UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2018-01670
Patent No. 8,679,069

PETITION FOR *INTER PARTES* REVIEW

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I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Mylan") seeks *inter partes* review ("IPR") of claim 1 of U.S. Patent 8,679,069 ("the '069 patent," EX1001). 35 U.S.C. ch. 31.

This Petition shows a reasonable likelihood that the prior art renders claim 1 unpatentable. 35 U.S.C. 314(a).

II. MANDATORY NOTICES

A. Real Parties-In-Interest

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

B. Related Matters

The '069 patent has been asserted in *Sanofi-Aventis U.S. LLC v. Mylan N.V.*, No. 2:17-cv-09105 (D.N.J.), filed October 24, 2017. Mylan, Biocon, and their real parties-in-interest are parties in this litigation. Becton Dickinson and Company supplies pens to Mylan, but has not been named as a party.

The '069 patent also has been asserted in *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812 (D. Del.). See EX1029 (*Markman* opinion); also EX1030 (*Markman* opinion in *Sanofi -Aventis U.S. LLC v. Eli Lily* and Co., No. 14-cv-113 (D. Del.) (consent judgment)). Mylan, Biocon, and their real parties-in-interest are not parties in this litigation.

Mylan has filed IPR2018-01675, IPR2018-01676, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682 and IPR2018-01684

against related patents.

C. Identification of Counsel and Service Information

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Please direct all correspondence to lead counsel and back-up counsel. 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 that the ’069 patent is available for IPR, and Mylan is not barred or estopped from requesting IPR on the identified grounds.

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

Mylan requests IPR and cancellation of claim 1 under pre-AIA 35 U.S.C. 103, as the reasons below set forth, supported with exhibits, including the Declaration of Karl R. Leinsing, EX1011.

Claim 1 was obvious over the prior art as follows:

Ground	Claims	Basis
1	1	U.S. Patent 6,221,046 (EX1013, "Burroughs")
2	1	U.S. Patent 6,235,004 (EX1014, "Steenfeldt-Jensen")
3	1	US Patent Publication 2002/0052578 (EX1015, "Møller") in combination with Steenfeldt-Jensen

V. STATEMENT OF REASONS FOR THE RELIEF REQUESTED

A. Summary of the Argument

The challenged claim relates to a drive mechanism for dispensing medicine, such as insulin and insulin analogs, from a pen-type injector. EX1001, Title, 1:13-22. At its core, the claim broadly recites a six-component structure forming this mechanism. Those six components include structural elements that are themselves claimed broadly. As shown below, however, each of the six components claimed was known and commonly used together in the prior art. Similarly, each of the structural elements for each of the components was known and commonly used in the prior art. Where there are differences between what the prior art disclosed and what is claimed,

the differences are merely "[t]he combination of familiar elements according to known methods." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). The claimed invention combined familiar elements in an obvious way. Claim 1 is therefore unpatentable over the prior art.

B. The '069 Patent[1]

1. Background

The '069 patent relates to a pen-type injector for self-administration of medicine, such as insulin and insulin analogs. EX1001, Title, 1:13-22. According to the '069 patent, such injectors are appropriate for patients who do not have formal medical training, including diabetes patients. *Id.*, 1:18-22. The '069 patent states that such injectors must be easy to use, as patients using the device may have impaired vision or other physical infirmities. *Id.*, 1:24-28.

The '069 patent specifically describes and claims a housing part containing a drive mechanism for dispensing medicine from an injector. The '069 patent issued with 3 claims, of which only claim 1 is challenged by this Petition. Claim 1 is an independent claim that recites:

[1] For uniformity, when discussing both the '069 patent and the prior art, description of the positioning and movement of components will be relative to the "button-end" of the device and the "needle-end" of the device.

1. 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 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.

Id., 6:37-60.

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

(1) "main housing" (4, gray), which houses the drive mechanism for dispensing medicine from a cartridge, *see, e.g.*, *id.*, 3:8-14, FIGS. 1-5;

(2) “dose dial sleeve” (70, green), which the user manipulates to set a specific dose for injection, *see, e.g.*, *id.*, 4:49-52, FIGS. 1-5, 9-11;

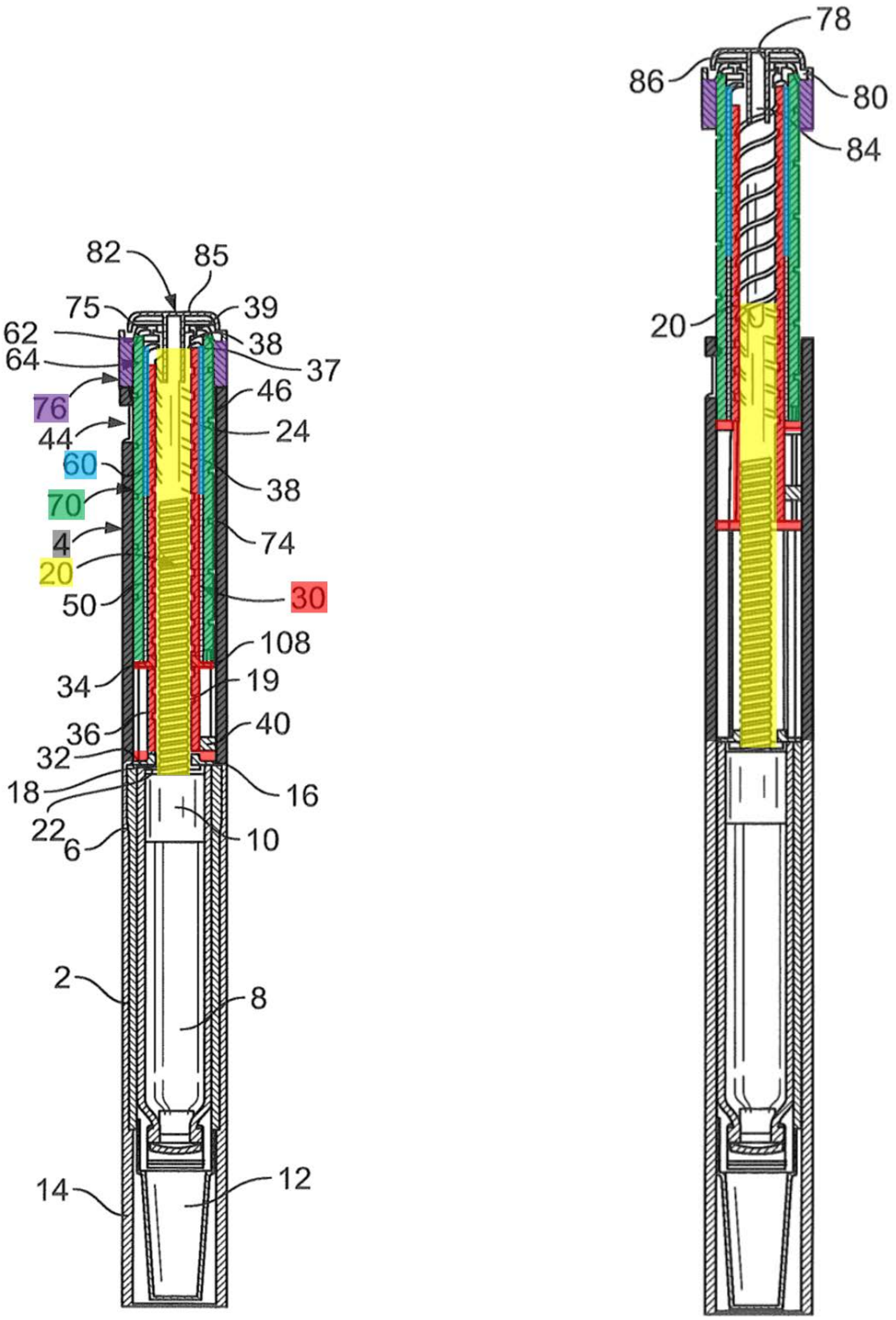
(3) “dose dial grip” (76, purple), which serves as a grip for the user to manipulate the dose dial sleeve, *see, e.g.*, *id.*, 5:3-8, 5:29-32, FIGS. 1-5, 9-11;

(4) “piston rod” (20, yellow), which is driven to move a piston provided within the cartridge to dispense medicine, *see, e.g.*, *id.*, 3:36-41, 6:23-25, FIGS. 1-5;

(5) “drive sleeve” (30, red), which drives the piston rod in order to move the piston, *see, e.g.*, *id.*, 3:51-60, 6:23-25, FIGS. 1-15, 9-11; and

(6) “tubular clutch” (60, blue), which releasably connects components within the drive mechanism for common movement during use, *see, e.g.*, *id.*, 1:57-59, 2:5-7, 5:29-32, 6:6-13, FIGS. 1-5, 9-11.

FIGS. 1 (left) and 2 (right) of the ’069 patent are reproduced below, with color-coding added to highlight the above components. *See* EX1011, ¶38.



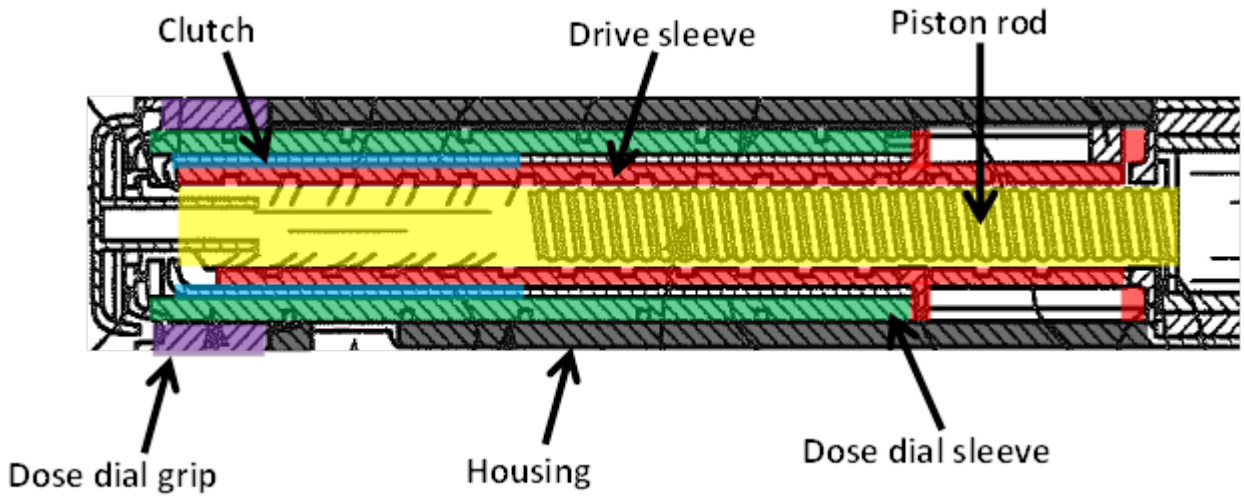
Each of the claimed components, along with other aspects of the disclosed injector, is described below, followed by a description of the injector's operation.

Brief Overview of the Disclosed Embodiment

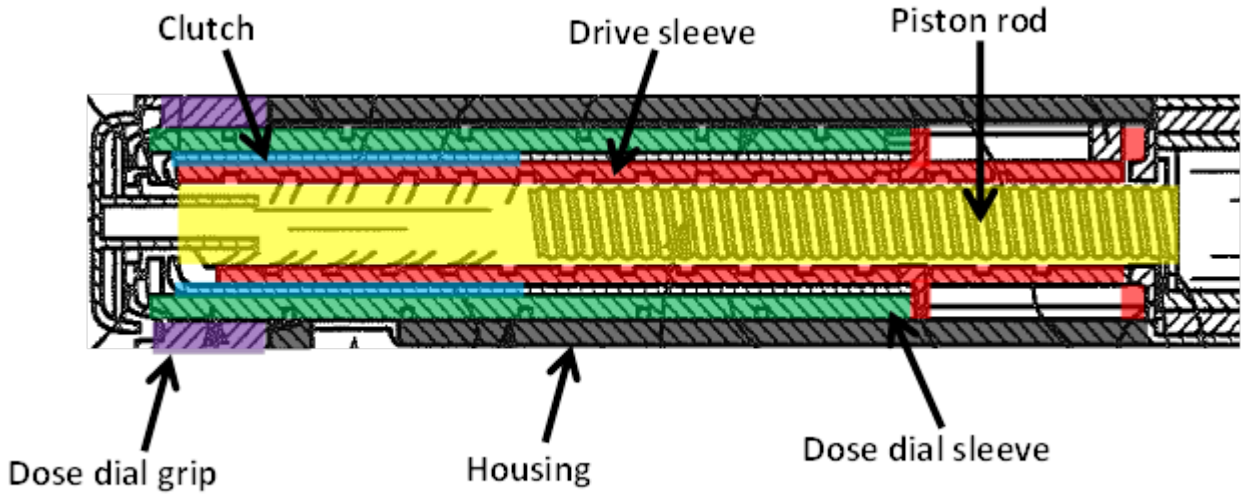
The '069 patent describes an injector having a housing that is formed from two parts: (1) first cartridge retaining part 2, which contains cartridge 8 from which medicine is dispensed, and (2) second main housing part 4 (gray). *See* EX1001, 3:8-17, FIG. 1. Second main housing part 4 houses the mechanism that drives piston 10 contained within the cartridge 8 to dispense medicine. *See id.*, FIG. 1; EX1011, ¶¶44-49.

For example, in an embodiment of an injector as taught by the '069 patent, at a needle-end[2] of housing part 4, insert 16 is provided. *Id.*, 3:29-30, FIG. 1. Insert 16 is fixedly connected to the housing, both rotationally and axially, and includes threaded circular opening 18, through which the needle-end of piston rod 20 (yellow) extends. *Id.*, 3:30-39, FIG. 1; EX1011, ¶¶50-51. Piston rod 20 includes first thread 19 that engages with the insert's threaded opening 18. EX1001, 3:36-39, FIG. 1. Piston rod 20 also includes pressure foot 22 at this end, which abuts piston 10 of cartridge 8. *Id.*, 3:39-41, FIG. 1.

[2] The specification refers to the needle-end of the device as its "first end," and the button-end as its "second end." *See, e.g.*, EX1001, 3:29-30, 3:52-53, 4:28-29, FIG. 1. Claim 1 refers to the needle-end of the device as its "distal end," and the button-end as its "proximal end." *See id.*, claim 1.



Partial view of FIG. 1 showing injector in a cartridge-full position, prior to dose setting (*see id.*, 2:38-40), annotated (*see* EX1011, ¶39)



Partial view of FIG. 2 showing injector in a maximum dose-dialed position (*see* EX1001, 2:41-42), annotated (*see* EX1011, ¶39)

Piston rod 20 also includes second thread 24 that extends from its button-end. *See* EX1001, 3:41-42, FIGS. 1-2; EX1011, ¶¶52-54. Drive sleeve 30 (red) extends about piston rod 20. EX1001, 3:51, FIG. 1. Drive sleeve 30 includes helical groove

38 extending along its internal surface that engages with second thread 24. *Id.*, 3:58-60, FIG. 1; EX1011. ¶¶55-58.

