

**Mylan Pharmaceuticals Inc.
and Pfizer, Inc.,***
Petitioners

v.

Sanofi-Aventis Deutschland GmbH
Patent Owner

IPR2018-01670	U.S. Patent No. 8,679,069
IPR2018-01675	U.S. Patent No. 8,603,044
IPR2018-01676	U.S. Patent No. 8,603,044
IPR2018-01678	U.S. Patent No. 8,992,486
IPR2018-01684	U.S. Patent No. 9,604,008
IPR2019-00122	U.S. Patent No. 8,992,486

January 15, 2020

Overview of IPR Grounds

IPRs -1670, -1675, -1676, -1678, -0122: Burroughs, Møller, and Steinfeldt-Jensen

The '069 Patent (-1670)		
Ground	Claims	Basis
1	1	Obvious over Burroughs (EX1013)
2	1	Obvious over Steinfeldt-Jensen (EX1014)
3	1	Obvious over Møller (EX1015) and Steinfeldt-Jensen

IPRs -1670, -1675, -1676, -1678, -0122: Burroughs, Møller, and Steinfeldt-Jensen

The '044 Patent (-1675)		
Ground	Claims	Basis
1	11, 14-15, 18-19	Obvious over Burroughs

The '044 Patent (-1676)		
Ground	Claims	Basis
1	11, 14-15, 18-19	Obvious over Steinfeldt-Jensen
2	11, 14-15, 18-19	Obvious over Møller and Steinfeldt-Jensen

IPRs -1670, -1675, -1676, -1678, -0122: Burroughs, Møller, and Steinfeldt-Jensen

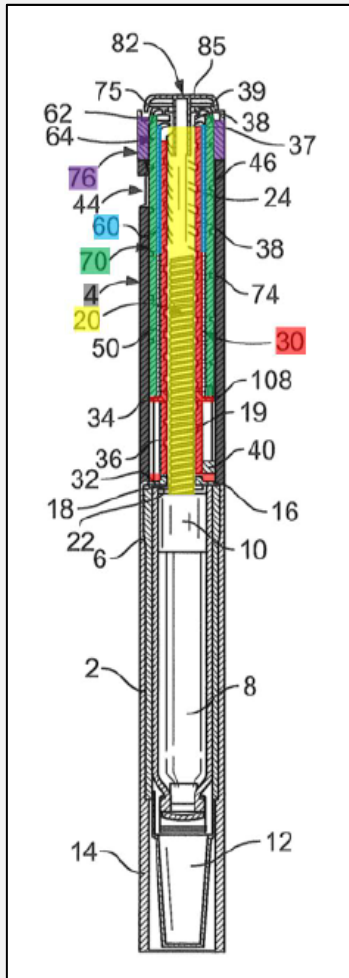
The '486 Patent (-0122)		
Ground	Claims	Basis
1	1-6, 12-18, 20, 23, 26-30, 32-33, 36, 38-40	Obvious over Burroughs

The '486 Patent (-1678)		
Ground	Claims	Basis
1	1-6, 12-18, 20, 23, 26-30, 32-33, 36, 38-40	Obvious over Steinfeldt-Jensen
2	1-6, 12-18, 20, 23, 26-30, 32-33, 36, 38-40	Obvious over Møller and Steenfeldt-Jensen

IPR -1684: Møller and Steinfeldt-Jensen

The '008 Patent (-1684)		
Ground	Claims	Basis
1	1, 3, 7, 8, 11, 17	Obvious over Møller and Steinfeldt-Jensen

IPRs -1670, -1675, -1676, -1678, -0122: Independent Claims Substantially Similar



“A housing part for a medication dispensing apparatus...comprising:”

- (1) “**a main housing** [4, gray] ... extending from a distal end to a proximal end;”
- (2) “**a dose dial sleeve** [70, green] positioned within said housing...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 sleeve¹**;”
- (3) “**a dose dial grip²** [76, purple] disposed near a proximal end of said dose dial sleeve;”
- (4) “**a piston rod** [20, yellow] provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;”
- (5) “**a drive sleeve³** [30, red] extending along a portion of said piston rod...comprising an internal threading near a distal portion...adapted to engage an external thread of said piston rod;”
- (6) “**a tubular clutch** [60, blue] 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”

“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 different⁴”

¹Not required in claim 1 of '486 patent.

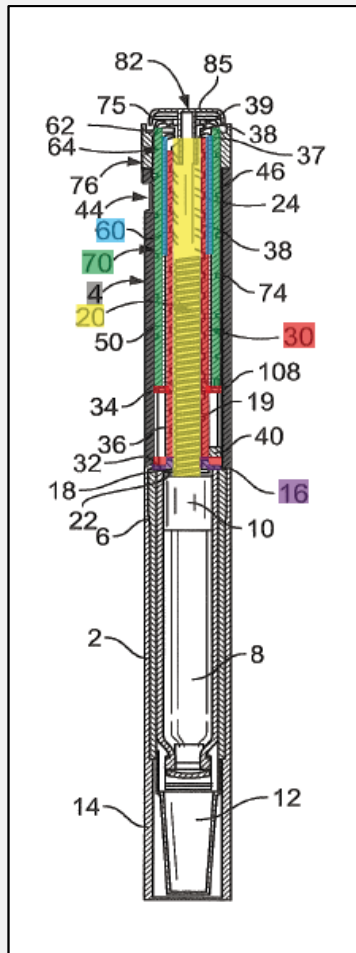
²Recited as “dose knob” in claim 1 of '486 patent.

³Recited as “driver” in claim 1 of '486 patent.

⁴Only required in claim 11 of '044 patent.

Source: Pet., 5-7 (citing EX1011, ¶38).

IPR -1684: Independent Claim 1



“A drive mechanism for use in a drug delivery device comprising:”

- (1) **“a housing [4, gray] comprising a helical thread;”**
- (2) **“a dose dial sleeve [70, green] having a threaded surface that is engaged with the helical thread of the housing;”**
- (3) **“an insert [16, purple] provided in the housing, where the insert has a threaded circular opening;”**
- (4) **“a drive sleeve [30, red] releasably connected to the dose dial sleeve and having an internal helical thread;”**
- (5) **“a piston rod [20, yellow] 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”**
- (6) **“a clutch [60, blue] 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.”**

Source: EX1011, ¶¶40-41; -1684 Pet., 6-8.

Sanofi's Response to Each Ground Repeats the Same Errors

Sanofi's Repeated Errors

Flawed premise: myopic focus on injection force

- Claims not limited to insulin pens
- Claims do not require low injection force
- Injection force just one of many design factors
- Cost and reliability are key

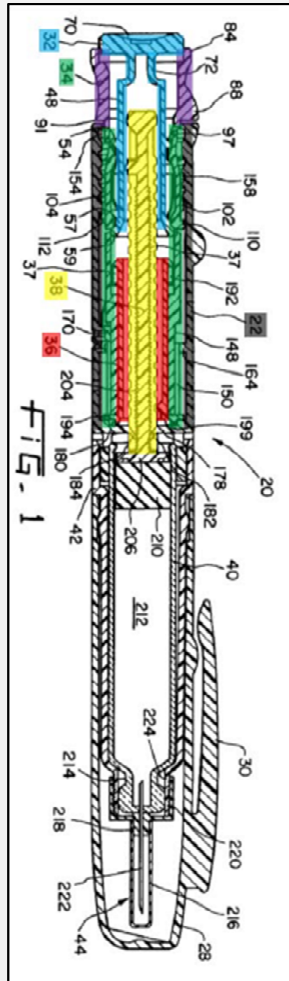
Flawed analysis of modifications

- Outsourced bases for testimony to named inventor
- Flawed inputs
- Ignored routine skill

Source: Pet. Reply, 3-4, 13-18; EX1048, ¶¶28-32; EX1095, ¶¶72-75; Pet. Resp. to Obs., 1.

Claims Are Obvious Over Burroughs

IPRs -1670, -1675, -0122: Burroughs Renders the Claims Obvious



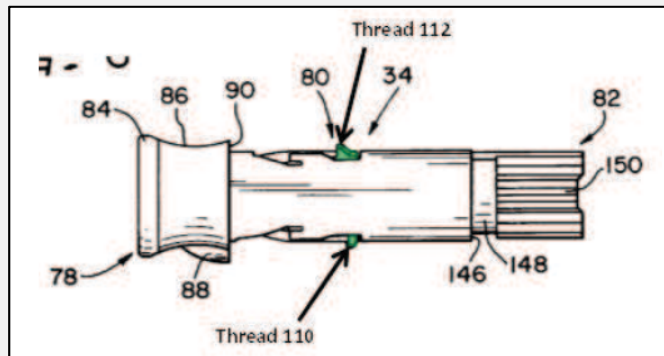
Burroughs describes an injector pen having:

- (1) **“a main housing** [housing 22, gray]...extending from a distal end to a proximal end;”
- (2) **“a dose dial sleeve** [dial mechanism 34, green] positioned within said housing...comprising a helical **[rib]** configured to engage a threading provided by said main housing, said helical **[rib]** provided along an outer surface of said dose dial sleeve;”
- (3) **“a dose dial grip [or dose knob]** [proximal portion 78, purple] disposed near a proximal end of said dose dial sleeve;”
- (4) **“a piston rod** [leadscrew 38, yellow] provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;”
- (5) **“a drive sleeve [or driver]** [nut 36, red] extending along a portion of said piston rod...comprising an internal threading near a distal portion...adapted to engage an external thread of said piston rod;”
- (6) **“a tubular clutch** [button 32, blue] located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip;”

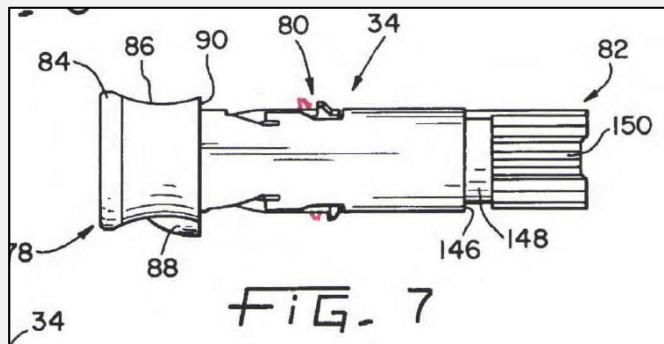
“wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch”

Source: Pet., 18-20 (citing EX1011, ¶¶125-28), 25-40.

Rib-to-Groove Connection: A Predictable Variation



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 ring 91 and surfaces 33, 35 of housing parts 24, 26. Rotation



While this invention has been described as having an exemplary design, the present invention can be further modified within the spirit and scope of this disclosure. This application is therefore intended to cover any variations, uses, or adaptations of the invention using these general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which this invention pertains, and which fall within the limits of the appending claims.

Source: EX1011, ¶165; EX1013, 10:34-38, 12:30-39; EX2103; Pet., 29-30, 40-42 (citing EX1011, ¶¶161-71).

Rib-to-Groove Connection: A Predictable Variation

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 (e.g., 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.

Source: EX1011, ¶¶169-70; Pet., 29-30, 40-42 (citing EX1011, ¶¶161-71).

Burroughs Modification: Sanofi's Strawman

Rationale not merely “that a POSA *could have* performed the proposed modification...” as alleged.

“If a person of ordinary skill can implement a predictable variation, §103 likely bars its patentability.”
KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 417 (2007).

Rib-to-groove and groove-to-rib engagements were known, interchangeable implementations.

- Sanofi does not dispute the modification's workability or that grooved dial sleeves were commonplace.

Source: *Pet.*, 40-42; EX1011, ¶¶166-71; *POR*, 18-19; *Pet. Reply*, 3-4; EX1095, ¶43.

Burroughs Modification: Sanofi's Strawman

Faced with predictable variation involving known threading solution:

- **Literal translation of Mr. Leinsing's general representation of modification**
- Ignores routine skill

Mr. Leinsing:

(showing annotated figures). When asked to sketch the proposed modification, I was not asked to detail the dimensions or shape of the additional threads. EX2163, 188:4-189:15. Instead, I was just tasked with clarifying what I meant by my proposed modification by annotating select figures of Burroughs, and so my annotations were intended as a general representation of the modification for clarification purposes, not as a basis for detailed force analysis. *Id.*

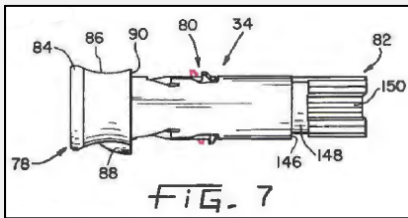
id., 193:15-21. I also explained how a person of ordinary skill would have appreciated that the additional threads would provide another surface for distributing forces during use. *See id.*, EX2163, 195:1-13, 96:1-197:21. And, while Dr. Slocum contends that I “did not believe any other modifications to the injector would be required” (EX2107, ¶185), my testimony was related to modifications to other distinct features or components of the device (*e.g.*, modifications to the housing’s internal threading, *see* EX2163, 195:14-25), and it was not meant to suggest that my proposed modification was limited to my rough sketch or an exact replica of the threads 110, 112 shown in Burroughs figure.

Source: POR, 19-22; EX2107, ¶¶170-93; Pet. Reply, 3-4; EX1095, ¶¶40-43.

