

Mylan Pharmaceuticals Inc. v. Sanofi-Aventis Deutschland GmbH

IPR2018-01670 (U.S. 8,679,069)

IPR2018-01675 (U.S. 8,603,044)

IPR2018-01676 (U.S. 8,603,044)

IPR2018-01678 (U.S. 8,992,486)

IPR2019-00122 (U.S. 8,992,486)

IPR2018-01684 (U.S. 9,604,008)

Oral Hearing
January 15, 2020

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

069, 044, 486 Patents: Challenged Independent Claims

069 Patent, claim 1	044 Patent, claim 11	486 Patent, claim 1
A housing part for a medication dispensing apparatus, said housing part comprising:	A housing part for a medication dispensing apparatus, said housing part comprising:	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 main housing, said main housing extending from a distal end to a proximal end;	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, <u>said helical groove provided along an outer surface of said dose dial sleeve;</u>	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>said helical groove provided along an outer surface of said dose dial sleeve;</u>	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 dial grip disposed near a proximal end of said dose dial sleeve;	a dose dial grip disposed near a proximal end of said dose dial sleeve;	a <u>dose knob</u> 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 piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;	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 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 <u>driver</u> extending along a portion of said piston rod, said <u>driver</u> comprising an internal threading near a distal portion of said <u>driver</u> , 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,	a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,	a tubular clutch located adjacent a distal end of said <u>dose knob</u> , said tubular clutch operatively coupled to said <u>dose knob</u> ,
wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.	wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch, <u>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.</u>	wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

008 Patent: Challenged Independent Claim

008 Patent, claim 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 threaded 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.

Claimed Invention of Challenged Patents

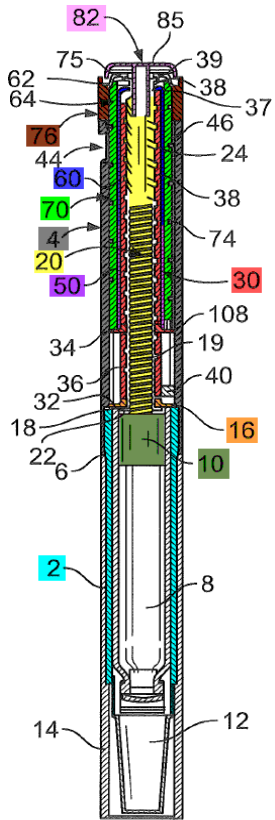
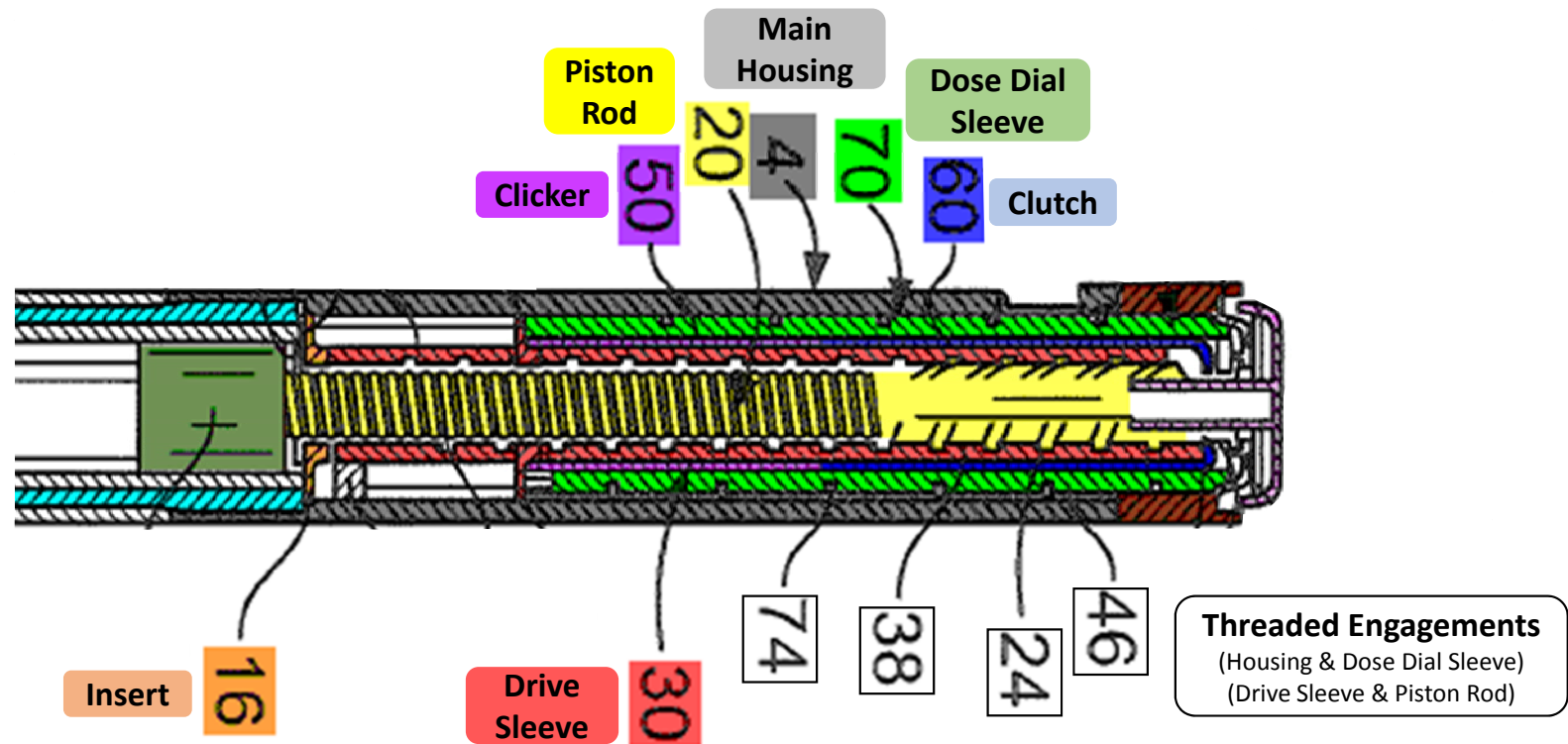


FIG. 1



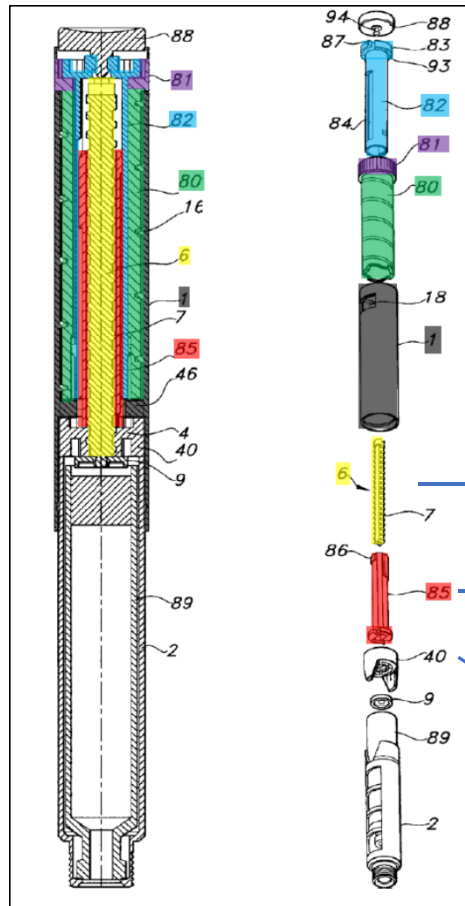
-1676 POR at 6-12; see also -1670 POR at 58-59; -1678 POR at 4-9

- 1. Obviousness Ground: Steinfeldt-Jensen's 5th Embodiment**
2. Obviousness Ground: Møller + Steinfeldt-Jensen's 5th Embodiment
3. Obviousness Ground: Møller + Steinfeldt-Jensen's 2nd Embodiment
4. Obviousness Ground: Burroughs
5. Objective Indicia of Nonobviousness

Obviousness: Steinfeldt-Jensen's 5th Embodiment

IPR, Ground	Challenged Claims
-01670, Ground 2	069 Claim 1
-01676, Ground 1	044 Claims 11, 14, 15, 18, 19
-01678, Ground 1	486 Claims 1-6, 12-18, 20, 23, 26-30, 32, 33, 36, 38, 40

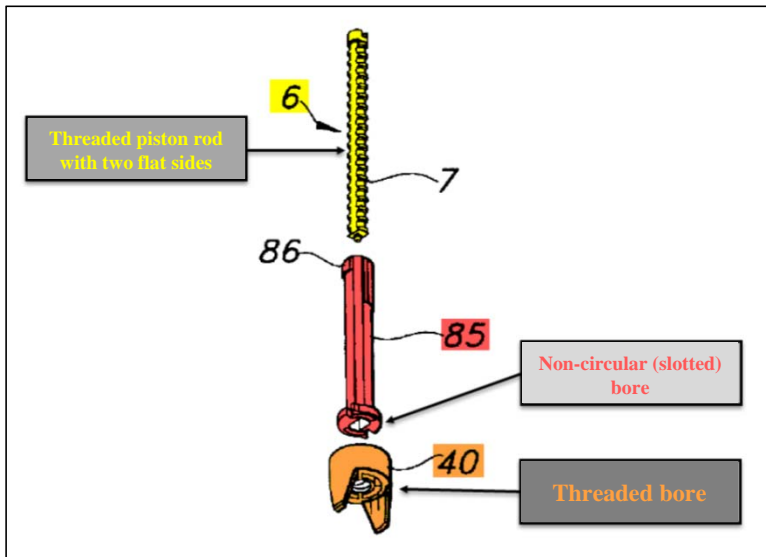
Steenfeldt-Jensen's 5th Embodiment



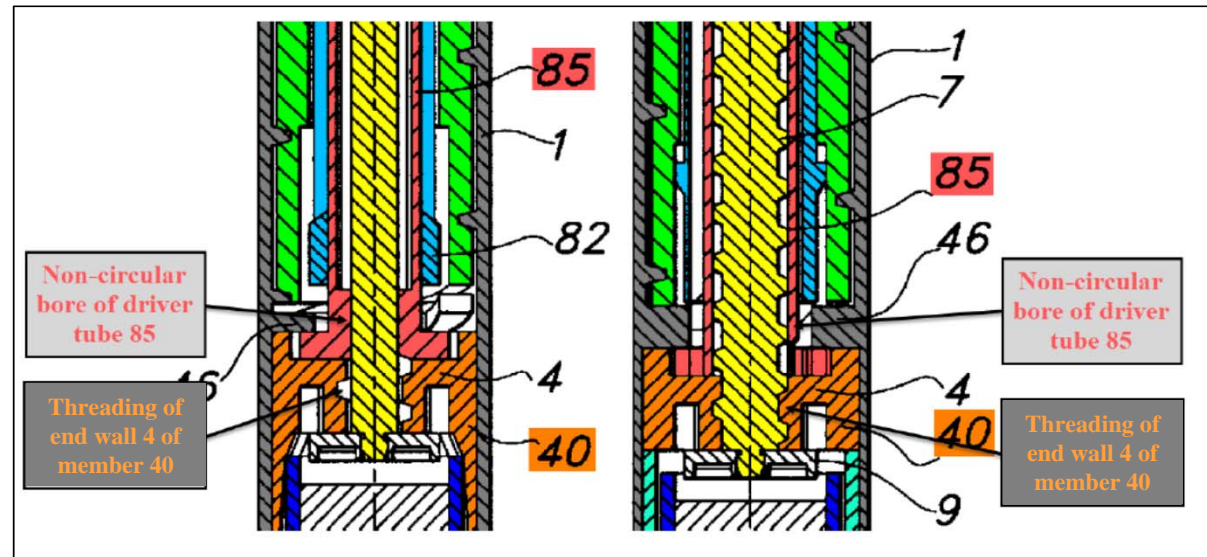
- Piston rod (6) with thread and non-circular cross-section
- Driver tube (85) with non-circular slot
- Member (40) threaded to piston rod

Missing Limitation from Steenfheldt-Jensen's 5th Embodiment

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**



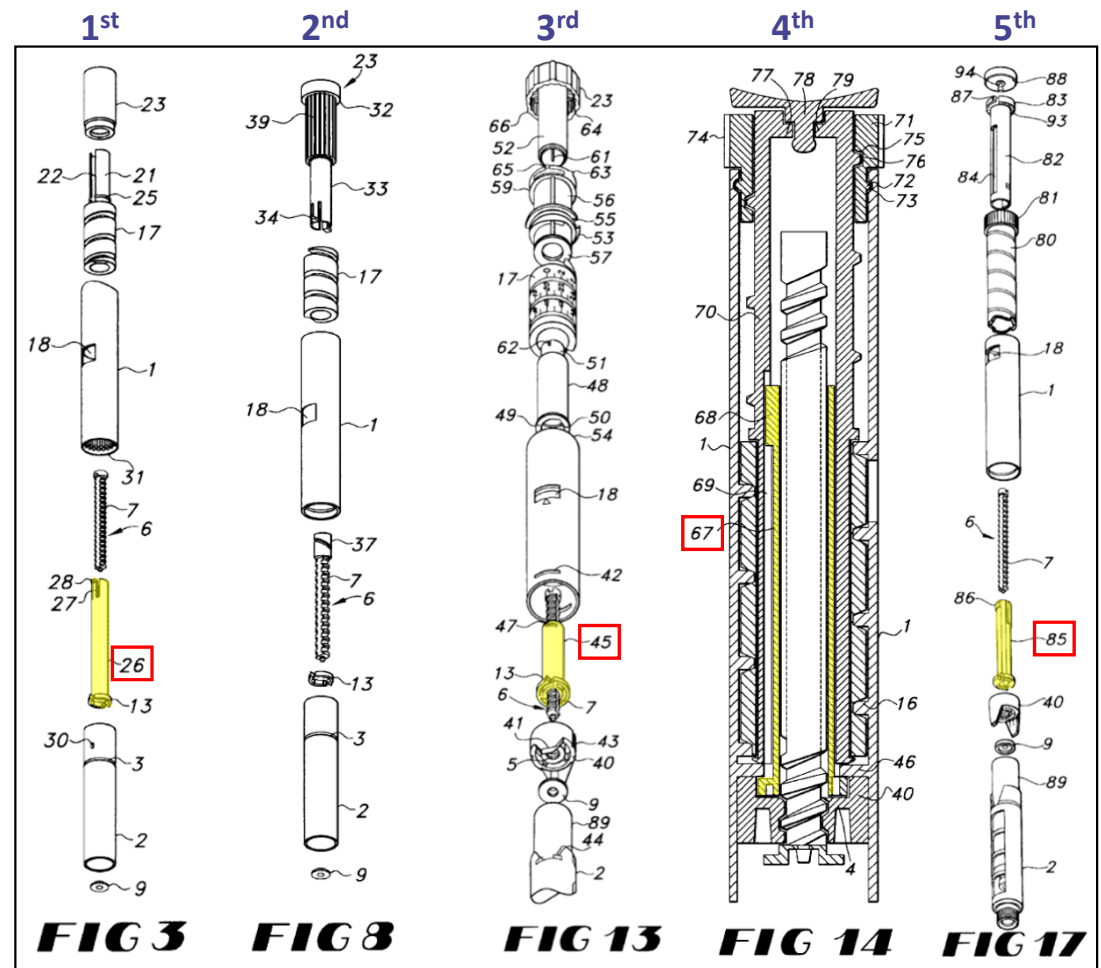
Ex. 1014 (Steenfeldt-Jensen), Fig. 17



Ex. 1014 (Steenfeldt-Jensen), Figs. 15 and 16

Steenfeldt-Jensen's Five Embodiments

- Embodiments 1, 3, 4, and 5 include a driver tube
- None includes a driver tube with internal threads



