

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 IPR2019-00122
Patent No. 8,992,486

PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	MANDATORY NOTICES	1
A.	Real Parties-In-Interest.....	1
B.	Related Matters.....	1
C.	Identification of Counsel and Service Information.....	2
III.	CERTIFICATIONS.....	3
IV.	IDENTIFICATION OF CHALLENGE AND STATEMENT OF THE PRECISE RELIEF REQUESTED	3
V.	STATEMENT OF REASONS FOR THE RELIEF REQUESTED	3
A.	Summary of the Argument.....	3
B.	The '486 Patent	4
1.	Background	4
2.	Prosecution History.....	12
C.	Level of Ordinary Skill in the Art.....	13
D.	Claim Construction	13
E.	The Prior Art	16
1.	Burroughs.....	16
2.	Steenfeldt-Jensen	18
3.	Møller.....	21
F.	Ground 1: Claims 1-6, 12-18, 20, 23, 26-30, 32, 33, 36, and 38-40 Were Obvious Over Burroughs.....	22
1.	Claim 1	22
a.	Element-by-element analysis.....	23
b.	Reason to modify and reasonable expectation of success	38
2.	Claim 2.....	40

3.	Claims 3-4	41
4.	Claim 5	43
5.	Claim 6	44
6.	Claims 12-13	45
7.	Claim 14-18 and 20	46
8.	Claim 23	55
9.	Claim 26	57
10.	Claims 27-29	58
11.	Claims 30 and 32	61
12.	Claim 33	64
13.	Claim 36	65
14.	Claims 38-40	66
VI.	CONCLUSION	68

LIST OF EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
1001	U.S. Patent 8,679,069, <i>Pen-Type Injector</i> (issued Mar. 25, 2014)
1002	U.S. Patent 8,603,044, <i>Pen-Type Injector</i> (issued Dec. 10, 2013)
1003	U.S. Patent 8,992,486, <i>Pen-Type Injector</i> (issued Mar. 31, 2015)
1004	U.S. Patent 9,526,844, <i>Pen-Type Injector</i> (issued Dec. 27, 2016)
1005	U.S. Patent 9,604,008, <i>Drive Mechanisms Suitable for Use in Drug Delivery Devices</i> (issued Mar. 28, 2017)
1006	File History for U.S. Patent 8,679,069
1007	File History for U.S. Patent 8,603,044
1008	File History for U.S. Patent 8,992,486
1009	File History for U.S. Patent 9,526,844
1010	File History for U.S. Patent. 9,604,008
1011	Expert Declaration of Karl Leinsing MSME, PE in Support of Petition for <i>Inter Partes</i> Review of U.S. Patent Nos. 8,679,069; 8,603,044; 8,992,486; 9,526,844 and 9,604,008

<u>Exhibit No.</u>	<u>Description</u>
1012	<i>Curriculum Vitae</i> of Karl Leinsing MSME, PE
1013	U.S. Patent 6,221,046 - A. Burroughs et al., “Recyclable Medication Dispensing Device” (issued Apr. 24, 2001)
1014	U.S. Patent 6,235,004 – S. Steinfeldt-Jensen & S. Hansen, “Injection Syringe” (issued May 22, 2001)
1015	U.S. Patent Application US 2002/0053578 A1 – C.S. Møller, “Injection Device” (pub’d May 2, 2002)
1016	U.S. Patent 6,932,794 B2 – L. Giambattista & A. Bendek, “Medication Delivery Pen” (issued Aug. 23, 2005)
1017	U.S. Patent 6,582,404 B1 – P.C. Klitgaard et al., “Dose Setting Limiter” (issued June 24, 2003)
1018	File History for U.S. Patent 6,582,404
1019	Plaintiffs’ Preliminary Claim Constructions and Preliminary Identification of Supporting Intrinsic and Extrinsic Evidence, <i>Sanofi-Aventis U.S. LLC v. Mylan GmbH</i> , No. 2:17-cv-09105 (D.N.J.)
1020	U.S. Patent 4,865,591 – B. Sams, “Measured Dose Dispensing Device” (issued Sep. 12, 1989)
1021	U.S. Patent 6,248,095 B1 – L. Giambattista et al., “Low-cost Medication Delivery Pen” (issued June 19, 2001)
1022	U.S. Patent 6,921,995 B1 – A.A. Bendek et al., “Medication

<u>Exhibit No.</u>	<u>Description</u>
	Delivery Pen Having An Improved Clutch Assembly” (issued July 13, 1999)
1023	U.S. Patent 5,226,895 – D.C. Harris, “Multiple Dose Injection Pen” (issued July 13, 1993)
1024	U.S. Patent 5,851,079 – R.L. Horstman et al., “Simplified Unidirectional Twist-Up Dispensing Device With Incremental Dosing” (issued Dec. 22, 1998)
1025	Application as filed: U.S. Patent App. 14/946,203 – R.F. Veasey, “Relating to a Pen-Type Injector” (filed Nov. 19, 2015)
1026	GB 0304822.0 – “Improvements in and relating to a pen-type injector” (filed Mar. 3, 2003) (‘844 Priority Doc.)
1027	WO 99/38554 – S. Steinfeldt-Jensen & S. Hansen, “An Injection Syringe” (pub’d Aug. 5, 1999) (Steenfeldt-Jensen PCT)
1028	Mylan GmbH and Biocon’s Preliminary Claim Constructions and Supporting Evidence Pursuant to L. Pat. R. 4.2, <i>Sanofi-Aventis U.S., LLC v. Mylan N.V.</i> , C.A. No. 17-cv-09105
1029	Memorandum Opinion, <i>Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.</i> , No. 16-cv-812 (filed Jan. 12, 2018)
1030	Memorandum Opinion, <i>Sanofi -Aventis U.S. LLC v. Eli Lilly and Co.</i> , No. 14-cv-113 (filed Jan. 20, 2015)
1031	N. Sclater & N.P. Chironis, Mechanisms & Mechanical Devices Sourcebook 191-95, “Twenty Screw Devices” (3d ed., July 2, 2001)

<u>Exhibit No.</u>	<u>Description</u>
1032	EP 0 608 343 B1 – L. Petersen & N.-A. Hansen, “Large Dose Pen” (pub’d Oct. 18, 1991)
1033	A.G. Erdman & G.N. Sandor, “Mechanical Advantage”, §3.7 in 1 Mechanism Design: Analysis and Synthesis (1984)
1034	WO 01/83008 – S. Hansen & T.D. Miller., “ <i>An Injection Device, A Preassembled Dose Setting And Injection Mechanism For An Injection Device, And A Method Of Assembling An Injection Device</i> ” (pub’d Nov. 8, 2001)
1035	K.J. Lipska et al., <i>Association of Initiation of Basal Insulin Analogs vs Neutral Protamine Hagedorn Insulin With Hypoglycemia-Related Emergency Department Visits or Hospital Admissions and With Glycemic Control in Patients With Type 2 Diabetes</i> , 320 J. Am. Med. Ass’n 53-62 (2018).

I. INTRODUCTION

Mylan Pharmaceuticals Inc. (“Mylan”) petitions for *inter partes* review (“IPR”) of claims 1-6, 12-18, 20, 23, 26-30, 32, 33, 36, and 38-40 of U.S. Patent No. 8,992,486 to Veasey (“the ’486 patent,” EX1003). *See* 35 U.S.C. 311. This Petition shows a reasonable likelihood that the prior art renders claims 1-6, 12-18, 20, 23, 26-30, 32, 33, 36, and 38-40 unpatentable.

II. MANDATORY NOTICES

A. Real Parties-In-Interest

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

B. Related Matters

The ’486 patent has been asserted in *Sanofi-Aventis U.S. LLC v. Mylan N.V.*, No. 2:17-cv-09105 (D.N.J.), filed October 24, 2017. Mylan and Biocon are parties in this litigation. Becton Dickinson and Company supplies pens to Mylan, but has not been named as a party.

It 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); *see also* EX1030 (Markman opinion construing terms of related patents in *Sanofi - Aventis U.S. LLC v. Eli Lilly and Co.*, No. 14-cv-113 (D. Del.) (consent judgment)). The real parties-in-interest listed above are not parties to these litigations.

Mylan has also filed IPR2018-01678, IPR2018-01679, and IPR2018-01696 against the '486 patent. Mylan has filed IPR2018-01670, IPR2018-01675, IPR2018-01676, 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 at the contact information above. Mylan consents to electronic mail service at 34943.682.palib1@atters.wsgr.com and the email addresses above. A power of attorney accompanies this petition. 37 C.F.R. §42.10(b).

III. CERTIFICATIONS

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

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

Mylan requests IPR and cancellation of claims 1-6, 12-18, 20, 23, 26-30, 32-33, 36, and 38-40 of the '486 patent under pre-AIA 35 U.S.C. 103, as the detailed statement of the reasons for the relief requested sets forth, supported with exhibit copies, and the Declaration of Karl R. Leinsing, EX1011.

Claims 1-6, 12-18, 20, 23, 26-30, 32-33, 36, and 38-40 are unpatentable on the following ground:

Ground	Claims	Basis
1	1-6, 12-18, 20, 23, 26-30, 32-33, 36, 38-40	Obvious over U.S. Patent No. 6,221,046 (EX1013, "Burroughs")

V. STATEMENT OF REASONS FOR THE RELIEF REQUESTED

A. Argument Summary

The challenged claims relate to a drive mechanism for dispensing medicine from a pen-type injector. The claims broadly recite a six-component structure that forms the pen-type injector. Those six components include structural elements that are themselves claimed in a broad manner. As shown below, however, each of the

six components claimed was already known and commonly used in the prior art as of the relevant date. And each of the structural elements for those components was already known and commonly incorporated into those components by 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). There is nothing new or non-obvious about what is claimed by the ’486 patent. The above-identified claims of the ’486 patent are therefore unpatentable over the prior art.

B. The ’486 Patent¹

1. Background

The ’486 patent relates to a pen-type injector for self-administering drugs such as insulin. EX1003, Title, 1:20-24; EX1011, ¶¶24, 27, 31-33. Independent claim 1 recites:

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

¹ For purposes of uniformity, when discussing both the ’486 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.

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

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

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

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

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

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

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

For ease of reference, the components of claim 1 are color-coded as follows:

(1) “main housing” (4, dark grey);

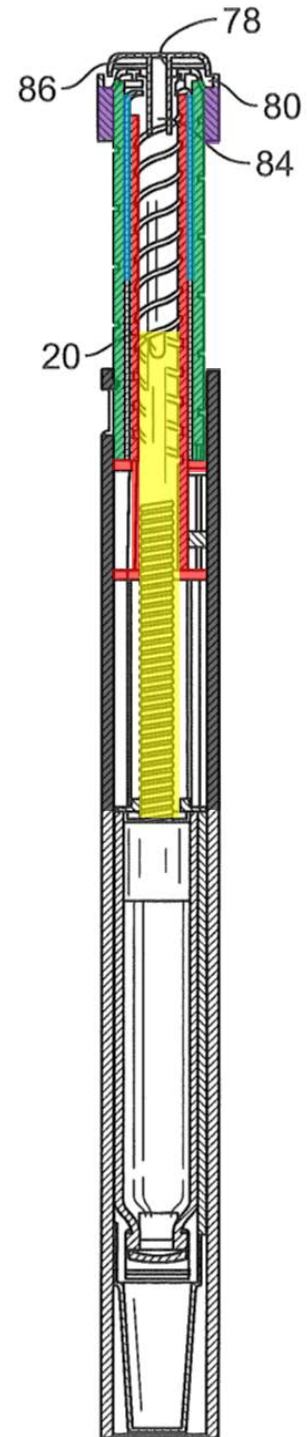
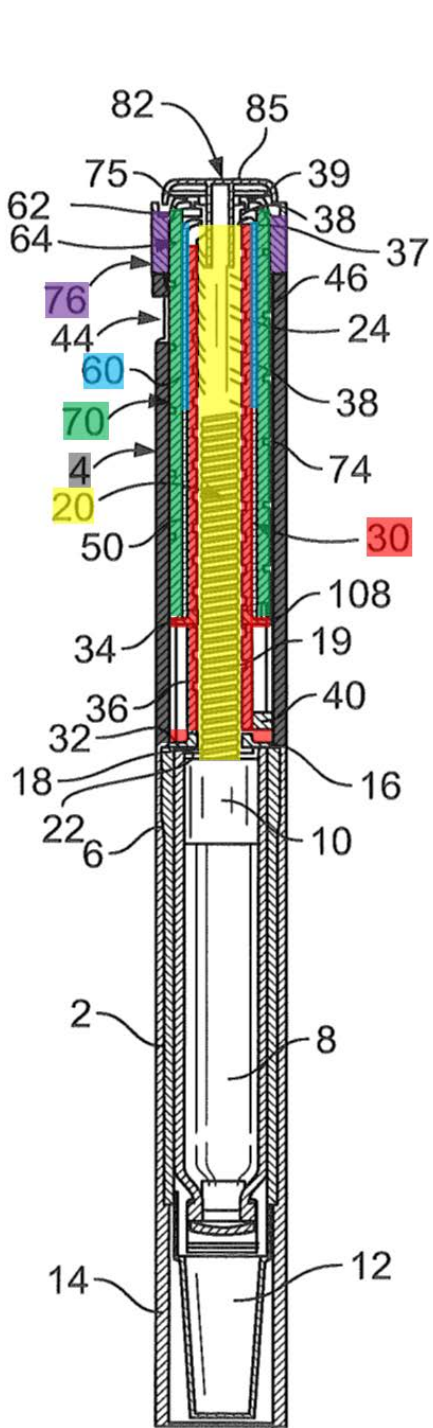
(2) “dose dial sleeve” (70, green);

(3) “dose knob” (76, purple);

(4) “piston rod” (20, yellow);

(5) “driver” (30, red); and

(6) “tubular clutch” (60, blue). EX1011, ¶36



Id., FIGS. 1-2 (annotated); EX1011, ¶38.

Brief Overview of the Disclosed Embodiments

The housing includes (1) cartridge retaining part 2, which holds the drug cartridge, and (2) main housing part 4, which houses the mechanism that drives the piston rod to dispense medicine. *See* EX1003, 3:27-38, FIG. 1. One embodiment includes insert 16 at the needle-end² of housing part 4. *Id.*, 3:49-50, FIG. 1. The insert is rotationally and axially fixed to the housing and includes threaded circular opening 18. The needle-end of piston rod 20 extends through the opening. *Id.*, 3:50-59, FIG. 1. Piston rod 20 includes first thread 19 that engages with the insert's threaded opening 18. *Id.*, 3:56-59, FIG. 1. Piston rod 20 also includes pressure foot 22 at this end, which abuts piston 10 of cartridge 8. *Id.*, 3:59-61, FIG. 1; EX1011, ¶¶43-51.

