

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN PHARMACEUTICALS INC.,  
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,  
Patent Owner.

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Case No. IPR2018-01675  
Patent No. 8,603,044

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**PETITION FOR *INTER PARTES* REVIEW**

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## LIST OF EXHIBITS

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

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

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
1027	WO 99/38554 – S.Steenfeldt-Jensen & S.Hansen, “An Injection Syringe” (pub’d Aug. 5, 1999) (Steenfeldt-Jensen PCT)
1028	Mylan GmbH and Biocon’s Preliminary Claim Constructions and Supporting Evidence Pursuant to L. Pat. R. 4.2, <i>Sanofi-Aventis U.S., LLC v. Mylan N.V.</i> , C.A. No. 17-cv-09105
1029	Memorandum Opinion, <i>Sanofi-Aventis U.S. LLC v. Merck Sharp &amp; Dohme Corp.</i> , No. 16-cv-812 (filed Jan. 12, 2018)
1030	Memorandum Opinion, <i>Sanofi -Aventis U.S. LLC v. Eli Lilly and Co.</i> , No. 14-cv-113 (filed Jan. 20, 2015)
1031	N. Sclater & N.P. Chironis, Mechanisms & Mechanical Devices Sourcebook 191-95, “Twenty Screw Devices” (3d ed., July 2, 2001)
1032	EP 0 608 343 B1 – L. Petersen & N.-A. Hansen, “Large Dose Pen” (pub’d Oct. 18, 1991)
1033	A.G. Erdman & G.N. Sandor, “Mechanical Advantage”, §3.7 in 1 Mechanism Design: Analysis and Synthesis (1984)
1034	WO 01/83008 – S. Hansen & T.D. Miller., “ <i>An Injection Device, A Preassembled Dose Setting And Injection Mechanism For An Injection Device, And A Method Of Assembling An Injection Device</i> ” (pub’d Nov. 8, 2001)
1035	K.J. Lipska et al., <i>Association of Initiation of Basal Insulin Analogs vs Neutral Protamine Hagedorn Insulin With Hypoglycemia-Related Emergency Department Visits or Hospital Admissions and With Glycemic Control in Patients With Type 2 Diabetes</i> , 320 J. Am. Med. Ass’n 53-62 (2018).

## **I. INTRODUCTION**

Petitioner (“Mylan”) petitions for *inter partes* review (“IPR”) of U.S. Patent 8,603,044 to Veasey et al., entitled “Pen-Type Injector” (“the ’044 patent,” EX1002). 35 U.S.C. 311.

This Petition shows a reasonable likelihood that prior art renders claims 11, 14, 15, 18, and 19 unpatentable.

## **II. MANDATORY NOTICES**

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

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

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

The ’044 patent has been asserted in *Sanofi-Aventis U.S. LLC, et al. v. Mylan GmbH, et al.*, No. 2:17-cv-09105 (D.N.J.), filed October 24, 2017. Mylan and Biocon entities listed above are parties to this litigation. Becton Dickinson and Company supplies pens to Mylan, but has not been named as a party.

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

Mylan has filed IPR2018-01676 also challenging claims 11, 14, 15, 18 and 19 of the '044 patent. Mylan has filed IPR2018-01670, IPR2018-01677, IPR2018-01678, IPR2018-01679, IPR2018-01680, IPR2018-01682, IPR2018-01684 and IPR2018-01696 against related patents.

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

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Please direct all correspondence to lead counsel and back-up counsel at the contact information above. Mylan consents to electronic mail service at

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

### **III. CERTIFICATIONS (37 C.F.R. §42.104(a))**

Mylan certifies that the '044 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 '044 patent claims 11, 14, 15, 18, and 19 under pre-AIA 35 U.S.C. 103, as Mylan's detailed statement of the reasons for the relief requested sets forth, supported with exhibits, including the Declaration of Karl Leinsing (EX1011).

Claims 11, 14, 15, 18, and 19 of the '044 patent were obvious over U.S. Patent 6,221,046 (EX1013, "Burroughs") (Ground 1).

### **V. STATEMENT OF REASONS FOR THE RELIEF REQUESTED**

#### **A. Summary of the Argument**

The challenged claims relate to a drive mechanism for dispensing medicine, such as insulin and insulin analogs, from a pen-type injector. EX1002, Title, 1:20-29. At its core, the challenged independent 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 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 a predictable way. Claims 11, 14, 15, 18, and 19 are therefore unpatentable over the prior art.

**B. ’044 Patent<sup>1</sup>**

**1. Background**

The ’044 patent relates to a pen-type injector for self-administration of medicine, such as insulin and insulin analogs. EX1002, Title, 1:20-29. According to the ’044 patent, such injectors are appropriate for patients who do not have formal medical training, including diabetes patients. *Id.*, 1:25-29. The ’044 patent states that such injectors must be easy to use, because patients using the device may have impaired vision or other physical infirmities. *Id.*, 1:23-31.

The ’044 patent specifically describes and claims a housing part containing a drive mechanism for dispensing medicine from an injector. The ’044 patent issued

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<sup>1</sup> For uniformity, when discussing both the ’044 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.

with 20 claims, of which this petition challenges only claims 11, 14, 15, 18, and 19.

Claim 11 is an independent claim from which claims 14, 15, 18, and 19 ultimately depend. Claim 11 recites:

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

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

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

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

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

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

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

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

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

*Id.*, 8:7-36.

Independent claim 11, therefore, recites six components that form the claimed device:

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

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

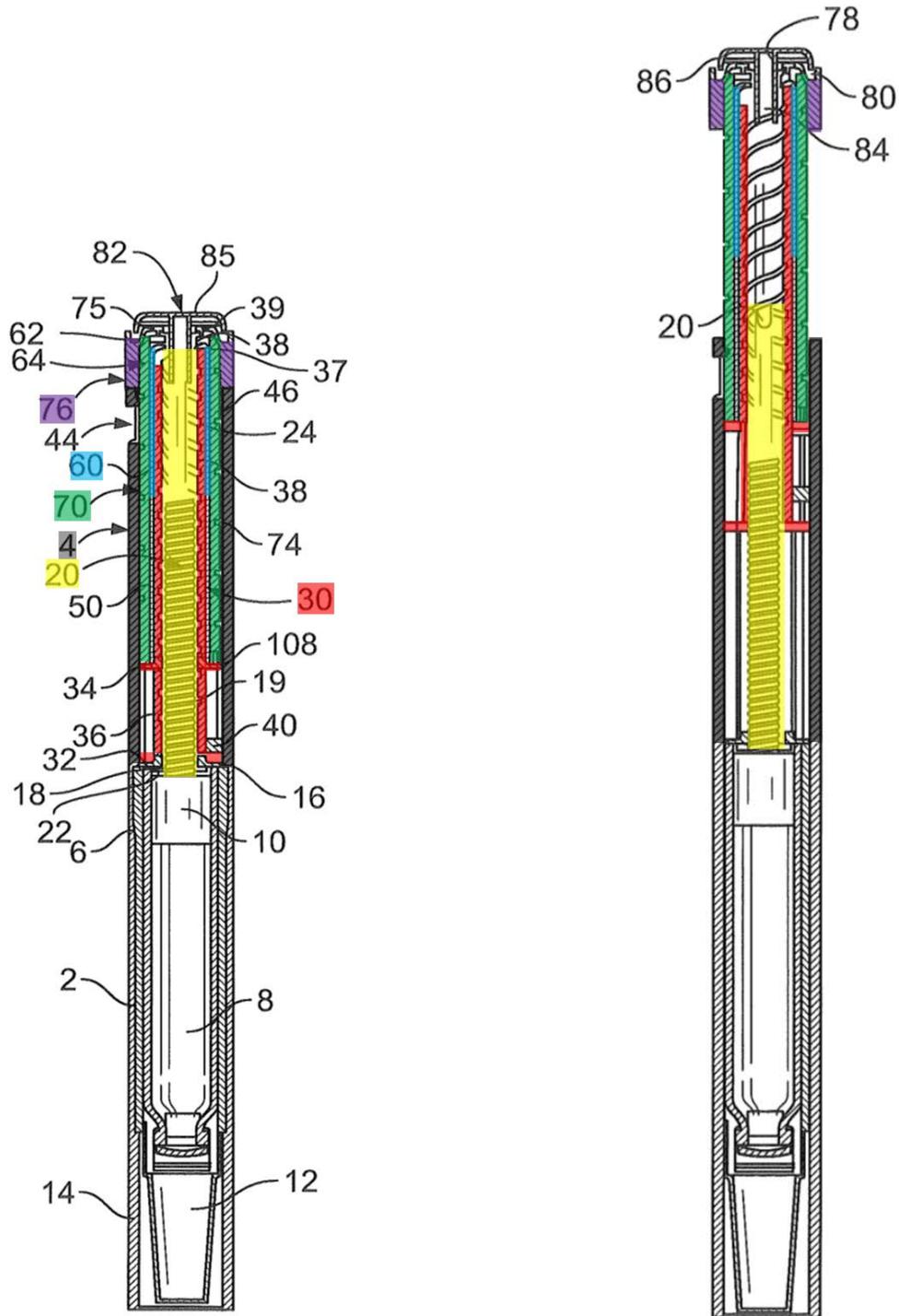
(3) a “dose dial grip” (76, purple), which is a grip for the user to manipulate the dose dial sleeve, *e.g.*, *id.*, 5:24-32, 50-53, FIGS. 1-5, 9-11;

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

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

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

FIGS. 1 (left) and 2 (right) of the '044 patent are reproduced below, with color-coding added to highlight the above components. 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.