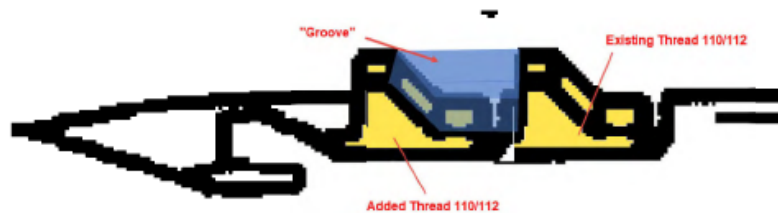
Burroughs Modification: Sanofi's Strawman

Faced with predictable variation involving known threading solution:

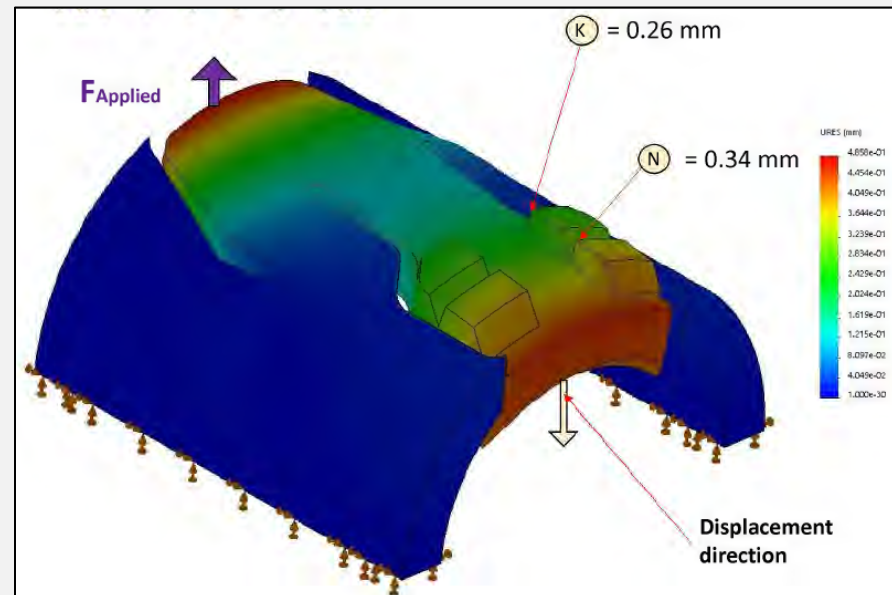
- **Literal translation of Mr. Leinsing's general representation of modification**
- Ignores routine skill



housing.”). I have illustrated a mock-up of this modification below using a cutaway of Burroughs’ Figures 7, and also provide Mr. Leinsing’s annotations of Burroughs’ Figures 6-8 showing the proposed modification.



Ex. 1013, Fig. 7 (modified and annotated)



Source: POR, 19-22; EX2107, ¶¶174-93, App'x D; Pet. Reply, 3-4; EX1095, ¶¶40-43.

Burroughs Modification: Sanofi's Strawman

Faced with predictable variation involving known threading solution:

- Literal translation of Mr. Leinsing's general representation of modification
- **Ignores routine skill**

Mr. Leinsing:

Instead, as I explained above, a person of ordinary skill would have appreciated that the nature of the rib-to-groove threaded connection between the dial mechanism and the housing would remain the same with an additional thread, and the person of ordinary skill also would have had the skill and knowledge to include a thread that would reasonably accomplish that function without detrimentally affecting the operation of the device. This would include, for example, shortening the height of the added thread or shifting the threading distally along the legs of the dial mechanism in order to minimize the amount of deflection the legs would need to undergo to disengage the dial mechanism from the housing. *See id.*, 202:12-203:22.

Source: POR, 19-22; EX2107, ¶¶174-93, App'x D; Pet. Reply, 3-4; EX1095, ¶¶40-43.

Burroughs Modification: Sanofi's Strawman

Even if Sanofi's figures were correct, they do not undercut the modification.

- Alleged 10% increase in width *advantageous* for some patients

Dr. Biggs: EX2111, 28. While Opticlik was a bit wider than SoloStar, width is not necessarily a disadvantage because it can aid patients with grip or agility problems. For example,

- Alleged 15% increase in injection force:
 - Speculative
 - No allegation that even speculative increase is problematic

Source: POR, 19-22; Pet. Reply, 3-4; EX1048, ¶50; EX2107, ¶192; EX1095, ¶41.

No Dispute Burroughs Meets “Clutch” Limitation Under Sanofi’s Proposed District-Court Construction

These IPRs apply broadest reasonable interpretation.

Construction proposed by Sanofi in district court:

- “[Tubular] structure that couples and decouples a moveable component from another component.”

Sanofi cannot dispute reasonableness of *its own* construction

- Same construction adopted by District Court of Delaware in previous case (*Sanofi v. Eli Lilly*)

Waiver: no dispute that Burroughs satisfies this construction.

Source: Pet., 16-17; POR, 6-8, 23-25; Pet. Reply, 1-2, 5-6; EX1019, 21-23; EX1030, 12; EX1095, ¶¶35-36, 45-47.

'044 Patent, Claim 11 (-1675): Burroughs' Pen Has First and Second leads

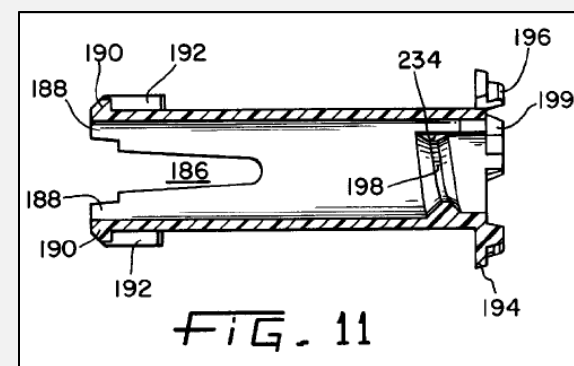
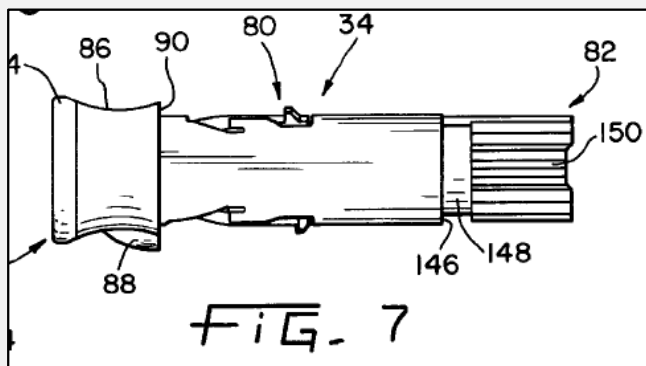
"wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different"

Dial mechanism 34 ("dose dial sleeve") has a "first lead":

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 ring 91 and surfaces 33, 35 of housing parts 24, 26. Rotation

Nut 36 ("drive sleeve") has a "second lead":

ring 91 and surfaces 33, 35 of housing parts 24, 26. Rotation of dial mechanism 34 causes rotation of nut 36 so that internal helical raised groove 198 of nut 36 rotates along external threads 208 of leadscrew 38 to cause nut 36 to axially retract a corresponding axial distance. Rotation of



Source: EX1013, 10:34-42, FIGS. 7, 11; -1675 Pet. at 36-40 (citing EX1011, ¶¶189-99).

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'044 Patent, Claim 11 (-1675): Lead Difference Known

"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"

Different leads = different rates of travel:

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

'044 Patent, Claim 11 (-1675): Lead Difference Known

"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"

Institution Decision: degree to which Exhibit 1015 impacts our analysis is lessened. Nonetheless, Mr. Leinsing's testimony on this point appears grounded in common sense and commensurate with the level of ordinary skill in the art, and Patent Owner will have an opportunity to explore Mr. Leinsing's opinion during trial.

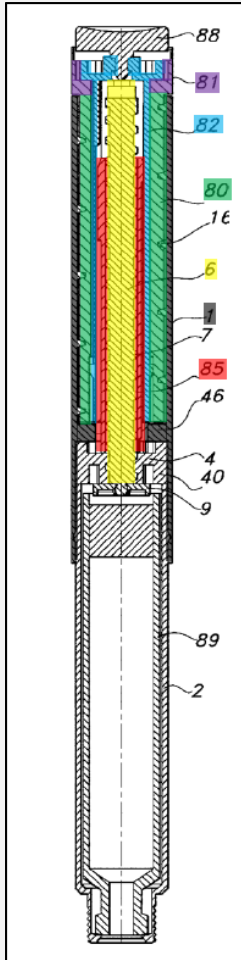
Sanofi asked Mr. Leinsing no questions on this testimony during trial

Source: -1675 Institution Decision, 24-26.

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Claims Are Obvious Over Steinfeldt-Jensen

IPRs -1670, -1676, -1678: Steenfeldt-Jensen Rendered the Claims Obvious



Steenfeldt-Jensen describes an injector pen having:

- (1) **“a main housing** [tubular housing 1, gray]...extending from a distal end to a proximal end;”
- (2) **“a dose dial sleeve** [scale drum 80, green] positioned within said housing...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;”
- (3) **“a dose dial grip [or dose knob]** [dose setting button 81, purple] disposed near a proximal end of said dose dial sleeve;”
- (4) **“a piston rod** [piston rod 6, yellow] provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;”
- (5) **“a drive sleeve [or driver]** [driver tube 85, red] extending along a portion of said piston rod...**comprising [a noncircular bore]...adapted to engage...said piston rod;**”
- (6) **“a tubular clutch** [bushing 82, blue] 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”

“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”

Source: Pet., 20-22 (citing EX1011, ¶¶130-33), 42-59.

Steenfeldt-Jensen's Piston Rod Drive

US 6,235,004 B1

1 INJECTION SYRINGE CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. application ser. No. 09/238,849 filed Jan. 28, 1999 now U.S. Pat. 6,004,297, which claims priority under 35 U.S.C. 119 of Danish application PA 1998 00130 filed Jan. 30, 1998 and of U.S. provisional application No. 60/073,820 filed Feb. 5, 1998, the contents of which are fully incorporated herein by reference.

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. A number of demands are set to such syringes. The setting of a dose must be easy and unambiguous and it must be easy to read the set dose. It must be possible with a minimum of trouble to cancel or change a wrongly set dose and when the dose is injected the dose setting must return to zero. When a disposable syringe is in question, i.e. a syringe which is disposed of when the cartridge is empty, the syringe must further be cheap and made of materials suited for recycling or burning without producing noxious gases. For these purposes the number of parts from which the syringe is constructed and the number of different kinds of materials used in the syringe should be kept at a minimum.

Most dose setting devices work with a threaded piston rod co-operating with a nut where the nut and the piston rod may be rotated relative to each other. The dose setting may be obtained by screwing the nut away from a stop to which it is returned during the injection by pressing the piston rod until the nut member abuts the stop. By other dose setting devices one of the elements, the nut or the piston rod, is kept inrotatable and the other is allowed to rotate a set angle depending on the set dose, whereby the piston rod is screwed a distance through the nut.

In most syringes for apportioning set doses it is preferred that the piston rod is backing up the piston upon which it works during the injection. To obtain this precaution is taken to prevent the piston rod from moving in a proximal direction.

The syringe according to EP 327 910 is of the type wherein a nut is screwed away from a stop. During the setting of the dose the screwing may be performed in both direction so that a too large set dose may be lowered just by rotating the nut in an opposite direction. Means are provided preventing that negative doses are set. The mutual rotation of the piston rod and the nut is obtained by rotating a cap relative to the pen housing and a set dose may be read on a scale and a pointer provided at adjacent edges of the housing and the cap, these edges being so shaped that the cap can only be mounted firmly on the housing when the pointer points zero on the scale. It may be seen as a weak point that doses larger than the one obtained by rotating the parts 360° must be calculated by adding the number pointed at on the scale and a number printed on the side of a tubular extension of the nut which is moved out from the proximal end of the housing proportionally with the dose set and which tubular extension is closed at its proximal end to form an injection button.

In EP 450 905 the above drawback is overcome by writing the numbers along a helical line on a tubular extension of the nut so that these number may successively be seen in a

5 window in a housing element enclosing said tubular extension. Hereby the size of the dose is indicated unambiguously but the user have to remember to set the dose setting device on zero before the next setting of a dose is performed. If this is forgotten a wrong dose may be set and the number may not be seen clearly in the window.

10 In EP 608 343 is described a pen having a dose setting mechanism wherein the dose is set by rotating a button through a ratchet coupled to a driver, the ratchet forming a unidirectional coupling which during the rotation of the button in one direction to set a dose rides or clicks over the teeth of the ratchet. The cylindrical side of the button carries numbers which shows the size of the set dose in a window when the button is screwed outward. When the button is screwed back the unidirectional coupling will transmit the rotation to the driver which has a nut co-operating with a threaded piston rod which is made inrotatable in a housing.

15 This thread connection has a pitch which makes the nut self locking on the piston rod. A set dose may be cancelled by drawing the engaging parts of the ratchet out of engagement against the force of a spring so that the rotation of the button is not transmitted to the driver and then press the button back to the housing. This pen fulfills all the objects mentioned only the dose cancelling procedure is a little troublesome as the dose set button cannot as it will come most naturally just be screwed back if a too large dose is set. Concomitantly forcing the coupling parts apart against the force of the spring and pressing or screwing the button back may be a little difficult and the demand for a spring necessitates use of metal parts in the syringe.

20 It is an object of the invention to provide a syringe which has the mentioned advantageous features without having the drawbacks known from existing syringes.