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.*, EX1003, 3:28-33. 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. Mylan refers to the relative directions of the needle-end and button-end as up and down, respectively.

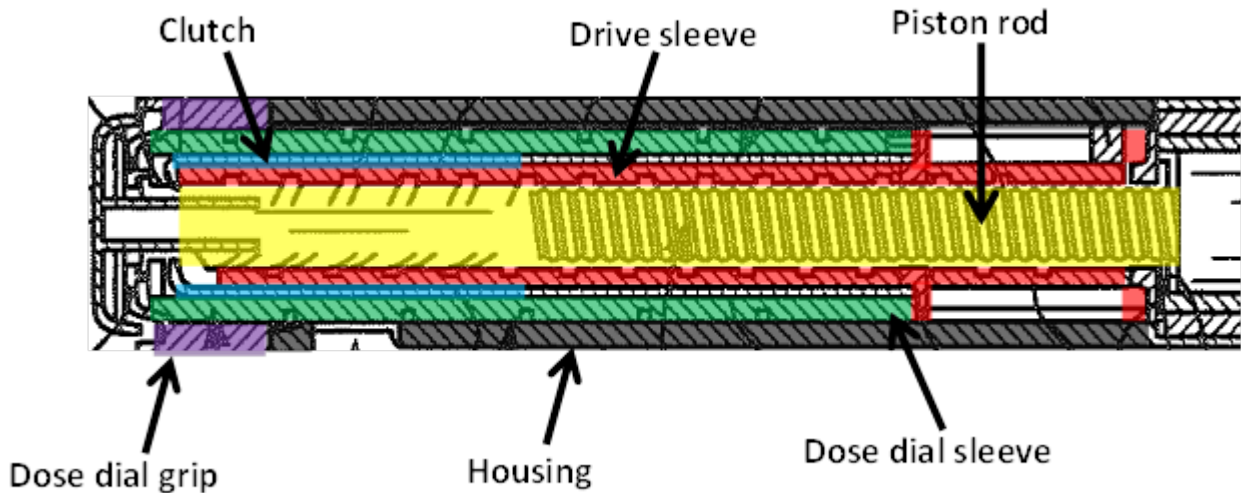


FIG. 1: Injector in a cartridge-full position, prior to dose setting

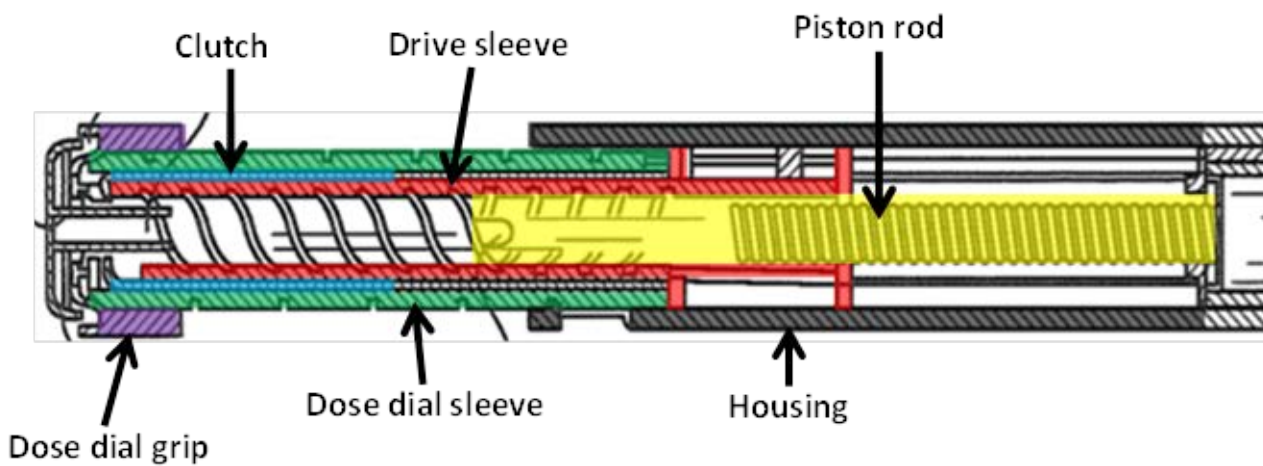


FIG. 2: Injector in a maximum dose-dialed position

EX1011, ¶39.

Piston rod 20 also includes second thread 24 that extends from its button-end. *See* EX1003, 3:61-62, FIGS. 1-2. Drive sleeve 30—elsewhere referred to as a “driver”—extends about piston rod 20 and includes internal helical groove 38 that engages with second thread 24. *Id.*, 4:4-13, FIG. 1; EX1011, ¶¶52-58.

Clutch 60 is “disposed about the drive sleeve, between the drive sleeve 30 and a dose dial sleeve 70.” *Id.*, 4:33-35, FIGS. 1, 6-7; EX1011, ¶¶65-67. Clutch 60 is “generally cylindrical” and located adjacent the button-end of driver 30. *See* EX1003, 4:50-52, FIG. 7. “The clutch 60 is keyed to the drive sleeve 30 by way of splines ... to prevent relative rotation between the clutch 60 and the driver 30.” *Id.*, 4:60-62. At its button-end, clutch 60 includes dog teeth 65. *See* EX1003, 4:58-60, FIGS. 1-2, 8. Teeth 65 releasably engage with the button-end of dose-dial sleeve 70. *See id.*, 6:29-31, FIG. 1. The specification does not explain how teeth 65 engage with dose-dial sleeve 70, though they presumably 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, ¶69 (citing EX1003, 5:22-24).

Dose-dial sleeve 70 is “provided outside of” the clutch 60 and “radially inward of” the housing 4. *Id.*, 5:6-5, FIG. 1; EX1011, ¶¶68-70. “A helical groove 74 is provided about an outer surface of the dose dial sleeve 70.” EX1003, 5:5-6, FIGS. 1-2, 12. “The main housing 4 is further provided with a helical rib 46, adapted to be seated in the helical groove 74” to allow for relative rotation. *Id.*, 5:9-11, FIGS. 15-16. Dose knob 76 (purple) “is disposed about an outer surface of the [button-end] of the dose dial sleeve 70.” *Id.*, 5:24-25, FIGS. 1-2. “The dose

knob 76 is secured to the dose dial sleeve 70 to prevent relative movement therebetween.” *Id.*, 5:27-29; EX1011, ¶¶71-73.

Operation of the Pen Injector

Dose setting: To set a dose, the user rotates dose knob 76 in one direction. *See* EX1003, 5:50-51; FIG. 9 (shown annotated below). At this stage, teeth 65 of clutch 60 are engaged to dose-dial sleeve 70. *See id.*, 5:50-59. Such engagement causes dose-dial sleeve 70, clutch 60, and driver 30 to rotate together out of the housing. *See id.*; FIG. 9. Driver 30 rotates up piston rod 20, toward its button-end, due to its engagement with piston rod 20’s second thread 24. *See id.*, 5:61-65. Piston rod 20 is prevented from rotating due to its opposing, threaded engagement with insert 16. *See id.*, 4:4-13, 6:1-3.

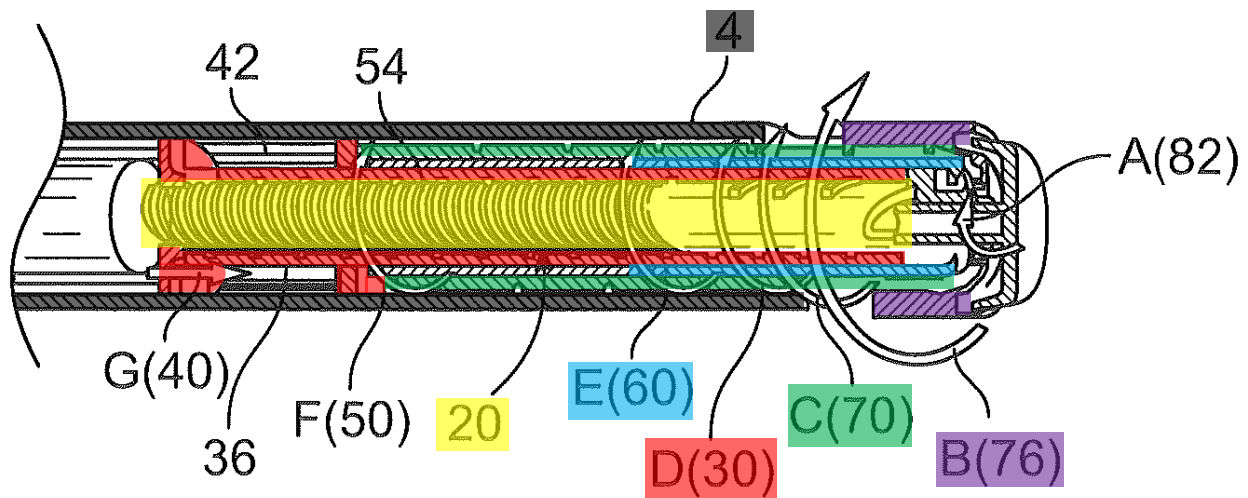


FIG. 9: Dialing up

EX1011, ¶81.

To dial-down a dose, the user rotates dose knob 76 in the opposite direction. *See id.*, 6:16-19; FIG. 10. “This causes the system to act in reverse,” where dose-dial sleeve 70, clutch 60, and driver 30 rotate together back into the housing. *See id.*, 6:19-20; FIG. 10. As such, driver 30 rotates down the piston rod 20, toward its needle-end, without corresponding rotation of the piston rod 20. *See id.*, 6:1-3, FIG. 10.

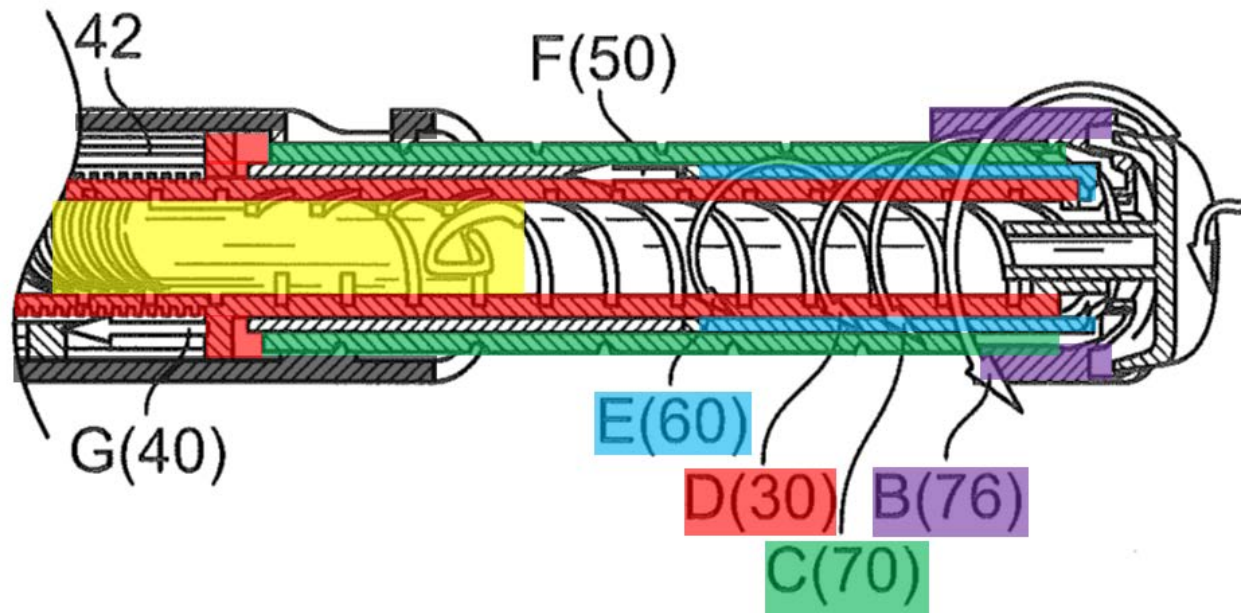


FIG. 10: Dialing down

EX1011, ¶84.

Injection: Once the dose is set, the user presses button 82, applying force toward the needle-end of the device. *See id.*, 6:28-29; FIG. 11; EX1011, ¶¶74-75. This displaces clutch 60 axially such that teeth 65 disengage from the dose-dial sleeve 70. EX1003, 6:29-31. Dose-dial sleeve 70 rotates back into housing 4 via

its threaded connection with the housing. *Id.*, 6:33-35; 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.*, 6:31-33, 6:38-40. Driver 30 also moves axially toward the needle-end, driving piston rod 20 to rotate through threaded opening 18, causing medicine to be dispensed from cartridge 8. *Id.*, 6:45-47.

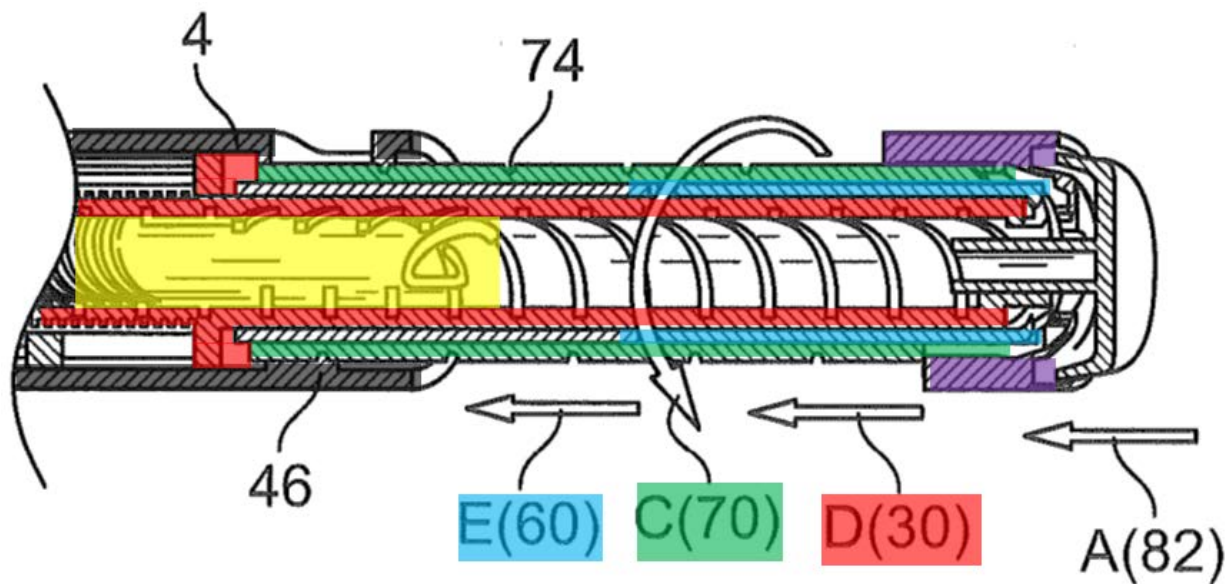


FIG. 11: Injecting dose

EX1011, ¶88.

