

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Case IPR2018-01680
Patent No. 9,526,844

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)
1016	U.S. Patent 6,932,794 B2 – L. Giambattista & A. Bendek,

<u>Exhibit No.</u>	<u>Description</u>
	“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.)
1027	WO 99/38554 – S.Steenfeldt-Jensen & S.Hansen, “An Injection

<u>Exhibit No.</u>	<u>Description</u>
	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)
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

Petitioners (“Mylan”) seek *inter partes* review (“IPR”) of claims 21-30 of U.S. Patent No. 9,526,844B2 to Veasey et al. (“the ’844 patent,” EX1004).

This petition shows a reasonable likelihood that the prior art renders claims 21-30 unpatentable. 35 U.S.C. 314(a).

II. MANDATORY NOTICES

A. Real Parties-In-Interest

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

B. Related Matters

The ’844 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.

The ’844 patent also has been asserted in *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812 (D. Del.). *See* EX1029 (*Markman* opinion). Related patents were also asserted in *Sanofi -Aventis U.S. LLC v. Eli Lilly and Co.*, No. 14-cv-113 (D. Del.) (consent judgment). *See* EX1030 (*Markman* opinion). The real parties-in-interest are not parties to these litigations.

Mylan is also challenging claims 21-30 of the ’844 patent in IPR2018-01682

and IPR2018-01689. Mylan has filed IPR2018-01670, IPR2018-01675, IPR2018-01676, IPR2018-001677, IPR2018-01678, IPR2018-01679, 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.

III. CERTIFICATIONS

Mylan certifies that the '844 patent is available for IPR and that Mylan is not barred or estopped from requesting IPR on the identified grounds.

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

Mylan requests IPR and cancellation of claims 21-30 of the '844 patent under pre-AIA 35 U.S.C. 102 and 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 21-30 of the '844 patent were unpatentable as follows:

Ground	Claims	Basis
1	21-29	Anticipated by U.S. Patent 6,932,794 (EX1016, "Giambattista")
2	24-29	Obvious over Giambattista in combination with U.S. Patent 6,235,004 (EX1014, "Steenfeldt-Jensen")
3	30	Obvious over Giambattista in combination with Klitgaard (EX1017, "Klitgaard")

V. STATEMENT OF REASONS FOR THE RELIEF REQUESTED

A. Argument Summary

The challenged claims relate to a drug delivery device used for dispensing medicine, such as insulin and insulin analogs, from a pen-type injector. EX1004, Title, 1:25-34. As shown below, however, the drug delivery device recited in each of claims 21-30 was disclosed or rendered obvious by the prior art. Moreover, 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). Claims 21-30 are therefore unpatentable over the prior art.

A. The ’844 Patent¹

1. Background

The ’844 patent relates to a pen-type injector for self-administration of medicine, such as insulin and insulin analogs. *See* EX1004, Title, 1:25-34. Such injectors are appropriate for patients who do not have formal medical training, including diabetes patients. *Id.*, 1:30-34. The ’844 patent states that such injectors must be easy to use, as patients using the device may have impaired vision or other physical infirmities. *Id.*, 1:35-40.

The ’844 patent describes and claims a drug delivery device. The ’844 patent issued with 30 claims, of which claims 21-30 are challenged by this Petition. Claim 21 is an independent claim that recites:

21. A drug delivery device comprising:
a housing comprising a dose dispensing end and a first thread;

¹ For uniformity, when discussing both the ’844 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 dose indicator comprising a second thread that engages with the first thread;

a driving member comprising a third thread;

a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;

a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;

a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing;

wherein:

the housing is disposed at an outermost position of the drug delivery device;

the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing;

the driving member is configured to rotate relative to the piston rod;

the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and

the piston rod and the driving member are configured to rotate relative to one another during dose dispensing;

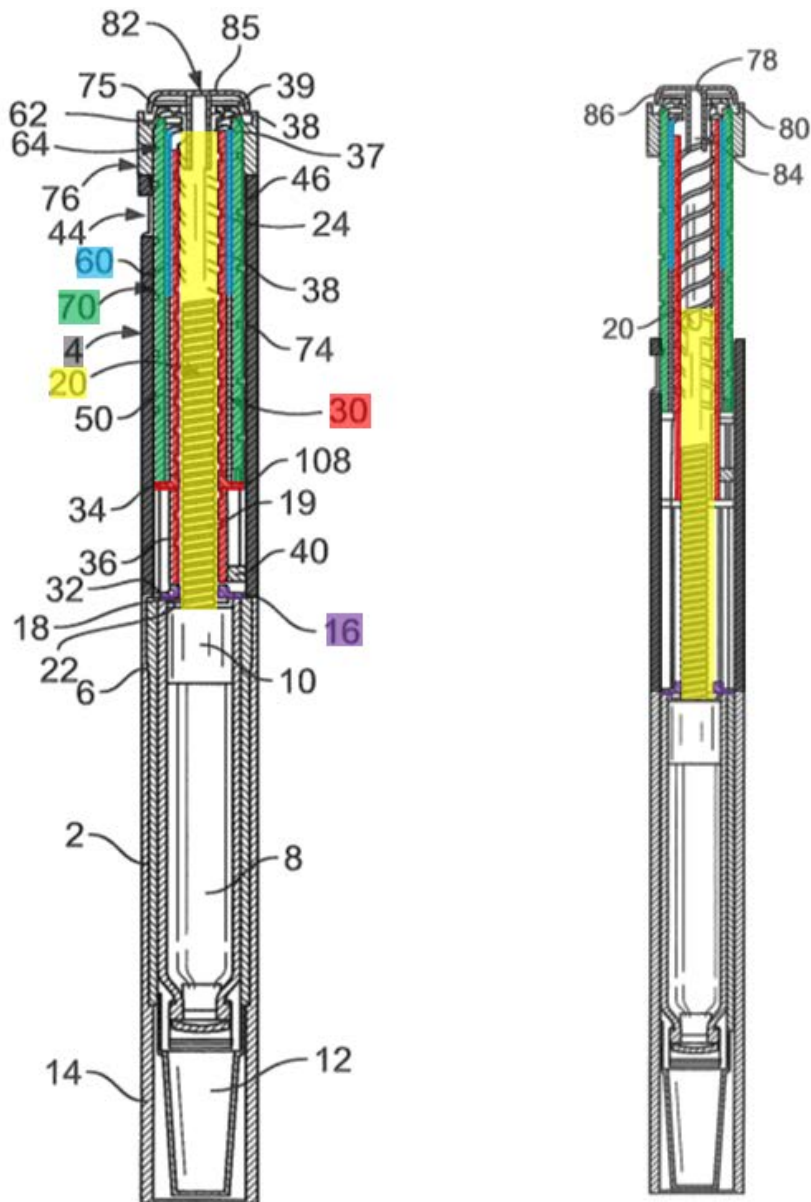
and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

Id., 8:16-49.

Claim 21, therefore, recites six components that form the claimed device
(noting color for annotated figures throughout the petition):

- (1) “housing” (4, grey);
- (2) “dose indicator” (70, green);
- (3) “piston rod” (20, yellow);
- (4) “driving member” (30, red);
- (5) “sleeve” (60, blue); and
- (6) “piston rod holder” (16, purple).

FIGS. 1 (left) and 2 (right) are reproduced below, with color-coding added to highlight the above components. *See* EX1011, ¶41.



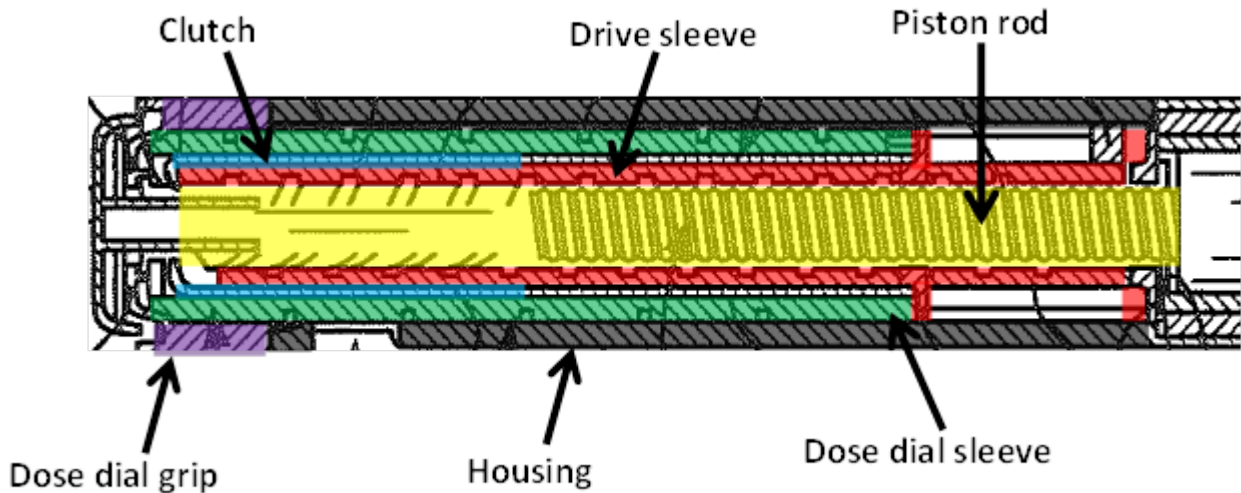
Brief Overview of the Claimed Components

The '844 patent describes an injector having a housing that is formed from two parts: (1) first cartridge retaining part 2, which contains cartridge 8 from which medicine is dispensed, and (2) second main housing part 4 (orange). *See* EX1004, 3:37-47, FIG. 1. Second main housing part 4 houses the mechanism that serves to drive piston 10 contained within cartridge 8 to dispense medicine. *See id.*, 1:44-47,

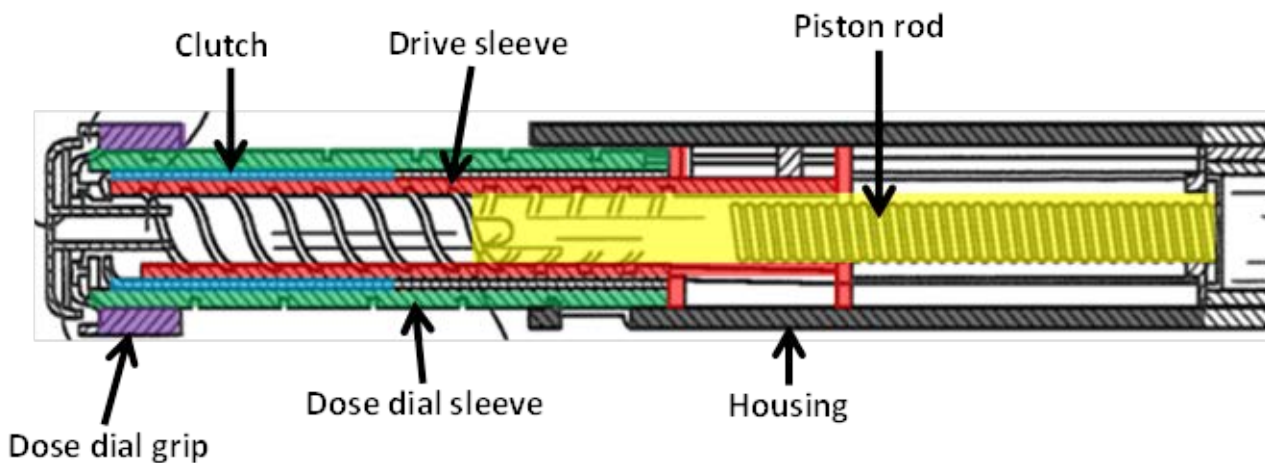
FIG. 1; EX1011, ¶¶44-49.

In an embodiment of an injector as taught by the '844 patent, at the needle-end² of housing part 4, an insert 16 is provided. EX1004, 3:58-60, FIG. 1. Insert 16 is fixedly connected to the housing, both rotationally and axially, and includes threaded circular opening 18, through which the needle-end of a piston rod 20 (yellow) extends. *Id.*, 3:58-4:1, FIG. 1; EX1011, ¶¶50-51. Piston rod 20 includes first thread 19 that engages with insert's threaded opening 18. EX1004, 3:65-4:1, FIG. 1. Piston rod 20 also includes pressure foot 22 at this end, which abuts piston 10 of cartridge 8. *Id.*, 4:1-3, FIG. 1; EX1011, ¶¶52-54.

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.*, EX1004, 3:8-14. Claim 1 refers to the needle-end of the device as its “distal end,” and the button-end as its “proximal end.” *See id.*, claim 1.



Partial view of FIG. 1 showing injector in a cartridge-full position, prior to dose setting (see *id.*, 2:38-40), annotated to highlight components (see EX1011, ¶42)



Partial view of FIG. 2 showing injector in a maximum dose-dialed position (see EX1004, 2:41-42), annotated to highlight components (see EX1011, ¶42)

Piston rod 20 also includes second thread 24 that extends from its button-end.

See EX1004, 4:3-9, FIGS. 1-2. Drive sleeve 30 (red) extends about piston rod 20.

Id., 4:13, FIG. 1. Drive sleeve 30 includes helical groove 38 extending along its

internal surface that engages with second thread 24. *Id.*, 4:20-23, FIG. 1; EX1011, ¶¶55-58.

Clutch 60 (blue) is “disposed about the drive sleeve 30, between the drive sleeve 30 and a dose dial sleeve 70” (green). EX1004, 4:42-44, FIGS. 1, 6-7. Clutch 60 is “generally cylindrical” and located adjacent the button-end of drive sleeve 30. *See id.*, 4:58-61, FIG. 1. “[C]lutch 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.*, 5:2-4. At its button-end, clutch 60 includes a plurality of dog teeth 65. *See id.*, 4:67-5:2, FIGS. 1-2, 8. Teeth 65 are configured to releasably engage with the button-end of dose dial sleeve 70.³ *See id.*, 2:39-42, 6:38-41, FIG. 1; EX1011, ¶¶65-67.

Dose dial sleeve 70 is “provided outside of” clutch 60 and “radially inward of” housing 4. *Id.*, 5:12-22, FIG. 1; EX1011, ¶¶68-70. “[H]elical groove 74 is provided about an outer surface of the dose dial sleeve 70.” EX1004, 5:14-15, FIGS. 1-2, 12. “[M]ain housing 4 is further provided with a helical rib 46, adapted to be seated in the

³ The specification does not specifically explain or show how the teeth 65 engage with the dose dial sleeve 70. As 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. *See* EX1011, ¶69; *see also id.* ¶24 n.1.

helical groove 74” to allow for relative rotation. EX1004, 4:18-20, FIGS. 15-16.

Dose dial grip 76 (purple) “is disposed about an outer surface of the [button-end] of the dose dial sleeve 70.” *Id.*, 5:34-35, FIGS. 1-2. “The dose dial grip 76 is secured to the dose dial sleeve 70 to prevent relative movement therebetween.” *Id.*, 5:37-39; *see also* EX1011, ¶¶71-73.

Operation of the Pen Injector

Dose setting: To set a dose, the user rotates dose dial grip 76 in one direction. *See* EX1004, 5:60-61, FIG. 9 (reproduced and color-coded below). At this stage, teeth 65 of clutch 60 are engaged with dose dial sleeve 70. *See id.*, 2:5-7; 5:29-32. Such engagement causes dose dial sleeve 70, clutch 60, and drive sleeve 30 to rotate together out of the housing. *See id.*, 5:60-63, FIG. 9. Drive sleeve 30 rotates up piston rod 20, toward its button-end, due to its engagement with piston rod 20’s second thread 24. *See id.*, 5:6-13. Piston rod 20 is prevented from rotating due to its opposing, threaded engagement with insert 16. *See id.*, 4:10-11, 6:11-13; *see also* EX1011, ¶¶78-82.