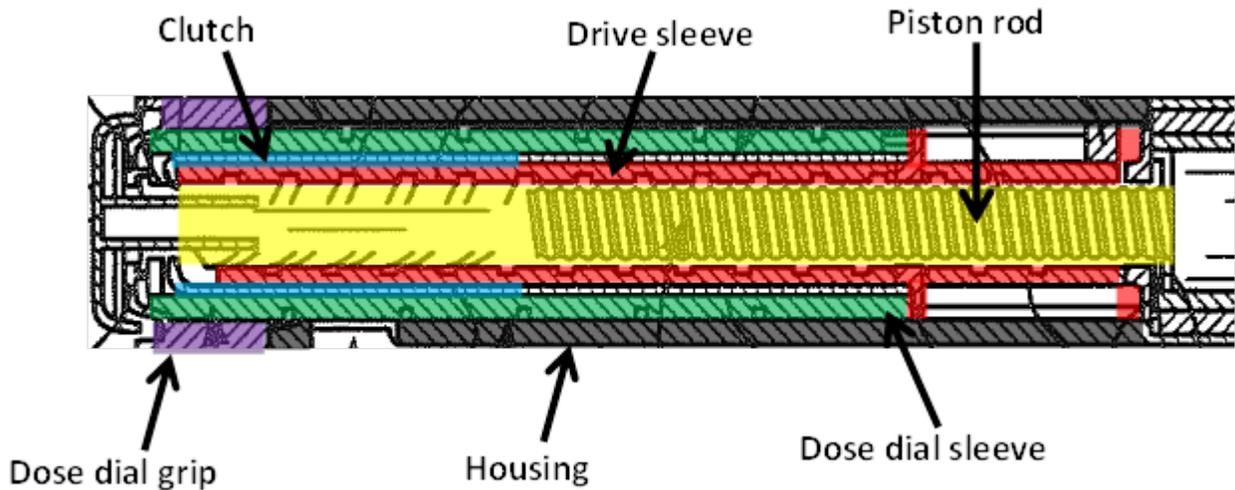
### *Brief Overview of the Disclosed Embodiments*

The '044 patent describes an injector having a housing formed from two parts: (1) a first cartridge-retaining part 2, which contains a cartridge 8 from which medicine is dispensed, and (2) a second main-housing part 4 (gray). EX1002, 3:27-38, FIG. 1. The second main-housing part 4 houses the mechanism that serves to drive a piston 10 contained within the cartridge 8 to dispense medicine. *Id.*, FIG. 1.

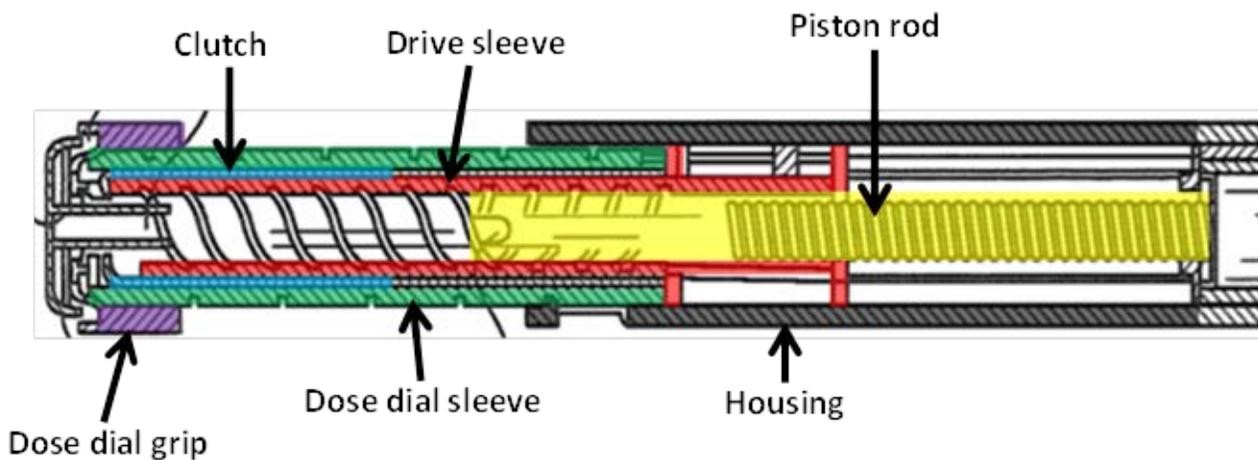
In an exemplary embodiment, at a needle-end<sup>2</sup> of the housing part 4, an insert 16 is provided. *Id.*, 3:49-50; FIG. 1. The insert 16 is fixedly connected to the housing, both rotationally and axially, and includes a threaded circular opening 18, through which the needle-end of a piston rod 20 (yellow) extends. *Id.*, 3:49-59; FIG. 1. The piston rod 20 includes a first thread 19 that engages with the insert's threaded opening 18. *Id.*, 3:56-59; FIG. 1. The piston rod 20 also includes a pressure foot 22 at this end, which abuts a piston 10 of the cartridge 8. *Id.*, 3:59-61; FIG. 1.

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<sup>2</sup> The specification refers to the needle-end of the device as its “first end,” and the button-end as its “second end.” *E.g.*, *id.*, 3:8-14. Claim 11 refers to the needle-end of the device as its “distal end,” and the button-end as its “proximal end.” *Id.*, claim 11.



**Partial view of FIG. 1 showing injector in a cartridge-full position, prior to dose setting (*id.*, 2:53-55), highlighting components (EX1011, ¶39)**



**Partial view of FIG. 2 showing injector in a maximum dose-dialed position (EX1002, 2:56-57), annotated to highlight components (EX1011, ¶39)**

The piston rod 20 also includes a second thread 24 that extends from its button-end. EX1002, 3:61-62; FIGS. 1-2. A drive sleeve 30 (red) extends about the piston rod 20. *Id.*, 4:4; FIG. 1. The drive sleeve 30 includes a helical groove 38 extending

along its internal surface that engages with the second thread 24. *Id.*, 4:11-14; FIG. 1.

Clutch 60 (blue) is “disposed about the drive sleeve 30, between the drive sleeve 30 and a dose dial sleeve 70 [green].” *Id.*, 4:33-35; FIGS. 1, 6-7. The clutch 60 is “generally cylindrical” and located adjacent the button-end of the drive sleeve 30. *Id.*, 4:49-51; FIG. 1. “The clutch 60 is keyed to the drive sleeve 30 by way of splines ... to prevent relative rotation between the clutch 60 and the drive sleeve 30.” *Id.*, 4:60-62. At its button-end, the clutch 60 includes a plurality of dog teeth 65. *Id.*, 4:58-60; FIGS. 1-2, 8. The teeth 65 are configured to releasably engage with the button-end of dose-dial sleeve 70.<sup>3</sup> *Id.*, 2:17-19, 6:27-30; FIG. 1.

Dose-dial sleeve 70 is “provided outside of” the clutch 60 and “radially inward of” the housing 4. *Id.*, 5:3-5; FIG. 1. “A helical groove 74 is provided about an outer surface of the dose dial sleeve 70.” *Id.*, 5:5-6; FIGS. 1-2, 12. “The main housing 4 is further provided with a helical rib 46, adapted to be seated in the helical groove 74” to allow for relative rotation. *Id.*, 5:9-11; FIGS. 15-16. “A dose dial grip 76 [purple] is

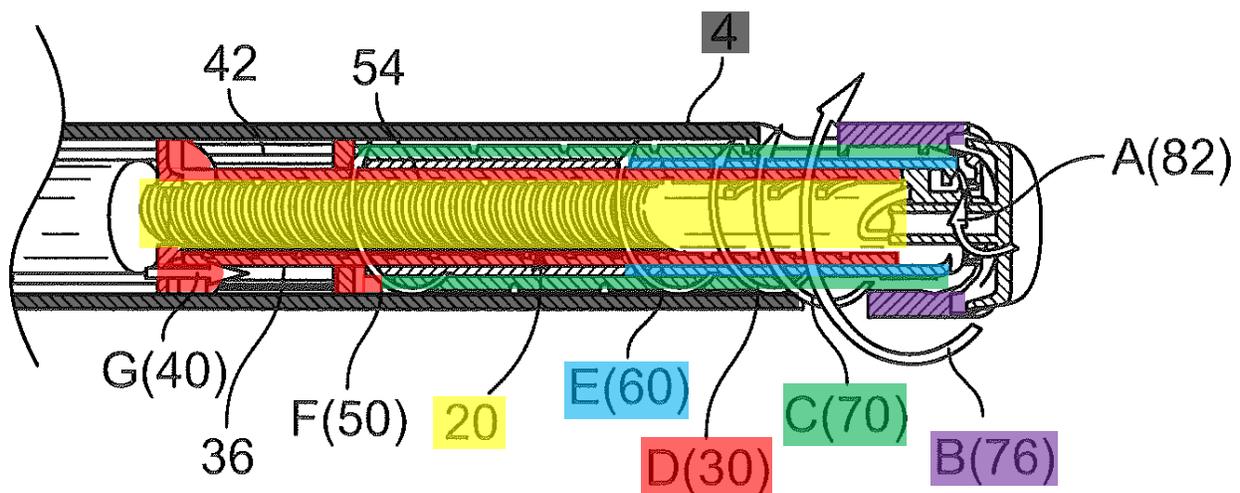
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<sup>3</sup> The specification does not specifically explain or show how the teeth 65 engage with the dose dial sleeve 70. As Mr. Leinsing explains, the teeth 65 engage with “an inwardly directed flange in the form of [a] number of radially extending members 75” provided at the dose dial sleeve 70’s button-end. EX1011, ¶196 (citing EX1002, 5:22-24).

disposed about an outer surface of the [button-end] of the dose dial sleeve 70.” *Id.*, 5:24-25; FIGS. 1-2. “The dose dial grip 76 is secured to the dose dial sleeve 70 to prevent relative movement therebetween.” *Id.*, 5:27-29.

