

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH,
Patent Owner.

Patent No. 8,992,486

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, “Medication Delivery Pen” (issued Aug. 23, 2005) |
| 1017 | U.S. Patent 6,582,404 B1 – P.C. Klitgaard et al., “Dose Setting |

| <u>Exhibit No.</u> | <u>Description</u> |
|---------------------------|--|
| | 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.) (filed Sep. 5 2018) |
| 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 Syringe” (pub’d Aug. 5, 1999) (Steenfeldt-Jensen PCT) |
| 1028 | Mylan GmbH and Biocon’s Preliminary Claim Constructions and |

| <u>Exhibit No.</u> | <u>Description</u> |
|---------------------------|---|
| | 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 (filed Sep. 5, 2018) |
| 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, <i>Mechanisms & Mechanical Devices Sourcebook</i> 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 <i>1 Mechanism Design: Analysis and Synthesis</i> (1984) |
| 1034 | WO 01/83008 – S. Hansen & T.D. Miller., “ <i>An Injection Device, A Preassembled Dose Setting And Injection Mechanism For An Injection Device, And A Method Of Assembling An Injection Device</i> ” (pub’d Nov. 8, 2001) |
| 1035 | K.J. Lipska et al., <i>Association of Initiation of Basal Insulin Analogs vs Neutral Protamine Hagedorn Insulin With Hypoglycemia-Related Emergency Department Visits or Hospital Admissions and With Glycemic Control in Patients With Type 2 Diabetes</i> , 320 J. Am. Med. Ass’n 53-62 (2018). |

I. INTRODUCTION

Mylan Pharmaceuticals Inc. (“Mylan”) petitions for *inter partes* review (“IPR”) of claims 51-57 of U.S. Patent No. 8,992,486 to Veasey (“the ’486 patent,” EX001). *See* 37 U.S.C. §311.

This Petition shows a reasonable likelihood that the prior art renders claims 51-57 unpatentable.

II. MANDATORY NOTICES

A. Real Parties-In-Interest

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

Mylan Pharmaceuticals Inc., Mylan Inc., and Mylan GmbH are subsidiaries of Mylan N.V.

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, Biocon, and their real parties-in-interest are parties in this litigation. Becton Dickinson and Company supplies pens to Mylan, but has not been named as a party.

The ’844 patent also has been asserted in *Sanofi-Aventis U.S. LLC v. Merck Sharp & Dohme Corp.*, No. 1:16-cv-00812 (D. Del.). Mylan, Biocon, and their real parties-in-interest are not parties in this litigation.

The '486 patent is related to U.S. Patent No. 8,679,069, U.S. Patent No. 7,918,833, U.S. Patent Application No. 10/790,225 (now abandoned), and GB Patent Application No. 0304822.

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 rtorczon@wsgr.com and dcarsten@wsgr.com. A power of attorney accompanies this petition. 37 C.F.R. 42.10(b).

III. CERTIFICATIONS

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

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

Mylan requests IPR and cancellation of claims 51-57 of the '486 patent under pre-AIA 35 U.S.C. 102 and pre-AIA 35 U.S.C. 103, as Mylan's detailed statement of the reasons for the relief requested sets forth, supported with exhibit copies, and the Declaration of Karl R. Leinsing, Ex. 1011.

Claims 51-57 of the '486 patent are unpatentable on these grounds:

| Ground | Claims | Basis |
|--------|-----------------|---|
| 1 | 51-55, 57 | Anticipation under §102 by U.S. Patent No. 6,221,046 (EX[Burroughs], “Burroughs”) |
| 2 | 54-55 | Obviousness under §103(a) over Burroughs |
| 3 | 51-53, 56-57 | Anticipation under §102 by U.S. Patent No. 6,235,004 (EX[Steenfeldt-Jensen], “Steenfeldt-Jensen”) |
| 4 | 56 | Obviousness under §103(a) over Steenfeldt-Jensen |
| 5 | 54-55 | Obviousness under §103(a) over Steenfeldt-Jensen in combination with Burroughs |
| 6 | 51-53, 56-57 | Anticipation under §102 by U.S. Patent No. 6,663,602 (EX[Møller], “Møller”) |
| 7 | 54-55 | Obviousness under §103(a) over Møller in combination with Burroughs |

V. STATEMENT OF REASONS FOR THE RELIEF REQUESTED

A. Summary of the Argument

The challenged claims relate to a clutch for use within a pen type drug delivery device. Numerous prior art injector pens used a clutch to couple and decouple moveable components from one another, and claims 51-57 of the '486 patent offer no structural or functional details beyond what was already well known and commonly used in prior art devices. 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). Accordingly, there is nothing new or non-obvious in claims 51-

57 of the '486 patent.

B. The '486 Patent¹

1. Background

Claims 51-57 of the '486 patent relate to a clutch within a pen-type injector for the self-administration of medicine. *See* EX1003, Pen-Type Injector, 10:31-59.

Independent claim 51 recites:

51. A clutch for use within a pen type drug delivery device,
said clutch comprising
a tubular body, said tubular body extending from a distal end to
a proximal end;
and said distal end of said tubular body having a diameter sized
such that said distal end of said tubular body may be positioned within
a proximal end of a dial member.

Dependent claims 52-57 depend directly or indirectly from claim 51 and describe

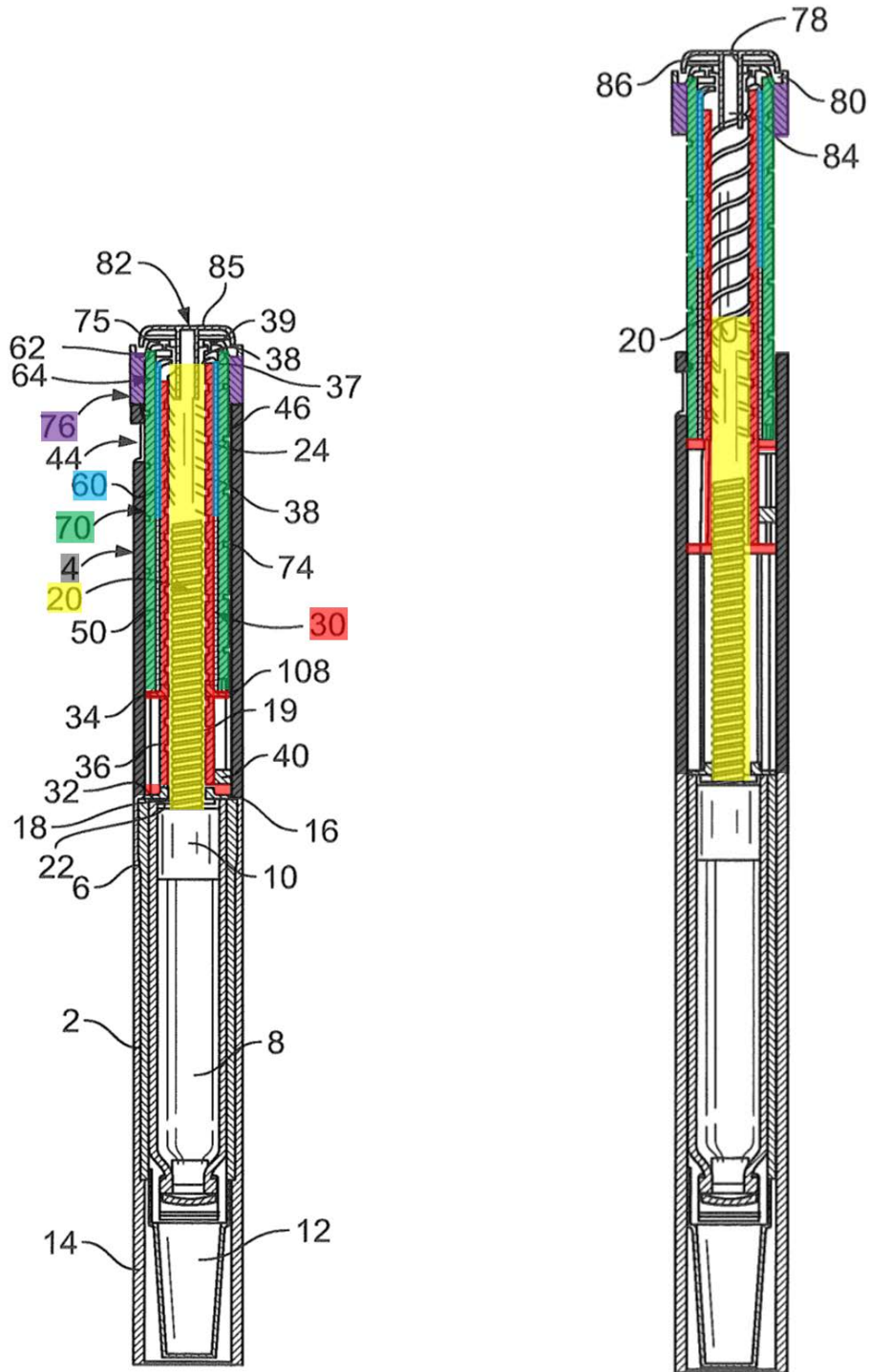
¹ For purposes of uniformity, when discussing both the '486 patent and the prior art, description of the positioning and movement of components will be relative to the “button-end” of the device and the “needle-end” of the device. EX1011, 32-33. In addition, as noted by Leinsing, the '486 patent shares a common specification with the other patents challenged, and the expert declaration citations are to the '069 patent (EX1001), unless otherwise noted. *Id.*, ¶24 n.4,

additional features of the clutch and associated pen components that were well known at the time of invention.

For ease of reference, the components of the pen taught by the '486 patent are color-coded as follows:

- (1) “main housing” (4, dark grey);
- (2) “dose dial sleeve” (70, green);
- (3) “dose knob” (76, purple);
- (4) “piston rod” (20, yellow);
- (5) “driver” (30, red); and
- (6) “tubular clutch” (60, blue).

FIGS. 1 (left) and 2 (right) of the '486 patent are reproduced below.

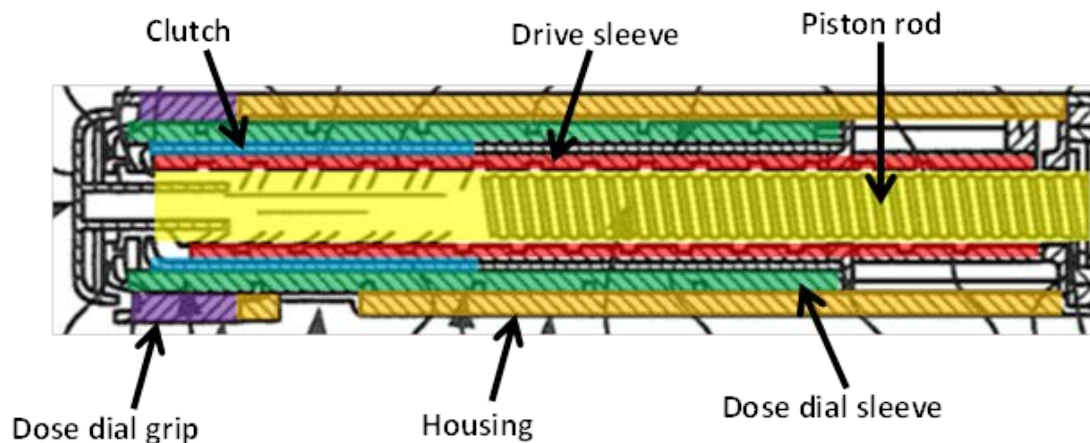


Id. FIGS. 1-2; EX1011, ¶38.

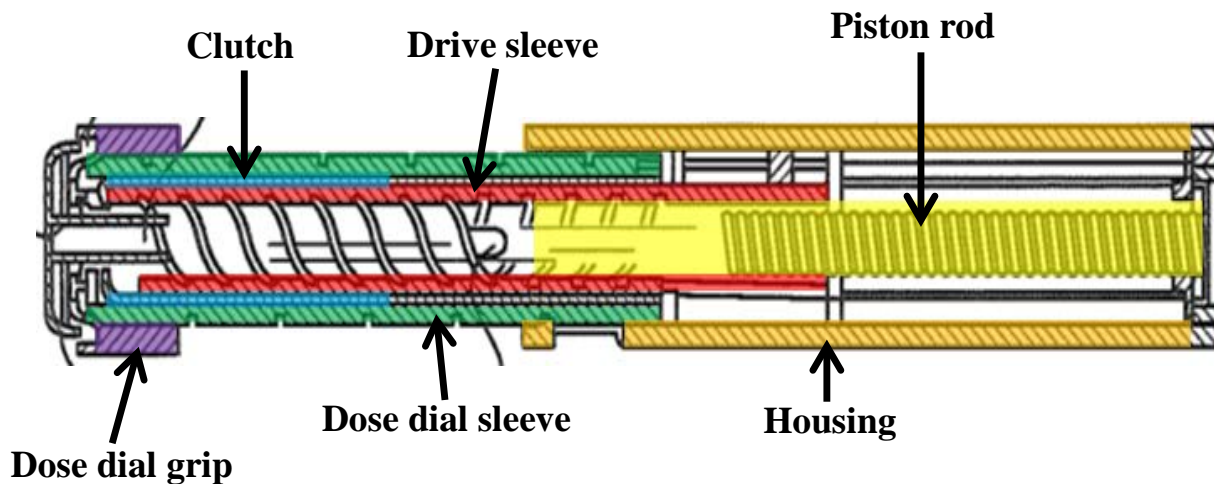
Brief Overview of the Disclosed Embodiments

The '486 patent describes an injector having a housing that is formed from two

parts: (1) a first cartridge retaining part 2, which contains a cartridge 8 from which medicine is dispensed, and (2) a second main housing part 4. *See id.*, 3:27-38, FIG. 1. The second main housing part 4 houses the drive mechanism, which includes a clutch that releasably couples the dose dial sleeve to the drive sleeve:



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* 1011, ¶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)

Clutch 60 is “disposed about the drive sleeve, between the drive sleeve 30 and a dose dial sleeve 70.” *Id.*, 4:33-35, FIGS. 1, 6-7. Clutch 60 is “generally cylindrical” and located adjacent the button-end of driver 30. *See id.*, 4:50-52, FIG. 7. “The clutch 60 is keyed to the drive sleeve 30 by way of splines ... to prevent relative rotation between the clutch 60 and the driver 30.” *Id.*, 4:60-62. At its button-end, clutch 60 includes dog teeth 65. *See* EX1003, 4:58-60, FIGS. 1-2, 8. Teeth 65 releasably engage with the button-end of dose dial sleeve 70. *See id.*, 6:29-31, FIG. 1. The specification does not explain how teeth 65 engage with dose dial sleeve 70, though they presumably engage with “an inwardly directed flange in the form of [a] number of radially extending members 75” provided at dose dial sleeve 70’s button-end. *See* EX1011, ¶69 (citing EX1003, 5:22-24).

