UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case No. IPR2018-01676
Patent No. 8,603,044

PETITION FOR *INTER PARTES* REVIEW

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Exhibit No.	**Description**
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I. INTRODUCTION

Petitioner ("Mylan") petitions for *inter partes* review of U.S. Patent 8,603,044 ("the '044 patent," EX1002). 35 U.S.C. 311. This petition shows a reasonable likelihood that claims 11, 14, 15, 18, and 19 are unpatentable.

II. MANDATORY NOTICES

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

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

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

This patent has been asserted in *Sanofi-Aventis U.S. LLC, et al. v. Mylan GmbH, et al.*, No. 2:17-cv-09105 (D.N.J.), filed October 24, 2017. Mylan, Biocon, and their real parties-in-interest listed above are parties to this litigation. Becton Dickinson and Company supplies pens to Mylan, but has not been named as a party.

The '044 patent also has been asserted in *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812 (D. Del.) and in *Sanofi -Aventis U.S. LLC v. Eli Lily and Co.*, No. 14-cv-113 (D. Del.) (consent judgment). *See* EX1029 (*Markman* opinion in *Merck*); EX1030 (*Markman* opinion in *Eli Lilly*). The real parties-in-interest are not parties to these litigations.

Mylan also challenges claims 11, 14, 15, 18, and 19 in IPR2018-01675. Mylan has filed IPR2018-01670, IPR2018-01677, IPR2018-01678, IPR2018-01679,

IPR2018-01680, IPR2018-01682, IPR2018-01684 and IPR2018-01696 against related patents.

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

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Please direct all correspondence to lead counsel and back-up counsel. Mylan consents to electronic mail service at 34943.682.palib1@matters.wsgr.com and the email addresses above. A power of attorney accompanies this petition.

III. CERTIFICATIONS

Mylan certifies the ’044 patent is available for IPR and that Mylan is not barred or estopped from requesting IPR on these grounds.

IV. IDENTIFICATION OF CHALLENGE; STATEMENT OF PRECISE RELIEF REQUESTED

Mylan requests IPR and cancellation claims 11, 14, 15, 18, and 19 under pre-AIA 35 U.S.C. 103, as explained below with exhibits, including an expert declaration from Karl Leinsing (EX1011), on the following grounds:

Ground	Claims	Basis
1	11, 14, 15, 18, 19	U.S. Patent 6,235,004 (EX1014, “Steenfeldt-Jensen”)
2	11, 14, 15, 18, 19	U.S. Patent 6,663,602 (EX1015, “Møller”) and Steenfeldt-Jensen

V. REASONS FOR RELIEF REQUESTED

A. Argument Summary

The challenged claims relate to a drive mechanism for dispensing medicine from a pen-type injector. EX1002, Title, 1:20-29. Independent claim 11 broadly recites a six-component structure forming this mechanism. These components include structural elements that are also claimed broadly. Yet, these component were known and commonly used together in the prior art. Similarly, the structural elements were known and commonly used together in the prior art. What differences exist between the prior art and claims 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 claims combined familiar elements in a predictable way. Claims 11, 14, 15, 18, and 19 are unpatentable over the prior art.

B. '044 Patent[1]

1. Background

The '044 patent relates to a pen-type injector for self-administrating medicine. EX1002, Title, 1:20-29. Such injectors are appropriate for patients who do not have formal medical training. *Id.*, 1:25-29. Thus, such injectors must be easy to use. *Id.*, 1:23-31. The patent describes and claims a housing part containing a drive mechanism for dispensing medicine from an injector. The patent issued with twenty claims, but this petition challenges only claims 11, 14, 15, 18, and 19. Claim 11 is independent; claims 14, 15, 18, and 19 depend from it. Claim 11 recites:

> 11. A housing part for a medication dispensing apparatus, said housing part comprising:
>
> 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

[1] For uniformity, component positioning and movement will be described relative to the device's "button-end" and the "needle-end".

provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;

a dose dial grip 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 drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, 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 dial grip, said tubular clutch operatively coupled to said dose dial grip,

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

wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different.

Id., 8:7-36.

Independent claim 11 recites six components forming the claimed device:

(1) "main housing" (4, gray), which houses the drive mechanism for dispensing medicine from a cartridge, *e.g.*, *id.*, 3:27-33, FIGS. 1-5;

(2) "dose dial sleeve" (70, green), which the user manipulates to set a specific dose for injection, *e.g.*, *id.*, 5:3-6, FIGS. 1-5, 9-11;

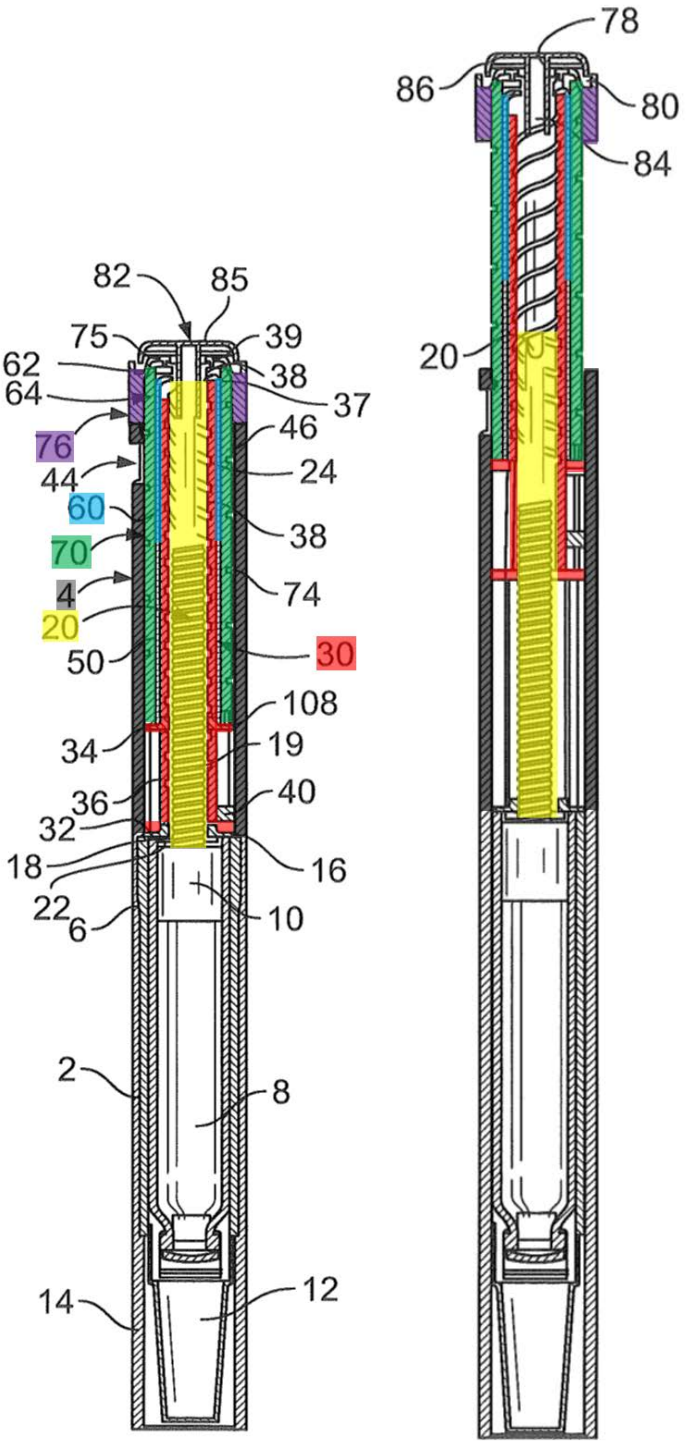
(3) “dose dial grip” (76, purple), which is a grip for the user to manipulate the dose dial sleeve, *e.g.*, *id.*, 5:24-32, 50-53, FIGS. 1-5, 9-11;

(4) “piston rod” (20, yellow), which is driven to move a piston provided within the cartridge to dispense medicine, *e.g.*, *id.*, 3:56-67, 6:44-46, FIGS. 1-5;

(5) “drive sleeve” (30, red), which drives the piston rod in order to move the piston, *e.g.*, *id.*, 4:4-13, 6:44-46, FIGS. 1-15, 9-11; and

(6) “tubular clutch” (60, blue), which releasably connects components within the drive mechanism for common movement during use, *e.g.*, *id.*, 2:1-3, 2:16-18, 5:50-53, 6:27-34, FIGS. 1-5, 9-11.

Below, annotated FIGS. 1 (left) and 2 (right) color-code these components. EX1011, ¶38.



Brief Overview of Embodiments

An injector housing has two parts: (1) first cartridge-retaining part 2, containing cartridge 8, and (2) second main-housing part 4 (gray). EX1002, 3:27-38, FIG. 1.

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

In an exemplary embodiment, insert 16 is at the needle-end[2] of housing part 4. *Id.*, 3:49-50; FIG. 1. Insert 16, fixed to the housing rotationally and axially, includes threaded circular opening 18, through which the needle-end of piston rod 20 (yellow) extends. *Id.*, 3:49-59; 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 also includes pressure foot 22, which abuts piston 10 of cartridge 8. *Id.*, 3:59-61; FIG. 1.

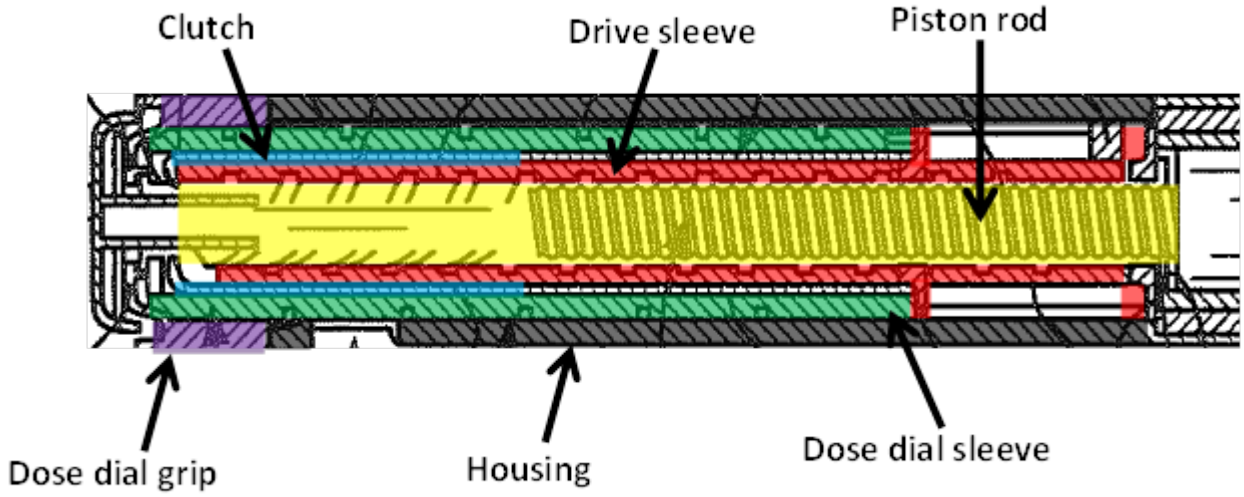


FIG. 1 (partial) cartridge-full position, before dose setting (*id.*, 2:53-55),

[2] In the specification, the needle-end is the device's "first end," the button-end is its "second end." *E.g.*, EX1002, 3:8-14. In claim 11, the needle-end is the device's "distal end," the button-end is its "proximal end." *Id.*, claim 11.

annotated (EX1011, ¶39)

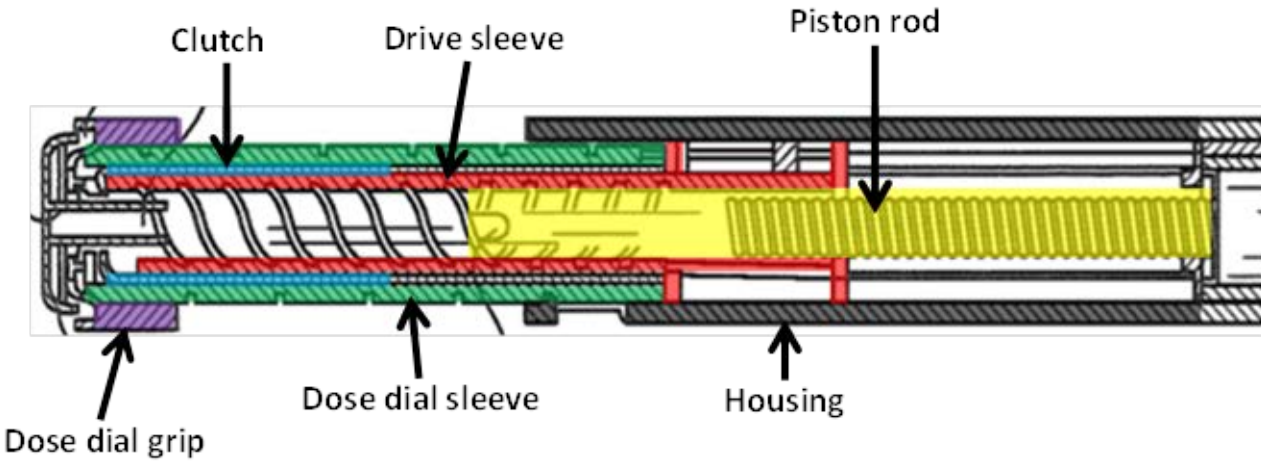


FIG. 2 (partial) maximum dose-dialed position (EX1002, 2:56-57), annotated (EX1011, ¶39)

Piston rod 20 also includes second thread 24 extending from its button-end. EX1002, 3:61-62; FIGS. 1-2. Drive sleeve 30 (red) extends about piston rod 20. *Id.*, 4:4; FIG. 1. Drive sleeve 30 includes helical groove 38 extending along its internal surface, engaging second thread 24. *Id.*, 4:11-14; FIG. 1.

Clutch 60 (blue) is "disposed about the drive sleeve 30, between the drive sleeve 30 and a dose dial sleeve 70 [green]." *Id.*, 4:33-35; FIGS. 1, 6-7. Clutch 60 is "generally cylindrical" and located adjacent drive sleeve 30's button-end. *Id.*, 4:49-51; FIG. 1. "The clutch 60 is keyed to the drive sleeve 30 by way of splines ... to prevent relative rotation between the clutch 60 and the drive sleeve 30." *Id.*, 4:60-62. Clutch 60 includes a plurality of button-end dog teeth 65. *Id.*, 4:58-60; FIGS. 1-2, 8.

Teeth 65 releasably engage dose-dial sleeve 70's button-end.[3] *Id.*, 2:17-19, 6:27-30; FIG. 1.

Dose-dial sleeve 70 is "provided outside of" clutch 60, "radially inward of" housing 4. *Id.*, 5:3-5; FIG. 1. Helical groove 74 is provided about an outer surface of dose-dial sleeve 70. *Id.*, 5:5-6; FIGS. 1-2, 12. Main housing 4 has helical rib 46, adapted to seat in helical groove 74 for relative rotation. *Id.*, 5:9-11; FIGS. 15-16. Dose-dial grip 76 (purple) is disposed about an outer surface at the button-end of dose-dial sleeve 70. *Id.*, 5:24-25; FIGS. 1-2. Dose-dial grip 76 is secured to dose-dial sleeve 70 to prevent relative movement. *Id.*, 5:27-29.

