UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PFIZER INC.,
Petitioner,

v.

SANOFI-AVENTIS DEUTSCHLAND GMBH
Patent Owner.

Patent No. 8,679,069
Patent No. 8,603,044
Patent No. 8,992,486
Patent No. 9,526,844
Patent No. 9,604,008

DECLARATION OF MR. CHARLES E. CLEMENS

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I, Charles E. Clemens, declare as follows:

I. QUALIFICATIONS

1. I have been retained by counsel on behalf of Petitioner, Pfizer Inc. ("Pfizer"), to provide technical analysis and opinions in this matter related to my experience and expertise. My opinions are based on my skills, knowledge, training, education, and experience in matters of this nature, and my examination of the materials utilized in preparing this report.

2. I received a Bachelor's Degree in Mechanical Engineering from San Diego State University in 1979.

3. I have over 40 years of experience as an engineer, executive and consultant in the medical device industry.

4. From 1981 to 1995, I worked at IVAC Corporation (now CareFusion a subsidiary of Becton Dickinson), a company that pioneered intravenous medication delivery systems. During my time at IVAC, I worked in multiple roles, including as a product designer, engineering manager, and technical director for the largest medication delivery system program the company had ever attempted, which resulted in launching the product in both the US and European markets. My work at IVAC involved design, development, marketing, launch, and manufacturing of numerous drug delivery devices and vital sign monitoring systems. My design and development work at IVAC lead to filing five patents on which I was a named

inventor. The focus of my work was on small mechanisms, plastic injection molded parts produced in quantities of millions, and precision assembly of parts to achieve high production quality and functional reliability. The mechanisms I designed with my group at IVAC commonly included mechanical components such as bearings, ratchets, rotating parts, and precision interfaces that could interact with electronics, for example, to count and set doses for intravenous injection systems. In 1990, I established and managed training for specialized design tools for Design for Manufacturing and Assembly (DFMA), a design process for optimizing assemblies and part count for small plastic devices produced in high quantities.

5. From 1995 to the present, I have been operating a medical device design and development consulting company as the Founder and Principal Consultant. My consulting company focuses on developing innovative medical device products and bringing them to market. During this time, I have worked extensively on dozens of medical device designs across many Clients in the areas of (a) liquid medication delivery devices, including intravenous ("IV") systems, (b) pen injectors, (c) respiratory care devices such as personal inhalers, (d) hemodialysis and other blood handling systems, and (e) in-vitro diagnostic systems utilizing small mechanisms that require controlling rotational and axial movements (among others). From 2005 to 2006, I also analyzed and optimized single and multiple use injector pen designs

for Verus Pharmaceuticals, which is a product that is now marketed as the Adrenaclick auto-injector.

6. I am identified as an inventor on 10 issued patents and 3 applications in the field of medical devices, including small mechanisms, plastic injection molding and assembly, patient medication delivery devices, and fluidic control devices.

7. I have worked with hundreds of plastic medical device assemblies and mechanisms throughout my career and have significant experience with medication delivery systems including pen type injection devices, prior art injection devices, and the injection devices that are disclosed by the challenged patents.

8. A copy of my *curriculum vitae*, attached as Exhibit 1012, contains further details on my education, experience, publications, patents, and other qualifications to render an expert opinion in this matter.

II. SCOPE OF WORK

9. I understand that petitions are being filed with the United States Patent and Trademark Office for *inter partes* review of:

(1) U.S. Patent No. 8,679,069 to Veasey et al. ("the '069 patent," EX1001), entitled "Pen-Type Injector";

(2) U.S. Patent No. 8,603,044 to Veasey et al. ("the '044 patent," EX1002), entitled "Pen-Type Injector";

(3) U.S. Patent No. 8,992,486 to Veasey et al. ("the '486 patent," EX1003), entitled "Pen-Type Injector";

(4) U.S. Patent No. 9,526,844 to Veasey et al. ("the '844 patent," EX1004), entitled "Pen-Type Injector"; and

(5) U.S. Patent No. 9,604,008 to Veasey ("the '008 patent," EX1005), entitled "Drive Mechanisms Suitable for Use in Drug Delivery Devices."[1]

10. I have been retained by Pfizer Inc. ("Pfizer") to offer an expert opinion on the patentability of the claims of the challenged patents. I receive hourly compensation for my services at a rate of $350 per hour, with half rate for non-working travel time. No part of my compensation is dependent on my opinions or on the outcome of this proceeding.

11. I have been specifically asked to provide my opinions on:

(1) Independent claim 1 and dependent claims 2-3 of the '069 patent;

(2) Independent claim 11 and dependent claims 14-15 and 18-19 of the '044 patent;

(3) Independent claim 1 and dependent claims 2-6, 12-18, 20, 23, 26-30, 32-33, 36, and 38-40 of the '486 patent;

[1] I will refer to these patents collectively as "the challenged patents."

(4) Independent claim 51 and dependent claims 52-57 of the ’486 patent;

(5) Independent claim 21 and dependent claims 22-30 of the ’844 patent; and

(6) Independent claim 1 and dependent claims 3, 7-8, 11, and 17 of the ’008 patent.[2]

12. In connection with this analysis, I have reviewed the challenged patents and relevant parts of their file histories (EX1006-EX1010). I have also reviewed and considered various other documents in arriving at my opinions, and may cite to them in this declaration. For convenience, a list of exhibits considered in arriving at my opinions is included as an appendix to this declaration.

III. LEGAL STANDARDS

13. I have been advised that a claim is not patentable under 35 U.S.C. § 102[3] if the claimed invention is not new. For the claim to be unpatentable because it is anticipated, all of its requirements must have been described in a single prior art reference, such as a publication or patent that predates the claimed invention.

[2] I will refer to these claims collectively as “the challenged claims.”

[3] Citations are to the relevant pre-AIA sections of Title 35 of the United States Code.

14. I have also been advised that the description in the prior art reference does not have to be in the same words as the claim, but all of the requirements of the claim must be there, either stated or necessarily implied, so that someone of ordinary skill in the relevant field looking at that one reference would be able to make and use the claimed invention.

15. I have been advised that a claimed invention is not patentable under 35 U.S.C. § 103 if it is obvious. A patent claim is unpatentable if the claimed invention would have been obvious to a person of ordinary skill in the field at the time the claimed invention was made. This means that even if all of the requirements of the claim cannot be found in a single prior art reference that would anticipate the claim, a person of ordinary skill in the relevant field who knew about all this prior art would have come up with the claimed invention.

16. I have further been advised that the ultimate conclusion of whether a claim is obvious should be based upon several factual determinations. That is, a determination of obviousness requires inquiries into: (1) the level of ordinary skill in the field; (2) the scope and content of the prior art; (3) what difference, if any, existed between the claimed invention and the prior art; and (4) any secondary evidence bearing on obviousness.

17. I have been advised that, in determining the level of ordinary skill in the field that someone would have had at the time the claimed invention was made,

I should consider: (1) the levels of education and experience of persons working in the field; (2) the types of problems encountered in the field; and (3) the sophistication of the technology.

18. I have also been advised that, in determining the scope and content of the prior art, in order to be considered as prior art, a reference must be reasonably related to the claimed invention of the patent. A reference is reasonably related if it is in the same field as the claimed invention or is from another field to which a person of ordinary skill in the field would look to solve a known problem.

19. I have been advised that any secondary evidence of nonobviousness may be considered as an indication that the claimed invention would not have been obvious at the time the claimed invention was made, and any secondary evidence of obviousness may be considered as an indication that the claimed invention would have been obvious at such time. Although I should consider any such evidence, I should also assign it appropriate relevance and importance when deciding whether the claimed invention would have been obvious.

20. I have been advised that a patent claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was independently known in the prior art. In evaluating whether such a claim would have been obvious, I may consider whether there is a reason that would have prompted a

person of ordinary skill in the field to combine the elements or concepts from the prior art in the same way as in the claimed invention.

21. I have been further advised that there is no single way to define the line between true inventiveness on the one hand (which is patentable) and the application of common sense and ordinary skill to solve a problem on the other hand (which is not patentable). For example, market forces or other design incentives may be what produced a change, rather than true inventiveness. I may consider whether the change was merely the predictable result of using prior art elements according to their known functions, or whether it was the result of true inventiveness. I may also consider whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent. I may consider whether the innovation applies a known technique that had been used to improve a similar device or method in a similar way. I may also consider whether the claimed invention would have been obvious to try, meaning that the claimed innovation was one of a relatively small number of possible approaches to the problem with a reasonable expectation of success by those skilled in the art.

22. I have also been advised, however, that I must be careful not to determine obviousness using the benefit of hindsight; many true inventions might seem obvious after the fact. I should put myself in the position of a person of ordinary

skill in the field at the time the claimed invention was made and I should not consider what is known today or what is learned from the teaching of the patent.

23. Finally, I have been advised that a means-plus-function limitation requires identification of both the claimed function and the structure in the written description necessary to perform that function. I have been advised that the statute does not permit limitation of a means-plus-function claim by adopting a function different from that explicitly recited in the claim. I have also been advised that the statute does not permit incorporating structure from the written description that is beyond what is necessary to perform the claimed function.

IV. OVERVIEW OF THE CHALLENGED PATENTS

24. The challenged patents relate to a pen-type injector for the self-administration of medicine, such as insulin and insulin analogs. *See* EX1001, Title, 1:13-22.[4] According to the challenged patents, users of pen-type injectors are

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[4] I note that the challenged patents share a common specification, except the specification of the '008 patent, which, in addition to the description found in the other challenged patents, describes two other embodiments (described more below) and includes a different background and summary than that contained in the other challenged patents. *See infra*, section IV.C. For simplicity, except where I

typically patients who do not have formal medical training, such as patients with diabetes. *See id.*, 1:18-22. As such, the challenged patents explain that the injector should be easy to use, as patients using the device may have impaired vision or other physical infirmities. *Id.*, 1:24-28. As an overview, I reproduce below the independent claims that I have been asked to analyze.

25. Independent claim 1 of the '069 patent claims a housing part containing a drive mechanism for dispensing medicine from a pen-type injector. *See id.*, Abstract, claim 1. Claim 1 of the '069 patent recites:

> 1. A housing part for a medication dispensing apparatus, said housing part comprising:
>
> a main housing, said main housing extending from a distal end to a proximal end;
>
> a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;

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specifically note, citations to the challenged patents' disclosure in this overview will be to the '069 patent (EX1001).

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

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

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

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

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

Id., 6:37-60.

26. Independent claim 11 of the ’044 patent similarly claims a housing part for a medication dispensing apparatus that contains substantially the same

limitations as claim 1 of the ’069 patent. *See* EX1002, Abstract, claim 11. Claim 11 of the ’044 patent recites:

> 1. A housing part for a medication dispensing apparatus, said housing part comprising:
>
> a main housing, said main housing extending from a distal end to a proximal end;
>
> a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve;
>
> a dose dial grip disposed near a proximal end of said dose dial sleeve;
>
> a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;
>
> a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said

> internal threading adapted to engage an external thread of said piston rod; and
>
> a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,
>
> wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, and
>
> wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different.

Id., 8:7-35.

27. Independent claim 1 of the ’486 patent also claims a housing part for a medication dispensing apparatus. *See* EX1003, claim 1. Claim 1 of the ’486 patent recites:

> 1. A housing part for a medication dispensing apparatus, said housing part comprising:
>
> a main housing, said main housing extending from a distal end to a proximal end;

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

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

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

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

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

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

Id., 6:59-7:12.

28. Independent claim 51 of the ’486 patent claims a clutch for use within a pen type drug delivery device. *See id.*, claim 51. Claim 51 of the ’486 patent 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.

Id., 10:31-37.

29. Independent claim 21 of the ’844 patent claims a drug delivery device. *See* EX1005, claim 21. Claim 21 of the ’844 patent recites:

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

30. Independent claim 1 of the ’008 patent claims a drive mechanism for use in a drug delivery device. *See* EX1005, claim 1. Claim 1 of the ’008 patent recites:

> 1. A drive mechanism for use in a drug delivery device comprising:
>
> a housing comprising a helical thread;
>
> a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing,
>
> an insert provided in the housing, where the insert has a threaded circular opening;

> a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread;
>
> a piston rod having a first thread and a second thread, wherein the first thread is engaged with the threading circular opening of the insert and the second thread is engaged with the internal helical thread of the drive sleeve; and
>
> a clutch located between the dose dial sleeve and the drive sleeve, wherein the clutch is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve.

Id., 17:28-45.

31. Below, I provide a brief overview of the injector device described in the challenged patents and claimed in varying scope. First, I explain the embodiment common to all the challenged patents. I explain each of the components that form the device of that embodiment. I follow this explanation with a description of how the components move relative to one another during the device's operation. I then provide a brief explanation of the second and third embodiments described in the '008 patent, focusing on the differences between those embodiments compared to the first embodiment.

32. Throughout my analysis, when I discuss the challenged patents and the prior art, I will refer to the positioning and movement of components as relative to the "button-end" of the device (*i.e.*, the end at which the user presses a button or otherwise applies force to dispense medicine) and the "needle-end" of the device (*i.e.*, the end by which the medicine is dispensed from the device).

33. I note here that the specifications of the challenged patents refer to the button-end of the device or a component as its "second end," and the needle-end of the device as its "first end." *See, e.g.*, EX1001, 3:29-30, 3:36-42, 3:52-53, FIG. 1. In addition, claim 1 of the '069 patent, claim 11 of the '044 patent, and claims 1 and 51 of the '486 patent refer to the button-end of the device or component as its "proximal" end, and the needle-end of the device or component as its "distal" end. *See* EX1001, claim 1; EX1002, claim 11; EX1003, claims 1, 51. I note that the use of "proximal" and "distal" in claim 1 of the '069 patent to refer to these relative positions is further confirmed by the use of those terms in claim 2. *See* EX1001, claim 2. Similarly, the use of "proximal" and "distal" in claim 11 of the '044 patent is confirmed by the use of those terms in claim 12. *See* EX1002, claim 12. The use of "proximal" and "distal" in claims 1 and 51 of the '486 patent is confirmed by the use of those terms in claims 3 and 52, respectively. *See* EX1003, claims 3, 52.

34. I further note that the challenged claims of the '844 patent refers to the needle-end of the device or component as the "dose dispensing end" or the "distal

end." *See* EX1004, claim 1. The claims also refer to the button-end of the device or component as the "proximal end." *See id.*, claim 27.

35. The specification of the '008 patent defines the "first end" as the "proximal end," which, according to the '008 patent, is the needle-end of the device or component. *See* EX1005, 4:54-57. The "second end" is defined as the "distal end," which, according to the '008 patent, is the button-end of the device or component. *See id.*, 4:58-61. I note that none of the challenged claims of the '008 patent recite or claim components relative to the "first," "second," "proximal," or "distal" ends. *See id.*, claims 1, 3, 7-8, 11, and 17.

A. Overview of the Components

36. Claim 1 of the '069 patent, claim 11 of the '044 patent, and claim 1 of the '486 patent each recites six components that form the claimed device:

(1) a "main housing" (4, annotated in gray in the figures below), which, according to the '069 patent, houses the drive mechanism for dispensing medicine from a cartridge, *see, e.g.*, EX1001, 3:8-14, FIGS. 1-5;

(2) a "dose dial sleeve" (70, green), which the user manipulates to set a specific dose for injection, *see, e.g.*, *id.*, 4:49-67, FIGS. 1-5, 9-11;

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

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

(5) a "drive sleeve"[6] (30, red), which drives the piston rod to move the piston, *see, e.g.*, *id.*, 3:51-60, 6:23-25, FIGS. 1-5, 9-11; and

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

37. Claim 51 of the '486 patent only claims the sixth component as a "clutch." *See* EX1003, claim 51. Also, I note that claim 51 and some of its dependent claims refer to an unclaimed "dial member" and an unclaimed "dose knob." *See id.*, claims 51-53, 57.

38. Reproduced below are FIGS. 1-2 of the '069 patent, where I have annotated each of the six components claimed by the '069 patent, the '044 patent,

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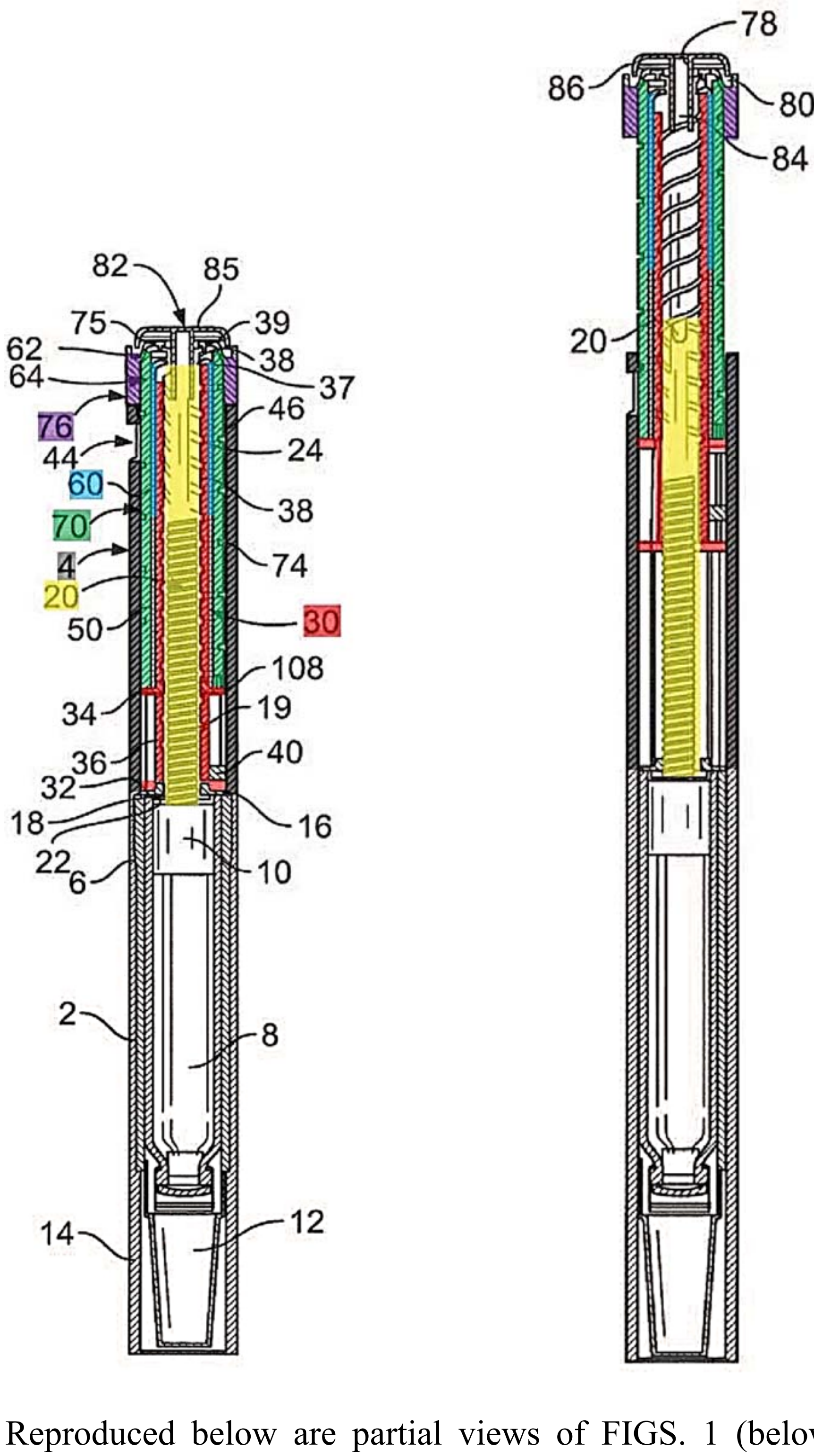
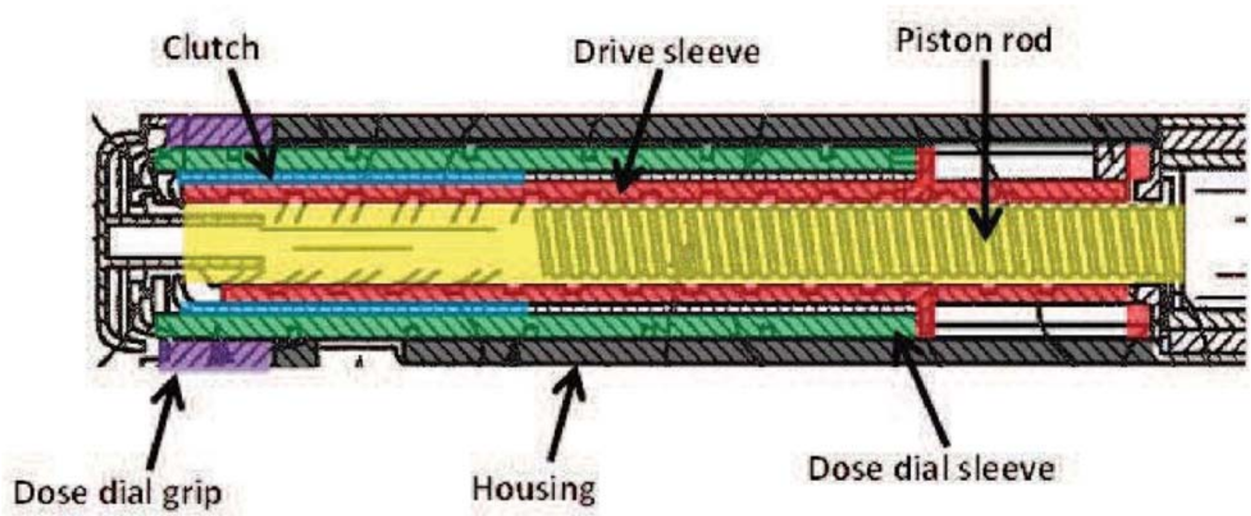
[5] Claim 1 of the '486 patent recites a "dose knob."

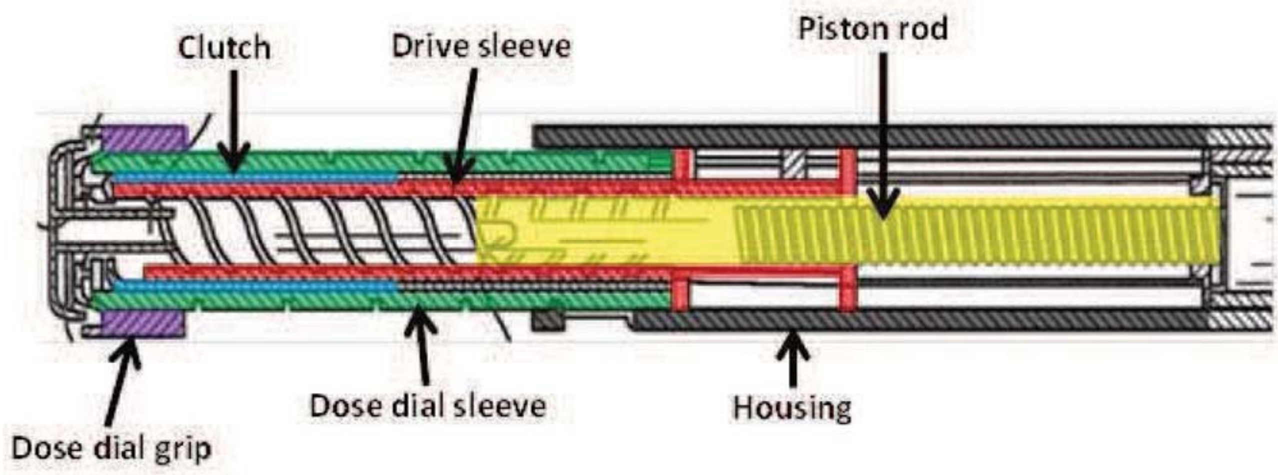
[6] Claim 1 of the '486 patent recites a "driver."

and the ’486 patent, with their corresponding color outlined above. FIG. 1 (left) shows the injector in a zero-dose-set position, where the cartridge is in a full position. FIG. 2 (right) shows the injector in a maximum-dose-set position, before dispensing from a full cartridge.



39. Reproduced below are partial views of FIGS. 1 (below-top) and 2 (below-bottom), showing the components (annotated and labeled) in greater detail:





40. Claim 1 of the ’008 patent and claim 21 of the ’044 patent also claim six components that form the claimed device:

(1) a “housing” (4, annotated in gray in the figures below), which houses the drive mechanism for dispensing medicine from a cartridge, *see, e.g.*, EX1005, 7:11-17, FIGS. 1-5;

(2) a "dose dial sleeve"[7] (70, green), which the user manipulates to set a specific dose for injection, *see, e.g.*, *id.*, 8:55-58, FIGS. 1-5, 9-11;

(3) an "insert"[8] (16, blue), which engages and holds a piston rod as the piston rod is driven by the drive sleeve, *See id.*, 7:33-39, 10:32-35, FIGS. 1-5;

(4) a "drive sleeve"[9] (30, red), which drives the piston rod to move the piston, *see, e.g.*, *id.*, 7:55-65, 10:32-35, FIGS. 1-5, 9-11;

(5) a "piston rod" (20, yellow), which is driven by the drive sleeve to move the piston within the cartridge to dispense medicine, *see, e.g.*, *id.*, 7:40-51, 10:32-35, FIGS. 1-5; and

(6) a "clutch"[10] (60, blue), which releasably connects components within the drive mechanism for common movement during use, *see, e.g.*, *id.*, 5:10-13, 9:36-39, 10:15-22, FIGS. 1-5, 9-11.

41. Reproduced below are FIGS. 1-2 of the '069 patent, which correspond to FIGS. 1-2 of the '008 patent and the '844 patent, except the feature labeled "47"

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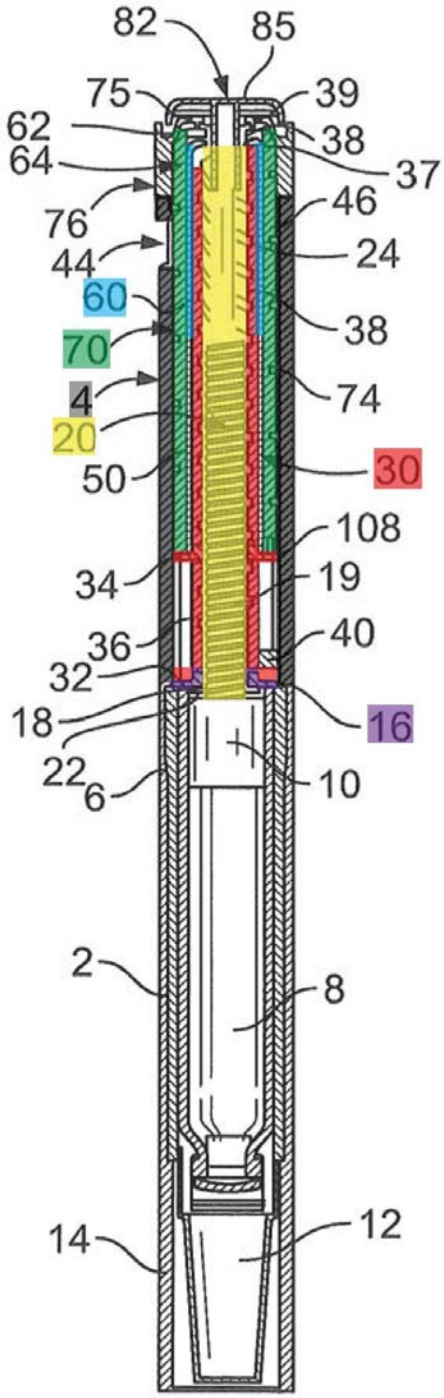
[7] Claim 21 of the '044 patent recites a "dose indicator."

[8] Claim 21 of the' 844 patent recites a "piston rod holder."

[9] Claim 21 of the '044 patent recites a "driving member."

[10] Claim 21 of the '044 patent recites a "sleeve."

in the figures of the ’008 patent is labeled “38” in the figures of the ’069 patent and the ’844 patent. *Compare* EX1001, FIGS. 1-2, *with* EX1004, FIGS. 1-2, *and* EX1005, FIGS. 1-2. In the figures below, I have annotated each of the six components claimed by the ’008 patent and the ’844 patent, with their corresponding color outlined above. FIG. 1 (left) shows the injector in a zero-dose-set position, where the cartridge is in a full position. FIG. 2 (right) shows the injector in a maximum-dose-set position, before dispensing from a full cartridge.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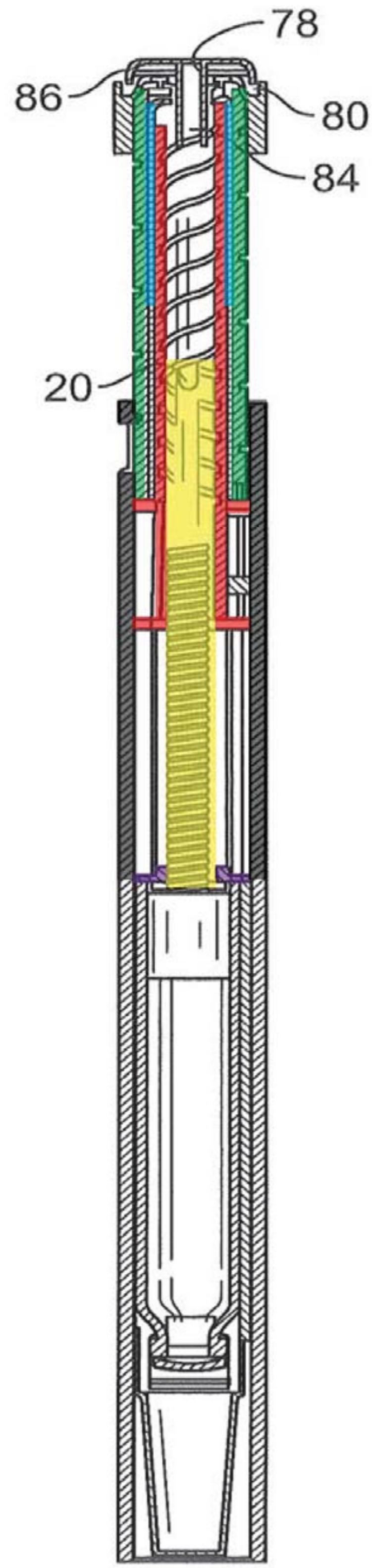
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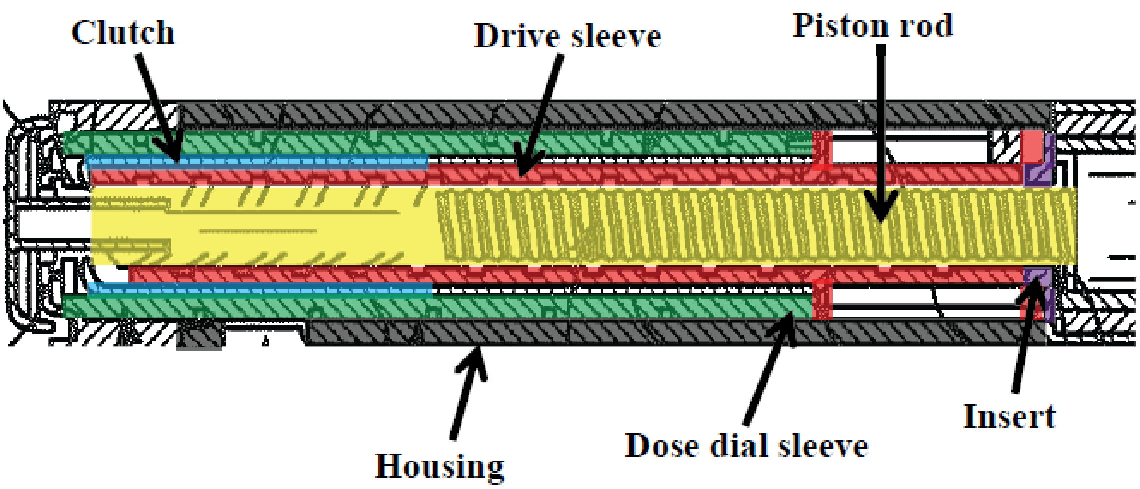
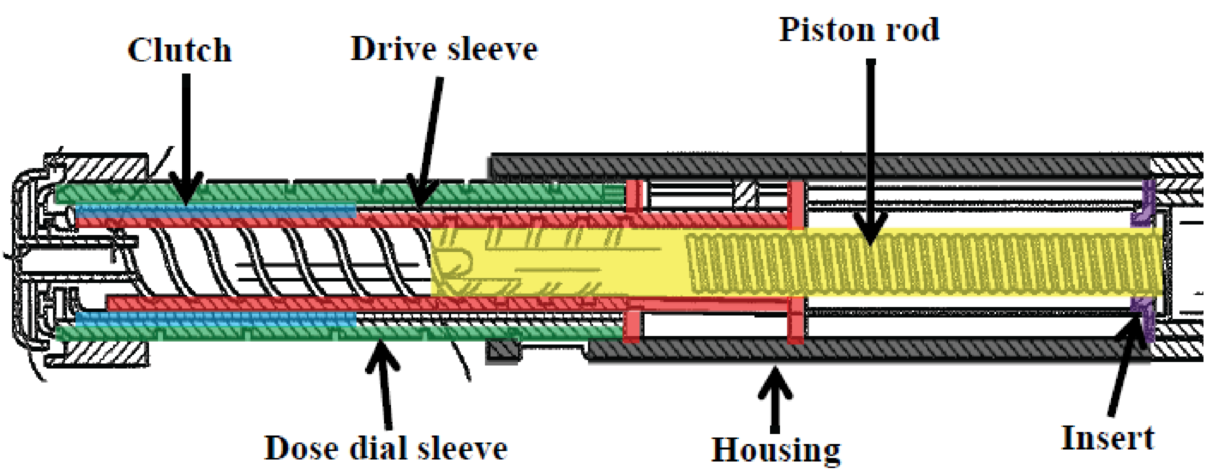
42. Reproduced below are partial views of FIGS. 1 (below-top) and 2 (below-bottom), showing the components (annotated and labeled) in greater detail:[11]





43. I note that many of the illustrated components shown in the figures and described in the specifications are not recited in the challenged claims. Even for

[11] For simplicity, I label the components using the terms described in the specifications of the ’008 patent and the ’844 patent.

those components that are recited in the challenged claims, the embodiment discussed in the specification includes many structural features and operative connections that are not recited. Before turning to the claims of the challenged patents, however, I discuss the components forming the embodiment described in the specifications, in turn below, including various unclaimed aspects of the device.

Main housing 4

44. The injector device includes a housing having two parts: a first cartridge retaining part 2, and a second main housing part 4, which are secured together. EX1001, 3:8-12. The first cartridge retaining part 2 retains "[a] cartridge 8 from which a number of doses of medicinal product may be dispensed." *Id.*, 3:15-16. The cartridge 8 has a piston 10, which is driven toward the needle-end of the device to expel medicine from the cartridge. *See id.*, 3:16-18.

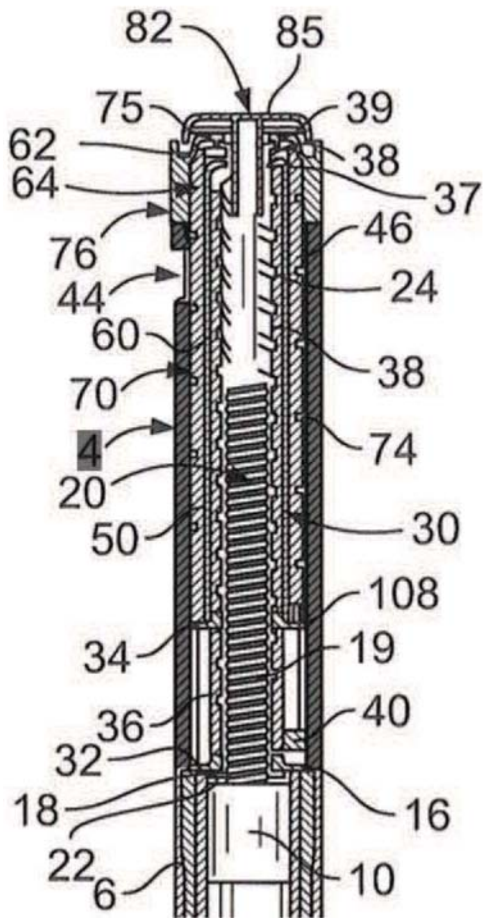
45. The main housing part 4 is the portion of the housing that contains the drive mechanism, which allows a user to set a certain dose and dispense that dose from the cartridge 8. *See generally id.*, FIGS. 1-5. The housing 4 contains a window 44 (*i.e.*, an opening) by which the user may view the outer surface of a dose dial sleeve 70 as it is rotated in and out of the housing 4, described further below. *See id.*, 4:53-55. The housing 4 also contains a helical rib 46 that extends a single sweep along the housing's inner surface. *See id.*, 4:55-58, FIGS. 1, 15-16. The rib 46 is

designed to sit within a helical groove 74 extending along the dose dial sleeve 70's outer surface. *Id.*, 4:55-58, FIGS. 1, 12, 14.

46. Splines 42 extend longitudinally along the inner surface of the main housing 4. *See id.*, 4:1-5, FIGS. 9-11, 15-16. The splines 42 serve to prevent the relative rotation of a nut 40, described more below. *See id.* They also serve a clicking function: a flexible arm 52 of a clicker 50 (also described below) drags over the splines to produce a click when the user dials up a dose during the dose-setting process. *See id.*, 5:36-39.

47. The main housing 4 also includes a first stop 100 on its inner surface that is provided between the button-end of the splines 42 and a needle-end of the helical rib 46. *See id.*, 4:59-60, FIG. 15. A second stop 102 is disposed at an opposite side, and is formed by a frame surrounding the window 44. *Id.*, 4:60-62, FIG. 16. These stops serve as a limit to the maximum length the dose dial sleeve 70 may be moved out of the housing 4, which in turn, sets the maximum dose that can be administered in a single injection. *See id.*, 5:44-47. The main housing 4 further includes a plurality of stops 110, which engage with a plurality of members 110 provided on a dose dial grip 76, described more below, when the set dose has been fully dispensed during injection. *See id.*, 6:26-34, FIGS. 14-15.

48. Reproduced below a partial view of FIG. 1, showing the main housing 4, which I have annotated gray:



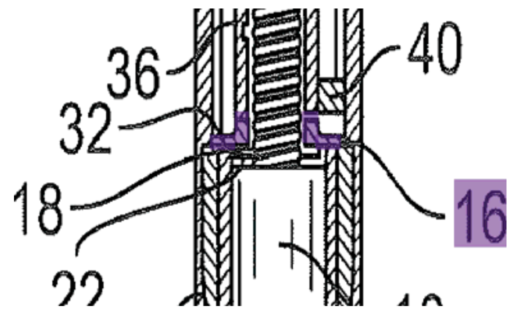
49. As shown in the above figure, the main housing part 4 extends from the button-end of the device toward the needle-end of the device.

Insert 16

50. The injector includes an insert 16, which is provided at the needle-end of the housing 4, and includes a threaded circular opening 18. *Id.*, 3:29-35. The threading within the opening 18 engages with a first threading 19 of a piston rod 20 (described below) to advance the piston rod and piston toward the needle-end of the device. *See id.*, 3:37-39. The insert 16 is fixed to the housing, both rotationally and axially. *Id.*, 3:30-31. The ’069 patent explains that in some embodiments, rather than being provided as a separate piece, the insert 16 “may be formed integrally with the

main housing 4 [in] the form of a radially inwardly directed flange having an internal thread." *Id.*, 3:33-35.

51. Below is a partial view of FIG. 1, depicting a portion of the device toward the housing part 4's needle-end, with the insert 16 shown in blue:



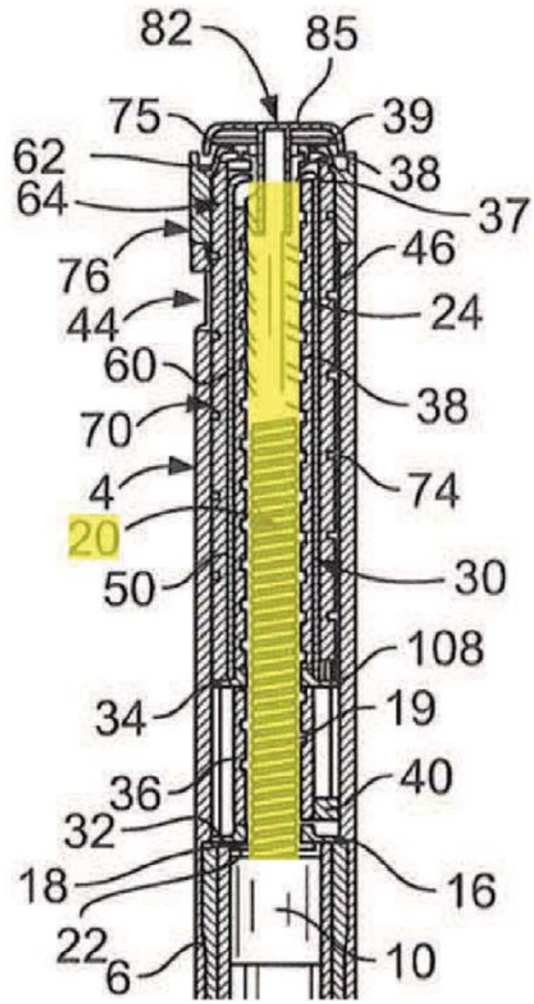
Piston rod 20

52. A piston rod 20, having a "generally circular [cross-]section," is provided within the housing 4. *See id.*, 3:37, FIGS. 1-5. When driven by the drive mechanism, the piston rod 20, via a pressure foot 22, pushes the piston 10 of the cartridge to dispense medicine. *See id.*, 3:40-41, 6:23-25.

53. The piston rod 20 includes a first thread 19 extending from the rod's needle-end toward its button-end. *Id.*, 3:36, FIG. 1. The first thread 19 engages with the threaded opening 18 of the insert 16. *See id.*, 3:37-39. The piston rod 20 also includes a second thread 24 that extends from the rod's button-end toward its needle-end. *Id.*, 3:41-44. The second thread 24 engages a helical groove 38 of a drive sleeve 30, described more below. *See id.*, 3:58-60. As shown in FIG. 1, "[t]he first thread 19 and the second thread 24 are oppositely disposed." *Id.*, 3:4849. As detailed more below, during injection, the second thread 24 is driven by the helical groove 38 of

the drive sleeve 30, while the first thread 19 controls how much the piston rod 20 advances through the insert 16 with each rotation of the piston rod.

54. Below is a partial view of FIG. 1, where I have annotated the piston rod 20 in yellow:



Drive sleeve 30

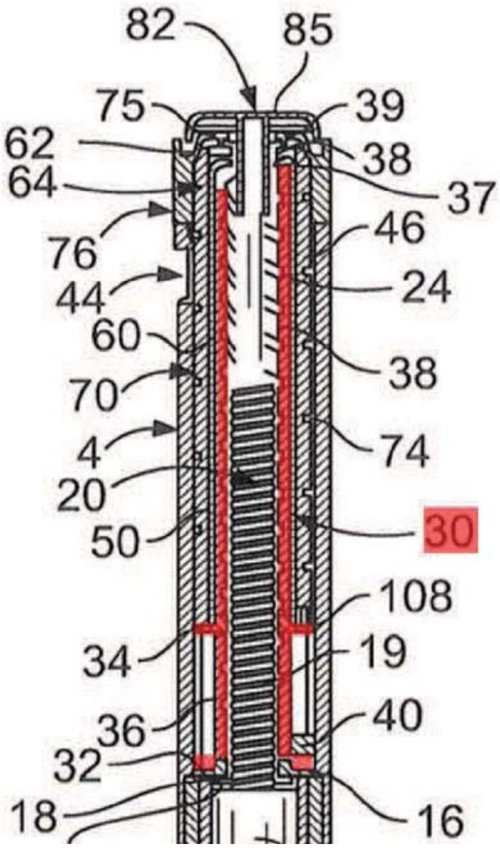
55. A drive sleeve 30 is provided around the piston rod 20. *Id.*, 3:51, FIGS. 1-5. “The drive sleeve 30 is generally cylindrical,” and includes “[a] helical groove 38 [that] extends along the internal surface of the drive sleeve 30.” *Id.*, 3:52-59. The

helical groove 38 engages with the second thread 24 of the piston rod 20. *Id.*, 3:59-60.

56. The drive sleeve 30 also includes a first radially-extending flange 32 provided at its needle-end, and a second radially-extending flange 34 spaced a distance from the first flange 32 toward the drive sleeve's button-end. *Id.*, 3:52-55. Extending between these two flanges is an intermediate thread 36, provided on the drive sleeve's outer surface. *Id.*, 3:55-58, FIGS. 6-7, 12-13. As shown in FIG. 1, at the zero-dose-set position, the needle-end side of the first flange 32 conforms to the button-end side of the insert 16. *See id.*, 3:61-62, FIG. 1. In addition, as shown in FIG. 13, the second flange 34 includes a radial stop 108 on its needle-end side, which, when abutting a radial stop 106 of a nut 40 (described below), serves to indicate to the user that the set-dose has reached the final amount that can be dispensed from the cartridge. *See id.*, 5:52-56, FIG. 13.

57. An extension 38 extends from the drive sleeve 30's button-end, and includes a radially outwardly directed flange 39 at its button-end. *See id.*, 4:6-11, FIG. 1. A shoulder 37 is formed between the drive sleeve's button-end and the flange 39. *Id.*, 4:6-11, FIG. 1. A flange 62 of a clutch 60, which is described more below, is positioned between the shoulder 37 and the flange 39. *Id.*, 4:34-37.

58. Below-left is a partial view of FIG. 1 and below-right is FIG. 13, where I have annotated the drive sleeve 30 in red:



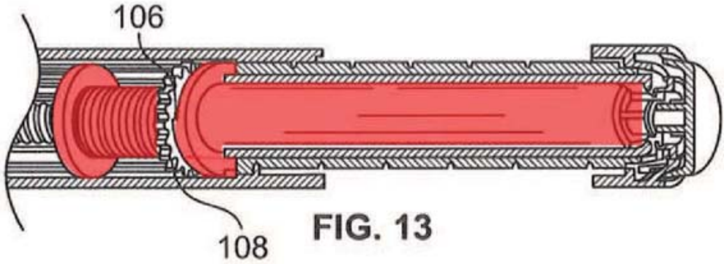
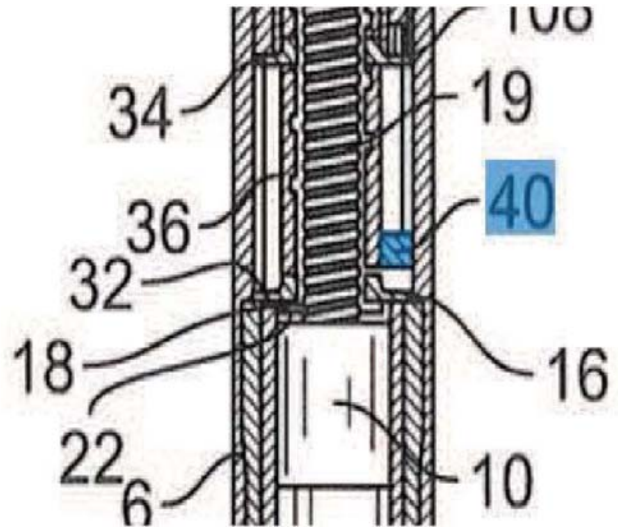


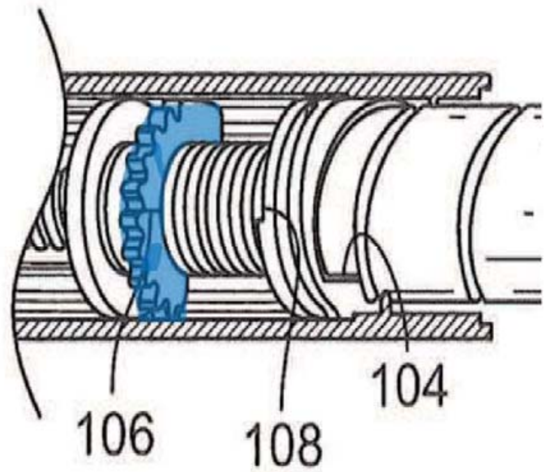
FIG. 13

Nut 40

59. "A nut 40 is located between the drive sleeve 30 and the main housing [4], disposed between the first flange 32 and the second flange 34 [of the drive sleeve 30]." *Id.*, 3:63-65. In the embodiment shown, the nut 40 is a half-nut having an internal thread that engages with the intermediate thread 36 of the drive sleeve 30. *Id.*, 3:65-67, FIGS. 6-7, 12-13. The nut 40 includes an outer surface that is keyed to the main housing's splines 42, which fixes the nut 40 rotationally, but allows the nut 40 to move axially relative to the housing. *See id.*, 4:1-5. The nut 40 also includes the radial stop 106 formed on the nut's button-end side, which abuts the drive sleeve's radial stop 108 at the final-dose position. *Id.*, 5:52-56, FIG. 13.

60. Below-left is a partial view of FIG. 1, toward the housing 4's needle-end, and below-right is a partial view of FIG. 12, where I have annotated the nut 40 blue:



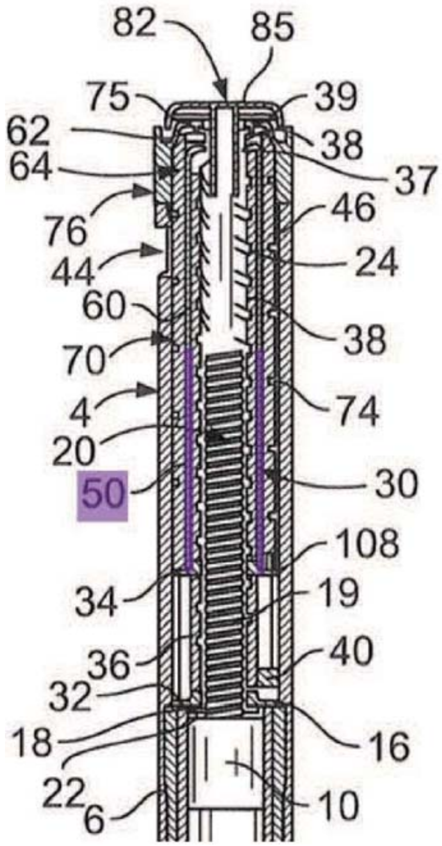


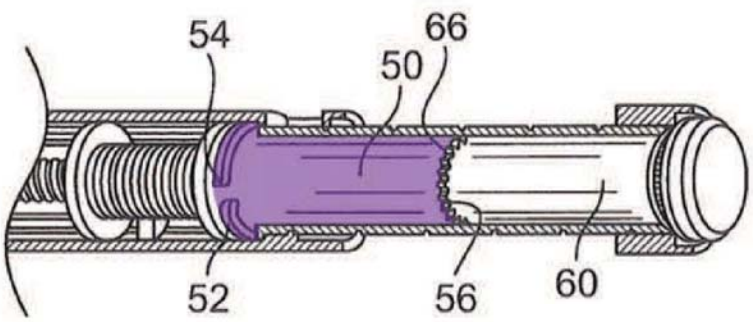
Clicker 50

61. A clicker 50 is "generally cylindrical" and "disposed about the drive sleeve 30, between the drive sleeve 30 and [the] dose dial sleeve 70." *Id.*, 4:12-14, 4:16. The clicker 50 is positioned adjacent to the button-end side of the drive sleeve's second flange 34. *Id.*, 4:15-16, FIGS. 1, 6-7.

62. At its needle-end, the clicker 50 includes a flexible, helically-extending arm 52 that has a radially directed toothed member 54 at a free end of the arm. *Id.*, 4:16-19, FIGS. 6-7. At its button-end, the clicker 50 includes a series of circumferentially-directed saw teeth 56, which selectively engage with corresponding saw teeth 66 of the clutch 60. *Id.*, 4:19-23, FIGS. 6-7.

63. Below-left is a partial view of FIG. 1 and below-right is FIG. 6, where I have annotated the clicker 50 purple:





64. In a not-shown embodiment, the clicker may include at least one spring member, which assists in resetting the clutch 60 after injection. *See id.*, 4:24-27.

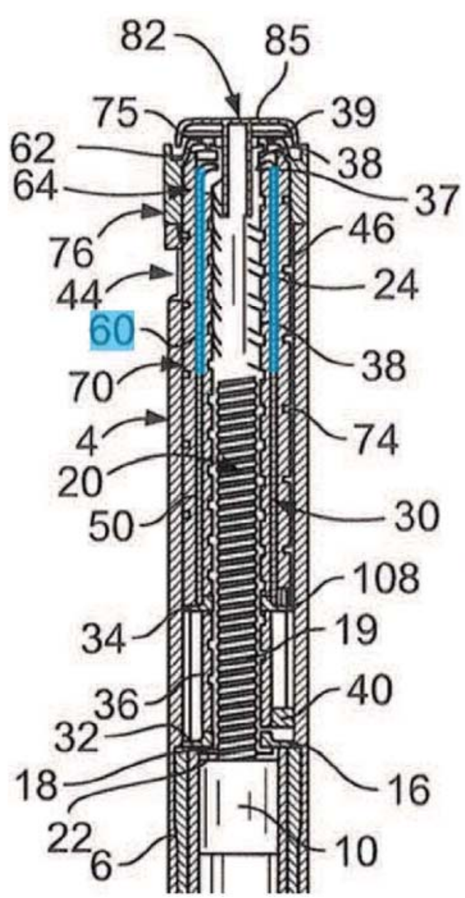
Clutch 60

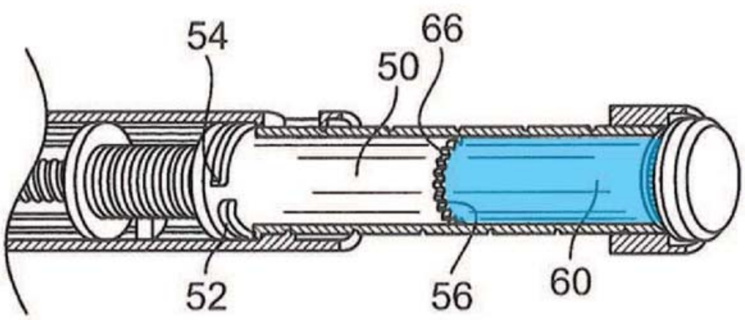
65. The clutch 60, which is "generally cylindrical," is located adjacent the button-end of the drive sleeve 30. *Id.*, 4:28-30. At its needle-end, the clutch 60 includes a series of circumferentially-directed saw teeth 66 that is adapted to engage with the saw teeth 56 of the clicker 50. *See id.*, 4:29-33, 6:14-16, FIGS. 67. At its button-end, the clutch 60 includes a plurality of dog teeth 65, which is adapted to

engage with the dose dial sleeve 30, which I explain more below. *See id.*, 4:37-39, FIG. 8.

66. Also at its button-end, the clutch 60 includes the radially, inwardly-directed flange 62 that is positioned between the shoulder 37 and flange 39 of the drive sleeve 30. *Id.*, 4:33-37; FIG. 1. The clutch 50 is further keyed to the drive sleeve 30 by not-shown splines, which prevent relative rotation between the clutch and the drive sleeve. *Id.*, 4:39-41.

67. Below-left is a partial view of FIG. 1 and below-right is FIG. 6, where I have annotated the clutch 60 blue:



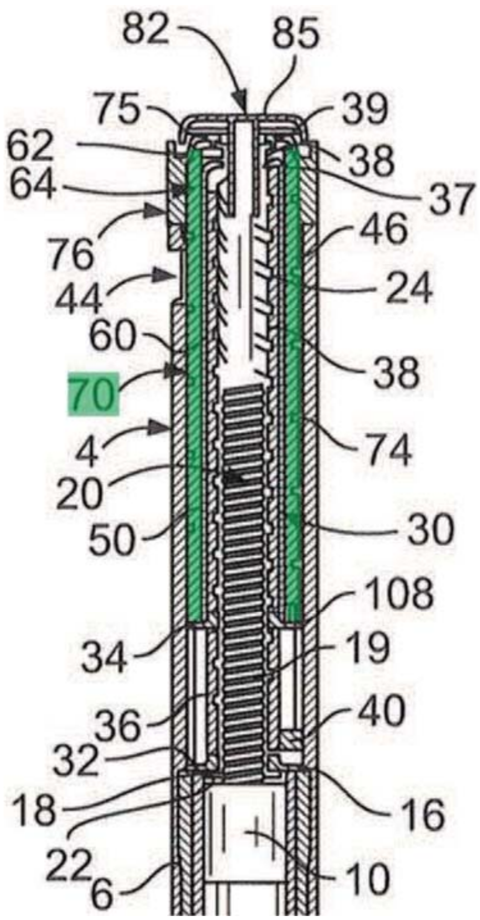


Dose dial sleeve 70

68. The dose dial sleeve 70 extends around the clicker 50 and the clutch 60, and is positioned within the main housing 4. *Id.*, 4:49-51, FIG. 1. The dose dial sleeve 70 includes a helical groove 74 that extends along its outer surface, which engages with the helical rib 46 provided on the main housing 4's inner surface. *Id.*, 4:51-52, 4:55-57, FIGS. 1, 12. The sleeve 70 may contain "a visual indication of the dose" currently dialed via reference numerals provided on the sleeve 70's outer surface, which can be viewed through the window 44 of the housing 4. *See id.*, 4:63-67.

69. At its button-end, the dose dial sleeve 70 includes "an inwardly directed flange in the form of [a] number of radially extending members 75." *Id.*, 5:1-3. Although the '069 patent does not explicitly explain the purpose of this structural element, it is my opinion that one of ordinary skill would have understood that the members 75 releasably engage with the dog teeth 65 of the clutch 60 during operation. *See id.*, 2:5-7, 6:7-9.

70. Below-left is a partial view of FIG. 1, and below-right is FIG. 12, where I have annotated the dose dial sleeve 70 green:



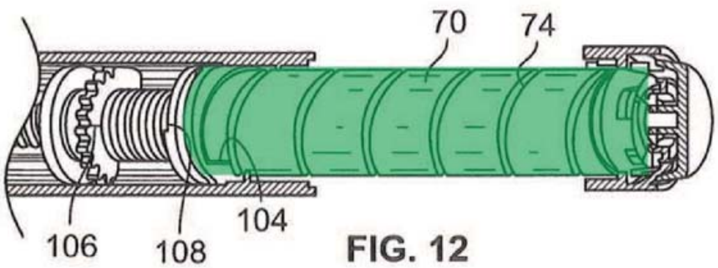


FIG. 12

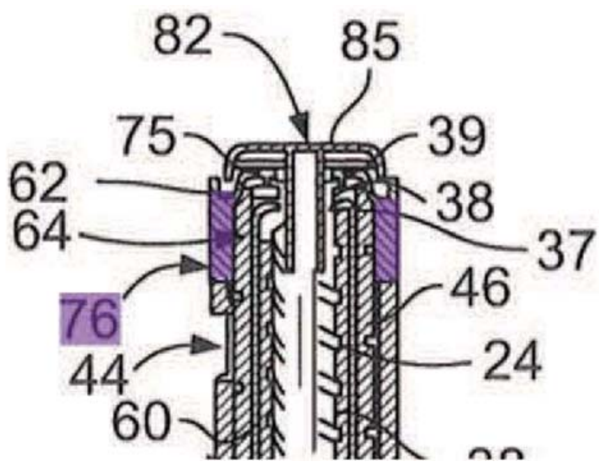
Dose dial grip 76

71. "A dose dial grip 76 is disposed about an outer surface of the [button-end] of the dose dial sleeve 70." *Id.*, 5:3-4. The grip 76 serves as an interface for the user to manipulate the dose dial sleeve 70 during the dose-setting process. *See id.*, 5:29-30.

72. In the embodiment shown, the outer diameter of the dose dial grip 76 corresponds to the main housing 4's outer diameter. *Id.*, 5:5-6, FIG. 1. "The dose dial grip 76 is secured to the dose dial sleeve 70 to prevent relative movement therebetween." *Id.*, 5:6-8. The grip 76 also includes a central opening 78 and an

annular recess 80 extending around the opening 78 at the grip's button-end. *See id.*, 5:8-11, FIG. 1. These features receive a button 82, described below. *See id.*, 5:8-11. At its needle-end, the dose dial grip 76 includes a plurality of members 110, which engage with the housing's plurality of stops 112 when the full dose has been dispensed. *See id.*, 6:26-34, FIGS. 14-15.

73. Below is a partial view of FIG. 1, toward the button-end of the housing 4, where I have annotated the dose dial grip 76 purple:

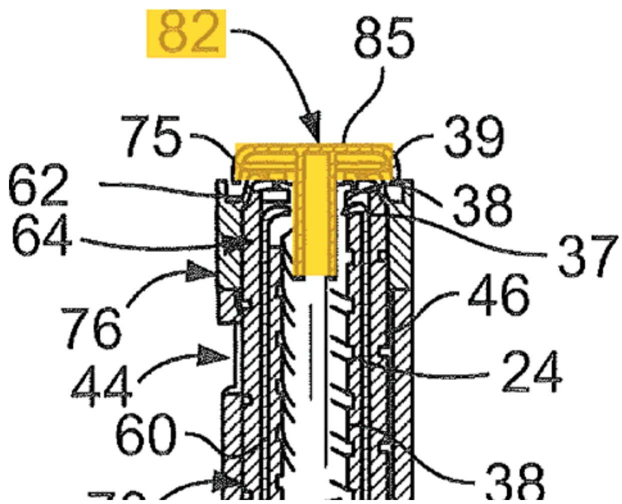


Button 82

74. The device also includes a button 82 "of generally `T' [cross-]section" that is provided at the device's button-end. *Id.*, 5:12-13. A stem 84 of the button 82 extends through the opening 78 of the dose dial grip 76 and through the inner diameter of the extension 38 of the drive sleeve 30. *Id.*, 5:13-14. The stem 84 is retained in the drive sleeve 30 in such a way that allows for limited axial movement of the button 82, but prevents rotational movement of the button 82 relative to the

drive sleeve 30. *See id.*, 5:14-18. A skirt 86 extends around a periphery of a head 85 of the button 82, and sits within the annular recess 80 of the dose dial grip 76. *Id.*, 5:19-22.

75. Below is a partial view of FIG. 1, toward the button-end of the housing 4, where I have annotated the button 82 in orange:



B. Overview of Injector's Operation

76. Operation of the device includes: (1) setting a desired dose; and (2) injecting the desired dose. During dose-setting, the user may "dial up" a dose (*i.e.*, increase the amount of medicine that will be dispensed) or "dial down" a dose (*i.e.*, decrease the amount of medicine that will be dispensed). Once the dose is set, the user applies an injecting force, directed toward the device's needle-end, to dispense the dialed-in amount of medicine.

77. For simplicity, in the figures that I have reproduced below, I have only annotated the six components that are claimed by claim 1 of the ’069 patent, claim 11 of the ’044 patent, and claim 1 of the ’486 patent.

Dose-setting: Dialing up a dose

78. To set a dose, the user grasps the dose dial grip 76 and rotates it in a given direction (*e.g.*, clockwise as viewed down from the button-end of the device, shown in FIG. 9, which is reproduced below). *See id.*, 5:29-30; FIG. 9. This action will rotate the dose dial sleeve 70, causing it to move along the housing’s helical rib 46 and axially out of the housing. *See id.*, 5:29-32, 5:40-44, FIG. 9. At this stage, the dog teeth 65 of the clutch 60 are engaged to members 75 of the dose dial sleeve 70. *See id.*, 2:5-7, 6:6-9, FIG. 9. This engagement causes the clutch 60 to rotate with and axially follow the dose dial sleeve 70. *See id.*

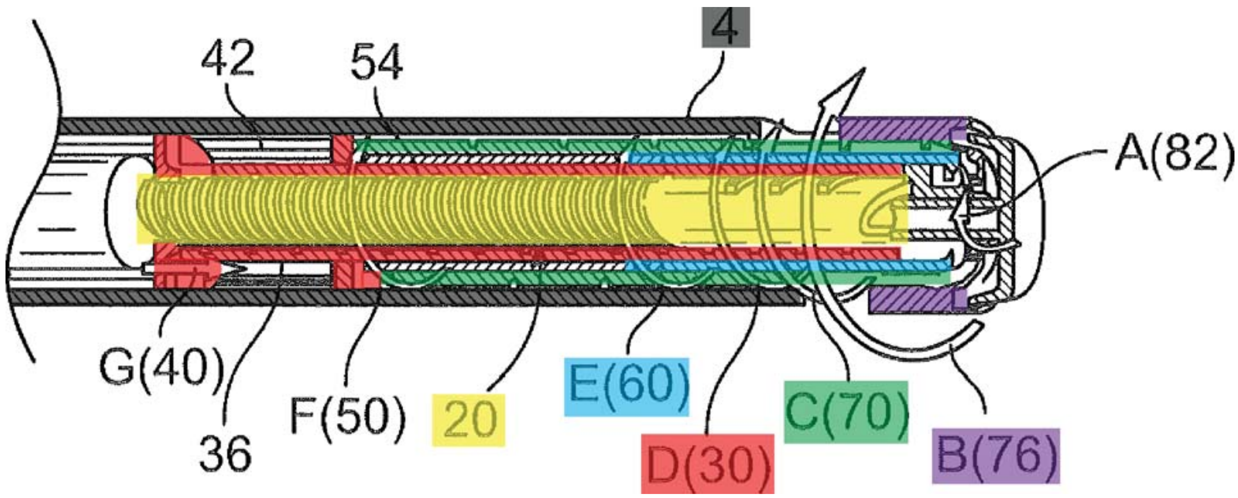
79. Because the clutch 60 is splined to the drive sleeve 30, the drive sleeve 30 (and the button 32, which is rotationally fixed to the drive sleeve) will follow the clutch 60’s rotation. *See id.*, 4:39-41, 5:29-32, 5:40-44, FIG. 9. The piston rod 20, however, will not because the first thread 19, which runs opposite to the second thread 24, prevents the rod 20 from following the drive sleeve’s rotation. *See id.*, 5:47-49, FIG. 9. As a result, the drive sleeve 30 climbs up the second thread 24 of the piston rod 20 toward the rod’s button-end. *See id.*, FIGS. 2, 4, 9. “The [outer] helical groove 74 on the dose dial sleeve 70 and the [inner] helical groove 38 in the

drive sleeve 30 have the same lead." *Id.*, 5:40-44. This causes the drive sleeve 30 to climb the piston rod 20 at the same rate the dose dial sleeve 70 extends from the housing 4. *Id.* When the limit of the dose dial sleeve's travel is reached (*i.e.*, the maximum dose able to be dispensed in one injection is reached), the radial stop 104 of the dose dial sleeve 70 abuts one of stops 100, 102 provided on the housing. *See id.*, 5:44-47. This prevents further rotation of the dose dial sleeve 70 out of the housing 4.

80. Meanwhile, the nut 40 follows the drive sleeve 30's axial movement, and advances along the intermediate thread 36 of the drive sleeve 30 toward the second flange 34 as the drive sleeve 30 rotates. *See id.*, 5:50-52, FIG. 9. When the final-dose position is reached (*i.e.*, no more fluid can be dispensed from the cartridge), the nut 40 reaches the second flange 34, and the nut's radial stop 106 abuts the second flange's radial stop 108, preventing the nut and the drive sleeve from further rotation during dialing up. *See id.*, 5:52-56, FIG. 13.

81. Also at this stage, the saw teeth 66 of the clutch 60 are engaged to the saw teeth 56 of the clicker 50. *See id.*, 5:30. This causes the clicker 50 to follow the clutch 60's rotation. *See id.*, 5:30-32, FIG. 9. While the clicker 50 rotates, the flexible arm 52 drags its toothed member 54 over the splines 42 of the housing 4, producing a click. *Id.*, 5:34-38. This provides "[a]udible and tactile feedback of the dose being

dialed." *Id.*, 5:33-34. "Preferably, the splines 42 are disposed such that each click corresponds to a unit dose." *Id.*, 5:38-39.



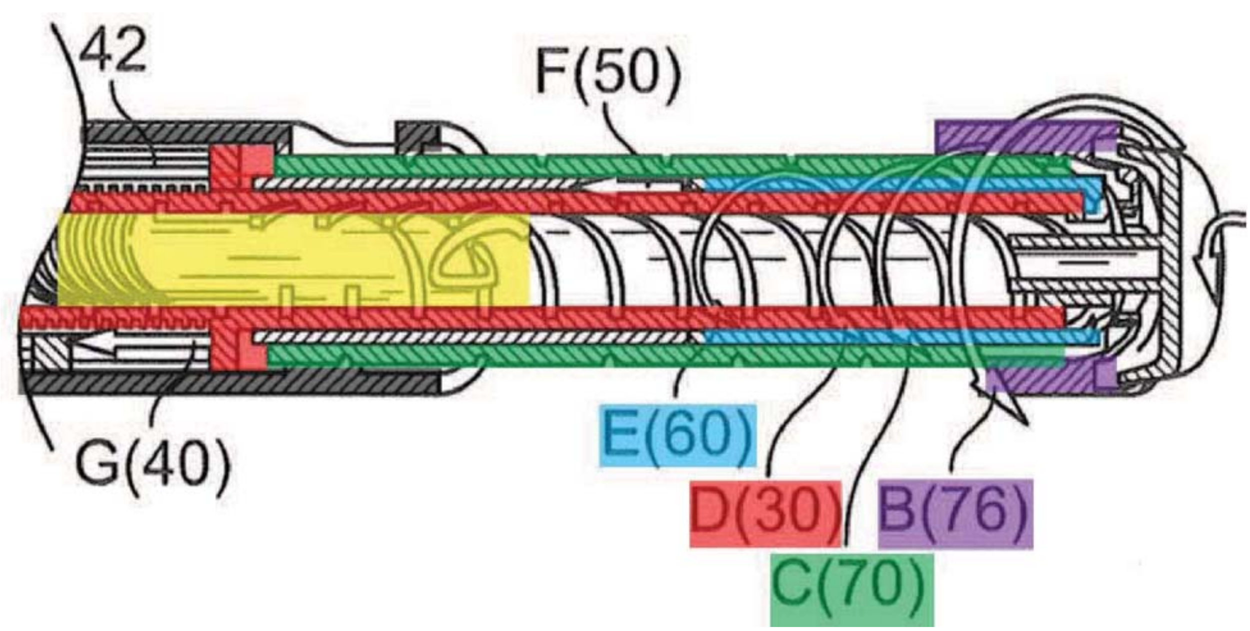
82. In sum, the following components rotate and move axially relative to the housing 4 when the user dials up a dose: (1) the dose dial grip 76; (2) the dose dial sleeve 70; (3) the drive sleeve 30; (4) the clutch 60; (5) the clicker 50; and (6) the button 82. *See id.*, 5:29-32, FIG. 9. The nut 40 moves axially, but does not rotate, relative to the housing 4. *See id.*, 5:50-52, FIG. 9. It also moves axially relative to the drive sleeve as it travels along the drive sleeve's intermediate thread. *See id.* The piston rod 20 does not rotate or move axially relative to the housing during dialing up. *See id.*, 5:47-49, FIG. 9.

Dose-setting: Dialing down a dose

83. If the user exceeds the desired dose, the user can counter-rotate the dose dial grip 76 to reduce the set amount, without dispensing medicine. *See id.*, 5:62-65, FIG. 10 (reproduced below). This causes the system to act in reverse: the dose

dial sleeve 70 rotates and moves axially back into the housing, which causes the clutch 60 to follow. *Id.*, 5:65-66, FIG. 10. The drive sleeve 30 and button 82 also follow, and the drive sleeve 30 rotates down the piston rod 20 toward its needle-end, while the nut 40 advances axially toward the drive sleeve's first flange 32. *See id.*, FIG. 10.

84. The clicker 50, however, advances axially, but does not rotate. *See id.*, 5:66-6:3, FIG. 10. The flexible arm 52 of the clicker 50 acts as a ratchet by engaging with the splines 42 of the housing 4 to prevent the clicker's counter-rotation. *See id.* Due to this resistance, the saw teeth 66 of the clutch 60 ride over the clicker 50's saw teeth 56, producing clicks corresponding to the reduction of dose. *See id.*, 5:67-6:3. "Preferably the saw teeth 56, 66 are so disposed that the circumferential extent of each saw tooth corresponds to a unit dose." *Id.*, 6:3-5.



85. In sum, the following components rotate and move axially relative to the housing 4 when the user dials down a dose: (1) the dose dial grip 76; (2) the dose dial sleeve 70; (3) the clutch 60; (4) the drive sleeve 30; and (5) the button 82. The clicker 50 does not rotate, but moves axially with those components. The nut 40 also moves axially toward the needle-end, and advances toward the first flange 32 of the drive sleeve 30. The piston rod 20 does not move during dialing down.

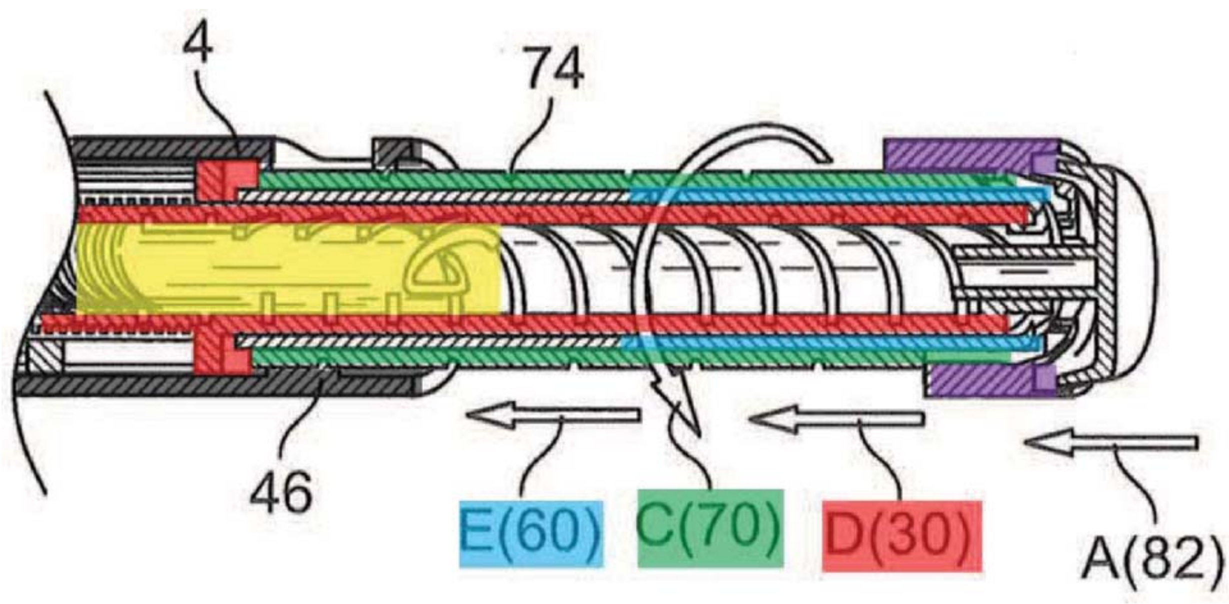
Injecting the dose

86. Once the desired dose has been set, the user depresses the button 82, which moves the drive sleeve 30 and the clutch 60 axially toward the device's needle-end. *See id.*, 6:6-22, FIG. 11 (reproduced below). The movement of the clutch 60 causes dog teeth 65 to disengage from the dose dial sleeve 70. *See id.*, 6:7-9. The dose dial sleeve 70 then counter-rotates back into the housing 4. *Id.*, 6:11-13, FIG. 11. The clutch 60, drive sleeve 30, and button 82 do not follow this rotation, instead only moving axially back into the housing. *See id.*, 6:9- 22, FIG. 11. The axial movement of the drive sleeve 30 toward the needle-end causes the first thread 19 of the piston rod 20 to rotate through the threaded opening 18 of the insert 16, and advance the piston 10 of the cartridge 8. *See id.*, 6:23-25, FIG. 11.

87. The drive sleeve 30 is prevented from rotating as it moves axially into the housing due to the clutch's engagement with the clicker. *See id.*, 6:14-18. Specifically, the clutch's axial movement causes the flexible arm 52 of the clicker

50 to deform. *See id.* This deformation exerts a biasing force to keep the clicker's saw teeth 56 engaged with the clutch's saw teeth 66. *See id.* As a result, counter-rotation of the drive sleeve 30 is prevented because the clicker's flexible arm 52 blocks the clicker from counter-rotating, which is transmitted to the drive sleeve through the clutch. *See id.* The piston rod 20 thus rotates relative to the drive sleeve 30, causing the second thread 24 to advance along the drive sleeve's helical groove 58 toward its button-end. *See id.*, 6:26-25. The nut 40 moves axially with the drive sleeve 30, and remains fixed relative to the drive sleeve 30.

88. Once the set dose has been dispensed, the dose dial sleeve 70 is prevented from further rotation when the plurality of members 110 of the dose dial grip 76 abuts the plurality of stops 112 formed on the main housing, indicating that the full dose has been dispensed and the injector has reached its zero-dose position. *See id.*, 6:26-34, FIGS. 14-16.



89. Therefore, during injection, the dose dial sleeve 70 and the piston rod 20 rotate and move axially relative to the housing toward the device's needle-end. The drive sleeve 30, clutch 60, clicker 50, nut 40, and button 82 do not rotate, but move axially relative to the housing toward the device's needle-end.

C. Overview of the Second and Third Embodiments of the '008 Patent

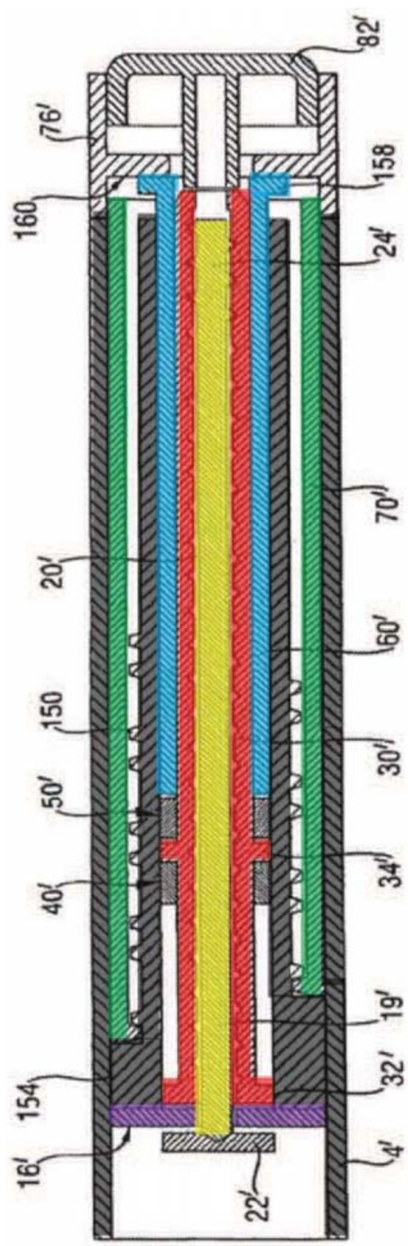
90. The first embodiment of the '008 patent and its accompanying description is identical to the embodiment described above for the challenged patents. While the other challenged patents only describe one embodiment, the '008 patent describes two additional embodiments. Below, I provide a brief overview of those additional embodiments, focusing on the key aspects of the embodiments that are different from the first.

Second embodiment: FIG. 17

91. The second embodiment described by the '008 patent is substantially identical to the first embodiment. *See* EX1005, 10:48-13:67, FIG. 17. The only difference is the addition of an inner housing 154, which is housed within the second main housing 4' and is secured both rotationally and axially to the housing 4'. EX1005, 10:65-11:7, FIG. 17. A helical thread 150 extends along the outer surface of the internal housing 154, which engages with a helical thread provided on an inner surface of a dose dial sleeve 70'. *See id.*, 11:4-5, 12:7-10, FIG. 17. Thus, rather than a helical groove provided on its outer surface, the dose dial sleeve in the second

embodiment includes an inner helical thread that engages with a helical thread providing on the outer surface of an internal housing 154 so that the dose dial sleeve may rotate out and back into the housing during use. *See id.*, 12:53-55, 13:39-41.

92. Below, I have reproduced FIG. 17, where I have annotated the six components claimed by the ’008 patent:



Third embodiment: FIGS. 18-24

93. The third embodiment described by the ’008 patent utilizes a rack-and-pinion mechanism to drive the piston rod. *See id.*, 14:1-17:26, FIGS. 18-24. Specifically, a rack 6” is located within a drive sleeve 18” and is fixed both axially and rotationally with respect to a housing 2”. *Id.*, 14:31-33. The drive sleeve 18” includes an internally threaded portion 20”, which extends along the length of the drive sleeve 18”. *See id.*, 14:34-36, 14:64-15:16. An internal toothed gear 22” is provided having helical teeth that match the pitch of the threaded portion 20”. *See id.*, 14:36-39. The ’008 patent states that the threaded portion 20” is a multi-start thread such that its lead is equal to the lead of the dose dial sleeve’s helical groove. *Id.*, 14:39-42. A piston rod 32” extends along the length of the rack 6” and includes the toothed gear 22” at its button-end. *See id.*, 14:53-59, FIG. 18.

94. To set a dose, the dose dial sleeve 32” is rotated out of the housing with the drive sleeve 18”, which rotates over the toothed gear 22”. *See id.*, 16:1-18. To deliver the set dose, a user presses a button, which applies an axial force toward the device’s needle-end. *See id.*, 16:25-28. During injection, the drive sleeve 18” moves axially toward the device’s needle-end, but is prevented from rotating relative to the housing. *See id.*, 16:36-45. This causes the toothed gear 22” to rotate against the rack 6”. *Id.*, 16:44-45. “The toothed gear 22”, together with the piston rod 32” on which it is mounted, move along the rack 6” a distance corresponding to one half of the

distance by which the drive sleeve 18" moves axially, creating a 2:1 mechanical advantage." *Id.*, 16: Thus, rather than a dual-threaded piston rod that engages with an internally-threaded drive sleeve and insert, the third embodiment incorporates a rack-and-pinion mechanism to drive the piston rod in a similarly geared manner, which I describe more below. *See supra*, section VIII.P.1, VIII.R.1.

D. Relevant Timeframe of the Challenged Patents

95. I understand that the challenged patents claim the benefit of priority to the same foreign patent application, which was filed March 3, 2003. *See* EX1001-EX1005, EX1026. Below, I state the relevant timeframe to which my analysis will apply for each of the challenged patents.

96. I understand that the '069 patent claims the benefit of priority to a series of applications, with the earliest application filed March 3, 2003. Accordingly, I have been advised that the '069 patent is entitled to a priority date no earlier than March 3, 2003, and the relevant timeframe for my analysis with regard to the '069 patent is prior to March 3, 2003.

97. Similarly, I understand that the '044 patent claims the benefit of priority to a series of applications, with the earliest application filed March 3, 2003. Accordingly, I have been advised that the '044 patent is entitled to a priority date no earlier than March 3, 2003, and the relevant timeframe for my analysis with regard to the '044 patent is prior to March 3, 2003.

98. I also understand that the ’486 patent claims the benefit of priority to a series of applications, with the earliest application filed March 3, 2003. Accordingly, I have been advised that the ’486 patent is entitled to a priority date no earlier than March 3, 2003, and the relevant timeframe for my analysis with regard to the ’486 patent is prior to March 3, 2003.

99. I also understand that the ’844 patent claims the benefit of priority to a series of applications, with the earliest application filed March 3, 2003. Accordingly, I have been advised that the ’844 patent is entitled to a priority date no earlier than March 3, 2003, and a relevant timeframe for my analysis with regard to the ’844 patent is prior to March 3, 2003.

100. The ’844 patent issued from U.S. Patent Application No. 15/156,616 (“the ’616 application”), which was filed on May 17, 2016. *See* EX1009, pp.12-34. I have been advised that any claim of the ’844 patent is entitled to a priority date earlier than the filing date of the ’616 application only if earlier applications to which the ’844 patent claims priority contain a written description supporting the given claim. In order to provide written description support, I have been informed that a person of ordinary skill must recognize from the earlier application that the inventor invented what is claimed, and it must reasonably convey that the inventor had possession of the claimed subject matter. I have been asked to evaluate whether the applications to which the ’844 patent claims priority actually or inherently disclose

the elements of claims 21-30 of the ’844 patent to a person of ordinary skill in the art at the time the earlier applications were filed. As I describe below, it is my opinion that the earlier applications to which the ’844 patent claims priority lack written description support for “a piston rod comprising ... an internal ... fourth thread that is engaged with [a] third thread” of a “driving member,” as recited in independent claim 21 of the ’844 patent.

101. For instance, the first earlier application to which the ’616 application claims priority is U.S. Patent Application No. 14/946,203 (“the ’203 application,” EX1025). It is my opinion that each of claims 21-30 lacks written description support in the ’203 application for a “piston rod” comprising “an internal ... fourth thread that is engaged with [a] third thread” of a “driving member.” *See* EX1004, claim 21. The ’203 application does not describe a piston rod that includes an internal thread, nor does it describe the piston rod that engages with external threads of a driving member. Instead, it exclusively describes an injector device that has a piston rod having external threading adapted to engage internal threading of a drive sleeve and an insert, both of which are located between the piston rod and the housing. *See, e.g.,* EX1025, p.4 (¶7), p.7 (¶¶38-39), p.11 (¶65), pp.14-19 (FIGS. 1-7, 9-13) (first threaded portion of piston rod 20 rotates “through” threaded opening in the insert 16 during dose dispensing), p.4 (¶¶6-7) (drive sleeve located between dose dial sleeve and piston rod), pp.7-8 (¶¶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"), pp.14-16 (FIGS. 1-5), p.18 (FIGS. 9-11), p.7 (¶40), p.10 (¶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). The '203 application also does not describe, either generally or specifically, replacing the described external threads of the piston rod with internal threads for engaging the threading of a driving member.