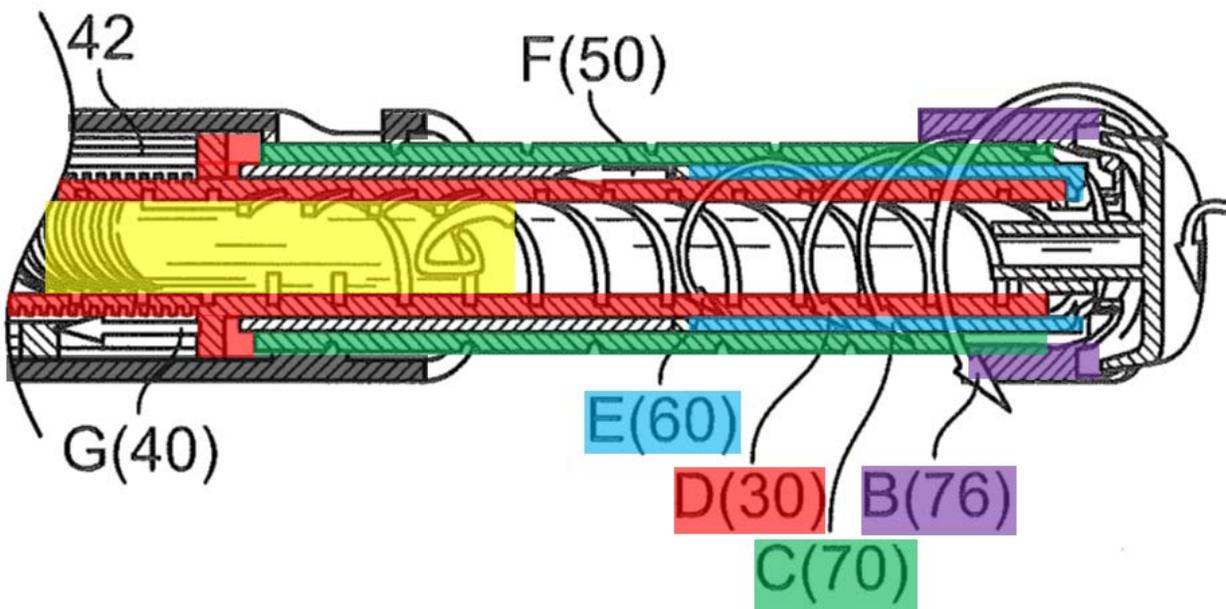
### *Operation of the Pen Injector*

**Dose setting:** To set a dose, the user rotates dose dial grip 76 in one direction. *Id.*, 5:50-51; FIG. 9 (reproduced and color-coded below). At this stage, the teeth 65 of the clutch 60 are engaged to dose-dial sleeve 70. *Id.*, 2:17-19; 5:50-53. Such engagement causes the dose-dial sleeve 70, the clutch 60, and the drive sleeve 30 to rotate together out of the housing. *Id.*, 5:50-53; FIG. 9. The drive sleeve 30 rotates up the piston rod 20, toward its button-end, due to its engagement with the piston rod 20’s second thread 24. *Id.*, 5:61-65. The piston rod 20 is prevented from rotating due to its opposing, threaded engagement with the insert 16. *Id.*, 4:1-2, 6:1-3.



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

The user also may dial down a dose, if needed. *Id.*, 6:16-19; FIG. 10 (reproduced and color-coded below). To dial down, the user rotates the dose-dial grip 76 in the opposite direction. *Id.*, 6:19; FIG. 10. “This causes the system to act in reverse,” where the dose-dial sleeve 70, the clutch 60, and the drive sleeve 30 rotate together back into the housing. *Id.*, 6:19-20; FIG. 10. As such, the drive sleeve 30 rotates down the piston rod 20, toward its needle-end, without corresponding rotation of the piston rod 20. *Id.*, 6:1-3, 6:16-20; FIG. 10.

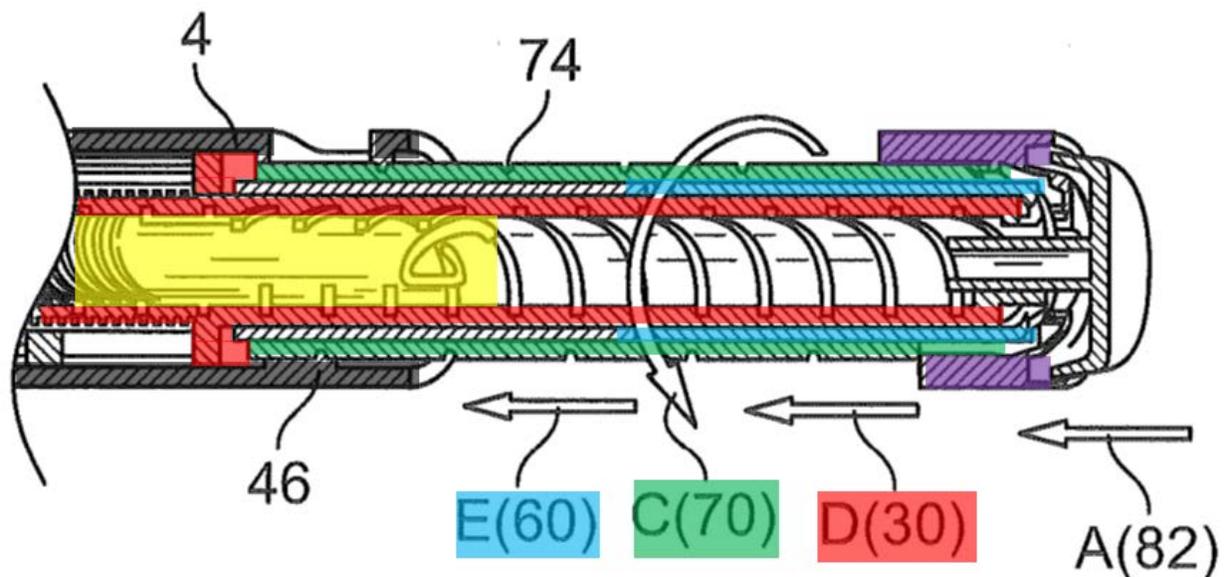


**FIG. 10: Dialing down (*id.*, 3:5-6), highlighting components (EX1011, ¶83)**

**Injection:** Once the dose is set, the user presses a button 82, applying a force toward the device’s needle-end. *Id.*, 6:27-28; FIG. 11 (reproduced and color-coded below). This displaces the clutch 60 axially such that the teeth 65 disengage from the dose-dial sleeve 70. *Id.*, 6:28-30. Dose-dial sleeve 70 rotates back into the

housing 4 via its threaded connection with the housing. *Id.*, 6:32-34; FIG. 11.

Now disengaged from the dose-dial sleeve 70, clutch 60 does not follow this rotation but instead moves axially toward the device's needle-end. *Id.*, 6:30-32, 6:37-39. The drive sleeve 30 also moves axially toward the needle-end, driving the piston rod 20 to rotate through the threaded opening 18, causing medicine to be dispensed from the cartridge 8. *Id.*, 6:44-46, FIG. 11.



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

## 2. Prosecution History

The '044 patent issued from U.S. Application 13/909,649 (the "'649 application"), which claims priority to GB Application No. 0304822.0, filed March 3, 2003. This is the '044 patent's earliest possible priority date.

During prosecution, the examiner rejected the '649 application's claims for

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

In response, applicants amended the claims to address rejections under §112 and to overcome the §103 rejection by requiring that the “helical groove” of the dose-dial sleeve be “provided along an outer surface of [the] dose dial sleeve.” EX1007, 211. Applicants argued that Walters did not disclose (1) a helical groove provided along an outer surface of a dose-dial sleeve, (2) a helical groove to engage a threading provided by a main housing, (3) a clutch as described in the ’649 application, or (4) a dose-dial sleeve that extends circumferentially around at least a portion of a tubular clutch. *Id.*, 211-12.

### **C. Level of Ordinary Skill in the Art**

For the purposes of this petition, the relevant timeframe is prior to March 3, 2003, the earliest priority date the ’044 patent claims. As Mr. Leinsing explains, a POSA at the relevant time would have had at least a bachelor’s degree in mechanical engineering, or an equivalent degree, and approximately three years of experience in medical-device design. EX1011, ¶104. 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 may be given their ordinary and accustomed meaning, consistent with the specification and how a POSA would have understood them. 37 CFR §42.100(b); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc).

The Patent Owner has taken positions regarding the meaning of certain claim terms in related litigations, and cannot now argue these positions are unreasonable. *Ex parte Schulhauser*, Appeal No. 2013-007847, slip op. 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.”). The relevant terms are listed below, along with Sanofi’s proffered construction for those terms.

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

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

**piston rod**: “A rod that engages with the drive sleeve ... to advance the piston

during dose dispensing.” EX1019, 27.

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

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

In related litigation with Sanofi, Mylan proffered preliminary means-plus-function constructions for “tubular clutch” and “clicker.” EX1028, 54-59, 65-68. The district court in that litigation has not yet issued 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 identifies the following corresponding structure. For the “tubular clutch” or “clutch,” the function is that, during dose setting, it “clutch[es], i.e., coupling and decoupling a movable component from another component,” or it “operates to reversibly lock two components in rotation.” *Id.*, 56. FIGS. 1, 5-11, component 60 provide the corresponding structure for the clutch. *Id.*, 54, 57; *also* EX1002, 2:16-18, 4:49-62, 4:63-65, 6:33-43.

For a clicker,<sup>4</sup> the function is “providing at least an audible feedback to a user

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<sup>4</sup> Even if the claim scope is indefinite, the Board still can determine whether embodiments plainly within the claim scope would have been obvious. *Ex parte*

when said dose dial grip is rotated.” EX1028, 67-68. FIGS. 6-8 provide the structure of the clicker, component 50. *Id.*, 62-63; EX1002, 2:20-22, 2:23-28, 2:29-35, 4:33-35, 4:36-48, 4:63-67.