Pen-Injector Operation

Dose setting: To set a dose, the user rotates dose dial grip 76 in one direction. *Id.*, 5:50-51; FIG. 9 (annotated below). Teeth 65 of clutch 60 engage dose-dial sleeve 70 (*id.*, 2:17-19; 5:50-53), causing dose-dial sleeve 70, clutch 60, and drive sleeve 30 to rotate out together. *Id.*, 5:50-53; FIG. 9. Drive sleeve 30 rotates up piston rod 20, toward the 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

[3] Teeth 65 engage "an inwardly directed flange in the form of [a] number of radially extending members 75" at dose dial sleeve 70's button-end. EX1011, ¶196 (citing EX1001, 5:22-24).

with insert 16. *Id.*, 4:1-2, 6:1-3.

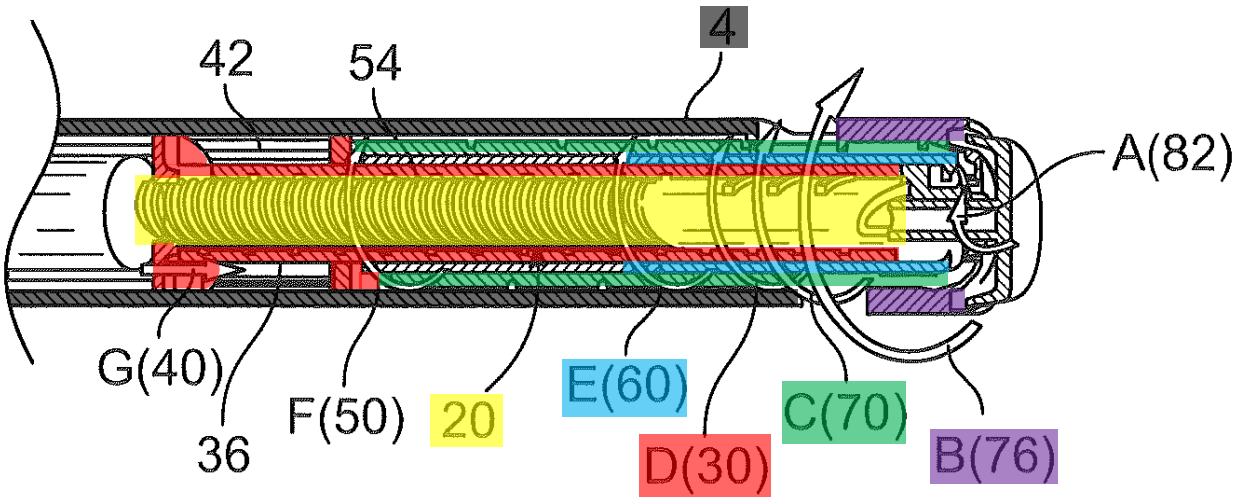


FIG. 9: Dialing up (*id.*, 3:3-4), annotated (EX1011, ¶78)

The user may dial down a dose. *Id.*, 6:16-19; FIG. 10 (annotated below). To dial down, the user rotates dose-dial grip 76 in the opposite direction, causing the system to act in reverse, whereby dose-dial sleeve 70, clutch 60, and drive sleeve 30 rotate back together. *Id.*, 6:19-20; FIG. 10. Drive sleeve 30 rotates down piston rod 20, toward the needle-end, without rotating piston rod 20. *Id.*, 6:1-3, 6:16-20; FIG. 10.

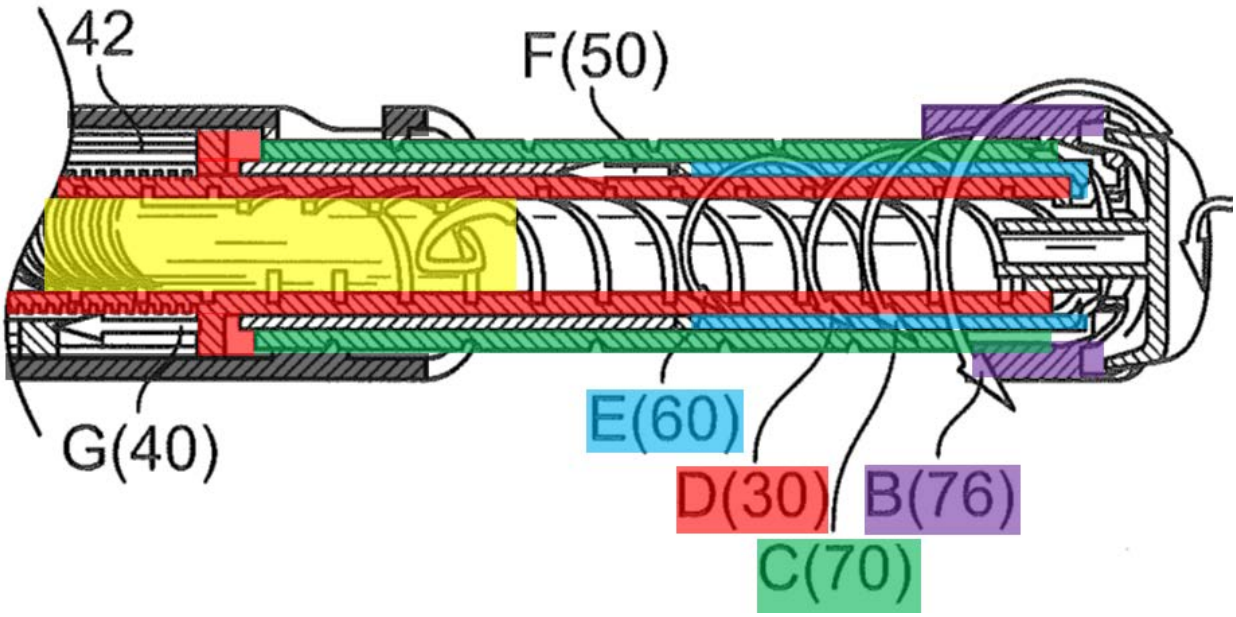


FIG. 10: Dialing down (*id.*, 3:5-6), annotated (EX1011, ¶83)

Injection: Once the dose is set, the user presses button 82, applying force toward the device's needle-end (*id.*, 6:27-28; FIG. 11 (annotated below)), displacing clutch 60 axially so teeth 65 disengage from dose-dial sleeve 70. *Id.*, 6:28-30. Dose-dial sleeve 70 rotates back into housing 4 via its threaded connection with the housing. *Id.*, 6:32-34; FIG. 11. Now disengaged from dose-dial sleeve 70, clutch 60 does not rotate but moves axially toward the needle-end. *Id.*, 6:30-32, 6:37-39. Drive sleeve 30 also moves axially toward the needle-end, driving piston rod 20 to rotate through threaded opening 18, causing medicine to dispense from cartridge 8. *Id.*, 6:44-46, FIG. 11.

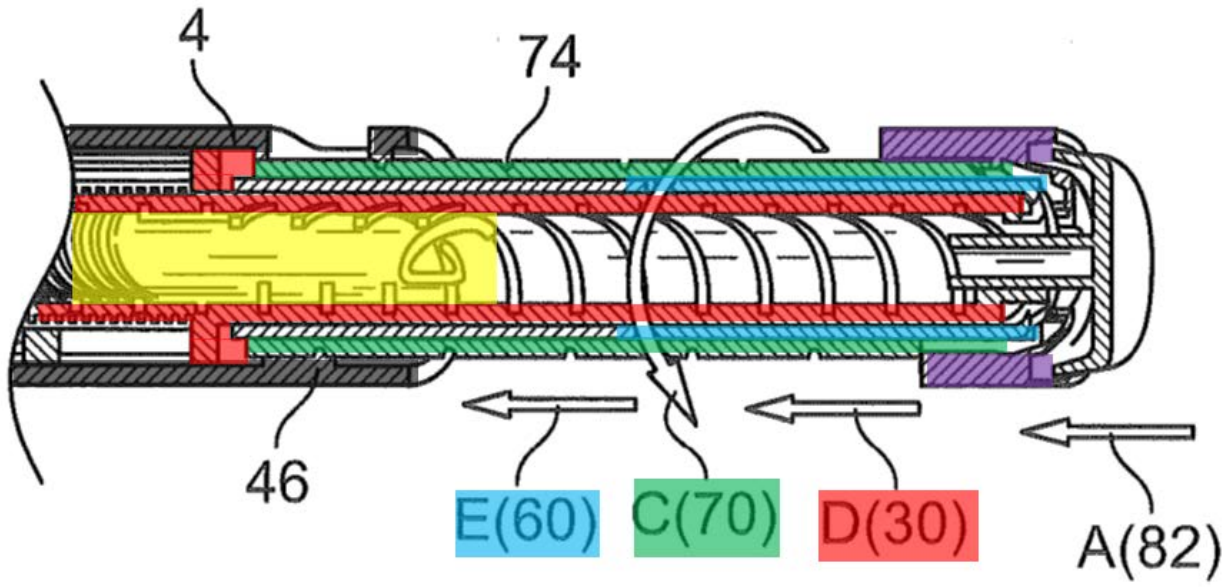


FIG. 11: Injecting dose (*id.*, 3:7-8), annotated (EX1011, ¶86)

2. Prosecution History

The ’044 patent issued from U.S. Application 13/909,649, which claims priority to March 3, 2003, the patent’s earliest possible priority date.

The examiner rejected the application claims for lack of written description and double-patenting. Additionally, claims 1-20 were rejected under §103 as obvious over European Patent EP 0937471 A2 (“Walters”). EX1007, 138.

Applicants amended claims to address the §112 rejection and overcame the §103 rejection by requiring the “helical groove” of the dose-dial sleeve be “provided along an outer surface of [the] dose dial sleeve.” EX1007, 211. Applicants argued Walters did not disclose (1) a helical groove along an outer surface of a dose-dial sleeve, (2) a helical groove to engage threading provided by a main housing, (3) a

clutch as described in the application, or (4) a dose-dial sleeve extending circumferentially around at least a portion of a tubular clutch. *Id.*, 211-12.

Applicants disclosed a Steenfeldt-Jensen PCT publication (WO99/38554) and a published application (US 2002/0052578 A1) that issued as the Møller reference. *Id.*, 38. The examiner did not apply these references to the challenged claims.

C. Level of Ordinary Skill

For this petition, 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, and three-year's experience. EX1011, ¶¶104-06. The POSA understood the basics of medical-device design and manufacturing, and the basic mechanical elements (e.g., gears, pistons) in drug-delivery devices. *Id.*

D. Claim Construction

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

The Patent Owner (Sanofi) has defined certain claim terms in related litigations, and cannot now argue its definitions are unreasonable. *Ex parte Schulhauser*, Appeal No. 2013-007847, slip op. 9 (PTAB Apr. 28, 2016) (precedential) ("A proper interpretation of claim language … at least encompasses the

broadest interpretation of the claim language for purposes of infringement."). Sanofi's proffered constructions are:

drive sleeve: "An essentially tubular component of essentially circular cross-section releasably connected to the dose-dial sleeve that drives the piston during dose dispensing." EX1019, 19.

main housing: "An exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components." EX1019, 21.

piston rod: "A rod that engages with the drive sleeve ... to advance the piston during dose dispensing." EX1019, 27.

threading: "A rib or groove on a first structure that engages a corresponding groove or rib on a second structure." EX1019, 30.

tubular clutch: "A tubular structure that couples and decouples a moveable component from another component." EX1019, 23.

In the related litigation with Sanofi, Mylan proffered preliminary means-plus-function constructions for "tubular clutch" and "clicker." EX1028, 54-59, 65-68. The court has not yet issued a claim construction. If a means-plus-function construction applies, corresponding structure is identified for the "tubular clutch" or "clutch". Its function, during dose setting, is "coupling and decoupling a movable component from another component," or "to reversibly lock two components in rotation." *Id.*, 56.

Component 60 in FIGS. 1, 5-11 is corresponding structure for the clutch. *Id.*, 54, 57; *also* EX1002, 2:16-18, 4:49-62, 4:63-65, 6:33-43.

For a clicker,[4] the function is "providing at least an audible feedback to a user when said dose dial grip is rotated." EX1028, 67-68. FIGS. 6-8 provide structure of the clicker, component 50. *Id.*, 62-63; EX1002, 2:20-22, 2:23-28, 2:29-35, 4:33-35, 4:36-48, 4:63-67.

The grounds rely on the ordinary and customary meaning of the claim terms as a POSA would have understood them, but also address the "tubular clutch" and "clicker" limitations as means-plus-function limitations.

E. Prior Art

Pen-type injectors were known before March 3, 2003, including many using the same six-component structure broadly claimed here. EX1011, ¶114.

1. Møller

Møller is pre-AIA §102(a) and (e) prior art. ; EX1015, cover; EX1011, ¶138. Møller describes a device for injecting set doses, including a similar six-component structure. EX1015, ¶22; EX1011, ¶139. As FIG. 1 (annotated below) shows, Møller

[4] 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).

discloses an injection device comprising:

(1) “housing 1” (**gray**), which houses the drive mechanism for dispensing medicine from a cartridge, EX1015, Abstract, ¶22;

(2) “dose setting drum 17” (**green**), which the user manipulates to set a specific injection dose, EX1015, ¶25;

(3) “dose setting button 18” (**purple**), which serves as a grip for the user to manipulate the dose-setting drum, EX1015, ¶29;

(4) “piston rod 4” (**yellow**), which is driven to dispense medicine from the cartridge, EX1015, ¶22;

(5) “connection bars 12” having “nut 13” (**red**), which drives the piston rod, EX1015, ¶¶22, 32; and

(6) “bottom 19” (**blue**), which rotationally decouples the dose-setting drum from the connection bars and nut during injection, EX1015, ¶¶26, 29, 33.

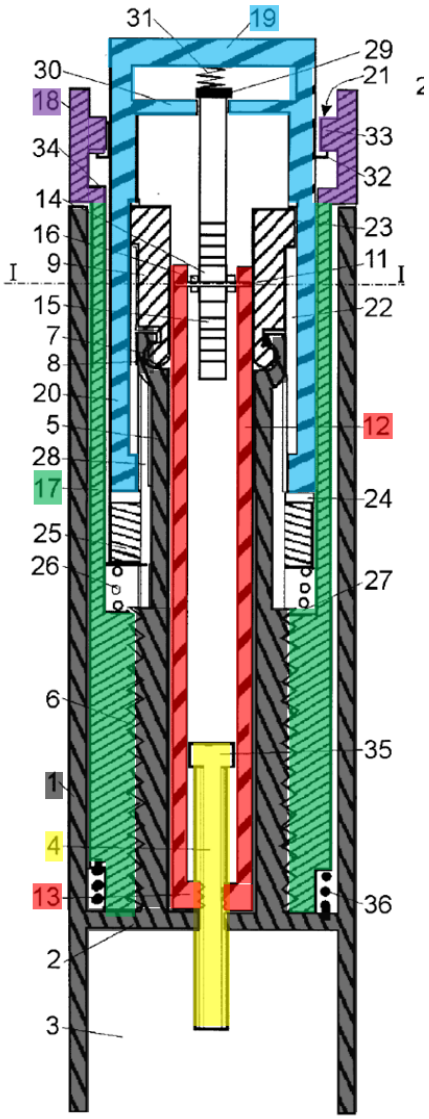


Fig. 1

EX1015, FIG. 1; EX1011, ¶139.

