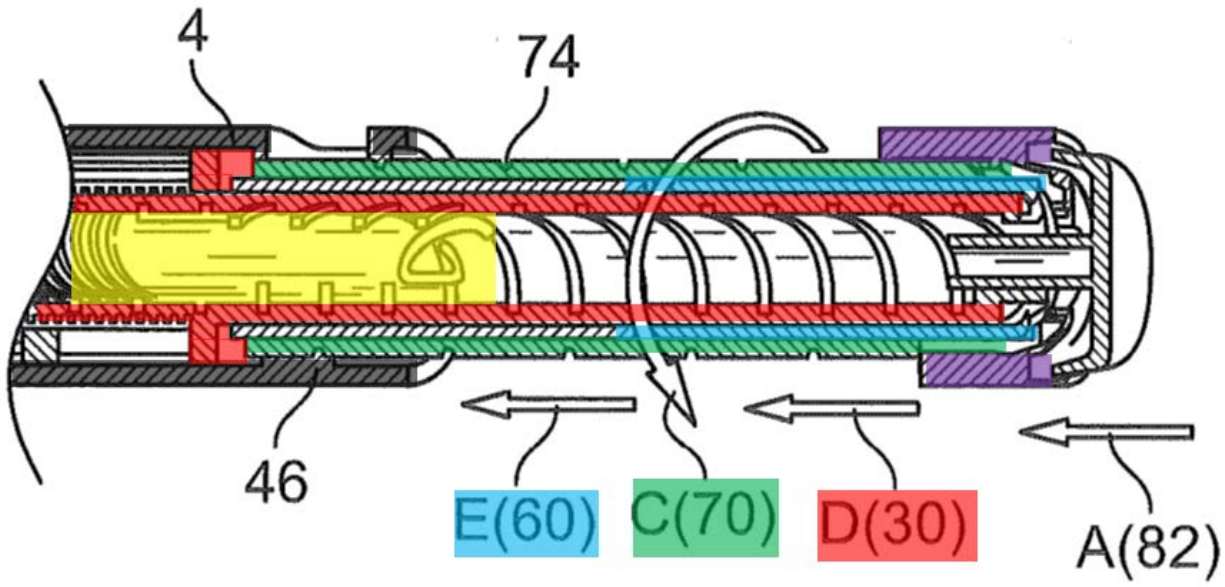


FIG. 11: Injecting dose

EX1011, ¶88.

2. Prosecution History

The patent issued from Application 12/944,544 ("the '544 application"), which claims priority to March 3, 2003. The claims were not rejected over art, but were allowed immediately after the applicant's response to a double-patenting rejection. EX1008, 113-115, 140, 146-152.

C. Level of Ordinary Skill

The relevant time is before March 3, 2003. A POSA at that time had at least a bachelor's degree in mechanical engineering, or an equivalent degree, plus three-years' experience. EX1011, ¶106. The POSA also understood the basics of

medical-device design and manufacturing, and mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices. *Id.*

D. Claim Construction

Claims should be given their ordinary and customary meaning, consistent with the specification, as a POSA understood them. 37 CFR §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc).

Patent Owner Sanofi has asserted claim-term meanings that it cannot now argue are unreasonable. *Ex parte Schulhauser*, Appeal No. 2013-007847, slip op. at 9 (PTAB Apr. 28, 2016) (precedential) (proper construction "at least encompasses the broadest interpretation of the claim language for purposes of infringement."). Sanofi's proffered constructions are:

"driver": "A component releasably connected to the dose dial sleeve that drives the piston during dose dispensing." EX1019, 25.

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

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

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

"tubular clutch": "A tubular structure that couples and decouples a moveable

component from another component." *Id.*, 23.

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

"insert": "Plain and Ordinary Meaning ….'an internal structure' as defined in each of the claims in which it appears." *Id.*, 32.

In related litigation with Sanofi, Mylan proffered a preliminary means-plus-function construction for "clutch," "clicker," and "insert." EX1028, 101-106, 112-116. The court has not yet ruled on claim construction. If means-plus-function applies, Mylan describes corresponding structure below. §42.104(b)(3).

As to "clutch," Mylan asserts the function is, during dose setting, it "clutch[es], i.e., coupling and decoupling a movable component from another component," or "reversibly locking two components in rotation." EX1028, 106. Mylan points to component 60 as the corresponding structure. *Id.*, 104; *see also* EX1003, abstract, 2:1-3, 2:16-35, 4:33-35, 4:45-67, 5:1-6, 5:44-60, 6:16-43; FIGS. 1, 5-11.

As to "clicker,"[2] Mylan asserts the function is "providing at least an audible feedback to a user when said dose dial grip is rotated." EX1028, 114-115. Mylan points to component 50 as the corresponding structure. *Id.*, 112-14; *see also* EX1003, 2:20-35, 4:33-48, 4:63-67, 5:1-5, 5:44-49, 5:51-57, 6:20-21, 6:35-43, FIGS. 1, 5-10.

As to "insert,"[3] Mylan asserts the function is "prevent[ing] the piston rod from rotating during dose setting and permit[ing] the piston rod to traverse axially towards the distal end during dose dispensing." EX1028, 115-16. FIGS. 1, 3-5, component 16, describe corresponding structure for an insert. *Id.* 115.

The grounds rely on the ordinary and customary meaning, but also address the "clutch," "clicker," and "insert" limitations as means-plus-function limitations.

E. Prior Art

Numerous pen-type injectors were known in the art before March 3, 2003, including many that used the same six-component structure of claim 1. EX1011,

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

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

¶14. The injectors relied on concentrically arranged components that operated to axially drive a threaded piston rod for injection. *Id.* While the specific structures varied, their general structure and operation were well-established. *Id.*; *also id.*, ¶¶114-23 (providing overview of well-known components). Claim 1 simply recites familiar—any differences between the claimed invention and what was known is merely a mixture of well-known features with predictable and well-understood functions. EX1011, ¶124.

1. Steenfeldt-Jensen

Steenfeldt-Jensen issued May 22, 2001 and is pre-AIA §102(b) prior art. A related PCT publication (EX1014, WO99/38554) was one of many references in an Information Disclosure Statement, but was not applied substantively in a rejection.

Steenfeldt-Jensen discloses syringes for dispensing medicine. *See* EX1014, Abstract; EX1011, ¶130-33. As annotated FIGS. 15-17 show (below), one embodiment[4] of a six-component structure has:

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[4] Steenfeldt-Jensen explains that analogous elements have the same reference number for multiple embodiments. EX1014, 7:49-51. Thus, while this discussion primarily focuses on the FIGS. 15-17 embodiment, a POSA would have understood that other embodiments inform the structure and operation of the FIGS.

(1) “tubular housing 1” (gray), which houses the drive mechanism for dispensing medicine (*e.g.*, EX1014, 5:38-54);

(2) “scale drum 80” (green), which the user manipulates to set a dose (*id.*, 11:51-55);

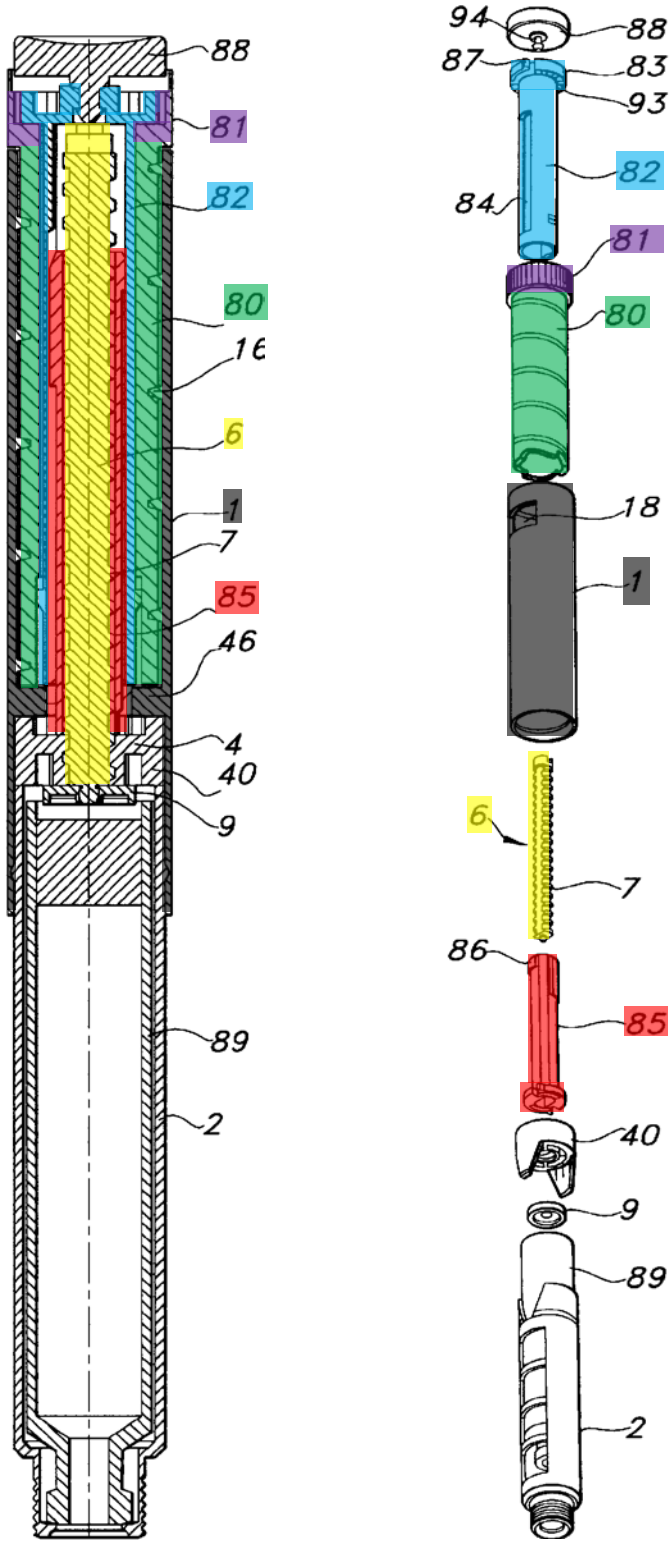
(3) “dose setting button 81” (purple), which serves as a grip to manipulate the scale drum (*id.*, 11:51-55);

(4) “piston rod 6” (yellow), which is driven to dispense medicine (*id.*, 5:57-65);

(5) “driver tube 85” (red), which rotates to drive the piston rod (*id.*, 2:47-53, 11:6-19, 11:52-12:13); and

(6) “bushing 82” (blue), which releasably connects the scale drum and the driver tube for rotational movement during injection (*id.*, 12:4-13).

15-17 embodiment, at least for elements having identical reference numbers. *See* EX1011, ¶131 n.13.



See EX1014, FIGS. 16-17; EX1011, ¶131.

2. Møller

Møller is pre-AIA §102(a) and (e) prior art. Møller was one of many references in an Information Disclosure Statement, but was not applied substantively in a rejection.

Møller described a device for injecting set doses. EX1015, ¶¶22-27; EX1011, ¶¶138-39, 141-43. As FIG. 1 (color-coded below) shows, Møller discloses a device comprising:

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

(2) "dose setting drum 17" (green), which the user manipulates to set a dose (*id.*, ¶25).

(3) "dose setting button 18" (purple), which serves as a grip to manipulate the drum (*id.*, ¶29).

(4) "piston rod 4" (yellow), which is driven to dispense medicine (*id.*, ¶22);

(5) "connection bars 12" having "nut 13 (red), which drives the piston rod (*id.*, ¶¶24, 32);

(6) "cup shaped element" (blue) having bottom 19 and tubular part 20 that rotationally decouples the drum and connection bars during injection (*id.*, ¶¶ 26, 29, 33).

A color-coded mapping of the above components is provided below with respect to Figure 1 of Møller. *See* EX1011, ¶139.

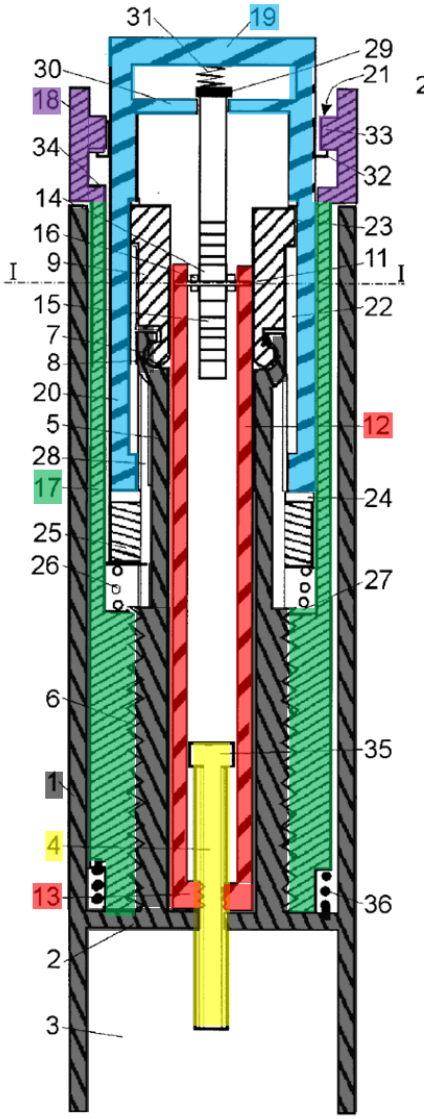


Fig. 1

F. Ground 1: Steenfeldt-Jensen

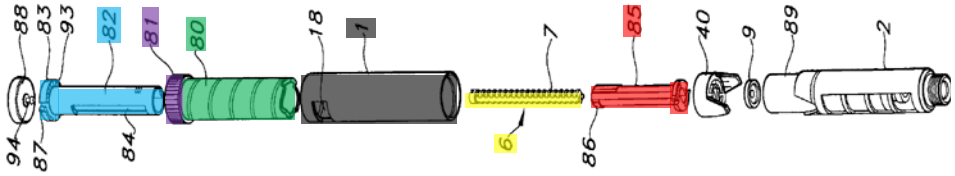
1. Claim 1

Steenfeldt-Jensen teaches a medication dispensing apparatus that meets claim 1's limitations, except Steenfeldt-Jensen's "driver" lacks internal threading.

