teaching of a similar dose-dial sleeve having a 'helical track.'" IPR2018-01678 (486-A2) Petition at 65; *see also* Ex. 1011, ¶¶ 352-353. For claim 1 of the 069 Patent and claim 11 of the 044 Patent, which, as noted above, additionally recite that the helical groove is "provided along an ***outer surface*** of said dose dial sleeve," Petitioner and Mr. Leinsing concede that Møller's dose-setting drum 17 does not disclose the claimed outer groove. They argue, however, that "a POSA would have found it obvious to modify the internal threading of [Møller's] drum 17 as an external threading that engaged the housing for the same rotational movement relative to the housing as disclosed in Steenfeldt-Jensen." IPR2018-01670 (069) Petition at 71; *see also* IPR2018-01676 (044-B) Petition at 57; Ex. 1011, ¶¶ 354-361. For the reasons I explain below, in my opinion a POSA would have not have been motivated to combine Møller with the groove on Steenfeldt-Jensen's dose scale drum 80 as Petitioner alleges, because Møller specifically references and teaches a POSA to avoid Steenfeldt-Jensen's teachings with respect to the helical groove. In a separate section (addressed further below), I explain that it is also my opinion that a POSA would not have been motivated to modify Møller's internal threads on dose-setting drum 17 to be external.

**a. Møller Teaches Away From a Combination With Steenfeldt-Jensen**

288. In my opinion, Møller teaches a POSA to avoid the teachings of the outer groove in the dose scale drum 80 as disclosed by Steenfeldt-Jensen. Thus, a

POSA would not have been motivated to combine Møller with Steenfeldt-Jensen's teachings.

289. Møller explains that one of his main objectives of his invention is to reduce the force required to inject medicament, and Møller's pen injector designs are specifically aimed at doing so. *See, e.g.*, Ex. 1015, ¶¶ 0004-0005 (explaining that high injection force "is not quite favorable, as especially [for] users having reduced finger strength"). One of the ways that Møller addresses this fundamental problem is by relying on "gearing" to achieve a mechanical advantage so that lower force is required by the user to expend medicament. *See id.* ¶ 0006. Møller also seeks to reduce the force required for injection by minimizing efficiency losses that are due to sliding friction between threaded surfaces by using rolling contact between highly efficient gear teeth. As a specific example of a system that has undesirable losses due to friction, Møller cites WO 99/38554 (Ex. 2153), which includes the same teachings of an externally-grooved dose setting drums as Steenfeldt-Jensen. I am informed that WO 99/38554 is a foreign related patent application. Specifically, Møller states:

> A similar gearing is provided in WO 99/38554 [Steenfeldt-Jensen's foreign related patent application] wherein the thread with the high pitch is cut in the outer surface of a dose setting drum and is engaged by a mating thread on the inner side of the cylindrical housing. ***However, by this kind of gearing relative large surfaces are sliding***

> ***over each other so that most of the transformed force is lost due to friction between the sliding surfaces***. Therefore a traditional gearing using mutual engaging gear wheels and racks is preferred.

Ex. 1015, ¶ 0008 (emphasis added). Møller then goes on to say that "[i]t is an objection of [Møller's] invention to provide an injection device, which combines the advantages of the devices according to the prior art ***without adopting their disadvantages***" (Ex. 1015, ¶ 0011), which a POSA would understand to include specific Steenfeldt-Jensen's threaded dose setting drum that was expressly noted as being disadvantageous three paragraphs before.

290. A POSA would have understood that Møller teaches away from applying Steenfeldt-Jensen's "thread with the high pitch [that] is cut in the outer surface of a dose setting drum" because when it is used for gearing then "relative large surfaces are sliding over each other so that ***most*** of the transformed force is lost due to friction between the sliding surfaces." *Id.* (emphasis added). In my opinion a POSA would not have had a reason to look to Steenfeldt-Jensen's threaded dose setting drum given Møller's statement to specifically avoid it.

291. Further, I note that although the last sentence of the paragraph 0008 in Møller states that a "gearing using mutual engaging gear wheels and racks is preferred," Møller does not advise using Steenfeldt-Jensen's externally-grooved dose scale drum. Instead, the two pen injector embodiments that Møller designed specifically lack the externally-grooved dose scale drum described by Steenfeldt-

Jensen. A POSA would have understood from these disclosures that Steenfeldt-Jensen's externally-grooved dose scale drum should be avoided when applying Møller's teachings.

292. Therefore, in my opinion, Møller teaches a POSA to avoid the teachings of the outer groove in the dose scale drum 80 taught by Steenfeldt-Jensen and so a POSA would not have been motivated to combine Møller with Steenfeldt-Jensen's teachings.

**b. A POSA Would Not Have Been Motivated to Make the Relied-Upon Combination Due to a Purported Benefit Alleged by Petitioner**

293. Even though Møller teaches a POSA to avoid Steenfeldt-Jensen's externally-groove dose setting drum, for the IPR2018-01670 (069) and IPR2018-01678 (486-A2) IPRs, Petitioner and Mr. Leinsing allege that there is an advantage to placing an external high-pitch thread taught by Steenfeldt-Jensen on Møller's dose-setting drum 17. Specifically, Petitioner alleges that "[b]ecause Steenfeldt-Jensen's threaded engagement is configured to reduce the friction between the sliding surfaces of the drum and housing, a POSA would have understood that this configuration would reduce the force needed to rotate the drum back into the housing during injection." IPR2018-01676 (044-B) Petition at 78; *see also* IPR2018-01670 (069) Petition at 86-87; Ex. 1011, ¶ 360.

294. I disagree that this alleged benefit would have motivated a POSA to make Petitioner's proposed combination. Møller itself already has a solution to this purported "problem." In Møller, the thread friction arising from the internal threads 6 of its dose-setting drum 17 is counteracted by a "helical reset spring 36," which is a torsional spring meant to bias the dose-setting drum 17 back into the housing 1 after it has been dialed out. Møller states that this spring "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 [*sic*] to exert on the injection button is only the force necessary to drive the piston rod into the ampoule to inject the set dose." Ex. 1015, ¶ 0033 (emphasis added). Neither Petitioner nor Mr. Leinsing has identified any reason why a POSA would abandoned the solution proposed by Møller's for a solution outside Møller. In sum, Mr. Leinsing creates a problem already addressed by Møller.[12]

[12] Indeed, as I explain in the next section, moving the threads from the interior of the dose-setting drum 17 to the exterior is not a good idea, because the losses due to friction are multiplied by the increase in distance the threads are moved from the pen injector's central axis. Thus, not only is there not a reason to use Steenfeldt-

295. Accordingly, it is my opinion that a POSA would not have been motivated to combine Møller with Steenfeldt-Jensen as Petitioner alleges for the challenged claims of the 069, 044, and 486 Patents.

### 3. The Combination of Møller and Steenfeldt-Jensen Does Not Teach or Render Obvious "said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing" [069 Patent Claim 1; 044 Patent Claim 11; 486 Patent Claim 1] and "said helical groove provided along an outer surface of said dose dial sleeve" [069 Patent Claim 1; 044 Patent Claim 11]

296. Claim 1 of the 069 Patent, claim 11 of the 044 Patent, and claim 1 of the 486 Patent each require a "dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing." Claim 1 of the 069 Patent and Claim 11 of the 044 Patent additionally require "said helical groove provided along an outer surface of said dose dial sleeve."

297. For the 069 Patent, 044 Patent, and 486 Patent, Petitioner identifies the combination of Møller's housing 1 (grey, below), wall 2, and tubular element 5

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Jensen's exterior threads, a POSA would not have wanted to when the threads could be formed on the interior.

(orange, below) as the claimed "main housing."[13] *See* IPR2018-01670 (069) Petition at 66-68; IPR2018-01676 (044-B) Petition at 52-54; IPR2018-01678 (486-A2) Petition at 60-61. For the 486 Patent, Petitioner argues that Møller's dose-setting drum 17 is the claimed "dose dial sleeve" that "engage[s] a threading provided by said main housing." *See* IPR2018-01678 (486-A2) Petition at 62-66. For the 069 Patent and 044 Patent, which additionally require that the helical groove of the dose dial sleeve is on its exterior surface, Petitioner argues that a POSA would have been motivated to modify Møller's internally-threaded dose-setting drum 17 to be externally-threaded as taught by Steenfeldt-Jensen's dose scale drum 80. *See* IPR2018-01670 (069) Petition at 68-71, 85-88; IPR2018-01676 (044-B) Petition at 54-57, 76-79.

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[13] I note that in certain places in its petitions, Petitioner annotates Figure 1 of Møller so that all three components—housing 1, wall 2, and tubular element 5—are grey, but in certain other places it annotates wall 2, which sits between housing 1 and tubular element 5, in purple. *See, e.g.*, IPR2018-01678 (486-A2) Petition at 97; *see also* IPR2018-01684 (008) Petition at 13-14 (shading Møller's housing 1 and tubular element 5 as the 008 Patent's claimed "housing" and shading wall 2 as the 008 Patent's claimed "piston rod holder").

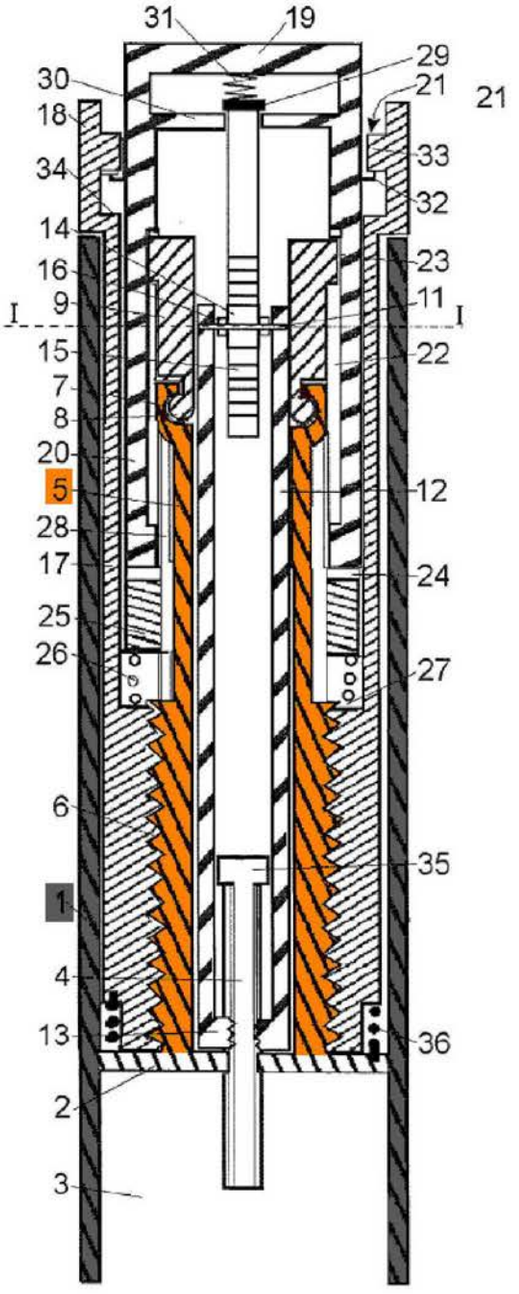



Fig. 1

**Ex. 1015, Fig. 1 (annotated).**

298. For the reasons specified below, I disagree with Petitioner's arguments and it is my opinion that Møller in combination with Steenfeldet-Jensen does not teach or render obvious these claim limitations.

#### 4. Møller Does Not Disclose a Dose Dial Sleeve That Engages a Threading of a "Main Housing"

299. As I explained above in the section on claim construction, it is my opinion that the broadest reasonable interpretation of a "main housing" that is consistent with the specifications of the challenged patents is a type of exterior housing that does not encompass separate or integrally-formed interior housings, which is consistent with both Sanofi's construction and the ordinary meaning in the context of the challenged patents. Because the threads on Møller's dose-setting drum 17 are engaged with Møller's tubular element 5, which is not the required "main housing" as I explain below, it is my opinion that Møller fails to disclose "said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing" as recited by claim 1 of the 069 Patent, claim 11 of the 044 Patent, and claim 1 of the 486 Patent.

300. In my opinion, a POSA would not have understood that Møller's tubular element 5 (orange, below) is a "main housing" within the meaning of the challenged patents. At best, it is an interior, not an exterior, housing. No part of tubular element 5 is on the exterior of the pen. Moreover, Møller treats tubular

element 5 as a component distinct from the housing 1 (grey, below), which unlike tubular element 5 is on the exterior of the pen and is therefore an exterior housing:

> ***Concentrically with the housing 1*** the wall 2 carries on its side turning away from the compartment 3 ***a tubular element 5*** which is at a part of it adjacent to the wall 2 provided with an outer thread 6 and which has at its free end a circumferential recess 7.

Ex. 1015, ¶ 0023 (emphasis added).

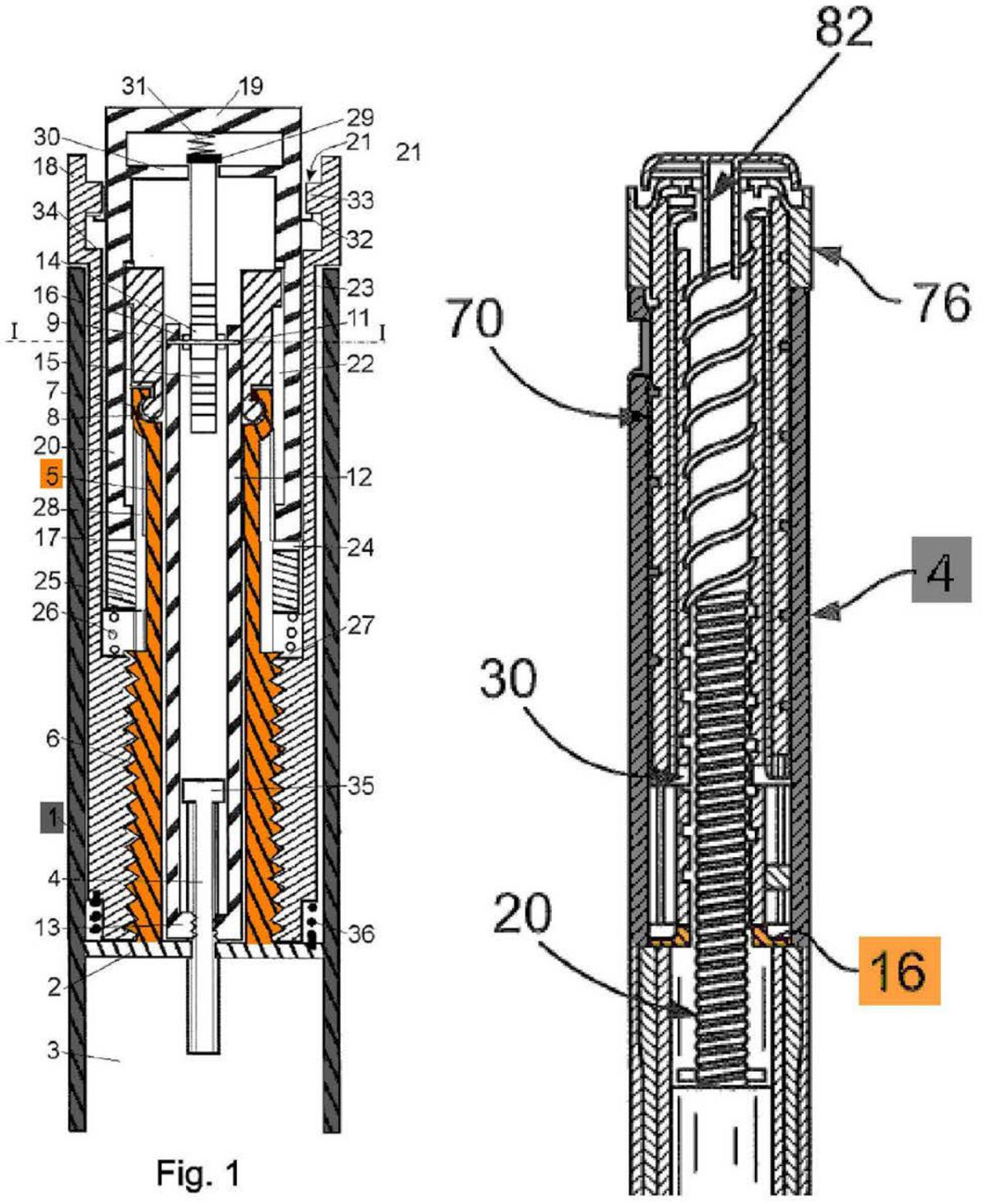



Fig. 1

**Ex. 1015, Fig. 1 (annotated) (left), Ex. 1002, Fig. 3 (annotated) (right).**

301. Notably, Møller's housing 1 (grey) and tubular element 5 (orange) correspond to main housing 4 (grey) and insert 16 (orange) that is depicted and described in all of the challenged patents, as shown above. Even though the tubular element 5 in Møller is depicted as being formed integrally with housing 1 (through wall 2), this is like the insert 16 and main housing 4 in the challenged patents. Specifically, the challenged patents state:

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

Ex. 1002, 3:49-55 (emphasis added). Thus, like Møller's tubular element 5 being formed integrally with the housing 1, which Møller identifies as distinct components, the insert 16 of the challenged patents can be formed integrally with the main housing 4, which the challenged patents identify as distinct components. Notably, the excerpted language above says that the "insert may be formed integrally with the main housing 4 [in] the form of a radially inwardly directed flange," and it does not say that the insert may be replaced by an inwardly directed flange of the main housing 4. In other words, the challenged patents treat a "main

housing" (an exterior housing) separate from an "insert" (interior housing), even if integrally formed.

302. Accordingly, it is my opinion that a POSA would have understood that because Møller's dose-setting drum 17 engages a threading on tubular element 5, which is an interior housing, and because there is no threading on Møller's housing 1, which is a main housing, Møller fails to teach a "dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing" a recited by claim 1 of the 069 Patent, claim 11 of the 044 Patent, and claim 1 of the 486 Patent.

#### 5. A POSA Would Not Have Been Motivated to Modify Møller's Internally-Threaded Dose Dial Sleeve to Be Externally-Threaded

303. As noted above, claim 1 of the 069 Patent and claim 11 of the 044 Patent additionally require that the claimed dose dial sleeve has a "helical groove provided along [its] outer surface." Because Møller's dose-setting drum 17 has at a thread provided along its inner surface, Petitioner and Mr. Leinsing argue that it would have been obvious to modify the dose-setting drum 17 such that its threads were external. *See* IPR2018-01670 (069) Petition at 68-71, 85-88; IPR2018-01676 (044-B) Petition at 54-57, 76-79; Ex. 1011, ¶¶ 347-361. I disagree as explained below.

304. As I already explained above, a POSA would not have been motivated to combine Møller with Steenfeldt-Jensen because Møller teaches a POSA to avoid the externally-grooved helical thread on Steenfeldt-Jensen's dose setting drum. Further, as I also explained above, the benefit of making this combination alleged by Petitioner and Mr. Leinsing fails, because Møller already proposes a solution to counteract the negative effects of thread friction at thread 6 of its dose-setting drum 17 (*i.e.*, the helical reset spring 36). *See* Ex. 1015, ¶ 0033.

305. Moreover, a POSA would not have wanted to make the proposed modification because it would have resulted in an inferior pen injector. First, placing the internal threads 6 of the dose-setting drum 17 on the outer surface, which would also mean putting interior threads on the inner surface of the Møller's housing 1, would lead to mechanical interference with Møller's helical reset spring. *See* Ex. 1015, Fig. 1 (element 36). This interference could cause the pen injector to malfunction. For example, the spring could get caught between the crest and root of the mating screw threads to jam and prevent rotation of the dose-setting drum 17, or the interaction between the screw threads and the spring could damage or break the spring, preventing it from working properly. Neither Petitioner or Mr. Leinsing have considered or explained how to avoid these problems.

306. Second, moving threads (and their inherent friction) from near the center of the pen injector to farther from the center of the pen injector, as Petitioner and Mr. Leinsing propose, would ***increase*** the parasitic torque (efficiency losses) due to friction during dose injection. As I have explained in the background of the technology section of this declaration, part of the force that the user puts into a pen injector goes into overcoming the frictional forces in the device. These frictional forces arise from thread surfaces that rub against each other during dose injection. If one were to move these thread interfaces farther away from the axis of rotation, however, the drag (parasitic) torque caused by this friction is multiplied by the distance of the threaded interface from the axis of rotation ($\tau = r \times F$) to create a larger parasitic drag that would likely frustrate a user. As I also explained in the background of the technology section of this declaration, reducing injection force was an important design objective and a POSA would have known to reduce the efficiency losses due to friction in furtherance of this objective. A POSA therefore would not have understood that moving the internal threads of Møller's dose-setting drum17 to its exterior would be beneficial, and a POSA would not have been motivated to make this change.

307. Notably, Steenfeldt-Jensen discloses an externally-threaded dose scale drum 80, but as shown below Steenfeldt-Jensen does not disclose an interior housing on which threads may be formed. Møller does disclose an interior

housing, and in fact requires the interior housing to support the gearbox 9 in its first embodiment. A POSA would have understood that when presented with an option to thread a dose dial sleeve with the interior of an exterior housing (as Petitioner proposes) or an exterior of an interior housing (as Møller does), it is better to do the latter to reduce losses due to thread friction.

308. Thus, even though Møller sets out to reduce injection force and minimize losses from friction, Petitioner and Mr. Leinsing argue that a POSA would have ignored these teachings (and the motivating design principles in pen injector design generally) and made a pen injector that is inferior. In my opinion, this is incorrect. A POSA would not have been motivated to modify Møller as Petitioner proposes, and thus it is my opinion that Møller and Steenfeldt-Jensen does not teach or render obvious a "dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve" as recited by claim 1 of the 069 Patent and claim 11 of the 044 Patent.

### 6. The Combination of Møller and Steenfeldt-Jensen Does Not Teach or Render Obvious "at least one flexible arm … and at least one spline … to provide said audible feedback" [044 Patent Claim 15]

309. Claim 15 of the 044 Patent requires "wherein said clicker comprises: at least one flexible arm, said flexible arm comprising at least one tooth member, and at least one spline, wherein when said dose dial grip is rotated, said at least one

flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback."

310. Møller does not disclose a clicker comprising a flexible arm and spline to provide audible feedback, and neither Petitioner nor Mr. Leinsing identify one. Instead, Petitioner and Mr. Leinsing identify protrusion 87 on the flange 83 of the bushing 82 in Steenfeldt-Jensen's fifth embodiment. IPR2018-01676 (044-B) Petition at 82-84; Ex. 1011, ¶¶ 310-312. Neither Petitioner nor Mr. Leinsing offer any explanation about how Møller would be modified to incorporate protrusion 87 from Steenfeldt-Jensen to form a clicker (*e.g.*, there is no description of where to place the protrusion 87 and any corresponding splines). Further, neither Petitioner nor Mr. Leinsing explain why a POSA would have been motivated to make any such modification. Møller already provides clicking during dose dialing via the interaction of teeth between cup-shaped element 19 and ring 25, and it does so without flexible arms and splines. *See* Ex. 1015, ¶¶ 0026-0027.

311. Accordingly, it is my opinion that Petitioner has failed to demonstrate that Møller combined with Steenfeldt-Jensen teach or render obvious claim 15 of the 044 Patent.

### 7. The Combination of Møller and Steenfeldt-Jensen Does Not Teach or Render Obvious "wherein said main housing further comprises a helical rib … adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve" [044 Patent Claim 19]

312. Claim 19 of the 044 Patent requires "wherein said main housing further comprises a helical rib, said helical rib adapted to be seated in said helical groove provided along said outer surface of said dose dial sleeve."

313. For this claim, Petitioner simply refers to the same arguments it made for claim 11 of the 044 Patent to argue that it would have been obvious to modify Møller's dose-setting drum 17 to have an external helical thread as taught by Steenfeldt-Jensen's externally-threaded dose scale drum 80. As I explained above in Sections XI.C.4, however, Møller does not disclose a dose dial sleeve with threads that engage a "main housing" (they engage tubular element 5, which is an interior, housing), a POSA would not have been motivated to combine Møller and Steenfeldt-Jensen because the former teaches away from the latter's externally-threaded dose dial sleeve, and a POSA would not have been motivated to move the threads on the interior of Møller's dose dial sleeve to the exterior (and thus farther away from the axis of rotation) due to increases in frictional torque and because of mechanical interference with helical reset spring 36.

314. Thus, it is my opinion that Møller in combination with Steenfeldt-Jensen does not teach or render obvious claim 19 of the 044 Patent.