Moller also discloses a second embodiment with largely equivalent components and operation. EX1015, ¶¶35-40, FIGS. 3-5; *see also* EX1011, ¶80-81 n.16.

Møller discloses each structural element, except Møller's dose-dial sleeve includes an inner helical thread to engage the housing, rather than an outer helical

groove. A POSA would have considered an outer helical groove to engage a housing to be an obvious modification. §V.F.2.

2. Steenfeldt-Jensen

Steenfeldt-Jensen is pre-AIA §102(b) prior art. EX1014, cover; EX1011, ¶130. Steenfeldt-Jensen discloses medicine-dispensing syringes. EX1014, Abstract; EX1011, ¶131. As FIGS. 16 and 17 (annotated below) show, Steenfeldt-Jensen disclosed one embodiment comprising a six-component structure:

(1) "tubular housing 1" (**gray**), which houses the drive mechanism for dispensing medicine from an ampoule, EX1014, 5:38-54;

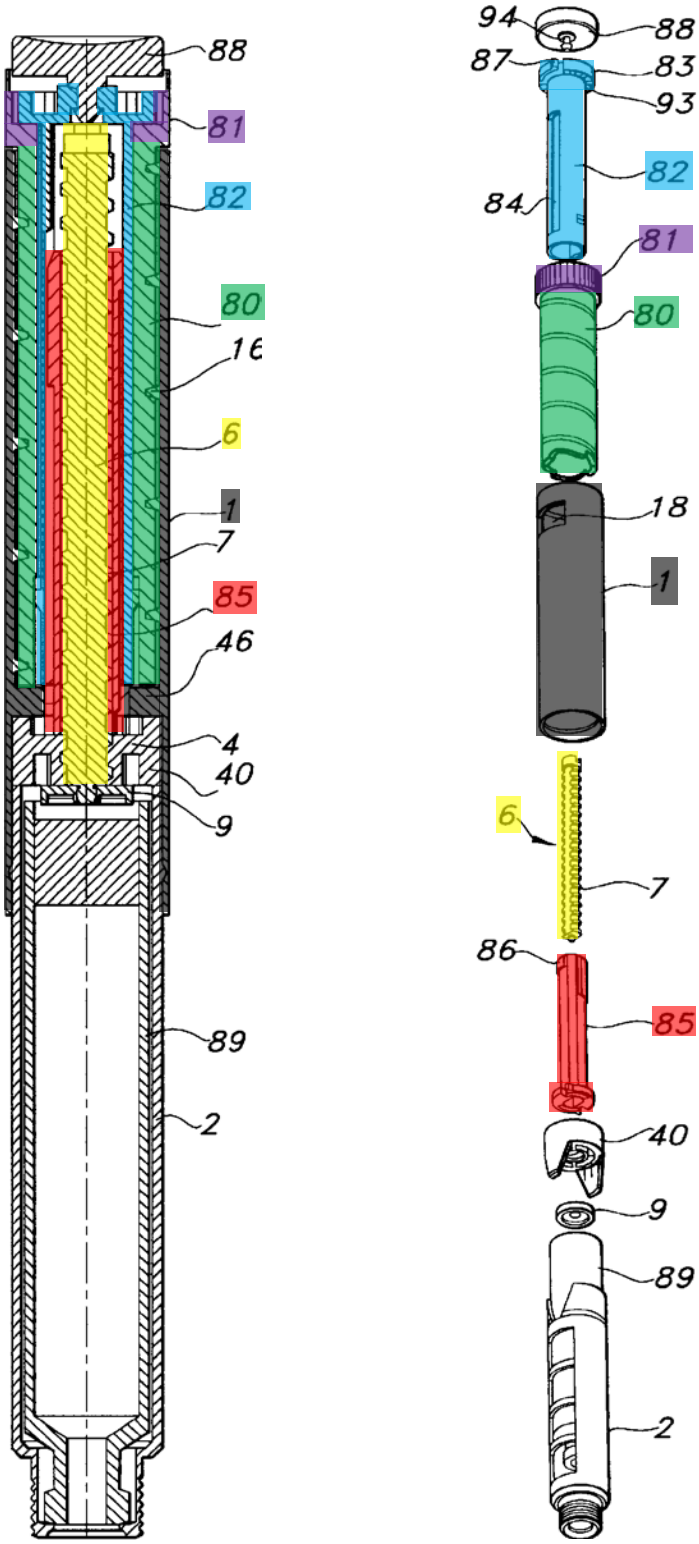
(2) "scale drum 80" (**green**), which the user manipulates to set a specific injection dose, EX1014, 11:51-55;

(3) "dose setting button 81" (**purple**), which serves as a grip for the user to manipulate the scale drum, EX1014, 11:51-55;

(4) "piston rod 6" (**yellow**), which is driven to move a piston provided within the ampoule to dispense medicine, EX1014, 5:57-65;

(5) "piston rod drive," having "driver tube 85" (**red**) and "member 40", which drives the piston rod, EX1014, 2:47-53, 11:6-19, 11:52-12:13; and

(6) "bushing 82" (**blue**), which releasably connects the scale drum and driver tube for rotational movement during injection, EX1014, 12:4-12.



EX1014, FIGS. 16 (left above), 17 (right above); EX1011, ¶139.

Steenfeldt-Jensen describes a piston-rod drive formed from two parts: driver tube 85 and member 40. Steenfeldt-Jensen rendered claim 1's "drive sleeve" obvious. §V.G.2.

F. Ground 1: Steenfeldt-Jensen

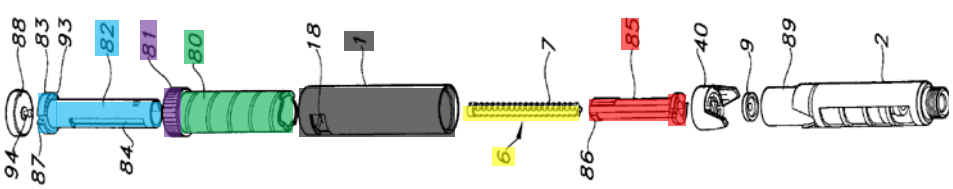
Steenfeldt-Jensen disclosed a single device comprising all claim 11 components, including the same structural limitations. If Steenfeldt-Jensen does not disclose a "drive sleeve", it would have been routine to modify the Steenfeldt-Jensen device to include one. A detailed discussion of reasons to modify Steenfeldt-Jensen follows the discussion of the individual claim elements. §V.G.2.

Independent Claim

1. Element-by-element analysis

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

'044 Patent	**Steenfeldt-Jensen**
[11.Preamble] A housing part for a medication dispensing apparatus, said	Steenfeldt-Jensen discloses a medicine-dispensing syringe: "The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses." EX1014, 1:12-15, FIGS.

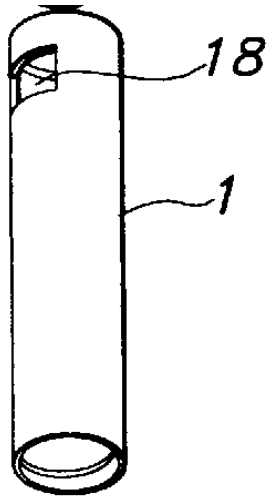
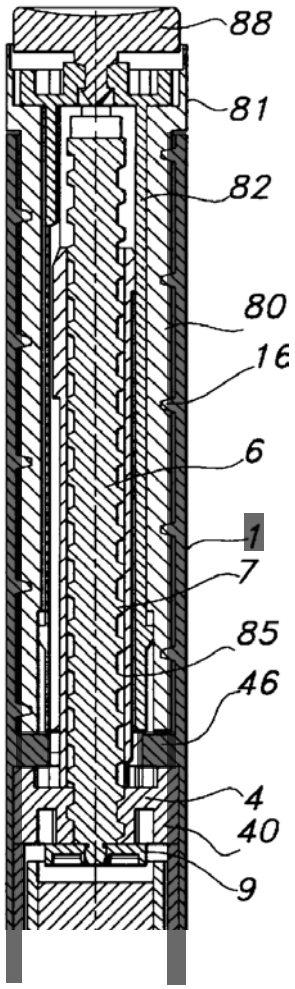
housing part comprising:	15-17; *also* Abstract; 5:38-44, FIGS. 15-17.[5]:  *Id.*, FIG. 17 (annotated above); EX1011, ¶262.

Steenfeldt-Jensen describes a medicine-dispensing syringe. EX1014, 1:12-15, FIGS. 15-17; EX1011, ¶261. The syringe includes tubular housing 1. EX1014, 5:38-44, FIGS. 15-17; EX1011, ¶263. As FIGS. 15-16 show, tubular housing 1 holds the drive mechanism for dispensing medicine from the syringe. EX1011, ¶261. Accordingly, Steenfeldt-Jensen taught claim 11's preamble.

Steenfeldt-Jensen taught "a main housing":

'044 Patent	**Steenfeldt-Jensen**
[11.1] a main housing, said main housing extending from a distal end to a proximal end;	Steenfeldt-Jensen discloses a main housing having proximal and distal ends: "The syringe comprise[s] a tubular housing 1[.]" EX1014, 5:38-44, FIGS. 15-17.

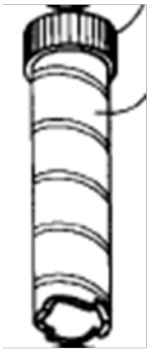
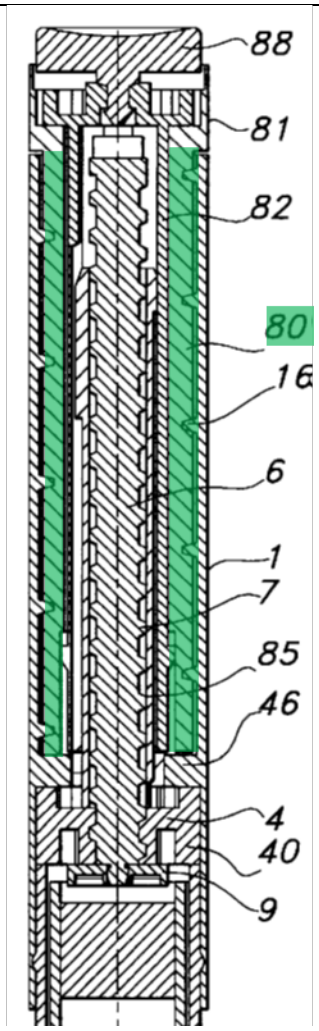
[5] Steenfeldt-Jensen assigns corresponding elements in the embodiments the same reference number. EX1014, 7:49-51. Thus, a POSA would have understood those embodiments informed the structure of the Figures 15-17 embodiment, at least for elements having identical reference numbers. EX1011, ¶131 n.13.

	"A medication delivery pen comprising ... a housing having proximal and distal ends[.]" *Id.*, claim 11.   *Id.*, FIG. 17 (left, partial; housing); FIG. 16 (right, partial; annotating housing (gray)); EX1011, ¶263.

As FIGS. 15-17 show, housing 1 extends from button-end (proximal end) to needle-end (distal end) of the syringe. EX1011, ¶263. Steenfeldt-Jensen thus taught the elements of the claimed "main housing."

Steenfeldt-Jensen taught "a dose dial sleeve":

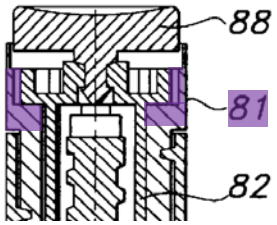
’044 Patent	**Steenfeldt-Jensen**
[11.2] a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;	Steenfeldt-Jensen discloses scale drum 80: “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 in a clockwise direction, 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 (left, partial; showing drum); FIG. 16 (right, partial; annotating drum (green)); EX1011, ¶264.

Steenfeldt-Jensen discloses that the syringe includes a dose-dial sleeve: scale drum 80. *Id.*, 11:20-22. FIGS. 15-16 show drum 80 within housing 1. EX1014, FIGS. 15-16; EX1011, ¶¶264-65. The drum includes a "helical groove provided along an outer surface" as a helical track, extending along the drum's outer wall. EX1014, 11:20-22, FIGS. 16-17; EX1011, ¶265. The helical track is "configured

to engage a threading provided by" housing 1 via helical rib 16, which extends along housing 1's inner wall. EX1014, 11:20-22, FIGS. 16-17; EX1011, ¶264. Steenfeldt-Jensen thus taught the claimed dose-dial sleeve.

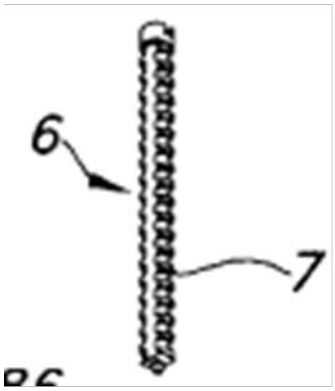
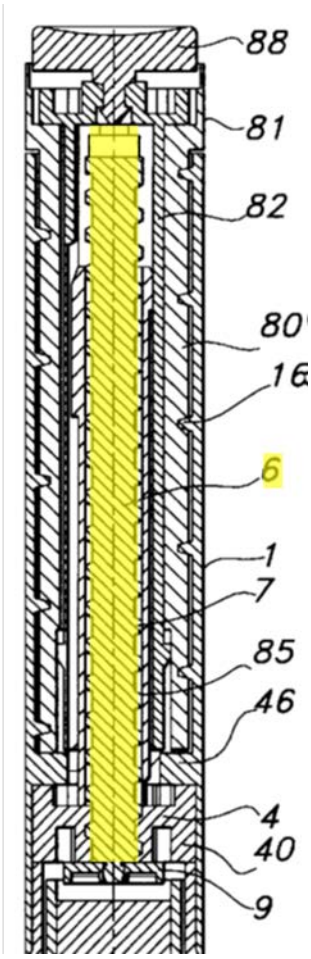
Steenfeldt-Jensen taught "a dose dial grip":

'044 Patent	**Steenfeldt-Jensen**
[11.3] a dose dial grip disposed near a proximal end of said dose dial sleeve;	Steenfeldt-Jensen discloses dose-setting button 81: "At its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81, which on its cylindrical outer wall is knurled to ensure a good finger grip." EX1014, 11:22-25; FIGS. 15-17.  *Id.*, FIG. 16 (above, partial; showing dose-setting button (purple)); EX1011, ¶267; *also* EX1014, 11:52-62.

Steenfeldt-Jensen discloses a "dose dial grip", dose-setting button 81, which the user rotates to set a dose. EX1014, 11:22-25, FIGS. 15-17; EX1011, ¶266. Dose-setting button 81 is at the button-end of scale drum 80. EX1014, FIGS. 15-

17; EX1011, ¶266. Accordingly, Steenfeldt-Jensen taught the elements of the claimed dose-dial grip.

Steenfeldt-Jensen taught "a piston rod":

'044 Patent	**Steenfeldt-Jensen**
[11.4] a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;	Steenfeldt-Jensen discloses piston rod 6: "A piston rod 6 having an external thread 7 mating the [internal] thread 5 of [a central bore of end wall 4] extends through said bore." EX1014, 5:57-58; *also id.*, FIGS. 15-17.  