Dose dial sleeve 70 is “provided outside of” the clutch 60 and “radially inward of” the housing 4. *Id.*, 5:6-5, FIG. 1. “A helical groove 74 is provided about an outer surface of the dose dial sleeve 70.” *Id.*, 5:5-6, FIGS. 1-2, 12. “The main housing 4 is further provided with a helical rib 46, adapted to be seated in the helical groove 74” to allow for relative rotation. *Id.*, 5:9-11, FIGS. 15-16. Dose knob 76 (purple) “is disposed about an outer surface of the [button-end] of the dose dial sleeve 70.” *Id.*, 5:24-25, FIGS. 1-2. “The dose knob 76 is secured to the dose dial sleeve 70 to prevent relative movement therebetween.” *Id.*, 5:27-29.

Operation of the Pen Injector

Dose setting: To set a dose, the user rotates dose knob 76 in one direction. *See id.*, 5:50-51; FIG. 9 (shown annotated below). At this stage, the teeth 66 of the clutch 60 are engaged to the dose dial sleeve 70. *See id.*, 5:50-59. Such engagement causes the dose dial sleeve 70, the clutch 60, and the driver 30 to rotate together out of the housing. *See id.*; FIG. 9. The driver 30 rotates up the piston rod 20, toward its button-end, due to its engagement with the piston rod 20's second thread 24. *See id.*, 5:61-65. The piston rod 20 is prevented from rotating due to its opposing, threaded engagement with the insert 16. *See id.*, 4:4-13, 6:1-3.

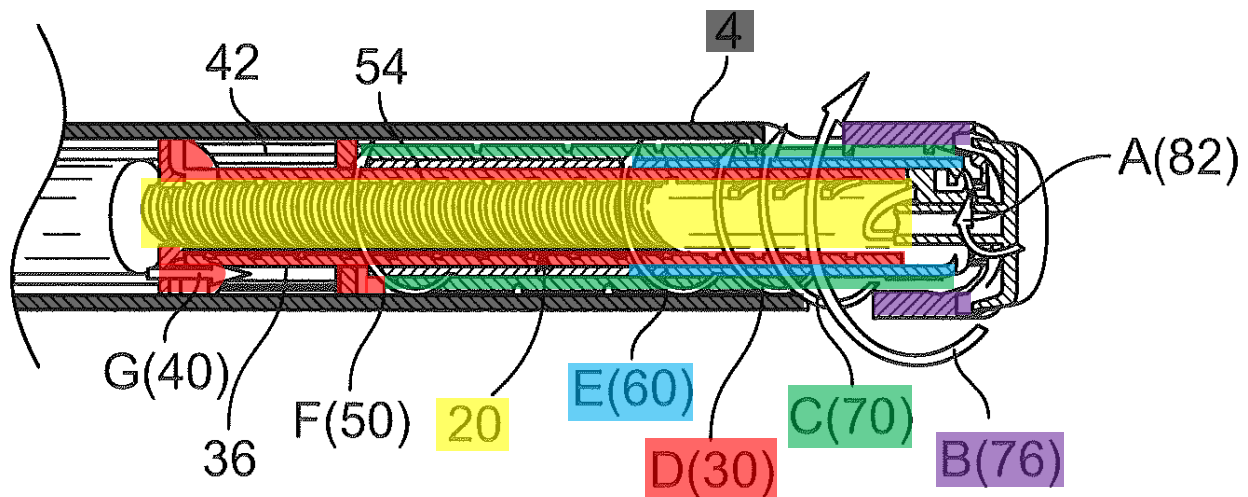


FIG. 9: Dialing up (*see id.*, 2:55-56), annotated to highlight components (*see* EX1011, ¶81)

The user also may dial down a dose. *See id.*, 6:27-30; FIG. 10 (reproduced and color-coded below). To dial-down a dose, the user rotates dose knob 76 in the

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

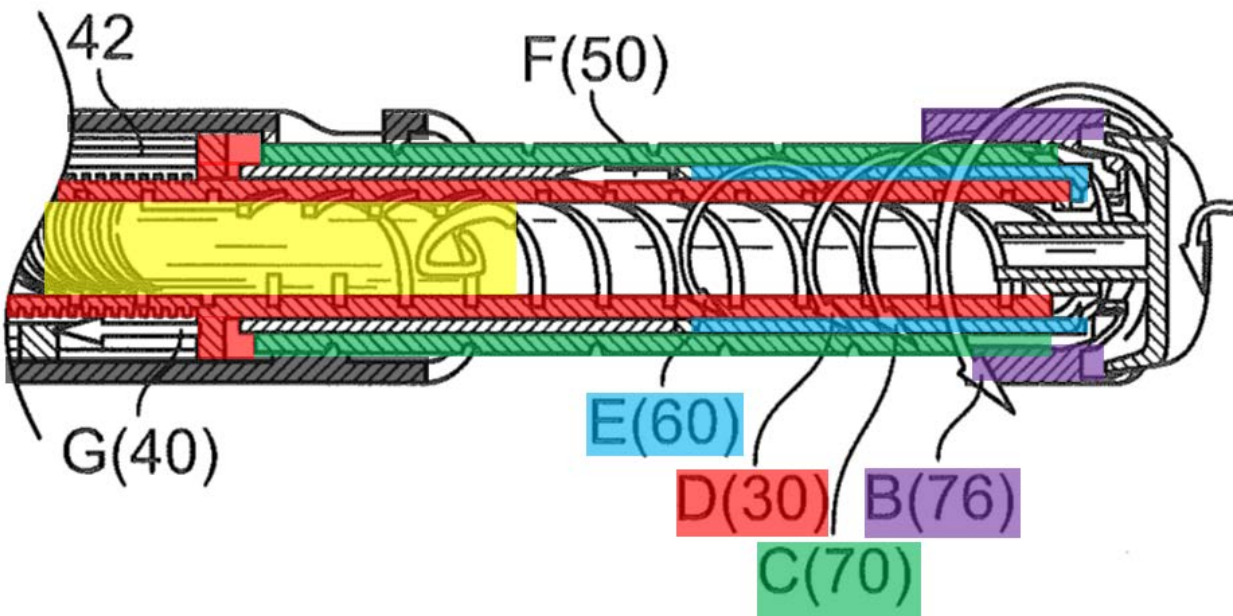


FIG. 10: Dialing down (*see id.*, 57-58), annotated to highlight components (*see EX[EXPERT]*, ¶84)

Injection: Once the dose is set, the user presses a button 82, applying a force toward the needle-end of the device. *See id.*, 6:28-29; FIG. 11. This displaces the clutch 60 axially such that the teeth 65 disengage from the dose dial sleeve 70. *Id.*, 6:29-31. Dose dial sleeve 70 rotates back into the housing 4 via its threaded connection with the housing. *Id.*, 6:33-35; FIG. 11. Now disengaged from the

dose dial sleeve 70, clutch 60 does not follow this rotation, and instead, moves axially toward the needle-end of the device. *See id.*, 6:31-33, 6:38-40. The driver 30 also moves axially toward the needle-end, driving the piston rod 20 to rotate through the threaded opening 18, causing medicine to be dispensed from the cartridge 8. *Id.*, 6:45-47.

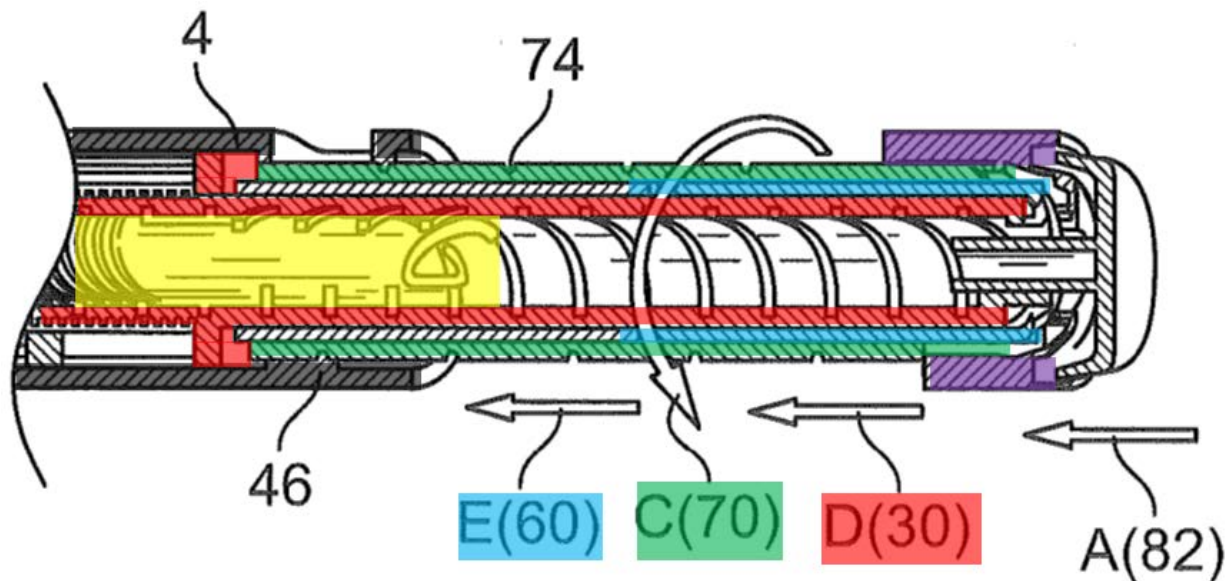


FIG. 11: Injecting dose (see *id.*, 2:59-60), annotated to highlight components (see EX1011, ¶88)

2. Prosecution History

No anticipation or obviousness rejections were applied to the claims during prosecution. The claims were allowed immediately following the applicant's response to a nonstatutory double patenting rejection. A Notice of Allowance followed. EX1008, 113-115, 140, 146-152.

Applicant submitted information disclosure statements including, *inter alia*, Burroughs, Møller, and a PCT application similar to Steinfeldt-Jensen, but these references were never applied in an art-based rejection under §§102 or 103. *See id.*, 110-115. A Notice of Allowance was issued on February 19, 2015. *Id.*, 146-152.

C. Level of Ordinary Skill in the Art

The relevant timeframe is prior to March 3, 2003, the earliest priority date claimed by the '486 patent. As described in the corresponding Declaration of Mr. Leinsing (EX1011), a POSA at the relevant time would have had at least a bachelor's degree in mechanical engineering, or an equivalent degree. *See* EX1011, ¶106. The POSA also would have understood the basics of medical device design and manufacturing and the basic mechanical elements (*e.g.*, gears, pistons) involved in drug delivery devices. *Id.*

D. Claim Construction

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

In the related *Sanofi v. Mylan* and *Sanofi v. Merck* litigation, Patent Owner Sanofi has taken positions regarding the meaning of certain claim terms, which it cannot now argue are unreasonable. *See Ex parte Schulhauser*, Appeal No. 2013-

007847, slip op. at 9 (PTAB Apr. 28, 2016) (precedential) (“A proper interpretation of claim language, under the broadest reasonable interpretation of a claim during prosecution, must construe the claim language in a way that at least encompasses the broadest interpretation of the claim language for purposes of infringement.”). The relevant terms are listed below, along with Sanofi’s proffered construction for those terms.

“clutch”: “A structure that couples and decouples a moveable component from another component.” EX1019, 22-24.

“tubular clutch”: “A tubular structure that couples and decouples a moveable component from another component.” *Id.*, 21-22.