25 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

30 a housing
a piston rod having a not circular cross-section and an outer thread

35 a piston rod drive comprising two elements

40 a) a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable, and

45 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,

50 a dose setting mechanism comprising a not self locking thread connection along which an injection button by rotation of a dose setting element relative to said housing is screwed out from the proximal end of the housing to project from this proximal end a distance determined by the angle of said rotation and which thread connection by axial returning of the injection button transforms this axial movement to a rotation of one of the piston drive elements relative to the other, which syringe according to the invention is characterised in that

55 a unidirectional coupling is provided between the nut member and the piston rod guide allowing rotation of these parts relative to each other in one direction but not

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

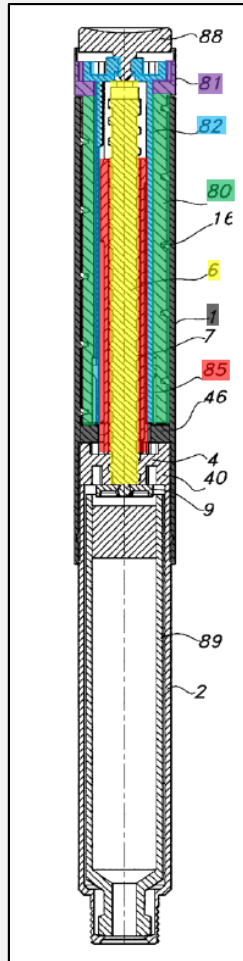
a) a piston rod guide in relation to which the piston rod is axially displaceable but not rotatable, and

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,

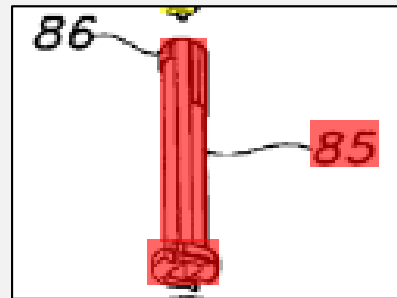
a dose setting mechanism comprising a not self locking

Source: EX1014, 46-53; Pet., 60-62.

The Piston Rod Drive of Steinfeldt-Jensen's Fifth Embodiment



FIGS. 16 and 17 illustrates still another embodiment. To maintain a clockwise rotation of a dose setting button for increasing the set dose the pawl mechanism working between the driver tube and the housing is turned so that it bars clockwise rotation and reluctantly allows anticlockwise rotation of the driver tube. Further the thread of the piston rod and the thread in the end wall of the housing is so designed that an anticlockwise rotation of the piston will screw the piston rod through said end wall and into the cartridge holder compartment. The piston rod has a not round cross-section and fits through the driver tube bore which has a corresponding not round cross-section. This way rotation is transmitted whereas the piston rod is allowed to move longitudinally through the driver tube.



Source: EX1014, FIGS. 16-17; Pet., 21.

Steenfeldt-Jensen Repeatedly Suggests an Internally Threaded Driver Tube

US 6,235,004 B1

3 in the opposite direction, the allowed rotation being one by which the piston rod is transported in a distal direction in the syringe, the coupling being so designed that a set initial reluctance has to be overcome before the rotation takes place.

During the setting of a dose a torque is exerted on the unidirectional coupling in the direction in which this coupling allows rotation after a set initial reluctance has been overcome. As this torque is a weak one resulting when the male and the female part of a not self locking thread connection is rotated relative to each other the initial reluctance can be made large enough to allow this rotation without causing any relative rotation of the parts in the coupling.

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.

According to the invention a click coupling providing an moderate resistance against rotation is established between the housing and the element rotated relative to the housing to set a dose. Hereby it is ensured that the position corresponding to a set dose is maintained and is not inadvertently altered. The clicks may be taken as an audible signal indicating the size of the set dose.

The unidirectional coupling may be a coupling comprising a pawl sliding over a pawl wheel with teeth having a steep front edge and a ramp shaped trailing edge, and the initial reluctance may be obtained by the fact that the trailing edges of the pawl wheel teeth has a depression engaged by a mating protrusion on the pawl.

A dose scale drum which has in its surface a helical track engaged by a helical rib on the inner side of the housing to form a not self locking thread connection between the housing and the drum may be coupled to the injection button to be moved axially with this button. This way the dose scale drum will be rotated relative to the housing when it is axially displaced with the injection button in said housing.

The thread connection by which the injection button is screwed out from the housing by setting a dose may be the thread connection between the dose scale drum and the 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.

A dose is set by rotating an element relative to the housing, and this element may be an element carrying the nut member and the unidirectional coupling so that the rotation is transmitted through said unidirectional coupling to the dose setting drum. The rotation transmitted is in the direction in which the coupling can run free when an initial reluctance is overcome. However, the force needed to screw the dose scale drum up along its thread is not large enough to overcome said reluctance and consequently the rotation is transmitted through the coupling.

In one embodiment of the syringe according to the invention the element rotated relative to the housing may be a part carrying the nut member and the unidirectional coupling through which the rotation is transmitted to the dose setting drum.

In another embodiment of the syringe according to the invention the element rotated relative to the housing may be the injection button and the not self locking thread connection which determines the lifting of the injection button may be an inner thread in a bore in the injection butt on engaging

an outer thread on an enlargement of the piston rod. When the injection button is screwed up along the thread of the housing a torque is exerted on the piston rod trying to rotate this piston rod in a distal direction in the syringe. This rotation is blocked by the unidirectional coupling which blocks rotation in the direction in which the piston rod is rotated relative to each other.

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.

According to the invention a click coupling providing an moderate resistance against rotation is established between the housing and the element rotated relative to the housing to set a dose. Hereby it is ensured that the position corresponding to a set dose is maintained and is not inadvertently altered. The clicks may be taken as an audible signal indicating the size of the set dose.

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an outer thread on an enlargement of the piston rod. When the injection button is screwed up along the thread of the housing a torque is exerted on the piston rod trying to rotate this piston rod in a distal direction in the syringe. This rotation is blocked by the unidirectional coupling which blocks rotation in the direction in which the piston rod is rotated relative to each other.

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Source: EX1014, 3:15-20, 3:44-47; Pet., 60-62.

Steenfeldt-Jensen Repeatedly Suggests an Internally Threaded Driver Tube

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12 must be provided. Altogether a moderate torque can be transmitted from the rotated ampoule holder 2 to the driver tube 26. As the hooks 28 at the proximal end of the driver tube 26 engage the slots 22 in the dose scale drum extension 21 the dose scale drum will be rotated and be screwed 5 upwards in the second division of the housing 1 and the injection button 23 will be lifted to protrude from the proximal end of the housing 1. As only a small torque is needed to screw up the dose scale drum this is obtained without releasing the unidirectional coupling to its clicking 19 release function mode. The size of the set dose can currently be seen on the part of the dose scale drum which is presented in the window 18. If a too large dose has been set the ampoule holder can be rotated in a clockwise direction until the number corresponding to the size of the wanted dose is presented in the window 18.

To inject the set dose the injection button 23 is pressed home into the housing 1. Thereby the dose scale drum 17 is pressed in the distal direction and due to the thread connection between said drum and the housing 1 a torque is exerted 20 on the drum rotating this drum in a clockwise direction. Said torque is via the slots 22 in the drum extension 21 and the hooks 28 at the end of the driver tube 26 and this tube itself transmitted to the piston rod guide 14. The pawls 13 on the piston rod guide are allowed to rotate in the clockwise 25 direction when the torque is strong enough to overcome the reluctance provided by the protrusions 29 on the pawls engaging the depressions 32 in the ramp shaped edges of the pawl wheel teeth.

Such a strong torque is provided if only the inject button 30 23 is pressed hard enough. The piston rod guide 14 will now rotate clockwise with the unidirectional coupling working in its clicking released mode and the piston rod will be rotated clockwise too and will thereby be screwed through the wall 4 further into the ampoule accommodating compartment 8. 35 The unidirectional coupling will never allow an anticlockwise rotation of the piston rod guide and the piston and this way it is ensured that the pressure foot 9 will never be drawn out of abutment with the piston in a not shown ampoule in the compartment 8.

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.

Another embodiment is described with reference to the FIGS. 6-10. Elements corresponding to elements in the embodiment described with reference to the FIGS. 1-5 are provided with the same reference numbers. Different from the embodiment in FIG. 1-5 is the fact that the injection button 23 and not the dose scale drum 17 is provided with an extension 33, and that the driver tube 26 is omitted. Further the injection button 23 is provided with a flange 32 which abuts the end of the housing when the injection button is pressed home. The extension 33 serves as a journal for the dose scale drum 17 which is free to rotate on this journal but bound to follow axial movements of the injection button 23 due to hooks 34 at the end of the extension 33. A longitudinal bore 35 in 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. The pitch of this thread connection is so that a not self locking thread connection is formed.

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To set a dose the injection button 23 is manually rotated in a clockwise direction. Thereby this button is screwed outwards from the housing 1 as the piston rod 6 will through the piston rod guide 14 and the unidirectional coupling be kept inrotatable although said unidirectional coupling is influenced by a torque in its release direction, however, due to the provided initial resistance the piston rod guide 14 will not immediately be rotated. When this drum is rotated due to the said drum 17 and the injection button 23 is screwed through the dose scale drum 17.

By this construction the injection button is screwed through the dose scale drum 17. A click connection is formed between the dose scale drum 17 and the injection button 23. According to the invention the injection button 23 is provided with protrusions 29 which engage the depressions 32 on the piston rod guide 14. When the injection button 23 is moved in the proximal direction the protrusions 29 will engage the depressions 32 and thereby prevent the rotation of the piston rod guide 14.

The housing 1 is provided with a member 40 having longitudinal recesses 43 which are engaged by the piston rod 6. The member 40 is held between a ring shaped wall 46 in the housing and the end wall 4 in the member 40. The ampoule holder 2 engage the slots 42 to lock the ampoule holder 2 to the housing 1.

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. A driver tube 45 is at one end provided with the pawl 13 which engages pawl wheel teeth in the member 40 and is held between a ring shaped wall 46 in the housing and the end wall 4 in the member 40 to keep the driver tube 45 from axial movement but allowing it to rotate. On its inner wall the driver tube 45 has a key engaging a longitudinal recess in the piston rod 6. Thereby rotation of the driver tube is transmitted to the piston rod 6 whereas the piston rod can move freely in the axial direction of the driver tube 45. On its outer wall the driver tube 45 has an outer thread 47 which engages an inner thread 50 in a nut member 48 which has at its distal end a flange 49 and is at its proximal end provided with a part 51 with reduced diameter to which part one end of a tubular part 52 which at its other end carries a button 23 is secured.

In the proximal end of the housing 1 a bushing 53 is secured to be non rotatable a non displaceable relative to said housing 1 the rotational locking being obtained by lugs 54 at the proximal end of the housing engaging recesses 55 at the periphery of the bushing 53. A guide member 56 is

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.

Source: EX1014, 7:44-47; Pet., 60-62.

Steenfeldt-Jensen: Sanofi's Flawed Rebuttal

No dispute that independent claims are obvious over Steenfeldt-Jensen as modified

Sanofi's attempts to escape Steenfeldt-Jensen's repeated suggestions do not withstand scrutiny:

- 1) Meaningless distinction between “rotating nut” and “threaded driver tube”
- 2) Strained attempt to limit suggestion to first embodiment
- 3) Flawed “friction” analysis
- 4) Speculative concerns about pawl mechanism

Source: POR, 27-43; Pet. Reply, 8-19.

Steenfeldt-Jensen Expressly Suggests Threaded Driver Tube

1) No difference between “rotating nut” and “threaded driver tube”

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,

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.

Rotating nut is a threaded driver

Sur-reply argues Steenfeldt-Jensen suggests rotating nut that is separate from driver

- Sanofi points to wall 4, but Steenfeldt-Jensen expressly states that wall 4 is *piston rod guide* as modified (i.e. no longer threaded)
- No plausible meaning other than threaded driver

Source: Pet. Reply, 8-9; EX1095, ¶¶63-65; EX1014, 2:46-52, 7:41-47; PO Sur-reply, 14-17.

Steenfeldt-Jensen Repeatedly Suggests Threaded Driver Tube

2) Threaded-driver teachings not limited to first embodiment

Numerous teachings of threaded driver tube throughout reference

- Only one provided during discussion of first embodiment
- Even that passage still relevant to fifth embodiment

Dr. Slocum admitted that first and fifth embodiments have “very similar” structures and force chains for dose-dispensing.

12 Q. Well, let me ask this: You agree with me that even if
13 a person of ordinary skill in the art would understand that
14 these passages apply only to embodiment 1, **embodiments 1 and 5**
15 **are very similar in terms of dispensing medicament; right?**
16 **A. For the dispensing part, correct.**
17 **Q. And the force chain between embodiments in 1 and 5 are**
18 **similar, too; correct?**
19 **A. For the force chain -- or for the dispensing, correct.**
20 Q. All right. So you agree with me that embodiments 1 and 5
21 are very similar in terms of dispensing medicament; correct?
22 A. Dispensing, correct.

Source: *Pet.*, 60-62; *Pet. Reply*, 9-13; *EX1054*, 306:23-307:19; *EX1095*, ¶¶66-70; *Pet. Obs.*, 2; *EX1115*, 531:12-22.