Clutch 60 (blue) is "disposed about drive sleeve 30, between drive sleeve 30 and dose dial sleeve 70 [green]." *Id.*, 4:12-14, FIGS. 1, 6-7. Clutch 60 is "generally cylindrical" and located adjacent the button-end of drive sleeve 30. *See id.*, 4:28-30, 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.*, 4:39-41. At its button-end, clutch 60 includes a plurality of dog teeth 65. *Id.*, 4:37-39, FIGS. 1-2, 8. Teeth 65 are configured to releasably engage with the button-end of dose dial sleeve 70.[3] *See id.*, 2:5-7, 6:6-9, FIG. 1; EX1011, ¶¶65-67.

Dose dial sleeve 70 is "provided outside of" clutch 60 and "radially inward of" housing 4. EX1001, 4:49-52, FIG. 1. "A helical groove 74 is provided about an outer surface of the dose dial sleeve 70." *Id.*, 4:51-52, FIGS. 1-2, 12. "The main housing 4 is further provided with a helical rib 46, adapted to be seated in the helical groove 74"

[3] The specification does not specifically explain or show how teeth 65 engage with dose dial sleeve 70. As Leinsing explains, teeth 65 engage with "an inwardly directed flange in the form of [a] number of radially extending members 75" provided at dose dial sleeve 70's button-end. *See* EX1011, ¶186 (citing EX1001, 5:1-3).

for relative rotation. *Id.*, 4:55-57, FIGS. 15-16; EX1011, ¶¶68-70. "A dose dial grip 76 [purple] is disposed about an outer surface of the [button-end] of the dose dial sleeve 70." EX1001, 5:3-4, FIGS. 1-2. "The dose dial grip 76 is secured to the dose dial sleeve 70 to prevent relative movement therebetween." *Id.*, 5:6-8; EX1011, ¶¶71-73.

Operation of the Pen Injector

Dose setting: To set a dose, the user rotates dose dial grip 76 in one direction. *See* EX1001, 5:29-30, FIG. 9 (reproduced and annotated below). At this stage, teeth 65 of clutch 60 are engaged to dose dial sleeve 70. *See id.*, 2:5-7, 5:29-32. Such engagement causes dose dial sleeve 70, clutch 60, and drive sleeve 30 to rotate together out of the housing. *See id.*, 5:29-32, FIG. 9. Drive sleeve 30 rotates up piston rod 20, toward its button-end, due to its engagement with piston rod 20's second thread 24. *See id.*, 5:40-44. Piston rod 20 is prevented from rotating due to its opposing, threaded engagement with insert 16. *See id.*, 3:48-49, 5:47-49; EX1011, ¶¶78-82.

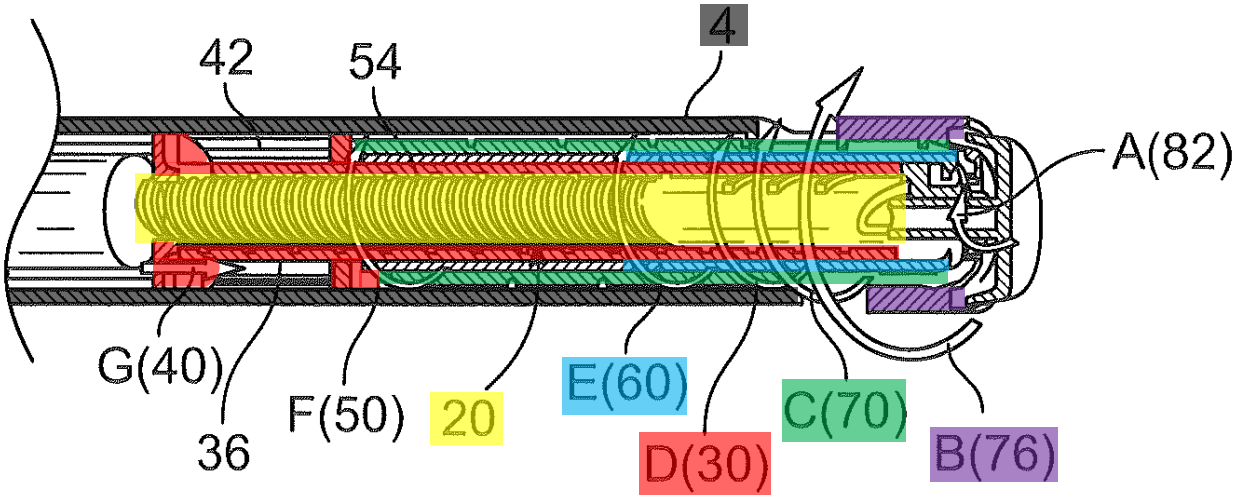


FIG. 9: Dialing up (*see id.*, 2:55-56), annotated to highlight components (*see* EX1011, ¶81)

The user also may dial down a dose, if needed. *See* EX1001, 5:62-65, FIG. 10 (reproduced and color-coded below). To dial-down a dose, the user rotates dose dial grip 76 in the opposite direction (*e.g.*, clockwise direction). *See id.*, 5:65, FIG. 10. "This causes the system to act in reverse," where dose dial sleeve 70, clutch 60, and drive sleeve 30 rotate together back into the housing. *See id.*, 5:65-66, FIG. 10. As such, drive sleeve 30 rotates down piston rod 20, toward its needle-end, without corresponding rotation of piston rod 20. *See id.*, 5:47-49, 5:62-66, FIG. 10; EX1011, ¶¶83-85.

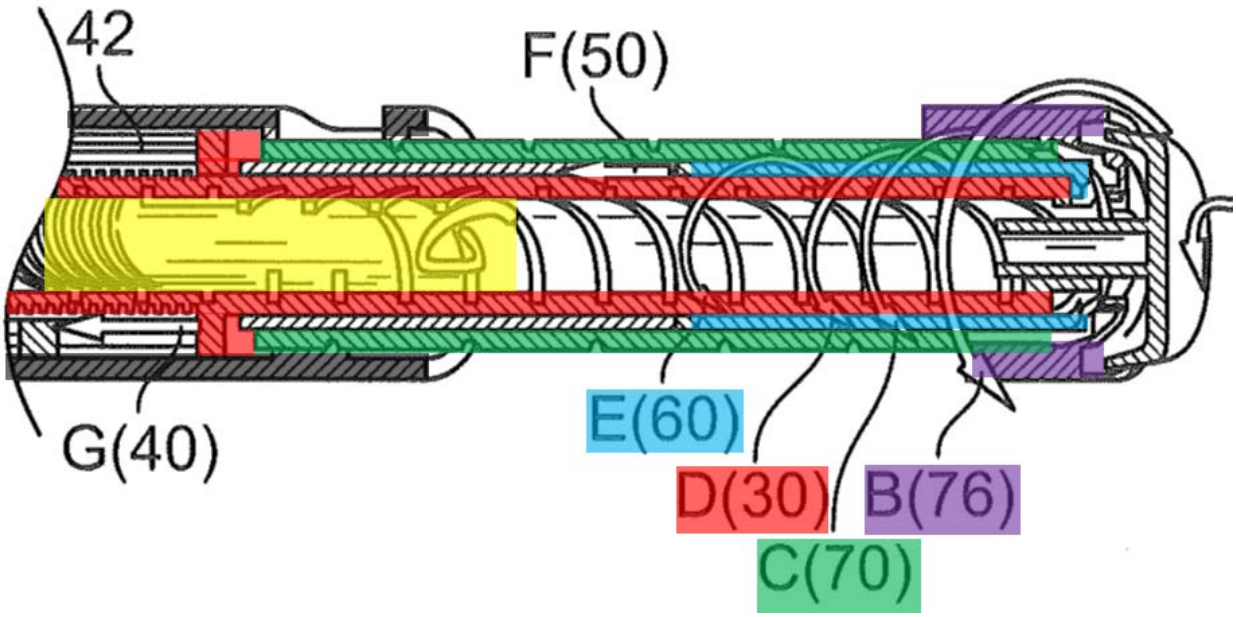


FIG. 10: Dialing down (*see id.*, 57-58), annotated to highlight components (*see* EX1011, ¶84)

Injection: Once the dose is set, the user presses button 82, applying a force toward the needle-end of the device. *See* EX1001, 6:6-7, FIG. 11 (reproduced and color-coded below). This displaces clutch 60 axially such that teeth 65 disengage from dose dial sleeve 70. *Id.*, 6:7-9. Dose dial sleeve 70 rotates into housing 4 via its threaded connection with the housing. *Id.*, 6:11-13; FIG. 11. Now disengaged from dose dial sleeve 70, clutch 60 does not follow this rotation, and instead, moves axially toward the needle-end of the device. *See id.*, 6:9-11, 6:16-18. Drive sleeve 30 also moves axially toward the needle-end, driving piston rod 20 to rotate through threaded opening 18, causing medicine to be dispensed from cartridge 8. *See id.*, 6:23-25, FIG. 11; EX1011, ¶¶86-89.

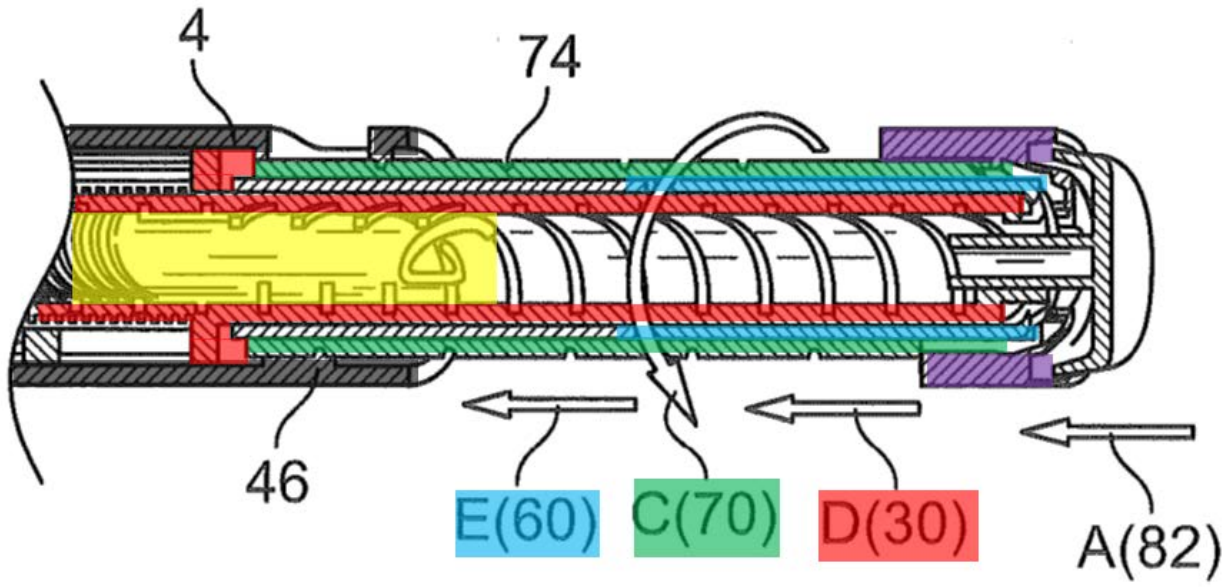


FIG. 11: Injecting dose (*see id.*, 2:59-60), annotated to highlight components (*see* EX1011, ¶86)

2. Prosecution History

The '069 patent issued from Application No. 12/944,544. During prosecution, pending claims 15, 17, and 19 were rejected under §103(a) as obvious over European Patent Application EP 0937471 ("Walters"), and under §112 for lack of written description. *See* EX1006, 165-66.

In response, in addition to amendments addressing the written-description rejection, applicants amended claim 15 to require the "helical groove" of the dose dial sleeve be "provided along an outer surface of said dose dial sleeve." *Id.*, 221. Applicants argued that Walters failed to disclose the helical groove and also failed to disclose a "clutch." *Id.*, 226. A Notice of Allowance followed. *Id.*, 238.

Møller (EX1015), as well as a related PCT publication of Steenfeldt-Jensen

(WO99/38554, EX1027), were two references applicants disclosed during prosecution. *Id.*, 179-80. Those references, however, were not applied substantively to the claims.

C. Level of Ordinary Skill

For the purposes of this Petition, the relevant timeframe is prior to March 3, 2003, the earliest possible priority date the '069 patent claims. As Leinsing explains, a POSA at the relevant time would have had at least a bachelor's degree in mechanical engineering, or an equivalent degree. *See* EX1011, ¶106. The POSA also would have understood the basics of medical-device design and manufacturing, and the basic mechanical elements (*e.g.*, gears, pistons) involved in drug delivery devices. *Id.*

D. Claim Construction

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

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

reasonable interpretation of a claim during prosecution, must construe the claim language in a way that at least encompasses the broadest interpretation of the claim language for purposes of infringement."). 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, 19-20.

"main housing": "An exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components." *Id.*, 21-23.

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

"thread/threaded/threading": "A rib or groove on a first structure that engages a corresponding groove or rib on a second structure." *Id.*, 30-31.

"tubular clutch": "A tubular structure that couples and decouples a moveable component from another component." *Id.*, 23-24.

Mylan notes further that in the related litigation with Sanofi, it proffered a preliminary means-plus-function construction for the claim term "tubular clutch." EX1028, Exhibit D, 80-85. The district court in that litigation has not yet set forth a claim construction. To the extent that the Board concludes that the broadest reasonable interpretation of those terms is a means-plus-function construction, Mylan

provides those constructions below. 37 C.F.R. 42.100(b) (claim terms to be given "broadest reasonable construction in light of the specification of the patent in which it appears"); 42.104(b)(3) ("Where the claim to be construed contains a means-plus-function or step-plus-function limitation as permitted under 35 U.S.C. 112(f), the construction of the claim must identify the specific portions of the specification that describe the structure, material, or acts corresponding to each claimed function").

As to function of the "clutch," Mylan asserts that the function is that during dose setting, it "clutch[es], i.e., coupling and decoupling a movable component from another component," or , during dose setting, it "operates to reversibly lock two components in rotation." EX1028, 82. Mylan points to FIGS. 1, 5-11, component 60, as the corresponding structure for the clutch. *Id.*, 80; *see also* EX1001, 2:5-7, 11:58-12:4, 4:42-44, 6:14-22.

E. Prior Art

Numerous pen-type injectors were known in the art before March 3, 2003, including many that used the same six-component structure claimed by claim 1. EX1011, ¶14. The injectors typically relied on concentrically-arranged cylindrical components that operated together to axially drive a threaded piston rod for injection. *Id.* While the specific structure of the components varied, their general structure and operation were well-established and standard. *Id.*; *also id.*, ¶¶114-23

(providing overview of common components). Claim 1 simply recites familiar features of these components—any differences between the claimed invention and what was known in the art is merely a mixture of well-known features with predictable and well-understood functions. EX1011, ¶124.

1. Burroughs

Burroughs, which issued in 2001 and is prior art under pre-AIA §102(b), disclosed a medication-dispensing pen for dispensing selectively measured dosages of medicine. *See* EX1013, 1:13-16. In particular, as shown in FIG. 1 and 2 (reproduced and color-coded below, EX1011, ¶126), Burroughs described a pen that comprises six components:

(1) "housing 22," having "first part 24" and "second part 26" (gray), which houses the drive mechanism for dispensing medicine from a cartridge, *see* EX1013, 7:15-20;

(2) "dial mechanism 34" (green), which the user manipulates to set a specific dose for injection, *see* EX1013, 10:38-42;

(3) "proximal portion 78" (purple), which serves as a grip for the user to manipulate the dial mechanism, *see* EX1013, 8:2-8;

(4) "leadscrew 38" (yellow), which is driven to dispense medicine within the cartridge, *see* EX1013, 9:26-34;

(5) "nut 36" (red), which drives the leadscrew, *see* EX1013, 9:12-25, 11:31-34;

and

(6) "button 32" (blue), which rotationally decouples the dial mechanism from the housing and the nut during injection, *see* EX1013, 11:13-34; EX1011, ¶¶125-28.