Infra,§V.F.1.a. Steenfeldt-Jensen suggests its driver can alternatively have internal threading, and a POSA would have reasonably expected success with this modification. *Infra*, §V.F.1.b. Claim 1 was obvious in view of Steenfeldt-Jensen.

a. Element-by-element analysis

If the preamble is limiting, Steenfeldt-Jensen taught it:

'486 Patent	Steenfeldt-Jensen
[1.Preamble] A housing part for a medication dispensing apparatus, said housing part comprising:	"The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge." EX1014, 1:12-13, FIGS. 15-17. "The present invention provides an injection syringe comprising a housing[.]" *Id.*, Abstract.  *Id.*, FIG. 17 (annotated); EX1011, ¶262.

Steenfeldt-Jensen describes a syringe for dispensing medicine. EX1014, 1:12-15, FIGS. 15-17; EX1011, ¶261. The syringe includes tubular housing 1. EX1014, 5:38-44, FIGS. 15-17; EX1011, ¶261.

Steenfeldt-Jensen taught "a main housing":

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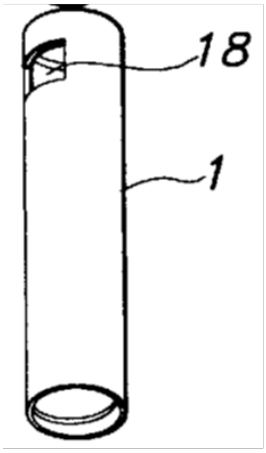
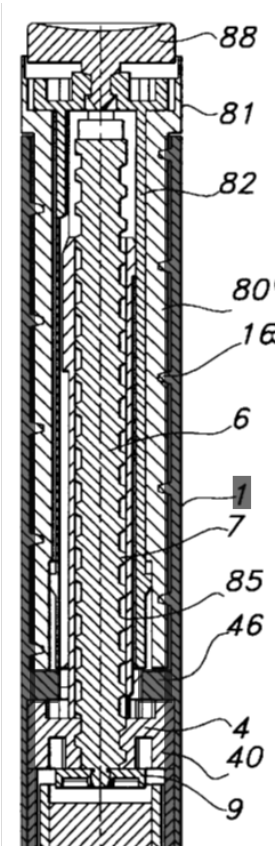
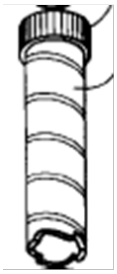
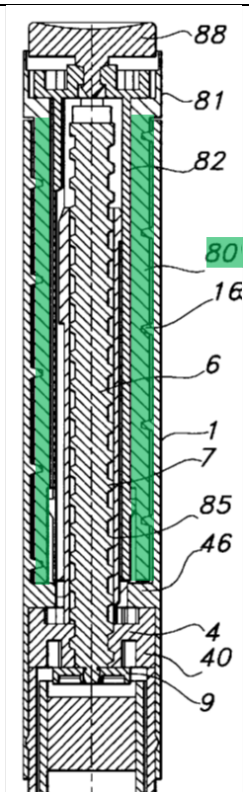
[1.1] a main housing, said main housing extending from a distal end to a proximal end;	"The syringe comprise[s] a tubular housing 1[.]" EX1014, 5:38-44, FIGS. 15-17. "A medication delivery pen comprising ... a housing having proximal and distal ends[.]" *Id.*, claim 11.   *Id.*, FIG. 17 (above-left, partial; showing housing), FIG. 16 (above-right, partial; housing (gray)); EX1011, ¶263.

As shown in FIGS. 15-17, housing 1 extends from a button-end ("proximal end") to a needle-end ("distal end"). EX1011, ¶263.

Steenfeldt-Jensen taught "a dose dial sleeve":

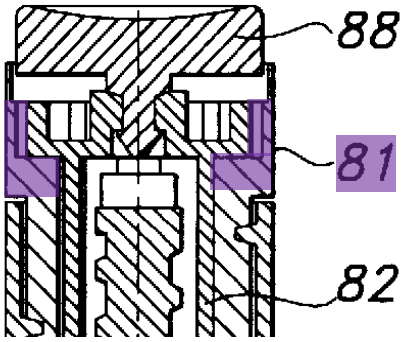
’486 Patent	Steenfeldt-Jensen
[1.2] a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;	“A scale drum 80 is in 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. “When a dose is set by rotating the dose setting button 81 …, the scale drum is screwed out of the housing[.]” *Id.*, 11:52-54. “When the injection button 88 is pressed to inject the set dose ... the anticlockwise rotation of the dose setting 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.” *Id.*, 12:4-9.

	  *Id.*, FIG. 17 (above-left, partial; showing scale drum), FIG. 16 (above-right; partial, scale drum (green)); EX1011, ¶264.

Scale drum 80 is positioned within housing 1, and has a "helical track" (groove) on its outer surface "engaged by a helical rib 16 along the inner wall of the housing 1." EX1014, 11:20-22, FIGS. 15-17; EX1011, ¶264. Steenfeldt-Jensen thus taught the dose-dial sleeve. EX1011, ¶265.

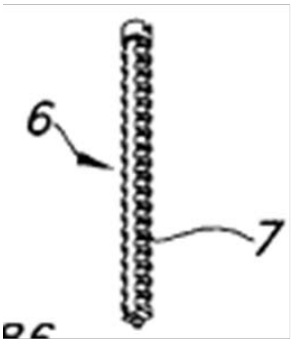
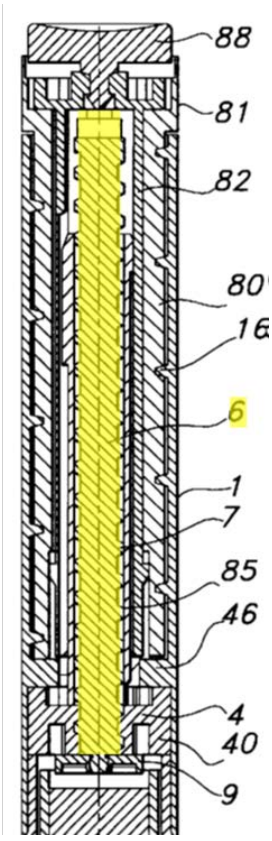
Steenfeldt-Jensen taught "a dose knob":

'486 Patent	Steenfeldt-Jensen
[1.3] a dose knob	"At its proximal end the scale drum 80 has a diameter

disposed near a proximal end of said dose dial sleeve;	exceeding the inner diameter of the housing to form a dose setting button 81, which … is knurled to ensure a good finger grip." EX1014, 11:22-25, FIGS. 15-17.  *Id.*, FIG. 16 (partial; dose setting button (purple)); EX1011, ¶267. "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 of the housing. . . . [A] set dose is reduced by rotating the dose setting button 81 in an anticlockwise location[.]" EX1014, 11:52-62.

Steenfeldt-Jensen explains scale drum 80 includes dose-setting button 81 at its button-end. EX1014, 11:22-25, FIGS. 15-17. The user rotates dose-setting button 81 to set a dose. *Id.*, 11:52-62; EX1011, ¶266. Steenfeldt-Jensen thus taught a "dose knob."

Steenfeldt-Jensen teaches "a piston rod":

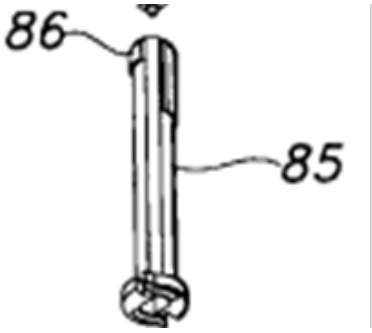
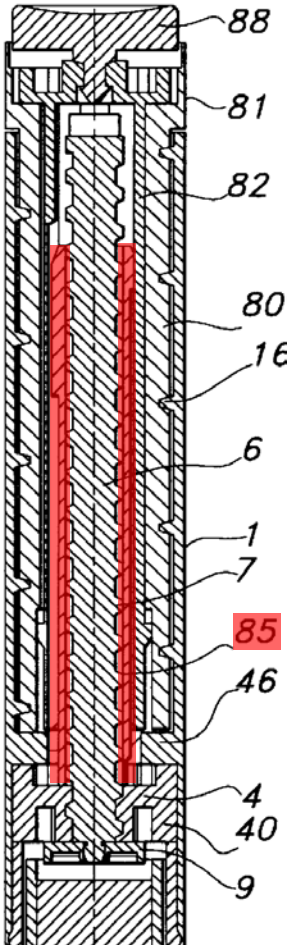
’486 Patent	Steenfeldt-Jensen
[1.4] a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;	“A piston rod 6 having an external thread 7 mating the [internal] thread 5 of [a central bore of end wall 4] extends through said bore.” EX1014, 5:55-58; *see also id.*, 11:11-15, FIGS. 15-17.   *Id.*, FIGS. 17 (above- left, partial; showing piston rod), 16 (above-right, partial; piston rod (yellow)); EX1011, ¶270. “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." EX1014, 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 [button-end] of the housing. The bushing [82] is kept non-rotated due to its coupling to the driver 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 working between the driver tube and the housing is sufficient[ly] reluctant to … prevent the bushing 82 from following this anticlockwise rotation." *Id.*, 11:52-62.

Steenfeldt-Jensen teaches piston rod 6. *Id.*, 5:55-58, 11:11-15; EX1011, ¶268. A pawl mechanism that works between driver tube 85 and member 40 prevents the piston rod's rotation relative to housing 1 during dose setting by barring rotation of driver tube 85, to which piston rod 6 is rotationally fixed. EX1014, 11:6-19, 11:52-62; EX1011, ¶¶269-71. When dose-setting button 81 rotates clockwise to set a dose, the pawl mechanism prevents driver tube 85 (and thus piston rod 6) from rotating. EX1014, 11:52-62; EX1011, ¶271. To dial-down a dose, dose-setting button 81 rotates anticlockwise, but rotation of driver tube 85

is still prevented due to the pawl mechanism's "sufficient reluctan[ce]." *See* EX1014, 11:52-62; EX1011, ¶271. Thus, Steenfeldt-Jensen taught the claimed piston rod.

Steenfeldt-Jensen taught "a driver":

'486 Patent	Steenfeldt-Jensen
[1.5] a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod; and	  *Id.*, FIGS. 17 (above-left, partial; showing driver tube), 16 (above-right, partial; driver tube (red)); EX1011, ¶273. "The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding

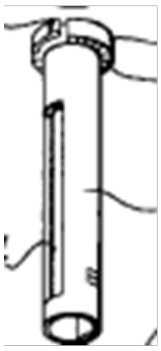
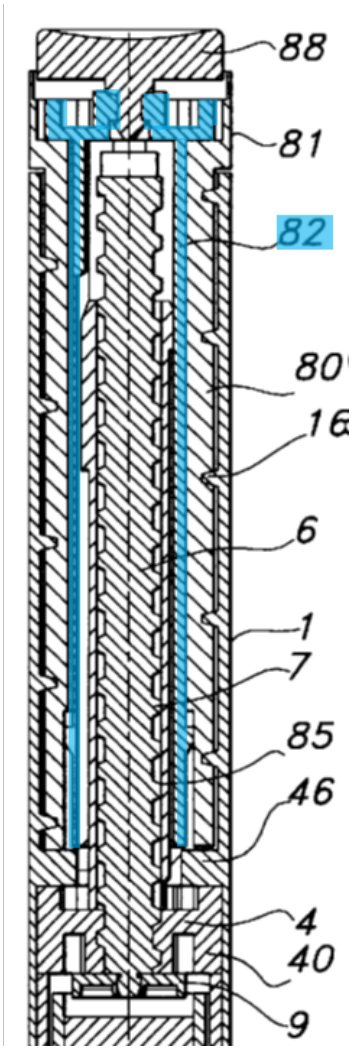
	not round cross-section. This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube." *Id.*, 11:6-19. "When the injection button 88 is pressed to inject the set dose .... The bushing [82] will rotate the driver tube 85 in an anticlockwise direction 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." *Id.*, 12:4-12.

Steenfeldt-Jensen teaches driver tube 85, which includes a non-circular bore through which piston rod 6 extends. *Id.*, 11:6-19, 12:4-12; EX1011, ¶273-76. Driver tube 85 drives piston rod 6 during injection to dispense medicine. *Id.*, 12:4-12; EX1011, ¶273-76. To drive piston rod 6, driver tube 85 rotationally engages with the rod through the non-circular bore, rather than "an internal threading near a distal portion." EX1011, ¶274.

As explained more in §V.F.1.b, a POSA would have considered it obvious to modify driver tube 85 to provide the "driver" of claim 1. EX1011, ¶275-79.

Steenfeldt-Jensen taught "a tubular clutch":

'486 Patent	Steenfeldt-Jensen
[1.6] a tubular clutch located adjacent a distal	"A bushing 82 having a flange 83 at its proximal end [button-end] and having a pair of opposite longitudinal

end of said dose knob, said tubular clutch operatively coupled to said dose knob,	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 driver tube 85 [are] coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements." EX1014, 11:26-33, FIG. 17.   *Id.*, FIGS. 17 (above-left, partial; showing bushing), 16 (above-right, partial; bushing (blue)); EX1011, ¶282.

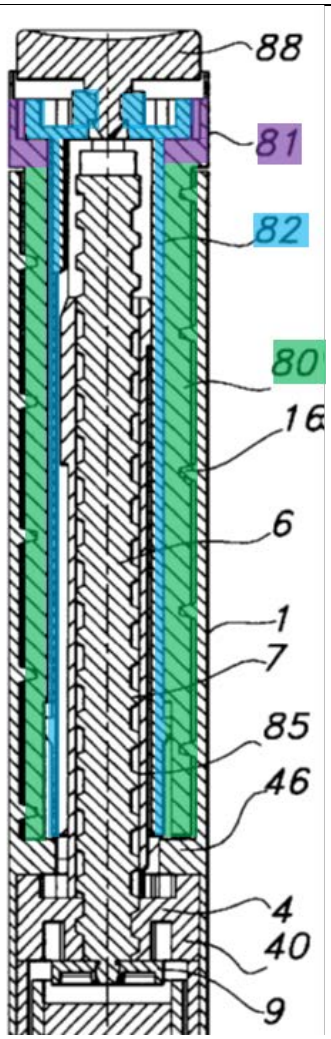
	"In the dose setting button [81] a compartment is provided having ... a bottom with a rosette of teeth …. The flange 83 of the bushing 82 is adopted in said compartment .... At its distal [needle-end] side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment." EX1014, 11:34-42, FIG. 17. "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." *Id.*, 12:1-3. "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 .... 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." *Id.*, 12:4-13.