2. Prosecution History

The '486 patent issued from Application No. 12/944,544 ("the '544 application") and claims priority to prior to March 3, 2003.

The claims were not rejected over art during prosecution, but were allowed immediately following the applicant's response to a double-patenting rejection. EX1008, 113-115, 140, 146-152.

C. Level of Ordinary Skill in the Art

The relevant time is before March 3, 2003, the earliest priority date claimed by the '486 patent. As described in the Leinsing declaration, a POSA at the relevant time would have had at least a bachelor's degree in mechanical engineering, or an equivalent degree, and practical design experience. EX1011, ¶106. The POSA also would have understood the basics of medical-device design and manufacturing, and basic mechanical elements (*e.g.*, gears, pistons) involved in drug-delivery devices. *Id.*; *see also id.*, ¶¶ 104-105, 107.

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

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

broadest interpretation of the claim language for purposes of infringement.”). The relevant terms are listed below, along with Sanofi’s proffered construction for those terms.

“driver”: “A component releasably connected to the dose dial sleeve that drives the piston during dose dispensing”. EX1019, 24.

“main housing”:³ “An exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components”. *Id.*, 20.

“piston rod”: “A rod that engages with the drive sleeve/driver/driving member to advance the piston during dose dispensing”. *Id.*, 25.

“thread/threaded/threading”: “A rib or groove on a first structure that engages a corresponding groove or rib on a second structure”. EX1019, 27.

“tubular clutch”: “A tubular structure that couples and decouples a moveable component from another component.” *Id.*, 21.

“clicker”: “A structure that provides audible and/or tactile feedback when the dose knob is rotated”. *Id.*, 29.

“insert”: “Plain and Ordinary Meaning. The term ‘insert’ is a structure as defined in each of the claims in which it appears.” *Id.*, 29.

³ This term was construed for the ’486, ’069, and ’044 patents.

In the related litigation with Sanofi, Mylan proffered a preliminary means-plus-function construction for “clutch,” “clicker,” and “insert.” EX1028, Exhibit E, 101-106, 112-116. The court in that litigation has not yet ruled on a claim construction. To the extent that the Board concludes that the broadest reasonable interpretation of those terms is a means-plus-function construction, Mylan provides those constructions below. 37 C.F.R. §§42.100(b), 42.104(b)(3).

As to function of the “clutch,” Mylan asserts that the function is that during dose setting, it “clutch[es], i.e., coupling and decoupling a movable component from another component,” or , during dose setting, it “operates to reversibly lock two components in rotation.” EX1028, 106. Mylan points to FIGS. 1, 5-11, component 60, as the corresponding structure for the clutch. *Id.*, 104; *see also* EX1003, 2:16-18, 4:49-62, 4:63-65, 6:36-44.

As to the function of a clicker, Mylan asserts is that the function is “provid[ing] audible clicks during dose setting, where each click is equal to a dose of medicament.” EX1028, 114-115. Mylan points to FIGS. 6-8 for the structure of the clicker, component 50. *Id.*, 131-134; *see also* EX1003, 2:20-22, 2:23-28, 2:29-35, 4:33-35, 4:36-48, 63-67.

As to the function of an insert, Mylan asserts that the function is “prevent[ing] the piston rod from rotating during dose setting and permit[ting] the piston rod to traverse axially towards the distal end during dose dispensing.” EX1028, 116. Mylan

points to FIGS. 1, 3-5, component 16, as the corresponding structure for the insert. *Id.* 115; *see also* EX1009,1:63-65, 3:58-64.

The ground presented below relies on the ordinary and customary meaning of the claim terms as they would be understood by a POSA. The ground also addresses the “clutch,” “clicker,” and “insert” limitations to the extent that those terms may be construed as means-plus-function limitations.

E. The Prior Art

1. Burroughs

Burroughs issued April 24, 2001 and is therefore prior art under §102(b). Burroughs discloses a medication dispensing pen for dispensing selectively measured dosages of medicine. *See* EX1013, 1:13-16. In particular, as shown in the annotated figure below, Burroughs describes a pen that includes six components like that of the claimed device:

(1) “housing 22,” having a “first part 24” and a “second part 26” (grey), which houses the drive mechanism for dispensing medicine from a cartridge (*Id.*, 7:15-20);

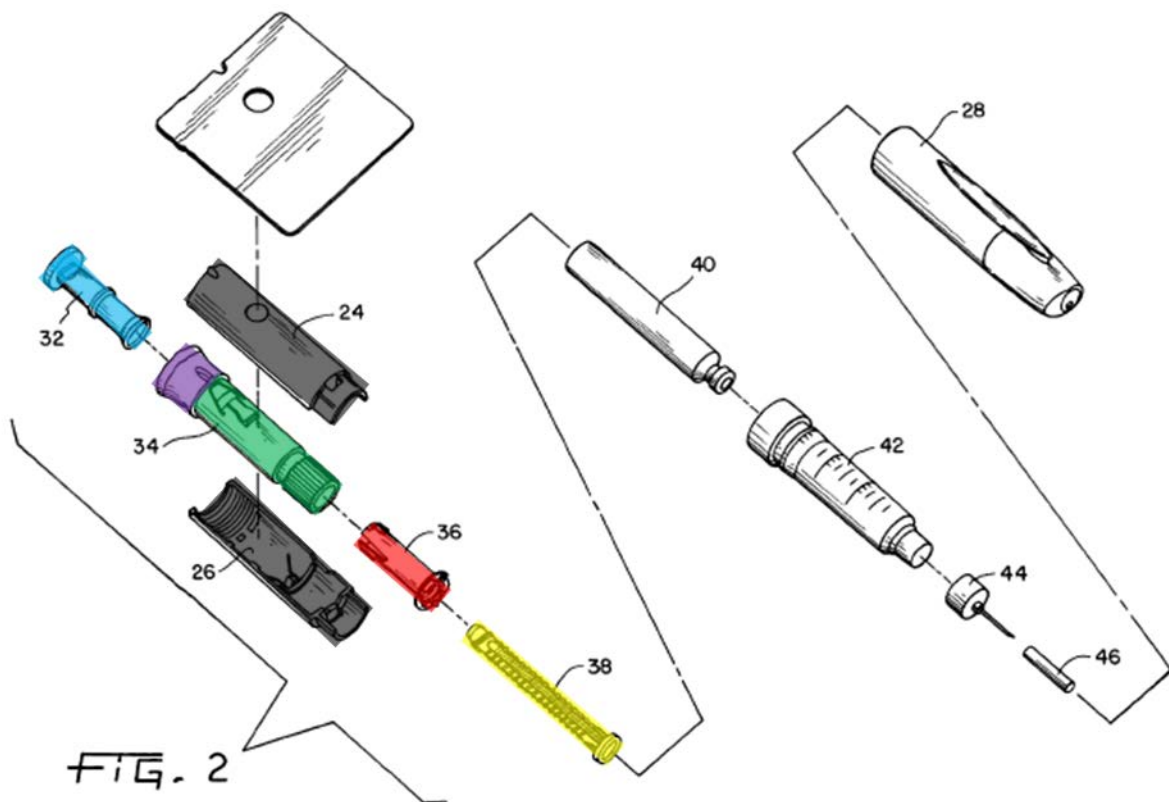
(2) “dial mechanism 34” (green), which the user manipulates to set a specific dose for injection (*id.*, 10:38-42);

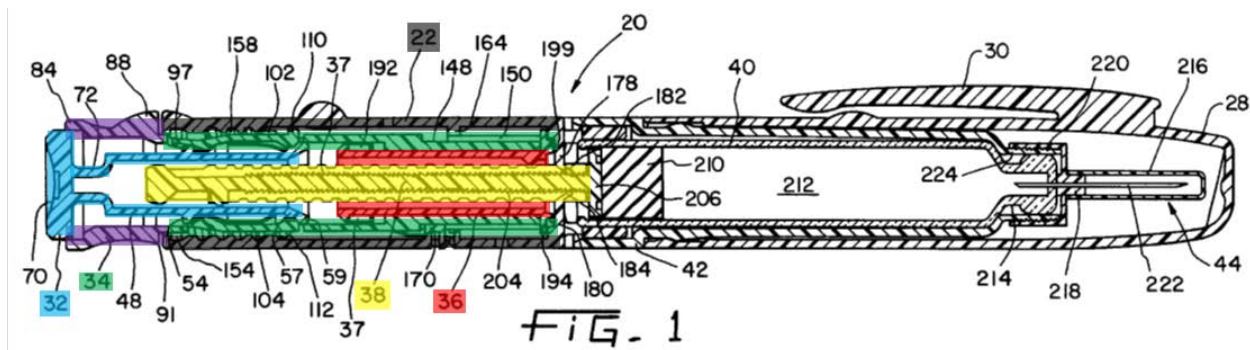
(3) “proximal portion 78” (purple), which is a portion of dial mechanism 34 that serves as a grip for the user to rotate the dial mechanism when setting a dose (*id.*, 8:2-8);

(4) “leadscrew 38” (yellow), which is driven to move a piston provided within the cartridge to dispense medicine (*id.*, 9:26-34);

(5) “nut 36” (red), which rotates and rides up leadscrew 38, then drives leadscrew 38 downward without relative rotation between the components during injection (*id.*, 9:12-25, 11:31-34); and

(6) “button 32” (blue), which rotationally decouples the dial mechanism from housing 22 and nut 36 during injection (*Id.*, 11:13-34). *See* EX1011, ¶126.





See EX1013, FIGS. 1-2; EX1011, ¶126.

2. Steinfeldt-Jensen

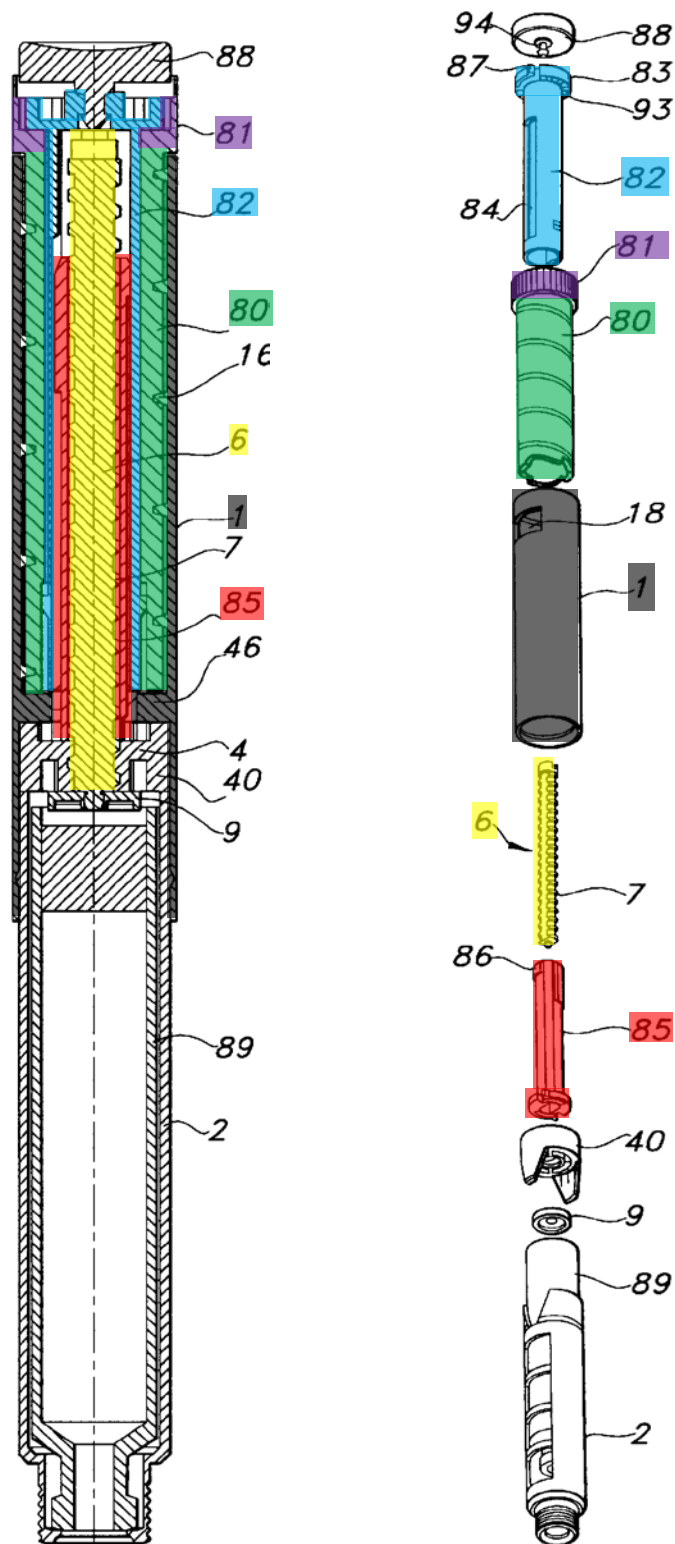
Steenfeldt-Jensen issued May 22, 2001 and is therefore prior art under pre-AIA §102(b). A related PCT publication (EX1014, WO99/38554) was one of many references submitted in an Information Disclosure Statement. It was not applied substantively in a rejection.

Steenfeldt-Jensen discloses injection syringes for dispensing medicine. *See* EX1014, Abstract. As shown in the annotated figure below, FIGS. 15-17 depict one embodiment⁴ of a syringe having a six-component structure:

⁴ Steinfeldt-Jensen explains that analogous elements in different embodiments are provided with the same reference number. *See* EX1014, 7:49-51. Thus, while the discussion herein primarily focuses on the embodiment shown in FIGS. 15-17, a POSA would have understood that disclosures relating to other embodiments

- (1) “tubular housing 1” (grey), which houses the drive mechanism for dispensing medicine from an ampoule (EX1014, 5:38-54);
- (2) “scale drum 80” (green), which the user manipulates to set a specific dose for injection (*id.*, 11:51-55);
- (3) “dose setting button 81” (purple), which serves as a grip for the user to manipulate the scale drum (*id.*, 11:51-55);
- (4) “piston rod 6” (yellow), which is driven to move a piston provided within the ampoule to dispense medicine (*id.*, 5:57-65);
- (5) “driver tube 85” (red), which rotates to drive the piston rod (*id.*, 2:47-53, 11:6-19, 11:52-12:13) and
- (6) “bushing 82” (blue), which releasably connects the scale drum and the driver tube for rotational movement during injection (*id.*, 12:4-13). *See* EX1011, ¶131.

inform the structure and operation of the embodiment of FIGS. 15-17, at least for elements having identical reference numbers. *See* EX, ¶131 n.13.