102. This is all true for all of the earlier applications to which the '844 patent claims priority. *See, e.g.*, EX1026 (foreign priority patent application), pp.7-8 (1:30-2:9), p.11 (5:19-27), p.12 (6:7-14), p.15 (9:2-4), p.17 (11:9-11), p.18 (claim 2), pp.21-31 (FIGS. 1-7, 9-13). I note that the first disclosure of an internally-threaded piston rod in this chain of applications appeared in claim 21 of the '616 application on May 17, 2016. EX1009, p.25, claim 24. There is no description in any of the priority documents of the '844 patent for a piston rod with internal threading that engages with external threading of the driving member, whether express or inherent. For this reason, I have also analyzed claims 21-30 of the '844 patent using May 17, 2016 as a relevant timeframe for my analysis, in addition to analyzing the claims through the relevant timeframe of March 3, 2003.

103. Finally, I understand that the '008 patent claims the benefit of priority to a series of applications, with the earliest application filed March 3, 2003. I have

thus been advised that the ’008 patent is entitled to a priority date no earlier than March 3, 2003, and the relevant timeframe for my analysis with regard to the ’008 patent is prior to March 3, 2003.

V. OVERVIEW OF THE LEVEL OF SKILL

104. I have been advised that “a person of ordinary skill in the art” is a hypothetical person to whom one could assign a routine task with reasonable confidence that the task would be successfully carried out. I have been advised that the relevant timeframe is prior to the relevant priority date, which I understand is March 3, 2003 for the ’069 patent, the ’044 patent, the ’486 patent, and the ’008 patent. For the ’844 patent, as I noted above, my analysis applies both a relevant timeframe of prior to March 3, 2003, and a relevant timeframe of prior to May 17, 2016.

105. The relevant technology field for the challenged patents is delivery devices for administering medicine. By virtue of my education, experience, and training, I am familiar with the level of skill in the art during the relevant timeframe.

106. In my opinion, a person of ordinary skill in the relevant field prior to March 3, 2003, 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. That person would also have approximately three years of practical experience with medical device design and manufacturing or at least an

understanding of the basics of medical device design and manufacturing, and the mechanical principles involved using elements (e.g., gears, pistons) commonly found in drug dispensing devices.

107. I understand that a person of ordinary skill in the art is presumed to be aware of the pertinent art. I discuss some of the most relevant art below.

VI. CLAIM CONSTRUCTION

108. I have been advised that, in the present proceeding, the claims of the challenged patents should generally be given their ordinary and customary meaning, which is the meaning that the claim would have had to a person of ordinary skill in the art at the time of the invention. Importantly, a person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification and its file history. I have followed these principles in my analysis throughout this declaration.

109. I also understand that the owner of the challenged patents has taken certain positions regarding the meaning of some of the claim terms in a related litigation. See EX1019. I have been advised that Sanofi has proposed the following constructions of certain claim terms that are relevant to:

1) **"drive sleeve"**: "An essentially tubular component of essentially circular cross-section releasably connected to the

dose dial sleeve that drives the piston during dose dispensing." *Id.*, pp.18-19.

2) **"driver" or "driving member"**: "A component releasably connected to the dose dial sleeve that drives the piston during dose dispensing." *Id.*, pp.24-27.

3) **"main housing"**: "An exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components." *Id.*, pp.20-21.

4) **"piston rod"**: "A rod that engages with the drive sleeve/driver/driving member to advance the piston during dose dispensing." *Id.*, pp.25-26.

5) **"the piston rod and the driving member are configured to rotate relative to one another during dose dispensing"**: "Plain and Ordinary Meaning. 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.*, p.25.

6) **"thread/threaded/threading"**: "A rib or groove on a first structure that engages a corresponding groove or rib on a second structure." *Id.*, pp.27-28.

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

8) **“clutch”**: “A structure that couples and decouples a moveable component from another component.” *Id.*, pp.22-23.

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

10) **“insert”**: “Plain and Ordinary Meaning .... The term `insert’ is a structure as defined in each of the claims in which it appears.” *Id.*, pp.29-30.

11) **“piston rod holder”**: “A structure 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.” *Id.*, pp.30-31.

110. I have been advised that Sanofi has represented in the district court proceedings that it considers the above constructions reasonable. I address some of these definitions in my analysis below. I reserve the right to provide my own analysis and constructions of the claim terms if required or requested.

111. I have also been advised that, in the related litigation, the patent challenger, Mylan, has taken the position that certain claim terms should be construed under a means-plus-function analysis. *See* EX1028. I understand that Mylan has taken the position that those claim terms, their functions, and corresponding structures include:

1) **<u>"tubular clutch" or "clutch"</u>**: The function of the "tubular clutch" or "clutch" is that during dose setting, it "clutch[es], i.e., coupl[es] and decoupl[es] a movable component from another component," or it "operates to reversibly lock two components in rotation." *See, e.g., id.*, pp.54-59. The corresponding structure for the clutch can be seen in FIGS. 1, 5-11, component 60 of the challenged patents. *See, e.g., id.*

2) **<u>"clicker"</u>**: The function of the clicker is that it "provid[es] at least an audible feedback to a user when said dose dial grip is rotated." *See, e.g., id.*, pp.65-68. The corresponding structure for the clicker can be seen in FIGS. 6-8, component 50 of the challenged patents. *See, e.g., id.*

3) **<u>"insert" or "holder"</u>**: The function of the "insert" or the "holder" 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." *See, e.g.*, *id.*, pp.114-116, 134-135. The corresponding structure for the insert or piston rod holder can be seen in FIGS. 1, 3-5, component 16 of the challenged patents. *See, e.g.*, *id.*

112. I address these constructions in certain parts of my analysis below.

VII. OVERVIEW OF THE SCOPE AND CONTENT OF THE ART

113. Below is a brief discussion of the knowledge of the field during the relevant timeframe and the main prior art references that I rely on for my opinion that the challenged claims are unpatentable.

A. Background of injector pen design

114. Prior to March 3, 2003, numerous pen-type injectors were known in the art, including many that used the same six-component structure reflected in the challenged claims. Such injectors typically included a pen-shaped housing containing concentrically-arranged cylindrical components that operate together to drive the axial movement of a threaded piston rod for dose dispensing. For instance, to facilitate dose-setting and injection, such pens typically included**:**

- an outer sleeve engaging a thread on the housing, which facilitates the setting of a particular dose by the user (i.e. a dose dial sleeve);
- an inner sleeve or nut that transfers axial or rotational movement of the dose dial sleeve to the piston rod (i.e. a drive sleeve); and

- a component that rotationally coupled/decoupled the dose dial sleeve and the drive sleeve during different stages of operation (i.e. a clutch).

See, e.g., EX1013-EX1017.

115. The specific structure of these components varied from pen to pen, but their general structure and operation typically adhered to the norms described below. Those skilled in the art were familiar with how such components, even with their slight variations in form, could be combined with the other standard components to produce a functional injector pen. Indeed, these components were sufficiently familiar that inventors of pen-type injector patents often trusted the person of ordinary skill to understand the disclosed embodiments without depicting or describing these features in great detail. *See* EX1017, 4:16-58, FIG. 3 (omitting description and illustration of components such as the housing, piston rod, injection button, and drug cartridge); EX1001, 4:24-27 (alternative embodiment of clicker and clutch not shown), 4:33-41, 6:4-13 (dose dial sleeve's engagement with dog teeth 65 of the clutch 60 not shown or described).

Dose dial sleeves

116. Dose dial sleeves typically had a threaded engagement with the housing to enable smooth, precise control for setting a dose. *See, e.g.*, EX1020, 12:66-13:3, FIG. 2; EX1014, 2:7-13, 2:54-62. Many included high-pitch threading that would translate axial force applied to an injector button into rotation that could then be

transmitted to other components. *See, e.g.,* EX1032, 1:17-54 (describing state of the art), 2:16-57; EX1014 (describing several embodiments where rotation of dial sleeve causes rotation of drive sleeve during injection). These components would typically rotate out of the pen's housing during dose setting and rotate back into the pen's housing during injection**.**

Drive sleeves

117. Threaded drive sleeves typically drove the piston rod in one of two ways. First, the drive sleeve could ride up the piston rod away from a stop, moving a distance corresponding to the dose set by the user, then move axially back down to the stop to dispense the set dose. *See, e.g.,* EX1017, 1:13-48 (describing state of the art). In such embodiments, the drive sleeve could: (1) push the piston rod with it during injection without relative rotation between the components (*see, e.g.*, EX1013, 10:1552, 11:13-51; EX1021, 4:34-44), or (2) cause rotation of the piston rod through a not-self-locking threaded engagement (*i.e.*, a threaded arrangement that allows for rotation between components when an axial load is applied), with such rotation urging the piston rod forward due to a second threaded engagement between it and another component (*see, e.g.,* EX1014, 7:48-8:43, FIGS. 6-10)**.**

118. Second, the drive sleeve could remain stationary during dose setting and then rotate in place during injection. *See, e.g., id.*, 11:6-12:13, FIGS. 15-17. In such embodiments, the drive sleeve may be a nut that rotates relative to a threaded

piston rod during injection, with the piston rod being rotationally fixed relative to the housing so that rotation of the nut moves the piston rod forward. *See, e.g.,* EX1032, 5:54-6:1. The drive sleeve also may be rotationally fixed with the piston rod, but allow axial movement of the piston rod, such that rotation of the drive sleeve is transmitted to the piston rod, which then moves forward due its engagement with a threaded opening provided in another component. *See, e.g.,* EX1014, 11:11-19, FIGS. 15-17; *see also* EX1017, 1:25-2:5 (contrasting a carrier-type driver and an axially fixed rotating-nut driver)**.**

Clutches

119. Injector pens commonly included a clutching mechanism to rotationally couple and decouple the dose dial sleeve and the drive sleeve. This allowed the rotation of the dose dial sleeve to be transmitted to the drive sleeve during one phase of operation (*i.e.* injection) but not the other (i.e. dose setting), which facilitated movement of the drive sleeve as I described above. This clutching function was accomplished by several types of structures. For example, clutches were often implemented by releasably engaged teeth or other protrusions on adjacent components. *See, e.g.*, EX1015, ¶¶29, 33. Such clutches could be engaged by default due to a biasing element urging the teeth into engagement, such that the components remain coupled until force applied to the pen's injection button overcomes the biasing force and disengages the teeth. *See, e.g.,* EX1015, ¶33. Alternatively, the

clutch could be disengaged by default until pressed into engagement by force applied to the injection button. *See, e.g.,* EX1017, 4:33-52; EX1014, 11:40-12:13**.**

Concentric arrangement of components

120. Injector pens often implemented the above components as concentrically arranged, telescoping cylinders, with standard mechanical engagements provided between these components to allow or prevent relative rotation and/or axial movement. For example, dose dial sleeves typically rotated up during dose setting due to a threaded engagement with the housing, while one or more internal components remained axially fixed. *See, e.g.,* EX1014, 7:48-8:33 (injection button 23 telescopically rotates up out of housing while riding up piston rod 6), 11:40-12:13 (scale drum 80 telescopically rotates up, with bushing 82 matching its axial but not rotational movement, as driver tube 85 remains axially and rotationally fixed); EX1015, 4:51-5:64 (dose-setting drum 17, cup shaped element, connection bars 12, and nut 13 rotate up together, riding up central piston rod). Providing threading, splines, clutches, or other features on these types of concentric components to achieve the desired relative movements during dose setting and injection was routine, predictable, and well within the abilities of a person of ordinary skill**.**

Gearing

121. Those skilled in the art recognized the advantages of using various types of gearing to provide a mechanical advantage during injection. For example, Klitgaard explained:

> To obtain a larger movement of the injection button a sort of gearing may be used so that the distance the injection button has to be moved is proportional with the injected dose but is a number of times the movement of the piston in the cartridge.

EX1017, 1:44-52**.**

122. Those skilled in the art understood that this mechanical advantage derived from basic principles of energy conservation: assuming negligible energy losses, where one component moves a first distance to drive another component a second distance, the mechanical advantage is proportional to the ratio of the first and second distances. *See* EX1033. Those skilled in the art also recognized that this mechanical advantage could be provided in different ways such as, for example, differential threading or rack-and-pinion systems. *See* EX1015, ¶¶3-9 (discussing both). Indeed, these types of mechanisms were well understood and widely used in a variety of settings. *See, e.g.,* EX1031 (showing various examples of differential threading).

Clickers

123. Those skilled in the art were also familiar with different ways to provide audible feedback, in the form of "click" sounds, to the user as a dose is set. For example, injector pens commonly used flexible arms dragging over splines or other recesses/protrusions (*see, e.g.,* EX1013, 9:4-8, 10:42-47; EX1014, 11:34-67) or teeth riding over one another (*see, e.g.,* EX1032, 3:10-26; EX1015, ¶¶27, 40). Such implementations were largely interchangeable since they share the same basic requirement—two components rotating relative to one another during dose setting—and the configurations of the components discussed above provide this very type of movement.

124. As explained below in section VIII, it is my opinion that the challenged claims simply recite familiar features of these standard pen components. Even where a single prior art reference does not disclose each recited feature in a single embodiment, such claims nevertheless recite a mixture of well-known features whose operation within injector pens was predictable and well understood. Nothing about the individual limitations or their ordered combination in the claims as a whole would have been unfamiliar or unexpected to a person of ordinary skill. Indeed, implementing functioning injector pens by arranging common, well-understood components to perform their regular functions—which is all that the challenged claims do—was merely part of the day-to-day activities of those skilled in the art.

B. Burroughs

125. U.S. Patent No. 6,221,046 ("Burroughs," EX1013) was published on April 24, 2001. I have been advised that Burroughs is prior art to the challenged patents under § 102(b) because Burroughs published over a year prior to March 3, 2003.

126. Burroughs discloses a medication-dispensing pen for dispensing selectively measured dosages of medicine. *Id.*, 1:13-16. Burroughs describes a pen that includes the six components claimed by claim 1 of the '069 patent, claim 11 of the '044 patent, claim 1 of the '486 patent. As shown in FIGS. 1 and 2 (which I have reproduced and annotated below), these components include:

> (1) a "housing 22," having a "first part 24 and a "second part 26" (gray), which houses the drive mechanism for dispensing medicine from a cartridge, *see id.*, 7:15-20;
>
> (2) a "dial mechanism 34" (green), which the user manipulates to set a specific dose for injection, *see id.*, 10:38-42;

(3) a “proximal portion 78” (purple),[12] located on the button-end of the dial mechanism 34, which serves as a knob or grip for the user to manipulate the dial mechanism, *see id.*, 8:2-8;

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

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

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[12] For consistency, I annotate the proximal portion 78 of the dial mechanism 34 in purple, which, as I explain more below, corresponds to the claimed “dose dial grip” (or “dose knob”) given its relative positioning and overall function to the user. *See infra*, section VIII.A.1. I note, however, that the proximal portion 78 is an integral part of the dial mechanism 34. *See* EX1013, 8:2-8, FIGS. 6-9. Nevertheless, to visually indicate the general location of the proximal portion 78, I annotate that part in purple, with the understanding that the proximal portion 78 is part of the dial mechanism 34, which is labeled in green. I note that an integrally- formed dose dial grip, like that disclosed in Burroughs, is structurally and functionally identical to the dose dial grip disclosed in the challenged patents (*i.e.*, rotationally and axially fixed to the dose dial sleeve), and thus consistent with the specification. *See, e.g.*, EX1001, 5:3-8.

(6) a "button 32" (blue), which acts as a clutch mechanism to rotationally decouple the dial mechanism from the housing and the nut during injection, *see id.*, 11:13-34.

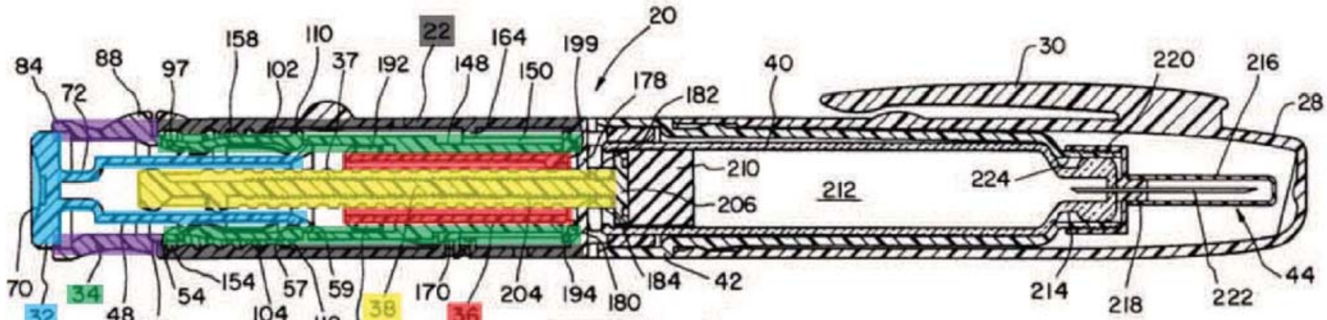

FiG. 1

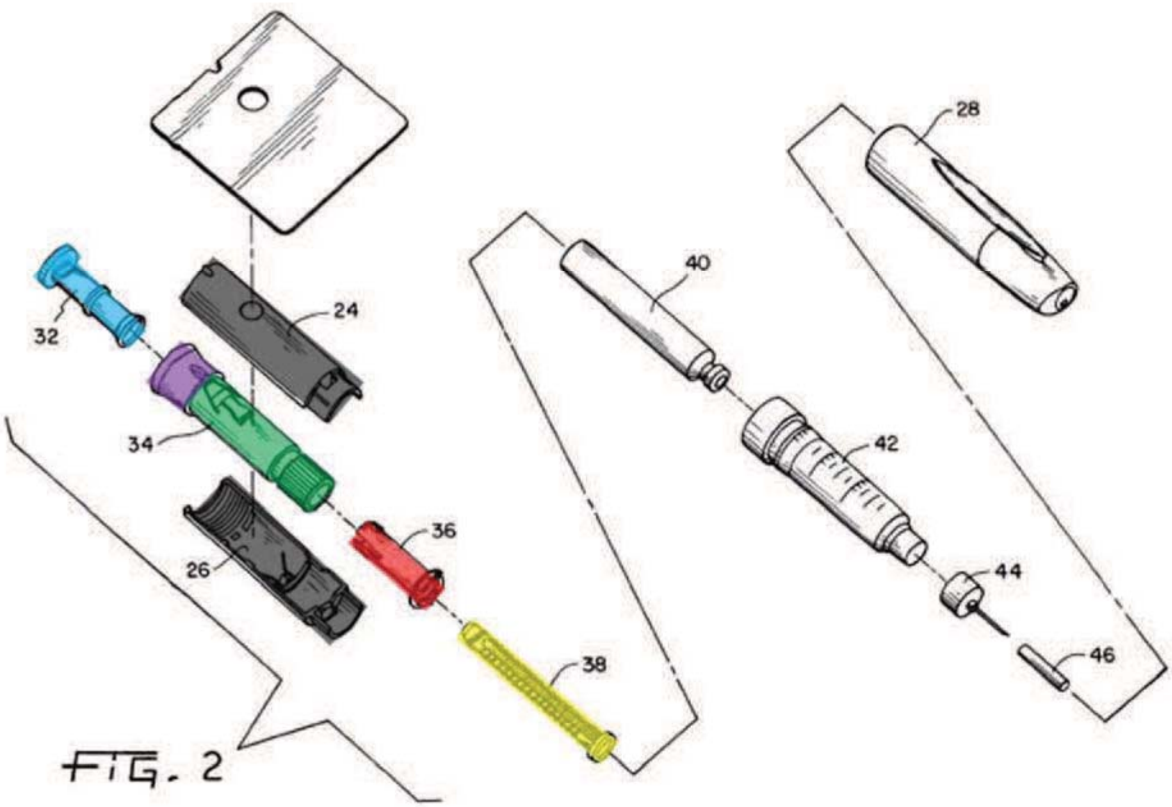

FiG. 2

127. As I explain in more detail below, in Burroughs' device, the user grasps the proximal portion 78 to rotate and axially move the dial mechanism 34 relative to

the housing 22 to set a dose. *See id.*, 8:2-8, 10:34-38, FIGS. 1, 6-9. The dial 34's rotation is transmitted to the nut 36, which rotates relative to and advances up the leadscrew 38. *See id.*, 10:38-42, FIGS. 1, 10-11. The leadscrew 38 does not follow the nut 36's rotation due to anti-backup tangs provided on the housing 22, which prevent the leadscrew 38's rotation toward the button-end of the device. *See id.*, 10:26-31. When ready to inject, the user depresses the button 32, which engages inner ramps of the dial 34, causing legs on the dial 34's outer surface to collapse inward into the dial 34. *See id.*, 8:11-20, 11:5-20, FIGS. 9, 14-15. With the inward motion of the legs of the dial 34, the dial 34 disengages from its threaded engagement with the housing 22, and moves axially relative to the housing 22 toward the device's needle-end without rotating. *See id.* The dial 34's axial movement also rotationally disengages it from the nut 36. *See id.*, 8:42-48, 9:16-18, 11:27-30, FIGS. 9-11. The axial movement of the dial 34 is transmitted to the nut 36, then to the leadscrew 38, which advances toward the needle-end of the device to dispense medicine. *See id.*, 11:27-30.

128. As I also detail below, it is my opinion that Burroughs describes each of the six components claimed by claim 1 of the '069 patent, claim 11 of the '044 patent, and claim 1 of the '486 patent, except that its "dose dial sleeve" (dial mechanism 34) includes a helical rib, rather than a helical groove. *See infra*, section VIII.A. But, it is my opinion that modifying Burroughs' dial mechanism 34 to

include a helical groove would have been considered obvious to a person of ordinary skill at the relevant time. *See infra*, section VIII.A.1. In addition, with regard to claim 11 of the '044 patent, Burroughs does not explicitly disclose that the "lead" of the "helical groove" of the "dose dial sleeve" is different than the "lead" of the "internal threading" of the "drive sleeve." Nevertheless, as described in greater detail below, to the same extent that is presumed by the '044 patent, it is my opinion that modifying Burroughs' device to include different leads would have also been readily apparent to, and within the skill and knowledge of, a person of ordinary skill at the relevant time. *See infra*, section VIII.A.1.

129. It is also my opinion that Burroughs discloses the "clutch" claimed by independent claim 51 of the '486 patent, and thus anticipates claim 51. *See infra*, section VIII.D.1.

C. Steenfeldt-Jensen

130. U.S. Patent No. 6,235,004 ("Steenfeldt-Jensen," EX1014) was published on May 22, 2001. I have been advised that Steenfeldt-Jensen is prior art to the challenged patents under 35 U.S.C. § 102(b) because Steenfeldt-Jensen published over a year prior to March 3, 2003.

131. Steenfeldt-Jensen describes injection syringes (pens) for dispensing medicine. *See* EX1014, Abstract. As shown in FIGS. 16 (left) and 17 (right), which I have reproduced and annotated below, Steenfeldt-Jensen describes an embodiment

of a syringe (*i.e.*, pen injector) that includes a six-component structure claimed by claim 1 of the ’069 patent, claim 11 of the ’044 patent, claim 1 of the ’486 patent:[13]

(1) a “tubular housing 1” (gray), which houses the drive mechanism for dispensing medicine from an ampoule, *see id.*, 5:38-54;

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

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[13] My analysis for the ’069 patent, the ’044 patent, and the ’486 patent focuses on the embodiment shown in FIGS. 15-17 of Steenfeldt-Jensen and its accompanying disclosure. I note, however, that Steenfeldt-Jensen explains that structural elements corresponding to structural elements described in other embodiments are provided with the same reference number. *See id.*, 7:49-51. Thus, with regard to Steenfeldt-Jensen’s description concerning its other embodiments, it is my opinion that a person of ordinary skill would have understood the description to inform the structure of the embodiment shown in FIGS. 15-17 at least for elements having identical reference numbers.

(3) a "dose setting button 81" (purple),[14] located on the button-end of the scale drum 80, which serves as a knob or grip for the user to manipulate the scale drum, *see id.*, 11:51-55;

(4) a "piston rod 6" (yellow), which is driven to move a piston provided within the ampoule to dispense medicine, *see id.*, 5:57-65;

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

(6) a "bushing 82" (blue), which releasably connects the scale drum and the driver tube for rotational movement during injection, *see id.*, EX, 12:4-13.

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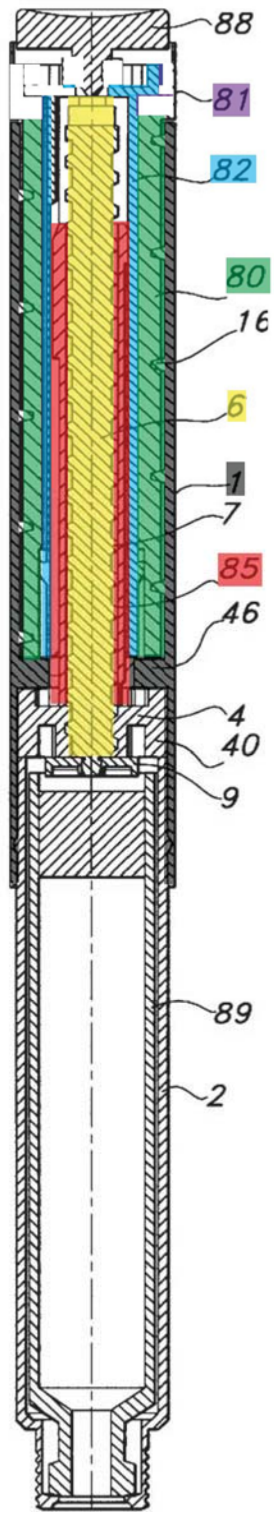
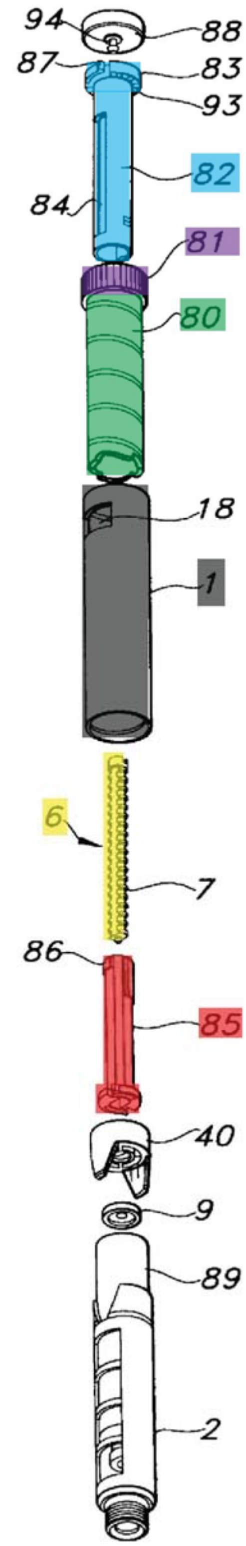
[14] Like Burroughs, Steenfeldt-Jensen discloses that the dose setting button 81 is an integral part of the scale drum 80. *See id.*, 11:20-25, FIGS. 15-17. But, for consistency and to visually indicate the portion of Steenfeldt-Jensen's device that corresponds to the claimed "dose dial grip" (or "dose knob"), I have annotated the dose setting button 81 in purple.





132. As I explain more below, in Steenfeldt-Jensen's device, the user grasps the dose setting button 81 to rotate and axially move the scale drum 80 relative to

the housing 1. *See id.*, 11:52-55. The bushing 82 moves axially with the scale drum 80 toward the device's button-end, but it does not rotate because it is prevented from doing so via a pawl mechanism acting between the piston rod drive's driver tube 85 and member 40. *See id.*, 11:55-62. Because the driver tube 85 is prevented from rotating, the piston rod 6 also does not rotate. *See id.*, 11:1519, 11:55-63. To inject, the user depresses a button to axially move the bushing 82 such that it engages with the dose setting button 81 so that the bushing 82 follows the scale drum 80's rotation back into the housing 1. *See id.*, 12:4-10. The bushing 82's rotation is transmitted to the driver tube 85, which the pawl mechanism reluctantly allows. *See id.*, 12:10-13. The piston rod 6, in turn, rotates, advancing through a member 40 to dispense medicine. *See id.*

133. As I explain further below, it is my opinion that the embodiment described in Steenfeldt-Jensen includes the same components having the same structural elements as those recited in claim 1 of the '069 patent, claim 11 of the '044 patent, and claim 1 of the '486 patent, except that its "drive sleeve," driver tube 85, does not contain an internal threading near a distal portion that engages with an external threading on the piston rod. *See infra*, section VIII.B. However, as I also explain below, it is my opinion that a person of ordinary skill would have found it apparent to provide an internal threading on the driver tube 85 that would drive the

piston rod 6 toward the device's needle-end during injection in view of Steenfeldt-Jensen's teachings.

134. Moreover, it is my opinion that Steenfeldt-Jensen discloses a "clutch" as claimed by claim 51 of the '486 patent, and thus anticipates that claim. *See infra*, section VIII.F.

135. In another embodiment, Steenfeldt-Jensen describes a syringe (*i.e.*, pen injector) that includes four components that are particularly relevant to the challenged claims of the '008 patent and the '844 patent. As shown in FIGS. 7 (left) and 8 (right), which I have reproduced and annotated below (FIG. 8 annotates only three of the components), these components include:[15]

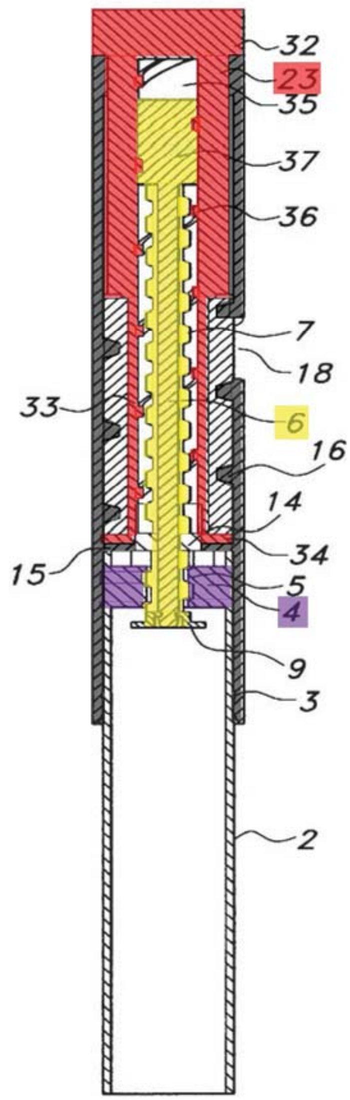
(1) a "housing 1" (annotated in gray below), which houses the drive mechanism for dispensing medicine from a cartridge, *see, e.g.*, EX1014, 5:38-44;

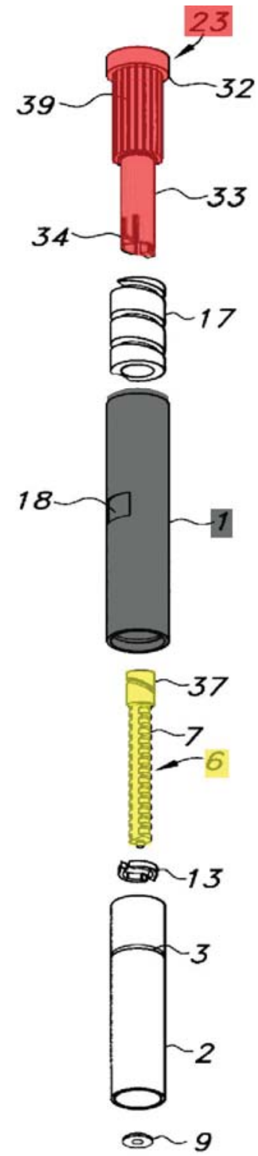
[15] My analysis for the '844 patent and the '008 patent focuses on the embodiment shown in FIGS. 6-10 of Steenfeldt-Jensen and its accompanying disclosure. Again, I note that Steenfeldt-Jensen explains that analogous structural elements described in other embodiments are provided with the same reference number. *See id.*, 7:49-51. Thus, I may cite to other embodiments with those elements.

(3) an "end wall 4" (purple), which engages and holds a piston rod as the piston rod is driven by the drive sleeve, *see, e.g.*, *id.*, 6:30-47;

(4) an "injection button 23" (red), which drives a piston rod to move the piston, *see, e.g.*, *id.*, 6:22-34, 7:48-8:24; and

(5) a "piston rod 6" (yellow), which is driven by the injection button to move the piston within the cartridge to dispense medicine, *see, e.g.*, *id.*, 7:60-8:12.





136. As I explain more below, in this embodiment, the user grasps and rotates injection button 23 to set a dose. *Id.*, 8:1-15. This screws injection button 23 out of the housing as it moves up a helical groove on the piston rod 6 that extends in one direction. *Id*. This movement of the injection button 23 "will draw [a] dose scale drum 17 with it." *Id.* To inject a dose, the user presses injection button 23, which then moves the button 23 downward without rotating relative to the housing. *See id.*,

8:16-33. The axial movement of the injection button 23 rotates piston rod 6 due to its threaded engagement between the button's internal helical rib 36 and the helical groove on the button-end of the piston rod 6. *Id*. 7:60-67, 8:25-33. This causes piston rod 6 to rotate through a threaded central bore of the end wall 4, which includes a thread that runs opposite to the helical groove of the piston rod 6. *See id.*, 8:35-33, FIGS. 7-8. As I explain more below, given this opposite threading on the piston rod 6, the axial distance traveled by injection button 23 during injection will be greater than the axial distance traveled by piston rod 6, which provides a mechanical advantage. *See infra*, section VIII.P.1, section VIII.R.1.

137. As I further explain below, Steenfeldt-Jensen discloses the use of a piston rod having two threads, one that engages an "insert" or "holder" and another that engages a "drive sleeve" or "driving member," as is claimed by claim 1 of the '008 patent and claim 21 of the '844 patent, respectively. *See infra*, section VIII.P.1, section VIII.R.1. And, as I also explain more below, it is my opinion that a person of ordinary skill would have considered it readily apparent to modify the device of Møller (described below) to include a dual-threaded piston rod as taught by Steenfeldt-Jensen.

D. Møller

138. U.S. Patent Application Publication No. 2002/0052578 ("Møller," EX1015) was published on March 2, 2002, and filed on June 14, 2001. I have been

advised that, because Møller was published before March 3, 2003, Møller is prior art to the challenged patents under § 102(a). In addition, I have been advised that, because Møller was filed prior to March 3, 2003, Møller is prior art to the challenged patents under § 102(e).

139. Like Burroughs and Steenfeldt-Jensen, Møller describes an injection device for injecting set doses of medicine that includes a six-component structure like that claimed by claim 1 of the ’069 patent, claim 11 of the ’044 patent, and claim 1 of the ’486 patent. *See, e.g.*, EX1015, Abstract, ¶1. As shown in FIG. 1 (reproduced and color-coded below), Møller describes an injection device that includes:[16]

[16] Møller describes a second embodiment, where "[f]or manufacturing reasons minor changes are made." *Id.*, ¶36. Møller thus states that "elements corresponding to elements in FIG. 1 and 2 are given the same references as these elements with a prefixed '1'." *Id.*, ¶35. Given this description, it is my opinion that a person of ordinary skill would have understood that elements of the first embodiment are structurally and functionally equivalent to the elements of the second embodiment to which they correspond. As such, while I focus my analysis on the embodiment shown in FIGS. 1-2, I will occasionally refer to corresponding elements of the second embodiment shown in FIGS. 3-5 to better inform the structure of the embodiment shown in FIGS. 1-2.

(1) a “housing 1” (gray), which houses the drive mechanism for dispensing medicine from a cartridge, *see id.*, Abstract, ¶22;

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

(3) a “dose setting button 18” (purple),[17] located on the button-end of the dose setting drum 17, which serves as a knob or grip for the user to manipulate the dose setting drum 17, *see id.*, ¶29;

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

(5) “connection bars 12” having a “nut 13” (red) with a flange at the distal end, which drives the piston rod 4, *see id.*, ¶¶24, 32;

(6) a “cup shaped element” having a bottom 19 and a tubular part 20 (blue), which forms an injection button that rotationally decouples the dose

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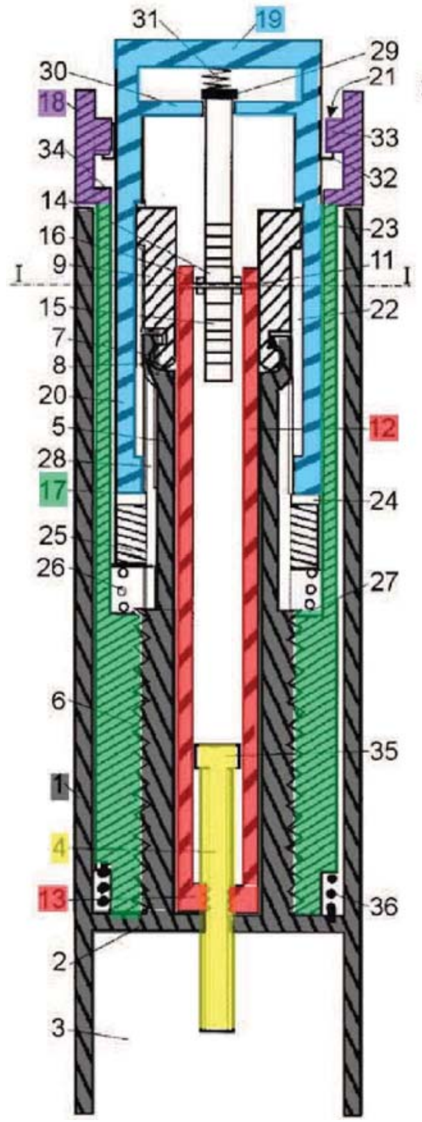
[17] Like Burroughs and Steenfeldt-Jensen, Møller discloses that the dose setting button 18 is an integral part of the dose setting drum 17. *See id.*, ¶25, FIG. 1. But, for consistency and to visually indicate the portion of Møller’s device that corresponds to the claimed “dose dial grip” (or “dose knob”), I have annotated the dose setting button 18 in purple.

setting drum 17 from the connection bars 12 with nut 13 during injection, *see id.*, ¶¶26, 29, 33.



140. In the same embodiment, Møller also describes an injection device having a six-component structure like that claimed by claim 1 of the ’008 patent and claim 21 of the ’844 patent. As shown in FIG. 1 (reproduced and annotated below), Møller describes an injection device that includes:

(1) a “housing 1” (gray), which houses the drive mechanism for dispensing medicine from a cartridge, *see id.*, Abstract, ¶22;

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

(3) a “partitioning wall 2” (purple), which engages and holds a piston rod as the piston rod is driven by the drive sleeve, *see, e.g.*, *id.*, ¶22;[18]

(4) “connection bars 12” having a “nut 13” (red), which drives the piston rod, *see id.*, ¶¶24, 32;

(5) a “piston rod 4” (yellow), which is driven to dispense medicine from the cartridge, *see id.*, ¶22; and

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[18] For consistency, I annotate the partitioning wall 2 in purple, which, as I explain more below, corresponds to the claimed “insert” or “holder” given its relative positioning and overall function to the piston rod. *See infra*, section VIII.P.1, VIII.R.1. The partitioning wall 2 is an integral part of the housing 1. *See* EX1015, ¶22, FIG. 1. To visually indicate the general location of the partitioning wall 2, I annotate that part in purple, with the understanding that it is part of the housing 1, which is labeled in gray. I note that an integrally-formed insert, like that disclosed in Møller, is expressly contemplated by the ’008 patent, and thus consistent with its specification. *See, e.g.*, EX1005, 7:37-39.

(6) a "cup shaped element" having a bottom 19 and a tubular part 20 (blue), which forms an injection button that rotationally decouples the dose setting drum 17 from the connection bars 12 with nut 13 during injection, *see id.*, ¶¶26, 29, 33.

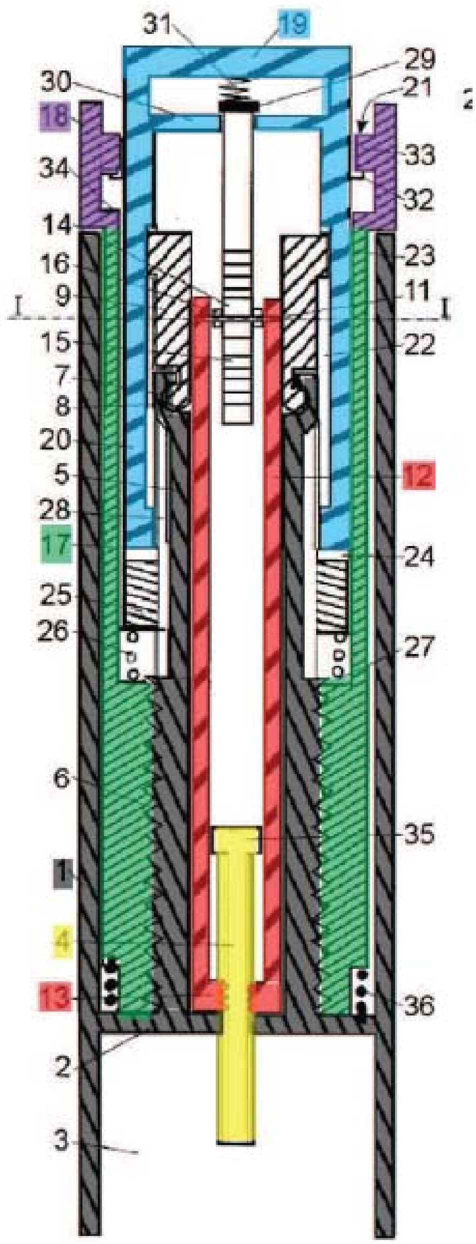

Fig. 1

141. As I detail more below, in Møller's device, the user grasps the dose setting button 18 to rotate and move axially the dose setting drum 17 relative to the housing 1. *See id.*, ¶29. Because the cup shaped element is engaged to the dose setting button 18, the drum 17's rotation is transmitted to the connection bars 12 through the cup shaped element. *See id.* This results in the nut 13 advancing along the piston rod 4 toward the button-end of the device. *See id.*, ¶30. The piston rod 4 does not rotate because of its non-circular cross-section that engages a corresponding non-circular cross-section in the housing 1. *See id.*, ¶22. For injection, the user depresses the cup shaped element, which disengages it from the dose setting drum 17. *See id.*, ¶¶32-33. The dose setting drum 17 is allowed to rotate back in, but the cup shaped element and connection bars 12 do not follow the rotation. *See id.* The cup shaped element and connection bars 12 move axially toward the needle-end of the device, causing the piston rod 4 to advance axially to dispense medicine. *See id.*, ¶32.

142. As I also detail more below, it is my opinion that Møller describes each of the components recited in claim 1 of the '069 patent and claim 11 of the '044 patent, except that its "dose dial sleeve" (dose setting drum 17) includes an inner helical thread to engage the housing, rather than an outer helical groove. *See infra*, section VIII.C.1. However, it is my opinion that providing an outer helical groove on the dose setting drum 17 to engage the housing 1 would have been obvious to a

person of ordinary skill based on the combination of Møller with Steenfeldt-Jensen. As I explain more below, because the threaded engagement would be retained between the same two components, a person of ordinary skill would have considered that providing a helical threading on the dose setting drum's outer diameter to be functionally equivalent to one provided on the dose setting drum's inner diameter. *See infra*, section VIII.C.1.

143. With regard to claim 1 of the '486 patent, it is my opinion that Møller describes each of the components recited in the claim, but to the extent that the helical threading of Møller's "dose dial sleeve" does not explicitly contain a "helical groove," providing such a groove would have been considered functionally equivalent to the helical threading disclosed by Møller in view of Steenfeldt-Jensen. *See infra*, section VIII.C.1. With regard to claim 51 of the '486 patent, as I explain below, it is my opinion that Møller describes the claimed "clutch." Accordingly, it is my opinion that Møller anticipates claim 51 of the '486 patent. *See infra*, section VIII.I.1.

144. Finally, with regard to claim 21 of the '844 patent and claim 1 of the '008 patent, Møller teaches the six-component structure claimed, except its "piston rod" does not contain two threads, for engaging an "insert" or "holder" and engaging a "drive sleeve" or "driving member." Nevertheless, as I explain more below, a person of ordinary skill would have considered it readily apparent to modify the

device of Møller to include a dual-threaded piston rod as taught by Steenfeldt-Jensen. *See infra*, section VIII.P.1, VIII.R.1.

E. Giambattista

145. U.S. Patent 6,932,794 ("Giambattista," EX1016) was published on August 23, 2005, and filed on April 3, 2003. As discussed above in Section IV.D, it is my opinion that claims 21-30 of the '844 patent are entitled to a priority date no earlier than May 17, 2016. I have been advised that, because Giambattista published more than one year before May 17, 2016, Giambattista is prior art to the '844 patent under § 102(b).

146. Giambattista describes an injection device for injecting set doses of medicine that includes a six-component structure. *See, e.g.*, EX1016, Abstract. As shown in FIGS. 2 and 7 (reproduced and color-coded below), Giambattista describes an injection device that includes:

(1) a "body 18" and "cartridge holder 14" (gray), which houses the drive mechanism for dispensing medicine from a cartridge, *see, e.g., id.*, 2:36-38, 2:663:13, FIGS. 2-3, 7, 11-12;

(2) a "dose knob 20" (green), which the user manipulates to set a specific dose for injection, *see, e.g.*, *id.*, 2:36-38, 3:10-15, 3:56-57, 3:60-67, 4:49-64, 5:8-19, 5:24-25, claims 6, 9, 15, FIGS. 2, 7-12;

(3) a "driver 24" (red), which drives a leadscrew, *see, e.g.*, *id.*, 2:36-38, 3:16-24, 5:16-24, FIGS. 2, 5, 7, 11-12;

(4) a "dosing ring adaptor 28" with "dosing ring 22" (blue), which releasably connects the dose knob and the driver for rotational movement during injection, *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;

(5) a "leadscrew 26" (yellow), which is driven by the driver to dispense medicine from the cartridge, *see, e.g.*, *id.*, 2:36-39, 3:16-24, 5:16-24, claim 7, FIGS. 2, 7, 11-12; and

(6) a "bulkhead 44" having "aperture 46" (purple), which engages and holds the leadscrew as the leadscrew is driven by the driver, *see, e.g.*, *id.*, 2:66-3:7, 5:20-24; *see also id.*, claim 8, FIGS. 3, 7.

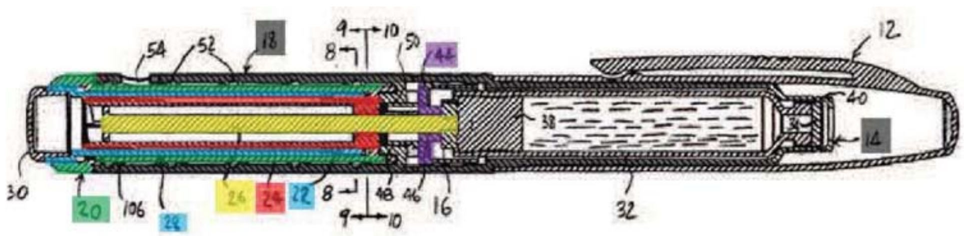

FIG. 7

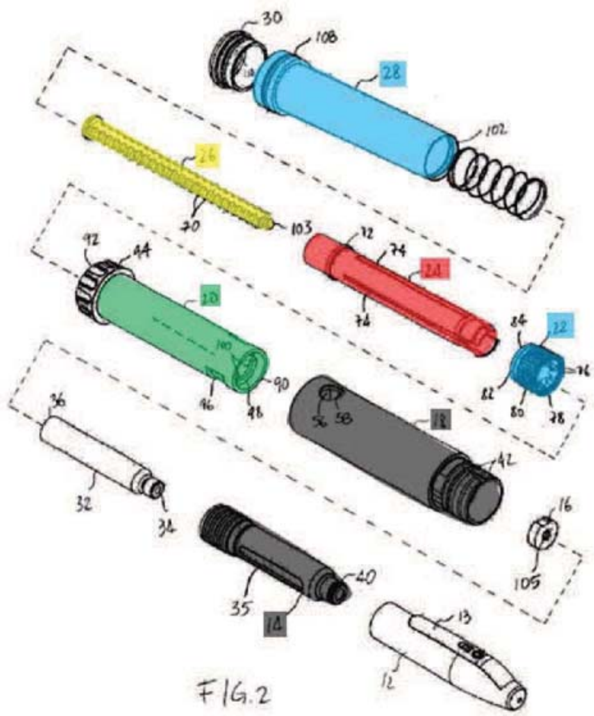

FIG. 2

147. As I detail more below, in Giambattista's device, the user grasps textured handle 94 of dose knob 20 to rotate and move axially dose knob 20 relative to the body 18 to set a desired dose. *See id.*, 3:56-66, 4:49-64. Depression of thumb button 30 causes engagement between teeth 100 on lip 98 of dose knob 20 and grooves 76 of dosing ring 22 so that dose knob 20's rotation back into the pen is transmitted to driver 24 to drive leadscrew 26 to dispense medication. *See id.*, 5:4-25. As leadscrew 26 cannot rotate because of its fixed positioning in aperture 46, rotation of driver 24 about leadscrew 26 causes the leadscrew 26 to axially translate against the plunger to dispense medication. *See id.*, 5:16-24. As I also detail more below, it is my opinion that Giambattista describes each of the components recited

in claim 21 of the ’044 patent, and thus anticipates the claim. *See infra*, section VIII.M.1.

F. Klitgaard

148. U.S. Patent No. 6,582,404 (“Klitgaard,” EX1017) was published on June 24, 2003, and filed on September 6, 2000. As discussed above in Section IV.D, claims 21-30 of the ’844 patent are entitled to a priority date no earlier than May 17, 2016. I have been advised that, because Klitgaard issued more than one year before May 17, 2016, Klitgaard is prior art to the ’844 patent under § 102(b). I have also been advised that because Klitgaard was filed prior to March 3, 2003, it is also prior art to the challenged patents under § 102(e).

149. Klitgaard describes a limiting mechanism to track the amount of medication administered from a drug injection device. EX1017, Abstract. A purpose of this limiting mechanism is to prevent the setting of a dose in an amount that exceeds the remaining supply of medication in the cartridge. *Id.* An embodiment of such a limiting mechanism is disclosed in FIG. 3 and its related description. Klitgaard discloses that nut member 32 is disposed between a dose setting member 30 and a driver 31 and tracks each set dose of medication delivered. *Id.*, 4:16-58. Dose setting member 30 is threaded out along internal threads of the housing to set a dose. *Id.*, 4:16-25. Nut member 32 simultaneously threads along a helical track on the outer surface of driver 31 pushed by the engagement of a ridge on the inner side

of dose setting element 30 with recess 34 in the outer wall of nut member 32. *Id.*, 4:26-37. Nut member 32 maintains its position on driver 31 during dose dispensing to "always indicate the total sum of set and injected doses" even when dose setting member 30 is forced to rotate relative to the housing and transmits rotational force to driver 31. *Id.*, 4:37-58.

VIII. Detailed Explanation Of The Grounds Of Unpatentability

150. As I explain in detail below, it is my opinion that each and every element of the claims of the challenged patents is found in the prior art. For ease of presenting my analysis, I group together grounds across the challenged patents that substantially overlap with one another. To indicate which ground applies to which patent, I provide the last three numbers of the patent in brackets to which the ground that follows applies.

151. Below I provide charts, which provide a high-level overview of each of the grounds applicable to each of the challenged patents:

The '069 patent:

1. The '069 grounds:

Ground	Claims	Basis
1	1-3	Obvious over Burroughs
2	1	Obvious over Steenfeldt-Jensen
3	1	Obvious over Møller in combination with Steenfeldt-Jensen

<u>The ’044 patent</u>:[19]

2. <u>The ’044-A grounds:</u>

Ground	Claims	Basis
1	11, 14-15, 18-19	Obvious over Burroughs

3. <u>The ’044-B grounds:</u>

Ground	Claims	Basis
1	11, 14-15, 18-19	Obvious over Steenfeldt-Jensen
2	11, 14-15, 18-19	Obvious over Møller in combination with Steenfeldt-Jensen

[19] I have been advised that two separate petitions are being filed for *inter partes* review of the ’044 patent. The first applies a ground based on Burroughs to claims 11, 14-15, and 18-19 of the ’044 patent. I will refer to this ground as the “’044-A” ground. The second applies grounds based on Møller and Steenfeldt-Jensen to claims 11, 14-15, and 18-18 of the ’044 patent. I will refer to these grounds as the “’044-B” grounds.

The ’486 patent:[20]

4. **The ’486-A1 ground:**

Ground	Claims	Basis
1	1-6, 12-18, 20, 23, 26-30, 32-33, 36, 38-40	Obvious over Burroughs

5. **The ’486-A2 grounds:**

Ground	Claims	Basis
1	1-6, 12-18, 20, 23, 26-30, 32-33, 36, 38-40	Obvious over Steenfeldt-Jensen
2	1-6, 12-18, 20, 23, 26-30, 32-33, 36, 38-40	Obvious over Møller in combination with Steenfeldt-Jensen

[20] I have been advised that three separate petitions are being filed for *inter partes* review of the ’486 patent. The first two petitions focus on claims 1-6, 12-18, 20, 23, 26-30, 32-33, 36, and 38-40. One applies a ground based on Burroughs. I will refer to this ground as the “’486-A1” ground. The other applies grounds based on Møller and Steenfeldt-Jensen. I will refer to these grounds as the “’486-A2” grounds. The third petition focuses on claims 51-57. I will refer to the grounds of this third petition as the “’486-B” grounds.

6. <u>The ’486-B grounds:</u>

Ground	Claims	Basis
1	51-55, 57	Anticipated by Burroughs
2	54-55	Obvious over Burroughs
3	51-53, 56-57	Anticipated by Steenfeldt-Jensen
4	56	Obvious over Steenfeldt-Jensen
5	54-55	Obvious over Steenfeldt-Jensen in combination with Burroughs
6	51-53, 56-57	Anticipated by Møller
7	54-55	Obvious over Møller in combination with Burroughs

<u>The ’844 patent</u>:[21]

7. <u>The ’844-A grounds:</u>

Ground	Claims	Basis
1	21-29	Anticipated by Giambattista

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[21] I have been advised that two separate petitions are being filed for *inter partes* review of the ’844 patent. The first petition applies grounds based on Giambattista against claims 21-30 of the ’844 patent. I will refer to these ground as the “’844-A” grounds. The second applies grounds based on Steenfeldt-Jensen against claims 21-

2	24-29	Obvious over Giambattista in combination with Steenfeldt-Jensen
3	30	Obvious over Giambattista in combination with Klitgaard

8. <u>The ’844-B grounds:</u>

Ground	Claims	Basis
1	21-29	Obvious over Steenfeldt-Jensen
2	30	Obvious over Steenfeldt-Jensen in combination with Klitgaard

<u>The ’008 patent:</u>

9. <u>The ’008-A grounds:</u>

Ground	Claims	Basis
1	1, 3, 7-8, 11, and 17	Obvious over Møller in combination with Steenfeldt-Jensen

30 of the ’844 patent. I will refer to the grounds of this second petition as the “’844-B” grounds.

A. ['069] Ground 1: Claim 1 is Obvious over Burroughs; ['044-A] Ground 1: Claims 11, 14, 15, and 18-19 are Obvious over Burroughs; ['486-A1] Ground 1: Claims 1-6, 12-18, 20, 23, 26-30, 32-33, 36, and 38-40 are Obvious over Burroughs

152. Below, my analysis first focuses on independent claim 1 of the '069 patent, independent claim 11 of the '044 patent, and independent claim 1 of the '486 patent, and then moves on to the dependent challenged claims of the '044 patent and the '486 patent. In cases where a given clause of one patent contains language that is identical or substantially identical to a clause of another patent, I group those clauses together. For those clauses that are substantially identical, I italicize those words that differ from the first-listed clause. The analysis that follows equally applies to each of the grouped clauses, except where I specifically note any differences. To indicate the patent to which the clause pertains, I provide brackets preceding a particular clause that contains the last three numbers of the patent to which it relates.

1. <u>Independent claim 1 of the '069 patent, independent claim 11 of the '044 patent, and independent claim 1 of the '486 patent</u>

153. It is my opinion that Burroughs describes a medication pen that includes the same six components claimed by claim 1 of the '069 patent, claim 11 of the '044 patent, and claim 1 of the '486 patent. Five of those components have the same structural elements as recited in the claims. For the sixth component, the "dose dial sleeve," Burroughs discloses a dial mechanism 34 that includes threads on its outer

surface. As I explain in more detail below, these threads form a “helical rib” that engages with a corresponding groove provided on the inner surface of a housing 22. As I also explain in more detail below, it is my opinion that a person of ordinary skill would have found it obvious to provide a helical groove, rather than a helical rib, on the outer surface of the dial mechanism 34 that engages with a corresponding thread on the housing 22.

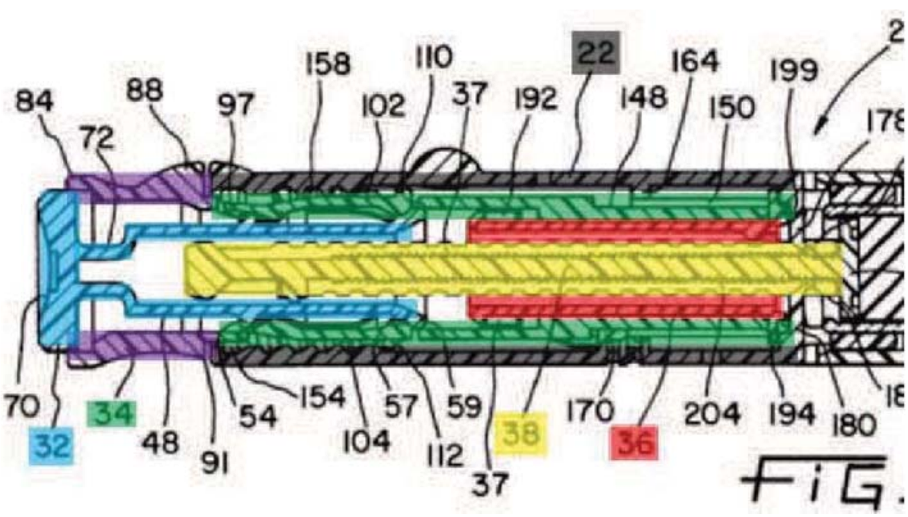
154. In addition, with regard to claim 11 of the ’044 patent, although Burroughs does not explicitly disclose a “dose dial sleeve” having a threading with a lead that is different from the lead of an internal threading of a “drive sleeve,” it is my opinion that a person of ordinary skill also would have found it apparent to configure the leads of the components’ respective threading to be different in view of the skill and knowledge of the person of ordinary skill presumed by the ’044 patent.

155. Each section of claim 1 of the ’069 patent, claim 11 of the ’044 patent, and claim 1 of the ’486 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

['069] Claim 1, preamble/['044] Claim 11, preamble/['486] Claim 1, preamble: A housing part for a medication dispensing apparatus, said housing part comprising:

156. Burroughs discloses "[a] multi-use medication dispensing pen". EX1013, Abstract. The device 20 includes a mechanism housing 22 that holds the drive mechanism for the pen. *See id.*, 7:14-19, FIGS. 1-2. Accordingly, Burroughs discloses "[a] housing part for a medication dispensing apparatus."

157. Below, I have reproduced an annotated, partial view of FIG. 1, which highlight the six components forming the drive mechanism of Burroughs' device in more detail:



['069] Claim 1.1/['044] Claim 11.1/['486] Claim 1.1: a main housing, said main housing extending from a distal end to a proximal end;

158. The housing 22 is formed by "a first part 24 and a second part 26," which "are secured together by ultrasonic welding ....", *Id.*, 7:17-20, FIGS. 1-3, 5. Reproduced below are FIGS. 3 and 5, which show the first part 24 (left) and the second part 26 (right) of the housing 22:

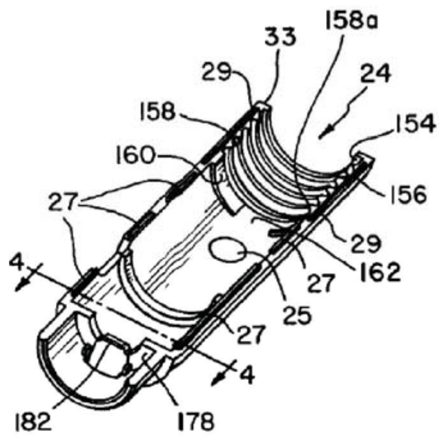


FIG. 3

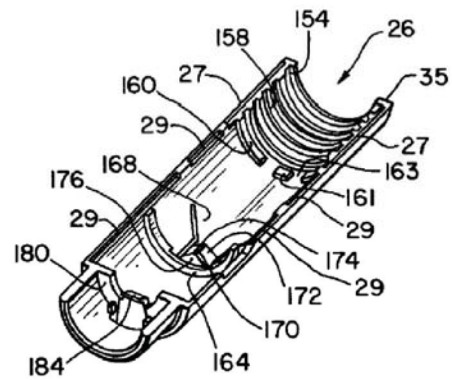
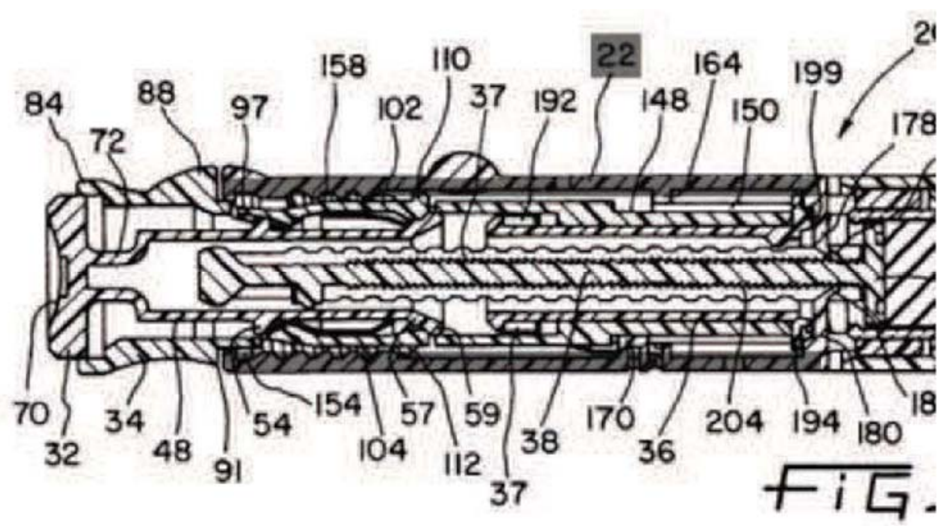


FIG. 5

159. Reproduced below is a partial view of FIG. 1, where I have annotated the mechanism housing 22 in gray:



160. As shown in FIG. 1, mechanism housing 22 extends from a needle-end to a button-end. *See id.*, FIG. 1. Burroughs thus discloses a "main housing," in the form of mechanism housing 22, that "extend[s] from a distal end to a proximal end."

[’069] Claim 1.2/[’044] Claim 11.2: a dose dial sleeve positioned within said housing,[22] said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, *said helical groove provided along an outer surface of said dose dial sleeve*;

[’486] Claim 1.2: a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing;

161. Burroughs’ device also includes a dial mechanism 34, which “is generally cylindrical in shape and is hollow throughout its axial length.” *Id.*, 7:65-67, FIGS. 1-2, 6-9. The dial mechanism 34 is positioned within the mechanism housing 22, as shown in the partial view of FIG. 1 reproduced below, where I have annotated the dial mechanism 34 in green:

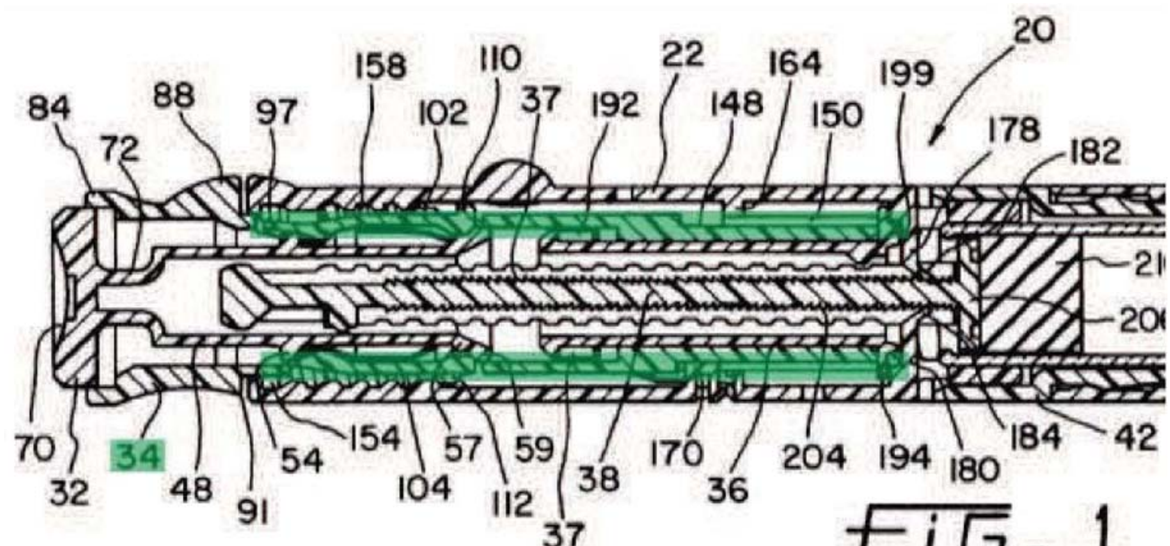


FIG. 1

[22] With respect to these claims, I understand that Sanofi has taken the position that “said housing” means “[t]he main housing.” *See* EX1019, pp.19-20. I apply this meaning to my analysis for these claims.

162. Burroughs discloses that the dial mechanism 34 includes an intermediate portion 80, which has on its outer surface a first U-shaped groove 100 and a second U-shaped groove 101. *Id.*, 8:2-4, 8:24-27; FIGS. 6-9. The grooves 100, 101 form flexible legs 102, 104, respectively. *See id.*, 8:24-29, FIGS. 6-9. Each leg 102, 104 respectively includes outwardly extending threads 110, 112 on their outer surface. *Id.*

163. I have reproduced FIGS. 6 (top) and 8 (bottom) below, which show the grooves 100, 101 that form flexible legs 102, 104:

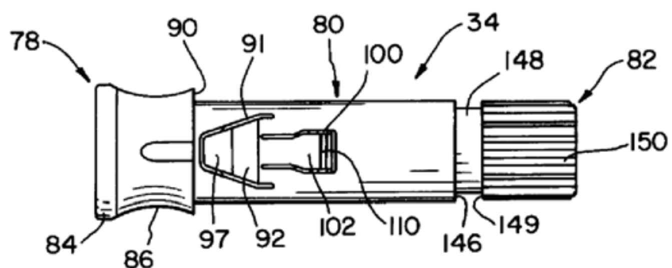


FIG. 6

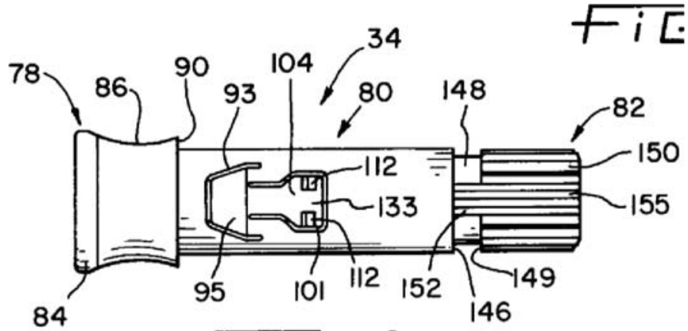


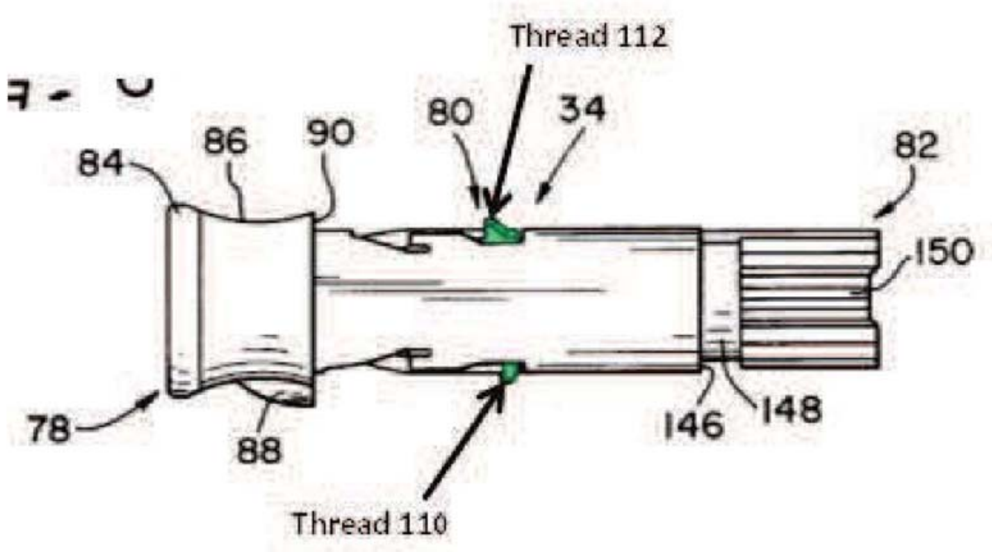
FIG. 8

164. Burroughs discloses that these threads 110, 112 are configured to releasably and rotationally engage with a helical spiral groove 158 provided on the inner surfaces of housing parts 24 and 26. *See id.*, 8:63-9:1, 10:31-34, FIGS. 3, 5.

The helical spiral groove 158 includes a "[c]ircumferential surface 160 [that] includes opening 162 and keyed opening 163 to allow threads 110 and 112 respectively to enter helical groove 158 during the commencement of the dosing process." *Id.*, 8:63-9:1. To commence the dosing process, the user rotates the dial mechanism 34 to its "zero-dose position," which aligns threads 110, 112 with openings 162, 163. *See id.*, 8:63-91, 10:31-34. Threads 110, 112 enter and engage into the helical groove 158, allowing the user to rotate the dial mechanism 34 to set a dose as "threads 110, 112 move within housing groove 158 in the proximal [*i.e.*, button-end] direction," increasing the distance between the dial mechanism's knob-end and the end of the housing. *See id.*, 10:34-38. During injection, as I explain more below, the legs 102, 104 deform inward into the dial mechanism 34 so that the threads 110, 112 disengage from the helical groove 158. *See id.*, 8:1120, 11:6-12.

165. In order to properly engage the housing's helical groove, threads 110, 112 also are positioned helically relative to one another to rotationally move within the groove. Indeed, this helical spacing can be seen best in FIG. 7, which I have reproduced below, annotating the threads 110, 112 (in green and labeled), which are shown as rib-like protrusions on the outer surface of the dial mechanism 34. *See also id.*, FIG. 1 (further showing helical positioning of threads 110, 112). Given this relative helical positioning, it is my opinion that a person of ordinary skill would have understood that the threads 110, 112 constitute a discontinuous "helical rib"

along the dial mechanism's outer surface that engages with a threading on the housing.



166. Thus, Burroughs teaches a "dose dial sleeve" in the form of a dial mechanism 34 that is "positioned within" the mechanism housing 22, and includes a "helical rib," rather than a "helical groove," that is "provided along an outer surface of" the dial mechanism 34 and "configured to engage a threading provided by" the housing 22. It is my opinion, however, that a person of ordinary skill would have found it obvious to add another helical rib next to the existing one, such that the threads 110, 112 form a "helical groove" that engages a threading provided by the housing.

167. As I noted above, the threads 110, 112 form a helical rib that releasably engages with a corresponding helical groove 158 of the housing to allow the dial 34 to rotate and move axially relative to the housing 22. Thus, Burroughs teaches the

use of a helical rib-to-groove threaded connection to accomplish relative rotation and axial movement between components.

168. The use of a rib-to-groove threaded connection is a common and well-known mechanism used for the purpose of achieving relative rotational and axial movement between components. At the relevant time, it was also a common and well-known mechanism used in pen-type injector devices to accomplish the same purpose. It was also known to use a threaded connection for achieving the relative rotational and axial movement between a device's dose dial sleeve and its main housing. For instance, Steenfeldt-Jensen described injector devices that include a dose scale drum having a helical groove on its outer surface configured to engage a helical rib on a housing's inner surface, which allows the drum to rotate and move axially relative to the housing. *See, e.g.*, EX1014, 6:7-17, 8:10-12, 9:52-56, 11:2022, FIGS. 2-3, 7-8, 12-13, 16-17. Other injection devices similarly incorporated a rib-to-groove threaded connection between a dose dial sleeve and a housing to allow for relative rotational and axial movement. *See, e.g.*, EX1020, 11:42-45, 12:63-13:3, FIGS. 2-3; EX1032, 1:17-20, 1:40-54 (describing prior art dose dial sleeves). These references illustrate that the placement of helical ribs on one component and its corresponding helical groove on the other component results in the same relative rotational and axial movement between the engaging components. Indeed, a person of ordinary skill would have understood that a single, protruding thread forms a rib,

and when more than one protruding thread is added, grooves and ribs are formed. A person of ordinary skill would have understood that the only difference is the length of the thread.

169. Given the above, it is my opinion that a person of ordinary skill would have understood that a rib-to-groove threaded connection would allow for the relative rotational and axial movement between the engaging components. A person of ordinary skill also would have understood that the relative placement of the helical rib and helical groove on the components to be largely interchangeable, with each circumstance (H.J., rib-to-groove, or groove-to-rib) resulting in the same relative movement between the parts.

170. With regard to Burroughs, it is my opinion that a person of ordinary skill would have understood that this principle would apply to the rotational operability between the dial mechanism 34 and the housing 22. Specifically, a person of ordinary skill would have understood that the rotational operability between the components would be retained if the threads 110, 112 of the dial mechanism were configured as two, parallel ribs that formed a discontinuous, helical groove for engaging the housing's threading. A person of ordinary skill also would have expected that such a helical groove would engage into and disengage from the housing's threading in substantially the same manner as the helical rib disclosed in Burroughs, thus retaining the dial mechanism's general operability.

171. I note that Burroughs itself contemplates modifications such as this, stating that "any variations, uses, or adaptions ... using these general principles" and those that "come within known or customary practice in the art" are "within the spirit and scope of this disclosure." EX1013, 12:30-39. It is my opinion that, at the relevant time, whether to provide the dial mechanism 34 with a helical rib or a helical groove to engage a threading on the housing to achieve the same rotational function as that disclosed by Burroughs falls within the routine variations contemplated by Burroughs.

172. Accordingly, based on the above, it is my opinion that Burroughs renders the claimed "dose dial sleeve" obvious.

['069] Claim 1.3/['044] Claim 11.3: a dose dial grip disposed near a proximal end of said dose dial sleeve;

['486] Claim 1.3: a dose *knob* disposed near a proximal end of said dose dial sleeve;

173. The dial mechanism 34 includes a "proximal portion 78" positioned at the dial mechanism's button-end. *Id.*, 8:2-6, FIGS. 1-2, 6-9. "Proximal portion 78 comprises enlarged diameter portion 84, tapered portion 86, and ring 90 extending about the circumference of proximal portion 78." *Id.* Reproduced below is FIG. 7, where I have annotated the proximal portion 78 purple:

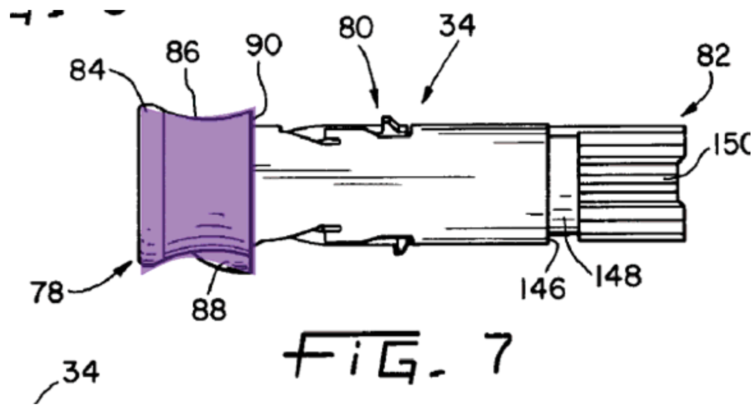
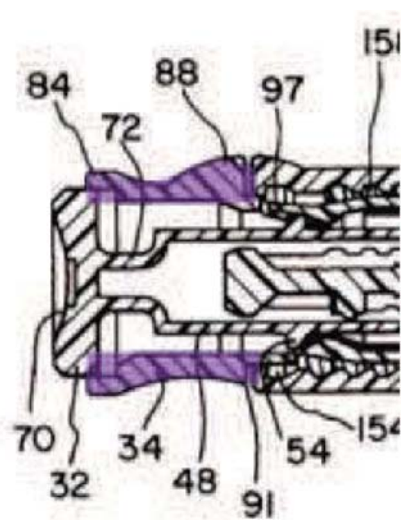


FiG. 7

174. Burroughs teaches that, to set a dose, the dial mechanism 34 is rotated such that "dial mechanism 34 retracts from housing 22, thereby increasing the axial distance between ring 91 [*sic*, 90] and surfaces 33, 35 housing parts 24, 26." *Id.*, 10:34-42. As shown in FIG. 1 (partially reproduced below, with proximal portion 78 annotated in purple), proximal portion 78 is positioned external to the housing 22, with the needle-end side of ring 90 sitting flush with the button-end side of the housing 22:[23]

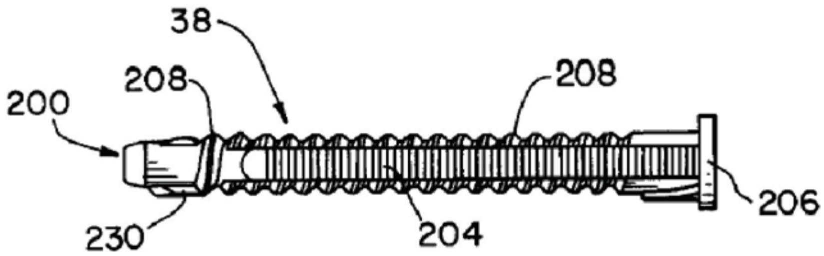


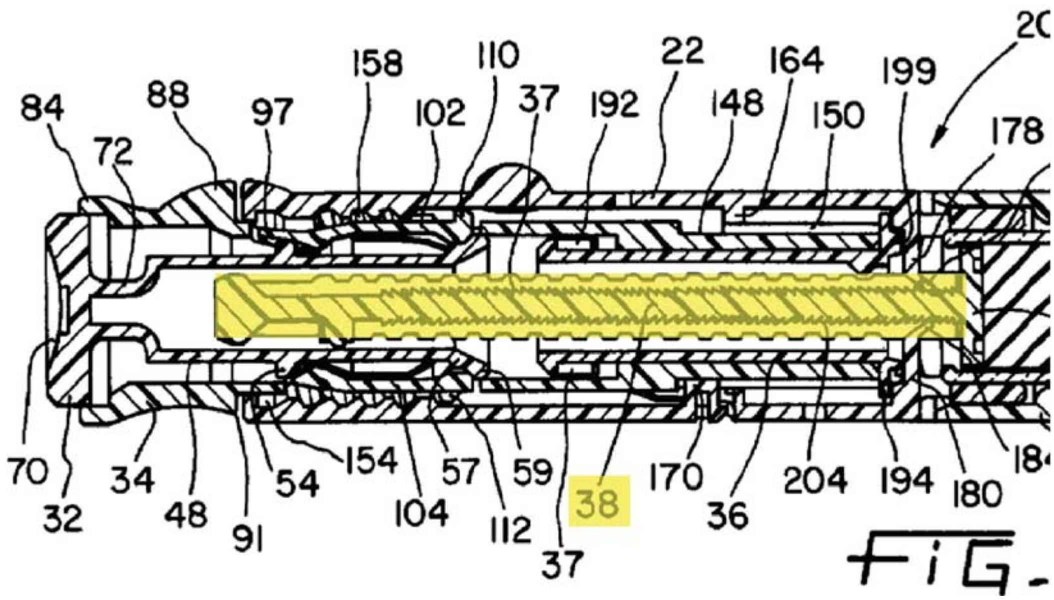
[23] I note here that ring 90 is mislabeled in FIG. 1 as "91".

175. Given this positioning, it is my opinion that a person of ordinary skill would have understood the proximal portion 78 of the dial mechanism 34 to constitute a "dose dial grip," or a "dose knob," for the user to grasp in order to rotate the dial mechanism 34 during dose setting. Thus, Burroughs teaches a "dose dial grip," or a "dose knob," in the form of a proximal portion 78 of the dial mechanism 34 that is "disposed near" a button-end of the dial mechanism.

['069] Claim 1.4/['044] Claim 11.4/['486] Claim 1.4: a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;

176. Burroughs describes that the device also includes a leadscrew 38. *See id.*, 9:26, FIGS. 12-13. On two opposing sides, the leadscrew 38 includes ratchet teeth 204, which extend along the length of the leadscrew 38 from its button-end to a plunger engagement portion 206 at the leadscrew's needle-end, which is positioned to engage a piston 210 of a cartridge 40. *See id.*, 9:26-34, FIGS. 1-2, 12-13. The leadscrew 38 also includes helical threads 208 that extend along its length. *Id.*, 9:30-31. Reproduced below are FIGS. 12 (top) and 1 (partial view, bottom). FIG. 12 provides a detailed view of the leadscrew 38. In FIG. 1, I have annotated the leadscrew 38 in yellow, which shows the component positioned within the housing 22:





177. Burroughs also discloses that the housing parts 24, 26 include "bulkhead ledges 178, 180, respectively." *Id.*, 9:8-11, FIGS. 1, 3, 5. These ledges include flexible tangs 182, 184, which are configured to engage with the ratchet teeth 204 in such a way that prevents the leadscrew's movement toward the button-end of the device. *Id.*, 9:8-11, 11:52-56, FIGS. 1, 3, 5. When a nut 36, which is engaged to helical thread 208 of the leadscrew 38, is rotated during the dose-setting process (explained more below), the leadscrew 38 is prevented from following this rotation due to its ratchet engagement with the flexible tangs 182, 184. *See id.*, 10:26-42.

Therefore, leadscrew 38 does not rotate relative to the housing 22 during a dose setting process.

178. Accordingly, Burroughs teaches a "piston rod" in the form of leadscrew 38 that is "provided within" the housing 22 and "is non-rotatable during a dose setting step relative to" the housing 22.

['069] Claim 1.5/['044] Claim 11.5: a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and,

['486] Claim 1.5: a *driver* extending along a portion of said piston rod, said *driver* comprising an internal threading near a distal portion of said *driver*, said internal threading adapted to engage an external thread of said piston rod; and,

179. Burroughs discloses a nut 36, which is "generally cylindrical in shape," and includes, on its inner surface and toward its needle-end, a helical thread 198. *Id.*, 9:13-25, FIGS. 1-2, 10-11. The nut 36 extends along a portion of the leadscrew 38, and the helical thread 198 engages with the helical threads 208 of the leadscrew 38. *See id.*, 9:30-32, 10:38-42, FIGS. 1, 10-11. Reproduced below are a partial view of FIG. 1 (top), and FIGS. 10 (bottom-left) and 11 (bottom-right). In FIG. 1, I have annotated the nut 36 in red. FIGS. 10 and 11 show a detail view of the outer and inner surfaces of the nut 36, respectively. As shown in FIG. 11, the helical thread 198 of the nut 36 is provided near a needle-end portion of the nut 36.