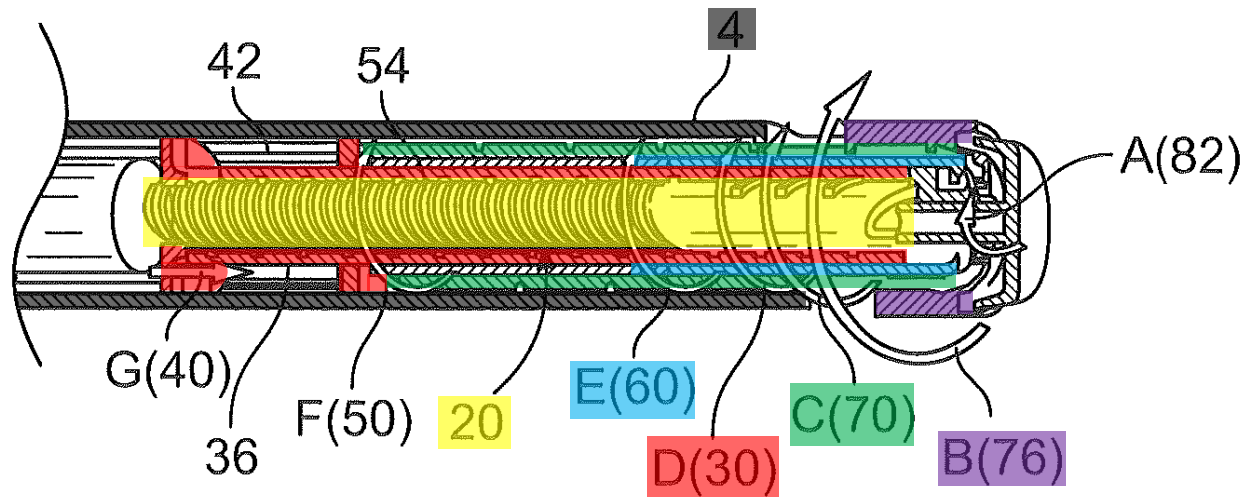


FIG. 9: Dialing up (*id.*, 2:55-56), annotated to highlight components (EX1011, ¶81)

The user also may dial down a dose. *See* EX1004, 6:27-30, FIG. 10 (reproduced and color-coded below). To dial-down a dose, the user rotates dose dial grip 76 in the opposite direction (*e.g.*, clockwise direction). *See id.*, 6:30, FIG. 10. “This causes the system to act in reverse,” where dose dial sleeve 70, clutch 60, and drive sleeve 30 rotate together back into the housing. *See id.*, 5:30-31, FIG. 10. As such, drive sleeve 30 rotates down piston rod 20, toward its needle-end, without corresponding rotation of piston rod 20. *See id.*, 6:4-13, FIG. 10; *see also* EX1011, ¶¶83-85.

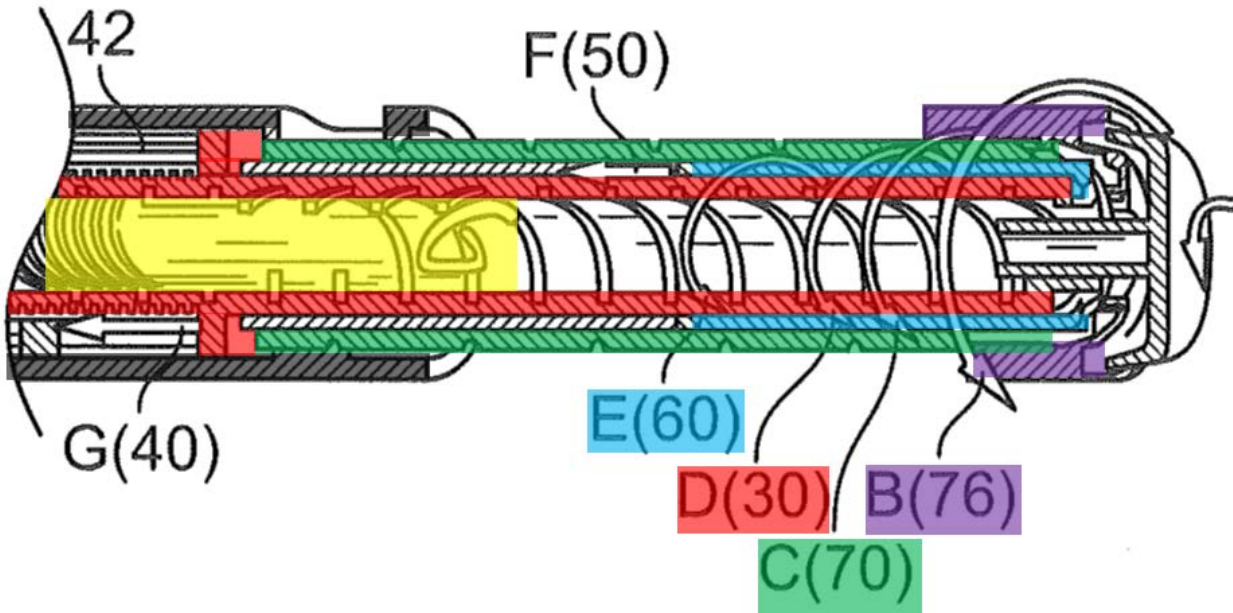


FIG. 10: Dialing down (*id.*, 57-58), annotated to highlight components (EX1011, ¶84)

Injection: Once the dose is set, the user presses button 82, applying a force toward the needle-end of the device. *See* EX1004, 6:38-39, FIG. 11 (reproduced and color-coded below). This displaces clutch 60 axially such that teeth 65 disengage from dose dial sleeve 70. *Id.*, 6:40-41. Dose dial sleeve 70 rotates back into housing 4 via its threaded connection with the housing. *Id.*, 6:43-45, 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.*, 6:42-43, 6:48-54. Drive sleeve 30 also moves axially toward the needle-end, driving piston rod 20 to rotate through threaded opening 18, causing medicine to be dispensed from cartridge 8. *See id.*, 6:55-58, FIG. 11; *see also* EX1011, ¶¶86-89.

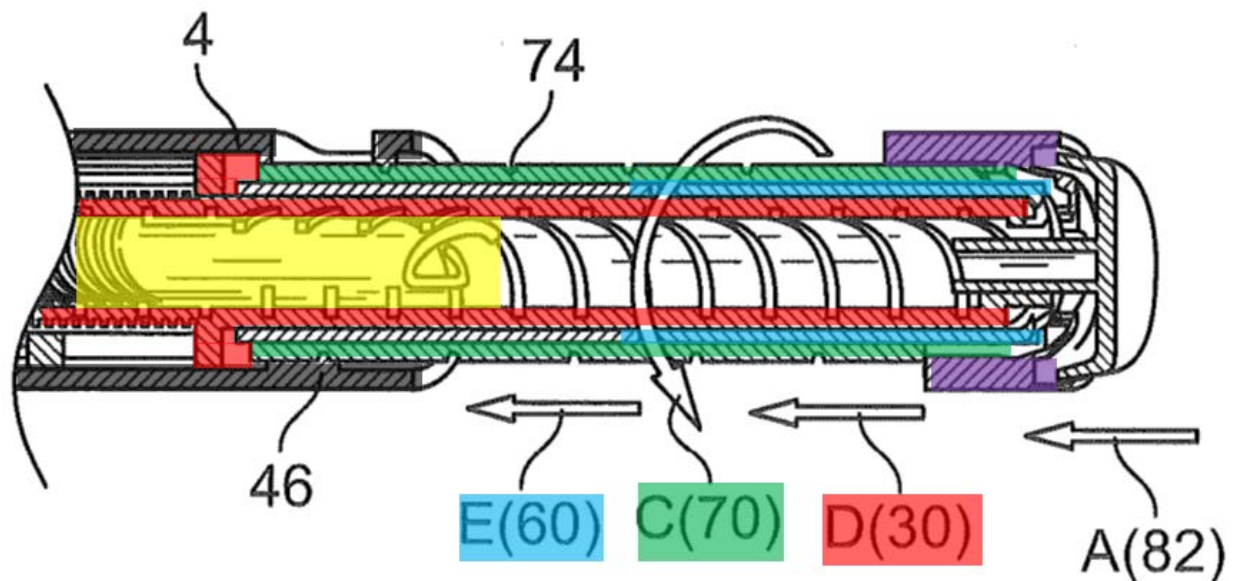


FIG. 11: Injecting dose (*id.*, 2:59-60), annotated to highlight components (EX1011, ¶88)

2. Prosecution History

The '844 patent issued from Application No. 15/156,616 ('616 application). During prosecution, pending claims 1-30 were rejected for non-statutory double patenting over claims 1-14 of U.S. Patent No. 7,918,833. *See* EX1009, 79-80. Applicants submitted a terminal disclaimer over the '833 patent. *Id.*, 117. Applicants later filed an RCE and amended claim 1 to specify that “during dose delivery the drive sleeve and the piston rod are configured to rotate relative to one another.” *Id.*, 141. A Notice of Allowance ensued. *Id.*, 164.

Klitgaard and a related PCT publication of Steinfeldt-Jensen (EX1027, WO99/38554) were submitted with over 200 other references in Information

Disclosure Statements. *Id.* at 46, 49. Neither was applied in a rejection.

3. Claims 21-30 Lack Written Description Support Before May 2016

The '616 application was filed on May 17, 2016. EX1004, cover. Although the '844 patent claims the benefit of the filing dates of earlier applications via U.S. Patent Application No. 14/946,203 (EX1025), filed on November 19, 2015, each of claims 21-30 lacks written description support under §112 in any of these priority documents and is not entitled to a priority date earlier than May 17, 2016. *See* Pre-AIA §§119 and 120; *In re Gosteli*, 872 F.2d 1008 (Fed. Cir. 1989).

To provide written description support, a priority document must clearly allow a POSA to recognize that the inventor invented what is claimed and must reasonably convey that the inventor had possession of the claimed subject matter. *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (“the hallmark of written description is disclosure”). The parent application “must actually or inherently disclose the elements of the later-filed claims.” *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 870 (Fed. Cir. 2010). “[A]ll the limitations must appear in the specification.” *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). “It is not sufficient ... that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to the modifications that the inventor might have envisioned, but failed to disclose.” *Id.* “[P]roof of priority requires written disclosure in the parent

application, not simply information and inferences drawn from uncited references[.]” *L.A. Biomedical Research v. Eli Lilly & Co.*, 849 F.3d 1049, 1057-58 (Fed. Cir. 2017). “[A]dequate written description does not ask what is permissible, rather, it asks what is disclosed.” *D Three Enterprises, LLC v. SunModo Corp.*, 890 F.3d 1042, 1052 (2018). “[T]he issue is whether a person skilled in the art would understand from the earlier application alone, without consulting the new matter ... that the inventor had possession of the claimed [element] when the [earlier] application was filed.” *Technology Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1333-34 (Fed. Cir. 2008).

Each of claims 21-30 of the ’844 patent lacks support in the ’203 application as well as the filings to which the ’203 application claims priority for a “piston rod” comprising an internal fourth thread that is engaged with a third thread of a “driving member.” See EX1011, ¶¶100-02. An internally-threaded piston rod limitation first appeared in claim 21 of the ’616 application as it was filed on May 17, 2016. EX1009, 24; EX1011, ¶102. Neither the ’203 application nor any of the applications to which it claims priority describes an internally threaded piston rod or engaging such internal threads with external threads of a driving member. EX1011, ¶¶101-02. Nor does the ’203 application or any of its priority applications contain a disclosure that external threads can be replaced with internal threads generically, much less specifically on the piston rod. *Id.*

To the contrary, the '203 application and each of the applications to which it claims priority repeatedly and uniformly describe the piston rod having external threads adapted to engage internal threads of two components (the drive sleeve and insert) that are “located” between the piston rod and the housing. *See, e.g.*, EX1025, 79, ¶¶7, 82, ¶¶38-39, 86, ¶¶65, FIGS. 1-7, 9-13 (first threaded portion of piston rod 20 rotates “through” threaded opening in the insert 16 during dose dispensing); EX1026, 2:1-5, 5:19-27, 11:9-11, Figs. 1-7, 9-13,⁴ claim 2 (same); EX1025, 79, ¶¶6-7 (drive sleeve located between dose dial sleeve and piston rod); EX1026, 1:30-2:9 (same); EX1025, 82, ¶¶39-41 (“second thread 24” of piston rod “is adapted to work within the helical groove 38” that “extends along the internal surface of the drive sleeve 30,” which drive sleeve “extends about the piston rod 20.”), FIGS. 1-5, 9-11; EX1026, 5:29-30, 6:7-14, FIGS. 1-5, 9-11 (same); EX1025, 82, ¶¶40, 85, ¶¶55 (button end of piston rod 20 extends all the way to stem 84 of button 82, which stem 84 is received into receiving recess 26 of piston rod 20);

⁴ Although the images of the figures from the GB application in EX1026 are difficult to view, the written description of the GB application confirms these figures are consistent with those in the '844 patent and the other patents in the priority chain (including the '203 application) in uniformly depicting external threads on the piston rod.

EX1026, 6:4-5, 9:2-4 (same); *see also* EX1011, ¶¶101-02.

There is thus no written description support in the priority documents for a piston rod with internal threading that engages with external threading of the driving member. Because the '203 application does not expressly or inherently describe a piston rod with internal threading that engages with external threading of the driving member, claims 21-30 of the '844 patent are entitled to a priority date no earlier than May 17, 2016.

B. Level of Ordinary Skill

For the purposes of this petition, the relevant timeframes include May 17, 2016 (the filing date of the '616 application) and March 3, 2003 (the earliest priority date claimed by the '844 patent). A POSA would include someone who had, through education or practical experience, at least the equivalent of a bachelor's degree in mechanical engineering, or a related field. EX1011, ¶¶105-06. 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.*

C. Claim Construction

For this petition, claim terms should be given their ordinary and accustomed 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.

driving member: “A component releasably connected to the dose dial sleeve that drives the piston during dose dispensing.” EX1019, 28.

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

piston rod: “A rod that engages with the driving member to advance the piston during dose dispensing.” *Id.*, 27.

the piston rod and the driving member are configured to rotate relative to one another during dose dispensing: “Plain and Ordinary Meaning” which is described as “during dose dispensing, the piston rod rotates while the driving member does not rotate, the driving member rotates while the piston rod does not rotate, or both rotate at different rates and/or directions.” *Id.*, 27 (citing ’844 Patent: 6:38-67, FIG. 11; claim 21).

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

clutch: “A structure that couples and decouples a moveable component from another component.” *Id.*, 24.

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

holder: “Plain and Ordinary Meaning, which a POSITA would understand to be ‘a structure that holds a referenced structure’ (e.g., a piston rod holder holds a piston rod).” *Id.*, 33.