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

#### **E. The Prior Art**

As Mr. Leinsing explains, and as addressed in further detail below (§V.F), claims 11, 14, 15, 18, and 19 would have been obvious to a POSA at the relevant time. Numerous pen-type injectors were known before March 3, 2003, including many that used the same six-component structure broadly claimed in the '044 patent.

Burroughs is prior art to the '044 patent under pre-AIA §102(b). Burroughs discloses a medication-dispensing pen for dispensing selectively measured dosages of medicine. EX1013, 1:13-16. In particular, as shown in FIGS. 1 and 2 (color-coded below), Burroughs describes a pen that comprises six components (EX1011, ¶126):

(1) a “housing 22,” having a “first part 24” and a “second part 26” (**gray**),

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*McAward*, App. No. 2015-006416 at 22 n.5 (PTAB 2017) (precedential); *Ex parte Tanksley*, 26 USPQ2d 1384, 1387 (BPAI 1991) (same).

which houses the drive mechanism for dispensing medicine from a cartridge,  
EX1013, 7:15-20; EX1011, ¶157;

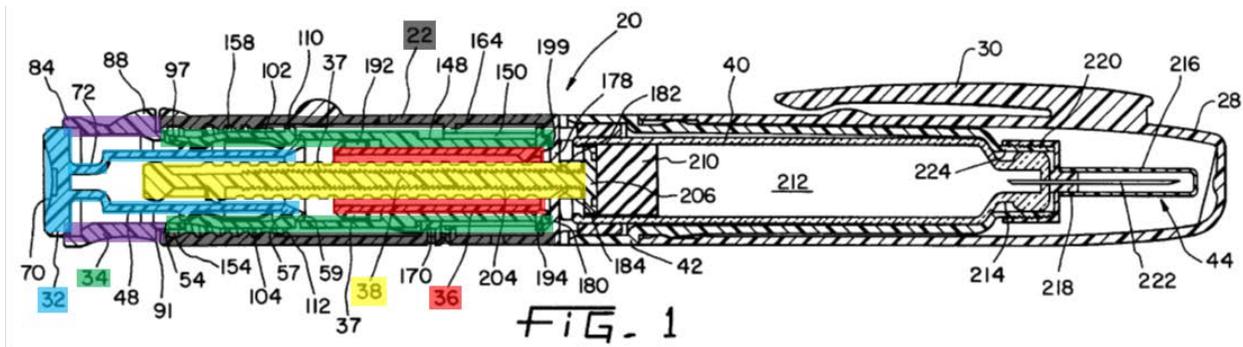
(2) a “dial mechanism 34” (**green**), which the user manipulates to set a specific dose for injection, EX1013, 10:38-42;

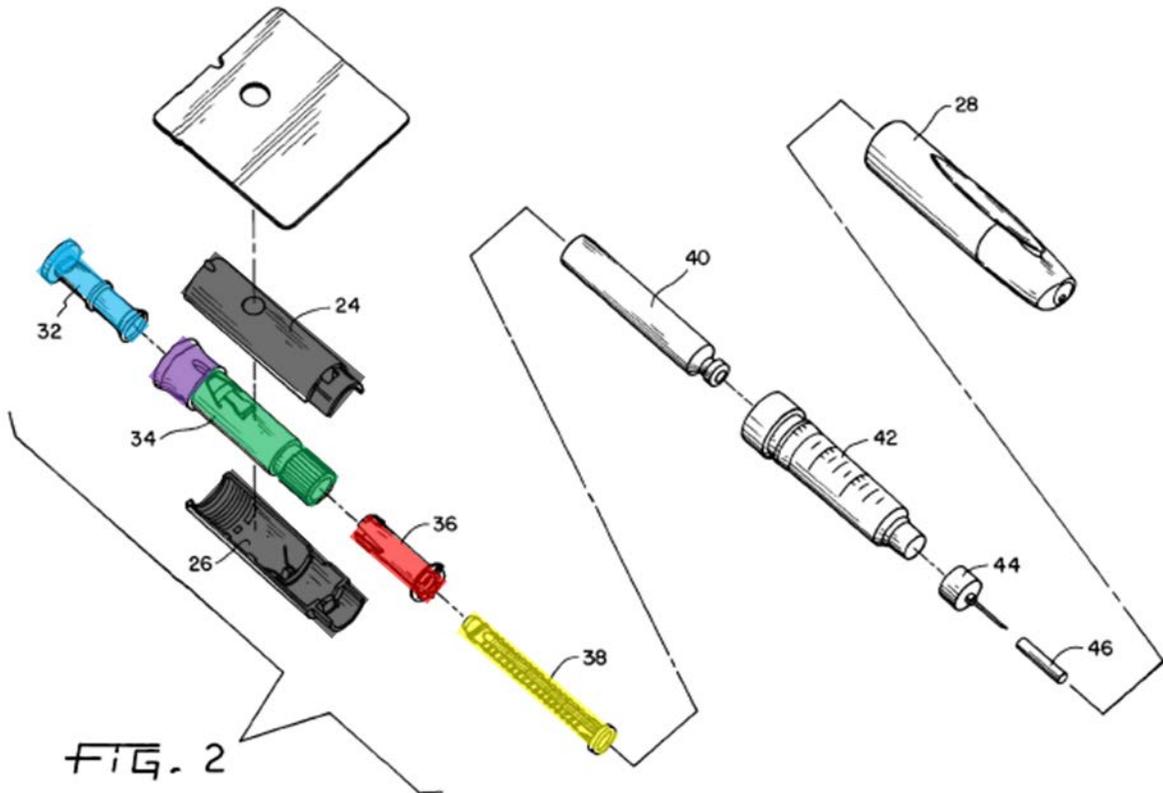
(3) a “proximal portion 78” (**purple**), which serves as a grip for the user to manipulate the dial mechanism, EX1013, 8:2-8;

(4) a “leadscrew 38” (**yellow**), which is driven to move a piston provided within the cartridge to dispense medicine, EX1013, 9:26-34;

(5) a “nut 36” (**red**), which drives the leadscrew, EX1013, 9:12-25, 11:31-34;  
and

(6) a “button 32” (**blue**), which rotationally decouples the dial mechanism from the housing and the nut during injection, EX1013, 11:13-34.





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

Burroughs discloses each of the six components in independent claim 11, except Burroughs’ “dose dial sleeve” (dial mechanism 34) includes a helical rib, rather than a helical groove. §V.F.1 (below). But a POSA at the relevant time would have considered modifying Burroughs’ dial mechanism 34 to include a helical groove instead to be an obvious alternative. §V.F.2.

**F. Ground 1: Claims 11, 14, 18, and 19 Were Obvious over Burroughs**

Burroughs disclosed a medication dispensing pen that includes the same six components broadly claimed by the ’044 patent. Five of those components include the same structural elements recited in independent claim 11. Regarding the sixth,

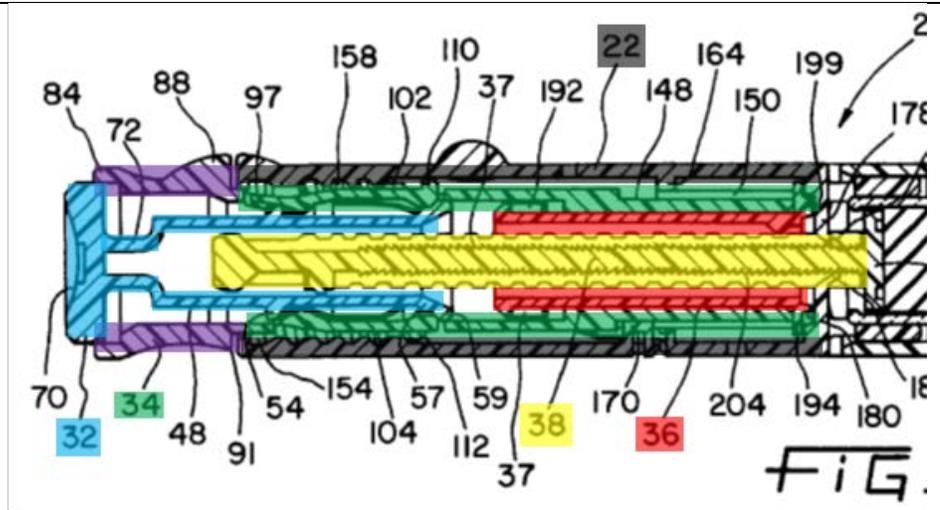
the claimed “dose dial sleeve,” Burroughs’ dial mechanism has threads on its outer surface that form a helical rib, which engages with the main housing’s helical groove, rather than an outer-surface helical groove engaging with main-housing threading as recited in independent claim 11. As discussed in §V.F.2 below, however, a POSA would have considered swapping 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 an obvious alternative.

*Independent Claim*

**1. Element-by-element analysis**

To the extent the preamble of claim 11 is limiting, Burroughs discloses it:

<b>'044 Patent</b>	<b>Burroughs</b>
<p>[11.Preamble] A housing part for a medication dispensing apparatus, said housing part comprising:</p>	<p>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.</p>



*Id.*, FIG. 1 (annotated above); EX1011, ¶157.

“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. *E.g.*, EX1013, Abstract, 7:15-17, FIG. 1; EX1011, ¶156. The device 20 includes a mechanism housing 22 containing the device’s drive mechanism. EX1013, 7:17-19, FIG. 1; EX1011, ¶156. Accordingly, Burroughs taught the preamble of claim 11.

Burroughs taught “a main housing” as recited in element [11.1]:

<b>'044 Patent</b>	<b>Burroughs</b>
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[11.1] a main housing, said main housing extending from a distal end to a proximal end;

Burroughs discloses a 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.