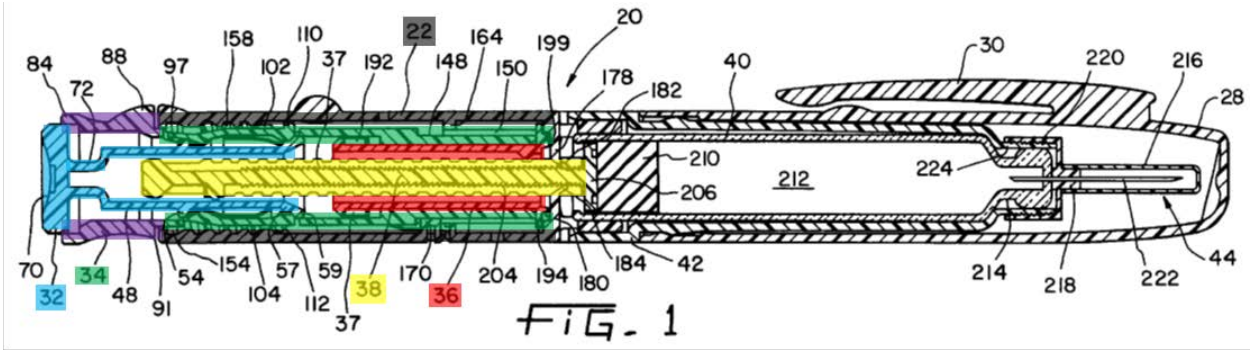


FIG. 1

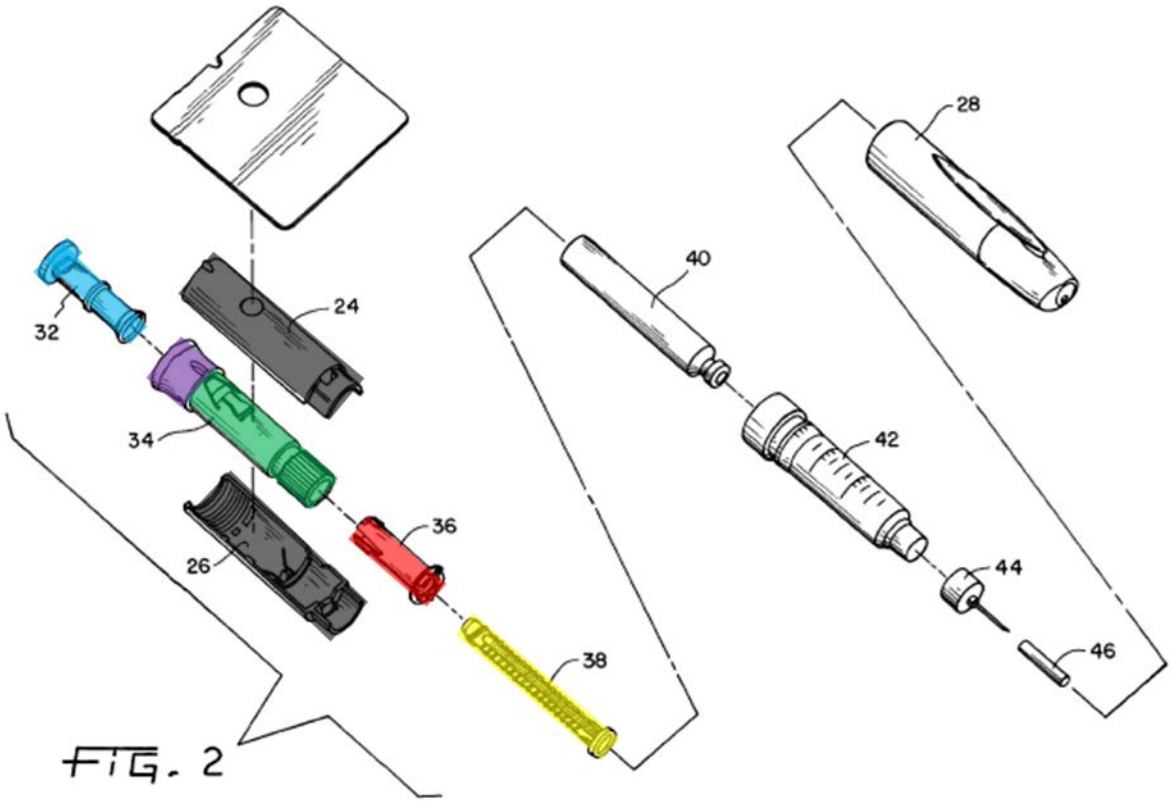


FIG. 2

See EX1013, FIGS. 1 (top above) and 2 (bottom above); EX1011, ¶126.

As detailed more below, Burroughs disclosed each of the six components of claim 1, except that its "dose dial sleeve" (dial mechanism 34) includes a helical rib,

rather than a helical groove. *See infra*, section V.F.1. But, modifying Burroughs' dial mechanism 34 to include a helical groove would have been considered obvious to a POSA at the relevant time. *See infra*, section V.F.2.

2. Steenfeldt-Jensen

Steenfeldt-Jensen issued in 2001 and is prior art under pre-AIA §102(b). Like Burroughs, Steenfeldt-Jensen disclosed injection syringes for dispensing medicine. *See* EX1014, Abstract. As shown in FIGS. 16 and 17 (reproduced and color-coded below), Steenfeldt-Jensen disclosed a syringe comprising a six-component structure (EX1011, ¶131):

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

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

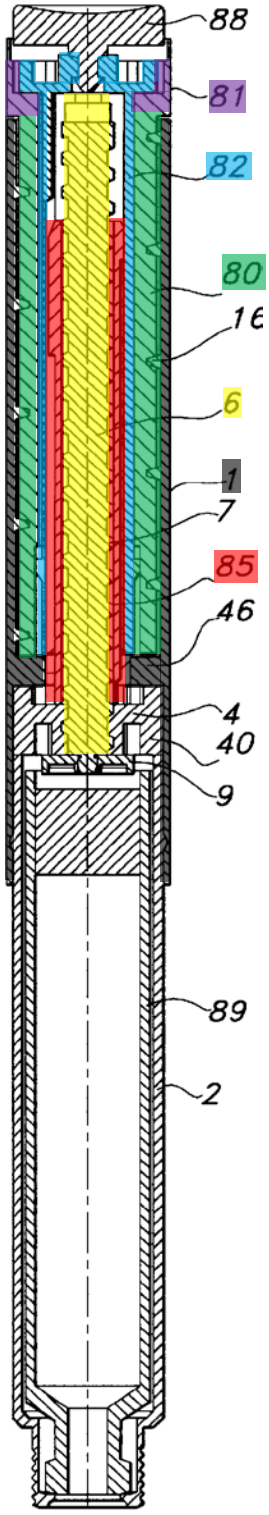
(3) "dose setting button 81" (purple), which serves as a grip for the user to manipulate the scale drum, *see* EX1014, 11:51-55;

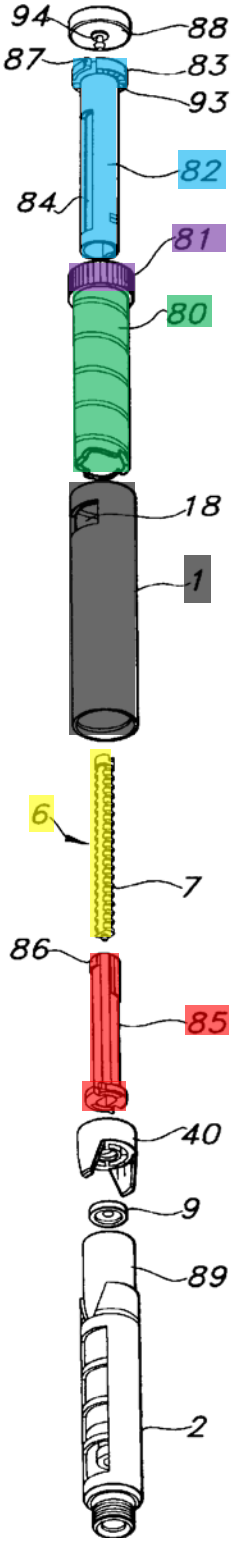
(4) "piston rod 6" (yellow), which is driven to dispense medicine from the ampoule, *see* EX1014, 5:57-65;

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

(6) "bushing 82" (blue), which releasably connects the scale drum and the

driver tube for rotational movement during injection, *see* EX1014, 12:4-13; EX1011, ¶¶130-33.





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

As further described below, the embodiment disclosed in Steenfeldt-Jensen includes the same components and structural elements as those recited in claim 1. *See infra*, section V.G.1. In order to drive the piston rod 6, the driver tube 85 rotationally engages with the rod through a bore having a non-circular cross-section, rather than "an internal threading near a distal portion." EX1011, ¶274. As discussed below in section V.G.2., a POSA would have found it obvious to modify Steenfeldt-Jensen's device such that driver tube 85 includes an internal threading near a distal portion for engagement with an external thread on the piston rod.

3. Møller

Møller is prior art to the '044 patent under pre-AIA 35 U.S.C. 102(a) and (e). Møller described an injection device for injecting set doses of medicine that includes a similar six-component structure. *See generally* EX1015, ¶¶22-27. As shown in FIG. 1 (reproduced and color-coded below, EX1011, ¶139), Møller discloses an injection device comprising:

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

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

(3) “dose setting button 18” (purple), which serves as a grip for the user to manipulate the dose setting drum, *see* EX1015, ¶28;

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

(5) “connection bars 12” having “nut 13” (red), which drives the piston rod, *see* EX1015, ¶¶24, 32; and

(6) “bottom 19” (blue), which rotationally decouples the dose setting drum from the connection bars and nut during injection, *see* EX1015, ¶¶26, 29, 33; EX1011, ¶¶138-39, 141-42.

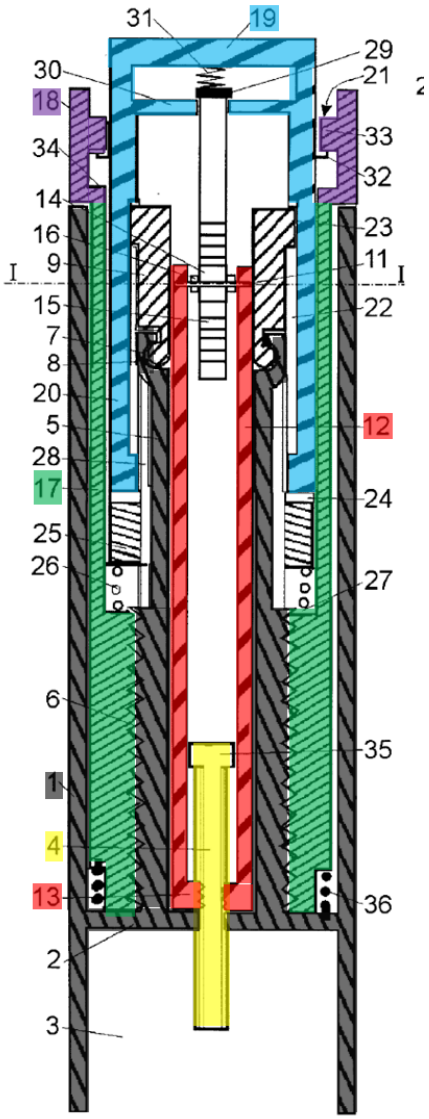


Fig. 1

EX1015, FIG. 1; EX1011, ¶139.

As detailed in section V.H.1, Møller discloses each of the structural elements recited in claim 1, except the "dose dial sleeve" includes an inner helical thread to engage the housing, rather than an outer helical groove. Providing an outer helical groove to engage a housing, however, would have been obvious in view of Steenfeldt-Jensen. *See infra*, section V.H.2.

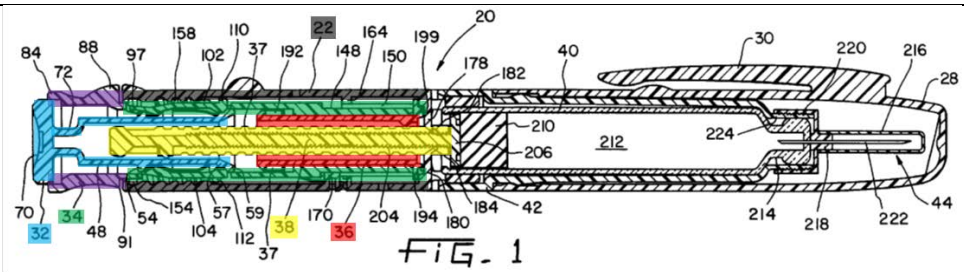
F. Ground 1: Claim 1 is Obvious over Burroughs

As explained above, Burroughs disclosed a medication dispensing pen that includes the same six components broadly claimed by claim 1. Five of those components include the same structural elements recited in claim 1. Regarding the sixth, the claimed "dose dial sleeve," Burroughs' dial mechanism has threads on its outer surface, which form a helical rib, that engage with a helical groove of the main housing, rather than a helical groove on its outer surface that engages with threading of the main housing as recited in claim 1. As discussed in section V.F.2 below, however, a POSA would have found it obvious to swap these features to provide a dial mechanism with a helical groove on its outer surface that on its outer surface that engages with a thread on the main housing.

1. Element-by-element analysis

To the extent the preamble is limiting, Burroughs taught it:

'069 Patent	**Burroughs**
[1.Preamble] A housing part for a medication dispensing apparatus, said housing part comprising:	Burroughs discloses a multi-use medication dispensing pen: "A multi-use medication dispensing pen made of a plastic material that is recyclable after the contents of the medication cartridge have been exhausted. The pen is made of a minimal number of parts, which include a housing[.]" EX1013, Abstract.

	 FIG. 1 *See id.*, FIG. 1 (annotated above); EX1011, ¶126. "Referring to FIGS. 1 and 2, there is shown an injection medication device 20 having the general appearance of a pen or mechanical pencil. The device comprises a mechanism housing 22 having a first part 24 and a second part 26 (FIG. 2)." EX1013, 7:15-19, FIGS. 1-2.

Burroughs discloses an injection medication device 20 for dispensing medicine. *See, e.g.*, EX1013, Abstract, 7:15-16, FIG. 1; EX1011, ¶126. Device 20 includes mechanism housing 22 containing the device's drive mechanism. *See* EX1013, 7:14-18, FIG. 1; EX1011, ¶126. Accordingly, Burroughs taught the preamble of claim 1.

Burroughs taught "a main housing" as recited in element [1.1]:

'069 Patent	**Burroughs**
[1.1] a main housing, said main housing extending from a distal end to a proximal end;	Burroughs discloses mechanism housing 22: "The device comprises a mechanism housing 22 having a first part 24 and a second part 26 (FIG. 2). Housing parts 24 and 26 are secured together by ultrasonic welding ...."