Mylan notes further that in the related litigation with Sanofi, it proffered a preliminary means-plus-function construction for the claim term “tubular clutch” and “clutch.” EX1028, Exhibit E, 102-106. The district court in that litigation has not yet set forth a claim construction. To the extent that the Board concludes that the broadest reasonable interpretation of those terms is a means-plus-function construction, Mylan provides those constructions below. 37 C.F.R. 42.100(b), 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

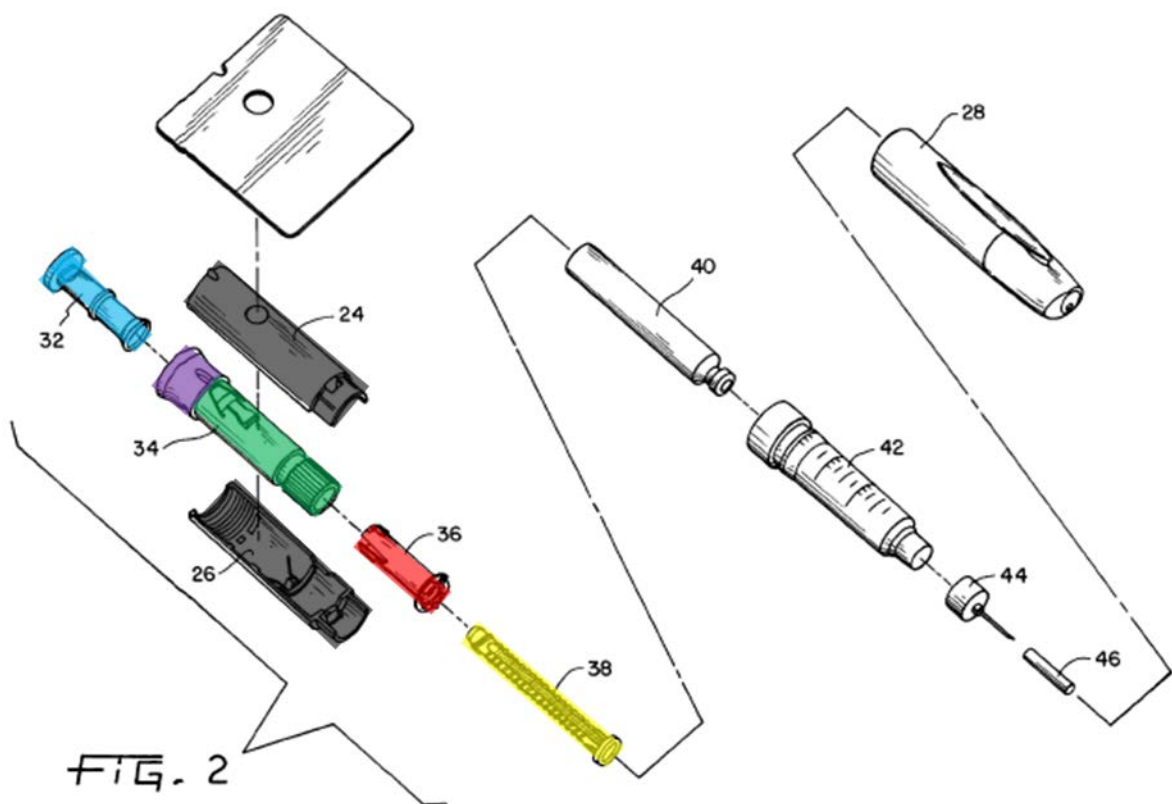
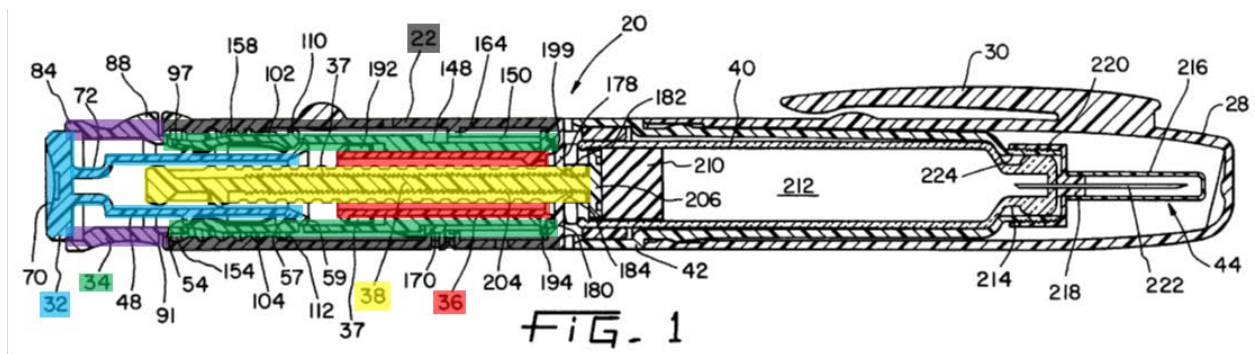
components in rotation.” EX1028, 103-104, 106. Mylan points to FIGS. 1, 5-11, component 60, as the corresponding structure for the clutch. *Id.* 101, 104; *see also* EX1003, 2:16-18. 4:49-62, 4:63-65; 6:36-44.

E. The Prior Art

As explained by Leinsing and addressed in further detail below, the claims would not have been considered new or non-obvious to a POSA at the relevant time. Numerous clutches for use in pen-type injectors were known before March 3, 2003, including many clutches with tubular bodies that fit at least partially within a dial member, as broadly claimed by the ’486 patent.

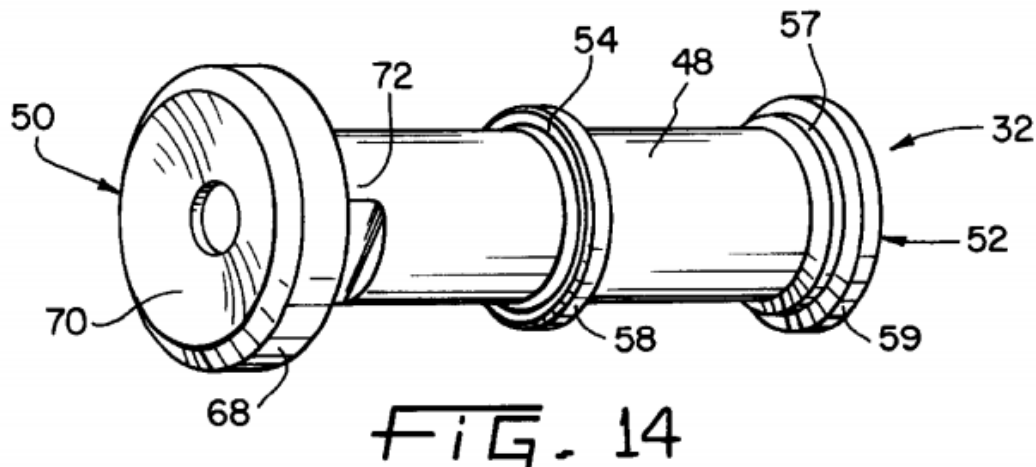
1. Burroughs

Burroughs issued April 24, 2001 and is therefore prior art under §102(b). Burroughs discloses a medication dispensing pen for dispensing selectively measured dosages of medicine. *See* EX1013, 1:13-16. The annotated figures below shows an embodiment of this clutch—*i.e.* “button 32” (**blue**)—that releasably couples a dose dial sleeve—*i.e.* “dial mechanism 34” (**green**)—to the threading of housing 22 (dark grey) (shown bifurcated as first part 24 and second part 26 in FIG. 2) and “nut 36” (**red**). *See id.*, 11:13-34; EX1011, ¶126. “Proximal portion 78” ([**purple**]) and “leadscrew 38” ([**yellow**]) are also color-coded for clarity.



See EX1013, FIGS. 1-2; EX1011, ¶126.

Figure 14 shows button 32 in greater detail:



EX1013, FIG. 14.

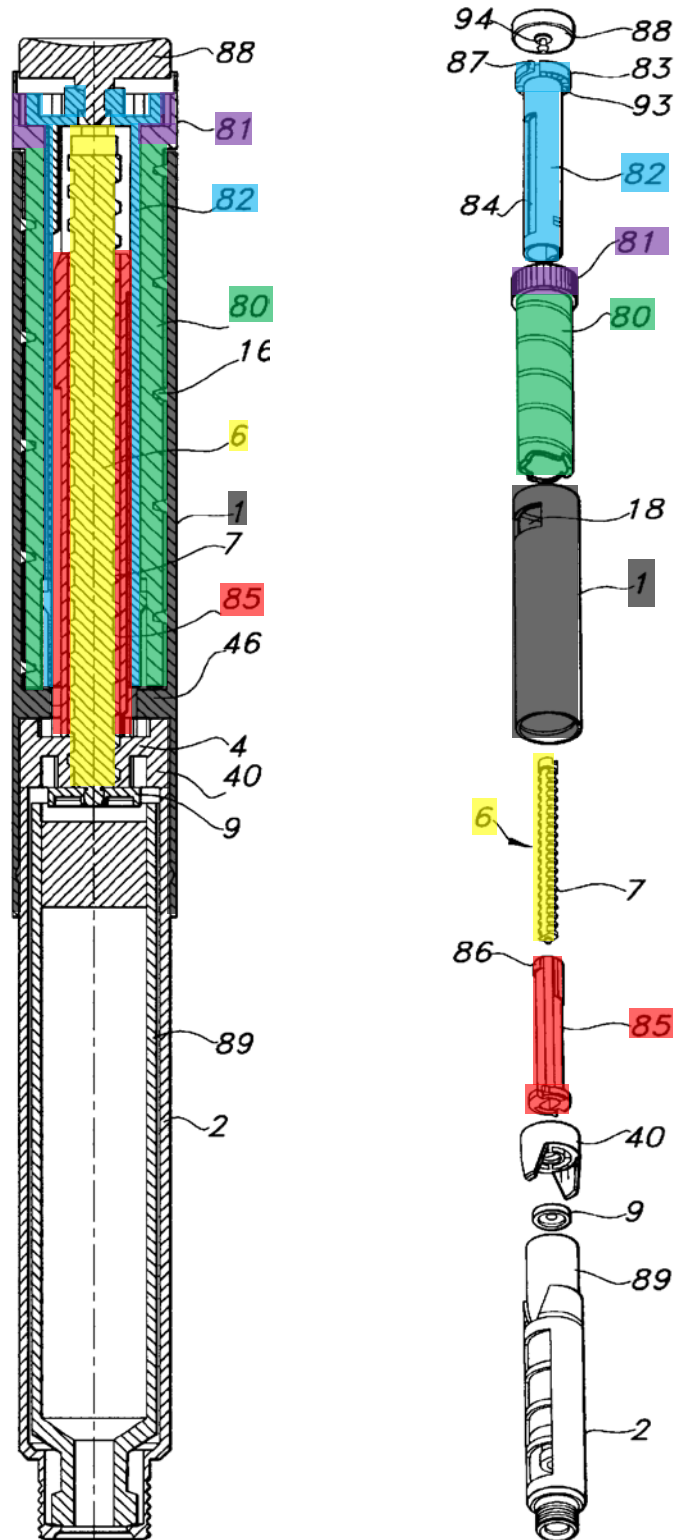
As shown in the figures above, the lower portion of the clutch (*i.e.* button 32) sits inside the dial mechanism 34. This portion includes “a hollow cylindrical portion 48” and “an enlarged diameter ring 54.” EX1013, 7:46-52, FIGS. 1-2, 14-15.

When a user administers a dose, the enlarged diameter ring 54 is pressed into engagement with “ramped inner surfaces 96” of “flexible sections 92 and 95 [of dial mechanism 34].” *Id.*, 8:11-20, FIGS. 6-9; *see also id.*, 11:5-12. “When button 32 is depressed, enlarged diameter portion 54 is also depressed and thereby pushes against ramped surfaces 96, which in turn forces fingers 94 outward and legs 102 and 104 [having threads 110, 112] inward. Dial mechanism 34 is then able to travel axially towards cartridge 40 during injection of the medical product.” *Id.*, 8:15-20.

On the interior surface of dial mechanism 34, “a plurality of splines 144 ... engage with teeth 192 ... provided on nut 36 when the clutch is engaged to set a dosage.” EX1013, 8:42-48, FIG. 9; *see also id.*, 9:16-18, FIGS. 10-11 (nut 36 having splines 192). Depressing button 32 moves dial mechanism 34 axially toward the cartridge thereby causing teeth 192 to disengage from splines 144. *Id.*, 11:27-30. This disengagement of the clutch “rotationally decoupl[es] dial mechanism 34 from nut 36.” *Id.*

2. Steenfeldt-Jensen

Steenfeldt-Jensen discloses injection syringes for dispensing medicine. *See* EX1014, Abstract. Steenfeldt-Jensen discloses injection syringes that utilize clutches to releasably couple drive-mechanism components. *See* EX1014, Abstract. The annotated figures below shows one such clutch (“bushing 82” (**blue**)). Additional components of this embodiment are color-coded for clarity, including “tubular housing 1” (**orange**), “scale drum 80” (**green**), “dose setting button 81” (**purple**), “piston rod 6” (**yellow**), and “piston rod drive” (**red**) comprising “driver tube 85” and “member 40.”



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

In this embodiment, “bushing 82” releasably connects scale drum 80 and driver

tube 85 during injection. *See id.*, 12:4-13. The bushing 82 has a smaller diameter than the scale drum 80 and button 81, and “is mounted in the scale drum 80.” *See* EX1014, 11:43-45, FIGS. 16-17. The button-end of the bushing 82 has a flange 83. *Id.*, 11:26. Bushing 83 sits in an internal cylindrical compartment of dose setting button 81. *Id.* 11:34-42; FIGS. 16-17..

The needle side of the flange 83 has “a rosette 93 of teeth which can be brought into engagement with [a corresponding] rosette at the bottom of the compartment.” *Id.* 11:40-42. The bushing 82 is configured in the scale drum 82 so that it “can be moved axially relative to the scale drum to make or not make the teeth of said rosettes engage each other.” *Id.*, 11:45-49. When the user presses the injection button 88 to administer a dose, “the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81.” *Id.*, 12:4-9. The bushing 82 will also “rotate the driver tub 85 in an anticlockwise direction” during administration of a dose. *Id.*, 12:9-10. In this way, the bushing couples components during injection that are otherwise uncoupled. *See id.*, 4-13.

3. Møller

Møller is prior art to the '044 patent under pre-AIA 35 U.S.C. §102(a) and (e). Møller describes pen-type injectors that include a clutch. The annotated figure below shows one embodiment of this clutch (*i.e.* the “cup shaped element” (**blue**)). Additional components are color-coded for clarity, including “housing 1” (grey),

“dose setting drum 17” (**green**), “dose setting button 18” (**purple**), “piston rod 4” (**yellow**), and a drive sleeve (**red**) comprising “connection bars 12” having a “nut 13.”