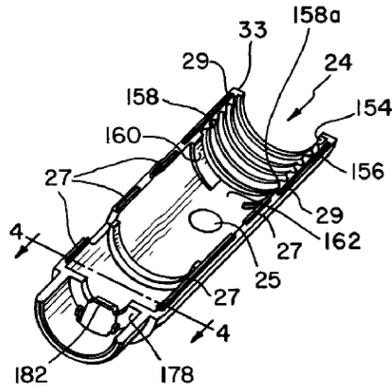


FIG. 3

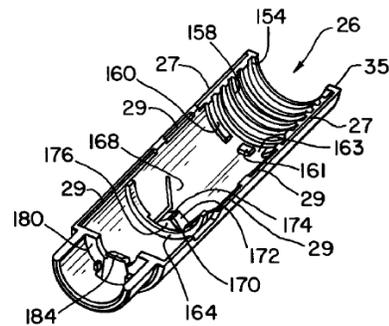


FIG. 5

*Id.*, FIGS. 3 (above-left), 5 (above-right); EX1011, ¶158.

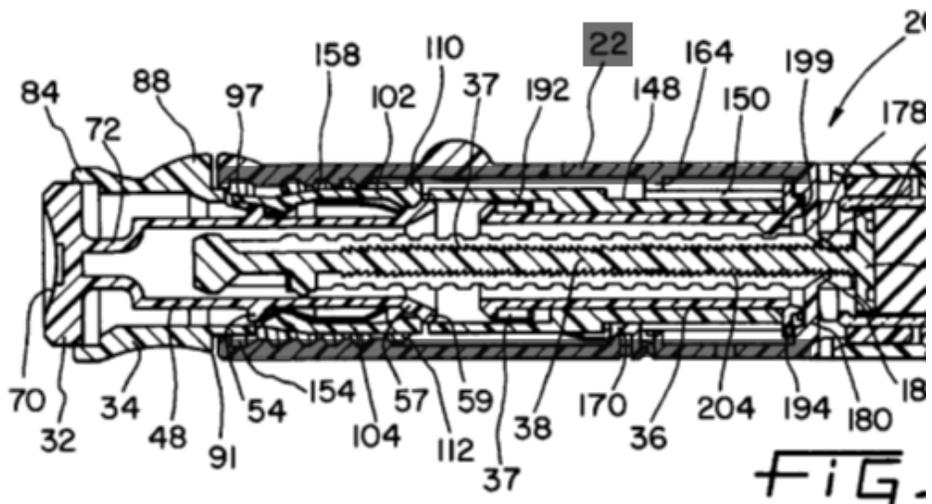
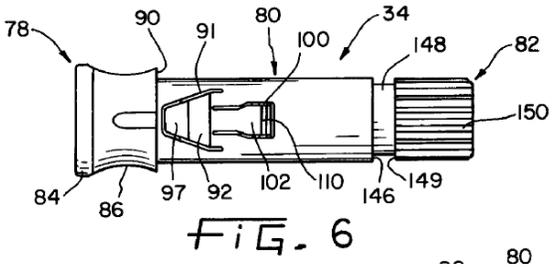


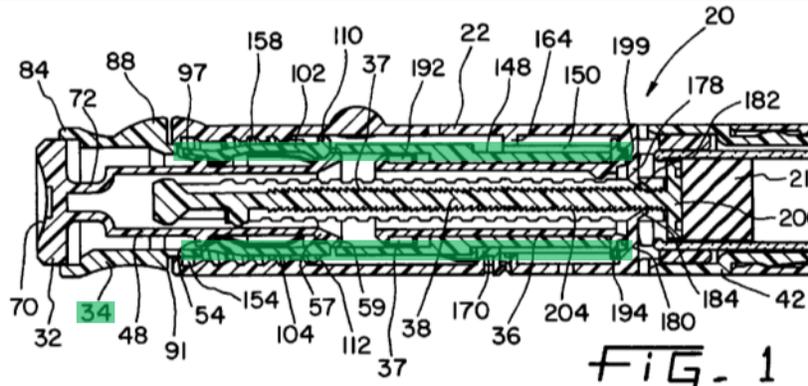
FIG.

*Id.*, FIG. 1 (partial, above; annotating housing gray); EX1011, ¶159.

The mechanism housing 22 includes a first part 24 and a second part 26 that are secured together to house the drive mechanism. EX1013, 7:18-20, FIGS. 1, 2, 3, 5; EX1011, ¶158. As shown in FIG. 1, the mechanism housing 22 extends from a button-end (referred to as the proximal end) to a needle-end (referred to as the distal end). EX1013, 7:9-13; EX1011, ¶160. Burroughs thus taught the claimed “main housing.”

Burroughs taught “a dose dial sleeve” as recited in element [11.2], but teaches a “helical rib” instead of “a helical groove”:

<b>'044 Patent</b>	<b>Burroughs</b>
<p>[11.2] a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;</p>	<p>Burroughs discloses a dial mechanism 34:</p> <p>“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.”</p> <p>EX1013, 7:65-67, FIGS. 1-2, 6-9.</p> 



*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; *also id.*, 10:28-34.

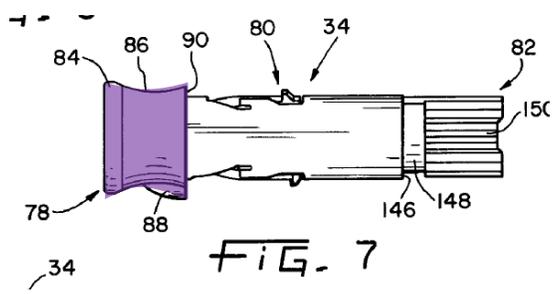
“Upon rotation of dial 34, threads 110, 112 move within housing groove 158 in the proximal [*i.e.*, button-end] direction as dial mechanism 34 retracts from housing

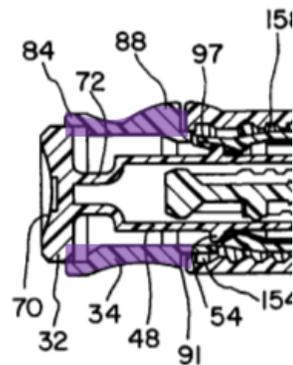
Burroughs discloses a “dose dial sleeve” in the form of dial mechanism 34. EX1013, 7:31-32, FIG. 2; EX1011, ¶¶162-65. The dial mechanism is positioned within housing 22, and includes, on its outer surface, threads 110, 112. EX1013, 7:65-67, 8:33-36, FIGS. 1-2, 6-9; EX1011, ¶166. Threads 110, 112 are configured to releasably engage a helical spiral groove 158 provided on an inner surface of the housing 22. EX1013, 8:62-9:1, FIGS. 1, 3, 5-9; EX1011, ¶167.

Threads 110, 112 are rib-like structures that fit into and move within helical spiral groove 158 of the 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. EX1013, FIGS. 6-9; EX1011, ¶164. As Mr. Leinsing explains, in order to properly engage with the helical spiral groove 158 for rotation, the 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.* EX1002, 3:42-44 (describing threads may include part threads). FIGS. 1 and 7 best show the helical positioning of the threads 110, 112. EX1011, ¶165. Thus, Burroughs discloses that the dial mechanism 34 includes a “helical rib,” in the form of threads 110, 112, along its outer surface that engages with a threading on the housing 22. EX1011, ¶166.

Accordingly, Burroughs taught the claimed “dose dial sleeve,” except it discloses a “helical rib” rather than a “helical groove.” But, as detailed further in §V.F.2, a POSA would have considered implementing the helical rib as a helical groove corresponding to helical threading on the housing an obvious alternative.

Burroughs taught “a dose dial grip” as recited in element [11.3]:

'044 Patent	Burroughs
<p>[11.3] a dose dial grip disposed near a proximal end of said dose dial sleeve;</p>	<p>Burroughs discloses a 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.</p> 



*Id.*, FIGS. 7 (top; annotating proximal portion purple), 1 (partial, bottom; annotating proximal portion 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, 10:34-38.

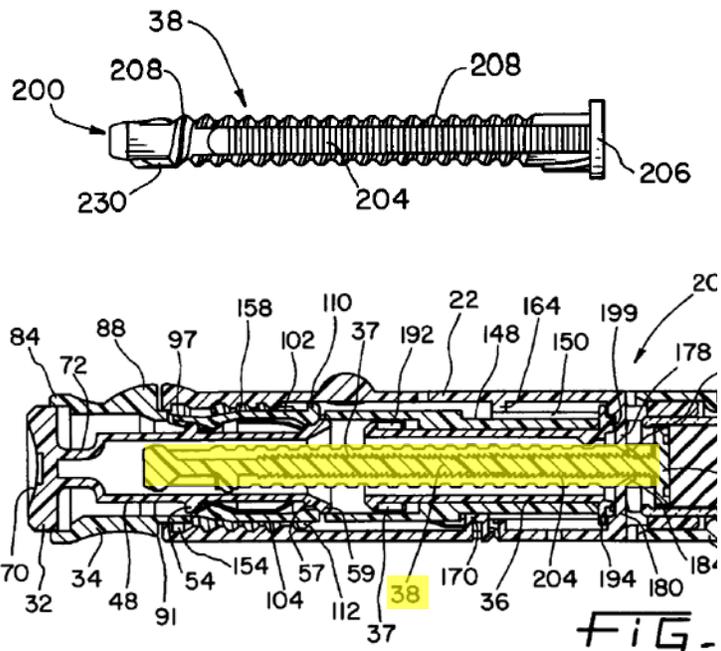
Burroughs discloses a “dose dial grip” in the form of a proximal portion 78 of the dial mechanism 34, located near a proximal end (*i.e.*, button-end) of the dial. EX1013, 8:2-6, FIGS. 1, 6-9; EX1011, ¶173. As shown in FIG. 1, the proximal portion 78 is externally positioned at housing 22’s proximal end, and thus constitutes a grip for the user to grasp in order to rotate the dial mechanism 34 during dose setting. EX1013, 10:34-42; EX1011, ¶175. Accordingly, Burroughs taught a “dose dial grip” as recited in claim 11.