### 8. Møller Does Not Teach or Render Obvious "a helical rib provided on an inner surface of said outer housing" [486 Patent Claim 4]

315. Claim 4 of the 486 Patent requires "wherein said window is located near a proximal end of said main housing and near a helical rib provided on an inner surface of said outer housing."

316. As with other claim limitations that I have analyzed above, Petitioner and Mr. Leinsing note that Møller does not disclose that its dose-setting drum 17 have external threads that engage with inner threads of the housing 1 ("a helical rib provided on an inner surface of said outer housing"), but that it would have been obvious to modify Møller's dose-setting drum 17 to have an external helical thread as taught by Steenfeldt-Jensen's externally-threaded dose scale drum 80. *See* IPR2018-01678 (486-A2) Petition at 77-81 (citing Mr. Leinsing's arguments for claim 1 of the 069 Patent and claim 11 of the 044 Patent); Ex. 1011, ¶ 391 (referring to his arguments for claim 1 of the 069 Patent and claim 11 of the 044 Patent at ¶¶ 355-361).

317. As I explained above in Section X.C.4., however, Møller does not disclose a dose dial sleeve with threads that engage a "main housing" (they engage tubular element 5, which is an interior housing), a POSA would not have been motivated to combine Møller and Steenfeldt-Jensen because the former teaches away from the latter's externally-threaded dose dial sleeve, and a POSA would not

have been motivated to move the threads on the interior of Møller's dose dial sleeve to the exterior (and thus farther away from the axis of rotation) due to increases in frictional torque and because of mechanical interference with helical reset spring 36.

318. Thus, it is my opinion that Møller in combination with Steenfeldt-Jensen does not teach or render obvious claim 19 of the 044 Patent.

### 9. Møller Does Not Teach or Render Obvious a Driver Comprising "a cylindrical shape" [486 Patent Claim 5]

319. Claim 5 of the 486 Patent requires "wherein said driver comprises a cylindrical shape."

320. [reserved]

321. Petitioner additionally, but incorrectly, argues that Møller's connection bars 12 and nut 13 are structurally and functionally equivalent to connection element 112 with nut 113. IPR2018-01678 (486-A2) Petition at 82; *see also* Ex. 1011, ¶ 395. As I explained above in Section XI.C.1. for this exact same argument, a POSA would not have understood that connection bars 12 and nut 13 are structurally and functionally equivalent to tubular connection element 112 and nut 113.

322. Petitioner also argues that "a POSA would have recognized connection bars 12 with nuts 13 could be formed as a tubular structure." IPR2018-

01678 (486-A2) Petition at 82; *see also* Ex. 1011, ¶ 395. I have also addressed this argument above. *See* Section X.C.1.

323. In my view, neither Petitioner nor Mr. Leinsing has provided a reason to modify Møller's first embodiment to form parallel connection bars 12 as "a tubular structure" as they allege, let alone as the connection element 112 of Møller's second embodiment.

### 10. Møller Does Not Teach or Render Obvious a Clicker Comprising "at least one flexible [extending] arm" [486 Patent Claims 18 and 20]

324. Both claims 18 and 20 of the 486 Patent require at least one flexible arm. Specifically, claim 18 of the 486 Patent requires "wherein said clicker comprises, at least one flexible arm, said flexible arm comprising at least one tooth member, and at least one spline, wherein when said dose knob is rotated, said at least one flexible arm deforms and drags said tooth member over said at least one spline so as to provide said audible feedback." Claim 20 of the 486 Patent requires "wherein said clicker generally comprises a cylindrical shape having a first and a second end, and said cylindrical shape is provided at said first end with at least one flexible extending arm."

325. As I explained for claim 15 of the 044 Patent in Section XI.C.6., above, Møller does not disclose a clicker comprising a flexible arm to provide audible feedback, and neither Petitioner nor Mr. Leinsing identifies one. Instead,

Petitioner and Mr. Leinsing identify protrusion 87 on the flange 83 of the bushing 82 in Steenfeldt-Jensen's fifth embodiment. IPR2018-01678 (486-A2) Petition at 88; Ex. 1011, ¶¶ 413-15. However, neither Petitioner nor Mr. Leinsing offers any explanation about how Møller would be modified to incorporate protrusion 87 from Steenfeldt-Jensen to form a clicker (*e.g.*, there is no description of where to place the protrusion 87 and any corresponding splines). Further, neither Petitioner nor Mr. Leinsing explains why a POSA would have been motivated to make any such modification. Møller already provides clicking during dose dialing via the interaction of teeth between cup-shaped element 19 and ring 25, and it does so without flexible arms and splines. *See* Ex. 1015, ¶¶ 0026-0027.

326. Accordingly, it is my opinion that Petitioner has failed to demonstrate that Møller combined with Steenfeldt-Jensen teaches or renders obvious claims 18 and 20 of the 486 Patent.

### 11. Møller Does Not Teach or Render Obvious a Dose Dial Sleeve That Is "radially inward of said main housing" [486 Patent Claim 26]

327. Claim 26 of the 486 Patent requires "wherein said dose dial sleeve is provided outside said tubular clutch and radially inward of said main housing."

328. Petitioner and Mr. Leinsing identify Møller's housing 1, wall 2, and tubular element 5 as the claimed "main housing." *See* IPR2018-01678 (486-A2) Petition at 60-61, 90-91; Ex. 1011, ¶¶ 345-346. As I explained above in Section

XI.C.4. for claim 1 of the 486 Patent, a "main housing" in the context of the 486 Patent does not encompass interior housing, even if integrally formed with the main housing, and thus Møller's wall 2 and tubular element 5 would not have been understood by a POSA to be the claimed "main housing."

329. Under Petitioner's incorrect view, however, Møller's dose-setting drum 17 (green) is not "radially inward" of the alleged main housing (grey), because it is not radially inward of the tubular element 5 as illustrated below. In fact, it is radially outside of tubular element 5 as illustrated below. Although the dose-setting drum 17 may be radially inward of Møller's housing 1, the claim limitation does not recite that the dose dial sleeve is radially inward of ***at least part of*** the main housing and a POSA would not have understood that the claim should be understood this way.

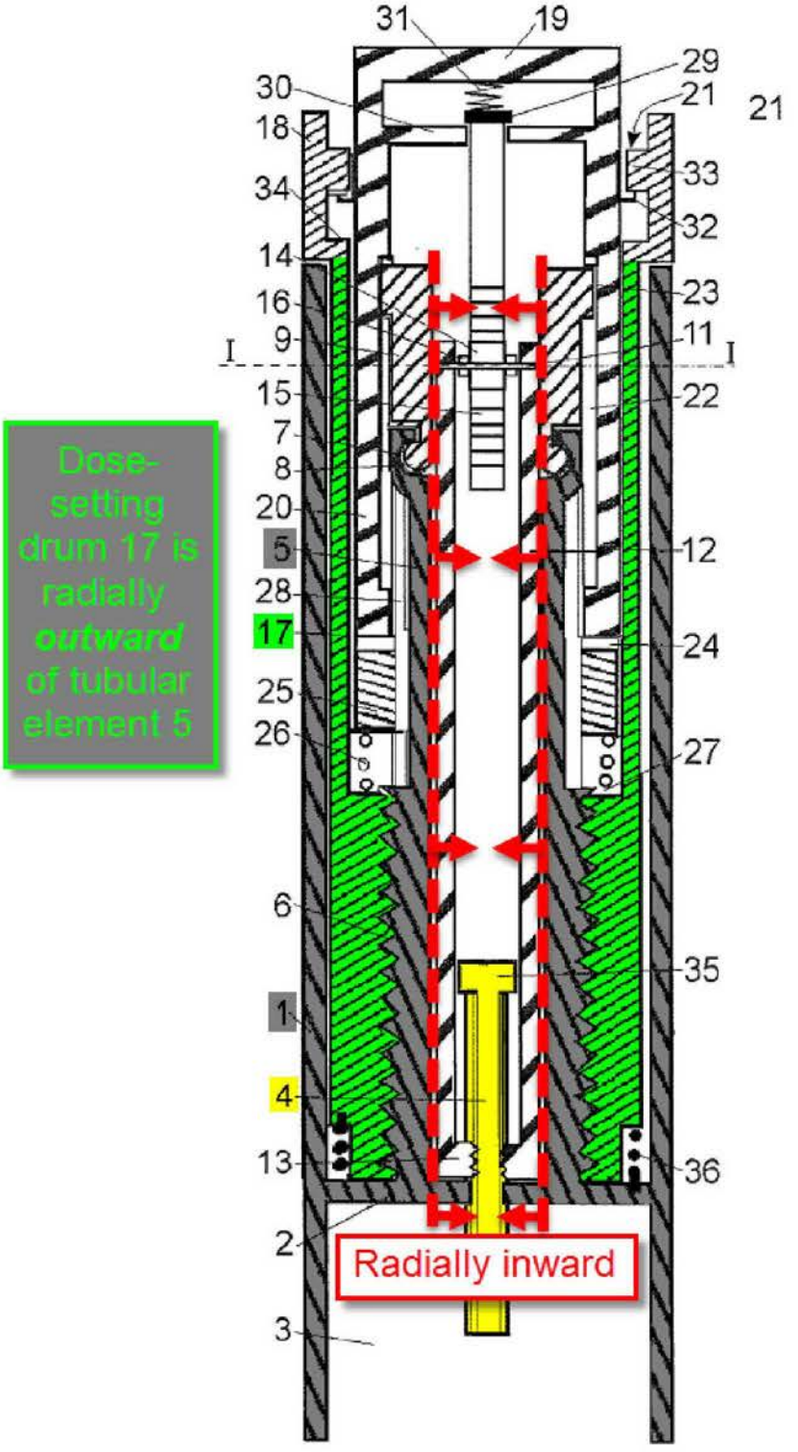



Fig. 1

**Ex. 1015, Fig. 1 (annotated)**

330. The piston rod 4 (yellow) is an example of a component that would be radially inward of the main housing under Petitioner's incorrect view of "main housing."

331. Accordingly, it is my opinion that Petitioner has failed to demonstrate that Møller combined with Steenfeldt-Jensen teaches or renders obvious claim 26 of the 486 Patent.

### 12. Møller Combined With Steenfeldt-Jensen Does Not Teach or Render Obvious a "radial stop positioned near an end of [a] helical groove" or "near a distal end of said helical groove" [486 Patent Claims 30 and 32]

332. Claim 30 of the 486 Patent requires "wherein said dose dial sleeve comprises at least one radial stop, said radial stop positioned near an end of said helical groove." Claim 32 of the 486 Patent depends on claim 30 and further requires "wherein said radial stop is positioned near a distal end of said helical groove."

333. Petitioner and Mr. Leinsing argue that it would have been "apparent" to modify Møller to include a radial stop on Møller's dose-setting drum 17 near the end of its helical groove. IPR2018-01678 (486-A2) Petition at 94-95; Ex. 1011, ¶¶ 431-439. To make this argument, both Petitioner and Mr. Leinsing refer to Steenfeldt-Jensen's third embodiment—not the fifth embodiment that Petitioner relies on to argue that the 486 Patent claims are obvious—and its teaching of a "saw tooth 91" on the button-end of a dose scale drum 18. In my opinion, neither

Petitioner not Mr. Leinsing has explained how a POSA would have implemented a tooth like Steenfeldt-Jensen's saw tooth 91 at an end a groove on Møller's dose-setting drum 17.

### D. Neither Møller nor Steenfeldt-Jensen Teaches or Renders Obvious Claim 56 of the 486 Patent [IPR2018-01679 (486-B) Grounds 3, 4, and 6]

334. I have been asked to provide an opinion on Petitioner's and Mr. Leinsing's arguments with respect to claim 56 of the 486 Patent. In IPR2018-01679 (486-B), Petitioner argues that claim 56 is unpatentable based on three grounds: (1) ground 3 – anticipation by Steenfeldt-Jensen; (2) ground 4 – obviousness over Steenfeldt-Jensen; and (3) ground 6 – anticipation by Møller. I have not been asked to provide an opinion on any of Petitioner's grounds in the 486-B petition with respect to claims 51-55 and 57, and I have not formed any opinions with respect to those claims.

335. Claim 56 depends from independent claim 51, which requires:

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

336. Claim 56 further recites:

> The clutch of claim 51, further comprising a plurality of axially extending teeth formed in an interior of a flange of said clutch.

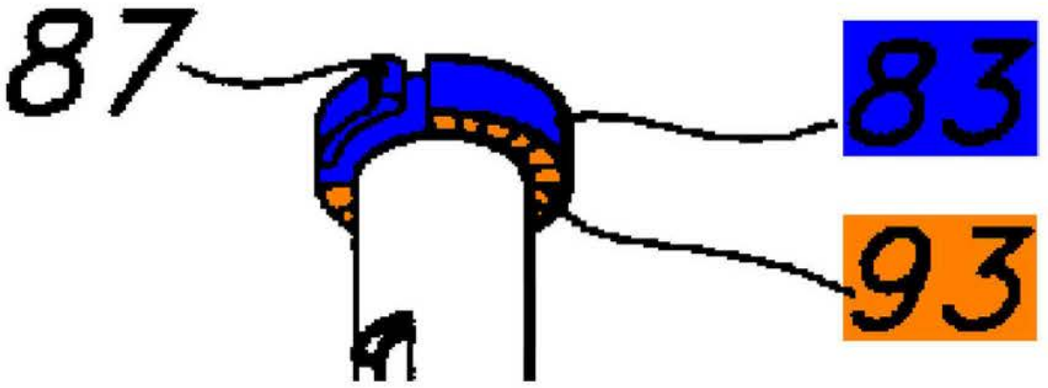
337. As I explained above in Section VIII.C., it is my opinion that the broadest reasonable interpretation consistent with the specifications for the term "an interior of a flange," where the flange is a disk-shaped flange, means "at the inner diameter of a flange."

338. As I explain below, it is my opinion that claim 56 is not taught or rendered obvious by either Steenfeldt-Jensen or Møller.

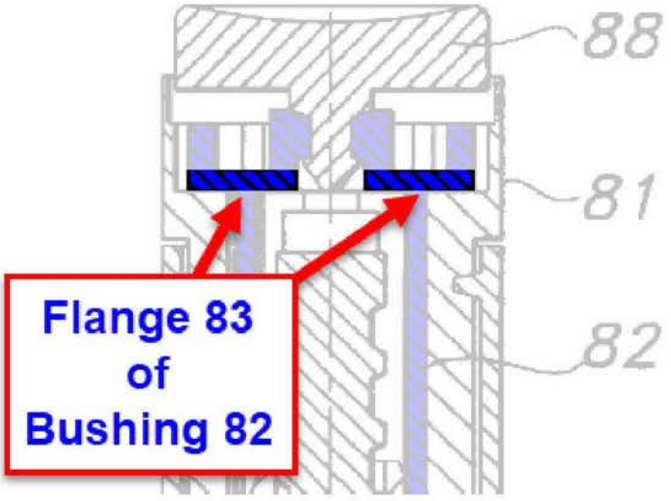
### 1. Steenfeldt-Jensen Does Not Teach Claim 56 [IPR2018-01679 (486-B) Ground 3]

339. Petitioner and Mr. Leinsing argue that Steenfeldt-Jensen discloses the teeth 93 on the flange 83 of bushing 82 in Steenfeldt-Jensen's fifth embodiment are the claimed "plurality of axially extending teeth formed in an interior of a flange." IPR2018-01679 (486-B) Petition at 42-43; Ex. 1011, ¶ 489. I disagree.

340. As I show below, Steenfeldt-Jensen describes a bushing 82 in its fifth embodiment that includes a flange 83 (shown in blue, below) having a rosette of teeth 93 (shown in orange, below). I have also included an image that isolates this flange 83 in Steenfeldt-Jensen's fifth embodiment pen injector.




**Ex. 1014, Fig. 17 (partial and annotated)**

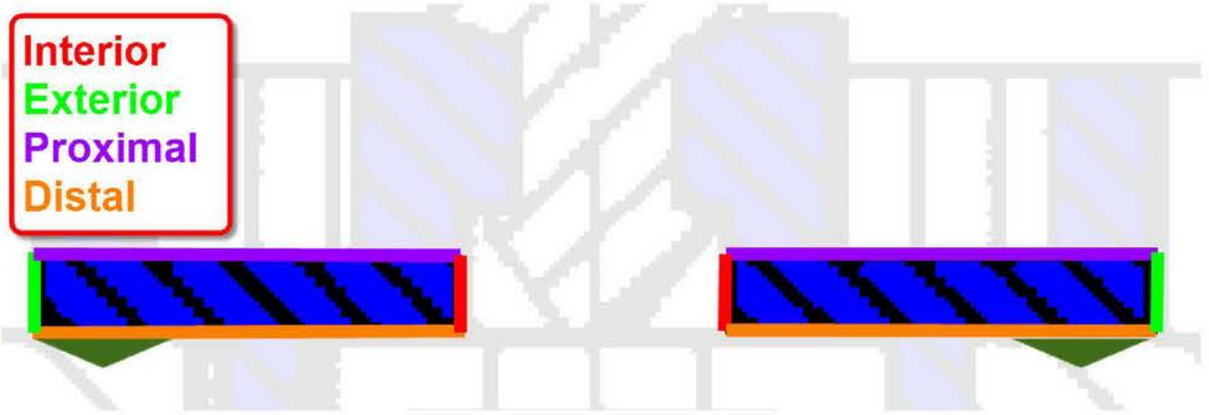



**Ex. 1014, Fig. 16 (cropped and annotated)**

341. A POSA would not have understood that these teeth are formed on an interior of a flange, because the teeth are not formed at an inner diameter of the flange. To be formed on the inner diameter of the flange, the teeth would have to be formed on the interior surface of Steenfeldt-Jensen's flange.

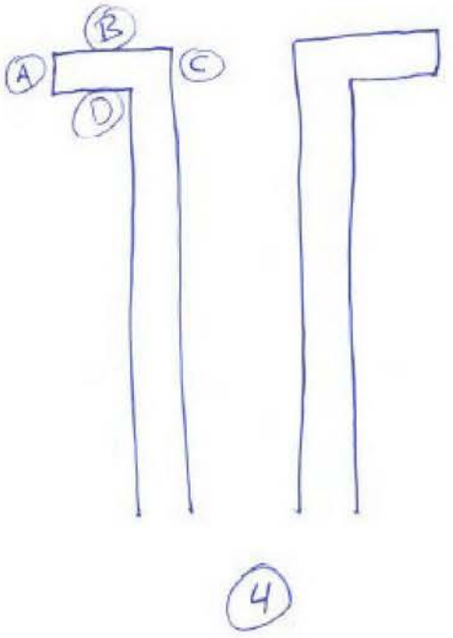
342. In the figure below, I identify the interior of Steenfeldt-Jensen's flange in red.

343. The exterior side of the flange, by contrast, I have identified in light green, below.




**Ex. 1014, Fig. 16 (cropped and annotated)**

344. Instead, a POSA would have understood that the rosette of teeth 93 are formed on the distal-side of the flange 83, which is shown in orange above. Indeed, Petitioner's expert Mr. Leinsing confirmed at his deposition that the "(D)" side of the flange depicted below, which corresponds to the location of the rosette of teeth 93 on Steenfeldt-Jensen's flange 83, would be the distal side of a flange. *See* Ex. 2163 at 155:7-9, 158:10-21.




**Ex. 2102 (partial)**

345. Mr. Leinsing also testified that side "(C)" "could be the interior" of the flange, which corresponds to what I have identified in red above as the interior of Steenfeldt-Jensen's flange 83. *See* Ex. 2163 at 148:9-20 (identifying internal threads of a flange in the 486 Patent as being "the thread … on the inside or inner diameter"), 155:13-18 (saying that the inner diameter of a flange similar to Steenfeldt-Jensen's flange 83 "could be the interior"), 158:10-21.

346. Therefore, in my opinion, Steenfeldt-Jensen does not teach a plurality of axially extending teeth formed in an interior of a flange" as required by claim 56.

### 2. Steenfeldt-Jensen Does Not Render Obvious Claim 56 [IPR2018-01679 (486-B) Ground 4]

347. Petitioner and Mr. Leinsing argue that "[t]o the extent is it not immediately apparent from FIG. 17 [of Steenfeldt-Jensen] and the corresponding description at col. 11:34-42 that the teeth of rosette 93 extend axially from an interior of flange 83," then "it would have been obvious to have the teeth extend axially toward the corresponding rosette to facilitate engagement." IPR2018-01679 (486-B) Petition at 47; *see also* Ex. 1011, ¶¶ 494-496. In other words, Petitioner and Mr. Leinsing are not saying it would be obvious to move the location of the rosette of teeth 93 relative to Steenfeldt-Jensen's flange 83, but rather that it would have been obvious to extend the rosette of teeth 93 axially.

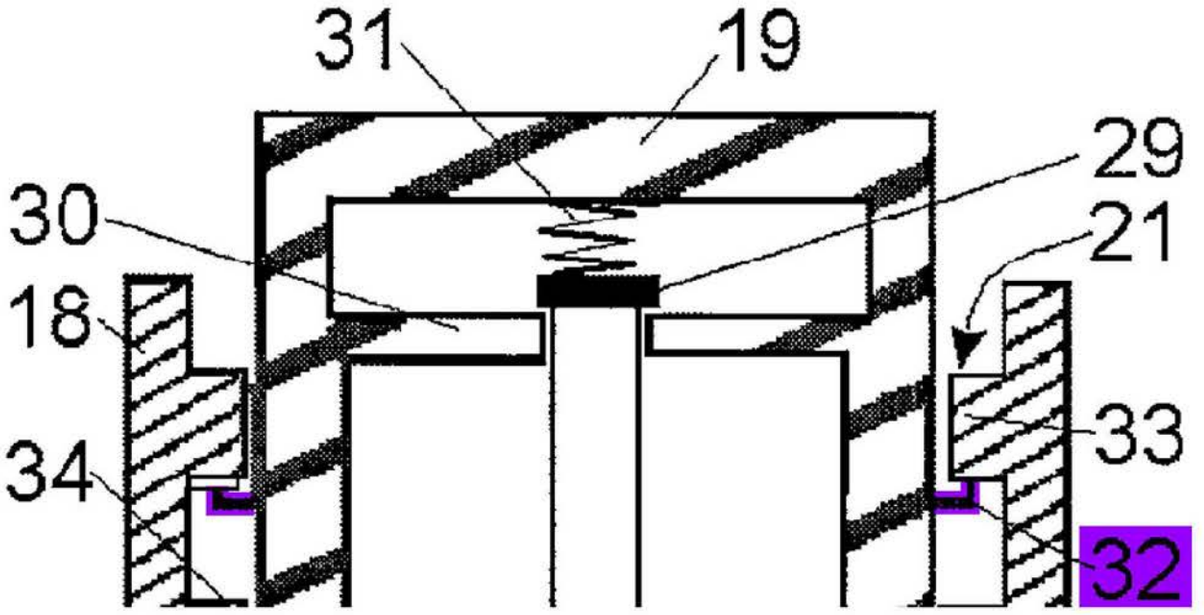
348. As I explained above, Steenfeldt-Jensen does not disclose that these teeth 93, axially extending or not, are formed on an interior of a flange (*i.e.*, at the inner diameter of the flange). Rather, Steenfeldt-Jensen discloses that they are formed on the distal side of flange 83.

349. Therefore, in my opinion, Steenfeldt-Jensen does not teach or render obvious a plurality of axially extending teeth formed in an interior of a flange" as required by claim 56.