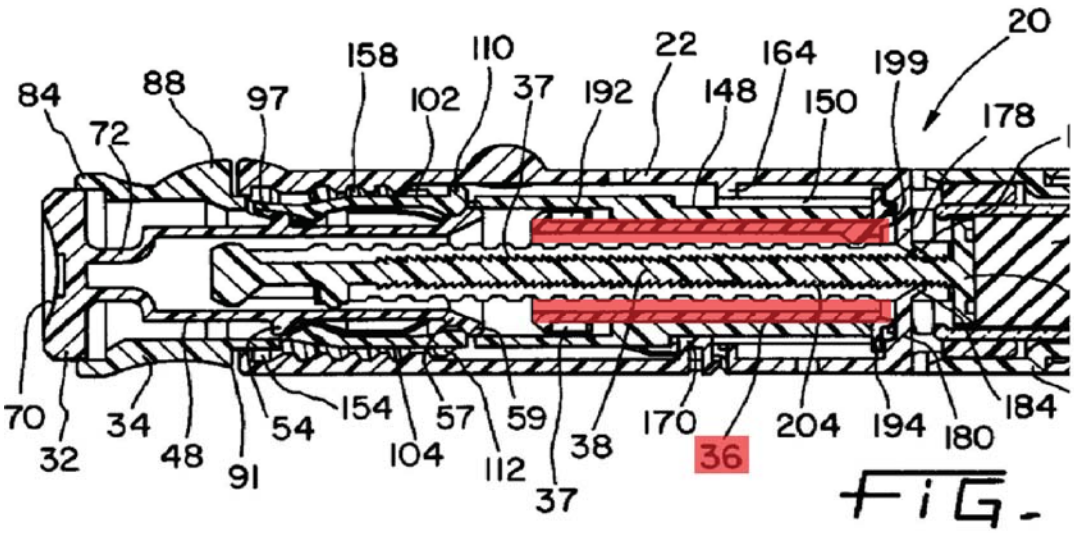


FIG. -

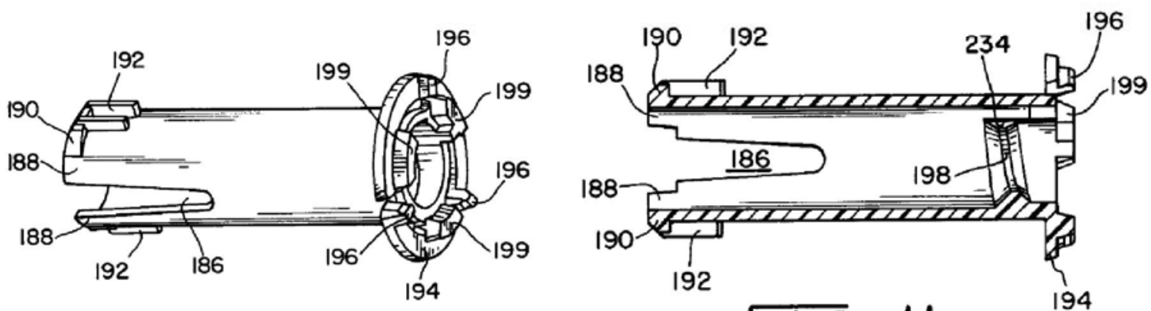


FIG. 11

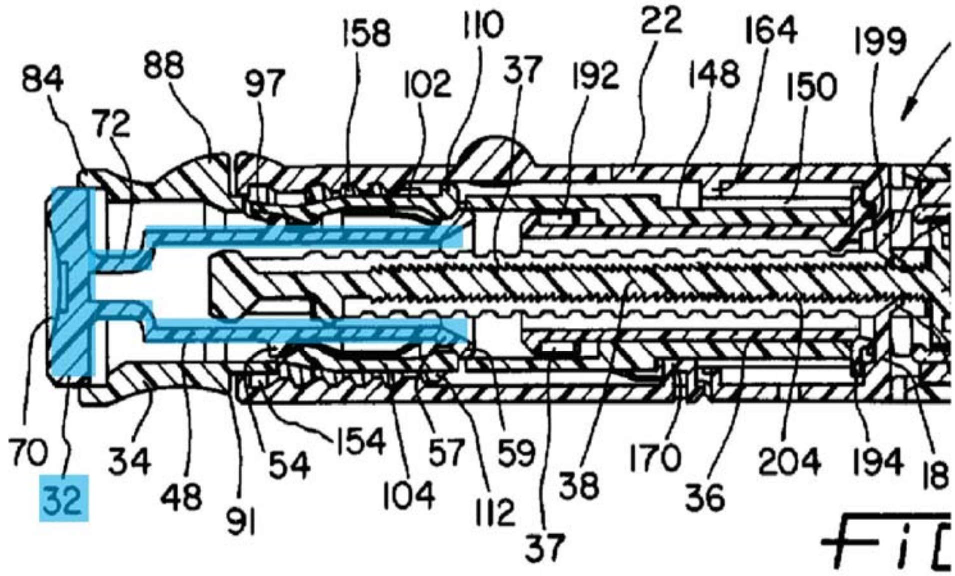
180. As Burroughs explains, during dose setting, teeth or splines 192 of the nut 36 engage with splines 144 provided on the dial mechanism 34. *Id.*, 8:42-48, 9:16-18, 10:21-26, FIGS. 1, 9-11. When engaged, the nut 36 follows the rotation of the dial mechanism 34, causing the helical groove 198 of the nut 36 to "rotate[]along external threads 208 of leadscrew 38 to cause nut 36 to axially retract a corresponding distance." *Id.*, 10:38-42. During injection, the dial mechanism's splines 144 disengage from the nut's teeth 192 so that the nut moves axially toward the device's needle-end, causing the leadscrew to advance to dispense medicine *See id.*, 11:27-34.

181. Accordingly, Burroughs teaches a "drive sleeve," or "driver," in the form of a nut 36, which "extends along a portion of" the leadscrew 38 and "compris[es] an internal threading near a distal portion ... adapted to engage an external thread of" the leadscrew 38. I also note, applying Sanofi's construction, the nut 36 is "releasably connected" to the dial mechanism 34 through teeth 192 that releasably engage splines 144 of the dial mechanism.

['069] Claim 1.6/['044] Claim 11.6: a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,

['486] Claim 1.6: a tubular clutch located adjacent a distal end of said dose *knob*, said tubular clutch operatively coupled to said dose *knob*,

182. The device of Burroughs also includes a button 32. Button 32 includes "a hollow cylindrical portion 48 having a proximal end [*i.e.*, button-end] 50." *Id.*, 7:46-47, FIGS. 1-2, 14-15. The cylindrical portion 48 has an enlarged diameter ring 54, which is configured to engage the dial mechanism 34. *Id.*, 7:4852. Below, I have reproduced a partial view of FIG. 1, where I have annotated button 32 in blue. I have also reproduced FIG. 14, which shows button 32 in greater detail.



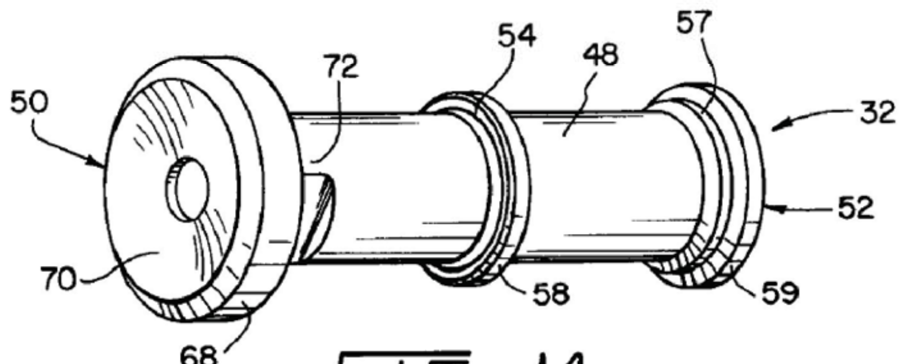


FiG. 14

183. As shown in the figures above, the button 32 is "tubular" in shape. It also serves as a "clutch" by disengaging the dial mechanism 34 from the housing 22 and the nut 36. Specifically, as I mentioned above, the dial mechanism 34 include flexible legs 102, 104 having threads 110, 112 that engage with internal threading provided on the housing during dose setting. *See, e.g.*, *id.*, 10:34-38, FIGS. 6-9. At its needle-end, the button 32 includes a "distal end 52" having "a first step 57" that "is used to prevent dial tabs 102 and 104 from collapsing inward," thus engaging the

threads 110, 112 with the housing's internal threading and coupling the dial mechanism 34 to the housing 22. *Id.*, 7:49-55. The dial mechanism 34 also includes splines 144 that engage splines 192 of the nut 36 to rotationally couple the components during dose setting. *See, e.g.*, *id.*, 10:21-26, FIG. 9, 11. After a dose has been set, the button 32 is depressed, which pushes the enlarged diameter ring 54 against ramped surfaces 96 positioned on the inner surface of the dial mechanism. *See id.*, 8:11-20, FIG. 9. By pushing against these ramped surfaces, the flexible legs 102, 104 are forced to collapse inward, disengaging the threads 110, 112 from the housing's helical groove 158. *See id.*, 8:11-20, 11:5-12. "Dial mechanism 34 is then able to travel axially towards cartridge 40 during injection of the medical product ...." *Id.*, 8:18-20. This axial movement also causes the dial mechanism's splines 144 to move out of its alignment with the nut's splines 192, which rotationally decouples the component prior to any axial movement of the nut. *See id.*, 11:27-30. Further axial movement of the dial mechanism 34 causes axial movement of the nut 36, which, in turn, moves the leadscrew 38 toward the device's needle-end to deliver the set dosage of medication. *Id.*, 11:31-34. Thus, the button 32 serves as a "clutch" by disengaging the dial mechanism 34 from its threaded connection with the housing 22, and its rotational coupling with the nut 36.

184. Further, as shown in FIG. 1 above, the button 32 extends through the proximal portion 78 of the dial mechanism 34 and into a button-end portion of the

dial mechanism 34, making the button 32 "located adjacent" a needle-end of the proximal portion 78 of the dial mechanism.

185. The button 32 is also "operatively coupled" to the proximal portion 78 of the dial mechanism 34. Burroughs discloses that the button 32 includes the first step 57 that "is used to prevent dial tabs 102 and 104 from collapsing inward." *Id.*, 7:54-55. The "second step 59 is used both to keep button 32 centered within dial mechanism 34 and also prevent button 32 from inadvertently falling or being removed from dial 34." *Id.*, 7:55-58. And, as I explained above, during injection, the button's enlarged diameter ring 54 engages with the inner ramped surfaces of the dial mechanism 34 to cause its disengagement from the housing 22 and the nut 36. Further axial movement of the button 32 as it is being pressed by the user is transferred to the dial mechanism 34 such that it moves toward the device's needle-end. *See id.*, 11:20-23. Thus, button 32 is "operatively coupled" to the proximal portion 78 of the dial mechanism 34 by engaging the dial 34 during dose setting to couple the dial 34 to the housing 22, and by engaging the dial 34 during dose dispensing to cause dial 34 to decouple from the housing 22 and transfer axial movement to the dial mechanism 34 to dispense medicine.

186. I note that this type of coupling to the "dose dial grip" (or "dose knob") is contemplated by the '069 patent, the '044 patent, and the '486 patent. Specifically, when describing the function of the claimed clutch, the challenged patents refer to

the clutch's operative engagement and disengagement with respect to the dose dial sleeve, rather than to the dose dial grip directly. *See, e.g.*, EX1001, 2:5-7, 6:6-9. And, as I explained above, a person of ordinary skill would have understood that the dog teeth 65 of the clutch 60 releasably engages with the dose dial sleeve 70's "radially extending members 75" during use to couple or decouple the dose dial sleeve's rotation. *See id.*, 5:1-3; *supra*, ¶69. Thus, claim 1 of the '069 patent, claim 11 of the '044 patent, and claim 1 of the '486 patent at least include instances where the clutch is "operatively coupled" to the "dose dial grip" or "dose knob" via the clutch's engagement with the dose dial sleeve.

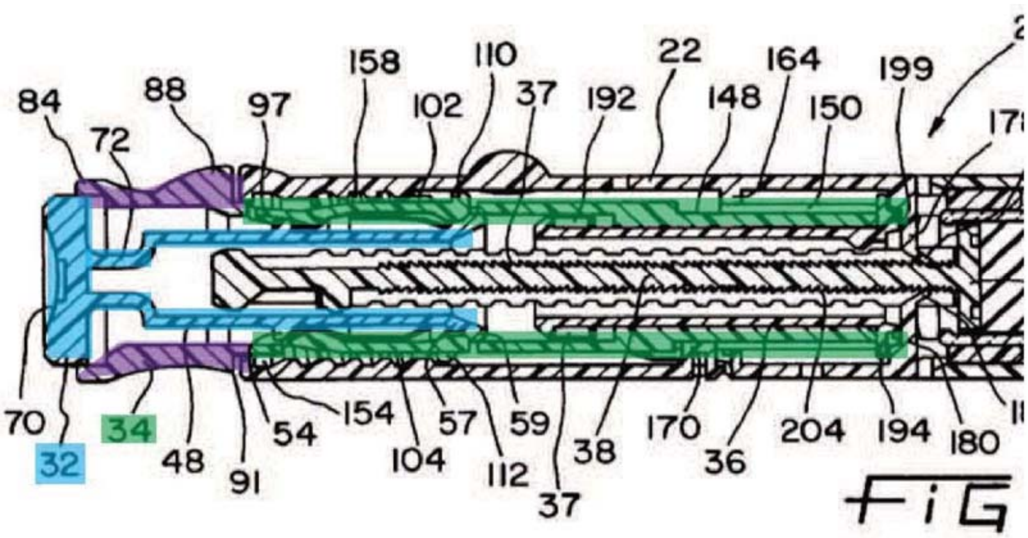
187. Accordingly, Burroughs discloses a "tubular clutch" in the form of a button 32 that is "located adjacent a distal end of" the dial mechanism's proximal portion 78 and is "operatively coupled" to the proximal portion 78.

['069] Claim 1.7/['486] Claim 1.7: wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

['044] Claim 11.7: wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, *and*

188. Burroughs shows that the dial mechanism 34 extends circumferentially around a portion of the button 32's needle-end. *See* EX1013, FIG. 1. To illustrate this relative position, I have reproduced a partial view of FIG. 1 below, where I have

annotated the dial mechanism 34 in green, and the button 32 in blue.[24] Thus, Burroughs discloses that the "dose dial sleeve extends circumferentially around at least a portion of said tubular clutch."



['044] Claim 11.8: wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different.

189. The term "lead" is a well-known unit of measure that quantifies the axial distance a threaded component moves relative to the component to which it is

[24] For visual purposes, I also annotate the proximal portion 78 (purple) of the dial mechanism 34 to illustrate the extent of the dial mechanism 34 disclosed by Burroughs. As I explained above, the proximal portion 78 corresponds to the claimed "dose dial grip" / "dose knob", and Burroughs discloses that the proximal portion 78 is integral with the dial mechanism 34. *See supra*, ¶¶173-75.

engaged after one complete revolution. *See, e.g.*, EX1005, 3:56-63. Thus, for components containing a helical thread, a person of ordinary skill would have understood that the component's thread contained a "lead" of a certain value.

190. As I explained above, Burroughs discloses a "dose dial sleeve" in the form of a dial mechanism 34 that includes a helical rib on its outer surface formed by threads 110, 112. *See* EX1013, 8:24-29, FIGS. 6-9; *supra*, ¶¶161-72. As I also explained above, a person of ordinary skill would have found it obvious to modify the threads 110, 112 to form a helical groove that engages with a threading on the housing's inner surface. *See supra*, ¶¶161-72. Given the helical, threaded nature of threads 110, 112, even when formed as a helical groove, a person of ordinary skill would have understood that the helical groove would have a "first lead," where, with each full revolution of the dial mechanism 34, the dial mechanism 34 would move axially relative to the housing 22 by a distance equal to the "first lead."

191. As I further explained above, Burroughs discloses a "drive sleeve" in the form of a nut 36 that includes a helical thread 198 configured to engage with an external threading on a leadscrew 38. *See* EX1013, 9:13-25, FIGS. 1-2, 10-11; *supra*, ¶¶179-81. Given the thread's helical nature, a person of ordinary skill would have also understood that the helical thread 198 would have a "second lead," where, with each full revolution of the nut 36, the nut 36 would move axially relative to the leadscrew 38 by a distance equal to the "second lead."

192. Burroughs does not explicitly disclose numerical values for the leads contained on the dial mechanism 34 and the nut 36. It also does not explicitly disclose whether the leads for the dial mechanism 34 and the nut 36 are the same or different. Nevertheless, as I detail below, in view of the disclosed embodiment of the ’044 patent and its accompanying disclosure, it is my opinion that a person of ordinary skill would have found it apparent that the leads of the helical groove of the dial mechanism 34 and the internal threading of the nut 36 could be configured to be the same or different, and would have readily understood how to configure the device of Burroughs to include different leads.

193. At the relevant time, a person of ordinary skill would have understood that the leads of threaded, moveable components in injector devices dictated the rate of axial travel of the components as they are rotated. As such, a person of ordinary skill often sought to design the leads to achieve a desired rate of axial travel when the component was rotated. For instance, with regard to Burroughs’ dial mechanism 34, a person of ordinary skill would have understood that the lead of the dial mechanism’s threading would dictate how much the dial mechanism 34 would retract out of the housing 22 during dose dialing. With regard to the nut 36, a person of ordinary skill would have understood that the lead of the nut’s threading would dictate how much the nut 36 would travel up the leadscrew 38 during dose dialing, which, in turn, would ultimately dictate the amount the leadscrew 38 would travel

axially into the cartridge during dispensing. And, because the dial mechanism 34 and the nut 36 are rotationally engaged during dose dialing, a person of ordinary skill would have understood that the number of rotations a user dialed the dial mechanism 34 would determine not only the length of axial travel of the dial 34, but also the length of travel of the nut 36, and thus the amount of dose dispensed by the leadscrew 38.

194. Given this, if it was desired that the dial mechanism 34 retract from the housing 22 at a rate equal to the rate at which the nut 36 climbed up the leadscrew 38, then a person of ordinary skill would have understood that the leads of those components should be the same. Similarly, if it was desired that the dial mechanism 34 retract from the housing 22 at a faster or slower rate than the rate at which the nut 36 climbed up the leadscrew 38, then a person of ordinary skill would have understood that the leads of those components should be different.

195. A person of ordinary skill would have also known that, by setting the lead of an external, helical thread of a "dose dial sleeve" larger than the lead of an internal, helical thread of a "drive sleeve," usability of the device during the dose setting process may be improved. For instance, in cases where only small doses of medicine are needed during an injection, a person of ordinary skill would have understood that such a configuration would allow the user to retract the dose dial sleeve larger distance than the distance needed for the drive sleeve to drive the piston

rod to deliver the small dose. Thus, due to the larger travel of the dose dial sleeve, the user may better perceive smaller changes in the dose during the dose setting process. *See* EX1015, 1:33-57 (explaining, as background, that such gearing addresses cases where, if the leads of the dose dial sleeve and the drive sleeve were equal, relatively small movements of the dose dial sleeve would be "difficult to feel").

196. As an initial matter, I note that this understanding of the person of ordinary skill's knowledge—that is, the skill and knowledge to adapt a device such that its "dose dial sleeve" contained a threading having a "first lead" different than a "second lead" of a threading of a "drive sleeve"—is appreciated by the '044 patent. Specifically, with regard to the embodiment disclosed, the '044 patent states "[t]he helical groove 74 on the dose dial sleeve 70 and the helical groove 38 in the drive sleeve 30 have the same lead." EX1002, 5:61-62. As such, the dose dial sleeve 70 extends from the main housing 4 at the same rate the drive sleeve 30 climbs the piston rod 20. *Id.*, 5:63-65. I note, however, that the '044 patent does not explicitly disclose that the leads may be different between the dose dial sleeve and the drive sleeve. Based on the embodiment alone, if the leads of the dose dial sleeve and the drive sleeve were configured to be different, the device would become inoperable. For example, the '044 patent describes that the drive sleeve 30 is rotationally engaged to the dose dial sleeve 70 during dose setting via the clutch 60, which

engages the dose dial sleeve 70 through dog teeth 65 cooperating with radially extending members 75 of the dose dial sleeve 70. *See id.*, 5:22-24, 6:2830; *supra*, ¶69. The clutch 60, in turn, is engaged with the drive sleeve 30 through splines on its inner surface and a radially inwardly directed flange 62 that is disposed between a shoulder 37 and a radially outwardly directed flange 39 of the drive sleeve 30. *See* EX1002, 4:54-62; *supra*, ¶¶65-67. The ’044 patent does not explicitly describe how the drive sleeve’s engagement with the dose dial sleeve (via the clutch) would be retained if the leads of the dose dial sleeve and the drive sleeve were different (causing, for example, the dose dial sleeve to retract from the housing at a faster rate than the drive sleeve climbs the piston rod). Indeed, if the leads were made to be different, the dog teeth 65 of the clutch 60 would not be able to maintain its engagement with the dose dial sleeve during dose setting due to the different rates of axial movement of the dose dial sleeve and the drive sleeve (to which the clutch 60 is connected), which would rotationally decouple the components during the dose setting process. The ’044 patent does not describe what modifications would be necessary to achieve a lead-difference between these components. It is my opinion that such a lead-difference would require a significant redesign of the device.

197. I have been advised that a patent must provide sufficient disclosure to enable a person of ordinary skill to make and use the claimed invention without undue experimentation. Thus, in order for claim 11 of the ’044 patent to be properly

enabled, I have been advised that this would mean that the '044 patent presumed it was within the ordinary skill and knowledge of those skilled in the art to appropriately adapt the disclosed embodiment to contain different leads for the dose dial sleeve and the drive sleeve while retaining its overall function during dose dialing based on the description of the disclosed embodiment alone. In other words, the '044 patent presumed that its description of the disclosed embodiment was sufficient to enable a person of ordinary skill to make and use a device with different leads without undue experimentation.

198. It is my opinion that the skill and knowledge presumed by the '044 patent applies to adapting the device of Burroughs to achieve a similar lead-difference. I note that the device of Burroughs is similarly situated. If the lead of the dial mechanism 34 were different (e.g., greater) from the lead of the nut 36, the splines 144 of the dial 34 and the splines 192 of the nut 36 would bind as they are forced together during the dose setting process due to the different rates of axial movement of the dial 34 relative to the nut 36. Thus, a person of ordinary skill would have to substantially modify the device to ensure that the splines would not bind and, thus, allow them to travel at different rates.

199. Given the above, based on what the '044 patent presumed was within the skill and knowledge of the person of ordinary skill to modify the disclosed embodiment to contain the claimed lead-difference, it is my opinion that a person of

ordinary skill using the same skill and knowledge would know how to configure the "first lead" of the external threading of the dial mechanism 34 to be larger, and thus different, than the "second lead" of the internal threading of the nut 36. As I explained above, such a lead difference would allow the user to better perceive small changes in the set dose due to the relatively larger stroke of the dial sleeve.

200. Accordingly, it is my opinion that a person of ordinary skill would have found it apparent to configure the device of Burroughs such that the "helical groove" of its dial mechanism 34 contained a lead that was different than a lead of the nut 36's internal threading.

2. Dependent claims 14-15 and 18-19 of the '044 patent and dependent claims 2-6, 12-18, 20, 23, 26-30, 32-33, 36, and 38-40 of the '486 patent

201. Each section of dependent claims 14-15 and 18-19 of the '044 patent and dependent claims 2-6, 12-18, 20, 23, 26-30, 32-33, 36, and 38-40 of the '486 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

['486] Claim 2: The housing part of claim 1, wherein said tubular clutch is directly coupled to said dose knob.

202. As I noted above, the button 32 includes a "distal end 52" having "a first step 57 and a second step 59," where the first step 57 "is used to prevent dial tabs 102 and 104 from collapsing inward, and [the] second step 59 is used both to

keep button 32 centered within dial mechanism 34 and also prevent button 32 from inadvertently falling or being removed from dial 34." EX1013, 7:49-58. As I also explained above, during injection, the button 32 presses the inner ramped surfaces of the dial mechanism 34 to cause its disengagement from the housing 22 and the nut 36 and transfers axial movement to the dial mechanism 34 to dispense the set dose. *See id.*, 11:5-12, 11:20-23. Given this coupling, and because the proximal portion 78 of the dial mechanism 34 is an integral part of the dial mechanism, the button 32 is "directly coupled to" the proximal portion 78 of the dial mechanism 34.

['486] Claim 3: The housing part of claim 1, wherein said main housing comprises a window through which at least a portion of an outer surface of said dose dial sleeve may be viewable.

203. Burroughs discloses that housing part 24 includes a lens 25. *Id.*, 10:314, FIGS. 2-3. "A series of numerals (not shown) are printed on the surface of intermediate portion 80 of dial mechanism 34." *Id.*, 10:5-6. Burroughs further discloses that "[t]hese numerals are helically spaced about the circumference of intermediate portion 80 ... to indicate a desired dosage." *Id.*, 10:7-9. "The lens 25 ... in housing part 24 is aligned with the numbers so that the appropriate number appears in the lens upon dialing up the dosage." *Id.*, 10:9-14. Below, I have reproduced FIG. 3, which shows housing part 24 and lens 25, which I have annotated in green:

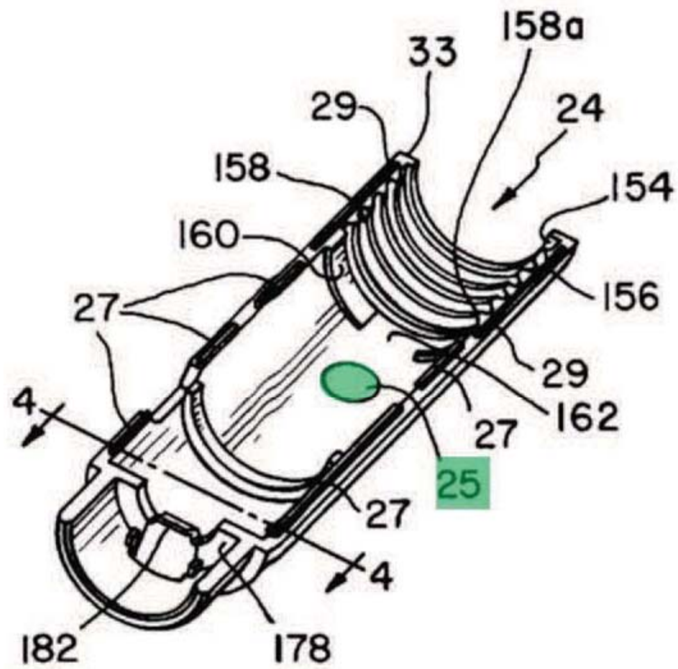


FIG. 3

204. Accordingly, Burroughs discloses that the mechanism housing 22 includes “a window,” in the form of a lens 25 in housing part 24, “through which at least a portion of an outer surface of” the dial mechanism 34 “may be viewable.”

[’486] Claim 4: The housing part of claim 3, wherein said window is located near a proximal end of said main housing and near a helical rib provided on an inner surface of said outer housing.

205. As an initial matter, I note that claim 4, which depends from claims 1 and 3, recites “said outer housing,” but this is the first time the term “outer housing” appears in those claims. Based on the context of these claims, and Sanofi’s proffered constructions for the terms “main housing” and “said housing” recited in claim 1, it is my opinion that a person of ordinary skill would understand the term “said outer

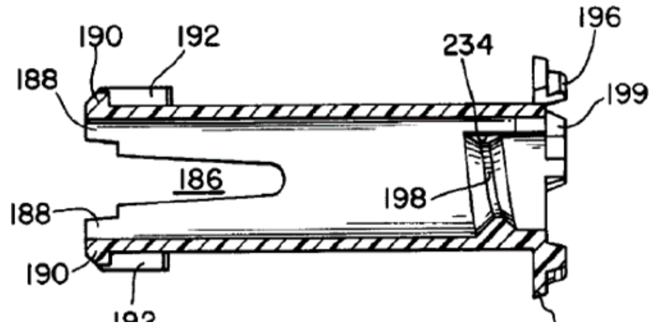
housing" to mean "the main housing," which I apply in my analysis below. *See supra*, ¶161 n.22.

206. As shown in FIG. 3 above, the lens 25 is shown to be located near the housing part 24's button-end and positioned near the helical groove 158, which is provided on the inner surface of the housing part 24, at its needle-end side. *See id.*, FIG. 3. As I explained above, it is my opinion that a person of ordinary skill would have found it obvious to configure dial mechanism 34 to have a "helical groove" that engages an internal threading of the housing 22, which a person of ordinary skill would have understood would include a corresponding "helical rib" to engage that "helical groove." *See supra*, ¶¶161-72.

207. Accordingly, Burroughs teaches that the lens 25 "is located near a proximal end" of the housing 22 and "near a helical rib provided on an inner surface of" the housing 22.

['486] Claim 5: The housing part of claim 1, wherein said driver comprises a cylindrical shape.

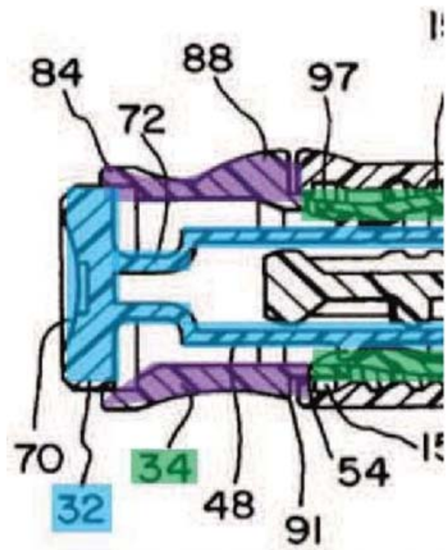
208. As I explained above, Burroughs discloses a "driver" in the form of a nut 36, which Burroughs discloses is "generally cylindrical in shape." *See* EX1013, 9:12-13, FIGS. 10-11; *supra*, ¶¶179-81. Below, I have reproduced FIG. 10, which further illustrates the nut 36's cylindrical shape:



209. Thus, Burroughs discloses a nut 36 that "comprises a cylindrical shape."

['486] Claim 6: The housing part of claim 1, wherein said dose knob extends circumferentially around at least a portion of said tubular clutch.

210. As I explained above, Burroughs discloses a "dose knob" in the form of the proximal portion 78 of the dial mechanism 34. *See supra*, ¶¶173-75. In FIG. 1, Burroughs shows that the proximal portion 78 of the dial mechanism 34 extends circumferentially around a button-end portion the button 32. To illustrate this positioning, I have reproduced a partial view of FIG. 1, toward the device's button-end, where I have annotated the button 32 in blue, the dial mechanism 34 in green, and the proximal portion 78 in purple:



211. Accordingly, Burroughs discloses that the proximal portion 78 of the dial mechanism 34 "extends circumferentially around at least a portion of" the button 32.

['486] Claim 12: The housing part of claim 1, wherein said driver comprises at least one flange.

212. Burroughs discloses that "the distal end [*i.e.*, needle-end] of nut 36 comprises a flange 194 ..., which contacts bulkhead ledges 178 and 180 [of the housing 22] to indicate to the user that the end of an injection has been reached." *Id.*, 9:18-22, FIGS. 10-11. I have reproduced FIG. 10 below, where I have annotated the flange 194 in orange:

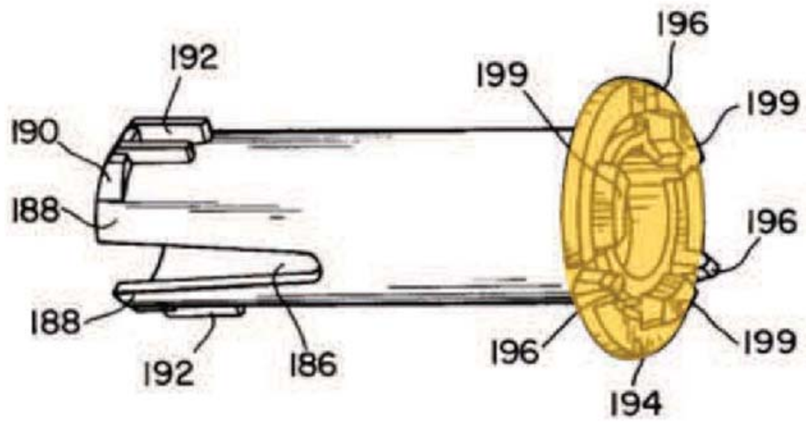


FIG. 10

213. Burroughs thus discloses that the nut 36 "comprises at least one flange," in the form of flange 194.

<u>['486] Claim 13: The housing part of claim 12, wherein said at least one flange is located near a distal portion of said driver.</u>

214. Burroughs discloses that the flange 194 of the nut 36 is positioned at the nut's needle-end. *See id.*, 9:18-22, FIGS. 10-11. Thus, Burroughs discloses that the flange "is located near a distal portion of" the nut 36.

<u>['044] Claim 14: The housing part of claim 11, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose dial grip is rotated.</u>

<u>['486] Claim 14: The housing part of claim *1*, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose *knob* is rotated.</u>

215. Burroughs discloses that housing part 26 "includes grooves formed therein to define a flexible leg 168 having an inwardly extending finger 170 at the end thereof (FIG. 5)." *See id.*, 9:4-6, FIG. 5. "Finger 170 includes tapered surfaces

172, proximal end 174, and a distal end 176." *Id.*, 9:6-8, FIG. 5. Burroughs also discloses that the distal portion 82 of the dial mechanism 34 includes "a series of elongated splines 150 extending externally about the circumference of distal portion 82." *Id.*, 8:52-56, FIGS. 6-9.

216. During dose setting, Burroughs discloses that when the user rotates the dial mechanism 34, via its proximal portion 78, "splines 150 [are caused] to move past housing finger 170." *See id.*, 10:42-44. "The rotation of each spline 150 past finger 170 constitutes a single unit dosage." *Id.*, 10:44-45. "As each spline 150 moves past finger 170, it causes a `click' to occur, thereby providing an audible indication of each unit of dosage dialed up." *Id.*, 10:45-47.

217. Thus, Burroughs discloses a "clicker" in the form of a flexible leg 168 having an inwardly extending finger 170 that rides over splines 150 of the dial mechanism 34 during dose setting. This mechanism provides "at least audible feedback," in the form of an audible click, to a user when the proximal portion 78 is rotated.

218. I note that Burroughs also teaches a "clicker" under a means-plus-function interpretation. The '044 patent and the '486 patent teach that, in dialing a dose, "flexible arm 52" with "toothed member 54" is dragged over "splines 42" to produce a click. EX1002, 5:54-60; EX1003, 5:54-60. In the alternative, when a dose is being dialed down, saw teeth 56 and saw teeth 66 ride over each other to produce

a click. *Id.*, 6:16-26; EX1003, 6:17-27. The structure taught by the ’044 patent and the ’486 patent that is used to provide the function of producing an audible click, therefore, is either a flexible arm being dragged over splines, or saw teeth riding over each other.

219. As I explained above, Burroughs discloses a clicker where a flexible arm in the form of flexible leg 168 having finger 170 drags over splines 150 of the dial mechanism 34 to produce an audible click. Accordingly, it is my opinion that Burroughs 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 that described by the ’044 patent and the ’486 patent.

[’486] Claim 15: The housing part of claim 14, wherein said clicker provides tactile feedback to a user when said dose knob is rotated.

220. Burroughs also discloses that, at the start of the dose setting process, the user rotates the proximal portion 78 of the dial mechanism 34 to set the dial 34 in the zero-dose position. *See* EX1013, 9:47-49, 9:59-61. Once the zero-dose position is reached, finger 170 engages splines 152 provided on the outer surface of the dial mechanism 34, which Burroughs discloses are extensions of splines 150. *See id.*, 8:59-61, 9:64-66, FIG. 8. “This zero-dose position is communicated to a user” by producing “a click as splines 152 engage finger 170,” and “caus[ing] a vibration in device 20 that can be felt by the user” due to finger 170’s movement into V-shaped recess 155 between splines 152. *Id.*, 9:62-66. Thus, Burroughs discloses that the

clicker "provides tactile feedback to a user," in the form of a vibration, when the proximal portion 78 of the dial mechanism 34 is rotated.

['486] Claim 16: The housing part of claim 14, wherein said clicker provides audible feedback when said dose knob is rotated in a dose increasing direction.

221. As I explained above, Burroughs discloses a "clicker" having a flexible leg 168 with a finger 170 that engages splines 150 when the dial mechanism 34 is rotated to provide "an audible indication of each unit dosage dialed up." *Id.*, 10:42-47. As such, Burroughs discloses that the clicker "provides audible feedback" when the proximal portion 78 of the dial mechanism 34 "is rotated in a dose increasing direction."

['486] Claim 17: The housing part of claim 14, wherein said clicker provides audible feedback when said dose knob is rotated in a dose decreasing direction.

222. Burroughs discloses that, during dose setting, "dosage may be made larger or smaller by rotating the dial assembly in either the clockwise or counterclockwise direction." *Id.*, 10:49-52. As I discussed above, when the dial mechanism 34 is rotated, splines 150 move past finger 170 to cause an audible indication in the form of a "click." *Id.*, 10:42-47. Although Burroughs only explicitly discloses that this movement provides an audible indication for "each unit dosage dialed up," it is my opinion that a person of ordinary skill would have understood that the same audible indication would be produced when the user rotated the dial

mechanism 34 in an opposite, dose decreasing position. Specifically, because Burroughs discloses that the dial mechanism 34 may be rotated in either direction to make the dose larger or smaller, a person of ordinary skill would have understood that the same mechanism for producing a "click" during dose dialing up—that is, the rotation of splines 150 past finger 170—would work the same to produce a "click" when the user rotates the dial mechanism 34 in the opposite direction to dial down a dose.

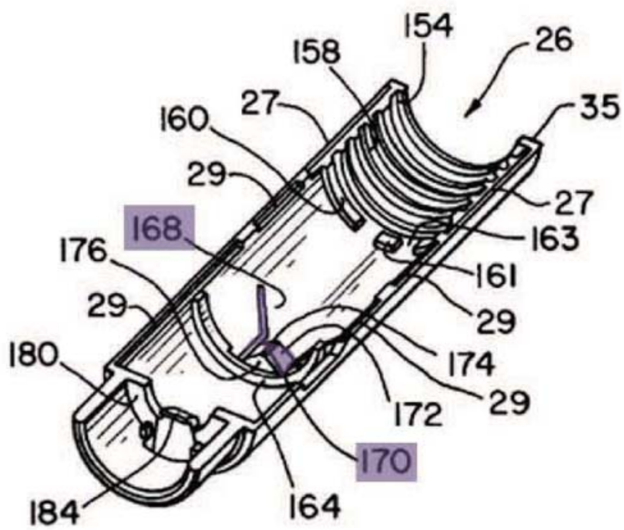
223. Accordingly, it is my opinion that Burroughs teaches that the clicker "provides audible feedback" when the proximal portion 78 of the dial mechanism 34 "is rotated in a dose decreasing direction."

['044] Claim 15: The housing part of claim 14, wherein said clicker comprises, [15.1] at least one flexible arm, said flexible arm comprising at least one tooth member, and [15.2] at least one spline, [15.3] wherein when said dose dial grip is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.

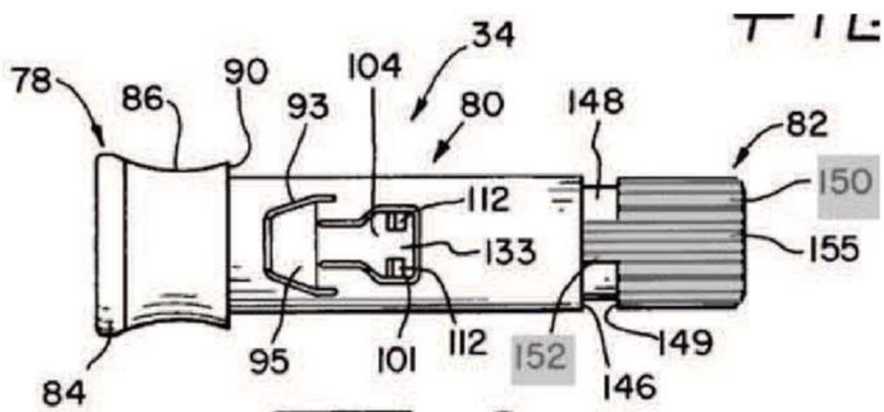
['486] Claim 18: The housing part of claim 14, wherein said clicker comprises, [18.1] at least one flexible arm, said flexible arm comprising at least one tooth member, and [18.2] at least one spline, [18.3] wherein when said dose *knob* is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.

224. As I noted above, Burroughs discloses a "clicker" that includes a flexible leg 168, provided on the inner surface of housing part 26, which has an inwardly extending finger 170 at its end. *See id.*, 9:4-6, FIGS. 2-3. It is my opinion that a person of ordinary skill would have understood the flexible leg to constitute a

"flexible arm," and the finger 170 to constitute a "tooth member" at its end. Below, I have reproduced FIG. 3, where I have annotated the flexible leg 168 and finger 170 in purple:



225. The "clicker" also includes "a series of elongated splines 150 extending externally about the circumference of distal portion 82" of the dial mechanism 34. *Id*., 8:52-61, FIGS. 6-9. Below, I have reproduced FIG. 8, where I have annotated the splines 150 (and their corresponding extensions 152) in gray:



226. As I also explained above, Burroughs discloses that when the user rotates the dial mechanism 34, via its proximal portion 78, "splines 150 [are caused] to move past housing finger 170," and "[a]s each spline 150 moves past finger 170, it causes a `click' to occur, thereby providing an audible indication of each unit of dosage dialed up." *See id.*, 10:42-47. Given the flexible nature of flexible leg 168, it is my opinion that a person of ordinary skill would have understood that the flexible leg 16 would deform and drag the finger 170 over the splines 150 to provide such audible indication.

227. Accordingly, Burroughs teaches that the "clicker" includes "at least one flexible arm," in the form of a flexible leg 168, having "at least one tooth member," in the form of a finger 170 at its end, and "at least one spline," in the form of a series of elongated splines 150, where when the proximal portion 78 of the dial mechanism 34 is rotated, the flexible leg 168 "deforms and drags" the finger 170 over the splines 150 "so as to provide said audible feedback."

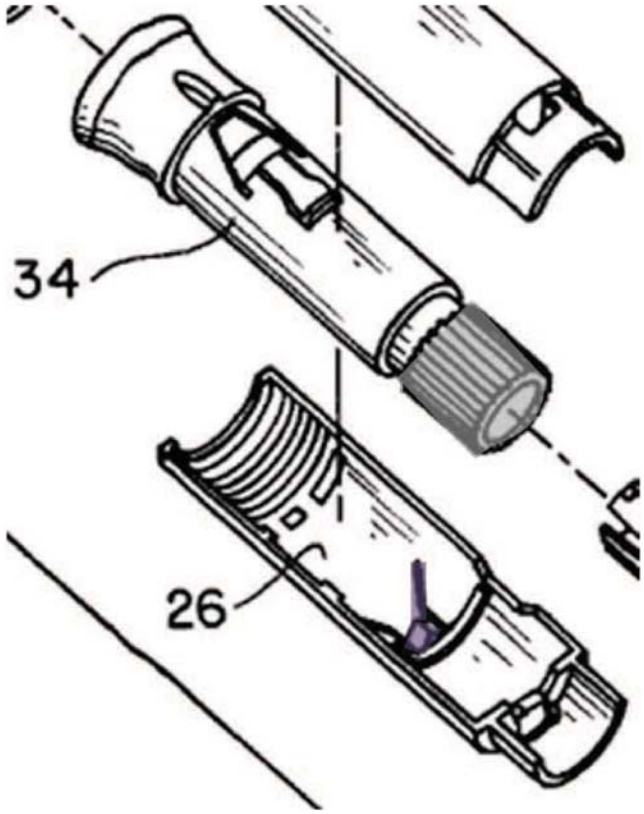
['486] Claim 20: The housing part of claim 14, wherein [20.1] said clicker generally comprises a cylindrical shape having a first and a second end, and [20.2] said cylindrical shape is provided at said first end with at least one flexible extending arm.

228. Burroughs discloses that the splines 150 extend externally about the circumference of distal portion 82 of the dial mechanism 34. *Id.*, 8:52-61, FIGS. 69. As shown in FIG. 8, the distal portion 82 having the splines 150 forms "a cylindrical

shape." *See id.*, FIGS. 6-8. Moreover, the cylindrical shape extends from "a first end" (*i.e.*, a button-end) to "a second end" (*i.e.*, a needle-end). *See id.*

229. Burroughs also discloses that the finger 170 of the flexible leg 168 is provided at the button-end of the splines 150 during use. For instance, when the user first rotates the dial mechanism 34 to bring it into its zero-dose position, the finger 170 is retained within a groove 148 positioned at the button-end of the splines 150. *See id.*, 8:59-61, 9:49-52. When the user rotates the dial mechanism 34 to its zero-dose position, the finger 170 engages with splines 152 (which are extensions of splines 150) at the button-end. *See id.*, 8:59-61, 9:59-61. The user can then retract the dial mechanism 34 slightly to put it in its dose-setting position, where the finger 170 remains engaged with the splines 150 at the button-end. *See id.*, 10:15-21. Thus, given this engagement and positioning with the button-end of the splines 150, it is my opinion that the "cylindrical shape," formed by the splines 150 on the distal portion 82, is "provided ... with" the finger 170 of the flexible leg 168 at its button-end.

230. Below, I have reproduced a partial view of FIG. 2, showing the clicker in detail, where I have annotated the splines 150 in gray and the flexible leg 168 having finger 170 in purple:



231. Accordingly, it is my opinion that Burroughs discloses that the "clicker generally comprises a cylindrical shape," in the form of the cylindrical shape of splines 150 extending circumferentially about distal portion 82, that "ha[s] a first and a second end," where the splines 150 of the distal portion 82 are "provided at [its] first end with" the flexible leg 168 having finger 170.

232. To the extent that the flexible arm of the clicker must be attached to, rather than simply provided with, the "cylindrical shape," it is also my opinion that it would have been readily apparent to a person of ordinary skill to have reversed the splines 150 and flexible leg 168 such that the flexible leg 168 was attached to the button-end of the cylindrical shape of the distal portion 52.

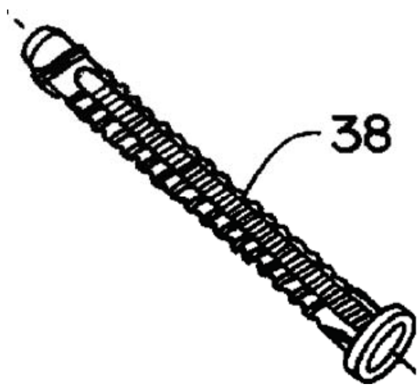
233. In pen-type injectors, the use of structures that provide an audible "click" to indicate to the user progression of a dose-dialing and/or dispensing-step was a well-known and commonly-used tool to the person of ordinary skill at the relevant time. *See, e.g.*, EX1021, 5:1-4 (ratchet fingers and ratchet); EX1022, 7:10-20 (clicker 42g engaging splines 22b; ridge 42d engaging grooves 38a); EX1023, 4:29-35, 6:3-7 (tang 94 engaging linear markings 96); EX1020, 13:3-5 (clicker mechanism 34), EX1024, 4:38-41, 6:28-37 (resilient arms 58 and detents 32). One method to accomplish such a feature was to provide a flexible, elongated arm that, when rotated relative to a series of ridges or splines, produce a clicking sound as the flexible arm moves over the splines and into the recesses formed between neighboring splines. *See, e.g.*, EX1014, 11:48-52, FIGS. 15-17; EX1024, 4:38-41, 6:28-37, FIGS. 2, 4; EX1020, 13:3-5, FIG. 4. A person of ordinary skill would have also understood that placement of the flexible arm and placement of the ridges or splines were largely interchangeable. For instance, Horstman incorporates a similar clicking mechanism as Burroughs, but instead provides the flexible arm (resilient arms 58) on the component that is rotated, and the ridges (detents 32) on the housing. *See* EX1024, 4:38-41, 6:28-37, FIG. 4. The effect, however, is the same: the flexible arm moves over the ridges and into recesses between neighboring ridges to produce audible clicks. *See id.*, 6:66-7:13.

234. With regard to Burroughs, it is my opinion that a person of ordinary skill would have understood that this principle would apply to the flexible leg 168 and splines 150. Specifically, a person of ordinary skill would have understood that the clicking operability between the components would be retained if the splines 150 were provided on the inner surface of the housing, and the flexible leg 168 were provided on the outer surface of the distal portion 82 of the dial mechanism 34. It would have been readily apparent to the person of ordinary skill to configure the splines 150 on the housing in order to retain the clicking function of the flexible arm as it initially engaged the extended splines 152, and then continued to engage the splines 150, during the dose setting process. A person of ordinary skill also would have expected that such an arrangement would operate in substantially the same manner as the clicker disclosed in Burroughs, thus retaining the clicker's general operability.

235. Thus, to the extent that the claim requires the flexible arm to be attached to the "cylindrical shape," it is my opinion that it would have been readily apparent to the person of ordinary skill to switch the features of Burroughs' clicker such that the splines 150 were provided on the housing 22, and the flexible arm 168 were provided on the distal portion 82.

['486] Claim 23: The housing part of claim 1, wherein said piston rod comprises a generally circular cross section.

236. Burroughs discloses that the leadscrew 38, which includes helical threads 208 extending along its axial length and ratchet teeth 204 located on two opposing sides, "fits within the cylindrical opening of nut 36." *Id*., 9:26-32, FIGS. 1-2, 12. Burroughs also shows that the leadscrew 38 includes a cross section that is "generally circular." To illustrate the "generally circular" cross-section of the leadscrew 38, I have reproduced below a partial view of FIG. 2 (left) and FIG. 12 (right), which show the leadscrew 38 in greater detail:



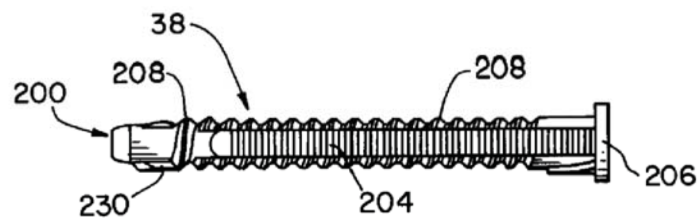


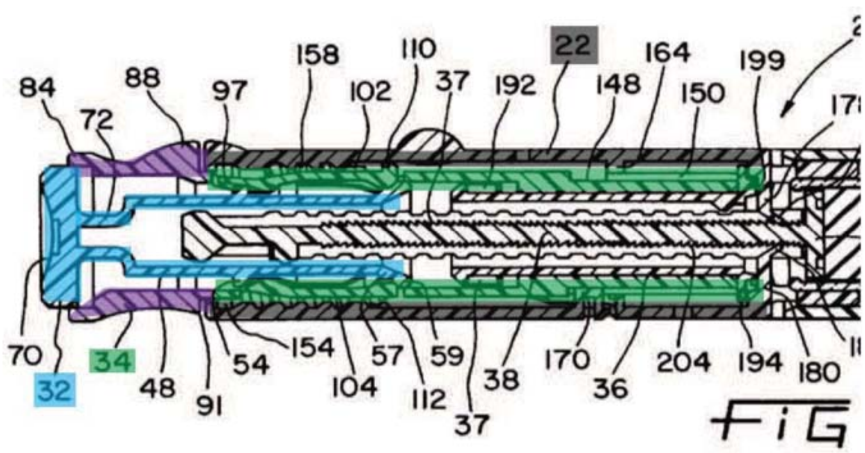
FIG. 12

237. Based on the above, it is my opinion that a person of ordinary skill would have understood the leadscrew 38 of Burroughs to have "a generally circular cross section."

['044] Claim 18: The housing part of claim 11, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.

['486] Claim 26: The housing part of claim 1, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.

238. As I noted above, Burroughs discloses that the dial mechanism 34 is positioned within the housing 22. *See supra*, ¶161. I also explained that Burroughs discloses that the button 32 extends within the dial mechanism 34. *See supra*, ¶¶182-87. Therefore, Burroughs discloses that the dial mechanism 34 "is provided outside" the button 32 and "radially inward of" the housing 22. To further illustrate the relative positioning between these components, I have reproduced a partial view of FIG. 1, where I have annotated the housing 22 in gray, the dial mechanism 34 in green, and the button 32 in blue:[25]



[25] Again, to illustrate the extent of the dial mechanism 34, I have also annotated the proximal portion 78 of the dial mechanism 34 in purple.

['044] Claim 19: The housing part of claim 11, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve.

['486] Claim 27: The housing part of claim 1, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve.

239. As I detailed above, it is my opinion that a person of ordinary skill would have found it obvious to configure the "helical rib" of Burroughs' dial mechanism 34 to be a "helical groove" that engages an internal threading of the housing 22. *See supra*, ¶¶166-72. A person of ordinary skill would have understood that a corresponding "helical rib" provided on the inner surface of the housing 22 would have been provided to engage the "helical groove" of the dial mechanism 34 to maintain the rotational engagement between the components during dose setting. Accordingly, it is my opinion that Burroughs renders this feature obvious.

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

240. As shown in FIGS. 3 and 5, the helical groove 158 of the housing 22 continuously extends an axial distance along the housing 22's inner surface. Thus, the helical groove 158 "extends for at least a single sweep of" the housing 22's inner surface. A person of ordinary skill would have understood that, even if provided as a helical rib, the rib would similarly "extend[] at least a single sweep of" the housing's inner surface to allow the user to sufficiently rotate the dial mechanism 34 out of the housing 22 during dose setting.

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

241. The "start" on a threading refers to the number of individual, helical threads that make the overall threading. For instance, for a "single-start thread," the threading consists of a single, helical thread, whereas a "double-start thread" consists of two, helical threads that are intertwined. The "start" on the thread determines the thread's "lead" (the axial distance the threaded component travels when rotated one full revolution) relative to the thread's "pitch" (the axial distance between consecutive ridges on the thread). *See, e.g.*, EX1005, 3:56-67. That is, the thread's "lead" is equal to the thread's "pitch" multiplied by its number of starts. So, for example, if the thread is a "single-start" thread, its "lead" is equal to its "pitch." If the thread is a "double-start" thread, its "lead" is twice its "pitch."

242. Whether a single-start thread or a multi-start thread is used depends on the choice and needs of the design engineer. For instance, with a multi-start thread having the same pitch as its single-thread counterpart, the lead is greater, allowing the user to axially move the component a greater distance over a smaller number of revolutions, allowing for more efficient movement. For many purposes, however, a single-start thread is often used. This is because, with higher axial loads, a multi-start thread is less likely to lock the components to one another when the components are not being rotated (due to a steeper angle of the helix). Nevertheless, if less force to rotate a component is desired, a person of ordinary skill would have understood

that the same effect could be accomplished with a single-start thread, provided at a high pitch. Moreover, single-start threads are comparatively easier to manufacture. Thus, a person of ordinary skill would have understood that a multi-start thread and a single-start thread have certain advantages and disadvantages, with each providing the same functionality: relative rotational movement between threaded components.

243. Burroughs does not explicitly disclose whether the helical groove 158 of the housing 22 is a single start thread. I note, however, due to the offset positioning of the threads 110, 112, a person of ordinary skill would have understood that the threads 110, 112 would likely be a single-start thread because, if each threads 110, 112 had their own start, the threads 110, 112 would not need to be offset. In any case, it is my opinion that a person of ordinary skill would have readily understood that the helical groove 158 may be provided as a "single start" thread or a "multi-start" thread and still achieve the same purpose. That is, a person of ordinary skill would have understood that a "single-start" thread, like a "multi-start" thread, could readily achieve the purpose of allowing for the rotational movement of the dial mechanism 34 relative to the housing 22 during dose dialing, and that each type of thread would have their own advantages or disadvantages. And, as I mentioned above, a person of ordinary skill also would have considered it readily apparent to provide a helical rib, rather than a helical groove, on the inner surface of the housing.

Even if provided as a helical rib, a person of ordinary skill would have understood that such an arrangement would have the same effect as a helical groove.

244. Accordingly, it is my opinion that a person of ordinary skill would have understood that the housing 22 may be provided with a "helical rib" that "comprises a single start helical rib."

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

245. Burroughs discloses a number of "radial stops" that prevent the user from rotating, or otherwise moving, a component during use. For instance, Burroughs discloses that the dial mechanism 34's threads 110, 112 include a proximal shoulder 130 and shoulder 138, respectively. *Id.*, 8:33-37. As shown in FIG. 9, which I have reproduced below, shoulders 130, 138 extend radially outward from the outer surface of the dial mechanism 34 and are provided at an end of the helical rib formed by threads 110, 112:

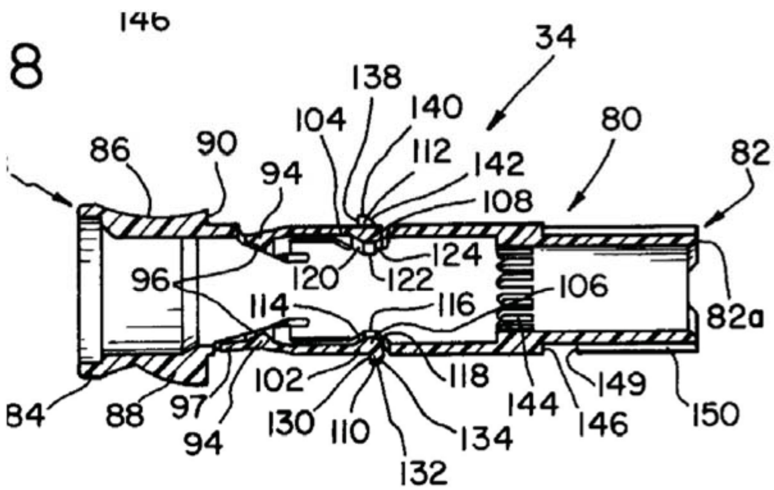


FIG. 9

246. Burroughs discloses that, prior to positioning the dial mechanism 34 into its zero-dose position, the user is prevented from axially retracting the dial mechanism 34 relative to the housing 22 due to the shoulders' engagement with circumferential surface 160 provided on the inner surface of the housing 22. *See id.*, 8:63-65, 9:54-56, FIGS. 3, 5, 9. Thus, the shoulders 130, 138 of the threads 110, 112 act as a "radial stop" by preventing the user from retracting the dial mechanism 34 before it is positioned into its zero-dose position. When modified as a "helical rib," a person of ordinary skill would have understood that retaining the shoulders 130, 138 on the button-end side of the helical rib would retain this function of preventing axial movement of the dial mechanism 34 prior to the dial mechanism 34 entering into its zero-dose position.

247. Accordingly, Burroughs teaches that the dial mechanism 34 includes "at least one radial stop," in the form of shoulders 130, 138, "positioned near an end of [the] helical rib."

248. Burroughs also teaches that a "radial stop" may be provided on a needle-end side of the ring 90 of the proximal portion 78. Specifically, Burroughs teaches that the device contains an "end-of-injection stop feature [that] limits axial movement of dial mechanism 34 and nut 36 relative to housing 22" when the entire dose has been dispensed. *Id.*, 11:45-46. Burroughs shows that this stop feature may be provided by "raised surface 199 of nut flange 194 [that] engage[s] bulkhead ledge 178 and 180 of housing 22." *Id.*, 11: 47-48, FIGS. 1, 3, 5, 10-11. Burroughs also discloses that "[i]n another embodiment, the end-of-injection stop may be designed to occur between ring 90 and proximal end surfaces 33, 35 of housing parts 24, 26, respectively." *Id.*, 11:47-50, FIGS. 1, 3, 5-9. Thus, a person of ordinary skill would have understood Burroughs as teaching that a "radial stop" may be provided on the needle-end side of the ring 90 of the proximal portion 78 to prevent the user from further moving the dial mechanism 34 and nut 36 axially toward the device's needle-end once the entire set dose has been dispensed. Below, I have reproduced FIG. 7, which shows ring 90, which radially extends from the outer surface of the housing 22, and is positioned near an end of the helical threading formed by threads 110, 112:

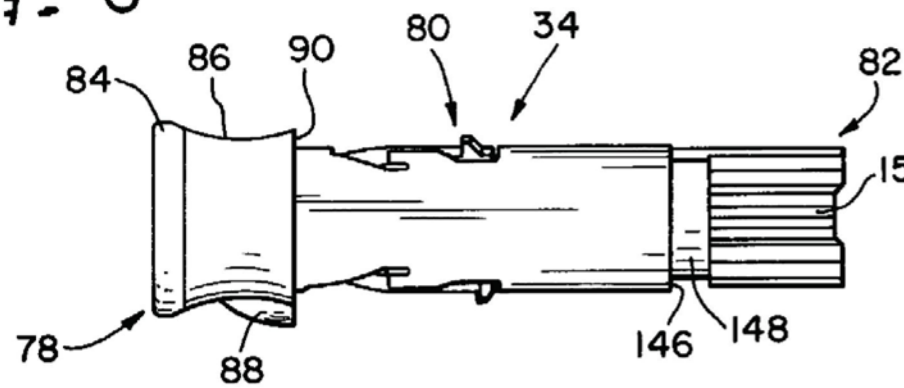


FiG. 7

249. Accordingly, it is my opinion that Burroughs teaches another "radial stop," in the form of a stop on the needle-end side of the ring 90 that engages with surfaces 33, 35 provided on the button-end side of the housing 22, that is "positioned near an end" of threads 110, 112.

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

250. As shown in FIG. 7 above, given the axial extent of the threads 110, 112, it is my opinion that a person of ordinary skill would have understood that the shoulders 130, 138 of threads 110, 112 were "positioned near a distal end [*i.e.*, needle-end] of" the helical threading formed by threads 110, 112, even when formed as a helical groove. In addition, a person of ordinary skill would have understood that any radial stop provided on the needle-end side of the ring 90 would be "positioned near a distal end of" the threading formed by threads 110, 112, even when formed as a helical groove.

['486] Claim 33: The housing part of claim 1, wherein if a user inadvertently dials said dose knob in one direction beyond a desired dose, said dose knob may be rotated in a second direction so as to allow said dialed dose to be reduced.

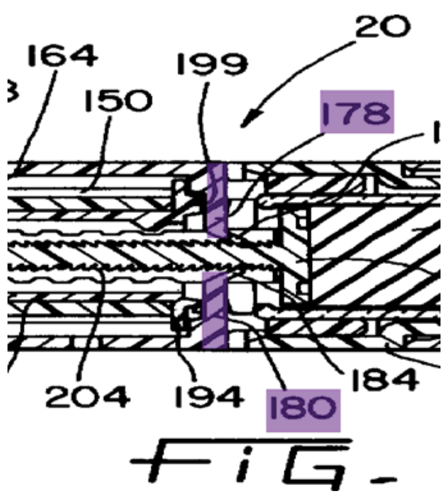
251. Burroughs discloses that, during dose setting, "dosage may be made larger or smaller by rotating the dial assembly in either the clockwise or counterclockwise direction." *Id.*, 10:49-52. Thus, a person of ordinary skill would have understood Burroughs to teach that "if a user inadvertently dial[ed]" the proximal portion 78 of the dial mechanism 34 "in one direction beyond a desired dose," the proximal portion 78 of the dial mechanism 34 "may be rotated in a second direction so as to allow [the] dialed dose to be reduced."

['486] Claim 36: The housing part of claim 1, wherein said housing part and said container comprises a disposable device.

252. First, I note that the claim term "container" does not appear in claim 1, which claim 36 depends. Nevertheless, I note that Burroughs contains a fluid "container" that contains a medicine in the form of a cartridge 40. *See, e.g.*, *id.*, 7:35, 2:42-44, FIGS. 1-2. Burroughs also discloses that the device is recyclable, "making disposal of the device environmentally desirable." *Id.*, 7:44-46. Accordingly, it is my opinion that a person of ordinary skill in the art would have understood that the device disclosed in Burroughs discloses that the housing 22 and a container, in the form of a fluid-filled cartridge 40, "comprises a disposable device."

[’486] Claim 38: The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main housing, said insert secured against rotation.

253. Burroughs discloses that the housing 22 includes bulkhead ledges 178, 180, which include flexible tangs 182, 184, respectively. *Id.*, 9:8-11, FIGS. 1, 3, 5. The flexible tangs 182, 184 are configured to engage with ratchet teeth 204 of leadscrew 38 to prevent its movement in the button-end direction during dose setting. *See id.*, 10:26-28, 11:51-55. The bulkhead ledges 178, 180 are integral parts of the housing 22, and thus are secured against rotation relative to the housing 22. I note that the ’486 patent expressly contemplates an insert that is integral with the housing, *see* EX1003, 3:53-55, and thus bulkhead ledges 178, 180 are consistent with the specification of the ’486 patent. Reproduced below is a partial view of FIG. 1, toward the device’s needle-end, where I have annotated bulkhead ledges 178, 180 in purple, which are shown to be provided at a needle-end of the housing 22:



254. Accordingly, Burroughs discloses "an insert," in the form of bulkhead ledges 178, 180, that is "provided at a distal end" of the housing 22, where the bulkhead ledges 178, 180 "are secured against rotation."

['486] Claim 39: The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main housing, and said insert secured against longitudinal motion.

255. As I discussed above, Burroughs discloses "an insert," in the form of bulkhead ledges 178, 180, that is "provided at a distal end" of the housing 22. Because the bulkhead ledges 178, 180 are integrally formed with the housing 22, the bulkhead ledges 178, 180 are "secured against longitudinal motion" relative to the housing 22.

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

256. As shown in FIG. 1, the bulkhead ledges 178, 180 form an opening, which allows leadscrew 38 to extend therethrough to allow it to engage a piston 210 of the cartridge 40 for dose dispensing, and which allows the flexible tangs 182, 184 to engage the ratchet teeth 204 of the leadscrew 38. *See id.*, 9:32-34, 10:26-28, 11:51-55, FIG. 1.

257. Accordingly, Burroughs discloses that the bulkhead ledges 178, 180 include "an opening extending therethrough, such that" the leadscrew 38 "is configured to extend through [the] opening."

B. ['069] Ground 2: Claim 1 is Obvious over Steenfeldt-Jensen; ['044-B] Ground 1: Claims 11, 14-15, and 18-19 are Obvious over Steenfeldt-Jensen; ['486-A2] Ground 1: Claims 1-6, 12-18, 20, 23, 26-30, 32-33, 36, and 38-40 are Obvious over Steenfeldt-Jensen

258. Like above, my analysis first focuses on the independent challenged claims of the '069 patent, the '044 patent, and the '486 patent, and then moves on to the dependent challenged claims of the '044 patent and the '486 patent. In cases where a given clause of one patent contains identical or substantially identical language as a clause of another patent, I group those clauses together. For those clauses that are substantially identical, I italicize those words that differ from the first-listed clause. The analysis that follows equally applies to each of the grouped clauses, except where I specifically note any differences. To indicate the patent to which the clause pertains, I provide brackets preceding a particular clause that contains the last three numbers of the patent to which it relates.

1. Independent claim 1 of the '069 patent, independent claim 11 of the '044 patent, and independent claim 1 of the '486 patent

259. As explained in detail below, it is my opinion that Steenfeldt-Jensen teaches a housing part for a medication dispensing apparatus that includes each and every element of claim 1 of the '069 patent, claim 11 of the '044 patent, and claim 1 of the '486 patent, and thus Steenfeldt-Jensen renders those claims obvious.

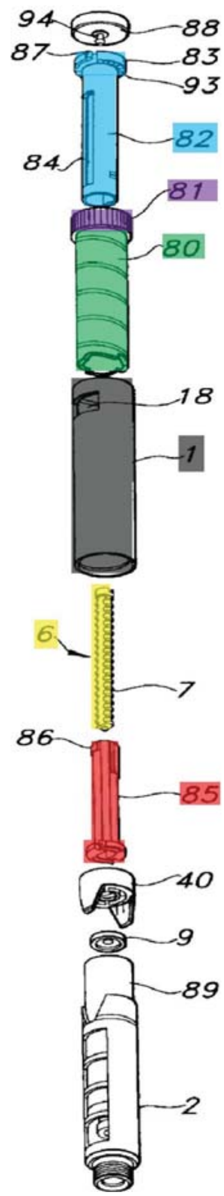
260. Each section of claim 1 of the '069 patent, claim 11 of the '044 patent, and claim 1 of the '486 patent is presented below in bold text followed by my

analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

['069] Claim 1, preamble/['044] Claim 11, preamble/['486] Claim 1, preamble: A housing part for a medication dispensing apparatus, said housing part comprising:

261. Steenfeldt-Jensen discloses "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; *see also id.*, Abstract. The syringe includes "a tubular housing 1," which houses the drive mechanism for dispensing medicine from the device. *See id.*, 5:38-44, FIGS. 15-17. Thus, Steenfeldt-Jensen teaches "[a] housing part for a medication dispensing apparatus."

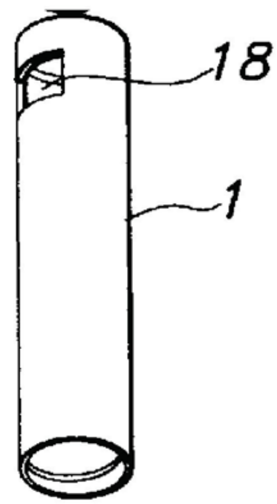
262. Below, I have reproduced an annotated FIG. 17 of Steenfeldt-Jensen, which highlights the six components forming the drive mechanism in more detail:

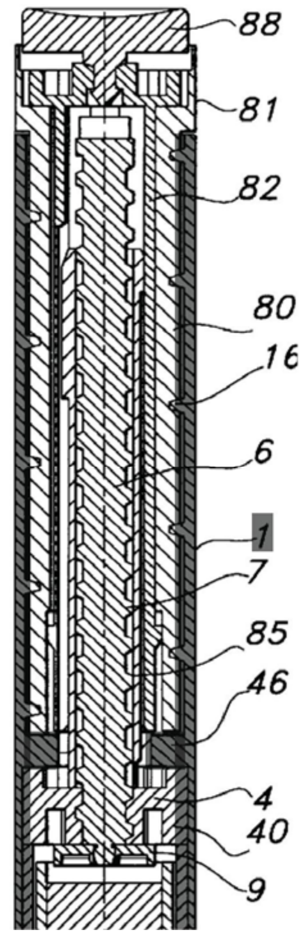


['069] Claim 1.1/['044] Claim 11.1/['486] Claim 1.1: a main housing, said main housing extending from a distal end to a proximal end;

263. Steenfeldt-Jensen's device includes a "main housing" in the form of a "tubular housing 1," which extends from a needle-end to a button-end. *See id.*, 5:38-44, claim 11, FIGS. 15-17. Below-left, I have reproduced a partial view of FIG. 17

that shows the tubular housing 1 in greater detail. Below-right, I have reproduced a partial view of FIG. 16, where I have annotated the tubular housing 1 in gray.



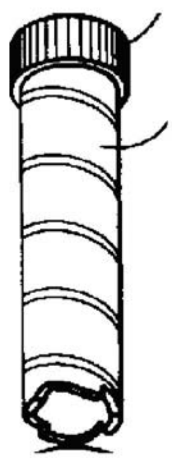


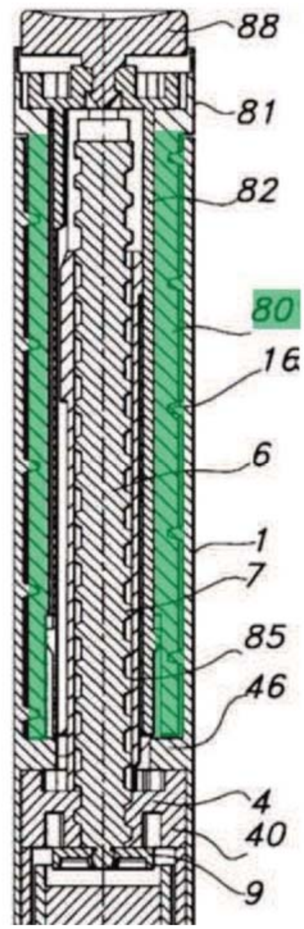
<u>['069] Claim 1.2/['044] Claim 11.2: a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, *said helical groove provided along an outer surface of said dose dial sleeve*;</u>

<u>['486] Claim 1.2: a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing;</u>

264. Steenfeldt-Jensen's device also includes a scale drum 80 that "is in its outer wall provided with a helical track [*i.e.*, a helical groove] which is engaged by a helical rib 16 along the inner wall of the housing 1." *Id.*, 11:20-22, FIGS. 15-17.

Via this groove-to-rib engagement, the scale drum 80 rotates and moves axially relative to the housing 1 during dose setting and injection. *See id.*, 11:52-54, 12:49. Below-left, I have reproduced a partial view of FIG. 17 that shows the scale drum 80 in greater detail. Below-right, I have reproduced a partial view of FIG. 16, where I have annotated the scale drum 80 in green, which shows the drum positioned within the housing 1.





265. Thus, Steenfeldt-Jensen teaches a "dose dial sleeve" in the form of a scale drum 80 that is "positioned within" the tubular housing 1 and has "a helical

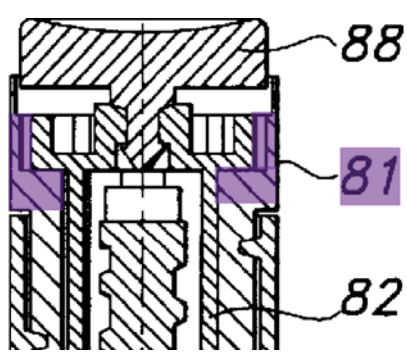
groove" that is "provided along an outer surface" and "configured to engage a threading provided by" the tubular housing 1.

['069] Claim 1.3/['044] Claim 11.3: a dose dial grip disposed near a proximal end of said dose dial sleeve;

['486] Claim 1.3: a dose *knob* disposed near a proximal end of said dose dial sleeve;

266. The scale drum 80, at its button-end, "has a diameter exceeding the inner diameter of the housing to form a dose setting button 81, which on its cylindrical outer wall is knurled to ensure a good finger grip." *Id.*, 11:22-25; FIGS. 15-17. As Steenfeldt-Jensen explains, during dose setting, the user rotates the dose setting button 81 to screw the scale drum 80 in and out of the housing. *See id.*, 11:52-62. Thus, Steenfeldt-Jensen teaches "a dose dial grip," or "a dose knob," in the form of a dose setting button 81 that is "disposed near a proximal end" of the dose scale drum 80.

267. Below, I have reproduced a partial view of FIG. 16, showing a portion of the device near its button-end, where I have highlighted the dose setting button 81 in purple:

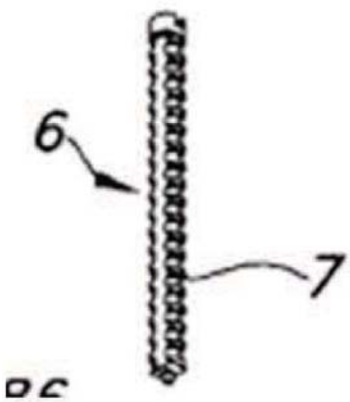


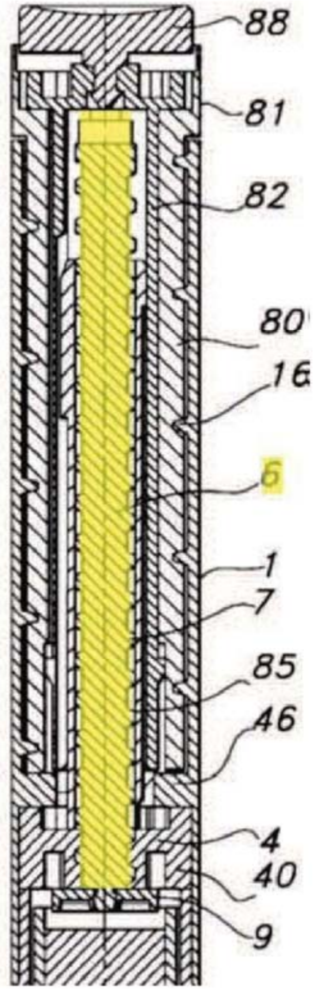
['069] Claim 1.4/['044] Claim 11.4/['486] Claim 1.4: a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;

268. The device further includes a piston rod 6, which has an external thread 7 that mates with an internal thread 5 of a central bore of an end wall 4. *See id.*, 5:55-58. In the device shown in FIGS. 15-17, the end wall 4 is provided as a separate member 40 that is rotationally and axially fixed within the housing. *See id.*, 8:35-42, FIGS. 15-17. Moreover, the piston rod 6 engages with member 40 such that "an anticlockwise rotation of the piston [rod] will screw the piston rod through said end wall and into the cartridge holder compartment." *Id.*, 11:11-15.

269. Steenfeldt-Jensen further describes that the device includes a driver tube 85 (described in further detail below), which includes a bore having a "not round cross-section" through which the piston rod 6, also having a not round cross-section, extends. *Id.*, 11:15-17. "This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube." *Id.*, 11:1719.

270. Below-left, I have reproduced a partial view of FIG. 17 that shows the piston rod 6 in greater detail. Below-right, I have reproduced a partial view of FIG. 16, where I have annotated the piston rod in yellow. As FIG. 16 shows, the piston rod is provided within the tubular housing 1.





271. Steenfeldt-Jensen also discloses that the driver tube 85 is operably connected to the member 40 via a pawl mechanism. *See id.*, 8:49-53, 11:6-11.[26] The

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[26] The portion of Steenfeldt-Jensen that particularly discusses the pawl mechanism is in the context of the driver tube 45 shown in FIGS. 11-13. *See id.*, 8:34-35, 8:49-53. Although not specifically annotated in FIGS. 15-17, I note that the driver tube 85 includes a pawl structure at its needle-end similar to that of driver tube 45, which includes a pawl 13 at its needle-end that engages with pawl teeth in the member 40.

pawl mechanism prevents rotation of the driver tube 85 relative to the housing in the clockwise direction, but reluctantly allows rotation in the anticlockwise direction. *See id.*, 11:6-11. Thus, during dose setting, when the user rotates the dose setting button 18 in the clockwise direction, the driver tube 85 is prevented from rotating due to the pawl mechanism. *Id.*, 11:52-57. Similarly, when "a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction," the driver tube 85 is again prevented from rotating because the pawl mechanism "is sufficient[ly] reluctant" so as to bar the driver tube's anticlockwise rotation. *See id.*, 11:57-62. Therefore, because Steenfeldt-Jensen discloses that the driver tube 85 does not rotate relative to the housing during dose setting, and because the piston rod 6 is rotationally fixed relative to the driver tube 85, the piston rod 6 also does not rotate relative to the housing during dose setting.

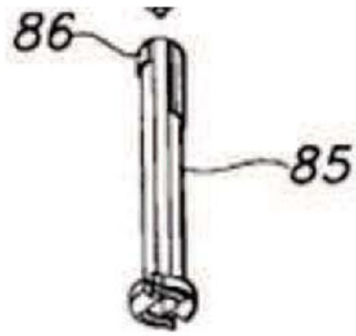
272. Accordingly, Steenfeldt-Jensen teaches a "piston rod" in the form of piston rod 6 that is "provided within" the housing 1 and "is non-rotatable during a dose setting step relative to" the housing 1.

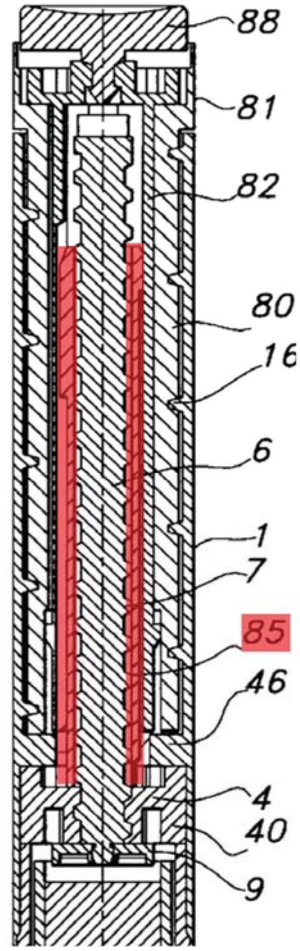
Compare id., FIG. 13*, with id.*, FIG. 17. Given this structural similarity, it is my opinion that a person of ordinary skill would have understood that the pawl mechanism of driver tube 85 engages with the member 40 in a similar manner as that described for driver tube 45. *See id.*, 8:49-53.

<u>['069] Claim 1.5/['044] Claim 11.5: a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and,</u>

<u>['486] Claim 1.5: a *driver* extending along a portion of said piston rod, said *driver* comprising an internal threading near a distal portion of said *driver*, said internal threading adapted to engage an external thread of said piston rod; and,</u>

273. As noted above, Steenfeldt-Jensen's device includes a driver tube 85 having a bore with a non-circular cross-section through which the piston rod 6, also having a non-circular cross-section, extends. *See id.*, 11:15-17. Due to this coupling, when the driver tube 85 is rotated in the anticlockwise direction in a manner sufficient to overcome the pawl mechanism's initial reluctance (*i.e.*, during injection, described more below), its rotation is transmitted to the piston rod 6, causing the rod to rotate through the internal threading provided in the member 40 and into the cartridge holder compartment. *See id.*, 11:6-19. Below-left is a partial view of FIG. 17, which shows the driver tube 85 in greater detail. Below-right is a partial view of FIG. 16, where I have annotated the driver tube 85 in red.





274. Based on the above, the driver tube 85 thus constitutes a "drive sleeve" or "driver" that "extend[s] along a portion of" the piston rod 6. And, applying Sanofi's construction of the term, the driver tube 85 is also "releasably connected" to the scale drum 80: the driver tube 85 couples to the scale drum 80's rotational movement only during the injection process. To drive the piston rod 6, the driver tube 85 rotationally engages with the rod through a bore having a non-circular cross-section, rather than "an internal threading near a distal portion." It is my opinion, however, that a person of ordinary skill would have found it obvious to modify the

Steenfeldt-Jensen's device such that the driver tube 85 includes an internal threading near a distal portion for engagement with an external thread on the piston rod.

275. Steenfeldt-Jensen expressly contemplates embodiments where the driver tube contains an internal threading that engages the piston rod's threading. *See id.*, 7:44-47. Specifically, after discussing its first embodiment, Steenfeldt-Jensen notes that "[e]mbodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention." *Id.* In other places, Steenfeldt-Jensen similarly notes that, when the injection button is pressed axially, movement of the button can be transformed into a rotation of: (1) the piston rod relative to the nut member; or (2) the nut member relative to the piston rod. *See id.*, 3:15-20; *see also id.*, 3:44-47 (similarly stating that the driver tube can "rotat[e] the piston rod (or the nut member) relative to the nut member (or the piston rod)").

276. In summarizing its invention, Steenfeldt-Jensen explains that the "piston rod guide" is a structure that in which "the piston rod is axially displaceable but not rotatable," whereas the nut element (or nut member) is a structure that allows for relative rotation of the piston rod via an internal thread mating with an external thread of the piston rod. *See id.*, 2:46-53. In view of this disclosure, together with the description provided for FIGS. 15-17, it is my opinion that a person of ordinary skill would have understood that the driver tube 85 includes a "piston rod guide" in

the form of its non-circular bore, which, consistent with Steenfeldt-Jensen's explanation, transmits rotational movement, but allows the piston rod to axially move relative to the bore. Similarly, a person of ordinary skill would have understood that the member 40 includes a "nut element" in the form of an opening in its end wall 4 that includes internal threading for engaging with the threading of the piston rod.

277. Given Steenfeldt-Jensen's suggestion that the "nut element" could be provided on the driver tube, while the "piston rod guide" could be provided on in the end wall 4, it is my opinion that a person of ordinary skill would have immediately recognized that the embodiment described in FIGS. 15-17 could be modified such that (1) the driver tube 85 included an internal threading for engaging the piston rod's external threading (*i.e.*, a "nut element"), and (2) the end wall 4 of the member 40 included a non-circular bore through which the piston rod extended to axially guide the piston rod (*i.e.*, a "piston rod guide"). In such a case, a person of ordinary skill would have considered the modified driver tube 85 to constitute a "drive sleeve" or "driver" having "an internal threading near a distal portion" of the driver tube 85 that is "adapted to engage an external thread" of the piston rod.

278. It is also my opinion that, with this modification, a person of ordinary skill in the art would have reasonably expected the device to operate in substantially the same manner. That is, a person of ordinary skill would have understood that,

when the driver tube 85 is rotated during injection, its internal threading would rotate within the external threading of the piston rod. Because (1) the driver tube 85 is prevented from moving axially relative to the housing due to its positioning between the housing's ring-shaped wall 46 and the member's end wall 4 (*see id.*, 8:48-53), and (2) the piston rod is prevented from rotating relative to the housing due to its engagement with the non-circular bore of the modified member 40, the driver tube's rotation would cause the piston rod to move axially through the end wall 4 of the member 40 to dispense medicine. A person of ordinary skill would have recognized that this would retain the same dispensing function for the device: transforming rotational movement of the driver tube into axial movement of the piston rod.

279. In view of the above, it is therefore my opinion that Steenfeldt-Jensen renders the claimed "drive sleeve" or "driver" obvious.

['069] Claim 1.6/['044] Claim 11.6: a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,

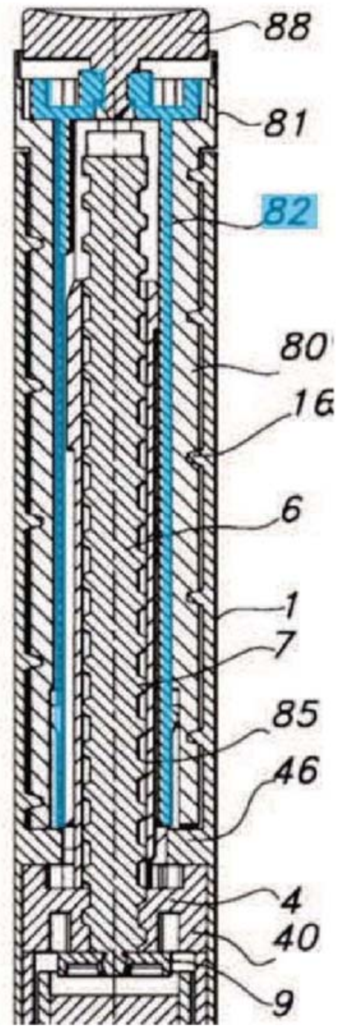
['486] Claim 1.6: a tubular clutch located adjacent a distal end of said dose *knob*, said tubular clutch operatively coupled to said dose *knob*,

280. Steenfeldt-Jensen's device further includes a bushing 82. *Id.*, 11:26, FIGS. 15-27. The bushing 82 has a flange 83 at its needle-end, and a pair of opposite longitudinal slots 84 through its side walls. *Id.*, 11:26-28. As shown in FIGS. 15-17, the bushing 82 fits within the scale drum 80, and over the driver tube 85, which has hooks 86 on its outer wall that engage with the slots 84 of the bushing 82. *Id.*, 11:28-

30. As a result, bushing 82 is coupled to the driver tube 85 in such a way that fixes the components rotationally to one another, but allows for relative axial movement between the components. *See id.*, 11:30-33.