EX1013, 7:17-20, FIGS. 1-3, 5.

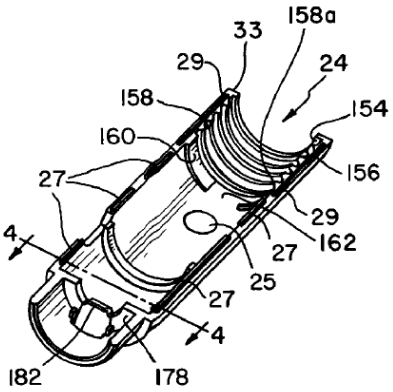


FIG. 3

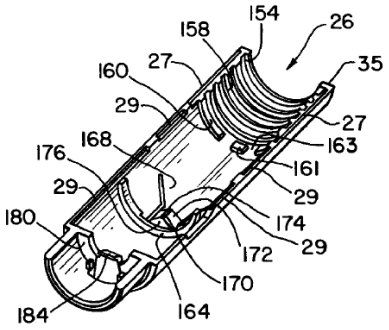


FIG. 5

See id., FIGS. 3 (above-left), 5 (above-right).

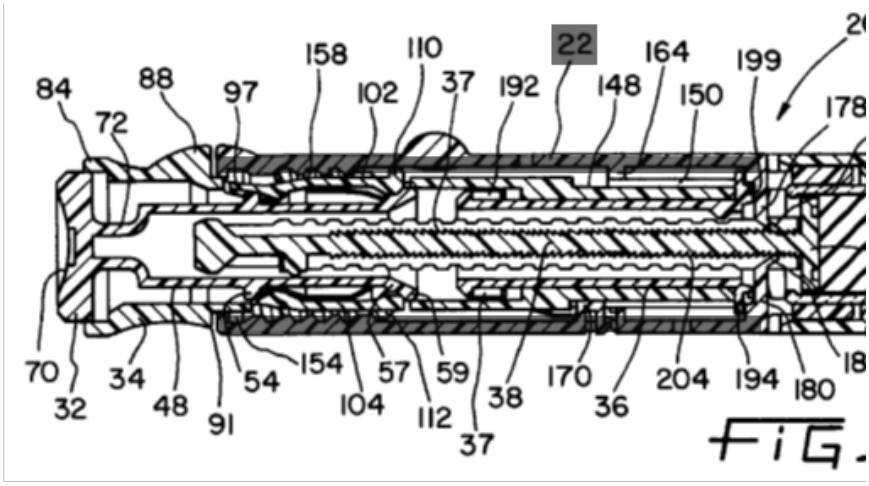


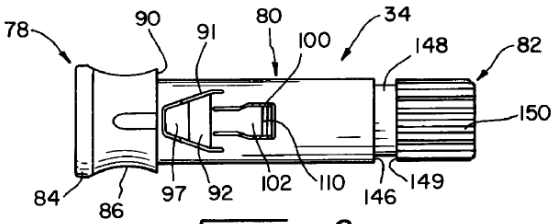
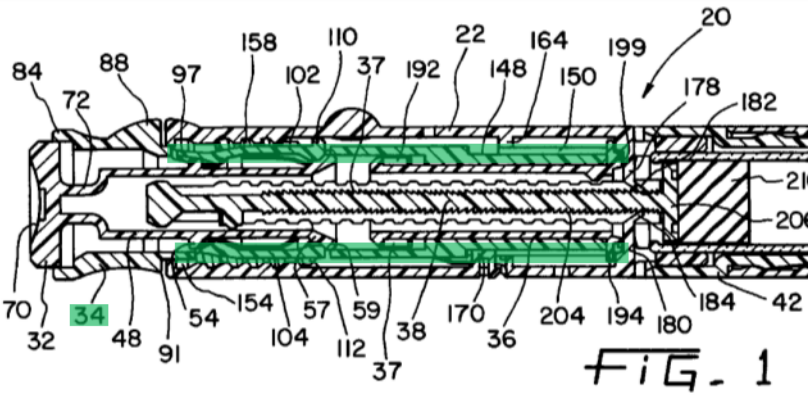
FIG.

See id., FIG. 1 (above; partial view annotating housing (gray)); EX1011, ¶159.

Mechanism housing 22 includes first part 24 and second part 26 that are secured together to house the drive mechanism. *See* EX1013, 7:19-20, FIGS. 1, 2, 3, 5; EX1011, ¶158. As shown in FIG. 1, mechanism housing 22 extends from a button-end (referred to as the proximal end) to a needle-end (referred to as the

distal end). *See* EX1013, 7:9-13; EX1011, ¶160. Burroughs thus taught the claimed "main housing."

Burroughs taught "a dose dial sleeve" as recited in element [1.2], but teaches a "helical rib" rather than "a helical groove":

'069 Patent	**Burroughs**
[1.2] a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;	Burroughs discloses dial mechanism 34: "Referring to FIGS. 6-9, dial mechanism 34 is shown in detail. Dial mechanism 34 is generally cylindrical in shape and is hollow throughout its axial length." EX1013, 7:65-67, FIGS. 1-2, 6-9.  FIG. 6  FIG. 1 *See id.*, FIGS. 6 (above-top), 1 (above-bottom; partial view annotating dial mechanism (green)); EX1011,

	¶161. "[D]ial mechanism 34 further includes a first U-shaped groove 100 (FIG. 6) and a second U-shaped groove 101 (FIG. 8) which form flexible legs 102, 104. Referring to FIG. 9, each leg 102, 104, respectively includes ... an outwardly extending threads 110, 112." EX1013, 8:24-29, FIGS. 6-9. "Housing parts 24 and 26 further form a helical spiral groove 158 and a circumferential surface 160. Circumferential surface 160 includes opening 162 and keyed opening 163 to allow threads 110 and 112 respectively to enter helical groove 158 during the commencement of the dosing process." *Id.*, 8:63-9:1, FIGS. 3, 5; *see also id.*, 10:31-34. "Upon rotation of dial 34, threads 110, 112 move within housing groove 158 in the proximal [button-end] direction as dial mechanism 34 retracts from housing 22 ...." *Id.*, 10:34-37.

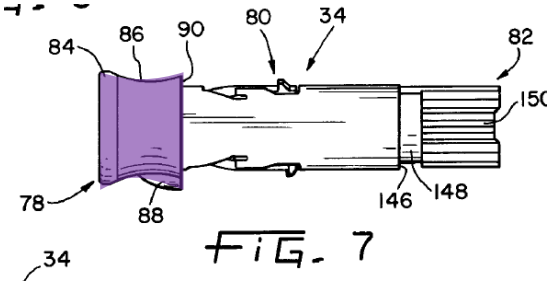
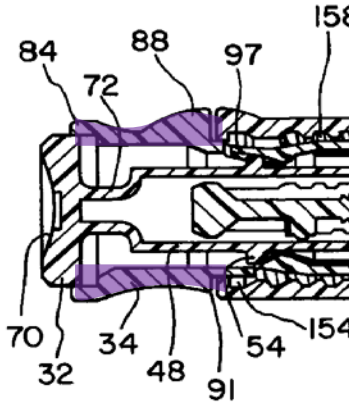
Burroughs discloses a "dose dial sleeve" in the form of dial mechanism 34. EX1013, 7:31-32, FIG. 2; EX1011, ¶166. The dial mechanism is positioned within housing 22, and includes on its outer surface threads 110, 112. EX1013, 7:65-67, 8:33-36, FIGS. 1-2, 6-9; EX1011, ¶¶161-63. Threads 110, 112 are configured to

releasably engage with helical spiral groove 158 provided on an inner surface of housing 22. *See* EX1013, 8:62-9:1, FIGS. 1, 3, 5-9; EX1011, ¶164.

Threads 110, 112 are shown to be rib-like structures that fit into and move within helical spiral groove 158 of housing parts 24, 26 to allow the dial mechanism to rotate and move axially away from the needle-end of the housing during the dose-setting phase. *See* EX1013, FIGS. 6-9; EX1011, ¶167. As Leinsing explains, in order to properly engage with helical spiral groove 158 for rotation, threads 110, 112 also must be positioned helically relative to one another, forming a discontinuous helical rib corresponding to the housing's helical groove. EX1011, ¶165; *cf.* EX1001, 3:42-44 (describing threads may include part threads). The helical positioning of the threads 110, 112 is best shown in FIGS. 1 and 7. EX1011, ¶165. Thus, Burroughs discloses that dial mechanism 34 includes a "helical rib," in the form of threads 110, 112, along its outer surface that engages with threading on housing 22. EX1011, ¶165.

Accordingly, Burroughs taught the claimed "dose dial sleeve," except it discloses a "helical rib" rather than a "helical groove." But, as detailed below in section V.F.2, a POSA would have considered it obvious to implement the helical rib as a helical groove corresponding to helical threading on the housing.

Burroughs taught "a dose dial grip" as recited in element [1.3]:

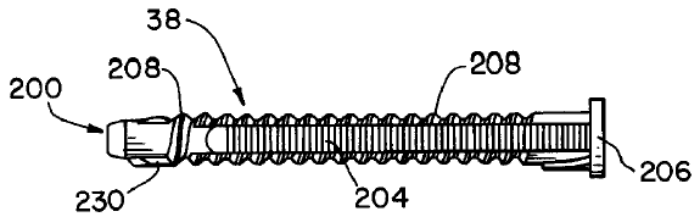
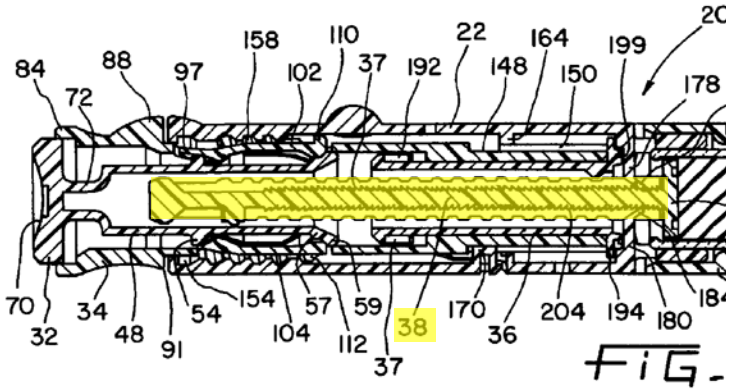
’069 Patent	Burroughs
[1.3] a dose dial grip disposed near a proximal end of said dose dial sleeve;	Burroughs discloses proximal portion 78: “Dial mechanism 34 comprises proximal portion 78, intermediate portion 80, and distal portion 82. Proximal portion 78 comprises enlarged diameter portion 84, tapered portion 86, and ring 90 extending about the circumference of proximal portion 78.” EX1013, 8:2-6, FIGS. 1-2, 6-9.  FIG. 7  *See id.*, FIGS. 7 (above-top; annotating proximal portion (purple)), 1 (above-bottom; partial view annotating proximal portion (purple)); EX1011, ¶¶173-74. “Upon rotation of dial 34, ... dial mechanism 34 retracts

	from housing 22, thereby increasing the axial distance between ring 91 [*sic*, 90] and surfaces 33, 35 of housing parts 24, 26." EX1013, 10:34-42.

Burroughs discloses a "dose dial grip" in the form of proximal portion 78 of dial mechanism 34, located near a proximal end (*i.e.*, button-end) of the dial. *See* EX1013, 8:2-6, FIGS. 1, 6-9; EX1011, ¶175. As shown in FIG. 1, proximal portion 78 is externally positioned at housing 22's button-end, and thus constitutes a grip for the user to grasp in order to rotate dial mechanism 34 during dose setting. *See* EX1013, 10:34-42; EX1011, ¶175. Accordingly, Burroughs taught a "dose dial grip" as recited in claim 1.

Burroughs taught "a piston rod" as recited in element [1.4]:

'069 Patent	**Burroughs**
[1.4] a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;	Burroughs discloses leadscrew 38: "Referring now to FIGS. 12 and 13, leadscrew 38 is shown having a ratchet teeth 204 located on two opposing sides of leadscrew 38 and axially extending along the length of leadscrew 38 from proximal end 200 [button-end] to plunger engagement portion 206. Helical threads 208 extend along the axial length of leadscrew 36 [*sic*, 38]. Leadscrew 38 fits within cylindrical opening of nut 36. As shown in FIG. 1,

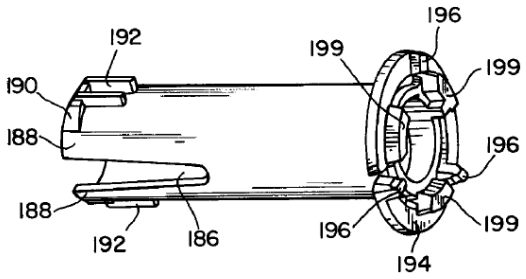
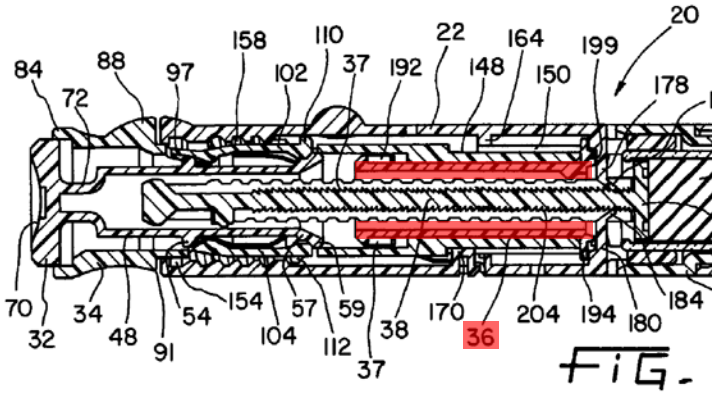
	plunger engagement portion 206 of leadscrew 38 is in engagement with piston 210 of cartridge 40." EX1013, 9:26-34, FIGS. 1-2, 12-13.   *See id.*, FIGS. 12 (above-top), 1 (above-bottom; partial view annotating leadscrew (yellow)); EX1011, ¶176. "Housing parts 24 and 26 include bulkhead ledges 178, 180, respectively, [which] include flexible tangs 182, 184, respectively." EX1013, 9:8-11, FIGS. 1, 3, 5. "Movement of leadscrew 38 is prevented in the proximal [button-end] direction due to anti-backup tangs 182, 184 being in engagement with ratchet teeth 204. This assures that head 206 of leadscrew 38 remains in constant engagement with piston 210 at all times." *Id.*, 11:52-56, FIG. 1. "Rotation of leadscrew 38 is prevented by key-keyway

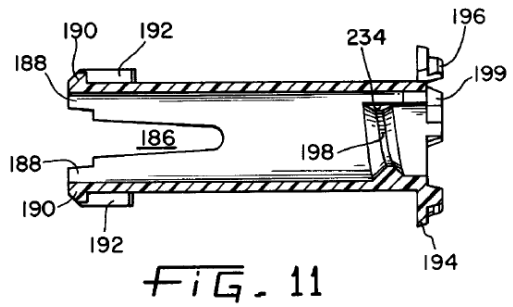
	type of engagement between the anti-backup tangs 182 and 184 and leadscrew 38. As shown in FIG. 1, tangs 182, 184 form a key, and leadscrew 38 forms a keyway which comes into contact with the sides of the key.... Rotation of dial mechanism 34 causes rotation of nut 36 so that internal helical raised groove 198 of nut 36 rotates along external threads 208 of leadscrew 38 to cause nut 36 to axially retract a corresponding axial distance." *Id.*, 10:26-42.