POSA Would Not Ignore Steenfheldt-Jensen's Express, Repeated Teachings

3) Sanofi's friction models are flawed

Skewed results: not showing net change in friction

Dr. Slocum admitted model does not account for corresponding reductions in friction

- Unmodified: piston rod rotates = friction at pressure foot (bearing full injection force)
- Modified: no piston-rod rotation = **total elimination** of friction at pressure foot

```
13 Q. It does not account for the elimination of force down
14 here; correct?
15 A. Correct.
16 Q. Okay. So if you include that elimination of force, the
17 51 percent number goes down; right?
18 A. Yeah, it will go down depending on how big the diameters
19 are.
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Source: Pet. Reply, 16; EX1095, ¶175; EX1014, FIG. 16; Pet. Obs., 4; EX1115, 561:19-563:6.

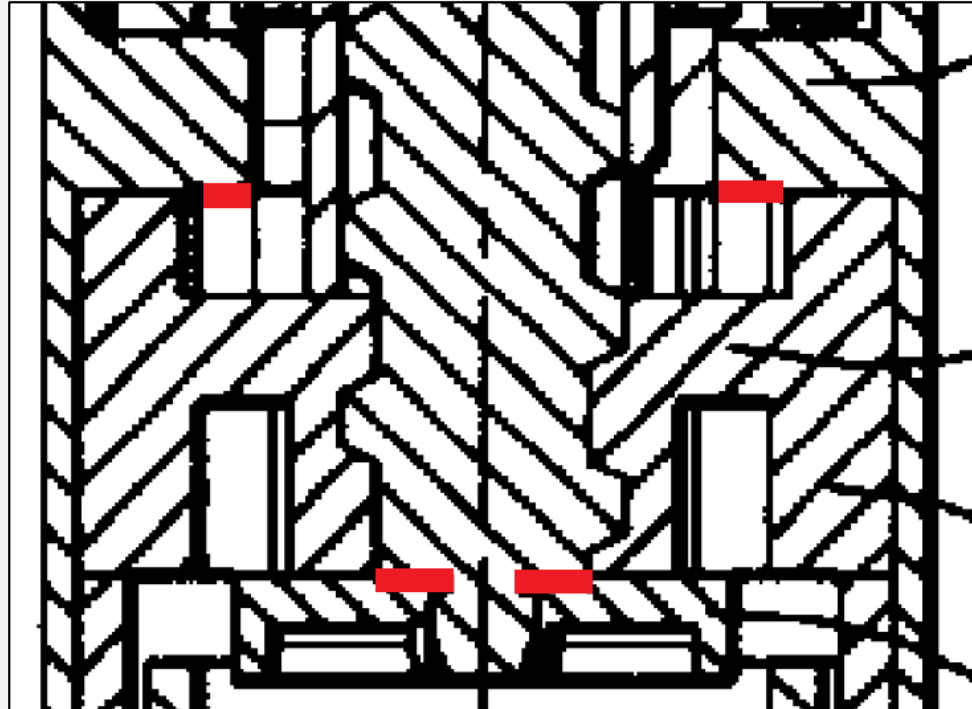
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POSA Would Not Ignore Steenfheldt-Jensen's Express, Repeated Teachings

3) Sanofi's friction models are flawed

Not net change: ignores total elimination of friction at pressure foot

13 Q. It does not account for the elimination of force down
14 here; correct?
15 A. Correct.
16 Q. Okay. So if you include that elimination of force, the
17 51 percent number goes down; right?
18 A. Yeah, it will go down depending on how big the diameters
19 are.



Source: *Pet. Reply*, 16; EX1095, ¶75; EX1014, FIG. 16; *Pet. Obs.*, 4; EX1115, 561:19-563:6.

POSA Would Not Ignore Steenfheldt-Jensen's Express, Repeated Teachings

3) Sanofi's friction models are flawed

Biased inputs further skew results.

- Named inventor (Mr. Veasey) controlled vast majority of inputs.

Okay. The first pitch diameter, the 12.0, where did that come?

A. That's from Mr. Veasey.

Q. Okay. The root diameter, where did that come from?

A. The 11.5, from Mr. Veasey.

Q. The lead, the distance traveled one complete rotation, where did that come from?

A. Mr. Veasey.

Q. Okay. The 6 under the flank angle alpha cosine, 6?

A. 6 degrees there.

Q. That came from?

A. Mr. Veasey.

Q. The coefficient of friction between back driven screw threads, 0.1?

A. Mr. Veasey.

Q. Okay. The piston rod for pitch diameter, that's from Veasey?

A. That's from Veasey.

Q. As is the root diameter, that's from Veasey?

A. Correct. And the lead.

Q. The lead is from Veasey.

A. And the flank angle.

Q. And the flank angle from Veasey.

Okay. And then the coefficient of friction, I think we already talked about those two 0.1s, those are from Veasey as well?

A. Yes. Just assuming the same type of lubricious plastic type interface.

Source: EX1054, 319:17-320:9, 322:7-20; Pet. Reply at 14-16; Pet. Obs., 2-3; EX1115, 546:18-552:23.

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POSA Would Not Ignore Steinfeldt-Jensen's Express, Repeated Teachings

3) Sanofi's friction models are flawed

Biased inputs further skew results.

- Dr. Slocum acquiesced to Mr. Veasey even when key input (coefficient of friction) contradicted Dr. Slocum's previously published views.
- **Initially denied 0.05 was reasonable but relented when confronted with his own book (showing 0.05-0.1 was reasonable).**
- Admitted he would have used 0.05 if Mr. Veasey had requested it.

During direct testimony:

Q Okay. Now, Mr. Leinsing testified yesterday that you could use a coefficient of friction of 0.05.
Do you agree with that?
A I heard that, but I do not agree.

Confronted with own book during cross:

Sliding contact bearings have coefficient of friction on the order of 0.05 to 0.1; correct?
A. That's what it says, yes.
Q. And that's your belief and that's your experience; right?
A. Yes. In general you can generalize like that, yes.
Q. So .05 is not an unreasonable thought if somebody with experience in designing injector pens as of the prior date had told you that; right?
A. Not necessarily. You could.

Source: Pet. Reply, 14-17; Pet. Obs., 3-4; EX1114, 463:13-16; EX1115, 555:5-12, 557:22-559:23.

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POSA Would Not Ignore Steinfeldt-Jensen's Express, Repeated Teachings

3) Sanofi's friction models are flawed

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- Initially denied 0.05 was reasonable but relented when confronted with his own book (showing 0.05-0.1 was reasonable).
- **Admitted he would have used 0.05 if Mr. Veasey had requested it.**

Admitting deference to Mr. Veasey:

Q. If Mr. Veasey had said .08, you would have used .08; right?
A. Correct.
Q. If Mr. Veasey said .05, you would have used .05; right?
A. They -- we would. Yes.
Q. Yes, because you'd defer to his experience, right, in the field of pin injectors. Right?
A. From what he said he measured.

But certainly if Mr. Veasey had told you it's fair to use 0.05, you wouldn't have batted an eye at that. You would have just input 0.05; right?
A. Yeah, because that's what he said he had measured, and I assumed that was fine.
Q. You know that Mr. Leinsing actually did design injector pens before the priority date. You were here for his testimony; right?
A. Yes.

Source: Pet. Reply, 14-17; Pet. Obs., 3-4; EX1114, 463:13-16; EX1115, 555:5-12, 557:22-559:23.

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POSA Would Not Ignore Steinfeldt-Jensen's Express, Repeated Teachings

3) Sanofi's friction models are flawed

Physical model ("rig")
also designed by Mr.
Veasey (or by employees
at his company, "DCA")



Source: *Pet. Reply*, 14-17; EX1053, 30:5-33:4.

Did you have more than one discussion with Rob Veasey?

A. Well, we had a discussion about the background. And then -- okay, thank you. In here it says that he told me about Steinfeldt-Jensen's fifth embodiment closely corresponds to the disposable FlexPen.

I didn't know that, but he knew that.

Q. Okay.

A. And then as I show later on in my report, using this collar friction rig model that he had made. So I'm pretty sure we had a second call about that rig.

Q. Okay. We'll get to the rig later. But the rig was prepared by Rob Veasey?

A. I don't know if he personally did it, but it came from DCA is my understanding.

POSA Would Not Ignore Steenfheldt-Jensen's Express, Repeated Teachings

3) Sanofi's friction models are flawed

Rig bias: Dr. Slocum again deferred to Mr. Veasey

- Mr. Veasey chose components tested on rig
- Mr. Veasey chose to use FlexPen as stand-in for Steenfheldt-Jensen
- Mr. Veasey chose to use components that Dr. Slocum noted were “much bigger, obviously than an actual injector pen”

Mr. Leinsing:

minimize any such impact in a pen injector. In addition, I also note that the collar friction rig used by Dr. Slocum is significantly bigger than an actual injector pen. A person of ordinary skill would not have considered such a rig to be relevant in the design of a pen injector with the proposed modification, and instead, would have considered its larger size to exaggerate the effects of “collar friction” compared to what would have been felt in a smaller pen device with the same modification.

Source: Pet. Reply, 14-17; EX1053, 30:5-33:13; EX2107, ¶¶245-54; EX1095, ¶174.

POSA Would Not Ignore Steinfeldt-Jensen's Express, Repeated Teachings

4) Speculative pawl issues

No evidence whatsoever that pawl would fail

Sanofi yet again ignores routine skill

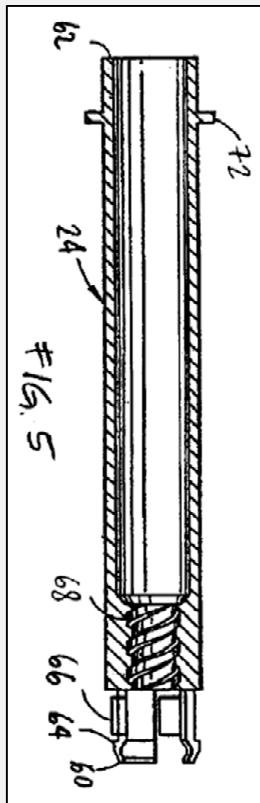
- Mr. Leinsing: configuring robust pawl mechanism was “routine task” for POSA

Source: Pet. Reply, 17-18; EX1095, ¶176.

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POSA Would Not Ignore Steinfeldt-Jensen's Express, Repeated Teachings

Actual pen designers used threaded drivers with rotating collars

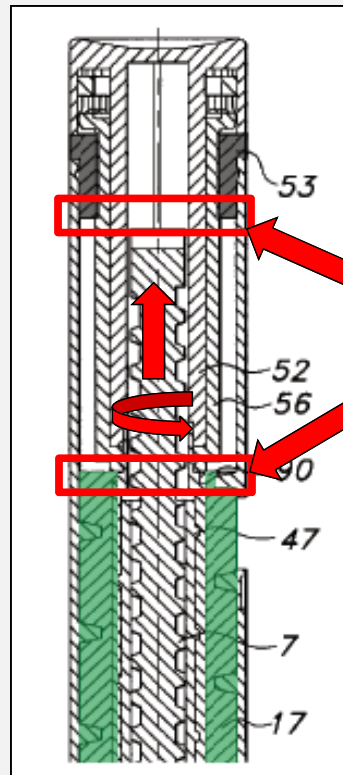


77. Finally, in my experience, the modification suggested by Steinfeldt-Jensen was a predictable type of drive mechanism that was known in the art. For example, Giambattista incorporates the use of a driver tube like that of Steinfeldt-Jensen, but with internal threading, which is analogous to the modification proposed in Steinfeldt-Jensen. Like Steinfeldt-Jensen, Giambattista's driver tube includes a pawl mechanism at its needle-end that axially secures the driver to the housing, but allows for one-way rotation during dose injection. See EX1016, 3:16-26, FIGS. 2-7. The housing, in turn, includes a rectangular aperture 26 in a bulkhead 44 (i.e., a "piston rod guide") through which the piston rod is axially displaceable. *Id.*, 3:1-26. Thus, despite Dr. Slocum's assertion that a person of ordinary skill "would never actually" provide an internally threaded driver tube, actual pen designers did pursue this approach, as illustrated by Giambattista. In