### 3. Møller Does Not Teach Claim 56 [IPR2018-01679 (486-B) Ground 6]

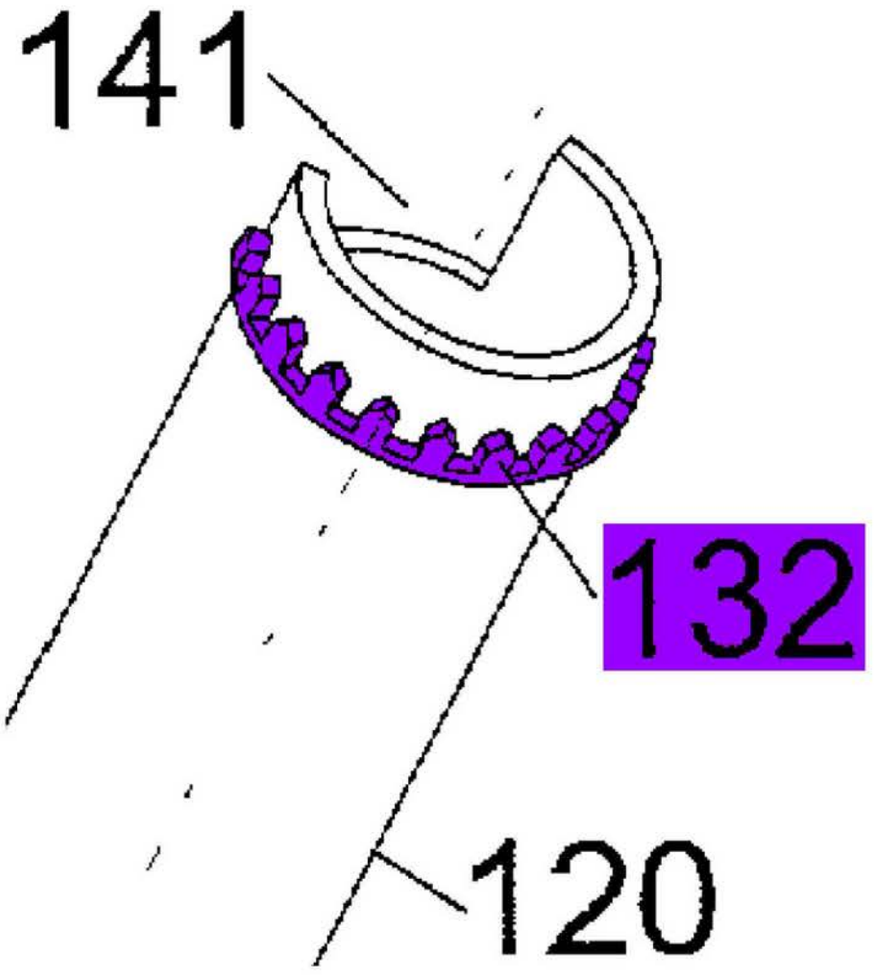
350. Petitioner and Mr. Leinsing argues that the "Δ-shaped protrusions 32 on the cup shaped element" in Møller's first embodiment are teeth that extend axially from an interior of a flange of a clutch. IPR2018-01679 (486-B) Petition at 58-60, Ex. 1011, ¶¶ 527-529. Petitioner and Mr. Leinsing further contend that teeth 132 formed on the exterior surface of tubular element 120 teaches claim 56. *Id.* I disagree.

351. First, as shown below, Møller does not depict, nor does it elsewhere describe, that the protrusions 32 are formed on a flange. As I explained above in Section VIII.C., a POSA would have understood that the ordinary meaning of a flange is a protrusion that extends outwardly and/or inwardly from the surface of a cylinder. A POSA would not have understood what is disclosed in Figure 1 or otherwise described in the Møller's first embodiment is a flange. Møller simply depicts two lines at a right-angle as being the protrusions 32 (purple), and there is no identification of any flange.




**Ex. 1015, Fig. 1 (partial and annotated)**

352. Second, teeth 132 on tubular element 120 in Møller's second embodiment are not formed on a flange. Instead, a POSA would have understood that they are formed on the exterior surface of the tubular element 120. That is, these teeth 132 (purple, below) extend axially from the exterior surface of the tubular element 120.




**Ex. 1015, Fig. 5 (partial and annotated)**

353. Third, even if protrusions 32 from Møller's first embodiment or teeth 132 from Møller's tubular element 120 could be interpreted as being formed on a flange, they are not formed in an interior of a flange as required by claim 52. Both protrusions 32 and tubular element 120 point in the proximal direction and would be formed on the proximal side of any such flange.

354. Therefore, in my opinion, Møller does not teach a plurality of axially extending teeth formed in an interior of a flange" as required by claim 56.

### E. The Combination of Møller and Steenfeldt-Jensen's Second Embodiment Does Not Render Obvious the Challenged Claims of the 008 Patent [IPR2018-01684 (008) Claims 1, 3, 7-8, 11, and 17]

355. I understand that Petitioner and Mr. Leinsing assert that Møller in combination with Steenfeldt-Jensen's second embodiment renders obvious claims 1, 3, 7-8, 11, and 17. I disagree. For the reasons discussed below, it is my opinion that a person of ordinary skill in the art would not have found the challenged claims obvious over the combination of Møller and Steenfeldt-Jensen.

#### 1. A POSA Would Not Have Been Motivated to Combine the Teachings of Møller and Steenfeldt-Jensen as Petitioner Contend

356. The challenged claims of the 008 Patent claim require, among other things:

- "a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread" and
- "a piston rod having a first thread and a second thread, wherein the first thread is engaged with the threaded circular opening of the insert and the second thread is engaged with the internal helical thread of the drive sleeve."

Ex. 1005, claim 1.

357. As I have explained above for claim 1 of the 069 Patent and claim 11 of the 044 Patent, Møller's connection bars 12 and nut 13 are not a drive sleeve.

Also, Møller does not disclose a piston rod having two threads as required by the challenged claims, and indeed, as I explained above, Møller specifically teaches away from using sliding contact threads to drive the piston rod because they are inefficient compared to using rolling contact gears and racks. In an attempt to overcome these deficiencies, Petitioner and Mr. Leinsing argue that a POSA would have been motivated to combine Møller with Steenfeldt-Jensen's second embodiment. *See, e.g.*, IPR2018-01684 (008) Petition at 18-19, Ex. 1011, ¶¶ 793-795, 832-837.

358. Specifically, Petitioner and Mr. Leinsing contend that a POSA would have been motivated to modify Møller as follows: "Rather than using Møller's complicated rack-and-pinion system to provide the mechanical advantage during injection, the drive sleeve would engage a dual-threaded piston rod as taught by Steenfeldt-Jensen." IPR2018-01684 (008) Petition at 41; *see also* Ex. 1011, ¶¶ 795, 833. In other words, Petitioner and Mr. Leinsing propose substituting Møller's direct gearing (which comprises gearbox 9, racks 10 and 15, gear wheels 14 and 16, connection bars 12 and nut 13, and non-rotatable piston rod 4) with Steenfeldt-Jensen's helical thread gearing (which comprises internally-threaded injection button 23 and rotatable piston rod 7).

359. As I explain below, however, it is my opinion that a POSA would not have been motivated to combine Møller with Steenfeldt-Jensen because Møller

precisely teaches away from Steenfeldt-Jensen's helical thread gearing and proposes using its direct gearing instead. Even if Møller did not teach away, it is my opinion that a POSA would not have been motivated to combine the teachings of Møller and Steenfeldt-Jensen for the reasons alleged by Petitioner and Mr. Leinsing.

### a. Møller Teaches Away From Steenfeldt-Jensen's Threaded Gearing

360. In my opinion, Møller specifically teaches away from Steenfeldt-Jensen's method of gearing, which relies on having helical threads of different leads between the injection button and ampoule piston.

361. As I have explained above, the use of a gear wheel and gear rack to achieve a mechanical advantage is key to Møller's disclosure, as rear teeth have rolling contact and thus none of the high frictional losses that sliding contact threads do. In the background section of the reference, Møller discusses other prior patent publications and notes their advantages and disadvantages. For example, Møller cites WO 99/38554 (Ex. 2153), which includes the same teachings of an externally-grooved dose setting drum as Steenfeldt-Jensen. I am informed that WO 99/38554 is a foreign related patent application. Specifically, Møller states:

> A similar gearing is provided in WO 99/38554 [Steenfeldt-Jensen's foreign related patent application] wherein the thread with the high

> pitch is cut in the outer surface of a dose setting drum and is engaged by a mating thread on the inner side of the cylindrical housing. ***However, by this kind of gearing relative large surfaces are sliding over each other so that most of the transformed force is lost due to friction between the sliding surfaces***. Therefore a traditional gearing using mutual engaging gear wheels and racks is preferred.

Ex. 1015, ¶ 0008 (emphasis added). That a sliding contact threaded mechanism would suffer from the effects of friction and as a result experience efficiency losses much greater than a rolling contact gear mechanism would have been known to a POSA. *See* Section V.B. Thus, a POSA would have understood that Møller was citing a critical disadvantage of Steenfeldt-Jensen's method of "gearing"[14], and that this specific gearing contributed to higher injection forces, which Møller was trying to avoid.

362. Møller then goes on to discuss these disadvantages in the context of Møller's design objectives for its proposed pen injectors:

> 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

[14] Note the use of the term "gearing" here is not meant to imply the use of gears, but rather to generically describe that a transmission is being used, where an input force is modified by some sort of mechanism.

> 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 <u>are avoided</u>, between the injection button and the piston rod***.

*Id.*, ¶ 0011 (emphasis added). A POSA reading this would have understood that the "disadvantages" referred here include the specific threaded dose setting drum taught by Steenfeldt-Jensen that Møller expressly notes as being disadvantageous in paragraph 8. Indeed, Steenfeldt-Jensen teaches a gearing by which there are, in Møller's words, "more transformations of rotational movement to linear movement and linear movement to rotational movement … between the injection button and piston rod" than there would be with a direct gearing that uses gear wheels and gear racks, and thus a POSA would have understood that Møller is saying to specifically avoid Steenfeldt-Jensen's teachings.

363. Given that Møller very clearly disparages Steenfeldt-Jensen's threaded gearing, it is my opinion that although "gear wheels and racks [are] preferred," a POSA would not have understood to use the threaded gearing taught by Steenfeldt-Jensen in the context of Møller's embodiments.

364. In my opinion, Mr. Leinsing mischaracterizes Møller's disclosure. He states that "Møller ***appreciated*** various ways of achieving such gearing in the art—including, inter alia, differential threading on rotationally coupled components—but ultimately chose a mechanism involving gear wheels engaging a rack in the

hopes of minimizing friction." Ex. 1011, ¶ 836 (emphasis added). In actuality, Møller ***disparaged*** various ways of achieving such gearing, specifically the way taught by Steenfeldt-Jensen. Møller ultimately chose a mechanism using gear wheels engaging a rack not "in hopes of minimizing friction," but specifically because it would avoid the friction resulting from Steenfeldt-Jensen's gearing.

365. Thus, it is my opinion that Møller teaches away from Steenfeldt-Jensen's threaded gearing, and a POSA would not have been motivated to implement one of the very things into Møller's embodiments that Møller says to avoid.

**b. Petitioner's Argument That a POSA Would Have Reasons for Making the Combination Is Flawed**

366. Petitioner and Mr. Leinsing assert that it would have been obvious to replace Møller's geared drive system for Steenfeldt-Jensen's threaded drive system due to purported similarities between Møller's pen injector and Steenfeldt-Jensen's second embodiment. Petitioner and Mr. Leinsing also allege that their proposed combination would provide advantages. I disagree with Petitioner and Mr. Leinsing for the reasons I explain below.

i. Petitioner's and Mr. Leinsing's Statements on the Similarities of the Møller and Steenfeldt-Jensen Are Inaccurate

367. Petitioner and Mr. Leinsing argue that the "usefulness and practicability of this combination would have been apparent to a POSA due to the

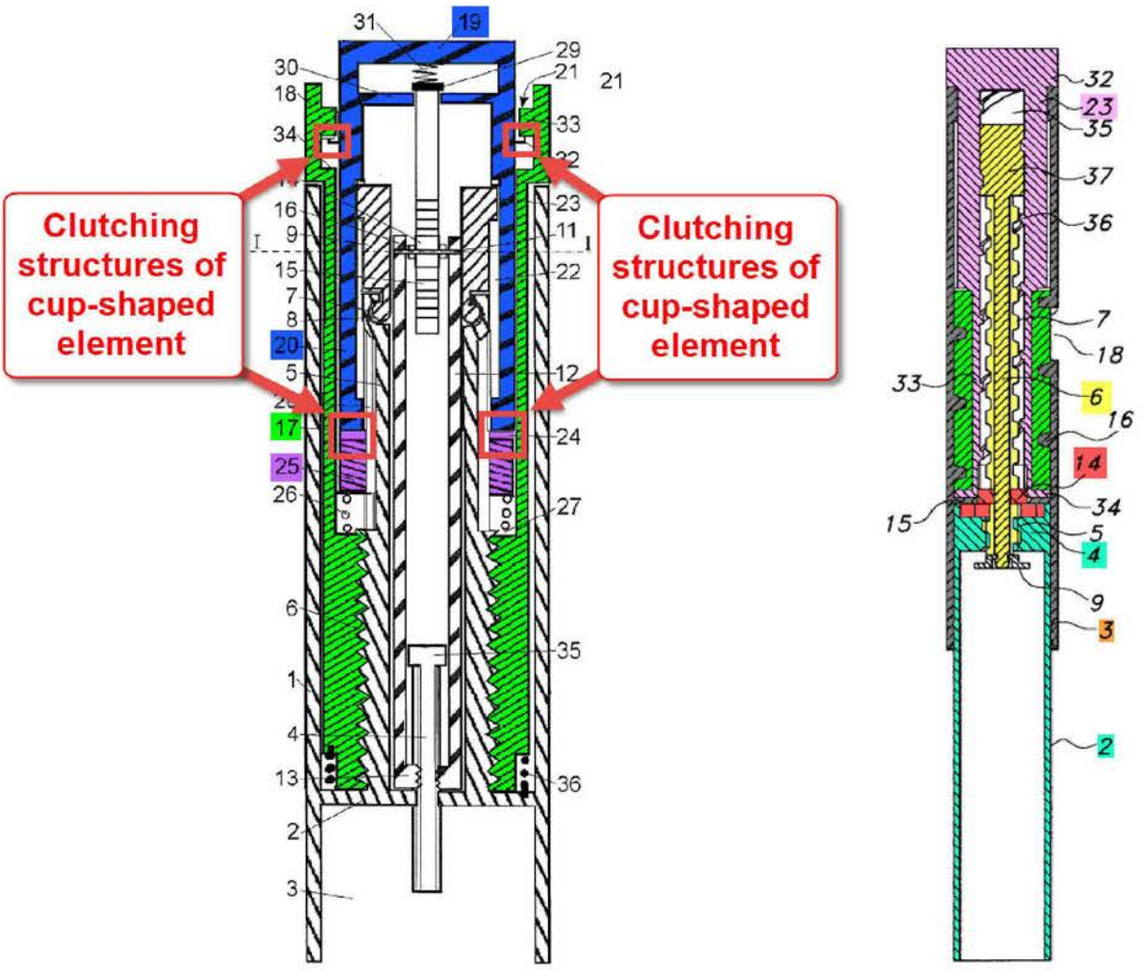
similar structures, operational principles, and objectives of the references," and further argues that "[t]he drive mechanisms also provide the same benefit." IPR2018-01684 (008) Petition at 41-42; Ex. 1011, ¶¶ 832-833. As I explain below, I disagree with Petitioner's and Mr. Leinsing's characterizations and the conclusions drawn from those mischaracterizations.

***i. Møller and Steenfeldt-Jensen have different structures and operational principles***

368. In my opinion, Møller and Steenfeldt-Jensen's second embodiment have fundamentally very different and non-interchangeable "gearing" mechanisms. Simply because two pen injectors both have gearing mechanisms does not mean that they are both similar, that one is interchangeable for the other, or that elements and features of one can be readily substituted into another. A POSA would have understood this, and Møller specifically distinguishes its pen injectors from prior pen injectors (like Steenfeldt-Jensen's) on the basis of these gearing mechanisms. As Møller emphasizes throughout the first page of its disclosure (and as I have explained above), the particular type of gearing can drastically impact a user's experience with that pen injector by making it harder or easier to depress the injection button to inject a dose. *See* Ex. 1015, ¶¶ 0004-0012. Møller specifically chose a type of direct gearing—by using gear wheels and gear racks—that avoided efficiency losses incurred by Steenfeldt-Jensen's "gearing" mechanism which uses sliding threaded contacts. If the gearing mechanisms taught by Møller and

Steenfeldt-Jensen were so similar as Petitioner alleges (which is not true), then there would be very little or even no need to develop different gearing mechanisms as Møller did.

369. The gearing mechanisms disclosed by Møller and Steenfeldt-Jensen are dissimilar in other ways besides the fact that one achieves a mechanical gearing with gear wheels and racks and the other uses helical threads, which result in higher frictional losses. Møller's gearing mechanism is activated by way of a cup-shaped component (elements 19 and 20), which acts as a clutch mechanism. By contrast, the drive mechanism of Steenfeldt-Jensen's second embodiment does not have, and does not need, a clutch to engage. A comparison showing how Møller's pen injector includes a clutch but Steenfeldt-Jensen's second embodiment does not is shown below. *Compare* Ex. 1015, ¶¶ 0026 (describing coupling of dose setting drum with cup-shaped element), 0033 (describing decoupling of dose setting drum with cup-shaped element for dose injection) *with* Ex. 1014, 8:25-33 (describing dose injection without mention of a clutch).




**Ex. 1015, Fig. 1 (annotated); Ex. 1014, Fig. 7 (annotated).**

370. Another dissimilarity is that Møller's piston rod can only be driven axially through a non-circular opening during dose injection, whereas Steenfeldt-Jensen has a dual-threaded piston rod that is screwed through a threaded opening during dose injection. *See* Ex. 1015, ¶¶ 0022, 0032; Ex. 1014, 8:25-33.

371. Therefore, it is my opinion that the driving mechanisms of Møller and Steenfeldt-Jensen are not similar and would not have suggested combinability to a POSA.

### *ii. Møller and Steenfeldt-Jensen also have different, conflicting objectives*

372. As I stated above, Petitioner and Mr. Leinsing assert that the drive mechanisms of Møller and Steenfeldt-Jensen provide the same benefit. In my opinion, this is incorrect and Møller notes that this is not the case.

373. As I have noted above, a principle objective of Møller is to design a pen injector with a gearing between the injection button and piston rod that reduces reliance on screw threads due to the efficiency losses that result from friction:

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

Ex. 1015, ¶ 0011 (emphasis added).

374. By contrast, Steenfeldt-Jensen does not explain that one of its design objectives is to provide a gearing without threads to avoid friction. A POSA would have understood that Steenfeldt-Jensen was more concerned with minimizing the number of pen injector parts and to have a pen injector intended for disposable use. *See, e.g.*, Ex. 1014, 1:23-30 ("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."), Ex. 1015, ¶ 0008 (discussing the threaded gearing of Steenfeldt-Jensen). Thus, it is my opinion that Møller and Steenfeldt-Jensen were pursuing different objectives in their designs. For example, whereas Møller was focused on reducing frictional contact via threads, which may require more parts, Steenfeldt-Jensen was focused on reducing the number of parts.

375. Thus, the different mechanisms of Møller and Steenfeldt-Jensen do not provide the same benefit and they are not designed to provide the same benefit. In my opinion, these divergent teachings would not have suggested combinability to a POSA.

ii. The Purported Advantages Resulting From the Combination Are Entitled to Little Weight and Do Not Provide Sufficient Reason to Combine

376. Even though the driving mechanisms of Møller and Steenfeldt-Jensen are not similar (as I just explained), Petitioner and Mr. Leinsing argue that there are alleged benefits to motivate a POSA to make the combination. As I explain below, I disagree.

377. Petitioner and Mr. Leinsing argue that a POSA would have wanted to substitute the driving mechanism of Steenfeldt-Jensen's second embodiment into Møller, allegedly because Møller's pen injector is prone to malfunction or insufficiently durable. *See* IPR2018-01684 (008) Petition at 42-43. Although Petitioner cites to Mr. Leinsing in support, I note that Mr. Leinsing at his

deposition testified that the forces on gear wheels (such as in Møller) are not so high that they would need to be made a particularly durable material like metal:

> Q. Don't you think that the gear wheels need to be strong and durable enough to withstand the forces, given their size relative to the other components in the pen?
> A. Not necessarily, and that wouldn't indicate whether it's reusable or disposable, and the forces are not again that high. The gears that I worked on for pen injectors were all plastic gears, and they worked fine.

Ex. 2163 at 140:8-16.

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

379. Petitioner also argues that the result of its proposed combination of Møller and Steenfeldt-Jensen would be a pen injector that was easier to use. Neither Petitioner nor Mr. Leinsing explains this assertion. IPR2018-01684 (008) Petition at 43, Ex. 1011, ¶¶ 835-37. If anything, Møller teaches that introducing

thread friction into the gearing mechanism, as Petitioner suggests, would make the pen injector ***harder*** to use by increasing the efficiency losses due to friction.

380. Petitioner and Mr. Leinsing also contend that "a POSA would have appreciated the trade-offs of [Møller's gearing and Steenfeldt-Jensen's gearing] and reasonably determined that the benefits of Steenfeldt-Jensen's approach outweighed any increase in friction." IPR2018-01684 (008) Petition at 43; *see also* Ex. 1011, ¶¶ 835-37. Mr. Leinsing does not cite any evidence for this, but I note that Møller discusses and compares threaded gearing and a rack-and-pinion system and specifically determined, contrary to Petitioner's argument, that the benefits of the latter outweighed Steenfeldt-Jensen's approach. Ex. 1015, ¶¶ 0008-0011.

381. Further, even if one assumes as correct that (1) Møller's pen is not durable and is prone to malfunction, that (2) a POSA would have wanted a pen with fewer parts than Møller's, and that (3) a POSA would have ignored Møller's teaching away from Steenfeldt-Jensen, it is my opinion that a POSA still would not have been motivated to make the combination proposed by Petitioner. That is, if a POSA was motivated to have a pen injector with fewer parts and did not care about the frictional losses from a threaded gearing, a POSA would have just used Steenfeldt-Jensen's second embodiment just by itself rather than making the proposed combination which would add a considerable amount of complexity and cost. This is because the proposed combination includes more parts that

Steenfeldt-Jensen's second embodiment alone (*e.g.*, the combination adds a clutch). Moreover, the proposed combination results in a pen injector with higher frictional losses than Møller and more parts than Steenfeldt-Jensen, which runs counter to what each reference teaches as one of its design objectives. *See* Ex. 1014, 1:27-30 (discussing keeping parts to a minimum), Ex. 1015, ¶¶ 0005-0011 (keeping frictional losses and injection force to a minimum).

382. In view of the above, it is my opinion that a POSA would not have been motivated to combine Møller with Steenfeldt-Jensen's second embodiment as Petitioner suggests, and neither Petitioner nor Mr. Leinsing have demonstrated otherwise. Accordingly, it is my opinion that Petitioner has failed to show that the challenged claims are obvious.

**c. The Combination of Møller and Steenfeldt-Jensen Does Not Disclose a Housing Having a Helical Thread That Is Engaged With the Thread of a Dose Dial Sleeve, Wherein an Insert Is Engaged With the Thread of a Dose Dial Sleeve, Wherein an Insert Is Provided Within Said Threaded Housing, as Required by Claim Limitations [1.1], [1.2], and [1.3] of the 008 Patent**

383. Claim 1 of the 008 Patent requires, among other things:

- "a housing comprising a helical thread"
- "a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing"

- "an insert provided in the housing, where the insert has a threaded circular opening."

i. Møller's "Housing" Does Not Comprise a Thread

384. Claim 1 of the 008 Patent recites both a "housing" and an "insert provided in the housing." In my opinion, a POSA would have understood that the claimed housing is different distinct from the claimed insert, which is provided in the housing.

385. Petitioner asserts that Møller's housing 1, wall 2, and tubular element 5 comprise the claimed "housing," but Petitioner also asserts that Møller's wall 2 is the "insert provided in the housing." IPR2018-01684 (008) Petition at 21-25.

386. In my opinion, if the claimed "housing" is Møller's housing 1, wall 2, and tubular element 5, then Petitioner has not identified any component in Møller as the claimed "insert provided in the housing."

387. If the claimed "insert provided in the housing" is wall 2, then Petitioner has not identified any component in Møller as the claimed "housing comprising a helical thread." This is because wall 2 is provided only in housing 1, which does not have a helical thread.

388. Petitioner also has not identified in Møller "where the insert has a threaded circular opening" as claimed—wall 2 has a non-circular and non-threaded opening. *See* Ex. 1015, ¶ 0022.

389. Thus, in my opinion Møller fails to teach a housing comprising a helical thread and an insert provided in the housing.

ii. The Combination of Møller and Steenfeldt-Jensen Does Not Teach or Render Obvious a Threaded Housing or Render Obvious a Threaded Housing and an Insert Provided in the Threaded Housing as Required by the Claims

390. Petitioner and Mr. Leinsing contend that both Møller's wall 2 and Steenfeldt-Jensen's wall 4 (from its third embodiment) disclose the claimed "insert provided in the housing." IPR2018-01684 (008) Petition at 25-28, Ex. 1011, ¶¶ 804-809.