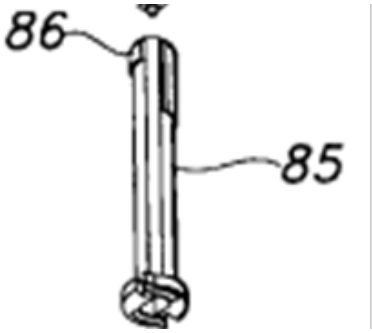
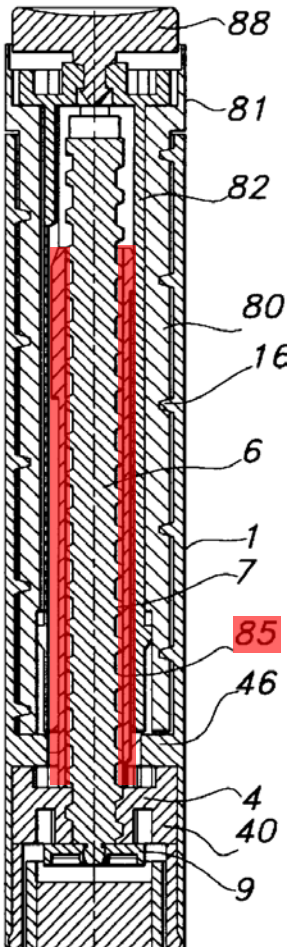
	Id., FIGS. 17 (left, partial; showing piston rod), 16 (right; partial; annotating piston rod (yellow)); EX1011, ¶270; also EX1014, 8:35-38; *also id.*, FIGS. 15-17. "To maintain a clockwise rotation of a dose setting button [81] for increasing the set dose the pawl mechanism working between the driver tube [85] and the housing is turned so that it bars clockwise rotation and reluctantly allows anticlockwise rotation of the driver tube. Further the thread of the piston rod and the thread in the end wall [4] of the housing [are] so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube." *Id.*, 11:6-19. "When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end [*i.e.*, button-end] of the housing. The bushing [82] is kept non-rotated due to its coupling to the driver tube which is locked against clockwise rotation and if a set dose is reduced by rotating the dose setting button 81 in an anticlockwise

	direction the pawl mechanism working between the driver tube and the housing is sufficient[ly] reluctant to rotate in its not blocking direction to prevent the bushing 82 from following this anticlockwise rotation." *Id.*, 11:52-62.

Steenfeldt-Jensen discloses piston rod 6. *Id.*, 5:55-58, FIGS. 15-17; EX1011, ¶268. Piston rod 6 is non-rotatable during a dose-setting step relative to housing 1 due to a pawl mechanism between driver tube 85 and member 40. EX1014, 11:6-19, 11:52-62; EX1011, ¶271. The pawl mechanism bars clockwise rotation of driver tube 85 relative to housing 1. EX1014, 11:6-19; EX1011, ¶271. When dose-setting button 81 rotates clockwise to dial-up a dose, corresponding rotation of scale drum 80 is not transmitted to driver tube 85. EX1014, 11:52-62; EX1011, ¶271. To dial-down a dose, dose-setting button 81 rotates anticlockwise, but corresponding rotation of scale drum 80 is still not transmitted to driver tube 85 due to the pawl mechanism's "sufficient reluctan[ce]" against anticlockwise rotation. EX1014, 11:52-62; EX1011, ¶271. Because piston rod 6 is coupled to driver tube 85 in such a way that "rotation is transmitted," and driver tube 85 does not rotate during dose setting, piston rod 6 also cannot rotate during a dose-setting step. EX1011, ¶271. Accordingly, Steenfeldt-Jensen taught the claimed "piston rod."

Steenfeldt-Jensen taught “a drive sleeve” as recited in element [11.5].

Steenfeldt-Jensen teaches:

’044 Patent	**Steenfeldt-Jensen**
[11.5] a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and	Steenfeldt-Jensen discloses driver tube 85 having a bore through which piston rod 6 extends and threaded end wall 4 at the needle-end:   *Id.*, FIGS. 17 (left, partial; showing piston rod drive), 16 (right, partial; annotating piston rod drive (red)); EX1011,

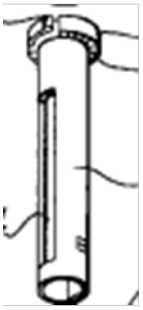
	¶273. "To maintain a clockwise rotation of a dose setting button [81] for increasing the set dose the pawl mechanism working between the driver tube [85] and the housing is turned so that it bars clockwise rotation and reluctantly allows anticlockwise rotation of the driver tube. Further the thread of the piston rod and the thread in the end wall [4] of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment." *Id.*, 11:6-15.

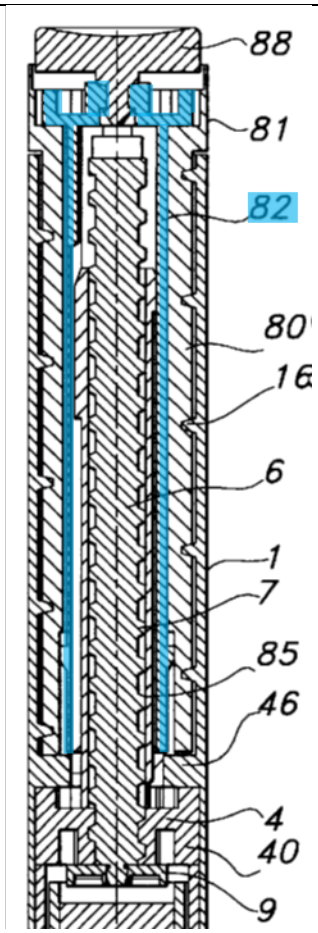
Steenfeldt-Jensen discloses a "drive sleeve" in the form of driver tube 85. *See* EX1011, ¶¶273-74. Driver tube 85 "extend[s] along a portion of" the piston rod 6 by having a bore with a non-circular cross-section through which piston rod 6, also having a non-circular cross-section, extends. EX1014, 11:15-17, FIGS. 15-16; EX1011, ¶¶273-74. Driver tube 85 couples to scale drum 80's rotational movement only during the injection process, which causes piston rod 6 to rotate through an internal threading provided in the member 40 and into the cartridge holder compartment. *See* EX1014, 11:6-19; EX1011, ¶273. 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.2, a POSA would have considered it obvious to modify the piston rod drive to provide claim 11's "drive sleeve".

Steenfeldt-Jensen taught "a tubular clutch":

'044 Patent	**Steenfeldt-Jensen**
[11.6] a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,	Steenfeldt-Jensen discloses bushing 82: "A bushing 82 having a flange 83 at its proximal end [*i.e.*, button-end] and having a pair of opposite longitudinal slots 84 through its side walls fits into the scale drum 80 and over the driver tube 85 which tube has on its outer wall hooks 86 engaging the slots 84 of the bushing 82 whereby the bushing 82 and the 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 (left, partial; showing bushing), 16 (right, partial; annotating bushing (blue)); EX1011, ¶282.

"In the dose setting button [81] a compartment is provided having ... a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment[.] At its distal side [*i.e.*, 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.

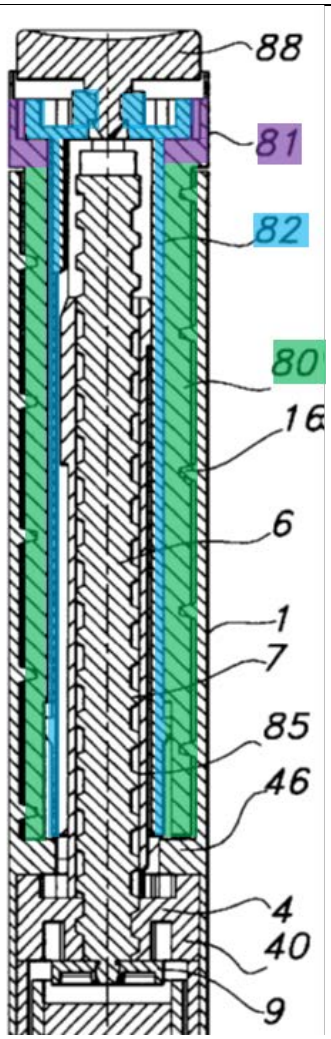
Steenfeldt-Jensen discloses the claimed "tubular clutch", bushing 82. As FIG. 17 shows, bushing 82 is a tubular structure. EX1014, 11:26-27, 12:4-13; FIGS. 15-17; EX1011, ¶283. Bushing 82's rosette of teeth 93 releasably engages corresponding teeth on dose-setting button 81. EX1014, 12:4-12; EX1011, ¶283. When engaged, dose-setting button 81's rotation transmits to driver tube 85 during injection. EX1014, 12:4-12; EX1011, ¶283. Thus, bushing 82 is a clutch because it releasably couples movement of dose-setting button 81 to driver tube 85. EX1011, ¶283.

Bushing 82 also operatively couples to dose-setting button 81 by releasable engagement of teeth 93 with corresponding teeth on the button. EX1011, ¶283. Bushing 82 is adjacent button 81's needle-end: flange 83 is within a compartment

in button 81, with the bushing's teeth 93 configured to engage with the button-compartment's bottom teeth. EX1014, 11:34-42, FIGS. 15-16; EX1011, ¶283. Accordingly, Steenfeldt-Jensen taught claim 11's "tubular clutch".

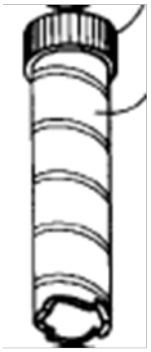
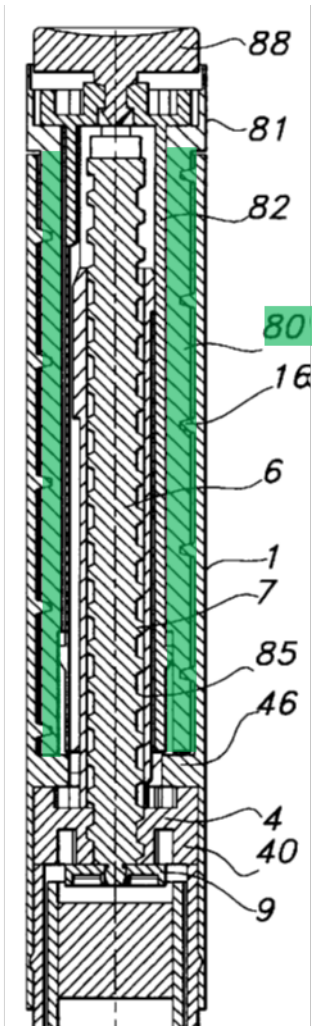
Finally, Steenfeldt-Jensen taught the relative positioning of the dose-dial sleeve and tubular clutch:

'044 Patent	**Steenfeldt-Jensen**
[11.7] wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, and	Steenfeldt-Jensen discloses that bushing 82 is provided within scale drum 80: "A bushing 82 ... fits into the scale drum 80[.]" EX1014, 11:26-28, FIGS. 15-16.

	 *Id.*, FIG. 16 (above; partial view annotating drum 80 (green) and bushing 82 (blue)); EX1011, ¶285.

Steenfeldt-Jensen shows that scale drum 80 "extends circumferentially around at least a portion of" bushing 82. EX1014, 11:26-28, FIGS. 15-16; EX1011, ¶285. Thus, Steenfeldt-Jensen taught this element.

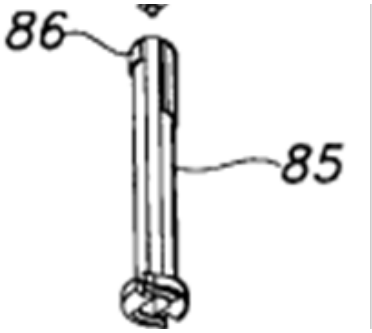
Steenfeldt-Jensen teaches a helical groove of a dose-dial sleeve and internal threading on a drive sleeve having respective leads:

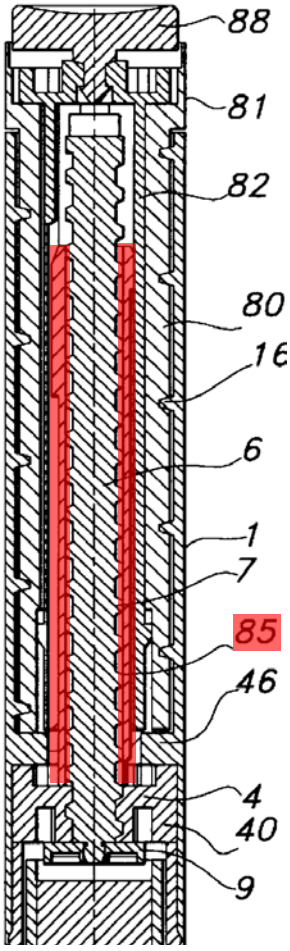
’044 Patent	Steenfeldt-Jensen
[11.8] wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different.	Steenfeldt-Jensen discloses a dose-dial sleeve having a first lead. *See* element [11.2], *supra*. Steenfeldt-Jensen discloses a dose-dial sleeve in scale drum 80: “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.  

Id., FIG. 17 (left, partial; showing drum); FIG. 16 (right, partial; annotating drum (green)); EX1011, ¶264.

Steenfeldt-Jensen discloses a drive sleeve having a second lead. *See* element [11.5], *supra*.

Steenfeldt-Jensen discloses a drive sleeve—driver tube 85 and member 40:





Id., FIGS. 17 (left, partial; showing piston rod drive), 16 (right, partial; annotating piston rod drive (red)); EX1011, ¶273.

"The present invention provides an injection syringe

	compris[ing] ... a piston rod drive[.]" EX1014, Abstract. "A medication delivery pen comprising ... a piston rod drive for driving said piston rod in a distal direction inside the cartridge, said piston rod drive including a first part having an internal thread mating the thread of said piston rod ..., [and] a second part mating with the not circular cross-section of said piston rod, wherein said first and second parts are rotatable relative to one another to drive the piston rod in an axial direction[.]" *Id.*, 14:9-40 (claim 11); *also id.*, 2:46-53 (describing parts as "a nut member" and a "piston rod guide," respectively). "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[.]" *Id.*, 8:35-37, FIGS. 15-17.

Steenfeldt-Jensen discloses a threaded "dose dial sleeve" in scale drum 80. *See* disclosure for element [11.2], *supra*; EX1014, 11:20-22, FIGS. 15-17; EX1011, ¶286. Additionally, Steenfeldt-Jensen discloses an internally-threaded "drive sleeve" in driver tube 85 and member 40. *See* disclosure for element [11.5], *supra*; EX1014, Abstract, 2:46-53, 8:35-37, 14:9-40, FIGS. 15-17; EX1011, ¶286. The spacing of drum 80's groove and of the internal thread mating the piston-rod's thread are different, indicating that the first and second leads are different. EX1011, ¶287. Accordingly, Steenfeldt-Jensen disclosed this element.