Source: Pet. Reply, 18-19; EX1016, 3:1-26, FIGS. 2-7; EX1095, ¶77.

'486 Claims 30 and 32 (-1678, Grounds 1-2): Steinfeldt-Jensen Teaches a "Radial Stop"

Steenfeldt-Jensen demonstrates the known and predictable use of "stops" to limit the length of travel of a rotating component:



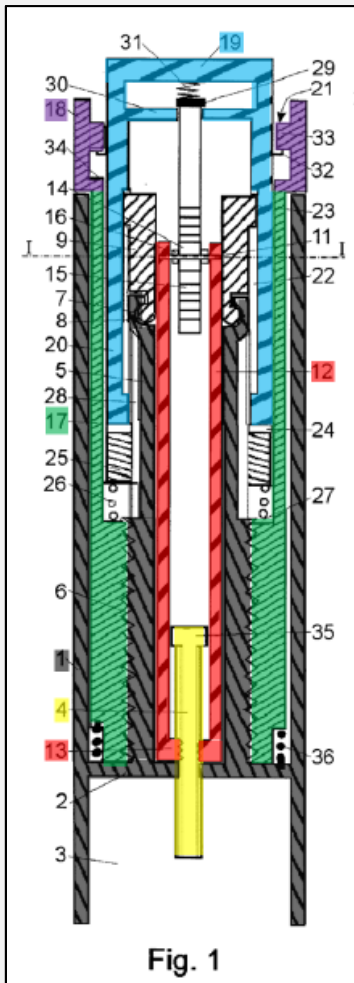
When the dose scale drum is displaced outwardly in the housing a steep front side of a saw tooth 91 at the proximal end of the dose scale drum 18 will abut a steep front side of a similar tooth 92 on the bushing whereby the rotation of the dose scale drum is stopped to indicate that a maximum dose has been set.

During dose-setting, tooth on dose scale drum (green) abuts corresponding tooth on bushing (gray) to stop scale drum's rotation when maximum axial length of travel is reached

Source: EX1014, 9:57-62, FIG. 12; -1678 Pet., 51-53 (citing EX1011, ¶¶327-32); -1678 Pet. at 94-95 (citing EX1011, ¶¶431-37).

Claims Are Obvious Over Møller and Steinfeldt-Jensen

IPRs -1670, -1676, -1678: Møller and Steinfeldt-Jensen Rendered the Claims Obvious



Møller describes an injector pen having:

- (1) **“a main housing** [housing 1, gray]...extending from a distal end to a proximal end;”
- (2) **“a dose dial sleeve** [dose setting drum 17, green] positioned within said housing...comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an **[inner]** surface of said dose dial sleeve;”
- (3) **“a dose dial grip [or dose knob]** [dose setting button 18, purple] disposed near a proximal end of said dose dial sleeve;”
- (4) **“a piston rod** [piston rod 4, yellow] provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;”
- (5) **“a drive sleeve [or driver]** [connection bars 12/nut 13, red] extending along a portion of said piston rod...comprising an internal threading near a distal portion...adapted to engage an external thread of said piston rod;”
- (6) **“a tubular clutch** [bottom 19/cup shaped element 20, blue] 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”

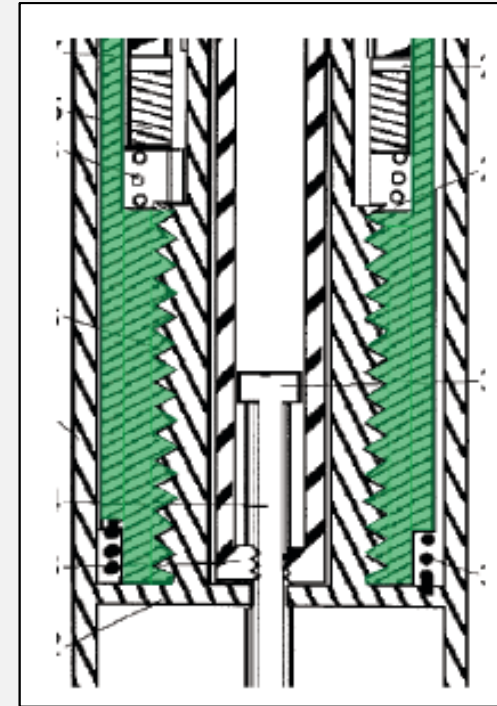
“wherein said helical groove of the dose dial sleeve has a first lead and said internal threading of said drive sleeve has a second lead, and wherein said first lead and said second lead are different”

Source: Pet., 22-24 (citing EX1011, ¶¶138-39, 141-42), 62-85.

IPRs -1670, -1676, -1678: Møller and Steinfeldt-Jensen Teach a Helical Groove

[0025] A tubular dose setting drum 17 fitting into the housing 2 is at an end provided with an internal thread mating and engaging the outer thread 6 of the tubular element 5 and has at its other end a part with enlarged diameter forming a dose setting button 18. 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.

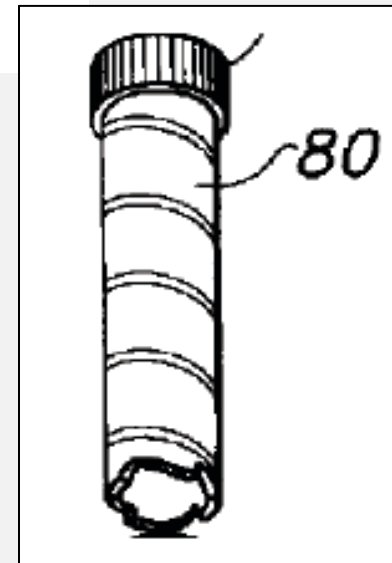
¶25, FIG. 1. The threading is shown in FIG. 1, which shows that the thread includes a helical groove formed between neighboring ridges of a helical, protruding rib. Indeed, a person of ordinary skill would have understood that a continuous, screw thread, like that of Møller, forms a rib and a groove—that is, a groove is formed between adjacent ridges of the rib. To illustrate this, I have



Source: EX1015, ¶25; EX1011, ¶350; -1678 Pet., 65.

IPRs -1670, -1676, -1678: Møller and Steinfeldt-Jensen Teach a Helical Groove

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 Steinfeldt-Jensen. Steinfeldt-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



Source: EX1011, ¶¶352-53; EX1014, FIG. 17; -1678 Pet., 65-66.

'069 & '044 Patents (-1670, -1676): Møller and Steenfeldt-Jensen Teach an Externally Grooved Drum

US 2002/0052578 A1

INJECTION DEVICE

[0001] The invention relates to syringes by which a dose can be set by rotating a dose setting member and by which an injection button elevates from an end of the syringe a distance proportional to the set dose and wherein the set dose can be injected by pressing home the injection button to its not elevated position.

[0002] An almost classic pen of this type is described in EP 327 910.

[0003] By setting a dose on this pen a tubular member forming an injection button is screwed up along a threaded piston rod a distance corresponding to the distance said piston rod must be moved to inject the set dose. The tubular member simply forms a nut which is during the dose setting screwed away from a stop and which is during the injection pressed back to abutment with said stop and the force exerted on the button is directly transmitted to the piston closing one end of an ampoule in the syringe which ampoule contains the medicament to be injected. When 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.

[0004] By time it has been wanted to store larger amount in the ampoules, typically 3 ml instead of 1,5 ml. As it has not been appropriate to make the syringe longer the ampoule is instead given a larger diameter, i.e. the area of the piston facing the medicament in the ampoule has been doubled and consequently the force which has to be exerted on the piston to provide the same pressure as previously inside the ampoule has been doubled. Further the distance the piston has to be moved to inject one unit of the medicament has been halved.

[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.

[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.

[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 transfer of force is due to friction between the sliding surfaces. Such a traditional gearing using mutual engaging racks is preferred.

[0009] From WO 96/26754 is known a housing encompassing set of gear wheels wherein two integrated gear wheels, the housing and a rack inside a plunger, the plunger is moved axially in the housing, this plunger can drive the first gear wheel, the integral gear wheel move along. Thereby the gear wheel is made to rotate the plunger movement but a short distance and this axial movement of the plunger is transmitted to a piston rod which presses into this ampoule. However, one of a number axial movements of the plunger being in engagement with the rack arrangement is provided in a direction out of the plunger is rotated to a corresponding distance where the first gear wheel thereafter the first set unit can be made the first gear wheel passing the set unit until a dose is set.

[0010] A danger of the rack and pinion arrangement is that during the injection the surface of the rack and pinion may be damaged.

[0011] In a preferred embodiment the gearing between the movements of the injection button and the nut is obtained by

[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.

[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.

[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

Mylan Exhibit - 1015
Mylan v. Sanofi

Source: EX1015, ¶¶6, 8; Pet., 70-71, 85-87.

'069 & '044 Patents (-1670, -1676): Møller and Steinfeldt-Jensen Teach an Externally Grooved Drum

[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.

[0012] This can be obtained by an injection device comprising a housing wherein a piston rod threaded with a first pitch is non rotatable but longitudinally displaceable guided, a nut engaging the thread of the piston rod which nut can be screwed along the threaded piston rod away from a defined position in the housing to set a dose and can be pressed back to said defined position carrying the piston rod with it when the set dose is injected, a dose setting drum which can be screwed outward in the housing along a thread with a second pitch to lift an injection button with it up from the proximal end of the housing, which injection device is according to the invention characterised in that a gearbox is provided which 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 and first pitch.

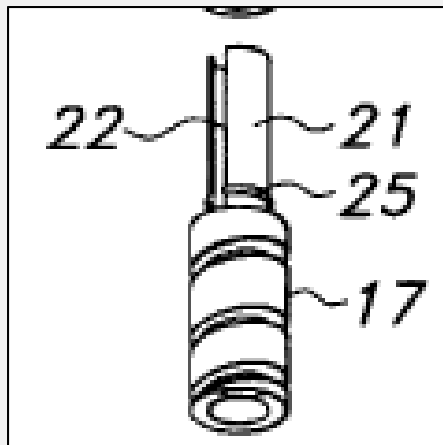
[0014] In such a device only the forces necessary to drive the dose setting drum are transformed by a thread with a high pitch whereas the forces necessary to move the piston by injection is transmitted to said piston through a conventional gear with constantly engaging gears and racks.

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

Source: EX1015, ¶¶11-12, 14, 33; Pet., 85-87.

'069 & '044 Patents (-1670, -1676): Møller and Steenfeldt-Jensen Teach a Helical Groove on the Outer Surface