In the related litigation with Sanofi, Mylan proffered preliminary means-plus-function constructions for “clutch,” “clicker,” and “holder.” EX1028, 121-123, 131-135. The district court in that litigation has not yet set forth a claim construction. To the extent that the Board concludes that the broadest reasonable interpretation of those terms is a means-plus-function construction, Mylan provides those constructions below. §§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, 123. Mylan points to component 60 as the corresponding structure for the clutch. *Id.*, 121; *see also* EX1004, 2:24-26, 4:58-5:4,

5:5-7, 6:46-54, FIGS. 1, 5-11.

As to the function of a clicker,⁵ 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, 134. Mylan points to component 50 as the corresponding structure. *Id.*, 131-134; *see also* EX1004, 2:27-29, 2:30-35, 2:36-42, 4:42-44, 4:45-57, 5:5-9, FIGS. 6-8.

As to the function of a holder,⁶ 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, 135. Mylan points to component 16 as the corresponding structure. *Id.* 134-135; *see also* EX1004, 1:63-65, 3:58-64, FIGS. 1, 3-5.

The grounds presented below rely on the ordinary and customary meaning of the claim terms as they would be understood by a POSA. The grounds also address

⁵ Even if the scope of the claim 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).

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

the “clutch,” “clicker,” and “holder” limitations to the extent that those terms may be construed as means-plus-function limitations.

D. Prior Art

1. Giambattista

Giambattista is prior art to the challenged claims of the ’844 patent under pre-AIA §102(b).⁷ Giambattista disclosed a medication delivery pen. *See* EX1016, Title, Abstract. As shown in FIGS. 2, 7, and 11 (reproduced and color-coded below), Giambattista disclosed a medication delivery pen comprising:

(1) “body 18” and “cartridge holder 14” (**grey**) disposed at an outermost position of the device that house the drug delivery components of the pen and comprise a dose dispensing end and a first thread, *see, e.g., id.*, 2:36-38, 2:66-3:13, FIGS. 2-3, 7, 11-12;

(2) “dose knob 20” (**green**) that is threadingly engaged with the first thread on the housing, disposed between the housing and the sleeve, configured to rotate away from the needle end during dose setting and toward the needle end during dose dispensing, *see, e.g., id.*, 2:36-38, 3:10-15, 3:56-57, 3:60-67, 4:49-64, 5:8-19, 5:24-

⁷ Because the effective filing date of the ’844 patent is May 17, 2016, post-AIA §102 applies. Whether or not pre- or post-AIA §102 is applied does not make any difference to the analysis. Thus, for consistency and convenience, this Petition refers to pre-AIA §102.

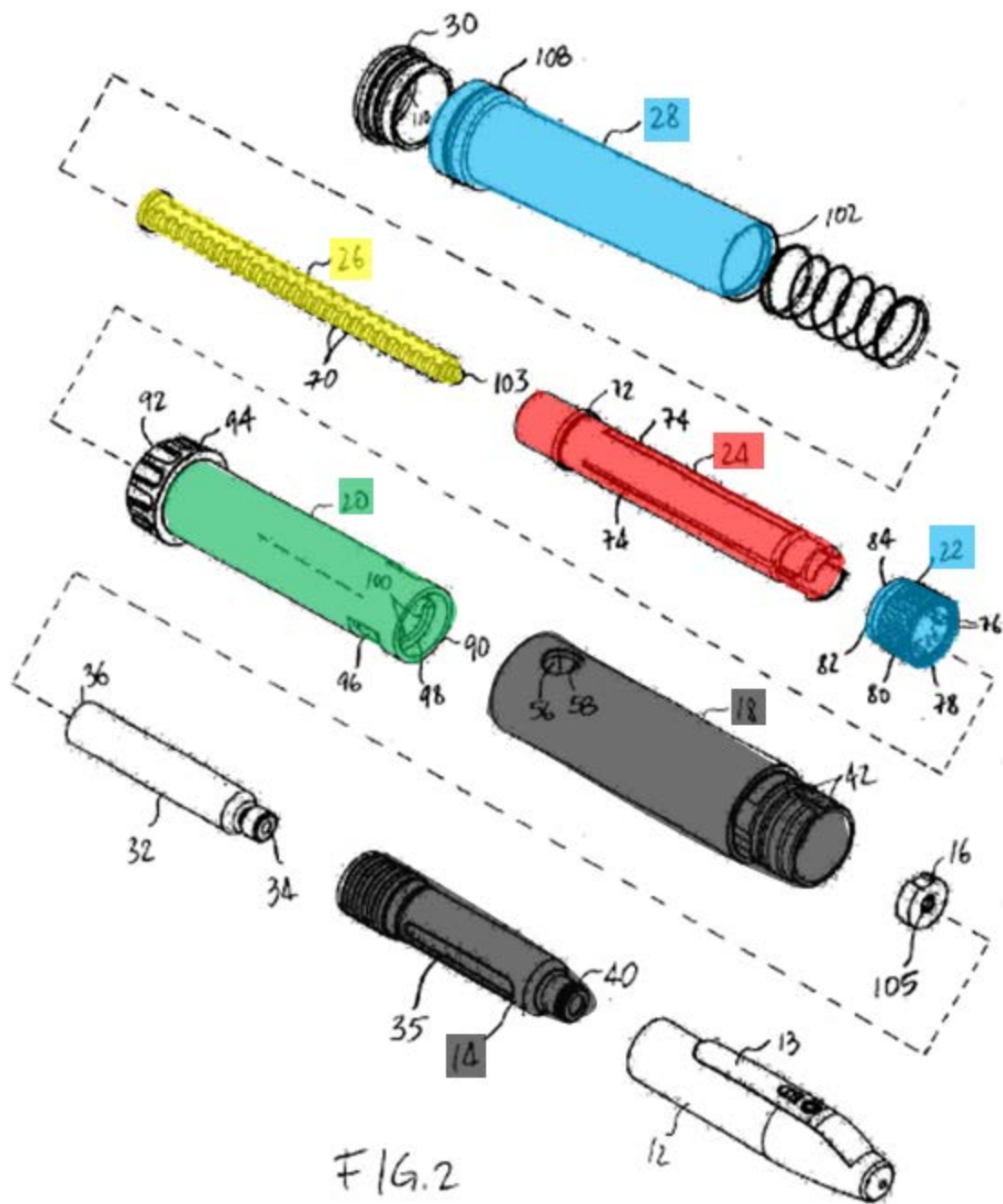
25.; claims 6, 9, 15, FIGS. 2, 7-12;

(3) “lead screw 26” (**yellow**) comprising a fourth thread , which is driven to move a piston provided within the cartridge axially towards the needle end to dispense medicine, *see, e.g., id.*, 2:36-39, 3:16-24, 5:16-24, claim 7, FIGS. 2, 7, 11-12;

(4) “driver 24” (**red**), which is threadingly engaged with the fourth thread of the piston rod, is configured to rotate relative to the piston rod, and drives the piston rod in order to move the piston when the piston rod and driving member rotate relative to one another during dose dispensing, *see, e.g., id.*, 2:36-38, 3:16-24, 5:16-24, FIGS. 2, 5, 7, 11-12;

(5) “dosing ring adaptor 28” with “dosing ring 22” (**blue**) that is disposed between the dose indicator and the driving member and which is releasably connected to the dose indicator, rotatably fixed relative to the driving member, and configured to traverse axially with the dose indicator, *see, e.g., id.*, 1:44-46, 2:36-39, 3:39-49, 4:49-61, 5:8-16, 5:26-28, claims 1, 13, Abstract, FIGS. 2, 7-9, 11-12; and

(6) “bulkhead 44” having “aperture 46” (**purple**), the bulkhead being rotatably fixed relative to the housing and configured to prevent the piston rod from rotating during dose setting but permit it to traverse axially towards the needle end of the device during dose dispensing, *see, e.g., id.*, 2:66-3:7, 5:20-24; *see also id.*, claim 8, FIGS. 3, 7; EX1011, ¶146.



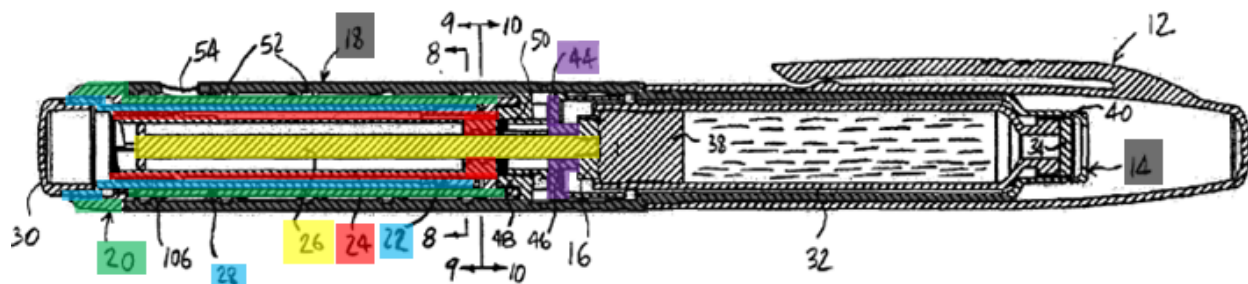


FIG. 7

EX1016, FIGS. 2, 7, 11 (annotated); EX1011, ¶146.

2. Steinfeldt-Jensen

Steenfeldt-Jensen is prior art to the '844 patent under pre-AIA §102(b). Steinfeldt-Jensen disclosed injection syringes for dispensing medicine. *See* EX1014, Abstract. The embodiment shown in FIGS. 15-17 is similar in structure and operation to the Giambattista's injector pen. In addition to its familiar concentric-sleeve arrangement, Steinfeldt-Jensen describes a radial protrusion 87 on the outer edge of bushing 82 (*i.e.* a clutch) that engages recesses on dose setting button 81. *Id.* 11:34-40, 11:62-67. During dose setting, radial protrusion 87 “will click from one of the axial recess[es]...to the next one, the recesses being so spaced that one click corresponds to a chosen change of the set dose, e.g. one unit or a half unit.” *Id.*, 11:62-67. Steinfeldt-Jensen's teachings regarding this clicker were familiar and readily applicable in the context of other injector pens. *See* EX1011, ¶¶61-64.

3. Klitgaard

Klitgaard is prior art to the challenged claims of the '844 patent under pre-AIA §102(b) and §102(e) (under the March, 3, 2003 earliest priority date). Klitgaard describes a limiting mechanism to track the amount of medication administered from a drug injection device to prevent the setting of a dose in an amount that exceeds the remaining supply of medication in the cartridge. EX1017, Abstract.

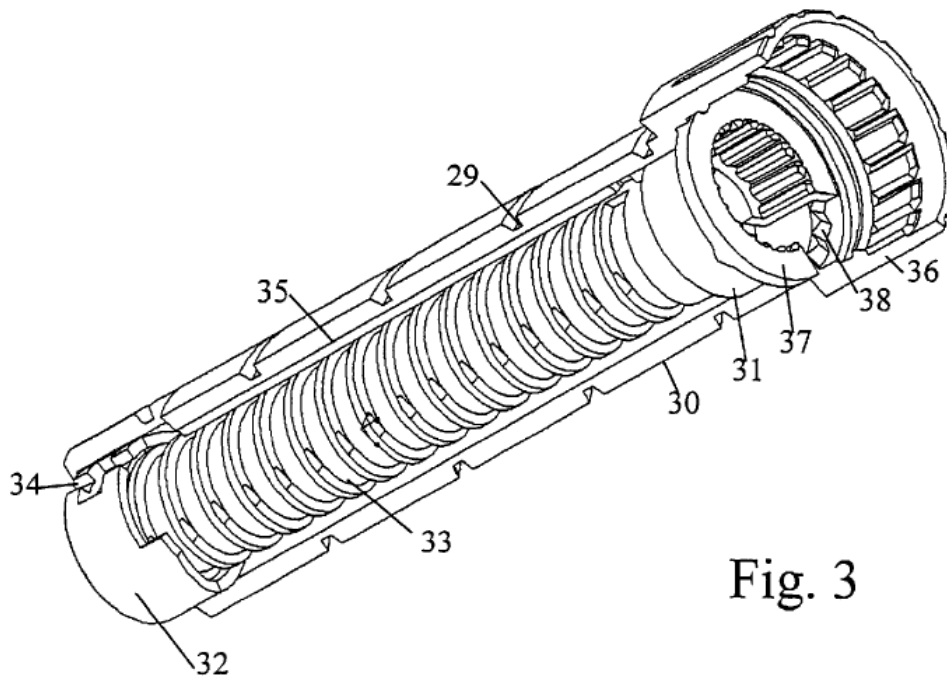


Fig. 3

FIG. 3 and its related description discloses nut member 32 that tracks each set dose of medication delivered to prevent setting a dosage that exceeds the remaining supply of medication. *Id.*, 4:16-58. Nut 32 is disposed between dose setting-member 30 and driver 31. *Id.*, 4:26-29. During dose setting, dose-setting member 30 is threaded out along internal threads of the housing. *Id.*, 4:16-25. At

the same time, nut member 32 screws up along a helical track on the outer surface of driver 31 due to engagement between a ridge on the inner side of dose-setting element 30 and recess 34 in the outer wall of nut member 32. *Id.*, 4:26-37. During dose dispensing, dose-setting member 30 is forced to rotate relative to the housing and transmits rotational force to driver 31, but nut member 32 maintains its position on driver 31 to “always indicate the total sum of set and injected doses.” *Id.*, 4:37-58; *see also* EX1011, ¶149.

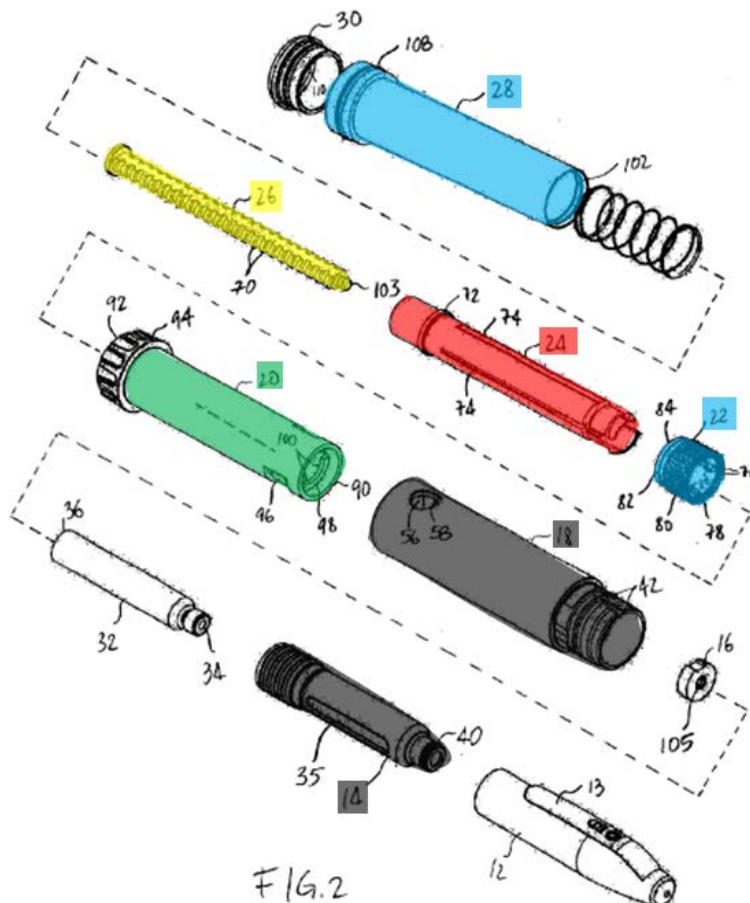
E. Ground 1: Giambattista Anticipates Claims 21- 29.