Bushing 82 is a tubular structure within scale drum 80. EX1014, 11:26-27, 12:4-13, FIGS. 15-17; EX1011, ¶283. Bushing 82 also is a clutch and operatively coupled to dose-setting button 81: a rosette of teeth 93 releasably engages with corresponding teeth on button 81 to transmit rotational movement of scale drum 80 to driver tube 85. EX1014, 11:34-40, 12:4-13; EX1011, ¶¶280-81, 283. During

dose setting, the teeth are disengaged so that, when button 81 is rotated, bushing 82 follows scale drum 80's axial movement, but does not follow its rotation due to the bushing's coupling to the driver tube 85. EX1014, 11:26-33, 11:52-62, 12:1-3; EX1011, ¶¶280-81, 283. During injection, the teeth engage, causing bushing 81 to follow scale drum 80's rotation, which is transmitted to driver tube 85 to drive piston rod 6. *See* EX1014, 12:4-12; EX1011, ¶283. Bushing 82 is also located adjacent the needle-end of button 81: flange 83 is provided within a compartment formed in button 81, with teeth 93 of the bushing being configured to engage teeth provided at the bottom of the button's compartment. *See* EX1014, 11:34-42, FIGS. 15-16; EX1011, ¶¶281-83. Steenfeldt-Jensen thus taught the claimed tubular clutch.

Finally, Steenfeldt-Jensen taught the relative positioning of the dose-dial sleeve and tubular clutch:

'486 Patent	Steenfeldt-Jensen
[1.7] wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.	"A bushing 82 . . . fits into the scale drum 80 . . . ." EX1014, 11:26-28, FIGS. 15-16.

	 *Id.*, FIG. 16 (above, partial; scale drum (green) and bushing (blue)); EX1011, ¶285.

Bushing 82 sits within scale drum 80. EX1014, 11:26-28, FIGS. 15-16; EX1011, ¶285. Scale drum 80 thus "extends circumferentially around at least a portion of" bushing 82.

b. Reason to modify and reasonable expectation of success

Steenfeldt-Jensen disclosed driver tube 85 that rotationally engages and drives piston rod 6 during dose-dispensing. *See* EX1011, ¶274. Driver tube 85 engages piston rod 6 via a non-circular bore, rather than an internal threading, but a POSA would have considered it obvious to modify the device to provide driver tube 85 with an internal threading near its distal portion. EX1011, ¶¶274. The modified device would have been understood to contain a "driver" having the claimed structural elements. EX1011, ¶274.

Steenfeldt-Jensen contemplates a modification in which the driver tube contains an internal threading that engages the piston rod's external threading. EX1011, ¶275. After describing its first embodiment, Steenfeldt-Jensen states that "[e]mbodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention." EX1014, 7:44-47; *see also id.*, 3:15-20 ("[M]ovement of [injection] button is transformed into a rotation of the piston rod (or the nut member) relative to the nut member (or the piston rod)."), 3:44-47 (dose scale drum may be "coupled to a driver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed"); EX1011, ¶275.

Elsewhere, Steenfeldt-Jensen explains the piston rod guide is a structure that allows the piston rod to move axially relative to it, but not rotatably, whereas the nut element is a structure that allows for relative rotation. *See* EX1014, 2:46-53, 3:15-20; EX1011, ¶276. In the context of FIGS. 15-17, a POSA would have understood that driver tube 85 includes a "piston rod guide" because its bore allows relative axial movement of the piston rod, but prevents relative rotation. EX1011, ¶276. Similarly, a POSA would have understood that member 40 includes a "nut element" due to its internal threading in wall 4. EX1011, ¶276. Given Steenfeldt-Jensen's suggestion that the "nut element" could be provided on the driver tube, and the "piston rod guide" could be provided on the member, a POSA would have reason 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. EX1011, ¶277. The modifications suggested by Steenfeldt-Jensen thus result in an injector pen meeting all limitations of claim 1. EX1011, ¶¶277.

A POSA would have reasonably expected such modification would result in the device operating in the same manner. EX1011, ¶278. A POSA would have understood that when the driver tube rotates during injection, the threaded engagement between the driver tube and the piston rod causes the piston rod to axially displace through the member's non-circular opening to dispense medicine.

EX1011, ¶278. Thus, the 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; EX1011, ¶278.

Accordingly, claim 1 was obvious over Steenfeldt-Jensen.

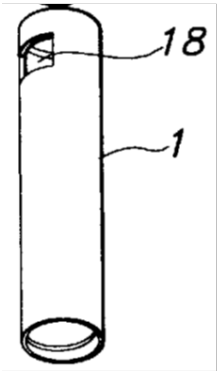
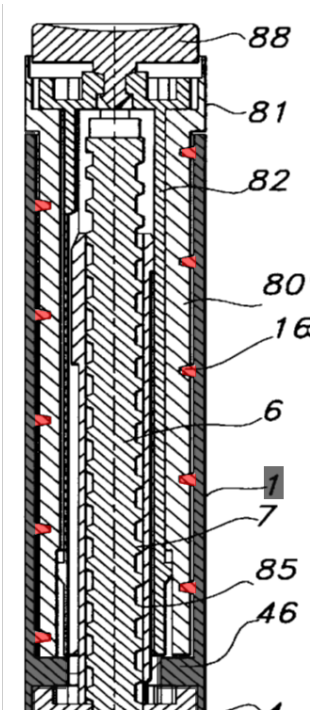
2. Claim 2

'486 Patent	
[2.] The housing part of claim 1, wherein said tubular clutch is directly coupled to said dose knob.	*See* disclosure accompanying claim 1.6, *supra*.

Steenfeldt-Jensen explains that bushing 82 is directly coupled to dose-setting button 81: teeth 93 of bushing 82 releasably engage teeth in the dose-setting button during injection to couple the components. *Id.*, 11:34-51, FIGS. 16-17; EX1011, ¶290. Accordingly, Steenfeldt-Jensen taught claim 2.

3. Claims 3-4

'486 Patent	
[3.] The housing part of claim 1, wherein said main housing comprises a window through	"Numbers 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 a window 18 provided in the

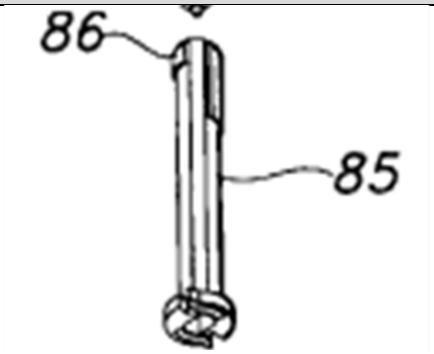
which at least a portion of an outer surface of said dose dial sleeve may be viewable.	side wall of the housing 1." EX1014, 6:18-21, FIG. 17.
[4.] The housing part of claim 3, wherein said window is located near a proximal end of said main housing and near a helical rib provided on an inner surface of said outer housing.	  *Id.*, FIGS. 17 (above-left, partial; showing housing); 16 (above-right, partial; housing (gray), rib (red)); EX1011, ¶293.

Housing 1 includes a window 18 through which numbers on the scale drum's outer surface is viewable. EX1014, 6:18-21, 7:31-33, FIG.17; EX1011, ¶¶291-92.

FIG. 17 shows that window 18 is located near the button-end of housing 1. EX1014, FIG. 17; EX1011, ¶¶293-94. Housing 1 includes helical rib 16 on its inner surface, which is shown to run along its length, including near window 18. EX1014, 11:20-22, FIGS. 15-17; EX1011, ¶293.

Accordingly, Steenfeldt-Jensen taught claims 3-4.

4. Claim 5

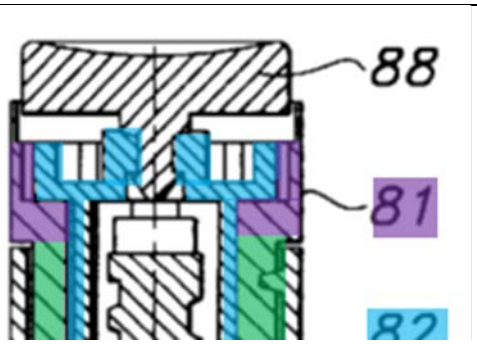
’486 Patent	
[5.] The housing part of claim 1, wherein said driver comprises a cylindrical shape.	 EX1014, FIG. 17 (partial; driver tube); EX1011, ¶295.

Driver tube 85 is shown to have a cylindrical shape. EX1011, ¶295.

Steenfeldt-Jensen thus taught claim 5.

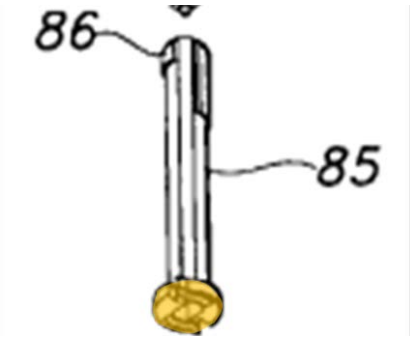
5. Claim 6

’486 Patent	
[6.] The housing part of claim 1, wherein said dose knob extends circumferentially around at least a portion of said tubular clutch.	“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 ….” EX1014, 11:22-25.

	 *Id.*, FIG. 16 (partial; bushing (blue), dose-setting button (purple)); EX1011, ¶296.

Flange 83 of bushing 82 sits within a compartment of dose-setting button 81. EX1014, 11:20-51, FIGS. 15-17. Dose-setting button 81 thus extends circumferentially around a portion of bushing 82. EX1011, ¶¶296-97. Accordingly, Steenfeldt-Jensen taught claim 6.

6. Claims 12-13

’486 Patent	
[12.] The housing part of claim 1, wherein said driver comprises at least one flange.	*See* disclosure accompanying claims 1.5 and 5, *supra*.  EX1014, FIG. 17 (partial; flange (orange)); EX1011, ¶298.
[13.] The housing part of claim 12, wherein said at least one flange	

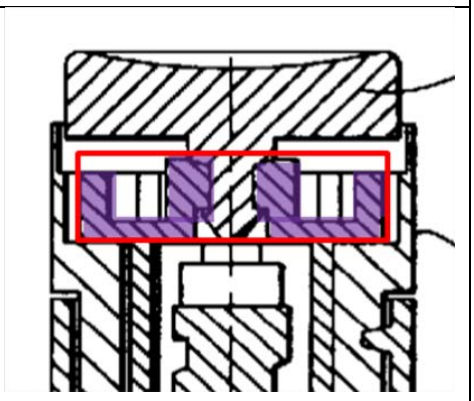
is located near a distal portion of said driver.	

Driver tube 85 includes a pawl formed as a flange at its needle-end. EX1014, 11:6-11, FIGS. 15-17; EX1011, ¶¶298-300. Accordingly, Steenfeldt-Jensen taught claims 12-13.

7. Claims 14-18 and 20

'486 Patent	
[14.] The housing part of claim 1, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose knob is rotated.	"In the dose setting button a compartment is provided having a cylindrical side wall circumferentially provided with longitudinal recesses …. 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, 11:34-40. "[R]otation 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…to the next one…." *Id.*, 11:62-67.
[15.] The housing part of claim 14, wherein said clicker provides tactile feedback to a user	"[A] click coupling providing [a] moderate resistance against rotation is established between the housing and the element rotated relative to the housing to set a dose." *Id.*, 3:21-24.

when said dose knob is rotated.	
[16.] The housing part of claim 14, wherein said clicker provides audible feedback when said dose knob is rotated in a dose increasing direction.	"[R]otation 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…to the next one …." *Id.*, 11:62-67.
[17.] The housing part of claim 14, wherein said clicker provides audible feedback when said dose knob is rotated in a dose decreasing direction.	*See* disclosure for claims 14-16, *supra*.
[18.] The housing part of claim 14, wherein said clicker comprises, at least one flexible arm, said flexible arm comprising at least	*See* disclosure for claims 14-16, *supra*.  *Id.*, FIG. 17 (partial; radial protrusion (purple)); EX1011,

one tooth member, and at least one spline, wherein when said dose knob is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.	¶310.
[20.] The housing part of claim 14, wherein said clicker generally comprises a cylindrical shape having a first and a second end, and said cylindrical shape is provided at said first end with at least one flexible extending arm.	  EX1014, FIG. 17 (partial; flange (purple)); EX1011, ¶313.

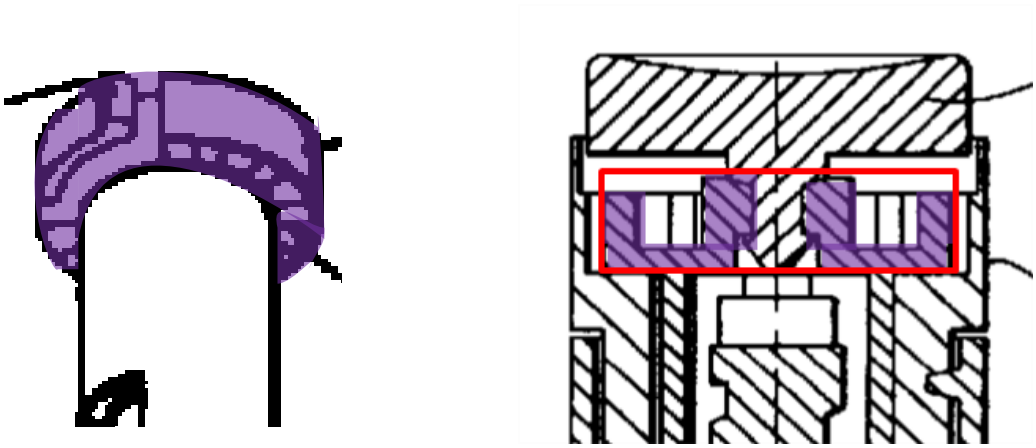
Flange 83 of bushing 82 includes radial protrusion 87, which drags over axial recesses on the compartment of dose-setting button 81 to produce clicks (audible feedback) when the user rotates dose-setting button 81. EX1014, 9:30-35, 9:48-50, 11:62-67; EX1011, ¶301-02. Steenfeldt-Jensen thus taught the clicker of claim 14.