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

3. Møller

Møller is prior art 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 structure as that of the '008 patent. *See generally* EX1015, ¶¶22-27. As shown in FIG. 1 (reproduced and color-coded below), Møller discloses an injection device comprising:

(1) “housing 1” (gray), which houses the internal components of the drug-delivery device. *See e.g.* EX1015, Abstract, ¶¶22-23.

(2) “dose setting drum 17 (green), which the user manipulates to set a specific dose for injection. *See e.g. id.*, ¶¶25-26.

(3) “wall 2” (purple), which is disposed within the housing. *See e.g. id.*, ¶¶22-23.

(4) “piston rod 4” (yellow), which provides translational axial movement within the drug-delivery device. *See e.g. id.*, ¶22.

(5) “connection bars 12” having “nut 13 (red), which drives the piston rod in order to move the piston. *See e.g. id.*, ¶¶24, 32.

(6) “bottom 19” (blue), which is positioned between the dose-dial sleeve and the drive sleeve. *See e.g. id.*, ¶¶ 26, 29, 33.

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

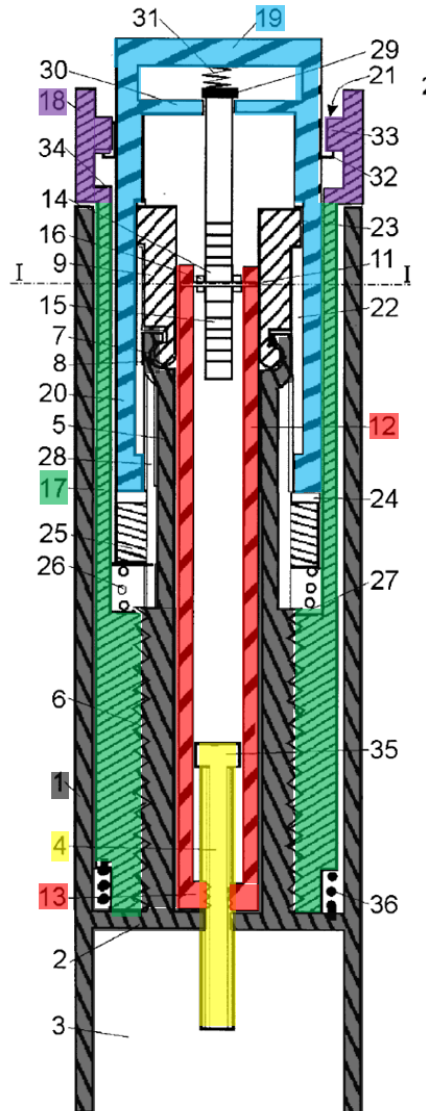


Fig. 1

**F. Ground 1: Claims 1-6, 12-18, 20, 23, 26-30, 32, 33, 36, and 38-40
Were Obvious Over Burroughs**

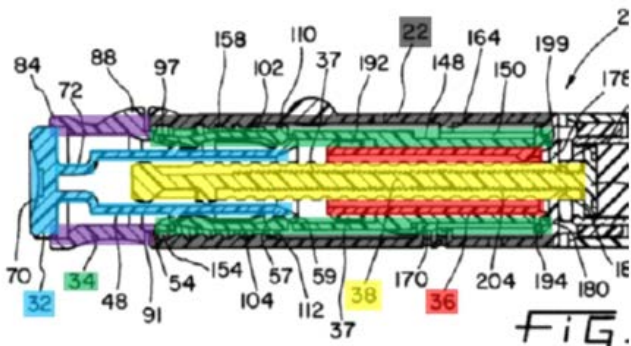
1. Claim 1

Burroughs describes a medication-dispensing pen that includes all features of claim 1 except the “dose dial sleeve” (dial mechanism 34) includes a helical rib, rather than a helical groove, on its outer surface to engage threading on the main

housing. *See infra*, §V.F.1.a. A POSA would have viewed helical ribs and helical grooves as interchangeable in the context of the threaded engagement between dial mechanism 34 and housing 22. *See infra*, §V.F.1.b. Accordingly, as explained further below, a POSA would have had reason to implement Burroughs’ rib-to-threading engagement as a groove-to-threading engagement and would have had a reasonable expectation of success in doing so. Claim 1 was therefore obvious in view of Burroughs. EX1011, ¶153.

a. Element-by-element analysis

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

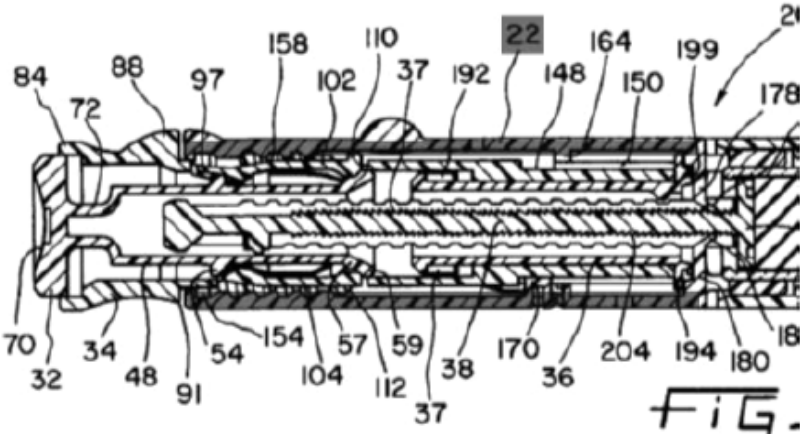
'486 Patent	Burroughs
[1.Preamble] A housing part for a medication dispensing apparatus, said housing part comprising:	<p data-bbox="586 1043 1414 1335">“A multi-use medication dispensing pen made of a plastic material that is recyclable after the contents of the medication cartridge have been exhausted. The pen is made of a minimal number of parts, which include a housing[.]” EX1013, Abstract.</p>  <p data-bbox="586 1778 1224 1816"><i>See id.</i>, FIG. 1 (annotated); EX1011, ¶157.</p>

	<p>“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.</p>
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Burroughs discloses an injection medication device 20 for dispensing medicine. *See, e.g.*, EX1013, Abstract, 7:15-16, FIG. 1. Device 20 includes housing 22, which contains the device’s drive mechanism. *See id.*, 7:14-18, FIG. 1; EX1011, ¶¶156-57. Accordingly, Burroughs teaches the preamble of claim 1.

Burroughs teaches “a main housing” as recited in element [1.1]:

'486 Patent	Burroughs
<p>[1.1] a main housing, said main housing extending from a distal end to a proximal end;</p>	<p>“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.</p> <div style="text-align: center;"> <p>FIG. 3 FIG. 5</p> </div> <p><i>See id.</i>, FIGS. 3 (above-left), 5 (above-right).</p>

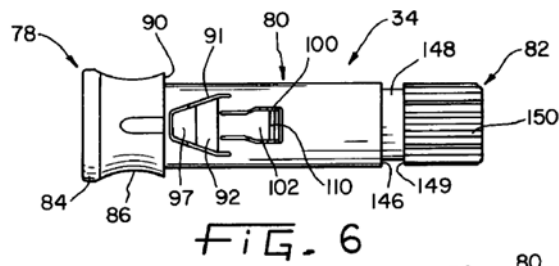
	 <p><i>See id.</i>, FIG. 1 (partial view annotating housing (gray)); EX1011, ¶159.</p>
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Housing 22 includes first part 24 and second part 26 that are secured together to house the drive mechanism. *See* EX1013, 7:19-20, FIGS. 1-3, 5. As shown in FIG. 1, housing 22 extends from a button-end (referred to as the proximal end) to a needle-end (referred to as the distal end). *See id.*, 7:9-13; EX1011, ¶160. Burroughs thus teaches the recited “main housing.” EX1011, ¶¶158-60.

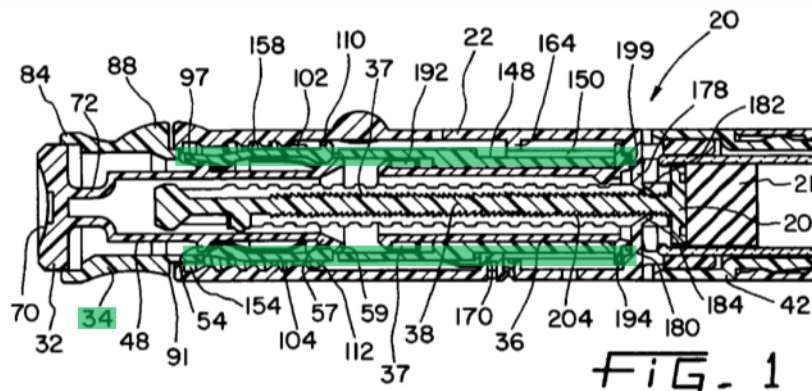
Burroughs teaches “a dose dial sleeve” as recited in element [1.2], except “a helical groove”:

'486 Patent	Burroughs
[1.2] a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a	“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.

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;



Id., FIG. 6.



Id., FIG. 1 (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

	<p>respectively to enter helical groove 158 during the commencement of the dosing process.” <i>Id.</i>, 8:63-9:1, FIGS. 3, 5; <i>see also id.</i>, 10:31-34.</p> <p>“Upon rotation of dial 34, threads 110, 112 move within housing groove 158 in the proximal [<i>i.e.</i>, button-end] direction as dial mechanism 34 retracts from housing 22[.]” <i>Id.</i>, 10:34-37.</p>
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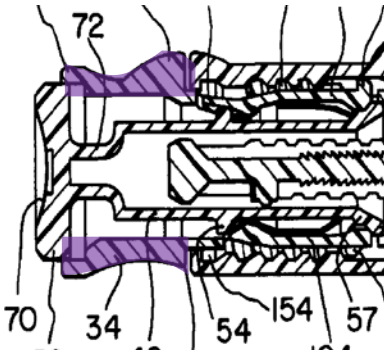
Burroughs discloses a “dose dial sleeve” in the form of dial mechanism 34. *Id.*, 7:31-32, FIG. 2; EX1011, ¶161-62. The dial mechanism is positioned within housing 22 and includes on its outer surface threads 110, 112. EX1013, 7:65-67, 8:33-36, FIGS. 1-2, 6-9; EX1011, ¶161-63. Threads 110, 112 are configured to releasably engage helical spiral groove 158 on an inner surface of housing 22. *See* EX1013, 8:62-9:1, FIGS. 1, 3, 5-9; EX1011, ¶164-67.

Threads 110, 112 are 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, ¶166-67. Threads 110, 112 are spaced apart on opposite sides of dial mechanism 34, so proper engagement of the threads with helical spiral groove 158 requires that they be positioned helically relative to one another, thereby forming a discontinuous helical rib corresponding to the

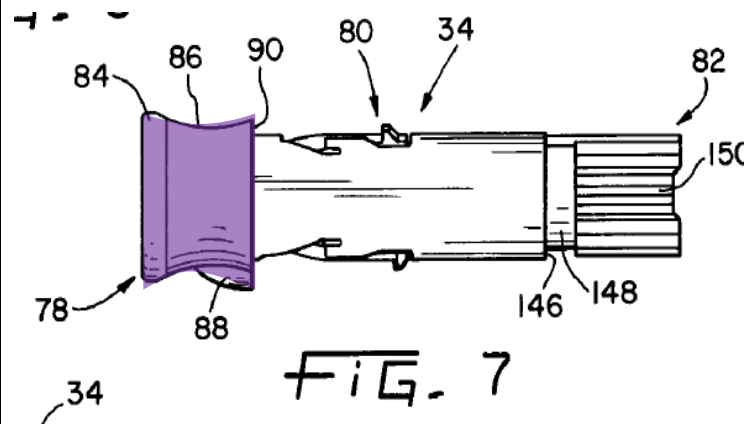
housing's helical groove. EX1011, ¶168-70; *cf.* EX1003, 3:42-44 (threads may include part threads). The helical positioning of threads 110, 112 is best shown in FIGS. 1 and 7. EX1011, ¶¶161, 165. Thus, Burroughs discloses that dial mechanism 34 includes a “helical rib” (threads 110, 112) along its outer surface that is configured to engage threading on the housing. EX1011, ¶164.

Burroughs teaches the recited “dose dial sleeve,” except it discloses a “helical rib” rather than a “helical groove.” EX1011, ¶170-72. But, as detailed below in §V.F.1.b, a POSA would have considered it routine to implement the helical rib as a helical groove corresponding to helical threading on the housing.

Burroughs teaches “a dose knob” as recited in element [1.3]:

'486 Patent	Burroughs
[1.3] a dose knob disposed near a proximal end of said dose dial sleeve;	<p>“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.</p> 

Id., FIG. 1 (partial view; proximal portion 78 annotated purple); EX1011, ¶174.

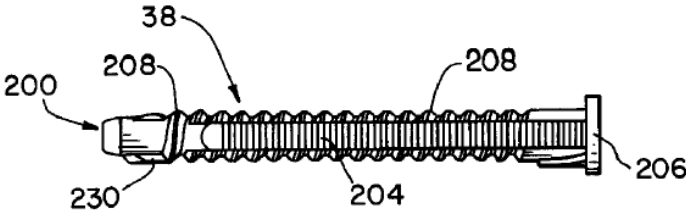
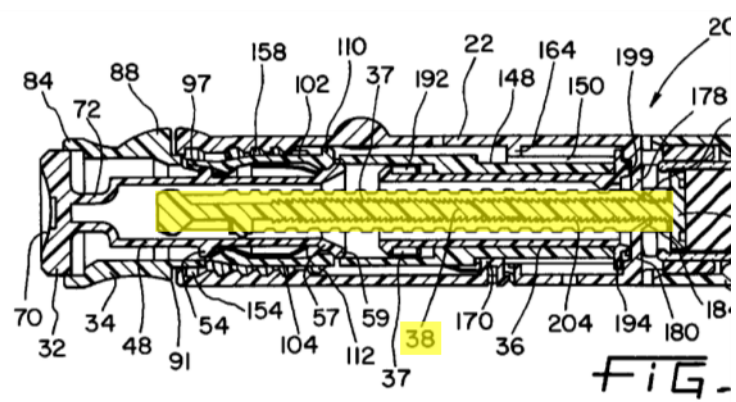


EX1013, FIG. 7 (proximal portion 78 annotated purple), EX1011, ¶173.