As explained above, Giambattista disclosed a medication-delivery pen that includes the same six components broadly claimed by the '844 patent.

1. Claim 21

Giambattista taught the preamble:

'844 Patent	Giambattista '794
[21.Preamble] A drug delivery device comprising:	“[A] medication delivery pen 10 may be used for the administration of various medications, including insulin.” EX1016, 2:26-35, FIG. 1, claim 1.



EX1016, FIG. 2; EX1011, ¶546.

Giambattista disclosed a drug delivery device in the form of medication delivery pen 10 that can be used for the administration of various medications, including insulin. *See, e.g.*, EX1016, 2:26-35, FIG. 1, claim 1; EX1011, ¶545. Accordingly, to the extent that it is limiting, Giambattista ‘794 taught the preamble of claim 21.

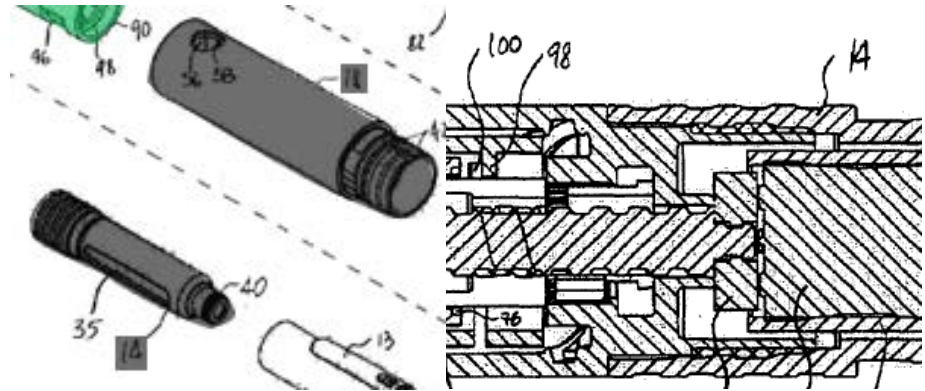
Giambattista disclosed element [21.1]:

’844 Patent	Giambattista ‘794
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[21.1] a housing comprising a dose dispensing end and a first thread;

“[P]en 10 generally includes ... a cartridge holder 14 ... [and] a body 18[.]” EX1016, 2:36-38.

FIG. 2, reproduced in part below, is an exploded view of the pen:



Id., FIGS. 2, 11 ; EX1011, ¶548.

“With reference to FIG. 3 [reproduced below], the body 18 is generally cylindrical, having threads or detents 42 onto which the cartridge holder 14 is formed to be mounted.... [A] dose setting thread 54, as known in the prior art, is formed on the interior of the body 18” EX1016, 2:66-3:12.

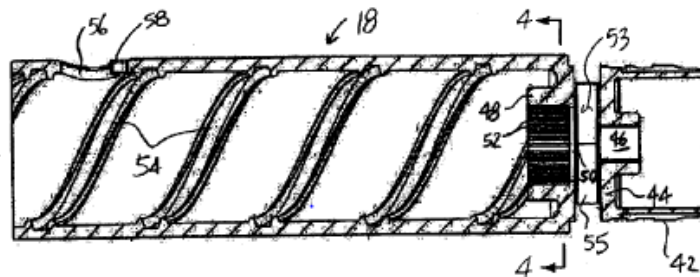
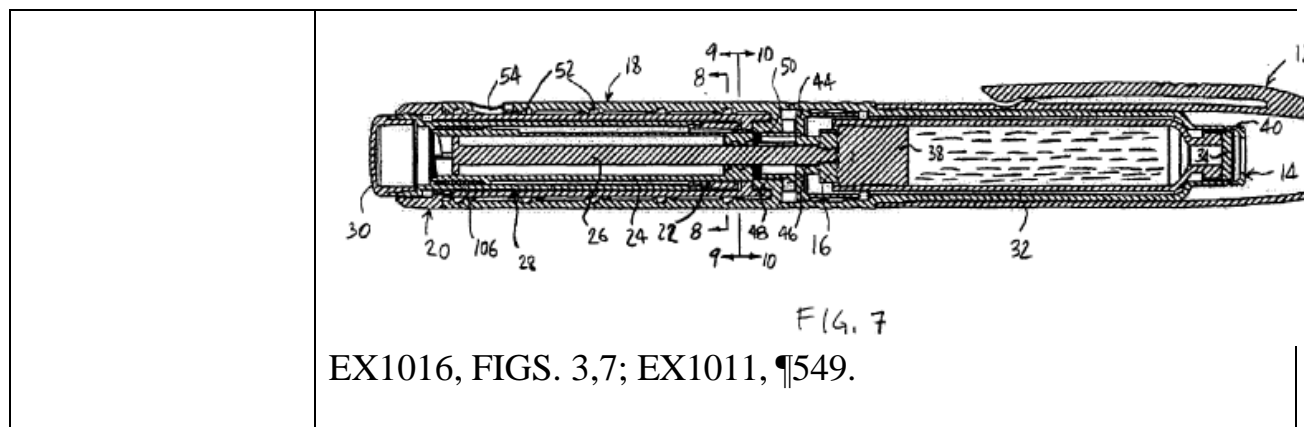


FIG. 3

Id. FIG. 3; EX1011, ¶549.



Giambattista taught the drug-delivery device comprises a housing in the form of body 18 and cartridge holder 14 that house the drug-delivery components of pen 10. EX1016, 2:36-40; *see also* FIGS. 2, 3, 7, 11. Cartridge holder 14 mounts onto threads or detents 42 of body 18. *Id.*, 2:66-3:1. A housing made of cartridge holder 14 and body 18 is consistent with the description of the housing in the '844 patent. *See, e.g.*, EX1004, 3:37-38 (“The pen-type injector comprises a housing having a first cartridge retaining part 2, and second main housing part 4.... [T]he cartridge retaining means 2 is secured within the second end of the main housing 4.”), FIGS. 1-5. Giambattista thus taught a housing in the form of body 18 and cartridge holder 14. EX1011, ¶547.

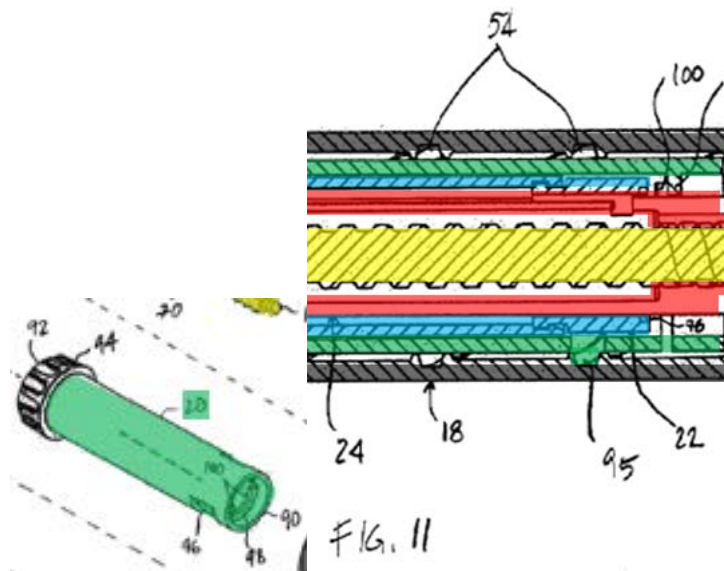
Giambattista taught the housing comprises a dose dispensing end. EX1016, 2:36-38, FIGS. 2, 7. During drug dispensing, medication is expelled from drug cartridge 32 through an elastomeric septum 34 and through a needle that is threadedly mounted onto threads 40 of cartridge holder 14. EX1016, 2:42-53. In FIGS. 2-3, 7, and 11-12, shown in the claim chart above, the dose-dispensing end

of the body is on the right side of the pen 10. EX1011, ¶547. Giambattista thus disclosed that the pen 10 comprises a housing having a dose-dispensing end.

Giambattista disclosed a housing comprising a first thread. “[A] dose setting thread 54, as known in the prior art, is formed on the interior of the body 18” *Id.*, 3:11-12, FIG. 3. Dose-setting thread 54 is a first thread of the housing, as recited in element 21.1. Giambattista ‘794 thus taught a drug-delivery device that comprises a “housing comprising a dose dispensing end and a first thread” as recited in element [21.1].

Giambattista disclosed element [21.2]:

’844 Patent	Giambattista ‘794
[21.2] a dose indicator comprising a second thread that engages with the first thread;	<p>“[P]en 10 generally includes ... dose knob 20[.]” EX1016, 2:36-38.</p> <p>“[D]ose knob 20 is generally tubular having open proximal and distal ends 90 and 92, respectively.” <i>Id.</i>, 3:56-57.</p> <p>“[D]ose knob 20 includes one or more thread portions 95 (FIG. 11) formed to threadedly engage the dose setting thread 54 of the body 18. Accordingly, the dose knob 20 may be rotated within the body 18 resulting in translation of that rotation to axial displacement of the dose knob 20 relative to the body 18 in setting a desired dosage.” <i>Id.</i>, 3:60-66; <i>see also</i> claims 6, 9, 15.</p>



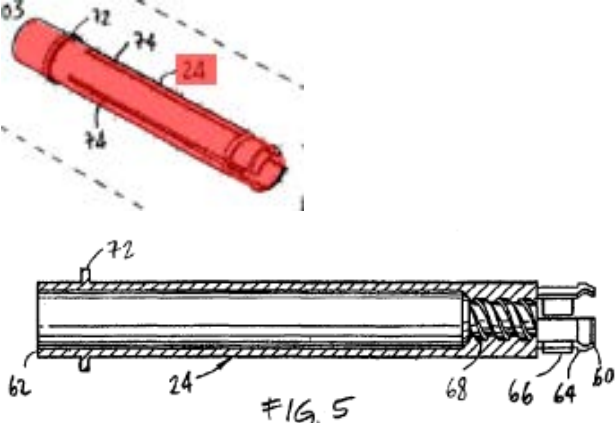
Id., FIGS. 2, 11; EX1011, ¶550.

“Dosage indicia (not shown) may also be disposed externally of the dose knob 20.” EX1016, 3:66-67; *see also id.*, 3:10-15 (window 56 and pointer 58 on body “to clearly point out a selected dosage level”), 5:24-25 (volume of the drug to be expelled is calibrated to the settings of the dose knob 20”), FIGS. 2-3.

Giambattista disclosed a “dose indicator” in the form of dose knob 20. EX1016], 2:36-38. Dose knob 20 is a generally tubular structure that fits “within the body 18” *Id.*, 3:56-64; *see also* FIGS. 7-12. “[D]ose knob 20 includes one or more thread portions 95 (FIG. 11) formed to threadedly engage the dose setting thread 54 of the body 18.” *Id.* at 3:60-62; claims 6, 9, 15. FIG. 11 shows thread portion 95 (second thread) engaged with dose setting thread 54 (first thread) of the

body 18. EX1011, ¶550. Giambattista disclosed that the dose knob 20 is “rotated within the body 18” to set “a desired dosage,” that “dosage indicia” may be disposed externally on dose knob 20 so that pointer 58 in window 56 on body 18 can “clearly point out a selected dosage level,” and that the “volume of the drug to be expelled is calibrated to the settings of the dose knob 20.” *Id.*, 3:10-15, 3:60-67, 5:24-25, FIGS. 2-3. Giambattista thus taught the drug-delivery device comprises a dose indicator comprising a second thread that engages with the first thread as recited in element [21.2]. EX1011, ¶551.

Giambattista disclosed element [21.3]:

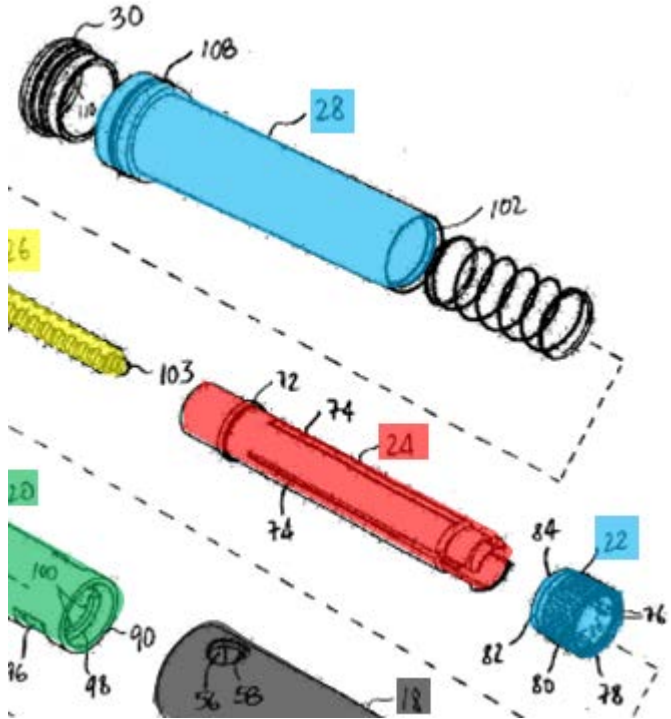
'844 Patent	Giambattista
[21.3] a driving member comprising a third thread;	<p data-bbox="586 1087 1422 1192">“[P]en 10 generally includes ... a driver 24[.]” EX1016, 2:36-38.</p>  <p data-bbox="586 1759 1422 1864"><i>Id.</i>, FIGS. 2, 5; <i>see also id.</i>, FIGS. 7-9, 11- 12; EX1011, ¶552.</p>

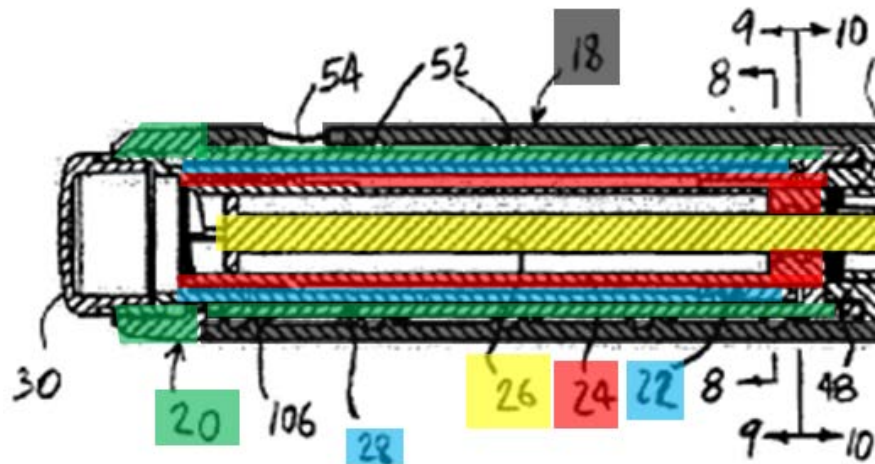
	<p>“With reference to FIG. 5 [above], ... the driver 24 is fixed axially relative to the body 18, yet is able to rotate relative thereto. Internal threads 68 are also provided to threadedly engage threads 70 of the leadscrew 26.” EX1016, 3:16-24.</p> <p>“[T]he driver 24 rotates with the dosing ring 22 ... and the threads 68 of the driver 24 rotate about the threads 70 of the leadscrew 26. Since the leadscrew 26 cannot rotate because of its fixed positioning in the aperture 46, the leadscrew 26 axially translates in a proximal direction to urge the spinner 16 against the plunger 38 in expelling medication from the drug cartridge 32.” <i>Id.</i>, 5:16-24.</p>
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Giambattista ‘794 disclosed a “driving member” in the form of “driver 24.” EX1016, 2:36-38; EX1011, ¶553. Driver 24 is a generally tubular structure that fits within body 18 and dose knob 20. EX1016, FIGS. 2, 5, 7-9, 11-12. As shown in FIG. 5, driver 24 comprises “[i]nternal threads 68 ... to threadedly engage threads 70 of the leadscrew 26.” EX1016, 3:16-24, FIG. 5. FIGS. 7 and 11-12 show internal threads 68 (third thread) engaged with threads 70 (fourth thread) of leadscrew 26. EX1011, ¶552. Driver 24 is configured to transfer force to the leadscrew and thereby drives leadscrew 26 towards the drug dispensing end by rotating its threads 68 about the threads 70 of the leadscrew 26. EX1016, 5:16-24.