Burroughs taught “a piston rod” as recited in element [11.4]:

'044 Patent	Burroughs
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[11.4] a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;

Burroughs discloses a 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 [*i.e.*, 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.



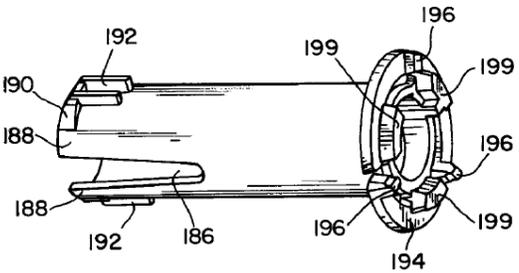
*Id.*, FIGS. 12 (top), 1 (partial, bottom; annotating

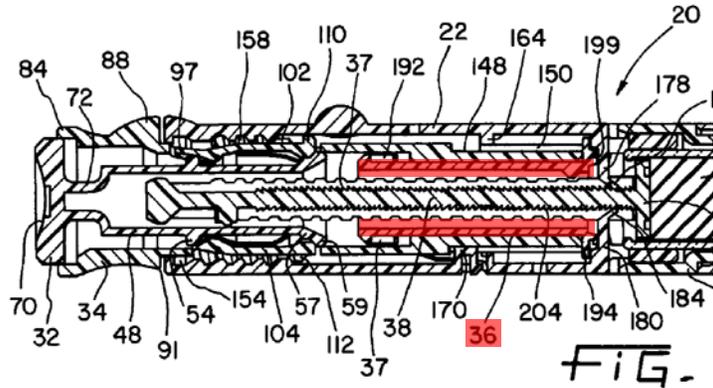
	<p>leadscrew yellow); EX1011, ¶176.</p> <p>“Housing parts 24 and 26 include bulkhead ledges 178, 180, respectively, ... [which] include flexible tangs 182, 184, respectively.” EX1013, 9:8-11, FIG. 1, 3, 5.</p> <p>“Movement of leadscrew 38 is prevented in the proximal [<i>i.e.</i>, button-end] direction 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, FIG. 1.</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....</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 to cause nut 36 to axially retract a corresponding axial distance.” <i>Id.</i>, 10:26-42.</p>
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Burroughs further discloses a “piston rod” in the form of a leadscrew 38. The leadscrew 38 is provided within the housing 22. EX1013, 9:26-27, FIGS. 1-2, 12-13; EX1011, ¶176. During dose setting, rotation of dial mechanism 34 causes

corresponding rotation of a nut 36, which engages external threads 208 of the leadscrew. EX1013, 10:26-42, FIG. 1; EX1011, ¶177. Rotation is not transmitted to the leadscrew 38, however, due to anti-backup tangs 182, 184 provided on the housing 22. EX1013, 10:26-42, FIG. 1; EX1011, ¶177. Leadscrew 38 does not rotate relative to the housing 22 during dose setting. EX1011, ¶177. Burroughs thus taught the claimed “piston rod.”

Burroughs taught “a drive sleeve” as recited in element [11.5]:

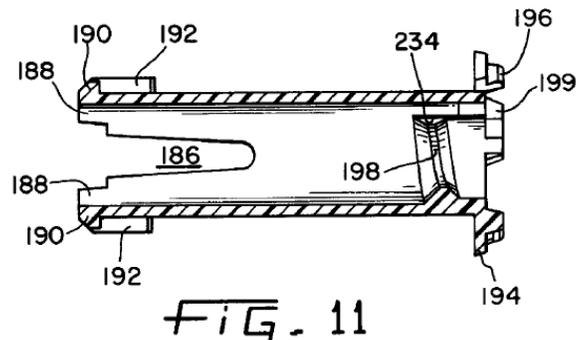
<b>'044 Patent</b>	<b>Burroughs</b>
<p>[11.5] a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and</p>	<p>Burroughs discloses a nut 36:</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, FIGS. 1-2, 10-11.</p>  <p>The diagram shows a cross-sectional view of a nut assembly. A central shaft (186) passes through a nut (196). The nut has an internal helical thread (198) on its inner surface. The shaft has external threads (190) that engage the nut's internal thread. The nut is secured to the shaft by a locking mechanism (192) that includes a spring (188) and a locking ring (194). The nut also has a flange (199) on its outer surface.</p>



*Id.*, FIGS. 10 (above-top), 1 (above-bottom; partial view showing nut (red)); EX1011, ¶179.

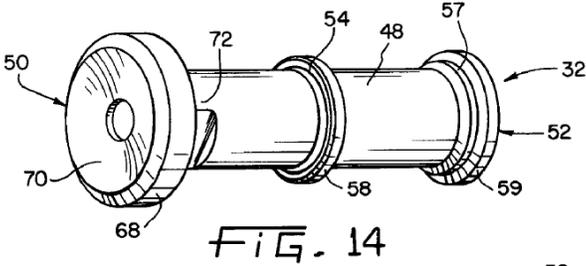
“Helical threads 208 extend along the axial length of leadscrew 36 [*sic*, 38]. Leadscrew 38 fits within cylindrical opening of nut 36.” EX1013, 9:30-32.

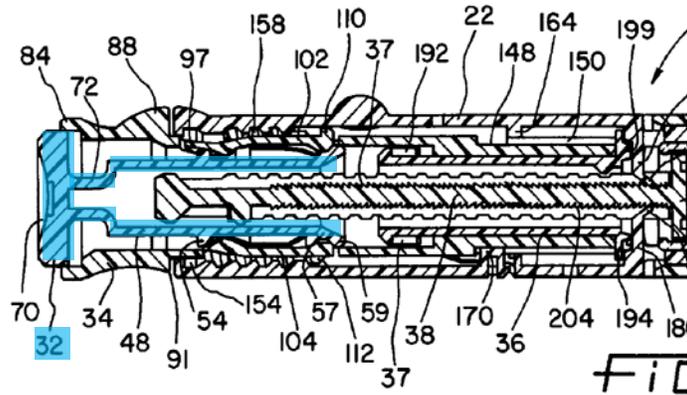
“Rotation of dial mechanism 34 causes rotation of nut 36 so that internal helical raised groove 198 of nut 36 rotates along external threads 208 of leadscrew 38 to cause nut 36 to axially retract a corresponding axial distance.” *Id.*, 10:38-42, FIG. 11 (below).



Burroughs discloses a “drive sleeve” in the form of a 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), a helical thread 198. EX1013, 9:13-25, FIGS. 1-2, 10-11; EX1011, ¶179. This thread engages the helical threads 208 of the leadscrew 38. EX1013, 9:30-32, FIGS. 1, 2, 10-13; EX1011, ¶179. As shown in FIG. 1, the nut 36 extends along a portion of the leadscrew 38. EX1013, FIG. 1; EX1011, ¶179. Accordingly, Burroughs taught a “drive sleeve” as recited in claim 11.

Burroughs taught “a tubular clutch” as recited in element [11.6]:

'044 Patent	Burroughs
<p>[11.6] a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,</p>	<p>Burroughs discloses a button 32:  “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 style="text-align: center;">FIG. 14</p>



*Id.*, FIGS. 14 (above-top), 1 ((bottom, partial, 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; *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; *also id.*,

	<p>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. EX1011, ¶¶182-87. Button 32 is cylindrical in shape (*i.e.*, tubular) and includes an enlarged diameter ring 54. 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. EX1013, 8:11-20, FIGS. 1, 9, 14, 15; EX1011, ¶183. This causes legs 102, 104 of dial 34, which includes threads 110, 112, to collapse inward, causing the threads’ disengagement from the housing’s helical groove 158. 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. 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.

EX1013, 11:27-30; EX1011, ¶183.

Thus, button 32 serves as a clutch that allows dial mechanism 34 to disengage from (1) its rotational connection with housing 22, and (2) its rotational connection with nut 36. EX1011, ¶183. As shown below in FIG. 1, button 32 is located adjacent a distal end of the proximal portion 78 of dial mechanism 34.

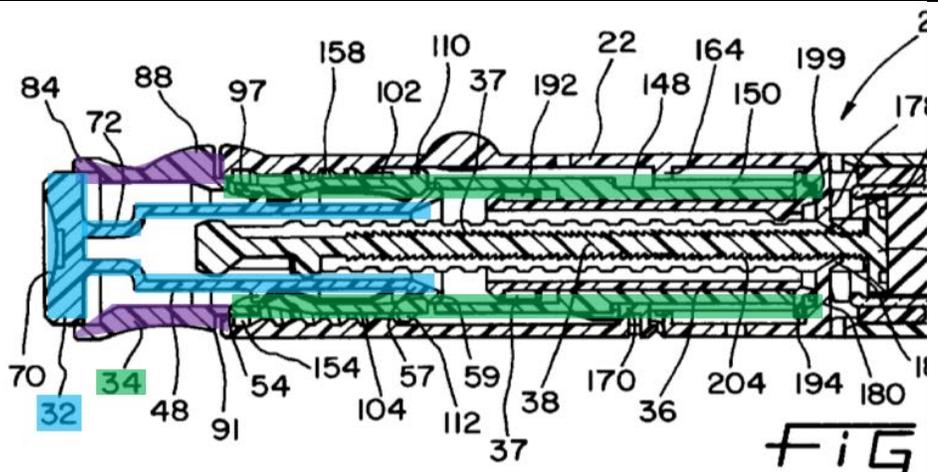
EX1013, FIG. 1; EX1011, ¶184. It is operatively coupled to this grip portion by virtue of its engagement with fingers 94 of dial mechanism 34. EX1013, FIGS. 1, 6-9, 14, 15; EX1011, ¶¶185-87; *cf.* EX1002, 2:5-7, 6:6-9 (describing operation of the clutch with respect to the dose dial sleeve).

Accordingly, Burroughs taught a “tubular clutch” as claimed in the ’044 patent.