2. Reason to modify; reasonable expectation of success

As described above, Steenfeldt-Jensen disclosed a piston-rod drive comprising driver tube 85 and member 40. A POSA would have considered it obvious to modify the FIGS. 15-17 embodiment to provide a "drive sleeve". EX1011, ¶274. From Steenfeldt-Jensen's teachings, a POSA would have known to provide driver tube 85 with internal threading near its distal portion. EX1011, ¶274. The modified device would have been understood to contain a "drive sleeve" having the structural elements of claim 11. EX1011, ¶274.

Steenfeldt-Jensen expressly contemplates a modification in which the driver tube contains internal threading that engages the piston rod's external threading. EX1011, ¶275. Specifically, 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; *also id.*, 3:15-20 ("When the injection button is pressed the movement of this 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 (stating 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 allows the piston rod to move axially (but not rotatably) relative to it, whereas the nut allows relative rotation of the piston rod. EX1014, 2:46-53, 3:15-20; EX1011, ¶276. In the context of the FIGS. 15-17 embodiment, a POSA would have understood that driver tube 85 includes a "piston rod guide" because it allows relative axial piston-rod movement, while preventing relative rotational movement due to its non-circular cross-section. EX1011, ¶276. Similarly, a POSA would have understood that member 40 includes a "nut element" due to its internal threading. EX1011, ¶276. Thus, given Steenfeldt-Jensen's suggestion that the "nut element" could be on the driver tube, and the "piston rod guide" could be on the member, a POSA would have reason to modify (1) driver tube 85 to include 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. In this case, a POSA would have considered the driver tube to be a component for driving the piston rod having internal threading near its distal portion for engaging external threading of the piston rod. EX1011, ¶277.

A POSA also would have reasonably expected such modification would have resulted in the device operating in the same manner. EX1011, ¶278. In this case, a POSA would have understood that when the driver tube rotates during injection, the threaded engagement between the driver tube and the piston rod

cause the piston rod to be axially displaced through the member's non-circular opening and into the ampoule. EX1011, ¶278. Thus, a POSA would have reasonably expected that the modified parts "perform[] the same function that [they] had been known to perform." *KSR*, 550 U.S. at 417; EX1011, ¶278.

Accordingly, claim 11 would have been obvious over Steenfeldt-Jensen.

Dependent Claims

Steenfeldt-Jensen teaches a clicker as recited in claim [14].

'044 Patent	**Steenfeldt-Jensen**
[14] The housing part of claim 11, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose dial grip is rotated.	Steenfeldt-Jensen discloses a clicker in the radial protrusions and axial recesses: "Therefore by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one, the recesses being so spaced that one click corresponds to a chosen change of the set dose." *Id.*, 11:62-67; *also, e.g., id.*, FIG. 17; EX1011, ¶303.

Steenfeldt-Jensen discloses a clicker in the radial protrusions and axial recesses, providing audible feedback to a user upon rotation of the dose-dial grip. EX1014, 9:30-35; 9:48-50; 11:62-67; FIGS. 6, 17; EX1011, ¶¶301-02.

If "clicker" is a means-plus-function limitation, Steenfeldt-Jensen still teaches it. The '044 patent teaches that in dialing a dose, "flexible arm 52" with "toothed member 54" is dragged over "splines 42" to produce a click. EX1002, 5:54-60. If a dose is being dialed down, saw teeth 56 and 66 ride over each other to produce a click. *Id.*, 6:16-26. Thus, the structure the '044 patent uses to provide an audible click is either a flexible arm being dragged over splines, or saw teeth riding over one another. EX1011, ¶303.

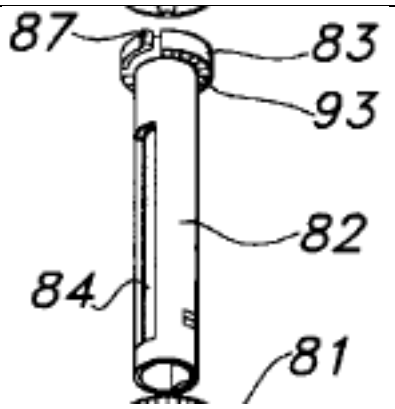
Steenfeldt-Jensen teaches identifies radial protrusion 87 as providing the clicking in the FIG. 15-17 embodiment. Radial protrusion 87 sits in a compartment of dose-setting button 81 with "axial recesses" (splines) and is "biased toward the side wall of the compartment." EX1014, 11:34-42; 11:52-67. When dose-setting button 81 rotates, "radial protrusion 87…will click from one of the axial recess[es] in the inner wall of the dose-setting button 81 to the next one…." *Id.*, 11:52-67. Thus, Steenfeldt-Jensen teaches using a flexible arm being dragged over splines to create an audible click, teaching the same structure performing the same function. EX1011, ¶303.

Accordingly, Steenfeldt-Jensen disclosed all elements unique to claim 14.

Steenfeldt-Jensen also teaches a clicker as recited in claim [15].

'044 Patent	**Steenfeldt-Jensen**
[15] The housing part of	Steenfeldt-Jensen discloses a clicker comprising at least

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 dial grip 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.	one flexible arm, the flexible arm comprising at least one tooth member: "The flange 83 of the bushing 82 … has at its periphery a radial protrusion 87 which is biased toward the side wall of the compartment." EX1014, 11:37-40; FIG. 17; EX1011, ¶304.  FIG. 17 (detail; annotating radial protrusion 87 (purple)); EX1011, ¶310. "[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*., 11:62-65; *also* Fig. 17; EX1011, ¶304.

	 Steenfeldt-Jensen further discloses a clicker comprising at least one spline via depressions 32 (*see, e.g.*, EX1014, 6:60-7:1), axial recesses 66 (*see, e.g.*, *id.*, 9:26-35), and axial recesses in the inner wall of dose-setting button 81 (*see, e.g.*, *id.*, 11:62-67).

A POSA would have understood that from FIG.17 that radial protrusion 87 is a "flexible arm" that includes a "tooth member" at its end for deforming and dragging into longitudinal recesses to produce a clicking noise. EX1014, 11:34-40, 11:62-67, FIG. 17. A person of ordinary skill would have also understood that the longitudinal recesses would form corresponding ridges or splines between neighboring recesses. EX1011, ¶311.

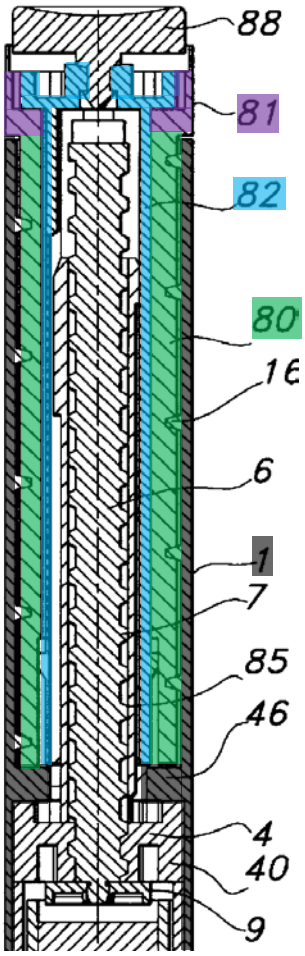
A person of ordinary skill would have understood Steenfeldt-Jensen to discloses a "clicker" having "at least one flexible arm" that includes "at least one tooth member," in the form of radial protrusion 87, and "at least one spline," formed between neighboring longitudinal recesses, such that, when the dose setting

button 81 is rotated, the radial protrusion 87 "deforms and drags" its "tooth member" over the splines formed by the longitudinal recesses to provide audible feedback. EX1011, ¶312.

Accordingly, Steenfeldt-Jensen disclosed all elements unique to claim 15.

Steenfeldt-Jensen teaches a dose-dial sleeve as recited in claim [18].

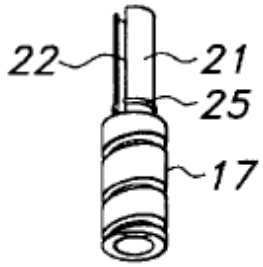
'044 Patent	**Steenfeldt-Jensen**
[18] The housing part of claim 11, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.	Steenfeldt-Jensen teaches a dose-dial sleeve provided outside of a tubular clutch and radially inward of a main housing. *See* elements [11.1], [11.2], [11.7], *supra*.

	 EX1014, FIG. 16 (above; partial view annotating drum (green) and bushing (blue)); EX1011, ¶319.

As discussed above, Steenfeldt-Jensen discloses a dose-dial sleeve provided outside a tubular clutch and radially inward of a main housing. *See* elements [11.1], [11.2], and [11.7], *supra*; EX1014, FIGS. 1, 2; EX1011, ¶319. Accordingly, Steenfeldt-Jensen disclosed all elements unique to claim 18.

Steenfeldt-Jensen teaches a main housing comprising a helical rib as recited in claim [19].

'044 Patent	**Steenfeldt-Jensen**
[19] The housing part of claim 11, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve.	Steenfeldt-Jensen discloses a dose-dial sleeve in dose-scale drum 17 having a helical groove on its outer surface, the helical groove engaging a rib on housing 1: "On the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. A dose scale drum 17 is in its outer wall provided with a helical gro[o]ve defining a corresponding external thread mating the inner thread just mentioned. The pitch angle of the threads exceeds the angle of friction for the materials forming the parts of the thread connection and consequently the thread connection is of the not self locking type which induce a relative rotation of the parts of the connection when those part[s] are moved axially relative to each other." EX1014, 6:7-17, FIG. 3 (below; partial view showing drum 17); *also id.* FIGS. 8, 13, 17 (illustrating other drum embodiments having helical groove on the outer surface); EX1011, ¶320; elements [11.1] and [11.2], *supra*.

As discussed above, Steenfeldt-Jensen discloses a main housing having a helical rib, the helical rib adapted to engage a helical groove on an outer surface of a dose-dial sleeve. *See* elements [11.1] and [11.2]; EX1014, FIGS. 3, 8, 13, 17; EX1011, ¶320. Accordingly, Steenfeldt-Jensen disclosed all elements unique to claim 19.

G. Ground 2: Møller and Steenfeldt-Jensen

Møller disclosed an injection device having the same six components in claim 11. For five of those components, Møller discloses the same structural limitations as in claim 11. For the "dose dial sleeve," Møller discloses dose-setting drum 17 with threading on its internal surface adapted to engage with the housing, instead of a "helical groove" on its outer surface.

Steenfeldt-Jensen discloses using a "dose dial sleeve," scale drum 80, including a "helical groove" on its outer surface for engaging the housing. As discussed below (§V.F.2), a POSA would have considered it obvious to modify Møller's drum 17 to include a "helical groove" on its outer surface, rather than its inner surface, from Møller and Steenfeldt-Jensen.

Independent Claim

1. Element-by-element analysis

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

'044 Patent	**Møller and Steenfeldt-Jensen**
[11.Preamble] A housing part for a medication dispensing apparatus, said housing part comprising:	Møller discloses a device for injecting medicine: "An injection device for injection of set doses of medicine from a cartridge[.]" EX1015, Abstract. "[A]n 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 (below; annotated); EX1011, ¶344.

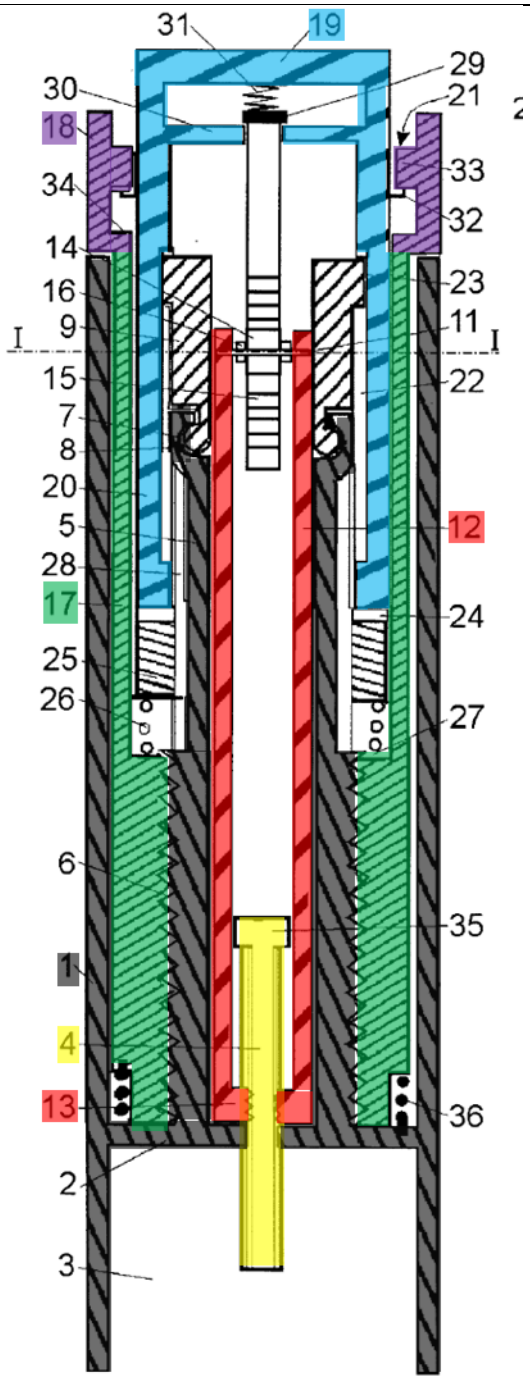

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Fig. 1

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 holding a drive mechanism for dispensing medicine. EX1015, ¶22, FIG. 1; EX1011, ¶343. Thus, Møller taught the preamble of claim 11.

Møller and Steenfeldt-Jensen taught "a main housing":

'044 Patent	**Møller and Steenfeldt-Jensen**
[11.1] a main housing, said main housing extending from a distal end to a proximal end;	Møller discloses housing 1: "[A]n 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, FIG. 1 (below; annotating housing (gray)); EX1011, ¶346. "Concentrically with the housing 1 the wall 2 carries on its side turning away from the compartment 3 a tubular element 5[.]" EX1015, ¶23.

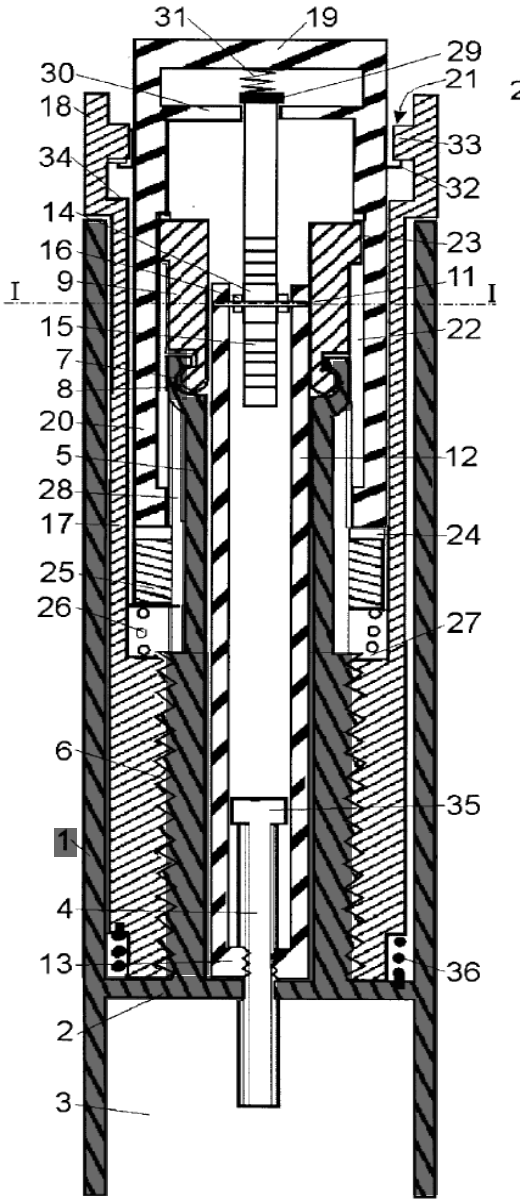


Fig. 1

Møller discloses a "main housing," housing 1. As FIG. 1 shows, housing 1 extends from a proximal end (button-end) to a distal end (needle-end). 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. EX1015, ¶23; EX1011, ¶345. The device's drive mechanism is inside this concentric space. EX1011, ¶¶343, 345. Accordingly, Møller taught a "main housing" as in element 11.1.