Giambattista thus taught the drug-delivery device comprises a driving member comprising a third thread as recited in element [21.3]; EX1011, ¶553.

Giambattista disclosed element [21.4]:

'844 Patent	Giambattista '794
<p>[21.4] a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;</p>	<p>“[P]en 10 generally includes ... dosing ring 22 ... [and] a dosing ring adaptor 28[.]” EX1016, 2:36-39.</p>  <p>The diagram is an exploded perspective view of a pen assembly. At the top is a black cap (30) with a white ring (108). Below it is a blue dosing ring (28) with a spring (102) at its rear. A yellow dosing ring adaptor (26) is shown below the blue ring. A red driving member (12) with a red dosing ring (24) is shown below the adaptor. A green sleeve (20) with a green dosing ring (22) is shown below the driving member. A grey base (18) with a grey dosing ring (22) is shown at the bottom. Various other components are labeled with numbers: 10, 103, 74, 84, 82, 80, 78, 76, 90, 48, 56, 58, 16, 100, 104, 106, 108, 110, 112, 114, 116, 118, 120, 122, 124, 126, 128, 130, 132, 134, 136, 138, 140, 142, 144, 146, 148, 150, 152, 154, 156, 158, 160, 162, 164, 166, 168, 170, 172, 174, 176, 178, 180, 182, 184, 186, 188, 190, 192, 194, 196, 198, 200, 202, 204, 206, 208, 210, 212, 214, 216, 218, 220, 222, 224, 226, 228, 230, 232, 234, 236, 238, 240, 242, 244, 246, 248, 250, 252, 254, 256, 258, 260, 262, 264, 266, 268, 270, 272, 274, 276, 278, 280, 282, 284, 286, 288, 290, 292, 294, 296, 298, 300, 302, 304, 306, 308, 310, 312, 314, 316, 318, 320, 322, 324, 326, 328, 330, 332, 334, 336, 338, 340, 342, 344, 346, 348, 350, 352, 354, 356, 358, 360, 362, 364, 366, 368, 370, 372, 374, 376, 378, 380, 382, 384, 386, 388, 390, 392, 394, 396, 398, 400, 402, 404, 406, 408, 410, 412, 414, 416, 418, 420, 422, 424, 426, 428, 430, 432, 434, 436, 438, 440, 442, 444, 446, 448, 450, 452, 454, 456, 458, 460, 462, 464, 466, 468, 470, 472, 474, 476, 478, 480, 482, 484, 486, 488, 490, 492, 494, 496, 498, 500, 502, 504, 506, 508, 510, 512, 514, 516, 518, 520, 522, 524, 526, 528, 530, 532, 534, 536, 538, 540, 542, 544, 546, 548, 550, 552, 554, 556, 558, 560, 562, 564, 566, 568, 570, 572, 574, 576, 578, 580, 582, 584, 586, 588, 590, 592, 594, 596, 598, 600, 602, 604, 606, 608, 610, 612, 614, 616, 618, 620, 622, 624, 626, 628, 630, 632, 634, 636, 638, 640, 642, 644, 646, 648, 650, 652, 654, 656, 658, 660, 662, 664, 666, 668, 670, 672, 674, 676, 678, 680, 682, 684, 686, 688, 690, 692, 694, 696, 698, 700, 702, 704, 706, 708, 710, 712, 714, 716, 718, 720, 722, 724, 726, 728, 730, 732, 734, 736, 738, 740, 742, 744, 746, 748, 750, 752, 754, 756, 758, 760, 762, 764, 766, 768, 770, 772, 774, 776, 778, 780, 782, 784, 786, 788, 790, 792, 794, 796, 798, 800, 802, 804, 806, 808, 810, 812, 814, 816, 818, 820, 822, 824, 826, 828, 830, 832, 834, 836, 838, 840, 842, 844, 846, 848, 850, 852, 854, 856, 858, 860, 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, 892, 894, 896, 898, 900, 902, 904, 906, 908, 910, 912, 914, 916, 918, 920, 922, 924, 926, 928, 930, 932, 934, 936, 938, 940, 942, 944, 946, 948, 950, 952, 954, 956, 958, 960, 962, 964, 966, 968, 970, 972, 974, 976, 978, 980, 982, 984, 986, 988, 990, 992, 994, 996, 998, 1000.</p>



Id., FIGS. 2, 7; EX1011, ¶554.

“[I]n a rest state, the dosing ring 22 is urged into a rest position with the grooves 76 being spaced from the teeth 100 of the dose knob 20. Accordingly, the dose knob 20 can be freely rotated without rotating the dosing ring 22.” EX1016, 4:49-53.

[T]humb button 30 is depressed With the interengagement of the grooves 76 and the teeth 100, the dosing ring 22 rotates with the dose knob 20. *Id.*, 5:8-16; *see also* claims 1, 13.

Once a dose has been administered, the thumb button 30 is released, causing the dosing ring 22 to return to its rest position. *Id.*, 5:26-28.

Giambattista disclosed a “sleeve” in the form of “dosing ring adaptor 28” and “dosing ring 22,” which may be formed together as a single part or formed

separately and joined together by mounting the dosing ring onto the dosing ring adaptor. EX1016, 2:36-39, 4:21-27; EX1011, ¶555. As shown in FIGS. 2, 7-9, and 11-12, dosing ring adaptor 28 and dosing ring 22 are a generally tubular structure that fits within body 18 and dose knob 20. Leadscrew 26 and driver 24 fit within the internal diameter of dosing ring adaptor 28 and dosing ring 22. *Id.*; *see also id.*, claims 1, 13 (dosing ring “disposed on said driver” and “dose knob coaxially disposed about said dosing ring”). Dosing ring adaptor 28 and dosing ring 22 are therefore a sleeve that is “disposed between the dose indicator and the driving member” as recited in element [21.4(i)]. EX1011, ¶555.

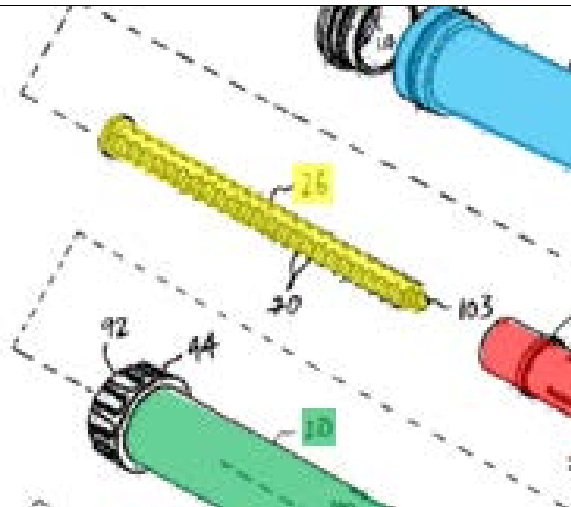
Giambattista disclosed that dosing ring adaptor 28 and dosing ring 22 are “releasably connected to the dose indicator” as recited in element [21.4(ii)]; EX1011, ¶556. Giambattista disclosed that “the dosing ring 22 and the dosing ring adaptor 28 are movable in concert with each other,” either because they are “formed unitarily” as a single piece or because they are “mounted” together. *Id.*, 4:21-27. Dosing ring adaptor 28 is releasably connected to dose knob 20 due to its connection to dosing ring 22, which has grooves 76 that releasably engage teeth 100 on lip 98 of dose knob 20. *Id.*, 3:39-40 (“Dosing ring 22 is formed with one or more grooves 76”), 4:49-51 (“teeth 100 of the dose knob 20”); *see also* claims 1, 13 (describing “selective” operative engagement and disengagement). When force is not being applied to the button, grooves 76 of dosing ring 22 are “spaced apart

from the teeth 100 of the dose knob,” permitting the dose knob to “be freely rotated without rotating dosing ring 22.” *Id.*, 4:49-53.

Depression of thumb button 30 causes “interengagement of the grooves 76” of the dosing ring adaptor 28 and the teeth 100 of the dose knob such that “the dosing ring 22 rotates with the dose knob 20.” *Id.*, 5:8-16; *see also id.* FIGS. 9-10, 12. Biasing means 106 urges the dosing ring adaptor 28 and dosing ring 22 “distally within the pen” such that the teeth 100 of the dose knob and the grooves 76 of the dosing ring 22 are “spaced apart” when the button is released and dosing ring 22 returns to a rest position. *Id.*, 4:37-44, 4:49-56, 5:26-28. Giambattista thus taught the drug delivery device comprises “a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator” as recited in element [21.4]; EX1011, ¶556.

Giambattista disclosed element [21.5]:

'844 Patent	Giambattista '794
[21.5] a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;	“[P]en 10 generally includes ... a leadscrew 26[.]” EX1016, 2:36-39.



Id., FIG. 2; *see also* FIGS. 7-12; EX1011, ¶557.

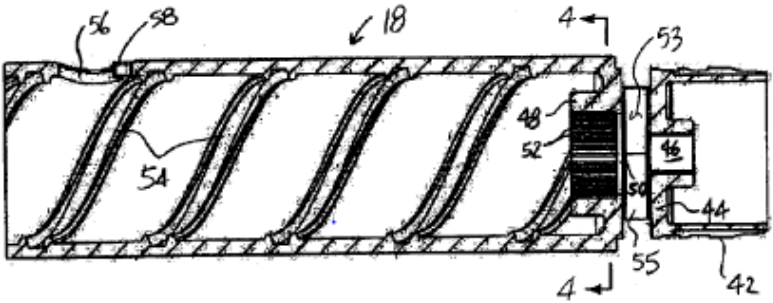
“[T]he threads 68 of the driver 24 rotate about the threads 70 of the leadscrew 26. Since the leadscrew 26 cannot rotate because of its fixed positioning in the aperture 46, the leadscrew 26 axially translates in a proximal direction to urge the spinner 16 against the plunger 38 in expelling medication from the drug cartridge 32.” EX1016, 5:16-24; *see also id.*, 3:22-24; claim 7.

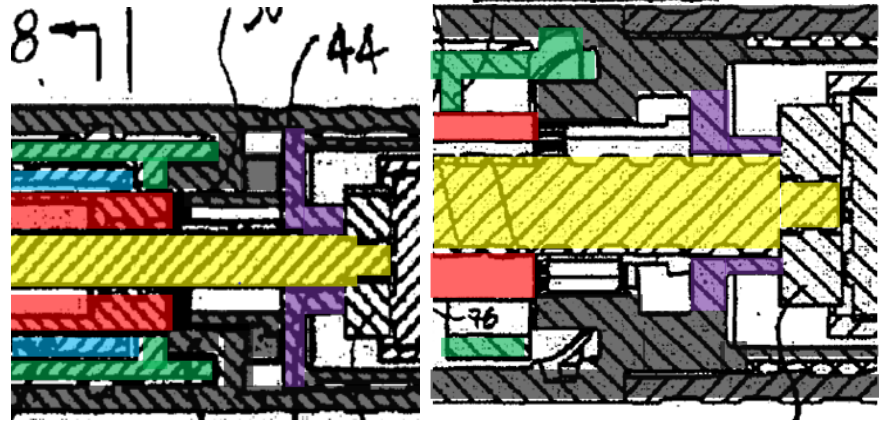
Giambattista disclosed a “piston rod” in the form of “leadscrew 26.”

EX1016, 2:36-39 . As shown in FIGS. 2-3, 7-12, leadscrew 26 has external thread 70 that is engaged with “internal threads 68” of driver 24. *Id.*, 3:22-24, 5:16-24; claim 7; EX1011, ¶557. Giambattista thus taught the drug-delivery device

comprises “a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;” as recited in element [21.5].

Giambattista disclosed element [21.6]:

'844 Patent	Giambattista '794
<p>[21.6] a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing;</p>	<p>“A bulkhead 44 extends across the interior of the body 18 through which an aperture 46 is formed. The aperture 46 is defined to allow the passage therethrough of the leadscrew 26, yet the aperture 46 is shaped (e.g., being rectangular) to prevent rotation of the leadscrew 26 therewithin.” EX1016, 2:66-3:6.</p>  <p style="text-align: center;">FIG. 3</p>



Id., FIG. 3, 7, 11; EX1011, ¶560.

“Since the leadscrew 26 cannot rotate because of its fixed positioning in the aperture 46, the leadscrew 26 axially translates in a proximal direction to urge the spinner 16 against the plunger 38 in expelling medication from the drug cartridge 32.” *Id.*, 5:20-24; *see also* claim 8.

Giambattista disclosed a “piston rod holder” in the form of “aperture 46” in “bulkhead 44” of body 18. EX1016, 2:66-3:6, FIG. 3, claim 8; EX1011, ¶559.. Bulkhead 44 holds leadscrew 26 within aperture 46. *Id.* Bulkhead 44 and aperture 46 prevent rotation of leadscrew 26 within aperture 46 “relative to said body.” *Id.* Giambattista expressly states that “aperture 46 is defined to allow the passage therethrough of the leadscrew 26,” that “the aperture 26 is shaped (.e.g., being rectangular) to prevent rotation of leadscrew therewithin,” and that “the leadscrew 26 axially translates ...to urge the spinner against the plunger 38 in expelling medication from the drug cartridge 32.” EX1016, 3:3-6, 5:20-24 EX1011, ¶561.. Giambattista thus taught the drug-delivery device comprises a piston rod holder

that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the dose dispensing end during dose dispensing. EX1011, ¶562.

Although claim 21 recites that the piston-rod holder permits the piston rod to traverse axially towards the distal end without providing any antecedent basis for the term “the distal end,” it later specifies that “the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.”

Whatever boundaries might be chosen for the term “configured to permit the piston rod to traverse axially towards the distal end,” it is satisfied by aperture 46 in bulkhead 44 being configured to permit axial movement of the leadscrew 26 towards the dose dispensing end during dose dispensing. EX1011, ¶563.

For the reasons discussed, Giambattista taught the drug-delivery device comprises “a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing” as recited in element [21.6]. EX1011, ¶563.

Giambattista disclosed element [21.7]:

'844 Patent	Giambattista '794
[21.7] wherein:	“[P]en 10 generally includes ... a cartridge holder 14 ... [and] a

the housing is disposed at an outermost position of the drug delivery device;

body 18[.]” EX1016, 2:36-38, FIG. 7.