-1676 POR 14-15; 1676 PO Sur-reply at 1; see also -1670 POR at 10-11; -1676 PO Sur-Reply at 7; -1678 POR at 15-16; -1678 PO Sur-Reply at 1

Premise Of Petitioner's Proposed Modification

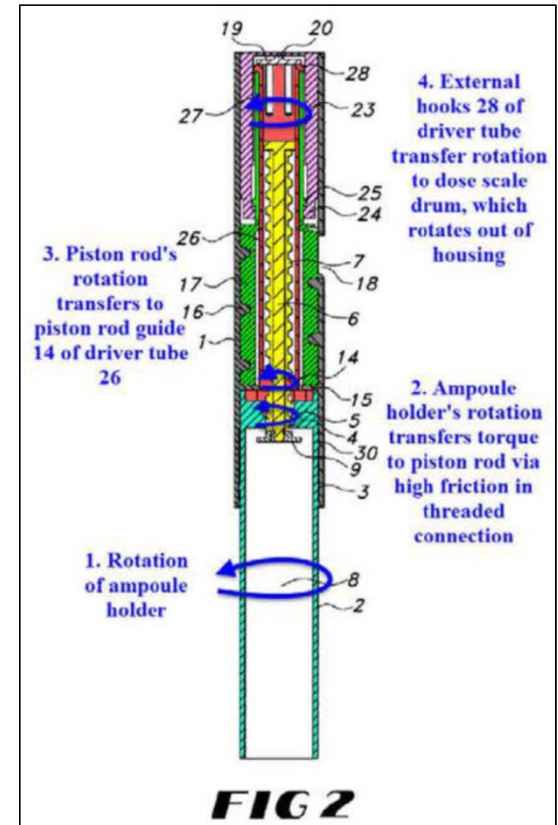
¶276. Thus, given Steinfeldt-Jensen's suggestion that the "nut element" could be on the driver tube, and the "piston rod guide" could be on the member, a POSA would have reason to modify (1) driver tube 85 to include internal threading for engaging the piston rod's external threading, and (2) member 40 to include a non-circular cross-section for axially guiding the piston rod. EX1011, ¶277. In this case, a POSA would have considered the driver tube to be a component for driving the piston rod having internal threading near its distal portion for engaging external threading of the piston rod. EX1011, ¶277.

A POSA also would have reasonably expected such modification would have resulted in the device operating in the same manner. EX1011, ¶278. In this

Steenfeldt-Jensen at 7:41-47

In the shown embodiment the end wall **4** with its threaded bore forms a nut member relative to which the piston rod is rotated by the piston rod guide **14** and the driver tube **26**. 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.

First Embodiment

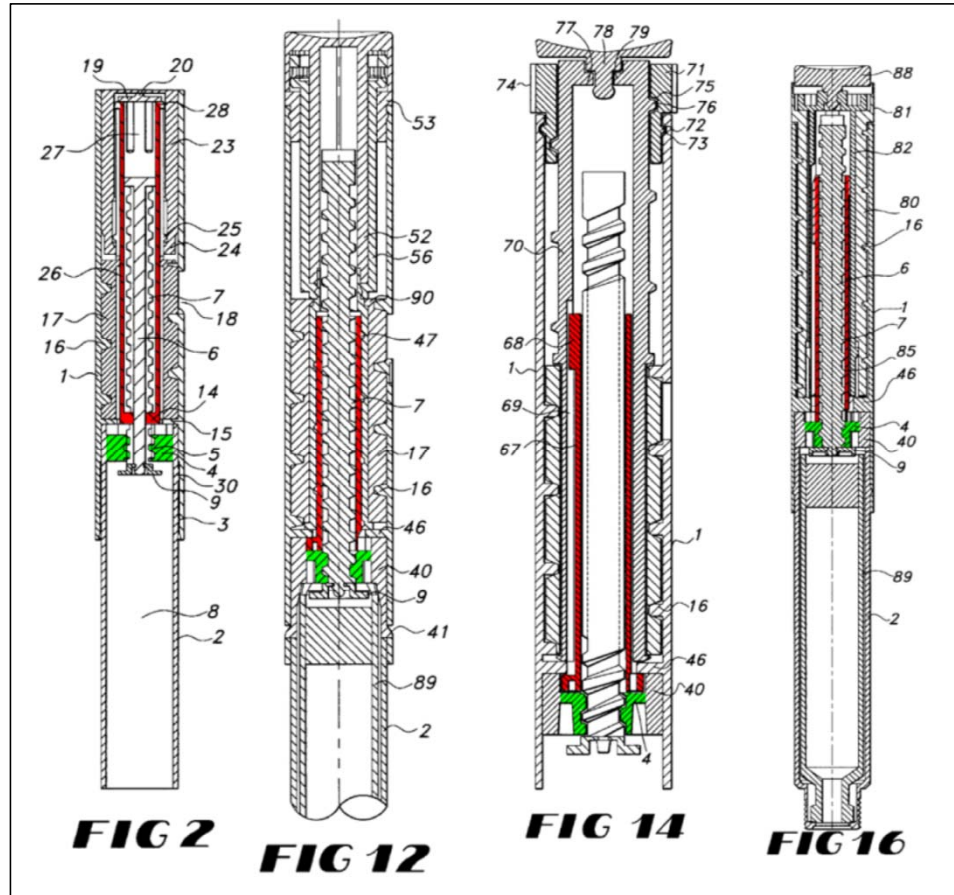


-01676 POR at 35; Ex. 2107 at ¶ 44

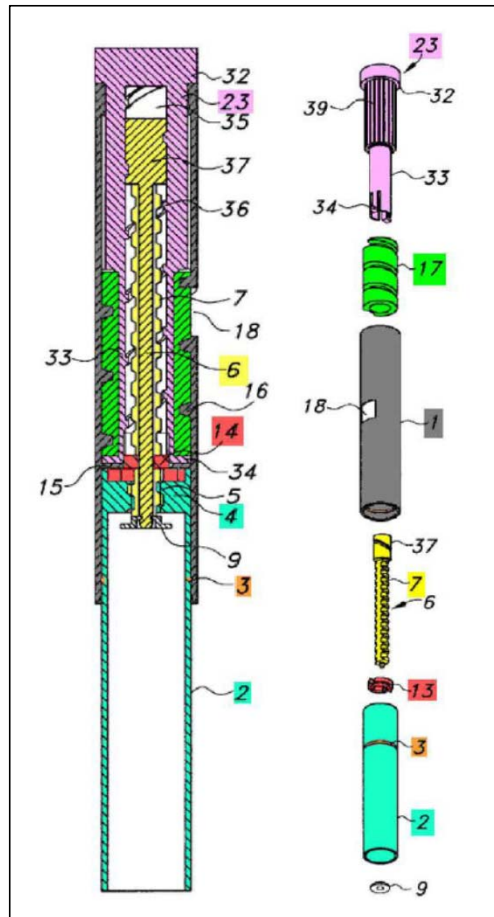
Steenfeldt-Jensen's Nut Element Is Distinct From The Driver Tube

Driver Tube

Nut Element



The Passage Cited By Petitioner Is Not Generally Applicable



Ex. 2107 at ¶ 140

Slocum Declaration

226. A POSA would have understood that this passage does not provide a general teaching having applicability to all of Steinfeldt-Jensen's embodiments. For example, with respect to Steinfeldt-Jensen's second embodiment, if a "piston rod guide" is provided in wall 4 and a nut member is provided in pawl wheel 13, then the pen injector of the second embodiment would not work. Specifically, a user would be able to dial a dose but not dispense one. This is because the threads from wall 4 are self-locking and now the piston rod 6 must move axially through piston rod guide in the ampoule holder wall, whereas in the depicted embodiment it screws through wall 4. See Ex. 2149 (showing a fair representation of

Ex. 2107 at ¶ 226

Steenfeldt-Jensen at 2:40-53

This is obtained by an-injection syringes for apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses, comprising

- a housing
- a piston rod having a not circular cross-section and an outer thread
- a piston rod drive comprising two elements
 - a) a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable, and
 - b) a **nut member which is rotatable** but not axially displaceable in the housing and which has an inner thread mating the thread of the piston rod to form a self locking thread connection,

Steenfeldt-Jensen at 3:15-20

When the injection button is pressed the movement of this button is transformed into a rotation of the piston rod (or the nut member) relative to the nut member (or the piston rod). When the button is pressed hard enough the initial reluctance is overcome so that the two elements, the piston rod and the nut member, are rotated relative to each other.

Steenfeldt-Jensen at 3:44-47

housing. In this case the dose scale drum must be coupled to a driver rotating the piston rod (or the nut member) relative to the nut member (or the piston rod) when the injection button is pressed.

Premise Of Petitioner's Proposed Modification

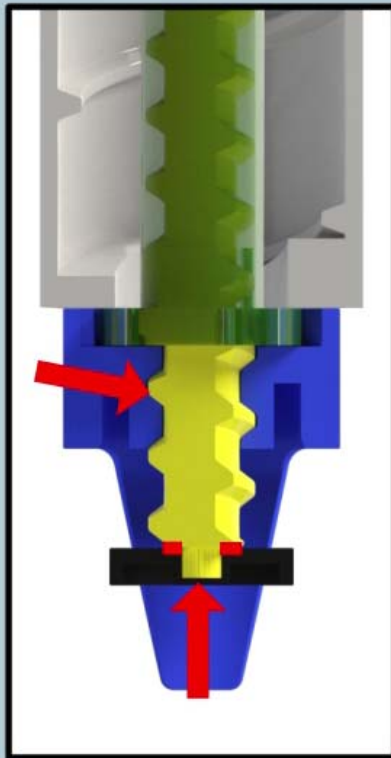
¶276. Thus, given Steinfeldt-Jensen's suggestion that the "nut element" could be on the driver tube, and the "piston rod guide" could be on the member, a POSA would have reason to modify (1) driver tube 85 to include internal threading for engaging the piston rod's external threading, and (2) member 40 to include a non-circular cross-section for axially guiding the piston rod. EX1011, ¶277. In this case, a POSA would have considered the driver tube to be a component for driving the piston rod having internal threading near its distal portion for engaging external threading of the piston rod. EX1011, ¶277.

A POSA also would have reasonably expected such modification would have resulted in the device operating in the same manner. EX1011, ¶278.

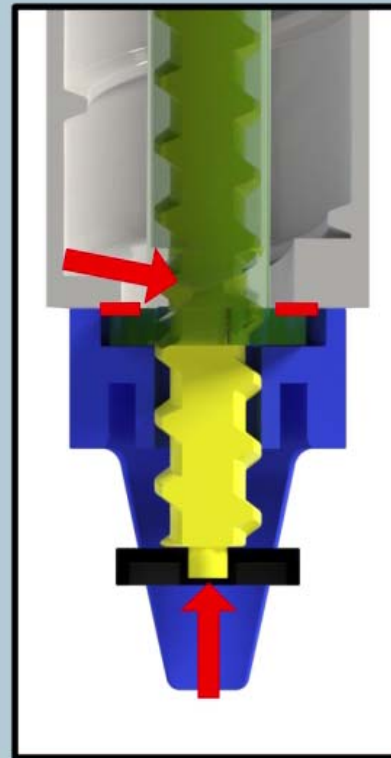
Petitioner's Modification Fundamentally Alters The Operation