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

'044 Patent	**Møller and Steenfeldt-Jensen**
[11.2] 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;	Møller discloses dose-setting drum 17: "A tubular dose setting drum 17 fitting into the housing 2 is at an end provided with an internal thread mating and engaging the outer thread 6 of the tubular element 5[.] 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 (below; annotating drum (green)); EX1011, ¶348.

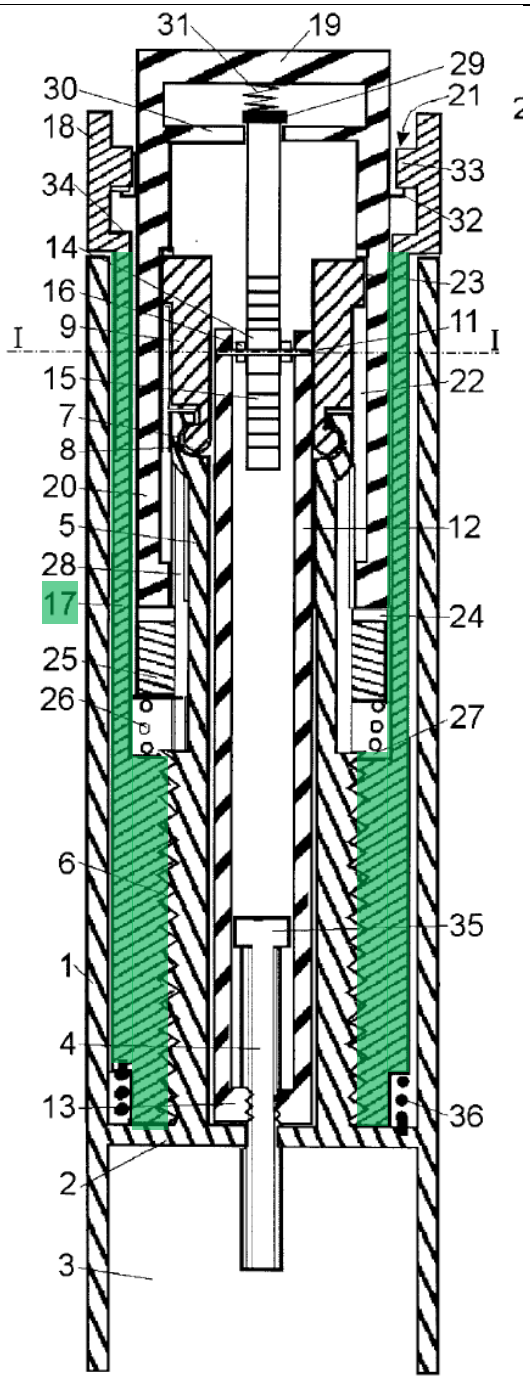
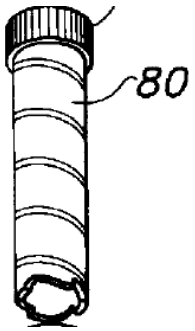


Fig. 1

Steenfeldt-Jensen discloses dose-scale drum 17 having a helical groove on its outer surface:

"On the inner wall of the second division of the housing

	1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. A dose scale drum 17 is in its outer wall provided with a helical gro[o]ve defining a corresponding external thread mating the inner thread just mentioned. The pitch angle of the threads exceeds the angle of friction for the materials forming the parts of the thread connection and consequently the thread connection is of the not self locking type which induce a relative rotation of the parts of the connection when those part[s] are moved axially relative to each other." EX1014, 6:7-17, FIG. 3 (below; partial view showing drum 80); *also id.* FIGS. 8, 13, 17 (illustrating other drum embodiments having helical groove on the outer surface). 

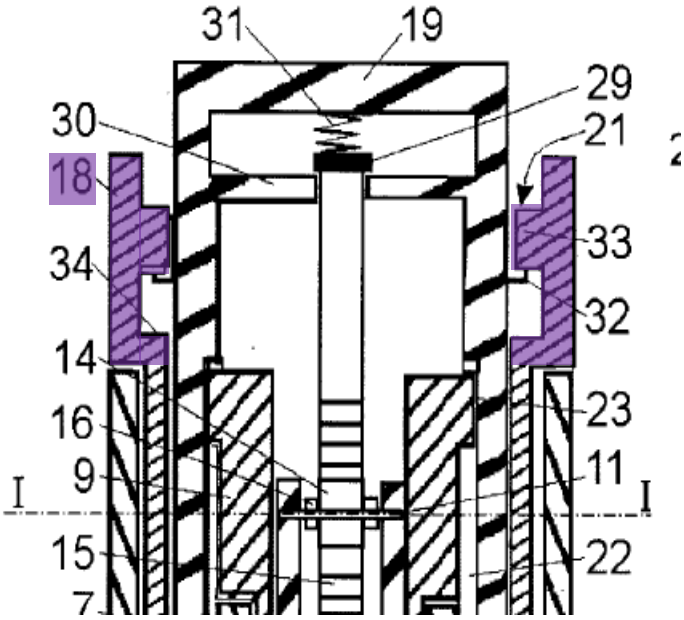
Møller discloses a "dose dial sleeve," dose-setting drum 17. Dose-setting drum 17 is positioned within housing 1. EX1015, ¶25; FIG. 1; EX1011, ¶347. It also includes a thread at its needle-end that engages corresponding thread 6 of tubular element 5, such that drum 17 can be screwed in and out of the housing during use. EX1015, ¶25; FIG. 1; EX1011, ¶350. As FIG. 1 shows, drum 17's

thread is internal, such that it engages the housing's inwardly-positioned tubular element 5. EX1015, ¶25, FIG. 1; EX1011, ¶350. Thus, although Møller discloses a thread on dose-setting drum 17 that engages thread of the housing, it does not disclose "a helical groove" "provided along an outer surface of" drum 17. EX1011, ¶349.

Steenfeldt-Jensen discloses a "dose dial sleeve" that includes "a helical groove" on its outer surface, adapted to engage threading on a housing. EX1011, ¶353. Specifically, Steenfeldt-Jensen discloses scale drum 17 that includes a helical groove on its outer wall that engages helical rib 16 on the housing. EX1014, 6:7-17, FIG. 3; EX1011, ¶354. This allows the drum to be rotationally moved relative to the housing. EX1014, 11:52-54, 12:4-9; EX1011, ¶354. Thus, Steenfeldt-Jensen discloses a "dose dial sleeve" that includes a "helical groove" on its outer surface configured to engage a corresponding rib on the housing.

As further explained below, a POSA would have considered it obvious to modify internal threading of drum 17 as an external threading that engaged the housing for the same rotational movement relative to the housing as disclosed in Steenfeldt-Jensen. *Infra*, §V.F.2. Accordingly, the Møller and Steenfeldt-Jensen combination rendered obvious the claimed "dose dial sleeve."

The Møller and Steenfeldt-Jensen combination taught "a dose dial grip" as recited in element [11.3]:

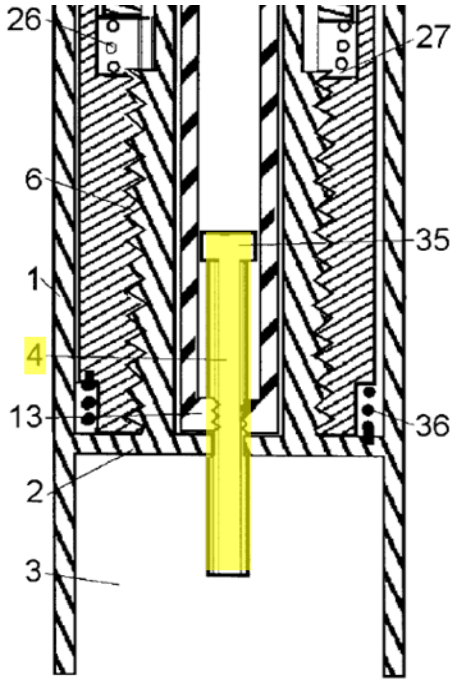
’044 Patent	Møller and Steenfeldt-Jensen
[11.3] a dose dial grip disposed near a proximal end of said dose dial sleeve;	Møller discloses dose-setting button 18: “[The] tubular dose setting drum 17 ...has at its other end [*i.e.*, button-end] a part with enlarged diameter forming a dose setting button 18.” EX1015, ¶25, FIG. 1 (below; partial view annotating button (purple)); EX1011, ¶362. 

Møller discloses a “dose dial grip,” dose-setting button 18. EX1011, ¶362. As FIG. 1 shows, dose-setting button 18 is at drum 17’s proximal end (button-end). EX1015, FIG. 1; EX1011, ¶362. Button 18 includes “an enlarged diameter’ relative to drum 17 such that button 18 is flush with the housing. EX1015, ¶25, FIG. 1; EX1011, ¶362. A POSA would have considered this feature to constitute a

grip for the user to grasp to rotate drum 17 out of housing 1 during dose setting. EX1015, ¶29; EX1011, ¶362. Thus, the Møller and Steenfeldt-Jensen combination taught a "dose dial grip" as recited in claim 11.

The Møller and Steenfeldt-Jensen combination taught "a piston rod":

'044 Patent	**Møller and Steenfeldt-Jensen**
[11.4] a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;	Møller discloses piston rod 4: "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 (below; annotating piston rod (yellow)); EX1011, ¶364.

	 Fig. 1

Møller discloses piston rod 4 is non-rotatable during dose setting. Specifically, because piston rod 4 fits within wall 2 of the housing in a way that prevents relative rotation, piston rod 4 does not rotate relative to housing 1, including during dose setting. EX1015, ¶28, FIG. 1; EX1011, ¶¶364-65. Thus, Møller taught the claimed "piston rod."

The Møller and Steenfeldt-Jensen combination taught "a drive sleeve":

'044 Patent	**Møller and Steenfeldt-Jensen**
[11.5] a drive sleeve extending along a	Møller discloses connection bars 12 and nut 13: "In [a] gearbox 9 a gear wheel assembly comprising two

portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and	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 (below; annotating connection bars and nut (red)); EX1011, ¶366.

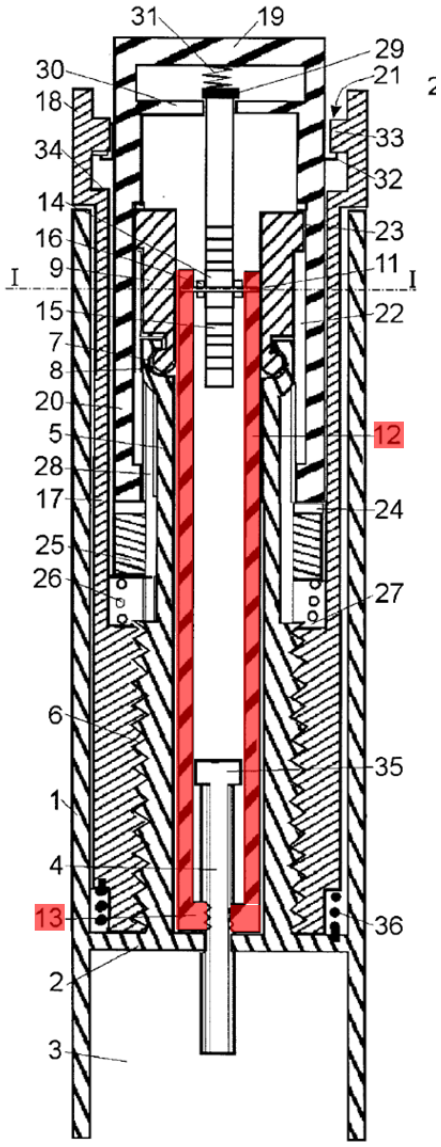


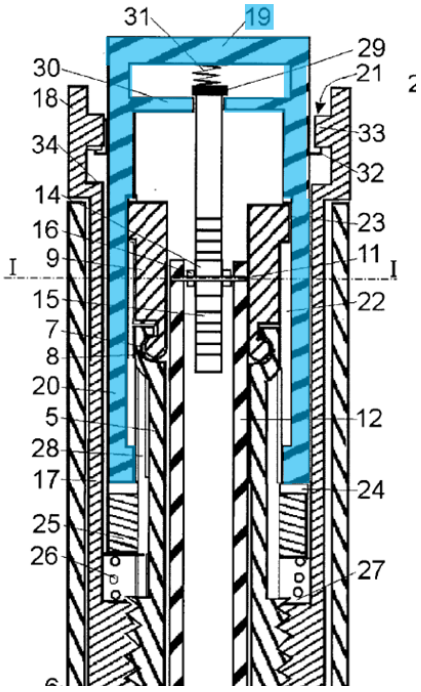
Fig. 1

"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 discloses a "drive sleeve" in the form of connection bars 12 having a nut 13 at its needle-end. *See* EX1011, ¶366. The nut 13 is internally-threaded, and engages with the thread of piston rod 4 to drive it during injection. EX1015, ¶¶24, 32, FIG. 1; EX1011, ¶367. To the extent connection bars 12 with nut 13 are not a "sleeve," Møller taught a sleeve in the form of a tubular connection element 112 with nut 113. *See* EX1015, ¶40, FIGS. 3-5; EX1011, ¶370. Given Møller's teaching that the tubular connection element 112 with nut 113 corresponds to connection bars 12 with nut 13, a POSA would have understood the components to be structurally and functionally equivalent. EX1011, ¶¶370-71. A POSA thus would have expected connection bars 12 with nut 13 could readily be formed as a tubular structure that encompasses piston rod 4, without affecting the device's operation. *Id.* Møller thus taught the claimed "drive sleeve."

The Møller and Steenfeldt-Jensen combination taught "a tubular clutch":

’044 Patent	Møller and Steenfeldt-Jensen
[11.6] a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,	“A bottom 19 in a deep cup shaped element, which has a tubular part 20 fitting into the dose setting drum 17 and encompassing the gearbox 9, forms an injection button. Coupling means between the dose setting drum 17 and the cup shaped element ensures that rotation of the dose setting drum 17 is transmitted to the cup shaped element. Further the inner wall of the tubular part 20 has longitudinal recesses 22 engaged by protrusions 23 on the gearbox 9 so that rotation of the dose setting drum 17 via the cup shaped element is transmitted to the gearbox 9.” EX1015, ¶26.  EX1015, FIG. 1 (partial view; cup-shaped element annotated blue); EX1011, ¶282.