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. A dose scale drum 17 is in its outer wall provided with a helical groove defining a corresponding external thread mating the inner thread just mentioned. The pitch angle of the threads exceeds the angle of friction for the materials forming the parts of the thread connection and consequently the thread connection is of the not self locking type which induce a relative rotation of the parts of the connection when these part are moved axially relative to each other.

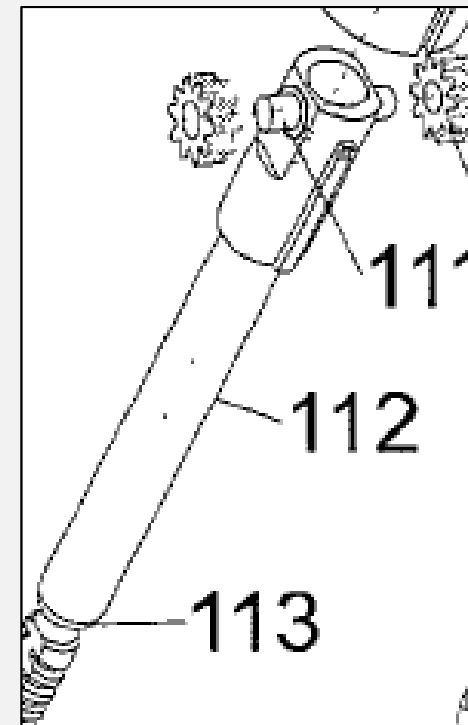


Source: EX1014, 6:7-17; Pet., 85-87.

'069 & '044 Patents (-1670, -1676): Møller and Steinfeldt-Jensen Teach a Drive “Sleeve”

[0035] FIGS. 3 and 4 shows a preferred embodiment wherein only one size gear wheel is used and wherein elements corresponding to elements in FIG. 1 and 2 are given the same references as these elements with a prefixed “1”.

[0040] A tubular connection element 112 connects the threaded piston rod 104 with the gearbox. At its end engaging the piston rod 104 the connection element has a nut 113 with an internal thread mating the external thread of the piston rod. At its end engaging the gear box the connection



Source: EX1015, ¶¶35, 40, FIG. 5; Pet., 74-77 (citing EX1011, ¶¶370-71).

Møller: Sanofi's Failed Rebuttal

- 1) References teach driver tube
- 2) References teach externally threaded dial sleeve
- 3) References teach main housing (-1678)

Source: POR, 43-57; Pet. Reply, 19-24; EX1095, ¶¶94-97, 101-06.

Sanofi's Failed Møller Rebuttal

1) References teach driver tube

- No dispute that tubular connection element 112 and nut 113 are a “sleeve”
- No meaningful difference between first and second embodiments (gears outside vs. inside)
 - Similar rack engagement, movement
 - Second embodiment simply uses one gear size instead of two

No “significant redesign”
as Sanofi alleges:

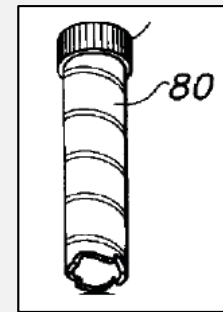
283. I disagree. The racks can easily engage the gear wheels whether they are inside the driver or outside the driver, and Møller's second embodiment illustrates how such an arrangement can be accomplished without having to substantially widen the pen as Dr. Slocum argues. Indeed, I note that Sanofi's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

Source: Pet. Reply, 19-21; EX1015, ¶¶12-13, 24, 30-32, 34-35, 39-40, FIGS. 1, 3-5; EX1095, ¶¶94-97.

Sanofi's Failed Møller Rebuttal

2) References teach externally threaded dial sleeve

No dispute that Steinfeldt-Jensen teaches this



Møller does not teach away:

- Addresses external threading on drum that is part of gearing (i.e. drum transforms force to piston rod)

[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.

[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.

Source: Pet. Reply, 21-24; EX1014, FIGS. 15-17; EX1015, ¶¶8, 11; EX1095, ¶¶101-06.

Sanofi's Failed Møller Rebuttal

2) References teach externally threaded dial sleeve

But Møller's drum not part of gearing

- Admitted by Dr. Slocum

Q. Are threads 6 at all involved in the gear, in the gearing transmission here?

A. No. Those are -- let's see, when we go

Externally threaded drum would not increase injection force.

- Not part of gearing force chain = not transforming injection force
- Optional reset spring can counteract even minimal reset force

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.

Source: Pet. Reply, 21-24; EX1015, ¶¶33; EX1054, 354:19-355:24; EX1095, ¶¶101-06.

Sanofi's Failed Møller Rebuttal

2) References teach externally threaded dial sleeve

Allegation of interference with reset spring yet another example of Sanofi ignoring routine skill of POSA

- Petition never suggested placing threads “precisely” on spring
- Sanofi presumes POSA incapable of simply moving spring
- Sanofi also ignores that reset spring is *optional*

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

Source: POR, 55-57; Pet. Reply, 24; EX1015, ¶33; EX1095, ¶¶105-06.

Sanofi's Failed Møller Rebuttal

3) References teach main housing (-1678)

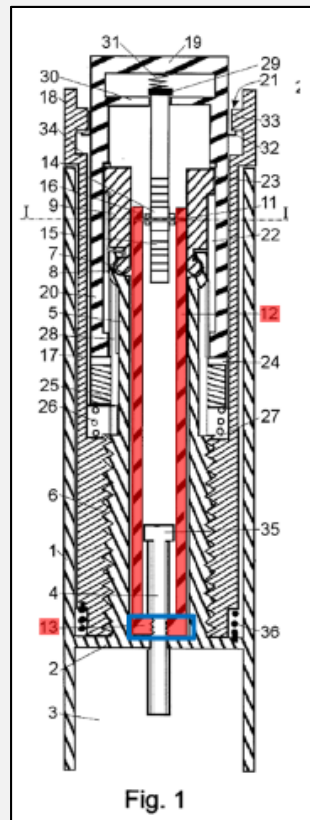
Sanofi imports limitations from different patent with different, later-filed disclosure

Source: -1678 POR, 54-55; -1678 Reply, 1-3, 20-21.

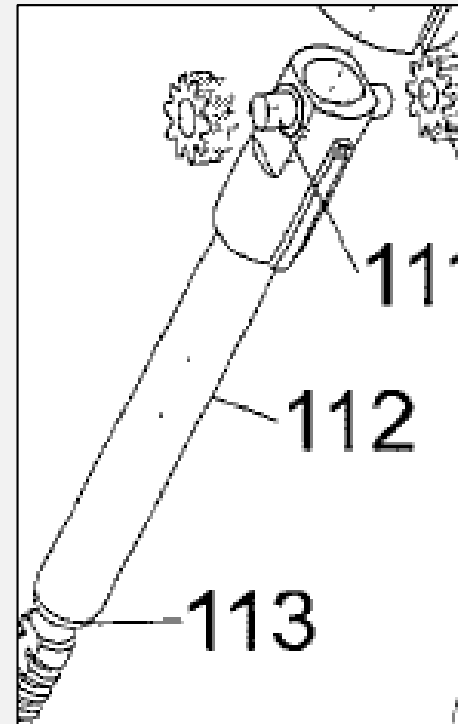
'486 Claim 5 (-1678, Ground 2): Møller and Steinfeldt-Jensen Teach a "Driver" that "Comprises a Cylindrical Shape"

Connection bars 12 includes nut 13

- **No dispute** that nut 13 has "a cylindrical shape":



No dispute that analogous driver (tubular connection element 112 and nut 113) has "cylindrical shape":



Source: -1678 Pet., 81-82 (citing EX1011, ¶¶394-95); -1678 Reply, 21-23.

'044 Claim 15 (-1676, Ground 2) and '486 Claims 18 and 20 (-1678, Ground 2): Møller and Steinfeldt-Jensen Teach a “Clicker” with a Flexible Arm

Møller and Steinfeldt-Jensen disclose predictable variations of “clickers”:

this drum up from the end of the housing 1. By the 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. A too high set dose can be reduced by rotating

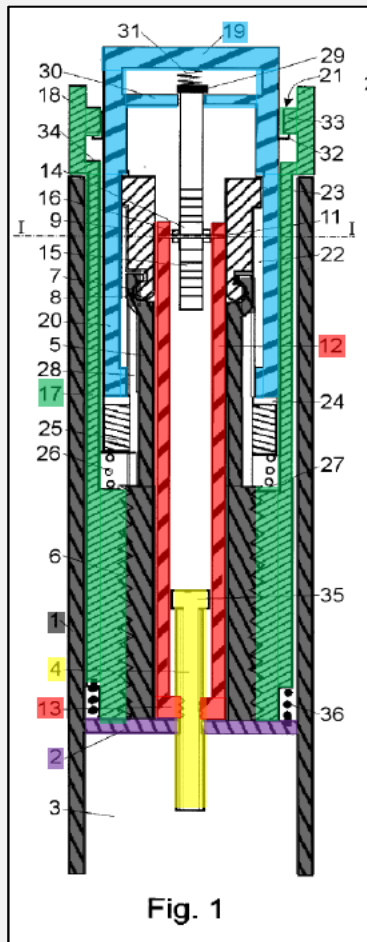
rotation. Therefore by the rotation of the dose setting button 81 in any direction the radial protrusion 87 on the flange 83 of the bushing 82 will click from one of the axial recess in the inner wall of the dose setting button 81 to the next one, the recesses being so spaced that one click corresponds to a chosen change of the set dose, e. g. one unit or a half unit.



Source: EX1015, ¶29; EX1014, 11:62-67, FIG. 17; -1678 Pet., 84-88 (citing EX1011, ¶¶413-15).

The '008 Claims Are Obvious Over Møller and Steinfeldt-Jensen

IPR -1684: Møller and Steinfeldt-Jensen Rendered the '008 Claims Obvious

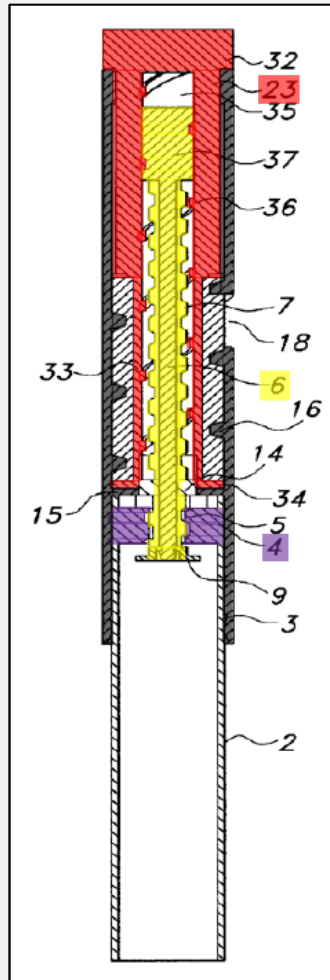


Møller describes an injector pen having:

- (1) “**a housing** [housing 1, gray] comprising a helical thread;”
- (2) “**a dose dial sleeve** [dose setting drum 17, green] having a threaded surface that is engaged with the helical thread of the housing;”
- (3) “**an insert** [wall 2, purple] provided in the housing . . .;”
- (4) “**a drive sleeve** [connection bars 12/nut 13, red] releasably connected to the dose dial sleeve and having an internal helical thread;”
- (5) “**a piston rod** [piston rod 4, yellow] having . . . a second thread, wherein . . . the second thread is engaged with the internal helical thread of the drive sleeve; and”
- (6) “**a clutch** [bottom 19/cup shaped element 20, blue] 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.”

Source: -1684 Pet., 13-15, 18-41.

IPR -1684: Møller and Steinfeldt-Jensen Rendered the '008 Claims Obvious

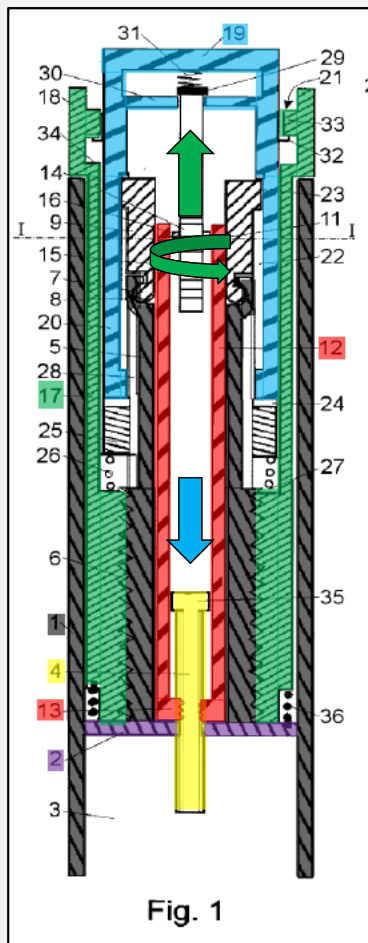


Steenfeldt-Jensen describes an injector pen having:

- (1) “**a housing** [housing 1, gray] comprising a helical thread;”
- (2) “**an insert** [wall 4, purple] provided in the housing, where the insert has a threaded circular opening;”
- (3) “**a drive sleeve** [injection button 23, red] releasably connected to the dose dial sleeve and having an internal helical thread;”
- (4) “**a piston rod** [piston rod 6, yellow] 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”

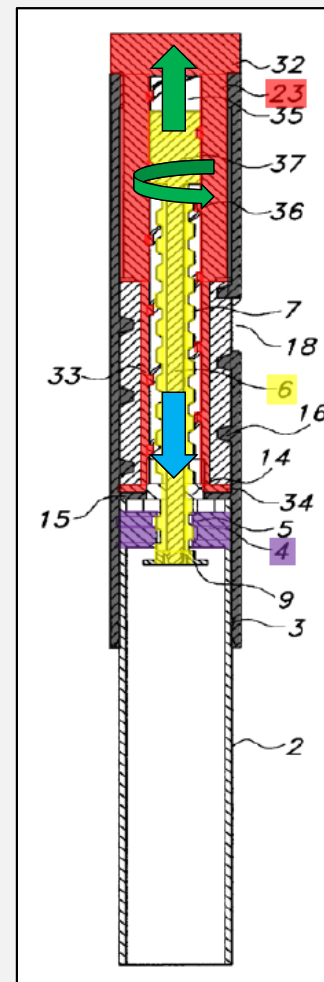
Source: -1684 Pet., 15-41.

IPR -1684: Møller and Steinfeldt-Jensen Teach Analogous Drive Mechanisms



Dose-setting (green arrows): Driver moves up and rotates

Dose-dispensing (blue arrow): Driver (red) moves down, but does not rotate



Source: EX1014, 7:48-8:33; EX1015, ¶¶30-31; -1684 Pet., 41-42 (citing EX1011, ¶¶832-37).

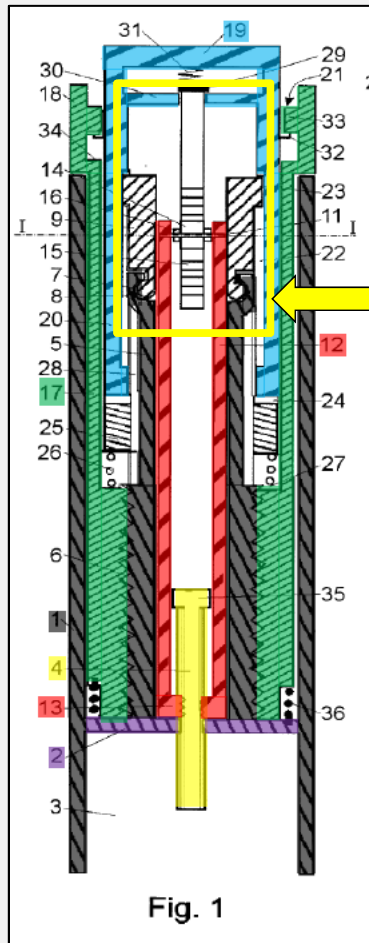
IPR -1684: Møller Teaches the Use of Direct Gearing

[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.

[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.

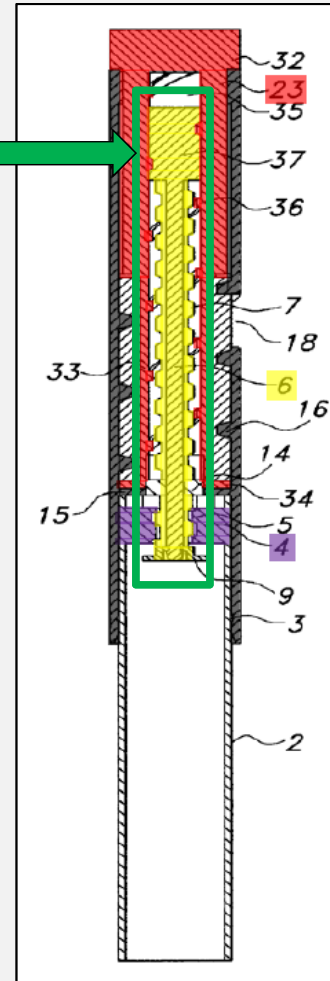
Source: EX1015, ¶¶6, 11; -1684 Pet., 41-44 (citing EX1011, ¶¶832-37).

IPR -1684: Steenfeldt-Jensen Teaches Achieving Direct Gearing with Fewer Parts



Dual-threaded piston rod

Rack-and-pinion system



Source: -1684 Pet., 13-18, 25-35, 41-44 (citing EX1011, ¶¶135-44, 804-23, 832-37); -1684 Pet. Reply, 1-5, 8-9. 64

Møller and Steinfeldt-Jensen: Sanofi's Failed Rebuttal

Sanofi's responses fail:

- 1) Møller does not teach away
- 2) Ample motivation, expectation of success
 - Clear advantages
 - Compatible operation
- 3) Clear teaching of threaded housing/insert

Source: -1684 Reply, 1-12; EX1095, ¶¶138-48.

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Møller and Steinfeldt-Jensen: Sanofi's Failed Rebuttal