Embodiment 5 in Steinfeldt-Jensen

Petitioner's "Alternative" Arrangement



Dose Injection

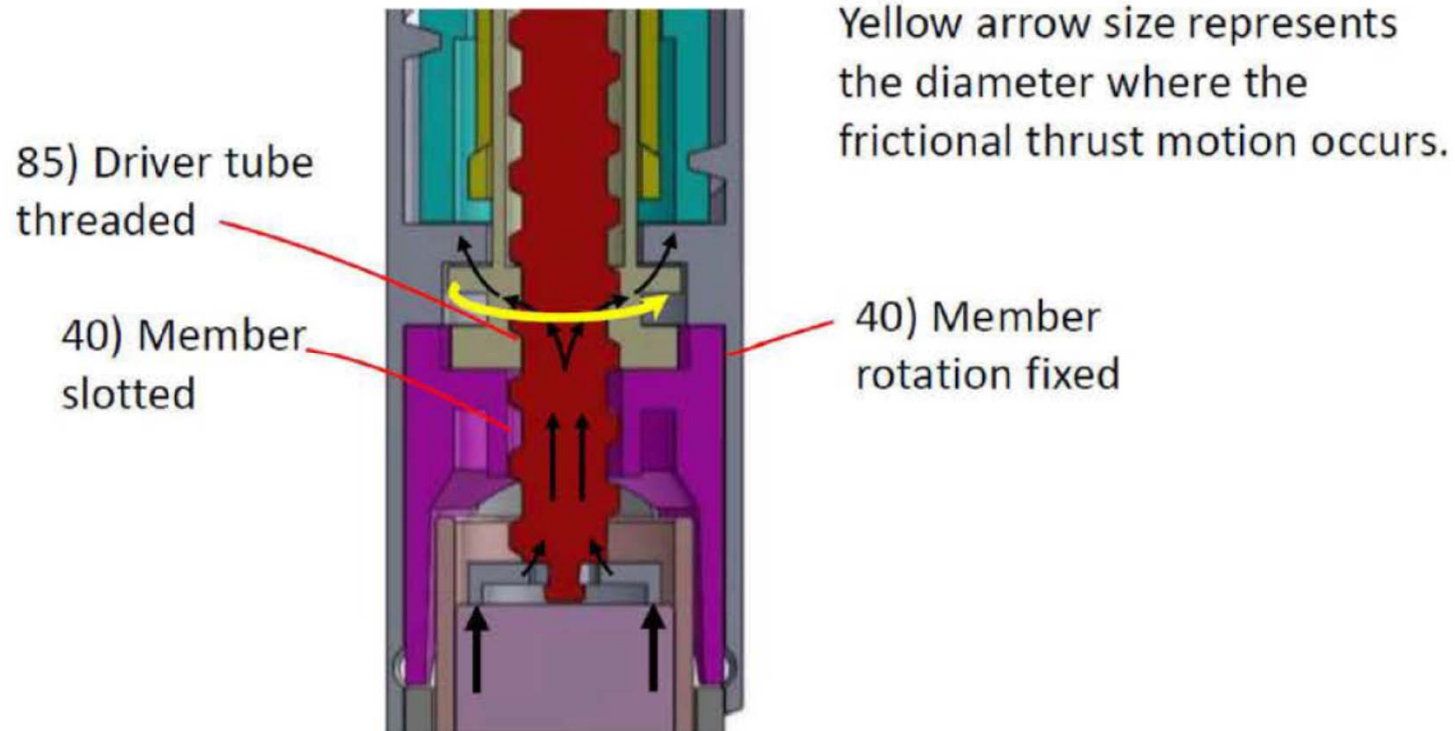


Force From Cartridge Piston

Force From Cartridge Piston

Petitioner's Modification Fundamentally Alters The Operation

Petitioner's Modified Embodiment 5



Dr. Slocum's Analytical Model

Screwthread Analysis.xls			
To determine forces and torques in Steinfeldt-Jensen pen injector			
By Alex Slocum, 6/20/2019			
Enter numbers in BOLD , results in RED			
(Be consistent with units! (in, lb or N, m or N, mm))			
Stage 1: User applies force to button creating torque input to actuate threaded piston rod			
User thumb force input	10	Fuser	N
Thread to be backdriven to create rotation			
Pitch diameter	12.0	Dpbd	mm
Root diameter	11.5	Dbr	mm
Lead (distance traveled with one complete rotation)	11.0	Leadbd	mm
Reference: Helix angle (degrees, radians)	16.3	0.284	
Flank angle alpha, cos(alpha)	6	0.995	cos(alpha)/degrees
Friction properties of backdriven thread			
Coefficient of friction between backdriven screw threads	0.1	mu/bd	
Actual Beta	1.09	beta/bd	
Actual screwthread efficiency (Slocum PMD page 709 Eq. 10.3.18)	72%	eta/bd	
Reference: efficiency for lowering a load (-100% if backdrivable)	197%	eta/L	

Resulting ampoule piston force			
<i>With spline and without rotating thrust surface (e.g., Steinfeldt-Jensen 5th Embodiment)</i>			
Ampoule piston force (output)	13.4	Finwtb	N
Amplification of user thumb force (Force user pushes/resulting ampoule piston force)	134%	Awtb	
Ideal amplification based only on thread pitch ratio	276%		
<i>With spline and rotating thrust surface (i.e., Steinfeldt-Jensen's 5th as Modified by Petitioner)</i>			
Ampoule piston force (output)	8.9	Finfb	N
Amplification of user thumb force (Force user pushes/resulting ampoule piston force)	89%	Atb	
Percent increase in injection force for modified 5th embodiment	51%		

Resulting ampoule piston force			
<i>With spline and without rotating thrust surface (e.g., Steinfeldt-Jensen 5th Embodiment)</i>			
Ampoule piston force (output)	13.4	Finwtb	N
Amplification of user thumb force (Force user pushes/resulting ampoule piston force)	134%	Awtb	
Ideal amplification based only on thread pitch ratio	276%		
<i>With spline and rotating thrust surface (i.e., Steinfeldt-Jensen's 5th as Modified by Petitioner)</i>			
Ampoule piston force (output)	8.9	Finfb	N
Amplification of user thumb force (Force user pushes/resulting ampoule piston force)	89%	Atb	
Percent increase in injection force for modified 5th embodiment	51%		
Leadscrew stresses and buckling load			
Length	30.0	Lpr	
Material	Detrin		
Young's Modulus	2800	Epr	Mi/s
Yield stress	69	sigma_maxpr	Mi/s
Root diameter area for full round shaft	8.55	A_dpr	mm^2
Root diameter area for shaft with flats	7.66	A_dprwf	mm^2
Twist for full round shaft	11.64	lprpr	mm^4
Twist for shaft with flats	9.58	lprprwf	mm^4
Buckle for full round shaft	5.82	Ipr	mm^4
Buckle for shaft with flats	3.93	Iprwf	mm^4

Injection Force Is An Important Design Consideration

Slocum Declaration

the diabetic population by the circumstances of their condition. Consideration of human factors is particularly relevant for pen injectors, since diabetic patients will have a large role in self-management of their disease and often self-administer insulin with the pen injector. Moreover, because insulin injections are often seen as inconvenient, painful, and/or traumatic for some patients, it can be critical to a patient's health that the pen injector is simple and easy to use; a pen injector that is too difficult presents another barrier to enabling patients to control and self-manage their disease, rather than being a tool with which patients can take care of themselves. *See, e.g.*, Ex. 2175 at 2, Ex. 2113 at 6, 10; Ex. 2135 at 7; Ex. 2111 at ¶ 14.

Ex. 2107 at ¶ 44

Injection Force Is An Important Design Consideration

Leinsing Apr. 3 2019 Deposition

17 Q. Trigger finger?

18 MR. TORCZON: Same objections.

19 A. Well, I think that's the index finger,
20 probably either weakness or strength thereof. And
21 we designed the pen so you can have very reduced
22 force of injection, because diabetic patients
23 typically don't have the strength to inject the
24 medicine like a patient without diabetes. So
25 there's a lot of focus in pen injectors to reduce
1 the force of injection.

2 Q. So you would agree, then, that reducing
3 the force of an injection is an important
4 consideration in injection design?

5 A. Yes.

Ex. 2163 at 80:17-81:5

Slocum Declaration

56. In terms of highly important design objectives for an insulin pen injector, many articles and studies highlight the importance and desirability of low injection force. See Ex. 2100 at 1-2, 5; Ex. 2144 at 5, 9; Ex. 2175 at 3 (noting that

Ex. 2107 at ¶ 56

044 Patent at 1:25-35

Such injectors have application where regular injection by persons without formal medical training occurs. This is increasingly common amongst those having diabetes where self-treatment enables such persons to conduct effective management of their diabetes.

These circumstances set a number of requirements for pen-type injectors of this kind. The injector must be robust in construction, yet easy to use both in terms of the manipulation of the parts and understanding by a user of its operation. In the case of those with diabetes, many users will be physically infirm and may also have impaired vision.

Injection Force Is Highly Relevant to Steinfeldt-Jensen

Steenfeldt-Jensen at 1:12-17

The invention relates to injection syringes of the kind apportioning set doses of a medicine from a cartridge containing an amount of medicine sufficient for the preparation of a number of therapeutic doses.

Such syringes are mainly made for users who have to inject themselves frequently, e. g. diabetics.

Injection Force Is Highly Relevant to Steinfeldt-Jensen

Leinsing D.N.J. Cross-Examination

Q. Okay. And specifically with respect to the FlexPen®, which lines up with Steinfeldt-Jensen's fifth embodiment, there were problems since day one of the FlexPen® having high injection force, right?

A. They did have a high injection force relative to some other pens, yes.

Ex. 2227 at 338:6-11

Leinsing D.N.J. Cross-Examination

"QUESTION: How does the next generation FlexPen® differ from the original FlexPen®?

"So I know some of those changes, like I said, when they went from the original to the final one, there might be some changes that are blurred in there, but the big change I know about for the Next Generation is the pen they flipped where the post and where their bore was on the pen and created a pivot bearing up near the button to reduce the friction."

"There were problems since day one of FlexPen® having high injection force. I mentioned that other journal that documented that, I think, in 2006. They made a design change. They went through a huge design process, and they flipped that button around."

Ex. 2227 at 338:23-339:10

Plutzner, Prefilled Insulin Device with Reduced Injection Force...

Conclusion

The modifications made to NGFP have resulted in a significant 30% reduction in injection force compared with FP. These changes have contributed to NGFP being considered more 'simple and comfortable' to use by patients. Importantly, the dose accuracy of NGFP is at least as good as FP, and our study suggests that NGFP may actually be significantly more accurate and precise than FP – deviation from set doses and the variance in the delivered dose were small with both pens but smallest with NGFP. Although the NGFP has not been tested in everyday use, this study suggests that the changes made are likely to enhance patient comfort and aid accurate insulin dosing.

Ex. 2175 at .005

Injection Force Is An Important Design Consideration

van der Burg, *Injection Force of SoloStar Compared...*

Injection force is a particularly important practical aspect of therapy for patients with type 1 or 2 diabetes, especially for those who have dexterity problems; these patients may have limited ability to self-inject insulin.⁴⁻⁷

Ex. 2100 at .002
[-01676 POR at 35 (citing Ex. 2107 at ¶ 56-57)]

Møller

[0005] This development is not quite favourable, as especially users having reduced finger strength have their difficulties in pressing the injection button, a problem that is further increased when still thinner needles are used to reduce the pain by injection. Also with quite small movements of the button it is difficult to feel whether the button is moved at all and by injection of one unit from a 3 ml ampoule the piston and consequently the injection button has to be moved only about 0,1 mm.

[0006] Consequently a wish for a gearing between the injection button and the piston has occurred so that the button has a larger stroke than has the piston. 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.

Ex. 1015 at [0005]-[0006]
[-01676 POR at 25, 58 (citing Ex. 2107 at ¶ 289)]

See also -1670 POR at 33; -1678 POR at 35, 57

Agenda

1. Obviousness Ground: Steinfeldt-Jensen's 5th Embodiment
2. **Obviousness Ground: Møller + Steinfeldt-Jensen's 5th Embodiment**
3. Obviousness Ground: Møller + Steinfeldt-Jensen's 2nd Embodiment
4. Obviousness Ground: Burroughs
5. Objective Indicia of Nonobviousness

IPR, Ground	Challenged Claims
-01670, Ground 3	069 Claim 1
-01676, Ground 2	044 Claims 11, 14, 15, 18, 19
-01678, Ground 2	486 Claims 1-6, 12-18, 20, 23, 26-30, 32, 33, 36, 38, 40

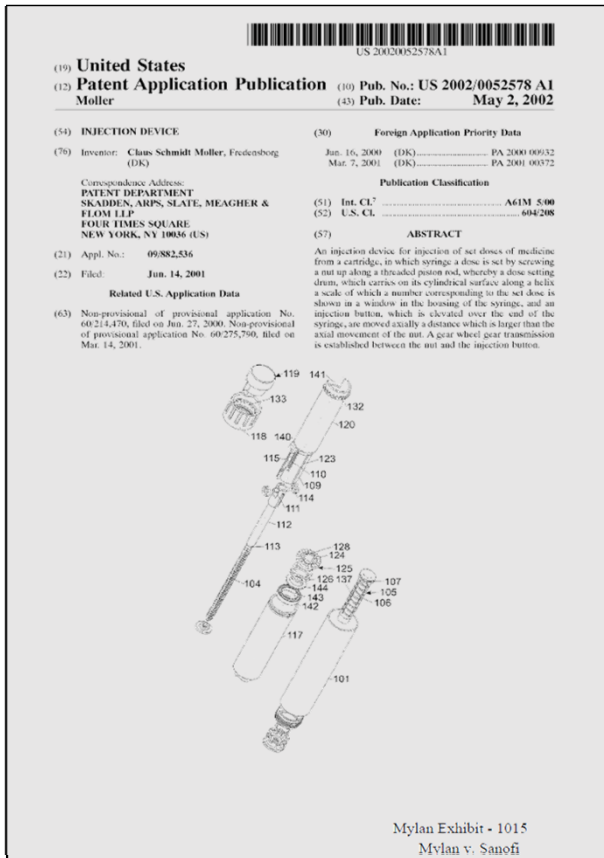
069, 044, 486 Patents: Challenged Independent Claims

069 Patent, claim 1	044 Patent, claim 11	486 Patent, claim 1
A housing part for a medication dispensing apparatus, said housing part comprising:	A housing part for a medication dispensing apparatus, said housing part comprising:	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 main housing, said main housing extending from a distal end to a proximal end;	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 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 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 dial grip disposed near a proximal end of said dose dial sleeve;	a dose dial grip disposed near a proximal end of said dose dial sleeve;	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 piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;	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 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 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 dial grip, said tubular clutch operatively coupled to said dose dial grip,	a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,	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.	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.	wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

1. Overview

2. Dose Dial Sleeve With an Outer Groove (069 Patent, 044 Patent, and 486 Claim 4)
3. Dose Dial Sleeve with a Threaded Engagement to a “Main Housing” (486 Patent)
4. Drive Sleeve (069 Patent, 044 Patent), or a Driver Comprising a Cylindrical Shape (486 Claim 5)
5. Clicker Comprising at Least One Flexible Arm and at Least One Spline (044 Claim 15, 486 Claims 18 & 20)

Møller's Primary Objective Is to Reduce Injection Force



Ex. 1015 (Møller)

Møller

[0005] This development is not quite favourable, as especially users having reduced finger strength have their difficulties in pressing the injection button, a problem that is further increased when still thinner needles are used to reduce the pain by injection. Also with quite small movements of the button it is difficult to feel whether the button is moved at all and by injection of one unit from a 3 ml ampoule the piston and consequently the injection button has to be moved only about 0,1 mm.

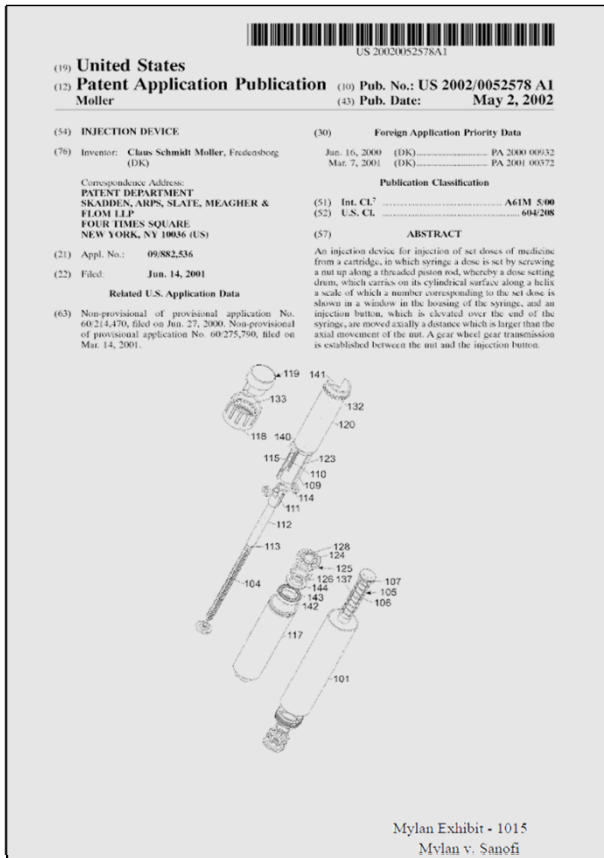
Ex. 1015 at ¶ 0005

Møller

[0006] Consequently a wish for a gearing between the injection button and the piston has occurred so that the button has a larger stroke than has the piston. 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.