“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 knob” in the form of proximal portion 78 of dial mechanism 34, with this portion disposed near a proximal end (*i.e.*, button-end) of the dial mechanism. *See* EX1013, 8:2-6, FIGS. 1, 6-9; EX1011, ¶¶173-75. As shown in FIG. 1, proximal portion 78 is externally positioned at housing 22’s proximal end, and thus constitutes a knob for the user to grasp to rotate dial mechanism 34 during dose setting. *See* EX1011, 10:34-42; EX1011, ¶¶173-75. Accordingly, Burroughs teaches the recited “dose knob.”

Burroughs teaches “a piston rod” as recited in element [1.4]:

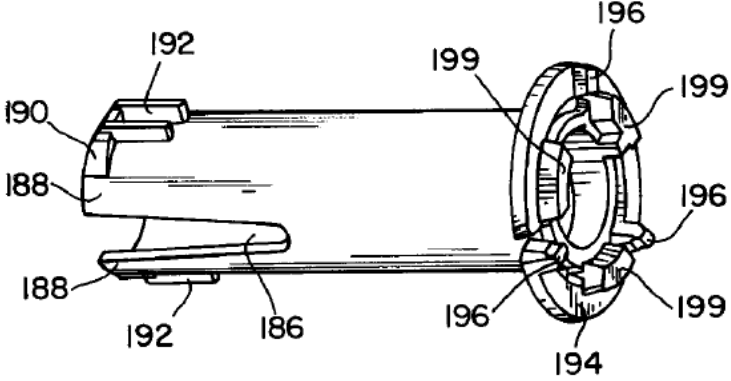
'486 Patent	Burroughs
<p>[1.4] a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;</p>	<p>“Referring now to FIGS. 12 and 13, leadscrew 38 is shown having a ratchet teeth 204 located on two opposing sides of leadscrew 38 and axially extending along the length of leadscrew 38 from proximal end 200 [<i>i.e.</i>, button end] to plunger engagement portion 206. Helical threads 208 extend along the axial length of leadscrew 36 [<i>sic</i>, 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.</p>  <p><i>Id.</i>, FIG. 12.</p>  <p style="text-align: right;">FIG.</p>

	<p><i>Id.</i>, FIG. 1 (partial view; leadscrew 38 annotated yellow); EX1011, ¶176.</p> <p>“Housing parts 24 and 26 include bulkhead ledges 178, 180, respectively, . . . [which] include flexible tangs 182, 184, respectively.” EX1013, 9:8-11.</p> <p>“Movement of leadscrew 38 is prevented in the proximal [<i>i.e.</i>, 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.” <i>Id.</i>, 11:52-56.</p> <p>“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.” <i>Id.</i>, 10:26-42.</p> <p><i>See also id.</i>, FIGS. 2-3, 5, 13</p>
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Burroughs discloses a “piston rod” in the form of leadscrew 38, which is provided within housing 22. *See* EX1013, 9:26-27, FIGS. 1-2, 12-13. During

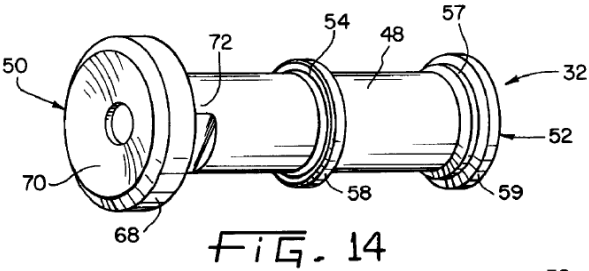
dose-setting, rotation of dial mechanism 34 causes corresponding rotation of nut 36, which engages external threads 208 of the leadscrew. *Id.*, 10:26-42, FIG. 1; EX1011, ¶177. Rotation is not transmitted to leadscrew 38, however, due to anti-backup tangs 182, 184 provided on housing 22. EX1013, 10:26-42, FIG. 1; EX1011, ¶177. Leadscrew 38 thus is not rotatable relative to housing 22 during dose setting. *Id.* Accordingly, Burroughs teaches the recited “piston rod.” EX1011, ¶178.

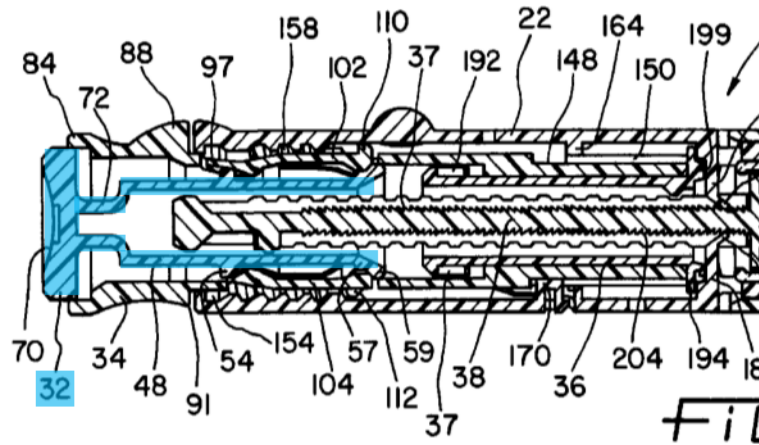
Burroughs teaches “a driver” as recited in element [1.5]:

'486 Patent	Burroughs
<p>[1.5] a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod; and</p>	<p>“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 350° about the inner surface of nut 36.” EX1013, 9:13-25.</p>  <p><i>Id.</i>, FIG. 10.</p>

Burroughs discloses a “driver” in the form of nut 36. *See id.*, 9:12-13, FIGS. 1-2, 10-11; EX1011, ¶¶180-81. Nut 36 rotates and rides up leadscrew 38 during dose setting and moves axially downward during injection, thereby pushing (or “driving”) leadscrew 38 down to deliver the dose. *See id.*, 11:27-35; EX1011, ¶¶180-81. Nut 36 includes helical thread 198 on its interior surface near its distal end (needle-end). EX1013, 9:13-25, FIGS. 1-2, 10-11. This thread engages helical threads 208 on leadscrew 38. *See id.*, 9:30-32, FIGS. 1, 2, 10-13. Figure 1 further shows that nut 36 extends along a portion of leadscrew 38. EX1011, ¶¶180-81. Accordingly, Burroughs teaches all aspects of the recited “driver.”

Burroughs teaches “a tubular clutch” as recited in element [1.6]:

'486 Patent	Burroughs
<p>[1.6] a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob,</p>	<p>“Referring to FIG. 14 and FIG. 15, button 32 comprises a hollow cylindrical portion 48 having a proximal end 50. Cylindrical portion 48 includes . . . an enlarged diameter ring 54[.]” EX1013, 7:46-52, FIGS. 1-2, 14-15.</p>  <p><i>Id.</i>, FIG. 14.</p>



Id., FIG. 1 (partial view; button 32 annotated 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[.]” EX1013, 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

	<p>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.” <i>Id.</i>, 8:42-48, FIG. 9; <i>see also id.</i>, 9:16-18, FIGS. 10-11 (nut 36 having splines 192).</p> <p>“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.” <i>Id.</i>, 11:13-20.</p> <p>“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.” <i>Id.</i>, 11:27-30.</p>
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Burroughs discloses a “tubular clutch” in the form of button 32. Button 32 is cylindrical in shape (tubular) and includes an enlarged diameter ring 54. *See* EX1013, 7:46-51, FIGS. 14, 15; EX1011, ¶182. Burroughs discloses that, when button 32 is depressed for injection, ring 54 pushes onto fingers 94 provided within dial mechanism 34’s internal surface. *Id.*, 8:11-20, FIGS. 1, 9, 14, 15. This causes the portion of legs 102, 104 that includes threads 110, 112 to move radially inward, which causes the threads to disengage from helical groove 158 of the housing. *See*

id., 8:15-20; EX1011, ¶183. This disengagement then allows dial mechanism 34 to freely move toward the device’s needle-end without rotating relative to the housing. *See* EX1013, 8:15-20, 11:5-20; EX1011, ¶¶184-85. 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, ¶¶185-87. Thus, button 32 serves as a clutch that allows dial mechanism 34 to disengage from (1) its rotational connection with the housing 22, and (2) its rotational connection with nut 36. *See* EX1011, ¶¶184-87.

As shown above in FIG. 1, button 32 is located adjacent a distal end of the proximal portion 78 of the dial mechanism 34. *See* EX1013, FIG. 1; EX1011, ¶¶184-85. It is operatively coupled to portion 78 (*i.e.* the dose knob) by virtue of its engagement with fingers 94 of the dial mechanism 34. *See* EX1013, FIGS. 1, 6-9, 14, 15; EX1011, ¶¶185-86; *cf.* EX1003, 2:5-7, 6:6-9 (describing operation of the clutch with respect to the dose-dial sleeve). Burroughs thus teaches all aspects of the “tubular clutch” recited in claim 1.

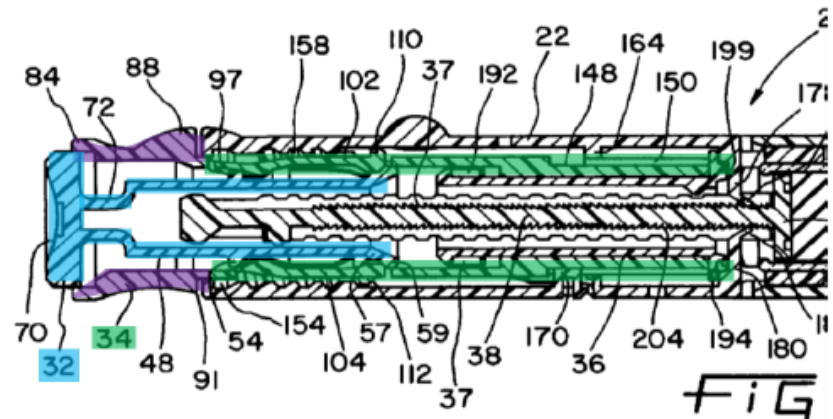
Accordingly, Burroughs teaches the recited “tubular clutch”.

Burroughs teaches the relative positioning of the dose-dial sleeve and the tubular clutch recited in element [1.7]:

'486 Patent	Burroughs
[1.7] wherein said dose	Burroughs shows that dial mechanism 34 extends

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

circumferentially around a significant portion of button 32:



EX1013, FIG. 1 (partial view; dial mechanism 34 annotated green, button 32 annotated blue); EX1011, ¶188.

Figure 1 shows that dial mechanism 34 (the dose-dial sleeve) extends circumferentially around at least a portion of button 32 (the clutch). *See* EX1013, FIG. 1; EX1011, ¶188. Accordingly, Burroughs teaches element [1.7].

b. Reason to modify and reasonable expectation of success

To the extent threads 110, 112 are not considered a “helical groove”, they nevertheless suggest such a groove. EX1011, ¶¶189-90. As explained above, the dial mechanism’s helical rib (threads 110, 112) engages with corresponding threading on the housing to facilitate relative rotation of the threaded components and corresponding axial displacement. *See* EX1013, 10:34-38, 10:60-63; EX1011, ¶¶189-90. Although Burroughs illustrates threads 110, 112 as protruding ribs, a

POSA would have been familiar with a limited number of interchangeable thread structures and recognized that Burroughs was merely depicting one such option. EX1011, ¶¶189-90. Providing threads 110, 112 as a protruding helical groove rather than as a protruding helical rib would have been apparent to a POSA, and a POSA would have recognized that such groove-to-rib implementation of the threading would be functionally equivalent and largely interchangeable with the depicted rib-to-groove implementation. *Id.*, ¶¶192-93. Selecting and implementing such threading was a routine task for a POSA and would have been viewed as no more than “the predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. at 417; EX1011, ¶¶193-96.

A POSA also would have had a reasonable expectation of success in implementing threads 110, 112 as protruding helical grooves. Grooved threading is a common, well-understood, predictable mechanism for providing the function of a thread (*i.e.* facilitating rotation and corresponding axial displacement of a threaded component), and a POSA would have recognized that using a groove rather than a rib to engage corresponding threading on the housing would not change the function or the principle of operation of the mechanism. EX1011, ¶168 (citing EX1014, Steinfeldt-Jensen). A POSA thus would have understood that a protruding u-shaped groove would operate in the same manner and provide the same function as the depicted ribs. EX1011, ¶170. Given the well-understood

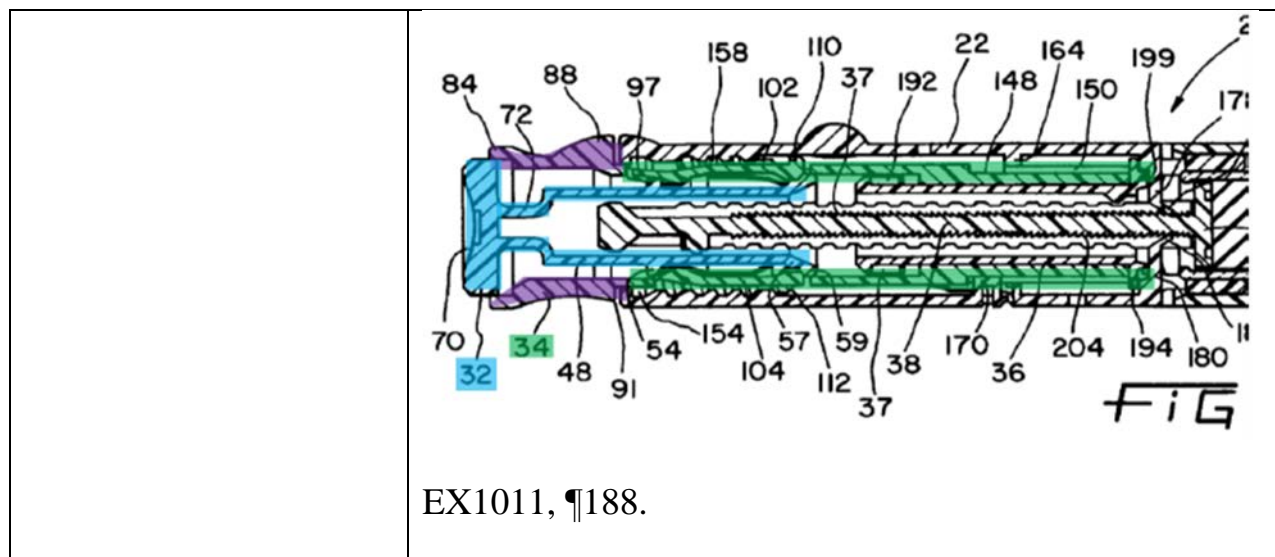
nature of the mechanism, the simplicity of its implementation, and the predictability of the modification, a POSA would have had no difficulty implementing this minor variation of the dial mechanism's threading. EX1011, ¶169. Implementing threads 110, 112 as a groove rather than a rib therefore would have been the use of well-known, familiar elements performing their same, predictable functions. *Id.*; *KSR*, 550 U.S. at 417.