1) No teach away: Sanofi again misapprehends Møller

Møller addresses external threading on drum with large surface area, not threaded gearing generally

[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.

[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.

Dual-threaded piston rod has small surface area compared to drum (i.e. much less friction)

Source: -1684 Reply, 1-5; EX1095, ¶¶138-41.

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Møller and Steinfeldt-Jensen: Sanofi's Failed Rebuttal

2) Ample motivation: clear advantages

Reference expressly states advantage of fewer components

Sanofi's POR disputes goal of minimizing parts at p. 34 despite admitting teaching of this goal at p. 32.

Steenfeldt-Jensen:

or burning without producing noxious gases. For these purposes the number of parts from which the syringe is constructed and the number of different kinds of materials used in the syringe should be kept at a minimum.

Source: -1684 Pet., 43; -1684 Reply, 7-9; EX1011, ¶¶835-54; EX1095, ¶¶145-46; -1684 POR, 32 (citing EX1014, 1:27-30).

Møller and Steinfeldt-Jensen: Sanofi's Failed Rebuttal

2) Ample motivation: clear advantages

POSA can balance injection-force and part-minimization goals

- Dr. Slocum admits “[t]here will of course be tradeoffs between cost and injection force....”

Sanofi argues Steinfeldt-Jensen’s threaded gearing “does not, and cannot,” provide reduced injection force

- Yet Sanofi touts SoloSTAR (with analogous gearing) as providing “greatly reduced injection force”

Source: -1684 Pet., 42-44; -1684 Reply, 7-9; EX1011, ¶¶835-37; EX1095, ¶¶145-46; -1684 POR, 32 (citing EX1014, 1:27-30); EX2107, ¶36.

Møller and Steinfeldt-Jensen: Sanofi's Failed Rebuttal

2) Ample motivation/expectation of success: compatible operation

Drive sleeves rotate and ride up to set dose, push straight down to inject

- Møller's pen operates same in combination as before
- Threaded gearing (with dual-threaded piston rod) operates same in combination as in Steinfeldt-Jensen

Sanofi only points to extraneous differences without even alleging they matter

- All relevant aspects of mechanisms same

Source: -1684 Pet., 41-44; -1684 Reply, 5-6; EX1011, ¶¶832-37; EX1095, ¶¶143-44; -1684 POR, 29-30

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Møller and Steinfeldt-Jensen: Sanofi's Failed Rebuttal

3) Recited housing and insert can be internal, integral

Sanofi contradicts specification, arguing wall 4 not “housing”, and wall 2 not “insert”, because they are internal and integrally formed

'008 patent:

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 enable the safe, correct, and comfortable handling of the drug delivery device or any of its mechanism. Usually, it is designed to house, fix, protect, guide, and/or engage with any of the inner components of the drug delivery device (e.g., the drive mechanism, cartridge, plunger, piston rod) by limiting the exposure to contaminants, such as liquid, dust, dirt etc. In general, the housing may be unitary or a multipart component of tubular or non-tubular shape. Usually, the

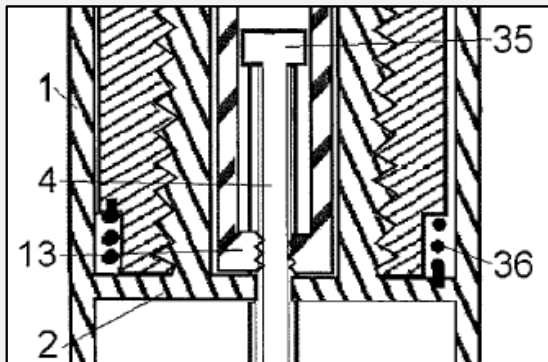
therethrough. Alternatively, the insert may be formed integrally with the main housing 4 having the form of a radially inwardly directed flange having an internal thread.

Source: -1684 Reply, 10-12; EX1095, ¶¶147-48; EX1005, 2:66-3:10, 7:33-39.

Møller and Steinfeldt-Jensen: Sanofi's Failed Rebuttal

Claim 3 (insert “secured in the housing against rotational and longitudinal motion”):

- Sanofi attacks references individually
 - Petition described application of Steinfeldt-Jensen’s direct-gearing mechanics, not bodily incorporation of rotating ampoule holder
- In combination, threaded flange **fixed** relative to housing



[0036] For manufacturing reasons minor changes are made. So the partitioning wall 102 and the tubular element 105 are made as two parts which are by the assembling of the device connected to each other to make the assembled parts act as one integral part. The same way the dose setting drum 117 and the dose setting button 118 are made as two parts, which are fixed firmly together.

Source: -1684 Pet., 41; -1684 Reply, 12-14; EX1015, ¶36, FIGS. 1, 3-5; EX1011, ¶¶832-34; EX1095, ¶149.

Experts: A Study in Contrasts

Source: EX1011, ¶¶1-8; EX1012; Mot. Excl., 5-7.

DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

Only Mr. Leinsing Has the Proper Expertise

“qualified as an expert by knowledge, skill, experience, training, or education” *but also* “based on sufficient facts or data” and “the product of reliable principles and methods” FRE 702.

Karl Leinsing:

- MS Mechanical Engineering
- Registered Professional Engineer
- Decades of experience with medical devices
- Decade of directly relevant experience right before claimed priority date
- Inventor on injector device patents
- Testimony based on relevant experience

Alexander Slocum:

- PhD Mechanical Engineering
- General focus and experience
- No relevant industry experience
- Testified that he “didn't have personal knowledge of the industry at the time of the invention, so I wanted to talk to [inventor Rob Veasey] who was clearly in the thick of it at the time.”

Source: EX1012; EX1053, 28:23-30:4; EX2108; Mot. Excl., 5-6.

Slocum's Faulty Reliance on Veasey

Sanofi mischaracterizes the issue as simply Slocum's lack of experience, but his faulty approach is the key failing

"the product of reliable principles and methods ... reliably applied ... to the facts of the case" FRE 702; cf. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 580 (1993).

Inventor testimony is interested and must be viewed with skepticism. *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 968 (Fed. Cir. 2014).

Uncritical adoption of inventor-supplied facts outside record is inherently unreliable basis for expert testimony

Slocum Uncritically Accepted Inventor Views

Q. Since you don't have experience in pen injectors, you can't say whether 0.08 or lower which is reasonable; right?

A. I have nothing to show a pen injector that has that coefficient of friction.

Q. Now, you asked Mr. Veasey in his experience what are typical coefficients of friction that they experience in the devices; right?

Q. You said you didn't agree with Mr. Leinsing's statement that a 0.05 coefficient of friction would be reasonable; right?

A. I think for the pen injectors, according to Mr. Veasey you would not get that, so I didn't see any evidence from him that in pen injectors you would use that.

A. I believe so, yes.

Q. And Mr. Veasey said .1. Right?

A. He said he measured .15, but he said to be super lubricious, you should assume .1, and that's what I did.

Q. If Mr. Veasey had said .08, you would have used .08; right?

A. Correct.

Q. If Mr. Veasey said .05, you would have used .05; right?

A. They -- we would. Yes.

Q. Yes, because you'd defer to his experience, right, in the field of pin injectors. Right?

A. From what he said he measured.

Source: EX1115, 554:19-555:12.

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Slocum Recognizes His Limits

Q. As of March, 2003, you had no personal experience designing injector pen devices; correct?

A. Correct.

Q. You've had some experience with syringes at various times in your career, but you hadn't worked professionally with injector pens until you were retained for this case; right?

A. I think that's correct.

Q. You agree with me though that in your experience, lubricious plastics can get lower than .1 coefficients of friction; right?

A. I do recall what you said and you could add lubrication and you could play with the friction value that way.

Q. So in your experience, lubricious plastics can get down to 0.08 or lower coefficients of friction; correct?

A. You could get there in some instruments, yes. I don't have any experience in pen injectors with that so I can't comment on that.

Source: *Pet. Obs.*; EX1115, 519:17-23, 554:9-18.

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Slocum Ignores Express Teachings

Q. And the POSA ignores those sentences from patents, correct?

A. Well, you read them and you say to yourself, that's stupid, and you keep moving on. You would never actually do that.

Q. And in your opinion, that passage was written by a lawyer. It was a lawyer add-on; right?

A. I think at the time when you asked me, I said, I can't imagine a POSA doing that. A lawyer must have added it in.