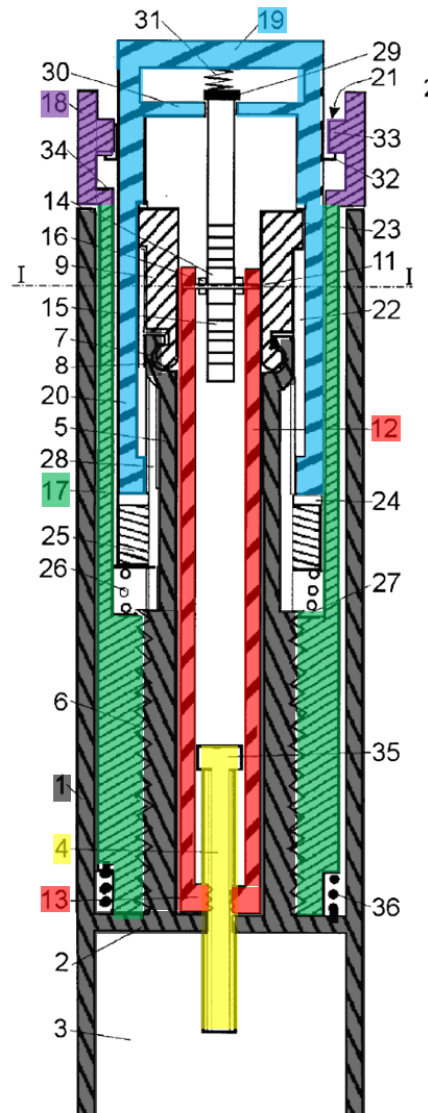


Fig. 1

See EX1015, FIG. 1; EX1011, ¶139

The cup shaped element releasably engages the dose dial sleeve during dose-setting and disengages during injection, thereby coupling and decoupling the dose dial sleeve (*i.e.* dose-setting drum 17) and the drive sleeve (*i.e.* connection bars 12 and nut

13). *See* EX1015, ¶¶ 26, 29, 33. The cup shape element thus operates as a clutch. This element includes a “bottom 19” that is pressed by the user during injection and a “tubular part 20” that sits within the button-end of dose setting drum 17. EX1015, ¶26, FIG. 1. The cup shaped element is releasably coupled to dose-setting button 18 via “Δ-shaped protrusions 32” that engage “Λ-shaped recesses in an inner ring 33 in the dose setting button 18.” *Id.*, ¶29, FIG. 1. This engagement “ensures that rotation of the dose setting drum 17 is transmitted to the cup shaped element.” *Id.*

During dose-setting, “[d]ue to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will be lifted with this drum up from the end of the housing 1.” *Id.*, ¶29; *see also id.*, ¶¶30-32 (explaining corresponding movements of other components during dose setting). During the “initial phase” of injection, “the A-shaped protrusions 32 on the cup shaped element will be drawn out of their engagement with the A-shaped recesses in the ring 33,” which allows dose-setting drum 17 to “rotate relative to the injection button” *Id.*, ¶32-33. With these components decoupled, the cup shaped element, nut 13, and piston rod 4 move axially toward the needle-end without rotating, which dispenses medicine from the device. *See id.*

Møller describes an analogous embodiment shown in FIGS. 3-5 with “elements corresponding to FIGS. 1 and 2 given the same references as these

elements with a prefixed ‘1’.” EX1015, ¶35; *see also id.*, ¶19-21. For example, element “132” in this embodiment corresponds to element “32” in FIG. 1.

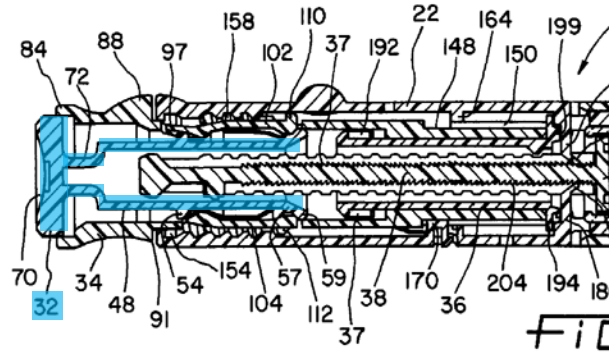
F. Ground 1: Claim 51-55 and 57 Were Anticipated by Burroughs

1. Claim 51 Was Anticipated by Burroughs

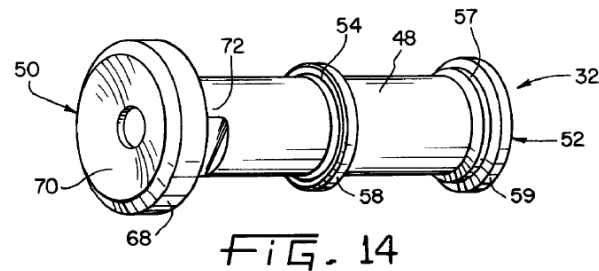
Burroughs discloses a clutch for use within a pen type drug delivery device as recited in claim 51.

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

| '486 Patent | |
|--|--|
| [51.Preamble] A clutch for use within a pen type drug delivery device, | Burroughs discloses a pen type drug delivery device that includes a clutch (button 32): “A multi-use medication dispensing pen made of a plastic material that is recyclable after the contents of the medication cartridge have been exhausted. The pen is made of a minimal number of parts, which include a housing” EX1013, Abstract. “Referring to FIG. 14 and FIG. 15, button 32 comprises a hollow cylindrical portion 48 having a proximal end 50. Cylindrical portion 48 includes ... an enlarged diameter ring 54” EX1013, 7:46-52, FIGS. 1-2. |



Id., FIG. 1 (partial view showing button 32 in blue);
EX1011, ¶448.



EX1013, FIG. 14; EX1011, ¶448..

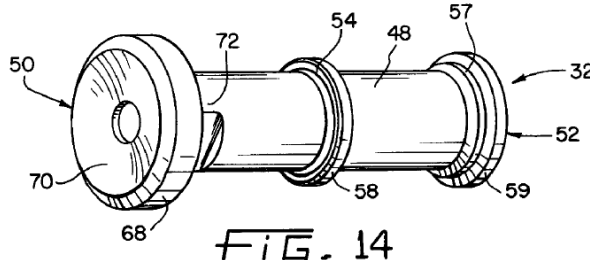
“As best shown in FIG. 9, the proximal ends of flexible sections 92 and 95 [of dial mechanism 34] each include fingers 94 having ramped inner surfaces 96 adapted for engagement with enlarged diameter portion 54 of button 32. When button 32 is depressed, enlarged diameter portion 54 is also depressed and thereby pushes against ramped surfaces 96, which in turn forces fingers 94 outward and legs 102 and 104 [having threads 110, 112] inward. Dial mechanism 34 is then able to travel axially towards cartridge 40 during injection of the medical product” *Id.*, 8:11-20; *see also id.*, 11:5-12, FIGS. 6-9.

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

Burroughs discloses a “clutch” for use in a pen-type delivery device in the form of a button 32. EX1011, ¶451. Button 32 is cylindrical in shape and includes an enlarged diameter ring 54. *See* EX1013, 7:46-51, FIGS. 14, 15. When button 32 is pressed for injection, ring 54 pushes onto fingers 94 provided within dial mechanism 34’s internal surface. EX1013, 8:11-20, FIGS. 1, 9, 14-15; EX1011, ¶450. This causes legs 102, 104 of the dial 34, which includes threads 110, 112, to collapse inward, causing the threads to disengage from the helical groove 158 of

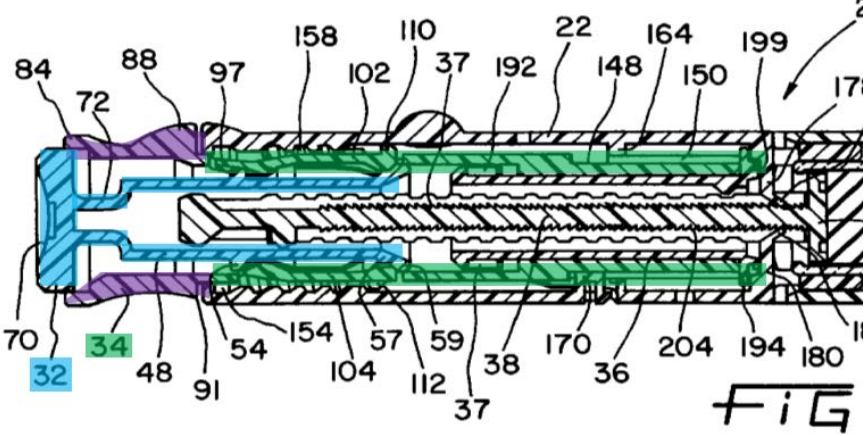
the housing. *See* EX1013, 8:15-20; EX1011, ¶450. Dial mechanism 34 is then free to move axially toward the device's needle-end without rotating relative to the housing. *See* EX1013, 8:18-20, 11:5-20; EX1011, ¶450. Moreover, the button 32 also causes the splines 144 of the dial mechanism 34 to disengage from splines 192 of the nut 36, which rotationally decouples the two components. *See* EX1013, 11:27-30; EX1011, ¶450. Thus, button 32 serves as a clutch that allows the dial mechanism 34 to disengage from (1) its rotational connection with the housing 22, and (2) its rotational connection with nut 36. *See* EX1011, ¶¶449-450.

Next, Burroughs discloses the shape of the clutch as recited in element [51.1]:

| '486 Patent | |
|--|--|
| [51.1] said clutch comprising a tubular body, said tubular body extending from a distal end to a proximal end; |  <p>EX1013, FIG. 14 (showing button 32); EX1011, ¶452.</p> |

Button 32 (*i.e.* the clutch) includes hollow cylindrical portion 48 (*i.e.* a tubular body) extending from a distal end 52 to a proximal end 50. *See* EX1013, 7:46-52, FIGS. 14, 15; EX1011, ¶452. Accordingly, Burroughs meets element [51.1].

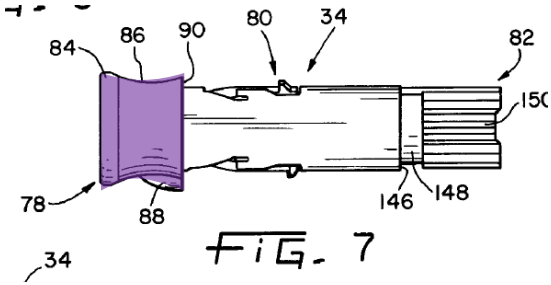
Finally, Burroughs teaches the relative positioning of the dial member and the tubular clutch as recited in element [51.2]:

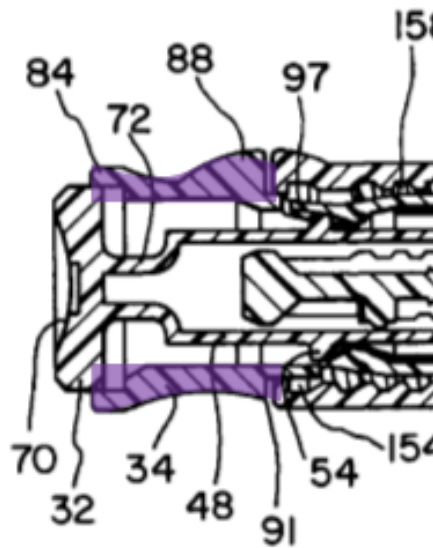
| '486 Patent | |
|---|--|
| <p>[51.2] and said distal end of said tubular body having a diameter sized such that said distal end of said tubular body may be positioned within a proximal end of a dial member.</p> | <p>Burroughs shows that the button 32 is provided within the dial mechanism 34:</p>  <p>See EX1013, FIG. 1; EX1011, ¶454.</p> |

As shown in the chart above, the distal end (*i.e.* needle end) of hollow cylindrical portion 48 (*i.e.* the tubular body) of button 32 fits within a proximal end of dial mechanism 34 (green) (*i.e.* the dial member). See EX1013, FIGS. 1, 14; EX1011, ¶454. The distal end of the hollow cylindrical portion thus has a diameter sized such that it may be positioned within a proximal end of a dial member as recited in element [51.2].

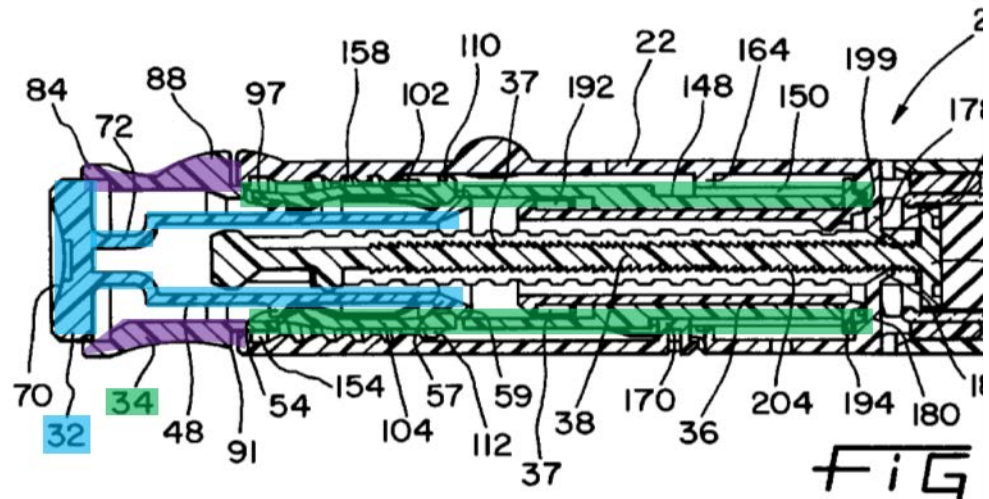
For at least the foregoing reasons, Burroughs anticipated claim 51.

2. Claim 52 Was Anticipated by Burroughs

| '486 Patent | |
|---|---|
| <p>[52.] The clutch of claim 51, wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob.</p> | <p>Burroughs discloses a dial mechanism 34:</p> <p>“Referring to FIGS. 6-9, dial mechanism 34 is shown in detail. Dial mechanism 34 is generally cylindrical in shape and is hollow throughout its axial length.” EX1013, 7:65-67, FIGS. 1-2, 6-9.</p> <p>“Dial mechanism 34 comprises proximal portion 78, intermediate portion 80, and distal portion 82. Proximal portion 78 comprises enlarged diameter portion 84, tapered portion 86, and ring 90 extending about the circumference of proximal portion 78.” EX1013, 8:2-6, FIGS. 1-2, 6-9.</p>  <p><i>Id.</i>, FIG. 7 (proximal portion 78 shown in purple); EX1011, 456.</p> |



EX1013, FIG. 1 (partial view showing proximal portion 78 in purple); EX1011, ¶457.