Accordingly, POSAs applying their ordinary creativity would have found it obvious to modify Burroughs as discussed above and would have had a reasonable expectation of success in doing so. EX1011, ¶¶198-200. Burroughs thus rendered claim 1 obvious.

2. Claim 2

Burroughs suggests the additional limitations of claim 2:

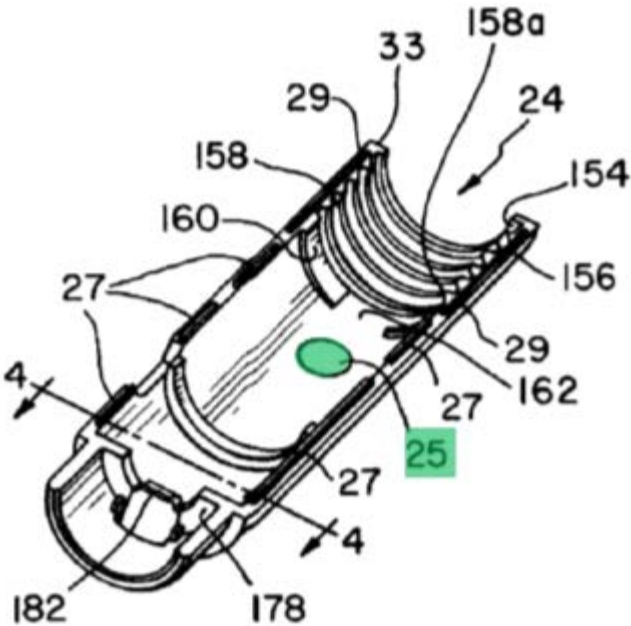
'486 Patent	
[2.] The housing part of claim 1, wherein said tubular clutch is directly coupled to said dose knob.	<i>See</i> disclosure accompanying elements 1.2, 1.3, and 1.6, <i>supra</i> . Figure 1 shows button 32 (annotated blue) directly coupled to dial mechanism 34 (annotated green), which includes proximal portion 78 (annotated purple):



Button 32 (the clutch) is releasably coupled to dial mechanism 34, which includes proximal portion 78 (the dose knob). Burroughs explains that button 32 engages dial mechanism via first step 57, which “prevent[s] dial tabs 102 and 104 from collapsing inward,” and second step 59, which “keep[s] button 32 centered within dial mechanism 34 and also prevent[s] button 32 from inadvertently falling or being removed from dial 34.” EX1013, 7:46-57, FIGS. 1, 14; EX1011, ¶202. Burroughs teaches that proximal portion 78 (the dose knob) is part of dial mechanism 34, so the direct coupling of button 32 to dial mechanism 34 teaches or at least suggests direct coupling of the clutch to the dose knob. EX1013, 7:46-8:8, FIGS. 1, 14; EX1011, ¶202. Burroughs therefore rendered claim 2 obvious.

3. Claims 3-4

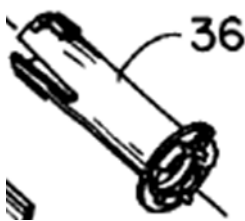
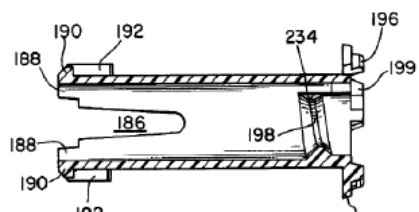
Burroughs teaches the additional limitations of claims 3-4:

'486 Patent	
<p>[3.] The housing part of claim 1, wherein said main housing comprises a window through which at least a portion of an outer surface of said dose dial sleeve may be viewable.</p>	<p>“As this displacement occurs, the segment of the dose-indicating scale which is visible through a window varies to show a linear increase in the number to indicate an increased dosage of liquid to be dispensed.” EX1013, 1:50-54.</p> <p>“A series of numerals . . . are printed on the surface of intermediate portion 80 of dial mechanism 34 . . . The lens 25 (FIG. 1) in housing part 24 is aligned with the numbers so that the appropriate number appears in the lens upon dialing up the dosage.” <i>Id.</i>, 10:5-12.</p>
<p>[4.] The housing part of claim 3, wherein said window is located near a proximal end of said main housing and near a helical rib provided on an inner surface of said outer housing.</p>	 <p style="text-align: center;">FIG. 3</p> <p>FIG. 3 (lens 25 annotated light green); EX1011, ¶203.</p>

Burroughs teaches that a portion of the main housing includes lens 25 (the window) through which at least a portion of an outer surface of dial mechanism 34 (dose-dial sleeve) may be viewable. EX1013, 1:50-54, 10:5-12, FIG. 3; EX1011, ¶¶203-4. Figures 2-3 show that lens 25 is located near the needle-end (“proximal end”) of housing part 24 (part of the main housing) and near helical groove 158 on the inner surface of the housing. *Id.*, FIGS. 2-3; EX1011, ¶¶203-4. A POSA would have recognized that helical groove 158 forms helically arranged ribs and grooves. EX1011, ¶¶205-7. Accordingly, Burroughs rendered claims 3-4 obvious.

4. Claim 5

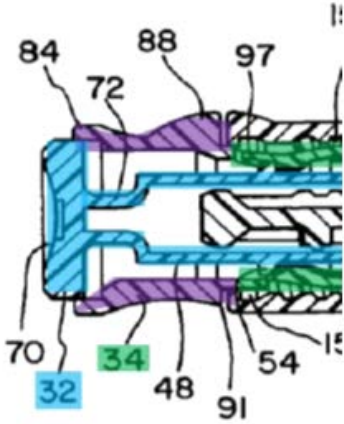
Burroughs teaches the additional limitations of claim 5:

'486 Patent	
<p>[5.] The housing part of claim 1, wherein said driver comprises a cylindrical shape.</p>	<div data-bbox="581 1129 824 1348">  </div> <p data-bbox="581 1390 1042 1432">EX1013, FIG. 2 (partial view).</p> <div data-bbox="587 1474 1003 1684">  </div> <p data-bbox="581 1726 1003 1768"><i>Id.</i>, FIG. 10; EX1001, ¶208.</p>

As shown in FIG. 2, nut 36 (the driver) has a cylindrical shape. *See, e.g.*, EX1013, FIG. 2; EX1011, ¶¶208-9. Thus, Burroughs rendered claim 5 obvious.

5. Claim 6

Burroughs teaches the additional limitations of claim 6:

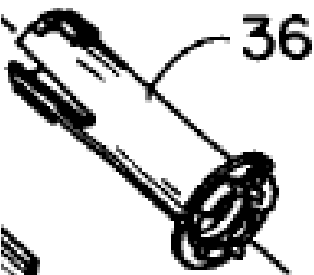
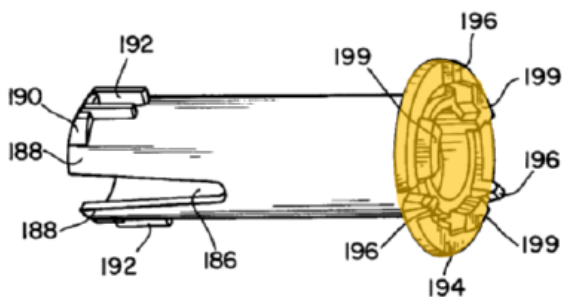
'486 Patent	
[6.] The housing part of claim 1, wherein said dose knob extends circumferentially around at least a portion of said tubular clutch.	<p><i>See</i> disclosure accompanying element 1.6, 1.7, and claim 2, <i>supra</i>.</p>  <p>EX1013, FIG. 1 (partial view; button 32 annotated blue, dial mechanism 34 annotated green, proximal portion 78 annotated purple); <i>see also id.</i>, FIG. 7; EX1011, ¶210.</p>

As shown in FIG. 1, at least a portion of button 32 (the clutch) is seated within proximal portion 78 (the dose knob) of dial mechanism 34. EX1013, 7:65-8:8; EX1011, ¶¶210-11. Burroughs thus teaches a dose knob that extends

circumferentially around at least a portion of the tubular clutch. Accordingly, Burroughs rendered claim 6 obvious.

6. Claims 12-13

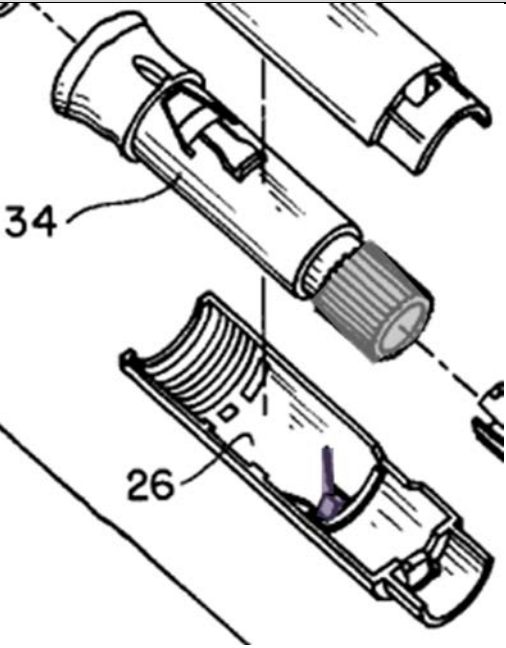
Burroughs teaches the additional limitations of claims 12-13:

'486 Patent	
<p>[12.] The housing part of claim 1, wherein said driver comprises at least one flange.</p>	<p>“The distal end of nut 36 comprises a flange 194 having, in the exemplary embodiment, three teeth 19 thereon.” EX1013, 9:18-20.</p>  <p><i>Id.</i>, FIG. 2.</p>
<p>[13.] The housing part of claim 12, wherein said at least one flange is located near a distal portion of said driver.</p>	 <p><i>Id.</i>, FIG. 10 (flange 194 annotated light orange); EX1011, ¶213.</p>

Nut 36 (the driver) includes flange 194 at its button-end (*i.e.* near its “distal portion”). EX1013, 9:16-20, FIGS. 2, 10; EX1011, ¶¶212-14. Accordingly, Burroughs rendered claims 12-13 obvious.

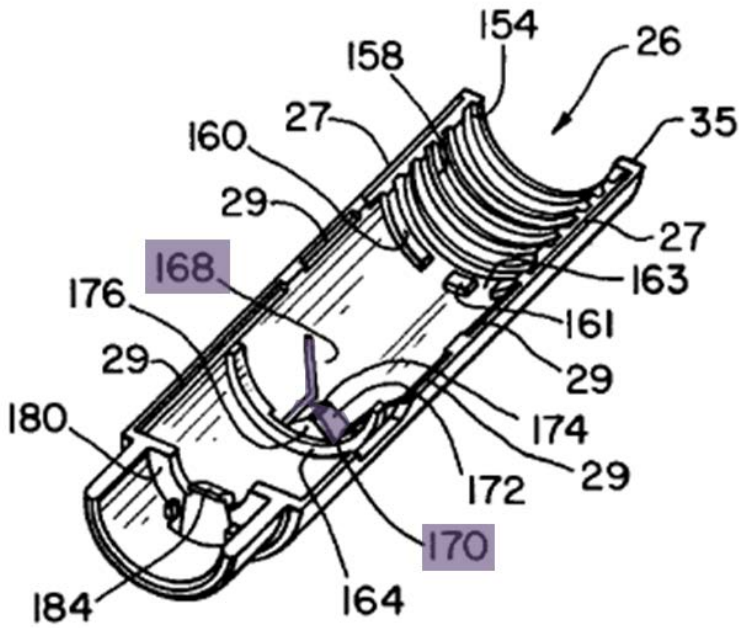
7. Claim 14-18 and 20

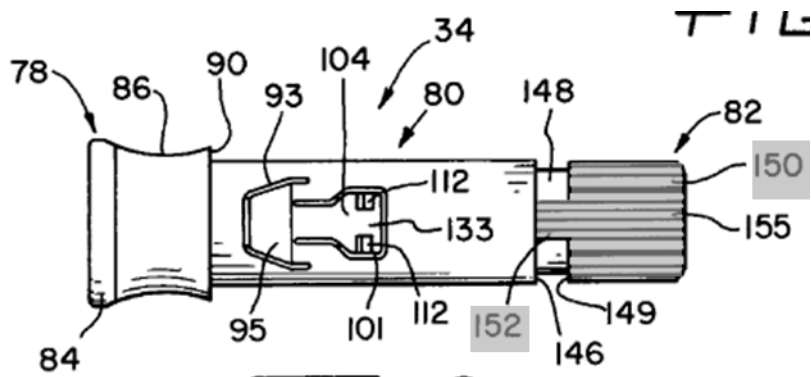
Burroughs teaches a clicker⁵ as recited in claims 14-18 and 20:

'486 Patent	
[14.] The housing part of claim 1, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose knob is rotated.	

⁵ Even if claim scope is indefinite, the Board nevertheless can determine whether embodiments plainly within the scope of the claim would have been obvious. *Ex parte McAward*, App. No. 2015-006416 at 22 n.5 (PTAB 2017) (precedential); *Ex parte Tanksley*, 26 USPQ2d 1384, 1387 (BPAI 1991) (same).