281. The flange 83 of the bushing 82 is adapted to be seated within a compartment provided in the dose setting button 81. *See id.*, 11:34-40, FIGS. 1517. The flange 83 has, on its needle-end side, a rosette 93 of teeth that can be brought into engagement with a corresponding rosette of teeth provided at the bottom of the compartment. *See id.*, 11:34-36, 11:40-42. The flange 83 is mounted in the compartment in such a way that allows limited, axial movement of the bushing 82 relative to the scale drum 80 "to make or not make the teeth of said rosettes engage each other." *Id.*, 11:43-49.

282. Below-left, I have reproduced a partial view of FIG. 17, which shows the bushing 82 in greater detail. Below-right, I have reproduced a partial view of FIG. 16, where I have annotated the bushing 82 in blue.



283. As shown in the figures above, bushing 82 is "tubular" in shape and is "located adjacent a distal end of" the dose setting button 81. It also "operatively coupled to" the dose setting button 81, and serves as a "clutch" due to its releasable engagement with the dose setting button 81 via the rosettes of teeth. Specifically, as Steenfeldt-Jensen explains, during dose setting, the rosette 93 on the flange 83 of the bushing 82 is kept out of engagement with the rosette of the dose setting button 81. *Id.*, 12:1-3. When the user rotates the dose setting button 81 to set a dose, the bushing 82 follows the scale drum 80's axial movement relative to the housing, but "is kept

non rotated due to its coupling to the driver tube [85]" by the pawl mechanism. *See id.*, 11:52-62. Steenfeldt-Jensen further explains that, once a dose is set, the user presses an injection button 88 to inject the dose, which causes the bushing 82 to move axially, engaging the rosette 93 with the rosette of the dose setting button 81. *Id.*, 12:4-5. This causes the bushing 82 to now follow the scale drum 80's anticlockwise rotation back into the housing, which is transmitted to the driver tube 85. *See id.*, 12:4-13. The resulting rotation of the driver tube 85 is sufficient to overcome the pawl mechanism's reluctance, causing the piston rod 6 to rotate and screw through the member 40 to dispense medicine. *See id.* Thus, the bushing 82 serves as a "clutch" by releasably coupling the rotational movement of the scale drum 80 to the driver tube 85 during injection.

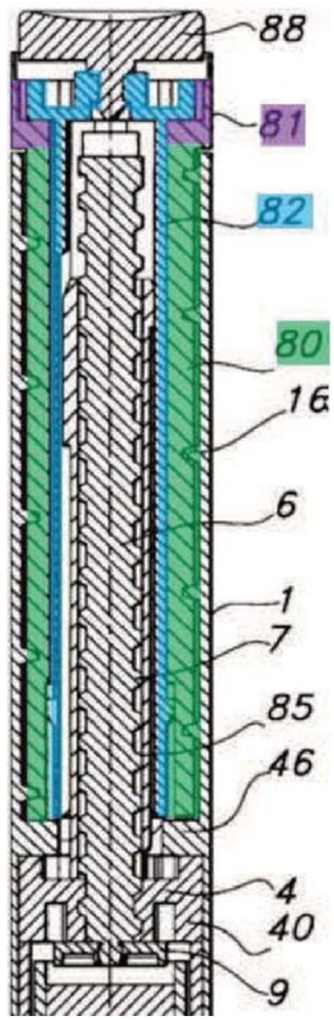
284. Accordingly, Steenfeldt-Jensen teaches a "tubular clutch" in the form of a bushing 82 that is "located adjacent a distal end of," and "operatively coupled to," the dose setting button 81.

['069] Claim 1.7/['486] Claim 1.7: wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

['044] Claim 11.7: wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, *and*

285. As I noted above, the bushing 82 fits into the scale drum 80. *See id.*, 11:28-30, FIGS. 15-16. Thus, the scale drum 80 "extends circumferentially around at least a portion of" the bushing 82. Below, I have reproduced a partial view of FIG.

16, where I have annotated the scale drum 80 in green and the bushing 82 in blue to further illustrate their relative positioning:[27]



[27] As I've done for previous grounds, I have also annotated the dose setting button 81, which is integrally formed with the scale drum 80, to illustrate the extent of the scale drum 80.

['044] Claim 11.8: wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different.

286. Steenfeldt-Jensen discloses that the scale drum 80's helical groove includes a "high pitch" that provides a non-self-locking threaded connection between the drum and the housing, which allows the drum to easily rotate back into the housing during injection when axially moved by the user. *See id.*, 6:7-17. Conversely, the nut member includes an internal threading having a pitch that results in a self-locking threaded connection between the nut member and the piston rod. *See id.*, 2:23-24, 2:50-53. As I explained above, a person of ordinary skill would have found it obvious to provide this threaded arrangement with the piston rod on the driver tube 85. *See supra*, ¶¶274-79.

287. As I also explained above, the pitch of a threading is related to the threading's lead where, depending on the number of "starts," the lead is a multiple of the threading's pitch. *See supra*, ¶241. Based on Steenfeldt-Jensen's description that the pitch of the scale drum 80's helical groove is large enough so as to be non-self-locking, while the pitch of the internal threading of the driver tube 85 is small enough so as to be self-locking, it is my opinion that a person of ordinary skill would have understood that this pitch-difference would result in the helical groove of the scale drum 80 having a "first lead" that is different from a "second lead" of the internal threading of the driver tube 85.

288. Accordingly, it is my opinion that Steenfeldt-Jensen renders obvious a "helical groove" of the scale drum 80 that has "a first lead" and an "internal threading" of the driver tube 85 that has "a second lead," where the first lead and the second lead are different.

2. Dependent claims 14-15 and 18-19 of the '044 patent and dependent claims 2-6, 12-18. 20, 23, 26-30, 32-33, 36, and 38-40 of the '486 patent

289. Each section of dependent claims 14-15 and 18-19 of the '044 patent and dependent claims 2-6, 12-18, 20, 23, 27-30, 32-33, 36, and 38-40 of the '486 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

['486] Claim 2: The housing part of claim 1, wherein said tubular clutch is directly coupled to said dose knob.

290. As I noted above, the flange 83 of the bushing 82 of Steenfeldt-Jensen sits within a compartment provided in the dose setting button 81. *See id.*, 11:3440, FIGS. 15-17. During dose setting, the rosette 93 of the flange 83 is disengaged from the corresponding rosette of teeth provided at the bottom of the dose setting button 81's compartment. *See id.*, 12:1-3. Once a dose is set, the user presses the injection button 88, which causes the bushing 82 to engage the rosette 93 with the rosette of the dose setting button 81. *Id.*, 12:4-5. This causes the bushing 82 to now follow the scale drum 80's anticlockwise rotation back into the housing, which is transmitted

to the driver tube 85. *See id.*, 12:4-13. The resulting rotation causes the driver tube 85 to rotate, which rotates the piston rod 6 through the member 40 to dispense medicine. *See id.* Because the rosette 93 of the bushing 82 engages with the rosette of teeth on the dose setting button 81, the bushing 82 (clutch) "is directly coupled to" the dose setting button 81.

['486] Claim 3: The housing part of claim 1, wherein said main housing comprises a window through which at least a portion of an outer surface of said dose dial sleeve may be viewable.

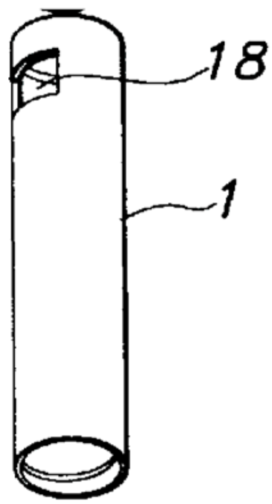
291. Steenfeldt-Jensen discloses that the housing 1 includes a window 18. *See id.*, 6:18-21, FIG. 17. "Numbers indicating set doses are printed on the outer wall of the dose drum 17 and the number corresponding to a set dose is shown in a window 18 provided in the side wall of the housing 1." *Id.*, 6:18-21; *see also* 7:1113. Thus, a person of ordinary skill would have understood that "a portion of an outer surface" of the scale drum 80 "may be viewable" through the window 18 of the housing 1.

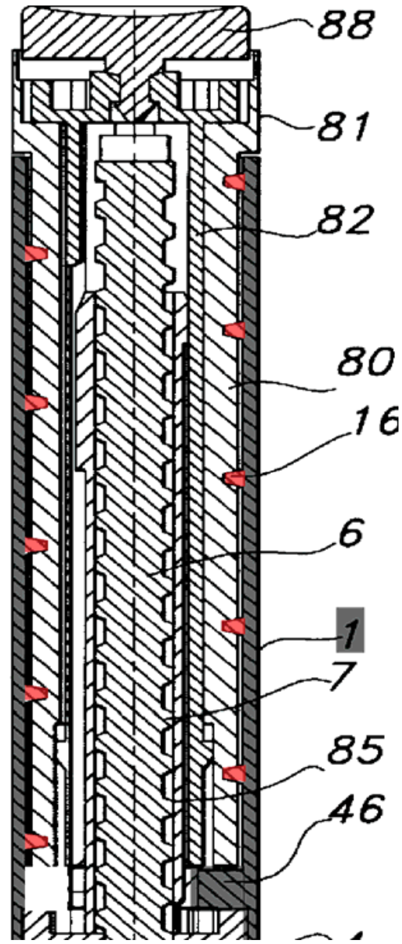
292. Accordingly, Steenfeldt-Jensen discloses that the housing 1 includes "a window," in the form of window 18, "through which at least a portion of an outer surface of" the scale drum 80 "may be viewable."

['486] Claim 4: The housing part of claim 3, wherein said window is located near a proximal end of said main housing and near a helical rib provided on an inner surface of said outer housing.[28]

293. As I explained above, Steenfeldt-Jensen discloses that the housing 1 includes a helical rib 16 on its inner surface that engages a helical groove on the scale drum 80. *Id.*, 11:20-22, FIGS. 15-17. Below, I have reproduced a partial view of FIG. 17 (left), where the window 18 is shown to be located near a button-end of the housing 1. I have also reproduced a partial view of FIG. 16 (right), where the helical rib 16 (annotated in red) is shown to extend along the length of the housing 1 (annotated in gray). Given the positioning of the window 18, and the extension of the helical rib 16, a person of ordinary skill would have understood that the window 18 is "located near" the helical rib 16.

[28] As I explained above, there is no antecedent basis for "said outer housing." For the purposes of my analysis, I will assume that this refers to the claimed main housing. *See supra*, ¶205.

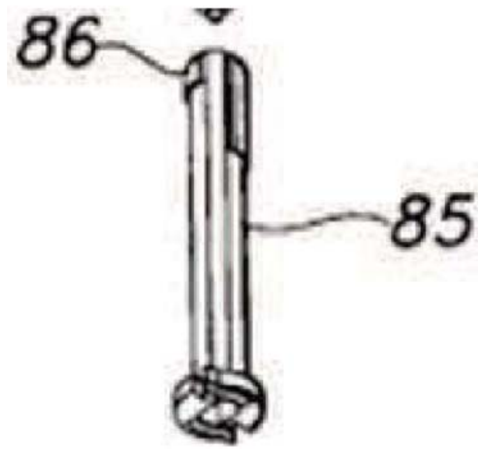




294. Accordingly, Steenfeldt-Jensen discloses that the window 18 "is located near a proximal end of" the housing 1 "and near a helical rib provided on an inner surface of" the housing 1.

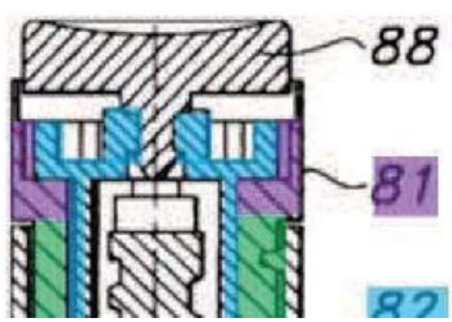
<u>['486] Claim 5: The housing part of claim 1, wherein said driver comprises a cylindrical shape.</u>

295. As shown in the partial view of FIG. 17 reproduced below, the driver tube 85 is cylindrical in shape. Thus, Steenfeldt-Jensen discloses this element.



['486] Claim 6: The housing part of claim 1, wherein said dose knob extends circumferentially around at least a portion of said tubular clutch.

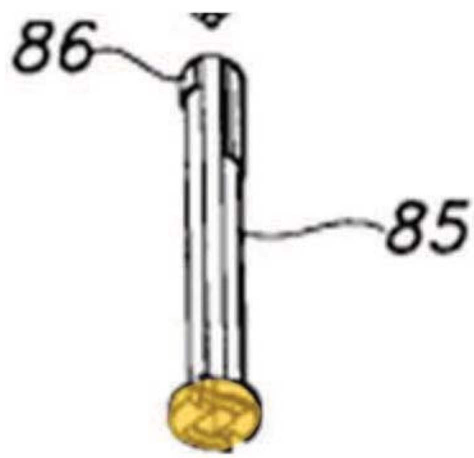
296. As I explained above, Steenfeldt-Jensen discloses a "dose knob" in the form of the dose setting button 81. *See supra*, ¶¶266-67. In FIG. 16, dose setting button 81 extends circumferentially around a button-end portion the bushing 82. To illustrate this positioning, I have reproduced a partial view of FIG. 16, toward the device's button-end, where I have annotated the bushing 32 in blue, the dose setting button 81 in purple, and the scale drum 80 in green:



297. Accordingly, Steenfeldt-Jensen discloses that the dose setting button 81 "extends circumferentially around at least a portion of" the bushing 82.

['486] Claim 12: The housing part of claim 1, wherein said driver comprises at least one flange.

298. As I explained above, Steenfeldt-Jensen discloses a "driver" in the form of the driver tube 85. *See supra*, ¶¶273-74. As shown in the partial view of FIG. 17 below, driver tube 85 includes a flange at its needle-end, which I have annotated in orange. As I explained above, a person of ordinary skill would have understood this flange to include the pawl 13 for engaging the pawl teeth in member 40. *See supra*, ¶271 n.26.



299. Accordingly, Steenfeldt-Jensen discloses that the driver tube 85 "comprises at least one flange."

['486] Claim 13: The housing part of claim 12, wherein said at least one flange is located near a distal portion of said driver.

300. The flange on the driver tube 85 is shown to be positioned at its needle-end. *See* FIG. 17. Thus, Steenfeldt-Jensen discloses that the flange "is located near a distal portion of" the driver tube 85.

<u>['044] Claim 14: The housing part of claim 11, further comprising a clicker providing at least an audible feedback to a user when said dose dial grip is rotated.</u>

<u>['486] Claim 14: The housing part of claim *1*, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose *knob* is rotated.</u>

301. Steenfeldt-Jensen discloses that the flange 83 of the bushing 82 has, at its periphery, a radial protrusion 87. *Id.*, 11:37-40, FIG. 17. The compartment of the dose setting button 81 contains longitudinal recesses along its cylindrical side wall. *Id.*, 11:34-40. Steenfeldt-Jensen discloses that, when a dose is set by rotating the dose setting button 81, "the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 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.

302. Accordingly, Steenfeldt-Jensen discloses a "clicker" that "provid[es] at least an audible feedback," in the form of a radial protrusion 87 that engages with recesses on the dose setting button 81 to produce a clicking noise as the dose setting button 81 is rotated.

303. With regard to the means-plus-function interpretation, as I explained above, the challenged patents teach that the structure used to provide the function of an audible click is either a flexible arm being dragged over splines, or saw teeth riding over one another. *See supra*, ¶218. As I noted above, Steenfeldt-Jensen

teaches a radial protrusion 87 as providing the clicking in the embodiment as shown in FIG. 15-17. The radial protrusion 87 sits in a compartment of dose setting button 81 that includes “axial recesses” and is “biased toward the side wall of the compartment.” EX1014, 11:34-42; 11:52-67. When dose setting button 81 rotates, “radial protrusion 87...will click from one of the axial recess[es] in the inner wall of the dose setting button 81 to the next one....” *Id.*, 11:52-67. It is my opinion that a person of ordinary skill would have understood the radial protrusion 87 to be a “flexible arm” that dragged over ridges (or splines) formed between the axial recesses. In my opinion, therefore, Steenfeldt-Jensen 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.

['486] Claim 15: The housing part of claim 14, wherein said clicker provides tactile feedback to a user when said dose knob is rotated.

304. Steenfeldt-Jensen teaches that the “click coupling provid[es] a[] moderate resistance against rotation ....” *Id.*, 3:21-27. In the context of the clicker of FIGS. 15-17, a person of ordinary skill would have understood that, when the dose setting button 81 was rotated relative to the bushing 82, the radial protrusion 87 would provide “a moderate resistance” as it rode over the ridges between the longitudinal recesses to click from one recess to the next. Such a resistance would have been understood to provide “tactile feedback” to the user when the dose setting button 81 was rotated.

305. I note that such an understanding is consistent with the understanding of the person of ordinary skill presumed by the ’486 patent. For example, the ’486 patent describes that the clicker provides “audible and tactile feedback of the dose being dialed” when the “flexible arm 52 deforms and drags the toothed member 54 over the splines 42 to produce a click.” EX1003, 5:54:60. The clicker of Steenfeldt-Jensen operates in a substantially identical manner. That is, the end of the radial protrusion 87 deforms and drags over the ridges formed between the longitudinal recesses to produce a click as the protrusion 87 enters into the neighboring recess. Thus, like the clicker described in the ’486 patent, a person of ordinary skill would have understood that the clicker of Steenfeldt-Jensen would provide a similar form of “tactile feedback.”

306. Accordingly, it is my opinion that a person of ordinary skill would have understood that Steenfeldt-Jensen discloses a clicker that “provides tactile feedback to a user when” the dose setting button 81 “is rotated.”

[’486] Claim 16: The housing part of claim 14, wherein said clicker provides audible feedback when said dose knob is rotated in a dose increasing direction.

307. Steenfeldt-Jensen discloses that “rotation of the dose setting button 81 in any direction” will cause “the radial protrusion 87 on the flange 83 of the bushing 82 [to] click from one of the axial recess in the inner wall of the dose setting button 81 to the next one ....” EX1014, 11:62-67. Thus, a person of ordinary skill would

have understood that when the dose setting button 81 was rotated in "a dose increasing direction" (clockwise direction), the radial protrusion 87 of the bushing 82 would click from one axial recess to the next to provide audible feedback to the user.

308. Accordingly, Steenfeldt-Jensen discloses that the clicker "provides audible feedback when" the dose setting button 81 "is rotated in a dose increasing direction."

['486] Claim 17: The housing part of claim 14, wherein said clicker provides audible feedback when said dose knob is rotated in a dose decreasing direction.

309. Because Steenfeldt-Jensen discloses that movement of the radial protrusion 87 over the longitudinal recesses of the dose setting button 81 will produce a click when the dose setting button 81 is rotated "in any direction," it is my opinion that the person of ordinary skill would have also understood that audible feedback would be provided when the dose setting button 81 was rotated in "a dose decreasing direction" (anticlockwise direction). Thus, Steenfeldt-Jensen discloses that the clicker "provides audible feedback when" the dose setting button 81 "is rotated in a dose decreasing direction."

['044] Claim 15: The housing part of claim 14, wherein said clicker comprises, [15.1] at least one flexible arm, said flexible arm comprising at least one tooth member, and [15.2] at least one spline, [15.3] wherein when said dose dial grip is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one splines so as to provide said audible feedback.

['486] Claim 18: The housing part of claim 14, wherein said clicker comprises, [18.1] at least one flexible arm, said flexible arm comprising at least one tooth member, and [18.2] at least one spline, [18.3] wherein when said dose *knob* is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.

310. As I noted above, Steenfeldt-Jensen discloses a "clicker" that "provid[es] at least audible feedback," in the form of a radial protrusion 87 provided on the flange 83 of the bushing 82. *See id.*, 11:37-40, FIG. 17. This radial protrusion 87 is "biased toward" the cylindrical side wall of dose setting button 81's compartment and engages with longitudinal recesses provided within the compartment's side wall to produce clicking noises during dose setting. *See id.*, 11:34-42, 11:62-67. Below is a partial view of FIG. 17, where I have annotated the radial protrusion 87 in purple:

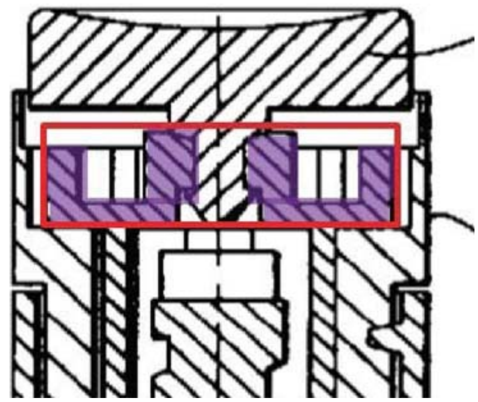
311. As illustrated in FIG. 17, it is my opinion that a person of ordinary skill would have understood that the radial protrusion 87 was a "flexible arm" that includes a "tooth member" at its end for deforming and dragging into longitudinal recesses to produce a clicking noise. *See id.*, 11:34-40, 11:62-67, FIG. 17. A person of ordinary skill would have also understood that the longitudinal recesses would form corresponding ridges or splines between neighboring recesses.

312. Accordingly, it is my opinion that a person of ordinary skill would have understood Steenfeldt-Jensen to discloses a "clicker" having "at least one flexible arm" that includes "at least one tooth member," in the form of radial protrusion 87, and "at least one spline," formed between neighboring longitudinal recesses, such that, when the dose setting button 81 is rotated, the radial protrusion 87 "deforms and drags" its "tooth member" over the splines formed by the longitudinal recesses to provide audible feedback.

['486] Claim 20: The housing part of claim 14, wherein [20.1] said clicker generally comprises a cylindrical shape having a first and a second end, and [20.2] said cylindrical shape is provided at said first end with at least one flexible extending arm.

313. As I noted above, Steenfeldt-Jensen describes a clicker having a radial protrusion 87 that is positioned on a flange 83 of the bushing 82. Below, I have reproduced a partial view of FIG. 17 (left), where I have annotated the flange in purple. Also below, I have reproduced a partial view of FIG. 16 (right), where I have encircled the flange in red. As shown in the figures below, a person of ordinary skill

would have understood that the flange is generally cylindrical in shape and has a first end (button-end) and a second end (needle-end). The radial protrusion 87 is shown to extend along the length of the flange such that it is "provided at" the flange's button-end.



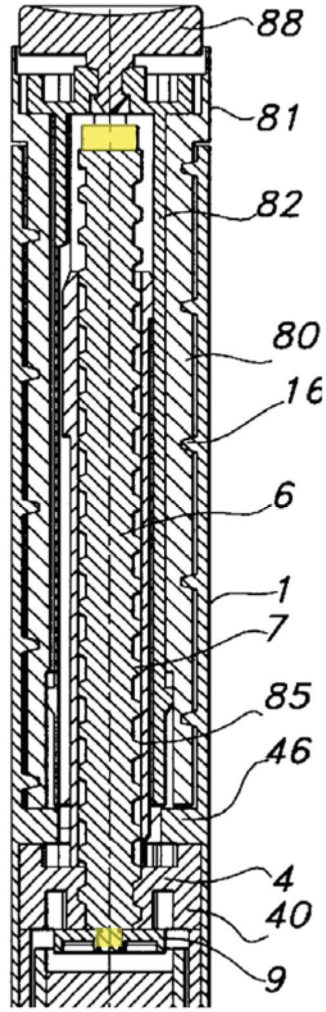
314. Accordingly, Steenfeldt-Jensen discloses a clicker that "generally comprises a cylindrical shape having a first and a second end," in the form of flange 83, which "is provided at said first end with at least one flexible extending arm," in the form of radial protrusion 87.

['486] Claim 23: The housing part of claim 1, wherein said piston rod comprises a generally circular cross section.

315. As I explained above, Steenfeldt-Jensen discloses a piston rod 6, which has a "not round" cross-section to prevent rotation relative to a component having a corresponding "not round' bore (in this case, member 40, modified as I discussed above). *See supra*, ¶¶275-79. The piston rod 6 also contains an external thread 7 that mates with an internal thread 5 (located near a distal portion of the driver tube 85,

modified as I discussed above) so that the piston rod 6 may be screwed into the ampoule holder to dispense medicine.

316. As an initial matter, I note that claim 23 of the '486 patent only requires that the piston rod has "a cross section" that is "generally circular." It does not require that the piston rod have a uniformly "generally circular cross section" along its entire length. Given this, it is my opinion that Steenfeldt-Jensen discloses that the piston rod 6 includes "a generally circular cross section" at the component's button-end and needle-end. For instance, Steenfeldt-Jensen discloses that the piston rod 6 includes, at its needle-end, a circular portion that fits into a pressure foot 9. *See* 5:61-65, FIGS. 15-17. In addition, FIGS. 16-17 of Steenfeldt-Jensen shows that the piston rod 6 contains, at its button-end, a non-threaded portion that a person of ordinary skill would have understood to have "a generally circular cross section." To further illustrate this, I have reproduced partial views of FIG. 17 (below-left) and FIG. 16 (below-right), where I have annotated the portions of the piston rod 6 that includes "a generally circular cross section" in yellow:



317. In addition, I note that the claim recites that the piston rod includes "a *generally* circular cross section." Thus, even if the piston rod 6 must have a *generally* circular cross-section along its length, it is my opinion that a person of ordinary skill would have understood that the piston rod 6 contains a "generally circular" cross-section along its length. First, I note that a person of ordinary skill in the art would have understood that the threaded piston rod described in the '486 patent would have a cross-section that was not perfectly circular due to the helical features of the first and second threads 19, 24 along the piston rod's length. *See* EX1003, 3: 56-67. I also

note that the ’486 patent does not describe at which point a cross-section becomes “generally” circular. In view of this, although the piston rod 6 contains a “not round cross-section” due to flattened portions for engaging a not-round bore, it is my opinion that a person of ordinary skill would have understood that the piston rod 6, with its helical, external thread 7 extending along its length, would include a “generally circular cross section.”

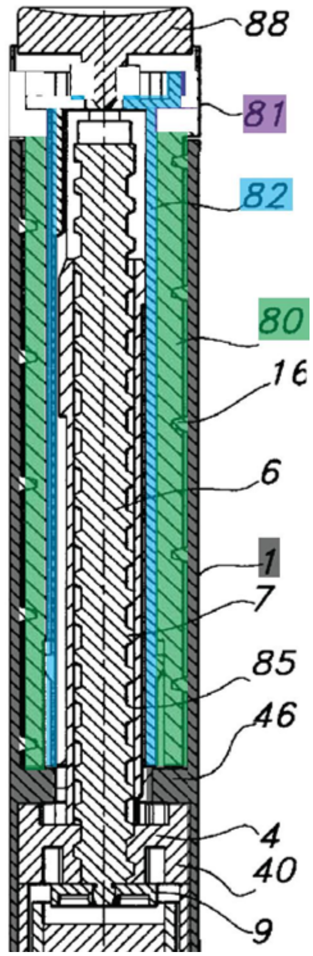
318. Accordingly, it is my opinion that a person of ordinary skill would have understood that the piston rod 6 “comprises a generally circular cross section.”

[’044] Claim 18: The housing part of claim 11, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.

[’486] Claim 26: The housing part of claim *1*, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.

319. As I explained above, Steenfeldt-Jensen discloses that the scale drum 80 is positioned within the housing 1. *See supra*, ¶¶264-265. Steenfeldt-Jensen also discloses that the bushing 82 fits into the scale drum 80. Therefore, Steenfeldt-Jensen discloses that the scale drum 80 “is provided outside” the bushing 82 and “radially inward of” the housing 1. To further illustrate the relative positioning between these components, below I have reproduced a partial view of FIG. 16 of Steenfeldt-Jensen,

where I have annotated the housing 1 in gray, the scale drum 80 in green, and the bushing 82 in blue:[29]



[29] To show the extent of the scale drum 80, I have also annotated the dose setting button 81 in purple.

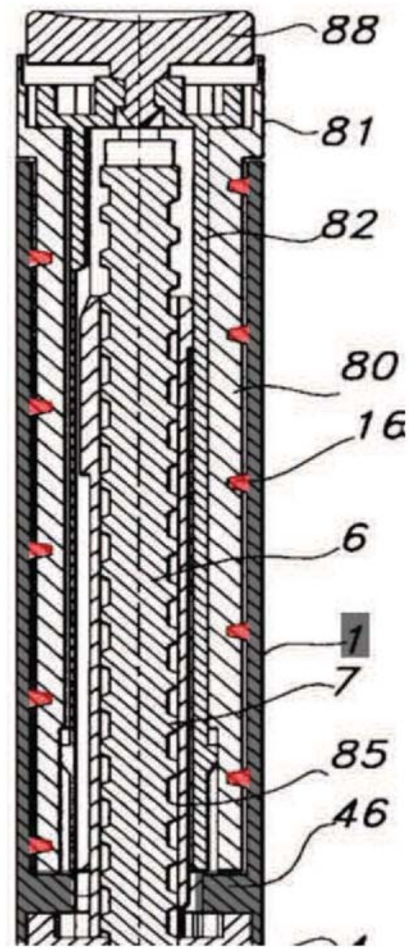
<u>['044] Claim 19: The housing part of claim 11, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve.</u>

<u>['486] Claim 27: The housing part of claim 1, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve.</u>

320. As I discussed above, Steenfeldt-Jensen discloses that the scale drum 80 includes a helical groove that extends along its outer surface and engages with a helical rib 16 provided along the inner surface of the housing 1. *See* EX1014, 11:20-22. Thus, Steenfeldt-Jensen discloses that the housing 1 "further comprises a helical rib," that is "adapted to be seated in" the helical groove provided along the outer surface of the scale drum 80.

<u>['486] Claim 28: The housing part of claim 27, wherein said helical rib extends for at least a single sweep of said inner surface of said main housing.</u>

321. As shown in the partial view of FIG. 16 reproduced below, the housing's helical rib 16, which I have annotated in red with the housing generally annotated in gray, is shown to extend along the housing's length. Thus, a person of ordinary skill would have understood that the helical rib 16 "extends for at least a single sweep of [the] inner surface of" the housing 1.



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

322. Steenfeldt-Jensen does not explicitly disclose whether the helical rib 16 is a single start rib. Nevertheless, it is my opinion that a person of ordinary skill would have found it readily apparent to provide the helical rib 16 as a single start helical rib.

323. As I explained above, a person of ordinary skill would have understood the mechanical differences between single-start threads and multi-start threads. *See supra*, ¶¶241-44. As I also explained above, Steenfeldt-Jensen discloses that the

inner surface of the housing 1 contains a helical rib 16 that engages a corresponding groove on the outer wall of the scale drum 80. *Id.*, 11:2022, FIGS. 15-17. Via this groove-to-rib engagement, the scale drum 80 rotates and moves axially relative to the housing 1 during dose setting and injection. *See id.*, 11:52-54, 12:4-9. Steenfeldt-Jensen teaches that this threaded engagement includes a high pitch, and a pitch angle that "exceeds the angle of friction for the materials forming" the drum and the housing. *Id.*, 6:7-17. Such a configuration results in a non-self-locking threaded connection between the drum and the housing, which allows the drum to easily rotate back into the housing during injection when axially moved by the user. *See id.*, 6:7-17.

324. A person of ordinary skill would have also understood that, for a single-start thread, this configuration would mean that the lead of the helical rib 16 would be correspondingly high, and equal to its high pitch. Thus, a person of ordinary skill would have understood that, when the user rotated the scale drum 80, the drum would move out of the housing at a relatively high rate. A person of ordinary skill would have understood that a relatively high lead would allow for a sufficiently large "stroke" of the scale drum 80 that would allow the user to better perceive changes in the dose during the dose setting process. If, on the other hand, the helical rib was provided as a multi-start thread with the same high pitch, the lead would be multiplied, resulting in an even larger lead. Indeed, Steenfeldt-Jensen refers to the

helical rib in the singular, which would have suggested to the person of ordinary skill that a single-start helical rib would be sufficient.

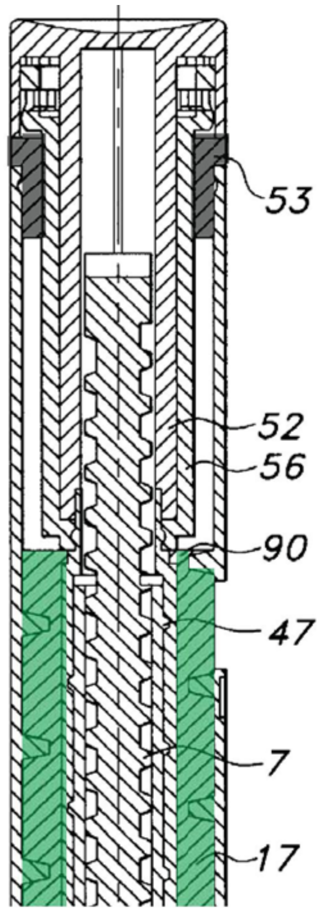
325. Accordingly, given the above, it is my opinion that a person of ordinary skill would have found it readily apparent to provide the helical rib 16 as "a single start helical rib."

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

326. Steenfeldt-Jensen does not explicitly disclose that the scale drum 80 includes "at least one radial stop" that is "positioned near an end of" the drum's helical groove. In another embodiment, however, Steenfeldt-Jensen discloses a dose scale drum 17 that similarly includes a helical groove on its outer surface that engages with a helical rib on the inner wall of the housing. *See id.*, 9:52-56. Steenfeldt-Jensen discloses that "[w]hen the dose scale drum is displaced outwardly in the housing a steep front side of a saw tooth 91 at the [button-end] of the dose scale drum [17] will abut a steep front side of a similar tooth 92 on the bushing [53] whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set." *Id.*, 9:57-62.

327. Steenfeldt-Jensen does not label these features in the corresponding figures for this embodiment (FIGS. 11-13), but a person of ordinary skill would have understood that the tooth 91 acts as a "radial stop" that serves to prevent further

movement of the dose scale drum during dose setting when the maximum dose for a single injection has been reached. Specifically, Steenfeldt-Jensen discloses that the bushing 53 is secured to the housing 1 to prevent rotational and longitudinal movement relative to the housing. *See id.*, 8:63-67, FIGS. 11-13. During dose setting, the scale drum 17, which is shown to be initially positioned an axial distance away from the bushing 53 toward the device's needle-end, rotates in the button-end direction. *See id.*, 9:36-46, Figs. 11-12. A person of ordinary skill would have understood that this would result in the scale drum 17's button-end being moved towards the needle-end of the bushing 53. Thus, a person of ordinary skill would have understood that when the scale drum 17 abutted the bushing 53, the tooth 91 would abut the tooth 92, which would indicate that the maximum travel of the scale drum 17 has been reached. To further illustrate the relative positioning of these components, I have reproduced a partial view of FIG. 12, where I have annotated the scale drum 17 in green and the bushing 53 in gray. As can be seen in the figure, any stop located at the scale drum's button-end would be "near an end of″ the helical groove provided on the drum's outer surface.



328. Given the above, it is my opinion that a person of ordinary skill would have understood Steenfeldt-Jensen as teaching the use of a "radial stop" on the scale drum "near an end" of its helical groove that serves to indicate the maximum length of travel for the scale drum during dose setting (and thus, the maximum dose that can be set for injection). It is also my opinion that a person of ordinary skill would have found it readily apparent to incorporate a similar "radial stop" on the scale drum 80 that would also serve as an indication to the user that the scale drum 80 has reached its maximum length of travel.

329. Specifically, while the maximum length of travel of the scale drum 17 of FIGS. 11-13 is the distance between the button-end of the scale drum 17 and the needle-end of the bushing 53, a person of ordinary skill would have understood that the maximum length of travel of the scale drum 80 would be the axial length of its helical groove. In this case, a person of ordinary skill would have understood that a "radial stop," like a protruding tooth, should be provided near the needle-end of the drum's helical groove. That way, if the user screwed the drum 80 out of the housing 1 by its maximum length of travel (i.e., the needle-end of the helical groove has reached the button-end of the helical rib 16), the stop would abut a corresponding stop provided on the housing 1 near the button-end of its helical rib 16. A person of ordinary skill would have understood that this stop would serve the same purpose as the stop of FIGS. 11-13: it would prevent the user from further rotating the drum 80 out relative to the housing 1, and would indicate to the user that the maximum set dose has been reached.

330. I note that the driver tube 85 includes hooks 86 that engages slots 84 of bushing 82. See EX1014, 11:26-33, FIGS. 15-17. The hooks 86 may serve as a stop by engaging the end of slots 84 when the bushing 82 axially retracted by its maximum length during dose setting, which would similarly indicate that the maximum dose has been set. Nevertheless, it is my opinion that a person of ordinary skill would have found it readily apparent to incorporate a radial stop, like that

disclosed in FIGS. 11-13, near an end of the helical groove of the scale drum 80 to set a maximum length of travel as desired by the design engineer. A person of ordinary skill would have viewed the hooks 86 and a protrusion, like a tooth, near an end of the drum's helical groove to be structurally and functionally equivalent as a radial stop. A person of ordinary skill would have understood that either could be used as a stop to set a desired maximum length of travel of the scale drum 80 during dose setting, and that the use of a stop near an end of the drum's helical groove to set a certain length of travel was a well-known, routine and predictable way to limit the length of axial travel of a component.

331. Accordingly, it is my opinion that a person of ordinary skill would have found it readily apparent to provide the scale drum 80 with "at least one radial stop," and would have found it readily apparent to position that radial stop "near an end of" the helical groove.

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

332. As I explained above, a person of ordinary skill would have understood that, because the maximum length of travel of the drum 80 is determined by the axial length of its helical groove, the radial stop should be positioned near the needle-end of the groove so that, when the maximum length of travel of the drum 80 was reached, the stop would abut a corresponding stop at the housing's button-end to prevent further movement. *See supra*, ¶¶326-31. Thus, it is my opinion that a person

of ordinary skill would have found it readily apparent to position the radial stop "near a distal end of" the helical groove.

['486] Claim 33: The housing part of claim 1, wherein if a user inadvertently dials said dose knob in one direction beyond a desired dose, said dose knob may be rotated in a second direction so as to allow said dialed dose to be reduced.

333. Steenfeldt-Jensen discloses that "a dose is set by rotating the dose setting drum 81 in a clockwise direction," and the set dose may be "reduced by rotating the dose setting button 81 in an anticlockwise direction." EX1014, 11:5262. Thus, Steenfeldt-Jensen discloses that "if a user inadvertently dials" the dose setting button 81 "in one direction beyond a desired dose," the dose setting button 81 "may be rotated in a second direction so as to allow said dialed dose to be reduced."

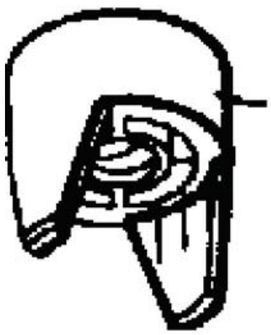
['486] Claim 36: The housing part of claim 1, wherein said housing part and said container comprises a disposable device.

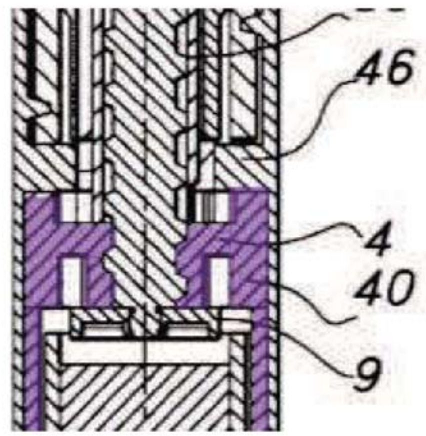
334. As I noted above, the claim term "container" does not appear in claim 1, which claim 36 depends. Nevertheless, I note that Steenfeldt-Jensen's device contains a fluid "container" that contains a medicine in the form of an ampoule. *See, e.g.*, *id.*, 5:33-35, 12:10-13, FIGS. 15-17. Steenfeldt-Jensen also expressly recognizes that it was well-known in the art to provide disposable syringes (*i.e.*, pen injectors), "i.e. a syringe which is disposed of when the cartridge is empty." *Id.*, 1:25-26. For these syringes, Steenfeldt-Jensen teaches that "the syringe must further be cheap and made of materials suited for recycling or burning without producing

noxious gases." *Id.*, 1: 24-26. It is my opinion that a person of ordinary skill would have found it readily apparent to manufacture the device of Steenfeldt-Jensen as a disposable syringe (pen injector), by, for example, forming the device's components from "materials suited for recycling or burning," as Steenfeldt-Jensen teaches. Accordingly, it is my opinion that Steenfeldt-Jensen teaches forming a syringe (pen injector) where the housing 1 and a container, in the form of a fluid-filled ampoule, "comprises a disposable device."

['486] Claim 38: The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main housing, said insert secured against rotation.

335. Steenfeldt-Jensen discloses that the syringe (pen injector) contains member 40. *See id.*, FIGS. 15-17. The member 40 "is mounted in an end of the housing," and "has at its periphery longitudinal recesses 43 which are engaged by not shown internal ribs in the housing to lock the member 40 against rotation relative to the housing." *Id.*, 8:35-42. Below, I have reproduced a partial view of FIG. 17 (left), which shows the member 40 in greater detail. I have also reproduced a partial view of FIG. 16 (right), toward the device's needle-end, where I have annotated the member 40 in blue. As shown in the figure, the member 40 is positioned at a needle-end of the housing 1.





336. Accordingly, Steenfeldt-Jensen discloses “an insert,” in the form of a member 40, which is “provided at a distal end of the” housing 1 and “secured against rotation.”

[’486] Claim 39: The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main housing, and said insert secured against longitudinal motion.

337. As I explained above, Steenfeldt-Jensen discloses “an insert,” in the form of a member 40, that is “provided at a distal end of the” housing 1. Steenfeldt-Jensen further describes that member 40 has “protrusions 41 engaging slots 42 in the housing to lock the member 40 to the housing.” *Id.*, 8:37-39, FIGS. 13, 17. A person of ordinary skill would have understood that the protrusions 41 served to secure the insert against longitudinal motion relative to the housing. Thus, Steenfeldt-Jensen discloses that the “insert [is] secured against longitudinal motion.”

<u>['486] Claim 40: The housing part of claim 39, wherein said insert comprises an opening extending therethrough, such that said piston rod is configured to extend through said opening.</u>

338. As I explained above, a person of ordinary skill would have understood that the member 40 includes a central bore through which the piston rod 6 extends. *See supra*, ¶¶275-79. A person of ordinary skill would have understood that the member 40 thus would have "an opening extending therethrough, such that" the piston rod 6 "extend[s] through [the] opening."

C. ['069] Ground 3: Claim 1 is Obvious over Møller in combination with Steenfeldt-Jensen; ['044-B] Ground 2: Claims 11, 14-15, and 18-19 are Obvious over Møller in combination with Steenfeldt-Jensen; ['486-A2] Ground 2: Claims 1-6, 12-18, 20, 23, 26-30, 32-33, 36, and 38-40 are Obvious over Møller in combination with Steenfeldt-Jensen

339. As I did above, my analysis first focuses on the independent challenged claims of the '069 patent, the '044 patent, and the '486 patent, and then moves on to the dependent challenged claims of the '044 patent and the '486 patent. In cases where a given clause of one patent contains identical or substantially identical language as a clause of another patent, I group those clauses together. For those clauses that are substantially identical, I italicize those words that differ from the first-listed clause. The analysis that follows equally applies to each of the grouped clauses, except where I specifically note any differences. To indicate the patent to

which the clause pertains, I provide brackets preceding a particular clause that contains the last three numbers of the patent to which it relates.

1. <u>Independent claim 1 of the ’069 patent, independent claim 11 of the ’044 patent, and independent claim 1 of the ’486 patent</u>

340. As explained in detail below, it is my opinion that Møller in combination with Steenfeldt-Jensen teaches each of the six components and their corresponding structural elements recited in claim 1 of the ’069 patent and claim 11 of the ’044 patent. In particular, Møller discloses all of the limitations recited by claim 1 of the ’069 patent and claim 11 of the ’044 patent, except Møller describes a “dose dial sleeve” having a threading on its inner surface that engages with a threading provided on a housing, rather than a helical groove provided on its outer surface. Steenfeldt-Jensen teaches the use of a “dose dial sleeve” having a helical groove on its outer surface for engagement with a housing’s threading. As I explain more below, it is my opinion that a person of ordinary skill would have found it readily apparent to include a “dose dial sleeve” having a helical groove on its outer surface based on the teachings of Møller and Steenfeldt-Jensen.

341. As I also explain below, it is my opinion that Møller teaches each of the six components and their structural elements claimed by claim 1 of the ’486 patent. To the extent that Møller does not explicitly disclose that its “dose dial sleeve” includes a “helical groove,” it is my opinion that a person of ordinary skill would

have readily provided a "helical groove" to engage a threading of the housing in view of the teachings of Steenfeldt-Jensen.

342. Each section of claim 1 of the '069 patent, claim 11 of the '044 patent, and claim 1 of the '486 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

['069] Claim 1, preamble/['044] Claim 11, preamble/ ['486] Claim 1, preamble: A housing part for a medication dispensing apparatus, said housing part comprising:

343. Møller describes "[a]n injection device for injection of set doses of medicine from a cartridge." EX1015, Abstract. As shown in FIG. 1, the device includes "an elongated cylindrical housing 1." *Id.*, ¶22, FIG. 1. The housing 1 includes a partitioning wall 2 that "divides the housing in a compartment containing a dose setting mechanism and a compartment 3 designed for the accommodation of a not shown ampoule." *Id.* Thus, Møller teaches "[a] housing part for a medication dispensing apparatus."

344. Below, I have reproduced an annotated, partial view of FIG. 1 of Møller, which highlights the six components that form a part of the drive mechanism in more detail:

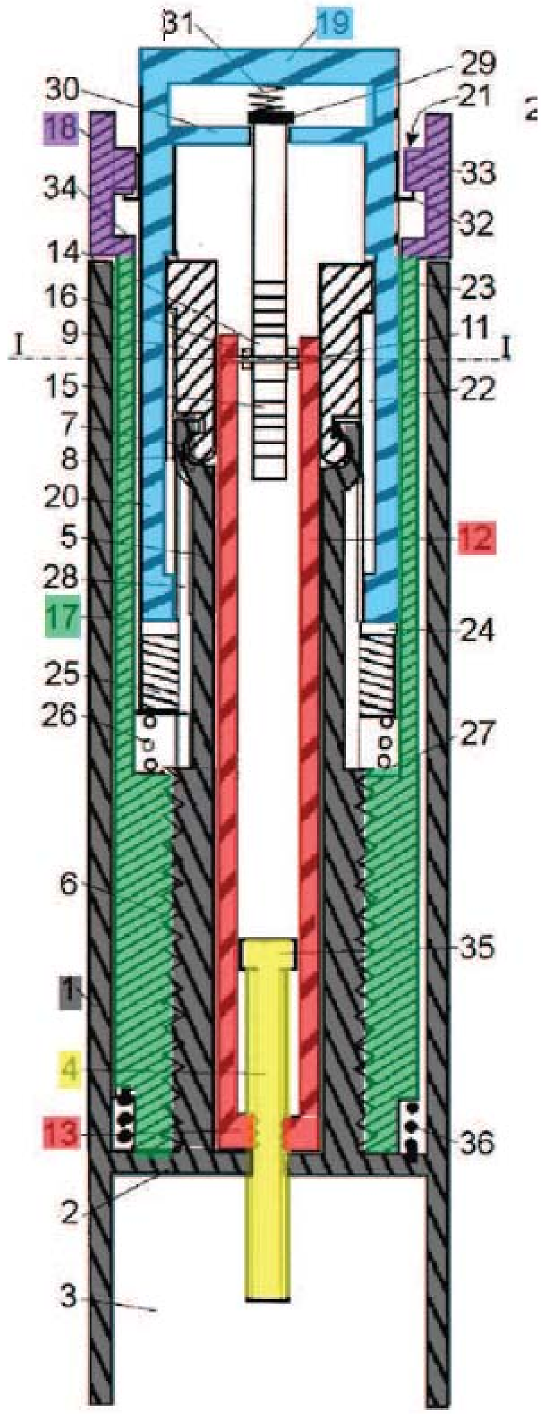

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Fig. 1

['069] Claim 1.1/ ['044] Claim 11.1/['486] Claim 1.1: a main housing, said main housing extending from a distal end to a proximal end;

345. Møller's device includes "an elongated cylindrical housing 1 ha[ving] a partitioning wall 2 ...." *Id.*, ¶22, FIG. 1. The housing 1 further includes a tubular element 5 that extends from the partitioning wall 2 towards the button-end of the device. *See id.*, ¶23, FIG. 1.

346. Below I have reproduced FIG. 1, where I have annotated the housing 1 in gray. As shown in FIG. 1, the housing 1 extends from a needle-end to a button-end. Accordingly, Møller discloses the claimed "main housing."

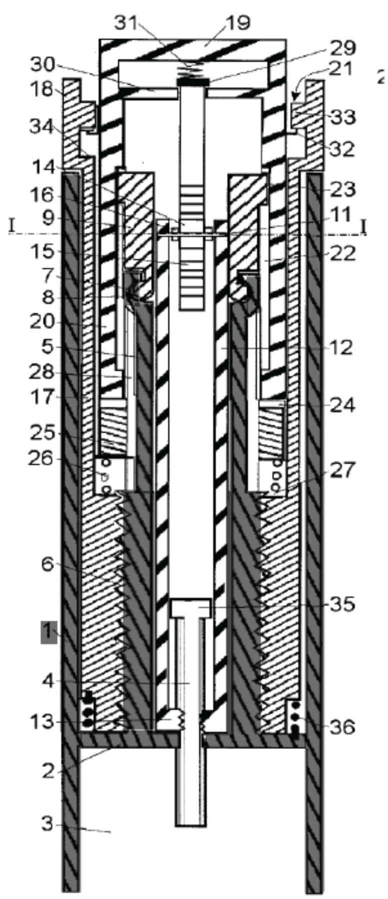


Fig. 1

<u>['069] Claim 1.2/['044] Claim 11.2: a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, *said helical groove provided along an outer surface of said dose dial sleeve*;</u>

<u>['486] Claim 1.2: a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing;</u>

347. The device described in Møller further includes "[a] tubular dose setting drum 17" that fits into the housing 1. *Id.*, ¶25, FIG. 1. Extending from its needle-end toward its button-end, the drum 17 contains an internal thread that "engag[es] [an] outer thread 6 of the tubular element 5" of the housing 1. *Id.* "Due to the engagement with the thread 6[,] the dose setting drum 17 may be screwed in and out of the housing to show a number on a not shown helical scale on its outer surface in a not shown window in the housing 1." *Id*. Thus, Møller discloses a "dose dial sleeve," in the form of a dose setting drum 17 that is "positioned with" the housing 1.

348. Reproduced below is FIG. 1, where I have annotated the dose setting drum 17 in green:

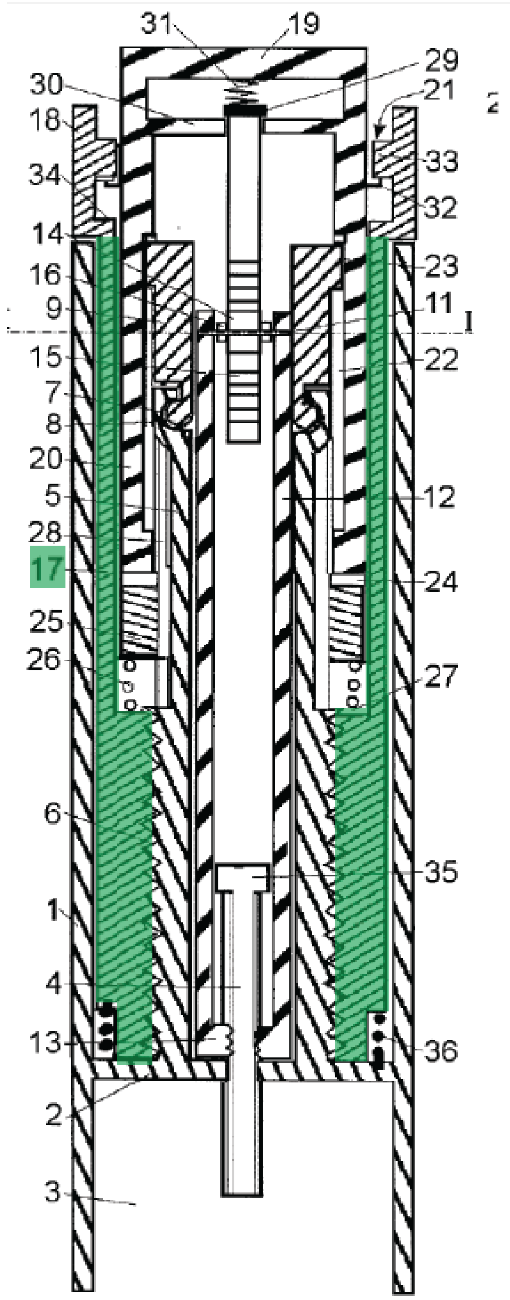
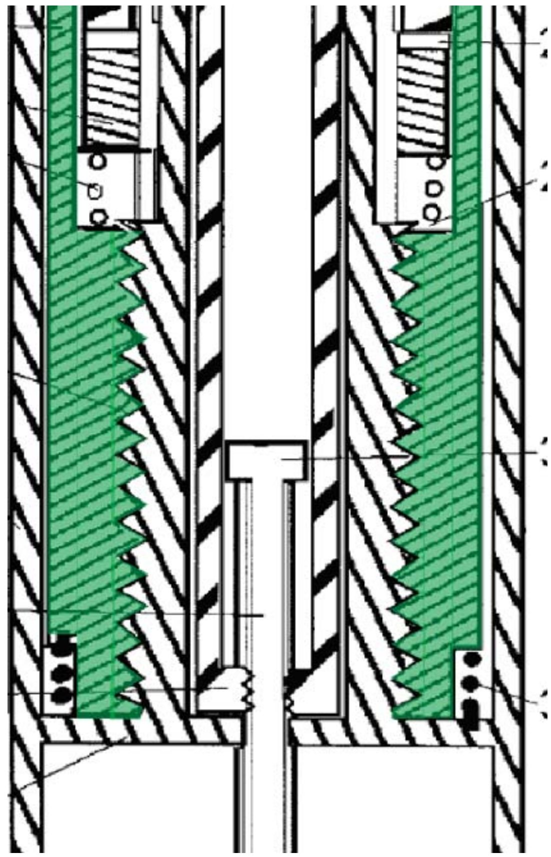


Fig. 1

349. Møller shows that the drum 17 has a threading on its internal surface, rather than along its outer surface, that is "configured to engage a threading provided by" the housing 1. Claim 1 of the '069 patent and claim 11 of the '044 patent both require that the "dose dial sleeve" contain a "helical groove" that is "provided along

an outer surface.” Claim 1 of the ’486 patent, on the other hand, only requires that the “dose dial sleeve” contain a “helical groove,” and does not specify the positioning of the groove. Thus, my analysis below will first focus on claim 1 of the ’486 patent, followed by my analysis of claim 1 of the ’069 patent and claim 11 of the ’044 patent.

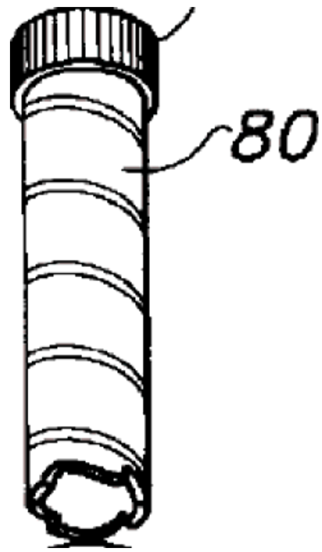
350. As I noted above, Møller describes that the drum 17 contains an internal thread that “engag[es] [an] outer thread 6 of the tubular element 5” of the housing 1, which allows the drum 17 to be screwed in and out of the housing. *Id.*, ¶25, FIG. 1. The threading is shown in FIG. 1, which shows that the thread includes a helical groove formed between neighboring ridges of a helical, protruding rib. Indeed, a person of ordinary skill would have understood that a continuous, screw thread, like that of Møller, forms a rib and a groove—that is, a groove is formed between adjacent ridges of the rib. To illustrate this, I have reproduced a partial view of FIG. 1 below, toward the device’s needle-end, which shows the threading, annotated in green, having a helical groove in greater detail:



351. Given the above, it is my opinion that a person of ordinary skill would have understood that the drum 17 of Møller has a "helical groove configured to engage a threading provided by" the housing 1, as recited in claim 1 of the '486 patent.

352. Moreover, to the extent that Møller does not disclose a "helical groove," a person of ordinary skill would have found it readily apparent to provide such a helical groove for engaging the housing in view of the teachings of Steenfeldt-Jensen. Steenfeldt-Jensen discloses numerous examples of dose dial sleeves that have a helical groove on its outer surface for engaging a threading on the housing.

See, e.g., EX1014, 11:20-25, FIG. 17. One such example is reproduced below, which is a partial view of FIG. 17, showing a dose scale drum 80 in greater detail:



353. Steenfeldt-Jensen discloses that the "scale drum 80 is in its outer wall provided with a helical track [*i.e.*, a helical groove] which is engaged by a helical rib 16 along the inner wall of the housing 1." EX1014, 11:20-25; *see also, e.g.*, *id.*, 6:7-17. This threaded arrangement is identical in function to the threaded arrangement of Møller: when the user rotates a dose knob (dose setting button 81), the drum "is screwed out of the housing," and when the user presses an injection button to inject the set dose, the drum rotates back into the housing via its threaded engagement with the housing. *See id.*, 11:52-12:9. Both Møller and Steenfeldt-Jensen illustrate a mechanism that was well-understood by those in the field at the relevant time: that a rib-to-groove threaded connection between components would allow for the relative rotational and axial movement between the engaging components. A person

of ordinary skill also would have understood that the relative placement of the helical rib and helical groove on the components to be largely interchangeable, with each circumstance (*e.g.*, rib-to-groove, or groove-to-rib) resulting in the same relative movement between the parts. Thus, to the extent Møller does not explicitly discloses a "helical groove" on the dose setting drum 17, it is my opinion that a person of ordinary skill would have found it readily apparent to provide such a helical groove for engaging a corresponding rib on the housing for relative movement between the parts during dose setting and injection. Accordingly, it is my opinion that Møller in combination with Steenfeldt-Jensen teaches this feature of claim 1 of the '486 patent.

354. With regard to claim 1 of the '069 patent and claim 11 of the '044 patent, which require the "helical groove" be "provided along an outer surface of [the] dose dial sleeve," Steenfeldt-Jensen teaches such a feature. *See, e.g.*, EX1014, Abstract, 1:12-15. The syringes (*i.e.*, pen injectors) disclosed in Steenfeldt-Jensen include a "dose dial sleeve," in the form of a dose scale drum, which contains a helical groove formed along its outer surface for engagement with a threading on the syringe's housing. *See, e.g.*, EX1014, 6:7-17, 11:20-25, FIGS. 2-3, 15-17. For instance, Steenfeldt-Jensen describes a syringe (pen injector) having a dose scale drum 17, which "in its outer wall [is] provided with a helical gro[o]ve." *Id.*, 6:7-17, FIG. 3. A housing 1 includes "a helical protruding rib 16" that engages with the dose scale drum 17's helical groove so that the dose scale drum 17 may be rotated and

axially moved in and out of the housing during use. *See id.*, 6:7-17, 7:17-21, FIGS. 1-3. Steenfeldt-Jensen further describes other embodiments having a dose scale drum with an outer helical groove for threaded engagement with the syringe's housing. *See, e.g.*, *id.*, 8:8-12, 9:52-56, 10:40-45, 11:20-22, FIGS. 8, 13, 17.

355. Based on the teachings of Møller and Steenfeldt-Jensen, it is my opinion that a person of ordinary skill would have found it readily apparent to modify Møller's dose setting drum 17 to include a helical groove on its outer surface for engaging a threading on the housing, like that taught by Steenfeldt-Jensen.

356. In discussing the background for its invention, I note that Møller discusses the device disclosed in Steenfeldt-Jensen. *See* EX1015, ¶8 (referencing EX1027). Specifically, Møller notes the prior art's use of "gearing between the injection button and the piston has occurred so that the button has a larger stroke than has the piston" to accommodate larger-sized ampoules that hold a greater amount of medicine. *See id.*, ¶¶4, 6. Møller explains that this type of gearing helps the user experience greater length of movement of the injection button when injecting a set dose, even in cases where the piston rod needs to move only a small amount to deliver the set dose. *See id.*, ¶¶4-6. This gearing also has the effect of reducing the force needed to move the injection button during injection, thus accommodating those users who have reduced finger strength. *See id.*, ¶¶4-5.

357. Møller specifically acknowledges Steenfeldt-Jensen's use of such a gearing in the form of "[a] thread with [a] high pitch is cut in the outer surface of a dose setting drum and is engaged by a mating thread on the inner side of the cylindrical housing." *Id.*, ¶8. In Steenfeldt-Jensen's case, when the dose setting drum is pressed back into the housing during injection, the drum's rotation is transmitted to a driver, which in turn, rotates to drive a piston rod axially. *See id.*, ¶8; *see also* EX1014, 12:4-13. Møller, however, notes that this type of rotational gearing results in relatively large surfaces sliding over each other "so that most of the transformed force is lost due to friction between the sliding surfaces." EX1015, ¶8. Thus, according to Møller, "a traditional gearing using mutual engaging gear wheels and racks is preferred." *Id.*, ¶8.

358. Møller then describes its injection device, "which combines the advantages of the devices according to the prior art without adopting their disadvantages." *Id.*, ¶¶11-12. In Møller's device, the high-pitch, threaded engagement between the dose setting drum and the housing is retained, but a gearbox is added in order to provide direct, axial gearing to drive the piston rod. *See id.*, ¶¶12-13. With this arrangement, Møller states that "only the forces necessary to drive the dose setting drum are transformed by a thread with a high pitch whereas the forces necessary to move the piston by injection is transmitted to said piston through a conventional gear ...." *Id.*, ¶14.

359. As I noted above, Steenfeldt-Jensen discloses numerous examples of dose dial sleeves that have a helical groove on its outer surface for engaging a threading on the housing. *See, e.g.*, EX1014, 6:7-17, FIGS. 3, 8, 13, 17. Steenfeldt-Jensen teaches that the helical groove includes a high pitch, and a pitch angle that "exceeds the angle of friction for the materials forming" the drum and the housing. *Id.*, 6:7-17. Such a configuration results in a non-self-locking threaded connection between the drum and the housing, which allows the drum to easily rotate back into the housing during injection when axially moved by the user. *See id.*, 6:7-17.

360. It is my opinion that a person of ordinary skill would have recognized the benefit to placing a threaded engagement like that taught by Steenfeldt-Jensen on a drum and housing like that of Møller's device. Specifically, a person of ordinary skill would have understood that the high-pitch threaded arrangement taught by Steenfeldt-Jensen reduces the force necessary to rotate the drum back into the housing during injection (and thus reduces the overall force needed during injection), even in cases where the dose setting drum includes an outer helical groove that engages the housing's threading. A person of ordinary skill also would have recognized that providing Møller's dose setting drum with a helical groove on its outer surface, rather than its inner surface, would result in the same relative rotational movement between the drum and housing, and would not affect the overall operation of the device. A person of ordinary skill also would have expected that such a

configuration would not appreciably affect the injection force needed to drive the piston rod, given Møller's direct-gear coupling to drive the rod.

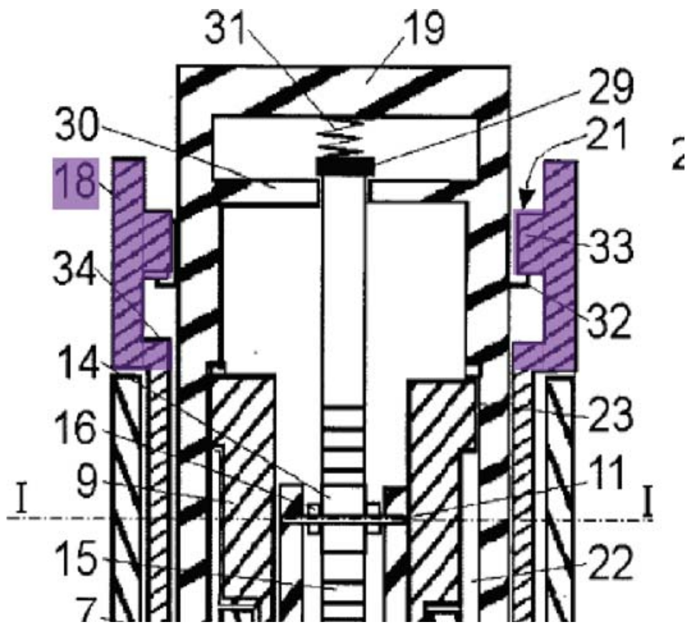
361. Indeed, I note that Møller expressly contemplates the use of a high-pitch threaded engagement between the drum and the housing, but it does not place any significance on the placement of that engagement. Thus, it is my opinion that a person of ordinary skill would have reasonably expected that an outer helical groove threading provided on the dose setting drum would result in the same rotational function as the inner threading shown in Møller. As such, given the above, it is my opinion that a person of ordinary skill would have found it apparent to provide the "helical groove" on the outer surface of the dose setting drum 17 for engaging a threading on the inner surface of the housing 1 in view of the teachings of Møller in combination with Steenfeldt-Jensen.

['069] Claim 1.3/['044] Claim 11.3: a dose dial grip disposed near a proximal end of said dose dial sleeve;

['486] Claim 1.3: a dose *knob* disposed near a proximal end of said dose dial sleeve;

362. Møller discloses that the dose setting drum 17 includes, at its button-end, "a part with enlarged diameter forming a dose setting button 18." EX1015, ¶25, FIG. 1. To set a dose, the user rotates the dose setting button 18 to screw the dose setting drum 17 up along the thread 6 of the housing's tubular element 5. *Id.*, ¶29,

FIG. 1. Reproduced below is a partial view of FIG. 1, toward the device's button-end, where I have highlighted the dose setting button 18 in purple:



363. Thus, Møller teaches a "dose dial grip," or a "dose knob," in the form of a dose setting button 18.

<u>['069] Claim 1.4/['044] Claim 11.4/['486] Claim 1.4: a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;</u>

364. Møller describes a piston rod 4 having a not-round cross-section, which "fits through a central opening in the [partitioning] wall 2 so that the piston rod 4 can be displaced longitudinally through the central opening in the wall 2 but not rotated relative to this wall." *Id.*, ¶23, FIG. 1. Because the piston rod 4 cannot rotate relative to the partitioning wall 2 of the housing 1 due to its non-circular engagement with the wall, the piston rod 4 cannot rotate during a dose setting step. Below, I have reproduced a partial view of FIG. 1, toward the needle-end of the device, where I

have annotated the piston rod 4 in yellow, which is shown to be provided within the housing:

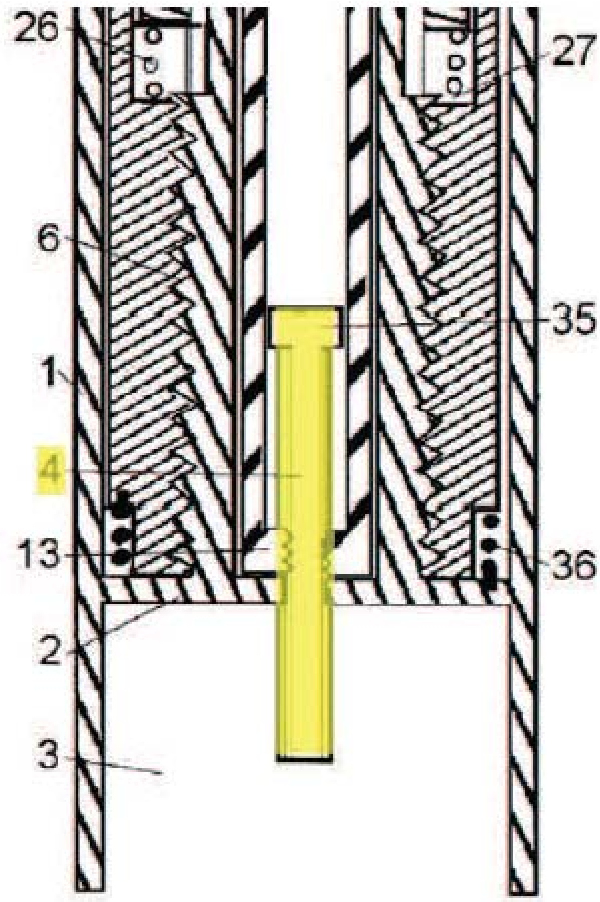


Fig. 1

365. Thus, Møller teaches a "piston rod" in the form of a piston rod 4 that is "provided within" the housing 1, and "is non-rotatable during a dose setting step relative to" the housing 1.

['069/'044] Claim 1.5/Claim 11.5: a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and,

['486] Claim 1.5: a *driver* extending along a portion of said piston rod, said *driver* comprising an internal threading near a distal portion of said *driver*, said internal threading adapted to engage an external thread of said piston rod; and,

366. Møller's device further includes a gearbox 9 that includes gear wheels "journaled on a shaft 11, which runs perpendicular to the longitudinal axis of the device between two axial connection bars 12." *Id.*, ¶24, FIG. 1. "The connection bars 12 project from the gear box towards the partition wall 2 and are connected to a nut 13" with a flange at the distal end, which "engages the thread of the piston rod 4." *Id.* FIGS. 1 and 2 are reproduced below, where I have annotated the connection bars 12 with nut 13 in red:

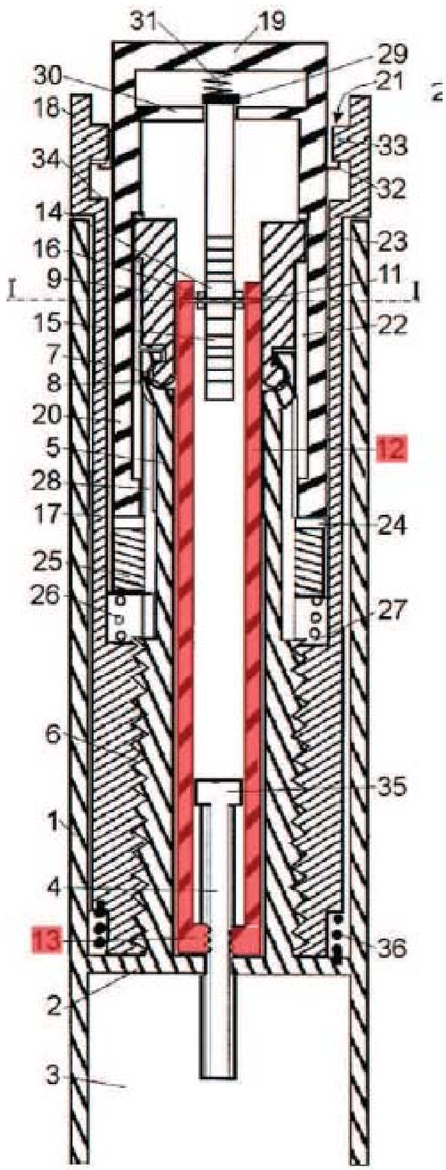


Fig. 1

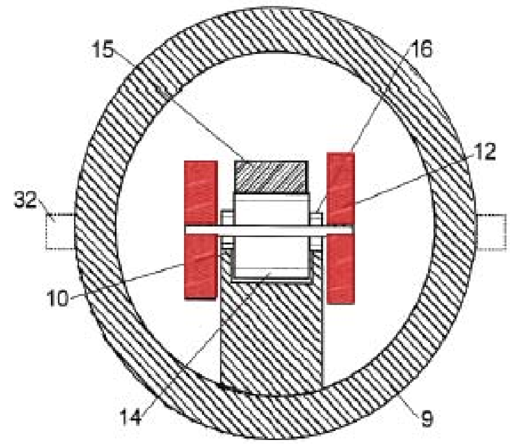


Fig. 2

367. As shown in FIG. 1 above, on opposing sides of the piston rod 4, the connection bars 12 extend along a portion of the rod's length. FIG. 2 shows the connection bars 12 as viewed looking down from the button-end of the device along the cross-section I-I shown in FIG. 1. *See id.*, ¶18. The needle-end of the connection bars 12 is formed by the nut 13, which encircles a portion of the piston rod 4's length

and has an internal threading that engages with the piston rod 4's external threading. *See id.*, ¶24, FIG. 1. Møller discloses that during dose setting, rotation of the dose setting drum 17 causes the connection bars 12 with nut 13 to rotate so that the component moves up along the piston rod's threading toward the rod's button-end. *See id.*, ¶30. And, as explained more below, to inject a set dose, the connection bars 12 with nut 13 are then disengaged from its rotational connection with the dose setting drum 17. *See id.*, ¶33. This allows the component to move axially and press the piston rod 4 through the partitioning wall 2 and into the compartment 3 to dispense the set dose of medicine. *See id.*, ¶32, FIG. 1.

368. I note here that claim 1 of the '069 patent and claim 11 of the '044 patent recite a "drive sleeve," while claim 1 of the '486 patent recites a "driver" instead. Under Sanofi's constructions of those terms, a "driver" is broader—it encompasses any component that is "releasably connected to the dose dial sleeve" and "drives the piston during dose dispensing." *See supra*, ¶109. A "drive sleeve," on the other hand, encompasses only "essentially tubular component[s] of essentially circular cross-section." *See id.*

369. Based on the above, it is my opinion that a person of ordinary skill would have understood the connection bars 12 with nut 13 to be a component that drives the piston rod, and that this component was a "driver," as recited in claim 1 of the '486 patent. Thus, it is my opinion that Møller discloses a "driver" in the form

of connection bars 12 with nut 13, which includes "an internal threading near a distal portion" of the connection bars 12 with nut 13 for "engag[ing] an external threading" of the piston rod 4. I also note, applying Sanofi's construction for the term, the connection bars 12 with nut 13 are "releasably connected" to the dose setting drum 17 through its releasable rotational connection to the drum 17, as explained more below. *See infra*, ¶109.

370. With regard to claim 1 of the '069 patent and claim 11 of the '044 patent, it is my opinion that a person of ordinary skill would have understood that Møller teaches the use of "an essentially tubular component" to drive the piston during dose dispensing. For instance, in a second embodiment, Møller incorporates the use of a tubular connection element 112 with a nut 113, which, as shown in FIGS. 3-5, is a fully enclosed, tubular component that encompasses the piston rod 104. *See id.*, ¶40. The tubular connection element 112 with nut 113 includes a structure that is substantially identical to that of connection bars 12 with nut 13. That is, much like connection bars 12, the tubular connection element 112 includes, at its button-end, two pins 111 that project perpendicular to the element's longitudinal axis and hold the device's gearing system. *See id.*, ¶40, FIGS. 3-5. The nut 13, having an internal threading, is provided toward the tubular connection element's needle-end. *See id.*, ¶40. Moreover, the tubular element 112 with nut 113 operates in the same manner as connection bars 12 with nut 13. The tubular connection element 112 with nut 113

is also configured to rotate up along the piston rod's external threading during dose setting, and to move axially toward the device's needle-end to drive the piston rod during injection. *See id.*, ¶¶35, 40. Indeed, as I noted above, Møller acknowledges the structural and functional equivalence between these components, noting that "elements corresponding to elements in FIGS. 1 and 2 are given the same references as these elements with a prefixed '1'." *Id.*, ¶35.

371. Given the above, it is my opinion that a person of ordinary skill would have considered the connection bars 12 with nut 13 to be essentially equivalent, in both structure and function, to the tubular element 112 with nut 113 shown in FIGS. 3-5. As a result, a person of ordinary skill would have expected that the connection bars 12 with nut 13 could readily be formed as a tubular structure that encompasses the piston rod 4, without affecting the device's operation. Thus, to the extent that the connection bars 12 with nut 13 as shown in FIGS. 1-2 are not considered an "essentially tubular component," it is my opinion that providing an "essentially tubular component," like the tubular structure of tubular connection element 112 with nut 113, to drive the piston during dose dispensing would have been readily apparent to those skilled in the art. Accordingly, with respect to claim 1 of the '069 patent and claim 11 of the '044 patent, it is my opinion that Møller teaches a "drive sleeve" that is an "essentially tubular component," which "extend[s] along a portion

of [the] piston rod," and includes "an internal threading near a distal portion" that is "adapted to engage an external thread of [the] piston rod."

<u>['069] Claim 1.6/['044] Claim 11.6: a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,</u>

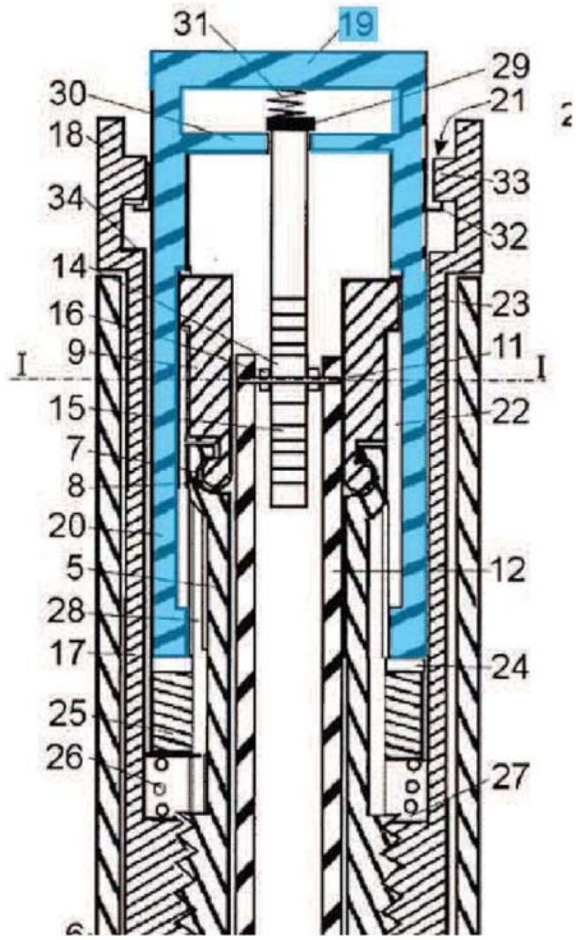
<u>['486] Claim 1.6: a tubular clutch located adjacent a distal end of said dose *knob*, said tubular clutch operatively coupled to said dose *knob*,</u>

372. Møller's device also includes "a deep cup shaped element," which has "a bottom 19" that forms an injection button and "a tubular part 20 [that] fit[s] into the dose setting drum 17 and encompass[es] the gearbox 9." *Id.*, ¶26, FIG. 1. The cup shaped element is releasably coupled to the dose setting drum 17 through "0-shaped protrusions 32 ... engaging A-shaped recesses in the inner ring 33 in the dose setting button 18." *Id.*, ¶29, FIG. 1.

373. To set a dose, the user rotates the dose setting button 18, which causes the dose setting drum 17 to rotate up along the thread 6 of the housing. *Id.*, ¶29. At this stage, the cup shaped element's protrusions 32 are engaged with the recesses in the dose setting button due to a spring 26 that biases the cup shaped element toward the button-end so that it remains engaged with the dose setting button. *See id.* This causes the cup shaped element to follow the dose setting drum's rotation, the rotation of which is transmitted to the gearbox 9 and the connection bars 12 with nut 13. *See id.*, ¶30. As a result, nut 13 screws up along the thread of the piston rod 4 toward its button-end. *Id.*

374. To inject a set dose, the bottom 19 of the cup shaped element is pressed by the user. *Id.*, ¶32. This action moves the cup shaped element axially toward the device's needle-end, which causes the protrusions 32 to disengage from the dose setting button 18. *Id.*, ¶33. As a result, the cup shaped element is decoupled from the dose setting drum 17, allowing the drum 17 to rotate freely back into the housing. *Id*. The cup shaped element moves axially toward the device's needle-end without following the drum's rotation. *Id.*, ¶32. The cup shaped element's axial movement is transmitted to the connection bars 12 with nut 13 through the gear box 9, which causes the nut 13 to press the piston rod 4 into the compartment 3 to dispense medicine. *Id.*

375. FIG. 1 is reproduced below, where I have highlighted the cup shaped element in blue:



376. As shown in FIG. 1 above, the cup shaped element is "tubular" in shape. It also serves as a "clutch" by coupling the rotation of the dose setting drum 17 to the connection bars 12 with nut 13 during dose setting, and decoupling that common rotation during injection. *See id.*, ¶¶29-30, 32-33, FIG. 1. Moreover, as shown in FIG. 1 above, the cup shaped element includes a tubular part 20 that extends from a button-end side of the dose setting button 18 through its needle-end into the dose setting drum 17, making the cup shaped element "located adjacent to a distal end" of the dose setting button 18. *See id.*, ¶26. And, as mentioned above, protrusions 32 of the cup shaped element are configured for releasable engagement with recesses

provided on the dose setting button 18, rendering the cup shaped element "operatively coupled to" the dose setting button 18. *See id.*, ¶¶29-30, 3233.

377. Accordingly, Møller teaches a "tubular clutch" in the form of a cup shaped element that is "located adjacent a distal end of" and "operatively coupled to" the dose setting button 18.

378. I also note that Møller teaches a "tubular clutch" even under the means-plus-function interpretation. As I noted above, the challenged patents identify element 60 as the clutch. For instance, the '069 patent discloses:

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

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

EX1001, 4:29-41.

379. The tubular clutch as described by the challenged patents, therefore, is "generally cylindrical," having a series of "circumferentially directed ... teeth" at is first, *i.e.*, needle-end, and also has a plurality of teeth at a second, *i.e.*, button-end. *Id*. The teeth on the needle-end engage with the clicker, and the teeth on the button-end engage with the dose dial sleeve. *See id.*, 5:29-36, 6:6-22. As taught by the challenged patents, 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.*, 4:39-41.

380. It is my opinion that Møller's cup shaped element and tubular element 120, which Møller discloses corresponds to the cup shaped element, operate in a similar manner using a similar structure. *Compare* EX1015, FIGS. 1, 5 *with* EX1001, FIGS. 6-8. Like clutch 60, the cup shaped element and the tubular element 120 includes a set of axially extending teeth at their button-end that releasably engage corresponding teeth in the dose setting button. *See id.*, ¶¶36, 39, FIGS. 3-5; *see also id.*, ¶¶29-30 (discussing similar structure of the cup shaped element), FIG.

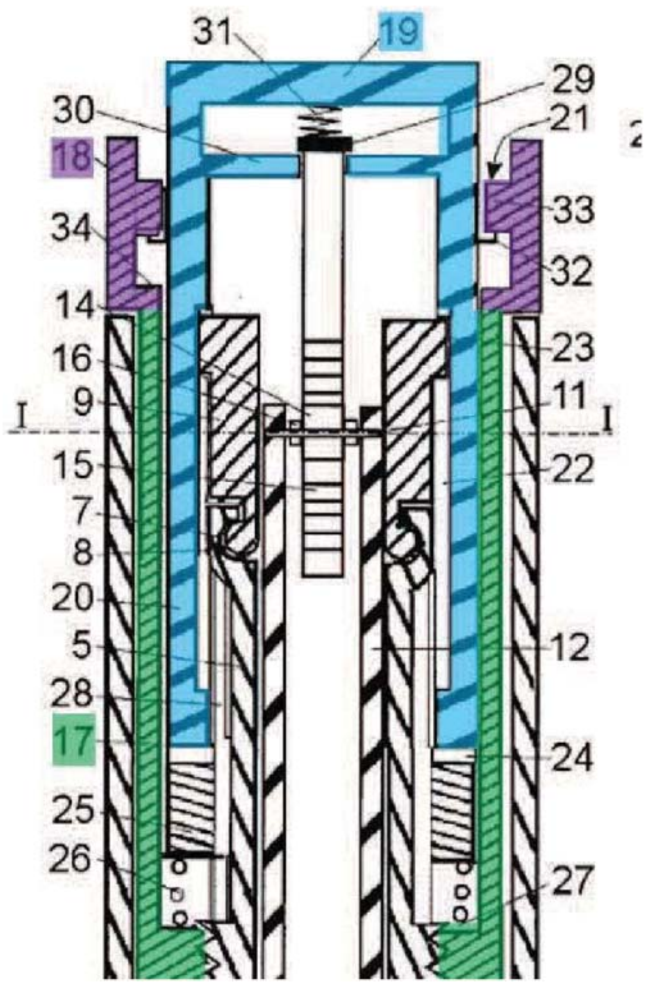
1. Both embodiments also include a biasing element (spring 26/126) that exerts upward force to keep the clutch engaged during dose setting. *See id.*, ¶¶27, 29, 39, FIGS. 3-5. The user then applies force to the button (bottom 19 or button 119), which pushes the teeth out of engagement to rotationally decouple the components during injection. *See id.*, ¶¶27, 29, 39, FIGS. 3-5. Thus, it is my opinion that cup shaped element and tubular element 120 not only have the structure of clutch 60 of the challenged patent, they also serve as a clutch because they releasably couple and decouple components of the pen during injection.

['069] Claim 1.7/['486] Claim 1.7: wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

['044] Claim 11.7: wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, *and*

381. As I noted above, the cup shaped element includes a tubular part 20 that extends into the dose setting drum 17. *See id.*, ¶26, FIG. 1. Thus, Møller teaches that the dose setting drum 17 "extends circumferentially around at least a portion of" the cup shaped element. Below, I have reproduced a partial view of FIG. 1, where I have annotated the dose setting drum 17 in green and the cup shaped element in blue to further illustrate their relative positioning:[30]

[30] Again, to illustrate the extent of the dose setting drum 17, I have also annotated the dose setting button 18, which I stated previously corresponds to the claimed



['044] Claim 11.8: wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different.