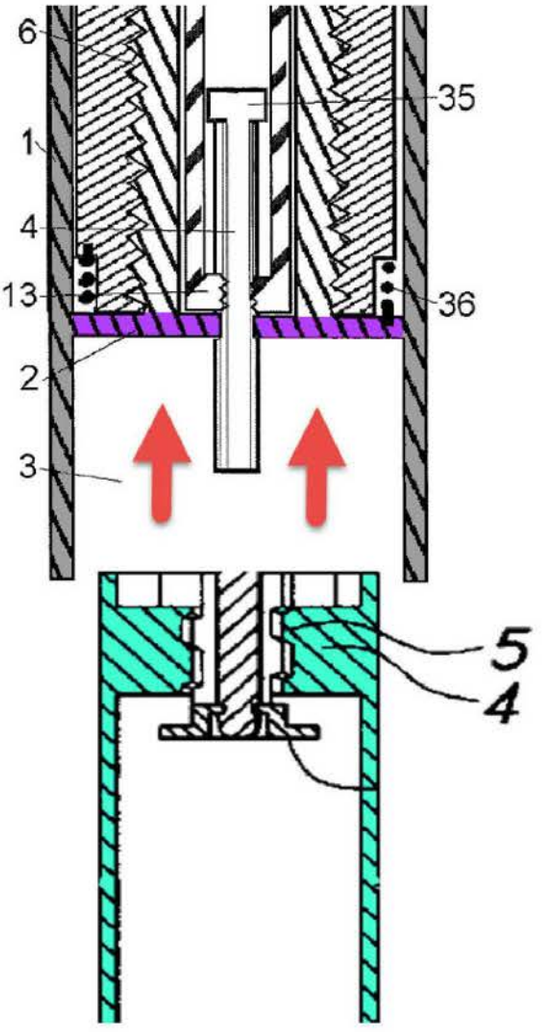
391. As I explained above, Møller cannot disclose both the claimed "housing comprising a helical thread" and the claimed "insert provided in the housing."

392. Petitioner and Mr. Leinsing do not clearly explain how Møller combined with Steenfeldt-Jensen's wall 4 teaches or renders obvious an "insert provided in the housing" while satisfying all other limitations of claim 1. To the extent that Petitioner and Mr. Leinsing argue that it would have been obvious to combine Steenfeldt-Jensen's wall 4 with Møller, I disagree as explained below.

393. First, if Petitioner and Mr. Leinsing are proposing that a POSA would have been motivated to replace Møller's non-circular (and non-threaded) wall 2, with Steenfeldt-Jensen's wall 4, then the combination does not disclose a "housing

comprising a helical thread" as required by claim 1. This is because wall 4 (the "insert") is provided only within housing 1 (the "housing"), but housing 1 does not comprise a helical thread.

394. Second, if Petitioner and Mr. Leinsing are proposing that a POSA would have been motivated to insert Steenfeldt-Jensen's wall 4 (turquoise, below) into Møller's housing 1 (dark grey below) to abut Møller's wall 2 (purple, below), I would disagree. A POSA would not have been motivated to have a structure such as wall 2, which already contains an opening for a piston rod, and insert an additional structure with an opening for a piston rod. There would be no purpose behind this combination, and it would needlessly waste material and take up space in a handheld device.




**Ex. 1014, Fig. 7 (partial, annotated) and Ex. 1015, Fig. 1 (partial, annotated)**

395. Therefore, it is my opinion that Møller in combination with Steenfelt-Jensen's third embodiment does not teach or render obvious claim 1 of the 008 Patent, at least because it does not teach or render obvious both a "housing comprising a helical thread" and an "insert provided in the housing" as required by the claim.

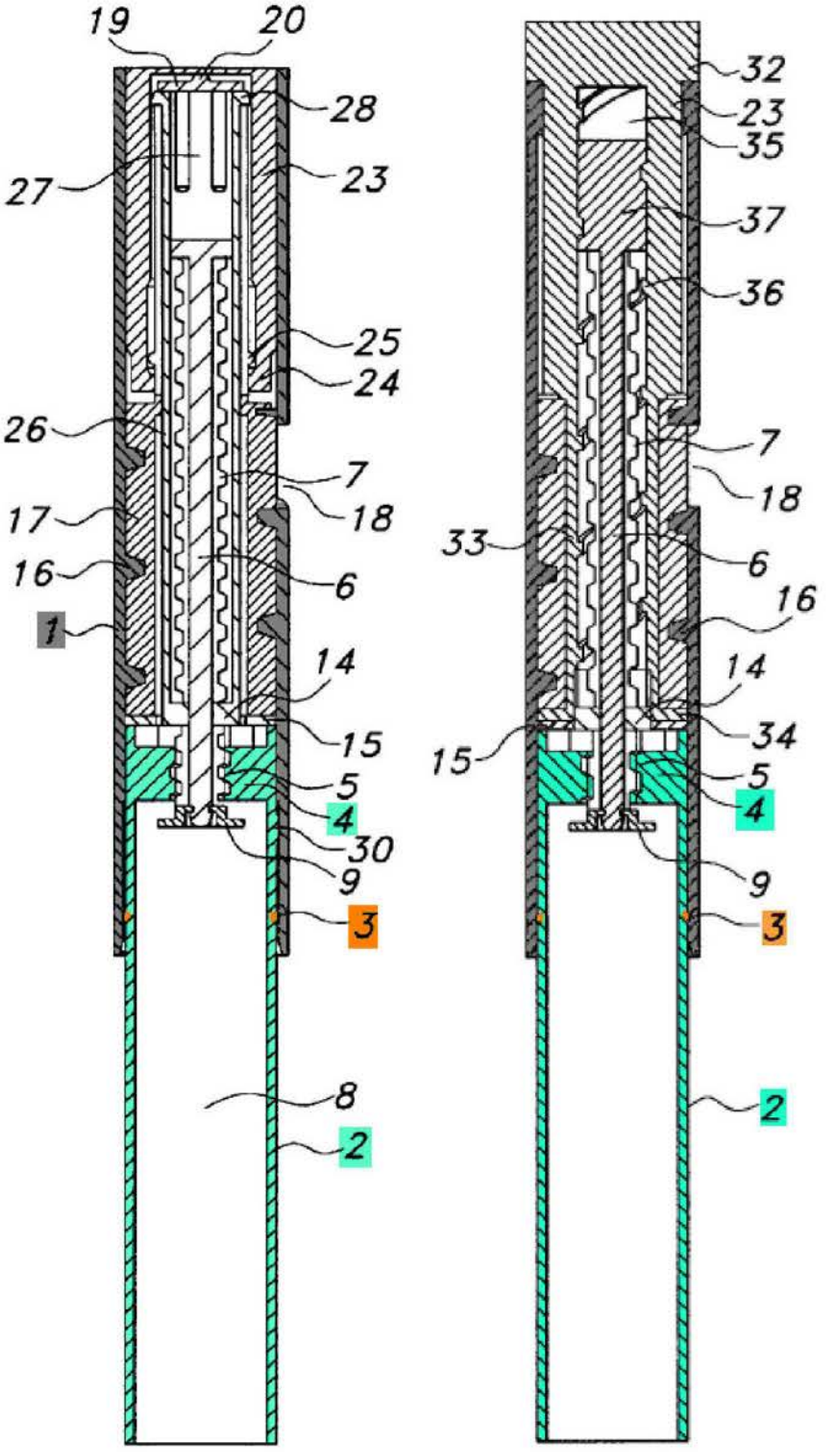
iii. The Combination of Møller and Steenfeldt-Jensen Does Not Disclose or Render Obvious an Insert Provided in the

Housing, Wherein the Insert is Secured in the Housing Against Rotational and Longitudinal Motion as Required by Claim 3

396. Claim 3 of the 008 Patent recites "wherein the insert is secured in the housing against rotational and longitudinal motion."

397. Petitioner and Mr. Leinsing again point to Møller's wall 2 and Steenfeldt-Jensen's wall 4. First, as I explained above, the combination of Møller and Steenfeldt-Jensen at the very least do not teach or render obvious both the insert and housing limitations.

398. Second, Steenfeldt-Jensen's wall 4 cannot be the insert of claim 3 because it is not "secured in the housing against rotational movement" as required by the claim. Specifically, in the description for the first embodiment (depicted below, left), Steenfeldt-Jensen says that the ampoule holder 2 (turquoise), of which wall 4 is part, is snapped into the tubular housing 1 (grey) "by a snap lock comprising a ring shaped bead 3" (orange), and that "[b]y this snap connection the ampoule holder 2 is secured in the housing 1 ***so that it can be rotated*** … relative to this housing." Ex. 1014, 5:38-46 (emphasis added), Fig. 2.




**Ex. 1014, Fig. 2 (left) (annotated), Ex. 1014, Fig. 7 (right) (annotated).**

399. A POSA would have understood that this same ampoule holder 2 (turquoise) with wall 4 is shown in the second embodiment (shown above and to the right) as having the same ring-shaped bead 3 (orange) that snaps into the housing 1 (grey) to allow rotational movement relative to the housing. *See* Ex. 1014, 7:48-67 (describing the differences between the first and second embodiments, which do not include the rotational movement of the ampoule holder 2 relative to the housing 1), Fig. 7.

400. A POSA therefore would have understood that Steenfeldt-Jensen fails to teach or render obvious an insert that is "secured in the housing against rotational … motion" as required by claim 3.

**d. The Combination of Møller and Steenfeldt-Jensen Does Not Disclose or Render Obvious a Dose Dial Sleeve Having a Threaded Outer Surface That Is Engaged With the Internal Helical Thread of the Housing as Required by Claim 11**

401. Claim 11 of the 008 Patent depends on claim 1 and further requires that "the helical thread of the housing is an internal helical thread and the dose dial sleeve has a threaded outer surface that is engage with the internal helical thread of the housing."

402. Petitioner identifies Møller's dose-setting drum 17 as the claimed dose dial sleeve, but this dose dial sleeve does not have a thread on the ***outer*** surface as required by claim 11. IPR2018-01684 (008) at Petition at 50-52; *see*

*also id.* at 53-54 (admitting that Møller's dose setting drum 17 lacks a thread on its outer surface when describing a modification to put "a helical groove on [the dose setting drum's] outer surface, rather than its inner surface ...."). Nonetheless, Petitioner argues that it would have been obvious to modify Møller's internally-threaded dose-setting drum 17 to have external threads as taught by Steenfeldt-Jensen's dose scale drum 80. I disagree for the reasons set forth below.

i. A POSA Would Not Have Been Motivated to Combine Møller With Steenfeldt-Jensen's Externally-Grooved Dose Scale Drum 80

403. In my opinion, a POSA would not have been motivated to combine Møller with Steenfeldt-Jensen's externally-grooved dose scale drum 80 as Petition and Mr. Leinsing propose.

404. First, a POSA would not have been motivated to combine Møller with Steenfeldt-Jensen, because Møller teaches away from Steenfeldt-Jensen's teachings as I explain above.

405. Second, as I explained in Sections XI.C.2. and XI.C.5. neither Petitioner nor Mr. Leinsing has identified a reason that a POSA would have found Møller's teachings for addressing undesirable thread to be deficient and looked outside of Møller for a solution. Indeed, Møller says that the thread friction arising from the internal threads 6 of its dose-setting drum 17 are already counteracted by a "helical reset spring 36," which is a torsional spring meant to bias the dose-

setting drum 17 back into the housing 1 after it has been dialed out. Specifically, Møller states that this spring "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 the ampoule to inject the set dose." Ex. 1015, ¶ 0033. Because Møller proposes a solution for the thread friction, and because neither Petitioner nor Mr. Leinsing has explained why this solution is deficient, Petitioner has failed to demonstrate a reason that would motivate a POSA to make the proposed modification (*i.e.*, replacing Møller's internal threads on dose-setting drum 17 with Steenfeldt-Jensen's exterior high-pitch thread).[15]

[15] Indeed, as I explain in the next section, moving the threads from the interior of the dose-setting drum 17 to the exterior is not a good idea, because the losses due to friction are multiplied by the increase in distance the threads are moved from the pen injector's central axis. Thus, not only is there not a reason to use Steenfeldt-Jensen's exterior threads, a POSA would not have wanted to when the threads could be formed on the interior.

ii. There Is No Motivation to Move the Threads on the Inner Surface of Møller's Dose Setting Drum to the Outer Surface in Order to Satisfy Claim 11

406. To the extent Petitioner and Mr. Leinsing argue that it would have been obvious to simply move the threads on the interior Møller's dose setting drum 17 to its exterior, I disagree. As I explained in Section XI.C.5., a POSA would not have wanted to make the proposed modification because it would have resulted in an inferior pen injector. First, placing the internal threads 6 of the dose-setting drum 17 on the outer surface, which would also mean putting interior threads on the inner surface of the Møller's housing 1, would lead to mechanical interference with Møller's helical reset spring. *See* Ex. 1015, Fig. 1 (element 36). This interference could cause the pen injector to malfunction. For example, the spring could get caught between the crest and root of the mating screw threads to jam and prevent rotation of the dose-setting drum 17, or the interaction between the screw threads and the spring could damage or break the spring, preventing it from working properly. Petitioner and Mr. Leinsing have neither considered nor explained how to avoid these problems.

407. Second, moving threads (and their inherent friction) from closer to the center of the pen injector to farther from the center of the pen injector, as Petitioner and Mr. Leinsing propose, would ***increase*** the parasitic torque (efficiency losses) due to friction during dose injection. As I have explained in the background of the

technology section of this declaration, part of the force that the user puts into a pen injector does not go to expelling medicament but rather to overcoming the frictional forces in the device. These frictional forces arise from thread surfaces that rub against each other during dose injection. If one were to move these thread interfaces farther away from the axis of rotation, however, the drag (parasitic) force caused by this friction is multiplied by the distance of the threaded interface from the axis of rotation ($\tau = r \times F$). As I also explained in the background of the technology section of this declaration, reducing injection force was an important design objective and a POSA would have known to reduce the efficiency losses due to friction in furtherance of this objective. A POSA therefore would not have understood that moving the internal threads of Møller's dose-setting drum17 to its exterior would be beneficial, and a POSA would not have been motivated to make this change.

408. Notably, Steenfeldt-Jensen discloses an externally-threaded dose scale drum 80, but as shown below Steenfeldt-Jensen does not disclose an interior housing on which threads may be formed. Møller does disclose an interior housing, and in fact requires the interior housing to support the gearbox 9 in its first embodiment. A POSA would have understood that when presented with an option to thread a dose dial sleeve with the interior of an exterior housing (as

Petitioner proposes) or an exterior of an interior housing (as Møller does), it is better to do the latter to reduce losses due to thread friction.

409. Thus, even though Møller sets out to reduce injection force and minimize losses from friction, Petitioner and Mr. Leinsing argue that a POSA would have ignored these teachings (and the motivating design principles in pen injector design generally) and made a pen injector that is inferior. In my opinion, this is incorrect. A POSA would not have been motivated to modify Møller as Petitioner proposes, and thus it is my opinion that Møller and Steenfeldt-Jensen does not teach or render obvious a claim 11 of the 008 Patent.

### F. Giambasttista, Whether Alone in Combination with Steenfeldt-Jensen or Klitgaard Do Not Render Challenged Claims 21-30 of the 844 Patent Unpatentable [IPR2018-01680 (844-A) Grounds 1, 2, 3]

410. I have been asked to provide an opinion on whether Petitioner's and Mr. Leinsing's arguments as to the patentability of challenged claims 21-30 of the 844 Patent based on Giambattista. According to Petitioner and Mr. Leinsing, Giambattista anticipates claims 21-29; Giambattista in view of Steenfeldt-Jensen render claims 24-29 obvious; and Giambattista in view of Klitgaard render claim 30 obvious. I disagree with the Petitioner and Mr. Leinsing, as I explain below.

#### 1. Giambattista Is Not Prior Art

411. As I stated above in Section VI.C, in my opinion, Giambattista is not prior art because the 844 Patent properly claims priority to the GB Application,

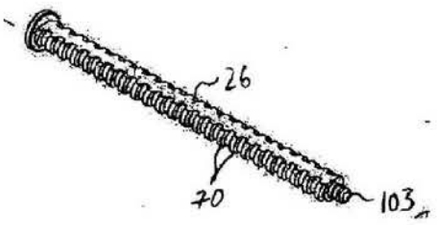
which fully supports an internally threaded piston rod engaged to an externally threaded drive sleeve.

412. Since Giambattista is not prior art, I understand that it cannot anticipate claims 21-30 and cannot form the basis of an obviousness challenge. In other words, because Giambattista is not prior art, Giambattista in combination with Steenfeldt-Jensen does not render claims 24-29 obvious, and Giambattista in combination with Klitgaard does not render claim 30 obvious.

### 2. Giambattista Does Not Disclose a Piston Rod With a Circular Cross Section

413. I understand that Mr. Leinsing argues that Giambattista discloses a circular piston rod. I disagree.

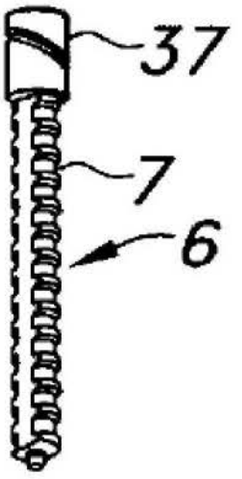
414. Leadscrew 26 has a non-circular cross section, as can be seen in Figure 2. As shown in that figure, leadscrew 26 has two flat sides:




415. If Giambatistta's leadscrew 26 had a circular cross-section, it would not work as intended since the flat sides of the leadscrew 26 (which make it non-circular) permit the leadscrew 26 to axially pass through a rectangular aperture 46 but the aperture does not allow the leadscrew 26 to rotate. When the leadscrew 26

moves axially, aperture 46 prevents rotation of the leadscrew 26. *See* Ex. 1016, 3:3-6 ("aperture 46 is defined to allow the passage therethrough of the leadscrew 26, yet the aperture 46 is shaped (e.g., ***being rectangular***) to prevent rotation of the leadscrew 26 therewithin.") (emphasis added). This is critical for the system to operate in the mode of a rotating nut driving a non-rotating leadscrew.

416. In my opinion, A POSA would characterize Giambattista's leadscrew 26 with its two flat sides as having a non-circular cross section. My opinion is confirmed by other prior art. Steenfeldt-Jensen, for example, discloses a piston rod (below right) having essentially the same shape as that of Giambattista's lead screw:




**Steenfeldt-Jensen (Ex. 1014)**

417. Steenfeldt-Jensen describes its piston rod as having a "***not*** round cross-section" and a "***non***-circular cross section." Ex. 1014.; Abstract. The non-circular cross-sectional shape serves the same purpose in Steenfeldt-Jensen as it

does in Giambattista. In Steenfeldt-Jensen the piston rod is designed to fit "through the driver tube bore which has a corresponding not round cross-section." *Id.*, 11:16-17. A POSA would understand that Steenfeldt-Jensen's piston rod has a non-circular cross-section because it is designed to slot through and be rotationally constrained by the non-circular bore in the driver tube 85.

418. I understand that Mr. Leinsing relies on the ends of Giambattista's leadscrew 26 to argue that it has a circular cross section. This interpretation of the claim is not reasonable and the characterization of Giambattista's leadscrew as having a circular cross-section is incorrect.

419. In the 844 Patent, the piston rod has a circular cross-section over its length because it is adapted to engage with and move rotationally and axially relative to the cylindrical bore in the drive sleeve. *See* Ex. 1004 at 3:65-66, 4:13-14, 6:55-58, Figs. 9-11.

420. In contrast, a POSA would understand that the cross-section of the leadscrew in Giambattista is non-circular over the entire length of the screw so that it can slot through and is rotationally constrained to the rectangular aperture 46 of the bulkhead 44.

421. Mr. Leinsing offers an additional argument that even though the leadscrew 26 has two flat sides, "the piston rod has circular helical threads along the majority of its length so it is understood to have a 'generally circular cross-

section' with flat sides." Ex. 1011, ¶ 577. I disagree again with Mr. Leinsing. A POSA would understand that the cross-section of the Giambattista leadscrew with two flat sides is not circular, and is instead shaped to fit through a generally rectangular slot. The claim also recites a piston rod with a circular cross section, not a *generally* circular cross section.

422. To a POSA, a circular cross-sectioned piston rod is mechanically different than one with a non-circular cross-section. The former has a substantially lower buckling force, which is important when it comes to minimizing lead screw diameter in order to maximize mechanism efficiency.

### 3. Giambattista in combination with Klitgaard Does Not Render Claim 30 Obvious

423. I understand that Mr. Leinsing opines that Giambattista in combination with Klitgaard renders claim 30 obvious. I disagree.

424. Mr. Leinsing states that Giambattista could be modified as follows: "nut member 32 as described in Klitgaard [FIG. 3] could be easily adapted and disposed between dosing ring adapter 28 and dose knob 20 to track each set dose of medicament delivered." Mr. Leinsing's modification does not work because if Klitgaard's nut member is positioned between the dosing ring adapter 28 and dose knob 20 of Giambattista, it would not operate to track each set dose of medicament because a user could still dial a dose beyond the amount of medicament remaining in Giambattista's drug cartridge 32.

425. In contrast to Mr. Leinsing's modification, Klitgaard's nut member does not allow a user to dial a dose beyond the amount of medicament remaining in a cartridge. FIG. 3 of Klitgaard (shown below) discloses that between dose setting member 30 (shown in yellow) and the driver 31 is a nut member 32 (shown in red) having internal threads that engage a helical track 33 that extends all along the length of the driver 31. Ex. 1017, 4:26-28.

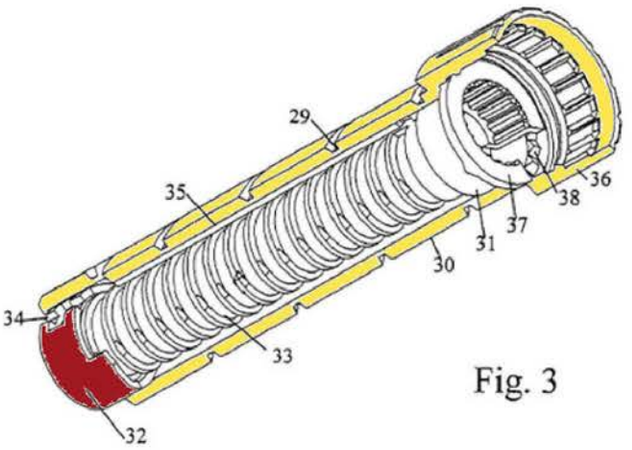


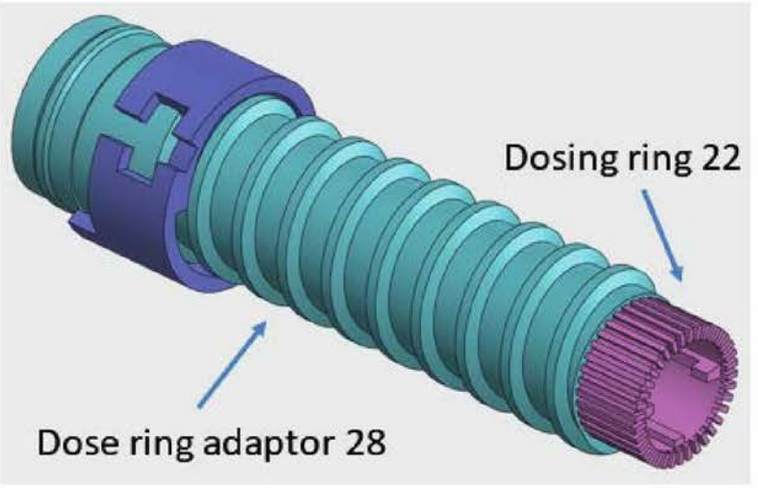

Fig. 3

**Ex. 1017, Fig. 3**

426. To set a dose, a user rotates the dose setting member 30, which rotates relative to the driver 31. *Id.*, 4:23-25. During this time, a ridge 35 of the dose setting member 30 engages with a recess 34 of the nut member 32 so that the nut member 32 rotates with the dose setting member 30 causing the nut member 32 to move along the helical track 33. *Id.*, 4:33-37. As a result, in Klitgaard, the position of the nut member 32 on the helical track 33 reflects the dosage dialed by the dose setting member 30. *Id.*

427. In Klitgaard, during dose dispensing, the driver 31 and the dose setting member 30 engage so that they do not rotate relative to one another causing the nut member 32 to maintain its position. *Id.*, 4:37-52. When a subsequent dose is dialed, the nut member 32 will again advance on the helical track 33. *Id.*, 4:26-29. The position of the nut member 32 on the helical track is thus indicative of the amount of medicament dispensed. Ex. 1017, 4:52-54. When the nut member 32 gets to the end of the helical track 33, no more doses can be dialed because the nut member 32 prevents dose setting member 30 from rotating to dial a dose. Ex. 1017, 4:54-58.