	<p>EX1013, FIG. 2 (partial view; housing finger 170 annotated purple, splines 150 annotated grey); EX1011, ¶230.</p> <p>“Housing part 26 includes grooves formed therein to define a flexible leg 168 having an inwardly extending finger 170 at the end thereof (FIG. 5).” EX1013, 9:4-6.</p> <p>“Rotation of dial mechanism 34 causes splines 150 to move past housing finger 170. The rotation of each spline 150 past finger 170 constitutes a single unit of dosage. As each spline 150 moves past finger 170, it causes a ‘click’ to occur, thereby providing an audible indication of each unit of dosage dialed up.” EX1013, 10:42-47; <i>see also id.</i> FIGS. 5, 8.</p>
[15.] The housing part of claim 14, wherein said clicker provides tactile feedback to a user when said dose knob is rotated.	<p>“The movement of finger 170 over first spline 152 and into V-shaped recess 155 between splines 152 causes a vibration in device 20 that can be felt by the user.” EX1013, 9:64-66; EX1011, ¶220.</p>
[16.] The housing part of claim 14, wherein said clicker provides audible feedback when said dose knob is rotated in a dose increasing	<p>“Once a dosage has been selected, that dosage may be made larger or smaller by rotating the dial assembly in either the clockwise or counterclockwise direction.” EX1013, 10:49-52; EX1011, ¶221.</p>

direction.	
[17.] The housing part of claim 14, wherein said clicker provides audible feedback when said dose knob is rotated in a dose decreasing direction.	See above disclosures for claims 14-16. EX1011, ¶222-23.
[18.] The housing part of claim 14, wherein said clicker comprises, at least one flexible arm, said flexible arm comprising at least one tooth member, and at least one spline, wherein when said dose knob is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.	<p>See claims 14-17, <i>supra</i>.</p> <p>“Housing part 26 includes grooves formed therein to define a flexible leg 168 having an inwardly extending finger 170 at the end thereof (FIG. 5).” EX1013, 9:4-6.</p>  <p>EX1013, FIG. 5 (flexible leg 168 and finger 170 annotated purple); EX1011, ¶224.</p>

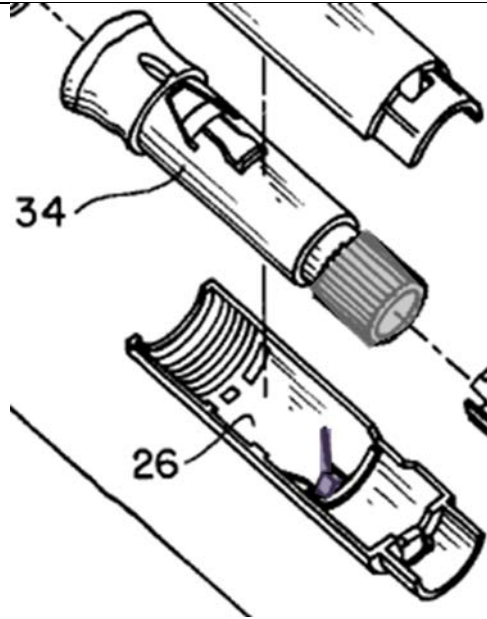


EX1013, FIG. 8 (splines 150, 152 annotated grey);
EX1011, ¶225.

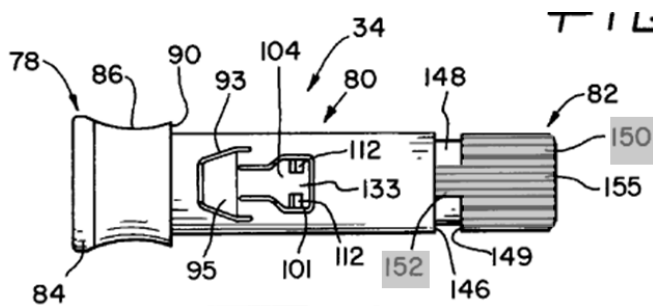
“Rotation of dial mechanism 34 causes splines 150 to move past housing finger 170. The rotation of each spline 150 past finger 170 constitutes a single unit of dosage. As each spline 150 moves past finger 170, it causes a ‘click’ to occur, thereby providing an audible indication of each unit of dosage dialed up.” EX1013, 10:42-47.

[20.] The housing part of claim 14, wherein said clicker generally comprises a cylindrical shape having a first and a second end, and said cylindrical shape is provided at said first end with at least

one flexible extending arm.



EX1013, FIG. 2 (partial view; housing finger 170 annotated purple, splines 150 annotated grey); EX1011, ¶230.



EX1013, FIG. 8 (splines 150, 152 annotated grey); EX1011, ¶225.

“In the initial radial position of dial mechanism 34 with respect to housing part 26, finger 170 of housing part 26 is located in groove 148 of dial mechanism 34. Groove 148 can be rotated by rotating dial mechanism 34 with respect to the housing.... Upon continued rotation of

	<p>dial 34 with respect to housing 26, splines 152 are moved into engagement with finger 170.”</p> <p>EX1013, 9:47-66.</p>
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Burroughs provides a clicker in the form of flexible leg 168, which includes flexible arm 170, operating in conjunction with splines 150 and 152, which are located at the bottom of dial mechanism 34. “Rotation of dial mechanism 34 causes splines 150 to move past housing finger 170”, which “causes a ‘click’ to occur, thereby providing an audible indication of each unit of dosage dialed up.” EX1013, 10:42-47; EX1011, ¶¶215-19. Burroughs thus teaches a clicker that provides “audible feedback to a user when said dose knob is rotated” as recited in claim 14.

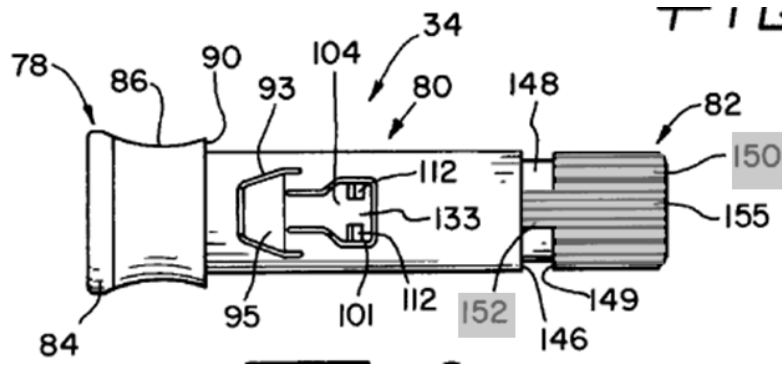
With respect to claim 15, Burroughs further explains that “movement of finger 170 over first spline 152 and into V-shaped recess 155 between splines 152 causes a vibration in device 20 that can be felt by the user.” EX1013, 9:64-66; EX1011, ¶220. Burroughs thus teaches the limitations of claim 15.

With respect to claims 16-17, Burroughs explains that the dialed dose “may be made larger or smaller by rotating the dial assembly in either the clockwise or counterclockwise direction.” EX1013, 10:49-52. Given the engagement of finger 170 with splines 150, 152, a POSA would have recognized that finger 170 would

drag over splines 150, 152, and therefore generate the “click” sound upon rotation of the dial assembly in either direction. EX1011, ¶¶221-23. Burroughs thus teaches a clicker that provides audible feedback when the dose knob is rotated in a dose increasing direction (claim 16) and a dose decreasing direction (claim 17).

With respect to claim 18, the clicker assembly described above includes flexible leg 168 (the flexible arm) with finger 170 (a tooth member) and splines 150, 152. EX1013, 9:4-6; 9:64-66, 10:42-47. Moreover, as noted above, Burroughs teaches that “[r]otation of dial mechanism 34 causes splines 150 to move past housing finger 170”, which “causes a ‘click’ to occur[.]” EX1013, 10:42-47. A POSA would have recognized that this interaction between flexible leg 168, with its finger 170, and splines 150, 152, flexible leg 168 deforms and drags finger 170 over splines 150, 152 to provide audible feedback. EX1011, ¶¶224-27. Burroughs thus teaches the additional limitations of claim 18.

With respect to claim 20, the clicker assembly described above includes splines 150, 152, which are arranged in a cylindrical configuration at the bottom of dial mechanism 34. EX1013, FIGS. 2, 8. The cylindrical shape of splines 150, 152 has a button-end (the “first end”, shown to the left below) and a needle-end (the “second end”, shown to the right below):



Id., FIG. 8 (splines 150, 152 annotated grey); EX1011, ¶225. Burroughs explains that in the initial position of dial mechanism 34, finger 170 “is located in groove 148 of dial mechanism 34”, which sits at the first end of splines 150, 152. EX1013, 9:47-66, FIG. 8; EX1011, ¶228-30. Finger 170 is part of flexible arm 178, so these components serve as a “flexible extending arm.” The “cylindrical shape” of splines 150, 152 is thus provided at its first end with a flexible extending arm. Burroughs thus teaches the additional limitations of claim 20. EX1011, ¶228-31.

To the extent “said cylindrical shape is provided at said first end with at least one flexible extending arm” requires that the arm be physically attached to the cylindrical shape, Burroughs nevertheless suggested such an arrangement, since a POSA would have recognized that the placement of the flexible arm and the splines were interchangeable. EX1011, ¶¶231-33. It would have been apparent to a POSA that Burroughs’ clicking assembly would operate the same with the placement of the splines and the flexible arm reversed (*i.e.*, with flexible leg 168

and its finger 170 formed on the cylindrical structure at the needle-end of dial mechanism and with splines 150, 152 located on the inner surface of the housing).

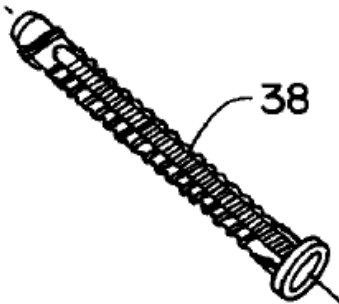
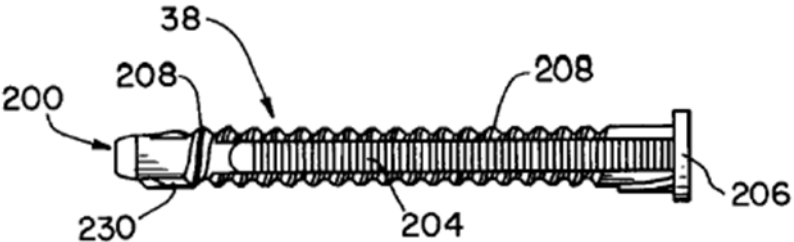
Id. Such configuration would have been a routine task for a POSA and would have been viewed as no more than “the predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. at 417; EX1011, ¶¶231-33. A POSA would have had a reasonable expectation of success in swapping the placement of these features, since this configuration would not change the principle of operation of the clicking mechanism and would merely have involved the use of well-known, familiar elements performing their same, predictable functions. *Id.*, ¶¶233-35; *KSR*, 550 U.S. at 417.

To the extent “clicker” is construed as a means-plus-function limitation, Burroughs teaches or at least suggests the corresponding structure. As taught by the ’486 patent, the helically extending arms of clicker 50 engage with splines on the housing to provide audible feedback of the dose being dialed. EX1003, 5:57-59. As taught by Burroughs, splines 150 and housing finger 170 provide at least an audible feedback to a user when said dose-dial grip is rotated. EX1013, 9:1-8, 9:47-66, 10:42-47 (clicking occurs as finger 170 on flexible leg 168 drags over splines 150, 152); EX1011, ¶219. Thus, both the ’486 patent and Burroughs teach the use of helical arm and splines to produce an audible click.

Accordingly, Burroughs rendered claims 14-20 obvious.

8. Claim 23

Burroughs teaches the additional limitations of claim 23:

'486 Patent	
<p>[23.] The housing part of claim 1, wherein said piston rod comprises a generally circular cross section.</p>	<p><i>See element 1.4, supra.</i></p> <p>“Thread 198 extends 350° about the inner surface of nut 36.” EX1013, 9:22-25.</p> <p>“Helical threads 208 extend along the axial length of leadscrew 36. Leadscrew 38 fits within the cylindrical opening of nut 36.” <i>Id.</i>, 9:30-32.</p> <p>“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.” <i>Id.</i>, 10:38-41.</p>  <p><i>Id.</i>, FIG. 2 (partial view; rotated)</p> 

	<i>Id.</i> , FIG. 12; EX1011, ¶¶236.
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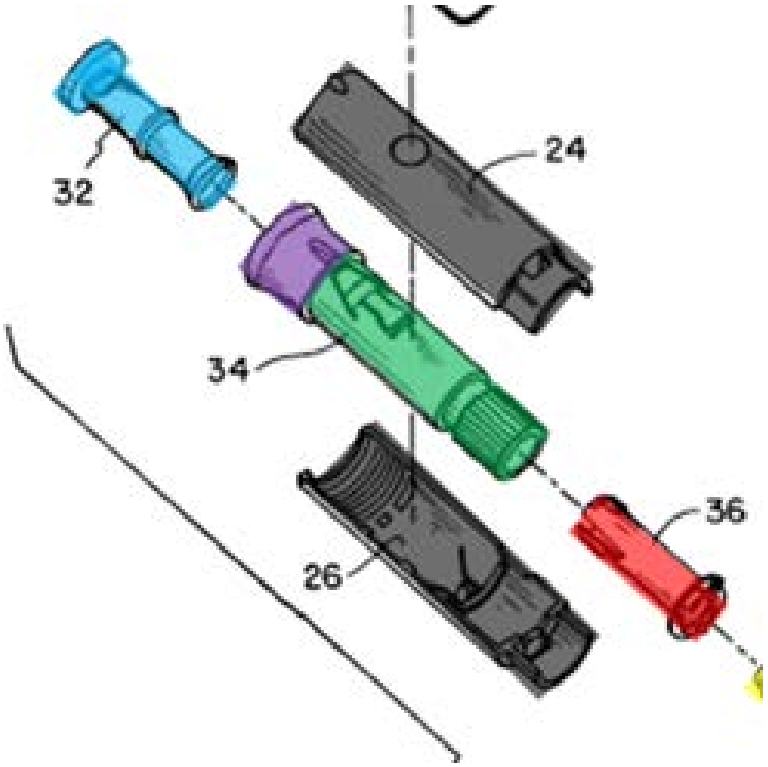
Claim 23 merely requires that the piston rod have “a” cross-section that is “generally circular.” As shown in FIGS. 2 and 12, plunger engagement portion 206 of leadscrew 38 has a circular cross-section. *See also* EX1013, 9:25-30 (identifying plunger engagement portion 206); EX1011, ¶¶236-37. The needle-end of leadscrew 38 also appears to have a circular cross-section. EX1013, FIGS. 2, 12; EX1011, ¶¶236-37. These features alone are sufficient to satisfy the additional limitations of claim 23.

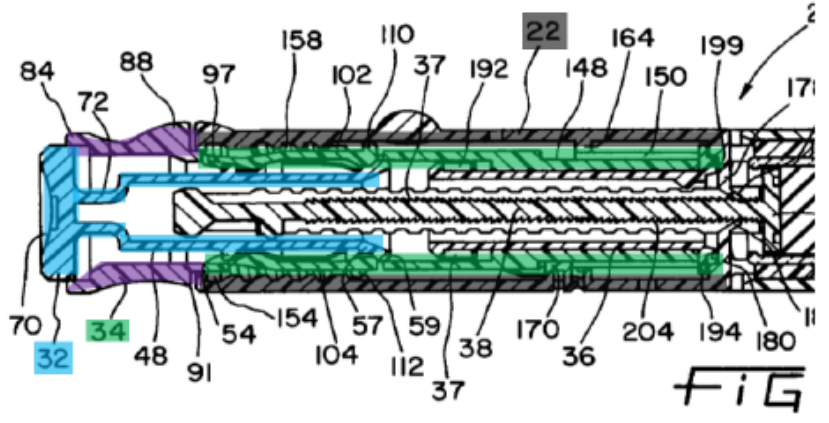
Even if claim 23 were construed as requiring a generally circular cross-section along the main body of the piston rod, the main body of leadscrew 38 still has a *generally* circular cross-section. *See* EX1013, FIGS. 2, 12; EX1011, ¶¶236-37. For example, threads 198 extend 350° about the inner surface of nut 36 (the driver), which is itself “generally cylindrical in shape”, and these threads engage helical threads 208 of leadscrew 38. EX1013, 9:12-32, 10:38-41. While the main body of leadscrew 38 is not *perfectly* circular, a POSA nevertheless would have viewed its cross-section as “generally” circular, particular since (1) even the piston rod described in the ’486 patent has a cross-section with certain non-circular features due to the threads themselves and (2) the ’486 offers no guidance as to the lower bound for what would be “generally” circular. EX1011, ¶¶236-37.