	"[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.*, ¶29. "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." *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 until the dose setting drum 17 abuts the wall 2." *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. *Also* EX[S-J], 11:26-42, 12:1-13, FIGS. 15-17

Møller teaches a "cup shaped element" (the clutch) that includes bottom 19 (the surface pressed by the user to inject a dose) and tubular part 20. EX1015, ¶26, FIG. 1; EX1011, ¶¶372-74, 376. As FIG. 1 shows, the cup-shaped element is seated within dose-setting button 18 (the dose knob) and passes through its entire length. The cup-shaped element is thus located adjacent the needle end (distal end) of dose-setting button 18. EX1011, ¶376. The cup-shaped element is operatively coupled to dose-setting button 18 via engagement of Δ-shaped protrusions 32 with corresponding recesses 33 in dose-setting button 18. EX1015, ¶29, FIG. 1; EX1011, ¶¶372-74, 376. The cup-shaped element serves as a clutch by rotationally coupling dose-setting button 18 and drum 17 (the dose-dial sleeve) to connection bars 12 and nut 13 (the driver) during dose setting, then rotationally decoupling those components during injection. EX1015, ¶¶29-30, 32-33, FIG. 1; EX1011, ¶376.

If "tubular clutch" is a means-plus-function limitation, the Møller and Steenfeldt-Jensen combination rendered it obvious. The '044 patent discloses

clutch 60. The ’044 patent states:

> 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) [normally engaged with clicker 50]. Each saw tooth comprises a longitudinally directed surface and an inclined surface. Towards the second end 64 of the clutch means 60 there is located a radially inwardly directed flange 62. The flange 62 of the clutch means 60 is disposed between the shoulder 37 of the drive sleeve 30 and the radially outwardly directed flange 39 of the extension 38. The second end of the clutch means 60 is provided with a plurality of dog teeth 65 (FIG. 8) [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.

EX1002, 4:50-62, 5:1-2, 2:16-18.

The ’044 patent thus describes the tubular clutch as “generally cylindrical,” having a series of “circumferentially directed ... teeth” at is first (needle) end, and also having a plurality of teeth at a second (button end). EX1002, 4:50-62. The teeth on the needle end engage the clicker, and the teeth on the button end engage the dose-dial sleeve. *Id.*, 5:1-5, 5:55-57, 6:27-34. The ’044 patent teaches the clutch is also keyed

to the drive sleeve (using splines) to prevent relative rotation between the clutch and drive sleeve. *Id.*, 4:60-62.

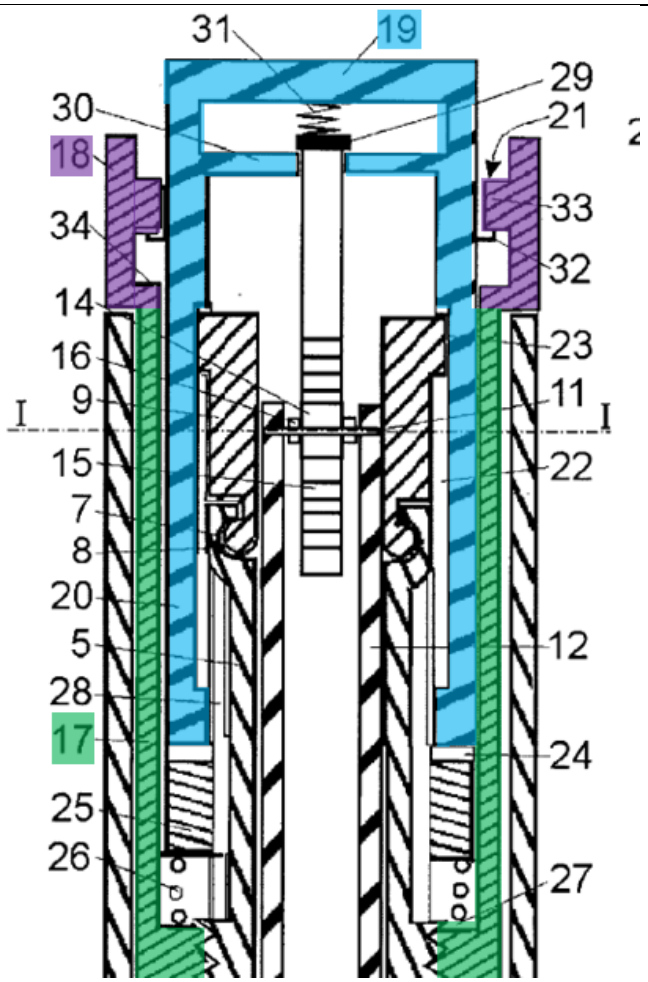
Møller's cup-shaped element operates in a similar manner using similar structure, as understood from Møller's second embodiment that includes a corresponding clutch: tubular element 120. *Compare* EX1015, FIGS. 1 *with* EX1001, FIGS. 6-8; EX1011, ¶380. Tubular element 120, which carries button 119, is 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 corresponding teeth 133 in dose setting button 118. *See* EX1015, ¶¶36, 39, FIGS. 3-5; EX1011, ¶380; *see also* EX1015, ¶¶29-30 (discussing similar structure of the cup shaped element), FIG. 1. Both embodiments also include a biasing element (spring 26/126) that exerts upward force to keep the clutch engaged during dose setting. *See* EX1015, ¶¶27, 29, 39, FIGS. 3-5; EX1011, ¶380. The user applies force to the button (bottom 19 or button 119), which pushes the teeth out of engagement to rotationally decouple the

components during injection. *See* EX1015, ¶¶27, 29, 39, FIGS. 3-5; EX1011, ¶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 a "tubular clutch" as claimed in claim 11.

The Møller and Steenfeldt-Jensen combination discloses the relative positioning between the dose-dial sleeve and the tubular clutch:

'044 Patent	**Møller and Steenfeldt-Jensen**
[11.7] wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, and	Møller discloses that bottom 19 extends into the dose setting drum 17: "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, FIG. 1 (below; annotating bottom (blue) and drum (green)); EX1011, ¶381.

As shown above in FIG. 1, dose setting drum 17 "extends circumferentially around at least a portion of" bottom 19. EX1015, FIG. 1; EX1011, ¶381. The Møller and Steenfeldt-Jensen combination thus disclosed this element.

The Møller and Steenfeldt-Jensen combination teaches a helical groove of a dose-dial sleeve and internal threading of a drive sleeve having respective leads:

'044 Patent	**Møller and Steenfeldt-Jensen**
[11.8] wherein said	Møller and Steenfeldt-Jensen disclose a dose-dial sleeve

helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different.	having a first lead. *See* element [11.2], *supra*. Møller discloses a dose-dial sleeve, dose-setting drum 17: "A tubular dose setting drum 17 fitting into the housing 2 is at an end provided with an internal thread mating and engaging the outer thread 6 of the tubular element 5[.] 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 (below; annotating drum (green)); EX1011, ¶348.

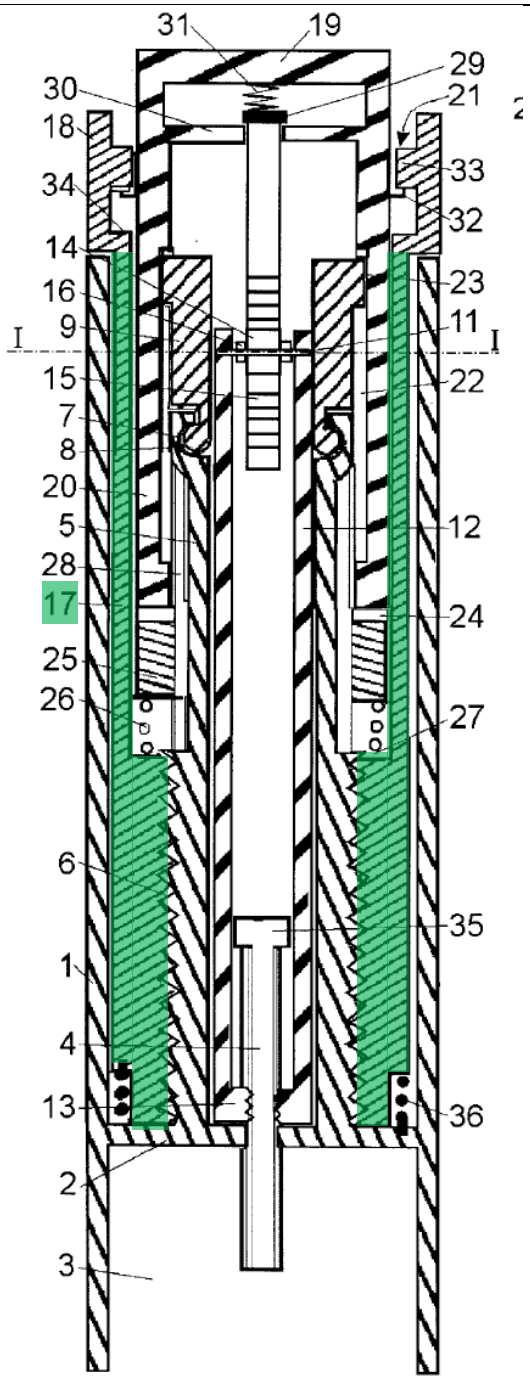
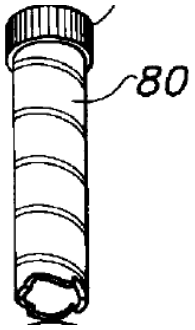
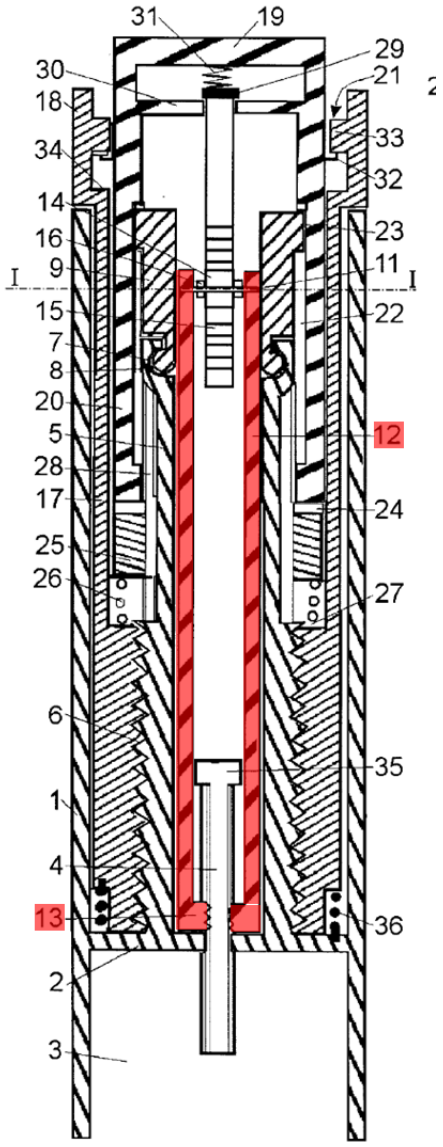


Fig. 1

Likewise, Steenfeldt-Jensen discloses a dose-dial sleeve, dose-scale drum 17 having a helical groove on its outer surface:

	"On the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. A dose scale drum 17 is in its outer wall provided with a helical gro[o]ve defining a corresponding external thread mating the inner thread just mentioned. The pitch angle of the threads exceeds the angle of friction for the materials forming the parts of the thread connection and consequently the thread connection is of the not self locking type which induce a relative rotation of the parts of the connection when those part[s] are moved axially relative to each other." EX1014, 6:7-17, FIG. 3 (below; partial view showing drum 80); *also id.* FIGS. 8, 13, 17 (illustrating other drum embodiments having helical groove on the outer surface).  Further, Møller discloses a drive sleeve having a second lead. *See* element [11.5], *supra*. Møller discloses a drive sleeve, the connection bars 12 and nut 13: "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 (below; annotating connection bars and nut (red)); EX1011, ¶366.

	 Fig. 1

Møller discloses a "drive sleeve" in the form of connection bars 12 having a nut 13 at its needle-end. *See* EX1011, ¶366. The nut 13 is internally-threaded, and engages with the thread of piston rod 4 to drive it during injection. EX1015, ¶¶24, 32, FIG. 1; EX1011, ¶367. To the extent connection bars 12 with nut 13 are not a "sleeve," Møller taught a sleeve in the form of a tubular connection element 112

with nut 113. *See* EX1015, ¶40, FIGS. 3-5; EX1011, ¶370. Given Møller's teaching that the tubular connection element 112 with nut 113 corresponds to connection bars 12 with nut 13, a POSA would have understood the components to be structurally and functionally equivalent. EX1011, ¶¶370-71. A POSA thus would have expected connection bars 12 with nut 13 could readily be formed as a tubular structure that encompasses piston rod 4, without affecting the device's operation. *Id.* Møller thus taught the claimed "drive sleeve."

2. Reason to modify; reasonable expectation of success

As noted above, Møller discloses a dose-dial sleeve having an internal thread that engages a main housing for rotational movement. Steenfeldt-Jensen discloses a dose-dial sleeve that includes an external helical groove that engages a main housing for rotational movement. As Mr. Leinsing explains, a POSA would have considered it obvious to place the drum's thread, Steenfeldt-Jensen's outer helical groove, to engage the housing for rotational movement. EX1011, ¶¶354-61.

Møller' background description expressly discusses the Steenfeldt-Jensen device. EX1015, ¶8 (referencing Steenfeldt-Jensen's related PCT publication). Møller specifically notes 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." *Id.*, ¶8. Møller, however,

notes what it views is a disadvantage of Steenfeldt-Jensen's device: since the force needed to drive the piston rod is linearly 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, ¶357. Møller thus concludes that "traditional gearing using mutual engaging gear wheels and racks is preferred." EX1015, ¶8.

Møller then goes on to describe its injection device, "which 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 on its outer surface for engaging 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; *see 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 one component relative to the other. *See* EX1014, 6:7-17; EX1011, ¶359.

A POSA would have recognized the benefit to placing a threaded engagement, like that in Steenfeldt-Jensen, on a drum and housing like that of Møller. EX1011, ¶360. Because Steenfeldt-Jensen's threaded engagement is configured to reduce the friction between the sliding surfaces of the drum and housing, a POSA would have understood that 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 such a configuration would retain the rotational movement between the drum and housing, and would not affect the operation of the device nor would it affect the force transferred to drive the piston rod, given Møller's use of a direct-gear coupling. 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. *E.g.*, EX1015, ¶¶12,14-15, claim 11. EX1011, ¶361.

A POSA thus would have had reason to incorporate a high-pitch helical groove as taught by Steenfeldt-Jensen on the outer surface of Møller's drum to

reduce the force necessary to rotate the drum relative to the housing. EX1011, ¶361. A POSA also would have reasonably expected that such a configuration would perform in the same manner as the inner threading of Møller's drum by allowing relative rotational movement between the drum and housing. EX1011, ¶361.

Accordingly, claim 11 was obvious over the combined teachings of Møller and Steenfeldt-Jensen.

Dependent Claims

The Møller and Steenfeldt-Jensen combination taught a clicker as recited in claim [14].