EX1013, FIG. 1; EX1011, ¶459.

Burroughs discloses a proximal portion 78 of dial mechanism 34 that may be used as a grip for the user to grasp in order to rotate the dial mechanism 34 during dose setting. *See* EX1013, 10:34-42. Proximal portion 78 thus serves as a dose

knob. EX1011, ¶458. As can be seen in FIG. 1, a proximal end of the tubular body of button 32 (*i.e.* the clutch) is configured to reside within an inner space of proximal portion 78 (*i.e.* the dose knob). EX1011, ¶459. Accordingly, Burroughs anticipated claim 52.

3. Claim 53 Was Anticipated by Burroughs

| '486 Patent | |
|---|--|
| [53.] The clutch of claim 52, wherein when said dose knob is activated to dispense a dose of a medicament contained within said pen type delivery device, said clutch is moved in a distal direction. | “Once the desired dosage has been set, ... recessed surface 70 of button 32 is pushed. As button surface 70 is pushed into dial mechanism 34, button distal end moves 52 moves out of engagement with legs 102 and 104. Dial mechanism 34 is thereby able to move forward because threads 110, 112 are not in engagement with groove 158.” EX1013, 11:13-20. |

In Burroughs, the dose knob is activated to dispense a dose of medicament by pressing button 32, which is then pushed through recessed surface 70, thus moving button 32 in a distal direction. *Id.*, 11:13-26; EX1011, ¶461. Thus, Burroughs anticipated claim 53.

4. Claim 54 Was Anticipated by Burroughs

| '486 Patent | |
|-------------|--|
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[54.] The clutch of claim 52, wherein said pen type drug delivery device further comprises a cartridge containing a medicament, said cartridge comprising a reservoir, a stopper, a septum and a ferrule.

“As shown in FIG. 1, plunger engagement portion 206 of leadscrew 38 is in engagement with piston 210 of cartridge 40.... Cartridge 40 is manufactured of glass and comprises a tube defining an inner chamber 212 which openly terminates at its distal end in a neck 214 having a cap 216 including a rubber disc 218 disposed thereover. Needle assembly 44 comprises an internally threaded base 220 and a delivery needle 222. Internally threaded base 220 is threaded onto externally threaded distal portion 224 of body 42. Needle cap 46 fits over needle 222 to prevent an inadvertent insertion of needle 222 into the patient. Cap 28 snaps onto cartridge body 42 to complete the pen-like mechanism.” EX1013, 9:32-46.

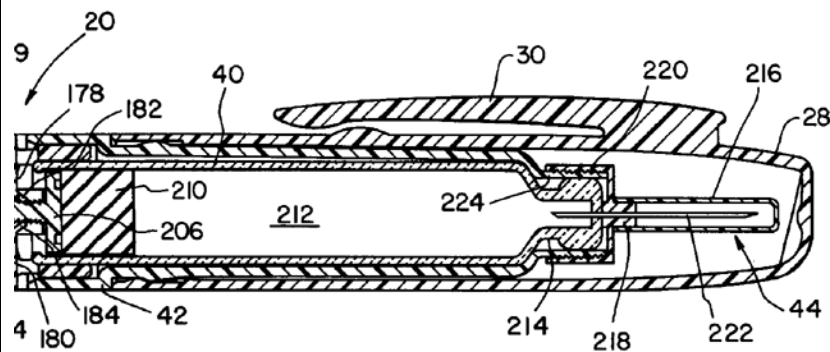


FIG. 1

Id., FIG. 1; EX1011, ¶464.

Burroughs teaches that its pen includes a medicinal cartridge 40, which is a glass tube defining an inner chamber 212 (*i.e.* a reservoir). *Id.*, 9:34-40, FIGS. 1-2. The cartridge also contains a piston 210 that is initially positioned at the button-end of the chamber and moves through the chamber as medicament is delivered, thus

functioning as a stopper separating the remaining medicament from the “used” portion of the chamber. *Id.*; EX1011, ¶463. The needle-end of the cartridge terminates at neck 214, which has a “cap 216 including a rubber disc 218 disposed thereover.” EX1013, 9:36-40. Rubber disc 218 thus operates as a septum while cap 216 operates as a ferrule, securing rubber disc 218 to the cartridge and structurally supporting the glass cartridge. EX1011, ¶464. Thus, Burroughs anticipated claim 54.

5. Claim 55 Was Anticipated by Burroughs

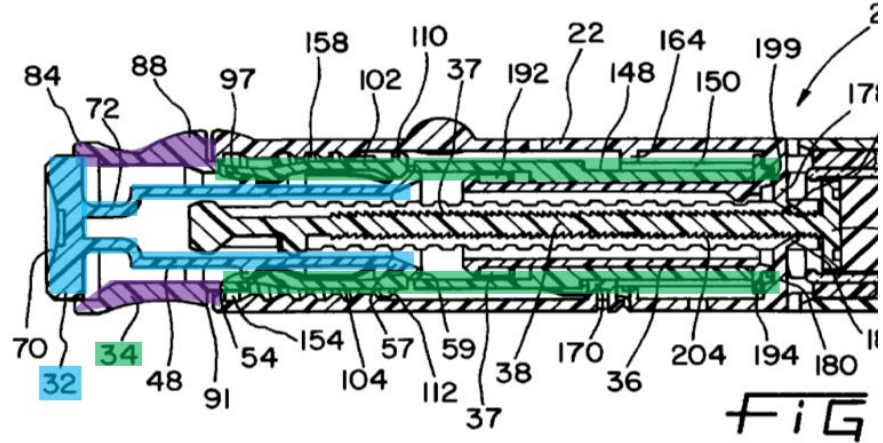
| '486 Patent | |
|---|--|
| [55.] The clutch of claim 54, wherein said cartridge comprises a multidose cartridge. | “A multi-use medication dispensing pen made of a plastic material that is recyclable after the contents of the medication cartridge have been exhausted.” EX1013, Abstract. |

Burroughs states that its device is a “multi-use medication dispensing” pen. EX1013, Abstract (emphasis added). A POSA would have recognized that the cartridge used in such a pen was a “multidose cartridge” as recited in claim 55. EX1011, ¶466. Thus, Burroughs anticipated claim 55.

6. Claim 57 Was Anticipated by Burroughs

| '486 Patent | |
|-------------|--|
|-------------|--|

[57.] The clutch of claim 51, wherein said clutch is positioned within an open proximal end of said dial member and located adjacent a distal end of said dose knob and operatively coupled to said dose knob, and wherein said dial member extends circumferentially around at least a portion of said clutch.



EX1013, FIG. 1 (annotated partial view showing dial mechanism 34 (green), button 32 (blue), and proximal portion 78 (purple)); EX1011, ¶467.

As explained above in sections V.F.1-2, Burroughs discloses the recited clutch (button 32), dial member (dial mechanism 34), and dose knob (proximal portion 78). *See also id.*, 8:2-6. Figure 1 shows that button 32 is positioned within an open proximal end of dial mechanism 34 and located adjacent a distal end of proximal portion 78. EX1011, ¶467. Moreover, button 32 is operatively coupled to proximal end 78 through its engagement with dial mechanism 34. *See supra*, section V.F.1 (explaining operation of button 32); EX1011, ¶468. Figure 1 further

shows that dial mechanism 34 extends circumferentially around at least a portion of button 32. EX1011, ¶469. Thus, Burroughs anticipated claim 57.

G. Ground 2: Claims 54-55 Were Obvious over Burroughs

| '486 Patent | |
|---|---|
| <p>[54.] The clutch of claim 52, wherein said pen type drug delivery device further comprises a cartridge containing a medicament, said cartridge comprising a reservoir, a stopper, a septum and a ferrule.</p> <p>[55.] The clutch of claim 54, wherein said cartridge comprises a multidose cartridge.</p> | <p>“As shown in FIG. 1, plunger engagement portion 206 of leadscrew 38 is in engagement with piston 210 of cartridge 40.... Cartridge 40 is manufactured of glass and comprises a tube defining an inner chamber 212 which openly terminates at its distal end in a neck 214 having a cap 216 including a rubber disc 218 disposed thereover. Needle assembly 44 comprises an internally threaded base 220 and a delivery needle 222. Internally threaded base 220 is threaded onto externally threaded distal portion 224 of body 42. Needle cap 46 fits over needle 222 to prevent an inadvertent insertion of needle 222 into the patient. Cap 28 snaps onto cartridge body 42 to complete the pen-like mechanism.” EX1013, 9:32-46.</p> |

As explained above in sections V.F.4-5, Burroughs discloses a multi-dose cartridge containing the elements recited in claim 54. In particular, Burroughs explains that the glass cartridge has an inner chamber 212 (the reservoir), piston 210 (the septum), and cap 216 (the ferrule) at the needle-end that includes rubber disc 218 (the stopper). EX1013, 9:32-40. While Burroughs does not explicitly

refer to these components using the terms recited in claim 54, a POSA would have immediately recognized these structures operate as a reservoir, septum, ferrule, and stopper, respectively. EX1011, ¶471. Notably, the '486 patent itself never describes any of the cartridge components recited in claim 54, stating only that “[a] cartridge 8 from which a number of doses of medicinal product may be dispersed is provided in the cartridge retaining part 2.” *Id.* at 3:34-37. This lack of disclosure underscores that the cartridge components recited in claim 54 would have been apparent to a POSA when considering a cartridge for use in an injector pen. EX1011, ¶472.

As to claim 55, Burroughs specifically teaches that its pen dispenses multiple doses of medication, and a POSA therefore would have understood that the cartridge would contain multiple doses of the medication. EX1013, Abstract. EX1011, ¶473.

Accordingly, Burroughs rendered claims 54 and 55 obvious.

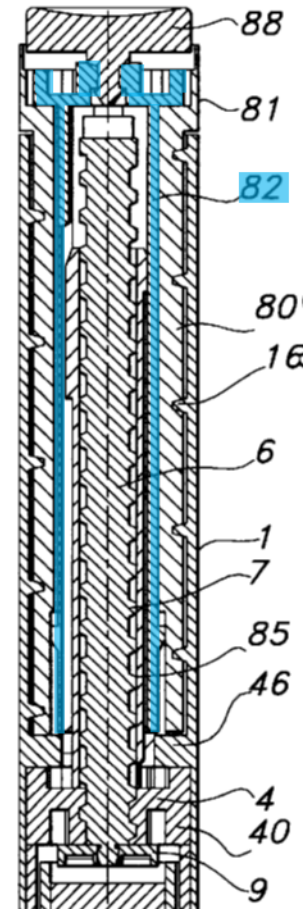
H. Ground 3: Claims 51-53 and 56-57 Were Anticipated by Steinfeldt-Jensen

1. Claim 51 Was Anticipated by Steinfeldt-Jensen

Steenfeldt-Jensen discloses a clutch for use within a pen type drug delivery device as recited in claim 51.

To the extent the preamble is limiting, it is disclosed by Steinfeldt-Jensen:

| '486 Patent | |
|---|---|
| <p>[51.Preamble] A clutch for use within a pen type drug delivery device,</p> | <p>Steenfeldt-Jensen discloses:</p> <p>“The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses.” EX1014, 1:12-15, FIGS. 15-17.</p> <p>“A bushing 82 having a flange 83 at its proximal end [<i>i.e.</i>, button-end] and having a pair of opposite longitudinal slots 84 through its side walls fits into the scale drum 80 and over the driver tube 85 which tube has on its outer wall hooks 86 engaging the slots 84 of the bushing 82 whereby the bushing 82 and the driver tube 85 [are] coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements.” EX1014, 11:26-33.</p> |



See id., FIGS. 17 (above-left; partial view showing bushing), 16 (above-right; partial view with bushing shown in blue); EX1011, ¶476.

“In the dose setting button [81] a compartment is provided having ... a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment At its distal side [*i.e.*, needle-end side] the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment.” EX1014, 11:34-42, FIG. 17.

“During the [dose] setting the rosette in the dose setting

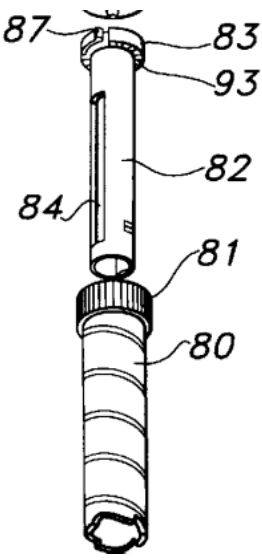
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| | <p>button [81] forces the rosette 93 on the flange 83 of the bushing 82 out of engagement.” <i>Id.</i>, 12:1-3.</p> <p>“When the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 The bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed further into an ampoule 89 in the ampoule holder 2.” <i>Id.</i>, 12:4-13.</p> |
|--|---|

Steenfeldt-Jensen describes an injection syringe for dispensing medicine. EX1014, 1:12-15, FIGS. 15-17; EX1011, ¶476. Steenfeldt-Jensen discloses the claimed “clutch” in the form of a bushing, as the flange 83 of bushing 82 has a rosette of teeth 93, which is configured to releasably engage corresponding rosettes on the button-end of dose setting button 81, which is positioned at the button-end of scale drum 80. *See* EX1014, 11:43-51, 12:4-12; EX1011, ¶¶477-479. These rosettes are disengaged during dose-setting so that the rotation of scale drum 80 is not transmitted to bushing 82 and driver tube 85. *See* EX1014, 12:1-3; EX1011, ¶479. Pressing the button causes axial displacement of bushing 82 relative to scale drum 80, which brings the rosettes into engagement, thereby rotationally coupling scale drum 80, bushing 82, and driver tube 85 during injection. *See* EX1014, 12:4-12; EX1011, ¶479. Thus, bushing 82 serves as a clutch because it releasably

engages with scale drum 80, thereby releasably coupling the rotation of scale drum 80 to driver tube 85. *See* EX1011, ¶479; *see also supra*, section V.E.1.