Steenfeldt-Jensen does not explicitly state the clicks also provide tactile feedback, but a POSA would have understood such feedback was produced. EX1011, ¶¶304-06. As an initial matter, the '486 patent describes a clicker that provides "tactile feedback" when the "flexible arm 52 deforms and drags the toothed member 54 over the splines 42 to produce a click." EX1003, 5:54:60; EX1011, ¶305. The clicker of Steenfeldt-Jensen operates in a substantially identical manner, and thus a POSA would have understood it to produce similar tactile feedback. EX1014, 11:34-40; 11:62-67; EX1011, ¶305; *see also* EX1014, 3:21-24 ("moderate resistance against rotation" provided by click coupling); EX1011, ¶304. Steenfeldt-Jensen thus taught claim 15.

Steenfeldt-Jensen explains that rotation of dose-setting button 81 "in any direction" causes radial protrusion 87 to click along the recesses. EX1014, 11:62-67. A POSA thus would have understood that audible feedback would be provided in both a dose-increasing direction and a dose-decreasing direction. EX1011, ¶¶307-09. Steenfeldt-Jensen thus taught claims 16-17.

Steenfeldt-Jensen teaches protrusion 87 as an arm that is "biased toward" the side wall of dose-setting button 81 so its end may click into the axial recesses. EX1014, 11:34-42, FIG. 17; EX1011, ¶¶310-312. As such, a POSA would have understood protrusion 87 is a "flexible arm" with a "tooth member" at its tip for deforming and dragging into the recesses. EX1011, ¶311. A POSA also would have understood the recesses to form ridges or splines therebetween. EX1011, ¶311. Steenfeldt-Jensen thus taught claim 18.

FIGS. 15-17 show that protrusion 87 is part of cylindrical flange 83:



EX1014, FIG. 17 (partial; annotated); EX1011, ¶313.

Flange 83 has first (button-end) and second (needle-end) ends, with flexible protrusion 87 extending along its length and thus "provided at" flange 83's button-end. EX1011, ¶¶313-314. Steenfeldt-Jensen thus taught claim 20.

If "clicker" is construed to be means-plus-function, Steenfeldt-Jensen taught it as well. The '486 patent teaches that during dose-dialing, "flexible arm 52" with

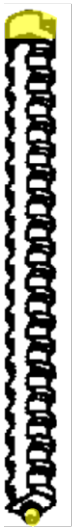
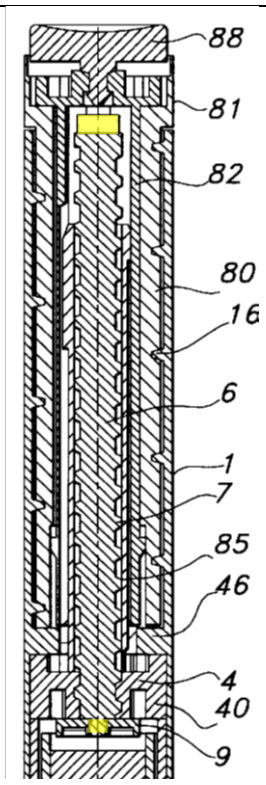
"toothed member 54" drags over "splines 42" to produce a click. EX1003, 5:57-59.

Steenfeldt-Jensen describes radial protrusion 87 "click[s] from one … axial recess … to the next one" to produce audible feedback. EX1014, 11:34-42, 11:52-67; EX1011, ¶303. As noted above, a POSA would have understood radial protrusion 87 to be a "flexible arm" having a "toothed member" that deformed and dragged over splines formed between the recesses. EX1011, ¶303. Thus, Steenfeldt-Jensen teaches the same structure performing the same function.

Accordingly, Steenfeldt-Jensen rendered claims 14-18 and 20 obvious.

8. Claim 23

'486 Patent	

[23.] The housing part of claim 1, wherein said piston rod comprises a generally circular cross section.	  EX1014, FIGS. 17 (above-left; partial, piston rod (yellow)), 16 (above-right; partial, piston rod (yellow)); EX1011, ¶316.

Claim 23 merely requires that the piston rod have "a" cross-section that is "generally circular." EX1011, ¶¶315-16. FIGS. 15-17 show piston rod 6 having a circular cross-section at both its button-end (non-threaded, circular portion) and needle-end (circular portion fitting into pressure foot 9). EX1014, 5:61-65, FIGS. 15-17; EX1011, ¶316. These features alone satisfy the limitations of claim 23.

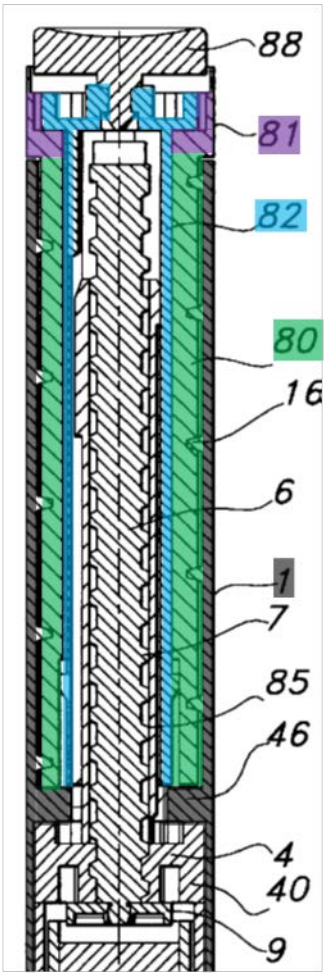
Even if the piston rod must have a generally circular cross-section along its entire length, piston rod 6 has a *generally* circular cross-section. Steenfeldt-Jensen

explains the "piston rod has a not round cross-section" due to flattened portions that allows the rod to "fit[] through the driver tube bore which has a corresponding not round cross section." EX1014, 11:15-19, FIGS. 15-17. Aside from the flattened sides, a POSA would have nevertheless viewed this cross-section as "generally" circular given the rod's helical threading, particular since (1) even the piston rod described in the '486 patent has a cross-section with certain non-circular features due to the threads themselves and (2) the '486 offers no guidance as to the lower bound for what would be "generally" circular. EX1011, ¶317.

Accordingly, Steenfeldt-Jensen rendered claim 23 obvious.

9. Claim 26

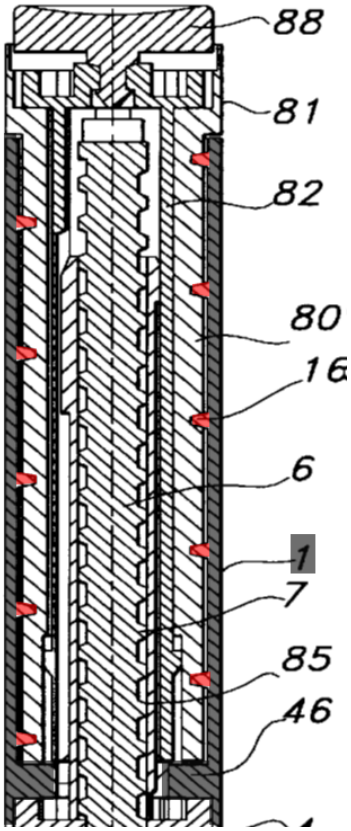
'486 Patent	
[26.] The housing part of claim 1, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.	*See* elements 1.2 and 1.7, *supra*.

	 EX1014, FIG. 16 (partial; housing (gray), scale drum (green), and bushing (blue)); EX1011, ¶319.

As shown in FIG. 16, scale drum 80 is provided outside bushing 82 and radially inward of housing 1. EX1011, ¶319. Accordingly, Steenfeldt-Jensen taught claim 26.

10. Claims 27-29

’486 Patent	

[27.] The housing part of claim 1, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along an outer surface of said dose dial sleeve.	*See* elements 1.1-1.2, *supra*. "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." *Id*., 11:20-22; *also* FIG. 16.  EX1014, FIG. 16 (partial; housing (gray), rib (red)); EX1011, ¶321.
[28.] The housing part of claim 27, wherein said helical rib extends for at least a single sweep of said inner surface of said main housing.	
[29.] The housing part of claim 27, wherein said helical rib comprises a single start helical rib.	

Housing 1 includes helical rib 16, which sits in a helical groove on the outer surface of scale drum 80. EX1014, 11:20-22, FIG. 16; EX1011, ¶320. Steenfeldt-Jensen thus taught claim 27.

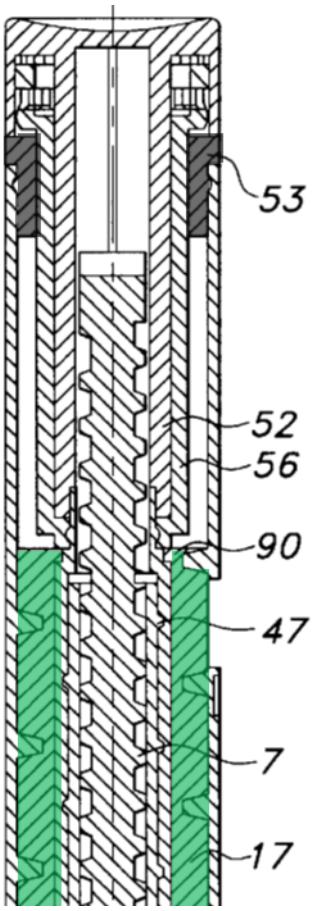
As to claim 28, FIGS. 15-16 show helical rib 16 extends for multiple sweeps along the internal surface of housing 1. EX1011, ¶321.

As to claim 29, a POSA would have understood helical rib 16 to be a "single start helical rib." EX1011, ¶¶322-325. While Steenfeldt-Jensen does not expressly discuss this aspect of helical rib 16, a POSA would have understood mechanical differences between single-start and multi-start threads, and been aware that single-start threads were the predominant type of thread in this context. EX1011, ¶¶241-44, 323. This understanding would have been reinforced by Steenfeldt-Jensen's reference to rib, singular. EX1011, ¶324. Moreover, Steenfeldt-Jensen describes the rib as having "a high pitch." EX1014, 6:7-17; EX1011, ¶324. Since multi-start threading significantly increases the lead of a thread compared to its pitch, a POSA would have understood single-start threading to suffice given the already high pitch. EX1011, ¶324.

Accordingly, Steenfeldt-Jensen rendered claims 27-29 obvious.

11. Claims 30 and 32

'486 Patent	
[30.] The housing part	"When the dose scale drum is displaced outwardly in the

of claim 1, wherein said dose dial sleeve comprises at least one radial stop, said radial stop positioned near an end of said helical groove.	housing a steep front side of a saw tooth 91 at the proximal end of the dose scale drum 18 will abut a steep front side of a similar tooth 92 on the bushing whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set." EX1014, 9:57-62; *also* FIGS. 12-13, 15-17.
[32.] The housing part of claim 30, wherein said radial stop is positioned near a distal end of said helical groove.	 EX1011, ¶327.

In another, similar embodiment, Steenfeldt-Jensen describes saw tooth 91 at a button-end of the scale drum, which abuts tooth 92 on the bushing's needle-end

to stop rotation of the drum. EX1014, 9:57-62, FIGS. 12-13. Although unlabeled in the figures, a POSA would have understood from Steenfeldt-Jensen that the tooth 91 acts as a "radial stop" to limit the length of travel of the scale drum and thus set the maximum dose for a single injection. EX1011, ¶¶326-27.

Given the above, a POSA would have understood Steenfeldt-Jensen as teaching the use of a "radial stop" near an end of the drum's helical drum to limit the drum's length of travel during dose-setting. EX1011, ¶328. For FIGS. 15-17, a POSA would have expected a radial stop, such as a protruding tooth, to be provided near the needle-end of scale drum 80, since it is this end that reaches the button-end of the housing when a maximum dose is set. EX1011, ¶¶328-32. A POSA would have understood that such a stop would serve the same purpose as the stop of FIGS. 11-13 and operate analogously by preventing further drum movement to indicate that the maximum set dose had been reached. *Id.*

Accordingly, Steenfeldt-Jensen renders obvious claims 30 and 32.

12. Claim 33

'486 Patent	
[33.] The housing part of claim 1, wherein if a user inadvertently dials said dose knob in one direction beyond a	*See* element 1.3, *supra*. "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 .... [A] set dose is reduced by rotating the dose setting button 81 in an anticlockwise

desired dose, said dose knob may be rotated in a second direction so as to allow said dialed dose to be reduced.	direction[.]" *Id.*, 11:52-62; *see also id.*, 1:20-22, 11:62-65.

Steenfeldt-Jensen teaches that, if a user inadvertently dials a set dose beyond what is desired, it may be reduced by rotating button 81 in the opposite direction. EX1014, 11:52-65; EX1011, ¶333. Accordingly, Steenfeldt-Jensen rendered claim 33 obvious.

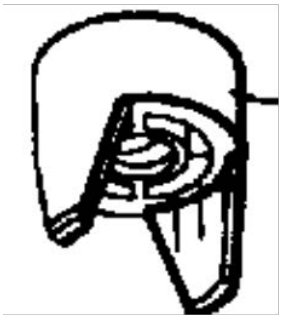
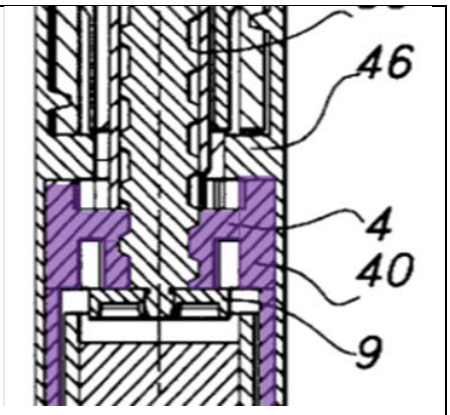
13. Claim 36

'486 Patent	
[36.] The housing part of claim 1, wherein said housing part and said container comprises a disposable device.	"When a disposable syringe is in question, i.e. a syringe which is disposed of when the cartridge is empty, the syringe must further be cheap and made of materials suited for recycling or burning without producing noxious gases." EX1014, 1:22-29.