'044 Patent	**Møller and Steenfeldt-Jensen**
[14] The housing part of claim 11, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose dial grip is rotated.	Møller discloses a clicker in the interaction between a rosette of V-shaped teeth at the edge of the open end of a cup-shaped element with V-shaped teeth 24: "At the edge of the open end of the cup shaped element a rosette of V-shaped teeth are provided, which teeth engage a corresponding rosette of V-shaped teeth 24 on a ring 25[.] Thereby a click coupling is established which makes a click noise when the V-shaped teeth at the edge of the cup shaped element by rotation of this element rides over the V-shaped teeth of the ring 25." EX1015, ¶27.

	"By the rotation of the cup shaped element the V-shaped teeth 24 at the edge of its open end will ride over the V-shaped teeth of the non rotatable ring 25 to make a click sound for each unit the dose is changed." EX1015, ¶29; *see also id.*, ¶40; EX1011, ¶399. Steenfeldt-Jensen also discloses another clicker, the radial protrusions and axial recesses: "[T]he guide member has at its proximal end at least one radial protrusion 65 which is biased to engage axial recesses 66 in an inner wall of the button to produce[] a click sound each time the button is rotated relative to the bushing so that the protrusion jump [sic] from one recess to the neighbour recess." EX1014, 9:30-35; *see also, e.g.*, *id.*, FIG. 6; EX1011, ¶400. "During the rotation of the button the radial protrusion 65 of the guide member 56 clicks from one axial recess 66 to the other." EX1014, 9:48-50. "Therefore by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one, the recesses being so spaced that one click corresponds to a chosen change of the set dose." *Id.*, 11:62-67; *see also, e.g.*, *id.*, FIG. 17.

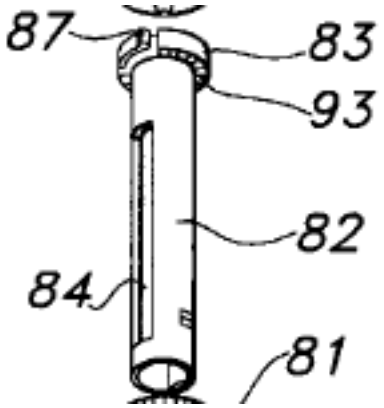
Møller discloses a clicker, a rosette of V-shaped teeth at the open-end edge of a cup-shaped element and V-shaped teeth 24, which provide an audible click to a user upon rotating the dose-dial grip. EX1015, ¶¶27-29, 40; FIG. 1; EX1011, ¶399.

Accordingly, Møller discloses all elements unique to claim 14. Furthermore, Steenfeldt-Jensen discloses a clicker in the radial protrusions and axial recesses, which provide audible feedback to a user upon rotating the dose-dial grip. EX1014, 9:30-35; 9:48-50; 11:62-67; FIGS. 6, 17; EX1011, ¶400. Accordingly, the Møller and Steenfeldt-Jensen combination rendered obvious claim 14.

If "clicker" is a means-plus-function limitation, Moller and Steenfeldt-Jensen still render the claims obvious for the reasons provided above when applying Steenfeldt-Jensen to claims 14 and 15. Moreover, Møller discloses the use of a rosette of V-shaped teeth at the edge of the open end of a cup-shaped element and V-shaped teeth 24, which provide an audible click to a user upon rotation of the dose-dial grip. EX1015, ¶¶27-29, 40; FIG. 1; EX1011, ¶402. One structure the '044 patent discloses for use as a clicker is saw teeth that ride over one another to produce a click. EX1002, 6:16-26. Thus, Møller also teaches a clicker having the same function and structure as that of the '044 patent.

The Møller and Steenfeldt-Jensen combination also taught a clicker as recited in claim [15].

’044 Patent	Møller and Steenfeldt-Jensen
[15] 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 dial grip 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.	Møller and Steenfeldt-Jensen each independently disclose a clicker. *See* claim [14], *supra*. Steenfeldt-Jensen further discloses a clicker comprising at least one flexible arm, said flexible arm comprising at least one tooth member: “The flange 83 of the bushing 82 … has at its periphery a radial protrusion 87 which is biased toward the side wall of the compartment.” EX1014, 11:37-40; FIG. 17; EX1011, ¶304.  FIG. 17 (detail; annotating radial protrusion 87 (purple)); EX1011, ¶310. “[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., 11:62-65; *also* Fig. 17; EX1011, ¶304.  Steenfeldt-Jensen further discloses a clicker comprising at least one spline via depressions 32 (*see, e.g.*, EX1014, 6:60-7:1), axial recesses 66 (*see, e.g.*, *id.*, 9:26-35), and axial recesses in the inner wall of dose-setting button 81 (*see, e.g.*, *id.*, 11:62-67). Steenfeldt-Jensen further discloses a clicker wherein when said dose dial grip 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. *See, e.g.*, EX1014, 6:42-7:1, 9:30-37, 11:62-67; EX1011, ¶311.

Møller discloses a clicker as described for claim 14 *supra*. A POSA would have understood that from FIG.17 that radial protrusion 87 is a "flexible arm" that includes a "tooth member" at its end for deforming and dragging into longitudinal recesses to produce a clicking noise. EX1014, 11:34-40, 11:62-67, FIG. 17. A

person of ordinary skill would have also understood that the longitudinal recesses would form corresponding ridges or splines between neighboring recesses. EX1011, ¶311.

A person of ordinary skill would have understood Steenfeldt-Jensen to discloses a "clicker" having "at least one flexible arm" that includes "at least one tooth member," in the form of radial protrusion 87, and "at least one spline," formed between neighboring longitudinal recesses, such that, when the dose setting button 81 is rotated, the radial protrusion 87 "deforms and drags" its "tooth member" over the splines formed by the longitudinal recesses to provide audible feedback. EX1011, ¶312.

Accordingly, the Møller and Steenfeldt-Jensen combination rendered obvious claim 15.

The Møller and Steenfeldt-Jensen combination taught a dose-dial sleeve:

'044 Patent	**Møller and Steenfeldt-Jensen**
[18] The housing part of claim 11, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.	Møller discloses a dose-dial sleeve in the form dose-setting drum 17. *See* element [11.2], *supra*; EX1015, FIG. 1 (detail; drum 17 in green, cup-shaped element in blue); EX1011, ¶423:

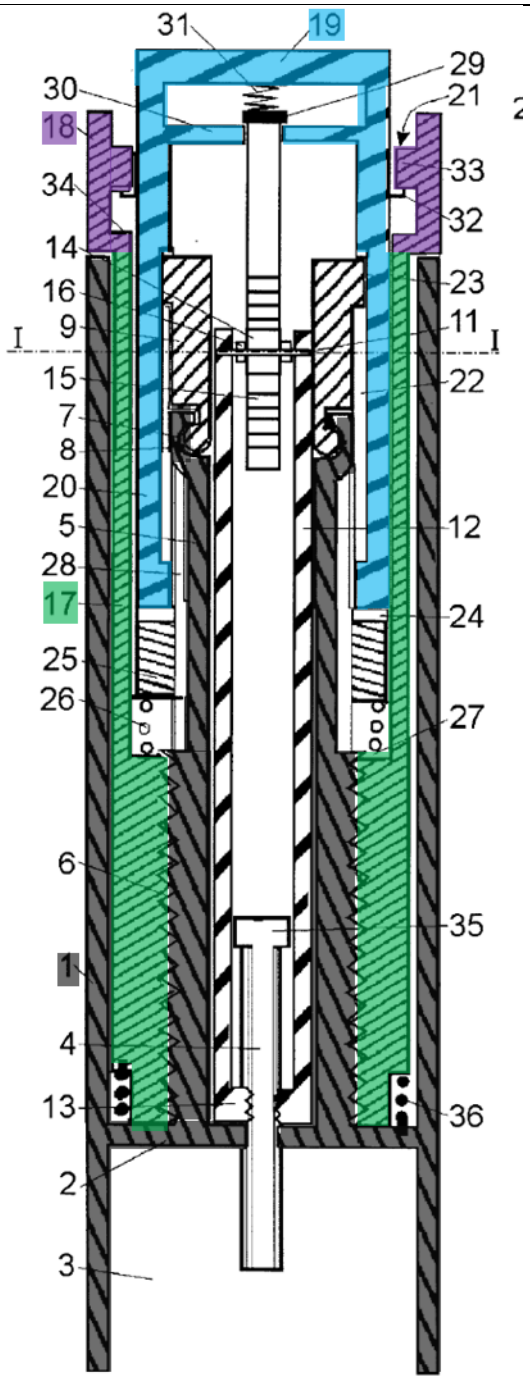
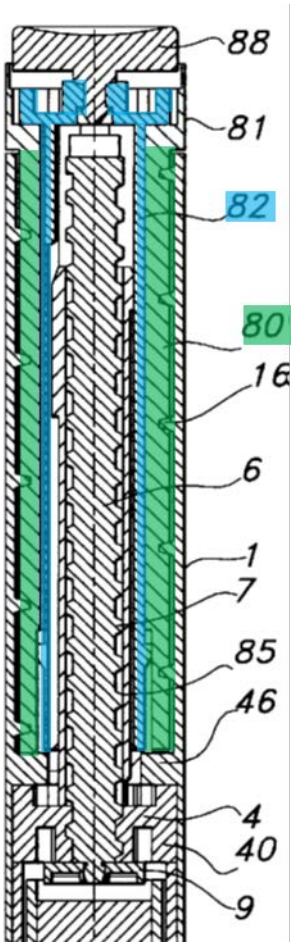


Fig. 1

Furthermore, dose setting drum 17 is located outside the tubular clutch of Møller (bottom 19). *See* element

	[11.7], *supra*. "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, FIG. 1. Likewise, the dose-dial sleeve of Steenfeldt-Jensen is provided outside of a tubular clutch and radially inward of a main housing. *See* elements [11.1], [11.2], [11.7], and claim [18], *infra*.  EX1014, FIG. 16 (above; partial view annotating drum

	(green) and bushing (blue)); EX1011, ¶319.

As discussed above, Møller and Steenfeldt-Jensen independently disclose a dose-dial sleeve outside a tubular clutch and radially inward of a main housing. *See* elements [11.1], [11.2], and [11.7], *supra*; EX1015, FIG. 1; EX1014, FIG. 16; EX1011, ¶319. Accordingly, the Møller and Steenfeldt-Jensen combination rendered obvious claim 18.

The Møller and Steenfeldt-Jensen combination taught a main housing comprising a helical rib.

'044 Patent	**Møller and Steenfeldt-Jensen**
[19] The housing part of claim 11, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve.	Møller and Steenfeldt-Jensen disclose a dose-dial sleeve having a helical groove provided along an outer surface of said dose-dial sleeve. *See* element [11.2], *supra*. Møller discloses a dose-dial sleeve in dose-setting drum 17, having a groove engaging a rib on Møller's main housing, *see* elements [11.1] and [11.2], *supra*. "A tubular dose setting drum 17 fitting into the housing 2 is at an end provided with an internal thread mating and engaging the outer thread 6 of the tubular element 5[.] 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 (below; annotating

drum (green)); EX1011, ¶438.

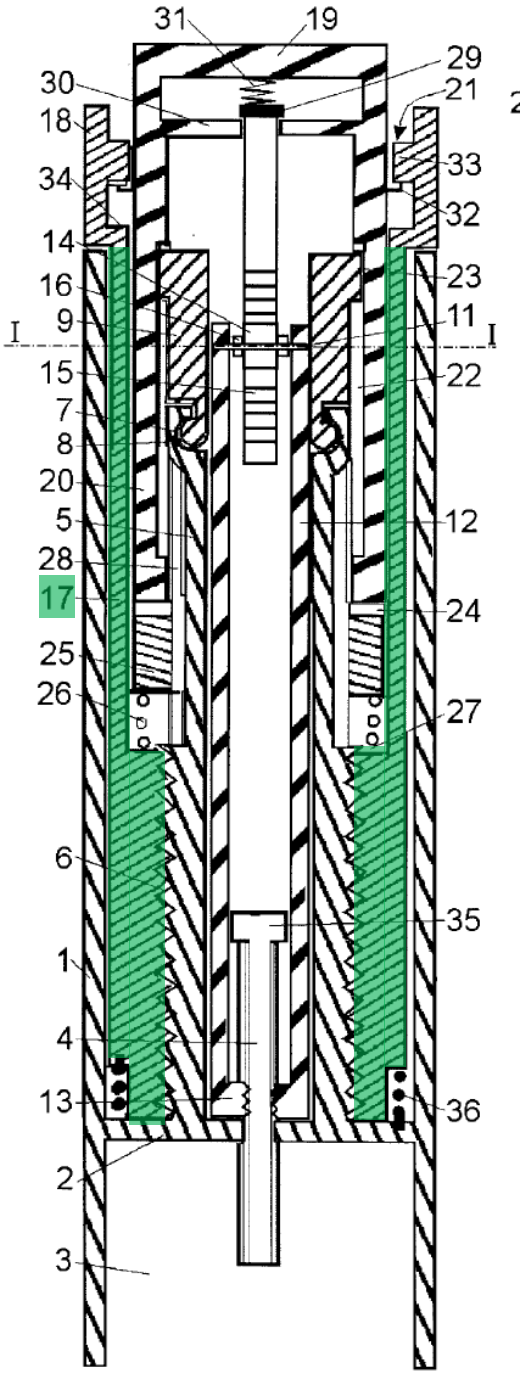
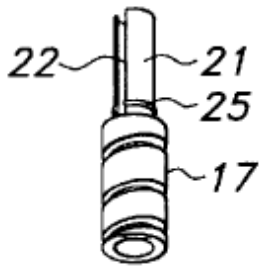


Fig. 1

Likewise, Steenfeldt-Jensen discloses a dose-dial sleeve, dose scale drum 17, having a helical groove on its outer

	surface, the helical groove engaging a rib on housing 1: "On the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. A dose scale drum 17 is in its outer wall provided with a helical gro[o]ve defining a corresponding external thread mating the inner thread just mentioned. The pitch angle of the threads exceeds the angle of friction for the materials forming the parts of the thread connection and consequently the thread connection is of the not self locking type which induce a relative rotation of the parts of the connection when those part[s] are moved axially relative to each other." EX1014, 6:7-17, FIG. 3 (below; partial view showing drum 17); *also id.* FIGS. 8, 13, 17 (illustrating other drum embodiments having helical groove on the outer surface). 

Møller discloses a main housing comprising a helical rib, said helical rib adapted to be seated in a helical groove provided along the outer surface of the dose-dial sleeve. *See* elements [11.1] and [11.2], *supra*. Likewise, Steenfeldt-

Jensen discloses a main housing comprising a helical rib, said helical rib adapted to be seated in a helical groove provided along the outer surface of the dose-dial sleeve. *See* elements [11.1] and [11.2], *supra*.

Accordingly, the Møller and Steenfeldt-Jensen combination rendered obvious claim 19.

VI. CONCLUSION

Claims 11, 14, 15, 18, and 19 are unpatentable. The unpatentability of this patent is not an abstract concern. The high cost of insulin products reduces patient compliance, with adverse effects for American diabetics. *See* EX1035, 2, 8. Mylan respectfully requests review of these claims.

/ 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 12,777, 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. 8,603,044 and Exhibits 1001-1035** by *Federal Express Next Business Day Delivery* on 10 September 2018 to 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