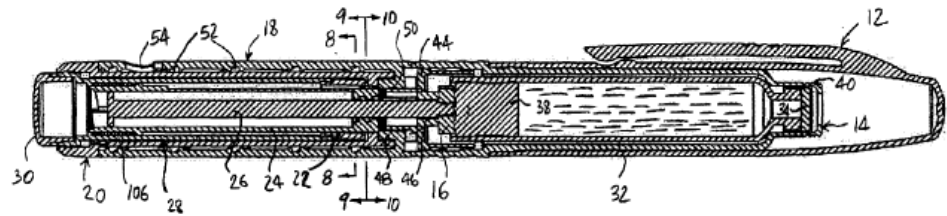
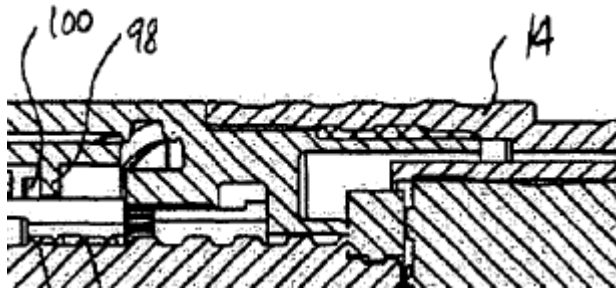


FIG. 7



Id., FIGS. 7, 11-12; EX1011, ¶565.

FIGS. 8-10 showing body 18 disposed at an outermost position of pen 10:

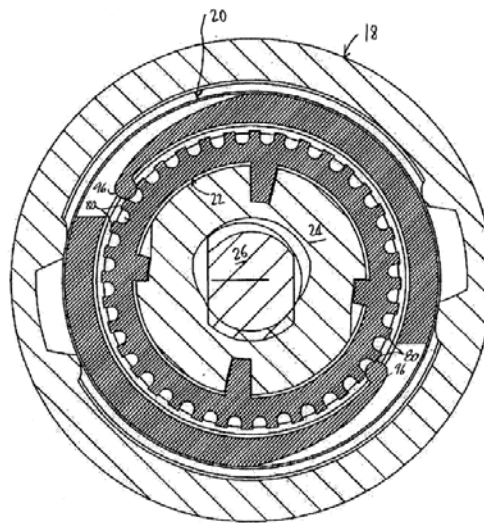


FIG. 8

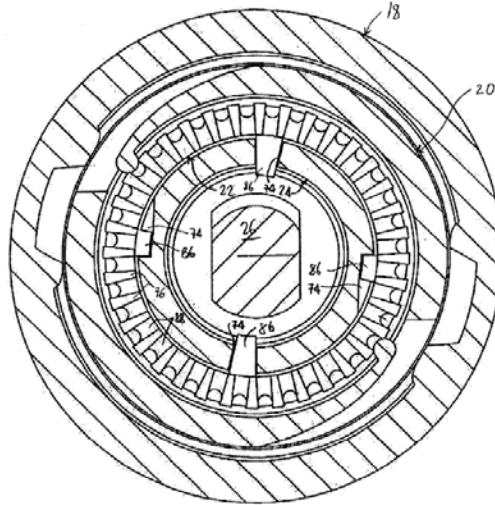


FIG. 9

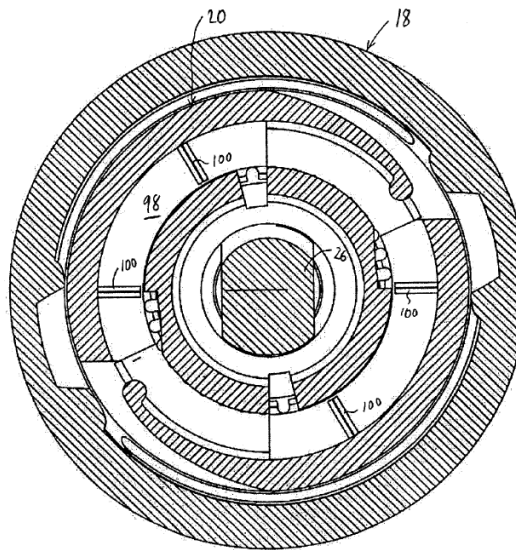


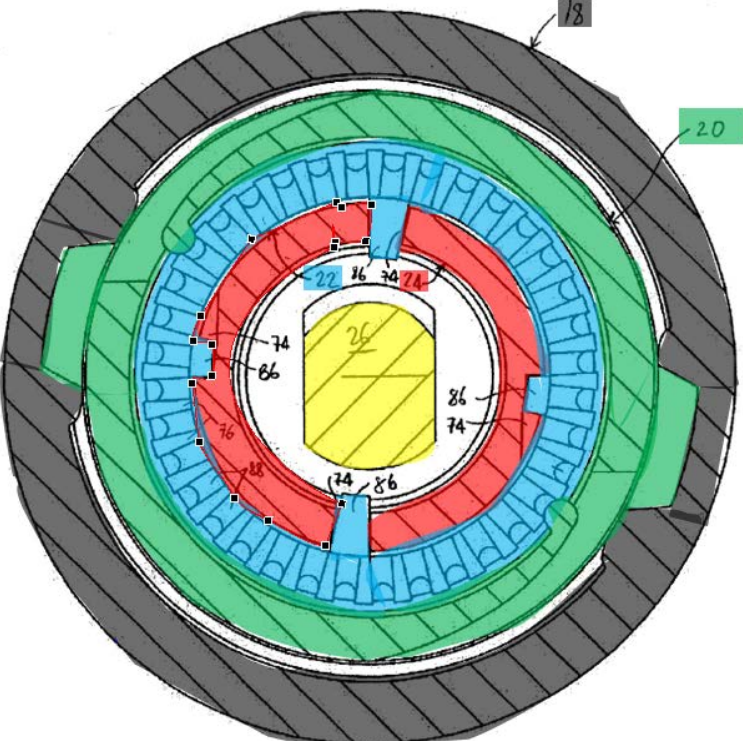
FIG. 10

EX1016, FIGS. 8-10; EX1011, ¶566.

As shown in FIGS. 7-12 of Giambattista'794, body 18 and cartridge holder 14 are disposed at an outermost position of the drug-delivery device. Although the '844 patent expresses a preference for using a removable cap 12 and a replaceable cap 14 to cover the cartridge retaining part 2 with outer dimensions similar to those

of the main housing 4, it does not define either cap as part of the housing, much less as a required part of the housing. EX1011, ¶565. Giambattista thus taught that “the housing is disposed at an outermost position of the drug delivery device” as recited in element [21.7].

Giambattista element [21.8]:

'844 Patent	Giambattista
<p>[21.8] the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing;</p>	 <p>FIG. 9</p>

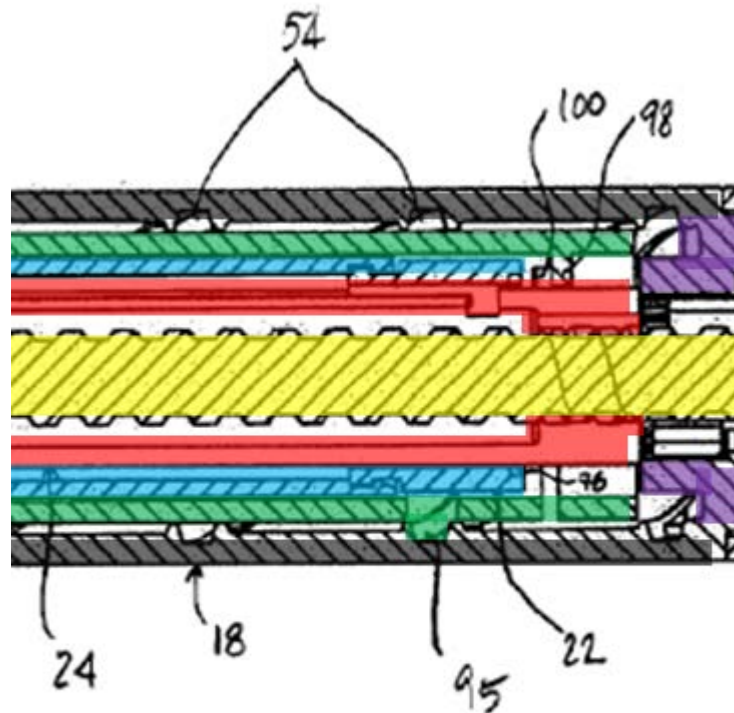


FIG. 11

EX1016, FIG. 9, 11, *See also id.* FIGS. 2, 8, 10-12;
EX1011, ¶568.

“[T]he dose knob 20 may be rotated within the body 18 resulting in translation of that rotation to axial displacement of the dose knob 20 relative to the body 18 in setting a desired dosage.” EX1016, 3:62-66; *see also id.*, 4:49-64; claims 6, 9, 15.

[T]umb button 30 is depressed. Initially, the applied force will act against the biasing means 106 causing initial straight-line motion of the dosing ring adaptor 28 and eventual interengagement of the grooves 76 and the teeth 100, as shown in FIG. 12. Additional force will

	cause the dose knob 20 to rotate in descending along the dose setting thread 54 in a proximal direction. <i>Id.</i> , 5:8-19.
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As shown in FIGS. 2, 7-12 of Giambattista, dose knob 20 is disposed between body 18 and dosing ring 22/dosing ring adaptor 28. EX1011, ¶568. Giambattista thus taught that “the dose indicator is disposed between the housing and the sleeve.” EX1011, ¶568.

Giambattista’794 also taught dose knob 20 “is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing” as required by claim 21. Giambattista taught “dose knob 20 may be rotated within the body 18 resulting in translation of that rotation to axial displacement of the dose knob 20 relative to the body 18 in setting a desired dosage.” EX1016, 3:60-66, 4:49-64, claims 6, 9, 15. Giambattista taught that dose knob 20 traverses axially out of the body during dose setting. EX1011, ¶569.

For example, FIGS. 7 and 11-12 depict dose knob 20 threaded all the way into body 18 via engagement of its thread 95 with internal threads 54 of body 18. EX1011, ¶569. Threads 54 extend from thread 95 of dose knob 20 towards the button-end of the device and do not extend towards the dose dispensing end of the device. In other words, the only axial direction in which dose knob 20 can traverse

during dose setting along threads 54 of body 18 is away from the dose dispensing end of the device. EX1011, ¶569. Giambattista confirms that dose knob 20 traverses axially away from the dose dispensing end during dose setting by disclosing that the dosing ring adaptor 28, biasing means 106, and dosing ring 22 translate with the dose knob 20 and that “dosing ring 22 slides axially long the driver 24 as a proper dose is selected.” EX1016, 4:49-64, FIG. 11.

In contrast, Giambattista taught that depression of thumb button 30 during dose dispensing (towards the dose dispensing end) pushes dosing ring adaptor 28 and dosing ring 22 in the opposite direction and causes “dose knob 20 to rotate in *descending along the dose setting thread 54 in a proximal direction.*” *Id.*, 5:8-19 (emphasis added), FIGS 7, 11-12; EX1011, ¶570. Dose knob 20 has a proximal end 90 and distal end 92, *id.*, 3:56-57, and FIGS. 2 and 11-12 disclose dose knob 20 has teeth 100 at its proximal end 90. The proximal direction in which dose knob 20 descends during dose dispensing corresponds to the same direction as the dose-dispensing end of the device. By teaching the dose knob descends in a proximal direction Giambattista thus taught that dose knob 20 is configured to (i) rotate and traverse axially away from the dose-dispensing end during dose setting and (ii) rotate and traverse axially towards the dose-dispensing end during dose dispensing. EX1011, ¶571.

Giambattista also incorporates by reference the prior-art teaching of axial displacement of the dose knob towards the dose-dispensing end during dose dispensing and away from the dose-dispensing end during dose setting. For example, Giambattista specifically identifies U.S. Patent No. 6,248,095 ('095 patent, EX1021) as illustrating how “a dose knob is manually rotated until a desired dose amount is set,” as is “commonly done,” and incorporates the '095 patent by reference. *Id.*, 1:8-19. In at least FIGS. 9-10 and the accompanying description, the '095 patent illustrates that the dose-set knob 7 translates axially away from the dose-dispensing end during dose setting but towards it during dose dispensing. EX1021, 4:22-53 (dose set knob 7 traverses axially out of body 5 during dose setting and returns within body “in a distal direction” to dispense medication from the vial), FIGS. 9-10. This disclosure further confirms the selective directionality of the axial displacement of the dose knob during dose setting and dose dispensing.

As discussed above, Giambattista therefore taught that “the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing” as recited in element [21.8].

Giambattista disclosed element [21.9]:

'844 Patent	Giambattista '794
[21.9] the driving member is configured to rotate relative to the piston rod;	<p>“With reference to FIG. 5, ...driver 24 is fixed axially relative to the body 18, yet is able to rotate relative thereto. Internal threads 68 are also provided to threadedly engage threads 70 of the leadscrew 26.” EX1016, 3:16-25; <i>see also</i> FIGS. 5, 7-9, 11-12.</p> <p>“With the interengagement of the grooves 76 and the teeth 100, the dosing ring 22 rotates with the dose knob 20. In turn, the driver 24 rotates with the dosing ring 22 ... and the threads 68 of the driver rotate about the threads 70 of the leadscrew 26.” <i>Id.</i>, 5:14-19.</p>

Giambattista disclosed driver 24 is configured to rotate relative to leadscrew 26. Driver 24 “is able to rotate relative” to body 18, whereas leadscrew 26 cannot rotate relative to body 18 because of its “fixed positioning in the aperture 46.” EX1016, 3:16-25, 5:14-24. Driver 24 drives leadscrew 26 towards the drug-dispensing end by rotating about the threads 70 of the leadscrew 26. *Id.*

Giambattista thus taught the “driving member is configured to rotate relative to the piston rod” as recited in element [21.9]. EX1011, ¶572.

Giambattista disclosed element [21.10].

'844 Patent	Giambattista '794
[21.10] the sleeve is	“[S]aid pen comprising ... a dosing ring non-rotatably

<p>rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and</p>	<p>disposed on said driver and axially slidable thereon and therealong[.]” EX1016, Claims 1, 13; <i>see also</i> Abstract, 1:44-46.</p> <p>“As best shown in FIG. 9, in assembling the pen 10, the dosing ring 22 is mounted onto the driver 24 with the splines 86 extending into the keyways 74. As a result, the dosing ring 22 cannot be rotated relative to the driver 24. However, the splines 86 are formed such to allow the dosing ring 22 to axially move along the length of the keyways 74. <i>Id.</i>, 3:39-49.</p> <p>“The dosing ring 22 slides axially long the driver 24 as a proper dose is selected.” <i>Id.</i>, 4:49-61.</p>
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Giambattista disclosed dosing-ring adaptor 28 and dosing ring 22 are rotatably fixed relative to driver 24 and configured to traverse axially with dose knob 20. Giambattista repeatedly disclosed that dosing ring 22 is “non-rotatably disposed on said driver and axially slidable thereon and therealong[.]” EX1016, Claims 1, 13; *see also* Abstract, 1:44-46. It taught that this may be accomplished by mounting dosing ring 22 onto the driver 24 with splines 86 of dosing ring 22 extending into keyways 74 of the driver 24 so that “the dosing ring 22 cannot be rotated relative to the driver 24” but the splines 86 “allow the dosing ring 22 to axially move along the length of the keyways 74.” *Id.*, 3:39-49. It also taught that when dose knob 20 translates axially during dose setting, “dosing ring 22 move[s] therewith” and also “slides axially long the driver 24 as a proper dose is selected.”