Accordingly, Burroughs rendered claim 23 obvious.

9. Claim 26

Burroughs teaches the additional limitations of claim 26:

'486 Patent	
<p>[26.] The housing part of claim 1, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.</p>	<p><i>See elements 1.2 and 1.7, supra.</i></p>  <p>EX1013, FIG. 2 (partial view; annotating button 32 (blue), dial mechanism 34 (green), proximal portion 78 (purple), and housing 22(gray)); EX1011, ¶126.</p>

	 <p>EX1013, FIG. 1 (partial view; same coloring as above); EX1011, ¶238.</p>
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As shown in FIG. 1, dial mechanism 34 (the dose-dial sleeve) is provided outside button 32 (the clutch) and radially inward of housing 22 (the main housing). EX1011, ¶238. Accordingly, Burroughs rendered claim 26 obvious.

10. Claims 27-29

Burroughs teaches the additional limitations of claims 27-29:

'486 Patent	
[27.] The housing part of claim 1, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided	

along an outer surface
of said dose dial sleeve.

[28.] The housing part
of claim 27, wherein
said helical rib extends
for at least a single
sweep of said inner
surface of said main
housing.

[29.] The housing part
of claim 27, wherein
said helical rib
comprises a single start
helical rib.

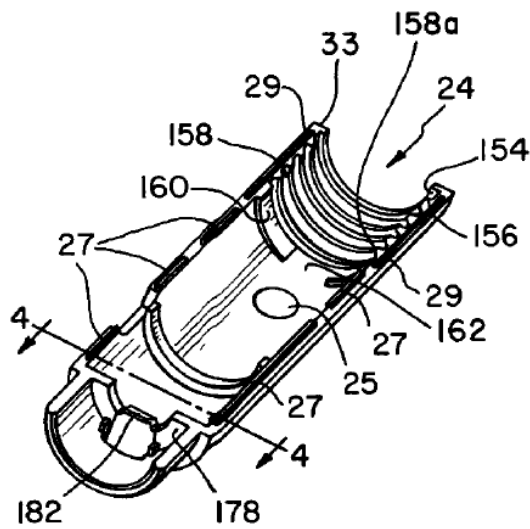


FIG. 3

EX1013, FIG. 3 (showing helical groove 158).

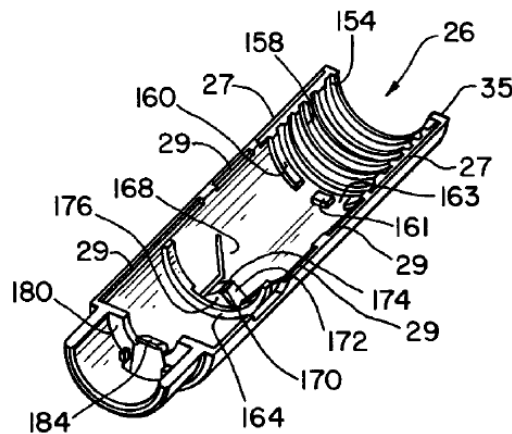


FIG. 5

Id., FIG. 5 (showing helical groove 158).

adapted to be seated in said helical groove provided along an outer surface of said dose dial sleeve,” as recited in claim 27.

With respect to claim 28, FIGS. 3 and 5 show that the threading on housing 22 “extends for at least a single sweep of said inner surface of said main housing”. EX1013, 8:65-9:1. The modification discussed above in §V.F.1.b would not affect this feature. EX1011, ¶¶240.

With respect to claim 29, Burroughs indicates that the threading on the housing a single starting position. Burroughs describes a “zero-dose radial position” of dial mechanism 34 that places threads 110, 112 (and keyway 133 within thread 112) into alignment with corresponding features of the housing thread. *See id.*, 8:62-9:11, 9:47-10:4, 10:28-38; EX1011, ¶¶241-43. For example, dose setting can only begin when keyway 133 aligns with key 161 in keyed opening 163. *See* EX1013, 10:28-38, FIGS. Burroughs’ description of the single starting position would have indicated to a POSA that the threading included a “single start” helical rib. EX1011, ¶243. The modification discussed above in §V.F.1.b would not impact this feature. EX1011, ¶¶241-44.

Accordingly, Burroughs rendered claims 27-29 obvious.

11. Claims 30 and 32

Burroughs teaches a “radial stop” as recited in claims 30 and 32:

'486 Patent	
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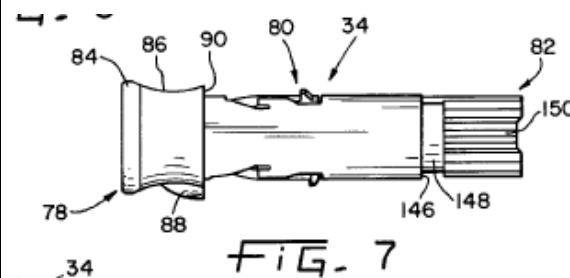
[30.] The housing part of claim 1, wherein said dose dial sleeve comprises at least one radial stop, said radial stop positioned near an end of said helical groove.

See elements 1.2 and 1.7 and claim 26, *supra*.

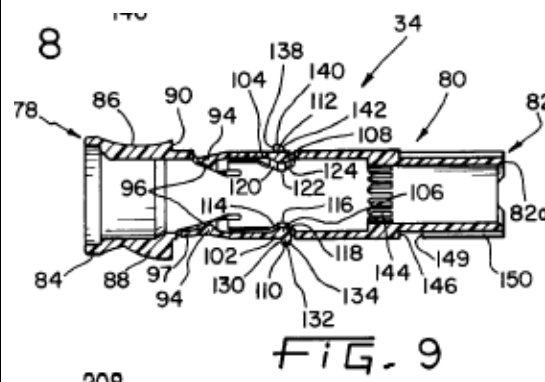
“[T]he insufficient remaining dose mechanism comprises a radial stop which ensures that the user cannot dial up a dosage greater than that remaining in the cartridge.” EX1013, 4:32-35.

“Once a predetermined maximum dosage has been dialed up, e.g. 60 unites, threads 110 and 112 have reached the proximal end of the helical groove 158. Dial mechanism 34 cannot be additionally rotated to further increase this maximum dosage due to an interference ledge at the end of helical groove 158.” *Id.* 10:65-11:1.

[32.] The housing part of claim 30, wherein said radial stop is positioned near a distal end of said helical groove.



Id., FIG. 7



Id., FIG. 9; see also *id.*, 4:24-27.

As shown in FIGS. 7 and 9, dial mechanism 34 (*i.e.* the dose-dial sleeve) includes “outwardly extending” threads 110, 112. EX1013, 8:25-41. These radial protrusions engage threading on the main housing to allow dial mechanism 34 to screw out of the housing during dose setting. *Id.*, 10:34-38. At a certain point, threads 110, 112 reach the end of the housing’s threading, at which point dial mechanism 34 “cannot be additionally rotated.” *Id.*, 10:65-11:1. A POSA would have recognized that this occurs when the lateral edge of the uppermost part thread (thread 112 as shown in FIG. 9) reaches a wall or other structure at the top end of the housing’s threading. EX1011, ¶¶245-249. In this way, the end of the housing’s thread and the lateral edge of thread 112 operate as stops to prevent further extraction of dial mechanism 34. *Id.* This lateral edge is a radially protruding structure (*i.e.* a radial stop) positioned near an end of threads 110, 112 (*i.e.* the helical groove, when modified as explained above in §V.F.1.b). Burroughs thus teaches the additional limitations of claim 30 and therefore rendered claim 30 obvious.

Claim 32 clarifies that the radial stop is located “near” a “distal end” of the helical groove. Although the ’486 patent does not explain which direction “distal” refers to, other claims suggest that it refers to the needle-end of the device. *See, e.g.*, EX1013, claim 7 (“during a dose dispensing step, said dose knob is activated in a distal direction”); EX1011, ¶¶250. Moreover, while the patent offers no

guidance for understanding the metes and bounds of what constitutes being “near” this distal end, a POSA nevertheless would have understood the above-identified “radial stop” to be “near” the distal end of threads 110, 112, since the lateral edge of the thread would be adjacent the thread’s bottom edge. EX1011, ¶250.

Burroughs thus rendered claim 32 obvious.

12. Claim 33

Burroughs teaches a “dose knob” as recited in claim 33:

'486 Patent	
[33.] The housing part of claim 1, wherein if a user inadvertently dials said dose knob in one direction beyond a desired dose, said dose knob may be rotated in a second direction so as to allow said dialed dose to be reduced.	<i>See</i> claims 16-17, <i>supra</i> .

Burroughs teaches that “dosage may be made larger or smaller by rotating the dial assembly in either the clockwise or counterclockwise direction.” *Id.*, 10:49-52. Accordingly, Burroughs rendered claim 33 obvious. EX1011, ¶¶251.

13. Claim 36

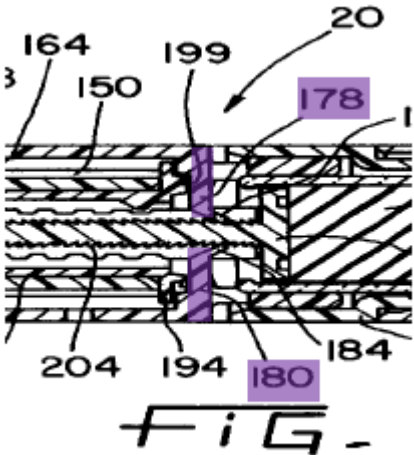
Burroughs teaches a “housing” as recited in claim 36:

'486 Patent	
[36.] The housing part of claim 1, wherein said housing part and said container comprises a disposable device.	<p>Burroughs is titled, “Recyclable Medication Dispensing Device.”</p> <p>“Injector pens may be reusable or disposable.” EX1013, 1:34-35.</p> <p>“In one embodiment, the device is made entirely out of a recyclable plastic material, except for the glass container, Steel needle and paper label.” <i>Id.</i>, 2:49-51.</p> <p>“Another advantage of the present invention is that the device is an inexpensive recyclable pen that is designed to allow a user to dose in single unit increments, which are each displayed in a single unit display.” <i>Id.</i>, 4:20-23.</p>

Burroughs is directed toward a recyclable device, and the POSA would understand that a device that a recyclable would also be capable of disposal. EX1013, 1:34-35, 2:49-51, 4:20-23; EX1011 ¶252. Accordingly, Burroughs rendered claim 36 obvious.

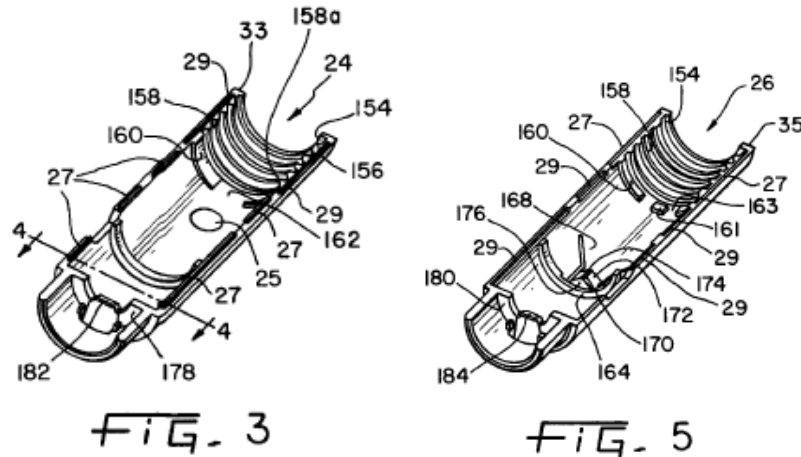
14. Claims 38-40

Burroughs teaches an insert⁶ as recited in claims 38-40:

'486 Patent	
<p>[38.] The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main housing, said insert secured against rotation.</p>	<p>“Housing parts 24 and 26 include bulkhead ledges 178, 180, respectively, to reduce the diameter through the proximal end of the housing. Ledges 178 and 180 include flexible tangs 182, 184, respectively.” EX1013, 9:8-11.</p> 
<p>[39.] The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main housing, and said insert secured against longitudinal motion.</p>	<p><i>Id.</i>, FIG. 1 (partial view; bulkhead ledges 178, 180 annotated purple); EX1011, ¶253.</p>

⁶ Again, even if indefinite, the Board nevertheless can determine whether embodiments plainly within the scope of the claim would have been obvious.

[40.] The housing part of claim 39, wherein said insert comprises an opening extending therethrough, such that said piston rod is configured to extend through said opening.



Id., FIGS. 3, 5.

Burroughs describes a bulkhead (*i.e.* the insert), which includes ledges 178 and 180, located toward the needle-end of main housing 22. EX1013, 9:8-11; *see also* FIG. 1. A POSA would have understood the bulkhead ledges to be fixed at a distal end of the main housing and secured against rotation (claim 38) and longitudinal motion (claim 39). *Id.*, 9:8-10 (bulkhead ledges 178 and 180 included as part of housing parts 24 and 26); *see also id.*, 9:56-59, 11:44-47 (bulkhead serves as stop for dial mechanism 34 and nut 36). Figures 3 and 5 (showing both halves of the housing) show that ledges 178 and 180, when joined, form a central opening extending through the bulkhead. EX1011, ¶253-54. Figure 1 further shows that leadscrew 38 (*i.e.* the piston rod) is configured to extend through this opening. Burroughs thus teaches all limitations of claims 38-40.

Accordingly, Burroughs rendered claims 38-40 obvious.

VI. CONCLUSION

For the reasons set forth above, claims 1-6, 12-18, 20, 23, 26-30, 32, 33, 36, and 38-40 of the '486 patent are unpatentable. The unpatentability of this patent is not an abstract concern. The high cost of insulin products reduces patient compliance, with adverse effects for American diabetics. *See* EX1035, 2, 8. Mylan therefore requests that an IPR of these claims be instituted.

/ Richard Torczon /

Reg. No. 34,448

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

Under the provisions of 37 C.F.R. §42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for Inter Partes Review totals 10,089, 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. 8,992,486 and Exhibits 1001-1035** by Federal Express Next Business Day Delivery on 29 October 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: 29 October 2018

/Wesley E. Derryberry /
Reg. No. 71,594