Burroughs further discloses a "piston rod" in the form of leadscrew 38. Leadscrew 38 is provided within housing 22. *See* EX1013, 9:26-27, FIGS. 1-2, 12-13; EX1011, ¶¶176-78. During dose setting, rotation of dial mechanism 34 causes corresponding rotation of nut 36, which engages external threads 208 of the leadscrew. EX1013, 10:26-42, FIG. 1; EX1011, ¶177. Rotation is not transmitted to leadscrew 38, however, due to anti-backup tangs 182, 184 provided on housing 22. EX1013, 10:26-42, FIG. 1; EX1011, ¶177. Leadscrew 38 does not rotate relative to housing 22 during dose setting. EX1011, ¶177. Burroughs thus taught the claimed "piston rod."

Burroughs taught "a drive sleeve" as recited in element [1.5]:

'069 Patent	**Burroughs**
[1.5] a drive sleeve	Burroughs discloses nut 36:

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	"Nut 36 is generally cylindrical in shape .... The interior surface of the distal end of nut 36 includes a helical thread 198. Thread 198 extends 350º about the inner surface of nut 36." EX1013, 9:13-25, FIGS. 1-2, 10-11.   FIG. *See id.*, FIGS. 10 (above-top), 1 (above-bottom; partial view showing nut (red)); EX1011, ¶179. "Helical threads 208 extend along the axial length of leadscrew 36 [*sic*, 38]. Leadscrew 38 fits within cylindrical opening of nut 36." EX1013, 9:30-32. "Rotation of dial mechanism 34 causes rotation of nut 36 so that internal helical raised groove 198 of nut 36 rotates along external threads 208 of leadscrew 38 to cause nut 36 to axially retract a corresponding axial distance." *Id.*, 10:38-42, FIG. 11 (below).

	 FIG. 11

Burroughs discloses a "drive sleeve" in the form of nut 36. EX1013, 9:12-13, FIGS. 1-2, 10-11; EX1011, ¶¶179-81. Nut 36 includes, on its interior surface and near its distal end (*i.e.*, needle-end), helical thread 198. EX1013, 9:13-25, FIGS. 1-2, 10-11; EX1011, ¶179. This thread engages helical threads 208 of leadscrew 38. *See* EX1013, 9:30-32, FIGS. 1-2, 10-13; EX1011, ¶179. As shown in FIG. 1, nut 36 extends along a portion of leadscrew 38. *See* EX1013, FIG. 1; EX1011, ¶179. Accordingly, Burroughs taught a "drive sleeve" as recited in claim 1.

Burroughs taught "a tubular clutch" as recited in element [1.6]:

'069 Patent	**Burroughs**
[1.6] a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,	Burroughs discloses button 32: "Referring to FIG. 14 and FIG. 15, button 32 comprises a hollow cylindrical portion 48 having a proximal end [*i.e.*, button-end] 50. Cylindrical portion 48 includes ... an enlarged diameter ring 54 ...." EX1013, 7:46-55, FIGS. 1-2, 14-15.

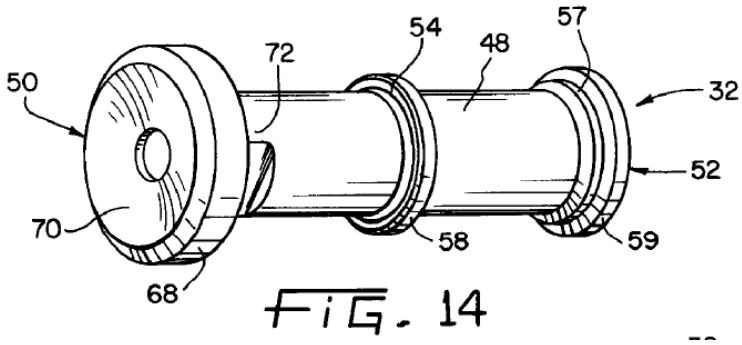
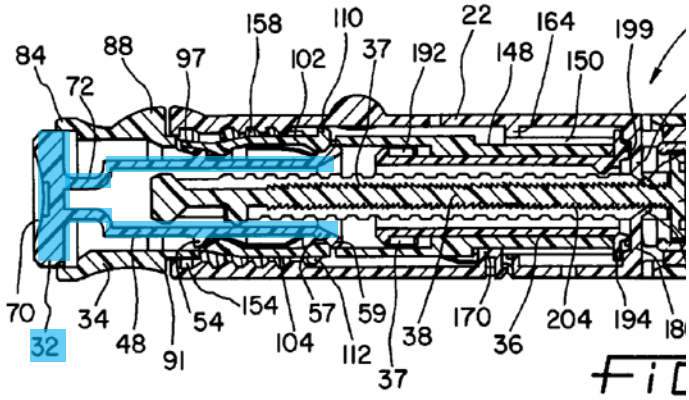


FIG. 14



See id., FIGS. 14 (above-top), 1 ((above-bottom; partial view annotating button (blue)); EX1011, ¶182.

"As best shown in FIG. 9, the proximal ends of flexible sections 92 and 95 [of dial mechanism 34] each include fingers 94 having ramped inner surfaces 96 adapted for engagement with enlarged diameter portion 54 of button 32. When button 32 is depressed, enlarged diameter portion 54 is also depressed and thereby pushes against ramped surfaces 96, which in turn forces fingers 94 outward and legs 102 and 104 [having threads 110, 112] inward. Dial mechanism 34 is then able to travel axially towards cartridge 40 during injection of the medical product ...." *Id.*, 8:11-20, FIG. 9; *see also id.*, 11:5-12.

	"Referring to FIG. 9, there are shown a plurality of splines 144 extending circumferentially about the interior surface of intermediate portion 80 of dial mechanism 34. Splines 144 ... engage with teeth 192 (FIGS. 10, 11) provided on nut 36 when the clutch is engaged to set a dosage." *Id.*, 8:42-48, FIG. 9; *see also id.*, 9:16-18, FIGS. 10-11 (nut 36 having splines 192). "Once the desired dosage has been set, ... recessed surface 70 of button 32 is pushed[.] Dial mechanism 34 is thereby able to move forward because threads 110, 112 are not in engagement with groove 158." *Id.*, 11:13-20. "As dial mechanism 34 is initially moved forward, splines 144 move out of engagement with splines 192 of nut 36 to disengage the clutch by rotationally decoupling dial mechanism 34 from nut 36 prior to any axial movement of nut 36." *Id.*, 11:27-30.

Burroughs discloses a "tubular clutch" in the form of button 32. EX1011, ¶187. Button 32 is cylindrical in shape (*i.e.*, tubular) and includes enlarged diameter ring 54. *See* EX1013, 7:46-51, FIGS. 14-15; EX1011, ¶183. Burroughs discloses that, when button 32 is depressed for injection, ring 54 pushes onto fingers 94 provided within dial mechanism 34's internal surface. EX1013, 8:11-20, FIGS. 1, 9, 14-15; EX1011, ¶183. This causes legs 102, 104 of dial 34, which

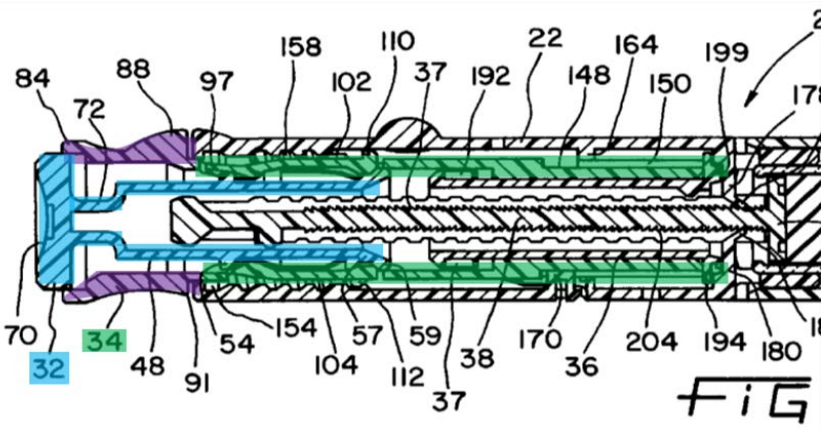
include threads 110, 112, to collapse inward, causing the threads' disengagement from the housing's helical groove 158. *See* EX1013, 8:15-20; EX1011, ¶183. Dial mechanism 34 is then free to move axially toward the device's needle-end, without rotating relative to the housing. *See* EX1013 8:18-20, 11:5-20; EX1011, ¶183. Moreover, button 32 also causes splines 144 of dial mechanism 34 to disengage from splines 192 of nut 36, which rotationally decouples the two components. *See* EX1013, 11:27-30; EX1011, ¶183.

Thus, button 32 serves as a clutch that allows dial mechanism 34 to disengage from (1) its threaded connection with housing 22, and (2) its rotational coupling with nut 36. *See* EX1011, ¶183. As shown above in FIG. 1, button 32 is located adjacent a needle-end of proximal portion 78 of dial mechanism 34. *See* EX1013, FIG. 1; EX1011, ¶184. It is operatively coupled to this grip portion by virtue of its engagement with fingers 94 of dial mechanism 34. *See* EX1013, FIGS. 1, 6-9, 14, 15; EX1011, ¶¶185-86; *cf.* EX1001, 2:5-7, 6:6-9 (describing operation of the clutch with respect to the dose dial sleeve).

Accordingly, Burroughs taught a "tubular clutch" as recited in claim 1.

Burroughs taught the relative positioning between the dose dial sleeve and the tubular clutch as recited in element [1.7]:

'069 Patent	**Burroughs**
[1.7] wherein said dose	Burroughs shows that button 32 is provided within dial

dial sleeve extends circumferentially around at least a portion of said tubular clutch.	mechanism 34:  *See* EX1013, FIG. 1 (above; partial view annotating dial mechanism (green) and button (blue)); EX1011, ¶188.

As shown in the claim chart above, dial mechanism 34 (green) "extends circumferentially around at least a portion of" button 32 (blue). *See* EX1013, FIG. 1; EX1011, ¶188. Accordingly, Burroughs taught this element.

2. Reason to modify and reasonable expectation of success

As explained above, Burroughs discloses a "helical rib" rather than a "helical groove" provided along the outer surface of dial mechanism 34. A POSA, however, would have known the alternative to reverse the features and configure threads 110, 112 as a "helical groove." EX1011, ¶166-69.

Burroughs describes threads 110, 112, which together form a helical rib, that releasably engages with a corresponding helical groove 158 of housing 22 to allow dial mechanism 34 to rotate relative to housing 22. *See* EX1013, 10:34-38, 10:60-

63. Burroughs thus taught the use of a helical rib-to-groove threaded connection to allow for relative rotational movement between housing 22 and dial mechanism 34. EX1011, ¶167.

The use of a rib-to-groove threaded connection is a common and well-known mechanism used for the purpose of providing relative rotational movement between components. EX1011, ¶168 (citing Steenfeldt-Jensen, EX1020, EX1032). At the time of invention, determining whether to place a helical rib on one component and a complementary helical groove on another engaging component would have been considered a routine task by the POSA, and would have been viewed as no more than "the predictable use of prior art elements according to their established functions." *KSR*, 550 U.S. at 417. Thus, the POSA would have considered the placement of a rib-to-groove connection to be largely interchangeable between its engaging parts. EX1011, ¶169.

Here, a POSA would have understood that the rotational operability between dial mechanism 34 and housing 22 would not change if helical threads 110, 112 were provided as two, parallel ribs that formed a helical groove for engaging a helical rib on the housing. EX1011, ¶170. The POSA also would have reasonably expected that the releasable connection between dial mechanism 34 and housing 22 would remain substantially the same. EX1011, ¶170. Knowing that a helical rib-to-groove connection would accomplish the relative rotational movement needed

between the dial mechanism and the housing, the POSA would have considered the choice as to whether the dial mechanism contained the groove and the housing contained the corresponding rib , or *vice versa*, to have been the use of well-known and familiar elements. EX1011, ¶170; *see also KSR*, 550 U.S. at 417. A POSA also would have reasonably expected that use of the elements in that configuration would have resulted in the elements performing their same, predictable functions (*e.g.*, rotational engagement). EX1011, ¶170; *see also KSR*, 550 U.S. at 417. Indeed, the disclosure of Burroughs encompasses such modifications to its device. EX1013, claim 1 (claiming generally that dial mechanism is "rotatably and axially shiftably mounted to" the housing); EX1011, ¶171.

Accordingly, a POSA would have considered it obvious to provide a helical groove, formed by two, parallel threads 110, 112, on the outer surface of the dial mechanism 34 of Burroughs. Claim 1 was obvious over Burroughs.

G. Ground 2: Claim 1 is Obvious over Steenfeldt-Jensen

As demonstrated by the claim charts and analysis below, Steenfeldt-Jensen disclosed a single device comprising all of the components, including the same structural limitations, recited by claim 1. To the extent that Steenfeldt-Jensen may not disclose a "drive sleeve" as required by challenged claim 1, it would have been obvious to modify Steenfeldt-Jensen's device to include such a drive sleeve. A

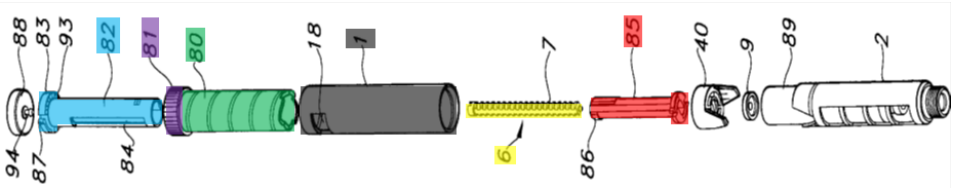
detailed discussion of the reason to modify Steenfeldt-Jensen follows the discussion of the individual claim elements. *See infra*, section V.G.2.

1. Element-by-element analysis

To the extent the preamble is limiting, it is taught by Steenfeldt-Jensen:

'069 Patent	**Steenfeldt-Jensen**
[1.Preamble] A housing part for a medication dispensing apparatus, said housing part comprising:	Steenfeldt-Jensen discloses an injection syringe for dispensing medicine: "The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses." EX1014, 1:12-15, FIGS. 15-17. "The present invention provides an injection syringe comprising a housing[.]" *Id.*, Abstract. "The syringe comprise[s] a tubular housing 1[.]" *Id.*, 5:38-44, FIGS. 15-17:[4]

[4] Steenfeldt-Jensen discloses that elements corresponding to elements described in other embodiments are provided with the same reference number. *See* EX1014, 7:49-51. Thus, a POSA reading Steenfeldt-Jensen would have understood that disclosure relating to other embodiments informed the structure of the embodiment

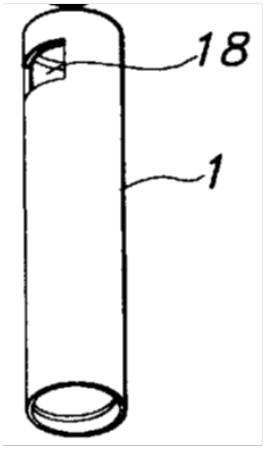
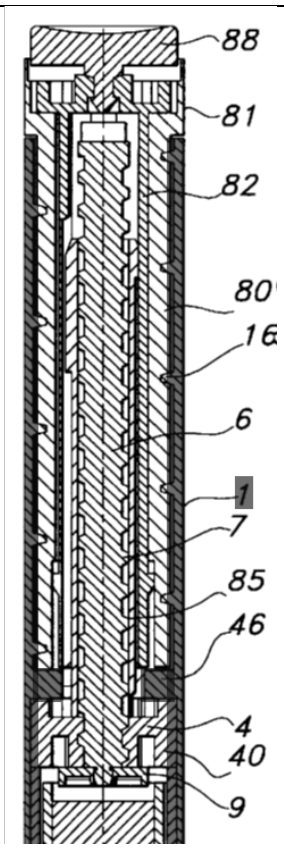
	 *See id.*, FIG. 17 (annotated above); EX1011, ¶262.