Ex. 1015 at ¶ 0006

Møller's Primary Objective Is to Reduce Injection Force



Ex. 1015 (Møller)

Møller

[0008] A similar gearing is provided in WO 99/38554 wherein the thread with the 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. However, by this kind of gearing relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces. Therefore a traditional gearing using mutual engaging gear wheels and racks is preferred.

Ex. 1015 at ¶ 0008

Møller

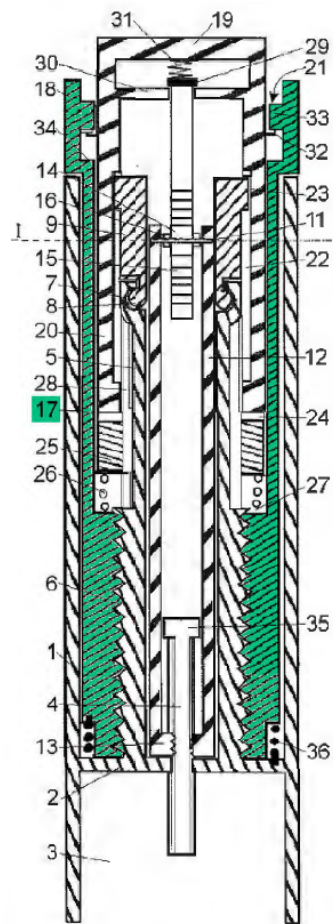
[0011] It is an objective of the invention to provide an injection device, which combines the advantages of the devices according to the prior art without adopting their disadvantages and to provide a device wherein is established a direct gearing, i.e. a gearing by which more transformations of rotational movement to linear movement and linear movement to rotational movement are avoided, between the injection button and the piston rod.

Ex. 1015 at ¶ 0011

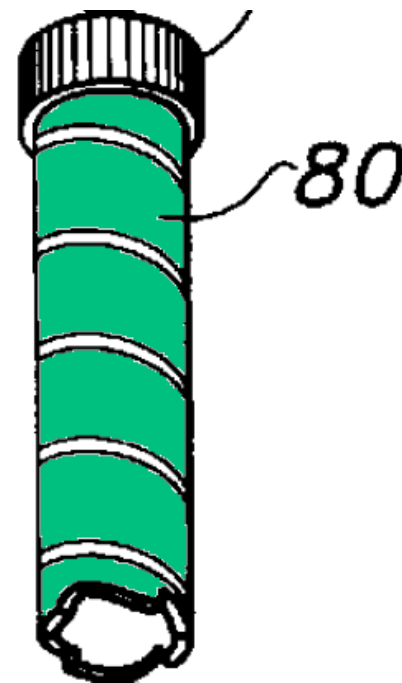
1. Overview
2. **Dose Dial Sleeve With an Outer Groove (069 Patent, 044 Patent, and 486 Claim 4)**
3. Dose Dial Sleeve with a Threaded Engagement to a “Main Housing” (486 Patent)
4. Drive Sleeve (069 Patent, 044 Patent), or a Driver Comprising a Cylindrical Shape (486 Claim 5)
5. Clicker Comprising at Least One Flexible Arm and at Least One Spline (044 Claim 15, 486 Claims 18 & 20)

Petitioner's Proposed Modification to Møller

- Petitioner proposes exchanging Moller's internal threads for Steenfeldt-Jensen's external grooves
- Petitioner argues that Steenfeldt-Jensen's high-pitched threads will have less friction

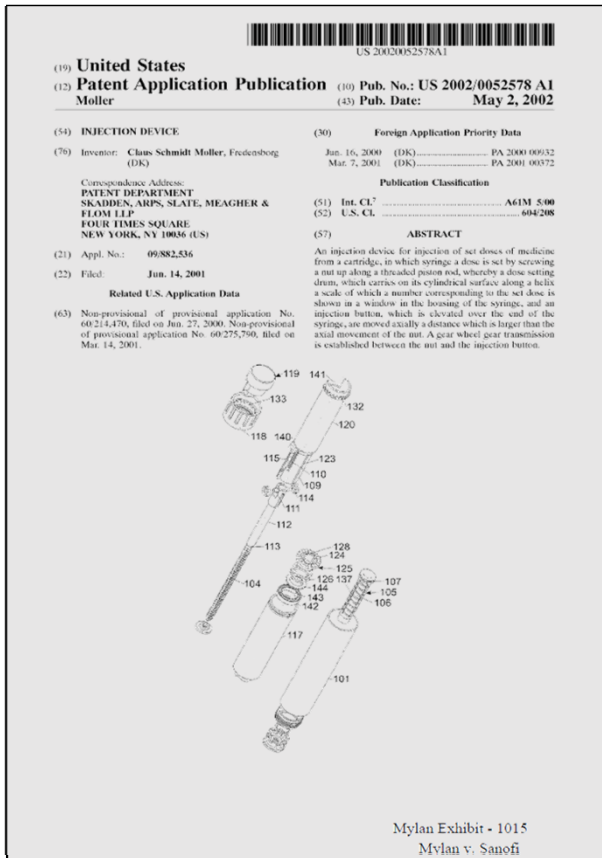


Ex. 1015 (Møller), Fig. 1



Ex. 1014 (Steenfeldt-Jensen), Fig. 17

Møller Teaches Away From Steinfeldt-Jensen's Dose Scale Drum



Ex. 1015 (Møller)

Møller

[0008] A similar gearing is provided in WO 99/38554 wherein the thread with the 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. However, by this kind of gearing relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces. Therefore a traditional gearing using mutual engaging gear wheels and racks is preferred.

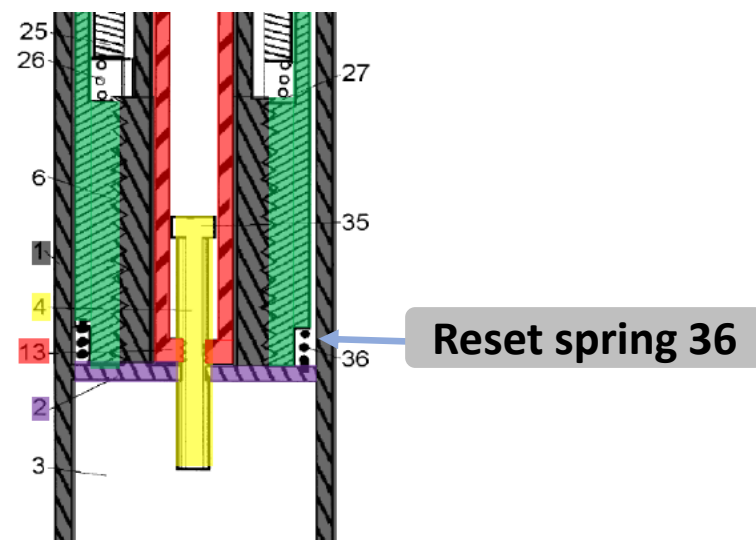
Ex. 1015 at ¶ 0008

Møller teaches a "helical reset spring 36" to overcome any problematic friction with dose dial sleeve threads

Møller

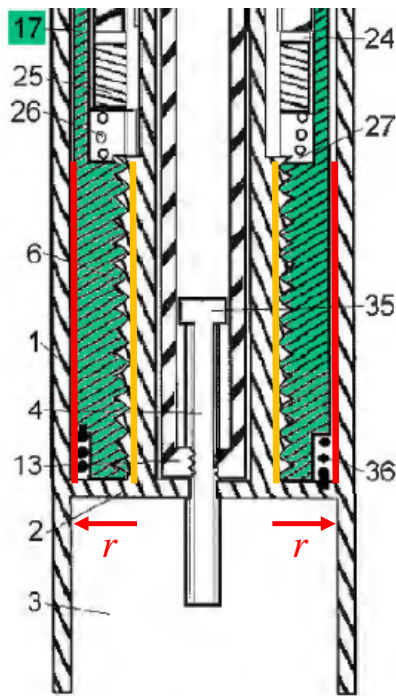
der 34 at the bottom of the dose setting button 18. Only a force sufficient to make the dose setting drum rotate to screw itself downward along the thread 6 is necessary as the force necessary to make the injection is transmitted to the piston rod 4 through the gearbox 9. **A helical reset spring 36** concentric with the dose setting drum can be mounted at the lower end of this drum and can have one end anchored in the dose setting drum 17 and the other end anchored in the wall 2. During setting of a dose this spring may be tighter coiled so that on the dose setting drum it exerts a torque approximately corresponding to the torque necessary to overcome the friction in the movement of the dose setting drum along the thread 6 so that the force which the user have to exert on the injection button is only the force necessary to drive the piston rod into an ampoule to inject the set dose.

Ex. 1015 at ¶ 0033



Ex. 1015 (Møller), Fig. 1

Moving the threads from Møller's dose-setting drum to the exterior increases the radius at which friction exists, thus multiplying drag



Ex. 1015 (Møller), Fig. 1

Slocum Declaration

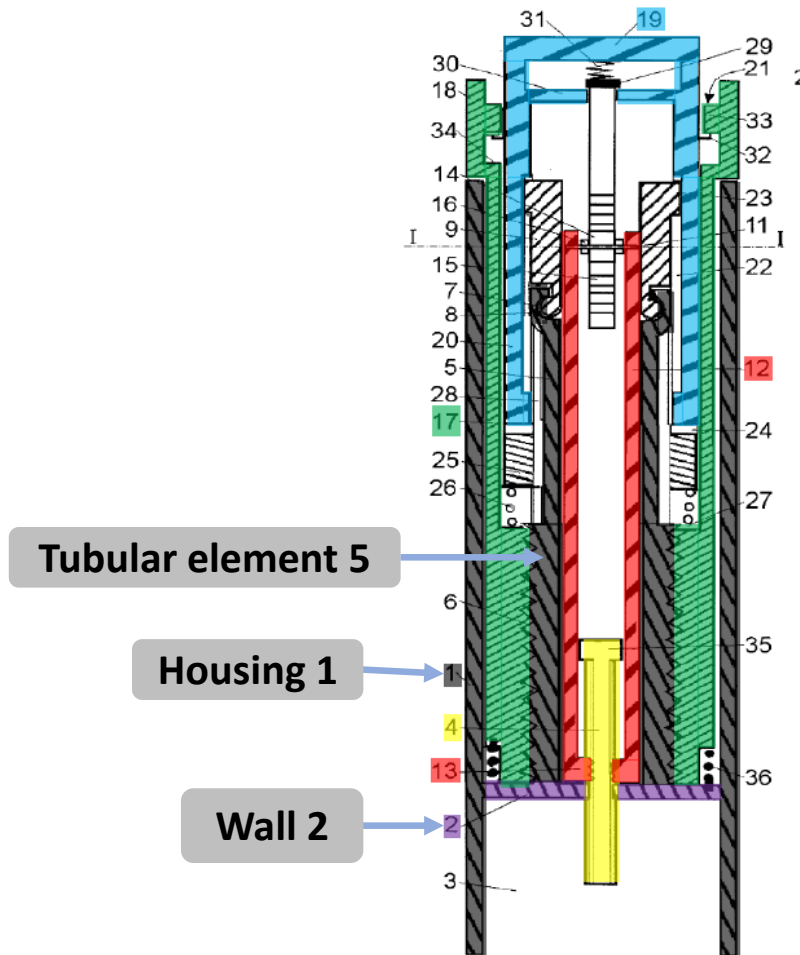
due to friction during dose injection. As I have explained in the background of the technology section of this declaration, part of the force that the user puts into a pen injector goes into overcoming the frictional forces in the device. These frictional forces arise from thread surfaces that rub against each other during dose injection.

If one were to move these thread interfaces farther away from the axis of rotation, however, the drag (parasitic) torque caused by this friction is multiplied by the distance of the threaded interface from the axis of rotation ($\tau = r \times F$) to create a larger parasitic drag that would likely frustrate a user. As I also explained in the

Ex. 2107 at ¶ 306

1. Overview
2. Dose Dial Sleeve With an Outer Groove (069 Patent, 044 Patent, and 486 Claim 4)
3. **Dose Dial Sleeve with a Threaded Engagement to a “Main Housing” (486 Patent)**
4. Drive Sleeve (069 Patent, 044 Patent), or a Driver Comprising a Cylindrical Shape (486 Claim 5)
5. Clicker Comprising at Least One Flexible Arm and at Least One Spline (044 Claim 15, 486 Claims 18 & 20)

Petitioner's Argument



Ex. 1015 (Møller), Fig. 1

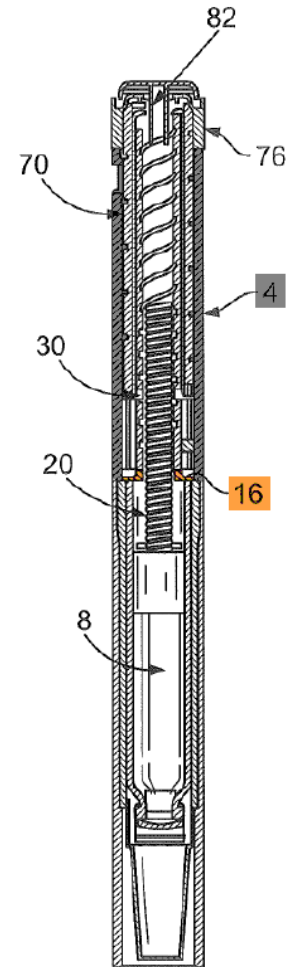
The “main housing” does not include an integrally formed inner housing, which is separately called the insert

486 Patent at 3:49-55

In the illustrated embodiment, an insert **16** is provided at a first end of the main housing **4**. The insert **16** is secured against rotational or longitudinal motion. The insert **16** is provided with a threaded circular opening **18** extending there-through. Alternatively, the insert may be formed integrally with the main housing **4** the form of a radially inwardly directed flange having an internal thread.