Id., 4:49-61. Giambattista thus taught “the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator” as recited in element [21.10]; EX1011, ¶573.

Giambattista disclosed element [21.11].

'844 Patent	Giambattista '794
[21.11] the piston rod and the driving member are configured to rotate relative to one another during dose dispensing;	<p>“Internal threads 68 are also provided to threadedly engage threads 70 of the leadscrew 26.” EX1016, 3:16-24; <i>see also</i> FIGS. 5, 7-9, 11-12.</p> <p>“[D]river 24 rotates with the dosing ring 22 ... and the threads 68 of the driver rotate about the threads 70 of the leadscrew 26. Since the leadscrew 26 cannot rotate because of its fixed positioning in the aperture 46, the leadscrew 26 axially translates in a proximal direction to urge the spinner 16 against the plunger 38 in expelling medication from the drug cartridge 32.” <i>Id.</i>, 5:16-24.</p>

Giambattista disclosed leadscrew 26 and driver 24 are configured to rotate relative to one another during dose dispensing. EX1016, 3:16-24. Driver 24 “is able to rotate relative” to body 18, whereas leadscrew 26 cannot rotate relative to body 18 because of its “fixed positioning in the aperture 46.” EX1016, 3:16-24, 5:16-24. Driver 24 drives leadscrew 26 towards the drug-dispensing end by rotating about threads 70 of leadscrew 26. *Id.* Giambattista thus taught “the piston

rod and the driving member are configured to rotate relative to one another during dose dispensing” as recited in element [21.11]. EX1011, ¶574.

Giambattista disclosed element [21.12]:

'844 Patent	Giambattista '794
[21.12] and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.	“[T]he driver 24 rotates with the dosing ring 22 ... and the threads 68 of the driver rotate about the threads 70 of the leadscrew 26. Since the leadscrew 26 cannot rotate because of its fixed positioning in the aperture 46, the leadscrew 26 axially translates in a proximal direction to urge the spinner 16 against the plunger 38 in expelling medication from the drug cartridge 32.” <i>Id.</i> , 5:16-24.

Giambattista disclosed leadscrew 26 is configured to traverse axially towards the dose-dispensing end during dose dispensing.

Driver 24 is configured to transfer force to the leadscrew and thereby drives leadscrew 26 towards the drug-dispensing end by rotating its threads 68 about threads 70 of the leadscrew 26. EX1016, 5:16-24. Giambattista thus taught “the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing,” as recited in element [21.12]. EX1011, ¶575.

For the reasons discussed above, each and every element of claim 21 and the subject matter of claim 21 as a whole is disclosed in Giambattista.

2. Claim 22

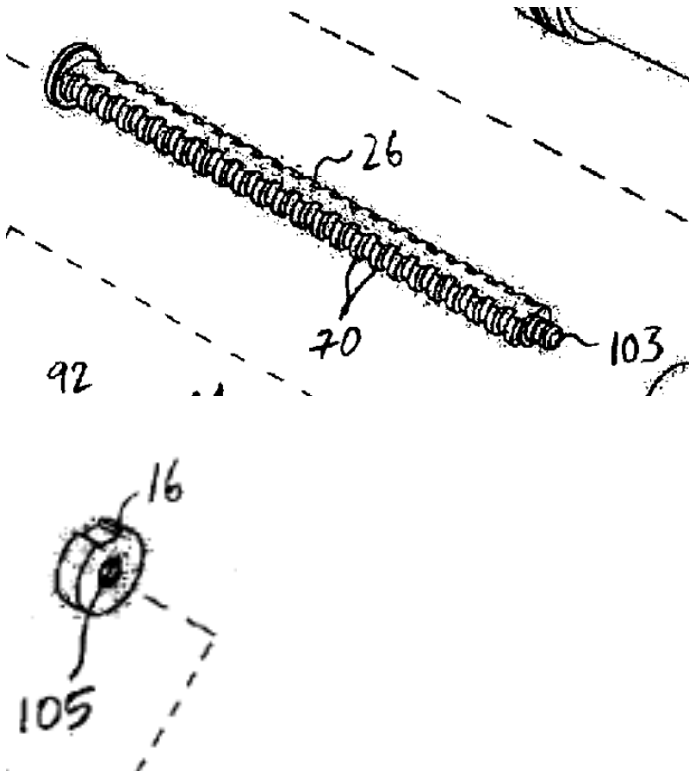
'844 Patent	Giambattista '794
<p>[22] The drug delivery device of claim 21 where the piston rod has a circular cross-section.</p>	 <p>EX1016, FIG. 2; EX1011, ¶577.</p> <p>“The leadscrew 26 may be of any conventional type and is formed with a threaded end 103. The spinner 16 includes a threaded aperture 105 formed to threadedly engage the threaded end 103 in mounting the spinner 16 onto the leadscrew 26.” EX1016, 4:28-33.</p>

FIG. 2 of Giambattista disclosed leadscrew 26 has a circular cross section at each of threaded end 103 and the opposite end of leadscrew 26. Claim 22 does not

recite that the piston rod has a uniformly circular cross section along its entire length. However, leadscrew 26 has circular helical threads along the majority of its length and is understood to have a “circular cross-section” with flat sides. EX1011, ¶577. Giambattista thus taught the “drug delivery device of claim 21 where the piston rod has a circular cross-section,” as recited in claim 22.

3. Claim 23

'844 Patent	Giambattista
23. The drug delivery device of claim 21 further comprising a clutch.	<p>“[D]osing ring 22 cannot be rotated relative to the driver 24.” EX1016, 3:43-47.</p> <p>“[I]n a rest state, ... the dose knob 20 can be freely rotated without rotating the dosing ring 22.” <i>Id.</i>, 4:49-53.</p> <p>“[T]humb button 30 is depressed. Initially, the applied force will act against the biasing means 106 causing initial straight-line motion of the dosing ring adaptor 28 and eventual interengagement of the grooves 76 and the teeth 100, as shown in FIG. 12 With the interengagement of the grooves 76 and the teeth 100, the dosing ring 22 rotates with the dose knob 20. In turn, the driver 24 rotates with the dosing ring 22[.]” <i>Id.</i>, 5:8-19; <i>see also</i> claims 1, 13.</p>

Clutch 60 of the '844 patent serves both as the “sleeve” as recited in element [21.4] as well as the clutch of claim 23. Giambattista disclosed dosing ring adaptor

28 and dosing ring 22, which act as a clutch. EX1011, ¶678. As discussed above, Sanofi has construed a clutch in the context of the '844 patent to mean a structure that couples and decouples a moveable component from another component. Dosing ring 22 and dosing ring adaptor 28 are “movable in concert with each other,” may be “formed unitarily” with one another and may be “unitarily formed” with the thumb button 30. EX1016, 4:21-36. Dosing ring 22 is rotationally fixed to driver 24, a moveable component that rotates during dose dispensing. *Id.*, 3:39-47, 5:16-19. Depression of button 30 rotationally couples dose knob 20 with dosing ring 22, thereby rotationally coupling dose knob 20 with driver 24. *Id.*, 4:49-53, 5:8-16; *see also* claims 1, 13. Thus, rotation of dose knob 20 during dose dispensing results in rotation of each of dosing ring 22 and driver 24. Once a dose has been administered, thumb button 30 is released, causing dosing ring 22 to return to its rest position such that rotation of dose knob 20 does not result in rotation of dosing ring 22 and driver 24. *Id.*, 5:26-28. Giambattista thus taught the “drug delivery device of claim 21 further comprising a clutch,” as recited in claim 23. EX1011, ¶578.

4. Claims 24, 25, and 29.

'844 Patent	Giambattista
[24] The drug delivery device of claim 23	<i>See</i> claim 23 above regarding “clutch” limitation.

where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

[25] The drug delivery device of claim 24 where the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.

[29] The drug delivery device of claim 21 further comprising a clicker that provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.

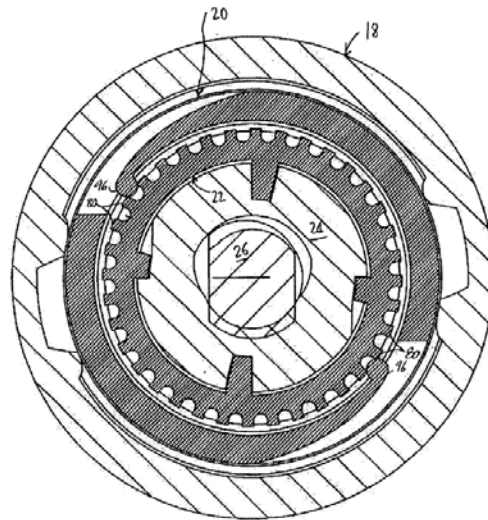


FIG. 8

EX1016, FIG. 8; EX1011, ¶¶580, 593..

“Dosing ring 22 is formed with ... a plurality of longitudinal ribs 80[.]” EX1016, 3:39-40.

“[R]atchet arms 96 are aligned with the longitudinal ribs 80 so that rotation of the dose knob 20 relative to the dosing ring 22 results in the ratchet arms 96 acting against the ribs 80 in a ratcheting manner giving a user an audible signal of such rotation. In contrast to the prior art, the dose knob 20 can freely rotate in both directions relative to the dosing ring 22 with the ratchet arms 96 acting against the ribs 80 during both rotational directions of the dose knob 20.” EX1016, 4:1-12.

“The subject invention, unlike the prior art, allows the dose knob 20 to be ‘dialed back’ freely if a desired dosage amount is inadvertently by-passed, without the undesirable and costly effect of expelling medication.”

	<p><i>Id.</i>, 4:49-64.</p> <p>“In a preferred embodiment, with a desired dosage amount being set, the ratchet arms 96 advantageously provide holding force to maintain the desired radial position of the dose knob 20 relative to the dosing ring 22, and, thus, to the driver 24. In other words, the dose knob 20 cannot rotate without overcoming this holding force.” <i>Id.</i>, 4:65-5:3.</p>
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As discussed above regarding claim 23, dosing ring 22 together with dosing ring adaptor 28 operate as a clutch. EX1011, ¶579. Giambattista disclosed that dosing ring 22 comprises a plurality of longitudinal ribs 80. EX1016, 3:39-40. Rotation of inwardly-biased ratchet arms 96 of dose knob 20 around longitudinal ribs 80 of dosing ring 22 gives “a user an audible signal of such rotation.” *Id.*, 4:1-8. Ratchet arms 96 act against the ribs 80 to give the user an audible signal “during both rotational directions of the dose knob 20,” *id.*, 4:8-12, including when dose knob 20 is “dialed back” when a “desired dosage amount is inadvertently bypassed,” *id.*, 4:49-64. Giambattista thus disclosed that dosing ring 22 provides audible clicks caused by the physical interaction with ratchet arms 96 during dose setting and dose cancelling. EX1011, 580.

Because the audible signal is created by action (i.e., impact) of the inwardly-biased ratchet arms 96 of dose knob 20 on longitudinal ribs 80 of dosing ring 22,

the user would have tactile feedback as well. EX1016, 4:1-8. In other words, the audible feedback is created by the tactile interaction. EX1011, ¶581; *see also* EX1004, 5:64-6:2 (noting that audible and tactile feedback is provided by dragging a toothed member over splines to provide a click).

In the pen disclosed by Giambattista, each click is equal to, and indicative of, a unit dose of medicament. Giambattista taught that engagement of longitudinal ribs 80 of dosing ring 22 with ratchet arms 96 when a desired dosage amount is being set “advantageously provide[s] holding force to maintain the desired radial position of the dose knob 20 relative to the dosing ring 22, and, thus, to the driver 24.” EX1016, 4:65-5:3. As Leinsing explains, the disclosure of Giambattista that the holding force at each longitudinal rib 80 is large enough to maintain the desired radial position of dose knob 20 to drive 24 establishes each audible signal (*i.e.*, click) at a unit dose of medicament. EX1011, ¶¶582, 594. FIG. 8 of Giambattista demonstrates that ribs 80 are evenly spaced around dosing ring 22, which means that each unit dose represented by each audible signal is the same. *Id.*, ¶¶584-585.

Giambattista thus taught a drug-delivery device where the clutch provides audible and tactile feedback indicative of unit doses of medicament, where the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament, and where the pen comprises a clicker that provides

audible clicks during dose cancelling, where each click is equal to a unit dose of medicament, as recited respectively in claims 24, 25, and 29. EX1011, ¶585.

Moreover, to the extent that “clicker” is construed to be means-plus-function, Giambattista teaches that limitation as well. The ’844 patent teaches that in dialing a dose, “flexible arm 52” with “toothed member 54” is dragged over “splines 42” to produce a click. EX1004, 5:64-6:3. If a dose is being dialed down, saw teeth 56 and 66 ride over each other to produce a click. *Id.*, 6:33-35. Thus, the structure taught by the ’844 patent that is used to provide an audible click is either a flexible arm being dragged over splines, or saw teeth riding over one another. EX1011, ¶596.

As discussed above, Giambattista teaches that ratchet arms 96 act against the ribs 80 to give the user an audible signal in both directions of rotation of dose knob 20. EX1016, 4:8-12. Thus, Giambattista teaches the use of a flexible arm being dragged over splines to create an audible click, and thus, teaches the same structure performing the same function.

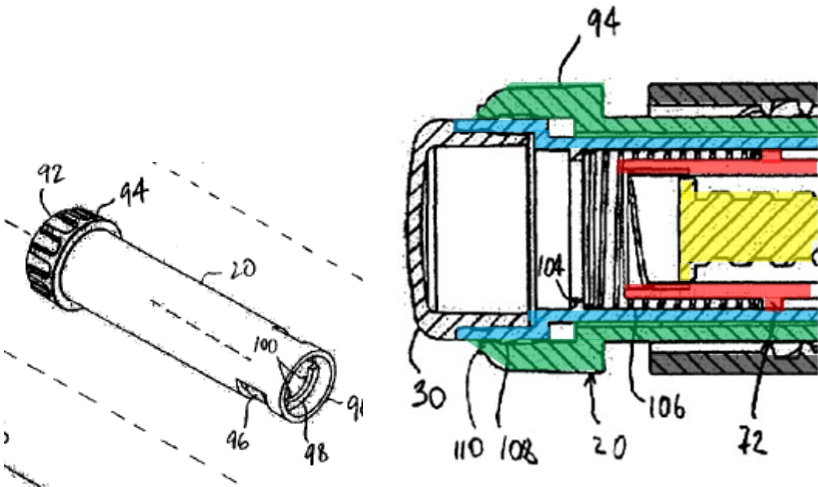
Accordingly, Giambattista discloses the additional limitations of claims 24-25, 29.

5. Claim 26

Giambattista disclosed that “the clutch allows the dose cancelling without dispensing medicament,” as recited in claim 26. As discussed above, in setting a

dose, dose knob 20 is rotated within body 18, and dosing-ring adaptor 28 and dosing ring 22, i.e., the clutch of Giambattista, move with dose knob 20, dosing ring 22 sliding axially along driver 24 as a proper dose is selected. EX1016, 4:49-61. Giambattista states further that “[t]he subject invention, unlike the prior art, allows dose knob 20 to be ‘dialed back’ freely if a desired dosage amount is inadvertently by-passed, without the undesirable and costly effect of expelling medication.” *Id.*, 4:61-64. Giambattista thus taught the “drug delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament,” as recited in claim 26. EX1011, ¶586.