Burroughs taught the relative positioning between the dose dial sleeve and the tubular clutch as recited in element [11.7]:

<b>'044 Patent</b>	<b>Burroughs</b>
[11.7] wherein said dose dial sleeve extends circumferentially around at least a	Burroughs shows that button 32 is provided within dial mechanism 34:

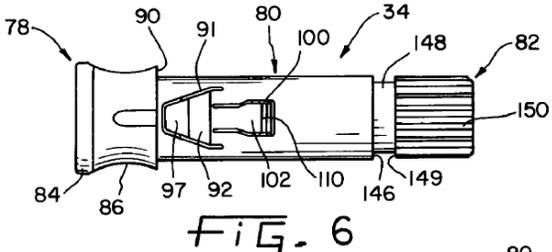
portion of said tubular clutch, and



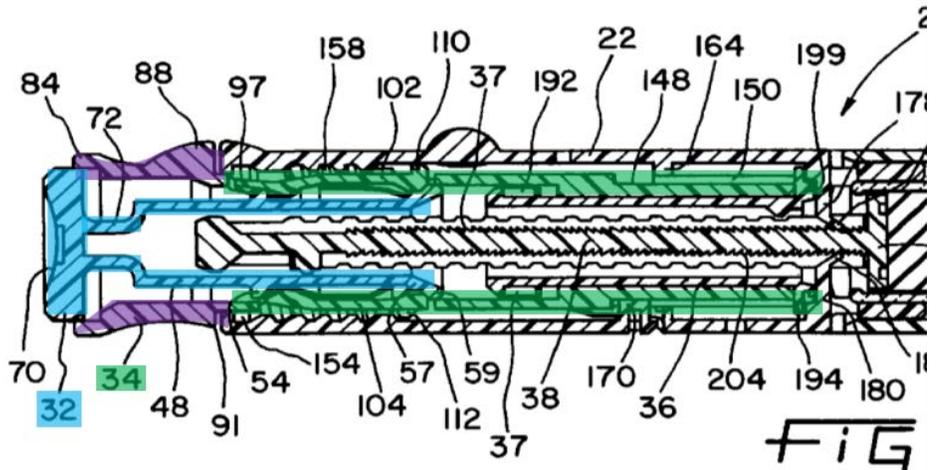
EX1013, FIG. 1 (above; partial view annotating dial mechanism (green) and button (blue)); EX1011, ¶188.

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

Burroughs teaches a helical groove of a dose dial sleeve and an internal threading of a drive sleeve having respective leads as recited in element [11.8].

'044 Patent	Burroughs
[11.8] wherein said helical groove of the dose dial sleeve has a first lead and said internal	<p>Burroughs discloses dial mechanism 34 having a first lead. <i>See</i> element [11.2], <i>supra</i>.</p> 

threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different.



EX1013, FIGS. 6 (top), 1 (bottom, partial annotating dial mechanism (green)); EX1011, ¶188.

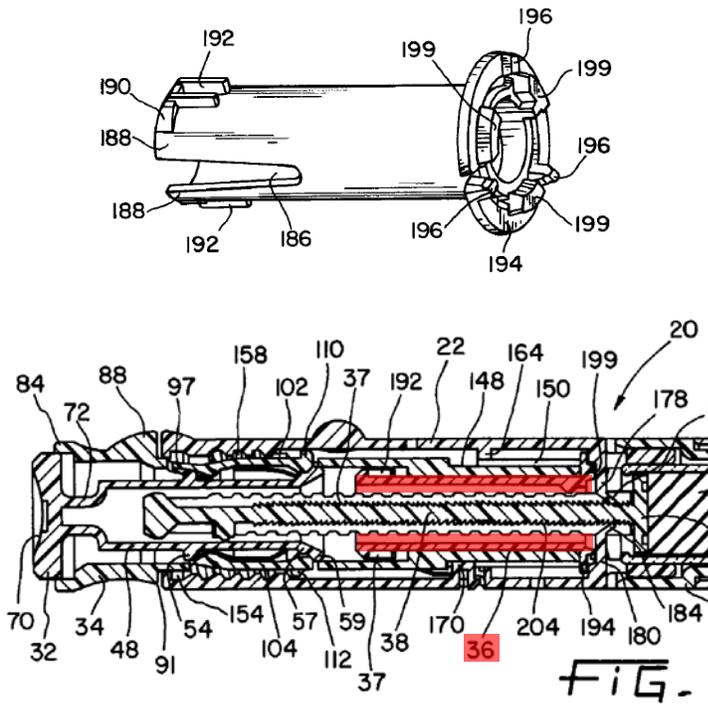
“Housing parts 24 and 26 further form a helical spiral groove 158 and a circumferential surface 160. Circumferential surface 160 includes opening 162 and keyed opening 163 to allow threads 110 and 112 respectively to enter helical groove 158 during the commencement of the dosing process.” *Id.*, 8:63-9:1, FIGS. 3, 5; *also id.*, 10:31-34.

“Upon rotation of dial 34, threads 110, 112 move within housing groove 158 in the proximal [*i.e.*, button-end] direction as dial mechanism 34 retracts from housing 22 ...” *Id.*, 10:34-37.

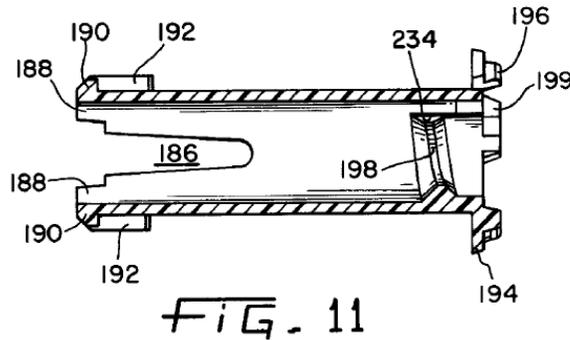
Further, Burroughs discloses a drive sleeve having a second lead. *See* element [11.5], *supra*.

“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, FIGS. 1-2, 10-11.



*Id.*, FIGS. 10 (top), 1 (bottom, partial; showing nut (red));  
EX1011, ¶179.



As discussed above, Burroughs discloses a threaded “dose dial sleeve” in the form of dial mechanism 34. *See* disclosure for element [11.2], *supra*; EX1013, 7:31-32, FIG. 2. Specifically, Burroughs discloses that dial mechanism 34 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, ¶166. Threads 110, 112 are configured to releasably engage with helical-spiral groove 158 provided on an inner surface of housing 22. EX1011, ¶167.

Additionally, as discussed above, Burroughs discloses an internally-threaded “drive sleeve” in the form of nut 36. *See* disclosure for element [11.5], *supra*; EX1013, 9:12-13, FIGS. 1-2, 10-11; EX1011, ¶181. Nut 36 includes on its interior surface and near its needle-end helical thread 198. EX1013, 9:13-25, FIGS. 1-2, 10-11; EX1011, ¶191. This thread engages helical threads 208 of leadscrew 38. EX1013, 9:30-32, FIGS. 1, 2, 10-13; EX1011, ¶191.

Burroughs does not specifically address the lead on threads 110 and 112, nor for helical thread 198. The POSA would understand that, to the extent that the lead on threads 110 and 112 is the same as the lead on helical thread 198, they would rotate at the same rate, and when the leads are different, the dose-dial sleeve and drive sleeve can be made to rotate at different rates. EX1011, ¶¶189-94, *cf.* EX1002, 5:61-65.

It would have been well within the level of skill of the ordinary artisan to determine the appropriate lead on threads 110 and 112 as well as for helical thread 198 to achieve the required relative rate of rotation of the dose-dial sleeve to the drive sleeve. EX1011, ¶195. As Burroughs is silent on the leads on threads 110

and 112 and helical thread 198, and, thus, does not expressly state that they have to be the same, a POSA would understand that Burroughs may have contemplated both the same and different. EX1011, ¶194. Moreover, all the '044 patent teaches regarding leads is that “helical groove 74 on the dose dial sleeve 70 and the helical groove in the drive sleeve 30 have the same lead,” allowing “dose dial sleeve 70 ... to extend from the main housing 4 and the drive sleeve 30 ... to climb the piston rod 20 at the same rate.” EX1002, 5:61-65. Because the '044 patent does not expressly discuss making the leads of the helical groove of the dose-dial sleeve and the lead of the internal threading of the drive sleeve different, the specification of the '044 patent concedes that a POSA had the skill to make the leads different, as well as the same. EX1011, ¶¶196-99.

## **2. Reason to modify and reasonable expectation of success**

Burroughs does not expressly disclose that a “helical groove” is provided along the outer surface of dial mechanism 34, but instead discloses a “helical rib.” A POSA, however, would have considered reversing the features and configuring threads 110, 112 as a “helical groove” to be an obvious alternative. EX1011, ¶170.

Burroughs describes threads 110, 112, which together form a helical rib, that releasably engage with corresponding helical groove 158 of housing 22 to allow dial mechanism 34 to rotate relative to housing 22. EX1013, 10:34-38, 10:60-63; EX1011, ¶183. 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, ¶171.

The use of a rib-to-groove threaded connection is a common and well-known mechanism used to provide relative rotational movement between components. EX1011, ¶168. At the time of invention, a POSA would have considered determining whether to place a helical rib on one component and a complementary helical groove on another engaging component to be a routine task, and would have been viewed it as no more than “the predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. at 417; EX1011, ¶171. 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 u-shaped, protruding grooves 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 choosing

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, ¶171; *also KSR*, 550 U.S. at 417. A POSA also would have reasonably expected that the use of the elements in that configuration would have resulted in the elements performing their same, predictable functions (*e.g.*, rotatable engagement). EX1011, ¶170; *also KSR*, 550 U.S. at 417. Indeed, Burroughs encompasses such modifications to its device. *E.g.*, EX1013, claim 1 (claiming generally that dial mechanism is “rotatably and axially shiftably mounted to” the housing).