55

Ex. 1003 at 3:49-55



Ex. 1003 (486 Patent), Fig. 1 41

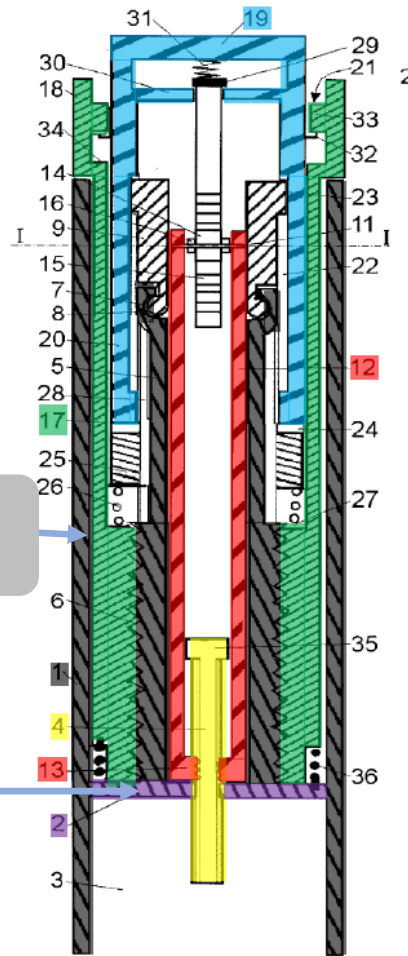
008 Patent Confirms Difference Between “Main Housing” and Inner Housing

008 Patent at 2:66-3:2

The term “housing” according to instant invention shall preferably mean any exterior housing (“main housing”, “body”, “shell”) or interior housing (“insert”, “inner body”) having a helical thread. The housing may be designed to

Ex. 1005 at 2:66-3:2

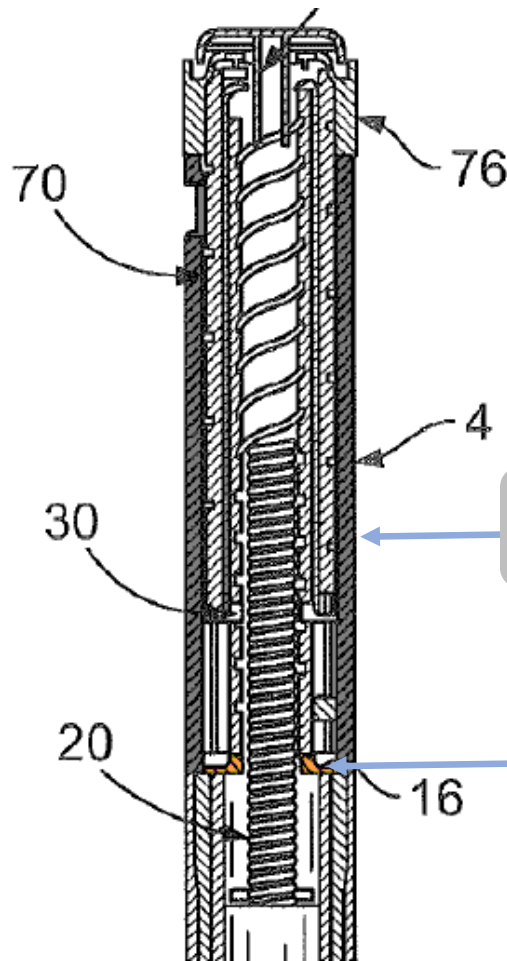
The "Main Housing" Corresponds to Møller's "Housing 1"



Housing 1
(exterior housing)

Wall 2
(integral interior
housing)

Ex. 1015 (Møller), Fig. 1



Main housing 4
(exterior housing)

Insert 16
(integral interior
housing)

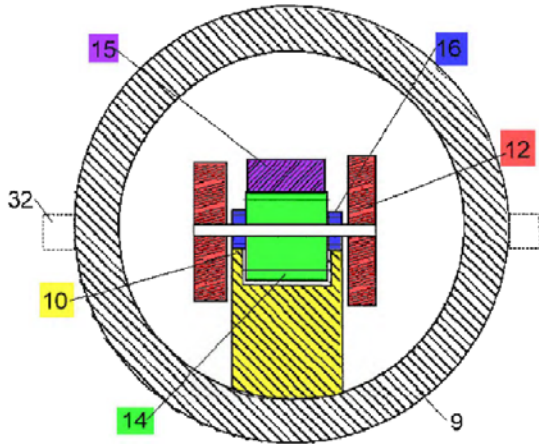
Ex. 1003 (486 Patent), Fig. 3

1. Overview
2. Dose Dial Sleeve With an Outer Groove (069 Patent, 044 Patent, and 486 Claim 4)
3. Dose Dial Sleeve with a Threaded Engagement to a “Main Housing” (486 Patent)
4. **Drive Sleeve (069 Patent, 044 Patent), or a Driver Comprising a Cylindrical Shape (486 Claim 5)**
5. Clicker Comprising at Least One Flexible Arm and at Least One Spline (044 Claim 15, 486 Claims 18 & 20)

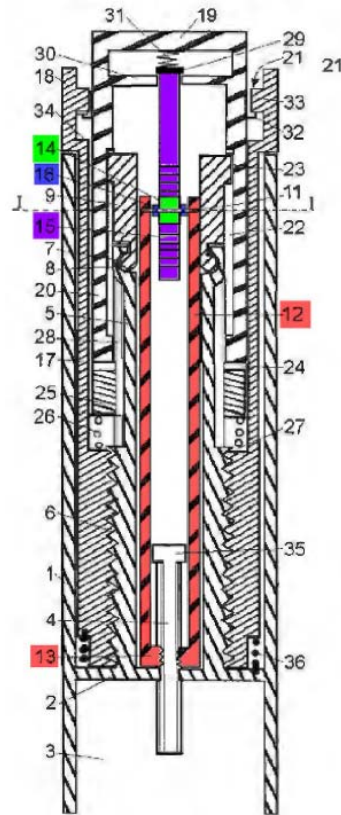
Petitioner Proposes Modifying Møller to Have a Drive Sleeve

Møller's 1st Embodiment

Connection Bars 12
(not a drive sleeve)



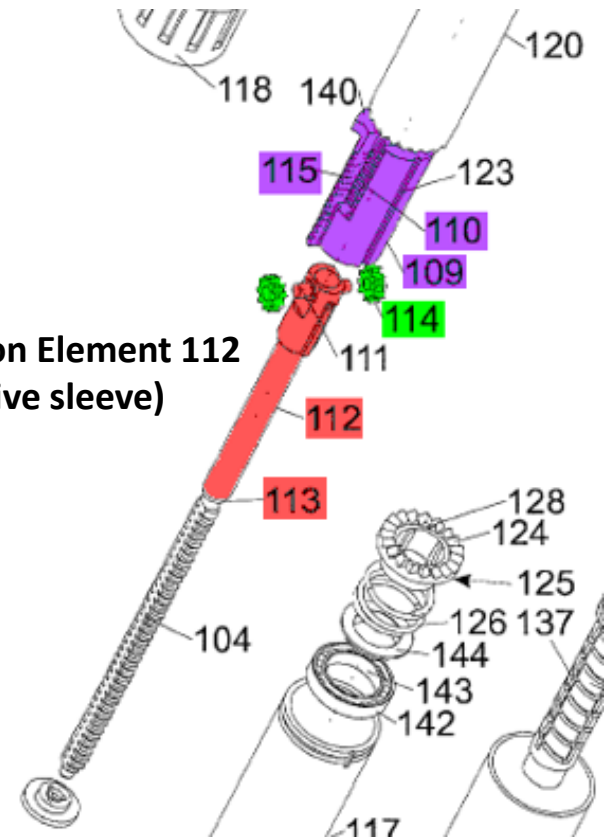
Ex. 1015 (Møller), Fig. 2



Ex. 1015 (Møller), Fig. 1

Møller's 2nd Embodiment

Connection Element 112
(a drive sleeve)



Ex. 1015 (Møller), Fig. 5

No Reason to Modify Møller's 1st Embodiment

Slocum Declaration

281. Thus, a POSA would not have understood connection bars 12 and nut 13 to be structurally and functionally equivalent to connection element 112 and nut 113 because the former allows for internal gear wheels and gear racks (or internal gear wheels that can engage with internal gear racks) and the latter does not. With the open configuration of connection bars 12 in the first embodiment, Møller's first embodiment can achieve a range of gearing ratios with differently-sized gear wheels and racks.

Ex. 2107 at ¶ 281

Slocum Declaration

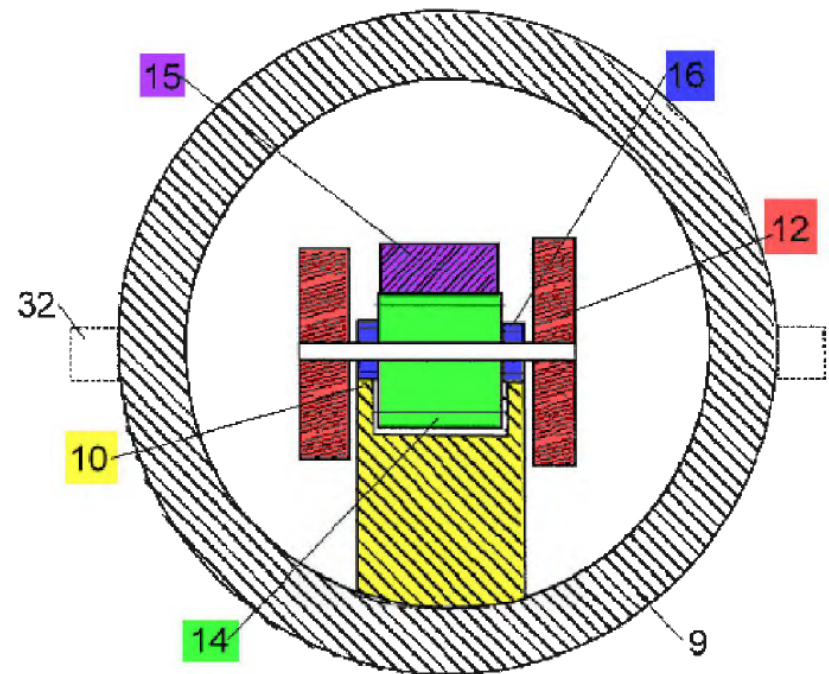
283. If a POSA were to form connection bars 12 along its entire length as a tubular element like connection element 112 in Møller's second embodiment, a POSA would have had to redesign other elements of Møller's first embodiment. The gear wheels 14 and 16 would have to be moved to the exterior of the now tubular element to engage with external gear racks 10 and 15. Whereas connection element 112 in the second embodiment has a pair of same-size gear wheels on opposing sides, here to maintain the gearing ratio of the first embodiment a POSA implementing connection bars 12 as the connection element 112 would have added two pairs of gear wheels (*i.e.*, a pair of gear wheels 14 and a pair of gear wheels 16), which results in four externally-mounted gear wheels that would engage four gear racks (two of rack 10 and two of rack 15). Looking at Figure 1 of Møller, these modifications would require increasing the diameter of the pen injector, which as I explained in Section V.C. is something a POSA would not want to do without good reason.

Ex. 2107 at ¶ 283

Engagement between gear wheels 16 (blue) and rack 10 (yellow) would be blocked if the connection bars (red) are formed as a sleeve

Leinsing Reply Declaration

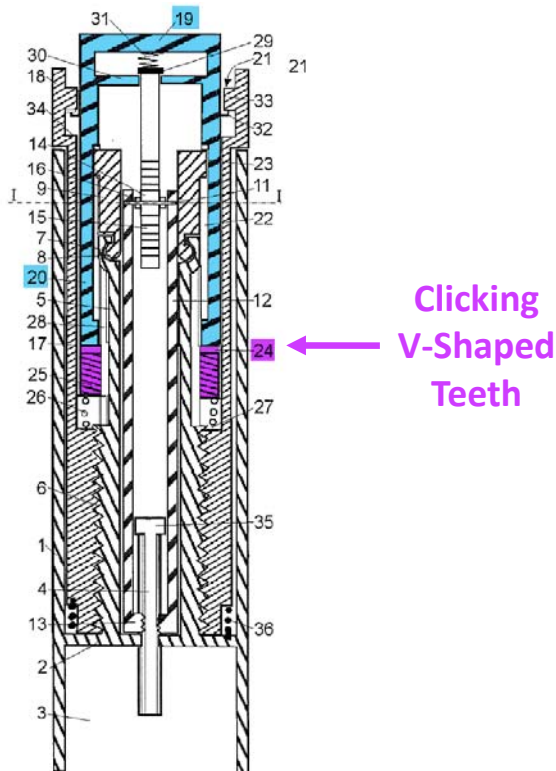
283. I disagree. The racks can easily engage the gear wheels whether they are inside the driver or outside the driver, and Møller's second embodiment illustrates how such an arrangement can be accomplished without having to substantially widen the pen as Dr. Slocum argues. Indeed, I note that Sanofi's own animations



Ex. 1015 (Møller), Fig. 2

1. Overview
2. Dose Dial Sleeve With an Outer Groove (069 Patent, 044 Patent, and 486 Claim 4)
3. Dose Dial Sleeve with a Threaded Engagement to a “Main Housing” (486 Patent)
4. Drive Sleeve (069 Patent, 044 Patent), or a Driver Comprising a Cylindrical Shape (486 Claim 5)
5. **Clicker Comprising at Least One Flexible Arm and at Least One Spline (044 Claim 15, 486 Claims 18 & 20)**

Møller already has a clicker: "V-shaped teeth" that ride over each other when rotating



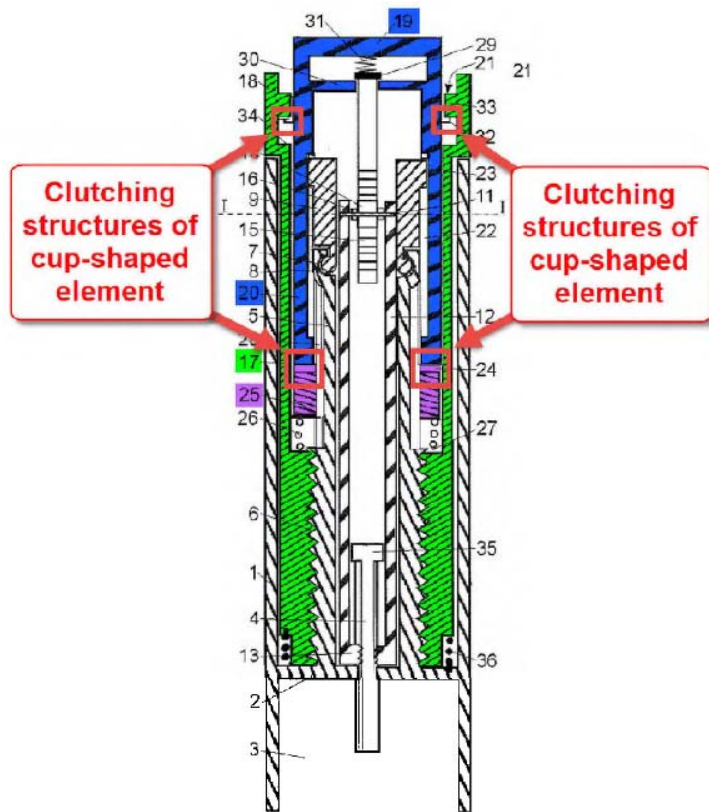
Ex. 1015 (Møller), Fig. 1

Møller

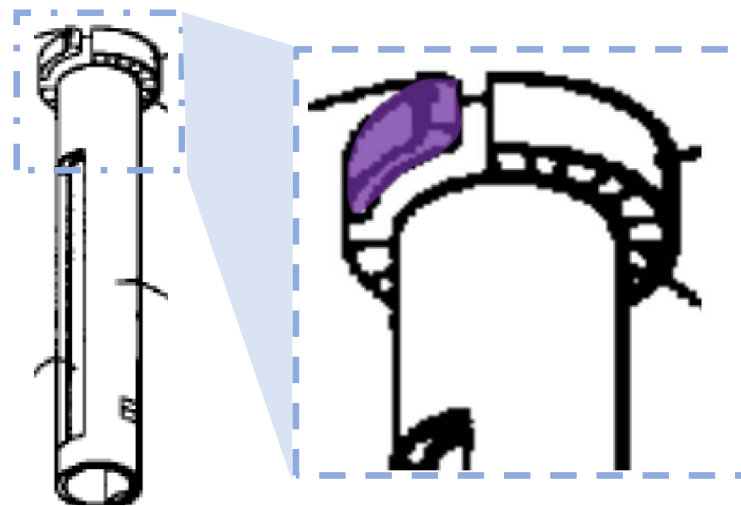
[0027] At the edge of the open end of the cup shaped element a rosette of V-shaped teeth are provided, which teeth engage a corresponding rosette of V-shaped teeth 24 on a ring 25 which is pressed against the edge of the cup shaped element by a spring 26 which is compressed between a not toothed side of the ring 25 and a round going shoulder 27 on the inner wall of the dose setting drum 17 at an inner end of the inner thread of this drum. 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 1. 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.