While the term "container" does not appear in claim 1, from which claim 36 depends, Steenfeldt-Jensen describes the device as having a fluid "container" in the form of an ampoule. EX1014, 5:33-35, 12:10-13, FIGS. 15-17; EX1011, ¶334. Steenfeldt-Jensen also recognizes it was known to manufacture similar devices to be disposable. EX1014, 1:22-29. A POSA would have known to manufacture Steenfeldt-Jensen's device to be disposable. EX1011, ¶XX. Accordingly, Steenfeldt-Jensen rendered claim 36 obvious.

14. Claims 38-40

<table>
<tr><td>'486 Patent</td><td></td></tr>
<tr><td>[38.] The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main housing, said insert secured against rotation.</td><td rowspan="2">"The end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5. A piston rod 6 having an external thread 7 mating the thread 5 of said bore extends through said bore." EX1014, 5:55-58.
"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 1." Id., 8:35-42.</td></tr>
<tr><td>[39.] The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main</td></tr>
</table>

housing, and said insert secured against longitudinal motion.	  *Id.*, FIG. 17 (above-left; partial, member), FIG. 16 (above-right; partial, member (purple)); EX1011, ¶335.
[40.] The housing part of claim 39, wherein said insert comprises an opening extending therethrough, such that said piston rod is configured to extend through said opening.	

Steenfeldt-Jensen describes member 40, which is positioned near the housing's needle-end, is secured against rotation and longitudinal motion relative to the housing. *See* EX1014, 8:35-42, FIGS. 15-17; EX1011, ¶¶335-37. Steenfeldt-Jensen thus taught claims 38-39.

Member 40 includes an opening through which piston rod 6 extends. *See* EX1014, FIGS. 15-17; EX1011, ¶338. The modified embodiment discussed in §V.F.1.b would also include such an opening. *Id.* Steenfeldt-Jensen thus taught claim 40.

G. Ground 2: Møller and Steenfeldt-Jensen

1. Claim 1

A POSA would have understood Møller disclosed an injection device having the same six components and structural elements of claim 1. Even if Møller's "dose dial sleeve" did not contain a "helical groove," Møller and Steenfeldt-Jensen's teaching rendered it obvious.

Møller describes two similar embodiments: a first embodiment shown in FIGS. 1-2 and a second embodiment shown in FIGS. 3-5. The general structure and operation of these embodiments are largely the same. *Compare*, EX1015, ¶22-34 *with id.*, ¶¶35-40; *compare id.*, FIGS. 1-2 *with id.*, FIGS. 3-5; EX1011, ¶139, n.16. Møller explains that numbers for elements in the second embodiment corresponding to elements from the first embodiment simply add "100" to the previous number (e.g., housing 1 becomes housing 101). EX1015, ¶35; EX1011, ¶139, n.16. A POSA therefore would have understood corresponding elements were structurally and functionally equivalent to the elements of the first embodiment, and reference may be made to the second embodiment for context. EX1011, ¶139, n.16. Accordingly, while the analysis below primarily focuses on the first embodiment, the claims were similarly unpatentable over the second embodiment.

If the preamble is limiting, Møller taught it:

’486 Patent	Møller and Steenfeldt-Jensen
[1.Preamble] A housing part for a medication dispensing apparatus, said housing part comprising:	“An injection device for injection of set doses of medicine from a cartridge[.]” EX1015, Abstract. “In the device shown in FIG. 1 an elongated cylindrical housing 1 has a partitioning wall 2 which divides the housing in a compartment containing a dose setting mechanism and a compartment 3 designed for the accommodation of a not shown ampoule.” *Id.*, ¶22.

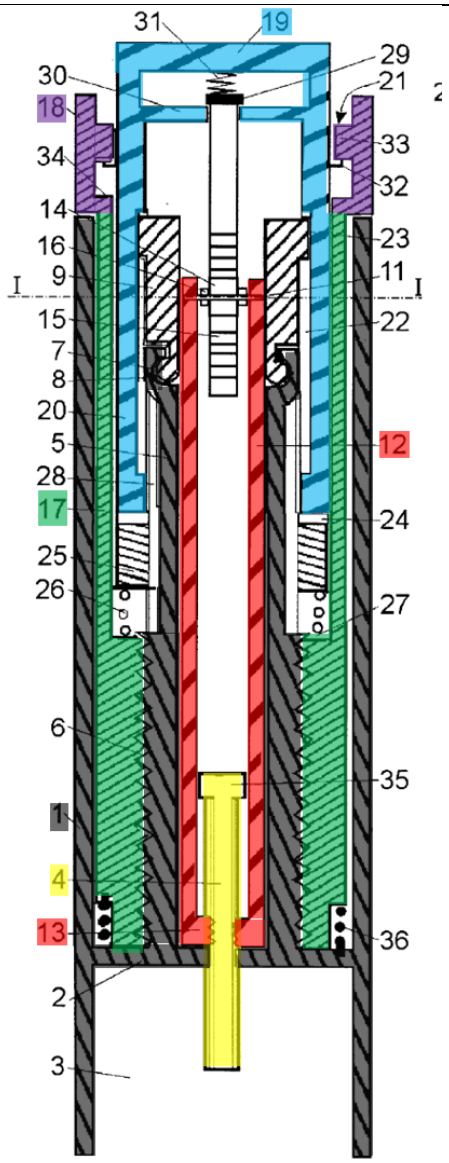


Fig. 1

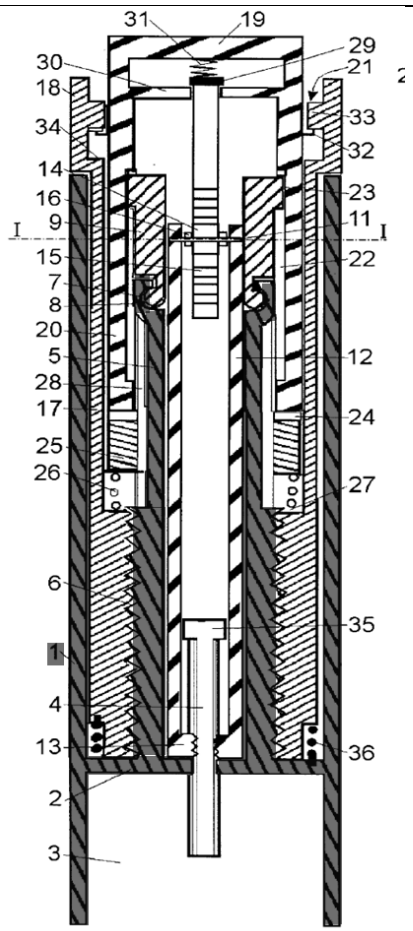
FIG. 1 (color-coded); EX1011, ¶344.

Møller discloses "[a]n injection device for injection of set doses of medicine from a cartridge." EX1015, Abstract; EX1011, ¶343. The device includes

housing 1 containing the drive mechanism for dispensing medicine. EX1015, ¶22, FIG. 1; EX1011, ¶343. Thus, Møller taught the preamble of claim 1.

Møller taught "a main housing":

'486 Patent	Møller and Steenfeldt-Jensen
[1.1] a main housing, said main housing extending from a distal end to a proximal end;	"In the device shown in FIG. 1 an elongated cylindrical housing 1 has a partitioning wall 2 which divides the housing in a compartment containing a dose setting mechanism and a compartment 3 designed for the accommodation of a not shown ampoule." EX1015, ¶22. "Concentrically with the housing 1 the wall 2 carries on its side turning away from the compartment 3 a tubular element 5[.]" *Id.*, ¶23.

	 Fig. 1 EX1015, FIG. 1 (housing (gray)); EX1011, ¶346; *see also* EX1015, FIGS. 3-5.

Møller taught a housing 1, which as shown in FIG. 1, extends from button-end to needle-end. *See* EX1015, FIG. 1; EX1011, ¶345. Housing 1 includes partitioning wall 2 and tubular element 5, which extends from wall 2 toward the device's button-end. *See* EX1015, ¶23; EX1011, ¶345. Therefore, Møller taught a "main housing."

Møller and Steenfeldt-Jensen taught "a dose dial sleeve":

'486 Patent	Møller and Steenfeldt-Jensen
[1.2] a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing;	"A tubular dose setting drum 17 fitting into the housing 2 [*sic*, 1] is at an end provided with an internal thread mating and engaging the outer thread 6 of the tubular element 5 .... Due to the engagement with the thread 6 the dose setting drum 17 may be screwed in and out of the housing[.]" EX1015, ¶25.

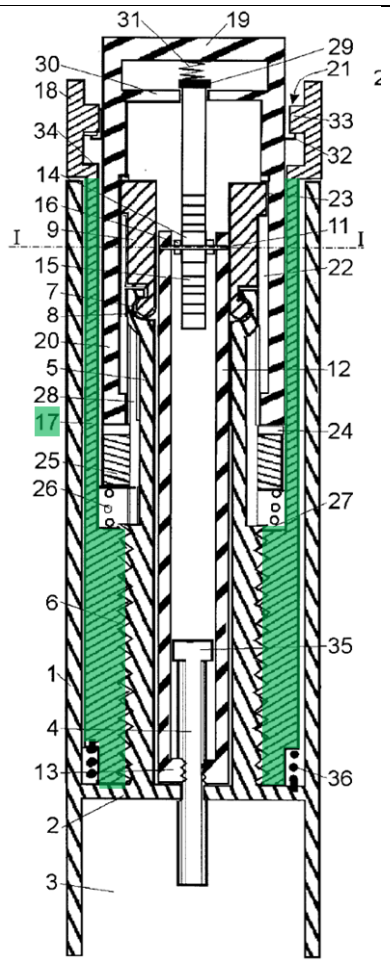
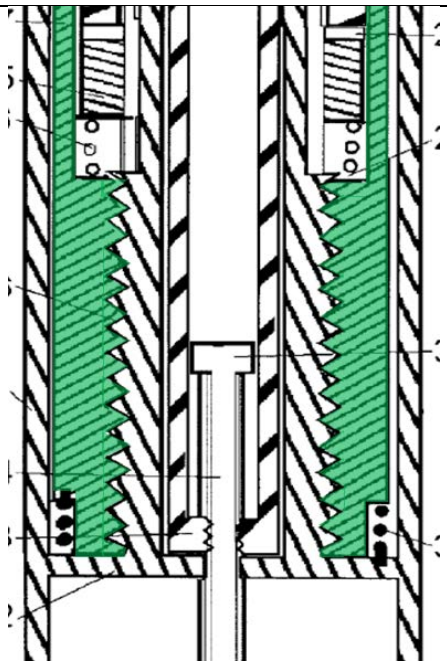


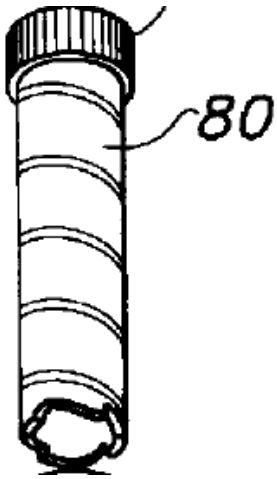
Fig. 1

EX1015, FIG. 1 (drum 17 (green)); EX1011, ¶348; *see also* EX1015, FIGS. 3-5.



EX1011, ¶350.

"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, 11:20-25; *see also id.* 11:52-12:9 (describing operation of scale drum 80).



Id., FIG. 17.

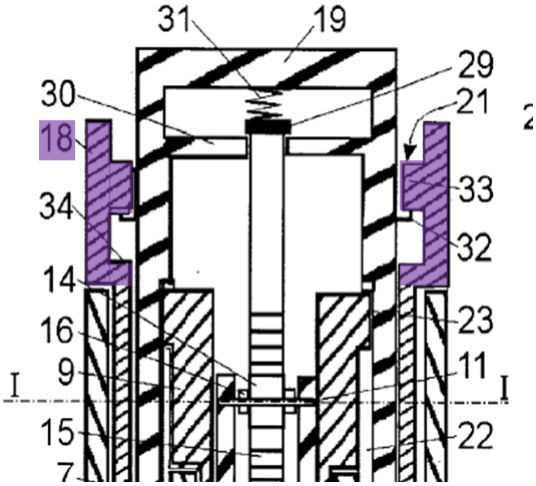
Møller explains that dose-setting drum 17 is within housing 1 and includes threading that engages thread 6 of tubular element 5, which is part of the device's housing. *See* EX1015, ¶25, FIG. 1; EX1011, ¶347. This threaded engagement allows dose-setting drum 17 to be screwed in and out of housing 1 when dialing and injecting a dose. *See* EX1015, ¶25, FIG. 1; EX1011, ¶¶347-48. Møller thus taught the recited "dose dial sleeve."

While Møller does not explicitly state that thread 6 on dose-setting drum 17 includes a helical "groove", a POSA would have understood the thread to contain one. EX1011, ¶¶349-51. Indeed, a POSA would have recognized that, even if the threading were configured as a rib, multiple passes of the rib would create a groove running therebetween. *Id.*

In any event, even if thread 6 were interpreted to lack a helical groove, a POSA would have known to implement thread 6 as a groove from Steenfeldt-Jensen's teaching of a similar dose-dial sleeve having a "helical track." EX1014, 11:20-25, FIG. 17. A POSA would have recognized that groove-to-rib and rib-to-groove threaded engagements were functionally equivalent and largely interchangeable. EX1011, ¶¶352-53. Selecting and implementing such threading was a routine task for a POSA and would have been viewed as no more than "the predictable use of prior art elements according to their established functions."

KSR, 550 U.S. at 417; EX1011, ¶353. A POSA also would have had a reasonable expectation of success implementing thread 6 as a helical groove given that grooved threading was a common and well-understood mechanism, and a POSA would have recognized that using a helical groove to screw dose-setting drum 17 in and out of housing 1 would not change the mechanism's function or the principle of operation. EX1011, ¶353.