428. Mr. Leinsing's modification attempts to adapt Klitgaard's nut member 32 for use in Giambattista. The problem with the modification is that Giambattista's dose ring 22 and dose ring adaptor 28 (components not present in Klitgaard) would interfere with the operation of nut member 32 and prevent it from dose tracking. According to Petitioner's modification, Klitgaard's helical track 33 is added on Giambattista's dose ring adaptor 28. The nut member 32 is rotated by the dose knob 20 during dose dialing which moves the nut member 32 along the added helical track. A screenshot from the animation submitted with Patent Owner's Response depicting the dose ring adaptor 28 with a helical track, the dosing ring 22, and the nut member 32 is shown below:




**Ex. 2167**

429. Mr. Leinsing's proposed modification would not work because when the nut member 32 gets to the end of the helical track on dose ring adaptor 28, the dose knob 20 (*i.e.*, the component that dials a dose) will still be able to rotate to dial a dose, even when there is no medicament remaining. This is because the dose ring adaptor 28 and dosing ring 22 would interfere with the operation of the nut member 32.

430. Specifically, Giambattista discloses that the dose ring adaptor 28 and dosing ring 22 can be snap fit or in an alternative embodiment, formed unitarily. In the embodiment where dose ring adaptor 28 is snap fitted to dosing ring 22, dose ring adaptor 28 rotates during dose dialing, whereas dosing ring 22 cannot, because dose ring 22 is rotationally fixed to the driver tube 24. As a result, when the proposed added nut member reaches the end of the helical track on dose ring adaptor 28, the dose knob 20 (not shown above) would continue to rotate. The

proposed nut member would not prevent rotation of the dose knob 20 even when there was no medicine remaining to be dispensed. This is not an issue in Klitgaard because Klitgaard's driver 31 is rotationally fixed during dose dialing. Exhibit 2167 is an animation of Mr. Leinsing's proposed modification to Giambattista that I have reviewed and found to be accurate illustrating this point.

431. In the alternative embodiment where dose ring adaptor 28 is formed unitarily with dose ring 22, dose ring adaptor 28 still would not be rotationally fixed when the nut member reached the end of the helical track. The driver 24 of Giambattista is designed not to rotate in the dose dialing direction. Ex. 1016, 3:26-37. The driver 24 includes ratchet fingers 66 that cooperate with ratchet teeth 52 to "provide a measure of protection against unwanted rearward movement of the leadscrew 26." Ex. 1016, 3:32-37.

432. A POSA would have understood that the "measure of protection" is actually low given that only a nominal torque is applied on the driver 24 during dose dialing. This is evidenced by the small size of ratchet teeth 52 relative to the diameter of the channel 50 shown in FIG. 4 of Giambattista. The torque applied by a user on the dose knob 20 to dial a dose, however, is much greater since a user is directly applying torque on the dose knob 20. In Petitioner's modification of Giambattista, when the nut member reaches the end of the helical thread, if a user continued to dial a dose, the applied torque would overcome the "measure of

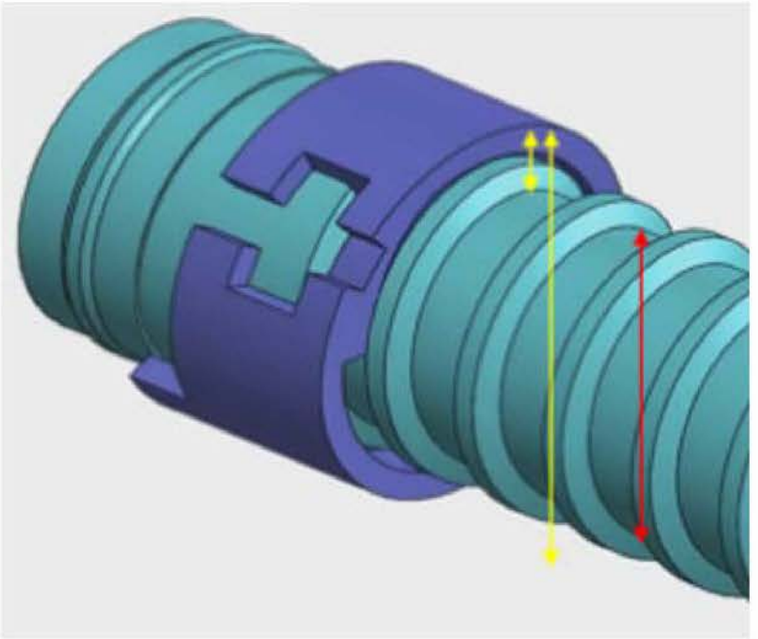
protection" provided by ratchet fingers 66 and ratchet teeth 52, thereby causing the dose ring adaptor 28 to rotate during dose dialing. Ex. 2168 is another animation of Mr. Leinsing's proposed modification to Giambattista that I have reviewed and found to be accurate illustrating this point.

### a. A POSA Would Not Be Motivated to Make Petitioner's Modification

433. I also note that Mr. Leinsing's modification would markedly increase the diameter of Giambattista, thereby impairing the user's ability to handle and operate the pen. A POSA, in my opinion, would therefore not have been motivated to make Petitioner's modification to Giambattista.

434. Klitgaard's nut member 32 is positioned between the driver 31 and the dose setting member 30. Ex. 1017, 4:26-32. In Petitioner's modification, the nut member is not positioned on Giambattista's driver 24, but on dose ring adaptor 28. Because dose ring adaptor 28 is larger in diameter than driver 24, a larger nut member is required, as well as a helical track, both of which must be positioned on the exterior of the dose ring adaptor 28. Because a helical track and nut member are now positioned on the exterior of dose ring adapter 28, the diameter of dose knob 20 and body 18 must also increase. This would proportionally increase the overall diameter of the pen by approximately 25%, which is not ergonomic and would impair the user's ability to handle and operate the dispensing apparatus.

Below is an annotated snap shot from the animation in Exhibit 2167, with arrows showing the increase in size due to Mr. Leinsing's modification:



435. In addition to the undesirable size increase, the proposed modification would increase the force required to inject a dose because the increased diameter causes increased frictional torque between the internal thread of body 18 and external thread of dose knob 20 (*i.e.*, the backdriving function). A POSA would understand that the increased size and resulting undesirable ergonomics, in combination with the increased frictional torque, would decrease the usability of the injection pen and make it harder for patients to use, especially in view of the various hand and wrist conditions frequently experienced by diabetic patients.

## XII. OBJECTIVE INDICIA

### A. The SoloSTAR Practices the Challenged Claims

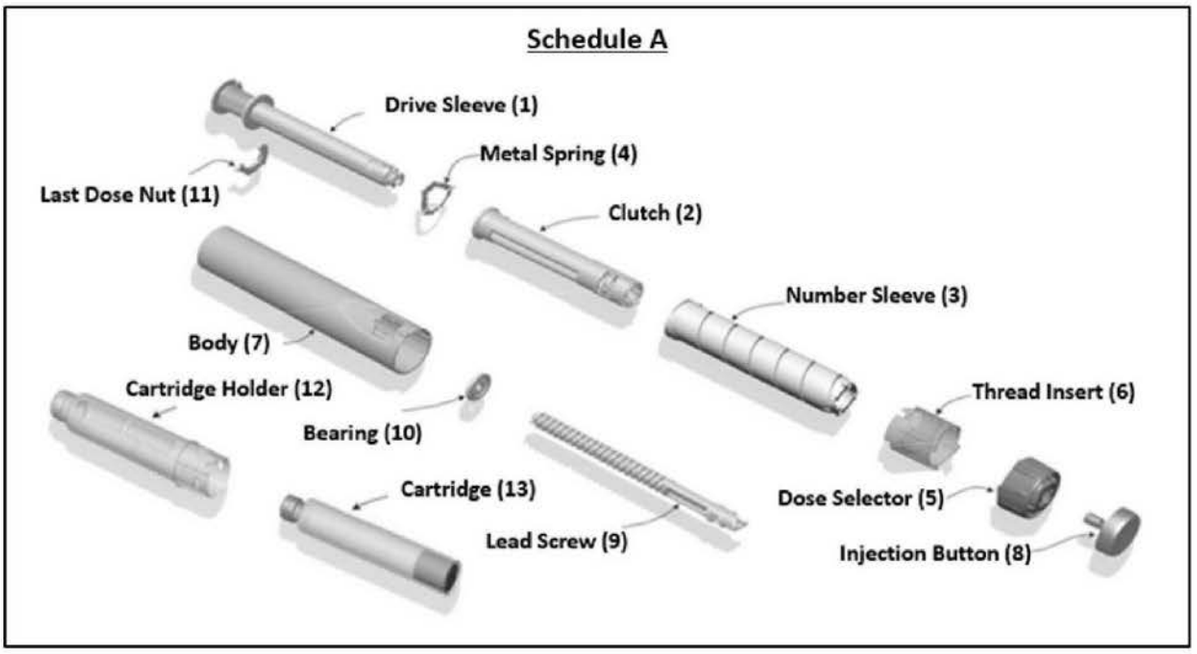
436. I have been asked to consider whether Sanofi's SoloSTAR pen injector ("SoloSTAR") practices any of the challenged claims. For the reasons set forth below, it is my opinion that Sanofi's SoloSTAR pen practices at least claim 1 of the '069 patent, claim 1 of the '486 patent, claims 21 and 30 of the '844 patent, and claim 1 of the '008 patent.

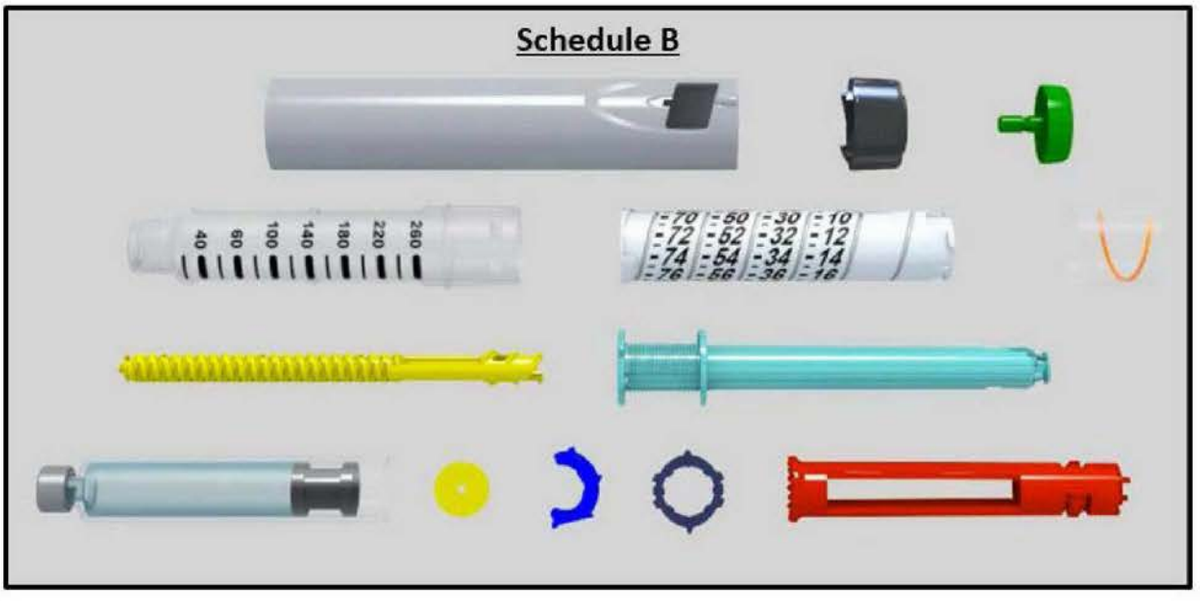
437. In forming my opinion, I conducted a physical examination of Sanofi's SoloSTAR device. I have also reviewed and considered materials relating to the SoloSTAR device, including animations that represent the assembly and operation of the SoloSTAR device. I analyzed the Lantus SoloSTAR, Apidra SoloSTAR, and Toujeo SoloSTAR, and Toujeo SoloSTAR Max and found that the mechanisms and functionality are identical.

438. Based on my analysis and physical inspection of the SoloSTAR device, it is my opinion that these animations accurately reflect the components and operation of the SoloSTAR device for the purposes they are used herein.

#### 1. SoloSTAR Components

439. For the following sections, I may refer to the part numbers and components illustrated in the following diagrams, which I will refer to as "Schedule A" and "Schedule B," respectively.




i. Housing

440. The SoloSTAR device includes a housing made up of a body and thread insert. During manufacture, the body (depicted on the left)(part 7 in Schedule A, above) and thread insert snap-fit together (depicted in the middle)(part

6 in Schedule A, above) to form a rigid, unitary housing structure (depicted on right). The thread insert 6 is axially and rotationally fixed near the end of the body 7.

441. The number sleeve (dose dial sleeve) (part 3 in Schedule A, above) is positioned in the body 7 and includes a threading along its outer surface that is configured to engage the threading provided by the thread insert 6 of the body 7.

442. The thread insert 6 of the body 7 includes a helical rib on its internal surface, as seen below in orange. The helical rib is adapted to engage the helical groove provided along the outer surface of the number sleeve 3. The thread insert 6 of the body 7 includes a window that allows the user to see the units of medicament to be dispensed, printed on the outer surface of the number sleeve 3.

ii. Integral Web Insert

443. The body 7 includes an integrally formed web insert (depicted below) that includes a threaded circular opening. The threaded circular opening of the

insert engages the thread on the distal portion of the lead screw (piston rod) (part 9 in Schedule A, above) and prevents the piston rod (lead screw) 9 from rotating during dose setting and permits the piston rod (lead screw) 9 to rotate and move axially during dose dispensing.

iii. Number Sleeve

444. The number sleeve (dose dial sleeve) 3 (depicted below) has even numbers and indication lines for odd numbers printed onto its surface, indicative of units of medicament, that are visible to the patient through a thread insert (dose window) 6. The number sleeve (dose dial sleeve) 3 includes a helical groove along its outer surface that engages with threading provided by the body 7, thereby permitting the number sleeve to rotate and move axially away from the dispensing end during dose setting and to rotate and move axially towards the dose dispensing end during dose injecting (dose dispensing).


iv. Dosage Selector

445. The Dosage selector (dose dial grip / dose knob) (part 5 in Schedule A, above)(also depicted below) is what the user grips and manipulates to increase or decrease a dose. The dosage selector 5 and number sleeve 3 are firmly clipped together during assembly and form an integral unit.

v.Radial Stop

446. There is a radial stop on number sleeve 3, which engages a feature on the thread insert 6 to positively stop the motion of the number sleeve 3when the maximum allowable dose to be dispensed is reached (*i.e.*, 80 IU).

vi.Lead Screw

447. The lead screw 9 (depicted below) consists of two oppositely disposed threads. The lead screw includes a first thread on its distal portion that engages with the threaded circular opening of the insert 6 and a second thread on its proximal portion that engages with the drive sleeve (part 1 in Schedule A, above). The lead screw 9 is non-rotatable during a dose setting step relative to body 7. The lead of the second thread is the same as the lead of the thread on the number sleeve 3. This arrangement, in combination with the oppositely disposed threading engaged with the threaded circular opening of the insert 6, allows the drive sleeve

1, which is rotationally fixed to the number sleeve 3 during dose selection, to ride up or down the lead screw 9 during dose selection without causing the lead screw 9 to rotate.

448. The lead screw 9 has threaded rod portions having a circular cross section and has at least two sets of threads. One set is the double thread on the distal end (right) that engages with the threaded insert 6 in the body 7, and the other set is the double thread on the proximal end (left) that engages with the drive sleeve 1.

vii. Drive Sleeve

449. The drive sleeve 1 (depicted below) includes double internal threading and extends along a portion of the lead screw 9. The drive sleeve 1 is adapted to engage the external threads (the second set of threads) of the lead screw 9.

450. The drive sleeve also has two radially extending flanges (at left, in the figure) with an outer (external) helical thread between the flanges.

viii.Clutch

451. During dose setting, the clutch (depicted below) (part 2 in Schedule A, above) remains meshed with the number sleeve 3 through a plurality of teeth. During dose dispensing, the plurality of teeth become unmeshed and the number sleeve 3 rotates independent of the clutch 2.

ix.Last Dose Nut

452. The last dose nut (depicted below) (part 11 in Schedule A, above) engages the threads between the two flanges located at the distal end of the drive sleeve 1. Since the last dose nut 11 is rotationally fixed to the body 7, it moved axially along the length of the drive sleeve 1 as drive sleeve 1 rotates. The axial movement of the last dose nut 11 corresponds to the selected dose. The last dose nut 11 eventually hits a stop that blocks the mechanism from dialing greater doses than the amount of medicine remain in the cartridge.

x.Cartridge Holder / Cartridge Retaining Part

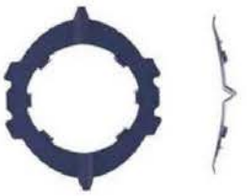
453. The cartridge holder (depicted below) (part 12 in Schedule A, above) receives the medicament cartridge and includes printing that helps the patient to determine, as an indication, how much medicament is left in the cartridge. The distal end of the cartridge holder 12 (at left) is threaded and allows the patient to attach a pen-injector needle. The cartridge holder 12 includes features that rotationally and axially secure it to the body 7.


xi. Clicker Arm

454. One of the clicker features on the tubular clutch comprises two flexible arms located at the proximal end of the tubular clutch (located in yellow box at right), each having at least one tooth member and corresponding splines on the internal surface of the number sleeve 3 (internal splines depicted below in lower figure). During dose delivery, the dosage selector 5 and number sleeve 3 rotate, while the tubular clutch 2 does not. As a result, the flexible arms deform and drag the corresponding tooth member over the splines on the internal surface of the number sleeve 3 to provide audible and tactile feedback.

xii. Metal Spring

455. The metal spring (depicted below) (part 4 in Schedule A) which is located between the distal end of the clutch 2 and the middle flange of the drive sleeve 1 is rotationally locked inside the body 7 by means of splines. During dose setting (i.e., dose increasing and dose cancelling), the teeth at the distal end of the clutch 2 ride over the metal spring 4 causing both an audible and tactile feedback.



xiii. Injection Button

456. The injection button (depicted below) (part 8 in Schedule A) is located at the proximal most portion of the pen. Pressing the injection button 8 moves the clutch 2 axially in the distal direction and compresses the metal spring 4.

xiv. Cartridge

457. The cartridge (depicted below) (part 13 in Schedule A, above) contains the medication. For Lantus SoloSTAR, the usable medication content is 300 insulin units. To allow for initial priming to remove air that may be trapped inside the cartridge 13, the mechanism is able to deliver up to 307 units.

xv. Bearing

458. The bearing (depicted below) (part 10 in Schedule A, above) connects the distal tip of the lead screw 9 and abuts the cartridge piston (or plunger) (black, above). During dose injection, the bearing evenly distributes the force from the lead screw 9 to the cartridge piston (or plunger).

xvi. Pen Cap

459. For the safety and convenience of the user, as well as for the protection of the cartridge 13, a pen cap has been incorporated as part of the pen system. There are snap features between cartridge holder 12 and pen cap that allow the pen cap to be fixed onto the cartridge holder 12. The removal method for

the cap is pull-off. The pen cap is also designed to protect the cartridge 13 from damage and dirt.

### 2. SoloSTAR Operation

#### a. Dose Setting/Selection

460. A pen injector needle is mounted onto the threaded portion of the cartridge holder 12 at the front end of the device. The needle is inserted under the skin, and the dose is delivered by pressing the injection button 8. During the dose setting step, the dose to be injected is selected by rotating the dosage selector 5 at the proximal end of the device. Dose setting includes increasing and decreasing the dose. The number of selected insulin units is visible through the thread insert 6.

461. To increase a dose, the dosage selector 5 is rotated clockwise and moves in the proximal direction. To decrease a dose (i.e. correct a dose), the dosage selector 5 is rotated in the counter clockwise direction and moves in the distal direction. Correction of the selected dose can be done without expelling insulin.

462. During dose setting, the dosage selector 5, number sleeve 3, tubular clutch 2, and drive sleeve 1 rotate and move axially together. During dose setting, the lead screw 9 does not move or rotate. *See* Ex. 2218.

463. The number sleeve 3 is locked to the dosage selector 5, and therefore, as the dosage selector 5 is rotated, the number sleeve 3 also rotates displaying

increasing or decreasing numbers through the thread insert 6 (dose window). During dose selection, the clutch 2 is engaged with the number sleeve 3 and transfers the rotation of the number sleeve 3 to the drive sleeve 1.

464. The metal spring 4 is located between the distal end of the clutch 2 and the middle flange of the drive sleeve 1 and locked to the body 7 by means of splines. Teeth at the distal end of the clutch 2 ride over ridges in the metal spring 4 causing both an audible and tactile feedback during dose setting.

465. During dose setting, the plurality of teeth on the proximal end of the clutch 2 remain meshed with the number sleeve 3.

466. The lead of the second thread of the lead screw 9 is the same as the lead of the thread on the number sleeve 3, allowing the drive sleeve 1, which is rotationally fixed to the number sleeve 3 during dose selection, to rotate along (up or down) the lead screw 9 during dose selection without imparting any rotational or axial motion to the lead screw 9 during dose setting.

467. The dosage selector 5 works with the thread insert 6 in the body 7 to provide a minimum dose limit (stop), preventing rotation beyond the 0 unit position when decreasing the dose.

468. The radial stop on the number sleeve 3 prevents the number sleeve 3 from rotating when a maximum dose of 80 units is reached.

469. The last dose nut 11 is located between the middle flange and the distal flange of the drive sleeve 1 and is connected via threads. While the drive sleeve 1 rotates during dose setting, the last dose nut 11 only moves axially since it is keyed to the body 7. The axial movement of the last dose nut 11 corresponds to the selected dose. The last dose nut 11 was designed to travel inside the mechanism to eventually hit a stop and block the mechanism from dialing a dose greater than the amount of medication remaining in the cartridge 13.

470. The mechanism is able to deliver up to 307 units to account for initial priming to remove air that may be trapped inside the cartridge 13. When the user attempts to dial more than 307 total units, the last dose nut 11 will hit a stop feature located on the middle flange of the drive sleeve 1. Torque is transmitted from last dose nut 11 to the body 7. The resisting torque from the stop feature is transmitted through the drive sleeve 1 to the clutch 2, the number sleeve 3, and finally to the patient's finger via the dosage selector 5.

**b. Dose Dispensing/Injecting**

471. To dispense the selected dose, the user presses the injection button 8 in the distal direction. The injection button 8 is located at the proximal end of the dosage selector 5 and operates the clutch mechanism. Pressing the button 8disengages clutch 2 and number sleeve 3 and therefore allows the number sleeve 3 to rotate back into the body 7. As the clutch 2 is disengaging from the number

sleeve 3, it compresses the metal spring 4 and by this action locks it with the drive sleeve 1 to prevent both the clutch 2 and the drive sleeve 1 from rotating relative to the body 7. As a result, by pressing the injection button 8, the drive sleeve 1 moves axially in the distal direction without rotation and the number sleeve 3 rotates back into the starting position ready for the next dose selection. The lead screw 9 is located radially inward from the drive sleeve 1 and body 7 and is connected to both via threaded interfaces. When the dose is being selected and the drive sleeve 1 is rotated, the lead screw 9 does not move. During dose dispensing, the drive sleeve 1 moves axially without rotation and, because of the threaded connection between the drive sleeve 1 and the lead screw 9, the lead screw 9 is forced to rotate. This rotation causes the lead screw 9, which is also in threaded engagement with the fixed integral web insert, to be driven axially in the distal direction. As the lead screw 9 advances axially, it exerts force on the cartridge bung and moves the bung axially to dispense medicament. Ratchet arms on the clutch 2 generate a gentle click during the injection that is caused by the number sleeve 3 rotating around the clutch.

### 3. The '069 Patent SoloSTAR® Analysis

472. For the reasons set forth below, it is my opinion that the SoloSTAR® device practices at least claim 1 of the '069 patent.