382. As I explained above, the term "lead" quantifies the axial distance a threaded component moves relative to the component to which it is engaged after

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"dose dial sleeve." *See supra*, ¶¶347-61. Like Burroughs and Steenfeldt-Jensen, Møller describes a dose setting button 18 that is integral with the dose setting drum 17. *See supra*, ¶139 n.17.

one complete revolution. *See supra*, ¶189; EX1005, 3:56-63. Related to this term is a thread's "pitch," which refers to the axial distance between consecutive ribs on a helical thread. *See* EX1005, 3:64-67. In cases where the thread is composed of a single, helical thread (referred to as a "single-start thread"), the thread's "lead" is equal to the thread's "pitch." In cases where the thread is composed of two or more helical threads (referred generally as a "multiple-start thread"), the thread's "lead" is equal to the "pitch" multiplied by the number of threads or "starts." So, for example, if a thread is composed of two "starts" (a "double start thread"), then the thread's "lead" is twice its "pitch."

383. As I discussed above, a person of ordinary skill would have considered it obvious to provide a helical groove on the outer surface of the dose setting drum of Møller for engaging with a threading provided on the housing. *See supra*, ¶¶355-61. A person of ordinary skill would have understood that this helical groove would have a "first lead," where, with each full revolution of the dose setting drum 17, the dose setting drum 17 would axially move relative to the housing 1 by a distance equal to the "first lead."

384. Similarly, as I discussed above, the connection bars 12 with nut 13 include an internal threading that engages an external threading of the piston rod 4. *See supra*, ¶¶366-71. A person of ordinary skill would have also understood that this threading has a "second lead," where, with each full revolution of the connection

bars 12 with nut 13, the component would axially move relative to the piston rod 4 by a distance equal to the "second lead."

385. Both Møller and Steenfeldt-Jensen discuss setting the pitch of the dose dial sleeve's external threading to be greater than the pitch of the drive sleeve's internal threading. *See, e.g.*, EX1015, ¶2:49-64; EX1014, 6:7-17 (stating threading of dose scale drum includes "a high pitch" such that its threaded connection with the housing is "of the not self locking type"), 2:23-24, 2:50-53 (stating internal threading of nut member to include a pitch such that its threaded connection with the piston rod is "self locking"). For example, Møller teaches that this type of pitch-difference provides "a gearing [such that] the movement of the injection button is made larger and the force, which has to be exerted on the injection button, is correspondingly reduced." EX1015, ¶¶6-7. This allows the user to perceive greater changes in movement of the dose setting drum 17 during dose setting for correspondingly small changes in movement of the piston rod 4 during dose dispensing. *See* EX1015, ¶¶5-6. Thus, Møller discloses that the piston rod is threaded with a threading of a "first pitch," while the dose setting drum 17 is screwed along a threading having a "second pitch." *See id.*, ¶12. The gearbox "provides a gearing between the axial movements of the injection button and the nut relative to the housing which gearing has a gearing ratio corresponding to the ratio of said second pitch and first pitch." *See id.*; *see also id.*, ¶14 (stating thread on dose setting drum contains a "high pitch"). Given this, it

is my opinion that a person of ordinary skill would have understood that Møller discloses that the pitch of the dose setting drum 17's threading is larger than the pitch of the nut 13's threading.

386. A person of ordinary skill would have also understood that, in order to achieve the larger stroke of the dose setting drum during dose setting relative to the stroke of the piston rod during injection, the pitch difference should be one that resulted in the dose setting drum's threading to have a lead larger than the lead provided in the nut's threading. As a result, it is my opinion that a person of ordinary skill would have understood that Møller's discussion of pitch differences also taught the setting of different leads for the threading of the dose setting drum 17 and nut 13. As such, the combination of Møller and Steenfeldt-Jensen render this feature obvious.

2. Dependent claims 14-15 and 18-19 of the '044 patent and dependent claims 2-6, 12-18, 20, 23, 27-30, 32-33, 36, and 38-40 of the '486 patent

387. Each section of dependent claims 14-15 and 18-19 of the '044 patent and dependent claims 2-6, 12-18, 20, 23, 27-30, 32-33, 36, and 38-40 of the '486 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

['486] Claim 2: The housing part of claim 1, wherein said tubular clutch is directly coupled to said dose knob.

388. As I explained above, to engage and disengage the dose setting drum 17's rotational movement from the connection bars 12 with nut 13 during use, Møller discloses that the cup shaped element includes protrusions 32 that releasably engage with the recesses in the dose setting button 18 such that the components are rotationally coupled when engaged, and rotationally decoupled when disengaged. *See supra*, ¶¶372-80. Møller thus discloses that the cup shaped element "is directly coupled to" the dose setting button 18.

['486] Claim 3: The housing part of claim 1, wherein said main housing comprises a window through which at least a portion of an outer surface of said dose dial sleeve may be viewable.

389. Møller discloses that the housing 1 includes a (not shown) window. *See* EX1015, ¶25. "Due to the engagement with the thread 6 the dose setting drum 17 may be screwed in and out of the housing to show a number on a not shown helical scale on its outer surface in [the] not shown window in the housing 1." Møller thus discloses that the housing 1 "comprises a window through which at least a portion of an outer surface of" the dose setting drum 17 "may be viewable."

['486] Claim 4: The housing part of claim 3, wherein said window is located near a proximal end of said main housing and near a helical rib provided on an inner surface of said outer housing.[31]

390. Møller does not explicitly disclose that the window is located near a button-end of the housing 1, near a helical rib provided on an inner surface of the housing 1. However, it is my opinion that a person of ordinary skill would have found it readily apparent to (1) provide a helical rib on the inner surface of the housing 1 for engagement with the helical groove provided on the dose setting drum 17, and (2) position the window near a button-end of the housing 1 and near the helical rib on the housing's inner surface.

391. First, as I explained above, a person of ordinary skill would have understood that, due to the threaded connection between the dose setting drum 17 and the housing 1, the threading on the dose setting drum 17 would include a helical groove along its surface that engaged with a corresponding helical rib on the threading 6 of the housing 1. *See supra*, ¶¶355-61. To the extent that the helical rib of the housing 1 is not provided on the "inner surface" of the housing 1, it is my opinion that a person of ordinary skill would have found it readily apparent to position the helical rib on the inner surface of the housing 1 for engaging a helical

[31] As I explained earlier, my analysis construes "said outer housing" to mean "the main housing." *See supra*, ¶205.

groove provided on the outer surface of the dose setting drum 17 in view of Steenfeldt-Jensen's teachings. That is, as I explained above with regard to claim 1 of the '069 patent and claim 11 of the '044 patent (both of which require placement of a helical groove on the dose dial sleeve's outer surface), based on the teachings of Møller and Steenfeldt-Jensen, a person of ordinary skill would have found it apparent to place a helical groove on the outer surface of the dose setting drum for engaging a corresponding helical rib on the inner surface of the housing 1, and would have expected such an arrangement to result in the same relative movement between the drum and the housing. *See supra*, ¶¶355-61. My analysis with respect to those claims applies equally here.

392. Second, with respect to the position of the window, it is my opinion that a person of ordinary skill would have placed the window near a button-end of the housing 1, which would be positioned near the helical rib of the housing 1. First, a person of ordinary skill would have understood that, during dose setting, the dose setting drum 17 would rotate out of the housing, moving axially away from the button-end of the housing. In order to properly view a helical scale provided on the dose setting drum's outer surface during dose setting, a person of ordinary skill would have understood that the window would need to be placed near the button-end of the housing so that the helical scale may be viewed as the drum is rotated and lifted away from the housing. Indeed, this is confirmed by Steenfeldt-Jensen, which

shows a window 18 of a housing 1 that is located near a button-end of the housing 1. *See* EX1014, FIG. 17. Moreover, a person of ordinary skill would have also understood that, for the dose setting drum 17 to rotate and axially move out of the housing 1, the helical rib also would be placed at least near a button-end of the housing 1 so that the dose setting drum 17 could extend out from the housing 1 by the axial length of the helical groove. This is also confirmed by Steenfeldt-Jensen, which shows that the helical rib 16 extends from a button-end to a needle-end of the housing 1. *See* EX1014, FIGS. 15-17. Thus, based on the teachings of Møller and Steenfeldt-Jensen, it is my opinion that a person of ordinary skill would have found it readily apparent that the window of the housing 1 would be "located near a proximal end of" the housing 1, and "near a helical rib provided on an inner surface of" the housing 1.

393. As I explained above, Steenfeldt-Jensen discloses that the housing 1 includes a helical rib 16 on its inner surface that engages a helical groove on the scale drum 80. *Id.*, 11:20-22, FIGS. 15-17. Below, I have reproduced a partial view of FIG. 17 (left), where the window 18 is shown to be located near a button-end of the housing 1. I have also reproduced a partial view of FIG. 16 (right), where the helical rib 16 (annotated in red) is shown to extend along the length of the housing 1 (annotated in gray). Given the positioning of the window 18, and the extension of

the helical rib 16, a person of ordinary skill would have understood that the window 18 is "located near" the helical rib 16

['486] Claim 5: The housing part of claim 1, wherein said driver comprises a cylindrical shape.

394. As I noted above, Møller discloses a "driver" in the form of connection bars 12 with nut 13. *See supra*, ¶¶366-71. A person of ordinary skill would have understood that the nut 13 "comprises a cylindrical shape." To illustrate this, I have reproduced FIG. 1 below, where I have annotated the connection bars 12 with nut 13 in red, and encircled nut 13 in blue, which shows the cylindrical shape of nut 13:

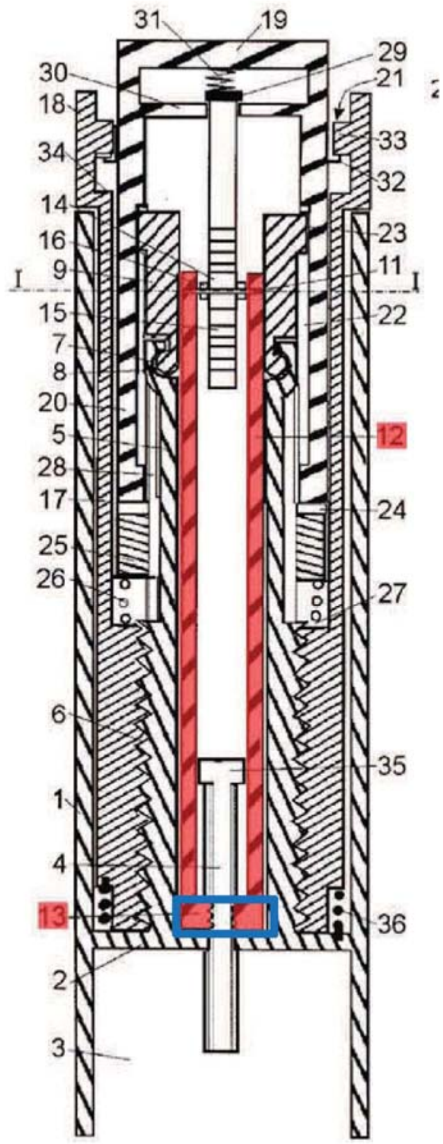


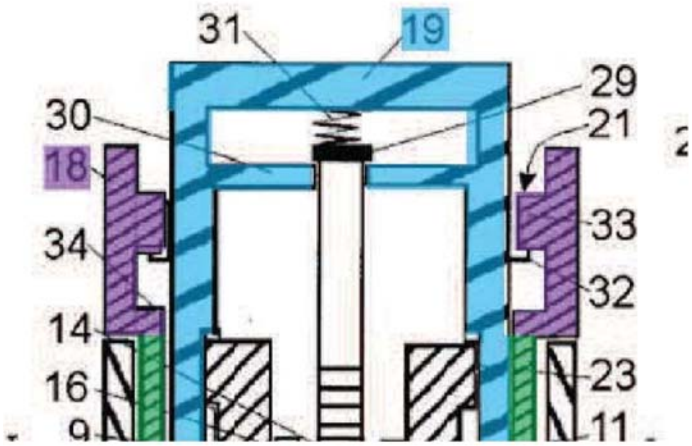
Fig. 1

395. Moreover, to the extent that the nut 13 is considered not to be "cylindrical" in shape, as I similarly explained above with regard to claim 1 of the '069 patent and claim 11 of the '044 patent, it is my opinion that Møller nevertheless teaches a "driver" that "comprises a cylindrical shape." *See supra*, ¶¶366-71. That is, Møller teaches a tubular connection element 112 with nut 113 that is tubular in

structure, and thus, "comprises a cylindrical shape." *See* EX1015, ¶¶40, FIGS. 304. As I explained above, it is my opinion that a person of ordinary skill would have considered the connection bars 12 with nut 13 to be essentially equivalent, in both structure and function, to the tubular element 112 with nut 113 shown in FIGS. 3-5. *See supra*, ¶¶355-61. As a result, a person of ordinary skill would have expected that the connection bars 12 with nut 13 could readily be formed as a tubular structure that encompasses the piston rod 4, without affecting the device's operation. Thus, to the extent that the connection bars 12 with nut 13 as shown in FIGS. 1-2 do not "comprise[] a cylindrical shape," it is my opinion that providing a "driver" having a "cylindrical shape," like the tubular structure of tubular connection element 112 with nut 113, to drive the piston during dose dispensing would have been readily apparent to those skilled in the art.

['486] Claim 6: The housing part of claim 1, wherein said dose knob extends circumferentially around at least a portion of said tubular clutch.

396. As I explained above, Møller discloses a "dose knob" in the form of the dose setting button 18. *See supra*, ¶¶362-63. In FIG. 1, dose setting button 18 extends circumferentially around a button-end portion the cup shaped element. To illustrate this positioning, I have reproduced a partial view of FIG. 1, toward the device's button-end, where I have annotated the cup shaped element in blue, the dose setting button 18 in purple, and the dose setting drum 17 in green:



397. Accordingly, Møller discloses that the dose setting button 18 "extends circumferentially around at least a portion of" the cup shaped element.

['044] Claim 14: The housing part of claim 11, further comprising a clicker, said clicker providing at least an audible feedback to a user when said dose dial grip is rotated.

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

398. Both Møller and Steenfeldt-Jensen disclose the use of a clicker to provide audible feedback to the user when the dose dial grip is rotated.

399. For example, Møller discloses that "[a]t the edge of the open end of the cup shaped element a rosette of V-shaped teeth are provided, which teeth engage a corresponding rosette of V-shaped teeth 24 on a ring 25 which is pressed against the edge of the cup shaped element by a spring 26 ...." EX1015, ¶27. "The ring is provided with an inner recess, which is engaged by a longitudinal rib 28 on the tubular element 5 so that the ring 25 can be displaced in the axial direction of the device but cannot be rotated relative to the housing." *Id.* "Thereby a click coupling

is established which makes a click noise when the V-shaped teeth at the edge of the cup shaped element by rotation of this element rides over the V-shaped teeth of the ring 25." *Id.* As a result, when the cup shaped element is rotated due to the user's rotation of the dose setting button 18 during dose setting, a clicking noise is produced as the teeth ride over one another. *Id.*, ¶29; *see also id.*, ¶40 (disclosing a similar clicker in its second embodiment).

400. Similarly, Steenfeldt-Jensen discloses the use of a clicker in its injection devices. *See, e.g.*, EX1014, 3:19-26. For instance, in one embodiment, Steenfeldt-Jensen discloses a pawl 13 that has a protrusion 29 at its end that engages with pawl wheel teeth 10 having depressions 32 into which the protrusion 29 rests. *See id.*, 6:54-7:1, FIGS. 3-4. Steenfeldt-Jensen teaches that when the pawl 13 is rotated by a sufficient amount of torque, the protrusion 29 is lifted out of the depression 32 into the next depression, which provides a clicking function to the user. *See id.* In another embodiment, a button-end of a guide member 56 "has at its [button-end] at least one radial protrusion 65 which is biased to engage axial recesses 66 in an inner wall of [a] button [23] to produce[] a click sound each time the button is rotated relative to the bushing so that the protrusion jump[s] from one recess to the neighbor[ing] recess." *Id.*, 9:30-35, 9:48-52, FIG. 13. In yet another embodiment, Steenfeldt-Jensen discloses a bushing 82, which has a flange 83 that has, at its periphery, a radial protrusion 87. *Id.*, 11:37-40, FIG. 17. The flange 83 is adopted into a

compartment of a dose setting button 81, which contains longitudinal recesses along its cylindrical side wall. *Id.*, 11:34-40. When a dose is set by rotating the dose setting button 81, "the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 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.

401. Accordingly, it is my opinion that the combination of Møller and Steenfeldt-Jensen teaches a "clicker" that "provid[es] at least audible feedback to a user when [the] dose dial grip is rotated."

402. With regard to the means-plus-function interpretation, as I explained above, the challenged patents teach that the structure used to provide the function of an audible click is either a flexible arm being dragged over splines, or saw teeth riding over one another. *See supra*, ¶218. As I also explained above, Steenfeldt-Jensen teaches a clicker having a structure and function of the clicker taught by the challenged patents. Moreover, it is also my opinion that Møller also discloses a clicker that has one of the structures for a clicker as taught by the challenged patents. Specifically, as I explained above, Møller discloses the use of a rosette of V-shaped teeth at the edge of the open end of a cup-shaped element and V-shaped teeth 24, which provides an audible click to a user upon rotation of the dose dial grip. *See* EX1015, ¶¶27-29, 40; FIG. 1. One of the structures taught by the challenged patents

that may be used as a clicker is saw teeth that ride over one another to produce a click. EX1001, 5:62-6:5. Thus, Møller also teaches a clicker having the same structure as that in the challenged patents and having the same function.

['486] Claim 15: The housing part of claim 1, further comprising a clicker, said clicker provides tactile feedback to a user when said dose knob is rotated.

403. Møller and Steenfeldt-Jensen do not explicitly disclose that the clicker "provides tactile feedback to a user" when the dose setting button is rotated. Nevertheless, it is my opinion that a person of ordinary skill would have understood that the clickers of both Møller and Steenfeldt-Jensen would provide sufficient resistance such that the user would experience tactile feedback when the dose setting button was rotated during dose setting.

404. For instance, as I noted above, Møller describes a clicker in the form of V-shaped teeth on the cup element that ride over corresponding teeth of the ring 25 during dose setting. A person of ordinary skill would have understood that this mechanism, where teeth of one component engage and ride over corresponding teeth of another component when rotated over one another, would have provided sufficient resistance that could be felt by the user, thus providing "tactile feedback."

405. Similarly, Steenfeldt-Jensen teaches that its "click coupling provid[es] a[] moderate resistance against rotation ...." *Id.*, 3:21-27. In the context of the clicker of FIGS. 15-17, a person of ordinary skill would have understood that, when the

dose setting button 81 was rotated relative to the bushing 82, the radial protrusion 87 would provide “a moderate resistance” as it rode over the ridges between the longitudinal recesses to click from one recess to the next. Such a resistance would have been understood to provide “tactile feedback” to the user when the dose setting button 81 was rotated.

406. I note that such an understanding is consistent with the understanding of the person of ordinary skill presumed by the ’486 patent. For example, the ’486 patent describes that the clicker provides “audible and tactile feedback of the dose being dialed” when the “flexible arm 52 deforms and drags the toothed member 54 over the splines 42 to produce a click.” EX1003, 5:54:60. The clicker of Steenfeldt-Jensen operates in a substantially identical manner. That is, the end of the radial protrusion 87 deforms and drags over the ridges formed between the longitudinal recesses to produce a click as the protrusion 87 enters into the neighboring recess. Similarly, the ’486 patent describes that a click is also produced when saw teeth 56 of the clicker 50 engage and ride over corresponding saw teeth 66 on the clutch 60 during dose-dialing down. *See* EX1003, 6:22-27. The clicker of Møller operates in a substantially identical manner: when V-shaped teeth of the cup shaped element engage and ride over corresponding teeth on the ring 25, a click is produced. Thus, like the clicker described in the ’486 patent, a person of ordinary skill would have

understood that the clickers of Møller and Steenfeldt-Jensen would provide a similar form of "tactile feedback."

407. Accordingly, it is my opinion that a person of ordinary skill would have understood that the combination of Møller and Steenfeldt-Jensen discloses a clicker that "provides tactile feedback to a user when [the] dose knob is rotated."

['486] Claim 16: The housing part of claim 14, wherein said clicker provides audible feedback when said dose knob is rotated in a dose increasing direction.

408. Both Møller and Steenfeldt-Jensen teach a clicker that provides audible feedback when the dose knob is rotated in a dose increasing direction. Specifically, Møller teaches that when dose setting button 18 is rotated to screw the dose setting drum 17 out of the housing (*i.e.*, in a "dose increasing direction"), the V-shaped teeth 24 ride over the V-shaped teeth of the ring 25 "to make a click sound for each unit the dose is changed." EX1015, ¶29. Steenfeldt-Jensen describes similar audible feedback when the dose is increased during dose setting. *See* EX1014, 11:62-67.

409. Accordingly, the combination of Møller and Steenfeldt-Jensen discloses a clicker that "provides audible feedback when [the] dose knob is rotated in a dose increasing direction."

['486] Claim 17: The housing part of claim 14, wherein said clicker provides audible feedback when said dose knob is rotated in a dose decreasing direction.

410. Both Møller and Steenfeldt-Jensen teach a clicker that provides audible feedback when the dose knob is rotated in a dose decreasing direction. For instance, Møller teaches that "[a] too high set dose can be reduced by rotating the dose setting button 18 in the opposite direction of the direction for increasing the dose." EX1015, ¶29. A spring "keep[s] the V-shaped teeth of the ring 25 and the cup shaped element in engagement." *Id.* Because ring 25 is non-rotatable relative to the housing, and because the cup shaped element rotates with the dose setting drum 17 due to its engagement with the dose setting button 18 during dose setting, a person of ordinary skill would have understood that the V-shaped teeth of the cup shaped element would similarly ride over the V-shaped teeth of the ring. Thus, a person of ordinary skill would have understood that the clicker of Møller would "provide[s] audible feedback when [the] dose knob is rotated in a dose decreasing direction."

411. Steenfeldt-Jensen similarly teaches a clicker that produces an audible sound when a dose is decreased. That is, Steenfeldt-Jensen teaches that movement of the radial protrusion 87 over the longitudinal recesses of the dose setting button 81 will produce a click when the dose setting button 81 is rotated "in any direction." *See* EX1014, 11:62-67. Thus, Steenfeldt-Jensen teaches that the clicker "provides audible feedback when [the] is rotated in a dose decreasing direction."

412. Accordingly, it is my opinion that the combination of Møller and Steenfeldt-Jensen teaches a clicker that "provides audible feedback when [the] dose knob is rotated in a dose decreasing direction."

['044] Claim 15: The housing part of claim 14, wherein said clicker comprises, [15.1] at least one flexible arm, said flexible arm comprising at least one tooth member, and [15.2] at least one spline, [15.3] wherein when said dose dial grip is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.

['486] Claim 18: The housing part of claim 1, wherein said clicker comprises, [18.1] at least one flexible arm, said flexible arm comprising at least one tooth member, and [18.2] at least one spline, [18.3] wherein when said dose knob is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback.

413. As I described above, both Møller and Steenfeldt-Jensen disclose the use of a clicker to provide audible feedback to the user when the dose dial grip is rotated. Indeed, both references evidence what was a common approach in the field at the relevant time: that an audible indication to the user during dose setting, in the form of a clicking noise, can be achieved through the use of extending protrusions that drag over ridges and then click into recesses during rotation.

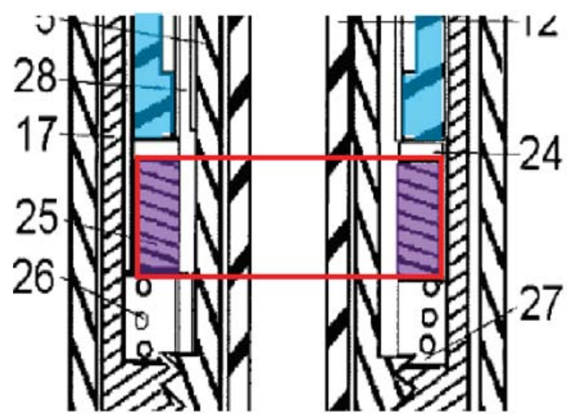
414. As I also explained above, Møller discloses the use of extending teeth on the cup shaped element that drag over corresponding teeth of a ring as the cup shaped element is rotated to produce a clicking noise. As I explained above, Steenfeldt-Jensen discloses that this identical function may be achieved through the use of a flexible arm that deforms and drags into depressions or recesses to produce

a clicking noise. For instance, the flexible arm of pawl 13 includes a "tooth member," in the form of a protrusion 29, which is dragged over teeth 10 into depressions 32 to produce a clicking noise. *See* EX1014, 6:54-7:1, FIG. 4. Similarly, a person of ordinary skill would have understood that the radial protrusions 65 and 87 were "flexible arms" having a "tooth member" for deforming and dragging into longitudinal recesses to produce a clicking noise. *See id.*, 9:30-35, 9:48-52, 11:34-40, 11:62-67, FIGS. 13, 17. A person of ordinary skill would have also understood that the longitudinal recesses would form corresponding splines therebetween. *See supra*, ¶¶310-12.

415. Given this identical function, it is my opinion that a person of ordinary skill would have found it apparent to configure the "clicker" of Møller to have a "flexible arm" with a "tooth member" that deforms and drags into recesses formed by splines as taught by Steenfeldt-Jensen. The person of ordinary skill would have understood that such configuration would retain the same clicking function disclosed by Møller, without affecting the overall functioning of the device. Accordingly, it is my opinion that the combination of Møller and Steenfeldt-Jensen renders this feature obvious.

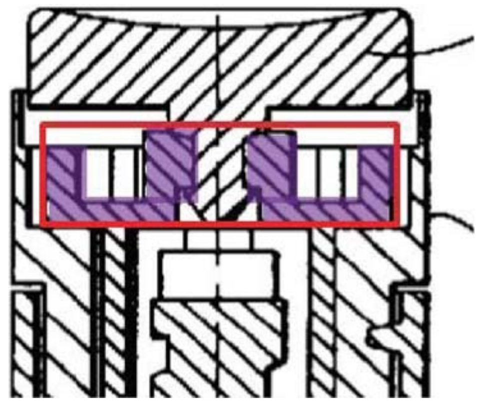
[’486] Claim 20: The housing part of claim 14, wherein [20.1] said clicker generally comprises a cylindrical shape having a first and a second end, and [20.2] said cylindrical shape is provided at said first end with at least one flexible extending arm.

416. Both Møller and Steenfeldt-Jensen teach a clicker that “generally comprises a cylindrical shape.” For instance, Møller teaches that the clicker includes a ring 25 having teeth that engage with corresponding teeth on the cup shaped element. *See* EX1015, ¶29, FIG. 1. As shown in the partial view of FIG. 1 below, where I have annotated the ring 25 in purple, the ring 25 generally comprises “a cylindrical shape” (encircled in red) having a first end (button-end) and a second end (needle-end). At its first end, the teeth are provided.



417. As I noted above, Steenfeldt-Jensen describes a clicker having a radial protrusion 87 that is positioned on a flange 83 of the bushing 82. Below, I have reproduced a partial view of FIG. 17 (left), where I have annotated the flange in purple. Also below, I have reproduced a partial view of FIG. 16 (right), where I have encircled the flange in red. As shown in the figures below, a person of ordinary skill would have understood that the flange is generally cylindrical in shape and has a

first end (button-end) and a second end (needle-end). The radial protrusion 87 is shown to extend along the length of the flange such that it is "provided at" the flange's button-end.



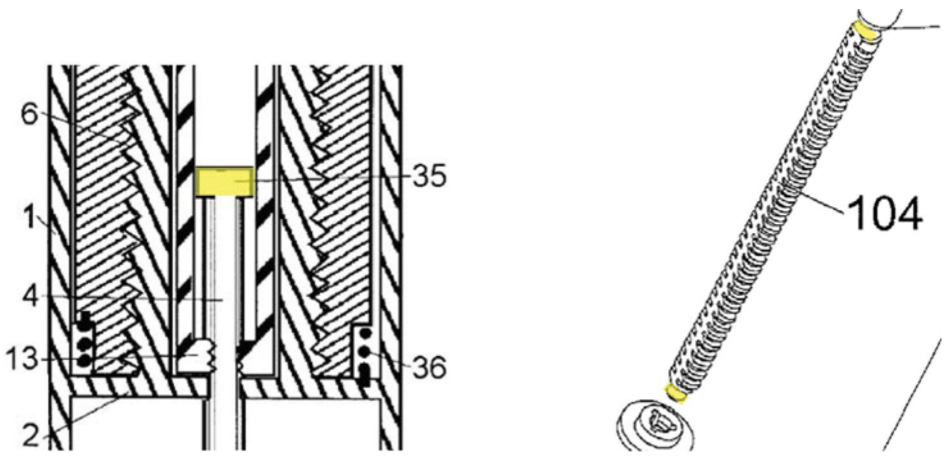
418. As I explained above, a person of ordinary skill would have understood that the clickers of Møller and Steenfeldt-Jensen perform identical functions. That is, both Møller and Steenfeldt-Jensen teach that a clicking indication can be provided by rotating one component having a protruding structure relative to another having recesses by which that protruding structure engages. Given this identical function, it is my opinion that a person of ordinary skill would have found it apparent to configure the "clicker" of Møller to have a "flexible arm" with a "tooth member" that deforms and drags into recesses formed by splines as taught by Steenfeldt-Jensen. A person of ordinary skill would have also found it readily apparent to provide the "flexible arm" at a "first end" of the ring 25 for engaging recesses provided on the cup shaped element. The person of ordinary skill would have understood that such configuration would retain the same clicking function disclosed

by Møller, without affecting the overall functioning of the device. Accordingly, it is my opinion that the combination of Møller and Steenfeldt-Jensen renders this feature obvious

['486] Claim 23: The housing part of claim 1, wherein said piston rod comprises a generally circular cross section.

419. As I noted previously, claim 23 of the '486 patent only requires that the piston rod has "a cross section" that is "generally circular." It does not require that the piston rod have a uniformly "generally circular cross section" along its entire length. Thus, although Møller discloses that the piston rod 4 has a "not round cross section," a person of ordinary skill would have understood Møller as teaching that the piston rod 4 has "a cross section" that is "generally circular" at its button-end, in the form of a stop 35, which limits the movement of the nut 13 up along the piston rod 4. *See* EX1015, ¶30. I note that such a "generally circular" cross section at the button-end of the piston rod 104 is further confirmed by FIG. 5, which Møller states corresponds to the piston rod 4. *See id.*, ¶35. In FIG. 5, the piston rod 104 is shown to have a "generally circular" cross section at its button-end. *See id.*, FIG. 5. It is also shown to have a "generally circular" cross section at its needle-end, which is used to engage a circular opening provided in a (unlabeled) pressure foot. *See id.* Given Møller's teaching that the piston rod 104 corresponds to the piston rod 4, it is my opinion that a person of ordinary skill would have found it readily apparent to utilize a piston rod like that shown in FIG. 5.

420. Below, I have reproduced partial views of FIGS. 1 (left) and 5 (right), which show the piston rod 4/104 in more detail, where I have annotated the "generally circular" cross-sections:



421. In addition, I note that the claim recites that the piston rod includes "a *generally* circular cross section." Thus, even if the piston rod 4/104 must have a *generally* circular cross-section along its length, it is my opinion that a person of ordinary skill would have understood that the piston rod 4/104 contains a "generally circular" cross-section along its length. First, I note that a person of ordinary skill in the art would have understood that the threaded piston rod described in the '486 patent would have a cross-section that was not perfectly circular due to the helical features of the first and second threads 19, 24 along the piston rod's length. *See* EX1003, 3: 56-67. I also note that the '486 patent does not describe at which point a cross-section becomes "generally" circular. In view of this, although the piston rod 4/104 contains a "not round cross-section" due to flattened portions for engaging a not-round opening of the partitioning wall 2 (*see, e.g.*, FIG. 5), it is my opinion that

a person of ordinary skill would have understood that the piston rod 4/104, with its helical, external thread extending along its length, would include a "generally circular cross section."

422. Accordingly, it is my opinion that a person of ordinary skill would have understood that the piston rod 6 "comprises a generally circular cross section."

['044] Claim 18: The housing part of claim 11, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.

['486] Claim 26: The housing part of claim 1, wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing.

423. As I explained above, Møller discloses that the dose setting drum 17 is positioned within the housing 1. *See supra*, ¶347. Moreover, Møller discloses that the cup shaped element includes a tubular part 20 that extends into the dose setting drum 17. *See supra*, ¶¶372-80. Møller thus discloses that the dose setting drum 17 "is provided outside" the cup shaped element and "radially inward of" the housing 1. To further illustrate the relative positioning between these components, below I have reproduced a partial view of FIG. 1 of Møller, where I have annotated the

housing 1 in gray, the dose setting drum 17 in green, and the cup shaped element in blue:[32]

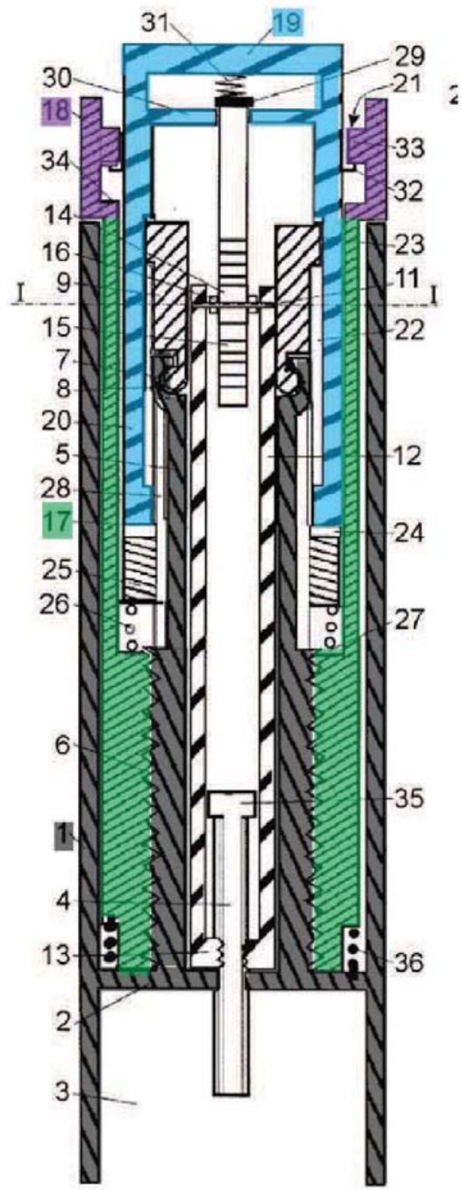


Fig. 1

[32] I also annotate the dose setting button 18 in purple to illustrate the extent of the dose setting drum 17.

['044] Claim 19: The housing part of claim 11, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve.

['486] Claim 27: The housing part of claim 1, wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve.

424. As I described above, it would have been obvious to configure Møller's dose setting drum 17 to include a helical groove provided along its outer surface that engages with a threading provided within the housing as taught by Steenfeldt-Jensen. *See supra*, ¶¶347-61. Steenfeldt-Jensen discloses that a corresponding helical rib is provided on the housing and sits within the helical groove of the dose dial sleeve. *See* EX1014, 11:20-22. Thus, a person of ordinary skill would have understood that a similar helical rib would be provided on the inner surface of the housing 1 to sit within the helical groove of the dose setting drum 17 for threaded engagement.

425. Accordingly, it is my opinion that the combination of Møller and Steenfeldt-Jensen teaches this claim element.

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

426. As I explained above, it is my opinion that a person of ordinary skill would have found it readily apparent from the teachings of Møller and Steenfeldt-Jensen to provide a helical rib on the inner surface of the housing. Moreover, Steenfeldt-Jensen teaches that the helical rib extends along the length of the inner surface of the housing. *See, e.g.*, EX1014, FIG. 16. Thus, a person of ordinary skill

would have found it apparent to provide a helical rib on the inner surface of the housing 1 that "extends for at least a single sweep."

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

427. Møller does not explicitly disclose whether the helical rib 16 is a single start rib. Nevertheless, it is my opinion that a person of ordinary skill would have found it readily apparent to provide the helical rib as a single start helical rib.

428. As I explained above, a person of ordinary skill would have understood the mechanical differences between single-start threads and multi-start threads. *See supra*, ¶¶241-44. As I also explained above, both Møller and Steenfeldt-Jensen teach the use of a high-pitch threaded arrangement between the dose setting drum and the housing. *See* EX1015, ¶¶5-6, 14; EX1014, 6:7-17; *supra*, ¶¶354-61.

429. A person of ordinary skill would have also understood that, for a single-start thread, this configuration would mean that the lead of the helical rib would be correspondingly high, and equal to its high pitch. Thus, a person of ordinary skill would have understood that, when the user rotated the dose setting drum 17, the drum would move out of the housing at a relatively high rate. A person of ordinary skill would have understood that a relatively high lead would allow for a sufficiently large "stroke" of the dose setting drum 17 that would allow the user to better perceive changes in the dose during the dose setting process. If, on the other hand, the helical rib was provided as a multi-start thread with the same high pitch, the lead would be

multiplied, resulting in an even larger lead. Indeed, Steenfeldt-Jensen refers to the use of a helical rib in the singular, which would have suggested to the person of ordinary skill that a single-start helical rib would be sufficient.

430. Accordingly, given the above, it is my opinion that a person of ordinary skill would have found it readily apparent from the teachings of Møller and Steenfeldt-Jensen to provide the helical rib as "a single start helical rib."

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

431. As I noted above, a person of ordinary skill would have found it readily apparent to provide a helical groove on the dose setting drum in view of the teachings of Møller and Steenfeldt-Jensen. *See supra*, ¶¶355-61.

432. It is my opinion that the combination of Møller and Steenfeldt-Jensen teaches the use of a "radial stop" that serves to limit the axial length of travel of a "dose dial sleeve," and a person of ordinary skill would have found it readily apparent to position the radial stop "near an end of [the] helical groove" of the dose setting drum 17 in order to properly limit its travel.

433. As I explained above, Steenfeldt-Jensen discloses a dose scale drum 17 that similarly includes a helical groove on its outer surface that engages with a helical rib on the inner wall of the housing. *See* EX1014, 9:52-56. Steenfeldt-Jensen teaches that "[w]hen the dose scale drum is displaced outwardly in the housing a steep front

side of a saw tooth 91 at the [button-end] of the dose scale drum [17] will abut a steep front side of a similar tooth 92 on the bushing [53] whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set." *Id.*, 9:57-62, FIGS. 11-13.

434. As I noted above, Steenfeldt-Jensen does not label all these features in the corresponding figures (FIGS. 11-13), but a person of ordinary skill would have readily understood from the description provided by Steenfeldt-Jensen that the tooth 91 acts as a "radial stop" that sets the maximum length of travel that the drum can move relative to the housing during dose dialing up, which would serve to indicate to the user that the maximum dose for a single injection has been reached. *See supra*, ¶¶326-31.

435. It is my opinion that, based on the teachings of Steenfeldt-Jensen, a person of ordinary skill would have found it readily apparent to incorporate a similar "radial stop" on the drum 17 that would also set the maximum length of travel that the drum can move out of the housing 1 during dose setting, which, in turn, would serve as an indication to the user that the maximum dose for a single injection has been reached.

436. While the "radial stop" disclosed in Steenfeldt-Jensen is provided on the drum's button-end, a person of ordinary skill would have understood that, to set the maximum length of travel that the dose setting drum 17 can move out of the

housing 1 during dose setting, the radial stop should be provided near the needle-end of the drum's helical groove. That way, if the user screwed the drum 17 out of the housing 1 by its maximum length of travel (*i.e.*, the needle-end of the helical groove has reached the button-end of the housing's threading), the stop would abut a corresponding stop provided on the housing 1 near the threading's button-end. A person of ordinary skill would have understood that this stop would serve the same purpose as the stop of FIGS. 11-13: it would prevent the user from further rotating the drum 17 out relative to the housing 1, and would indicate to the user that the maximum set dose has been reached.

437. Accordingly, it is my opinion that a person of ordinary skill would have found it readily apparent from the teachings of Møller and Steenfeldt-Jensen to provide the dose setting drum 17 with "at least one radial stop," and would have found it readily apparent to position that radial stop "near an end of" the helical groove.

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

438. As I explained above, the combination of Møller and Steenfeldt-Jensen teaches a radial stop at an end of the helical groove.

439. Moreover, as I also explained above, a person of ordinary skill would have understood that the radial stop should be positioned near the needle-end of the groove so that, when the maximum length of travel of the dose setting drum 17 out

of the housing 1 was reached, the stop would abut a corresponding stop at the housing's button-end to prevent further movement. Thus, it is my opinion that a person of ordinary skill would have found it readily apparent to position the radial stop "near a distal end of" the drum's helical groove.

['486] Claim 33: The housing part of claim 1, wherein if a user inadvertently dials said dose knob in one direction beyond a desired dose, said dose knob may be rotated in a second direction so as to allow said dialed dose to be reduced.

440. Both Møller and Steenfeldt-Jensen discloses that the dose knob may be rotated in an opposite direction to reduce a set dose. *See* EX1015, ¶29; EX1014, 11:52-62. Thus, the combination of Møller and Steenfeldt-Jensen teaches this feature.

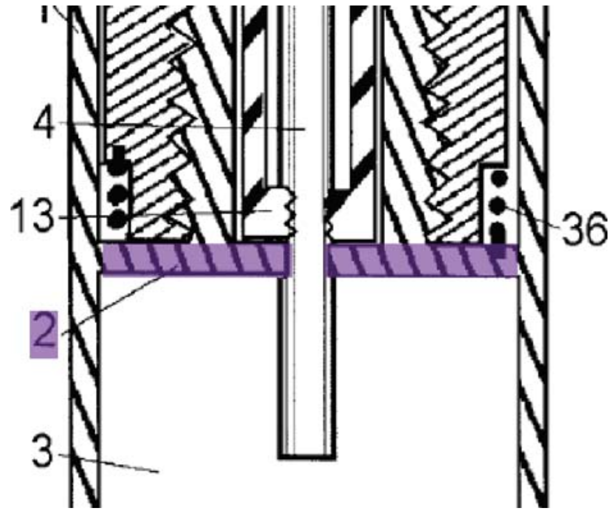
['486] Claim 36: The housing part of claim 1, wherein said housing part and said container comprises a disposable device.

441. As I noted previously, the term "container" appears for the first time in claim 36. Nevertheless, Møller and Steenfeldt-Jensen discloses a fluid "container" in the form of a medicine-containing ampoule. *See* EX1015, ¶¶22, 32; EX1014, 5:33-35, 12:10-13, FIGS. 15-17. Møller does not explicitly disclose that its device is "disposable." Nevertheless, Steenfeldt-Jensen recognizes that it was well-known in the art to provide disposable syringes, "i.e. a syringe which is disposed of when the cartridge is empty." EX1014, 1:25-26. For these syringes, Steenfeldt-Jensen teaches that "the syringe must further be cheap and made of materials suited for

recycling or burning without producing noxious gases." *Id.*, 1: 24-26. It is my opinion that a person of ordinary skill would have found it readily apparent to manufacture a device like that taught by the combination of Møller and Steenfeldt-Jensen as a disposable pen injector, by, for example, forming the device's components from "materials suited for recycling or burning," as Steenfeldt-Jensen teaches. Accordingly, it is my opinion that Steenfeldt-Jensen teaches forming a pen injector where the housing 1 and a container, in the form of a fluid-filled ampoule, "comprises a disposable device."

['486] Claim 38: The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main housing, said insert secured against rotation.

442. Møller teaches that the housing 1 includes "a partitioning wall 2." *See* EX1015, ¶22. The piston rod 4 "has a not round cross section by which it fits through a central opening in the wall 2 so that the piston rod 4 can be displaced longitudinally through the central opening in the wall 2 but not rotated relative to this wall." *Id.* Below, I have reproduced a partial view of FIG. 1, toward the device's needle-end, where I have annotated the partitioning wall 2 in purple. Because the partitioning wall 2 is formed integrally with the housing 1, a person of ordinary skill would have understood that the wall 2 is "secured against rotation."



443. Accordingly, the combination of Møller and Steenfeldt-Jensen discloses “an insert,” in the form of a partitioning wall 2, that is “provided at a distal end of the” housing 1 and is “secured against rotation.”

['486] Claim 39: The housing part of claim 1, further comprising an insert, said insert provided at a distal end of the main housing, and said insert secured against longitudinal motion.

444. As I explained above, Møller discloses “an insert,” in the form of a partitioning wall 2, that is “provided at a distal end of the” housing 1. Because the partitioning wall 2 is integrally formed with the housing 1, a person of ordinary skill would have understood that the partitioning wall 2 is “secured against longitudinal motion.” Thus, the combination of Møller and Steenfeldt-Jensen discloses this feature.

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

445. As I explained above, Møller discloses that the piston rod 4 "fits through a central opening in the wall 2." EX1015, ¶22. Thus, Møller teaches that the insert "comprises an opening extending therethrough, such that [the] piston rod is configured to extend through [the] opening."

D. ['486-B] Ground 1: Claims 51-55 and 57 are Anticipated by Burroughs

446. Below, my analysis first focuses on independent claim 51 of the '486 patent, and then moves on to dependent claims 52-55 and 57. It is my opinion that Burroughs anticipates each of these claims.

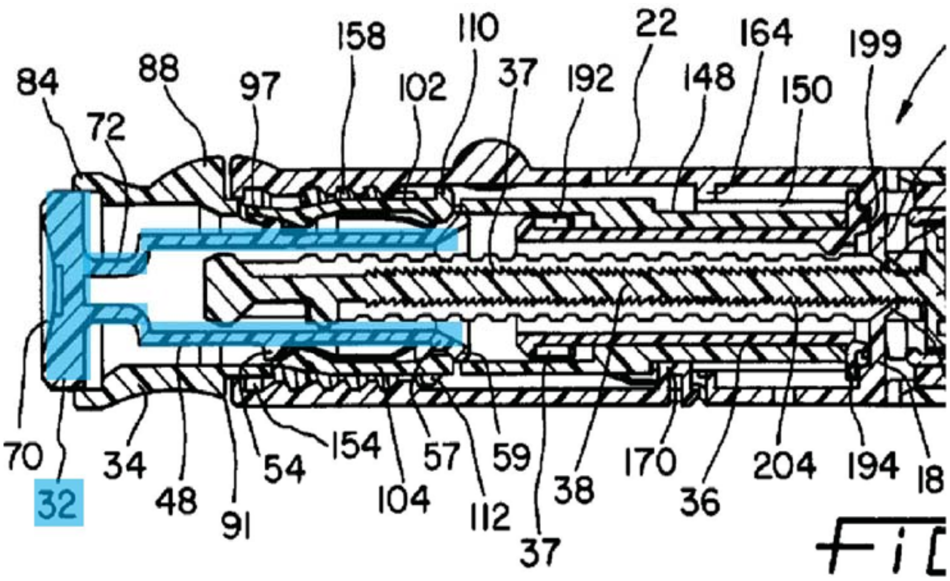
1. Independent claim 51 of the '486 patent

447. As explained below, it is my opinion that Burroughs discloses a "clutch" having the structural elements recited by claim 51 of the '486 patent, and thus anticipates the claim. Each section of claim 51 is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

['486] Claim 51, preamble: A clutch for use within a pen type drug delivery device, said clutch comprising:

448. Burroughs discloses "[a] multi-use medication dispensing pen made of a plastic material that is recyclable after the contents of the medical cartridge have

been exhausted." EX1013, Abstract. The injection medication device 20 includes a button 32 positioned within a mechanism housing 22 of the device. *See id.*, 7:14-19, 7:46-47, FIGS. 1-2, 14-15. Below, I have reproduced a partial view of FIG. 1, where I have annotated button 32 in blue. I have also reproduced FIG. 14, which shows button 32 in greater detail.



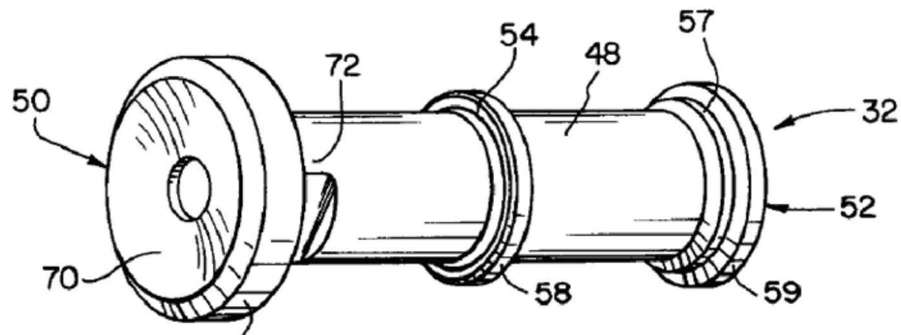


FIG. 14

449. Button 32 serves as a "clutch" by disengaging a dial mechanism 34 from the housing 22 and a nut 36. Specifically, button 32 includes "a hollow

cylindrical portion 48," which has an enlarged diameter ring 54 that is configured to engage the dial mechanism 34. *Id.*, 7:46-52, FIGS. 1-2, 14-15. The dial mechanism 34 includes flexible legs 102, 104 that have threads 110, 112 on their outer surface. *See id.*, 8:24-29, 10:34-38, FIGS. 6-9. These threads 110, 112 engage with a helical spiral groove 158 provided on the inner surface of the housing 22 during dose setting, which allows a user to rotate the dial mechanism 34 to set a dose. *See id.*, 8:62-9:1, 10:34-38, FIGS. 3, 5-9. The dial mechanism 34 also includes splines 144 along its inner surface that engage splines 192 located on the outer surface of the nut 36 to rotationally couple the components during dose setting. *See, e.g.*, *id.*, 10:21-26, FIG. 9, 11. With such coupling, when the user rotates the dial mechanism 34 to set a dose, the nut 36 also rotates, resulting in the nut 36 riding up an external threading of a leadscrew 38 to which the nut 36 is engaged. *See id.*, 10:38-42.

450. After a dose has been set, the user presses the button 32, which presses the enlarged diameter ring 54 toward the needle-end of the device. *See id.*, 8:11-20, 11:5-12, 14-20. This causes the enlarged diameter ring 54 to push against ramped surfaces 96 positioned on the inner surface of the dial mechanism 34. *See id.*, 8:11-20, 11:5-12, FIG. 9. By pushing against these ramped surfaces, the flexible legs 102, 104 are forced to collapse inward, disengaging the threads 110, 112 from the housing's helical groove 158. *See id.*, 8:11-20, 11:5-12. "Dial mechanism 34 is then able to travel axially towards cartridge 40 during injection of the medical

product ....” *Id.*, 8:18-20. This axial movement also causes the dial mechanism’s splines 144 to move out of its alignment with the nut’s splines 192, which rotationally decouples the component prior to any axial movement of the nut. *See id.*, 11:27-30. Further axial movement of the dial mechanism 34 causes axial movement of the nut 36, which, in turn, moves the leadscrew 38 toward the device’s needle-end to deliver the set dosage of medication. *Id.*, 11:31-34. Thus, the button 32 serves as a “clutch” by disengaging the dial mechanism 34 from its threaded connection with the housing 22, and its rotational coupling with the nut 36.

451. Accordingly, Burroughs discloses “[a] clutch,” in the form of a button 32, “for use within a pen type drug delivery device.”

<u>[’486] Claim 51.1: a tubular body, said tubular body extending from a distal end to a proximal end; and</u>

452. Burroughs discloses that the “button 32 comprises a hollow cylindrical portion 48,” which includes “a proximal end 50” at its button-end, and “a distal end 52” at its needle-end. As shown in FIG. 14 below, the hollow cylindrical portion 48 of the button 32 is “tubular”:

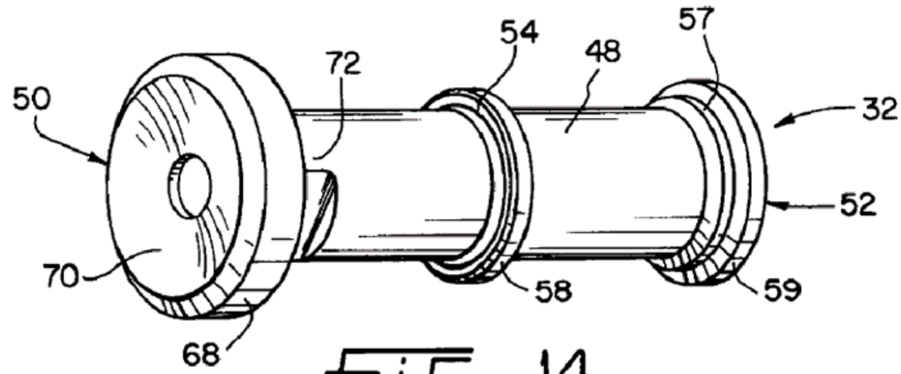


FIG. 14

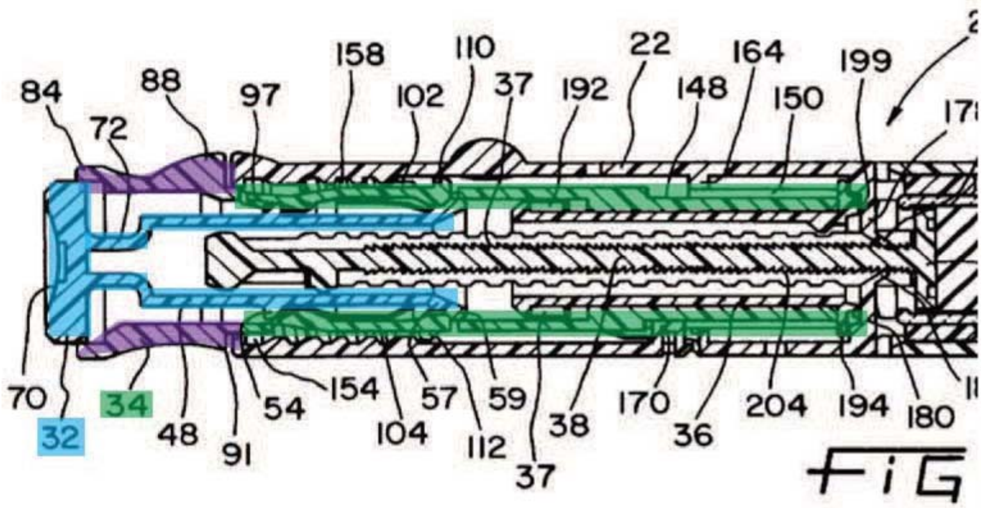
453. Accordingly, Burroughs discloses that the button 32 includes "a tubular body," in the form of a hollow cylindrical portion 48, that "extend[s] from a distal end to a proximal end."

['486] Claim 51.2: 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.

454. In FIG. 1, Burroughs shows that the button 32's needle-end is positioned within an inner space of the dial mechanism 34, which forms a "dial member" for the device. *See* EX1013, FIG. 1. To illustrate this relative position, I have reproduced a partial view of FIG. 1 below, where I have annotated the dial mechanism 34 green, and the button 32 blue.[33] Thus, Burroughs discloses that the

[33] For visual purposes, I also annotate the proximal portion 78 (purple) of the dial mechanism 34 to illustrate the extent of the dial mechanism 34 disclosed by Burroughs. As I explain below, the proximal portion 78 corresponds to the "dose knob" recited in certain dependent claims, given its relative positioning and overall

"distal end" of the button 32 "ha[s] a diameter sized such that said distal end of" the button 32 "may be positioned within a proximal end of" the dial mechanism 34.



2. Dependent claims 52-55 and 57 of the '486 patent

455. Each section of dependent claims 52-55 and 57 of the '486 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

['486] Claim 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.

456. Burroughs discloses that the dial mechanism 34 includes a "proximal portion 78" positioned at the dial mechanism's button-end. *Id.*, 8:2-6, FIGS. 1-2, 6-

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function to the user, and Burroughs discloses that the proximal portion 78 is integral with the dial mechanism 34. *See supra*, ¶126 n.12.

9. “Proximal portion 78 comprises enlarged diameter portion 84, tapered portion 86, and ring 90 extending about the circumference of proximal portion 78.” *Id.* Reproduced below is FIG. 7, where I have annotated the proximal portion 78 purple:

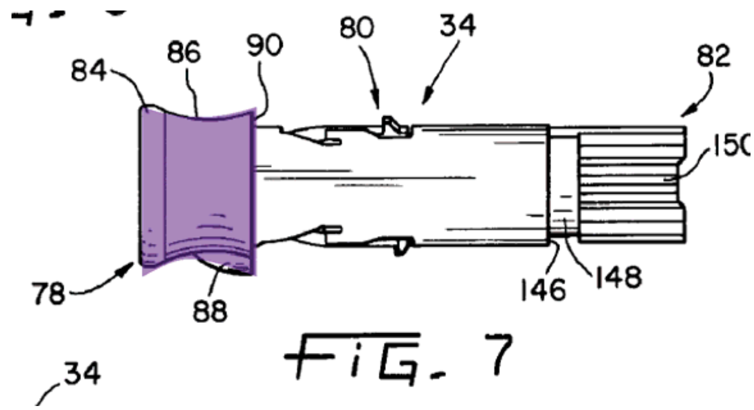
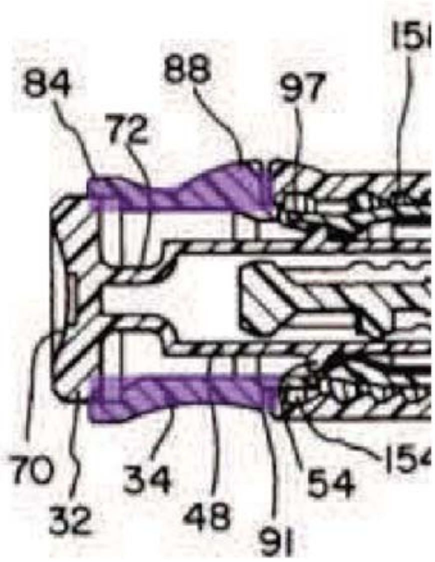


FIG. 7

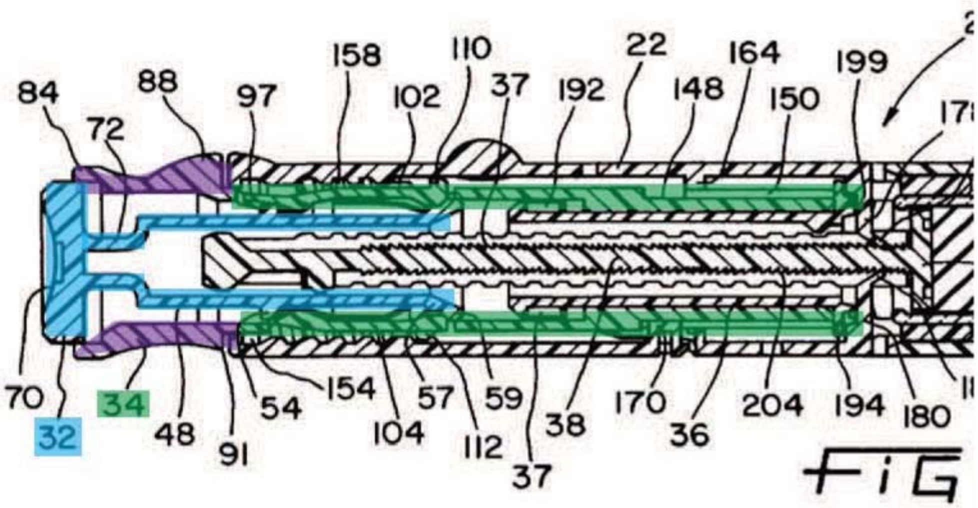
457. Burroughs teaches that, to set a dose, the dial mechanism 34 is rotated such that “dial mechanism 34 retracts from housing 22, thereby increasing the axial distance between ring 91 [*sic*, 90] and surfaces 33, 35 housing parts 24, 26.” *Id.*, 10:34-42. As shown in FIG. 1 (partially reproduced below, with proximal portion 78 annotated in purple), proximal portion 78 is positioned external to the housing 22, with the needle-end side of ring 90 sitting flush with the button-end side of the housing 22[34]:

[34] I note here that ring 90 is mislabeled in FIG. 1 as “91”.



458. Given this positioning, it is my opinion that a person of ordinary skill would have understood the proximal portion 78 of the dial mechanism 34 to constitute a "dose knob" for the user to grasp in order to rotate the dial mechanism 34 during dose setting. Thus, Burroughs teaches a "dose knob" in the form of a proximal portion 78 of the dial mechanism 34.

459. Also in FIG. 1, Burroughs shows that the button-end of the button 32 is positioned within the proximal portion 78 of the dial mechanism 34. Below, I have reproduced a partial view of FIG. 1, which I have annotated the button 32 in blue, the dial mechanism 34 in green, and the proximal portion 78 in purple:



460. Accordingly, Burroughs discloses that the "proximal end" of the button 32 "is configured to reside within an inner space of" the proximal portion 78 of the dial mechanism 34.

['486] Claim 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.

461. As I mentioned above, Burroughs discloses that, to inject a set dose, the user presses down on the button 32 toward the device's needle-end. *See id.*, 11:13-16. This disengages the dial mechanism 34 from the housing, allowing the dial mechanism 34 (and proximal portion 78) to move axially toward the device's needle-end, which causes the nut 36 to axially move the leadscrew 38 to dispense medicine. *See id.*, 11:16-20, 11:27-34. Thus, when the button 32 is pressed to disengage the dial mechanism 34, the dial mechanism 34 along with its proximal portion 78 is "activated" to move axially in order to dispense the set dose. *See id.*, 11:5-6, 11:18-

20. The button 32 continues to move axially with the dial mechanism 34 toward the device's needle-end until the entire set dose has been dispensed. *See id.*, 11:20-23.

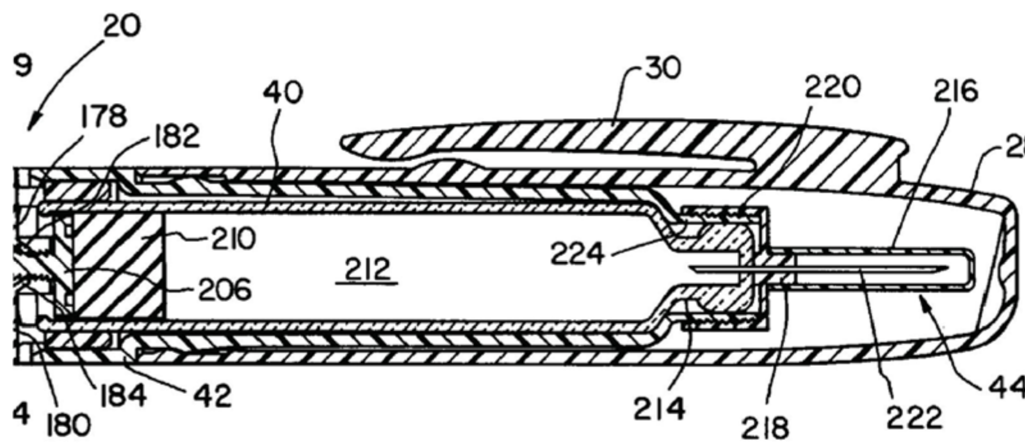
462. Accordingly, Burroughs discloses that, when the proximal portion 78 of the dial mechanism 34 "is activated to dispense a dose of a medicament contained within" the device 20, the button 32 "is moved in a distal direction."

['486] Claim 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.

463. Burroughs discloses a cartridge 40 housed within a cartridge retainer 42, which is permanently secured to housing parts 24 and 26 of the housing 22. *See id.*, 9:34-36, FIGS. 1-2. "Cartridge 40 is manufactured of glass and comprises a tube defining an inner chamber 212 ...." *Id.*, 9:36-37. Burroughs discloses that the cartridge 40 contains medicine, which would be held within the cartridge's inner chamber 212, which forms a "reservoir." *See id.*, Abstract, 2:42-48. The cartridge 40 also contains a piston 210, which is in engagement with a plunger engagement portion 206 of the leadscrew 38. *Id.*, 9:32-34. When the leadscrew 38 is advanced axially during dose dispensing, the plunger engagement portion 206 pushes the piston 210 toward the needle-end of the cartridge such that medicine from the inner chamber 212 is dispensed from the cartridge. *See id.*, 2:44-48. Thus, piston 210 functions as "a stopper" because it abuts the piston rod that axially drives medicine

from the cartridge and separates the remaining medicine from the "used" portion of the chamber.

464. The inner chamber 212 openly terminates at its distal end [*i.e.*, needle-end] in a neck 214 having a septum secured by a ferrule (not labeled). *See id.*, 9:36-40. Although not labeled, a person of ordinary skill would have understood that Burroughs discloses a septum and a ferrule in FIG. 1, which is partially reproduced below, toward the device's needle-end, showing the cartridge assembly in greater detail. A person of ordinary skill would have understood that the needle 222, which is secured by a rubber disc 218 in cap 216, accesses the cartridge by a needle-penetrable port, which is called a septum. *See id.*, 9:36-40. The septum is secured to the cartridge by a ferrule.



ĪG. 1

465. Accordingly, Burroughs discloses a pen-type drug delivery device that includes "a cartridge containing a medicament," in the form of cartridge 40, which

contains "a reservoir," in the form of an inner chamber 212, "a stopper," in the form of a piston 210, "a septum," and "a ferrule."

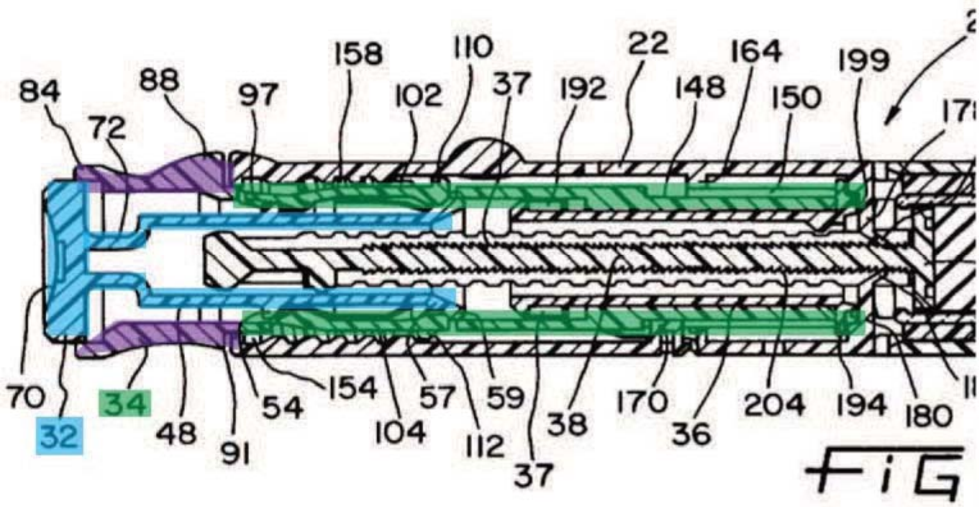
['486] Claim 55: The clutch of claim 54, wherein said cartridge comprises a multidose cartridge.

466. Burroughs discloses that the device 20 is "[a] multi-use medication dispensing pen ... that is recyclable after the contents of the medication cartridge have been exhausted." *Id.*, Abstract. Burroughs discloses that the user can select a certain dose by rotating the dial mechanism 34 in either direction to make the dose larger or smaller. *Id.*, 5:62-65, 10:49-52. Thus, because Burroughs discloses that the device can be used to dispense varying, set doses of medicine over multiple uses, a person of ordinary skill would have understood that Burroughs discloses that the cartridge 40 comprises "a multidose cartridge."

['486] Claim 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.

467. As shown in FIGS. 1 and 9, the button-end of the dial mechanism 34 is open, which receives the button 32 within. *See id.*, FIGS. 1, 9. Further, as shown in FIG. 1, the button 32 extends through the proximal portion 78 of the dial mechanism 34 and into the dial mechanism 34, making the button 32 "located adjacent" a needle-end of the proximal portion 78 of the dial mechanism 34, and where the dial mechanism 34 "extends circumferentially around at least a portion" of the button 32.

See id., FIG. 1. To illustrate this relative positioning, I reproduce a partial view of FIG. 1 below, where I have annotated the button 32 in blue, the proximal portion 78 in purple, and the dial mechanism 34 in green:



468. The button 32 is also "operatively coupled" to the proximal portion 78 of the dial mechanism 34 due to its selective engagement with the inner ramped surfaces of the dial mechanism to cause its disengagement from the housing and nut. I note that this type of indirect coupling to the "dose knob" is contemplated by the '486 patent. Specifically, when describing the function of the claimed clutch, the '486 patent refers to the clutch's operative engagement and disengagement with respect to the dial member (referred to as the "dose dial sleeve" in the specification), rather than to the dose knob (referred to as the "dose dial grip" in the specification) directly. *See, e.g.*, EX1003, 2:17-19, 6:28-31. Thus, claim 57 of the '486 patent at least includes instances where the clutch is "operatively coupled" to the dose knob via its selective engagement with the dial member.

469. Accordingly, Burroughs discloses that the button 32 "is positioned within an open proximal end" of the dial mechanism 34 and "located adjacent a distal end of" the dial mechanism's proximal portion 78. The button 32 is also "operatively coupled to" the proximal portion 78, and the dial mechanism 34 "extends circumferentially around at least a portion of" the button 32.

E. ['486-B] Ground 2: Claims 54-55 are Obvious over Burroughs

470. As I explained above, it is my opinion that Burroughs discloses the elements of claims 54 and 55, and thus renders those claims anticipated. To the extent that Burroughs does not explicitly disclose these elements, however, it is my opinion that Burroughs renders them obvious. Each section of claims 54-55 of the '486 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

<u>['486] Claim 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.</u>

471. As I explained above, Burroughs describes that the device 20 includes a cartridge 40 that contains medicine with a reservoir, and further includes a stopper, a septum, and a ferrule at its needle-end. *See supra*, ¶¶463-65. I note, however, that Burroughs does not explicitly refer to these components using the terms recited in the claim. Nevertheless, it is my opinion that a person of ordinary skill would have

immediately recognized that these structures functionally operate as the terms recited.

472. It was well-known by those skilled in the art that cartridges used to hold and dispense medicine from pen-type injectors often contained a reservoir for holding the medicine within the cartridge, a stopper for abutting the piston rod of the drive mechanism, a septum from separating the inner contents of the reservoir from an external chamber or environment, and a ferrule for providing securement of the septum to the cartridge. Indeed, I note that the ’486 patent describes that its device includes “a cartridge 8 from which a number of doses of medicinal product may be dispensed,” but the ’486 patent never describes any of the cartridge components recited in claim 54. *See* EX1003, 3:34-37. Thus, the ’486 patent itself appreciates that these components were well-known and commonly used in cartridges for pen-type injectors. Accordingly, it is my opinion that, to the extent Burroughs does not explicitly disclose each of the cartridge components claimed in claim 54, a person of ordinary skill would have considered those components to be included in injector cartridges from the teachings of Burroughs.

[’486] Claim 55: The clutch of claim 54, wherein said cartridge comprises a multidose cartridge.

473. As I also explained above, Burroughs discloses a multi-use medication dispensing pen where the user can select a variable dose during a given use until the contents of the cartridge have been exhausted. *See supra*, ¶466. To the extent that

Burroughs does not explicitly disclose that its cartridge is “a multi-dose cartridge,” I note that, like Burroughs, the ’486 patent itself acknowledges that a cartridge is “a multidose cartridge” by disclosing “[a] cartridge 8 from which a number of doses of medicinal product may be dispensed. *See* EX1003, 3:34-37. Thus, it is my opinion that, because Burroughs specifically teaches that its pen is “a multi-use” pen, a person of ordinary skill would have understood that the cartridge contained within the pen would contain multiple doses of the medication.

F. [’486-B] Ground 3: Claims 51-53 and 56-57 are Anticipated by Steenfeldt-Jensen

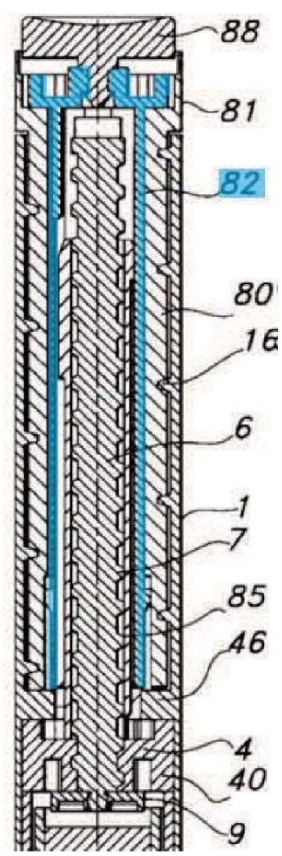
474. Below, my analysis first focuses on independent claim 51 of the ’486 patent, and then moves on to dependent claims 52-53 and 56-57. It is my opinion that Steenfeldt-Jensen anticipates the elements of each of these claims.

1. <u>Independent claim 51 of the ’486 patent</u>

475. As explained below, it is my opinion that Steenfeldt-Jensen discloses a “clutch” having the structural elements claimed by claim 51 of the ’486 patent, and thus anticipates that claim. Each section of claim 51 is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

['486] Claim 51, preamble: A clutch for use within a pen type drug delivery device, said clutch comprising:

476. Steenfeldt-Jensen discloses "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; *see also id.*, Abstract. The syringe includes "a tubular housing 1," which contains a bushing 82 that, as I explain more below, serves as a "clutch." *See id.*, 5:38-44, 11:26, FIGS. 15-17. Below-left, I have reproduced a partial view of FIG. 17, which shows the bushing 82 in greater detail. Below-right, I have reproduced a partial view of FIG. 16, where I have annotated the bushing 82 in blue.



477. The bushing 82 has a flange 83 at its needle-end, and a pair of opposite longitudinal slots 84 through its side walls. *Id.*, 11:26-28. As shown in FIGS. 15-17, the bushing 82 fits within a scale drum 80, and over a driver tube 85, which has hooks 86 on its outer wall that engage with the slots 84 of the bushing 82. *Id.*, 11:28-30. As a result, bushing 82 is coupled to the driver tube 85 in such a way that fixes the components rotationally to one another, but allows for relative axial movement between the components. *See id.*, 11:30-33.

478. The flange 83 of the bushing 82 is adapted to be seated within a compartment provided in a dose setting button 81 of the scale drum 80. *See id.*, 11:34-40, FIGS. 15-17. The flange 83 has, on its needle-end side, a rosette 93 of teeth that can be brought into engagement with a corresponding rosette of teeth provided at the bottom of the compartment. *See id.*, 11:34-36, 11:40-42. The flange 83 is mounted in the compartment in such a way that allows limited, axial movement of the bushing 82 relative to the scale drum 80 "to make or not make the teeth of said rosettes engage each other." *Id.*, 11:43-49.

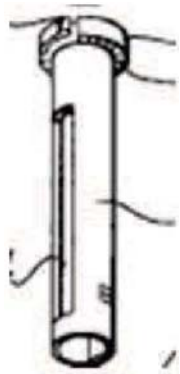
479. As Steenfeldt-Jensen explains, during dose setting, the rosette 93 on the flange 83 of the bushing 82 is kept out of engagement with the rosette of the dose setting button 81. *Id.*, 12:1-3. When the user rotates the dose setting button 81 to set a dose, the bushing 82 follows the scale drum 80's axial movement relative to the tubular housing 1, but "is kept non rotated due to its coupling to the driver tube [85]"

due to a pawl mechanism. *See id.*, 11:52-62. Steenfeldt-Jensen further explains that, once a dose is set, the user presses an injection button 88 to inject the dose, which causes the bushing 82 to move axially, engaging the rosette 93 with the rosette of the dose setting button 81. *Id.*, 12:4-5. This causes the bushing 82 to now follow the scale drum 80's anticlockwise rotation back into the housing, which is transmitted to the driver tube 85. *See id.*, 12:4-13. The resulting rotation of the driver tube 85 is sufficient to overcome the pawl mechanism's reluctance, causing the piston rod 6 to rotate and screw through a member 40 to dispense medicine from the device. *See id.* Thus, the bushing 82 serves as a "clutch" by releasably coupling the rotational movement of the scale drum 80 to the driver tube 85 during injection.

480. Accordingly, Steenfeldt-Jensen teaches "[a] clutch," in the form of a bushing 82, "for use within a pen type drug delivery device."

['486] Claim 51.1: a tubular body, said tubular body extending from a distal end to a proximal end; and

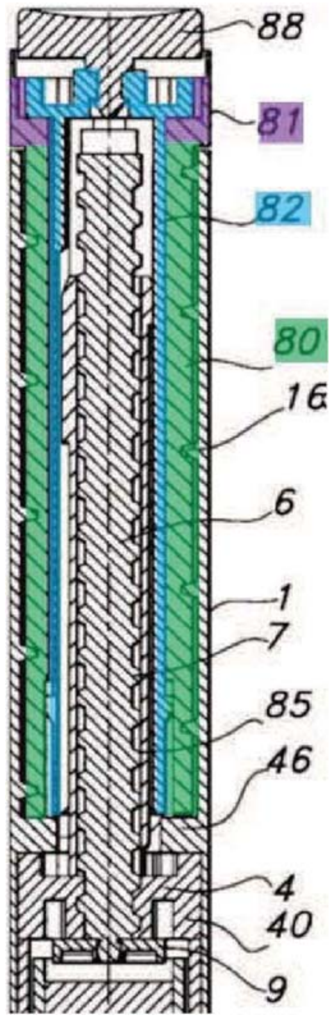
481. As shown in FIG. 17 (reproduced partially below to show bushing 82 in greater detail), bushing 82 is formed by a "tubular body" that extends from a needle-end ("a distal end") to a button-end ("a proximal end"). Thus, Steenfeldt-Jensen discloses this element.



['486] Claim 51.2: 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.

482. As I noted above, Steenfeldt-Jensen discloses that the bushing 82 fits into the scale drum 80 such that a needle-end of the bushing 82 may be positioned within a button-end of the scale drum 80. *See id.*, 11:28-30, FIGS. 15-16. To illustrate this relative position, I have reproduced a partial view of FIG. 1 below, where I have annotated the dial mechanism 34 green, and the button 32 blue.[35] Thus, Steenfeldt-Jensen discloses that the "distal end" of the bushing 82 "ha[s] a diameter sized such that [the] distal end of" the bushing 82 "may be positioned within a proximal end of" the scale drum 80.

[35] As I've done for previous grounds, because it is integrally formed with the scale drum 80 (which corresponds to the recited "dial member"), I have also annotated the dose setting button 81, which, as I explain below, corresponds to the "dose knob" recited in certain dependent claims of the '486 patent.



2. **Dependent claims 52-53 and 56-57 of the ’486 patent**

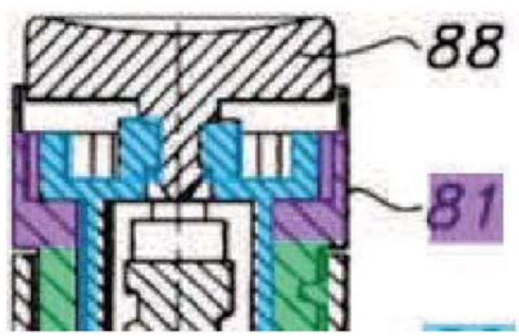
483. Each section of dependent claims 52-53 and 56-57 of the ’486 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

[’486] Claim 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.

484. Steenfeldt-Jensen discloses that the scale drum 80, at its button-end, “has a diameter exceeding the inner diameter of the housing to form a dose setting

button 81, which on its cylindrical outer wall is knurled to ensure a good finger grip." *Id.*, 11:22-25; FIGS. 15-17. As Steenfeldt-Jensen explains, during dose setting, the user rotates the dose setting button 81 to screw the scale drum 80 in and out of the housing. *See id.*, 11:52-62. Thus, Steenfeldt-Jensen teaches "a dose knob" in the form of a dose setting button 81.

485. Moreover, FIG. 16 shows that the button-end of the bushing 82 is positioned within the dose setting button 81. Below, I have reproduced a partial view of FIG. 16, showing a portion of the device near its button-end, where I have highlighted the bushing 82 in blue, the dose setting button 81 in purple, and the scale drum 80:



486. Accordingly, Steenfeldt-Jensen discloses that the "proximal end" of the bushing 82 "is configured to reside within an inner space of" the dose setting button 81.

['486] Claim 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.

487. As noted above, to inject a set dose of medicine, the user presses an injection button 88, which causes the bushing 82 to move axially and engage the rosette 93 with the rosette of the dose setting button 81. *Id.*, 12:4-5. This causes the bushing 82 to follow the anticlockwise rotation of the scale drum 80 and dose setting button 81 and move axially back into the housing toward the device's needle-end. *See id.*, 12:4-13. The bushing 82's rotation is transmitted to the driver tube 85, causing the piston rod 6 to rotate and screw through the member 40 to dispense medicine from the device. *See id.*

488. Accordingly, when the dose setting button 81 "is activated to dispense a dose of medicament contained within [the] pen type delivery device," due to the user's pressing of the injection button 88, the bushing 82 "is moved in a distal direction" in order to rotate the driver tube 85 to cause the dose to be dispensed from the device.

['486] Claim 56: The clutch of claim 51, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch.

489. As I noted above, the flange 83 of the bushing 82 contains, on its needle-end side, a rosette 93 of teeth that are configured to engage with a corresponding rosette of teeth on the bottom of a compartment of the dose setting button 81 when the injection button 88 is pressed to move those teeth into

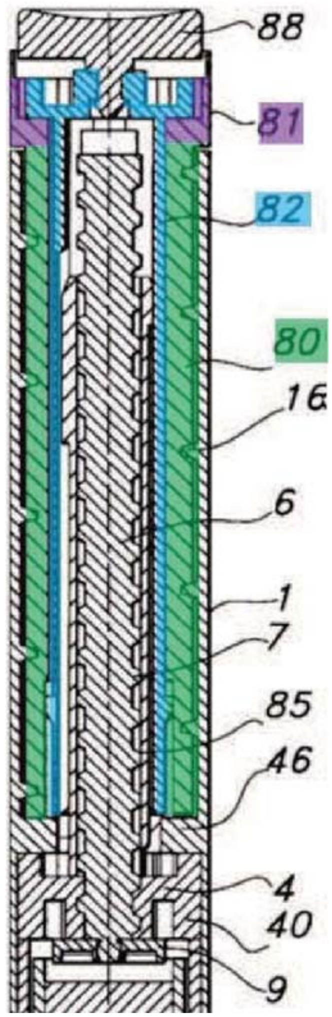
engagement. *See id.*, 11:34-36, 11:40-42. I have reproduced a partial view of FIG. 17 below, which shows the flange 83 of the bushing 82 having axially extending teeth formed on its interior:

490. Accordingly, Steenfeldt-Jensen discloses that the bushing 82 includes "a plurality of axially extending teeth formed on an interior of a flange," in the form of a rosette 93 of teeth provided on a needle-end side of the flange 83 of the bushing 82.

['486] Claim 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.

491. As shown I explained above, the bushing 82 fits within the scale drum 80, and includes a flange 83 that sits within a compartment of the dose setting button 81, which is located at the scale drum 80's button-end. *See id.*, 11:28-30, 11-34-42, FIGS. 15-17. Thus, the bushing 82 "is positioned within an open proximal end" of the scale drum 80, which "extends circumferentially around at least a portion of" the bushing 82, and is "located adjacent a distal end of" the dose setting button 81. To

illustrate this relative positioning, I have reproduced a partial view of FIG. 16 below, where I have highlighted the bushing 82 in blue, the dose setting button 81 in purple, and the scale drum 80 in blue:



492. The bushing 82 is also "operatively coupled to" the dose setting button 81 because, as I explained above, the rosette 93 of teeth provided on the needle-end of the bushing's flange 83 releasably engages with a corresponding resetting of teeth on the bottom of the dose setting button 81's compartment during injection. *See id.*, 12:4-13.

493. Accordingly, Steenfeldt-Jensen discloses that the bushing 82 "is positioned within an open proximal end" of the scale drum 80 and "located adjacent a distal end of" the dose setting button 81. The bushing 82 is also "operatively coupled to" the dose setting button 81, and the scale drum 80 "extends circumferentially around at least a portion of" the bushing 82.

G. ['486-B] Ground 4: Claim 56 is Obvious over Steenfeldt-Jensen ['486] Claim 56: The clutch of claim 51, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch.

494. As I explained above, it is my opinion that Steenfeldt-Jensen discloses the elements of claim 56, and thus renders the claim anticipated. That is, because Steenfeldt-Jensen discloses that the needle-end side of the flange 83 contains "a rosette 93 of teeth which can be brought into engagement with the rosette at the bottom of the compartment" of the dose setting button 81, Steenfeldt-Jensen discloses "axially extending teeth" on an interior of a flange of the bushing 82. *See supra*, ¶¶489-90.

495. However, to the extent that Steenfeldt-Jensen does not explicitly disclose "axially extending teeth." and to the extent that it is not immediately apparent from FIG. 17 and its corresponding description, it is my opinion that Steenfeldt-Jensen renders the claim obvious. That is, because the bushing's rosette 93 of teeth should extend so that they engage into a corresponding rosette on the bottom of the compartment of the dose setting button 81 to allow the components to

sufficiently engage, it is my opinion that a person of ordinary skill would have immediately recognized that extending the rosette 93 of teeth axially would facilitate that engagement. A person of ordinary skill would have also expected that an axially-extending rosette 93 of teeth would properly and sufficiently engage with the corresponding rosette of teeth on the bottom of the dose setting button's compartment such that the two components would rotationally couple during dose dispensing.