6. Claim 27

'844 Patent	Giambattista
<p>[27] The drug delivery device of claim 24 further comprising a button seated in an annular recess of a dose dial grip on a proximal end of the dose indicator, where the button is rotatable relative to the dose indicator.</p>	<p>See claim 24 above.</p>  <p>EX1016, FIGS. 2, 11; EX1011, ¶587.</p> <p>“The dose knob 20 is generally tubular having open</p>

	<p>proximal and distal ends 90 and 92, respectively. A textured handle 94 is formed in proximity to the distal end 92 which is engageable by a user to rotate the dose knob 20 in setting the pen 10 to a desired dosage amount.” EX1016, 3:56-60; <i>see also</i> FIGS. 7, 11-12.</p> <p>“[T]he thumb button 30 is of any conventional design and formed to snap onto the dose ring adaptor 28. The thumb button 30 may be unitarily formed with the dose ring adaptor 28.” <i>Id.</i>, 4:33-36.</p> <p>“[T]he dose knob 20 can be freely rotated without rotating the dosing ring 22.” <i>Id.</i>, 4:49-53.</p> <p>“[D]osing ring 22 and the dosing ring adaptor 28 are movable in concert with each other. In an alternative embodiment, the dosing ring adaptor 28 and the dosing ring 22 may be formed unitarily.” <i>Id.</i>, 4:21-27.</p>
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Giambattista disclosed thumb button 30 seated in an annular recess of a textured handle 94 of dose knob 20 on a proximal end of dose knob 20, where the button is rotatable relative to dose knob 20. EX1011, ¶587. “A textured handle 94 is formed in proximity to the distal end 92 which is engageable by a user to rotate the dose knob 20 in setting the pen 10 to a desired dosage amount.” EX1016, 3:56-60. As shown in FIG. 2, the distal end 92 of dose knob 20 corresponds with the proximal end of the dose dial sleeve depicted in, for example, FIGS. 1-5 of the ’844 patent. As shown in FIGS. 2, 7, 11-12 of Giambattista, thumb button 30 is

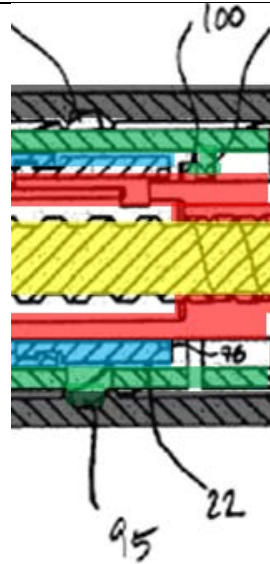
seated in an annular recess of textured handle 94. EX1011, ¶588. Thumb button 30 is snapped onto or formed integrally with dose ring adaptor 28. EX1016, 4:33-36. Dosing ring 22 is “movable in concert with” dosing ring adaptor 28 or the two “may be formed unitarily.” *Id.*, 4:21-27. In a rest state, “dose knob 20 can be freely rotated without rotating the dosing ring 22.” *Id.*, 4:49-53. Because thumb button 30 is snapped onto or formed integrally with dosing-ring adaptor 28 (which is movable in concert or formed integrally with dosing ring 22), thumb button 30 is also rotatable relative to dose knob 20.

Giambattista thus disclosed the “drug delivery device of claim 24 further comprising a button seated in an annular recess of a dose dial grip on a proximal end of the dose indicator, where the button is rotatable relative to the dose indicator,” as recited in claim 27.

7. Claim 28

'844 Patent	Giambattista
[28] The drug delivery device of claim 27 where axial movement of the button caused by distally applied pressure to the button initiates dose delivery by displacing the clutch	<i>See</i> claim 27 above.

axially with respect to the dose indicator and driving member.



EX1016, FIG. 11; EX1011, ¶589.

“Referring to FIG. 11, in a rest state, the dosing ring 22 is urged into a rest position with the grooves 76 being spaced from the teeth 100 of the dose knob 20.

Accordingly, the dose knob 20 can be freely rotated without rotating the dosing ring 22.” *Id.*, 4:49-53.

“The dosing ring 22 slides axially long the driver 24 as a proper dose is selected.” *Id.*, 4:59-61.

“[T]humb button 30 is depressed. Initially, the applied force will act against the biasing means 106 causing initial straight-line motion of the dosing ring adaptor 28 and eventual interengagement of the grooves 76 and the teeth 100, as shown in FIG. 12.... In turn, the driver 24 rotates with the dosing ring 22 [T]he leadscrew 26 axially translates in a proximal direction to urge the spinner 16 against the plunger 38 in expelling

	<p>medication from the drug cartridge 32.” <i>Id.</i>, 5:8-28; <i>see also</i> claims 1, 13.</p> <p>“With the snap 20 ring connection, the driver 24 is fixed axially relative to the body 18, yet is able to rotate relative thereto.” <i>Id.</i>, 3:19-21</p>
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Giambattista disclosed that depression of thumb button 30 initiates dose delivery by displacing the dosing ring adaptor 28 and dosing ring 22 axially with respect to the dose knob 20 and driver 24. EX1011, ¶589. In a rest state, grooves 76 of dosing ring 22 are spaced from teeth 100 of dose knob 20, and rotation of dose knob 20 thus does not rotate the dosing ring (and thereby the driver). *Id.*, 4:49-53. Dose delivery is initiated by depressing the button, which is snapped into or formed integrally with dosing ring adaptor 28. *See, e.g.*, FIG. 11. Depression of the button thus depresses the dosing ring adaptor 28, and thereby depresses the dosing ring 22 mounted on or integrally formed with the dosing-ring adaptor 28 relative to the dose knob 20 until the grooves 76 of the dosing ring 20 come into contact with the teeth 100 of the dose knob 20. *Id.*, 5:8-28, FIGS. 11-12; *see also* claims 1, 13. This constitutes axial movement of the button caused by distally applied pressure to the button initiating dose delivery by displacing dosing-ring adaptor 28 and dosing ring 22 axially with respect to the dose knob. EX1011, ¶590. As thumb button 30, dosing-ring adaptor 28 and dosing ring 22 move

axially in concert towards the dose-dispensing end, driver 24 cannot move axially with them because driver 24 “is fixed axially relative to the body 18.” EX1016, 3, 19-21, 4:59-61. In other words, depression of thumb button 30 also causes axial displacement of dosing-ring adaptor 28 and dosing ring 22 with respect to driver 24. Giambattista thus taught the “drug delivery device of claim 27 where axial movement of the button caused by distally applied pressure to the button initiates dose delivery by displacing the clutch axially with respect to the dose indicator and driving member” as recited in claim 28. EX1011, ¶591.

F. Ground 2: Giambattista Renders Claims 24-29 Obvious in Further View of Steinfeldt-Jensen

As explained above, Giambattista ‘794 disclosed each and every element of claims 21-29. To the extent Giambattista’s disclosure regarding its clicking feature does not teach that each click is equal to a unit dose, Steinfeldt-Jensen’s express teaching of this feature was readily applicable to Giambattista.

Claim 24 requires that the audible feedback be indicative of unit doses of medicament, and claims 25 and 29 require that each click equal a unit dose of medicament. *See supra*, sections V.E.4. Steinfeldt-Jensen taught a clicking system that, like the system disclosed in Giambattista, operates by having a protrusion extend into a number of depressions such that the spacing of the depressions causes tactile and audible signal as the protrusion snaps into the

depressions. *See, e.g.*, EX1014, 6:48-54, 11:37-40, 11:62-67. Clicker means were well known elsewhere in the art. *See, e.g.*, EX1013, 10:42-52. EX1011, ¶¶61-64, 598-599.

Steenfeldt-Jensen expressly taught that “[t]he angular spacing of the depressions are appropriately made so that a dose of one unit is set when the protrusion is moved from one depression to the neighbouring depression so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose.” EX1014, 6:48-53. Steenfeldt-Jensen thus confirms through an express disclosure the expert’s testimony that the clicker described in Giambattista as providing an audible signal arising from physical contact of the protrusion across the depressions necessarily also provides tactile feedback because the interaction of the protrusion as it moves from one depression to another is both “heard and felt.” EX1011, ¶599.

Steenfeldt-Jensen also elaborates that the spacing between each depression “are appropriately made so that a dose of one unit is set” for each click “so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose.” EX1014, 6:48-53; EX1011, ¶600.. Steenfeldt-Jensen would have provided a reason to a POSA to likewise arrange longitudinal ribs 80 so that a dose of one unit is set for each click so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose. EX1011,

¶601. A POSA would have had a reasonable expectation of success in so arranging the longitudinal ribs because it would be a simple matter of calculating the axial translation of leadscrew 26 acquired from each rotation of dose knob 20 and multiplying that distance by the area of the plunger against the medication in the drug cartridge to calibrate to a desired unit dose. *Id.*, ¶602.

Moreover, to the extent that “clicker” is construed to be means-plus-function, the combination of Steenfeldt-Jensen and Giambattista teaches that limitation as well. As discussed above, Giambattista teaches the use of a flexible arm being dragged over splines to create an audible click, and thus, teaches the same structure performing the same function. To the extent that Giambattista might not expressly state that one click is equal to a unit dose of medicament, Steenfeldt-Jensen supplies that limitation.

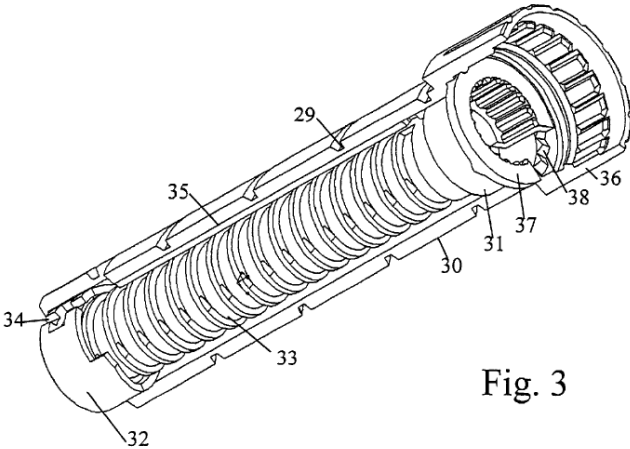
Steenfeldt-Jensen also teaches the use of a flexible arm being dragged over splines to create an audible click, and thus, teaches the same structure performing the same function as both Giambattista and the '844 patent. Steenfeldt-Jensen expressly teaches that the spacing between each depression “are appropriately made so that a dose of one unit is set” for each click “so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose.” EX1014, 6:48-53. Thus, it would have been obvious to a POSA to place the splines of Giambattista such that each click corresponds to a set dose so that the

number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose. EX1011, ¶602.

Each of claims 24-29 is thus obvious over Giambattista for the reasons discussed in Ground 1 above, in further view of Steinfeldt-Jensen, as discussed herein.

G. Ground 3: Giambattista in Further View of Klitgaard Renders Claim 30 Obvious.

As discussed above in Ground 1, Giambattista ‘794 anticipates claim 21. Claim 30 further requires the device comprise a nut that tracks each set dose of medicament delivered. Employing a nut in the drug delivery pen of Giambattista to track each set dose of medicament would have been obvious in view of Klitgaard.

'844 Patent	Giambattista & Klitgaard
[30] The drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered.	 <p data-bbox="971 1711 1058 1753">Fig. 3</p>

	<p>EX1017, FIG. 3; EX1011, ¶605.</p> <p>“During the setting of a dose the nut member 32 is ... rotated with the dose setting member 30 relative to the driver 31 so that the position of the nut member 32 on this driver is dependent on the dose set. When the dose is injected ... the dose setting member 30 is ... forced to rotate relative to the housing [and] the rotation will be transmitted to the driver 31 ... and during this rotation the nut member 32 will maintain its position on the driver 31. This way the position of the nut member 32 on the driver 31 will always indicate the total sum of set and injected doses. When the length of the helical track 33 in the driver 31 is adapted to the amount of medicine in a cartridge the nut member 32 will reach the end of the track 33 and stop for setting a dose larger than the amount remaining in the cartridge.” EX1017, 4:33-58.</p>
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Klitgaard disclosed an injection device for dispensing medicine. *See* EX1017, Abstract. In Klitgaard, the “driver is provided with a track having a length which is related to the total amount of liquid in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of this dose setting member.” EX1017, Abstract. Because the track follower moves further into the track “[e]ach time a dose is set and injected,” it tracks each dose of medication that is set and prevents setting of a dose larger than the remaining liquid in the cartridge. *Id.*; EX1011, ¶604.

For example, FIG. 3 and its related description disclose nut member 32 that tracks each set dose of medication delivered to prevent setting a dosage that exceeds the remaining supply of medication in the cartridge. EX1017, 4:16-58. During dose setting, dose-setting member 30 is threaded out from internal threads on a housing. *Id.*, 4:16-25. At the same time, nut member 32 screws up along a helical track on the outer surface of driver 31 due to engagement between a ridge on the inner side of dose setting element 30 and recess 34 in the outer wall of nut member 32. *Id.*, 4:26-37. During dose-dispensing, dose setting member 30 is forced to rotate relative to the housing and transmits rotational force to driver 31, but nut member 32 maintains its position on driver 31 to “always indicate the total sum of set and injected doses.” *Id.*, 4:37-58. EX1011, ¶605.

Klitgaard expressly discussed a reason that a POSA would have had to employ a nut that tracks each set dose of medicament delivered. Klitgaard explained that this type of dose-tracking nut would be used to “always indicate the total sum of set and injected doses” and prevent setting a dose that exceeds the remaining available supply of medication in the cartridge. EX1017, 4:52-58, Abstract. Klitgaard further explains that “it is convenient if a limiting device is provided which makes it impossible to set a dose that exceeds the amount of medicament which is left in the cartridge.” *Id.*, 1:34-37. As Leinsing confirms, these same benefits would be desirable in the Giambattista drug-delivery device discussed above regarding claim 21. EX1011,

¶¶606-607.

A POSA would have had a reasonable expectation of success in incorporating such a nut into the drug delivery pen of Giambattista. EX1011, ¶608. For example, nut member 32 as described in Klitgaard could be easily adapted and disposed between dosing ring adapter 28 and dose knob 20 to track each set dose of medicament delivered. *Id.* These components have the concentric arrangement and relative movement identified by Klitgaard as the foundation for applying its nut. *Id.*; *see also id.*, ¶¶59-60, 149.

Accordingly, claim 30 was obvious over the combination of the teachings of Giambattista and Klitgaard.

VI. CONCLUSION

For the reasons set forth above, claims 21-30 are unpatentable. The unpatentability of these claims patent is not an abstract concern. The high cost of insulin products reduces patient compliance, with adverse effects for American diabetics. *See* EX1035, 2, 8. Mylan respectfully requests, therefore, that an IPR of the challenged 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 12,757, which is less than the 14,000 allowed under 37 C.F.R. 42.24(a)(i). In accordance with 37 C.F.R. 42.24(a), this word count does not include table of contents, table of authorities, mandatory notices under §42.8, certificate of service or word count, or appendix of exhibits or claim listing.

/Richard Torczon/

Reg. No. 34,448

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, I certify that I caused to be served a true and correct copy of the foregoing: **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,679,844 and Exhibits 1001-1035** by Federal Express Next Business Day Delivery on 10 September 2018 on the Patent Owner's correspondence address of record for the subject patent as follows:

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Respectfully submitted,

Dated: 10 September 2018

/Richard Torczon/
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