### a. Claim 1

i. [1a - preamble] A housing part for a medication dispensing apparatus, said housing part comprising:

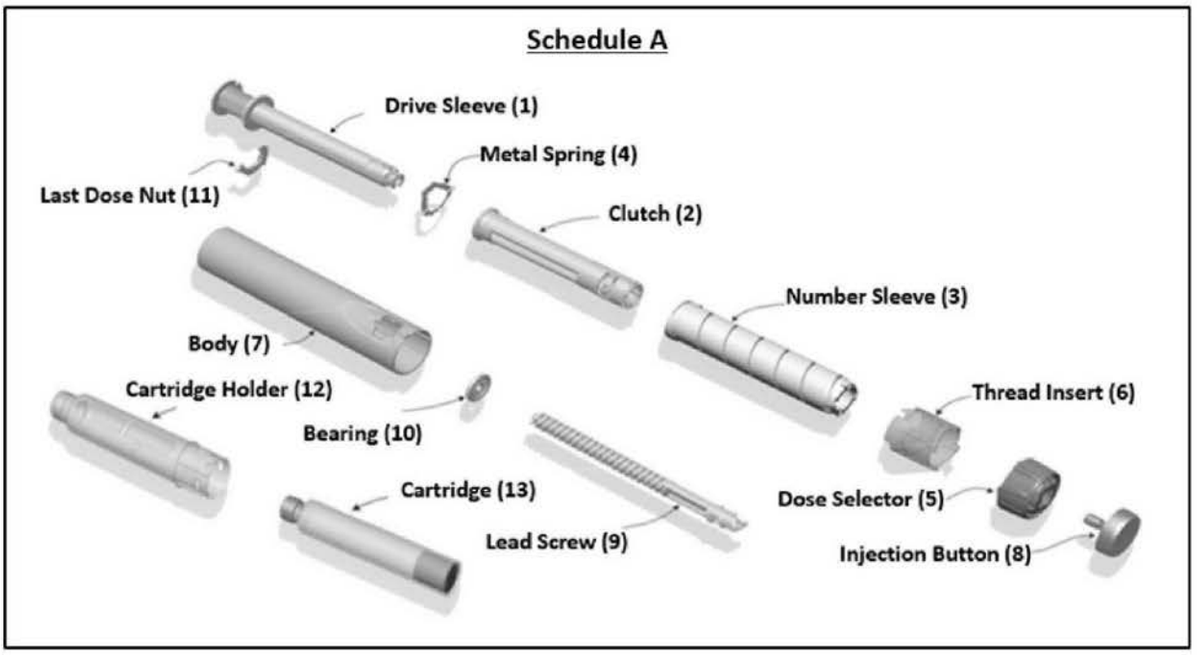
473. The preamble of claim 1 recites "[a] housing part for a medication dispensing apparatus, said housing part comprising." Ex. 1001, 6:37-38. I understand that a claim preamble is generally not considered to be limiting. Thus, it may not be necessary to show that this language is met by the SoloSTAR in order to conclude that SoloSTAR practices the claim. Nevertheless, to the extent that the preamble to claim 1 is considered to be limiting, it is practiced by the SoloSTAR.

474. The SoloSTAR device includes a housing part for a medication dispensing apparatus. *See* Ex. 1001, 1:13-15 ("The present invention relates to pen-type injectors, that is to injectors of the kind that provide for administration by injection of medicinal products from a multidose cartridge."). The SoloSTAR is a medication dispensing apparatus.

> **1.1.1 Description of SoloStar®**
>
> SoloStar® injection system is a device that provides a method of accurately injecting a selected dose of insulin through a single lumen hypodermic needle. SoloStar® is intended to be used for self-injection by patients. Patients who are not able to handle the device properly (according to Health Care Professional's assessment) require assistance from a third person. SoloStar® system is a disposable insulin injection system that by design, cannot be reused.

Ex. 2161 at 4.

475. The components of the SoloSTAR are shown in the figure below, which provides an exploded view showing each of the individual components of the device.




476. As discussed below, because those components and their functions correspond to the components and functions recited in the rest of claim 1.

477. My physical inspection of the SoloSTAR product further reinforces my opinion. Below is an image of the components from an actual SoloSTAR device. This image further confirms that the SoloSTAR device is a "housing part for a medication dispensing apparatus" as recited in the preamble of claim 1:

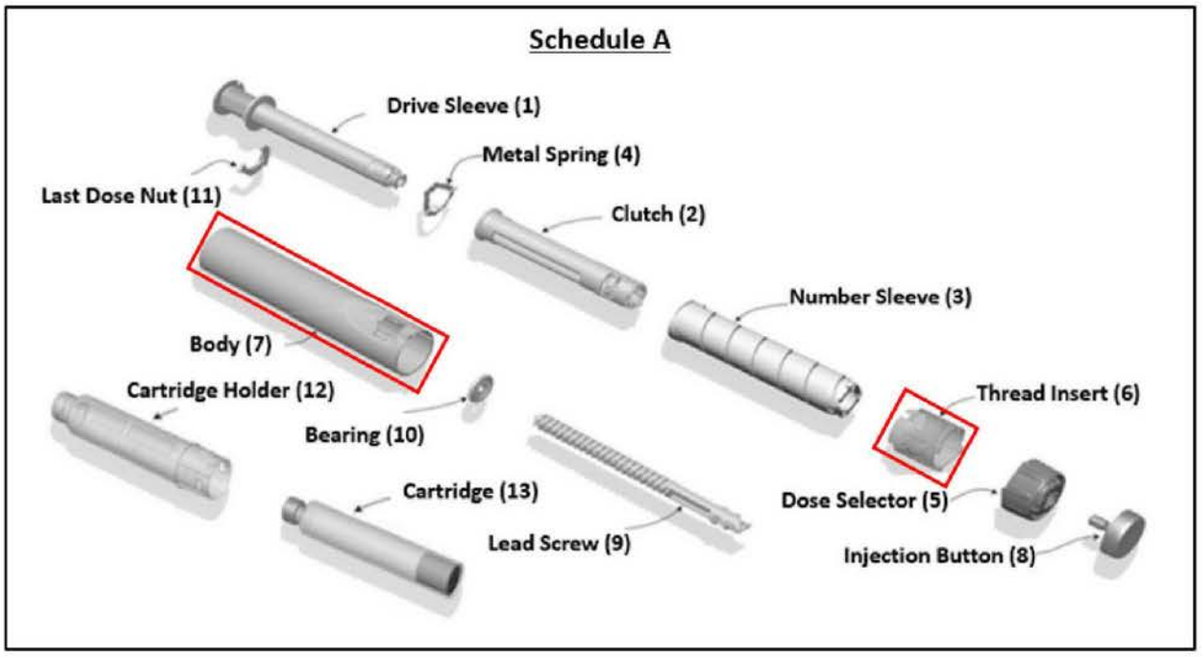

478. Thus, to the extent that the preamble to claim 1 is considered to be limiting, it is practiced by the SoloSTAR.

ii. [1b] a main housing, said main housing extending from a distal end to a proximal end;

479. Claim 1 further recites "a main housing, said main housing extending from a distal end to a proximal end." Ex. 1001, 6:39-40. As explained in Section VIII, I understand that Sanofi proposed that a "main housing" should be construed to mean "an exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components." Under this construction of "main housing," and for the reasons set forth below, it is my opinion that the SoloSTAR device practices this claim limitation. I also understand that the Court in the Mylan DNJ Action held that the term "main housing" should be given its plain and ordinary meaning and that therefore no express construction is required. As described Section VIII, it is my opinion that Sanofi's proposed construction is consistent with the ordinary meaning of the term

"main housing" as it would have been understood by a person of ordinary skill in the art in the context of the challenged patents. Again, it is my opinion that a POSA would have understood that the ordinary meaning of the term "main housing" as used in the challenged patents specifies a type of exterior housing, even if comprised of multiple exterior housing pieces, that does not encompass separate or integrally-formed interior housing. Under this construction of "main housing," and for the reasons set forth below, it is my opinion that SoloSTAR device practices this claim limitation.

480. As depicted below, the SoloSTAR includes a main housing.




481. The SoloSTAR main housing comprises the Thread Insert (6) and the Body (7), which snap-fit together and form a rigid, unitary structure.

482. The Thread Insert forms part of the main housing since the window portion forms part of the exterior wall device (i.e., an exterior surface that one can see and touch).

483. The main housing extends from a distal end (*i.e.*, the portion of the main housing that is closest to the medication dispensing end) to a proximal end (*i.e.*, the portion of the main housing that is closest to the dose button).

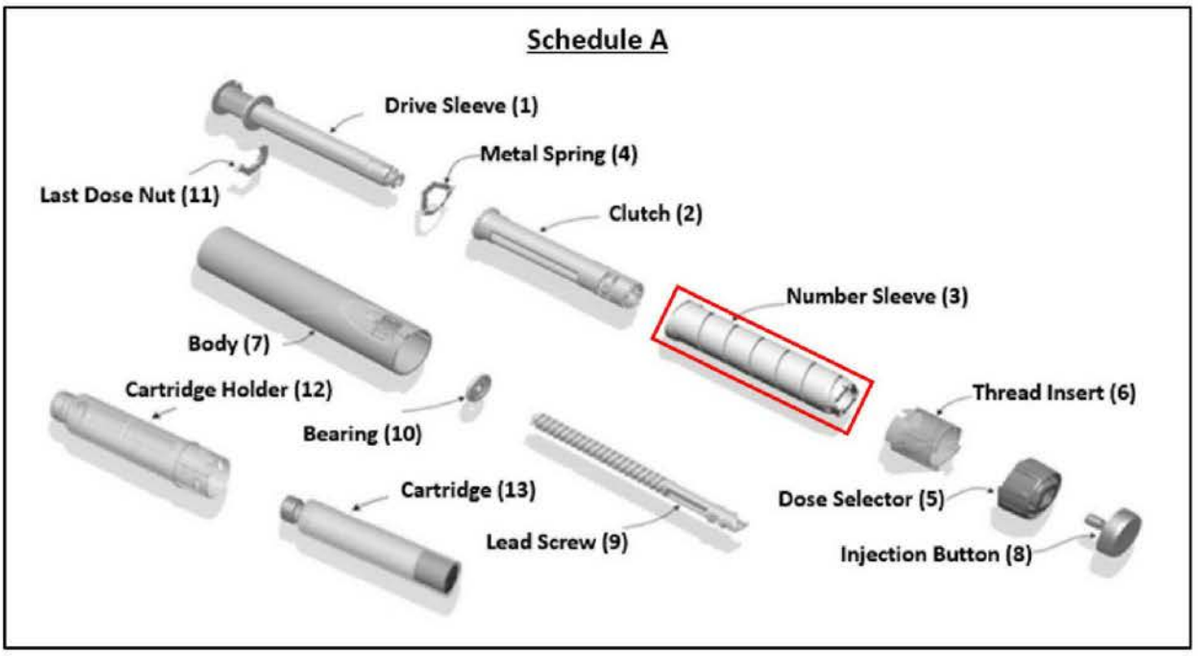

484. Thus, the SoloSTAR device has a main housing (comprising Thread Insert (6) and Body (7)) extending from a distal end to a proximal end, under any construction.

iii. [1c] a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main

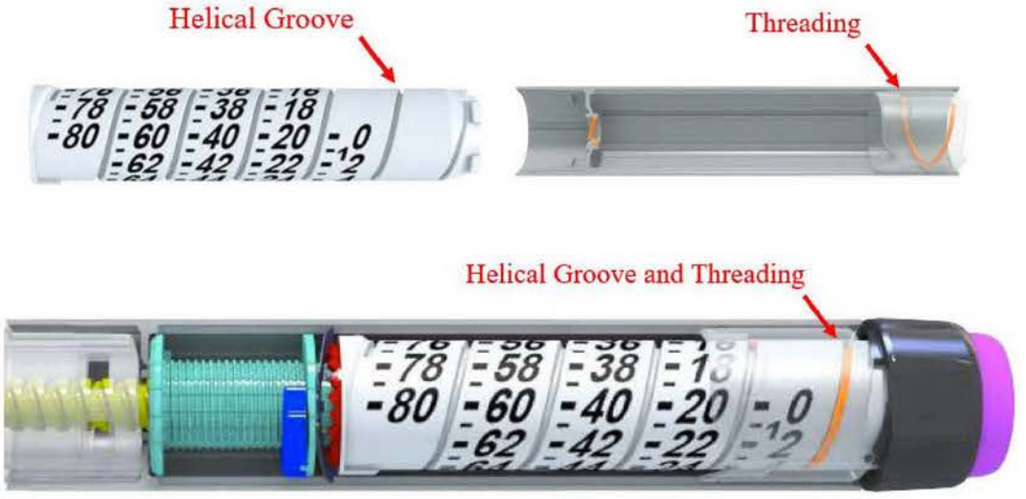
housing, said helical groove provided along an outer surface of said dose dial sleeve;

485. Claim 1 further recites "a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve." Ex. 1001, 6:41-45. In my opinion, a person of ordinary skill in the art would understand that "said housing," in the context of claim 1, is a reference to "the main housing." It is my opinion that the SoloSTAR device practices this claim limitation.

486. As depicted below, the SoloSTAR includes a dose dial sleeve (labeled as the "Number Sleeve (3)").



487. The dose dial sleeve (3) is positioned within the main housing (6, 7). The dose dial sleeve (3) includes a helical groove on its outer surface that is configured to engage a threading provided by the main housing (6, 7).

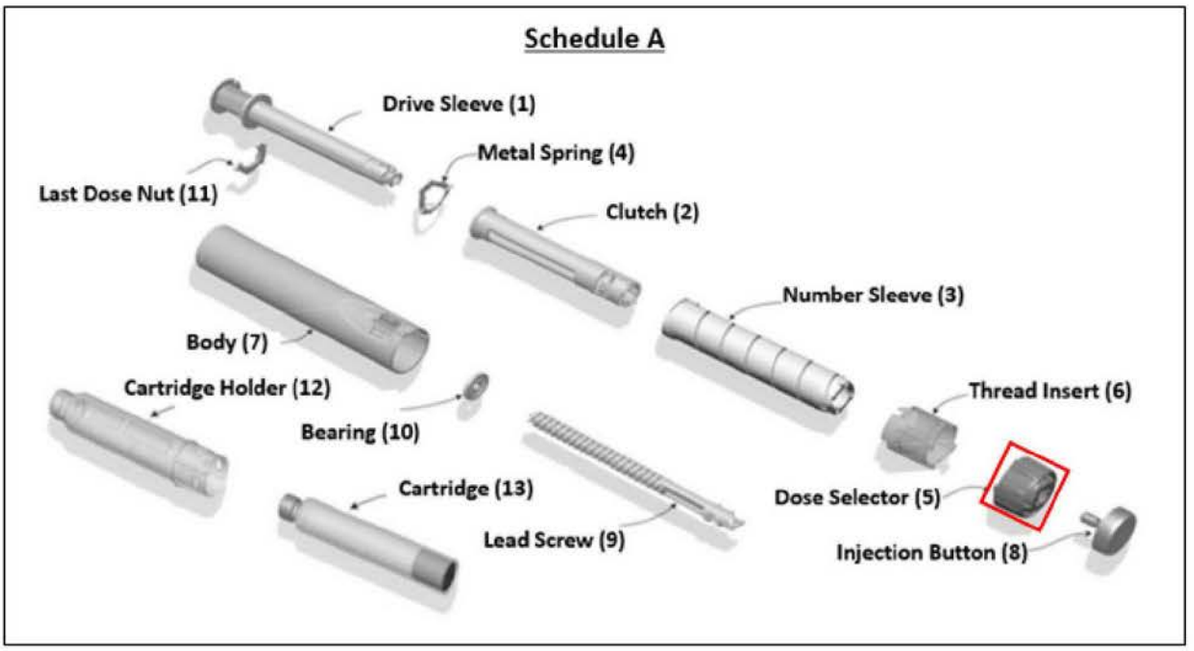



488. Thus, the SoloSTAR device has a dose dial sleeve, positioned within the main housing and has a helical groove on the outer surface of the dose dial sleeve that is configured to engage a threading provided by the main housing.

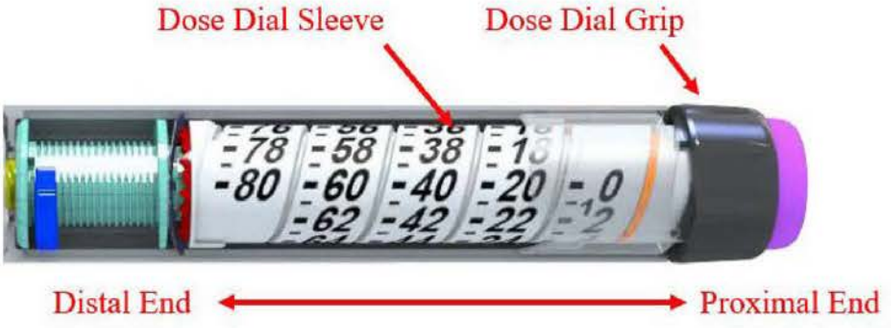
iv. [1d] a dose dial grip disposed near a proximal end of said dose dial sleeve;

489. Claim 1 further recites "a dose dial grip disposed near a proximal end of said dose dial sleeve." Ex. 1001, 6:46-47. It is my opinion that the SoloSTAR device practices this claim limitation.

490. As depicted below, the SoloSTAR device includes a dose dial grip ("labeled as the "Dose Selector (5)").




491. The dose dial grip (5) is disposed near a proximal end of the dose dial sleeve (20).




492. The *Principles of Operation of the SoloSTAR* document explains that the dosage selector (dose dial grip) and number sleeve (dose dial sleeve) are firmly clipped together and form an integral unit. The document further explains that the dosage selector (dose dial grip) is rotated to increase or decrease the selected dose.

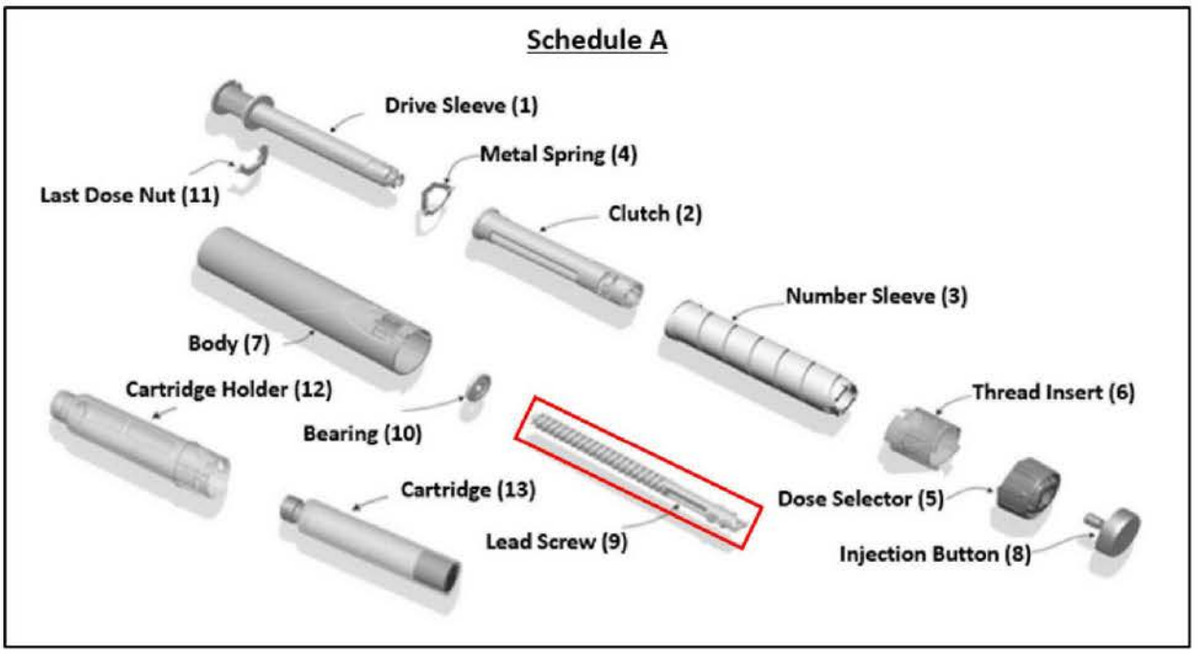
> When selecting the dose, the dosage selector (5) is turned clockwise to increase and counter clockwise to decrease the selected dose. Correction of the selected dose can be done without expelling insulin. Dosage selector and number sleeve are firmly clipped together and form an integral unit. The number sleeve has even numbers and indication lines for uneven numbers printed onto its surface which are visible to the patient through a thread insert (dose window) (6). The thread insert is rotated over the number sleeve and snapped into the body (7).

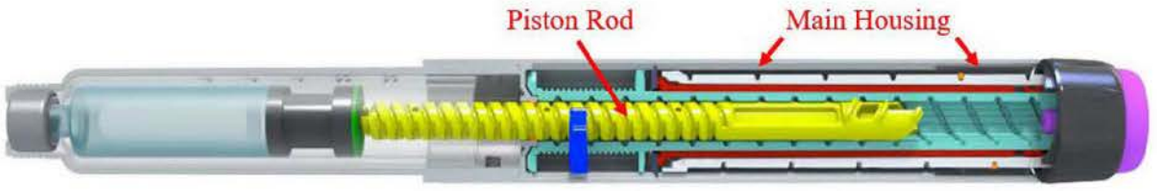
493. Thus, the SoloSTAR device has a dose dial grip disposed near the proximal end of said dose dial sleeve.

v. [1e] a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;

494. Claim 1 further recites "a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing." Ex. 1001, 6:48-50. It is my opinion that the SoloSTAR device practices this claim limitation.

495. As depicted below, the SoloSTAR device includes a piston rod (labeled as "Lead Screw (9)") provided within the main housing.




496. The piston rod (9) is non-rotatable during a dose setting step relative to said main housing (6, 7). The *Principles of Operation of the SoloSTAR* document explains that when the dose is selected and drive sleeve is rotated the lead screw (piston rod (60)) does not move.

> Once the dose is selected the patient has to push onto the injection button (8) to inject the insulin. The injection button is located next to the dosage selector and operates the clutch mechanism. Pressing the button disengages clutch and number sleeve and thereby allows the number sleeve to rotate back into the body. While the clutch is disengaging from the number sleeve it compresses the metal spring and thereby locks with the drive sleeve to prevent the latter from rotating relative to the number sleeve and body. By pressing the injection button and rotating the number sleeve back the drive sleeve moves in axially without rotation. The lead screw (9) is located inside the drive sleeve and body and is connected to both via threaded interfaces. While the dose is selected and the drive sleeve is rotated the lead screw does not move. When the drive sleeve is pushed in, the lead screw rotates and by this action, advances axially towards the cartridge bung. The connection between lead screw and cartridge bung is the bearing (10) which applies the force from the mechanism onto the bung evenly.

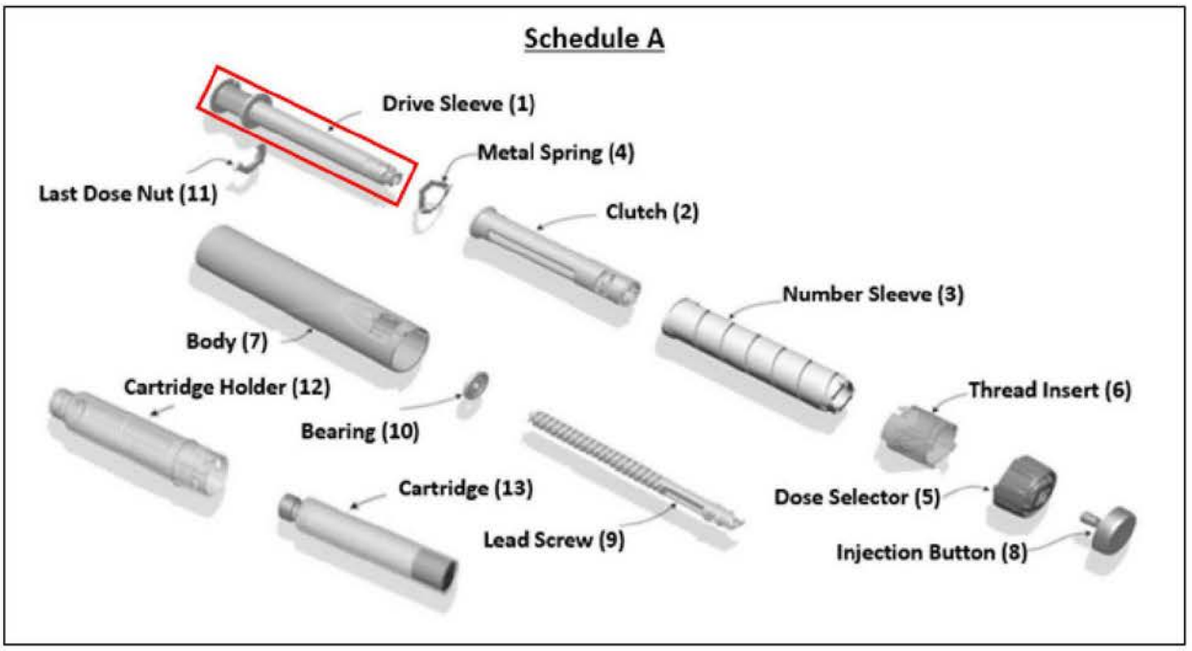
Ex. 2161 at 7.