Q. And you have no evidence that this is just a lawyer add-on, do you?

A. I have no evidence.

Source: EX1054, 310:2-6; Pet. Obs.; EX1115, 526:3-12.

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Dr. Slocum's Opinions Are Not Based on the Prior Art

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 **Pub. 2011** Ex. 2100 at 1-2, 5; **Pub. 2007** Ex. 2144 at 5, 9; **Pub. 2008** Ex. 2175 at 3 (noting that the manufacturer of the FlexPen received complaints about high injection force and that the “Next Generation FlexPen” was introduced to overcome this problem), 5

(noting that lower injection force “contributed to three out of four patients finding [the pen with lower injection force] ‘simpler and more comfortable’ to use.”), **Pub. 2007** Ex. 2159 at 4 (noting the grip and pinch strength for diabetics is significantly lower than for non-diabetics), **Pub. 2009** Ex. 2116 at 4, 7; **Pub. 2010** Ex. 2135 at 4 (“In a study comparing usability and patient preference for different pen injectors, patients preferred the pen with the lowest injection force.”), **Pub. 2013** Ex. 2123 at 2 (“Injection force is also a key element in the design of an insulin pen,[] as lower injection forces are associated with simpler operation, more comfortable use,[] and less injection-site pain.”).

Source: EX2107, ¶156.

Achieving Acceptable Injection Force Is Not the Same As Avoiding *Any* Increase

POSAs had reasons beyond minimizing injection force:

Mr. Leinsing:

7 Q. And so you would agree with me, then, that
8 the designer of a pen injector would avoid designs
9 or features that would make a pen injector hard to
10 use. Is that fair? Harder to use.

11 A. I think that becomes relative. You're
12 balancing between, as we know from listening to the
13 news these days, the cost of an injector. There's
14 pros and cons to every different feature. So each
15 manufacturer has to consider the different pros and
16 cons.

17 Sometimes cost is more of a factor, as we
18 hear. Some patients can't afford the injections,
19 so they'll reduce components, maybe add a little
20 more force, but reduce the cost. It becomes a
21 decision between a syringe versus a pen injector
22 versus a more expensive pen injector.

Source: EX2163, 87:7-22; Pet. Reply at 13-14 (citing EX1095, ¶72).

Sanofi's Weak Evidence of Alleged Secondary Considerations Does Not Outweigh Mylan's Evidence of Obviousness

Source: Pet. Reply, 24-28; EX1060, ¶16.
DEMONSTRATIVE EXHIBIT – NOT EVIDENCE

No Secondary Considerations

- (1) No Nexus
- (2) No Long-Felt, Unmet Need
- (3) No Industry Praise
- (4) No Commercial Success

Source: Pet. Reply, 24-27.

No Presumed Nexus

“A patent claim is not coextensive with a product that includes a ‘critical’ unclaimed feature that is claimed by a different patent and that materially impacts the product’s functionality[.]”

Fox Factory, Inc. v. SRAM, LLC, 2018-2024, 2018-2025,
Slip op. at 13 (Fed. Cir. Dec. 18, 2019)

No Nexus

(1) Lantus is a critical unclaimed feature that is claimed by a different patent and that materially impacts the product's functionality.

The "overwhelming consideration" is "the insulin itself":

In U.S. medical practice, the choice of insulin pen will be, to a large extent, determined by the choice of insulin, as particular insulins are specific to certain makes of insulin pen. Anecdotal reports suggest that many patients prefer

Lantus, not SoloStar, drove commercial performance:

The focus of selling communications, and real value for the patient, is Lantus itself. It is important to keep SoloSTAR firmly placed within the context of the Lantus brand.

8.6 Other traps to avoid

- **Selling the pen without selling the insulin**
- Positioning the pen as more important or equal with the importance of the insulin – our long term advantage comes from the insulin properties, and should not be sacrificed for any short term gain

Source: EX1048, ¶¶25-28 (citing EX1045, 527); EX1060, ¶¶38-45, 49-50 (citing EX2145, 15, 22); Pet. Reply, 24-25, 29.

No Nexus

- (2) Insulin pens are “largely fungible” and the patents simply are not important.
- (3) None of an 80-unit cartridge, a particular stroke length or injection force is the invention.

Source: Pet. Reply, 24-25, 29; EX1095, ¶¶154-56; EX1048, ¶¶20-22, 25-28, 30-35, 37-41, 46-56; EX1060, ¶¶29-35, 38-45, 52-56, 66-69; EX1055, 28:14-29:22, 86:20-87:6, 88:14-19, 103:18-104:6, 104:14-105:3-5; EX1056, 69:9-70:10.

Grabowski Ignored Effect of Blocking Patents and Market Exclusivity

A blocking patent undercuts the nexus with the challenged patent.

Galderma Labs. L.P. v. Tolmar, Inc., 737 F.3d 731, 740-41 (Fed. Cir. 2013).

US000100376A

United States Patent [19] Patent Number: **6,100,376**
Dörsching [43] Date of Patent: ***Aug. 8, 2000**

[54] **A¹, B¹, MODIFIED INSULIN DERIVATIVES HAVING AN ALTERED ACTION PROFILE.**
 [73] Inventor: **Michael Dörsching**, Bosteln, Germany
 [75] Assignee: **Heescht Aktiengesellschaft**, Frankfurt am Main, Germany
 [1*] Notice: This patent is subject to a terminal disclaimer.
 [21] Appl. No.: **08/642,794**
 [22] Filed: **Apr. 16, 1997**

Related U.S. Application Data
 [62] Division of application No. 08/584,293, Sep. 12, 1994, Pat. No. 5,656,722, which is a continuation of application No. 08/036,881, Apr. 9, 1993, abandoned, which is a continuation of application No. 07/829,510, Aug. 29, 1992, abandoned, which is a continuation of application No. 07/431,044, Nov. 6, 1989, abandoned.

[57] **ABSTRACT**
 New insulin derivatives of the formula II with an iso-electric point between 5 and 8.5, with improved stability in weekly acid solution, and with a special action profile, and

12 Claims, No Drawings

Mylan Exhibit 1171
 Mylan v. Sanofi - IPR2017-01526

Expired: November 2009

US0005656722A

United States Patent [19] Patent Number: **5,656,722**
Dörsching [43] Date of Patent: **Aug. 12, 1997**

[54] **A¹, B¹, MODIFIED INSULIN DERIVATIVES HAVING AN ALTERED ACTION PROFILE.**
 [73] Inventor: **Michael Dörsching**, Bosteln, Germany
 [75] Assignee: **Heescht Aktiengesellschaft**, Frankfurt am Main, Germany
 [21] Appl. No.: **08/459**
 [22] Filed: **Sep. 12, 1994**

Related U.S. Application Data
 [62] Continuation of Ser. No. 46,481, Apr. 9, 1993, abandoned, which is a continuation of Ser. No. 325,230, Aug. 19, 1992, abandoned, which is a continuation of Ser. No. 431,264, Nov. 6, 1989, abandoned.

[57] **ABSTRACT**
 New insulin derivatives, the use thereof, and a pharmaceutical composition containing them

15 Claims, No Drawings

Mylan Exhibit 1172
 Mylan v. Sanofi - IPR2017-01526

Expired: September 2014

Source: EX1079 ('376 Patent); EX1091 ('722 Patent); Pet. Reply, 25-26; EX1060, ¶¶61-65.

No Long-Felt, Unmet Need

- (1) No Need For Another Insulin Pen
- (2) Other Pens Were Available, Easy to Use, and Largely Fungible with SoloSTAR
- (3) Injection Force Was Not a Primary Concern

Source: Pet. Reply, 26-27; EX1048, ¶¶27, 29-30, 32-47, 49, 51-53, 56; EX1060, ¶¶30-35, 57-60, 63-67; EX1060, ¶¶57-65; EX1056, 52:6-9, 71:4-16.

No Industry Praise

- (1) Sanofi-funded, -authored, or –edited publications, infomercials, and press releases are not Industry Praise. *ABT Sysys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1361 (Fed. Cir. 2015).
- (2) The Awards Do Not Attest to Inventiveness Nor Praise the Claims or Features (e.g., Injection Force) Sanofi Attributes to Claims.

Source: *Pet. Reply*, 27; EX1060, ¶¶57-60; EX1055, 79:6-81:19.

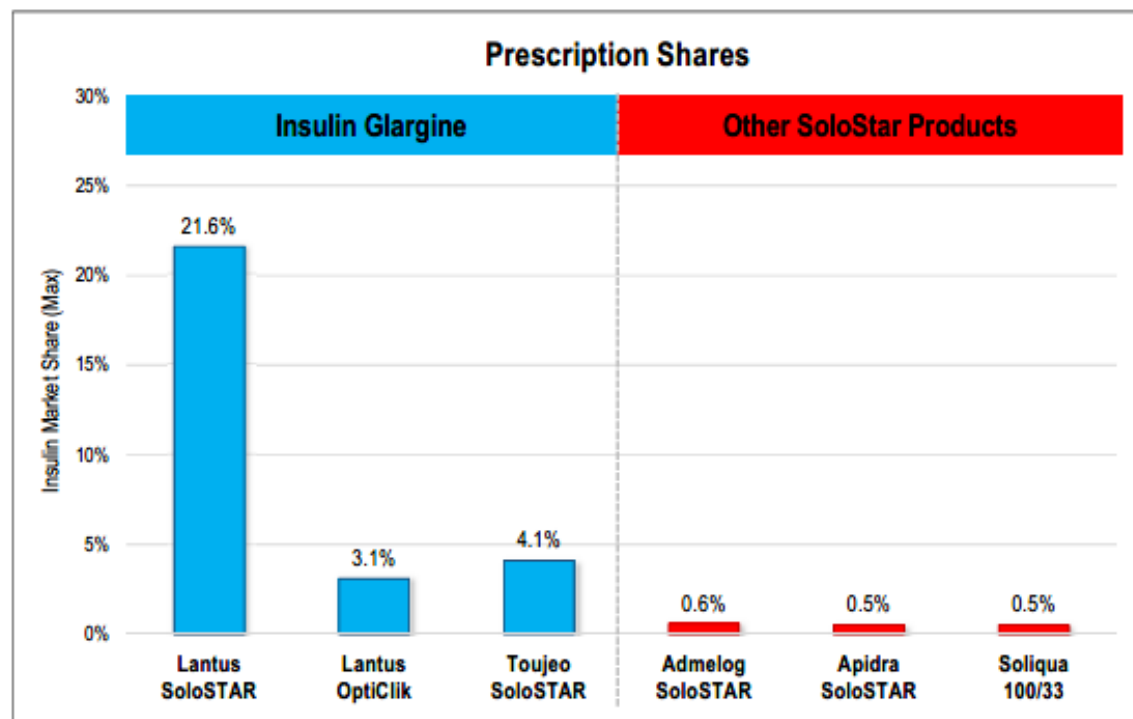
No Commercial Success

- (1) No Benchmarks for Evaluating Success
- (2) Applies Faulty Pens-Only Market Definition
- (3) Dr. Grabowski Never Evaluated Profitability
- (4) Formulary Status Does Not Demonstrate Commercial Success

Source: Pet. Reply, 28; EX1060, ¶¶17-28, 70-71.

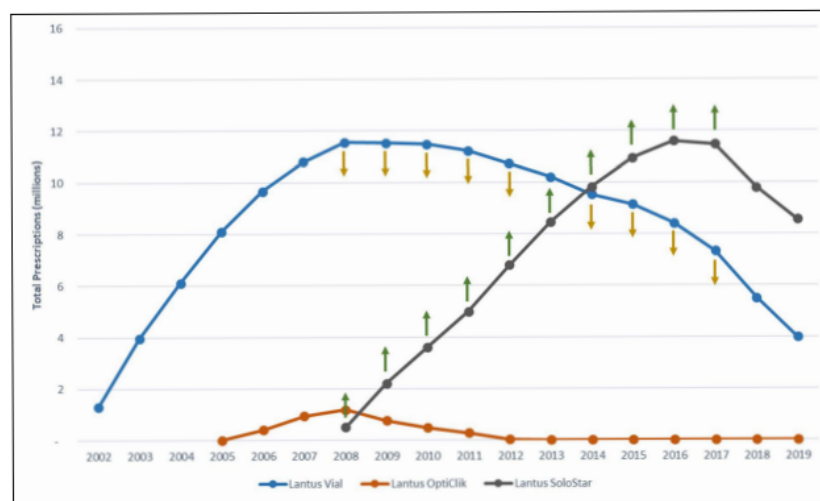
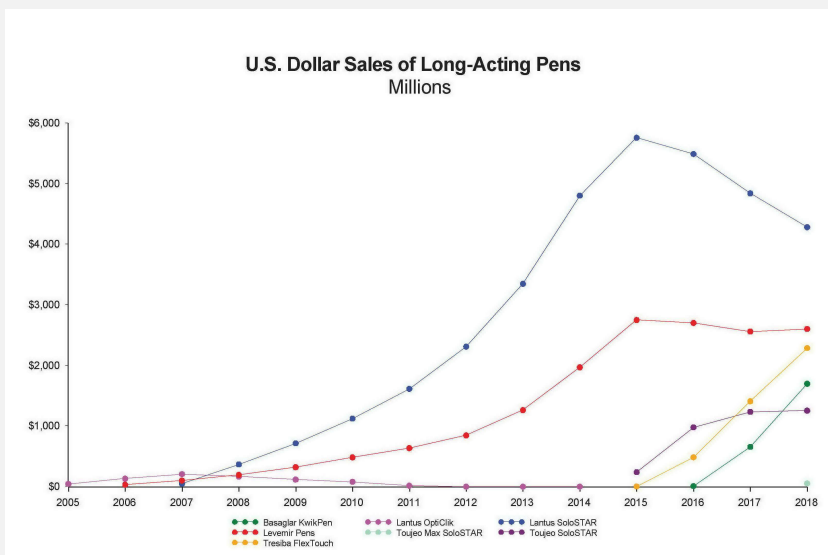
No Commercial Success

(5) Lantus is key: Apidra and Ademelog SoloSTAR sales below “deficient” Lantus OptiClik sales



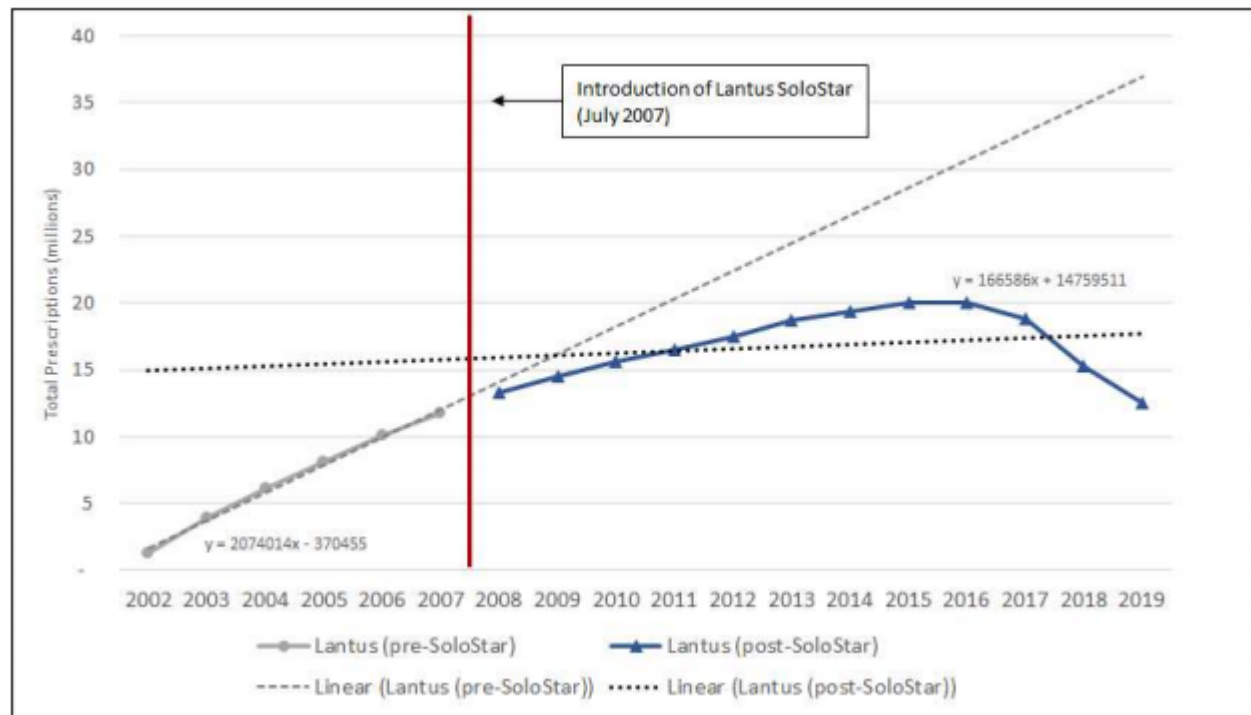
Source: Pet. Reply, 28; EX1060, ¶¶17-28, 70-71, Attachment B-10 (underlying data).

Grabowski's Artificially Narrow Relevant Market



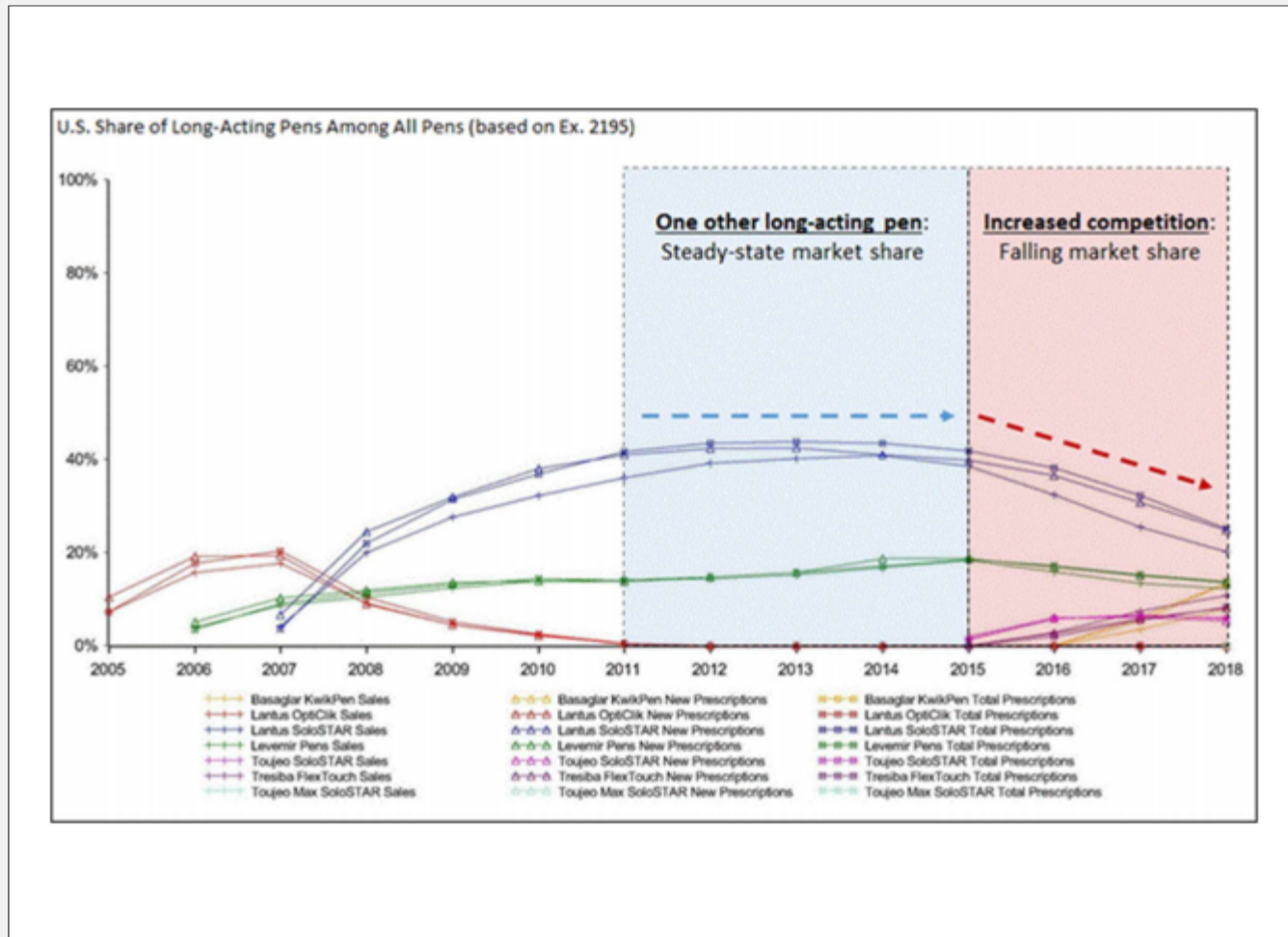
Source: EX2196; EX1060, ¶41, 47.

Prescription Growth Slowed Following Introduction of SoloSTAR



Source: EX2045; Pet. Reply, 26; EX1169 (McDuff Decl.), ¶133-39.

Lost Market Share After 2015 Does Not Demonstrate Commercial Success



Source: Pet. Reply, 28-29; EX1060, ¶¶30-35.