Accordingly, Steenfeldt-Jensen teaches a “clutch” as recited in the preamble of claim 51.

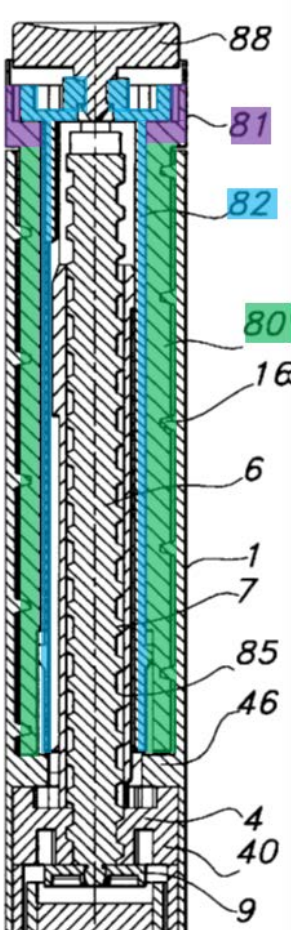
Next, Steenfeldt-Jensen discloses the shape of the clutch as recited in element [51.1]:

| '486 Patent | |
|--|---|
| [51.1] said clutch comprising a tubular body, said tubular body extending from a distal end to a proximal end; |  <p data-bbox="584 1417 1088 1459">EX1014, FIG. 17; EX1011, ¶481.</p> |

As explained above, Steenfeldt-Jensen discloses the clutch in the form of bushing 82. As shown in FIG. 17, the bushing 82 has a “tubular body extending from a distal end to a proximal end.” *See* EX1014, 11:26-27, 12:4-13; FIGS. 15-

17. Accordingly, Steinfeldt-Jensen teaches a clutch with the structural features recited in element [51.1].

Finally, Steinfeldt-Jensen teaches the relative positioning of the dial member and the tubular clutch recited in element [51.2]:

| '486 Patent | |
|---|--|
| <p>[51.2] and said distal end of said tubular body having a diameter sized such that said distal end of said tubular body may be positioned within a proximal end of a dial member.</p> | <p>Steenfeldt-Jensen discloses that bushing 82 is provided within scale drum 80:</p> <p>“A bushing 82 ... fits into the scale drum 80”</p> <p>EX1014, 11:26-28, FIGS. 15-16.</p>  <p>The diagram is a vertical cross-section of a mechanical assembly. At the top, a cap or cover (88) is shown with internal components (81). Below this, a green-shaded cylindrical component (80) represents the scale drum. Inside the scale drum, a blue-shaded cylindrical component (82) represents the bushing. The assembly includes various other parts labeled with numbers: 16, 6, 1, 7, 85, 46, 4, 40, and 9. The bushing 82 is positioned within the scale drum 80, and the entire assembly is housed within a larger structure.</p> |

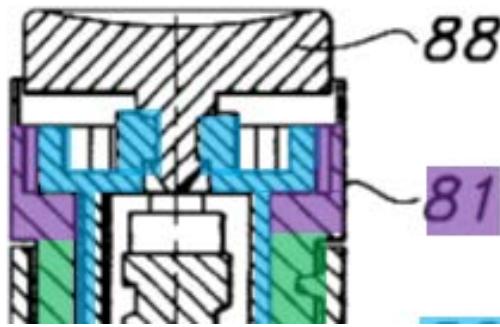
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| | <i>See id.</i> , FIG. 16 (above; color-coded partial view showing drum 80 (green) and bushing 82 (blue)); EX1011, ¶482. |
|--|---|

As shown above, scale drum 80 extends circumferentially around the distal portion of the bushing 82 (i.e. its needle-end). *See* EX1014, 11:26-28, FIGS. 15-16; EX1011, ¶482. As explained above in section V.E.1, scale drum 80 corresponds to the recited “dial member”—also referred to as the “dose dial sleeve” in the specification—since the user “dials” a dose for injection by rotating scale drum 80. Accordingly, a “distal end” of the bushing’s tubular body has a diameter sized such that this distal end “may be positioned within a proximal end of a dial member” as recited in element [51.2].

For at least the foregoing reasons, Steenfeldt-Jensen anticipated claim 51.

2. Claim 52 Was Anticipated by Steenfeldt-Jensen

| '486 Patent | |
|--|--|
| [52.] The clutch of claim 51, wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob. | Steenfeldt-Jensen discloses that bushing 82 is provided within scale drum 80: “A bushing 82 ... fits into the scale drum 80” EX1014, 11:26-28, FIGS. 15-16. |



Id., FIG. 16 (color-coded partial view showing drum (green) and bushing (blue)).; EX1011, ¶485.

“In the dose setting button a compartment is provided having a cylindrical side wall circumferentially provided with longitudinal recesses and a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment and has at its periphery a radial protrusion 87 which is biased toward the side wall of the compartment. At its distal side the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment.” EX1014, 11:34-42.

“When a dose is set by rotating the dose setting button 81 in a clockwise direction, the scale drum is screwed out of the housing” *Id.*, 11:52-54.

Steenfeldt-Jensen discloses that a dose knob, referred to as “dose setting button 81,” is located at the proximal end of scale drum 80. EX1014, 11:20-25 (dose setting button 81 “knurled [on its outer wall] to ensure a good finger grip”); EX1011, ¶484.. As shown in FIGS. 15-17, the needle-end portion of the clutch’s

tubular body resides within an inner space of dose setting button 81. EX1014, 11:26-33; EX1011, ¶485.. Accordingly, Steenfeldt-Jensen discloses that “said proximal end of said tubular body is configured to reside within an inner space of a dose knob.” Thus, Steenfeldt-Jensen anticipated claim 52.

3. Claim 53 Was Anticipated by Steenfeldt-Jensen

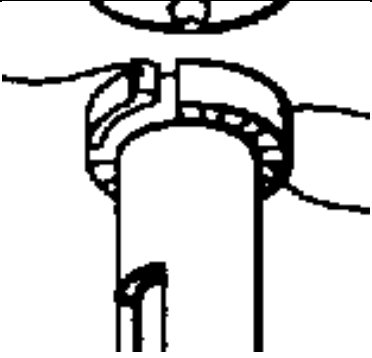
| '486 Patent | |
|---|--|
| [53.] The clutch of claim 52, wherein when said dose knob is activated to dispense a dose of a medicament contained within said pen type delivery device, said clutch is moved in a distal direction. | <p>“During the [dose] setting the rosette in the dose setting button [81] forces the rosette 93 on the flange 83 of the bushing 82 out of engagement.” EX1014, 12:1-3.</p> <p>“When the injection button 88 is pressed to inject the set dose the said rosettes are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 The bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed further into an ampoule 89 in the ampoule holder 2.” <i>Id.</i>, 12:4-13.</p> |

Bushing 82 has a rosette of teeth 93 at its needle-end that releasably engages a corresponding rosette of teeth in a compartment of dose setting button 81. *See id.*, 11:34-42, FIGS. 15-17; EX1011, ¶487. During dose-setting, these teeth are held out of engagement, but when the user activates the dose knob by pressing injection button 88, bushing 82 moves in the distal direction (*i.e.* toward the needle

end of the device), causing rosette 93 to engage the corresponding teeth of dose setting button 81. EX1014, 12:1-10. With the clutch thus engaged, dose scale drum 80 and bushing 82 rotate and move axially together toward the needle-end of the device. *See id.*, 12:4-13; EX1011, ¶487. The rotation of bushing 82 is then transmitted to driver tube 85, which moves the piston rod downward to dispense a dose of a medicament contained within the pen. EX1014, 12:4-13. Accordingly, when the dose knob is activated to dispense medicament, the clutch is moved in a distal direction. EX1011, ¶488. Thus, Steenfeldt-Jensen anticipated claim 53.

4. Claim 56 Was Anticipated by Steenfeldt-Jensen

| '486 Patent | |
|---|---|
| [56.] The clutch of claim 51, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch. | “In the dose setting button [81] a compartment is provided having ... a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment At its distal side [<i>i.e.</i> , needle-end side] the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment.” EX1014, 11:34-42, FIG. 17. |

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| |  <p><i>See id.</i>, FIG. 17 (partial view showing rosette 93 of teeth); EX1011, ¶489.</p> |
|--|---|

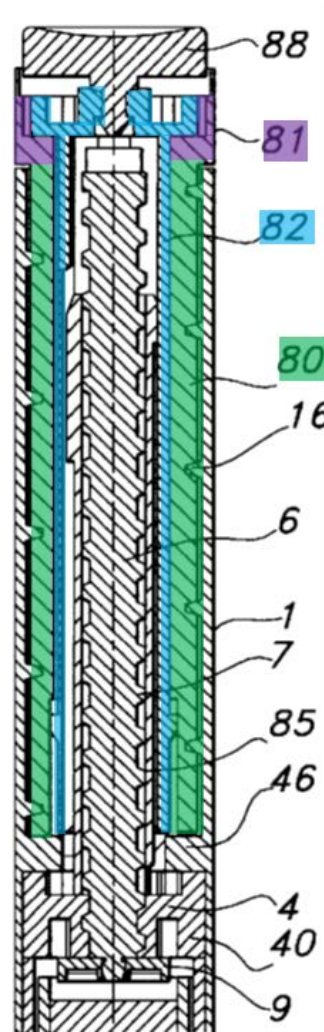
As explained above in section V.H.3, bushing 82 includes a rosette of teeth 93. These teeth extend axially from a flange 83 at the needle-end of bushing 82. *Id.*, 11:40-42 (“[T]he flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment [in dose setting button 81].”), FIG. 17; *see also* EX1011, ¶489. Figure 17 also shows that teeth 93 extend axially and are formed in an interior of flange 83. Thus, Steinfeldt-Jensen anticipated claim 56.

5. Claim 57 Was Anticipated by Steinfeldt-Jensen

| '486 Patent | |
|--|---|
| [57.] The clutch of claim 51, wherein said clutch is positioned within an open proximal end of said dial member and located adjacent a | “A bushing 82 having a flange 83 at its proximal end [<i>i.e.</i> , button-end] and having a pair of opposite longitudinal slots 84 through its side walls fits into the scale drum 80 and over the driver tube 85 which tube has on its outer wall hooks 86 engaging the slots 84 of the bushing 82 whereby the bushing 82 and the driver |

distal end of said dose knob and operatively coupled to said dose knob, and wherein said dial member extends circumferentially around at least a portion of said clutch.

tube 85 [are] coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements.” EX1014, 11:26-33.



See *id.*, FIGS. 16; EX1011, ¶491..

“In the dose setting button [81] a compartment is provided having ... a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment At its distal side [*i.e.*, needle-end side] the flange 83 has a rosette 93 of teeth which can be brought into

| | |
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| | engagement with the rosette at the bottom of the compartment.” EX1014, 11:34-42. |
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As discussed above in sections V.H.1-2 , Steinfeldt-Jensen discloses the recited clutch (bushing 82), dial member (dose scale drum 80), and dose knob (dose setting button 81). *See id.*, 11:20-25; FIGS. 15-17. Figures 15-16 show that bushing 82 is positioned within an open proximal end of dose scale drum 80 and located adjacent a distal end (*i.e.* button-end) of dose setting button 81. EX1011, ¶491. As discussed above in section V.H.3, bushing 82 is operatively coupled to dose setting button 81. EX1011, ¶492. Figures 15-16 also show that dose scale drum 80 extends circumferentially around at least a portion of bushing 82. *See also id.*, 11:34-42, FIG. 17; EX1011, ¶493. Thus, Steinfeldt-Jensen anticipated claim 57.

I. Ground 4: Claim 56 Was Obvious over Steinfeldt-Jensen

| '486 Patent | |
|---|--|
| [56.] The clutch of claim 51, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch. | “In the dose setting button [81] a compartment is provided having ... a bottom with a rosette of teeth having a triangular cross-section. The flange 83 of the bushing 82 is adopted in said compartment At its distal side [<i>i.e.</i> , needle-end side] the flange 83 has a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the |

| | |
|--|---------------------------------|
| | compartment.” EX1014, 11:34-42. |
|--|---------------------------------|

As discussed above in section V.H.4, Steinfeldt-Jensen teaches a clutch (*i.e.* bushing 82) with a flange 83 having “*a rosette 93 of teeth* which can be brought into engagement with the rosette at the bottom of the compartment.” *Id.*, 11:40-42 (emphasis added). Steinfeldt-Jensen does not explicitly state in the teeth of rosette 83 extend in an axial direction. To the extent it is not immediately apparent from FIG. 17 and the corresponding description at col. 11:34-42 that the teeth of rosette 93 extend axially from an interior of flange 83, a POSA would have found it obvious to implement the teeth in this manner. EX1011, ¶495. That is, since the corresponding rosette of teeth is at the bottom of the compartment axially below flange 83, it would have been obvious to have the teeth extend axially toward the corresponding rosette to facilitate engagement. *Id.* A POSA would have had a reasonable expectation of success given the simplicity and predictability of this rosette-based clutching mechanism. *Id.* Thus, Steinfeldt-Jensen rendered claim 56 obvious.