497. Thus, the SoloSTAR device has a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing.

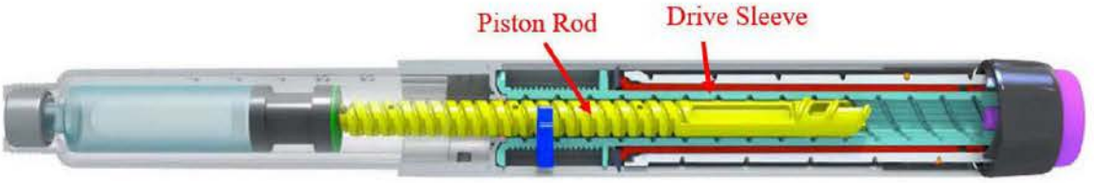
vi. [1f] a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod; and

498. Claim 1 further recites "a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal threading near a distal portion of said drive sleeve, said internal threading adapted to engage an external thread of said piston rod." Ex. 1001, 6:51-55. It is my opinion that the SoloSTAR device practices this claim limitation.

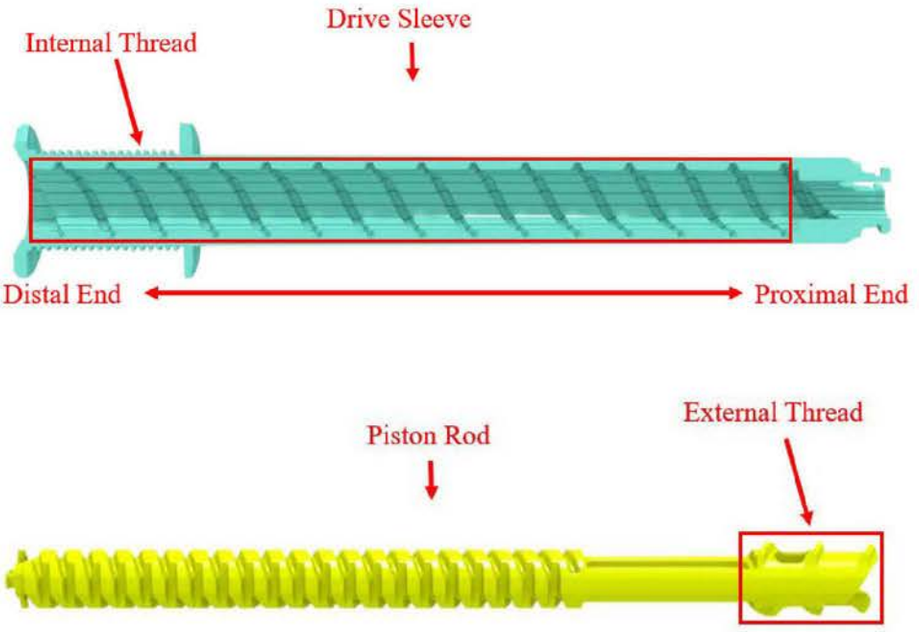
499. As depicted below, the SoloSTAR device includes a drive sleeve (labeled as "Drive Sleeve (1)").




500. The drive sleeve (1) extends along a portion of the piston rod (lead screw (9)).




501. The drive sleeve (1) comprises an internal thread near a distal portion of the drive sleeve, and the internal thread of the drive sleeve (1) is adapted to engage an external thread of said piston rod (lead screw (9)). The external thread of lead screw (9) and internal thread of drive sleeve (1) each comprise a double-start thread (i.e. two threads angularly disposed from each other by 180 degrees).




502. The *Principles of Operation of the SoloSTAR* document explains that the internal thread of the drive sleeve (1) is adapted to engage an sleeve and body and is connected to both via threaded interfaces." Ex. 2161 at 7.

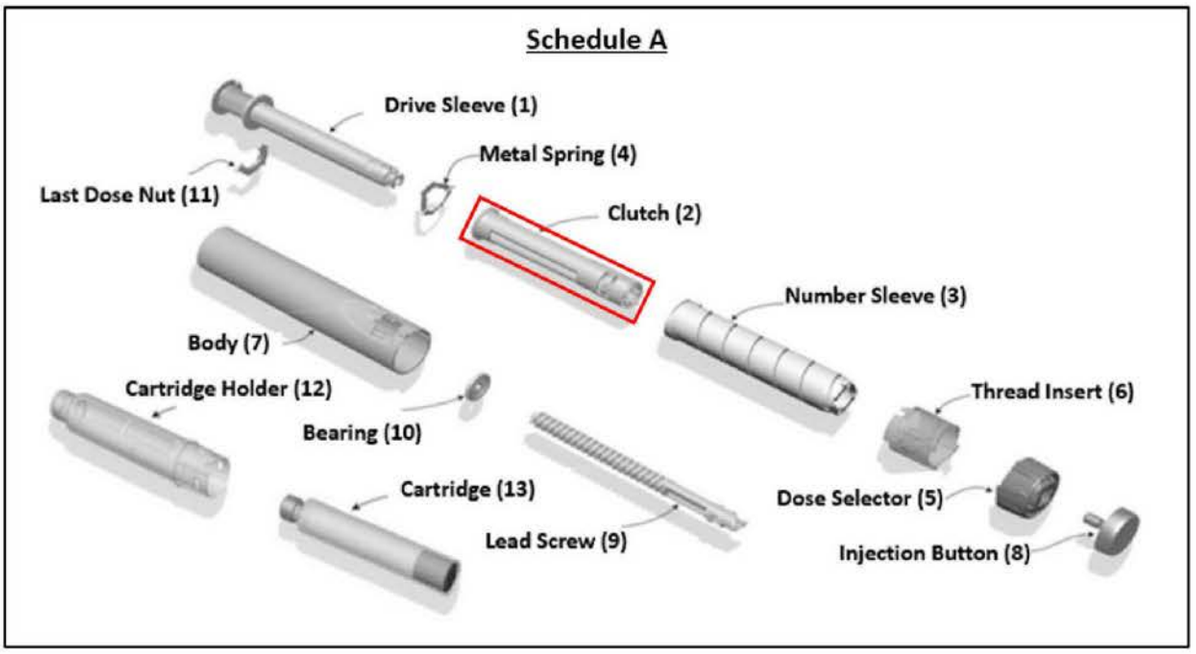
503. Thus, the SoloSTAR device has a drive sleeve extending along a portion of said piston rod, said drive sleeve comprising an internal thread near a distal portion of said drive sleeve, said internal thread adapted to engage an external thread of said piston rod.

vii. [1g] a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip,

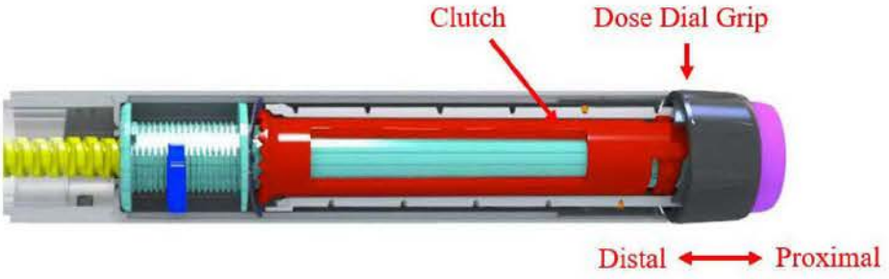
504. Claim 1 further recites "a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip." Ex. 1001, 6:56-58. As explained in Section VIII, I understand that the Court

in the Mylan DNJ Action construed "clutch" according to its plain and ordinary meaning, which is "a component that can operate to reversibly lock two components in rotation." I further understand that the parties to the Mylan DNJ Action agreed that "tubular clutch" should be construed in conformity with the construction for "clutch." I agree with this as well. Under this construction of "tubular clutch," and for the reasons set forth below, it is my opinion that the SoloSTAR device practices this claim limitation.

505. As depicted below, the SoloSTAR device includes a tubular clutch (labeled as "Clutch (2)").




506. The tubular clutch (2) is located adjacent a distal end of the dose dial grip (5).



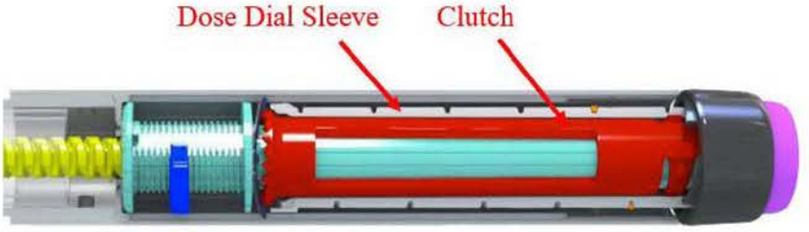

507. The *Principles of Operation of the SoloSTAR* document explains that the tubular clutch (2) is also operatively coupled to the dose dial grip (i.e., "dosage selector") via the dose dial sleeve (i.e., "number sleeve (3)"): "The number sleeve is locked to the dosage selector and therefore turns as well, displaying increasing or decreasing numbers inside the thread insert (dose window). During the dose selection the clutch is engaged with the number sleeve and transfers the rotation of the number sleeve to the drive sleeve." Ex. 2161 at 8. This document further explains that the tubular clutch (2) couples and decouples the number sleeve (3) and the drive sleeve (1), which are both moveable components, and that the tubular clutch (2) is operatively coupled to the dose dial grip (5): "During the dose selection the clutch is engaged with the number sleeve and transfers the rotation to the drive sleeve. . . The injection button is located next to the dosage selector and operates the clutch mechanism. Pressing the button disengages clutch and number sleeve and thereby allows the number sleeve to rotate back into the body."

508. Thus, the SoloSTAR has a tubular clutch located adjacent a distal end of said dose dial grip, said tubular clutch operatively coupled to said dose dial grip.

viii. [1h] wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

509. Claim 1 further recites "wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch." Ex. 1001, 6:59-60. It is my opinion that the SoloSTAR device practices this claim limitation.

510. In the SoloSTAR device, the tubular clutch (2) is located radially inward of the dose dial sleeve (3). As depicted below, the dose dial sleeve (3) of the SoloSTAR extends circumferentially around at least a portion of the clutch (2).




511. Thus, the SoloSTAR device has a dose dial sleeve that extends circumferentially around at least a portion of said tubular clutch.

512. Therefore, because the SoloSTAR device practices each limitation of claim 1, it is my opinion that the SoloSTAR device practices claim 1 of the '069 patent.

### 4. The '486 Patent SoloSTAR® Analysis

513. For the reasons set forth below, it is my opinion that the SoloSTAR® device practices claims at least claim 1of the '486 patent.

#### a. Claim 1

i. [1a - preamble] A housing part for a medication dispensing apparatus, said housing part comprising:

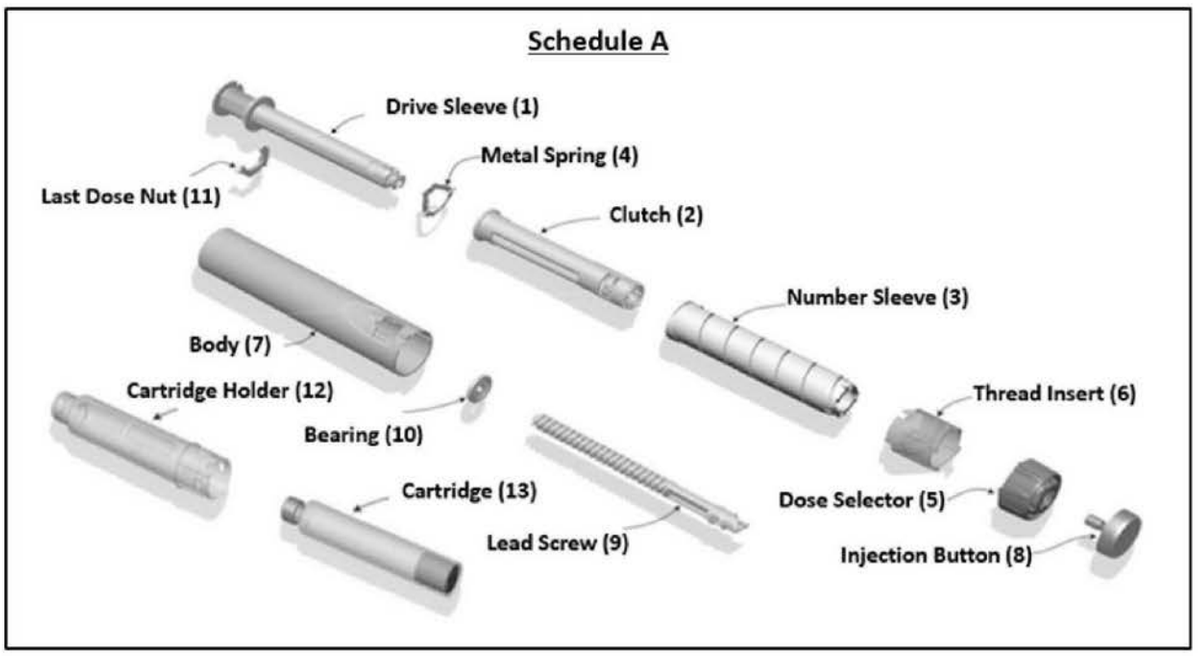
514. The preamble to claim 1 recites "[a] housing part for a medication dispensing apparatus, said housing part comprising." Ex. 1003, 6:59-60. I understand that a claim preamble is generally not considered to be limiting. Thus, it may not be necessary to show that this language is met by the SoloSTAR in order to conclude that SoloSTAR practices the claim. Nevertheless, to the extent that the preamble to claim 1 is considered to be limiting, it is practiced by the SoloSTAR.

515. The SoloSTAR device includes a housing part for a medication dispensing apparatus. *See* Ex. 1003, 1:20-22 ("The present invention relates to pen-type injectors, that is to injectors of the kind that provide for administration by injection of medicinal products from a multidose cartridge."). The SoloSTAR is a medication dispensing apparatus.

> **1.1.1 Description of SoloStar®**
>
> SoloStar® injection system is a device that provides a method of accurately injecting a selected dose of insulin through a single lumen hypodermic needle. SoloStar® is intended to be used for self-injection by patients. Patients who are not able to handle the device properly (according to Health Care Professional's assessment) require assistance from a third person. SoloStar® system is a disposable insulin injection system that by design, cannot be reused.

Ex. 2161 at 4.

516. The SoloSTAR is shown in the Schedule A diagram below, which provides an exploded view showing each of the individual components of the device. As discussed below, because those components and their functions correspond to the components and functions recited in the rest of claim 1, this document further confirms that the SoloSTAR is "a housing part for a medication dispensing apparatus," as recited in the preamble of claim 1.

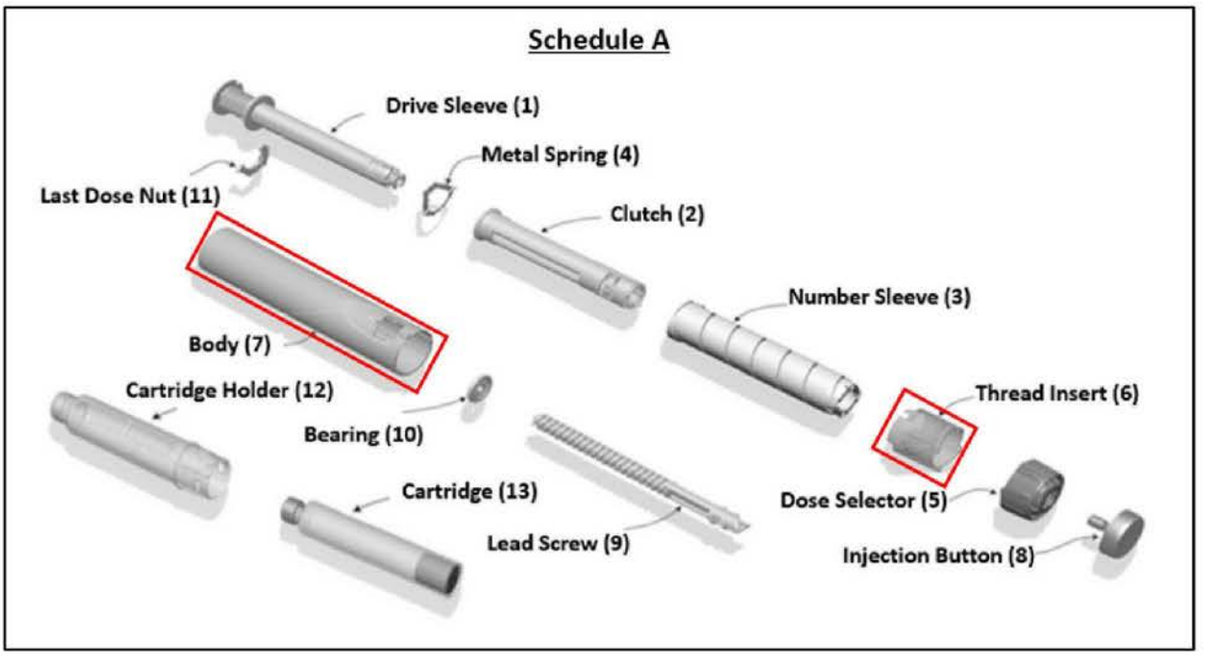



ii. [1b] a main housing, said main housing extending from a distal end to a proximal end;

517. Claim 1 further recites "a main housing, said main housing extending from a distal end to a proximal end." Ex. 1003, 6:61-62. As explained in Section III.A., I understand that Sanofi proposed that a "main housing" should be

construed to mean "an exterior unitary or multipart component configured to house, fix, protect, guide, and/or engage with one or more inner components." Under this construction of "main housing," and for the reasons set forth below, it is my opinion that the SoloSTAR device practices this claim limitation. I also understand that the Court in the Mylan DNJ Action held that the term "main housing" should be given its plain and ordinary meaning and that therefore no express construction is required. As described Section III.A., it is my opinion that Sanofi's proposed construction is consistent with the ordinary meaning of the term "main housing" as it would have been understood by a person of ordinary skill in the art in the context of the challenged patents. Again, it is my opinion that a POSA would have understood that the ordinary meaning of the term "main housing" as used in the challenged patents specifies a type of exterior housing, even if comprised of multiple exterior housing pieces, that does not encompass separate or integrally-formed interior housing. Under this construction of "main housing," and for the reasons set forth below, it is my opinion that SoloSTAR device practices this claim limitation.

518. As depicted below, the SoloSTAR includes a main housing.




519. The SoloSTAR main housing comprises the Thread Insert (6) and the Body (7), which snap-fit together and form a rigid, unitary structure.

520. The Thread Insert forms part of the main housing since the window portion forms part of the exterior wall device (i.e., an exterior surface that one can see and touch).

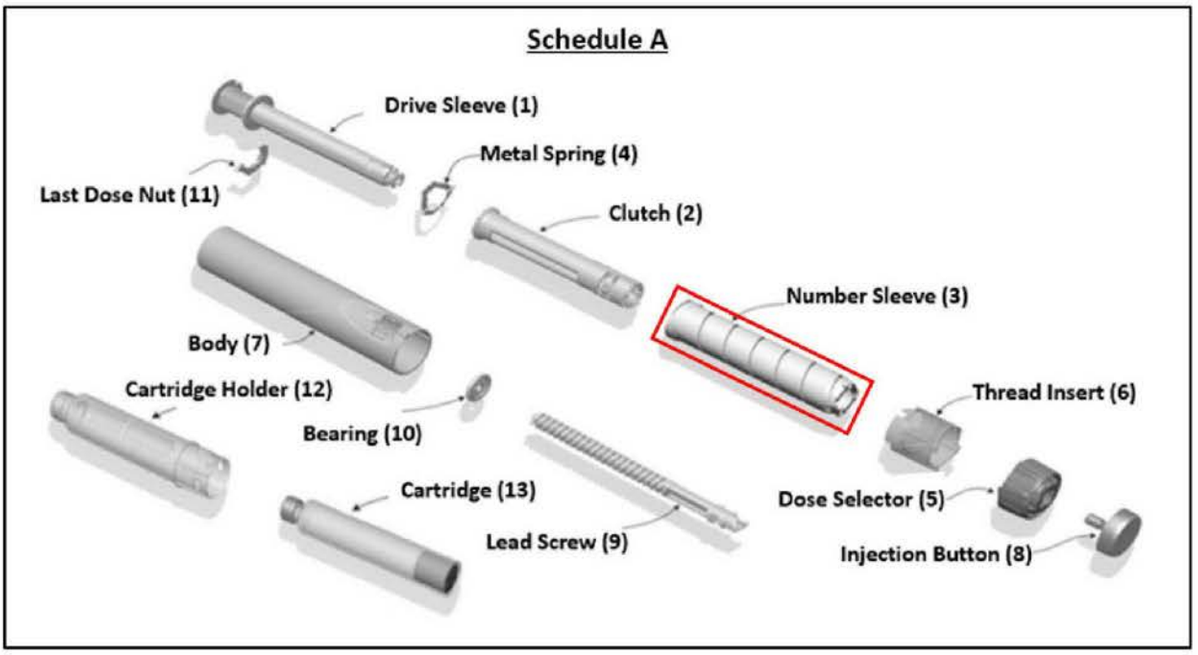
521. The main housing extends from a distal end (*i.e.*, the portion of the main housing that is closest to the medication dispensing end) to a proximal end (*i.e.*, the portion of the main housing that is closest to the dose button).


522. Thus, the SoloSTAR device has a main housing (comprising Thread Insert (6) and Body (7) extending from a distal end to a proximal end, under any construction.

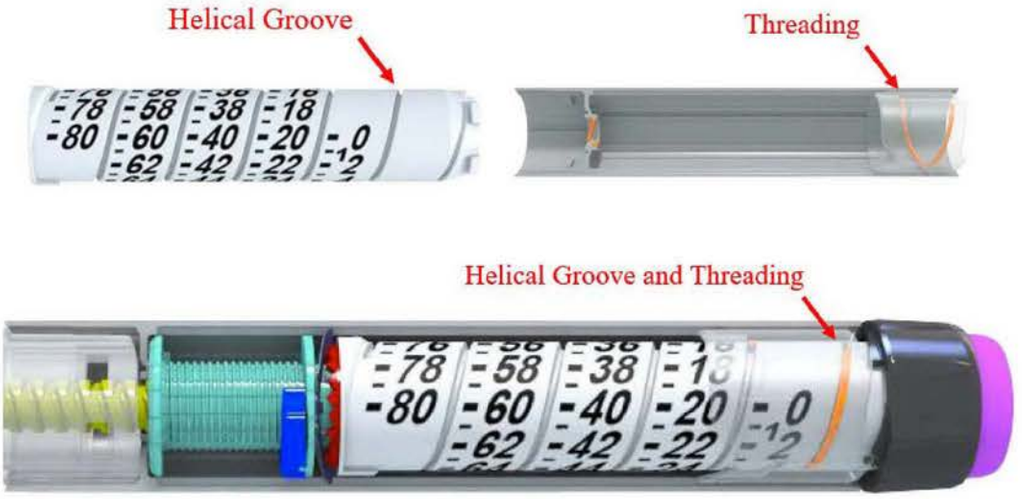
iii. [1c] a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing;

523. Claim 1 further recites "a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing." Ex. 1003, 6:63-65. In my opinion, a person of ordinary skill in the art would understand that "said housing," in the context of claim 1, is a reference to "the main housing." It is my opinion that the SoloSTAR device practices this claim limitation.

524. As depicted below, the SoloSTAR includes a dose dial sleeve (labeled as the "Number Sleeve (3)").




525. The dose dial sleeve (3) is positioned within the main housing (6, 7). The dose dial sleeve (3) includes a helical groove on its outer surface that is configured to engage a threading provided by the main housing (6, 7).

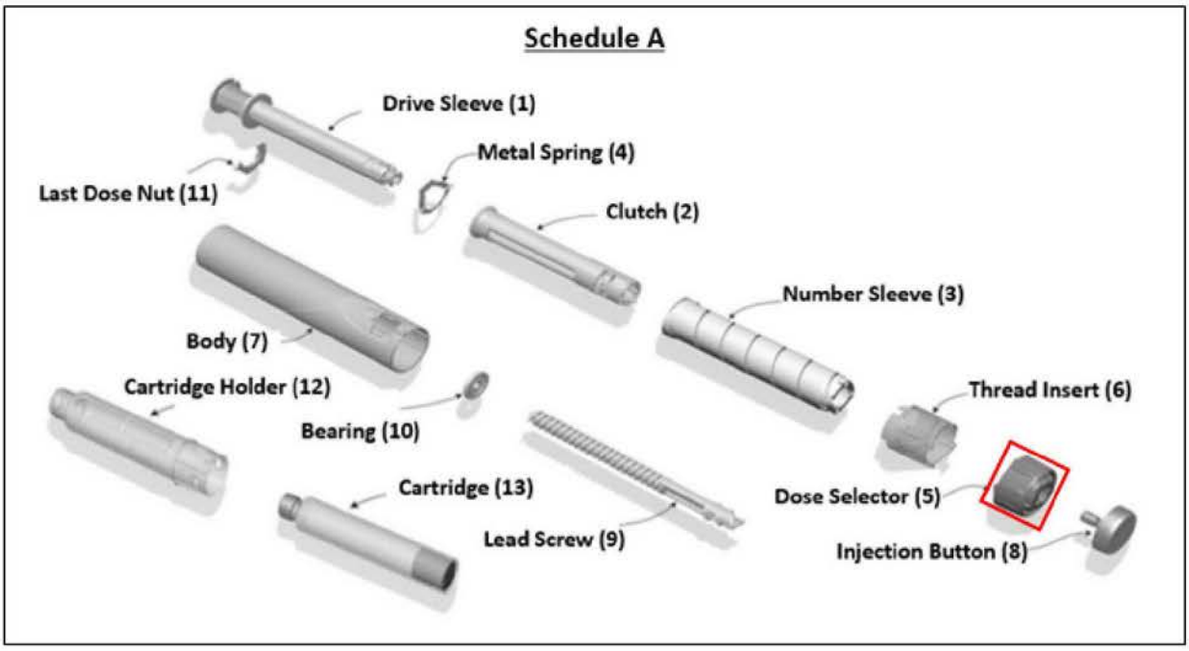


526. Thus, the SoloSTAR device has a dose dial sleeve, positioned within the main housing and has a helical groove on the outer surface of the dose dial sleeve that is configured to engage a threading provided by the main housing.