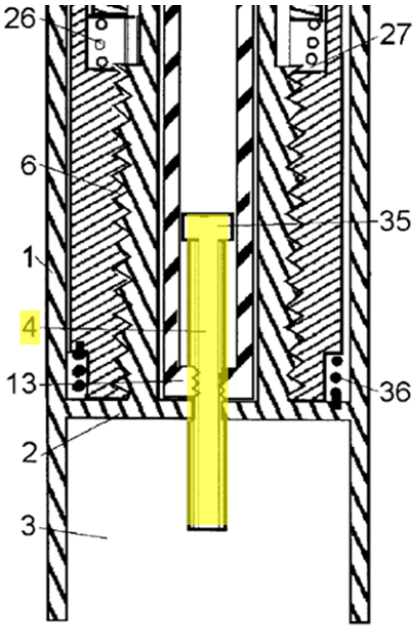
Møller taught "a dose knob":

'486 Patent	Møller and Steenfeldt-Jensen
[1.3] a dose knob disposed near a proximal end of said dose dial sleeve;	"[The] tubular dose setting drum 17 . . . has at its other end a part with enlarged diameter forming a dose setting button 18." EX1015, ¶25; *also id.*, ¶28.  *Id.*, FIG. 1 (partial; button 18 (purple)); EX1011, ¶362.

Møller describes dose-setting button 18 at the button-end of drum 17. EX1015, ¶25, FIG. 1. To set a dose, the user rotates the dose setting button 18 to

screw the dose setting drum 17 along the thread 6 of the housing. *Id.*, ¶29; EX1011, ¶¶362-63. Thus, Møller taught the recited "dose knob."

Møller taught "a piston rod":

'486 Patent	Møller and Steenfeldt-Jensen
[1.4] a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;	"A threaded piston rod 4 has a not round cross section by which it fits through a central opening in the wall 2 so that the piston rod 4 can be displaced longitudinally through the central opening in the wall 2 but not rotated relative to this wall." EX1015, ¶22.  Fig. 1 *Id.*, FIG. 1 (partial; piston rod (yellow)); EX1011, ¶364.

Møller describes piston rod 4 that fits through an opening in partitioning wall 2 of housing 1 so that the rod can move axially, but cannot rotate relative to the wall of housing 1. EX1015, ¶¶22-23. Because piston rod 4 does not rotate relative to the housing, it does not rotate during dose-setting. EX1011, ¶364-65. Thus, Møller taught the recited "piston rod."

Møller taught "a driver":

'486 Patent	Møller and Steenfeldt-Jensen
[1.5] a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod; and	"In [a] gearbox 9 a gear wheel assembly comprising two integral gear wheels is journaled on a shaft 11, which runs perpendicular to the longitudinal axis of the device between two axial connection bars 12. The connection bars 12 project from the gear box towards the partition wall 2 and are connected to a nut 13 which adjacent to the wall 2 engages the thread of the piston rod 4." EX1015, ¶24.

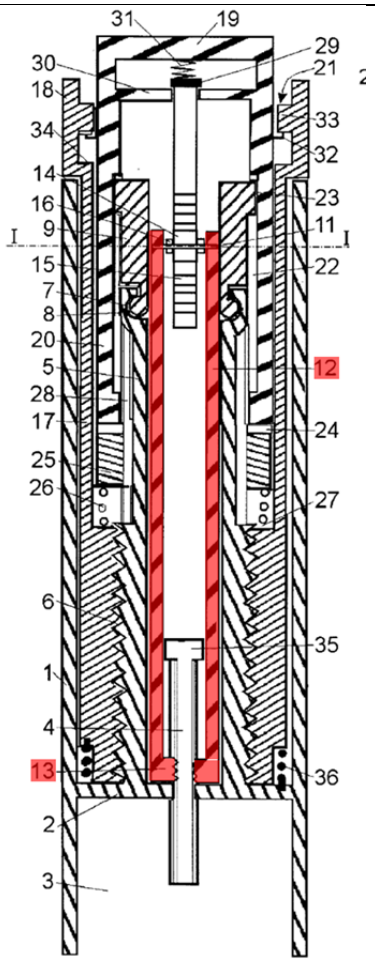


Fig. 1

Id., FIG. 1 (connection bars 12 and nut 13 (red)); EX1011, ¶366.

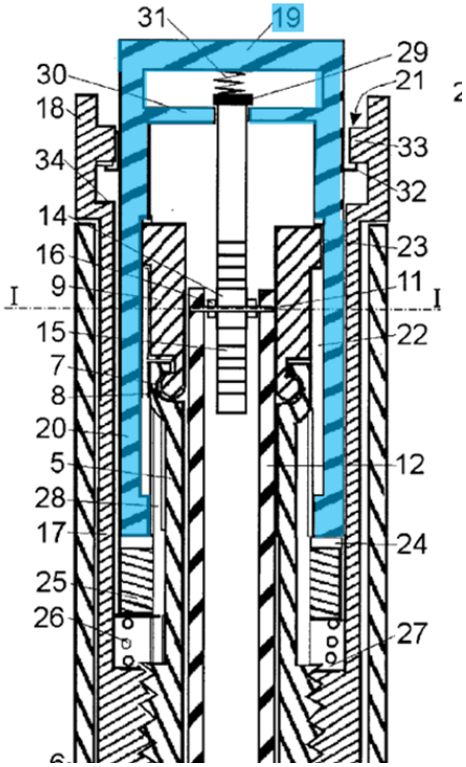
"The rotation of dose setting button 18 and the cup shaped element is further transmitted to the gearbox 9 .... The rotation of the gearbox 25 [*sic*, 9] is through the connection bars 12 transmitted to the nut 13, which is this way screwed up along the thread of the piston rod 4 and lifted away from its abutment with the wall 2 when a dose i[s] set." EX1015, ¶30.

	"To inject a dose the injection button is pressed by pressing on the bottom 19 .... Through the gear box 9 the force is transformed and is transmitted through the connection bars 12 to the nut 13 which will press the piston rod 4 into the compartment 3 until the dose-setting drum 17 abuts the wall 2." *Id.*, ¶32.

Møller teaches a "driver" in the form of connection bars 12 having nut 13 at its needle-end. Nut 13 is internally-threaded and engages the thread of piston rod 4. EX1015, ¶24, FIG. 1; EX1011, ¶¶366-67. Connection bars 12 and nut 13 operate as a "driver" by rotating and riding up piston rod 4 during dose-setting, then pushing straight down during injection to drive the piston rod into the chamber below. EX1015, ¶¶30-33, FIG. 1; EX1011, ¶367. Møller thus taught the recited "driver." EX1011, ¶¶368-69.

Møller teaches "a tubular clutch":

'486 Patent	Møller and Steenfeldt-Jensen
[1.6] a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively	"A bottom 19 in a deep cup shaped element, which has a tubular part 20 fitting into the dose setting drum 17 …, forms an injection button. Coupling means between the dose setting drum 17 and the cup shaped element ensures that rotation of the dose setting drum 17 is transmitted to the cup shaped element. Further the inner wall of the tubular part 20 has longitudinal recesses 22 engaged by protrusions 23 on the gearbox 9 so that

coupled to said dose knob,	rotation of the dose setting drum 17 via the cup shaped element is transmitted to the gearbox 9." EX1015, ¶26.  EX1015, FIG. 1 (partial; cup-shaped element (blue)); EX1011, ¶375. "[T]he coupling 21 ... may comprise Δ-shaped protrusions 32 on the cup shaped element engaging Λ-shaped recesses in an inner ring 33 in the dose setting button 18." EX1015, ¶29. 'To set a dose the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 6. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will be lifted with this drum up from the end of the housing 1." *Id.* "The rotation of dose setting button 18 and the cup shaped

	element is further transmitted to … the connection bars 12 transmitted to the nut 13, which is this way screwed up along the thread of the piston rod 4 and lifted away from its abutment with the wall 2 when a dose i[s] set." *Id.*, ¶30. "To inject a set dose the injection button is pressed by pressing on the bottom 19 .... Through the gear box 9 the force is transformed and is transmitted through the connection bars 12 to the nut 13 which will press the piston rod 4 into the compartment 3 …." *Id.*, ¶32. "During the initial phase of the movement of the injection button the Δ-shaped protrusions 32 on the cup shaped element will be drawn out of their engagement with the Λ-shaped recesses in the ring 33. The dose-setting drum 17 can now rotate relative to the injection button[.]" *Id.*, ¶33.

Møller describes a cup-shaped element that includes bottom 19 and tubular part 20. EX1015, ¶26, FIG. 1; EX1011, ¶372. As shown in FIG. 1, the cup-shaped element is extends into dose-setting drum 17. EX1011, ¶¶372, 376. The cup-shaped element is thus located adjacent the needle-end of dose-setting button 18. EX1011, ¶376. The cup-shaped element is operatively coupled to dose-setting button 18 via the engagement of Δ-shaped protrusions 32 with corresponding recesses 33 in dose-setting button 18. *See* EX1015, ¶29, FIG. 1; EX1011, ¶¶372, 376. The cup-shaped element serves as a clutch by rotationally coupling drum 17

to connection bars 12 and nut 13 during dose setting, then rotationally decoupling those components during injection. *See* EX1015, ¶¶29-30, 32-33, FIG. 1; EX1011, ¶¶373-377.

If "tubular clutch" is construed as a means-plus-function limitation, Møller taught it. The '486 patent discloses clutch 60:

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

EX1003, 4:50-62, 5:1-2, 2:17-19; *see also* EX1011, ¶378.

The tubular clutch, therefore, is "generally cylindrical," having a series of "circumferentially directed ... teeth" at its first end (needle-end), and also has a

plurality of teeth at its second end (button-end). *Id.*, 4:50-62. The needle-end teeth engage the clicker, and the button-end teeth engage the dose-dial sleeve. *Id.*, 54:50-62, 5:1-2, 2:17-19. The clutch is also keyed to the drive sleeve, through the use of splines, to prevent relative rotation between the clutch and drive sleeve. *Id.*, 4:60-62.

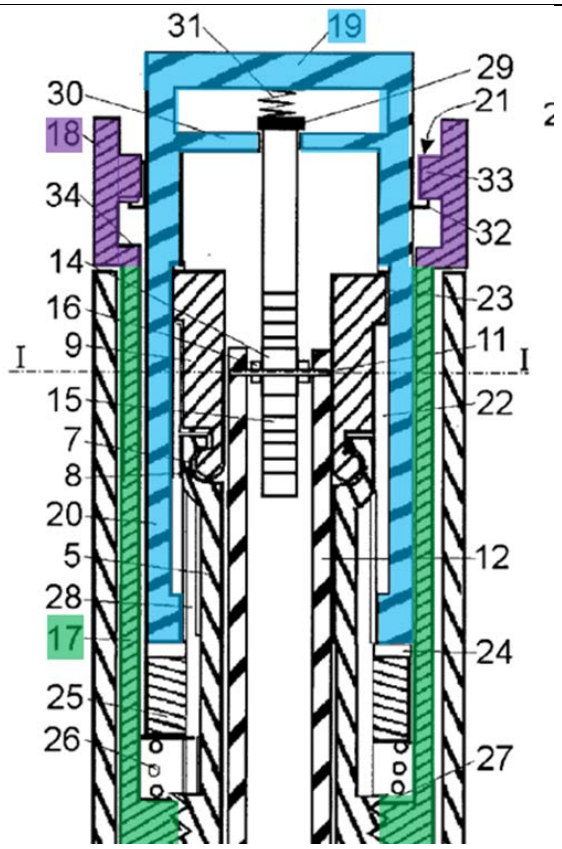
Møller's cup-shaped element operates in a similar manner using similar structure, as understood from Møller's second embodiment having a corresponding tubular element 120. *Compare* EX1015, FIGS. 1 *with* EX1001, FIGS. 6-8; EX1011, ¶380. Tubular element 120 is seated within dose-setting button 118 and is operatively coupled to button 118 via teeth 132, which releasably engage corresponding teeth 133 in button 118. EX1015, ¶¶36, 38-40, FIGS. 3-5; EX1011, ¶380. Tubular element 120 acts functionally the same as cup shaped element by coupling dose-setting button 118 and drum 117 to tubular element 112 with nut 113 during dose setting, then rotationally decouples those components during injection. *See* EX1011, ¶380. Like clutch 60, tubular element 120 includes a set of axially extending teeth 132 at its button-end that releasably engage teeth 133 in dose-setting button 118. *See* EX1015, ¶¶36, 39, FIGS. 3-5; EX1011, ¶380; *see also* EX1015, ¶¶29-30, FIG. 1. Both embodiments also include a biasing element (spring 26/126) that exerts upward force to keep the clutch engaged during dose setting. *See* EX1015, ¶¶27, 29, 39, FIGS. 3-5; EX1011, ¶380. The user applies force to the button (bottom 19 or button 119), which disengages the teeth to

rotationally decouple the components during injection. *See* EX1015, ¶¶27, 29, 39, FIGS. 3-5; EX1011, ¶380. Thus, cup shaped element and tubular element 120 not only have the structure of clutch 60, they also serve as a clutch because they releasably decouple components during injection. *See* EX1011, ¶380.

Accordingly, Møller taught the recited "tubular clutch."

Møller teaches the recited positioning of the components:

'486 Patent	Møller and Steenfeldt-Jensen
[1.7] wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.	"A bottom 19 in a deep cup shaped element, which has a tubular part 20 fitting into the dose-setting drum 17 and encompassing the gearbox 9, forms an injection button." EX1015, ¶26.

	 *Id.*, FIG. 1 (partial; annotating cup-shaped element blue and dose-setting drum 17 green); EX1011, ¶381.

As shown above in FIG. 1, dose-setting drum 17 "extends circumferentially around at least a portion of" the cup-shaped element. EX1015, FIG. 1; EX1011, ¶381. Møller thus taught the limitations of element [1.7].

Accordingly, claim 1 was obvious over Møller and Steenfeldt-Jensen.

2. Claim 2

'486 Patent	Møller and Steenfeldt-Jensen
[2.] The housing part of	*See* elements 1.6 and 1.7, *supra*.

claim 1, wherein said tubular clutch is directly coupled to said dose knob.	