Steenfeldt-Jensen describes an injection syringe for dispensing medicine. EX1014, 1:12-15, FIGS. 15-17; EX1011, ¶261. The syringe includes a housing part in the form tubular housing 1. EX1014, 5:38-44, FIGS. 15-17; EX1011, ¶261. As shown FIGS. 15-16, tubular housing 1 holds the drive mechanism for dispensing medicine from the syringe. *See* EX1011, ¶261. Accordingly, Steenfeldt-Jensen taught the preamble of claim 1.

Steenfeldt-Jensen taught "a main housing" as recited in element [1.1]:

'069 Patent	**Steenfeldt-Jensen**
[1.1] a main housing, said main housing extending from a distal end to a proximal end;	Steenfeldt-Jensen discloses tubular housing 1: "The syringe comprise[s] a tubular housing 1[.]" EX1014, 5:38-44, FIGS. 15-17. "A medication delivery pen comprising ... a housing having proximal and distal ends[.]" *Id.*, claim 11.

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

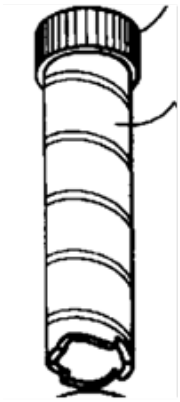
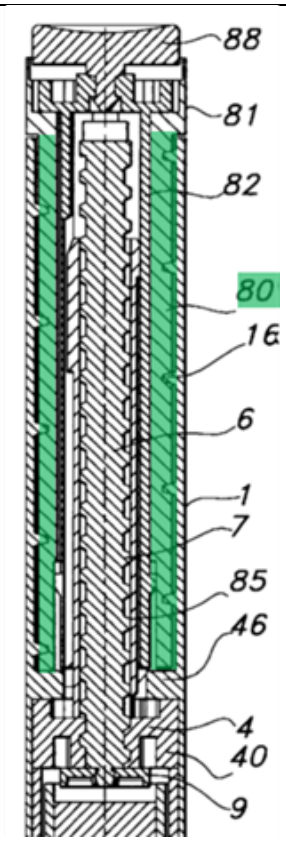
	  *See id.*, FIG. 17 (above-left; partial view showing housing); FIG. 16 (above-right; partial view annotating housing (gray)); EX1011, ¶263.

As shown in FIGS. 15-17, housing 1 extends from a button-end (referenced as the proximal end) to a 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" as recited in element [1.2]:

'069 Patent	**Steenfeldt-Jensen**
[1.2] a dose dial sleeve	Steenfeldt-Jensen discloses scale drum 80:

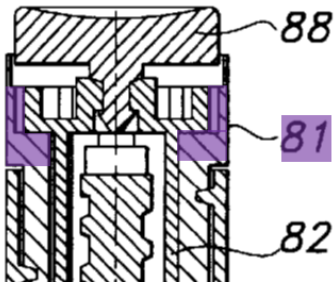
positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;	"A scale drum 80 is in its outer wall provided with a helical track which is engaged by a helical rib 16 along the inner wall of the housing 1." EX1014, 11:20-22, FIGS. 15-17. "When a dose is set by rotating the dose setting button 81 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.

	  *See id.*, FIG. 17 (above-left; partial view showing drum); FIG. 16 (above-right; partial view annotating drum (green)); EX1011, ¶264.

Steenfeldt-Jensen discloses that the syringe includes a "dose dial sleeve" in the form of scale drum 80. EX1014, 11:20-22. As shown in FIGS. 15-16, drum 80 is positioned within housing 1. *Id.*, FIGS. 15-16; EX1011, ¶264. The drum includes a "helical groove provided along an outer surface" in the form a helical track, which extends along the drum's outer wall. EX1014, 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. *See*

EX1014, 11:20-22, FIGS. 16-17; EX1011, ¶265. Steenfeldt-Jensen thus taught the claimed "dose dial sleeve."

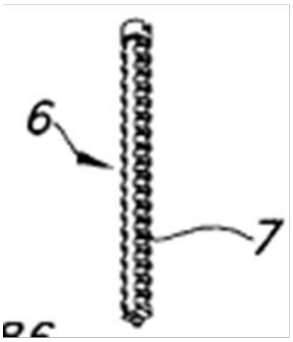
Steenfeldt-Jensen taught "a dose dial grip" as recited in element [1.3]:

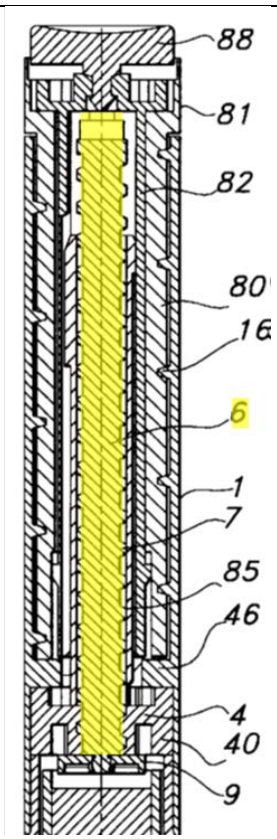
'069 Patent	**Steenfeldt-Jensen**
[1.3] a dose dial grip disposed near a proximal end of said dose dial sleeve;	Steenfeldt-Jensen discloses dose setting button 81: "At its proximal end the scale drum 80 has a diameter exceeding the inner diameter of the housing to form a dose setting button 81, which on its cylindrical outer wall is knurled to ensure a good finger grip." EX1014, 11:22-25; FIGS. 15-17.  *See id.*, FIG. 16 (above; partial view above showing dose setting button (purple)); EX1011, ¶267. "When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing and the dose setting button is lifted away from the proximal end of the housing.... [A] set dose is reduced by rotating the dose setting button 81 in an anticlockwise location[.]" EX1014, 11:52-62.

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

Steenfeldt-Jensen taught "a piston rod" as recited in element [1.4]:

'069 Patent	**Steenfeldt-Jensen**
[1.4] a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;	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, 5:55-58; *see also id.*, FIGS. 15-17.





See id., FIGS. 17 (above-left; partial view showing piston rod), 16 (above-right; partial view annotating piston rod (yellow)); EX1011, ¶270.

"The end wall 4 with the internal thread 5 is provided in a separate member 40 which is mounted in an end of the housing[.]" EX1014, 8:35-38; *see 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

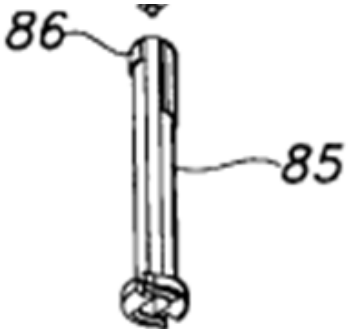
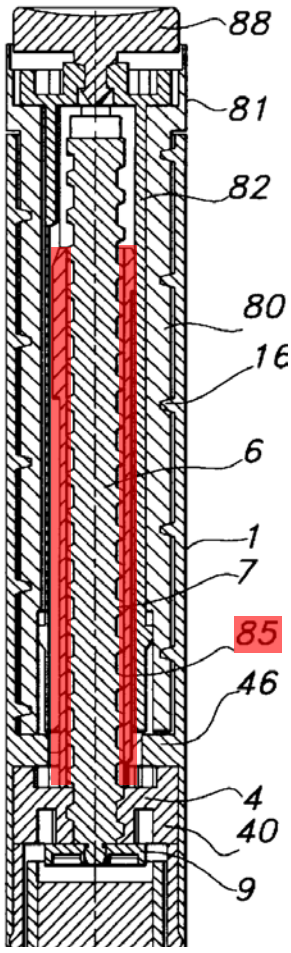
	thread in the end wall [4] of the housing [are] so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding 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 [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 a "piston rod" in the form of 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 that works between driver tube 85 and member 40. *See* EX1014, 11:6-19, 11:52-62; EX1011, ¶271. The pawl mechanism bars clockwise rotation of driver tube 85 relative to housing 1. *See* EX1014, 11:6-19; EX1011, ¶271. Thus, when dose setting-button 81 is rotated clockwise to dial-up a dose, the corresponding rotation of scale drum 80 is not transmitted to driver tube 85 due to the pawl mechanism. *See* EX1014, 11:52-62; EX1011, ¶271. Moreover, if a user needs to dial-down a dose, dose setting-button 81 is rotated anticlockwise, but the 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. *See* EX1014, 11:52-62; EX1011, ¶271. Thus, because piston rod 6 is coupled to driver tube 85 in such a way that "rotation is transmitted," and because driver tube 85 does not rotate during dose setting, piston rod 6 also does not rotate during a dose setting step. *See* EX1011, ¶¶271-72. Accordingly, Steenfeldt-Jensen taught the claimed "piston rod."

Steenfeldt-Jensen rendered obvious "a drive sleeve" as recited in element [1.5]:

'069 Patent	**Steenfeldt-Jensen**
[1.5] a drive sleeve extending along a portion of said piston rod, said drive sleeve	Steenfeldt-Jensen discloses driver tube 85:

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	  *See 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

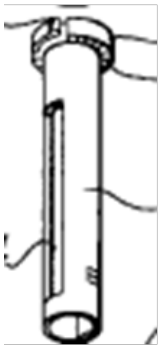
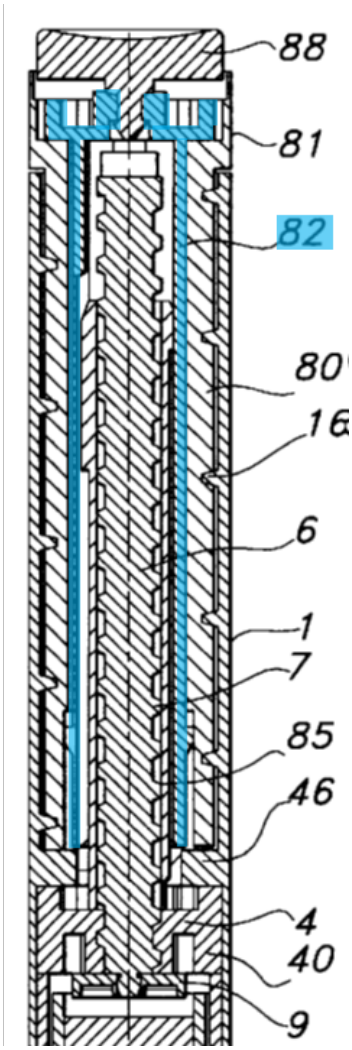
	said end wall and into the cartridge holder compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube." *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 [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. "When the injection button 88 is pressed to inject the set dose ... [t]he bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed further into an ampoule 89 in the ampoule holder 2." *Id.*, 12:4-12.

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 section V.G.2, a POSA would have considered it obvious to modify driver tube 85 to provide the "drive sleeve" of claim 1. EX1011, ¶275-79.

Steenfeldt-Jensen taught "a tubular clutch" as recited in element [1.6]:

'069 Patent	**Steenfeldt-Jensen**
[1.6] 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.   *See id.*, FIGS. 17 (above-left; partial view showing bushing), 16 (above-right; partial view 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 [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.

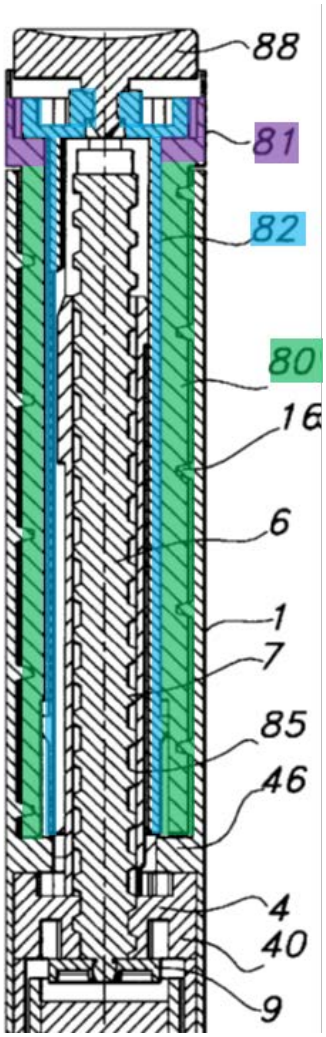
Steenfeldt-Jensen discloses the claimed "tubular clutch" in the form of bushing 82. As shown in FIG. 17, bushing 82 is a tubular structure. *See* EX1014, 11:26-27, 12:4-13, FIGS. 15-17; EX1011, ¶283. Bushing 82 also is a clutch due to a rosette of teeth 93, which releasably engage with corresponding teeth on dose setting button 81. *See* EX1014, 12:4-12; EX1011, ¶¶280-281. During dose setting, the teeth of bushing 82 are disengaged from the teeth of dose setting button

81. EX1014, 12:1-3; EX1011, ¶283. When button 81 is rotated, bushing 82 follows scale drum 80's axial movement out of the housing, but does not follow its rotation due to the bushing's coupling to the driver tube 85. EX1014, 11:26-33, 11:52-62; EX1011, ¶¶280, 283. During injection, the bushing becomes engaged to button 81, causing bushing 81 to follow scale drum 80's rotation, which is transmitted to driver tube 85 to drive piston rod 6. *See* EX1014, 12:4-12; EX1011, ¶283. Thus, bushing 82 serves as a clutch because it releasably couples movement of scale drum 80 to driver tube 85. *See* EX1011, ¶283.

Bushing 82 is also operatively coupled to dose setting button 81 due to the releasable engagement of teeth 93 with corresponding teeth on the button. *See* EX1011, ¶¶281, 283. Bushing 82 is also located adjacent the needle-end of button 81: flange 83 is provided within a compartment formed in button 81, with teeth 93 of the bushing being configured to engage with teeth provided at the bottom of the button's compartment. *See* EX1014, 11:34-42, FIGS. 15-16; EX1011, ¶¶281, 283. Accordingly, Steenfeldt-Jensen taught the "tubular clutch" of claim 1.

Finally, Steenfeldt-Jensen taught the relative positioning of the dose dial sleeve and the tubular clutch as recited in element [1.7]:

'069 Patent	**Steenfeldt-Jensen**
[1.7] wherein said dose dial sleeve extends	Steenfeldt-Jensen discloses that bushing 82 is provided within scale drum 80:

circumferentially around at least a portion of said tubular clutch.	"A bushing 82 ... fits into the scale drum 80 ...." EX1014, 11:26-28, FIGS. 15-16.  *See id.*, FIG. 16 (above; partial view annotating drum (green) and bushing (blue)); EX1011, ¶285.