Ex. 1015 at ¶ 0027

Møller's Clicker Is Not Interchangeable with Steenfheldt-Jensen's



Ex. 1015 (Møller), Fig. 1



Ex. 1014 (Steenfeldt-Jensen), Fig. 17

1. Obviousness Ground: Steinfeldt-Jensen's 5th Embodiment
2. Obviousness Ground: Møller + Steinfeldt-Jensen's 5th Embodiment
- 3. Obviousness Ground: Møller + Steinfeldt-Jensen's 2nd Embodiment**
4. Obviousness Ground: Burroughs
5. Objective Indicia of Nonobviousness

IPR, Ground	Challenged Claims
-01684, Ground 1	008 Claims 1, 3, 7-8, 11, 17

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 threaded 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.

3. The drive mechanism of claim 1, wherein the insert is secured in the housing against rotational and longitudinal motion.

7. The drive mechanism of claim 1, wherein the threaded surface of the dose dial sleeve has a first lead.

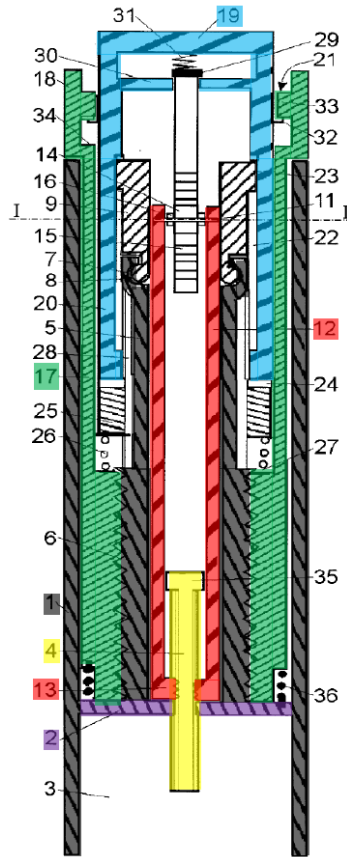
8. The drive mechanism of claim 7, wherein the first thread of the piston rod has a second lead.

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.

17. The drive mechanism of claim 1 where the first and second threads of the piston rod are oppositely disposed.

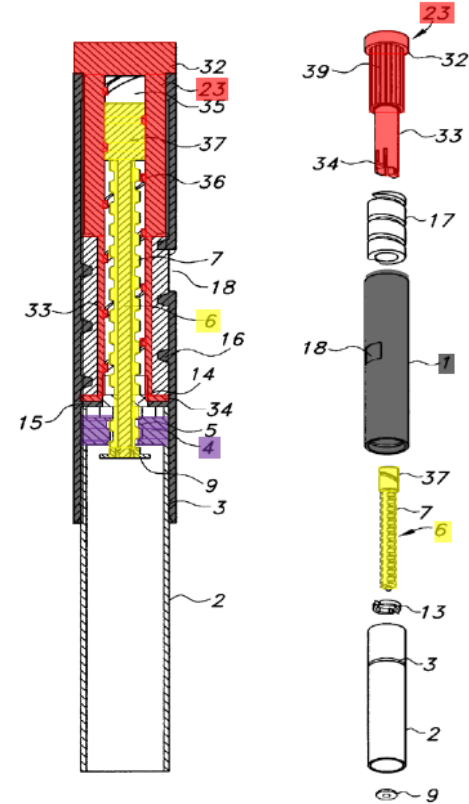
1. **No motivation to combine Møller with Steinfeldt-Jensen's 2nd embodiment**
2. Does not render obvious both a housing comprising a helical thread and an insert provided in the housing
3. Does not render obvious an insert secured in the housing (008 Patent Claim 3)
4. Does not render obvious a housing having an internal helical thread (008 Patent Claim 11)

Møller's 1st Embodiment



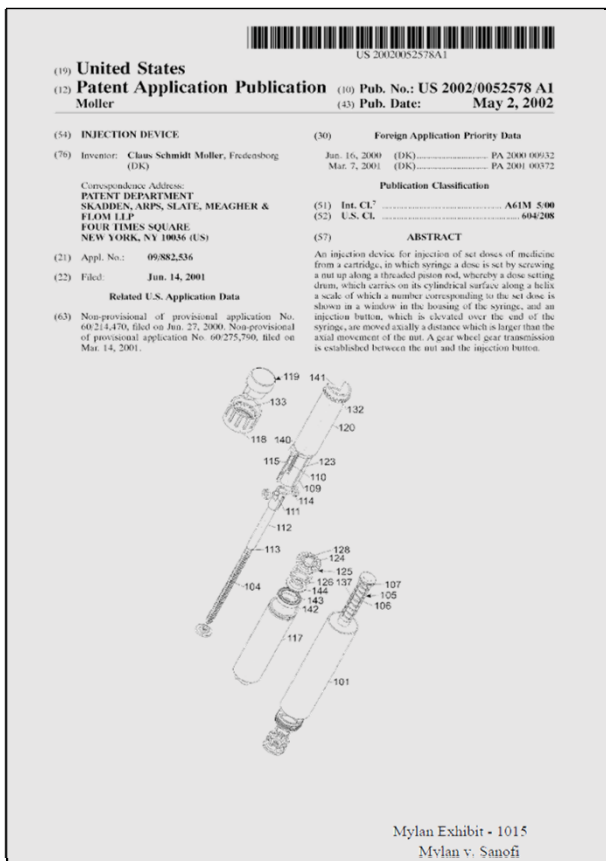
Ex. 1015 (Møller), Fig. 1

Steenfeldt-Jensen's 2nd Embodiment



Ex. 1014 (Steenfeldt-Jensen), Figs. 7, 8

Møller Sets Out to Reduce Injection Force



Ex. 1015 (Møller)

Møller

[0005] This development is not quite favourable, as especially users having reduced finger strength have their difficulties in pressing the injection button, a problem that is further increased when still thinner needles are used to reduce the pain by injection. Also with quite small movements of the button it is difficult to feel whether the button is moved at all and by injection of one unit from a 3 ml ampoule the piston and consequently the injection button has to be moved only about 0,1 mm.

Ex. 1015 at ¶ 0005

Møller

[0006] Consequently a wish for a gearing between the injection button and the piston has occurred so that the button has a larger stroke than has the piston. 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.

Ex. 1015 at ¶ 0006

Petitioners Ignore Møller's Express Teaching Away from Threaded Gearing

Møller

[0008] A similar gearing is provided in WO 99/38554 wherein the thread with the 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. However, by this kind of gearing relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces. Therefore a traditional gearing using mutual engaging gear wheels and racks is preferred.

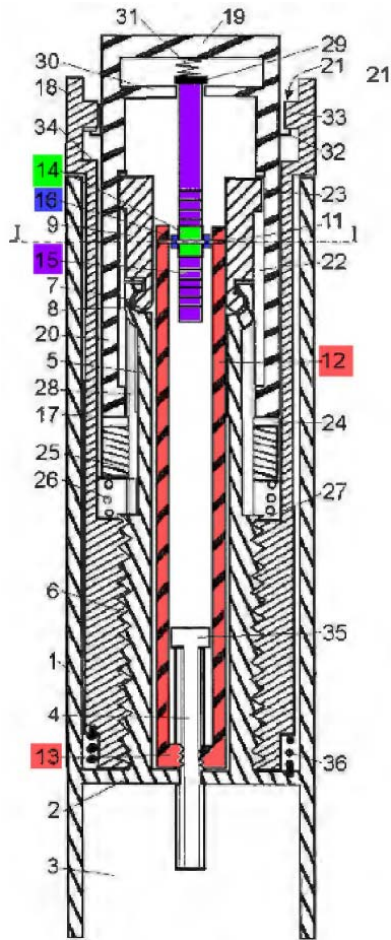
Ex. 1015 at ¶ 0008

Møller

[0011] It is an objective of the invention to provide an injection device, which combines the advantages of the devices according to the prior art without adopting their disadvantages and to provide a device wherein is established a direct gearing, i.e. a gearing by which more transformations of rotational movement to linear movement and linear movement to rotational movement are avoided, between the injection button and the piston rod.

Ex. 1015 at ¶ 0011

Møller Teaches Using a Gearing with Rolling Contact, Not Sliding Contact



Ex. 1015 (Møller), Fig. 1

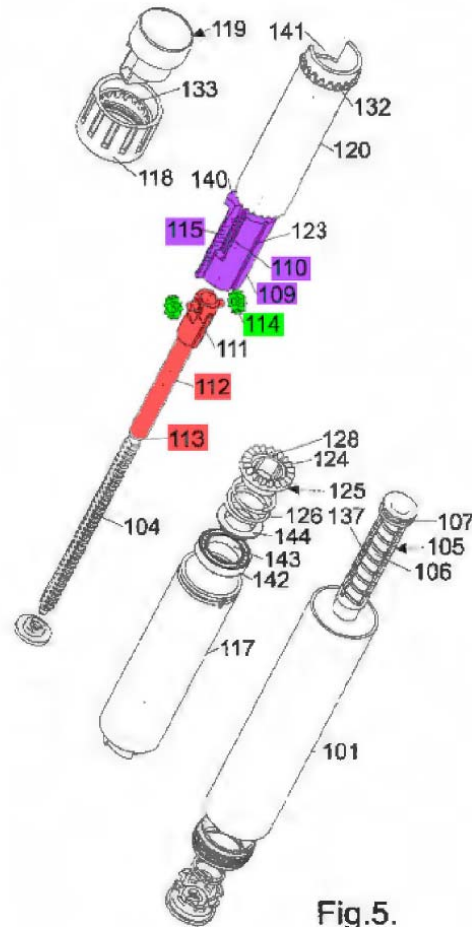


Fig. 5.

Ex. 1015 (Møller), Fig. 5

Petitioners Concede that Møller Criticizes Steenfeldt-Jensen's Teachings

Petitioners' Reply

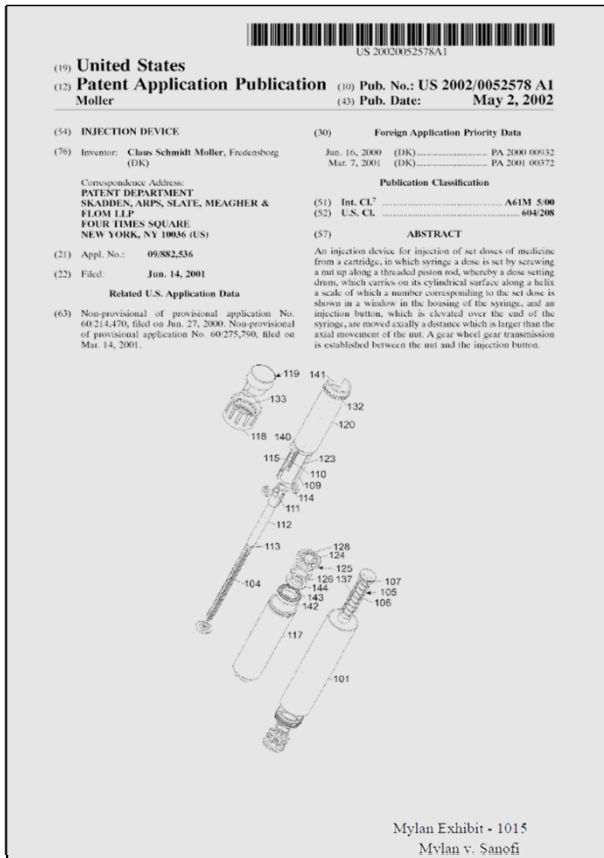
Sanofi misapprehends what Møller is actually criticizing. Citing Møller paragraphs 8 and 11, Sanofi alleges that Møller “intentionally avoids the disadvantageous high-pitched helical thread described by Steenfeldt-Jensen” in favor of “a ‘direct gearing’—i.e., a gearing which does not rely on screw mechanics between the injection button and piston rod during injection.” POR 25-26. However, Møller is not criticizing all gearing that relies on screw mechanics, nor is it criticizing the particular screw mechanics of Steenfeldt-Jensen’s second embodiment that were applied in the combination. Rather, Møller specifically addresses the drum-based gearing of Steenfeldt-Jensen’s first and fifth embodiments.

-01684 Reply at 1-2

-01684 Reply at 1-2

59

Møller Teaches Away from Threaded Gearing, Whether on a Drum or Spindle



Ex. 1015 (Møller)

Møller

[0007] In EP 608 343 a gearing is obtained by the fact that a dose setting element is screwed up along a spindle having a thread with a high pitch. When said dose setting element is pressed back in its axial direction the thread will induce a rotation of said dose setting element, which rotation is via a coupling transmitted to a driver nut with a fine pitch which driver nut will force a threaded not rotatable piston rod forward.

Ex. 1015 at ¶ 0007

Møller

[0008] A similar gearing is provided in WO 99/38554 wherein the thread with the 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. However, by this kind of gearing relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces. Therefore a traditional gearing using mutual engaging gear wheels and racks is preferred.