As explained above, Møller describes a cup-shaped element having Δ-shaped protrusions 32 that directly engage recesses on dose-setting button 18 during dose setting. *See* EX1015, ¶¶29, 32, FIG. 1; EX1011, ¶388. Møller taught teaches the additional limitations of claim 2.

3. Claims 3-4

’486 Patent	Møller and Steenfeldt-Jensen
[3.] The housing part of claim 1, wherein said main housing comprises a window through which at least a portion of an outer surface of said dose dial sleeve may be viewable.	“Due to the engagement with the thread 6 the dose setting drum 17 may be screwed in and out of the housing to show a number on a not shown helical scale on its outer surface in a not shown window in the housing 1.” EX1015, ¶25; *also id.*, Abstract. *Also* EX1014, 6:18-21, 7:31-33, FIGS. 2, 3, 6, 8, 15, 17 (describing similar window 18).
[4.] The housing part of claim 3, wherein said window is located near a proximal end of said main housing and near a helical rib provided on an inner surface of said outer housing.	

Møller teaches that an un-shown window permits housing 1 "to show a number on a not shown helical scale" on the outer surface of dose-setting drum 17. EX1015, ¶25, Abstract; EX1011, ¶389. Møller thus taught claim 3.

Møller does not explicitly state where the window would be in its housing, but a POSA would have placed the window "near a proximal end of" the housing and "near a helical rib provided on an inner surface" of the housing. EX1011, ¶390.

First, while Møller also does not depict a helical groove on the inner surface of the housing, Steenfeldt-Jensen teaches this feature. *See* EX1014, 11:20-22, FIGS. 15-17; EX1011, ¶391. A POSA would have known to put the threaded engagement for housing 1 and dose-setting drum 17 between the housing's *inner* surface and the drum's *outer* surface as Steenfeldt-Jensen taught. EX1011, ¶¶355-61, 391.

Møller expressly discusses the device disclosed in Steenfeldt-Jensen, explaining Steenfeldt-Jensen's use of a "thread with [a] high pitch [that] is cut in the outer surface of a dose-setting drum and is engaged by a mating thread on the inner side of the cylindrical housing." *See* EX1015, ¶8 (referencing EX1027). Møller, however, notes what it views is a disadvantage of Steenfeldt-Jensen's device: since the force needed to drive the piston rod is transferred via the drum's threaded rotation with the housing, "most of the transformed force is lost due to

friction between the sliding surfaces" of the drum and housing. *Id.*, ¶8; EX1011, ¶¶356-57. Møller thus concludes that "traditional gearing using mutual engaging gear wheels and racks is preferred." EX1015, 2:5-6.

Møller states its injection device, "combines the advantages of the devices according to the prior art without adopting their disadvantages." *Id.*, ¶¶11-12. Møller's injection device retains the dose-setting drum that threadedly engages the housing, but includes a gearbox that provides direct gearing to drive the piston rod. *Id.*, ¶11-12; EX1011, ¶358. Møller states "[i]n such a device only the forces necessary to drive the dose-setting drum are transformed by a thread with a high pitch whereas the forces necessary to move the piston by injection is transmitted to said piston through a conventional gear[.]" EX1015, ¶14; *also id.*, ¶33; EX1011, ¶358.

As Møller recognized, Steenfeldt-Jensen discloses numerous embodiments of dose-dialing sleeves having a helical groove provided on the outer surface for engaging a rib on the housing. *See, e.g.*, EX1014, 6:7-17, FIGS. 3, 8, 13, 17. Steenfeldt-Jensen teaches that the helical groove has a high pitch, and that its pitch angle is such that it "exceeds the angle of friction for the materials forming" the drum and housing. EX1014, 6:7-17; *also* EX1011, ¶359. This results in a non-self-locking threaded connection between the components such that relative

rotation between the components can be easily induced by axial movement of a component. *See* EX1014, 6:7-17; EX1011, ¶359.

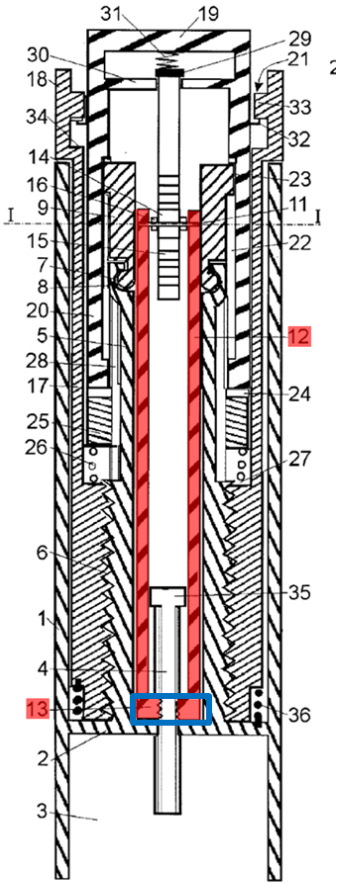
A POSA would have recognized the benefit to placing a threaded engagement, like that of Steenfeldt-Jensen, on a drum and housing like Møller. EX1011, ¶360. Because the threaded engagement in Steenfeldt-Jensen is configured to reduce sliding friction between the drum and housing, a POSA would have understood this configuration would reduce the force needed to rotate the drum back into the housing during injection. EX1011, ¶360. A POSA also would have understood and reasonably expected that the configuration would retain rotational movement between the drum and housing and would not affect operation of the device. EX1011, ¶360. Indeed, Møller expressly contemplates the use of a high-pitched threaded engagement between the drum and housing, and does not place any significance on the placement of that engagement. *See, e.g.*, EX1015, 2:50-65, 3:19-23, claim 11. A POSA thus would have had reason to position a high-pitch rib-to-groove connection taught by Steenfeldt-Jensen between the inner surface of housing 1 and the outer surface of drum 17 of Møller's drum, and would have reasonably expected the configuration would perform in the same manner as the inner threading of Møller's drum. EX1011, ¶391.

Second, a POSA would have naturally placed the window near the button-end of the housing so that the numbers on the outer surface of the dose-dial sleeve

would be visible for the full range of dial-able doses. EX1011, ¶392. In any event, Steenfeldt-Jensen teaches the recited placement of the window. *See* EX1014, FIGS. 15-17; EX1011, ¶392.

Accordingly, claims 3-4 were obvious over Møller and Steenfeldt-Jensen.

4. Claim 5

’486 Patent	Møller and Steenfeldt-Jensen
[5.] The housing part of claim 1, wherein said driver comprises a cylindrical shape.	*See* EX1015, FIGS. 1, 3-5.  Fig. 1 EX1011, ¶394.

Møller discloses a "driver" in the form of connection bars 12 with nut 13. A POSA would have understood the nut 13 to have a cylindrical shape. EX1011, ¶394. To the extent nut 13 is not considered "cylindrical," as explained above, Møller teaches a corresponding driver, in the form of tubular connection element 112 with nut 113, that is structurally and functionally equivalent to connection bars 12 with nut 13. EX1011, ¶395. Tubular connection element 112 comprises a cylindrical shape, and a POSA would have recognized connection bars 12 with nut 13 could be formed as a tubular structure. EX1015, FIG. 5; EX1011, ¶395. Accordingly, Møller taught claim 5.

5. Claim 6

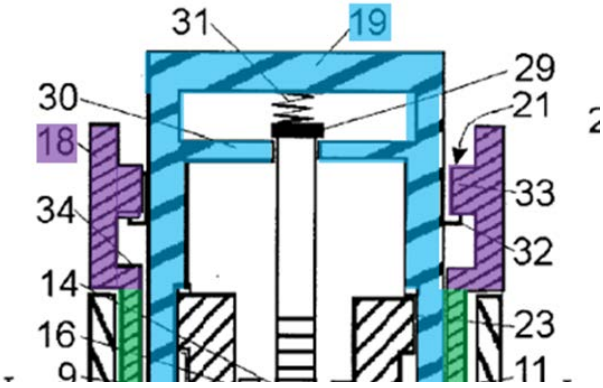
'486 Patent	Møller and Steenfeldt-Jensen
[6.] The housing part of claim 1, wherein said dose knob extends circumferentially around at least a portion of said tubular clutch.	 EX1015, FIG. 1 (partial; cup-shaped element (blue), dose-setting button 18 (purple)); EX1011, ¶396.

FIG. 1 of Møller shows dose-setting button 18 extends circumferentially around a portion of the cup-shaped element. EX1011, ¶396-97. Accordingly, Møller taught claim 6.

6. Claims 12-13

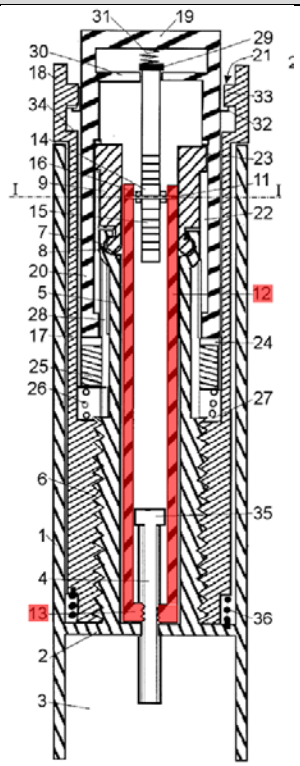
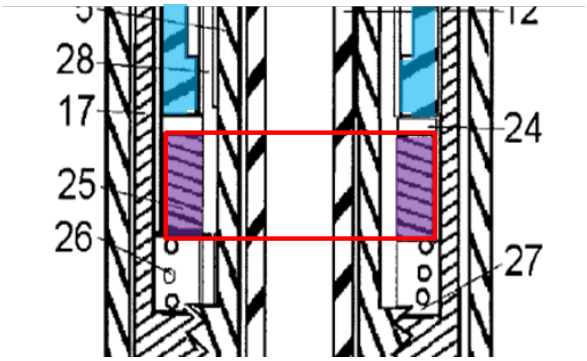
’486 Patent	Møller and Steenfeldt-Jensen
[12.] The housing part of claim 1, wherein said driver comprises at least one flange.	 Fig. 1
[13.] The housing part of claim 12, wherein said at least one flange is located near a distal portion of said driver.	EX1015, FIG. 1; EX1011, ¶¶366-67.

FIG. 1 depicts nut 13 situated at the needle-end of the connection bars 12 that includes inwardly-extending features (flange) to engage the piston rod 4. EX1015, ¶ 24; *see also id.*, ¶40, FIGS. 3-5. Steenfeldt-Jensen also discloses a

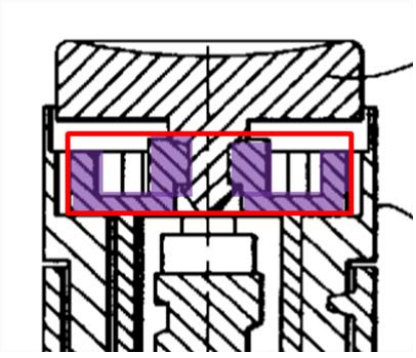
flange at the needle-end of the driver. *See supra*, V.F.6. Accordingly, claims 12-13 were obvious over Møller and Steenfeldt-Jensen.

7. Claims 14-18, 20

Møller and Steenfeldt-Jensen taught a clicker:

<table>
<tr><th>’486 Patent</th><th>Møller and Steenfeldt-Jensen</th></tr>
<tr><td>[14.] The housing part of claim 1, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose knob is rotated.</td><td rowspan="3">“At the edge of the open end of the cup shaped element a rosette of V-shaped teeth … engage a corresponding rosette of V-shaped teeth 24 on a ring 25 which is pressed against the edge of the cup shaped element by a spring 26 …. Thereby a click coupling is established which makes a click noise when the V-shaped teeth at the edge of the cup shaped element by rotation of this element rides over the V-shaped teeth of the ring 25.” EX1015, ¶27; see also id., ¶40.
 

EX1011, ¶416.
“By the rotation of the cup shaped element the V-shaped teeth 24 … will ride over the V-shaped teeth of the non</td></tr>
<tr><td>[15.] The housing part of claim 14, wherein said clicker provides tactile feedback to a user when said dose knob is rotated.</td></tr>
<tr><td>[16.] The housing part of claim 14, wherein said clicker provides audible feedback when</td></tr>
</table>

said dose knob is rotated in a dose increasing direction.	rotatable ring 25 to make a click sound for each unit the dose is changed. A too high set dose can be reduced by rotating the dose setting button 18 in the opposite direction of the direction for increasing the dose." EX1015, ¶29.
[17.] The housing part of claim 14, wherein said clicker provides audible feedback when said dose knob is rotated in a dose decreasing direction.	"In the dose setting button a compartment is provided having a cylindrical side wall circumferentially provided with longitudinal recesses …. 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, 11:34-40.
[18.] The housing part of claim 14, wherein said clicker comprises, at least one flexible arm, said flexible arm comprising at least one tooth member, and at least one spline, wherein when said dose knob is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as	"[B]y 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 one." *Id*., 11:62-67.   *Id*., FIG. 17 (partial; flange (purple)); EX1011, ¶417.

to provide said audible feedback.	
[20.] The housing part of claim 14, wherein said clicker generally comprises a cylindrical shape having a first and a second end, and said cylindrical shape is provided at said first end with at least one flexible extending arm.	

Both Møller and Steenfeldt-Jensen teach the use of a clicker. EX1011, ¶¶398-400. Møller explains that the needle-end of cup-shaped element has "a rosette of V-shaped teeth" that "engage a corresponding rosette of V-shaped teeth 24" on ring 25. EX1015, ¶27. The rosettes operate as a "click coupling" by "mak[ing] a click noise," in other words, providing audible feedback, when the teeth ride over each other during rotation. *Id.*, ¶27, FIG. 1; EX1011, ¶399. Steenfeldt-Jensen teaches radial protrusion 87 on flange 83 that engages recesses in dose-setting button 81 during dose setting. EX1014, 11:37-40, FIG. 17; *also id.*,

3:19-26, 6:54-7:1, 9:30-35, 9:48-52, FIGS. 3-4, 13 (teaching other clicker embodiments). Thus, both Møller and Steenfeldt-Jensen taught a clicker as recited in claim 14.