Accordingly, a POSA would have considered it obvious to provide a helical groove, formed by protruding, grooved threads 110, 112, on the outer surface of Burroughs’ dial mechanism 34. Claim 11 was obvious over Burroughs.

*Dependent Claims*

Burroughs teaches a clicker as recited in claims [14] and [15].

<b>'044 Patent</b>	<b>Burroughs</b>
[14] The housing part of claim 11, further comprising a clicker, said clicker providing at least an audible feedback to a user when	Burroughs discloses a clicker in the form of finger 170 and splines 150:  “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

<p>said dose dial grip is rotated.</p> <p>[15] The housing part of claim 14, wherein said clicker comprises:</p> <p>at least one flexible arm, said flexible arm comprising at least one tooth member, and</p> <p>at least one spline, wherein when said dose dial grip is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.</p>	<p>causes a ‘click’ to occur, thereby providing an audible indication of each unit of dosage dialed up.” EX1013, 10:42-47, FIGS. 2, 5, 6; EX1011, ¶217; <i>also</i> EX1013, 9:63-66.</p>
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Burroughs teaches a clicker in the form of splines 150 and a tooth member described as “housing finger 170.” EX1013, 10:42-47, FIGS. 2, 5, 6; EX1011, ¶216. Burroughs further discloses that audible and tactile feedback is provided in

the form of a “click” when a user rotates the dose dial grip. EX1013, 9:63-66, 10:42-47, FIGS. 2, 5, 6; EX1011, ¶217, ¶220.

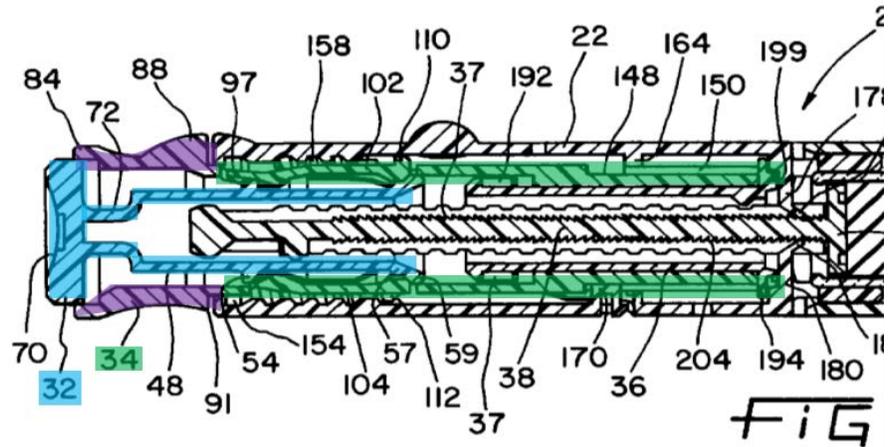
To the extent “clicker” is construed as a means-plus-function limitation, Burroughs teaches or at least suggests the corresponding structure identified in §V.D. The ’044 patent shows the helically extending arms of clicker 50 engage with splines on the housing to provide audible feedback of the dose being dialed. EX1002, 2:20-22. As Burroughs taught, 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, ¶218.

Accordingly, Burroughs rendered obvious claims 14 and 15.

Burroughs teaches a dose dial sleeve as recited in claim [18].

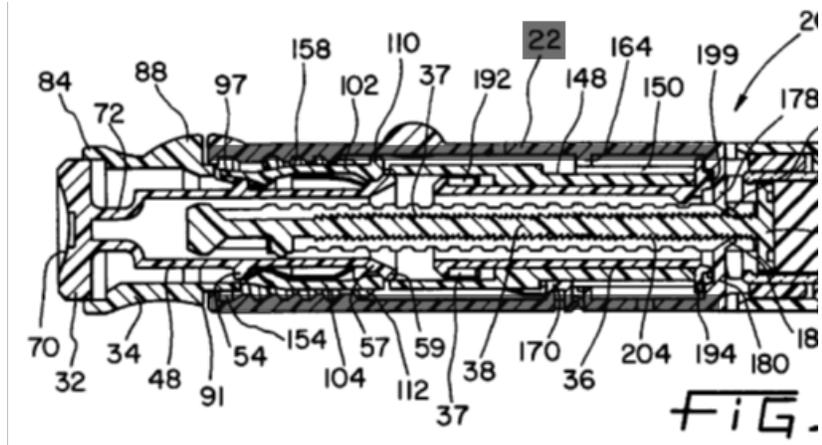
<b>'044 Patent</b>	<b>Burroughs</b>
[18] The housing part of claim 11, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main	Burroughs discloses a dose dial sleeve in the form of dial mechanism 34. <i>See</i> element [11.2], <i>supra</i> .  Furthermore, dial mechanism 34 is located outside the tubular clutch of Burroughs (button 32). <i>See</i> element [11.7], <i>supra</i> .

housing.

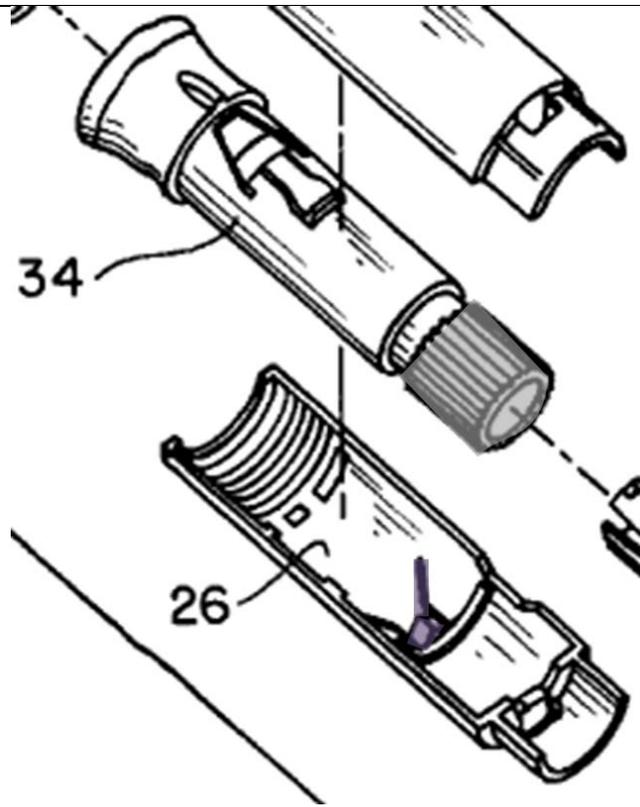


EX1013, FIG. 1 (above, partial; annotating dial mechanism (green) and button (blue)); EX1011, ¶238.

Furthermore, the dose dial sleeve of Burroughs is located radially inward of the main housing. *See* element [11.1], *supra*.



EX1013, FIG. 1 (above, partial; annotating housing (gray)); EX1011, ¶159.



EX1013, FIG. 2 (depicting orientation of dial mechanism 34 (dose-dial sleeve) outside button 32 (tubular clutch) and inward of parts 24 and 26 of the main housing); EX1011, ¶230 (partial; annotating splines 150 (gray) and finger 170 (purple)).

As discussed above, Burroughs discloses a dose-dial sleeve provided outside a tubular clutch and radially inward of a main housing. *See* elements [11.1], [11.2], and [11.7], *supra*; EX1013, FIGS. 1, 2; EX1011, ¶238. Accordingly, Burroughs rendered obvious claim 18.

Burroughs teaches a main housing as recited in claim [19], except for the requirement for a *rib* on a housing and a corresponding *groove* on a dose dial sleeve. *See* element [11.2], *supra*. As discussed above, a POSA would have considered modifying Burroughs to include all elements of claim [19] to be obvious.

<b>'044 Patent</b>	<b>Burroughs</b>
<p>[19] The housing part of claim 11, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve.</p>	<p>Burroughs discloses a main housing comprising a thread, said thread adapted to be seated in a thread provided along the outer surface of a dose-dial sleeve. <i>See</i> element [11.2], <i>supra</i>.</p> <p>“Housing parts 24 and 26 further form a helical spiral groove 158 and a circumferential surface 160.</p> <p>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.” EX1013, 8:63-9:1, FIGS. 3, 5; <i>also id.</i>, 10:31-34; EX1011, ¶¶166-72.</p>

Accordingly, Burroughs taught the claimed “main housing,” except it discloses a “helical rib” on the dose-dial sleeve, rather than a “helical groove.” *See* element [11.2], *supra*. As detailed above, a POSA would have considered it

obvious to implement the helical rib as a helical groove corresponding to helical threading on the housing.

Accordingly, Burroughs rendered obvious claim 19.

## **VI. CONCLUSION**

For the reasons set forth above, claims 11, 14, 15, 18, and 19 are unpatentable. The unpatentability of these claims is not an abstract concern. The high cost of insulin products reduces patient compliance, with adverse effects for American diabetics. EX1035, 2, 8. Mylan respectfully requests institution of review for these claims.

/ Richard Torczon /

Reg. No. 34,448

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

Under the provisions of 37 C.F.R. §42.24(d), the undersigned hereby certifies that the word count for the foregoing Petition for Inter Partes Review totals 7,551, which is less than the 14,000 allowed under 37 C.F.R. 42.24(a)(i). In accordance with 37 C.F.R. 42.24(a), this word count does not include table of contents, table of authorities, mandatory notices under §42.8, certificate of service or word count, or appendix of exhibits or claim listing.

Dated: 10 September 2018

/ Richard Torczon /  
Reg. No. 34,448

**CERTIFICATE OF SERVICE**

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, I certify that I caused to be served a true and correct copy of the foregoing **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,603,044 and Exhibits 1001-1035** by *Federal Express Next Business Day Delivery* on 10 September 2018 to the Patent Owner's correspondence address of record for the subject patent as follows:

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

Respectfully submitted,

Dated: 10 September 2018

/ Richard Torczon / \_\_\_\_\_  
Reg. No. 34,448