Ex. 1015 at ¶ 0008

Møller

[0011] It is an objective of the invention to provide an injection device, which combines the advantages of the devices according to the prior art without adopting their disadvantages and to provide a device wherein is established a direct gearing, i.e. a gearing by which more transformations of rotational movement to linear movement and linear movement to rotational movement are avoided, between the injection button and the piston rod.

Ex. 1015 at ¶ 0011

No Evidence to Show that Møller Had Durability Problems

Leinsing June 3, 2019 Deposition

Q. Don't you think that the gear wheels need to be strong and durable enough to withstand the forces, given their size relative to the other components in the pen?

A. Not necessarily, and that wouldn't indicate whether it's reusable or disposable, and the forces are not again that high. The gears that I worked on for pen injectors were all plastic gears, and they worked fine.

Ex. 2163 at ¶ 140:8-16

Slocum Declaration

378. Moreover, to the extent there were any durability concerns, a POSA could through the selection of materials and dimensioning alleviate those concerns.

I also note that the commercial embodiment of Møller's pen injector, the Novo Nordisk Novo4, uses a rack and gear mechanism and does not appear to suffer from durability issues. Indeed, it is a reusable pen injector. Novo Nordisk, which also manufactured the commercial embodiment of Steinfeldt-Jensen (*i.e.*, the FlexPen), thus was able to commercially implement Møller without throwing out its entire gearing mechanism as Petitioner suggests a POSA would have done.

Ex. 2107 at ¶ 378

Modified Pen Injector Would be Harder to Use

Slocum Declaration

Neither Petitioner nor Mr. Leinsing explains this assertion. IPR2018-01684 (008) Petition at 43, Ex. 1011, ¶¶ 835-37. If anything, Møller teaches that **introducing thread friction into the gearing mechanism**, as Petitioner suggests, would make the pen injector *harder* to use by increasing the efficiency losses due to friction.

Ex. 2107 at ¶ 379

Sur-reply

6. The differences matter – a rotating piston rod increases the frictional losses in the device. *See, e.g.*, EX2107, ¶ 234. Thus, if Steinfeldt-Jensen's rotating piston rod was incorporated into Møller, **the piston rod would rub against the cartridge during dose dispensing, which introduces a new source of friction into Møller.** Friction

-01684 Sur-reply at 7

1. No motivation to combine Møller with Steinfeldt-Jensen's 2nd embodiment
2. **Does not render obvious both a housing comprising a helical thread and an insert provided in the housing**
3. Does not render obvious an insert secured in the housing (008 Patent Claim 3)
4. Does not render obvious a housing having an internal helical thread (008 Patent Claim 11)

The plain language treats the insert as distinct from the threaded housing

008 Patent, Claim 1

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 threaded 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.

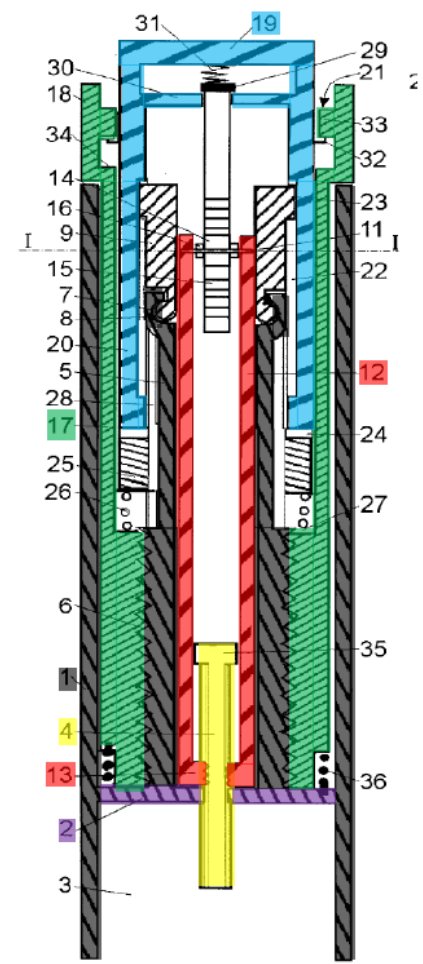
There Is No Threaded Housing and an Insert Provided in the Housing

The Petition identifies Møller's wall 2 as the "insert"

008 Patent, Claim 1

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;

Ex. 1005 at claim 1



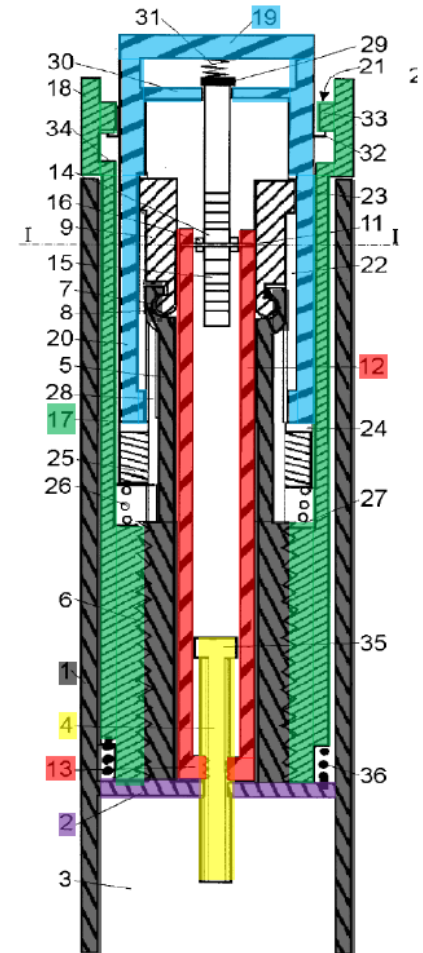
Ex. 1015 (Møller), Fig. 1

The 008 Patent Specification Does Not Support Petitioners' Position

008 Patent at 7:33-39

In the illustrated embodiment, an insert 16 is provided at a first end of the main housing 4. The insert 16 is secured against rotational or longitudinal motion. The insert 16 is provided with a threaded circular opening 18 extending therethrough. Alternatively, the insert may be formed integrally with the main housing 4 having the form of a radially inwardly directed flange having an internal thread.

Ex. 1005 at 7:33-39



Ex. 1015 (Møller), Fig. 1

1. No motivation to combine Møller with Steinfeldt-Jensen's 2nd embodiment
2. Does not render obvious both a housing comprising a helical thread and an insert provided in the housing
3. **Does not render obvious an insert secured in the housing (008 Patent Claim 3)**
4. Does not render obvious a housing having an internal helical thread (008 Patent Claim 11)

Petitioners' Proposed Combination

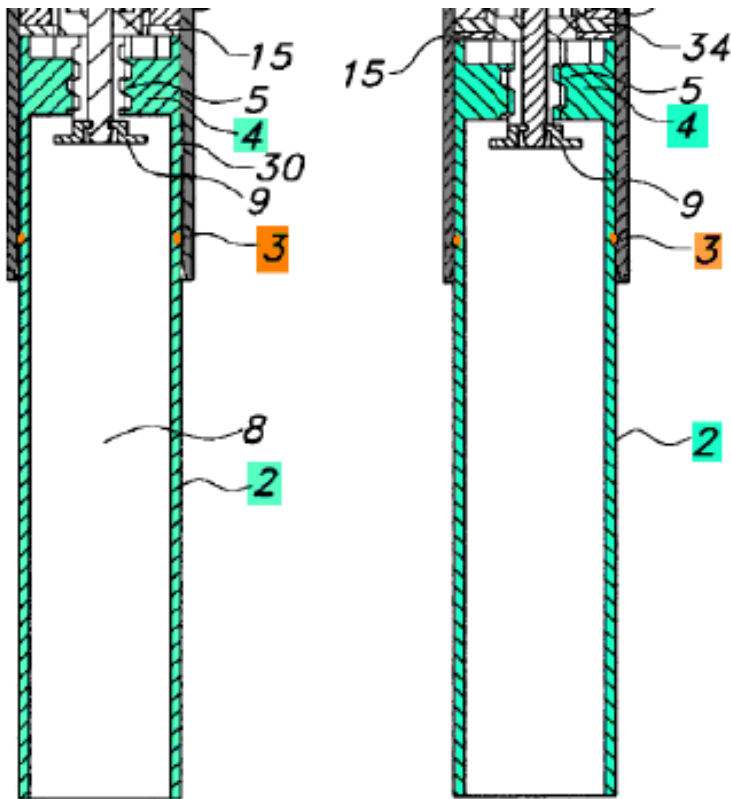
The Petition relies on wall 4 of Steinfeldt-Jensen for the proposed combination and argues that it “is secured in the housing against rotational and longitudinal motion” as required by claim 3

-01684 Petition

Both Møller and Steinfeldt-Jensen teach the use of an insert that is secured in the housing against rotational and longitudinal motion. The proposed modification would make use of wall 4 of Steinfeldt-Jensen or a comparable component that also has a circular internal thread and is secured to the housing. Wall 4 is secured in the housing against rotational and longitudinal motion. EX1014, 5:55-57, 7:41-47, FIG. 7;

-01684 Petition at 45

The Combination Does Not Teach an Insert That Is Secured Against Rotation



Ex. 1014 (Steenfeldt-Jensen), Figs. 2, 7

Steenfeldt-Jensen

The syringe comprise a tubular housing 1 which is by a partition 15 divided into a first and a second division into the first one of which an ampoule holder 2 is snapped by a snap lock comprising a ring shaped bead 3 on the ampoule holder 2 which bead is snapped into a corresponding circumferential groove in the inner wall of the housing 1 near an open end thereof. By this snap connection the ampoule holder 2 is secured in the housing 1 so that it can be rotated but not axially displaced relative to this housing.

Ex. 1014 at 5:38-46

1. No motivation to combine Møller with Steinfeldt-Jensen's 2nd embodiment
2. Does not render obvious both a housing comprising a helical thread and an insert provided in the housing
3. Does not render obvious an insert secured in the housing (008 Patent Claim 3)
4. **Does not render obvious a housing having an internal helical thread (008 Patent Claim 11)**

1. Obviousness Ground: Steinfeldt-Jensen's 5th Embodiment
2. Obviousness Ground: Møller + Steinfeldt-Jensen's 5th Embodiment
3. Obviousness Ground: Møller + Steinfeldt-Jensen's 2nd Embodiment
4. **Obviousness Ground: Burroughs**
5. Objective Indicia of Nonobviousness

IPR, Ground	Challenged Claims
-01670, Ground 1	069 Claim 1
-01675, Ground 1	044 Claims 11, 14, 15, 18, 19
-00122, Ground 1	486 Claims 1-6, 12-18, 20, 23, 26-30, 32, 33, 36, 38, 40

Obviousness Ground: Burroughs

- 1. Does not teach or render obvious a dose dial sleeve comprising a helical groove (069 Patent, 044 Patent, 486 Patent)**
2. Does not teach or render obvious a tubular clutch (069 Patent, 044 Patent, 486 Patent)

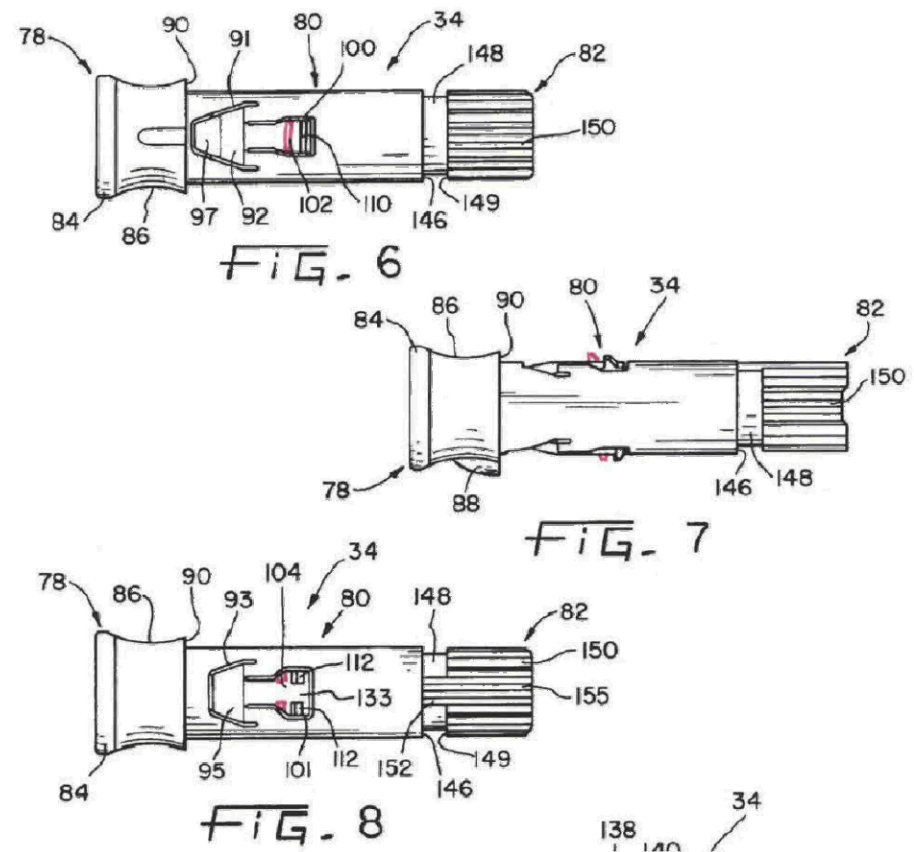
Petitioner's Modification: Adding Threads to Form a Groove

Leinsing June 3, 2019 Deposition

Q. Are there any additional modifications that would be made to the Burroughs pen depicted and described to make your proposed modification work?

A. I was just looking at it again. I don't -- I think it's a pretty simple modification, so it would not require much or really any modification in order to satisfy that element.

Ex. 2163 at 186:11-5, 195:14-21



Ex. 2103

[Ex. 2107 ¶ 171]

Dr. Slocum's Testimony

Slocum Declaration

181. First, a person of ordinary skill in the art would not have been motivated to attempt this modification because it would significantly increase the amount of stress experienced by legs 102 and 104 of the dial mechanism 34 during injection, which increases the likelihood of breakage and decreases the useful life of the pen injector.

Ex. 2107 at ¶ 181

Slocum Declaration

186. As shown in the calculations below I developed and incorporated into a spreadsheet (which includes the scaling law equations I developed and are included in Appendices D and F), if no changes are made to Burroughs' device other than the addition of the new threads and providing sufficient downward deflection of the legs for the new thread to clear the helical groove 158 during injection, the force and stress experienced by the legs increases by approximately 30 to 40 percent.

Ex. 2107 at ¶ 186

Response to Petitioner's Reply

Petitioner Reply

² Even if these concerns were real, Sanofi does not address routine design-arounds. EX1095, ¶¶42-43 (e.g., different rib heights, shifting of threading).

-01670 Reply at 4

Slocum August 28, 2019 Deposition

The height of the thread would be the same, it has to be because of the first thread if it's going to engage. The width of the thread, I put in variables, and the variable is defining the pitch, that has to stay the same.