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

2. Reason to modify and reasonable expectation of success

As described above, Steenfeldt-Jensen disclosed a driver tube 85 that rotationally engages piston rod 6 to drive the rod during dose dispensing. *See* EX1011, ¶274. Driver tube 85 engages piston rod 6 via a non-circular bore, rather than an internal threading, but a POSA would have considered it obvious to modify the device of FIGS. 15-17 to provide driver tube 85 with an internal threading near its distal portion. EX1011, ¶¶274. In this case, the modified device would have been understood to contain a "drive sleeve" of claim 1 having the claimed structural elements. EX1011, ¶274.

Steenfeldt-Jensen expressly contemplates a modification in which the driver tube contains an 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; *see 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 the dose scale drum may be "coupled to a driver rotating the piston rod (or the nut member) relative to the

nut member (or the piston rod) when the injection button is pressed"); EX1011, ¶275.

Elsewhere, Steenfeldt-Jensen explains that the piston rod guide is a structure that allows the piston rod to move axially relative to it, but not rotatably, whereas the nut element is a structure that allows for relative rotation of the piston rod. *See* EX1014, 2:46-53, 3:15-20; EX1011, ¶276. As Leinsing explains, in the context of the embodiment shown in FIGS. 15-17, a POSA would have understood this to mean that driver tube 85 includes a "piston rod guide" because it allows relative axial movement of the piston rod, while preventing relative rotational movement due to its non-circular bore. EX1011, ¶276. Similarly, a POSA would have understood that member 40 includes a "nut element" due to its internal threading in its end wall 4. EX1011, ¶276. Thus, given Steenfeldt-Jensen's suggestion that the "nut element" could be provided on the driver tube, and the "piston rod guide" could be provided on the member, a POSA would have reason to modify (1) driver tube 85 to include an internal threading for engaging the piston rod's external threading, and (2) member 40 to include a non-circular cross-section for axially guiding the piston rod. EX1011, ¶277. The modifications suggested by Steenfeldt-Jensen thus result in an injector pen meeting all limitations of claim 1. EX1011, ¶¶277.

A POSA also would have reasonably expected that 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 is rotated during injection, the threaded engagement between the driver tube and the piston rod would have caused the piston rod to be axially displaced through the member's non-circular opening and into the ampoule. EX1011, ¶278. Thus, the POSA would have reasonably expected that the modified parts would be "performing the same function that [they] had been known to perform." *See KSR*, 550 U.S. at 417; EX1011, ¶278.

Accordingly, in view of the above, claim 1 was obvious over Steenfeldt-Jensen.

H. Ground 3: Claim 1 is Obvious over the Combination of Møller and Steenfeldt-Jensen

Møller disclosed an injection device having the same six components of claim 1. Like Burroughs, for five of those components, Møller discloses the same structural limitations as recited in claim 1. For the "dose dial sleeve," Møller discloses dose setting drum 17 having threading on its internal surface adapted to engage the housing, instead of a "helical groove" on its outer surface. EX1011, ¶340. Steenfeldt-Jensen discloses the use of a "dose dial sleeve" in the form of a scale drum 80 with a "helical groove" on its outer surface for engagement with a housing. *Id.* As discussed further below in section V.G.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, in view of the teachings of Møller and Steenfeldt-Jensen.

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

1. Element-by-element analysis

To the extent the preamble is limiting, the combination of Møller and Steenfeldt-Jensen taught it:

'069 Patent	**Møller and Steenfeldt-Jensen**

[1.Preamble] A housing part for a medication dispensing apparatus, said housing part comprising:	Møller discloses an injection device for the injection of medicine: "An injection device for injection of set doses of medicine from a cartridge ...." EX1015, Abstract. "In the device shown in FIG. 1 an elongated cylindrical housing 1 has a partitioning wall 2 which divides the housing in a compartment containing a dose setting mechanism and a compartment 3 designed for the accommodation of a not shown ampoule." *Id.*, ¶22, FIG. 1 (below; annotated); EX1011, ¶344.

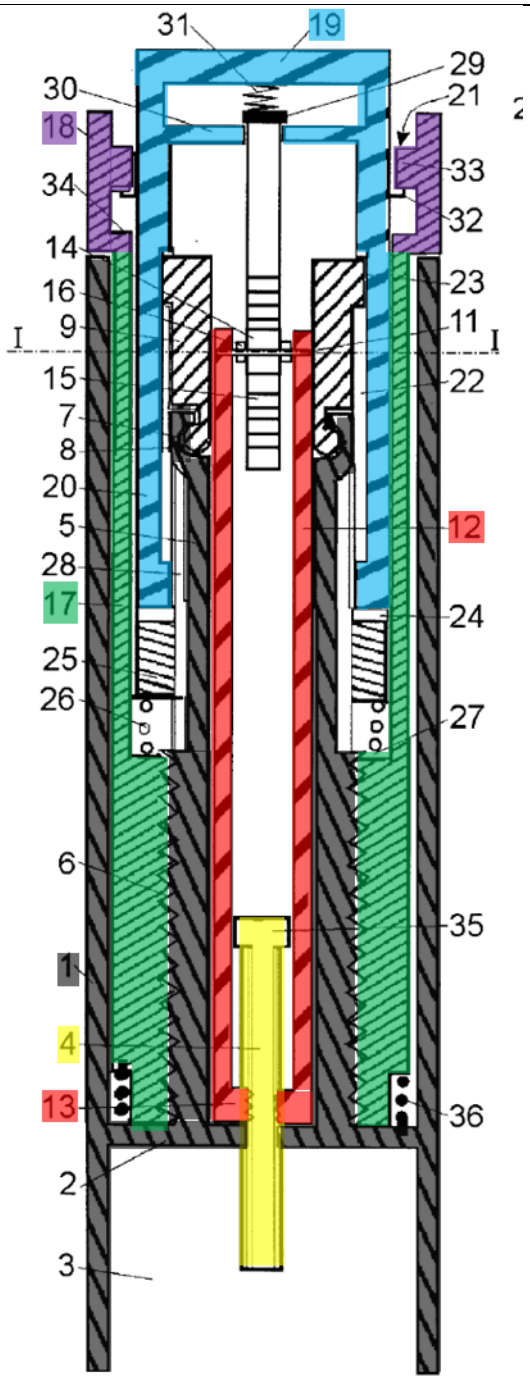

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Fig. 1

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

The combination of Møller and Steenfeldt-Jensen taught "a main housing" as recited in element [1.1]:

'069 Patent	**Møller and Steenfeldt-Jensen**
[1.1] a main housing, said main housing extending from a distal end to a proximal end;	Møller discloses housing 1: "In the device shown in FIG. 1 an elongated cylindrical housing 1 has a partitioning wall 2 which divides the housing in a compartment containing a dose setting mechanism and a compartment 3 designed for the accommodation of a not shown ampoule." EX1015, ¶22, 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.

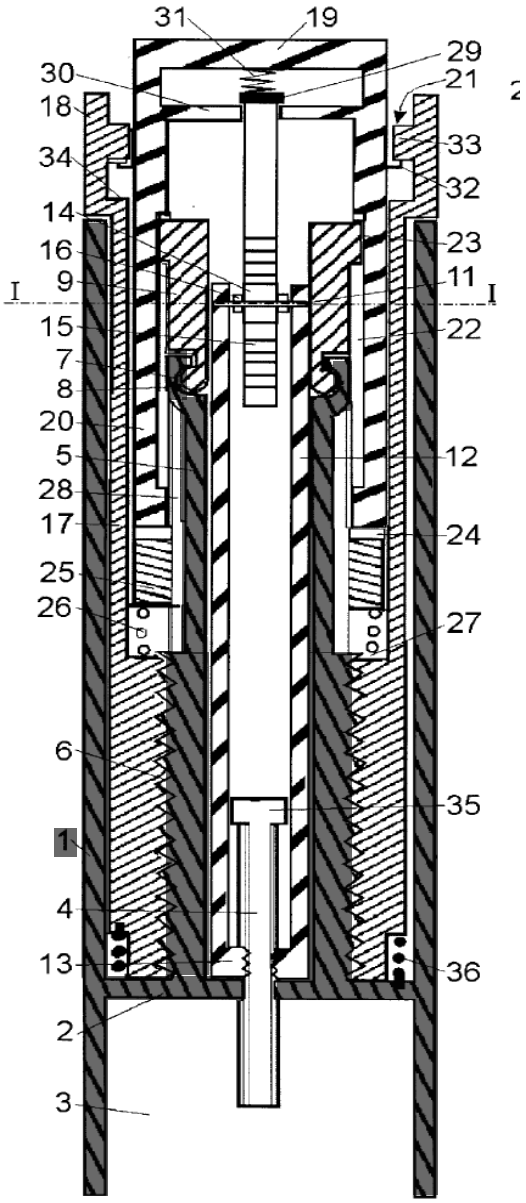


Fig. 1

Møller discloses a "main housing," in the form of housing 1. As shown in FIG. 1, housing 1 extends from a proximal end (button-end of device) to a distal end (needle-end of device). *See* EX1015, FIG. 1; EX1011, ¶345. Housing 1

includes partitioning wall 2 and tubular element 5, which extends from wall 2 toward a button-end of the device. *See* EX1015, ¶23; EX1011, ¶345. Inside this concentric space, the drive mechanism for the device is contained. *See* EX1015, ¶22, FIG. 1; EX1011, ¶¶343, 345. Therefore, Møller taught a "main housing" as recited in claim 1.

The combination of Møller and Steenfeldt-Jensen taught "a dose dial sleeve" as recited in element [1.2]:

'069 Patent	**Møller and Steenfeldt-Jensen**
[1.2] a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, 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 [*sic*, 1] is at an end provided with an internal thread mating and engaging the outer thread 6 of the tubular element 5 .... Due to the engagement with the thread 6 the dose setting drum 17 may be screwed in and out of the housing ...." EX1015, ¶25, FIG. 1 (below; annotating drum (green)); EX1011, ¶348.

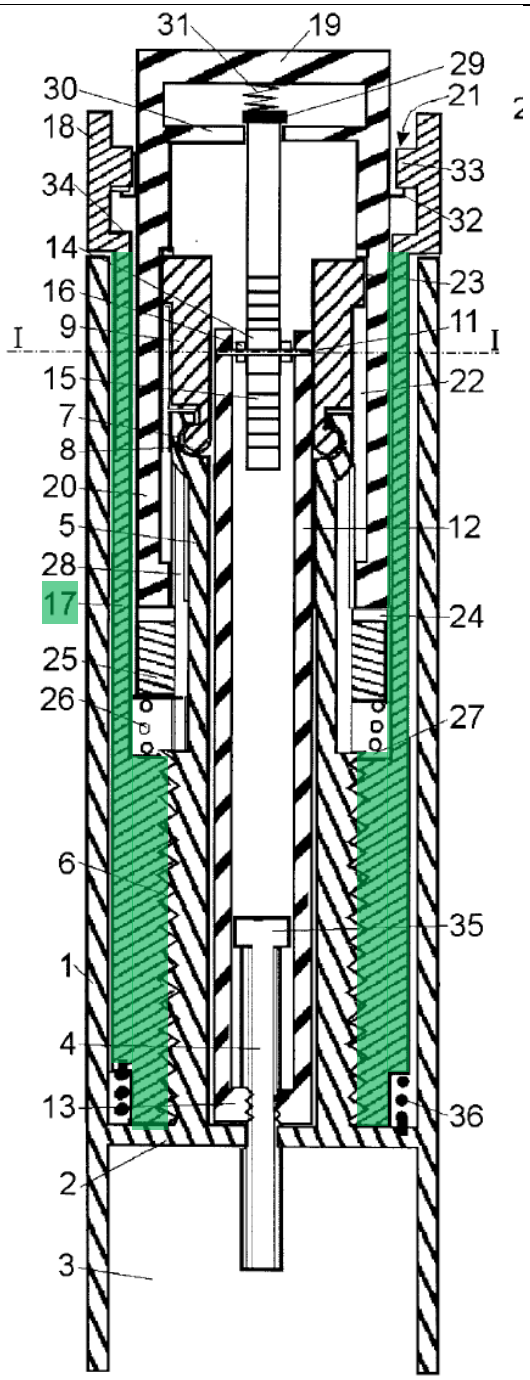
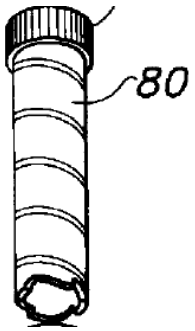


Fig. 1

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; *see also id.* FIGS. 8, 13, 17 (below; partial view showing drum 80) (illustrating other drum embodiments having helical groove on the outer surface); EX1011, ¶352. 

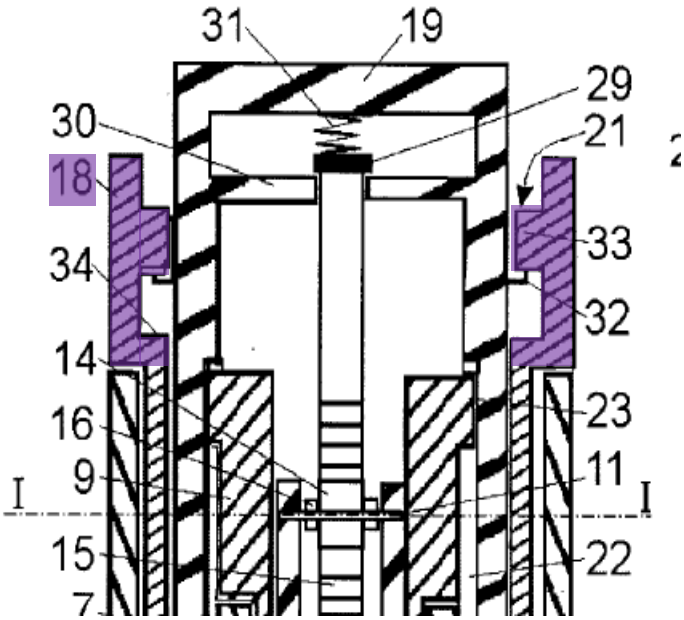
Møller discloses a "dose dial sleeve" in the form of dose setting drum 17. Dose setting drum 17 is positioned within housing 1. *See* EX1015, ¶25, FIG. 1; EX1011, ¶347. It also includes a thread at its needle-end that engages with corresponding thread 6 of the housing's tubular element 5, such that drum 17 can

be screwed in and out of the housing during use. *See* EX1015, ¶25; FIG. 1; EX1011, ¶¶347, 350. As shown in FIG. 1, drum 17's thread is internal, such that it engages with inwardly-positioned tubular element 5 of the housing. EX1015, ¶25, FIG. 1; EX1011, ¶350. Thus, although Møller discloses a thread on dose setting drum 17 that engages with a thread of the housing, it does not disclose "a helical groove" that is "provided along an outer surface of" drum 17. *See* EX1011, ¶349.

Steenfeldt-Jensen discloses several embodiments of a "dose dial sleeve" that includes "a helical groove" on its outer surface adapted to engage with a threading on a housing. EX1011, ¶353. In one embodiment, Steenfeldt-Jensen discloses scale drum 17 that includes a helical groove on its outer wall that engages with helical rib 16 provided 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 with a corresponding rib on the housing.