If "clicker" is construed to be means-plus-function, Møller and Steenfeldt-Jensen taught it as well. The '486 patent teaches that during dose-dialing, "flexible arm 52" with "toothed member 54" drags over "splines 42" produce a click during dialing-up and saw teeth 55 riding over saw teeth 66 produce a click during dialing-down. EX1003, 5:57-59, 6:22-27. The clickers of Møller (teeth) and Steenfeldt-Jensen (flexible arm and splines) include the same structure and same function as that disclosed by the '486 patent. EX1011, ¶402; *supra*, §V.F.7.

As to claim 15, a POSA would have recognized that both Møller's clicker (teeth riding over each other) and Steenfeldt-Jensen's clicker (a flexible arm being dragged over splines) would involve sufficient force with each click to provide tactile feedback that can be felt by the user. EX1011, ¶¶403-05; *also supra*, §V.F.7. This understanding is consistent with the '486 patent, which states that the clicker provides audible and tactile feedback during clicks produced by a flexible arm dragging over splines during dose-dialing up, and saw teeth riding over another during dose-dialing down. EX1003, 5:54-60, 6:22-27.

As to claims 16 and 17, Møller and Steenfeldt-Jensen both teach clickers that provide audible feedback when the dose knob is rotated in the dose increasing

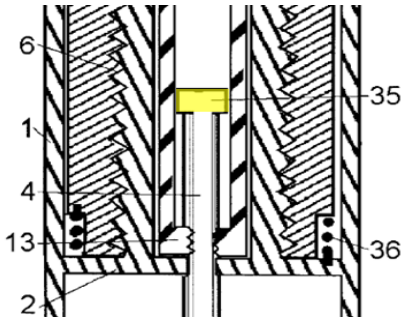
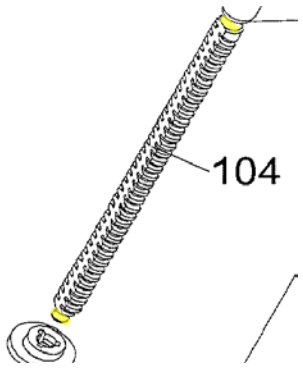
direction and the dose decreasing direction. *See* EX1015, ¶29 ("A too high set dose can be reduced by rotating the dose setting button 18 in the opposite direction of the direction for increasing the dose."); EX1014, 11:62-67 ("[R]otation of the dose setting button 81 in any direction" produces clicks); EX1011, ¶¶408-12.

As to claim 18, Møller's clicker produces clicks when teeth ride over each other. Steenfeldt-Jensen teaches radial protrusion 87 (a flexible arm) dragging over axial ridges and recesses to produce clicks. EX1011, ¶¶413-14. Given the identical function and similar placement on rotating sleeves, a POSA would have viewed them as interchangeable. *Id.*, ¶¶414-15. A POSA would have had reason to implement a clicker such as Steenfeldt-Jensen's in a device like Møller's. Such implementation would have been a routine task involving the combination of common, well-understood components performing their same, predictable function. *Id.*, ¶¶114-15, 123-24.

As to claim 20, Møller's and Steenfeldt-Jensen's clickers are situated on cylinders with two ends. EX1011, ¶¶416-17. Steenfeldt-Jensen's flexible arm is provided at one such end. EX1014, FIG. 17; EX1011, ¶417. As explained above, a POSA would have had reason to implement this type of clicker in Møller's pen. EX1011, ¶418. The references thus taught claim 20.

8. Claim 23

'486 Patent	Møller and Steenfeldt-Jensen

[23.] The housing part of claim 1, wherein said piston rod comprises a generally circular cross section.	*See* elements 1.4-1.5, *supra*.   EX1015, FIG. 5 (partial; piston rod 104 annotated yellow); EX1011, ¶420.

As noted above, claim 23 merely requires that the piston rod have "a" cross-section that is "generally circular." Piston rod 4 includes a "generally" circular cross-section at its button-end, which is confirmed by the cross-section shown in corresponding piston rod 104 of FIG. 5. EX1015, FIGS. 1, 5; EX1011, ¶419. The needle-end of piston rod 104 also includes a "generally" circular cross-section to engage a circular opening in a pressure foot, which a POSA would have readily recognized would be included in the corresponding piston rod of FIG. 1. EX1015, FIG. 5; EX1011, ¶419.

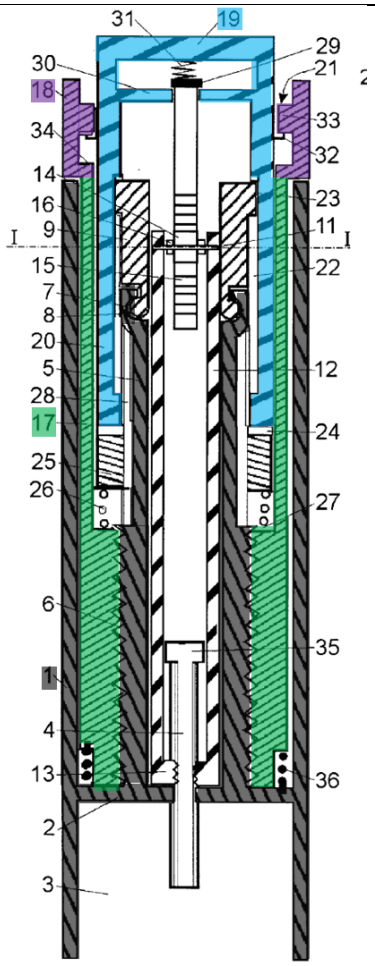
Even if claim 23 required a generally circular cross-section along the entire length of the piston rod, a POSA would have understood the piston rod of Møller, described as having a non-circular cross-section to engage wall 2, to include a

"generally" circular cross-section along its length. EX1011, ¶421. A POSA would have viewed this cross-section as "generally" circular given the rod's helical threading, particular since (1) even the piston rod described in the '486 patent has a cross-section with certain non-circular features due to the threads themselves and (2) the '486 offers no guidance as to the lower bound for what would be considered "generally" circular. EX1011, ¶421.

Accordingly, Møller and Steenfeldt-Jensen rendered claim 23 obvious.

9. Claim 26

'486 Patent	Møller and Steenfeldt-Jensen

[26.] The housing part of claim 1, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.	 Fig. 1 *Id.*, FIG. 1 (housing (gray), dose-setting drum (green), cup-shaped element (blue)); EX1011, ¶423.

As shown in FIG. 1, dose-setting drum 17 is provided outside of the cup-shaped element and radially inward of housing 1. EX1011, ¶423. Accordingly, Møller and Steenfeldt-Jensen rendered claim 26 obvious.

10. Claims 27-29

’486 Patent	Møller and Steenfeldt-Jensen
[27.] The housing part of claim 1, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along an outer surface of said dose dial sleeve.	*See* elements 1.1-1.3, claim 4; *supra*, §V.F.10.
[28.] The housing part of claim 27, wherein said helical rib extends for at least a single sweep of said inner surface of said main housing.	
[29.] The housing part of claim 27, wherein said helical rib comprises a single start helical rib.	

As explained above, a POSA would have had reason to provide the drum of Møller with a helical groove on its outer surface to mate with a corresponding helical rib on the housing's inner surface in view of Steenfeldt-Jensen. *See supra*, §V.G.3. A POSA would have recognized that modified in this manner, Møller's pen would include a main housing comprising a helical rib adapted to be seated in the helical groove on the outer surface of dose-setting drum 17. EX1011, ¶424.

As to claim 28, Møller shows a thread 6 and Steenfeldt-Jensen shows a helical rib that both extend for several sweeps. EX1014, FIG. 16; EX1015, FIG. 1. Thus, a POSA would have known to provide a helical rib on the housing's inner surface that "extends for at least a single sweep." EX1011, ¶426.

As to claim 29, as explained above, a POSA would have understood the mechanical differences between single-start threads and multi-start threads. EX1011, ¶428. Also, both Møller and Steenfeldt-Jensen teach the use of a high-pitch threaded arrangement between the dose setting drum and the housing. *See* EX1015, ¶¶5-6, 14; EX1014, 6:7-17; EX1011, ¶428. As explained above, a POSA would have understood that with such arrangement, a single-start thread would be sufficient for the drum's axial movement during dose-setting. *See supra*, §V.F.10; EX1011, ¶429.

Accordingly, claims 27-29 were obvious over Møller and Steenfeldt-Jensen.

11. Claims 30 and 32

’486 Patent	Møller and Steenfeldt-Jensen
[30.] The housing part of claim 1, wherein said dose dial sleeve comprises at least one radial stop, said radial stop positioned near an end of said helical groove.	“When the dose scale drum is displaced outwardly in the housing a steep front side of a saw tooth 91 at the proximal end of the dose scale drum 18 will abut a steep front side of a similar tooth 92 on the bushing whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set.” EX1014, 9:57-62; *also* FIGS. 12-13, 15-17.
[32.] The housing part of claim 30, wherein said radial stop is positioned near a distal end of said helical groove.	

As discussed above, a POSA had reason to implement the threading on Møller’s dose setting drum as a helical groove in view of Steenfeldt-Jensen’s teachings. *Supra*, §V.G.3. It also would have been apparent to position the radial stop “near an end” of the groove to properly limit the drum’s travel. EX1011, ¶¶432-33. For example, Steenfeldt-Jensen describes an embodiment where a tooth on the scale drum operates as a stop to indicate maximum dose. EX1014, 9:57-62,

EX1011, ¶¶433-34; *also supra*, §V.F.11. A POSA had reason to apply this teaching to Møller's dose-setting drum to similarly limit travel and prevent over-dialing. EX1011, ¶435-37. This stop would naturally be provided near the needle-end of the groove, since this would be the last point of contact between the drum and the housing as the drum rotated out of the housing toward the maximum dose. *Id.* The references thus taught the additional limitations of claims 30 and 32.

12. Claim 33

'486 Patent	Møller and Steenfeldt-Jensen
[33.] The housing part of claim 1, wherein if a user inadvertently dials said dose knob in one direction beyond a desired dose, said dose knob may be rotated in a second direction so as to allow said dialed dose to be reduced.	"A too high set dose can be reduced by rotating the dose setting button 18 in the opposite direction of the direction for increasing the dose." EX1015, ¶40.

Møller explains that the user can reduce by rotating the dose-setting button in an "opposite direction of the direction for increasing the dose." EX1015, ¶40; EX1011, ¶440. Claim 33 was thus obvious over Møller and Steenfeldt-Jensen.

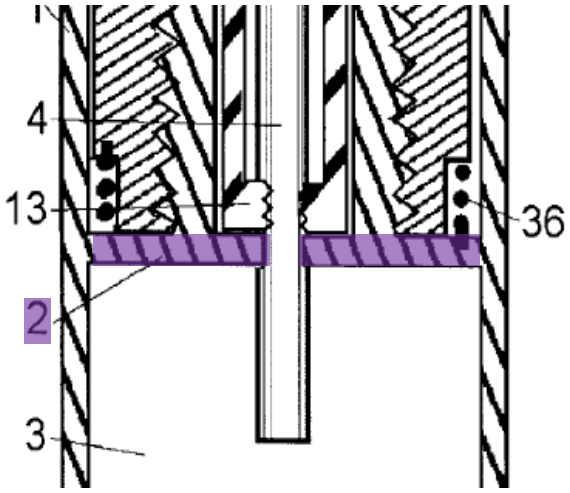
13. Claim 36

'486 Patent	Møller and Steenfeldt-Jensen
[36.] The housing part of claim 1, wherein said housing part and said container comprises a disposable device.	"When a disposable syringe is in question, i.e. a syringe which is disposed of when the cartridge is empty, the syringe must further be cheap and made of materials suited for recycling or burning without producing noxious gases. For these purposes the number of parts from which the syringe is constructed and the number of different kinds of materials used in the syringe should be kept at a minimum." EX1014, 1:22-29.

Møller describes a fluid "container" in the form of a medicine-containing ampoule. EX1015, ¶¶22, 32; EX1011, ¶441. While Møller does not explicitly state that its pen is disposable, a POSA would nevertheless have appreciated that users were able to dispose of such pens, especially in view of Steenfeldt-Jensen's recognition that disposable pens were known in the art. EX1014, 1: 22-29; EX1011, ¶441; *also supra*, §V.F.13. Accordingly, Møller and Steenfeldt-Jensen rendered claim 36 obvious.

14. Claims 38-40

Møller and Steenfeldt-Jensen teach an insert:

’486 Patent	Møller and Steenfeldt-Jensen
[38.] The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main housing, said insert secured against rotation.	*See* elements 1.1, 1.4.  EX1011, ¶442.
[39.] The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main housing, and said insert secured against longitudinal motion.	
[40.] The housing part of claim 39, wherein said insert comprises an opening extending therethrough, such that	

said piston rod is configured to extend through said opening.	

Møller explains piston rod 4 fits through "a central opening in the wall 2 so that the piston rod 4 can be displaced longitudinally through the central opening in the wall 2 but not rotated relative to this wall." EX1015, ¶22. Møller thus teaches an insert in the form of wall 2 that is positioned near the needle-end of the housing. EX1011, ¶442. Because wall 2 is integrally formed with housing 1, it is secured against rotation (claim 38) and longitudinal motion (claim 39) relative to the housing. EX1011, ¶¶442-44.

As to claim 40, wall 2 includes an opening through which piston rod 4 extends. EX1015, ¶22, FIG. 1; EX1011, ¶445.

Accordingly, Møller and Steenfeldt-Jensen rendered claims 38-40 obvious.

VI. CONCLUSION

The challenged claims are unpatentable. Mylan requests that IPR 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 13,959, which is less than the 14,000 allowed under 37 C.F.R. 42.24(a)(i). In accordance with 37 C.F.R. 42.24(a), this word count does not include table of contents, table of authorities, mandatory notices under §42.8, certificate of service or word count, or appendix of exhibits or claim listing.

Dated: 10 September 2018

/ Richard Torczon /
Reg. No. 34,448

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, I certify that I caused to be served a true and correct copy of the foregoing: **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,992,486 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:

McDonnell Boehnen Hulbert & Berghoff LLP
300 S. Wacker Drive 32nd Floor
Chicago IL 60606

Respectfully submitted,

Dated: 10 September 2018

/Richard Torczon /
Reg. No. 34,448