J. Ground 5: Claim 51-53 and 56-57 Were Anticipated by Møller

1. Claim 51 Was Anticipated by Møller

Møller describes two similar embodiments: a first embodiment shown in FIGS. 1-2 and a second embodiment shown in FIGS. 3-5. The general structure

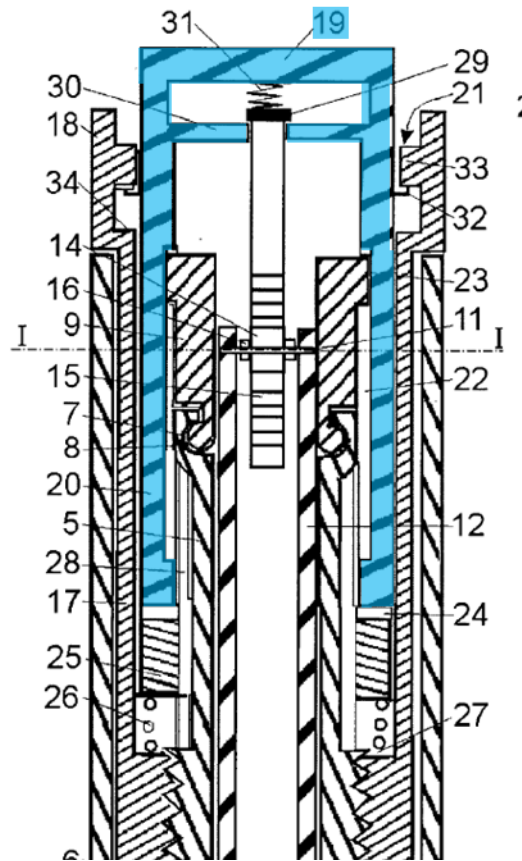
and operation of these embodiments are largely the same. *Compare*, EX1015, ¶22-34 *with id.*, ¶¶35-40; *compare id.*, FIGS. 1-2 *with id.*, FIGS. 3-5. Møller explains that the second embodiment, shown in FIGS. 3-5, is a preferred embodiment that uses only one gear-wheel size and notes that numbers for elements in this embodiment that correspond to elements from the first embodiment simply add 100 to the previous number (e.g., housing 1 becomes housing 101). EX1015, ¶35. A POSA therefore would have understood that, unless the second embodiment depicted or described a feature differently, the 100-series elements would be assumed to operate in a manner similar to the corresponding elements of the first embodiment. EX1011, ¶139 n.16. Accordingly, while the analysis below primarily explains anticipation in terms of the first embodiment, the claims were similarly anticipated by the second embodiment as well. *Id.*

Møller discloses a clutch for use within a pen type drug delivery device as recited by claim 51.

To the extent the preamble is limiting, it is disclosed by Møller:

| '486 Patent | |
|--|--|
| [51.Preamble] A clutch for use within a pen type drug delivery device, | Møller discloses: “A bottom 19 in a deep cup shaped element, which has a tubular part 20 fitting into the dose setting drum 17 and encompassing the gearbox 9, forms an injection button. Coupling means between the dose setting drum 17 and |

the cup shaped element ensures that rotation of the dose setting drum 17 is transmitted to the cup shaped element. Further the inner wall of the tubular part 20 has longitudinal recesses 22 engaged by protrusions 23 on the gearbox 9 so that rotation of the dose setting drum 17 via the cup shaped element is transmitted to the gearbox 9.”



EX1015, ¶26, FIG. 1 (annotating bottom (blue));
EX1011, ¶510.

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

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| | <p>“To set a dose the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 8. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will be lifted with this drum up from the end of the housing 1.” <i>Id.</i>, ¶29.</p> <p>“The rotation of dose setting button 18 and the cup shaped element is further transmitted to the gearbox 9 The rotation of the gearbox 25 [<i>sic</i>, 9] is through the connection bars 12 transmitted to the nut 13, which is this way screwed up along the thread of the piston rod 4 and lifted away from its abutment with the wall 2 when a dose $i[s]$ set.” <i>Id.</i>, ¶30.</p> <p>“To inject a set dose the injection button is pressed by pressing on the bottom 19 Through the gear box 9 the force is transformed and is transmitted through the connection bars 12 to the nut 13 which will press the piston rod 4 into the compartment 3 until the dose-setting drum 17 abuts the wall 2.” <i>Id.</i>, ¶32.</p> <p>“During the initial phase of the movement of the injection button the Δ-shaped protrusions 32 on the cup shaped element will be drawn out of their engagement with the Λ-shaped recesses in the ring 33. The dose-setting drum 17 can now rotate relative to the injection button” <i>Id.</i>, ¶33.</p> |
|--|---|

Møller teaches a “cup shaped element”, which act as a clutch. EX1011, ¶510. Møller’s first embodiment includes a “cup shaped element” (the clutch) that includes bottom 19 (the surface pressed by the user to inject a dose) and tubular part 20. EX1015, ¶26, FIG. 1; EX1011, ¶510. As shown in FIG. 1, the cup shaped element is seated within dose setting button 18 (the dose knob) and passes through its entire length. The cup shaped element is thus located adjacent the needle end (*i.e.* the distal end) of dose setting button 18. EX1011. The cup shaped element is operatively coupled to dose setting button 18 via the engagement of Δ -shaped protrusions 32 with corresponding recesses 33 in dose setting button 18. *See* EX1015, ¶29, FIG. 1; EX1011, ¶511. The cup shaped element serves as a clutch by rotationally coupling dose setting button 18 and drum 17 (the dose dial sleeve) to connection bars 12 and nut 13 (the driver) during dose setting, then rotationally decoupling those components during injection. *See* EX1015, ¶¶29-30, 32-33, FIG. 1; EX1011, ¶512.

To the extent that “tubular clutch” is construed as being a means-plus-function limitation, Møller discloses it. The ’486 patent discloses clutch 60. According to the ’486 patent:

The clutch means 60 is generally cylindrical and is provided at a first end with a series of circumferentially directed saw teeth 66 (see FIG. 7) [and is normally engaged with clicker 50]. Each saw tooth

comprises a longitudinally directed surface and an inclined surface. Towards the second end 64 of the clutch means 60 there is located a radially inwardly directed flange 62. The flange 62 of the clutch means 60 is disposed between the shoulder 37 of the drive sleeve 30 and the radially outwardly directed flange 39 of the extension 38. The second end of the clutch means 60 is provided with a plurality of dog teeth 65 (FIG. 8) [that are adapted to engage with the dose dial sleeve]. The clutch 60 is keyed to the drive sleeve 30 by way of splines (not shown) to prevent relative rotation between the clutch 60 and the drive sleeve 30.

EX1003, 4:50-62, 5:1-2, 2:17-19.

The tubular clutch as described by the '486 patent, therefore, is “generally cylindrical,” having a series of “circumferentially directed ... teeth” at its first, i.e., needle, end, and also has a plurality of teeth at a second, i.e., button end. *Id.*, 4:50-62. The teeth on the needle end engage with the clicker, and the teeth on the button end engage with the dose dial sleeve. *Id.*, 54:50-62, 5:1-2, 2:17-19. As taught by the '486 patent, the clutch is also keyed to the drive sleeve, through the use of splines, to prevent relative rotation between the clutch and drive sleeve. *Id.*, 4:60-62.

Bottom 19 and tubular element 120 of Møller operates in a similar manner using a similar structure. *Compare* EX1015, FIGS. 1, 5 *with* EX1003, FIGS. 6-

8. For example, like clutch 60, tubular element 120 includes a set of axially extending teeth 132 at its button end that releasably engage corresponding teeth 133 in dose setting button 118. *See* EX1015, ¶¶36, 39, FIGS. 3-5; EX1011, ¶516; *see also* EX1015, ¶¶29-30 (discussing similar structure of the cup shaped element), FIG. 1. Both of Møller’s embodiments also include a biasing element (spring 26/126) that exerts upward force to keep the clutch engaged during dose setting. *See* EX1015, ¶¶27, 29, 39, FIGS. 3-5; EX1011, ¶516. The user then applies force to the button (bottom 19 or button 119), which pushes the teeth out of engagement to rotationally decouple the components during injection. *See* EX1015, ¶¶27, 29, 39, FIGS. 3-5; EX1011, ¶516. Thus, bottom 19 and tubular element 120 not only have the structure of clutch 60 of the ’844 patent, they also serve as a clutch because they releasably decouple the components during injection. *See* EX1011, ¶517.

Accordingly, Møller taught a “tubular clutch” as claimed in claim 51.

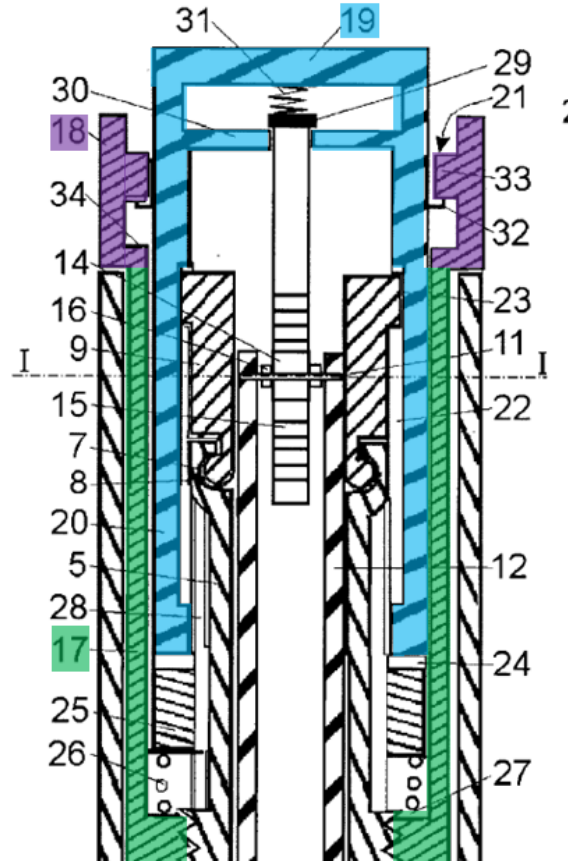
Next, Møller discloses the shape of the clutch as recited in element [51.1]:

| '486 Patent | |
|--|---|
| [51.1] said clutch comprising a tubular body, said tubular body extending from a distal end to a proximal end; | <i>See</i> Møller Chart for [51.Preamble], <i>supra</i> . |

Møller’s “clutch,” *i.e.*, the cup shaped element, is tubular in shape. In particular, it has a “tubular part 20” fitting into the dose setting drum 17. EX1015, ¶26, FIG. 1; EX1011, ¶518. In addition, tubular part 20 of bottom 19 extends along a portion of the length of the pen-type injector of Møller, that is, from a distal end to a proximal end. Accordingly, Møller teaches a clutch with a “tubular body” as recited in claim 51.

Finally, Møller teaches the structure of the clutch’s tubular body relative to a dial member as recited in element [51.2]:

| '486 Patent | |
|--|---|
| [51.2] and said distal end of said tubular body having a diameter sized such that said distal end of said tubular body may be positioned within a proximal end of a dial member. | Møller discloses that the bottom 19 extends into the dose setting drum 17: “A bottom 19 in a deep cup shaped element, which has a tubular part 20 fitting into the dose setting drum 17 and encompassing the gearbox 9, forms an injection button.” EX1015, ¶26. |



EX1015, FIG. 1 (below; annotating bottom (blue) and drum (green)); EX1011, ¶519.

Dose setting drum 17 of Møller corresponds to the dial member recited in claim 51. Specifically, as explained in section V.E.3 above, the user manipulates the dose setting drum a specific dose for injection. *See* EX1015, ¶25. As shown above in FIG. 1, dose setting drum 17 extends circumferentially around tubular part 20 of the cup shaped element. Accordingly, tubular part 20 (*i.e.* the “tubular body”) of the cup shaped member has a diameter sized such that a distal end of tubular part 20 “may be positioned within a proximal end of a dial member” as recited in claim 51. *See* EX1015, FIG 1; EX1011, ¶520.

For at least the foregoing reasons, Møller anticipated claim 51 of the '486 patent.

2. Claim 52 Was Anticipated by Møller

| '486 Patent | |
|---|--|
| <p>[52.] The clutch of claim 51, wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob.</p> | <p>“[T]he coupling 21 ... may comprise Δ-shaped protrusions 32 on the cup shaped element engaging - shaped recesses in an inner ring 33 in the dose setting button 18.” EX1015, ¶29, FIG. 1.</p> <p>“To set a dose the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 8. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will be lifted with this drum up from the end of the housing 1.” <i>Id.</i>, ¶29.</p> <p>“During the initial phase of the movement of the injection button the Δ-shaped protrusions 32 on the cup shaped element will be drawn out of their engagement with the Λ-shaped recesses in the ring 33. The dose-setting drum 17 can now rotate relative to the injection button” <i>Id.</i>, ¶33. <i>See also id.</i>, FIG. 1.</p> |

As explained above in section V.E.3, dose setting button 18 serves as a grip for the user to manipulate dose setting drum 17, *see* EX1015, ¶29, and thus corresponds to the “dose knob” recited in claim 52. EX1011, ¶522. Figure 1 of Møller shows that a proximal end of tubular part 20 (*i.e.* the recited “tubular body”

of the clutch) is configured to reside within an inner space of dose setting button 18 (*i.e.* the recited “dose knob”). EX1011, ¶524. In particular, Møller’s cup shaped element includes a coupling 21 with “ Δ -shaped protrusions 32 on the cup shaped element engaging Λ -shaped recesses in an inner ring 33 in the dose setting button 18.” EX1015, ¶29. Figures 3-5 show an analogous embodiment where the cup shaped element has a tubular part 120 whose proximal end is configured to reside within an inner space of a dose setting button 118. *See id.*, ¶¶35-38. Accordingly, Møller anticipated claim 52 of the ’486 patent.