As described more below, a POSA would have found it obvious to modify the 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. *See infra*, section V.H.2. Accordingly, the combination of Møller and Steenfeldt-Jensen taught the claimed "dose dial sleeve." EX1011, ¶¶354-61.

The combination of Møller and Steenfeldt-Jensen taught "a dose dial grip" as recited in element [1.3]:

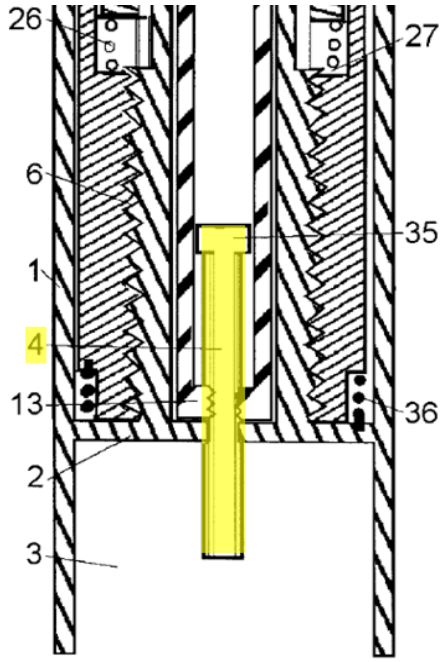
'069 Patent	**Møller and Steenfeldt-Jensen**
[1.3] a dose dial grip disposed near a proximal end of said dose dial sleeve;	Møller discloses dose setting button 18: "[The] tubular dose setting drum 17 ... has at its other end [*i.e.*, button-end] a part with enlarged diameter forming a dose setting button 18." EX1015, ¶25, FIG. 1 (below; partial view annotating button (purple)); EX1011, ¶362; *see also* EX1015, ¶29. 

Møller discloses a "dose dial grip" in the form of dose setting button 18. EX1011, ¶362. As shown in FIG. 1, dose setting button 18 is provided at a proximal end (button-end) of drum 17. EX1015, FIG. 1; EX1011, ¶362. Button

18 includes “an enlarged diameter’ relative to the drum 17 such that, as shown in FIG. 1, is provided flush with the housing. *See* EX1015, ¶25, FIG. 1; EX1011, ¶362. Møller discloses that to set a dose, dose setting button 18 is rotated to screw dose setting drum 17 out of the housing. *See* EX1015, ¶29; EX1011, ¶362. Thus, the combination of Møller and Steenfeldt-Jensen taught a “dose dial grip” as recited in claim 1.

The combination of Møller and Steenfeldt-Jensen taught “a piston rod” as recited in element [1.4]:

’069 Patent	**Møller and Steenfeldt-Jensen**
[1.4] a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;	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 that is non-rotatable during dose setting. Specifically, because piston rod 4 fits within wall 2 of the housing in such a way that prevents relative rotation, piston rod 4 does not rotate relative to housing 1, including during a dose setting step. EX1015, ¶23, FIG. 1; EX1011, ¶¶364-65. Thus, Møller taught the claimed "piston rod."

The combination of Møller and Steenfeldt-Jensen taught "a drive sleeve" as recited in element [1.5]:

'069 Patent	**Møller and Steenfeldt-Jensen**
[1.5] a drive sleeve	Møller discloses connection bars 12 and nut 13:

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	"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.

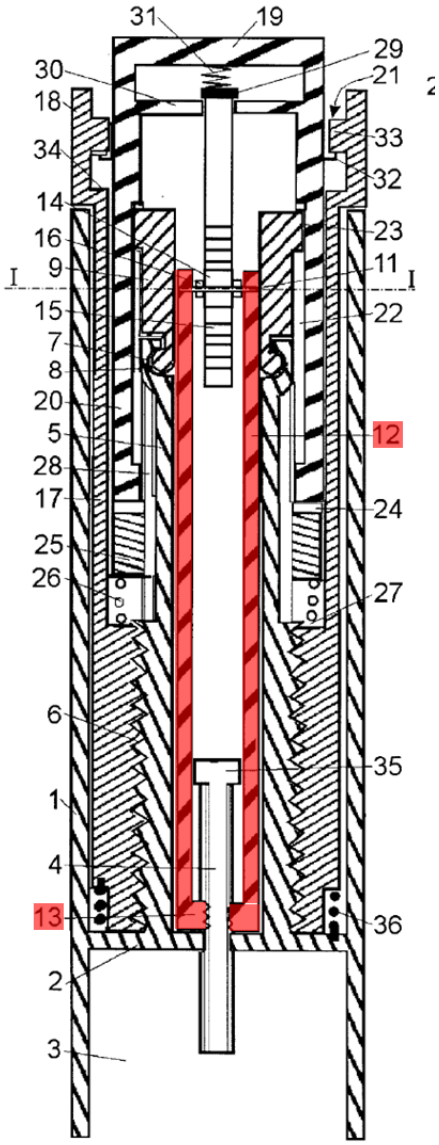


Fig. 1

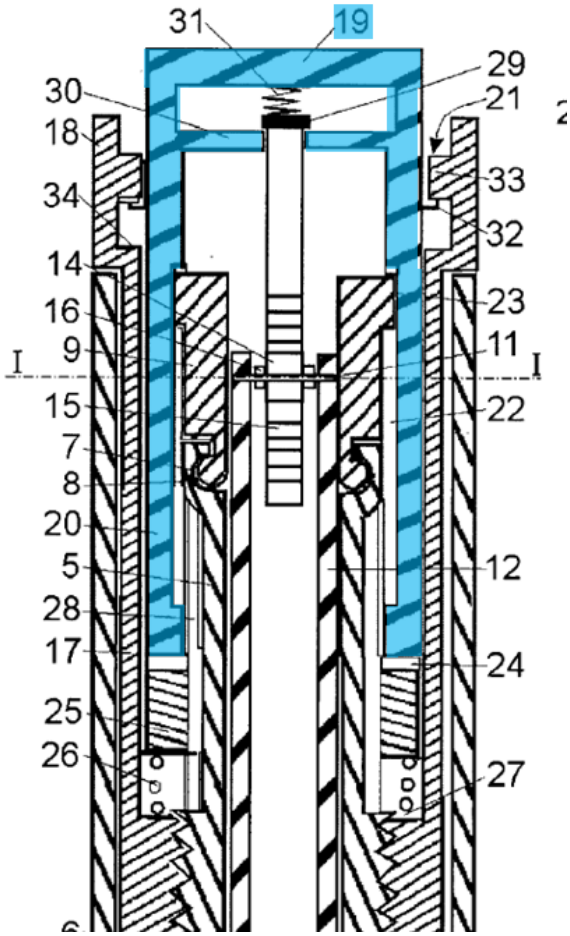
"The rotation of dose setting button 18 and the cup shaped element is further transmitted to the gearbox 9 .... The rotation of the gearbox 25 [*sic*, 9] is through the connection bars 12 transmitted to the nut 13, which is this way screwed up along the thread of the piston rod 4 and lifted away from 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 combination of Møller and Steenfeldt-Jensen taught "a tubular clutch" as recited in element [1.6]:

'069 Patent	**Møller and Steenfeldt-Jensen**
[1.6] a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,	Møller discloses a cup shaped element: "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, FIG. 1 (below; annotating bottom (blue)); EX1011, ¶375.



"[T]he coupling 21 ... may comprise Δ-shaped protrusions 32 on the cup shaped element engaging Λ-shaped recesses in an inner ring 33 in the dose setting button 18." EX1015, ¶29, FIG. 1.

'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.

Møller teaches a "cup shaped element," which acts as a clutch by rotationally coupling the dose setting drum 17 to connection bars 12 with nut 13 during dose setting, and rotationally decoupling those components during injection. *See* EX1015, ¶¶29-30, 32-33, FIG. 1; EX1011, ¶¶372-74, 376. The cup shaped element includes bottom 19, which forms an injection button, and tubular part 20,

which fits into dose setting drum 17. EX1015, ¶26, FIG. 1; EX1011, ¶¶372, 376. As shown in FIG. 1, the cup shaped element is seated within dose setting button 18 and passes through its entire length, making it located adjacent the needle-end (*i.e.* the distal end) of dose setting button 18. EX1011, ¶376. The cup shaped element is operatively coupled to dose setting button 18 via the engagement of Δ-shaped protrusions 32 with corresponding recesses 33 in dose setting button 18. *See* EX1015, ¶29, FIG. 1; EX1011, ¶¶372-74, 376.

To the extent "tubular clutch" is construed as a means-plus-function limitation, the combination of Møller and Steenfeldt-Jensen renders it obvious. The '069 patent discloses clutch 60:

> The clutch means 60 is generally cylindrical and is provided at a first end with a series of circumferentially directed saw teeth 66 (see FIG. 7) [and is normally engaged with clicker 50]. Each saw tooth comprises a longitudinally directed surface and an inclined surface. Towards the second end 64 of the clutch means 60 there is located a radially inwardly directed flange 62. The flange 62 of the clutch means 60 is disposed between the shoulder 37 of the drive sleeve 30 and the radially outwardly directed flange 39 of the extension 38. The second end of the clutch means 60 is provided with a plurality of dog teeth 65 (FIG. 8) [that are adapted to engage with

the dose dial sleeve]. The clutch 60 is keyed to the drive sleeve 30 by way of splines (not shown) to prevent relative rotation between the clutch 60 and the drive sleeve 30.

EX1001, 4:29-41, 4:47-48, 2:5-7; *see also* EX1011, ¶378.

The tubular clutch as described by the '069 patent, therefore, is "generally cylindrical," having a series of "circumferentially directed ... teeth" at its first end (needle-end), and also has a plurality of teeth at its second end (button-end). *Id.*, 4:29-41; EX1011, ¶379. The teeth on the needle-end engage with the clicker, and the teeth on the button-end engage with the dose dial sleeve. *Id.*, 2:5-7, 4:29-41, 4:47-48; EX1011, ¶379. As taught by the '069 patent, the clutch is also keyed to the drive sleeve, through the use of splines, to prevent relative rotation between the clutch and drive sleeve. *Id.*, 5:2-4; EX1011, ¶379.

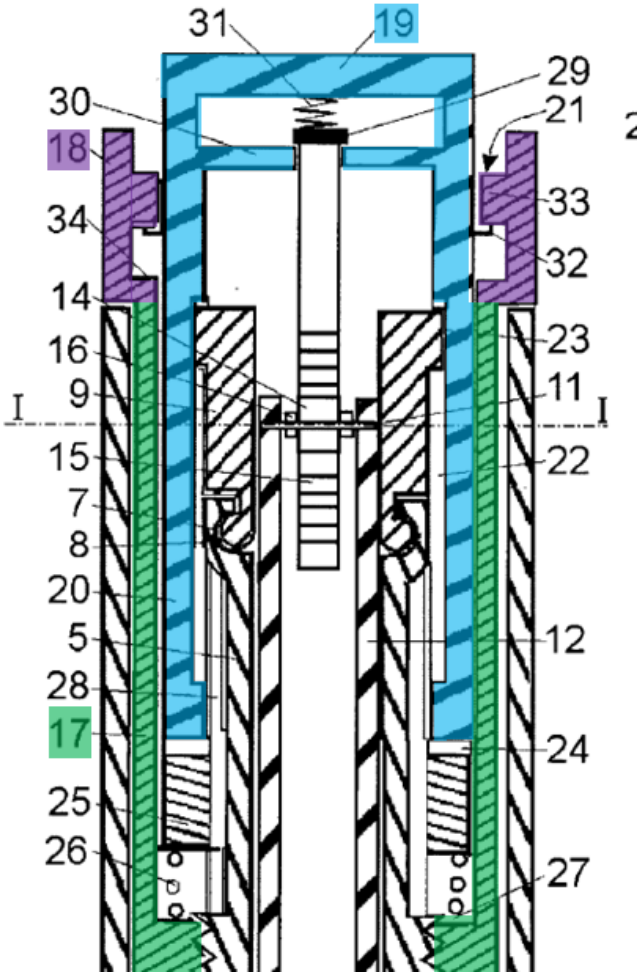
Møller's cup-shaped element operates in a similar manner using similar structure, as understood from Møller's second embodiment that includes a corresponding clutch: tubular element 120. *Compare* EX1015, FIGS. 1 *with* EX1001, FIGS. 6-8; EX1011, ¶380. Tubular element 120, which carries button 119, is 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.

Therefore, Møller taught a "tubular clutch" as claimed in claim 1.

The combination of Møller and Steenfeldt-Jensen discloses the relative positioning between the dose dial sleeve and the tubular clutch as recited in element [1.7]:

'069 Patent	**Møller and Steenfeldt-Jensen**
[1.7] wherein said dose	Møller discloses that cup shaped element extends into

dial sleeve extends circumferentially around at least a portion of said tubular clutch.	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" cup shaped element. *See* EX1015, FIG. 1; EX1011,

¶381. The combination of Møller and Steenfeldt-Jensen thus discloses this element.

2. Reason to modify and 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. A POSA would have found it obvious to place the drum's thread, in the form of an outer helical groove as taught by Steenfeldt-Jensen, to engage the housing for rotational movement. EX1011, ¶¶354-61.

In providing background to its invention, Møller expressly discusses the device disclosed in Steenfeldt-Jensen. *See* EX1015, ¶8 (referencing EX1027). Møller 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." EX1015, ¶8. Møller, however, explains 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. *See id.*; EX1011, ¶357. Møller concludes that "traditional gearing using mutual engaging gear wheels and racks is preferred." EX1015, ¶8.

Møller goes on to describe its device, "which combines the advantages of the devices according to the prior art without adopting their disadvantages." *Id.*, ¶11. Møller's 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.*, ¶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; *see also id.*, ¶33; EX1011, ¶358.

As Møller recognized, Steenfeldt-Jensen discloses numerous embodiments of dose dial sleeves having a helical groove provided on its outer surface for engagement with 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 disclosed in Steenfeldt-Jensen, on a drum and housing like

that of Møller. EX1011, ¶360. Because the threaded engagement in Steenfeldt-Jensen 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 that such a configuration 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. *See, e.g.*, EX1005, ¶¶12, 14, claim 1; 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 in order 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 1 was obvious over the combination of the teachings of Møller and Steenfeldt-Jensen.

VI. CONCLUSION

For the reasons set forth above, claim 1 is 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, therefore, that an IPR of this claim be instituted.

/Richard Torczon/
Reg. No. 34,448

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

Under the provisions of 37 C.F.R. §42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for Inter Partes Review totals 13,886, which is less than the 14,000 allowed under 37 C.F.R. 42.24(a)(i). In accordance with 37 C.F.R. 42.24(a), this word count does not include table of contents, table of authorities, mandatory notices under §42.8, certificate of service or word count, or appendix of exhibits or claim listing.

/Richard Torczon/
Reg. No. 34,448

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, I certify that I caused to be served a true and correct copy of the foregoing: **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,679,069 and Exhibits 1001-1035** by *Federal Express Next Business Day Delivery* on 10 September 2018 on the Patent Owner's correspondence address of record for the subject patent as follows:

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

Respectfully submitted,

Dated: 10 September 2018

/Richard Torczon/
Reg. No. 34,448