496. Accordingly, to the extent Steenfeldt-Jensen does not explicitly disclose this element, it nevertheless renders it obvious.

H. ['486-B] Ground 5: Claims 54-55 are Obvious over Steenfeldt-Jensen in combination with Burroughs

497. As I explained below, it is my opinion that claims 54 and 55 are rendered obvious by the combination of Steenfeldt-Jensen and Burroughs. Each section of claims 54-55 of the '044 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

['486] Claim 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.

498. Steenfeldt-Jensen discloses that the device includes an ampoule 89 positioned with an ampoule holder 2. *Id.*, 12:10-13, FIGS. 15-16. Steenfeldt-Jensen

further discloses that the syringe (pen injector) allows "a liquid from an ampoule can be apportioned in a number of individually set do[ses]." *Id.*, 5:33-35. Thus, a person of ordinary skill would have understood that the ampoule 89 constituted "a cartridge containing a medicament." Steenfeldt-Jensen does not explicitly describe in detail the individual components that make up the ampoule 89.

499. Burroughs, however, discloses a cartridge 40 contained within a housing 22 of a pen-type injector device. *See id.*, 9:34-36, FIGS. 1-2. "Cartridge 40 is manufactured of glass and comprises a tube defining an inner chamber 212 . . .." *Id.*, 9:36-37. Burroughs discloses that the cartridge 40 contains medicine, which would be held within the cartridge's inner chamber 212, which forms a "reservoir." *See id.*, Abstract, 2:42-48. The cartridge 40 also contains a piston 210, which is in engagement with a plunger engagement portion 206 of the leadscrew 38. *Id.*, 9:32-34. When the leadscrew 38 is advanced axially during dose dispensing, the plunger engagement portion 206 pushes the piston 210 toward the needle-end of the cartridge such that medicine from the inner chamber 212 is dispensed from the cartridge. *See id.*, 2:44-48. Thus, piston 210 functions as "a stopper" because it abuts the piston rod that axially drives medicine from the cartridge and separates the remaining medicine from the "used" portion of the chamber.

500. As I explained above, the inner chamber 212 openly terminates at its distal end [*i.e.*, needle-end] in a neck 214 having a septum secured by a ferrule (not

labeled). *See id.*, 9:36-40; *supra*, ¶¶463-65. Although not labeled, a person of ordinary skill would have understood that Burroughs discloses a septum and a ferrule in FIG. 1. A person of ordinary skill would have understood that the needle 222, which is secured by a rubber disc 218 in cap 216, accesses the cartridge by a needle-penetrable port, which is called a septum. *See id.*, 9:36-40. The septum is secured to the cartridge by a ferrule.

501. It was well-known to those skilled in the art that cartridges used to hold and dispense medicine from pen-type injectors often contained a reservoir for holding the medicine within the cartridge, a stopper for abutting the piston rod of the drive mechanism, a septum from separating the inner contents of the reservoir from an external chamber or environment, and a ferrule for securing the septum to the cartridge. Burroughs discloses such an arrangement, and it is my opinion that a person of ordinary skill would have considered those components readily apparent from the teachings of Burroughs.

502. It is also my opinion that it would have been obvious to incorporate a cartridge like that of Burroughs into an injection pen like that of Steenfeldt-Jensen. As I noted above, the components recited by claim 54 are common and well-understood components of medicine-containing cartridges for pen-type injectors. Indeed, I note that the ’486 patent describes that its device includes “a cartridge 8 from which a number of doses of medicinal product may be dispensed,” but the ’486

patent never describes any of the cartridge components recited in claim 54. *See* EX1003, 3:34-37. Thus, the ’486 patent itself confirms that these components were well-known and commonly used in cartridges of this type.

503. Accordingly, it is my opinion that a person of ordinary skill would have readily incorporated those components into the ampoule 89 of Steenfeldt-Jensen based on Steenfeldt-Jensen’s teachings of a use of a medicine-containing ampoule in a pen-type injector. Alternatively, it is my opinion that a person of ordinary skill would have readily understood that a cartridge having a reservoir, a stopper, a septum, and a ferrule would be a well-known cartridge that was commonly use in a pen-type injector, and would have incorporated such a cartridge into the device of Steenfeldt-Jensen based on the teachings of Burroughs.

[’486] Claim 55: The clutch of claim 54, wherein said cartridge comprises a multidose cartridge.

504. Steenfeldt-Jensen discloses an injector device where “a liquid from an ampoule can be apportioned in a number of individually set do[ses].” *Id.*, 5:33-35. Thus, Steenfeldt-Jensen discloses an ampoule that can dispense multiple doses of a medicine after a number of uses.

505. Similarly, Burroughs discloses “[a] multi-use medication dispensing pen ... that is recyclable after the contents of the medication cartridge have been exhausted.” *Id.*, Abstract. Burroughs discloses that the user can select a certain dose by rotating the dial mechanism 34 in either direction to make the dose larger or

smaller. *Id.*, 5:62-65, 10:49-52. Thus, because Burroughs discloses that the device can be used to dispense varying, set doses of medicine over multiple uses, a person of ordinary skill would have understood that Burroughs discloses that the cartridge 40 comprises “a multidose cartridge.”

506. As I noted above, a person of ordinary skill would have also understood that Burroughs discloses a medicine-containing cartridge having a reservoir, a stopper, a septum, and a ferrule for dispensing multiple doses of medicine. Thus, a person of ordinary skill would have readily expected that such a commonly-used cartridge would be appropriate to apportion a number of individually set doses using a device like that of Steenfeldt-Jensen. As such, it is my opinion that a person of ordinary skill would have found it obvious to incorporate “a multidose cartridge” having a reservoir, a stopper, a septum, and a ferrule in the multi-use injector device of Steenfeldt-Jensen.

507. Thus, the combination of Steenfeldt-Jensen and Burroughs renders this element obvious.

I. [’486-B] Ground 6: Claims 51-53 and 56-57 are Anticipated by Møller

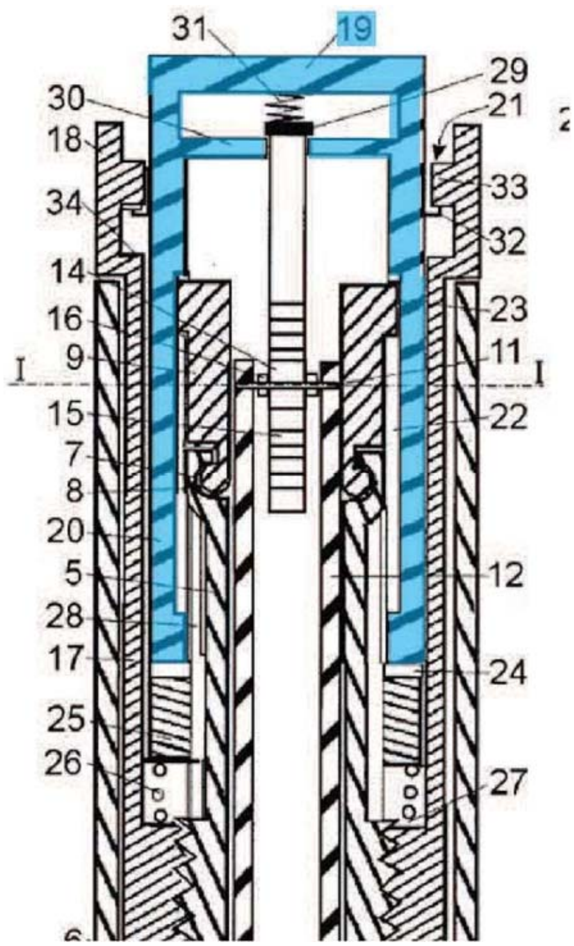
508. Below, my analysis first focuses on independent claim 51 of the ’486 patent, and then moves on to dependent claims 52-53 and 56-57. It is my opinion that Møller anticipates the elements of each of these claims.

1. **Independent claim 51 of the ’486 patent**

509. As explained below, it is my opinion that Møller discloses a “clutch” having the structural elements claimed by claim 51 of the ’486 patent, and thus anticipates that claim. Each section of claim 51 is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

[’486] Claim 51, preamble: A clutch for use within a pen type drug delivery device, said clutch comprising:

510. Møller describes “[a]n injection device for injection of set doses of medicine from a cartridge.” EX1015, Abstract. As shown in FIG. 1, the device includes “an elongated cylindrical housing 1,” where “a deep cup shaped element” is positioned within. *Id.*, ¶¶22, 26, FIG. 1. The cup shaped element has “a bottom 19” that forms an injection button and “a tubular part 20 [that] fit[s] into the dose setting drum 17 and encompass[es] the gearbox 9.” *Id.*, ¶26, FIG. 1. As I explain more below, the cup shaped element serves as a “clutch.” FIG. 1 is reproduced below, where I have highlighted the cup shaped element in blue:



511. The cup shaped element is releasably coupled to a dose setting drum 17 through "0-shaped protrusions 32 ... engaging A-shaped recesses in the inner ring 33 in the dose setting button 18." *Id.*, ¶29, FIG. 1. To set a dose, the user rotates a dose setting button 18, which causes the dose setting drum 17 to rotate up along the thread 6 of the housing. *Id*. At this stage, the cup shaped element's protrusions 32 are engaged with the recesses in the dose setting button due to a spring 26 that biases the cup shaped element toward the button-end so that it remains engaged with the dose setting button. *See id*. This causes the cup shaped element to follow the dose setting drum's rotation, the rotation of which is transmitted to a gearbox 9 and

connection bars 12 with nut 13. *See id.*, ¶30. As a result, nut 13 screws up along the thread of a piston rod 4 toward its button-end. *Id.*

512. To inject a set dose, the bottom 19 of the cup shaped element is pressed by the user. *Id.*, ¶32. This action moves the cup shaped element axially toward the device's needle-end, which causes the protrusions 32 to disengage from the dose setting button 18. *Id.*, ¶¶32-33. As a result, the cup shaped element is decoupled from the dose setting drum 17, allowing the drum 17 to rotate freely back into the housing. *Id.*, ¶33. The cup shaped element moves axially toward the device's needle-end without following the drum's rotation. *Id.*, ¶32. The cup shaped element's axial movement is transmitted to the connection bars 12 with nut 13 through the gear box 9, which causes the nut 13 to press the piston rod 4 into the compartment 3 to dispense medicine. *Id.* Thus, the cup shaped element serves as a "clutch" because it couples the rotation of the dose setting drum 17 to the connection bars 12 with nut 13 during dose setting, and decouples that common rotation during injection.

513. Accordingly, Møller discloses "[a] clutch," in the form of a cup shaped element, for use within a pen type drug delivery device.

514. I also note that Møller teaches a "tubular clutch" even under the means-plus-function interpretation. As I noted above, the challenged patents identify element 60 as the clutch. For instance, the '069 patent discloses:

> The clutch means 60 is generally cylindrical and is provided at a first end with a series of circumferentially directed saw teeth 66 (see FIG. 7) [and is normally engaged with clicker 50]. Each saw tooth comprises a longitudinally directed surface and an inclined surface. Towards the second end 64 of the clutch means 60 there is located a radially inwardly directed flange 62. The flange 62 of the clutch means 60 is disposed between the shoulder 37 of the drive sleeve 30 and the radially outwardly directed flange 39 of the extension 38. The second end of the clutch means 60 is provided with a plurality of dog teeth 65 (FIG. 8) [that are adapted to engage with the dose dial sleeve]. The clutch 60 is keyed to the drive sleeve 30 by way of splines (not shown) to prevent relative rotation between the clutch 60 and the drive sleeve 30.

EX1001, 4:29-41.

515. The tubular clutch as described by the challenged patents, therefore, is "generally cylindrical," having a series of "circumferentially directed ... teeth" at is first, *i.e.*, needle-end, and also has a plurality of teeth at a second, *i.e.*, button-end. *Id*. The teeth on the needle-end engage with the clicker, and the teeth on the button-

end engage with the dose dial sleeve. *See id.*, 5:29-36, 6:6-22. As taught by the challenged patents, 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.*, 4:39-41.

516. It is my opinion that Møller's cup shaped element and tubular element 120, which Møller discloses corresponds to the cup shaped element, operate in a similar manner using a similar structure. *Compare* EX1015, FIGS. 1, 5 *with* EX1001, FIGS. 6-8. Like clutch 60, the cup shaped element and the tubular element 120 includes a set of axially extending teeth at their button-end that releasably engage corresponding teeth in the dose setting button. *See id.*, ¶¶36, 39, FIGS. 3-5; *see also id.*, ¶¶29-30 (discussing similar structure of the cup shaped element), FIG. 1. Both embodiments also include a biasing element (spring 26/126) that exerts upward force to keep the clutch engaged during dose setting. *See id.*, ¶¶27, 29, 39, FIGS. 3-5. 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 id.*, ¶¶27, 29, 39, FIGS. 3-5.

517. Thus, it is my opinion that cup shaped element and tubular element 120 not only have the structure of clutch 60 of the challenged patent, they also serve as a clutch because they releasably couple and decouple components of the pen during injection.

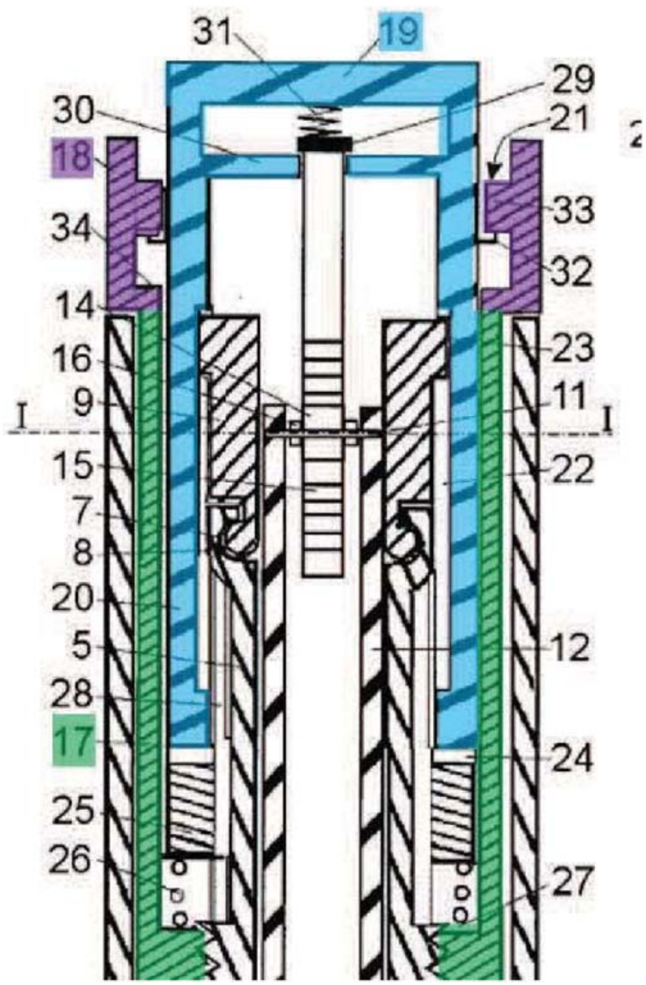
['486] Claim 51.1: a tubular body, said tubular body extending from a distal end to a proximal end; and

518. As I noted above, the cup shaped element includes "a tubular part 20 [that] fit[s] into the dose setting drum 17 and encompass[es] the gearbox 9." *Id.*, ¶26, FIG. 1. The cup shaped element thus includes a "tubular body," in the form of a tubular part 20. As further shown in FIG. 1, the tubular part 20 extends from a needle-end to a button-end. Accordingly, Møller discloses that the cup shaped element includes "a tubular body" that "extend[s] from a distal end to a proximal end."

['486] Claim 51.2: 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.

519. As I explained, the cup shaped element includes "a tubular part 20 [that] fit[s] into the dose setting drum 17," which corresponds to the recited "dial member." *Id.*, ¶26, FIG. 1. To illustrate this relative position, I have reproduced a partial view of FIG. 1 below, where I have annotated the dose setting drum 17 in green, and the cup shaped element in blue.[36]

[36] Because it is integrally formed with the scale drum 80 (which corresponds to the recited "dial member"), I have also annotated the dose setting button 81, which, as I explain below, corresponds to the "dose knob" recited in certain dependent claims of the '486 patent.



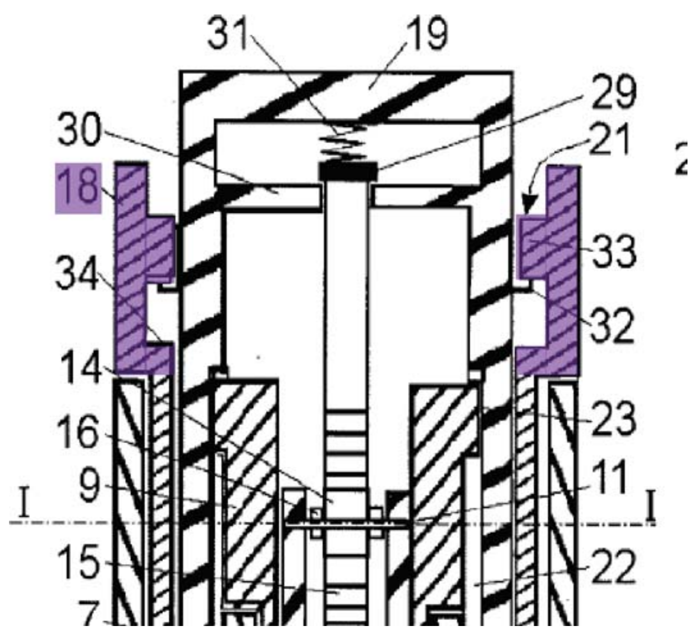
520. Thus, Møller discloses that the "distal end" of the tubular part 20 of the cup shaped element "ha[s] a diameter sized such that said distal end of" the tubular part 20 "may be positioned within a proximal end of" the dose setting drum 17.

2. <u>Dependent claims 52-53 and 56-57 of the '486 patent</u>

521. Each section of dependent claims 52-53 and 56-57 of the '486 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

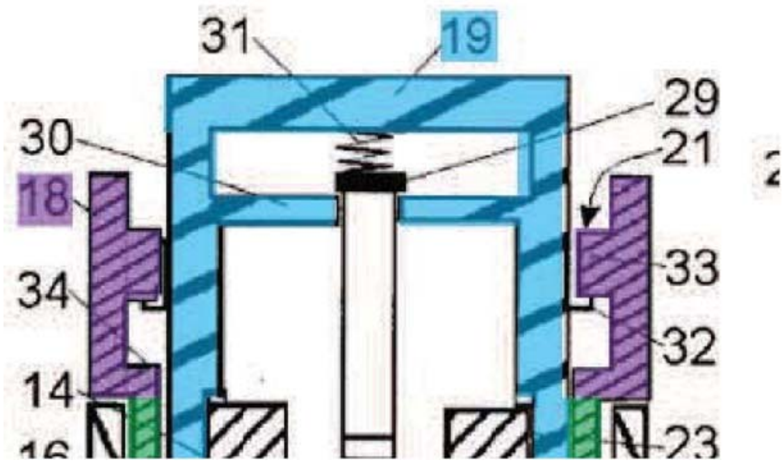
['486] Claim 52: The clutch of claim 51, wherein said proximal end of said tubular body is configured to reside within an inner space of a dose knob.

522. Møller discloses that the dose setting drum 17 includes, at its button-end, "a part with enlarged diameter forming a dose setting button 18." EX1015, ¶25, FIG. 1. To set a dose, the user rotates the dose setting button 18 to screw the dose setting drum 17 up along the thread 6 of the housing's tubular element 5. *Id.*, ¶29, FIG. 1. Thus, Møller discloses "a dose knob," in the form of a dose setting button 18. Reproduced below is a partial view of FIG. 1, toward the device's button-end, where I have highlighted the dose setting button 18 in purple:



523. Also in FIG. 1, Møller shows that the button-end of the cup shaped element is sized to be positioned within the dose setting button 18. To illustrate this, I have reproduced below a partial view of FIG. 1 toward the button-end of the device,

where I have annotated the cup shaped element in blue, the dose setting drum 17 in green, and the dose setting button 18 in purple:



524. Accordingly, Møller discloses that the "proximal end" of the cup shaped element "is configured to reside within an inner space of" the dose setting button 18 of the dose setting drum 17.

['486] Claim 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.

525. As I noted above, to inject a set dose, the bottom 19 of the cup shaped element is pressed by the user. *Id.*, ¶32. This action moves the cup shaped element axially toward the device's needle-end, which causes the protrusions 32 to disengage from the dose setting button 18. *Id.*, ¶¶32-33. As a result, the cup shaped element is decoupled from the dose setting drum 17, allowing the drum 17 (and its dose setting button 18) to rotate freely back into the housing. *Id.*, ¶33. The cup shaped element moves axially toward the device's needle-end without following the drum's rotation. *Id.*, ¶32. The cup shaped element's axial movement is transmitted to the connection

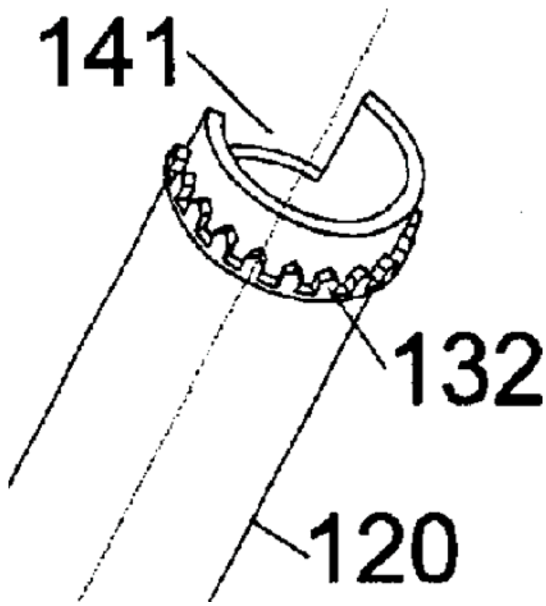
bars 12 with nut 13 through the gear box 9, which causes the nut 13 to press the piston rod 4 into the compartment 3 to dispense medicine. *Id.*

526. Accordingly, when the dose setting button 18 "is activated to dispense a dose of a medicament contained within" the device, via the user pressing the bottom 19 of the cup shaped element to start injection, the cup shaped element "is moved in a distal direction" to disengage from the dose setting button 18 and transmit its axial movement to the piston rod 4 to dispense medicine.

['486] Claim 56: The clutch of claim 51, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch.

527. As I explained above, the cup shaped element is releasably coupled to a dose setting drum 17 through "0-shaped protrusions 32 ... engaging A-shaped recesses in the inner ring 33 in the dose setting button 18." *Id.*, ¶29, FIG. 1. As I also explained above, Møller describes a second embodiment, where "[f]or manufacturing reasons minor changes are made," and thus "elements corresponding to elements in FIG. 1 and 2 are given the same references as these elements with a prefixed `1'." *Id.*, ¶¶35-36. Given this description, it is my opinion that a person of ordinary skill would have understood that elements of the first embodiment are structurally and functionally equivalent to the elements of the second embodiment to which they correspond. As such, a person of ordinary skill would have understood that the second embodiment shown in FIGS. 3-5 informed the structure of the embodiment shown in FIGS. 1-2.

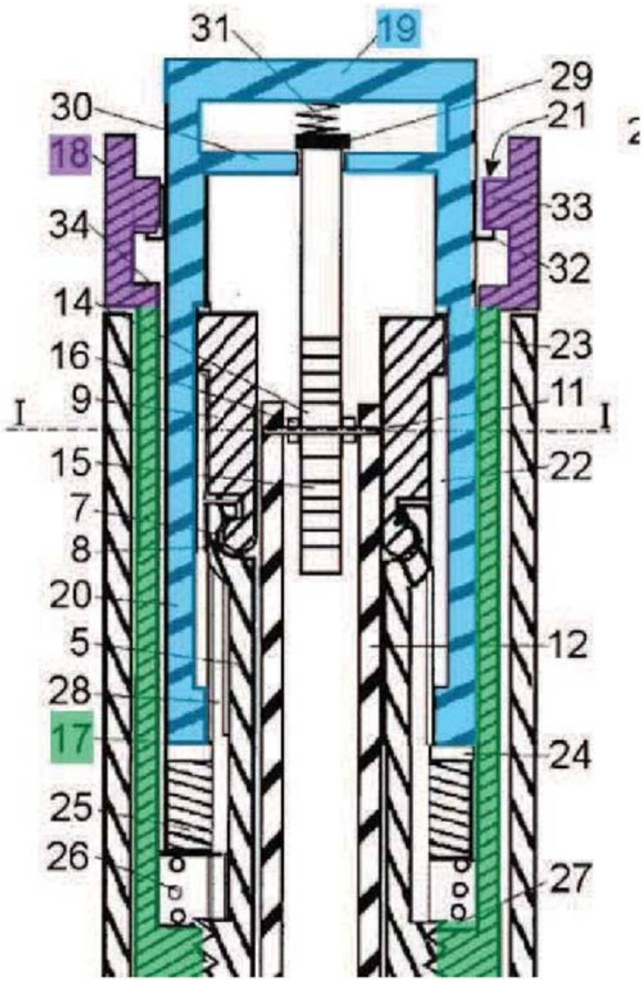
528. In the second embodiment, Møller shows that the protrusions 132 extend axially from a radially interior portion of a flange on a tubular element 120, as shown below in a partial view of FIG. 5, which shows the button-end of the tubular element 120 in greater detail:



529. Based on Møller's disclosure that protrusions 132 correspond to the protrusions 32 of the cup shaped element shown in FIG. 1, it is my opinion that a person of ordinary skill would have understood that the protrusions 32 were "a plurality of axially extending teeth formed on an interior of a flange of˝ the cup shaped element.

['486] Claim 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.

530. As I noted above, the cup shaped element includes "a tubular part 20 [that] fit[s] into the dose setting drum 17," making the cup shaped element be "positioned within an open proximal end of" the dose setting drum 17 such that the dose setting drum 17 "extends circumferentially around at least a portion of" the cup shaped element. *See id.*, ¶26, FIG. 1. Moreover, as shown in FIG. 1 above, the cup shaped element includes a tubular part 20 that extends from a button-end side of the dose setting button 18 through its needle-end into the dose setting drum 17, making the cup shaped element "located adjacent to a distal end" of the dose setting button 18. *See id.*, ¶26. To illustrate this relative positioning, I have reproduced FIG. 1, where I have annotated the cup shaped element in blue, the dose setting drum 17 in green, and the dose setting button 18 in purple:



531. And, as mentioned above, protrusions 32 of the cup shaped element are configured for releasable engagement with recesses provided on the dose setting button 18, rendering the cup shaped element "operatively coupled to" the dose setting button 18. *See id.*, ¶¶29-30, 32-33.

532. Accordingly, Møller discloses that the cup shaped element "is positioned within an open proximal end of" the dose setting drum 17 and is "located adjacent a distal end of" and "operatively coupled to" the dose setting button 18. The

dose setting drum 17 also “extends circumferentially around at least a portion of” the cup shaped element.

J. [’486-B] Ground 7: Claims 54-55 are Obvious over Møller in combination with Burroughs

533. As I explained below, it is my opinion that claims 54 and 55 are rendered obvious by the combination of Møller and Burroughs. Each section of claims 54-55 of the ’044 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

[’486] Claim 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.

534. Møller discloses that the device’s housing includes “a compartment 3 designed for the accommodation of a not shown ampoule.” *Id.*, ¶22. Møller further discloses that the device allows “for injection of set doses of medicine from a cartridge.” *Id.*, Abstract. Thus, a person of ordinary skill would have understood that Møller discloses “a cartridge containing a medicament,” in the form of an ampoule having medicine contained within, for dispensing set doses of the medicine. Møller, however, does not explicitly describe in detail the individual components that make up the ampoule.

535. Burroughs, however, discloses a cartridge 40 contained within a housing 22 of a pen-type injector device. *See* EX1013, 9:34-36, FIGS. 1-2. "Cartridge 40 is manufactured of glass and comprises a tube defining an inner chamber 212 ...." *Id.*, 9:36-37. Burroughs discloses that the cartridge 40 contains medicine, which would be held within the cartridge's inner chamber 212, which forms a "reservoir." *See id.*, Abstract, 2:42-48. The cartridge 40 also contains a piston 210, which is in engagement with a plunger engagement portion 206 of the leadscrew 38. *Id.*, 9:32-34. When the leadscrew 38 is advanced axially during dose dispensing, the plunger engagement portion 206 pushes the piston 210 toward the needle-end of the cartridge such that medicine from the inner chamber 212 is dispensed from the cartridge. *See id.*, 2:44-48. Thus, piston 210 functions as "a stopper" because it abuts the piston rod that axially drives medicine from the cartridge and separates the remaining medicine from the "used" portion of the chamber.

536. As I explained above, the inner chamber 212 openly terminates at its distal end [*i.e.*, needle-end] in a neck 214 having a septum secured by a ferrule (not labeled). *See id.*, 9:36-40; *supra*, ¶¶463-65. Although not labeled, a person of ordinary skill would have understood that Burroughs discloses a septum and a ferrule in FIG. 1. A person of ordinary skill would have understood that the needle 222, which is secured by a rubber disc 218 in cap 216, accesses the cartridge by a needle-

penetrable port, which is called a septum. *See id.*, 9:36-40. The septum is secured to the cartridge by a ferrule.

537. It was well-known to those skilled in the art that cartridges used to hold and dispense medicine from pen-type injectors often contained a reservoir for holding the medicine within the cartridge, a stopper for abutting the piston rod of the drive mechanism, a septum from separating the inner contents of the reservoir from an external chamber or environment that allows for penetration by a hypodermic needle, and a ferrule for securing the septum to the cartridge. Burroughs discloses such an arrangement, and in my opinion that a person of ordinary skill would have considered those components readily apparent from the teachings of Burroughs.

538. It is also my opinion that it would have been obvious to incorporate a cartridge like that of Burroughs into an injection pen like that of Møller. As I noted above, the components recited by claim 54 are common and well-understood components of medicine-containing cartridges for pen-type injectors. Indeed, I note that the ’486 patent describes that its device includes “a cartridge 8 from which a number of doses of medicinal product may be dispensed,” but the ’486 patent never describes any of the cartridge components recited in claim 54. *See* EX1003, 3:34-37. Thus, the ’486 patent itself confirms that these components were well-known and commonly used in cartridges of this type.

539. Accordingly, it is my opinion that a person of ordinary skill would have readily incorporated those components into the ampoule of Møller based on Møller's teachings of using a medicine-containing ampoule in a pen-type injector. Alternatively, it is my opinion that a person of ordinary skill would have readily understood that a cartridge having a reservoir, a stopper, a septum, and a ferrule would be a well-known cartridge that was commonly use in a pen-type injector, and would have incorporated such a cartridge into the device of Møller based on the teachings of Burroughs.

['486] Claim 55: The clutch of claim 54, wherein said cartridge comprises a multidose cartridge.

540. Møller further discloses a pen-type injector that allows "for injection of set doses of medicine from a cartridge." *Id.*, Abstract. Thus, Steenfeldt- Møller discloses a cartridge (or ampoule) that can dispense multiple doses of a medicine after a number of uses.

541. Similarly, Burroughs discloses "[a] multi-use medication dispensing pen ... that is recyclable after the contents of the medication cartridge have been exhausted." *Id.*, Abstract. Burroughs discloses that the user can select a certain dose by rotating the dial mechanism 34 in either direction to make the dose larger or smaller. *Id.*, 5:62-65, 10:49-52. Thus, because Burroughs discloses that the device can be used to dispense varying, set doses of medicine over multiple uses, a person

of ordinary skill would have understood that Burroughs discloses that the cartridge 40 comprises “a multidose cartridge.”

542. As I noted above, a person of ordinary skill would have also understood that Burroughs discloses a medicine-containing cartridge having a reservoir, a stopper, a septum, and a ferrule for dispensing multiple doses of medicine. Thus, a person of ordinary skill would have readily expected that such a commonly-used cartridge would be appropriate to inject set doses of medicine using a device like that of Møller. As such, it is my opinion that a person of ordinary skill would have found it obvious to incorporate “a multidose cartridge” having a reservoir, a stopper, a septum, and a ferrule in the multi-use injector device of Møller.

543. Thus, the combination of Møller and Burroughs renders this element obvious.

K. [’844-A] Ground 1: Claims 21-29 are Anticipated by Giambattista

544. As explained in detail below, it is my opinion that Giambattista teaches a drug delivery device that includes each and every element of claims 21-29 of the ’844 patent, and thus Giambattista anticipates those claims. Like above, my analysis first focuses on the independent challenged claim 21 of the ’844 patent, and then moves on to the dependent challenged claims of the ’844 patent. Each claim section is presented below in bold text followed by my analysis of that part of the claim. The

analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

1. Independent claim 21 of the ’844 Patent

[’844] Claim 21, preamble: A drug delivery device comprising:

545. Giambattista discloses “a medication delivery pen 10 maybe used for the administration of various medications, including insulin[.]” EX1016, 2:26-35, FIG. 1, claim 1. Thus, Giambattista teaches a drug delivery device.”

546. Below, I have reproduced an annotated FIG. 2 of Giambattista, which highlights certain components of the pen:

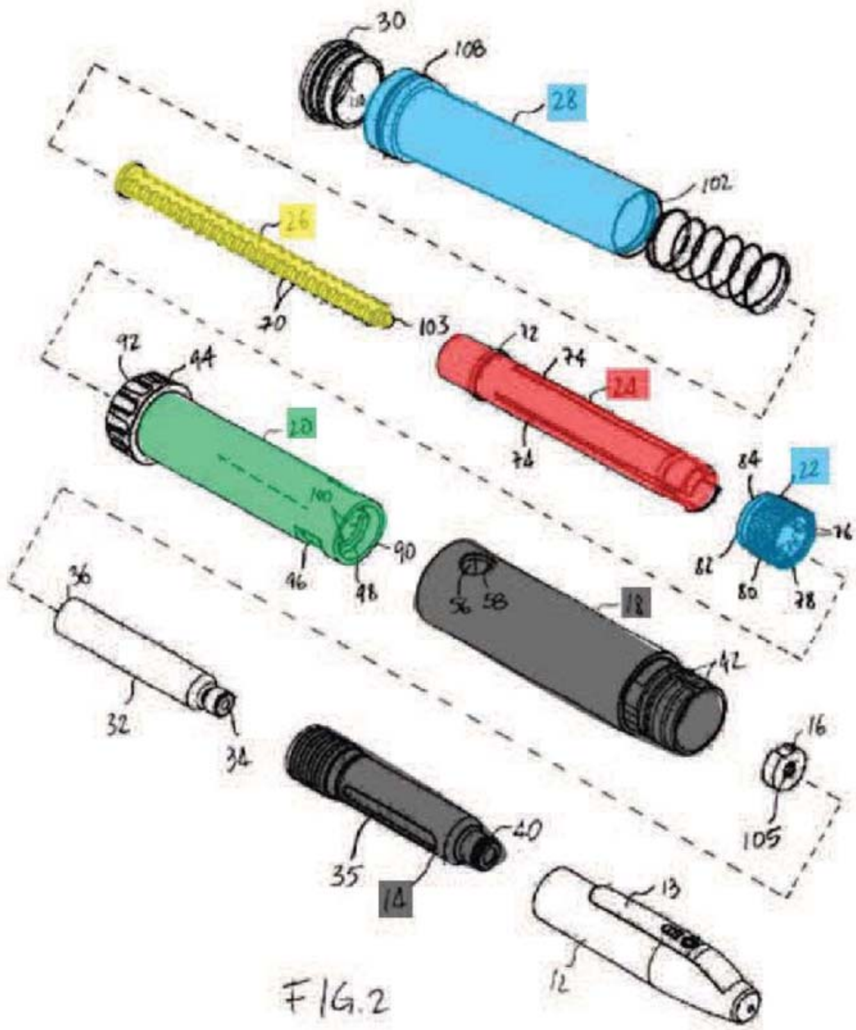


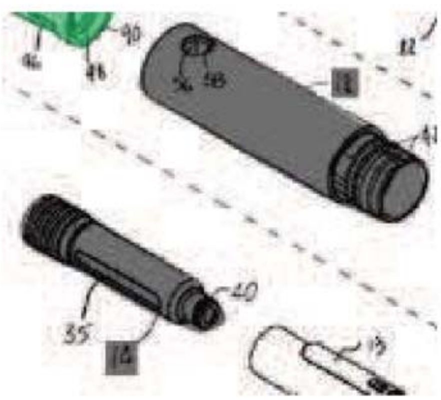
FIG. 2

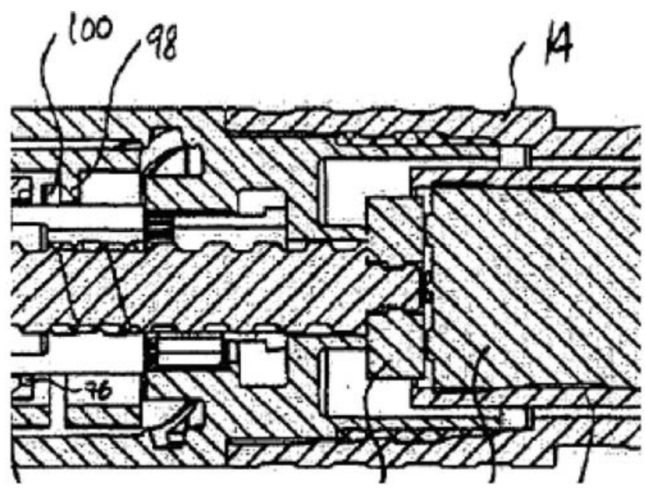
<u>['844] Claim 21.1: a housing comprising a dose dispensing end and a first thread;</u>

547. As shown in FIG. 2 above, Giambattista's device includes a "housing" in the form of body 18 and cartridge holder 14 that mounts onto body 18. EX1016, 2:36-40, 2:66-3:1; *see also* FIGS. 2, 3, 7, 11. As discussed above, the '844 patent describes the housing similarly as comprising a cartridge retaining part 2 and a main housing part 4. EX1004, 3:37-38. The dose dispensing end of the housing is disposed opposite the button end of the device where a needle mounts onto threads 40 of

cartridge holder 14. EX1016, 2:42-53. Body 18 comprises a dose setting thread 54 (i.e., first thread) on its interior surface. *Id*., 3:11-12, FIG. 3. Giambattista thus teaches a drug delivery device that comprises a "housing comprising a dose dispensing end and a first thread."

548. Below left, I have reproduced a partial view of FIG. 2 that shows the body 18 and cartridge holder 14 in greater detail, in which I have annotated the housing in gray. Below-right, I have reproduced a partial view of FIGS. 11 showing in greater detail where cartridge holder 14 mounts onto body 18.





549. Below, I have reproduced FIG. 3, which depicts internal threads 54 on body 18, which satisfy the first thread limitation. I have also reproduced FIG. 7 for context. FIGS. 3 and 7 disclose a housing in the form of body 18 and cartridge holder 14.

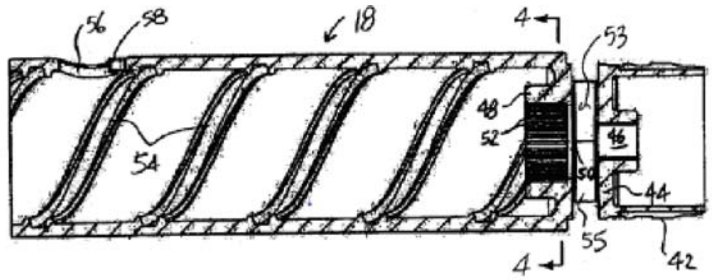


FIG. 3

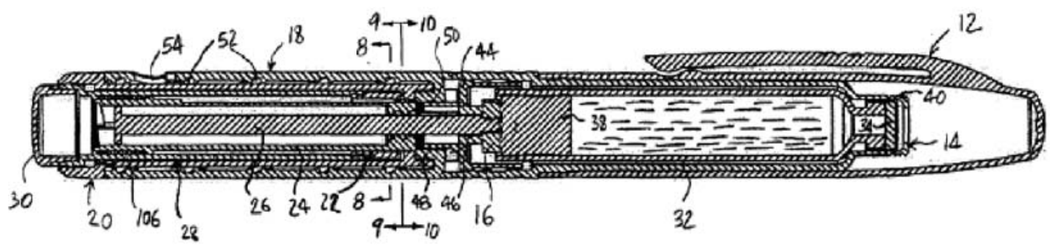
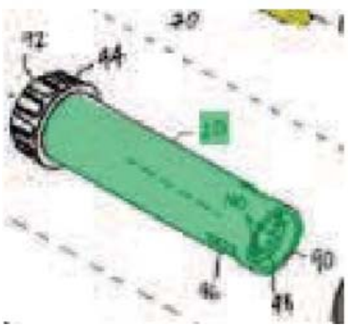


FIG. 7

<u>['844] Claim 21.2: a dose indicator comprising a second thread that engages with the first thread;</u>

550. Giambattista's device also includes a dose knob 20 that include "one or more thread portions 95 (FIG. 11) formed to threadedly engage the dose setting thread 54 of the body 18." *Id*., 2:36-38, 3:60-66. Below, I have reproduced partial, annotated views of Figures 2 (left) and 11 (right). FIG. 2 shows dose knob 20 in green. FIG. 11 shows thread portion 95 engaged with dose setting thread 54 of body 18. I have annotated dose knob 20 in green and body 18 in gray.



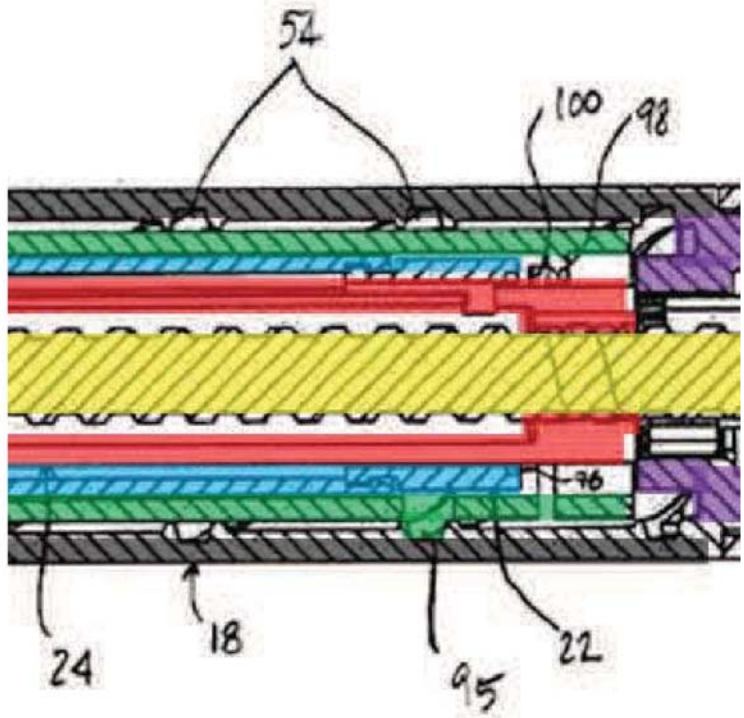


FIG. 11

551. Thread portion 95 satisfies the second thread limitation. Via the threaded engagement of thread portion 95 with dose setting thread 54, dose knob 20 rotates and moves axially relative to the body 18 during dose setting and injection. *See id.*, 3:60-66, 5:24-25, claims 6, 9, 15. Dosage indicia may be disposed externally on dose knob 20 and may be viewed via window 56 in body 18. *See id.*, 3:10-15, 3:66-67, FIGS. 2-3. Giambattista thus teaches a "dose indicator" in the form of dose knob 20 comprising a second thread that engages with a first thread.

[¶844] Claim 21.3: a driving member comprising a third thread;

552. Giambattista's device also includes driver 24 that includes "[i]nternal threads 68" that are "provided to threadedly engage threads 70 of the leadscrew 26." *Id.*, 2:36-38, 3:16-24. Below, I have reproduced a partial, annotated view of Figures 2 (left) and 5 (right). FIG. 2 shows driver 24 annotated in red. FIG. 5 shows internal threads 68, which satisfy the third thread limitation.

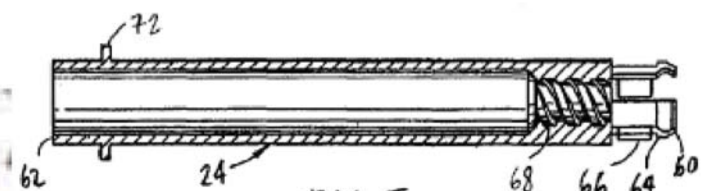
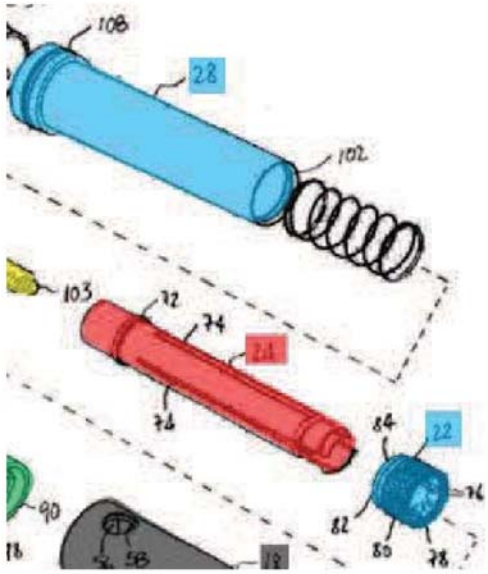


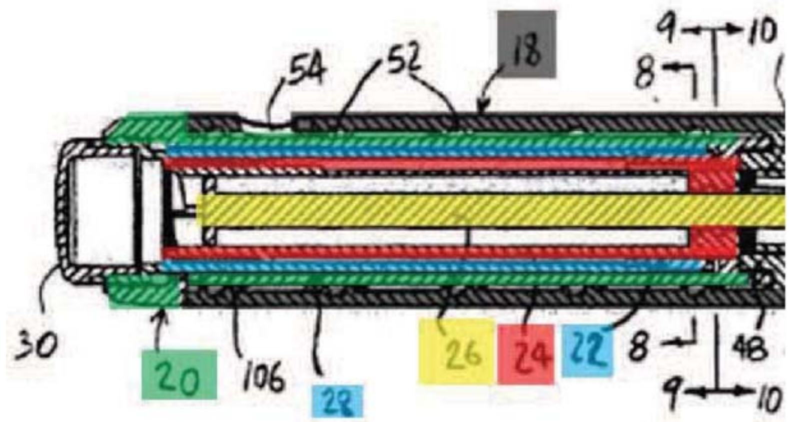
FIG. 5

553. Threads 68 of driver 24 rotate about the threads 70 of leadscrew 26 when driver 24 rotates with dosing ring 22 to dispense medication. *See id.*, 5:1624. Giambattista thus teaches a "driving member comprising a third thread" in the form of driver 24.

['844] Claim 21.4: a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;

554. Giambattista's device also includes dosing ring 22 and dosing ring adaptor 28. *Id.*, 2:36-39. Below, I have reproduced a partial, annotated view of Figures 2 (top) and 7 (bottom). FIGS. 2 and 7 each show dosing ring 22 and dosing ring adaptor 28 annotated in blue.





555. Dosing ring 22 and dosing ring adaptor may be formed integrally as a single part or they may be formed separately and joined by mounting dosing ring 22 onto dosing ring adaptor 28. *Id.*, 4:21-27. FIGS. 2, 7-9, and 11-12 show that each of dosing ring 22 and dosing ring adaptor 28 (and the two when joined together) is a sleeve having a generally tubular structure. They also disclose that dosing ring adaptor 28 and dosing ring 22 are located coaxially within body 18 and dose knob 20 and coaxially around driver such that they are located between the dose knob 20

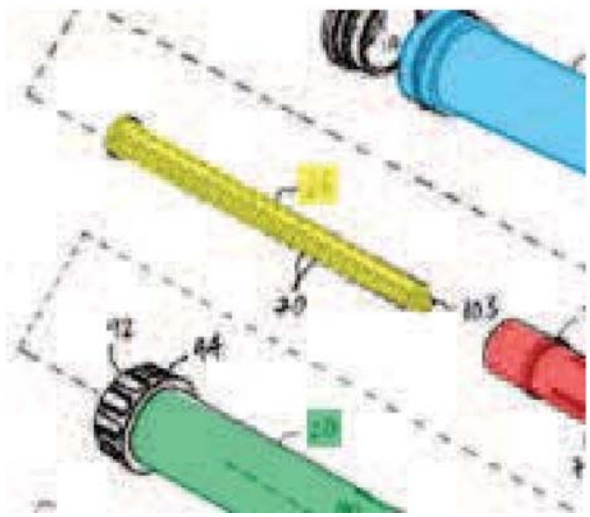
and driver 24. Claims 1 and 13 specifically recite that the dosing ring is "disposed on said driver" and that the dose knob is coaxially disposed about the dosing ring. Giambattista thus discloses the sleeve disposed between the dose indicator and driving member.

556. Giambattista also discloses that dosing ring 22 and dosing ring adaptor 28 are releasably connected to dose knob 20. "Dosing ring 22 is formed with one or more grooves 76[.], *Id.*, 3:39-40. Dose knob 20 has teeth 100 on its lip 98. *Id.*, 4:49-51. During dose setting, grooves 76 of dosing ring 22 are "spaced apart from the teeth 100 of the dose knob," which permits the dose knob to "be freely rotated without rotating dosing ring 22." *Id.*, 4:49-53. During dose dispensing, thumb button 30 is depressed to engage grooves 76 of dosing ring 22 with teeth 100 of dose knob so that dosing ring 22 rotates with dose knob 20. *Id.*, 5:8-16, FIGS 9-10, 12. Once dose dispensing is complete, thumb button 30 is released and dosing ring 22 disengages from dose knob 20 as biasing means 106 urges dosing ring 22 distally within the pen so that the teeth and grooves are once again spaced apart. *Id.*, 4:37-44, 4:49-56, 5:26-28. Dosing ring 22 is thus releasably connected to dose knob 20. *See also* claims 1, 13 (selective operative engagement and disengagement). Because dosing ring 22 and dosing ring adaptor are either formed as a single component or joined together into a single component and thus move "in concert" with one another, *id.*, 4:21-27, both dosing ring 22 and dosing ring adaptor 28 are releasably

connected to dose knob 20. Giambattista thus teaches a "a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator" in the form of dosing ring 22 and dosing ring adaptor 28.

['844] Claim 21.5: a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;

557. The device further includes leadscrew 26, which has an external threads 70 that mates with internal threads 26 driver 24. *See id.*, 2:36-39, 3:22-24, 5:16-24, claim 7. Below, I have reproduced a partial view of FIG. 2 that shows leadscrew 26 with external threads 70. I have annotated the piston rod in yellow.



558. Accordingly, Giambattista teaches a piston rod comprising an external fourth thread that is engaged with the third thread in the form of leadscrew 26.

<u>['844] Claim 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;</u>

559. The device comprises a piston rod holder in the form of a bulkhead 44 of body 18, the bulkhead 44 having aperture 46 configured to prevent leadscrew 26 from rotating during dose setting and permit leadscrew 26 to traverse axially towards the distal end during dose dispensing.

560. Body 18 includes a "bulkhead 44" that extends across the interior of the body" and in which bulkhead "aperture 46 is formed." *Id.,* 3:1-3." I have reproduced FIG. 3 (top), and partial view of FIGS. 7 (bottom left) and 11 (bottom right) below. I have annotated FIGS. 7 and 11 to show the housing in gray, the portion of the housing that forms the piston rod holder in purple, the dose indicator in green, the sleeve in blue, the driving member in red, and the piston rod in yellow. As shown in FIGS. 3, 7, and 11, bulkhead 44 is integral with and fixed to the remainder of body 18 via wall 55. Wall 55 may be continuous or, as illustrated in FIG. 7, wall 55 may be discontinuous. *Id.*, 3:6-10. In either case, aperture 46 and bulkhead 44 remain rotationally fixed to the portion of body 18 having dose setting threads 54.

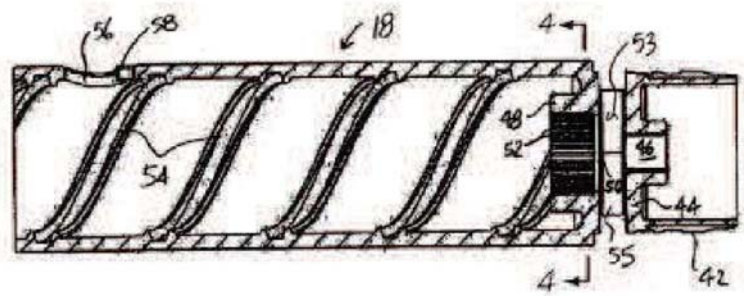
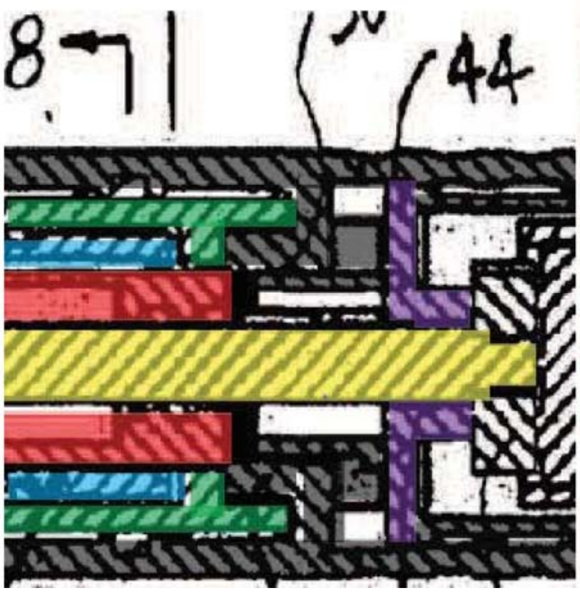
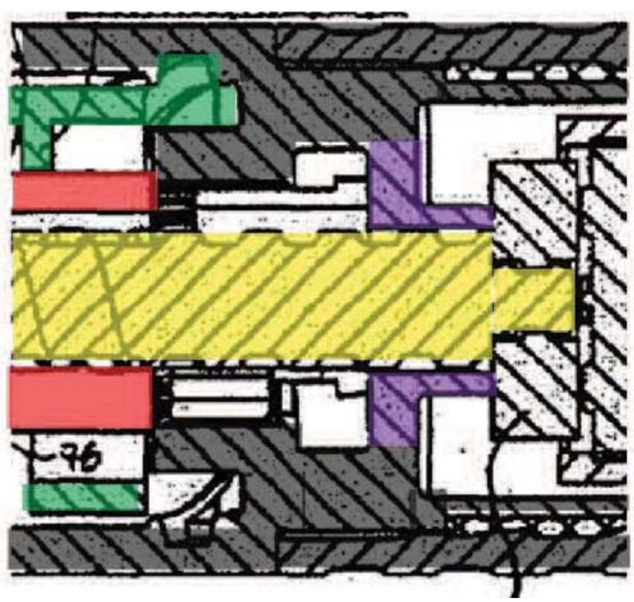


FIG. 3





561. "The aperture 46 is defined to allow the passage therethrough of the leadscrew 26, yet the aperture 26 is shaped (e.g., being rectangular) to prevent rotation of leadscrew 26 therewithin. *Id.*, 3:3-6. As the bulkhead is part of body 18, the shape of the aperture is thus "formed to prevent rotation of said leadscrew relative to said body." *Id.*, claim 8.

562. Giambattista ’794 expressly discloses that aperture 46 in bulkhead 44 prevents leadscrew 26 from rotating during dose setting and permits the piston rod to traverse axially towards the distal end during dose dispensing:

> 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.

563. Although Giambattista describes the translation as occurring “in a proximal direction” and claim 21 recites axial translation “towards the distal end during dose dispensing,” it is necessarily the case that the proximal direction in Giambattista is the same direction as the “distal” direction in claim 21. Claim 21 introduces the term “the distal end,” without previously identifying a distal end. However, claim 21 also specifies that “the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.” Because claim 21 recites that the piston rod holder permits axial translation of the leadscrew towards the distal end during dose dispensing and specifies that the leadscrew axially translates towards the dose dispensing end during dose dispensing, a piston rod holder configured to permit translation towards the dose dispensing should be sufficient to

satisfy the "towards the distal end during dose dispensing" limitation. For the reasons discuss above, Giambattista '794 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."

['844] Claim 21.7: wherein: the housing is disposed at an outermost position of the drug delivery device;

564. As discussed above with respect to claim 21.1, pen 10 comprises a housing in the form of body 18 and cartridge holder 14 that mounts onto body 18. EX1016, 2:36-40, 2:66-3:1; *see also* FIGS. 2, 3, 7, 11. Below, I have reproduced FIG. 2 and a partial view of FIGS. 11-12 (the view being essentially the same in both FIGS. 11-12) that show the body 18 and cartridge holder 14 disposed at an outermost position of the drug delivery device.

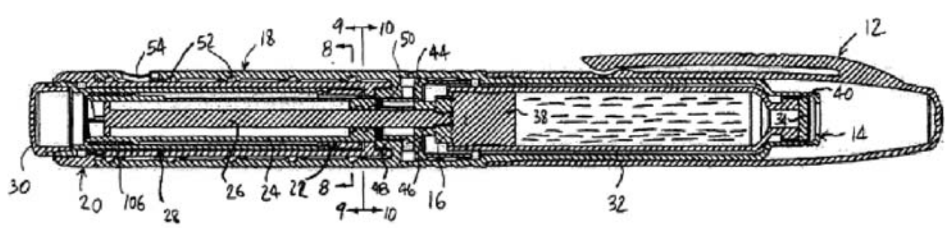
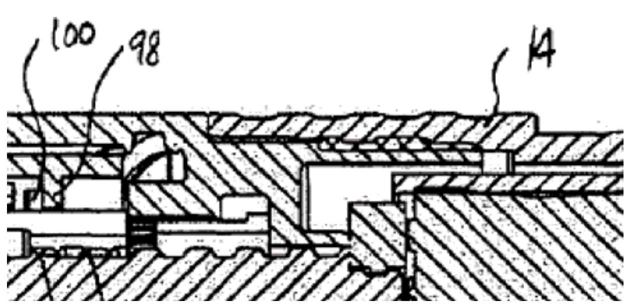


FIG. 7



565. FIG. 7 depicts a cap 12 disposed outside a portion of cartridge holder 14. The ’844 patent described a removable cap 12 and a replaceable cap 14 being respectively “retained over” part of the cartridge retaining part 2 and covering cartridge retaining part 2. EX1004, 3:48-57. The ’844 patent nonetheless defines the housing as comprising each of the cartridge retaining part 2 and main housing part 4 and does not define the housing as including the caps. *Id.*, 3:37-38. The ’844 patent nowhere states that the cartridge retaining part 2 must remain uncovered by a cap for the housing to be disposed at an outermost position of the device.

566. Below, I have reproduced FIGS. 8-10, which also depict body 18 at an outermost position of the drug delivery device:

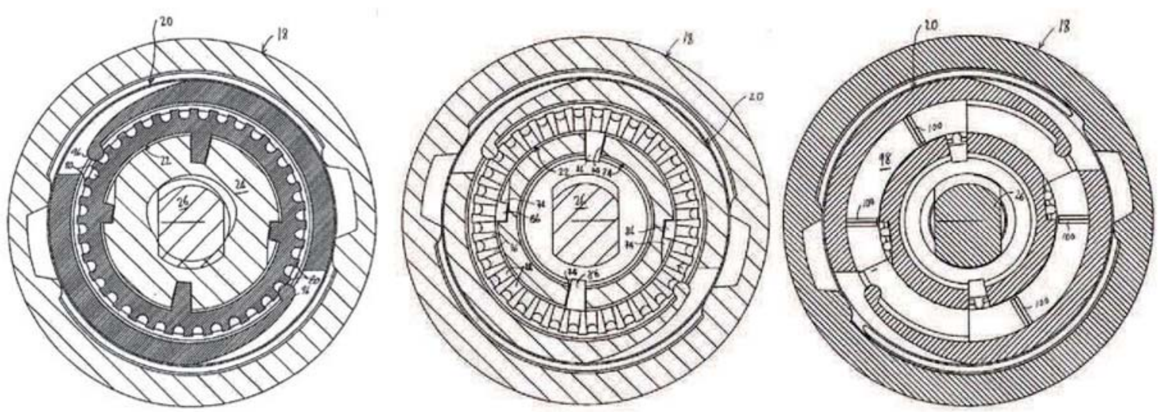


FIG. 8 FIG. 9 FIG. 10

567. For the reasons discussed herein, Giambattista discloses the housing is disposed at an outermost position of the drug delivery device.

['844] Claim 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;

568. As discussed above with respect to claim 21.2, pen 10 comprises a dose indicator in the form of dose knob 20. EX1016, 2:36-38. Below, I have reproduced FIG. 9 and a partial view of FIG. 11 and added color annotations to identify the dose knob 20 in green disposed between the housing (gray) and the sleeve (blue). This spatial relationship is also disclosed in FIGS. 2, 7-9, and 12.

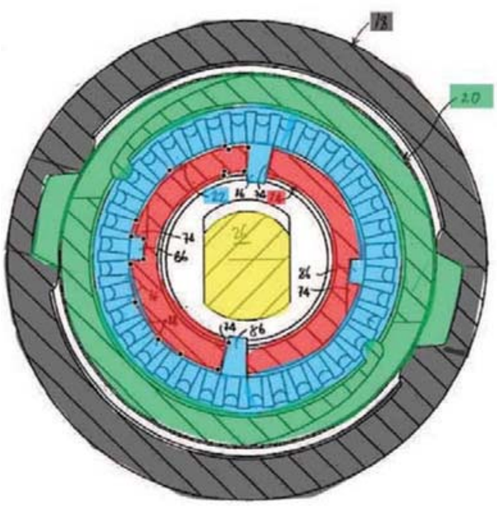


FIG. 9

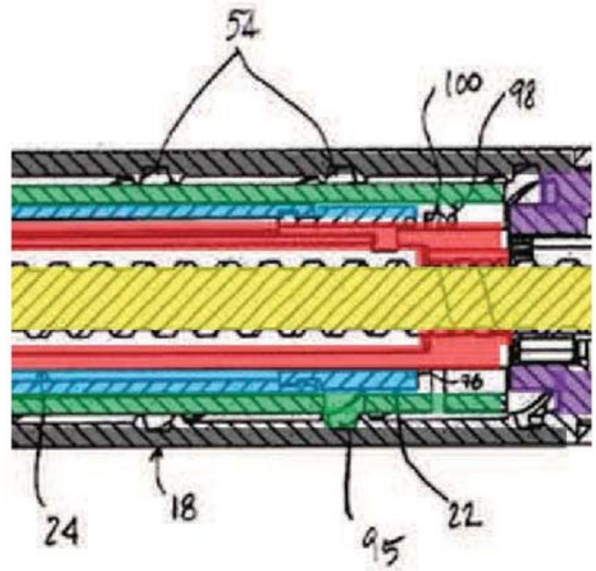


FIG. 11

569. Giambattista states that "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.", *Id*., 3:60-66, 4:49-64, claims 6, 9, 15. In each of FIGS. 7 and 11-12, for example, dose knob 20 is threaded all the way into body 18 with thread 95 of dose knob 20 engaging with internal threads 54

of body 18. At this threaded position, threads 54 extend from thread 95 of dose knob 20 towards the button-end of the device. Threads 54 do not extend towards the dose dispensing end of the device. Thus, 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. Giambattista thus teaches that dose knob 20 traverses axially out of the body during dose setting.

570. Giambattista also 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." *Id.*, 4:49-64, FIG. 11. In contrast, during dose dispensing, thumb button 30 is depressed towards the dose dispensing end and thereby pushes dosing ring adaptor 28 and dosing ring 22 towards the dose dispensing end and causes "dose knob 20 to rotate in descending along the dose setting thread 54 in a proximal direction." *Id.*, 5:8-19. Dose knob 20 has a proximal end 90 on which teeth 100 are disposed. *Id.*, 3:56-57 & FIGS. 2, 11-12. As shown in FIGS. 2, 11-12, the proximal direction (towards proximal end 90) in which dose knob 20 descends during dose dispensing corresponds to the same direction as the dose dispensing end of the device.

571. For the reasons discussed herein, Giambattista discloses 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.

['844] Claim 21.9: the driving member is configured to rotate relative to the piston rod;

572. As discussed above regarding claim 21.3, Giambattista's device also includes driver 24. *Id.*, 2:36-38, 3:16-24. Giambattista discloses that driver 24 is configured to rotate relative to leadscrew 26. Specifically, 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 '794 thus teaches the "driving member is configured to rotate relative to the piston rod." configured to rotate relative to the piston rod.

[¶844] Claim 21.10: the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator;

573. As discussed above regarding claim 21.4, Giambattista's device includes a sleeve in the form of dosing ring 22 mounted onto dosing ring adaptor 28. *Id.*, 2:36-39, 4:21-27. Giambattista discloses 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. Giambattista teaches an embodiment

wherein this is 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. Giambattista also teaches 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. As discussed above, dosing ring 22 is integrally formed with, or mounted onto, dosing ring adaptor 28, *id.*, 4:21-27, which means that dosing ring 22 and dosing ring adaptor 28 as a whole are rotatably fixed relative to driver 24 and configured to traverse axially with dose knob 20. Giambattista '794 thus teaches "the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator."

[¶844] Claim 21.11: the piston rod and the driving member are configured to rotate relative to one another during dose dispensing;

574. As discussed above regarding claim 21.4, Giambattista's device includes driver 24 that includes "[i]nternal threads 68" that are "provided to threadedly engage threads 70 of the leadscrew 26." *Id.*, 2:36-38, 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, 3:16-25, 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 '794 thus teaches "the

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

[¶844] Claim 21.12: the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

575. Giambattista '794 discloses that leadscrew 26 is configured to traverse axially towards the dose dispensing end during dose dispensing. For example, 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 '794 thus teaches "the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing."

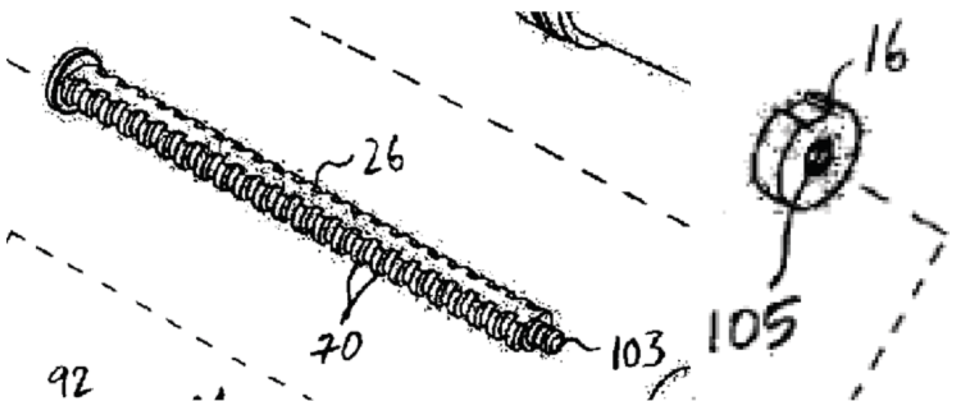
2. Dependent claims 22-29 of the '844 patent

576. Each section of dependent claims 22-29 of the '844 patent is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

['844] Claim 22: The drug delivery device of claim 21 where the piston rod has a circular cross-section.

577. Giambattista discloses that leadscrew 26 has a circular cross section at each of threaded end 103 and the opposite end of leadscrew 26. I have reproduced below partial views of FIG. 2 showing close-ups of leadscrew 26 and spinner 16. FIG. 2 depicts threaded end 103 having a circular cross section configured to engage

with circular threaded aperture 105 in spinner 16. FIG. 2 also depicts the opposite end of leadscrew 26 having a circular cross section. Giambattista thus discloses that leadscrew 26 has a circular cross section. Although this claim limitation does not require a circular cross section through-out the length of the piston rod, the piston rod has circular helical threads along the majority of its length so it is understood to have a "generally circular cross-section" with flat sides.



<u>['844] Claim 23: The drug delivery device of claim 21 further comprising a clutch.</u>

578. Giambattista '794 discloses dosing ring adaptor 28 and dosing ring 22, which act as a clutch. As references in Section VI above, Sanofi has construed a clutch in the '844 patent to mean a structure that couples and decouples a moveable component from another component. As I have explained above, dosing ring 22 and dosing ring adaptor 28 are "movable in concert with each other," may be "formed unitarily" with one another, and they may also 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.*, 3:3947, 5:16-19.

Dosing ring 22 via grooves 76 releasably engages teeth 100 of dose knob 20 to rotationally couple dose knob 20 with driver 24, when thumb button 30 is depressed. *Id.*, 4:49-53, 5:8-16; *see also* claims 1, 13. Thus, when dose knob 20 rotates during dose dispensing, this rotational movement is transmitted to driver 24 via dosing ring 22. Once dose dispensing is complete, thumb button 30 is released, causing grooves 76 of dosing ring 22 to disengage from teeth 100 of dose knob 20, thereby rotationally decoupling driver 24 from dose knob 20. *Id.*, 5:26-28. For the reasons discussed above, Giambattista '794 disclosed the "drug delivery device of claim 21 further comprising a clutch."

['844] Claim 24: The drug delivery device of claim 23 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

579. As I discussed above for claim 23, dosing ring 22 and dosing ring adaptor 28 operate as a clutch. Giambattista '794 discloses that this clutch provides audible and tactile feedback indicative of unit doses of medicament.

580. For example, Giambattista discloses 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. Dosing ring 22 thus provides audible clicks caused by

the physical interaction with ratchet arms 96 during dose setting. I have reproduced below FIG. 8, which depicts the ribs 80 of dosing ring 22 that provide these clicks.

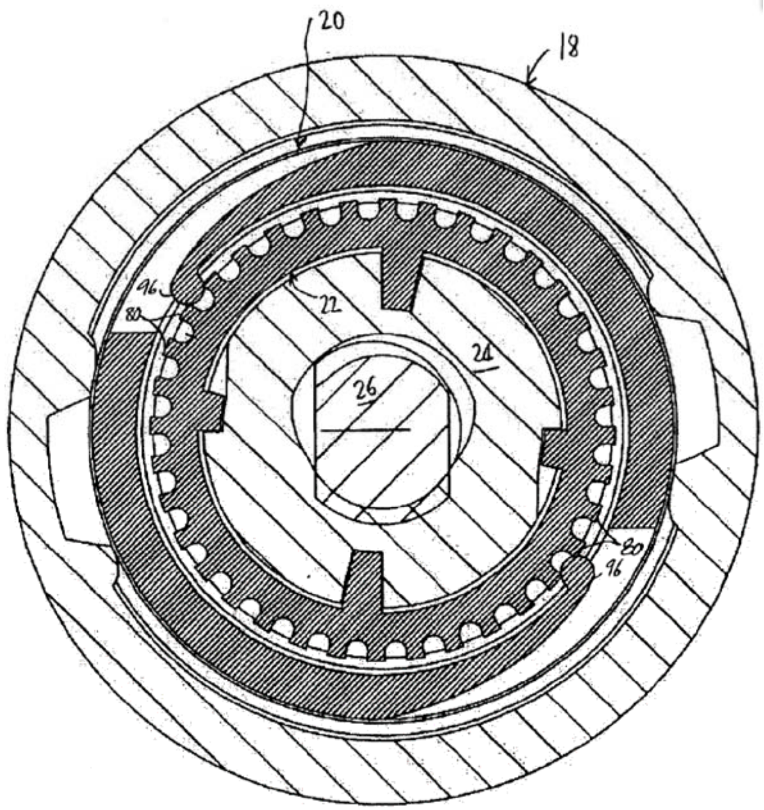


FIG. 8

581. Of course, the user necessarily would have tactile feedback as well as audible feedback because the audible signal is created by the physical impact of the inwardly-biased ratchet arms 96 of dose knob 20 on longitudinal ribs 80 of dosing ring 22. EX1016, 4:1-8. Indeed, the audible feedback is created by the tactile interaction. This is the same means by which the ’844 patent creates audible and tactile feedback. EX1004, 5:64-6:2 (noting that audible and tactile feedback is provided by dragging a toothed member over splines to provide a click).

582. In the embodiment in Giambattista discussed above, each click is equal to, and indicative of, a unit dose of medicament. Giambattista teaches 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. Giambattista's disclosure 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 that each audible signal (i.e., click) as a unit dose of medicament. In other words, rotation of dose knob 20 to set a dose occurs in discrete unit doses defined by each click. Once a dose is set for a given number of unit doses, dose knob 20 will maintain that setting until a different dose is set comprising a different number of unit doses.

583. As discussed above, Giambattista discloses the drug delivery device of claim 23 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

['844] Claim 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.

584. As discussed above with respect to claim 24, the dosing ring 22 operates as a clutch and provide audible clicks during dosing setting and are indicative of unit doses of medicament. Claim 25 further requires that the clutch produce audible

clicks during dose cancelling and that each dose is equal to a unit dose of medicament. Giambattista discloses each of these aspects for its clicker. For example, it discloses that 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, would include when dose knob 20 is "dialed back" when a "desired dosage amount is inadvertently by-passed," *id.*, 4:49-64. Giambattista thus discloses that the clutch produces audible clicks during dose cancelling.

585. FIG. 8 of Giambattista discloses ribs 80 that are evenly spaced around dosing ring 22, meaning that each unit dose represented by each audible signal is the same. Giambattista thus renders obvious 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.

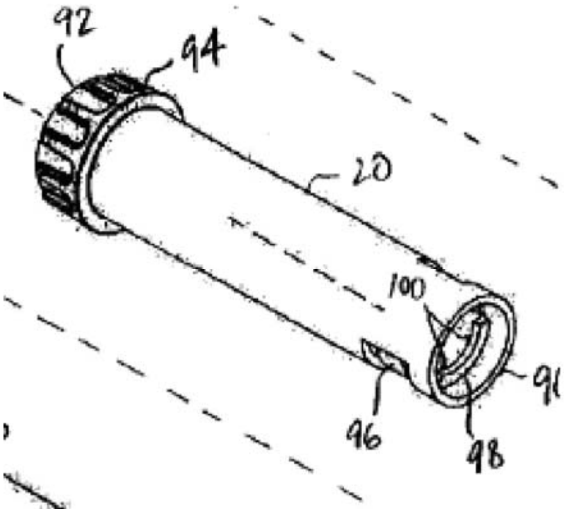
['844] Claim 26: The drug delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament.

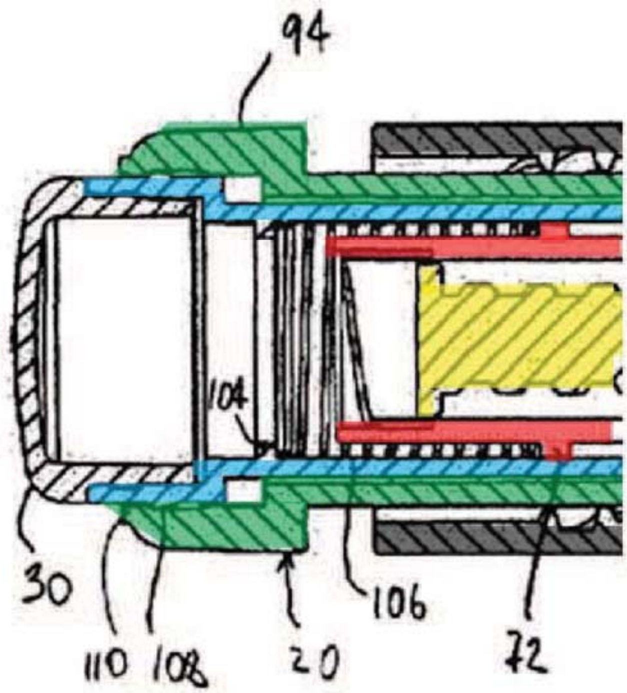
586. When setting a dose, Giambattista discloses that dose knob 20 traverses axially when it is rotated relative to body 18, causing dosing ring adaptor 28 and dosing ring 22 (the clutch of Giambattista '794) to move with the dose knob 20 and dosing ring 22 to slide axially along driver 24 as a dose is selected. EX1016, 4:49-61. Giambattista states: "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." *Id.*, 4:61-

64. Giambattista ’794 thus teaches the “drug delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament.”

['844] Claim 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.

587. Giambattista discloses thumb button 30 seated in an annular recess of 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. It states: “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. Giambattista’s FIGS. 2 and 11 discloses that the distal end 92 of dose knob 20 corresponds with the proximal end of the dose dial sleeve depicted in FIGS. 1-5 of the ’844 patent. I have reproduced partial views of FIGS. 2 (left) and 11 (right) below and added color annotations to FIG. 11 to indicate dose knob 20, including textured handle 94, in green at the distal end (i.e., button end) of dose knob 20.



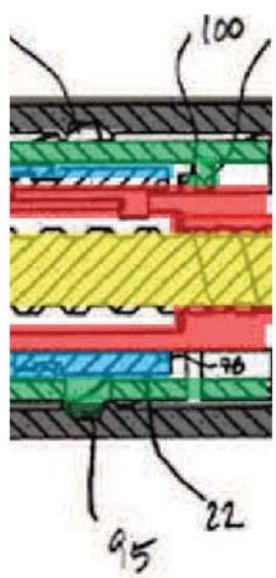


588. FIGS. 2, 7, and 11-12 of Giambattista show that thumb button 30 is seated in an annular recess of textured handle 94. Thumb button 30 is snapped onto or formed integrally with dose ring adaptor 28. EX1016, 4:33-36. Dosing ring 22 is "movable in concert with" dosing ring adaptor 28 or the two "may 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. As just discussed, Giambattista '794 teaches 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."

['844] Claim 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 axially with respect to the dose indicator and driving member.

589. Giambattista '794 discloses that dose delivery is initiated by depression of thumb button 30 to displace the dosing ring adaptor 28 and dosing ring 22 axially with respect to the dose knob 20 and driver 24. At rest, grooves 76 of dosing ring 22 are spaced from teeth 100 of dose knob 20 as shown in the partial view of FIG. 11 I have reproduced below. I have annotated dose knob 20 in green and dosing ring 22 and dosing ring adaptor 28 in blue. Because the teeth and grooves are unengaged in this state, rotation of dose knob 20 does not rotate the dosing ring or the driver. *Id.*, 4:49-53.



590. As disclosed in Giambattista, depression of thumb button 30 initiates dose delivery. As shown in the partial view of FIG. 11 I have reproduced and annotated below, thumb button 30 may be snapped into dosing ring adaptor 28. Alternatively, thumb button 30 may be unitarily formed with dosing ring adaptor 28 and/or dosing ring 22. *Id.*, 4:21-27, 4:33-36. In either embodiment, depression of button 30 depresses dosing ring adaptor 28 and dosing ring 22 relative to the dose knob 20 such that the grooves 76 of the dosing ring 20 contact and engage with teeth 100 of dose knob 20. *Id.*, 5:8-28, FIGS. 11-12; *see also claims* 1, 13. In other words, axial movement of the button caused by distally applied pressure to the button initiates dose delivery by displacing dosing ring adaptor 28 and dosing ring 22 axially with respect to the dose knob.

591. Although 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. Depression of thumb button 30 thus axially displaces dosing ring adaptor 28 and dosing ring 22 relative to driver 24. Accordingly, Giambattista '794 teaches 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."

['844] Claim 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.

592. As I discussed above for claims 24 and 25, dosing ring 22 provides audible clocks during dose setting, including dose cancelling, and each click is equal to a unit dose of medicament.

593. For example, Giambattista discloses 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 by-passed," *id.*, 4:49-64. Dosing ring 22 thus provides audible clicks caused by the physical interaction with ratchet arms 96 during dose setting and dose cancelling. I have reproduced below FIG. 8, which depicts the ribs 80 of dosing ring 22 that provide these clicks.

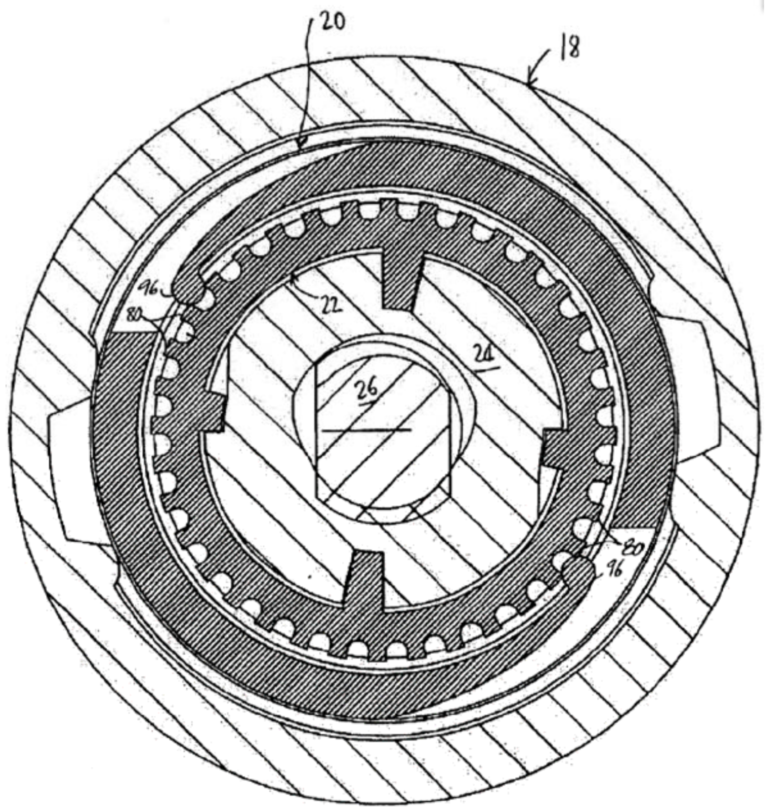


FIG. 8

594. In the embodiment in Giambattista discussed above, each click is equal to, and indicative of, a unit dose of medicament. Giambattista teaches 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. Giambattista's disclosure 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 that each audible signal (i.e., click) as a unit dose of medicament. In other words, rotation of dose knob 20 to set

a dose occurs in discrete unit doses defined by each click. Once a dose is set for a given number of unit doses, dose knob 20 will maintain that setting until a different dose is set comprising a different number of unit doses. FIG. 8 of Giambattista discloses ribs 80 that are evenly spaced around dosing ring 22, meaning that each unit dose represented by each audible signal is the same. The number and spacing of these ribs can correlate to units or fractions of a dose.

595. As discussed above, Giambattista renders obvious 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.

596. With regard to the means-plus-function interpretation, the ’844 patent teaches that the structure used to provide the function of an audible click is either a flexible arm being dragged over splines, or saw teeth riding over one another. *See* EX1004, 5:64-6:3, 6:27-37. As I noted above, Giambattista teaches that the dosing ring 22 comprises a plurality of longitudinal ribs 80, which inwardly-biased ratchet arms 96 of dose knob 20 rotate relative to in order to give “a user an audible signal of such rotation.” EX1016, 3:39-40, 4:1-8. It is my opinion that a person of ordinary skill would have understood the ratchet arms 96 to be “flexible arms” that drag over “splines” in the form of longitudinal ribs 80 to produce audible feedback. In my opinion, therefore, 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.

L. ['844-A] Ground 2: Claims 24-29 are Obvious over Giambattista in combination with Steenfeldt-Jensen

597. As explained in detail in ['844-A] Ground 1 above, it is my opinion that Giambattista teaches a drug delivery device that includes each and every element of claims 21-29 of the '844 patent, and thus anticipates those claims. Claims 24-29 are also obvious in further view of Steenfeldt-Jensen, which reference I have discussed in detail above. For example, I discussed the clicker disclosed in Steenfeldt-Jensen in at least Sections VIII.B-D above with respect to claims 14-15 of the '844 patent and claims 14-18 and 20 of the '486 patent. As I explained above, Steenfeldt-Jensen discloses the drug delivery device comprises a clicker provide audible and tactile feedback to a user when the dose setting button is rotated.

598. Steenfeldt-Jensen discloses that the flange 83 of the bushing 82 has, at its periphery, a radial protrusion 87. *Id.*, 11:37-40, FIG. 17. The compartment of the dose setting button 81 contains longitudinal recesses along its cylindrical side wall. *Id.*, 11:34-40. Steenfeldt-Jensen discloses that, when a dose is set by rotating the dose setting button 81, "the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 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.

599. Steenfeldt-Jensen expressly teaches that the clicks are "heard and felt during the dose setting rotation[.]" EX1014, 6:48-53. This disclosure expressly confirms my opinion above 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." Indeed, the clicker disclosed in Steenfeldt-Jensen also provides audible feedback through physical contact in a similar manner to that disclosed in Giambattista.

600. As discussed above, because Steenfeldt-Jensen discloses that movement of the radial protrusion 87 over the longitudinal recesses of the dose setting button 81 will produce a click when the dose setting button 81 is rotated "in any direction," it is my opinion that the person of ordinary skill would have also understood that audible feedback would be provided when the dose setting button 81 was rotated during dose cancelling.