3. Claim 53 Was Anticipated by Møller

| '486 Patent | |
|---|--|
| [53.] The clutch of claim 52, wherein when said dose knob is activated to dispense a dose of a medicament contained within said pen type delivery device, said clutch is moved in a distal direction. | <p>“To inject a set dose the injection button is pressed by pressing on the bottom 19 Through the gear box 9 the force is transformed and is transmitted through the connection bars 12 to the nut 13 which will press the piston rod 4 into the compartment 3 until the dose-setting drum 17 abuts the wall 2.” EX1015, ¶32.</p> <p>“During the initial phase of the movement of the injection button the Δ-shaped protrusions 32 on the cup shaped element will be drawn out of their engagement with the Λ-shaped recesses in the ring 33. The dose-setting drum 17 can now rotate relative to the injection button....” <i>Id.</i>, ¶33.</p> |

As explained in section V.E.3, the user sets a dose by rotating dose setting button 18 (*i.e.* the “dose knob”), which causes dose setting drum 17 to rotate and move axially away from the needle-end of the pen. *Id.*, ¶29, FIGS. 1, 5. This rotation is transferred to other components via the clutch due to “Δ-shaped protrusions 32 on the cup shaped element engaging Λ-shaped recesses in an inner ring 33 in the dose setting button 18.” *Id.*, ¶29. The user then presses bottom 19 to deliver a dose. As explained by Møller, “[d]uring the initial phase of the movement of the injection button the Δ-shaped protrusions 32 on the cup shaped element will be drawn out of their engagement with the Λ-shaped recesses in the ring 33.” *Id.*, 5:44-47. Accordingly, the cup shaped element moves in the distal direction, releasing the clutched engagement of the Δ-shaped protrusion with the Λ-shaped recess. *Id.*; EX1011, ¶525. Once the clutch releases, the dose setting drum will “rotate to screw itself downward along the thread 6,” bringing the clutch in the distal direction (*i.e.* toward the needle-end of the device). EX1015, ¶33; EX1011, ¶526. Thus, Møller anticipated claim 53.

4. Claim 56 Was Anticipated by Møller

| '486 Patent | |
|---|---|
| [56.] The clutch of claim 51, further comprising a plurality of axially extending | “A bottom 19 in a deep cup shaped element, which has a tubular part 20 fitting into the dose setting drum 17 and encompassing the gearbox 9, forms an injection button. Coupling means between the dose setting drum 17 and |

teeth formed in an interior of a flange of said clutch.

the cup shaped element ensures that rotation of the dose setting drum 17 is transmitted to the cup shaped element. Further the inner wall of the tubular part 20 has longitudinal recesses 22 engaged by protrusions 23 on the gearbox 9 so that rotation of the dose setting drum 17 via the cup shaped element is transmitted to the gearbox 9.” EX1015, ¶26, FIG. 1..

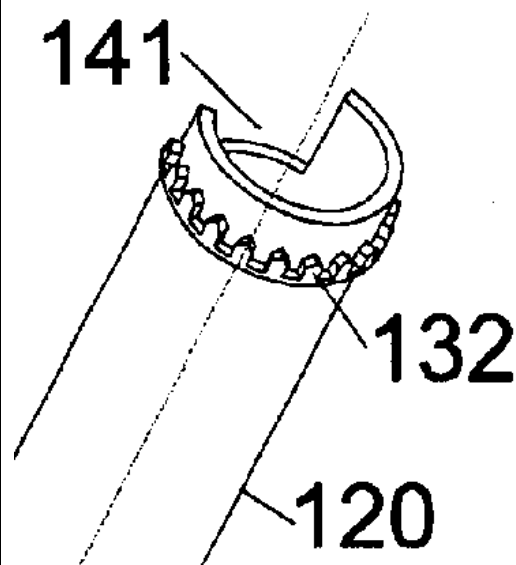


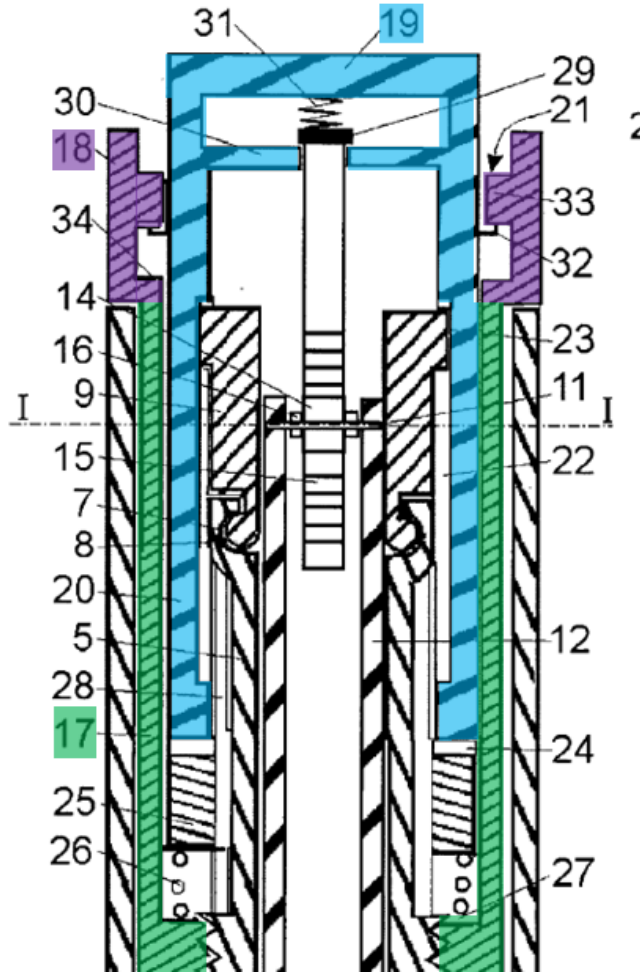
FIG. 5 (showing a plurality of axially extended teeth 132 formed in an interior of a flange of the clutch); EX1011, ¶528.

Møller discloses that the cup shaped element (*i.e.* the recited clutch) has a coupling 21 with “***Δ-shaped protrusions 32 on the cup shaped element engaging Δ-shaped recesses*** in an inner ring 33 in the dose setting button 18.” EX1015, ¶29 (emphasis added). As can be seen in FIGS. 1 and 5, those protrusions (teeth 32 in FIG.1 and teeth 132 in FIG. 5) extend axially from an interior of a flange of the

clutch. EX1011, ¶528. The cup shaped element (*i.e.* the clutch) thus contains a plurality of axially extended teeth 32 (or) formed in an interior of a flange to facilitate the clutch’s interaction with the dose setting button 18 and dose-setting drum 17. EX1011, ¶529. The same is true of teeth 132, button 118, and drum 117, respectively, in the embodiment shown in FIGS. 3-5. Thus, Møller anticipated claim 56 of the ’486 patent.

5. Claim 57 Was Anticipated by Møller

| '486 Patent | |
|---|---|
| [57.] The clutch of claim 51, wherein said clutch is positioned within an open proximal end of said dial member and located adjacent a distal end of said dose knob and operatively coupled to said dose knob, and wherein said dial member extends circumferentially around at least a portion of said clutch. | “A bottom 19 in a deep cup shaped element, which has a tubular part 20 fitting into the dose setting drum 17 and encompassing the gearbox 9, forms an injection button. Coupling means between the dose setting drum 17 and the cup shaped element ensures that rotation of the dose setting drum 17 is transmitted to the cup shaped element. Further the inner wall of the tubular part 20 has longitudinal recesses 22 engaged by protrusions 23 on the gearbox 9 so that rotation of the dose setting drum 17 via the cup shaped element is transmitted to the gearbox 9.” EX1015, ¶26. |



EX1015, FIG. 1 (cup shaped element shown in blue);
EX1011, ¶530.

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

“To set a dose the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 8. Due to the coupling 21 the cup shaped element will follow the rotation of the dose-setting drum 17 and will

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| | be lifted with this drum up from the end of the housing 1.” <i>Id.</i> , ¶29. |
|--|---|

As shown above, claim 57 recites three aspects of the clutch: (1) the clutch is “positioned within an open proximal end of said dial member and located adjacent a distal end of said dose knob”, (2) the clutch is operatively coupled to said dose knob, and (3) the dial member “dial member extends circumferentially around at least a portion of said clutch.” Møller discloses a clutch with each of these features.

First, FIG. 1 shows that the cup shaped element (*i.e.* the clutch) is positioned within an open proximal end of dose-setting drum 17 (*i.e.* the dial member) and located adjacent a distal end of dose-setting button 18 (*i.e.* the dose knob). The cup shaped element of the embodiment shown in FIGS. 3-5 is similarly positioned with respect to drum 117 and button 118. EX1011, ¶530-532.

Second, Møller explains that the cup shaped element has “Δ-shaped protrusions 32” that engage “Δ-shaped recesses in an inner ring 33 in the dose setting button 18.” EX1015, ¶29; *see also id.*, ¶39 (referring to tubular clutch as elements 132 and 133); *supra*, section section V.J.4. As explained in section V.E.3, dose-setting drum 17 and its dose-setting button 18 are coupled to the clutch via these protrusions/recesses during the dosing step so that they rotate together.

EX1015, ¶29; EX1011, ¶532. The embodiment shown in FIGS. 3-5 operates in an analogous manner, with dose-setting drum 117 and its dose-setting button 118 similarly coupled to the clutch during the dosing step.

Third, FIG.1 shows that dose-setting drum 17 extends circumferentially around at least a portion of the cup shaped element. EX1011, ¶532. The analogous embodiment shown in FIGS. 3-5 similarly shows drum 117 extending circumferentially around at least a portion of the cup shaped element. .

Thus, Møller anticipated claim 57.

K. Grounds 5 and 7: Claims 54-55 Were Obvious over Each of Steinfeldt-Jensen and Møller Combined with Burroughs

As explained above in sections V.H.1-2 and V.J.1-2, Steinfeldt-Jensen and Møller each disclose embodiments meeting all limitations of claims 51-52. Claim 54 depends from claim 52 and further recites that the “pen type drug delivery device further comprises a cartridge containing a medicament, said cartridge comprising a reservoir, a stopper, a septum and a ferrule.” Claim 55 depends from claim 54 and further recites that the “cartridge comprises a multidose cartridge.”

With respect to claim 54, Steinfeldt teaches a pen for delivering user-specified doses from a cartridge containing medicine. EX1014, 12:18-22, 13:1-5. Møller similarly discloses a pen injector that can be dialed to deliver a specific dose of medicine from a cartridge. *See* EX1015, ¶¶1, 4. While neither reference

explicitly describes the structure of these cartridges, a POSA would have found it obvious to use the type of cartridge recited in claim 54.

As explained above, the '486 patent never describes any of the components of *its* cartridge. The '486 patent states only that its cartridge is a “multidose” cartridge and that “a number of doses of medicinal product may be dispersed is provided in the cartridge retaining part 2.” *Id.*, 3:34-37; *see also id.*, 1:20-22 (similarly referring to “multidose cartridge” without specifying cartridge components). This lack of disclosure underscores that the components of the cartridge recited in claim 54 would have been apparent to a POSA in the context of an injector pen dispensing multiple user-specified doses. EX1011, ¶502.

To the extent “a cartridge containing a medicament, said cartridge comprising a reservoir, a stopper, a septum and a ferrule” was not obvious in view of the disclosure of Steinfeldt-Jensen (for purposes of Ground 5) or Møller (for purposes of Ground 7) alone, these features would nevertheless have been obvious in view of Burroughs’ teachings. *See supra*, sections V.F.4-5 (discussing Burroughs’s disclosure of an injector pen that uses a multi-dose cartridge with a reservoir, septum, stopper, and ferrule); *see also* EX1013, 9:32-46.

1. Reason to Modify and Reasonable Expectation of Success

A POSA would have had a reason to incorporate the multi-dose cartridge taught by Burroughs into both the injector pen taught by Steinfeldt-Jensen

(Ground 6) and the injector pen taught by Møller (Ground 7). As discussed in section V.E, Burroughs, Steinfeldt-Jensen, and Møller each teach injector pens that dispense medicine from a cartridge. Thus, Burroughs, Steinfeldt-Jensen, and Møller are within the same field of endeavor as the claimed invention and further address the same problem, *i.e.* the design of pen-type injection devices. Burroughs is thus analogous art to Steinfeldt-Jensen, Burroughs, and the '486 patent.

A POSA would have considered the relevant features of Burroughs, Steinfeldt-Jensen, and Møller, *see supra*, sections V.E.1-3, to be similar to the features of the pen-type injector disclosed by the '486 patent. Moreover, a POSA would have recognized that both Steinfeldt-Jensen and Møller taught multi-dose injector pens with cartridges configured for multiple uses. *See* EX1014, 1:12-15 (cartridge contains “an amount of medicine sufficient for the preparation of a number of therapeutic doses”); EX1015, 1:13-52; 3:24-28 (discussing user-specified doses, large ampoules, and small injections). A POSA would have looked to Burroughs—a reference describing a pen-type injector similar to those of Steinfeldt-Jensen and Møller—as a means of enhancing the cartridge used in injector devices. EX1011, ¶¶502, 538. Accordingly, to the extent Steinfeldt-Jensen and Møller did not already teach a cartridge with features such as a reservoir, a stopper, a septum, and a ferrule, a POSA would have been motivated to

use Burroughs' cartridge to facilitate delivery of multiple separate doses from the same cartridge. EX1011, ¶506.

Thus, a POSA would have had a reason to combine the injector mechanisms of Steinfeldt-Jensen and Møller—each of which discuss delivery of multiple doses—with the cartridge of Burroughs to provide an injector pen with a cartridge having features facilitating the delivery of multiple doses from the same cartridge. EX1011, ¶506. Moreover, the POSA would have had a reasonable likelihood of success, due to the congruent features across these references (e.g., similar use of piston rods to dispense medicine from a cartridge) and the predictability of piston rod and cartridge operation. *Id.*

VI. CONCLUSION

For the reasons set forth above, claims 51-57 of the '486 patent are unpatentable. The unpatentability of this patent is not an abstract concern. The high cost of insulin products reduces patient compliance, with adverse effects for American diabetics. *See* EX1011, [XX]. Mylan requests, therefore, that an IPR of this claim be instituted.

Dated: 9 September 2018

/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 **XX,XXX**, which is less than the 14,000 allowed under 37 C.F.R. 42.24(a)(i). In accordance with 37 C.F.R. 42.24(a), this word count does not include table of contents, table of authorities, mandatory notices under §42.8, certificate of service or word count, or appendix of exhibits or claim listing.

Dated: 9 September 2018/Richard Torczon/

Reg. No. 34,448

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§42.6(e) and 42.105, I certify that I caused to be served a true and correct copy of the foregoing: **PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,992,486 and Exhibits 1001-10XX** by *Federal Express Next Business Day Delivery* on this day, July XX, 2018 on the Patent Owner's correspondence address of record for the subject patent as follows:

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