Now, if you want to change other features of the actual tooth itself, I didn't need to consider that aspect. But the pitch and the height, those are fixed by the design that is there.

Ex. 1054 at 281:9-18

-01679 Reply at 4 (see also -01670 Reply at 9; -00122 Reply at 9); -01670 Sur-reply at 6; -01675 Sur-reply at 10; -00122 Sur-reply at 10

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Petition argument: Protruding grooves

-01675 Petition

A POSA also would have had a reasonable expectation of success in implementing threads 110, 112 as protruding helical grooves. Grooved threading

-01675 Petition at 41

-00122 Petition

Here, a POSA would have understood that the rotational operability between dial mechanism 34 and housing 22 would not change if helical threads 110, 112 were provided as u-shaped, protruding grooves for engaging a helical rib on the housing. EX1011, ¶170. The POSA also would have reasonably expected that the

-00122 Petition at 39

Institution Decision

At this stage, Petitioner's assertion that its proposed modification of threads 110, 112 to be protruding helical grooves represents a "predictable use of prior art elements according to their established functions" with a

-01675, ID at 23-24; -00122, ID at 23

Reply argument: Duplication of threads

-01675 Reply

says nothing about cutting into the threads to make this modification. **In context, turning a single thread into a “protruding groove” indicates duplication of the thread.** There is nothing convoluted about treating two threads as forming the

-01675 Reply at 5, -00122 Reply at 5

Obviousness Ground: Burroughs

1. Does not teach or render obvious a dose dial sleeve comprising a helical groove (069 Patent, 044 Patent, 486 Patent)
2. **Does not teach or render obvious a tubular clutch (069 Patent, 044 Patent, 486 Patent)**

Claim Construction – “Tubular Clutch”

Patent Owner’s Construction
District Court of N.J. Construction

“a tubular component that can operate to reversibly lock two components in rotation”

-01670 POR at 7-8, -01675 POR at 11-13, -00122 POR at 11-13

Petitioner’s Construction

“a tubular structure that couples and decouples a moveable component from another component”

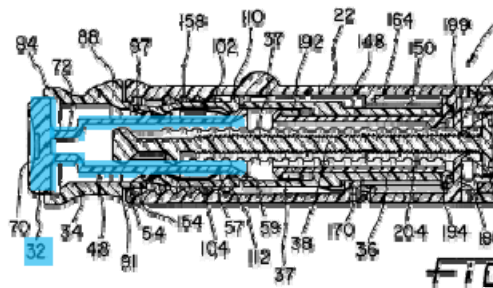
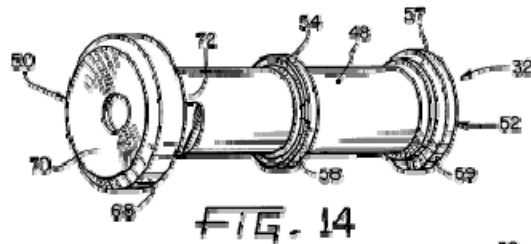
-01670 Reply at 1, -01675 Reply at 3, -00122 Reply at 3

District Court of New Jersey Claim Construction Order

transmission engages and disengages the clutch without ever setting a dose. The Court concludes that neither party has overcome the presumption that "clutch" has its ordinary meaning, which is: "a component that can operate to reversibly lock two components in rotation."⁸

Ex. 2165 at 13.

Petitioner's Theory: Button 32



Ex. 1013, Figs. 1, 14

-01670 Petition

Thus, button 32 serves as a clutch that allows dial mechanism 34 to disengage from (1) its threaded connection with housing 22, and (2) its rotational coupling with nut 36. See EX1011, ¶183. As shown above in FIG. 1, button 32 is

-01670 Petition at 39

Button 32 Does Not Lock The Dial And Housing In Rotation

Slocum Declaration

the dial 34 and housing 22 are not reversibly locked *in rotation* because the engagement between threads 110, 112 and helical groove 158 is specifically designed to allow the dial 34 to rotate *relative to* the housing. Burroughs explains

Ex. 2107 at ¶ 207

Burroughs

158a, as shown in FIGS. 3 and 8. Upon rotation of dial 34, threads 110, 112 move within housing groove 158 in the proximal direction as dial mechanism 34 retracts from housing 22, thereby increasing the axial distance between

Ex. 1013 at 10:34-37

Button 32 Does Not “Reversibly Lock” The Dial And Nut

Slocum Declaration

reversibly lock the dial to the nut. Moreover, Burroughs makes it clear that the operation of button 32 is not what causes these splines to engage with one another. As Burroughs explains, the splines 144 and splines 192 are brought into engagement with each other by the user retracting the dial from the zero-dose position during dose setting:

Ex. 2107 at ¶ 208

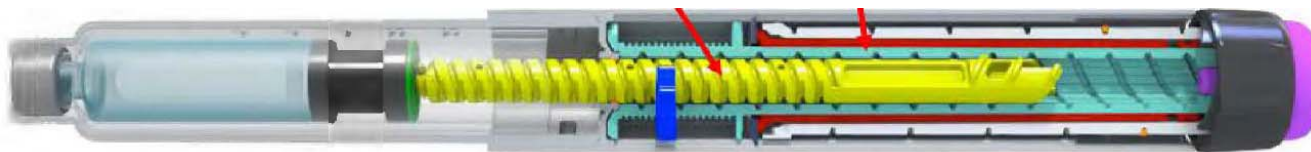
Burroughs

In its zero-dose position, 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. As dial mechanism 34 is retracted, ledge 149 is moved past housing finger 170 resulting in housing finger 170 being in engagement with splines 150. In addition, splines 144 of dial mechanism 34 are moved into engagement with splines 192 of nut 36 so that the adjacent lateral surfaces on the splines 144 and 196 will engage each other (FIGS. 4 and 11). When the surfaces are engaged, rotation of dial mechanism 34 causes corresponding rotation of nut 36. Rotation of leadscrew 38 is

Ex. 1013 at 10:15-26

- Overview
- Background and State of the Art
- Obviousness Ground: Steinfeldt-Jensen's 5th Embodiment
- Obviousness Ground: Møller + Steinfeldt-Jensen's 5th Embodiment
- Obviousness Ground: Møller + Steinfeldt-Jensen's 2nd Embodiment
- Obviousness Ground: Burroughs
- **Objective Indicia of Nonobviousness**

- The Lantus® SoloSTAR® practices:
 - 069 Patent claim 1
 - 486 Patent claim 1
 - 008 Patent claim 1
- Petitioners have not provided any evidence rebutting Sanofi's showing that SoloSTAR® practices these challenged claims.



Slocum Declaration

650. In my opinion, the claimed components and interfaces, such as the threaded engagements, piston rod, drive sleeves/driving members, dose stops, and clutch enable an injection device with (i) low injection force, (ii) short or long injection stroke length for low or high dose per injection, and (iii) a relatively small number of components that decrease the complexity and cost of the device. The

Ex. 2107 at ¶ 650

Long-Felt but Unmet Need for an Easy to Use Pen

Dr. Robin Goland, M.D.

22. For patients dealing with a lifelong condition like diabetes that requires daily medication/care, anything that can be done to reduce the burden of living with such a condition is a huge benefit. In particular, ease of use is key for the self-administration. My type 2 diabetes patients, for example, are typically middle aged or elderly, and have conditions that may cause a variety of physical and/or cognitive impairments.

Ex. 2111 at ¶ 22

Peer-Reviewed Studies: Needs Before SoloSTAR®

advances SOL close to the ideal mechanical disposable device. Indeed, some of the features such as addressing the unmet needs of the patient, which included better differentiation features and a lower injection force compared with existing devices that will be discussed, were identified during the development programme in user testing and subsequently incorporated into the end product.

Ex. 2116 at .003

Slocum Declaration

646. For an initial matter, the OptiClik had many drawbacks as a device. For example, the OptiClik was a direct drive system (having no mechanical advantage), and thus had very high injection forces. The OptiClik also had a very large external dimensions, making it less convenient to carry around. Since the OptiClik was a reusable device, and had a very high part count, which made it more expensive and difficult to manufacture compared to disposable injector pens. Finally, the OptiClik did not automatically reset after injection, thereby requiring the user to undertake additional steps prior to injecting the next dose.

Ex. 2107 at ¶ 646

Goland Declaration

27. Prior to the launch of Lantus[®] SoloSTAR[®] pen, there were two pens on the market in the United States administering a long-acting insulin or insulin analog, Lantus[®] OptiClik[®] and Levemir[®] FlexPen[®]. Neither of these pens, however, satisfied the long-felt need for an easy-to-use, disposable pen.

Ex. 2111 at ¶ 27

Goland Declaration

31. The Lantus[®] SoloSTAR[®] pen fulfilled the long-felt, but unmet need for an easy-to-use, low injection force pen for administering a long-acting insulin glargine formulation.

Ex. 2111 at ¶ 31

SoloSTAR® Received Industry Praise



- DBA Gold, International Export, and Grand Prix Awards
 - DCA Press Release: “SoloSTAR® is the first disposable insulin pen to combine very low injection force (which provides a smooth injection experience for patients) with 80 units maximum dose capability, an important breakthrough.” Ex. 2121 at 3



- Good Design Award by the Chicago Athenaeum Museum of Architecture and Design (Ex. 2201)
 - SoloSTAR® devices were put into the museum’s permanent Design Collection. Ex. 2109, ¶ 73



- Prix Galien USA 2009 Award
 - “recognize[s] innovative biopharmaceutical drugs and medical technologies” and “is considered...equivalent to the Nobel Prize”
 - Sanofi and DCA were both finalists. Ex. 2109, ¶ 73

Lantus® SoloSTAR® is Commercially Successful

Grabowski Declaration

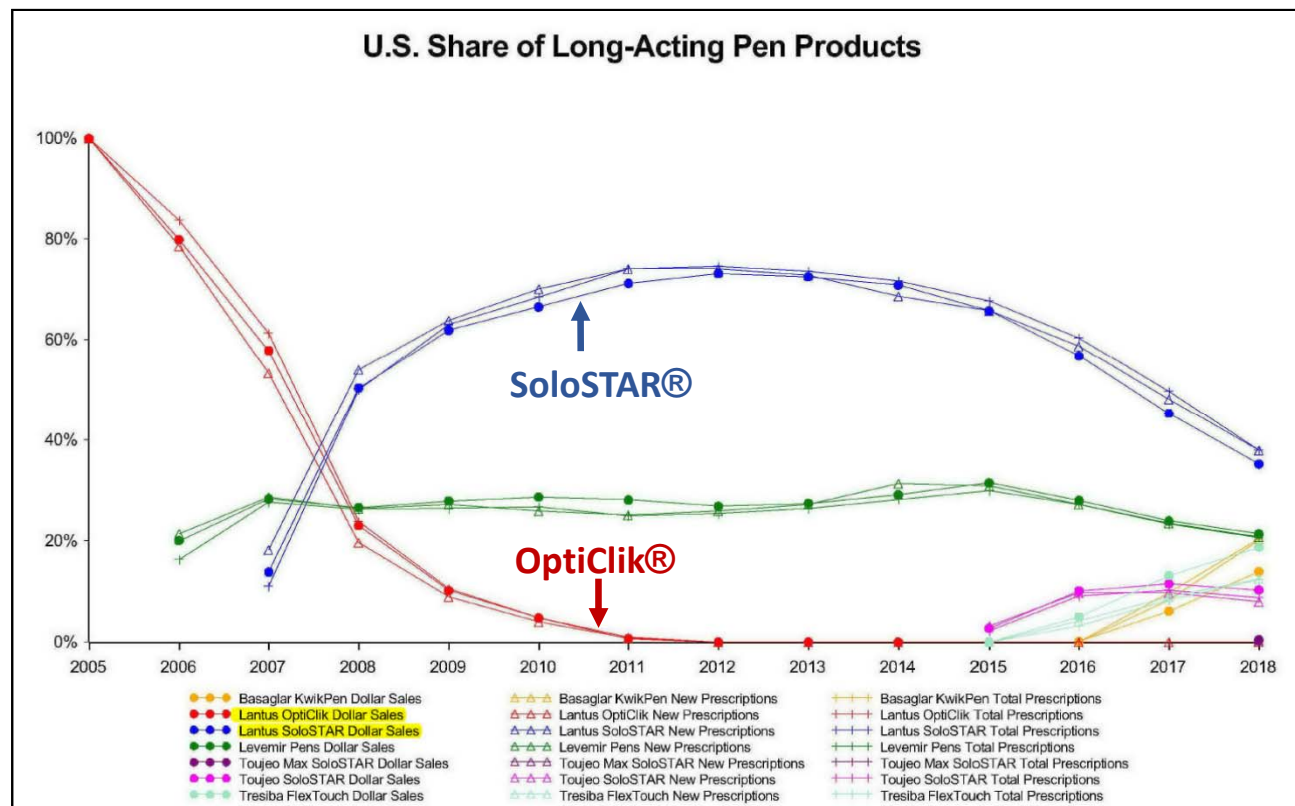
32. My analysis of the Lantus® SoloSTAR® using IMS Health data shows that in 2007, the year of launch, U.S. dollar sales of the Lantus® SoloSTAR® were approximately \$50 million, and rose to \$4.3 billion by 2018, representing an 8,526 percent increase in sales. (See Exhibit 2187.) The trends observed in sales can also

Ex. 2109 at ¶ 32

- McDuff's Data:
 - Lantus® SoloSTAR® is the number one insulin product in recent years, and the third most-prescribed insulin product of the last twenty years. Ex. 1060; Ex. 2318.

Nexus Between Commercial Success and Challenged Claim

- Lantus® SoloSTAR® vastly outperformed Lantus® OptiClik®
- OptiClik® used the same Lantus® insulin but did not practice the patent



Ex. 2199

-01670 POR at 65-66; -01670 PO Sur-Reply at 23; see also -01678 POR at 77; -01678 PO Sur-Reply at 23; -01680 POR at 55; -01680 PO Sur-Reply at 20; -01684 POR at 60-61; -01684 PO Sur-Reply at 19.

Commercial Success Not Due to Blocking Patents

- **Blocking Patents Covered Glargine, Not Pens**
 - No disincentive to develop non-glargine insulin pens
 - Levemir FlexPen sold while Blocking Patents were enforceable
 - EX2318, 80:2-81:15; EX2109 ¶ 25
- **Safe-Harbor Research Exemption**
 - Allowed development even of glargine pens in spite of Blocking Patents
 - Eli Lilly developed glargine pens while Blocking Patents were enforceable
 - EX2318, 82:7-83:2
- **Blocking Patents Expired by 2015**
 - No disincentive after expiration
 - EX2318, 79:7-11

The undersigned hereby certifies that on January 8, 2020, the foregoing
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