601. Steenfeldt-Jensen also provides express disclosure teaching the audible feedback as being indicative of unit doses of medicament (as required by claims 24-28) and that each click is equal to a unit dose of medicament, as required by claims 25 and 29. Steenfeldt-Jensen expressly teaches 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." In other words, Steenfeldt-Jensen expressly teaches it is "appropriate," or beneficial, to arrange the clicker so that a dose of one unit is set for each click and so that the number of clicks heard and felt during the dose setting rotation corresponds to the size of the set dose. A person of ordinary skill in the art would have had good reason to arrange the longitudinal ribs 80 so that a dose of one unit is set for each click in the clicker of Giambattista to accomplish the same aim.

602. A person of ordinary skill in the art would have had a reasonable expectation of success in arranging the longitudinal ribs to be equal to a unit dose. Doing so 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.

M. ['844-A] Ground 3: Claim 30 is Obvious over Giambattista in combination with Klitgaard

603. As explained in detail in ['844-A] Ground 1 above, it is my opinion that Giambattista teaches a drug delivery device that includes each and every element of claim 22 of the '844 patent, and thus anticipates that claim. Claim 30 recites: "**The drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered.**" As I will explain in detail below, claim 30 is obvious over Giambattista in further view of Klitgaard.

604. Klitgaard describes an injection device for dispensing medicine comprising a limiting mechanism to track the amount of medication administered. EX1017, Abstract. 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. By configuring a track follower to move further on the track "[e]ach time a dose is set and injected," the track follower's location reflects the cumulative amount of medication that has been delivered and prevents setting of a dose larger than the remaining liquid in the cartridge. *Id.*

605. An embodiment of such a limiting mechanism is disclosed in FIG. 3 and its related description. Klitgaard discloses that nut member 32 is disposed between dose setting member 30 and driver 31 and tracks each set dose of medication delivered. *Id.*, 4:16-58. Dose setting member 30 is threaded out along internal threads of the housing to set a dose. *Id.*, 4:16-25. Nut member 32 simultaneously threads along a helical track on the outer surface of driver 31 pushed by the engagement of a ridge on the inner side of dose setting element 30 with recess 34 in the outer wall of nut member 32. *Id.*, 4:26-37. Nut member 32 maintains its position on driver 31 during dose dispensing to "always indicate the total sum of set and injected doses" even when dose setting member 30 is forced to rotate relative to

the housing and transmits rotational force to driver 31. *Id.*, 4:3758. I have reproduced Klitgaard FIG. 3 below for convenient reference.

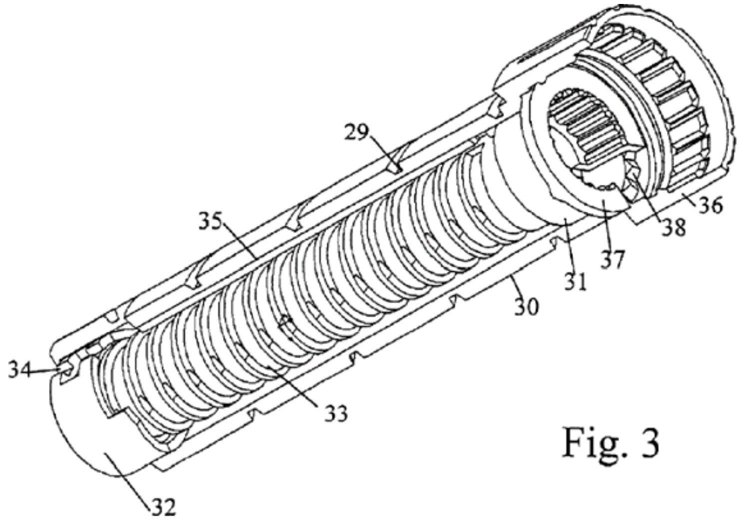


Fig. 3

606. Klitgaard provides at least two express reasons for a person of ordinary skill in the art to employ a nut that tracks each set dose of medicament delivered. The first is to "always indicate the total sum of set and injected doses." EX1017, 4:52-58, Abstract. The second is to prevent setting a dose that exceeds the remaining available supply of medication in the cartridge. *Id.* Klitgaard elaborates 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.

607. These same benefits would be desirable in the Giambattista drug delivery device discussed above regarding claim 21. It can avoid the problem of a user believing he or she has administered a particular dose when in fact the user has not administered the full dose because the insufficient medication remained in the cartridge. It provides accurate feedback to the user regarding the amount of

medication that remains to be injected before it is injected. It can also avoid wasteful disposal of cartridges while a sufficient amount of medication remains that would be motivated by uncertainty about whether the amount of medication remaining in the cartridge is sufficient to administer the desired dose. Each of these motivations would apply equally to the drug delivery device disclosed in Giambattista.

608. A person of ordinary skill in the art would have had a reasonable expectation of successfully incorporated such a tracking nut into the drug delivery pen of Giambattista. Nut member 32 as described in Klitgaard could be employed between dosing ring adapter 28 and dose knob 20 to track each set dose of medicament delivered. This could be accomplished by disposing a helical track on the outer surface of dosing ring adapter 28. Dose knob 20 could be adapted to have a ridge on its inner surface that engages with a recess in the outer wall of a nut member. The nut member would thread along the helical track as dose knob 20 rotates in setting the dose while dosing ring adapter 28 remains rotationally decoupled from dose knob 20 via clutch action of dosing ring 22 and dosing ring adaptor 28, discussed above. The lead of the helical track can be adjusted so that the axial position of the nut member on the helical track is proportional to the remaining dosage in the cartridge. During dose dispensing, dosing ring adapter 28 rotates with dose knob 20 due to engagement of the dose knob 20 and dosing ring 22, as discussed at length above. This means that the axial location of the nut member relative to the

dosing ring adapter 28 will not change during dose dispensing. Thus, the nut member will maintain its position on dosing ring adapter 28 to always indicate the total sum of set and injected doses. Once the nut member reaches the end of the helical track, additional dose setting is prevented by engagement of the ridge and the recess between the nut member and dose knob 20. This prevents the device from being set to a dose that is larger than the remaining medication in the cartridge. As just outlined, a person of ordinary skill in the art could thus readily apply the dose tracking and dose limiting concept taught in Klitgaard to the pen disclosed in Giambattista.

609. Further, dose tracking and limiting devices were common in the art more than one year before the earliest claimed filing date of the '844 patent. *See, e.g.*, WO 01/83008, EX1034, 7:35-8:5 ("The second arm 36 has on its backside a not shown cam, situated near the centre 34. This cam is movable locked in the spiral shaped track of driver 27. In this way the number of rotations the driver 27 can perform relatively to the second arm 32 and the rod guiding part 20 is limited, and the total length of the track is adapted to the total amount of medicine in the cartridge 13 thereby ensuring that a dose larger than the amount of medicine remaining in the cartridge 13 cannot be set."); U.S. Patent Publication 2002/0007154 to Hansen et al., EX10XX, [0041] (same).

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

N. ['844-B] Ground 1: Claims 21-29 is Obvious over Steenfeldt-Jensen

611. As explained in detail below, it is my opinion that Steenfeldt-Jensen teaches a drug delivery device that includes each and every element of claims 2129 of the '844 patent, except that driver tube 85 lacks internal threads engaged to external threads of the piston rod. In Steenfeldt-Jensen, internal threads of member 40 instead engage the external threads of piston rod 6. I include below a detailed discussion of whether a person of ordinary skill in the art would have reason to modify Steenfeldt-Jensen to place the internal threads in driver tube 85 and reasonable expectation of obtaining a device falling within the scope of the claims by doing so. As before, my analysis first focuses on the independent challenged claim 21 of the '844 patent, and then moves on to the dependent challenged claims of the '844 patent. Each claim section is presented below in bold text followed by my analysis of that part of the claim. The analysis identifies exemplary disclosure of the cited references relative to the corresponding claim elements, and it is not meant to be exhaustive.

1. Independent claim 21

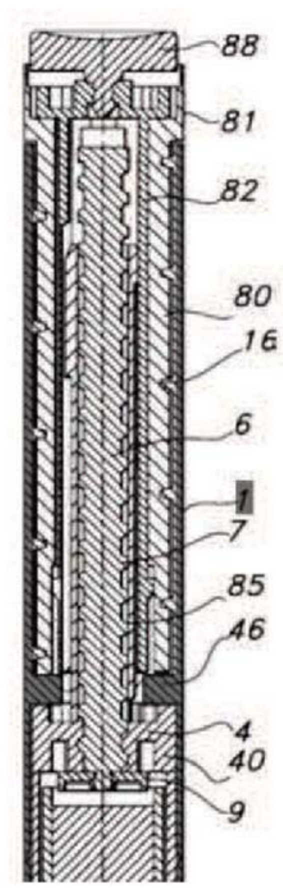
['844] Claim 21, preamble: A drug delivery device comprising:

612. Steenfeldt-Jensen discloses "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; *see also id.*, Abstract. Thus, Steenfeldt-Jensen teaches "a drug delivery device."

['844] Claim 21.1: a housing comprising a dose dispensing end and a first thread;

613. Steenfeldt-Jensen injection syringe (pen injector) includes "a tubular housing 1 ...[into] which an ampoule holder 2 is snapped." *See id.*, 5:38-44, FIGS. 15-17. Claim 11 of Steenfeldt-Jensen recites that housing comprises proximal and distal ends. I have reproduced FIG. 16 and annotated the housing in gray.



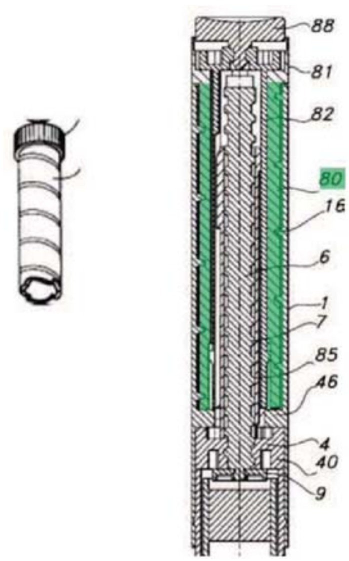
614. FIGS. 15-17 depict housing 1 and ampoule holder 2 extending from a button end (the proximal end in Steenfeldt-Jensen) to a needle or dose dispensing

end of the syringe. "On the inner wall of the second division of the housing 1 a helical protruding rib 16 is provided defining an inner thread with a high pitch. EX1014, 6:7-11; *see also id.*, 3:34-44, 11:20-22. This inner thread is the first thread recited in claim 21.1. Thus, Steenfeldt-Jensen teaches the drug delivery device comprises a housing comprising a dose dispensing end and a first thread.

['844] Claim 21.2: a dose indicator comprising a second thread that engages with the first thread;

615. Steenfeldt-Jensen's device also includes a "dose indicator" in the form of dose scale drum 17 or scale drum 80 that includes a "helical groove provided along an outer surface" in the form a helical track, which extends along the drum's outer wall. EX1014, 3:34-44, 6:7-11, 11:20-22, FIGS. 16-17. Steenfeldt-Jensen's helical track is engaged by a helical rib 16 along the inner wall of the housing 1." *Id.*, 11:20-22, FIGS. 15-17. Via this groove-to-rib engagement, the scale drum 80 rotates and moves axially relative to the housing 1 during dose setting and injection. *See id.*, 11:52-54, 12:4-9.

616. Below, I have reproduced partial, annotated views of Figures 17 (left) and 16 (right). FIG. 16 shows dose scale drum 80 in green. FIGS. 16 and 17 show helical grooves on the outer wall of dose scale drum 80. These helical grooves are the second thread recited in claim 21. FIG. 16 shows helical grooves of the dose scale drum 80 engaged with the inner thread of the housing 1.

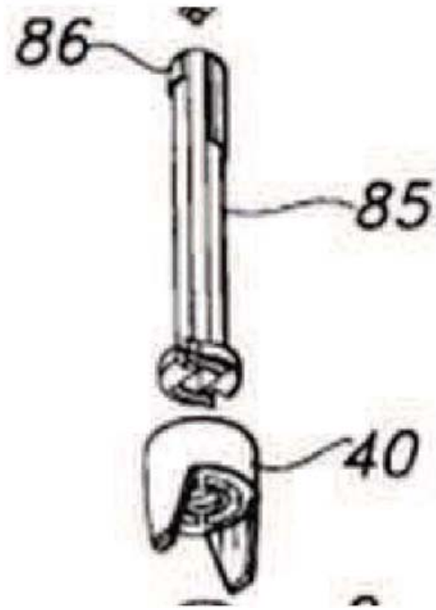


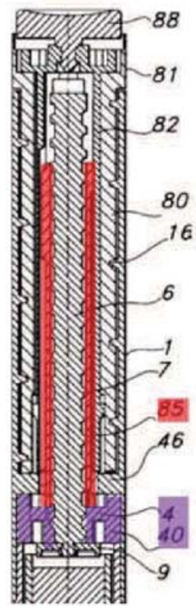
617. Numbers on dose scale drum indicating set doses may be viewed through a window in the housing via a window. *Id.*, 6:18-21, 7:11-16, 9:52-56, 10:40-45. Steenfeldt-Jensen states that analogous elements in different embodiments are provided with the same reference number. *See id.*, 7:49-51. FIG. 17 shows an embodiment in which window 18 exposes scale drum 80 to view to serve as a dose indicator.

['844] Claim 21.3: a driving member comprising a third thread;

618. Steenfeldt-Jensen repeatedly describes its syringes as including a "piston rod drive" that includes driver tube 85 and member 40. *See, e.g.*, EX1014, Abstract, 2:46-53, claims 1, 6, 11. Driver tube 85 is a sleeve that is rotationally coupled to the piston rod due to its unthreaded, non-circular cross-section. *Id.* Member 40 is an element that has a threaded circular opening and that is fixed to the

housing. *Id.* I have reproduced below a partial view of FIG. 17 (left) and FIG. 16 (right) depicting Steenfeldt-Jensen's piston rod drive.





619. As shown in FIG. 16, driver tube 85 is a drive sleeve that extends along a portion of piston rod 6. As explained further regarding element 21.4 below, driver tube 85 is releasably connected to scale drum 80 and couples to scale drum 80's rotational movement only during the injection process.

620. To drive piston rod 6, driver tube 85 rotationally engages with the rod through a bore having a non-circular cross-section, rather than "an internal threading near a distal portion." As I explain below, a person of ordinary skill in the art would have considered it obvious to modify the piston rod drive to provide the "driving member" of claim 21.

621. As I have explained earlier, Steenfeldt-Jensen discloses a piston rod drive comprising driver tube 85. Driver tube 85 does not have internal threading in the embodiment shown in FIGS. 15-17. However, Steenfeldt-Jensen suggests a modified embodiment. In the modified embodiment, driver tube 85 does have internal threading that engages with external threading on piston rod 6. Further, in the modified embodiment driver tube 85 rotates relative to piston rod 6 during injection to drive the piston rod through member 40. Member 40 loses its internal threading but becomes a non-threaded piston rod guide that is configured to prevent rotation of piston rod 6 relative to the housing while allowing axial displacement. In such an embodiment, a person of ordinary skill in the art would have considered driver tube 85 to meet all limitation of the recited "driving member" and member 40 to meet all limitations of the recited "piston rod holder."

622. Steenfeldt-Jensen expressly contemplates a modification in which the driver tube contains an internal threading that engages the piston rod's external threading. Steenfeldt-Jensen teaches this type of embodiment in general terms when it describes a driving mechanism that includes two elements: (1) a "piston rod guide" relative to which the piston rod is "axially displaceable but not rotatable" and (2) a "nut member" that is "rotatable but not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod ...." EX1014, 2:40-53. Steenfeldt-Jensen then describes alternative ways to drive the piston rod: rotation of

the scale drum can rotate the piston rod relative to the nut member, or rotation of the scale drum can rotate the nut member relative to the piston rod. *Id.*, 3:15-20, 3:41-47. In the embodiment where rotation of the scale drum rotates the nut member relative to the piston rod, the piston rod would be prevented from rotating relative to a piston rod guide so that the rotating nut would drive the piston rod through the piston rod guide.

623. The former approach reflects the operation of the embodiment shown in FIGS. 15-17 where driver tube 85 is rotationally coupled to piston rod 6 and rotation of scale drum 80 during injection rotates driver tube 85 and piston rod 6 relative to member 40, which is essentially a fixed "nut member". See EX1014, 11:6-19; 12:4-12. But Steenfeldt-Jensen teaches that embodiments using the fixed-nut approach can be implemented by the rotating-nut approach). EX1014, 7:41-47 ("Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention."); *see also id.*, 3:15-20, 3:44-47 (fixed and rotating drive nuts interchangeable).

624. Based on these teachings, a person of ordinary skill in the art would have understood Steenfeldt-Jensen to suggest that driver tube 85 could be implemented with internal threading as a rotating nut element and that member 40 could be implemented as a fixed piston rod guide that prevents rotation of piston rod

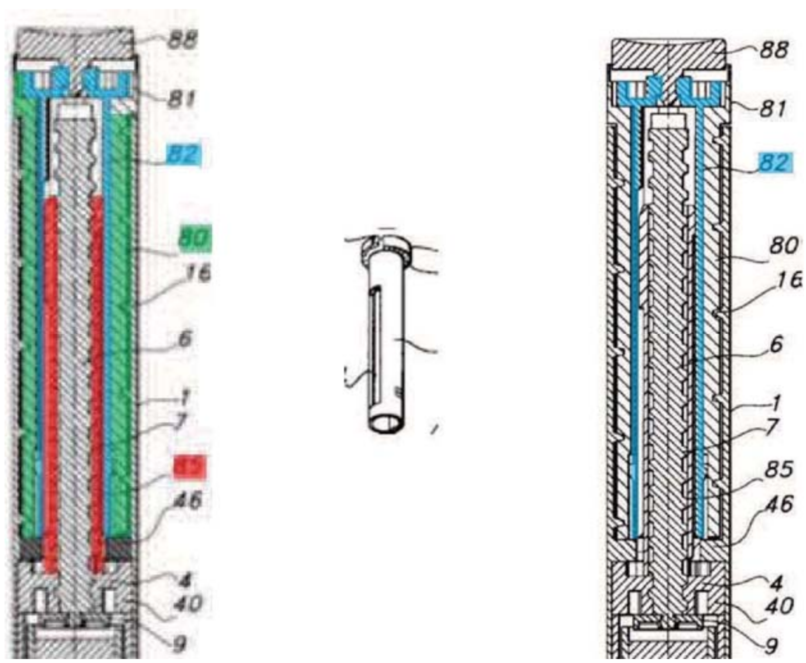
6 relative to the housing. A person of ordinary skill in the art therefore would have had reason to modify driver tube 85 to include an internal threading for engaging the external threading of piston rod 6 and to modify member 40 to include a non-circular cross-section for preventing rotation of piston rod 6 relative to the housing while permitting axial displacement.

625. A person of ordinary skill in the art would have reasonably expected success with the suggested embodiment. She would have been familiar with the structure and operation of drive nuts that rotate to push a non-rotating piston rod forward. Steenfeldt-Jensen's disclosure regarding the interchangeability of fixed-nut and rotating-nut embodiments confirms that such modifications simply used familiar elements in a predictable manner.

626. As I have explained below, a person of ordinary skill in the art would have recognized that all other aspects of the device could operate in the same manner as before. The modification thus would not change the device's principle of operation. Indeed, the design and operation of the rotating-nut version of driver tube 85 would have been routine and predictable. The modification merely uses well-known, familiar elements to perform the same, predictable functions. It is therefore my opinion that claim 21 as a whole was obvious over Steenfeldt-Jensen.

['844] Claim 21.4: a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;

627. Steenfeldt-Jensen's device also includes bushing 82. *Id.*, 11:26-33. Below, I have reproduced two partial, annotated views of FIG. 16 (left and right) and a partial view of FIG. 17 (middle). FIGS. 16 and 17 below each show bushing 82 annotated in blue.



628. FIG. 16 shows that bushing 82 is a tubular structure that is disposed between dose scale drum 80 and driver tube 85. *See also* EX1014, 11:26-27, 12:413. Steenfeldt-Jensen thus discloses the sleeve disposed between the dose indicator and driving member.

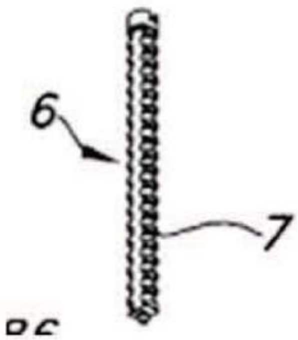
629. Steenfeldt-Jensen also discloses that bushing 82 is releasably connected to dose scale drum 80. Bushing 82 has a rosette of teeth 93 that are configured to releasably engage with corresponding teeth on dose setting button 81. *See* EX1014,

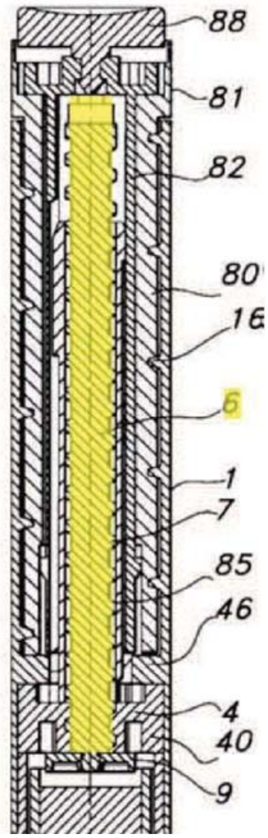
12:4-12. Because dose setting button 81 is integrally formed with scale drum 80, bushing 82's releasable connection to dose setting button 81 also makes it releasably connected with scale drum 80. EX1014, 11:22-25.

630. When the rosettes of bushing 82 are engaged with those of scale drum 80, rotation of dose setting button 81 is transmitted to driver tube 85 during dose dispensing. See EX1014, 12:4-12. Rotation is transmitted from bushing 82 to driver tube 85 via out wall hooks 86 of driver tube 85 engaging slots 84 of bushing 82. Bushing 82 thus serves as a clutch because it releasably couples movement of moveable dose setting button 81 of scale drum 80 to moveable driver tube 85. Steenfeldt-Jensen thus teaches a "a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator" in the form of dosing ring 22 and dosing ring adaptor 28.

<u>['844] Claim 21.5: a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;</u>

631. The device further includes piston rod, which has an external thread 7 that mates with internal thread 5 of central bore of end wall 4. *See id.*, 5:55-58. Below, I have reproduced a partial view of FIGS. 16 (right) and 17 (left) that shows leadscrew 6 with external thread 7. I have annotated the piston rod in yellow in FIG. 16.





632. End wall 4 with internal thread 5 is part of separate member 40, a component of the piston rod drive. *Id*., 8:35-38. As discussed above with respect to the driving member element and as will be discussed below in further detail, it would have been obvious for external thread 7 of the piston rod to mate with internal threads of driver tube 85.

['844] Claim 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;

633. Steenfeldt-Jensen disclosed a "piston rod holder" in the form of member 40. Member 40 is fixed against rotation relative to the housing. EX1014,

8:35-42 (longitudinal recesses 43 of member 40 with internal ribs of housing 1 "lock the member 40 against rotation relative to the housing").

634. Because member 40 will not rotate relative to the housing, it is configured to prevent the piston rod from rotating relative to the housing as well via the interaction of its pawl wheel teeth with the pawl wheel of driver tube 85 during dose setting. *Id.*, 8:48-53, 11:6-19, 11:52-62. The pawl mechanism is configured to prevent clockwise rotation of driver tube 85 relative to housing 1. See EX1014, 11:6-19. When dose setting-button 81 is rotated clockwise to dial-up a dose, the corresponding rotation of scale drum 80 is not transmitted to driver tube 85 (or thereby to the piston rod) because of the pawl mechanism. See EX1014, 11:52-62.

635. Anticlockwise rotation of dose setting-button 81 and scale drum 80 also is not transmitted to driver tube 85 (or thereby to the piston rod) during dose setting (e.g., when cancelling a dose) due to the pawl mechanism's "sufficient reluctan[ce]" against anticlockwise rotation. See EX1014, 11:52-62. As piston rod 6 is rotationally coupled to driver tube 85 such that "rotation is transmitted" between the two components, EX1014, 11:15-19, and because driver tube 85 does not rotate during dose setting as explained above, piston rod 6 also does not rotate during dose setting.

636. I will discuss further below why it would have been obvious to a person of ordinary skill to modify the piston rod drive so that the internal threads of the piston rod drive are located on driver tube 85 instead of on member 40 and so that

member 40 (instead of driver tube 85) mates with the not circular cross section of the piston rod. With this modification, member 40 would still be rotatably fixed to the housing because swapping the internal threads between the member 40 and driver tube 85 need have no effect on how member 40 is connected to the housing. This modification also would continue to prevent the piston rod from rotating relative to the housing during dose setting because the piston rod will be unable to rotate relative to the housing due to the engagement of its not circular cross section with modified member 40, which remains rotatably fixed relative to the housing.

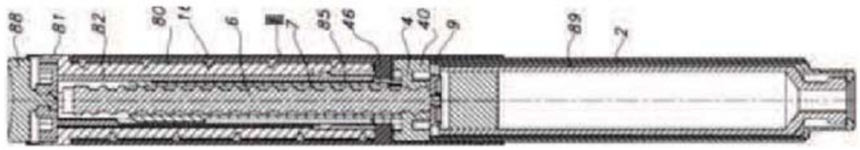
637. Both modified and unmodified member 40 permits the piston rod to traverse axially towards the dose dispensing end during dose dispensing. Before modification, the "thread of the piston rod and the thread in the end wall [4] of the housing [are] so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment." *Id.*, 11:11-15. "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 ... [and t]he bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed further into an ampoule 89 in the ampoule holder 2." *Id.*, 12:4-12.

638. Instead of the driver tube transferring rotation to piston rod 6 because of their not circular mating such that piston rod 6 threads through member 40, internal threads of modified driver tube 85 rotate about external threads of piston rod 6. Because modified member 40 prevents the not circular cross section of piston rod 6 from rotating relative to the housing, rotation of the threads of driver tube 85 about threads of piston rod 6 would push piston pod 6 axially through member 40 towards the dose dispensing end.

639. Thus, swapping the location of the threads and the non-circular cross section as between driver tube 85 and member 40 would result in member 40 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.

['844] Claim 21.7: wherein: the housing is disposed at an outermost position of the drug delivery device;

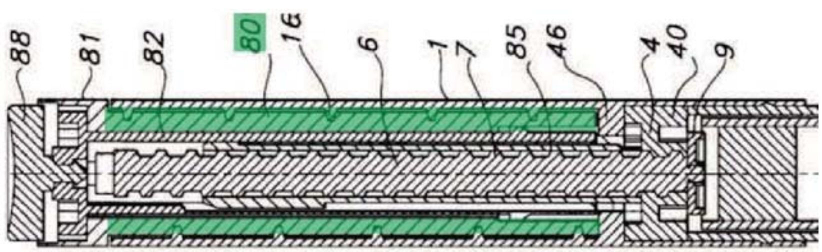
640. As discussed above with respect to claim 21.1, Steenfeldt-Jensen's syringe (pen injector) comprises a housing in the form of a tubular housing 1 and an ampoule holder 2 that snaps into the housing 1. EX1014, 5:38-44, FIGS. 1517. Below, I have reproduced FIG. 16, annotated with housing 1 and ampoule holder 2 in gray, which shows housing 1 and ampoule holder 2 disposed at an outermost position of the drug delivery device.



641. For the reasons discussed herein, Steenfeldt-Jensen discloses the housing is disposed at an outermost position of the drug delivery device.

<u>['844] Claim 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;</u>

642. As discussed above with respect to claim 21.2, the syringe (pen injector) comprises a dose indicator in the form of scale drum 80. Below, I have reproduced FIG. 16 and added color annotations to identify the scale drum 80 in green disposed between the housing 1 and the bushing 82.



This spatial relationship is also disclosed in FIGS. 15 and 17.

643. Steenfeldt-Jensen states that an outer wall of scale drum 80 engages with an inner wall of housing 1 and that bushing 82 fits into scale drum 80." EX1014, 11:20-28. This description discloses that scale drum 80 is disposed between housing 1 and bushing 82.

644. Scale drum 80 is configured to (i) rotate clockwise and traverse axially away from the dose dispensing end during dose setting and (ii) rotate counterclockwise and traverse axially towards the dose dispensing end during dose dispensing. *Id*., 11:52-54,12:4-9.

645. For the reasons discussed herein, Steenfeldt-Jensen discloses 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.

['844] Claim 21.9: the driving member is configured to rotate relative to the piston rod;

646. Steenfeldt-Jensen discloses that member 40 rotates relative to piston rod 6. EX1014, 11:11-18. During dose dispensing, pawl 13 engages pawl teeth provided in the member 40 to allow for rotation between member 40 and driver tube 85 during dose dispensing. EX1014, 8:48-53, 11:6-19, 11:52-62, 12:4-12. Member 40 thus rotates relative to the piston rod because the piston rod 6 is coupled to the driver tube 85 in such a way that "rotation is transmitted." EX1014, 11:15-19.

647. As I will discuss in detail below, it would have been obvious to modify the piston rod drive so that the internal threads of the piston rod drive are located on driver tube 85 instead of member 40 and so that member 40 (instead of driver tube

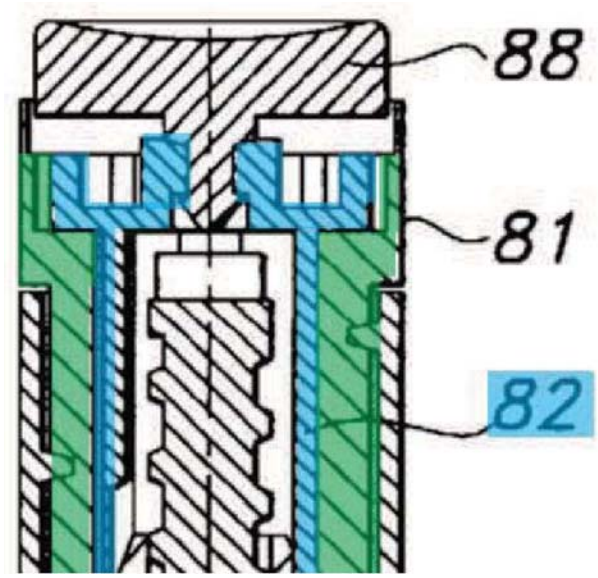
85) mates with the not circular cross section of the piston rod. In such an embodiment, driver tube 85 rotates relative to piston rod 6 during dose dispensing.

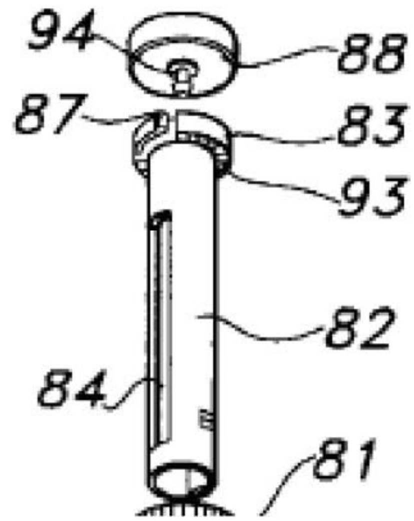
[¶844] Claim 21.10: the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator;

648. As discussed above regarding claim 21.4, Steenfeldt-Jensen's device includes a sleeve in the form of bushing 82.

649. Steenfeldt-Jensen teaches that bushing 82 is fixed so that it cannot rotate with respect to driver tube 85. Driver tube 85 "has on its outer wall hooks 86 engaging the slots 84 of the bushing 82 whereby the bushing 82 and the 30 driver tube 85 is coupled to each other so that rotation but not longitudinal displacement is transmitted between said two elements." *Id.*, 11:26-33; *see also id.*, 11:55-56 ("bushing [82] is kept non-rotated due to its coupling to the driver tube").

650. Steenfeldt-Jensen also teaches that bushing 82 is configured to traverse axially with the dose indicator. FIGS. 15-17 show that flange 83 of bushing 82 extends over scale drum 80 at the button end of the device. I have reproduced below partial views of FIGS. 16 (left) and 17 (right). I have annotated FIG. 16 to show bushing 82 in blue and scale drum 80 in green.





651. Steenfeldt-Jensen discloses that bushing 82 is configured to axially traverse out of the housing with scale drum 80 to permit scale drum 80 to traverses axially out of the housing by depicting flange 83 of bushing 82 extending over the proximal end of scale drum 80. "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. In order for bushing 82 to traverse axially out of the housing (up in FIG. 16), bushing 82 must also traverse axially out of the housing to permit scale drum 80 to move in that direction. This is so because the bottom surface of flange 83 would otherwise obstruct the upward motion of scale drum 80. Longitudinal slots 84 through side walls of bushing 82 permit bushing 82 to translate axially without transmitting longitudinal (i.e., axial) displacement to the driver tube 85. EX1014, 11:26-33. Bushing 82 is thus configured to traverse axially with scale drum 80 during dose setting.

652. Bushing 82 is also configured to traverse axially with scale drum 80 during dose dispensing. “When the injection button 88 is pressed to inject the set dose said rosettes [on upper surface of dose setting button 81 and distal surface of flange 83 of bushing 82] are pressed into engagement so that the bushing 82 will follow the anticlockwise rotation of the dose setting button 81 ... when the scale drum 80 is pressed back into said housing.”, *Id.*, 12:4-9. FIGS. 15-16 disclose that injection button 88 pushes scale drum 80 back into the housing via bushing 82. Thus, bushing 82 is configured to traverse axially towards the dose dispensing end with scale drum 80 during dose dispensing.

653. Accordingly, Steenfeldt-Jensen teaches the “the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator.”

[¶844] Claim 21.11: the piston rod and the driving member are configured to rotate relative to one another during dose dispensing;

654. Steenfeldt-Jensen discloses that member 40 rotates relative to piston rod 6. EX1014, 11:11-18. During dose dispensing, pawl 13 engages pawl teeth provided in the member 40 to allow for rotation between member 40 and driver tube 85 during dose dispensing. EX1014, 8:48-53, 11:6-19, 11:52-62, 12:4-12. Member 40 thus rotates relative to the piston rod because the piston rod 6 is coupled to the driver tube 85 in such a way that “rotation is transmitted.” EX1014, 11:15-19.

655. As I will discuss in detail below, it would have been obvious to modify the piston rod drive so that the internal threads of the piston rod drive are located on driver tube 85 instead of member 40 and so that member 40 (instead of driver tube 85) mates with the not circular cross section of the piston rod. In such an embodiment, driver tube 85 rotates relative to piston rod 6 during dose dispensing.

[¶844] Claim 21.12: the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

656. Piston rod 16 is configured to traverses axially towards the dose dispensing end during dose dispensing. This is true as the syringe (pen injector) is disclosed in Steenfeldt-Jensen and remains true if the syringe is modified as I have proposed to swap the internal threads of member 40 with the non-circular cross section of driver tube 85. Before modification, the "thread of the piston rod and the thread in the end wall [4] of the housing [are] so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment." *Id.*, 11:11-15. "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 ... [and t]he bushing [82] will rotate the driver tube 85 in an anticlockwise direction which the pawl mechanism reluctantly allows an[d] the piston rod [6] is thereby screwed further into an ampoule 89 in the ampoule holder 2." *Id.*, 12:4-12. The

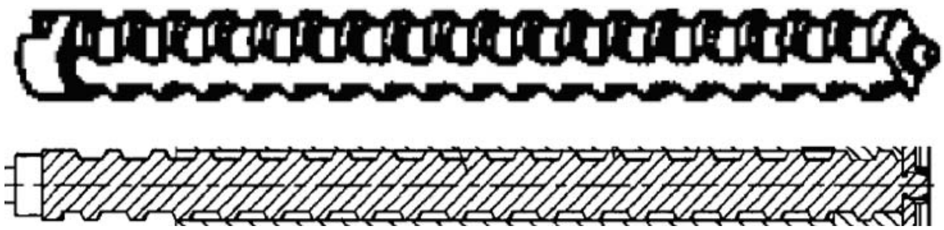
piston rod 6 is thus configured to traverse axially towards the dose dispensing end during dose dispensing in the device as disclosed in Steenfeldt-Jensen.

657. Swapping the location of the threads and the non-circular cross section as between driver tube 85 and member 40 would retain the result of piston rod 6 being configured to traverse axially towards the dose dispensing end during dose dispensing. As discussed above, instead of the driver tube transferring rotation to piston rod 6 because of their not circular mating such that piston rod 6 threads through member 40, internal threads of modified driver tube 85 rotate about external threads of piston rod 6. Because modified member 40 prevents the not circular cross section of piston rod 6 from rotating relative to the housing, rotation of the threads of driver tube 85 about threads of piston rod 6 would push piston pod 6 axially through member 40 towards the dose dispensing end. Thus, swapping the location of the threads and the non-circular cross section as between driver tube 85 and member 40 would retain a piston rod that is configured to traverse axially towards the dose dispensing end during dose dispensing.

2. Dependent claims 22-29 of the '844 patent

['844] Claim 22: The drug delivery device of claim 21 where the piston rod has a circular cross-section.

658. Steenfeldt-Jensen discloses that piston rod 6 has a circular cross section at each of its proximal and distal ends. I have reproduced below partial views of FIGS. 16 (bottom) and 17 (top) showing close-ups of piston rod 6.



These figures depict each end of piston rod 6 as having a circular cross section Steenfeldt-Jensen thus discloses that piston rod 6 has a circular cross section.

[’844] Claim 23: The drug delivery device of claim 21 further comprising a clutch.

659. Steenfeldt-Jensen discloses bushing 82, which acts as a clutch. As references in Section VI above, Sanofi has construed a clutch in the ’844 patent to mean a structure that couples and decouples a moveable component from another component. As I have explained above, bushing 82 of Steenfeldt-Jensen meets the sleeve limitation of element [21.4], as well as the clutch limitation of claim 23.

660. The ’844 patent does not require the clutch to be a different component than the sleeve. Indeed, the ’844 patent does not specifically discuss a “sleeve” that is disposed between the “dose indicator” and the “driving member,” and is also releasably connected to the “dose indicator.” Instead, the ’844 patent discloses “clutch 60” that is “disposed about the drive sleeve 30, between the drive sleeve 30 [claimed driving member] and a dose dial sleeve 70 [claimed dose indicator].” EX1004. 4:42-44. Clutch 60 is “generally cylindrical.” *Id.*, 4:59-60.

661. As taught by the ’844 patent, when a dose is dialed, clicker 50 and clutch 60 are engaged, and drive sleeve 30, clicker 50, clutch means 60, and dose

dial sleeve 70 rotate with the dose dial grip 76. *Id.*, 5:60-63. The dose is dispensed by depressing button 82, which displaces clutch 60 axially with respect to dose dial sleeve 70 and permits rotation with respect to clutch 60 and the dose indicator (dose dial sleeve 70). This confirms that the 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.

['844] Claim 24: The drug delivery device of claim 23 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

662. As I discussed above for claim 23 and element [21.4], bushing 82 operates as a clutch. Steenfeldt-Jensen further discloses that bushing 82 provides audible clicks and tactile feedback during dose setting that are indicative of unit doses of medicament.

663. Steenfeldt-Jensen discloses that the flange 83 of the bushing 82 has, at its periphery, a radial protrusion 87. *Id.*, 11:37-40, FIG. 17. The compartment of the dose setting button 81 contains longitudinal recesses along its cylindrical side wall. *Id.*, 11:34-40. Steenfeldt-Jensen discloses that, when a dose is set by rotating the dose setting button 81, "the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 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.

664. Steenfeldt-Jensen expressly teaches that the clicks are "heard and felt during the dose setting rotation[.]" EX1014, 6:48-53. This teaches that there is both

audible clocks and tactile feedback arising from physical contact of the protrusion across the depressions. Steenfeldt-Jensen thus renders obvious the drug delivery device of claim 23 wherein the clutch provides audible clicks and tactile feedback indicative of unit doses of medicament.

['844] Claim 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.

665. As discussed in Sections V.B-D above and with regard to claim in this section, dosing ring 22 is a clutch that provides audible clicks during dose setting that are indicative of unit doses of medicament. Steenfeldt-Jensen discloses that movement of the radial protrusion 87 over the longitudinal recesses of the dose setting button 81 will produce a click when the dose setting button 81 is rotated "in any direction." *Id.*, 11:62-67. It is my opinion that the person of ordinary skill would have also understood that audible clicks are provided when the dose setting button 81 was rotated during dose cancelling.

666. Steenfeldt-Jensen also provides express disclosure teaching that each click is equal to a unit dose of medicament, as required by claims 25. Steenfeldt-Jensen expressly teaches 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." *Id*., 6:48-53.

667. Steenfeldt-Jensen thus renders obvious the drug delivery device of claim 24 wherein the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.

['844] Claim 26: The drug delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament.

668. I have addressed claim 24 above. Steenfeldt-Jensen teaches the importance of the device being configured to permit dose cancelling without dispensing medicament, stating: "It must be possible with a minimum of trouble to cancel or change a wrongly set dose" and explaining that a dose may be cancelled by preventing the cancelling rotation from being "transmitted to the driver." EX1014, 1:20-22, 2:24-28.

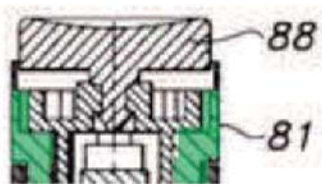
669. In discussing FIGS. 15-17, Steenfeldt-Jensen discloses that the bushing 82 permits dose cancelling without rotating the bushing 82 and driving tube 85 to dispense the dose: "When a dose is set ... bushing is kept non rotated due to its coupling to the drive tube which is locked against clockwise rotation and if a set dose is reduced by rotating the dose setting button 81 in an anticlockwise direction the pawl mechanism ... is sufficient[ly] reluctant to rotate in its not blocking direction to prevent the bushing 82 from following this anticlockwise rotation." *Id.*, 11:52-62 (emphasis added). The "bushing 82 will follow the anticlockwise rotation of the dose

setting button 81" when injection button 88 is depressed, and only then will the bushing "rotate the driver tube 85" so that "the piston rod is thereby screwed further into an ampoule 89 in the ampoule holder 2." *Id.*, 12:1-13. In other words, when injection button 88 is not depressed (i.e., during dose setting and dose cancelling), scale drum 80 and its dose setting button 81 may rotate up or down without dispensing medicament. Steenfeldt-Jensen thus suggests the "drug delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament."

['844] Claim 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.

670. Steenfeldt-Jensen discloses a "dose dial grip" in the form of dose setting button 81 that the user rotates to set a dose. See EX1014, 11:22-25, 11:5262, FIGS. 15-17. Dose setting button 81 is located at the proximal (i.e., button-end) of scale drum 80. *Id.* FIGS. 15-17 depict injection button 88 seated in an annular recess of dose setting button 81 of scale drum 80 on a proximal end of scale drum 80. Injection button 88 fits within the cylindrical outer wall of dose setting button 81. EX1014, 11:22-25, 12:4-9 (injection button 88 presses bushing 82 into engagement with scale drum 80); FIGS. 15-17.

671. I have reproduced partial views of FIGS. 16 (left) and 17 (right) below and added color annotations to FIG. 16 to indicate scale drum 80, including dose setting button 81, in green at the distal end (i.e., button end) of scale drum 80.



672. Steenfeldt-Jensen also discloses that injection button 88 is rotatable with respect to scale drum 80. FIGS. 15-17 depict that "injection button 88 is rotatably mounted with a pivot pin 94 journaled in an end wall of the bushing 82." *Id.*, 11:49-51. Bushing 82 is rotatable with respect to scale drum 80 during dose setting. *Id.*, 11:52-62 ("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 ... [but the] bushing is kept non-rotated"). The pivot pin mounting of injection button 88 onto bushing 82 means that injection button 88 is rotatable relative to scale drum 80 during dose dispensing as well during dose setting. Accordingly, Steenfeldt-Jensen renders obvious 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."

673. As just discussed, Steenfeldt-Jensen '794 teaches 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."

['844] Claim 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 axially with respect to the dose indicator and driving member.

674. Steenfeldt-Jensen discloses that depression of injection button 88 initiates dose delivery by displacing bushing 82 axially with respect to scale drum 80 and driver tube 85. When in a rest state, rosettes on the distal (bottom) surface of flange 83 of bushing 82 are spaced apart from rosettes on the bottom of the compartment formed in dose setting button 81. EX1014, 11:34-42, 12:1-3, FIG. 17. Dose setting button 81 is part of scale drum 80. Rotation of the scale drum 80 thus does not rotate the bushing or thereby rotate the driving tube 85 or piston rod 6 when the rosettes between dose setting button 81 and bushing 82 are spaced apart.

675. A "protrusion on the outer wall of the bushing 82" that engages "recesses in the inner wall of the scale drum 80" permits "limited movement of the bushing in the scale drum so ... that the bushing can be moved axially relative to the scale drum to make or not make the teeth of said rosettes engage each other." *Id.*, 11:43-49. Dose delivery is initiated by depressing injection button 88. Injection button 88 is mounted into bushing 82 "with a pivot pin 94 journaled in an end wall of the bushing 82." *Id.*, 11:49-51. Depression of injection button 88 thus depresses bushing 82 relative to scale drum 80 until the rosettes of bushing 82 and scale drum

80 come into contact with one another. *Id.*, 12:4-12. The distally-applied pressure that depresses injection button 88 also presses the scale drum 80 "back into said housing," thereby rotating driver tube 85 and piston rod in an anticlockwise direction *Id.* This rotation screes the piston rod "further into an ampoule 89" to dispense the dose. *Id.* Axial movement of the injection button 88 caused by distally applied pressure to the injection button 88 thus initiates dose delivery by displacing the bushing axially with respect to scale drum 80.

676. When injection button 88 and bushing move axially in concert towards the dose dispensing end, driving tube 85 cannot move axially with them. This is because driving tube 85 is fixed axially relative to the housing due to the disposition of its distal flange (i.e., pawl) between ring shaped wall 46 and the end wall 4 in the member 40. *See id.*, 8:48-53, FIGS. 15-17. Depression of injection button 88 thus causes axial displacement of bushing 82 with respect to driving tube 85.

677. Accordingly, Steenfeldt-Jensen suggests 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."

['844] Claim 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.

678. As I discussed above for claim 23 and element [21.4], bushing 82 operates as a clutch. Steenfeldt-Jensen further discloses that bushing 82 provides audible clicks and tactile feedback during dose setting and dose cancelling indicative of unit doses of medicament, wherein each click is equal to a unit dose of medicament.

679. Steenfeldt-Jensen discloses that the flange 83 of the bushing 82 has, at its periphery, a radial protrusion 87. *Id.*, 11:37-40, FIG. 17. The compartment of the dose setting button 81 contains longitudinal recesses along its cylindrical side wall. *Id.*, 11:34-40. Steenfeldt-Jensen discloses that, when a dose is set by rotating the dose setting button 81, "the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 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.

680. Steenfeldt-Jensen expressly teaches that the clicks are "heard and felt during the dose setting rotation[.]" EX1014, 6:48-53. This teaches that there is both audible clocks and tactile feedback arising from physical contact of the protrusion across the depressions.

681. As discussed in Sections V.B-D above, because Steenfeldt-Jensen discloses that movement of the radial protrusion 87 over the longitudinal recesses of the dose setting button 81 will produce a click when the dose setting button 81 is rotated "in any direction" *id.*, 11:62-67, it is my opinion that the person of ordinary skill would have also understood that audible clicks are provided when the dose setting button 81 was rotated during dose cancelling.

682. Steenfeldt-Jensen also provides express disclosure teaching the audible feedback as being indicative of unit doses of medicament (as required by claims 24-28) and that each click is equal to a unit dose of medicament, as required by claims 25 and 29. Steenfeldt-Jensen expressly teaches 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." *Id.*, 6:48-53.

683. Steenfeldt-Jensen thus renders obvious the drug delivery device of claim 21 wherein the device comprises a clicker that provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament, as recited in claim 29.

684. With regard to the means-plus-function interpretation, as I explained above, the challenged patents teach that the structure used to provide the function of

an audible click is either a flexible arm being dragged over splines, or saw teeth riding over one another. *See supra*, ¶218. As I noted above, Steenfeldt-Jensen teaches a radial protrusion 87 as providing the clicking in the embodiment as shown in FIG. 15-17. The radial protrusion 87 sits in a compartment of dose setting button 81 that includes "axial recesses" and is "biased toward the side wall of the compartment." EX1014, 11:34-42; 11:52-67. When dose setting button 81 rotates, "radial protrusion 87...will click from one of the axial recess[es] in the inner wall of the dose setting button 81 to the next one...." *Id.*, 11:52-67. It is my opinion that a person of ordinary skill would have understood the radial protrusion 87 to be a "flexible arm" that dragged over ridges (or splines) formed between the axial recesses. In my opinion, therefore, Steenfeldt-Jensen 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.

O. ['844-B] Ground 2: Claim 30 is Obvious over Steenfeldt-Jensen in combination with Klitgaard

685. As explained above, it is my opinion that Steenfeldt-Jensen suggests a drug delivery device that includes each and every element of claims 21-29 of the '844 patent, and thus renders those claims obvious. Claim 30 also requires that the "drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered. This too would have been obvious over Steenfeldt-Jensen, in further view of Klitgaard.

686. Klitgaard describes an injection device for dispensing medicine comprising a limiting mechanism to track the amount of medication administered. EX1017, Abstract. 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. By configuring a track follower to move further on the track "[e]ach time a dose is set and injected," the track follower's location reflects the cumulative amount of medication that has been delivered and prevents setting of a dose larger than the remaining liquid in the cartridge. *Id.*

687. An embodiment of such a limiting mechanism is disclosed in FIG. 3 and its related description. Klitgaard discloses that nut member 32 is disposed between dose setting member 30 and driver 31 and tracks each set dose of medication delivered. *Id.*, 4:16-58. Dose setting member 30 is threaded out along internal threads of the housing to set a dose. *Id.*, 4:16-25. Nut member 32 simultaneously threads along a helical track on the outer surface of driver 31 pushed by the engagement of a ridge on the inner side of dose setting element 30 with recess 34 in the outer wall of nut member 32. *Id.*, 4:26-37. Nut member 32 maintains its position on driver 31 during dose dispensing to "always indicate the total sum of set and injected doses" even when dose setting member 30 is forced to rotate relative to

the housing and transmits rotational force to driver 31. *Id.*, 4:3758. I have reproduced Klitgaard FIG. 3 below for convenient reference.

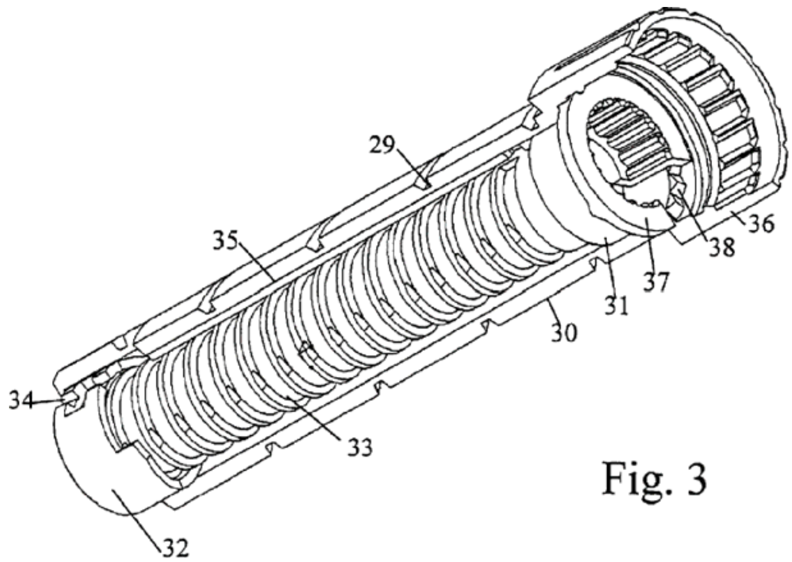


Fig. 3

688. Klitgaard provides at least two express reasons for a person of ordinary skill in the art to employ a nut that tracks each set dose of medicament delivered. The first is to "always indicate the total sum of set and injected doses." EX1017, 4:52-58, Abstract. The second is to prevent setting a dose that exceeds the remaining available supply of medication in the cartridge. *Id.* Klitgaard elaborates 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.

689. These same benefits would be desirable in the Steenfeldt-Jensen drug delivery device discussed above regarding claim 21. It can avoid the problem of a user believing he or she has administered a particular dose when in fact the user has not administered the full dose because the insufficient medication remained in the cartridge. It can also avoid wasteful disposal of cartridges while a sufficient amount

of medication remains that would be motivated by uncertainty about whether the amount of medication remaining in the cartridge is sufficient to administer the desired dose. Each of these motivations would apply equally to the drug delivery device disclosed in Steenfeldt-Jensen.

690. A person of ordinary skill in the art would have had a reasonable expectation of successfully incorporated such a tracking nut into the drug delivery pen of Steenfeldt-Jensen. The functionality of the drug delivery device in Steenfeldt-Jensen could be maintained while adding the tracking feature for the maximum amount of medicament remaining in the cartridge.

691. Nut member 32 as described in Klitgaard could be employed between bushing 82 and scale drum 80 to track each set dose of medicament delivered. This could be accomplished by disposing a helical track (e.g., partial threads) on the outer surface of bushing 82. Scale drum 80 could be adapted to have a ridge on its inner surface that engages with a recess in the outer wall of a nut member. The nut member would thread along the helical track as scale drum 80 rotates in setting the dose while bushing 82 remains rotationally decoupled from driver tube 85, as discussed above. The lead of the helical track can be adjusted so that the axial position of the nut member on the helical track is proportional to the remaining dosage in the cartridge. During dose dispensing, bushing 82 rotates with scale drum 80 due to engagement of the rosettes discussed at length above. This means that the axial location of the

nut member relative to the bushing 82 will not change during dose dispensing. Thus, the nut member will maintain its position on bushing 82 to always indicate the total sum of set and injected doses. Once the nut member reaches the end of the helical track, additional dose setting is prevented by engagement of the ridge and the recess between the nut member and scale drum 80. This prevents the device from being set to a dose that is larger than the remaining medication in the cartridge. As just outlined, a person of ordinary skill in the art could thus readily apply the dose tracking and dose limiting concept taught in Klitgaard to the pen disclosed in Steenfeldt-Jensen.

692. Further, dose tracking and limiting devices were common in the art more than one year before the earliest claimed filing date of the ’844 patent. See, e.g., EX1034, 7:35-8:5 (“The second arm 36 has on its backside a not shown cam, situated near the centre 34. This cam is movable locked in the spiral shaped track of driver 27. In this way the number of rotations the driver 27 can perform relatively to the second arm 32 and the rod guiding part 20 is limited, and the total length of the track is adapted to the total amount of medicine in the cartridge 13 thereby ensuring that a dose larger than the amount of medicine remaining in the cartridge 13 cannot be set.”).

693. Accordingly, claim 30 was obvious over the combination of the teachings of Steenfeldt-Jensen and Klitgaard.

P. ['844-C] Ground 1: Claims 21-29 are Obvious over Møller in combination with Steenfeldt-Jensen

694. As explained in further detail below, it is my opinion that claims 2129 were obvious over the combination of Møller in view of Steenfeldt-Jensen. In my opinion, a person of ordinary skill in the relevant field of art would have had reasons to combine the teachings of Møller and Steenfeldt-Jensen as described below, along with reasonable expectations of success in doing so.

695. Møller and Steenfeldt-Jensen describe drug delivery pens with drive sleeves that operate in a similar manner. In both pens, a threaded driver rotates up a piston rod during dose setting, then moves axially downward without rotating to drive the piston rod into the chamber below. *See* EX1014, 7:60-8:33, FIGS. 7-8; EX1015, ¶¶29-30, 32-33, FIGS. 1, 5. In the FIG. 8 embodiment of Steenfeldt-Jensen, the user rotates the driver directly to set a dose. In Møller, the user rotates a knob on a dose dial sleeve that, in turn, rotates the drive sleeve to set a dose. Nevertheless, both drive sleeves have the same principle of operation: rotating up the piston rod to set a dose, moving straight down to dispense a dose. Both pens also provide a similar benefit: the use of a geared injection mechanism to produce a mechanical advantage. In Steenfeldt-Jensen, the gearing is achieved using a dual-threaded piston rod. In Møller, the gearing is achieved using a rack-and-pinion mechanism. Again, however, the principle of operation is the same: the gearing increases the stroke of

the injection button relative to the piston rod, which reduces the force required to dispense the dose.

696. Given the similar principles of operation and the similar goals of each pen, I believe a person of ordinary skill in the art would have had reason to combine Møller's dose-setting approach (i.e. rotating a dose dial sleeve to rotate a drive sleeve up a piston rod) with Steenfeldt-Jensen's dose-dispensing approach (i.e. using axial movement of a drive sleeve to rotate a dual-threaded piston rod for a geared injection stroke). As I explain in more detail below, a person of ordinary skill would have recognized that this combination provided various benefits and would be reasonably practicable given the similar structure and operation of the drivers and the familiar, predictable nature of the components involved.

1. <u>Independent claim 21 of the '844 patent</u>

697. It is my opinion that the combination of Møller and Steenfeldt-Jensen teaches the same components recited in independent claim 21 of the '844 patent. I address the teachings regarding individual claim elements below, followed by a separate section in which I explain why those of ordinary skill in the art would have had reason to combine the references as I propose and why they would have reasonably expected success in doing so.

698. As an initial matter, I note that Møller describes two similar embodiments: a first embodiment shown in FIGS. 1-2 and a second embodiment

shown in FIGS. 3-5. Møller makes clear that 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 numbers for elements in the second embodiment that correspond to elements from the first embodiment simply add 100 to the previous number (e.g., housing 1 becomes housing 101). *Id.*, ¶35. In my opinion, a POSA would have understood corresponding elements in the first and second embodiments to have similar structures and functions unless otherwise indicated. To avoid redundancy, my analysis below primarily addresses Møller's first embodiment. Nevertheless, the corresponding elements of the second embodiment would have provided analogous teachings to a person of ordinary skill.

<u>['844] Claim 21, preamble: A drug delivery device comprising:</u>

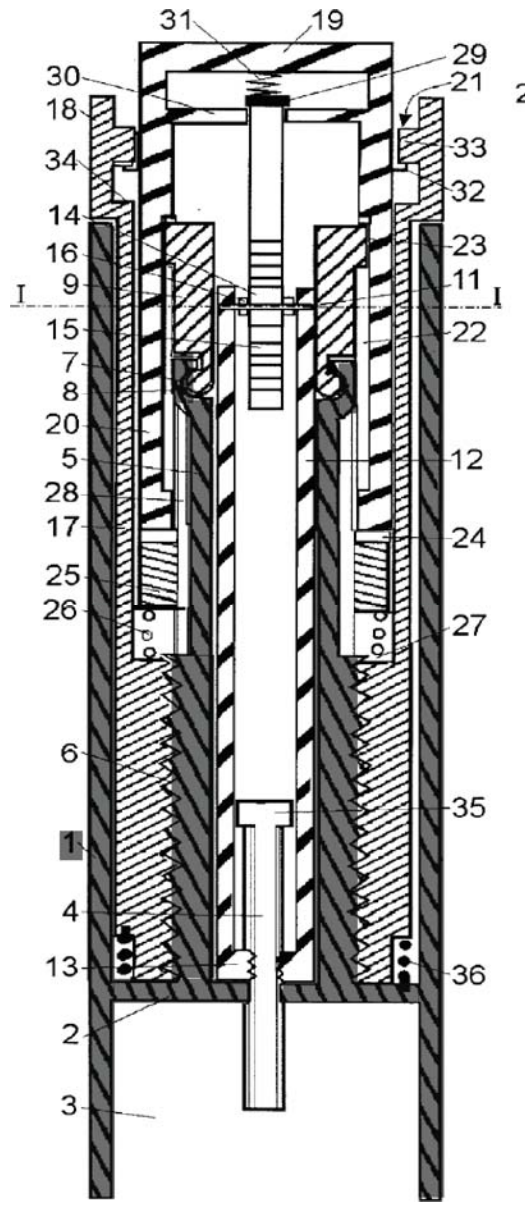
699. Both Møller and Steenfeldt-Jensen disclose drug delivery pens. *See* EX1015, Abstract, EX1014, Abstract. The drive mechanisms in both Møller and Steenfeldt-Jensen facilitate the dispensing of a user-selected dosage of medication. *See* EX1015, ¶¶14, 33, claim 11; EX1014, 8:25-33. Thus, in my opinion, the combination of Møller in view of Steenfeldt-Jensen teaches a drug delivery device.

<u>['844] Claim 21.1: a housing comprising a dose dispensing end and a first thread;</u>

700. In my opinion, element [21.1] is taught by housing 1 of Møller, which includes a dispensing end and a first thread 6. Møller explains that its drug delivery

pen has "a housing having a proximal end and a distal end" EX1015, claim 1; *see also id*., claims 5, 11, 15. A person of ordinary skill would have understood that the end of the housing where the needle is positioned is the dose dispensing end. For example, Møller explains that "[w]hen the piston is pressed into the ampoule the medicament is pressed out through a needle mounted through a closure at the other end of the ampoule." *Id*. ¶3. This dose dispensing end is opposite to the end having the button, which is manipulated by a user. *See id*., ¶¶22-23, 25.

701. Møller also makes clear that the housing has a first thread. *See id*., ¶23, FIG 1. As shown in the annotated version of FIG. 1 below, housing 1, which I have annotated in gray, comprises thread 6. *Id.,* FIG. 1; *see also id*., FIGS. 3-5 (showing similar housing 101 in second embodiment); EX1014, 5:38-46; FIG. 7-8 (also showing similar housing).

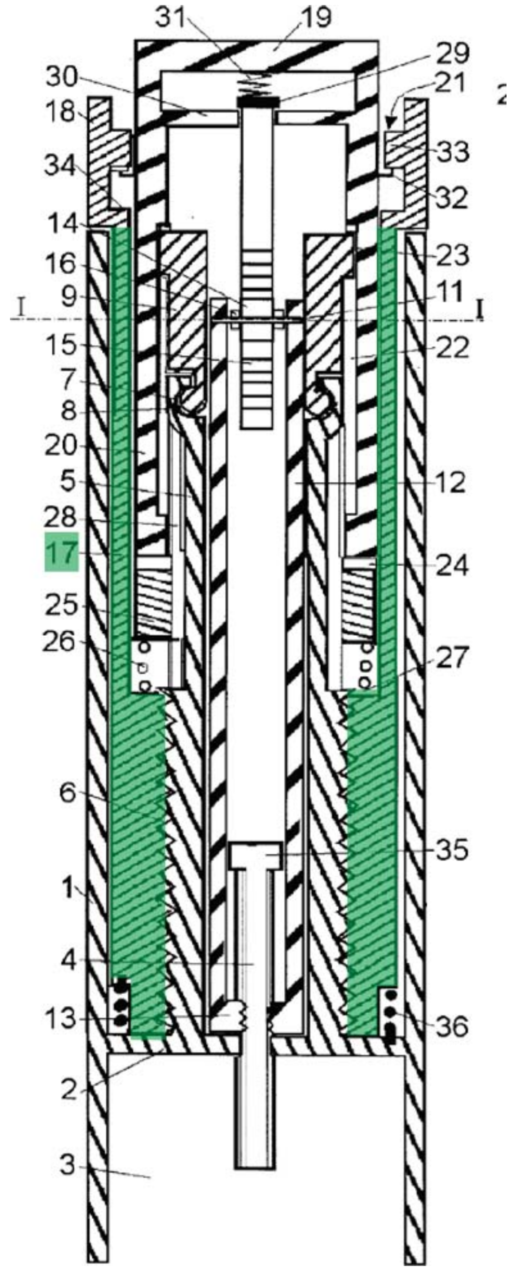


702. Therefore, the combination of Møller and Steenfeldt-Jensen teaches a housing comprising a dose dispensing end and a first thread as recited in element [21.1].

['844] Claim 21.2: a dose indicator comprising a second thread that engages with the first thread;

703. In my opinion, Møller teaches a dose indicator in the form of dose setting drum 17. EX1015, ¶29; *see also id.*, FIGS. 3-5 (showing similar drum 117). The dose setting drum 17 of Møller provides a second thread that engages the first thread (thread 6) of housing 1. *Id*., ¶29.

704. Møller teaches that the dose setting drum 17 can have numbers on its outer surface. *Id*., ¶25. As the dose setting drum 17 is screwed out of the housing, these numbers, which indicate the dialed dosage, can be seen through a window on the housing. *Id*. In my opinion, a person of ordinary skill would understand that dose setting drum 17 serves as a dose indicator.



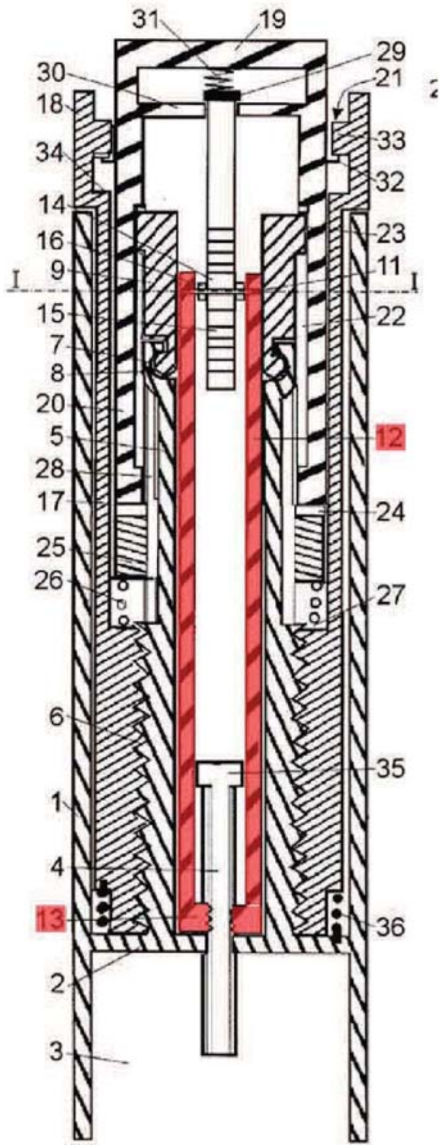
705. As shown in the annotated version of FIG. 1 above, where I have annotated the drum 17 in green, dose setting drum 17 also has a thread that engages with thread 6 of the housing 1. *Id.*, ¶¶25, 29, FIG. 1. Møller specifically explains that "[t]o set a dose the dose setting button 18 is rotated to screw the dose-setting drum

17 up along the thread 6." *Id.*, ¶29. Thus, it is my opinion that the combination of Møller and Steenfeldt-Jensen teaches a dose indicator comprising a second thread that engages with the first thread. *Id.*; *see also* EX1014, 7:51-67; FIG. 7-8.

['844] Claim 21.3: a driving member comprising a third thread;

706. In my opinion, the combination of Møller and Steenfeldt-Jensen teaches a driving member comprising a third thread. Møller and Steenfeldt-Jensen teach the use of drive members that operates in a similar manner. Møller teaches connection bars 12 and nut 13 in the embodiment of FIGS. 1-2, as well as analogous elements (tubular connection element 112 and nut 113) in the embodiment of FIGS. 3-5. EX1015, ¶40, FIGS. 3-5. Steenfeldt-Jensen teaches injection button 23 in the embodiment shown in FIGS. 6-10. EX1014, 7:48-8:33, FIGS. 6-10. Each of these components drives the movement of the piston rod in a similar way: rotating up the piston during dose setting, then moving axially downward without rotating to drive the piston rod into the chamber below. I describe the structure and operation of these components in more detail below.

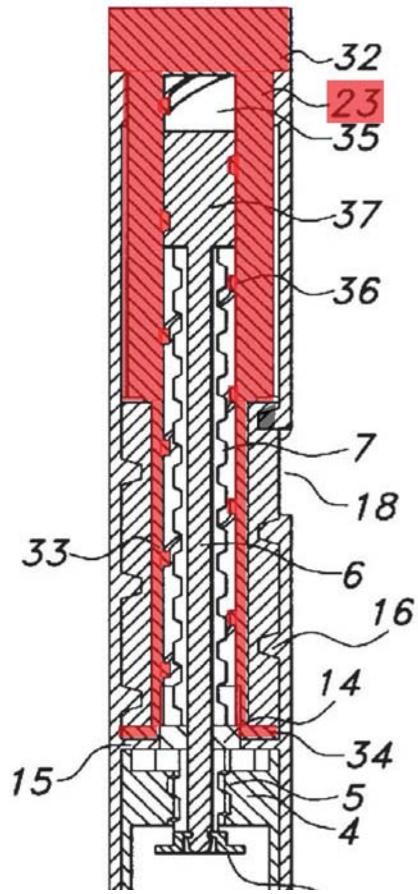
707. Figure 1 of Møller shows connection bars 12 with nut 13 (annotated in red below), which drive the movement of the piston rod 4:



708. This driving member has the recited "third thread", which is disposed on nut 13. *Id.*, ¶¶30-31, FIG. 1. With the clutch engaged, rotation of the dose setting button 18 is transmitted to these components, which rotate up the piston rod to set a dose. *Id.* ¶30. When the user presses the injection button, connection bars 12 and nut 13 move axially, carrying the piston downward. *Id.*, ¶¶31-32.

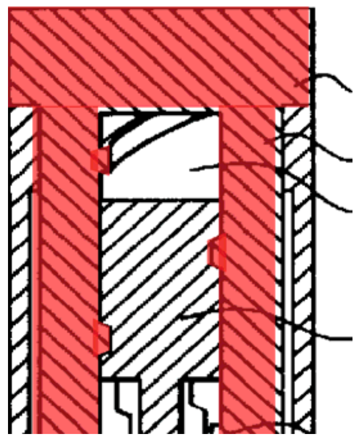
709. Møller's second embodiment describes a similar driving member: tubular connection element 112 and nut 113. *Id.,* FIGS. 3-5. Tubular connection element 112 and nut 113 form a fully enclosed, tubular component that encompasses the piston rod 104. *See* EX1015, ¶40. The tubular connection element 112 with nut 113 includes a structure that is substantially identical to that of connection bars 12 with nut 13. That is, much like connection bars 12, the tubular connection element 112 includes, at its button-end, two pins 111 that project perpendicular to the element's longitudinal axis and hold the device's gearing system. *See id*., ¶40, FIGS. 3-5. The nut 113, having an internal threading, is provided toward the tubular connection element's needle-end. *See id.,* 6:45-48. Moreover, the tubular element 112 with nut 113 operates in the same manner as connection bars 12 with nut 13 and thus also teaches a driving member as recited in [21.3].

710. Steenfeldt-Jensen also teaches a driving member in the form of injection button 23. Below, I have reproduced a partial view of FIG. 7, where I have annotated the injection button 23 in red.



711. Much like the Møller's driving member, injection button 23 of Steenfeldt-Jensen drives the movement of the piston rod during injection, thus functioning as a "driving member." *Id.*, 6:42-53, 7:55-67, 8:25-33. The downward force "drives the piston rod to rotation in a clockwise direction" due to the not-self-locking threaded engagement between "an internal helical rib 36" on the injection button and "a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod...." *Id.*, 7:60-67, 8:25-33. A person of ordinary skill would have understood that a not-self-locking thread was a thread whose lead was large enough that axial load force could cause rotation of the shaft.

712. As noted above, injection button 23 also teaches the recited "third thread." As shown in an annotated, partial view of FIG. 7 below, the injection button 23 comprises a helical rib 36 that engages with a corresponding helical groove in the enlargement 37 of the piston rod:



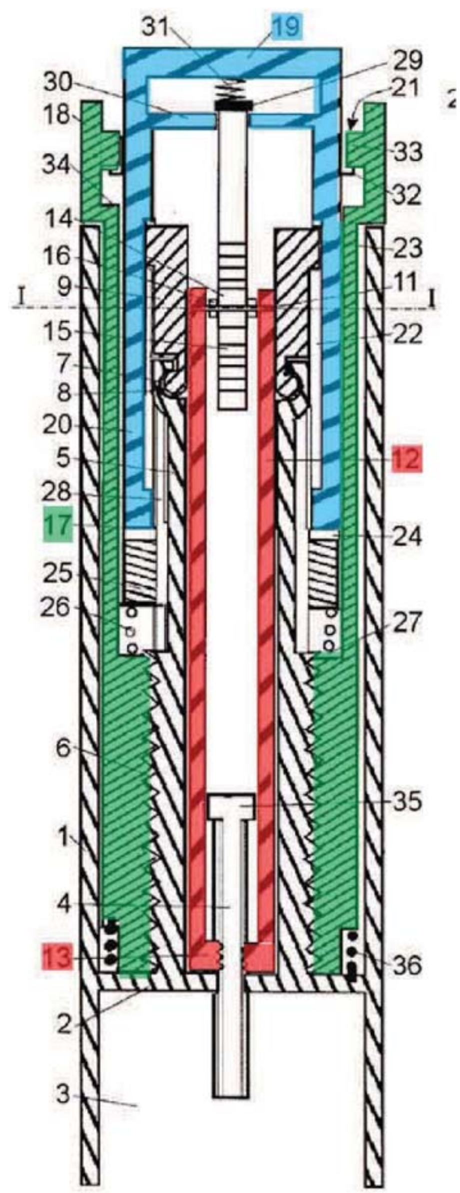
713. Specifically, "the injection button and its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6." *Id.*, 7:55-67. In my opinion, the internal helical rib 36 provides a third thread.

714. Thus, the combination of Møller and Steenfeldt-Jensen the recited driving member having a third thread.

<u>['844] Claim 21.4: a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;</u>

715. In my opinion, the combination of Møller and Steenfeldt-Jensen teaches a sleeve as claimed in element [21.4]. Møller teaches a "cup shaped element" with tubular part 20 that is disposed within the housing 1 of the drug delivery pen.

See EX1015, ¶¶26-27, FIG. 1. As Møller explains, "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." *Id*. As shown in the annotated FIG. 1 below, the tubular part 20 (i.e. a sleeve) of the cup shaped element is disposed between (1) the dose setting drum 17 and (2) the connection bars 12 with nut 13.



716. FIGS. 3-5 show a similar configuration, with tubular element 120 being disposed between (1) dose setting drum 117 and (2) tubular connection element 112 with nut 113. The proposed combination with Steenfeldt-Jensen would not impact this positioning of the components.

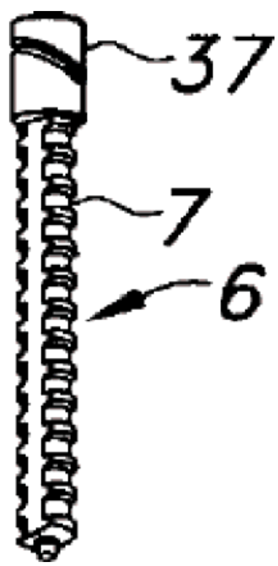
717. Further, a person of ordinary skill in the art would have appreciated that tubular part 20 of the cup shaped element is not permanently secured to dose setting drum 17 (the dose indicator) due to the releasable engagement of protrusions 32. *See* EX1015, ¶¶29, 32-33. A POSA thus would have understood that tubular part 20 of the cup shaped element is "releasably connected to the dose indicator." Again, a person of ordinary skill would have recognized that the second embodiment of Møller taught a similar configuration of tubular element 120. Therefore, in my opinion, the combination of Møller and Steenfeldt-Jensen teaches a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator.

['844] Claim 21.5: a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;

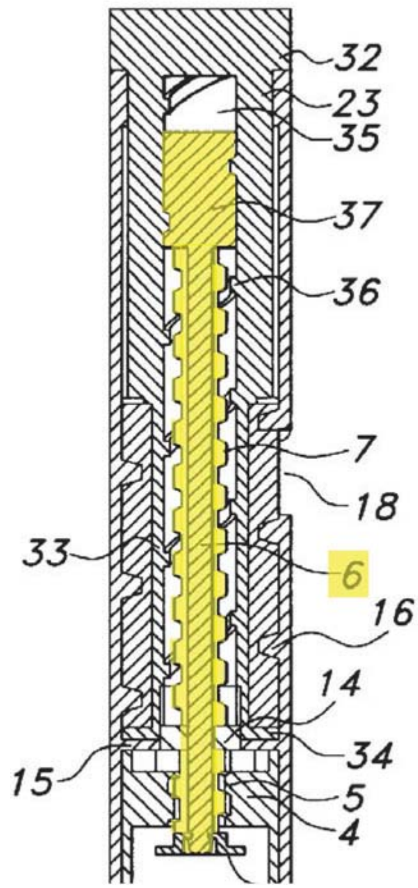
718. In my opinion, the combination of Møller and Steenfeldt-Jensen teaches the piston rod as recited in element [21.5]. Both Møller and Steenfeldt-Jensen teach the use of a piston rod that is driven forward during injection to administer a dosage of medication. *See* EX1015, ¶¶22-23, 30, 33; EX1014, 7:60-67, 8:25-33, FIGS. 7-8. Møller teaches piston rod 4 while Steenfeldt-Jensen teaches

piston rod 6, and each of these piston rods has an external thread that engages an internal thread on the driving member. *See e.g.* EX1015, ¶32, FIG. 1; EX1014, 7:60-67, FIG. 7-8. This common feature of the piston rods would have further emphasized the practicability of the combination. For example, the similar interface between the driving members and piston rods would have simplified the combination, since significant redesign would not be required to make Steenfeldt-Jensen's dual-threaded piston rod work with Møller's concentric sleeves.

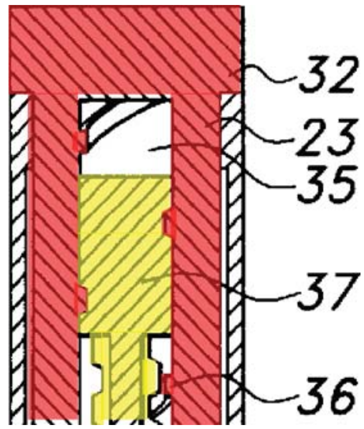
719. Turning to the specific features of Steenfeldt-Jensen's piston rod, the thread referenced above can be seen at the top of piston rod 6 in FIG. 8:



720. Annotated FIG. 7 (partial view) below shows the relationship of piston rod 6 (shown in yellow) to the other pen components.



721. As shown more clearly in the annotated version of FIG. 7 of Steenfeldt-Jensen below, a thread at the top of piston rod 6 (the helical groove in the enlargement 37 of the piston rod, annotated in yellow) engages the internal thread 36 of the injection button 23 (*i.e.*, the recited "third thread," annotated in red). EX1014, 7:60-67.

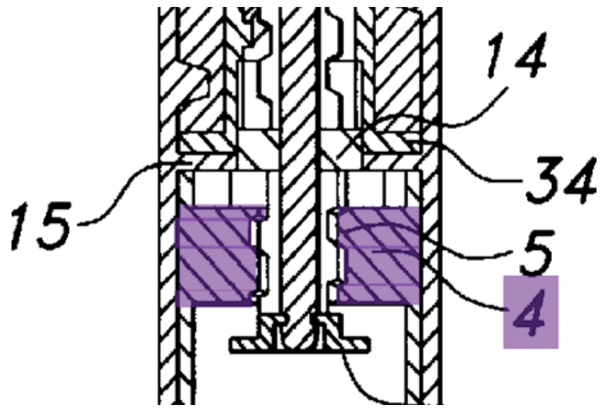


722. Thus, in my opinion, Steenfeldt-Jensen's piston rod 6 constitutes a piston rod comprising "an external fourth thread that is engaged with the third thread" as recited in element [21.5].

<u>['844] Claim 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;</u>

723. In my opinion, the combination of Møller and Steenfeldt-Jensen teaches the piston rod holder as recited in element [21.6]. Both Møller and Steenfeldt-Jensen teach an element that holds the piston rod, is rotatably fixed relative to the housing and configured as recited in the claim. Møller teaches the use of wall 2. *See* EX1015, ¶22, FIG. 1. Steenfeldt-Jensen teaches the use of end wall 4. *See* EX1014, 5:55-6:6. While the combination of teachings that I discuss below focuses on Steenfeldt-Jensen's threaded piston rod holder, the similar structure and function the two references' piston rod holders would have further emphasized the routine nature of the combination.

724. Turning to the particular structure and operation of Steenfeldt-Jensen's piston rod holder, the pen includes end wall 4, which engages piston rod 6 throughout operation:



725. In my opinion, a person of ordinary skill in the art would have understood that end wall 4 is "rotatably fixed relative to the housing" since it is an integral part of the housing. *See id.*, 5:66-6:41 (describing analogous wall 4 in an earlier embodiment). I note that the '844 patent itself indicates that its insert 16, which operates as the piston rod holder, can be integrally formed with the housing or provided as a distinct component. EX1004, 3:58-64.

726. Steenfeldt-Jensen explains that during dose setting, is prevented from rotating by a pawl mechanism situated above *Id.*, 8:1-8. While Steenfeldt-Jensen does not provide implementation details for the pawl mechanism of this embodiment, its description of a similar pawl mechanism in an earlier embodiment would have suggested to the reader that the pawl mechanism's teeth in FIGS. 6-10 were provided on the top surface of the wall 4. *See id.*, 5:66-6:6. Accordingly,

features of wall 4 operate to "prevent the piston rod from rotating during dose setting."

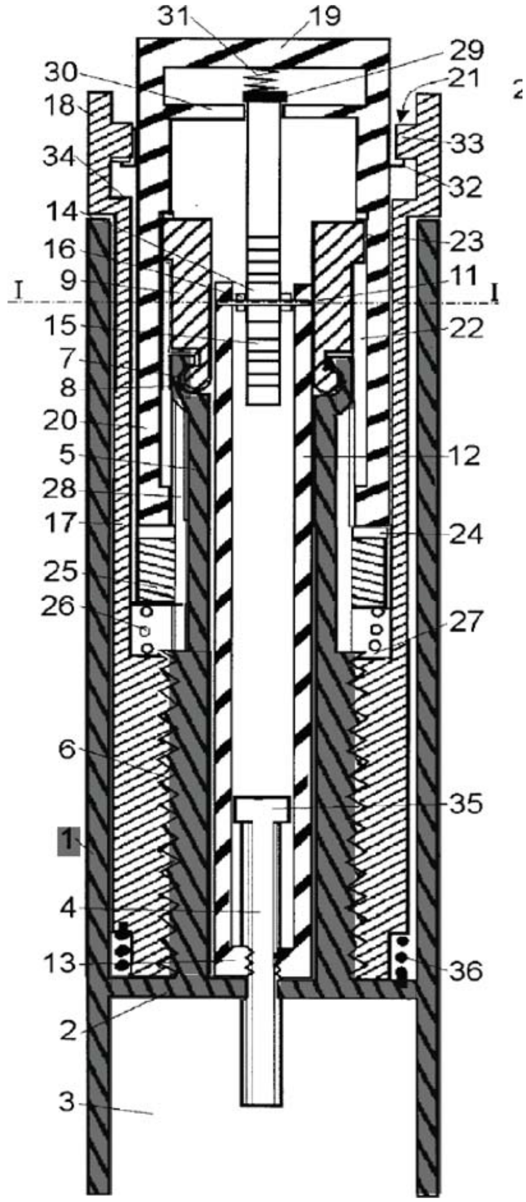
727. As to the last recited feature of the piston rod holder, it would have been readily apparent to a person of ordinary skill that the piston rod traverses through the threaded opening of wall 4 during dose dispensing. Specifically, the axial movement of the injection button 23 "drives the piston rod to rotation in a clockwise direction", and this rotation causes the piston rod to move down through the threaded opening. *Id.*, 8:25-33. Wall 4 thus permits the piston rod to traverse axially towards the distal end during dose dispensing.

728. I also note that, to the extent the piston rod holder may be construed as a means-plus-function, the function and structure of Steenfeldt-Jensen's piston rod holder discussed above also meets the recited function and corresponding structure that I addressed in section VI. The '844 patent describes an insert 16 (the "holder") that is provided at the needle-end of housing 4 and "secured against rotational or longitudinal motion." EX1004, 3:58-60. Insert 16 is also described as having "a threaded circular opening 18 extending therethrough." *Id.*, 3:60-62. The patent also notes that the insert can be "formed integrally with the main housing 4 [in] the form of a radially inwardly directed flange having an internal thread." *Id.*, 3:62-64. As I explained above, wall 4 with its threaded opening has precisely such a structure.

729. Therefore, in my opinion, the combination of Møller and Steenfeldt-Jensen teaches a piston rod holder 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.

['844] Claim 21.7: the housing is disposed at an outermost position of the drug delivery device;

730. In my opinion, the combination of Møller and Steenfeldt-Jensen teaches element [21.7]. EX1015, ¶¶22-23. For example, as shown in FIG. 1 of Møller, the housing 1 (annotated in gray) is in the outermost position relative to the other components of the drug deliver pen:

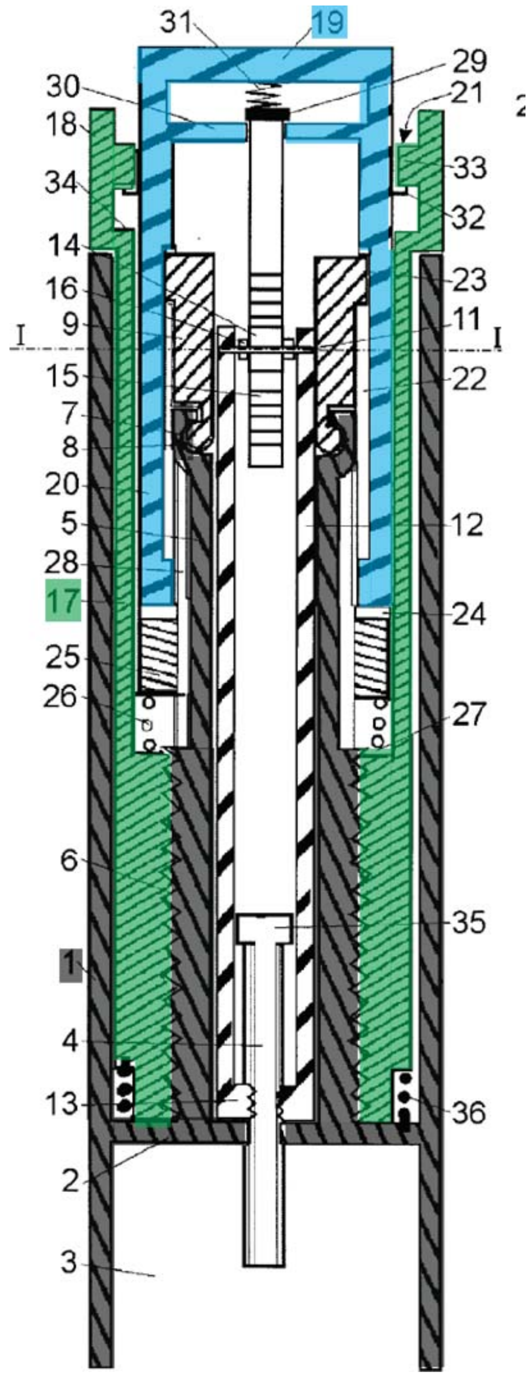


731. Steenfeldt-Jensen's housing, and indeed virtually all injector pen housings, is similarly situated. *See* EX1014, 5:38-46; FIG. 7-8. Accordingly, it is my opinion that the combination of Møller and Steenfeldt-Jensen teaches that the housing is disposed at an outermost position of the drug delivery device.

['844] Claim 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;

732. In my opinion, the dose setting drum 17 in the combination of Møller and Steenfeldt-Jensen teaches element [21.8]. As discussed above for element [21.2], the dose setting drum 17 of Møller provides a dose indicator. *See* EX1015, ¶¶25, 29, FIG. 1; *see also id.* ¶40, FIGS. 3-5 (showing analogous drum 117).

733. Based on the disclosures of Møller, it would have been apparent to a person of ordinary skill in the relevant field of art that dose setting drum 17 is positioned between the housing (housing 1) and the sleeve (tubular part 20 of the cup shaped element). Below, I have annotated FIG. 1, where the drum 17 is annotated in green, the housing 1 is annotated in gray, and the cup shaped element is annotated in blue:



734. For example, Møller explains that "the dose setting drum 17 may be screwed in and out of the housing." *Id.*, ¶25; *see also id.*, ¶29. Thus, it is apparent

that the dose indicator is seated within the housing. Further, "[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, FIGS. 1, 35. Based on this description and the accompanying figures, it is also obvious that the dose indicator is positioned circumferentially outwards from the cup shaped element. Accordingly, the dose indicator is disposed between the housing and the sleeve.

735. Further, the dose indicator (dose setting drum 17) of Møller is configured to rotate upwards towards the proximal end of the drug delivery pen during dose setting. Møller explains that "[t]o set a dose the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 6." EX1015, ¶29. That is, during dose setting, the dose indicator (dose setting drum 17) rotates and traverses axially away from the dose dispensing end as recited in element [21.8]. *Id.*

736. Still further, dose setting drum 17/117 of Møller is configured to rotate and move downwards towards the dose dispending end during injection. Møller explains that "[t]o inject a set dose the injection button is pressed by pressing on the bottom 19. In the initial phase of the pressing the spring 31 is compressed where after the pressing force is directly transmitted to the head 29 ... until the dose-setting drum 17 abuts the wall 2." EX1015, ¶32. That is, during dose dispending, the dose

indicator (dose setting drum 17) rotate and traverse axially towards the dose dispensing end as recited in element [21.8]. *Id*.

737. Accordingly, it is my opinion that the combination of Møller and Steenfeldt-Jensen teaches 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.

['844] Claim 21.9: the driving member is configured to rotate relative to the piston rod;

738. As discussed above for element [21.3], the injection button 23 of Steenfeldt-Jensen provides a driving member in the combination of Møller and Steenfeldt-Jensen. *See* EX1014, 7:55-67. In my opinion, the injection button 23 of Steenfeldt-Jensen also teaches element [21.9].

739. As I explain in detail below, a person of ordinary skill in the relevant field of art would have a reason to combine the teachings of Møller and Steenfeldt-Jensen to make use of Steenfeldt-Jensen's teachings regarding its driving member (injection button 23), piston rod (piston rod 6), and piston rod holder (wall 4). *See id*., 7:48-8:33, FIGS. 6-10.

740. Steenfeldt-Jensen explains that "[t]o set a dose the injection button 23 is manually rotated in a clockwise direction", which causes the button to rotate out from the housing while the piston rod is prevented from rotating. *Id.*, 8:1-12.

741. Conversely, during injection, the injection button 23 is prevented from rotating while moving axially downward as it "drives the piston rod to rotation in a clockwise direction...." *Id.*, 8:25-33. A person of ordinary skill would have appreciated both of these processes involve relative rotation of the injection button 23 and the piston rod 6.

742. As I explained above with respect to element [21.3], Møller teaches a driving member with a similar structure and operation. This driving member also rotates relative to the piston rod when dialing a dose, though such rotation does not occur during injection. *Id.* ¶30-32. Both Møller's and Steenfeldt-Jensen's driving member thus satisfy element [21.9].

743. As I explain in more detail below in my discussion of the proposed combination, a person of ordinary skill would have had reason to combine the teachings of Møller and Steenfeldt-Jensen to provide an injector with Møller's style of concentric dose-setting components and Steenfeldt-Jensen's dose-dispensing mechanism. The driving member as implemented in the proposed combination (i.e. with Steenfeldt-Jensen's style of driving member) would also satisfy element [21.9] for the reasons I provided above with respect to Steenfeldt.

744. Accordingly, it is my opinion that the combination of Møller and Steenfeldt-Jensen teaches a driving member that is "configured to rotate relative to the piston rod" as recited in element [21.9].

['844] Claim 21.10: the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator;

745. As discussed above for element [21.4], the tubular part 20 of the cup shaped element of Møller provides the recited sleeve. *See* EX1015, ¶¶26-27, FIG. 1. This sleeve is rotatably fixed to the connection bars 12 with nut 13 (Møller's driving member) and configured to traverse axially with the dose setting drum 17 (Møller's dose indicator). *Id.*, ¶¶26-27, 29; *see also id.* FIGS. 3-5 (showing analogous configuration of the second embodiment). A person of ordinary would have recognized that the combination with Steenfeldt-Jensen discussed below would not impact this aspect of Møller's configuration.

746. First, Møller teaches that tubular part 20 of the cup shaped element is rotatably fixed to the driving member. These components rotate together relative to the housing during dose setting, and they move axially together without rotating during dose dispensing. *See* EX1015, ¶¶29-30, 32. As explained below, the combination with Steenfeldt-Jensen would still involve the same relative movements of the dial indicator, sleeve, and driving member.

747. Second, Møller teaches that tubular part 20 of the cup shaped element traverses axially with the dose indicator. These components rotate and move axially upward together during dose setting, and despite being rotationally coupled during injection, they move axially downward together as the button is pressed to deliver a dose. *See id.*; *see also id.*, ¶26 ("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.").

748. Therefore, in my opinion, the combination of Møller and Steenfeldt-Jensen teaches a sleeve that is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator as recited in element [21.10].

['844] Claim 21.11: the piston rod and the driving member are configured to rotate relative to one another during dose dispensing;

749. As I explained above with respect to element [21.9], the combination of Møller and Steenfeldt-Jensen teaches a driving member and piston rod that rotate relative to one another during dose setting *and* dose dispensing. *See* EX1014, 8:1-12; 8:25-33. That discussion thus also demonstrates why the combination teaches a piston rod and a driving member that are "configured to rotate relative to one another during dose dispensing", as recited in element [21.11].

['844] Claim 21.12: the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

750. Both Møller and Steenfeldt-Jensen teach piston rods that traverse axially towards the dose dispensing end during dose dispensing. Indeed, this is how any piston-rod-driven injector would have operated, since the axial movement of the piston rod is what causes the dispensing of the medicine. In any event, Møller explains that the movement of connection bars 12 with nut 13 "will press the piston rod 4 into the compartment 3 until the dose-setting drum 17 abuts the wall 2."

EX1015, ¶32, FIGS. 1, 3-5. Likewise, a person of ordinary skill in the art would have recognized that piston rod 6 of Steenfeldt-Jensen also advances axially toward the needle end to dispense the desired dose of medication. *See* EX1014, 7:17-40, 7:60-67, 8:25-33, FIG. 7-8. Thus, in my opinion, a person of ordinary skill in the art would have appreciated that the combination of Møller and Steenfeldt-Jensen teaches that the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing, as recited in element [21.11].

751. **Reason to Combine and Expectation of Success:** In my opinion, a person of ordinary skill in the relevant field of art would have had a reason to combine the teachings of Møller and Steenfeldt-Jensen. Møller and Steenfeldt-Jensen teach injector pens that operate in a similar manner. In both Møller and Steenfeldt-Jensen, a drive sleeve rotates upward during dose setting and drives straight down during injection to administer the drug. *See* EX1015, ¶¶30-31 (describing the movement of connection bars 12 and nut 13 during dose dialing and injection); EX1014, 6:42-7:29 (describing the movement of injection button 23 during dose dialing and injection). In addition to the similar operation of their components, Møller and Steenfeldt-Jensen also seek to achieve the same goal: using a geared injection mechanism to produce a mechanical advantage.

752. In my opinion, given the similar structure, operation, and goals of each pen, a person of ordinary skill in the art would have had reason to combine their

teachings to achieve those goals. In particular, I believe a person of ordinary skill in the art would have had reason to combine Møller's dose-setting approach (i.e. rotating a dose dial sleeve to rotate a drive sleeve up a piston rod) with Steenfeldt-Jensen's dose-dispensing approach (i.e. using axial movement of a drive sleeve to rotate a dual-threaded piston rod for a geared injection stroke). A person of ordinary skill would have been able to achieve this by combining Møller's concentric dose indicator, clutch, and drive sleeve with Steenfeldt-Jensen's drive sleeve, dual-threaded piston rod, and threaded piston rod holder. The similar structure and operation of their drive sleeves would have made such a combination readily workable.

753. The resulting combination would operate in the same overall manner as the existing disclosure of Møller. Specifically, the user would rotate a knob on the dose indicator that would, in turn, rotate the drive sleeve to set a dose. Pressing the injection button would then rotationally decouple the dose indicator and the drive, and the drive sleeve would then move axially without rotating, just as in Møller. The drive sleeve's dose-dispensing, however, would operate as taught by Steenfeldt-Jensen. Rather than using Møller's complicated rack-and-pinion system to provide the mechanical advantage during injection, the drive sleeve would engage a dual-threaded piston rod as taught by Steenfeldt-Jensen. The resulting rotation of the

piston rod would drive the piston rod down through the threaded piston rod holder to dispense the dose, again as taught by Steenfeldt-Jensen.

754. In my opinion, a person of ordinary skill in the relevant field of art would have recognized various benefits of the combination. As noted above, both references are concerned with providing a mechanical advantage by increasing the stroke of the injection button relative to the stroke of the piston rod. A person of ordinary skill would have appreciated that Steenfeldt-Jensen makes use of simpler piston-driving mechanism and the simplification of and reduction of internal components is an advantageous and desired objective in the industry. Use of a single, dual-threaded rod to provide the mechanical advantage, rather than Møller's complicated rack-and-pinion system, would also result in a more durable, stress-tolerant device.

755. Further, Møller itself appreciated that the piston-driving mechanism can be accomplished in different ways. Møller explains that the purpose of its piston-driving mechanism is to obtain a mechanical advantage by providing gearing between the driver and the piston rod `so that the button has a larger stroke than has the piston." EX1015, ¶6. `By such a gearing the movement of the injection button is made larger and the force, which has to be exerted on the injection button, is correspondingly reduced." *Id*. Møller appreciated various ways of achieving such gearing in the art—including, inter alia, differential threading on rotationally

coupled components—but ultimately chose a mechanism involving gear wheels engaging a rack in the hopes of minimizing friction. *Id.*, ¶¶7-11. In my opinion, it would have been apparent to combine Møller and Steenfeldt-Jensen in the manner described because the dual-threaded piston rod of Steenfeldt-Jensen would provide the same type of mechanical advantage described in Møller, but by using much fewer, simpler parts.

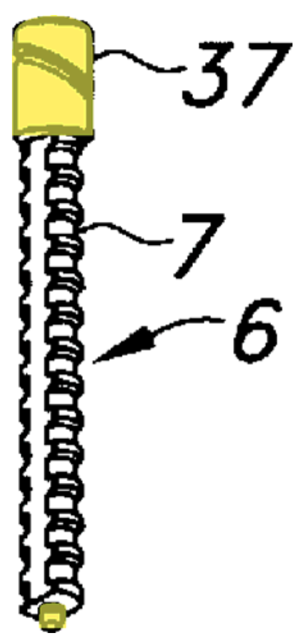
756. In my opinion, a person of ordinary skill would have recognized these benefits and therefore had reason to combine Møller and Steenfeldt-Jensen as I explained above. Further, as I noted above, Møller and Steenfeldt-Jensen have the same overall structure and the same movement of their drive sleeves during dose-setting and dose-dispensing. *See* EX1015, ¶¶30-31; EX1014, 8:1-33. Given these structural and operational similarities, each of the combined features would have been operating in the same manner and for the same purpose as before. The proposed combination thus would have involved the use of familiar components performing their usual, predictable functions. Accordingly, it is my opinion that a person of ordinary skill would have reasonably expected to succeed in creating an injector pen as I described above.

2. Dependent claims 22-29 of the '844 patent

757. It is my opinion that the combination of Møller in view of Steenfeldt-Jensen renders obvious dependent claims 22-29 of the '844 patent.

['844] Claim 22: The drug delivery device of claim 21 where the piston rod has a circular cross-section.

758. As I noted previously, claim 23 of the '844 patent only requires that the piston rod has "a circular cross-section." It does not require that the piston rod have a uniformly "circular cross-section" along its entire length. Moreover, as I explained above with regard to claim 21, a person of ordinary skill in the art would have found it obvious to combine Møller and Steenfeldt-Jensen in a manner that utilizes the piston rod 6 of Steenfeldt-Jensen. The enlargement 37 of piston rod 6 is cylindrical in shape and includes a circular cross-section. *See* EX1014, 7:60-67, 8:45-48, FIG. 7-8. The distal portion (the needle-facing end) of the rod similarly has a circular cross-section. *See id.*, FIGS. 7-8. Below, I have reproduced a partial view of FIG. 8, showing the cylindrical shape of enlargement 37, which I have annotated in yellow:



759. I also note that a person of ordinary skill in the art would have understood that the threaded piston rod described in the ’844 patent would have a cross-section that was not perfectly circular due to the helical features of the first and second threads 19, 24 along the piston rod’s length. *See* EX1004, 3: 56-67. Thus, based on the ’844 patent, a person of ordinary skill would have understood that a threaded component would include a “circular cross-section” along its length, even though the helical features make that cross-section not perfectly circular. In view of this, to the extent the piston rod must have a “circular cross-section” along its entire length, it is my opinion that a person of ordinary skill would have understood that the piston rod 6, with its circular helical, external thread 7 extending along its length, would have a “circular cross-section.”

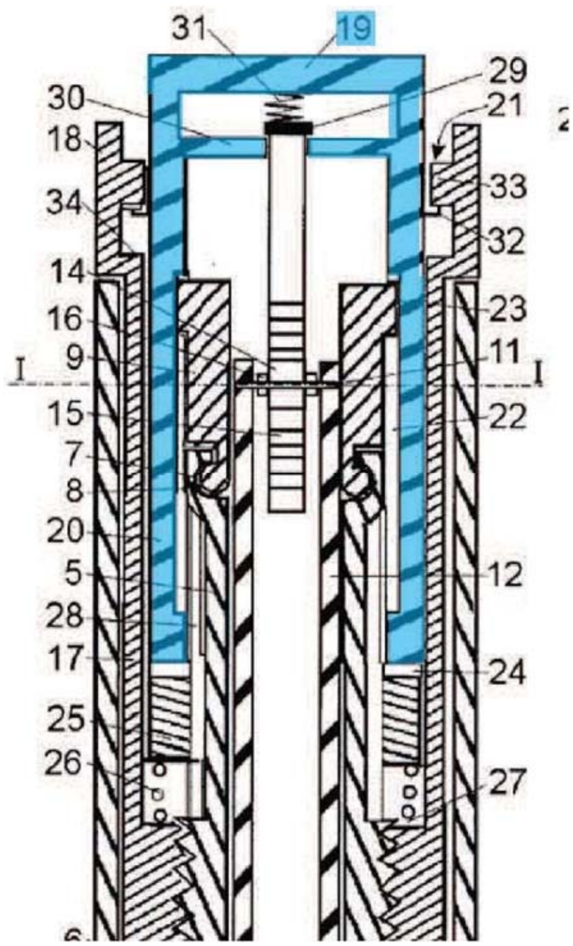
760. Accordingly, it is my opinion that a person of ordinary skill would have understood that the combination of Møller and Steenfeldt-Jensen teaches a piston rod that has a “generally circular cross section.”

<u>[’844] Claim 23: The drug delivery device of claim 21 further comprising a clutch.</u>

761. The combination of Møller and Steenfeldt-Jensen teaches a clutch in the form of a “cup shaped element.” *See* EX1015, ¶26, FIG. 1. The cup shaped element is releasably coupled to the dose setting drum 17 through “0-shaped protrusions 32 ... engaging A-shaped recesses in the inner ring 33 in the dose setting button 18.” *Id.*, ¶29, FIG. 1. During dose setting, the cup shaped element’s

protrusions 32 are engaged with the recesses in the dose setting button due to a spring 26 that biases the cup shaped element toward the button-end so that it remains engaged with the dose setting button. *See id.*, ¶29. As a result, the cup shaped element rotates with the dose setting drum 17 as it moves out of the housing 1, the rotation of which is transmitted to the driver. *See id.*, ¶30. During dose dispensing, the bottom 19 of the cup shaped element is pressed by the user. *Id.*, ¶32. This action moves the cup shaped element axially toward the device's needle-end, which causes the protrusions 32 to disengage from the dose setting button 18. *Id.*, ¶33. As a result, the cup shaped element is decoupled from the dose setting drum 17, allowing the drum 17 to rotate freely back into the housing, while the cup shaped element and the driver move axially toward the device's needle-end without following the drum's rotation. *Id.*, ¶¶32-33. Thus, the cup shaped element serves as a "clutch" by coupling and decoupling the rotational movement of the dose setting drum to the mechanism's driver.

762. FIG. 1 is reproduced below, where I have highlighted the cup shaped element in blue:



763. As I noted previously, the ’844 patent does not require the clutch to be a different component than the sleeve, and a person of ordinary skill would have understood that the clutch 60 disclosed by the ’844 patent serves both as a “sleeve” as recited in claim 21 as well as a “clutch” as recited in claim 23. Thus, a person of ordinary skill would have similarly understood the cup shaped element to be both a “sleeve” and a “clutch.”

764. Accordingly, the combination of Møller and Steenfeldt-Jensen teaches a “clutch.”

['844] Claim 24: The drug delivery device of claim 23 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

765. The combination of Møller and Steenfeldt-Jensen teaches a "clutch" that "provides audible and tactile feedback indicative of unit doses of medicament." In fact, both Møller and Steenfeldt-Jensen teach the use of audible or tactile feedback as signals regarding the selected dosage of medication to be administered. *See* EX1015, ¶¶27, 29; EX1014, 3:21-27, 6:48-53.

766. As I explained above, the combination of Møller and Steenfeldt-Jensen teaches a "clutch" in the form of cup shaped element. Møller discloses a "click coupling" whereby a click noise is produced when the cup shaped element is rotated. EX1015, ¶27; *see also id.*, ¶29. Specifically, cup shaped element includes "a rosette of V-shaped teeth" that engage "a corresponding rosette of V-shaped teeth 24 on a ring 25 which is pressed against the edge of the cup shaped element by a spring 26." EX1015, ¶27. This established a click coupling "which makes a click noise when the V-shaped teeth at the edge of the cup shaped element by rotation of this element rides over the V-shaped teeth of the ring 25." *Id.* Møller further explains that "[b]y rotation of the cup shaped element the V-shaped teeth 24 at the edge of its open end will ride over the V-shaped teeth of the non rotatable ring 25 to make a click sound for each unit the dose is changed." *Id.*, ¶29. Thus, Møller discloses that the cup shaped element provides at least audible feedback, in the form of click noises, that are indicative of unit doses of medicament.

767. Although Møller does not explicitly disclose that the teeth of the cup shaped element provide “tactile feedback” when the teeth ride over the corresponding teeth of the ring 25, it is my opinion that a person of ordinary skill would have understood that such a mechanism would provide sufficient increase and decrease in resistance such that “tactile feedback” is provided. This understanding is consistent with the understanding of the person of ordinary skill presumed by the ’844 patent. For example, the ’844 patent describes that “audible and tactile feedback of the dose being dialed is provided by the clicker 50 and the clutch means 60.” EX1004, 5:64-65. The ’844 patent further describes that, during dose-dialing down, saw teeth 66 of the clutch 60 ride over corresponding saw teeth 56 of the clicker 50 to provide a clicking function. *See id.*, 6:33-37. This mechanism is substantially identical to the teeth provided on the cup shaped element of Møller.

768. Accordingly, it is my opinion that the combination of Møller and Steenfeldt-Jensen teaches a cup shaped element that “provides audible and tactile feedback indicative of unit doses of medicament.”

['844] Claim 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.

769. Møller discloses that “[a] too high set dose can be reduced by rotating the dose setting button 18 in the opposite direction of the direction for increasing the dose.” EX1015, ¶29. As I noted above, a spring “keep[s] the V-shaped teeth of the

ring 25 and the cup shaped element in engagement." *Id.* Because ring 25 is non-rotatable relative to the housing, and because the cup shaped element rotates with the dose setting drum 17 due to its engagement with the dose setting button 18 during dose setting, a person of ordinary skill would have understood that the V-shaped teeth of the cup shaped element would similarly ride over the V-shaped teeth of the ring when the user dials down a dose (*i.e.*, "dose cancel[s]"). As I also noted above, Møller teaches that the teeth of the cup element produce "a click sound for each unit the dose is changed." *Id.*, ¶29.

770. Accordingly, the combination of Møller and Steenfeldt-Jensen teaches that the cup shaped element "provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament."

['844] Claim 26: The drug delivery device of claim 24 where the clutch allows the dose cancelling without dispensing medicament.

771. As discussed above with regard to claim 24, the combination of Møller and Steenfeldt-Jensen teaches a clutch in the form of a "cup shaped element." *See supra*, ¶¶765-68. It is my opinion that a person of ordinary skill would have understood that the cup shaped element of Møller would allow for dose cancelling without dispending medication. Specifically, Møller explains that "[a] too high set dose can be reduced by rotating the dose setting button 18 in the opposite direction of the direction for increasing the dose." EX1015, ¶29; *see also id.*, 4:51-5:3. A person of ordinary skill would have understood that this would have caused the

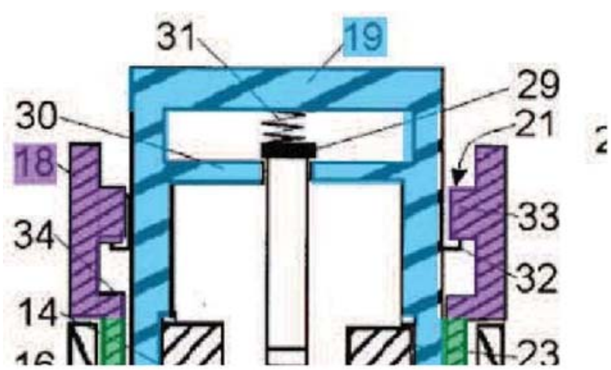
system to act in reverse: the cup shaped element would rotate back into the housing 1 with the dose setting drum 17, while the driver would travel down the piston rod's threading, without axially displacing the piston rod. A person of ordinary skill would have understood that this would not result in the dispensing of medicine. A person of ordinary skill would have also understood Steenfeldt-Jensen as teaching a similarly reversible system, where "[a] to[o] high set dose can be reduced by rotating the button in an anti clockwise direction," which causes the driver to travel down the piston rod's threading, without axially displacing the piston rod. *See* EX1014, 9:46-47.

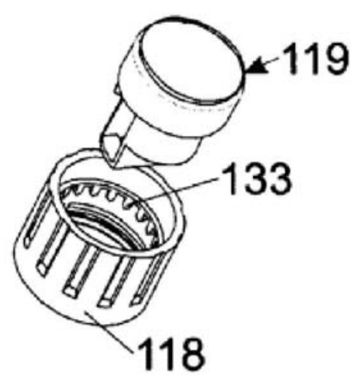
772. Thus, the combination of Møller and Steenfeldt-Jensen teaches a cup shaped element that "allows the dose cancelling without dispensing medicament."

['844] Claim 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.

773. Møller teaches a button in the form of a "bottom 19" (or alternatively "button 119"). EX1015, 4:45-50, 5:20-23, 5:36-37, 6:24-27. Møller explains that the bottom 19 "form[s] the injection button." EX1015, 4:45-50; *see also id.*, 5:2023. "To inject a set dose the injection button is pressed by pressing on the bottom 19." *Id.*, 5:36-37. Møller also discloses another embodiment that teaches the use of "a button 119," which Møller states corresponds to the bottom 19. EX1015, ¶¶3536, 38-39, FIG. 5.

774. Møller also shows that the bottom 19 (and the button 119) is disposed in an annular recess of a dose setting button 18 (and corresponding dose setting button 118) provided at the button-end of the tubular dose setting drum 17. *See* EX1015, ¶25, FIGS. 1, 5. Møller teaches that the dose setting button 18/118 serve as a "dose dial grip" for the user to rotate the dose setting drum during the dose-setting process. *See* EX1015, ¶¶29, 36. Below, I have a reproduced partial views of FIGS. 1 (left) and 5 (right), where, in FIG. 1, I have annotated the bottom 19 in blue, the dose setting button 18 in purple, and a portion of the button-end of the dose setting drum 17 in green. As shown in the figures, the bottom/button are seated in an "an annular recess of" the dose setting button, which is provided at the button-end of the dose setting drum. *See also id.*, FIGS. 3-4.





775. In addition, it is my opinion that a person of ordinary skill would have understood that the bottom 19 is "rotatable relative" to the dose setting drum. As explained above, the cup shaped element disengages from the dose indicator during

injection, which allows the cup shaped element, and therefore bottom 19, to rotate relative to the drum. *See, e.g.*, EX1015, ¶¶32-33.

776. Thus, the combination of Møller and Steenfeldt-Jensen teaches "a button," in the form of button 19/119, which is "seated in an annular recess of" a dose setting button "on a proximal end of the" dose setting drum, "where the button is rotatable relative to the" dose setting drum.

['844] Claim 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 axially with respect to the dose indicator and driving member.

777. As I explained above, Møller discloses a button in the form of bottom 19 (or alternatively button 119). *See* EX1015, 4:45-50, 5:36-37, 6:24-27, 6:37-44, FIG. 1, 5. As Møller explains, to initiate an injection, the bottom 19 is pressed toward the needle-end of the device. *Id.*, 5:36-44. This "distally applied pressure" causes the bottom 19 to move axially to initiate dose delivery. *Id.*, 5:36-44 ("To inject a set dose the injection button is pressed by pressing on the bottom 19. In the initial phase of the pressing the spring 31 is compressed where after the pressing force is directly transmitted."). "During the initial phase of the movement of the injection button the 0-shaped protrusions 32 on the cup shaped element will be drawn out of their engagement with A-shaped recesses in the ring 33." EX1015, ¶33. A person of ordinary skill would have understood this to mean that the cup shaped element is displaced axially with respect to the dose setting drum and driver.

778. Accordingly, it is my opinion that the combination of Møller and Steenfeldt-Jensen teaches that "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."

['844] Claim 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.

779. Møller teaches a "clicker" in the form of ring 25. As I explained above, ring 25 includes a rosette of V-shaped teeth 24 that engage with a corresponding rosette of V-shaped teeth on the cup shaped element to provide a "click coupling" that results in audible clicks being made during dose cancelling, where each click represents a unit-dose change. *See supra*, ¶¶398-402. Accordingly, the combination of Møller and Steenfeldt-Jensen teaches a device that includes "a clicker," in the form of ring 25 having teeth 24, "that provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament."

780. Moreover, the combination of Møller and Steenfeldt-Jensen teaches a "clicker" that has one of the structures for a clicker as taught by the '844 patent. As I explained above, Møller discloses the ring 25 includes V-shaped teeth 24 that slip-engage with corresponding teeth of the cup shaped element, which provides an audible click to a user upon rotation of the dose dial grip. *See* EX1015, ¶¶27-29, 40; FIG. 1. One of the structures that is taught by the '844 patent that may be used as a

clicker is saw teeth that ride over one another to produce a click. EX1004, 6:27-37. Thus, the combination of Møller and Steenfeldt-Jensen also teaches a clicker having the same structure as that in the ’844 patent and having the same function.

Q. [’844-C] Ground 2: Claim 30 is Obvious over Møller in combination with Steenfeldt-Jensen and Klitgaard

781. As explained in detail in above, it is my opinion that the combination of Møller and Steenfeldt-Jensen teaches a drug delivery device that includes each and every element of claim 21 of the ’844 patent, and thus renders obvious that claim. As I will explain in detail below, claim 30 is obvious over the combination of Møller and Steenfeldt-Jensen in further view of Klitgaard.

[’844] Claim 30: The drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered.

782. Klitgaard describes an injection device for dispensing medicine comprising a limiting mechanism to track the amount of medication administered. EX1017, Abstract. 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 (or nut) coupled to the dose setting member to follow rotation of this dose setting member.” EX1017, Abstract. By configuring a track follower or nut to move further on the track “[e]ach time a dose is set and injected,” the track follower’s or nut’s location reflects the cumulative amount of medication that has been injected and prevents setting of a dose larger than the remaining liquid in the cartridge. *Id*.

783. An embodiment of such a limiting mechanism is disclosed in FIG. 3 and its related description. Klitgaard discloses that nut member 32 is disposed between dose setting member 30 and driver 31 and tracks each set dose of medication delivered. *Id.*, 4:16-58. Dose setting member 30 is threaded out along internal threads of the housing to set a dose. *Id.*, 4:16-25. Nut member 32 simultaneously threads along a helical track on the outer surface of driver 31 pushed by the engagement of a ridge on the inner side of dose setting element 30 with recess 34 in the outer wall of nut member 32. *Id.*, 4:26-37. Nut member 32 maintains its position on driver 31 during dose dispensing to "always indicate the total sum of set and injected doses" even when dose setting member 30 is forced to rotate relative to the housing and transmits rotational force to driver 31. *Id.*, 4:3758. I have reproduced Klitgaard FIG. 3 below for convenient reference.

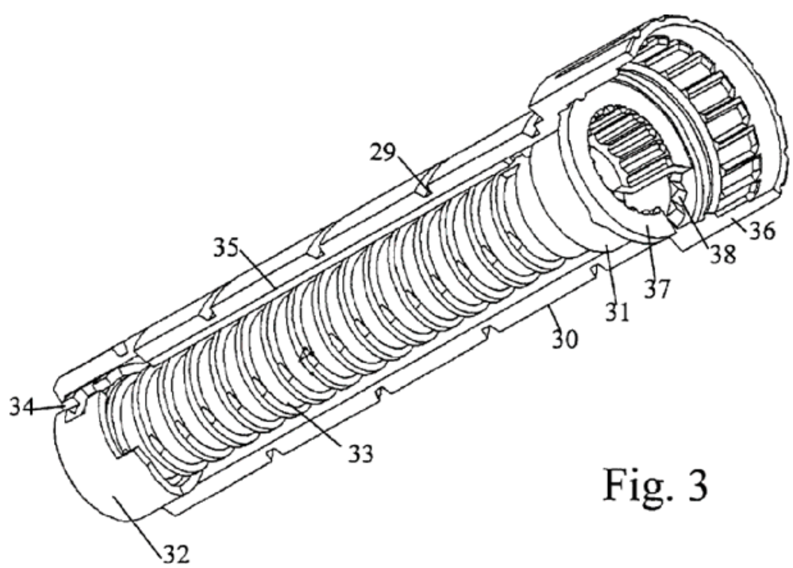


Fig. 3

784. Klitgaard provides at least two express reasons for a person of ordinary skill in the art to employ a nut that tracks each set dose of medicament delivered.

The first is to "always indicate the total sum of set and injected doses." EX1017, 4:52-58, Abstract. The second is to prevent setting a dose that exceeds the remaining available supply of medication in the cartridge. *Id.* Klitgaard elaborates 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.

785. These same benefits would be desirable in the drug delivery device based on the combination of Møller and Steenfeldt-Jensen discussed above regarding claim 21. For example, it can avoid the problem of a user believing he or she has administered a particular dose when in fact the user has not administered the full dose because the insufficient medication remained in the cartridge. It can also avoid wasteful disposal of cartridges while a sufficient amount of medication remains that would be motivated by uncertainty about whether the amount of medication remaining in the cartridge is sufficient to administer the desired dose. Each of these motivations would apply equally to the drug delivery device based on the combination of Møller and Steenfeldt-Jensen.

786. A person of ordinary skill in the art would have had a reasonable expectation of successfully incorporated such a tracking nut into the drug delivery device based on the combination of Møller and Steenfeldt-Jensen. The functionality of the drug delivery device would be maintained while adding the tracking feature for the maximum amount of medicament remaining in the cartridge.

787. A person of ordinary skill would have recognized that Klitgaard's dose-tracking nut could be implemented between adjacent, concentric sleeves that rotate relative to one another during dose-setting and but not during dose-dispensing. Given this understanding, a person of ordinary skill would have recognized that a nut such as nut member 32 in Klitgaard could be employed, for example, between the drive sleeve (e.g., tubular connection element 112 with nut 113) and tubular part 105 to track each set dose of medicament delivered. *See* EX1015, FIG. 5. Tubular connection element 112 rotates relative to part 5 during dose-setting but moves axially without relative rotation during dose-dispensing. This relationship provides the basis for placing a dose-tracking nut as described in Klitgaard.

788. This implementation of a dose-tracking nut in this location could be accomplished by, as taught by Klitgaard, disposing a helical track on the outer surface of tubular connection element 112 (i.e. the drive sleeve) adjacent tubular part 105. As taught by Klitgaard, the opposing surface of tubular part 105 could be provided with a ridge that engages with a recess in the outer wall of a nut member so that nut member remains rotationally, but not axially, fixed to the tubular part 105. The nut member would thread along the helical track as tubular connection element 112 rotates and traverses axially during dose setting. The lead of the helical track can be adjusted so that the axial position of the nut member on the helical track is proportional to the remaining dosage in the cartridge.

789. During dose dispensing, as discussed above, tubular connection element 112 moves axially without rotation relative to the tubular part 105. This means that the axial location of the nut member relative to the tubular connection element will not change during injection. Once the nut member reaches the end of the helical track, the nut member will prevent additional dose setting. This prevents the device from being set to a dose that is larger than the remaining medication in the cartridge. As just outlined, a person of ordinary skill in the art would have known to readily apply the dose tracking and dose limiting concept taught in Klitgaard to the drug delivery device based on the combination of Møller and Steenfeldt-Jensen. I note that the combination of Møller and Steenfeldt-Jensen's teachings that I discussed above would not impact the movement of the drive sleeve during dose-setting or dose-dispensing. Accordingly, the application of Klitgaard's teachings would not be impacted by this combination.

790. Further, I note that dose tracking and limiting devices were common in the art well before March 3, 2003. *See, e.g.*, EX1034, 7:35-8:5 ("The second arm 36 has on its backside a not shown cam, situated near the centre 34. This cam is movable locked in the spiral shaped track of driver 27. In this way the number of rotations the driver 27 can perform relatively to the second arm 32 and the rod guiding part 20 is limited, and the total length of the track is adapted to the total amount of medicine

in the cartridge 13 thereby ensuring that a dose larger than the amount of medicine remaining in the cartridge 13 cannot be set.”).

791. Accordingly, it is my opinion that the combination of Møller, Steenfeldt-Jensen, and Klitgaard teaches a drug delivery device that includes “a nut that tracks each set dose of medicament delivered.

R. [’008] Ground 1: Claims 1, 3, 7-8, 11, and 17 are Obvious over Møller in combination with Steenfeldt-Jensen

792. As explained in further detail below, it is my opinion that claims 1, 3, 7, 8, 11, and 17 were obvious over the combination of Møller in view of Steenfeldt-Jensen.

793. In my opinion, a person of ordinary skill in the relevant field of art would have had reasons to combine the teachings of Møller and Steenfeldt-Jensen as described below, along with reasonable expectations of success in doing so.

794. Møller and Steenfeldt-Jensen describe drug delivery pens with drive sleeves that operate in a similar manner. In both pens, a threaded driver rotates up a piston rod during dose setting, then moves axially downward without rotating to drive the piston rod into the chamber below. *See* EX1014, 7:60-8:33, FIGS. 7-8; EX1015, ¶¶29-30, 32-33, FIGS. 1, 5. In the FIG. 8 embodiment of Steenfeldt-Jensen, the user rotates the driver directly to set a dose. In Møller, the user rotates a knob on a dose dial sleeve that, in turn, rotates the drive sleeve to set a dose. Nevertheless, both drive sleeves have the same principle of operation: rotating up the piston rod to

set a dose, moving straight down to dispense a dose. Both pens also provide a similar benefit: the use of a geared injection mechanism to produce a mechanical advantage. In Steenfeldt-Jensen, the gearing is achieved using a dual-threaded piston rod. In Møller, the gearing is achieved using a rack-and-pinion mechanism. Again, however, the principle of operation is the same: the gearing increases the stroke of the injection button relative to the piston rod, which reduces the force required to dispense the dose.

795. Given the similar principles of operation and the similar goals of each pen, I believe a person of ordinary skill in the art would have had reason to combine Møller's dose-setting approach (i.e. rotating a dose dial sleeve to rotate a drive sleeve up a piston rod) with Steenfeldt-Jensen's dose-dispensing approach (i.e. using axial movement of a drive sleeve to rotate a dual-threaded piston rod for a geared injection stroke). As I explain in more detail below, a person of ordinary skill would have recognized that this combination provided various benefits and would be reasonably practicable given the similar structure and operation of the drivers and the familiar, predictable nature of the components involved.

1. <u>Independent claim 1 of the '008 patent</u>

796. It is my opinion that the combination of Møller and Steenfeldt-Jensen teaches the same six components recited in claim 1 of the '008 patent. I address the teachings regarding individual claim elements below, followed by a separate section

in which I explain why those of ordinary skill in the art would have had reason to combine the references as I propose and why they would have reasonably expected success in doing so.

797. As an initial matter, I note that Møller describes two similar embodiments: a first embodiment shown in FIGS. 1-2 and a second embodiment shown in FIGS. 3-5. Møller makes clear that 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 numbers for elements in the second embodiment that correspond to elements from the first embodiment simply add 100 to the previous number (e.g., housing 1 becomes housing 101). *Id.*, ¶35. In my opinion, a POSA would have understood corresponding elements in the first and second embodiments to have similar structures and functions unless otherwise indicated. To avoid redundancy, my analysis below primarily addresses Møller's first embodiment. Nevertheless, the corresponding elements of the second embodiment would have provided analogous teachings to a person of ordinary skill.

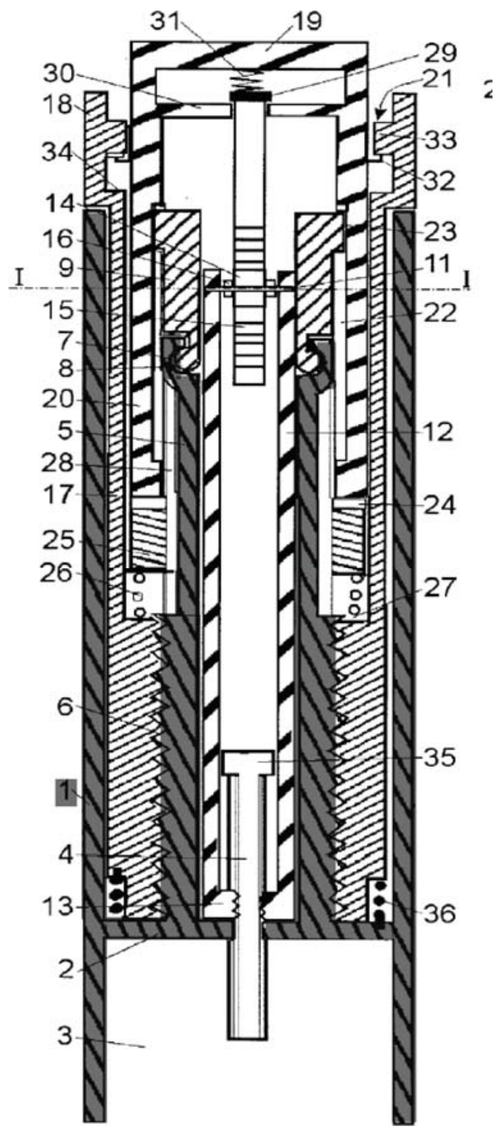
['008] Claim 1, preamble: A drive mechanism for use in a drug delivery device comprising:

798. Both Møller and Steenfeldt-Jensen disclose drive mechanisms that are used in drug delivery pens. *See* EX1015, Abstract, EX1014, Abstract. The drive mechanisms in both Møller and Steenfeldt-Jensen facilitate the dispensing of a user

selected dosage of medication. *See* EX1015, ¶¶14, 33, claim 11; EX1014, 8:25-33. Thus, in my opinion, the combination of Møller in view of Steenfeldt-Jensen teaches a drive mechanism for use in a drug delivery device.

['008] Claim 1.1: a housing comprising a helical thread;

799. The drug delivery pen of Møller makes use of a housing 1. Møller also makes clear that the housing has a helical thread. *See* EX1015, ¶23, FIG 1. As shown in the annotated version of FIG. 1 below, housing 1 comprises thread 6.



Id., FIG. 1; *see also id.*, FIGS. 3-5 (showing similar housing 101 in second embodiment); EX1014, 5:38-46; FIG. 7-8 (also showing similar housing).

800. Therefore, the combination of Møller and Steenfeldt-Jensen teaches a housing comprising a helical thread as recited in element [1.1].

['008] Claim 1.2: a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing,

801. In my opinion, Møller teaches a dose dial sleeve in the form of dose setting drum 17. EX1015, ¶29; *see also id.*, FIGS. 3-5 (showing similar drum 117). The dose setting drum 17 of Møller provides a second thread that engages the first thread (thread 6) of housing 1. *Id.*, ¶29.

802. Møller teaches that the dose setting drum 17 can have numbers on its outer surface. *Id.*, ¶25. As the dose setting drum 17 is screwed out of the housing, these numbers, which indicate the dialed dosage, can be seen through a window on the housing. *Id*. In my opinion, a person of ordinary skill would understand that dose setting drum 17 serves as a dose dial sleeve.

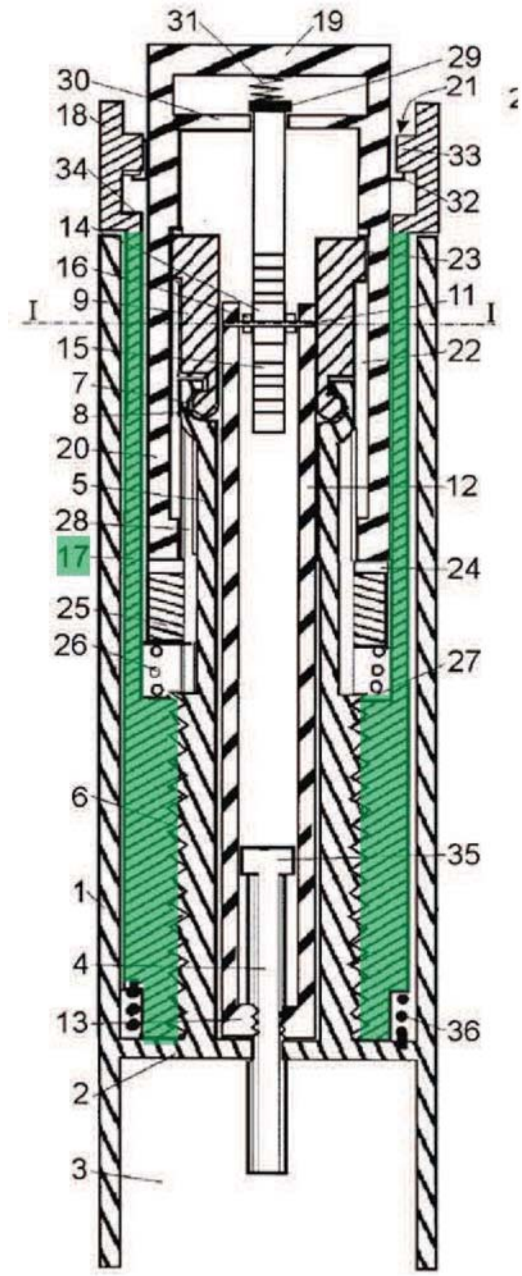


Fig. 1

803. As shown in the annotated version of FIG. 1 above, dose setting drum 17 also has a threaded surface that engages thread 6 of the housing 1. *Id.*, ¶¶25, 29, FIG. 1. Møller specifically explains that "[t]o set a dose the dose setting button 18 is rotated to screw the dose-setting drum 17 up along the thread 6." *Id.*, ¶29. Thus, it is

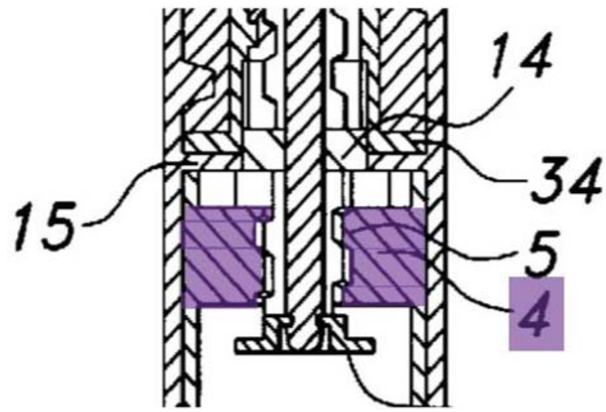
my opinion that the combination of Møller and Steenfeldt-Jensen teaches a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing. *Id*.; *see also* EX1014, 7:51-67; FIG. 7-8.

['008] Claim 1.3: an insert provided in the housing, where the insert has a threaded circular opening;

804. In my opinion, the combination of Møller and Steenfeldt-Jensen teaches the insert as recited in element [21.6]. Both Møller and Steenfeldt-Jensen teach an element that holds the piston rod, is rotatably fixed relative to the housing and configured as recited in the claim. Møller teaches the use of wall 2. *See* EX1015, ¶22, FIG. 1. Steenfeldt-Jensen teaches the use of end wall 4. *See* EX1014, 5:55-6:6. While the combination of teachings that I discuss below focuses on Steenfeldt-Jensen's threaded piston rod holder, the similar structure and function the two references' piston rod holders would have further emphasized the routine nature of the combination.

805. In my opinion, a person of ordinary skill in the relevant field of art would have appreciated that wall 4 is an insert. I note that the '008 patent itself indicates that its insert 16 can be integrally formed with the housing or provided as a distinct component. EX1005, 7:33-39.

806. Turning to the particular structure and operation of Steenfeldt-Jensen's piston rod holder, the pen includes end wall 4, which engages piston rod 6 throughout operation:



EX1014, FIG. 7 (end wall 4 annotated purple).

807. Steenfeldt-Jensen explains that "[t]he end of the ampoule holder 2 inserted in the housing 1 is closed by a wall 4 having a central bore with an internal thread 5." EX1014, 5:55-57. Further, the threaded bore of wall 4 "forms a nut member relative to which the piston rod is rotated by the piston rod guide 14 and the driver tube 26." EX1014, 7:41-43.

808. I also note that, to the extent the insert may be construed as a means-plus-function, the function and structure of Steenfeldt-Jensen's insert discussed above also meets the recited function and corresponding structure that I addressed in section VI. The '008 patent describes an insert 16 (the "holder") that is provided at the needle-end of housing 4 and "secured against rotational or longitudinal motion." EX1005, 7:33-39. Insert 16 is also described as having "a threaded circular opening 18 extending therethrough." *Id*. The patent also notes that the insert can be "formed integrally with the main housing 4 [in] the form of a radially inwardly

directed flange having an internal thread." *Id.* As I explained above, wall 4 with its threaded opening has precisely such a structure.

809. Therefore, in my opinion, the combination of Møller and Steenfeldt-Jensen teaches the insert recited in element [1.3].

['008] Claim 1.4: a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread;

810. In my opinion, the combination of Møller and Steenfeldt-Jensen teaches a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread. Møller and Steenfeldt-Jensen teach the use of drive sleeves that operate in a similar manner. Møller teaches connection bars 12 and nut 13 in the embodiment of FIGS. 1-2, as well as analogous elements (tubular connection element 112 and nut 113) in the embodiment of FIGS. 3-5. EX1015, ¶40, FIGS. 35. Steenfeldt-Jensen teaches injection button 23 in the embodiment shown in FIGS. 6-10. EX1014, 7:48-8:33, FIGS. 6-10. Each of these components drives the movement of the piston rod in a similar way: rotating up the piston during dose setting, then moving axially downward without rotating to drive the piston rod into the chamber below. I describe the structure and operation of these components in more detail below.

811. Figure 1 of Møller shows connection bars 12 and nut 13 (both annotated red below), which drive the movement of the piston rod 4.

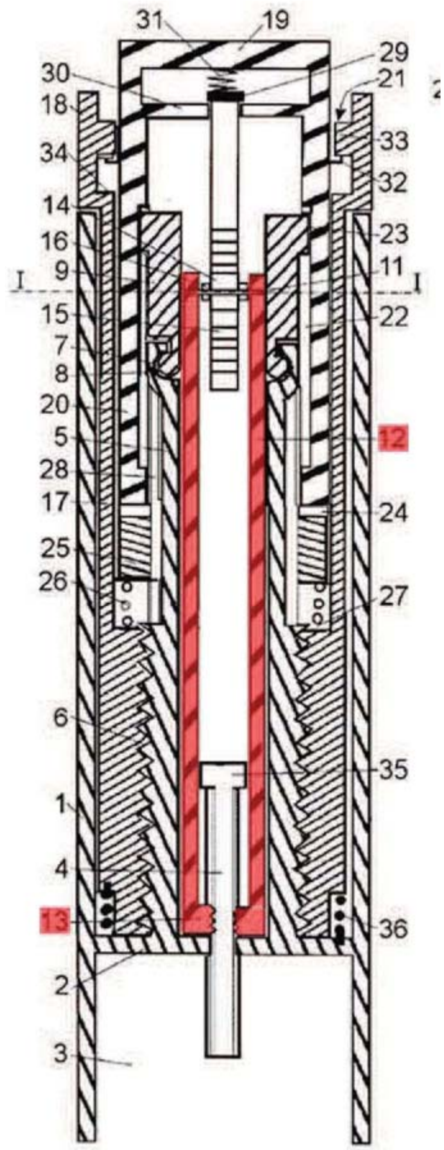


Fig. 1

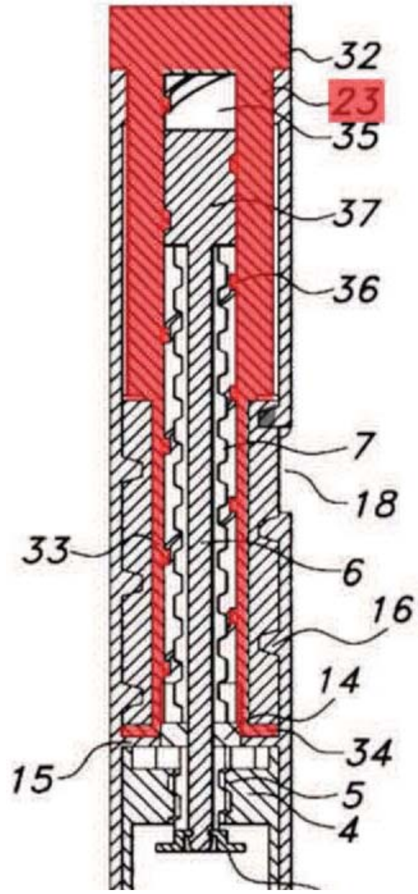
EX1015, FIG. 1.

812. This driver is releasably connected to dose setting button 17 (the dose dial sleeve) via the operation of the cup shaped element (the clutch), and it has an internal helical thread, which is disposed on nut 13. *Id.*, ¶¶30-31, FIG. 1. With the clutch engaged, rotation of the dose setting button 18 is transmitted to these

components, which rotate up the piston rod to set a dose. *Id.* ¶30. When the user presses the injection button, connection bars 12 and nut 13 move axially, carrying the piston downward. *Id.*, ¶¶31-32.

813. Møller's second embodiment describes a similar drive sleeve: tubular connection element 112 and nut 113. *Id.,* FIGS. 3-5. Tubular connection element 112 and nut 113 form a fully enclosed, tubular component that encompasses the piston rod 104. *See* EX1015, ¶40. The tubular connection element 112 with nut 113 includes a structure that is substantially identical to that of connection bars 12 with nut 13. That is, much like connection bars 12, the tubular connection element 112 includes, at its button-end, two pins 111 that project perpendicular to the element's longitudinal axis and hold the device's gearing system. *See id.*, ¶40, FIGS. 3-5. The nut 113, having an internal threading, is provided toward the tubular connection element's needle-end. *See id.,* ¶40. Moreover, the tubular element 112 with nut 113 operates in the same manner as connection bars 12 with nut 13 and thus also teaches a driving member as recited in [21.3].

814. Steenfeldt-Jensen also teaches a driving member in the form of injection button 23:

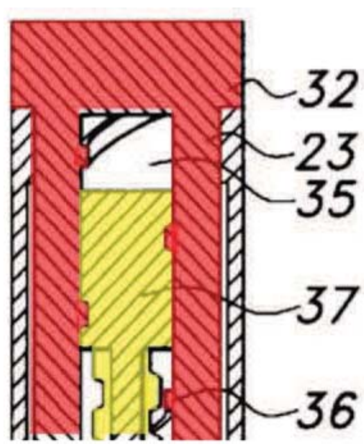


EX1014, FIG. 7 (injection button 23 annotated red).

815. Much like the Møller's drive sleeve, injection button 23 of Steenfeldt-Jensen drives the movement of the piston rod during injection, thus functioning as a "drive sleeve." *Id*., 6:42-53, 7:55-67, 8:25-33. The downward force "drives the piston rod to rotation in a clockwise direction" due to the not-self-locking threaded engagement between "an internal helical rib 36" on the injection button and "a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod...." *Id*., 7:60-67, 8:25-33. A person of ordinary skill would have understood that

a not-self-locking thread was a thread whose lead was large enough that axial load force could cause rotation of the shaft.

816. As shown in an annotated version of FIG. 7 below, the injection button 23 comprises a helical rib 36 that engages with a corresponding helical groove in the enlargement 37 of the piston rod:



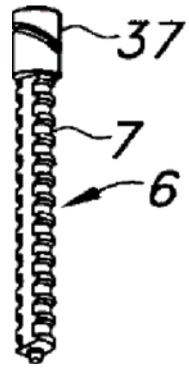
817. Specifically, "the injection button and its extension 33 is provided with an internal helical rib 36 engaging a corresponding helical groove in an enlargement 37 at the proximal end of the piston rod to form a thread connection between said button 23 and said piston rod 6." *Id.*, 7:55-67. This drive sleeve thus includes the recited internal helical rib. Moreover, as explained above, both this drive sleeve and those in Møller are releasably connected to a dose dial sleeve.

818. Thus, the combination of Møller and Steenfeldt-Jensen teaches a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread as recited in element [1.4].

<u>['008] Claim 1.5: a piston rod having a first thread and a second thread, wherein the first thread is engaged with the threaded circular opening of the insert and the second thread is engaged with the internal helical thread of the drive sleeve; and</u>

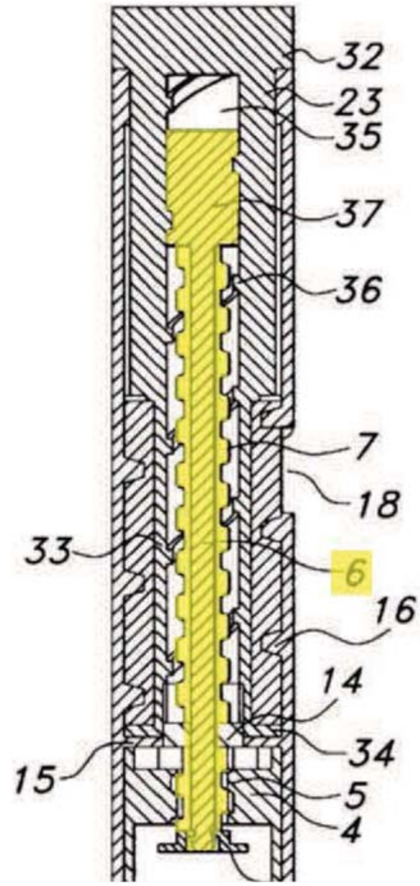
819. In my opinion, the combination of Møller and Steenfeldt-Jensen teaches the piston rod as recited in element [1.5]. Both Møller and Steenfeldt-Jensen teach the use of a piston rod that is driven forward during injection to administer a dosage of medication. See EX1015, ¶¶22-23, 30, 33; EX1014, 7:60-67, 8:25-33, FIGS. 7-8. Møller teaches piston rod 4 while Steenfeldt-Jensen teaches piston rod 6, and each of these piston rods has an external thread that engages an internal thread on the drive sleeve. *See e.g.* EX1015, ¶32, FIG. 1; EX1014, 7:6067, FIG. 7-8. This common feature of the piston rods would have further emphasized the practicability of the combination. For example, the similar interface between the drive sleeves and piston rods would have simplified the combination, since significant redesign would not be required to make Steenfeldt-Jensen's dual-threaded piston rod work with Møller's concentric sleeves.

820. Turning to the specific features of Steenfeldt-Jensen's piston rod, the thread referenced above can be seen at the top of piston rod 6 in FIG. 8:



821. Piston rod 6 has two threads. First, the piston rod has external threads 7, which engage "the internal thread of the end wall 4". EX1014, 8:45-48 Second, the piston rod has a thread at the top of piston rod 6 (the helical groove in the enlargement 37 of the piston rod) that engages the internal thread 36 of the injection button 23. *Id*., 9:60-65.

822. Annotated FIG. 7 below more clearly shows the threaded engagements with injection button 23 and internal thread 5 of wall 4:

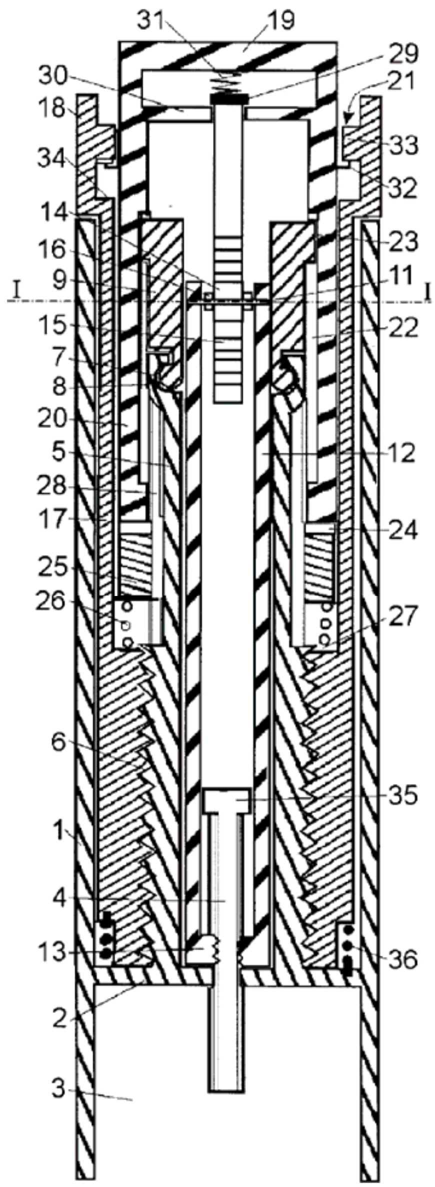


823. Thus, the combination of Møller and Steenfeldt-Jensen provides for a piston rod having a first thread and a second thread. A first thread engages with the threaded circular opening of the insert (wall 4). A second thread engages with a corresponding thread on a drive sleeve (button 23).

['008] Claim 1.6: a clutch located between the dose dial sleeve and the drive sleeve, wherein the clutch is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve.

824. Møller discloses a "cup shaped element" positioned between the dose dial sleeve and the drive sleeve. *See* EX1015, 4:45-51, 5:36-44. In my opinion, the cup shaped element of Møller as part of the combination of Møller in view of Steenfeldt-Jensen teaches a clutch located between the dose dial sleeve and the drive

sleeve, wherein the clutch is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve.



825. Møller explains that "[t]o inject a set dose the injection button is pressed by pressing on the bottom 19." EX1015, ¶32. As a result, "force is transformed and is transmitted through the connection bars 12 to the nut 13 which will press the piston rod 4 into the compartment 3 until the dose-setting drum 17 abuts the wall 2." *Id.*; *see also id.*, ¶¶28-29. The cup shaped element (*i.e.* the clutch) is disposed between the connection bars 12 and nut 13 of Møller, and dose setting drum 17. As shown in annotated FIG. 1 above, the cup shaped element is located between the dose dial sleeve and the drive sleeve, wherein the bottom is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve. Møller's second embodiment teaches an analogous component, tubular structure 120, that is structurally and operationally similar to the cup shaped element. *See id.*, ¶¶38-40, FIGS. 3-5.

826. The combination of Møller and Steenfeldt-Jensen teaches the recited clutch even under a means-plus-function construction. It is my opinion that Møller teaches a "clutch" having the structure and function of the clutch disclosed by the '008 patent.

827. The '008 patent identifies element 60 as the clutch, stating:

> The clutch 60 is generally cylindrical and is provided at a first end with a series of circumferentially directed saw teeth 66 (see FIG. 7) [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 60 there is located a radially inwardly directed flange 62. The flange 62 of the clutch 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 60 is provided with a plurality of dog teeth 65 (FIG. 8) [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.

EX1005, 8:34-47.

828. The clutch as described by the ’008 patent, therefore, is “generally cylindrical,” having a series of “circumferentially directed... teeth” at is first, i.e., needle, end, and also has a plurality of teeth at a second, i.e., button end. *Id*. The teeth on the needle end engage with the clicker, and the teeth on the button end engage with the dose dial sleeve. *Id.*, 8:21-47, 9:36-39. 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.*, 8:34-47.

829. It is my opinion that the cup shaped element and tubular element 120 of Møller have the same structure and function as the clutch of the ’008 patent. *Compare* EX1015, FIGS. 1, 5 *with* EX1005, FIGS. 6-8. 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; *see also* EX1015, ¶¶29-30 (discussing similar structure of the cup shaped element), FIG. 1. Both embodiments also include a biasing element (spring 26/126) that exerts upward force to keep the clutch engaged during dose setting. *See* EX1015, ¶¶27, 29, 39, FIGS. 3-5. 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.

830. Thus, it is my opinion that bottom 19 and tubular element 120 not only have the structure of clutch 60 of the ’008 patent, they also provide the same function because they releasably decouple components of the pen during injection.

831. Thus, the combination of Møller and Steenfeldt-Jensen teaches the clutch of element [1.6].

832. **Reason to Modify and Expectation of Success:** In my opinion, a person of ordinary skill in the relevant field of art would have had a reason to combine the teachings of Møller and Steenfeldt-Jensen. Møller and Steenfeldt-

Jensen teach injector pens that operate in a similar manner. In both Møller and Steenfeldt-Jensen, a drive sleeve rotates upward during dose setting and drives straight down during injection to administer the drug. *See* EX1015, ¶¶30-31 (describing the movement of connection bars 12 and nut 13 during dose dialing and injection); EX1014, 6:42-7:29 (describing the movement of injection button 23 during dose dialing and injection). In addition to the similar operation of their components, Møller and Steenfeldt-Jensen also seek to achieve the same goal: using a geared injection mechanism to produce a mechanical advantage.

833. In my opinion, given the similar structure, operation, and goals of each pen, a person of ordinary skill in the art would have had reason to combine their teachings to achieve those goals. In particular, I believe a person of ordinary skill in the art would have had reason to combine Møller's dose-setting approach (i.e. rotating a dose dial sleeve to rotate a drive sleeve up a piston rod) with Steenfeldt-Jensen's dose-dispensing approach (i.e. using axial movement of a drive sleeve to rotate a dual-threaded piston rod for a geared injection stroke). A person of ordinary skill would have been able to achieve this by combining Møller's concentric dose indicator, clutch, and drive sleeve with Steenfeldt-Jensen's drive sleeve, dual-threaded piston rod, and threaded piston rod holder. The similar structure and operation of their drive sleeves would have made such a combination readily workable.

834. The resulting combination would operate in the same overall manner as the existing disclosure of Møller. Specifically, the user would rotate a knob on the dose indicator that would, in turn, rotate the drive sleeve to set a dose. Pressing the injection button would then rotationally decouple the dose indicator and the drive, and the drive sleeve would then move axially without rotating, just as in Møller. The drive sleeve's dose-dispensing, however, would operate as taught by Steenfeldt-Jensen. Rather than using Møller's complicated rack-and-pinion system to provide the mechanical advantage during injection, the drive sleeve would engage a dual-threaded piston rod as taught by Steenfeldt-Jensen. The resulting rotation of the piston rod would drive the piston rod down through the threaded piston rod holder to dispense the dose, again as taught by Steenfeldt-Jensen.

835. In my opinion, a person of ordinary skill in the relevant field of art would have recognized various benefits of the combination. As noted above, both references are concerned with providing a mechanical advantage by increasing the stroke of the injection button relative to the stroke of the piston rod. A person of ordinary skill would have appreciated that Steenfeldt-Jensen makes use of simpler piston-driving mechanism and the simplification of and reduction of internal components is an advantageous and desired objective in the industry. Use of a single, dual-threaded rod to provide the mechanical advantage, rather than Møller's

complicated rack-and-pinion system, would also result in a more durable, stress-tolerant device.

836. Further, Møller itself appreciated that the piston-driving mechanism can be accomplished in different ways. Møller explains that the purpose of its piston-driving mechanism is to obtain a mechanical advantage by providing gearing between the driver and the piston rod "so that the button has a larger stroke than has the piston." EX1015, ¶6. `By such a gearing the movement of the injection button is made larger and the force, which has to be exerted on the injection button, is correspondingly reduced." *Id*. Møller appreciated various ways of achieving such gearing in the art—including, inter alia, differential threading on rotationally coupled components—but ultimately chose a mechanism involving gear wheels engaging a rack in the hopes of minimizing friction. *Id.*, ¶¶7-11. In my opinion, it would have been apparent to combine Møller and Steenfeldt-Jensen in the manner described because the dual-threaded piston rod of Steenfeldt-Jensen would provide the same type of mechanical advantage described in Møller, but by using much fewer, simpler parts.

837. In my opinion, a person of ordinary skill would have recognized these benefits and therefore had reason to combine Møller and Steenfeldt-Jensen as I explained above. Further, as I noted above, Møller and Steenfeldt-Jensen have the same overall structure and the same movement of their drive sleeves during dose-

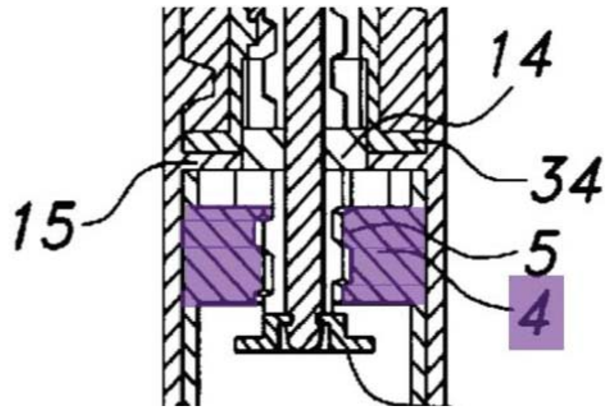
setting and dose-dispensing. *See* EX1015, ¶¶30-31; EX1014, 8:1-33. Given these structural and operational similarities, each of the combined features would have been operating in the same manner and for the same purpose as before. The proposed combination thus would have involved the use of familiar components performing their usual, predictable functions. Accordingly, it is my opinion that a person of ordinary skill would have reasonably expected to succeed in creating an injector pen as I described above.

2. Dependent claims 3, 7, 8, 11, and 17 of the '008 patent

838. It is my opinion that the combination of Møller and Steenfeldt-Jensen also renders obvious dependent claims 3, 7, 8, 11, and 17 of the '008 patent.

['008] Claim 3: The drive mechanism of claim 1, wherein the insert is secured in the housing against rotational and longitudinal motion.

839. As I explained for element [1.3], both Møller and Steenfeldt-Jensen teach the use of an insert that is secured in the housing against rotational and longitudinal motion. *See* EX1014, 5:55-57, 7:41-43; *see also* EX1015, ¶22, FIG. 1. Further, as I explained for element [1.3], the proposed combination of Møller in view of Steenfeldt-Jensen would utilize the threaded wall 4 of Steenfeldt-Jensen.



EX1014, FIG. 7.

840. This component, which constitutes an "insert" as I explained above with respect to element [1.3], is secured in the housing against rotational and longitudinal motion because it is an integral part of the housing. EX1014, 5:55-57, 7:41-47, FIG. 7. Steenfeldt-Jensen also teaches analogous threaded inserts that are provided as a separate structure that is then fixed to the housing. *See id.*, 8:34-44 (describing member 40). A person of ordinary skill would have recognized that this implementation of the threaded insert would have been interchangeable with the insert shown in FIG. 8.

841. Thus, in my opinion, the combination of Møller and Steenfeldt-Jensen teaches an insert that is secured in the housing against rotational and longitudinal motion.

['008] Claim 7: The drive mechanism of claim 1, wherein the threaded surface of the dose dial sleeve has a first lead.

842. As I explained for element [1.2], Møller teaches a dose setting drum 17/117 (i.e. a dose dial sleeve) with a threaded surface. EX1015, ¶¶25, 29. Møller

makes clear that this thread surfaces comprises a helical thread. *See id.* It was well understood that any helical thread would have a "lead," which is the linear distance traversed during one full rotation of the threaded component. Accordingly, a person of ordinary skill would have recognized that the thread surface of dose setting drum 17/117 has a first lead.

<u>['008] Claim 8: The drive mechanism of claim 7, wherein the first thread of the piston rod has a second lead.</u>

843. As I explained for element [1.5], Steenfeldt-Jensen teaches a piston rod 6 with a first thread 7. As noted above with respect to claim 8, a person of ordinary skill would have understood that the lead is a property of any threading.

844. As an initial matter, I note that claim 8 does not recite that the second lead is *different* from the first lead. Accordingly, the combination of Møller and Steenfeldt-Jensen meets the limitations of claim 8 due to their teaching of the threads referenced in claims 7 and 8, each of which has its own lead.

845. To the extent claims 7 and 8 are construed as requiring that the first and second leads be different, Steenfeldt-Jensen would nevertheless teach that feature. The difference in the leads of thread 7 on Steenfeldt-Jensen's piston rod and the helical thread on dose setting drum 17/117 of Møller would have been apparent to a person of ordinary skill in the art for several reasons. First, Steenfeldt-Jensen illustrates numerous embodiments where the lead of the piston rod's thread is different from that of the corresponding dose scale drum. *See, e.g.,* EX1014, FIGS

2, 7, 12, 16. Steenfeldt expressly describes such threading as having a "high pitch", which it notes is important for the operation of the dose scale drum, since it requires a not-self-locking engagement between it and the housing. *Id.,* 6:7-17. A thread's pitch (distance between adjacent threads) and lead (linear distance traveled for one rotation) are the same for single start threads.

846. A person of ordinary skill would have recognized that this type of high-pitch threading was also present in Møller, since it too requires a not-self-locking engagement between the dose setting drum 17 and the housing. This is because axial force must be able to drive rotation of the drum when the user presses the injection button. Indeed, Møller expressly notes the "high pitch" threading on a dose setting drum compared to the "fine pitch" on the piston rod thread in another injector pen reference. EX1015, ¶¶6-7. Given Steenfeldt-Jensen's discussion of high-pitch threading on its dose scale drum, Møller's similar need for such threading, and Møller's discussion of differential threading with respect to dose setting drums and piston rods, the combination of these references teaches the limitations of claim 8 even if interpreted as requiring different leads.

['008] Claim 11: The drive mechanism of claim 1, wherein the helical thread of the housing is an internal helical thread and the dose dial sleeve has a threaded outer surface that is engaged with the internal helical thread of the housing.

847. As I explained for element [1.1] and [1.2], Møller teaches a housing 1 with an internal helical thread 6. Møller also teaches a dose setting drum 17 that has

a threaded surface that is engaged with the internal helical thread 6 of the housing 1. *See* EX1015, ¶¶25, 29. As shown in FIG. 1 of Møller, the helical thread 6 of housing 1 is engaged with a threaded surface of the dose setting drum 17:

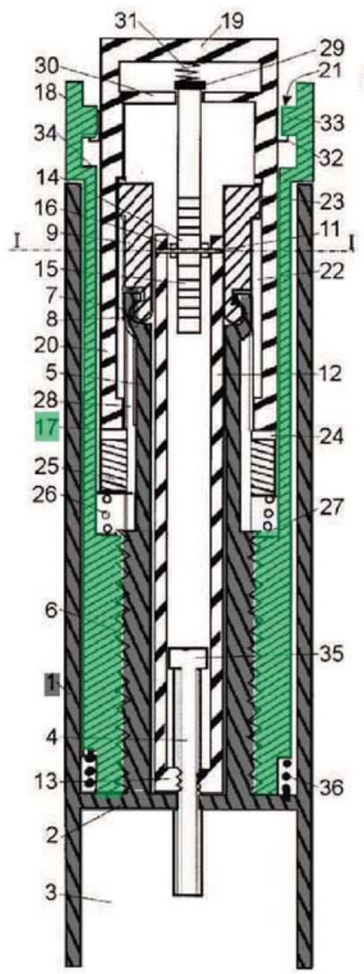


Fig. 1

848. The helical thread 6 of the housing 1 of Møller is a helical thread that is disposed internally. The helical thread 6 is engaged with a corresponding thread on the dose setting drum 17.

849. To the extent that the thread on the dose setting drum 17 is not considered to provide a threaded outer surface, it is my opinion that such feature

would have been obvious a person of ordinary skill in the relevant field of art. Steenfeldt-Jensen describes a number of pen injectors (syringes) with dose scale drums having outer helical grooves for engagement with threading on the housing. *See, e.g.,* EX1014, FIG. 8; *see also id.*, 6:7-17, 7:17-21, 8:8-12, 9:52-56, 10:40-45, 11:20-22, FIGS. 1-3, 7-8, 11-17.

850. In my opinion, a person of ordinary skill in the art would have recognized the benefit to placing a threaded engagement like that taught by Steenfeldt-Jensen on a drum and housing like that of Møller's device. Specifically, a person of ordinary skill in the art would have understood that the high-pitch threaded arrangement taught by Steenfeldt-Jensen reduces the force necessary to rotate the drum back into the housing during injection and thus reduces the overall force needed during injection. A person of ordinary skill in the art also would have recognized that providing Møller's dose setting drum with a helical groove on its outer surface, rather than its inner surface, would result in the same relative rotational movement between the drum and housing, and would not affect the overall operation of the device. A person of ordinary skill in the art also would have expected that such a configuration would not meaningfully increase the injection force needed to drive the piston rod and would essentially be interchangeable. Indeed, countless injector pens in the art provided such threading on the outer surface of their "dose dial sleeves."

851. Møller expressly contemplates the use of a high-pitch threaded engagement between the drum and the housing, but it does not place any significance on the placement of that engagement. In my opinion, a person of ordinary skill in the art would have reasonably expected that an outer helical groove threading provided on the dose setting drum would result in the same rotational function as the inner threading shown in Møller. Such implementation would have been a routine task for a person of ordinary and would have resulted in a familiar arrangement of well-known elements performing their same, predictable function.

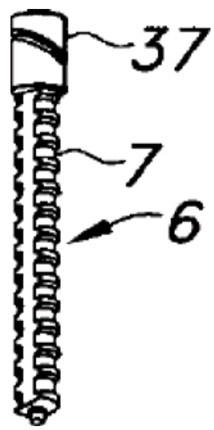
852. Thus, the combination of Møller and Steenfeldt-Jensen teaches the drive mechanism of claim 1, wherein the helical thread of the housing is an internal helical thread and the dose dial sleeve has a threaded outer surface that is engaged with the internal helical thread of the housing.

['008] Claim 17: The drive mechanism of claim 1 where the first and second threads of the piston rod are oppositely disposed.

853. As I explained for element [1.5], Steenfeldt-Jensen teaches a piston rod 6 with first and second threads. In my opinion, the combination of Møller and Steenfeldt-Jensen teaches a piston rod 6 where the first and second threads of the piston rod are oppositely disposed.

854. In my opinion, the external threads 7 of Steenfeldt-Jensen teach the first recited thread. EX1014, 8:45-48 ("The piston rod 6 engages by its external thread 7 the internal thread of the end wall 4 and is at its end in the ampoule holder terminated

by a pressure foot 9 relative to which the piston rod 6 is rotatable.”). Next, Steenfeldt-Jensen also teaches the second recited thread on an enlargement 37 of the piston rod 6.



EX1014, FIG. 8 (partial view); *see also id.*, 7:60-67 (discussing this not-self-locking thread).

855. Figure 8 shows that the two threads have opposite-handed orientations. Indeed, the threads *must* be in opposite directions in order for the piston rod to function, since rotation of the piston rod must cause the drive sleeve and insert to move in opposite directions along the rod. First, the piston rod must move up into the dose sleeve. Second, the piston rod must move away from dose sleeve and toward the cartridge to dispense medication. Thus, in my opinion, the combination of Møller and Steenfeldt-Jensen teaches the drive mechanism of claim 1 where the first and second threads of the piston rod are oppositely disposed.

S. ['069] Ground 1: Claims 2-3 are Obvious over Burroughs

856. It is my opinion that Burroughs also renders obvious dependent claims 2 and 3 of the '069 patent.

['069] Claim 2.1: The housing part of claim 1, further comprising a cartridge retaining part operatively coupled to said main housing, said cartridge retaining part comprising a fluid container, wherein said fluid container defines a medicament filled reservoir with a movable plunger at a proximal end and an outlet at a distal end, said cartridge piston movable by said piston rod to be advanced toward an outlet of said fluid container when said piston rod is moved distally;

857. As I explained above, Burroughs renders obvious the housing part of claim 1 of the '069 patent. *See supra*, ¶¶152-200.

858. Burroughs further discloses a housing part comprising a cartridge retainer 42. *See* EX1013, 9:32-41, FIGS. 1-2. This cartridge retainer 42 is "operatively coupled" to the housing 22 by permanent securement to housing parts 24 and 26. *Id.* This cartridge retainer 42 comprises a cartridge 40 defining an inner chamber 212 that serves as a "fluid container" to house a liquid medication product. *See id.*, Abstract, 2:42-44.

859. Burroughs discloses that the cartridge 40 also contains a piston 210, which is in engagement with a plunger engagement portion 206 of the leadscrew 38. *Id.*, 9:32-40. When the leadscrew 38 is advanced during dose dispensing, the plunger engagement portion 206 pushes the piston 210 toward the needle-end of the cartridge such that medicine from the inner chamber 212 is dispensed from an outlet of the

cartridge. *See id.*, 2:44-48. Accordingly, Burroughs teaches a housing part comprising a cartridge 40 that "defines a medicament filled reservoir with a movable plunger," whereby the plunger advances the piston toward an outlet at the distal end of the cartridge.

['069] Claim 2.2: wherein during a dose setting step, said dose dial grip, is rotated and moves away from said proximal end of said main housing so that a dose of a medicament contained within said medicament filled reservoir can be selected.

860. Burroughs also discloses that, at the start of the dose setting process, the user grasps the dial mechanism 34 to set the dial in the zero-dose position. *See id.*, 9:47-49, 9:59-61. Once the zero-dose position is reached, the "dial mechanism 34 may be axially retracted a predetermined distance, e.g. 3 to 5 mm, to engage the clutch mechanism. This places dial mechanism 34 into the dose-setting position." *See id.*, 10:15-18. Rotating the "dial mechanism 34 retracts from housing 22, thereby increasing the axial distance between ring 91 [*sic*, 90] and surfaces 33, 35 housing parts 24, 26." *See id.*, 10:34-42. After each unit rotation of the dial mechanism, "a single numeral appears in the lens 25 … indicating the current dose selected." *See id.*, 10:48-49. Accordingly, Burroughs teaches that "during a dose setting step," the dial mechanism 34 "is rotated and moves away from said proximal end of said main housing so that a dose of a medicament contained within said medicament filled reservoir can be selected."

['069] Claim 3: The housing part of claim 2, wherein said dose dial grip is operatively configured to said tubular clutch so that, during said dose setting step, said tubular clutch, said dose dial sleeve, and said dose dial grip rotate and move in a proximal direction in relation to said main housing.

861. As I explained above, Burroughs renders obvious the housing part of claim 1 of the '069 patent. *See supra*, ¶¶857-61.

862. Burroughs also discloses a housing part comprising a dial mechanism 34 (dose dial sleeve) with a proximal portion 78 (dose dial grip) that serves as a knob or grip for the user to manipulate the dial mechanism. *See* EX1013, 8:2-8, 10:38-42, FIGS. 1-2. The housing part further comprises a button 32 (tubular clutch) which acts as a clutch mechanism to rotationally decouple the dial mechanism from the housing and the nut during injection. *Id.* 11:5-12, FIGS. 1-2.

863. During the dose setting step, the user grasps and rotates the proximal portion 78 of the dial mechanism 34. *See id.* 9:47-54. To commence the dosing process, the user rotates the dial mechanism 34 to its "zero-dose position," which aligns threads 110, 112 on the dial mechanism with openings 162, 163 on the housing. *See id.*, 8:63-91, 10:31-34. Once the "zero position" is set, the dial mechanism 34 is axially retracted and, threads 110, 112 are forced into and engage into the helical groove 158 by distal button surface 57. *See id.*, 11:3-4. The user is now able to rotate the dial mechanism 34 to set a dose as "threads 110, 112 move within housing groove 158 in the proximal [*i.e.*, button-end] direction," increasing the distance between the dial mechanism's knob-end and the end of the housing. *See*

id., 10:34-38. Since the proximal portion 78 of the dial mechanism 34 abuts and surrounds the end 68 of the button 32 with the forced wedge fit of button surface 57 under the threads 110 and 112, turning the dial mechanism 34 while setting the dose also causes the button 32 to rotate and move in a proximal direction in relation to the main housing 22. *See id.*, FIG. 1., 7:47-58. Thus, the proximal portion 78 of the dial mechanism 34 is "operatively configured" with the button 32, such that during the dose setting step the dial mechanism 34 including its proximal portion 78 and button 32 rotate and move in a proximal direction in relation to the main housing.

IX. Concluding Statements

864. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross-examination in this case and that cross-examination will take place within the United States. If cross-examination is required of me, I will appear for cross-examination within the United States during the time allotted for cross-examination.

865. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: May 1, 2019 By: ______________________

Charles E. Clemens

X. APPENDIX - LIST OF EXHIBITS

Exhibit No.	Description
1001	U.S. Patent 8,679,069, *Pen-Type Injector* (issued Mar. 25, 2014)
1002	U.S. Patent 8,603,044, *Pen-Type Injector* (issued Dec. 10, 2013)
1003	U.S. Patent 8,992,486, *Pen-Type Injector* (issued Mar. 31, 2015)
1004	U.S. Patent 9,526,844, *Pen-Type Injector* (issued Dec. 27, 2016)
1005	U.S. Patent 9,604,008, *Drive Mechanisms Suitable for Use in Drug Delivery Devices* (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
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. Steenfeldt-Jensen & S. Hansen, "Injection Syringe" (issued May 22, 2001)
1015	U.S. Patent Application US 2002/0053578 A1 — C.S. Møller, "Injection Device" (pub'd May 2, 2002)
1016	U.S. Patent 6,932,794 B2 — L. Giambattista & A. Bendek, "Medication Delivery Pen" (issued Aug. 23, 2005)
1017	U.S. Patent 6,582,404 B1 — P.C. Klitgaard et al., "Dose Setting Limiter" (issued June 24, 2003)

Exhibit No.	Description
1019	Plaintiffs' Preliminary Claim Constructions and Preliminary Identification of Supporting Intrinsic and Extrinsic Evidence, *Sanofi-Aventis U.S. LLC v. Mylan GmbH*, No. 2:17-cv-09105 (D.N.J.) (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 Supporting Evidence Pursuant to L. Pat. R. 4.2, *Sanofi-Aventis U.S., LLC v. Mylan N.V.*, C.A. No. 17-cv-09105 (Sep. 5, 2018)

Exhibit No.	Description
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., “*An Injection Device, A Preassembled Dose Setting And Injection Mechanism For An Injection Device, And A Method Of Assembling An Injection Device*” (pub’d Nov. 8, 2001)