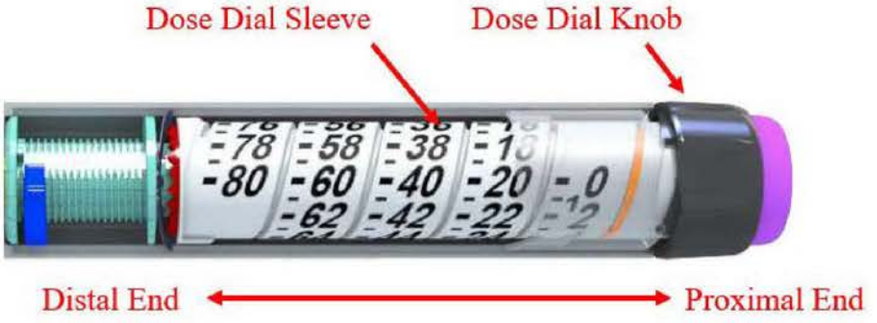
iv. [1d] a dose knob disposed near a proximal end of said dose dial sleeve;

527. Claim 1 further recites "a dose knob disposed near a proximal end of said dose dial sleeve." Ex. 1003, 6:66-67. It is my opinion that the SoloSTAR device practices this claim limitation.

528. As depicted below, the SoloSTAR device includes a dose knob (labeled as "Dosage Selector (5)").




529. The dose knob (5) is disposed near a proximal end of the dose dial sleeve (3).




530. The *Principles of Operation of the SoloSTAR* document explains that the dosage selector and number sleeve (dose dial sleeve) are firmly clipped together and form an integral unit. The document further explains that the dosage selector (dose dial grip) is rotated to increase or decrease the selected dose.

> When selecting the dose, the dosage selector (5) is turned clockwise to increase and counter clockwise to decrease the selected dose. Correction of the selected dose can be done without expelling insulin. Dosage selector and number sleeve are firmly clipped together and form an integral unit. The number sleeve has even numbers and indication lines for uneven numbers printed onto its surface which are visible to the patient through a thread insert (dose window) (6). The thread insert is rotated over the number sleeve and snapped into the body (7).

Ex. 2161 at 6.

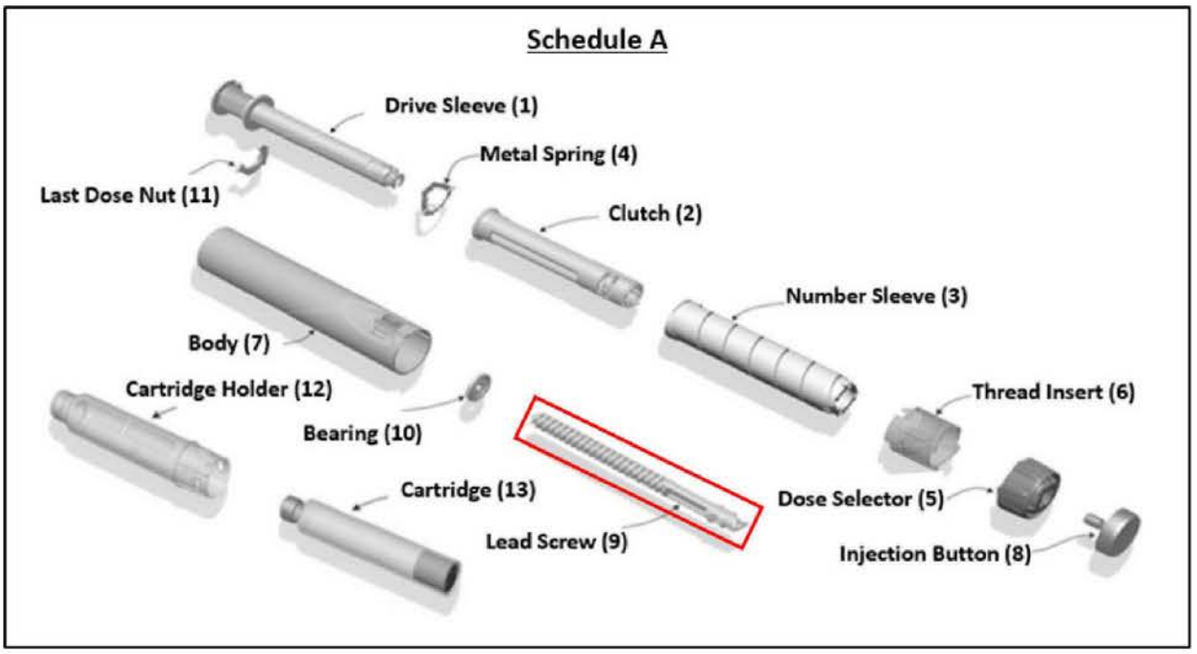
531. Thus, the SoloSTAR device has a dose dial grip disposed near the proximal end of said dose dial sleeve.

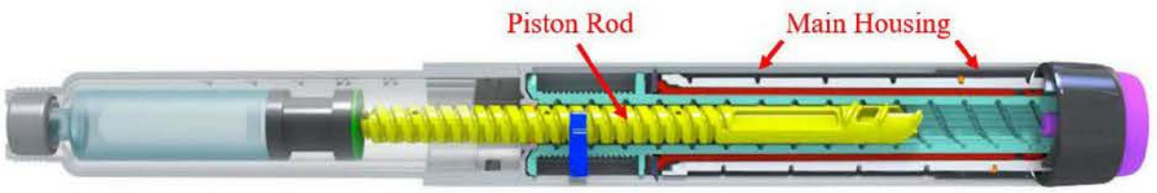
v. [1e] a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing;

532. Claim 1 further recites "a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main

housing." Ex. 1003, 7:1-3. It is my opinion that the SoloSTAR device practices this claim limitation.

533. As depicted below, the SoloSTAR device includes a piston rod (labeled as "Lead Screw (9)") provided within the main housing (6, 7).




534. The piston rod (9) is non-rotatable during a dose setting step relative to said main housing (6, 7). The *Principles of Operation of the SoloSTAR* document explains that when the dose is selected and drive sleeve (1) is rotated, the piston rod (9) does not move.

> Once the dose is selected the patient has to push onto the injection button (8) to inject the insulin. The injection button is located next to the dosage selector and operates the clutch mechanism. Pressing the button disengages clutch and number sleeve and thereby allows the number sleeve to rotate back into the body. While the clutch is disengaging from the number sleeve it compresses the metal spring and thereby locks with the drive sleeve to prevent the latter from rotating relative to the number sleeve and body. By pressing the injection button and rotating the number sleeve back the drive sleeve moves in axially without rotation. The lead screw (9) is located inside the drive sleeve and body and is connected to both via threaded interfaces. While the dose is selected and the drive sleeve is rotated the lead screw does not move. When the drive sleeve is pushed in, the lead screw rotates and by this action, advances axially towards the cartridge bung. The connection between lead screw and cartridge bung is the bearing (10) which applies the force from the mechanism onto the bung evenly.

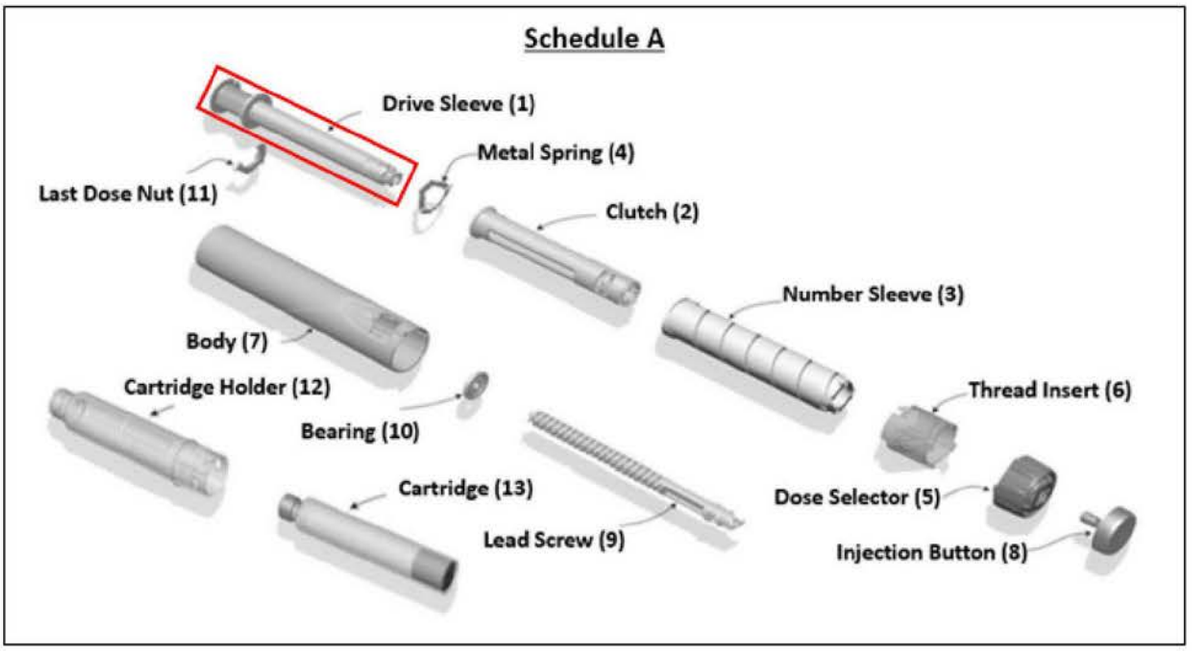
Ex. 2161 at 7.

535. Thus, the SoloSTAR device has a piston rod provided within said housing, said piston rod is non-rotatable during a dose setting step relative to said main housing.

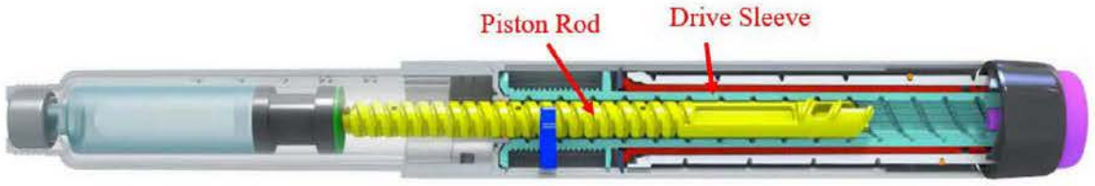
vi. [1f] a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod; and,

536. Claim 1 further recites "a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod." Ex. 1003, 7:4- 7. It is my opinion that the SoloSTAR device practices this claim limitation.

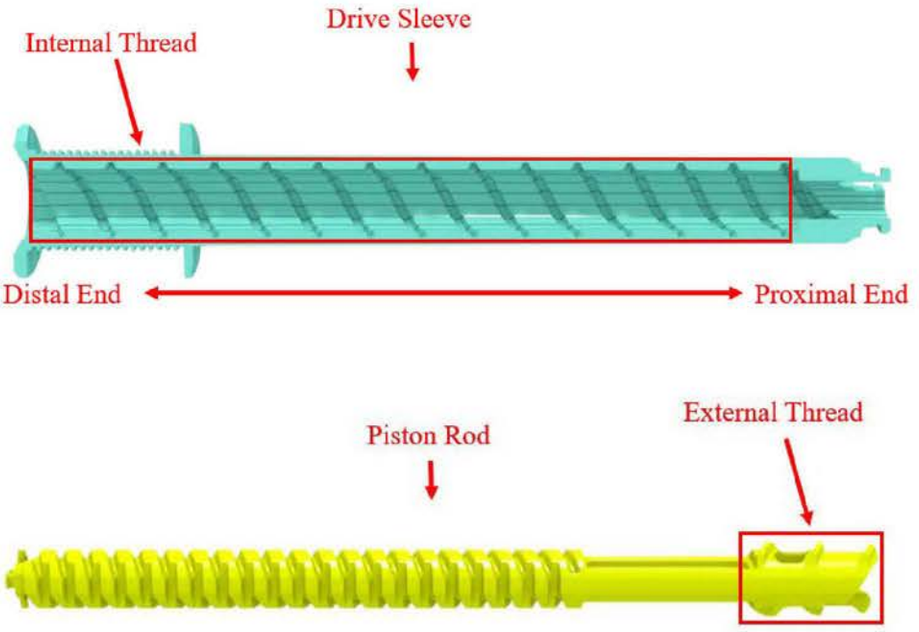
537. As depicted below, the SoloSTAR device includes a driver (labeled as "Drive Sleeve (1)").




538. The driver (1) extends along a portion of the piston rod (9).




539. The driver (1) comprises an internal thread near a distal portion of the drive sleeve, and the internal thread of the driver (1) is adapted to engage an external thread of said piston rod (9). The external thread of lead screw (9) and internal thread of driver (drive sleeve (1)) each comprise a double-start thread (i.e. two threads angularly disposed from each other by 180 degrees).




540. The *Principles of Operation of the SoloSTAR* document explains that the internal thread of the driver (1) is adapted to engage an external thread of the lead screw (9): "The lead screw (9) is located inside the drive sleeve and body and is connected to both via threaded interfaces." Ex. 2161 at 7.

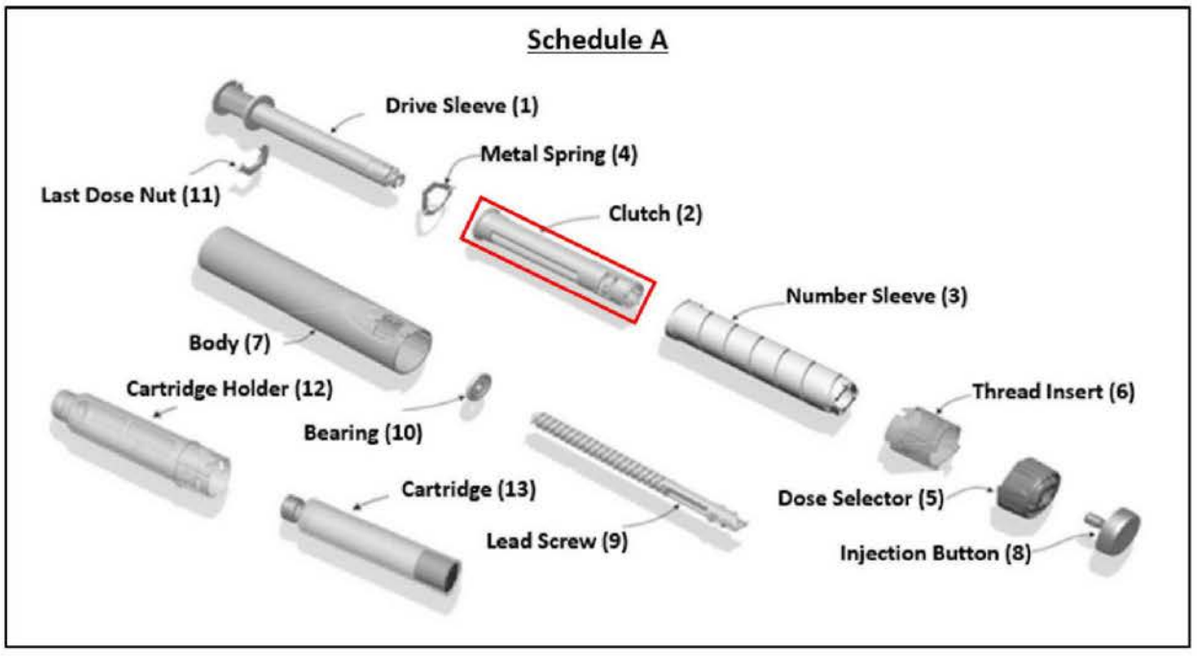
541. Thus, the SoloSTAR device has a driver extending along a portion of said piston rod, said driver comprising an internal threading near a distal portion of said driver, said internal threading adapted to engage an external thread of said piston rod.

vii. [1g] a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob,

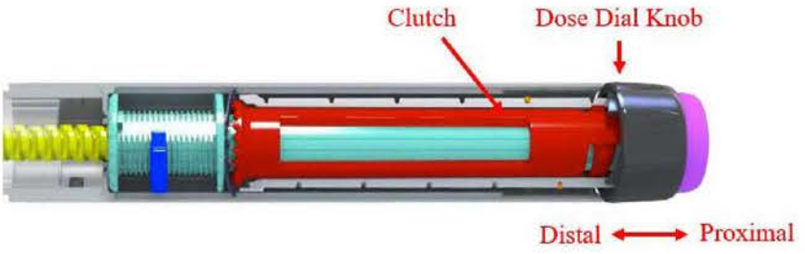
542. Claim 1 further recites "a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob." Ex.

1003, 6:8-10. As explained in Section VIII, I understand that the Court in the Mylan DNJ Action construed "clutch" according to its plain and ordinary meaning, which is "a component that can operate to reversibly lock two components in rotation." I further understand that the parties to the Mylan DNJ Action agreed that "tubular clutch" should be construed in conformity with the construction for "clutch." I agree with this as well. Under this construction of "tubular clutch," and for the reasons set forth below, it is my opinion that the SoloSTAR device practices this claim limitation.

543. As depicted below, the SoloSTAR device includes a tubular clutch (labeled as "Clutch (2)").




544. The tubular clutch (2) is located adjacent a distal end of the dose knob (5).




545. The *Principles of Operation of the SoloSTAR* document explains that the tubular clutch (2) is also operatively coupled to the (i.e. "dosage selector") via the number sleeve (3): "The number sleeve is locked to the dosage selector and therefore turns as well, displaying increasing or decreasing numbers inside the thread insert (dose window). During the dose selection the clutch is engaged with the number sleeve and transfers the rotation of the number sleeve to the drive sleeve." Ex. 2161 at 8.

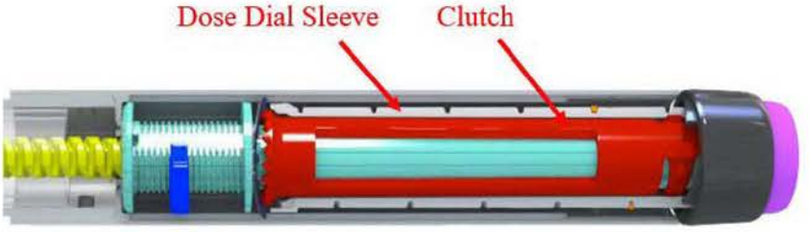
546. This document further explains that the tubular clutch (2) couples and decouples the number sleeve (3) and the drive sleeve (1), which are both moveable components, and that the tubular clutch (2) is operatively coupled to the dose knob (5): "During the dose selection the clutch is engaged with the number sleeve and transfers the rotation to the drive sleeve. . . The injection button is located next to the dosage selector and operates the clutch mechanism. Pressing the button disengages clutch and number sleeve and thereby allows the number sleeve to rotate back into the body." Ex. 2161 at 9.

547. Thus, the SoloSTAR has a tubular clutch located adjacent a distal end of said dose knob, said tubular clutch operatively coupled to said dose knob.

viii. [1h] wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch.

548. Claim 1 further recites "wherein said dose dial sleeve extends circumferentially around at least a portion of said tubular clutch." Ex. 1003, 7:11-12. It is my opinion that the SoloSTAR device practices this claim limitation.

549. In the SoloSTAR device, the tubular clutch (2) is located radially inward of the dose dial sleeve (3). As depicted below, the dose dial sleeve (3) of the SoloSTAR extends circumferentially around at least a portion of the clutch (2).




550. Thus, the SoloSTAR device has a dose dial sleeve that extends circumferentially around at least a portion of said tubular clutch.

### 5. The '844 Patent SoloSTAR® Analysis

551. For the reasons set forth below, it is my opinion that the SoloSTAR® device practices at least claims 21 and 30 of the '844 patent.

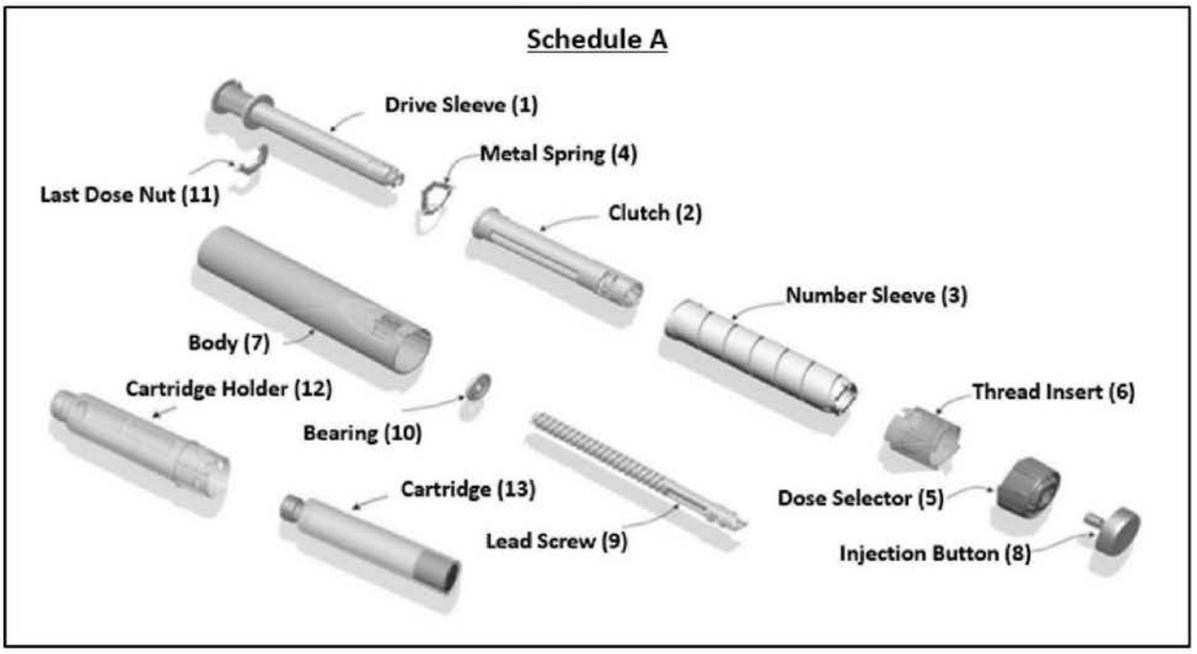
#### a. Claim 21

i. [21a – preamble] A drug delivery device comprising:

552. The preamble of claim 21 recites "[a] drug delivery device comprising." Ex. 1004, 8:16. I understand that a claim preamble is generally not considered to be limiting. Thus, it may not be necessary to show that this language is met by the SoloSTAR in order to conclude that SoloSTAR practices the claim. Nevertheless, to the extent that the preamble to claim 21 is considered to be limiting, it is practiced by the SoloSTAR.

553. The SoloSTAR device is a drug delivery device. *See* Ex. 1004, 1:25-27 ("The present invention relates to pen-type injectors, that is to injectors of the kind that provide for administration by injection of medicinal products from a multidose cartridge."). The *Principles of Operation of the SoloSTAR* document explains that SoloSTAR is a "device that provides a method of accurately injecting a selected dose of insulin through a single lumen hypodermic needle." Ex. 2161 at 4.

554. The SoloSTAR is shown in the Schedule A diagram below, which provides an exploded view showing each of the individual components of the device. As discussed below, because those components and their functions correspond to the components and functions recited in the rest of claim 1, this document further confirms that the SoloSTAR is "a drug delivery device," as recited in the preamble of claim 21.




555. As discussed below, because those components and their functions correspond to the components and functions recited in the rest of claim 1.

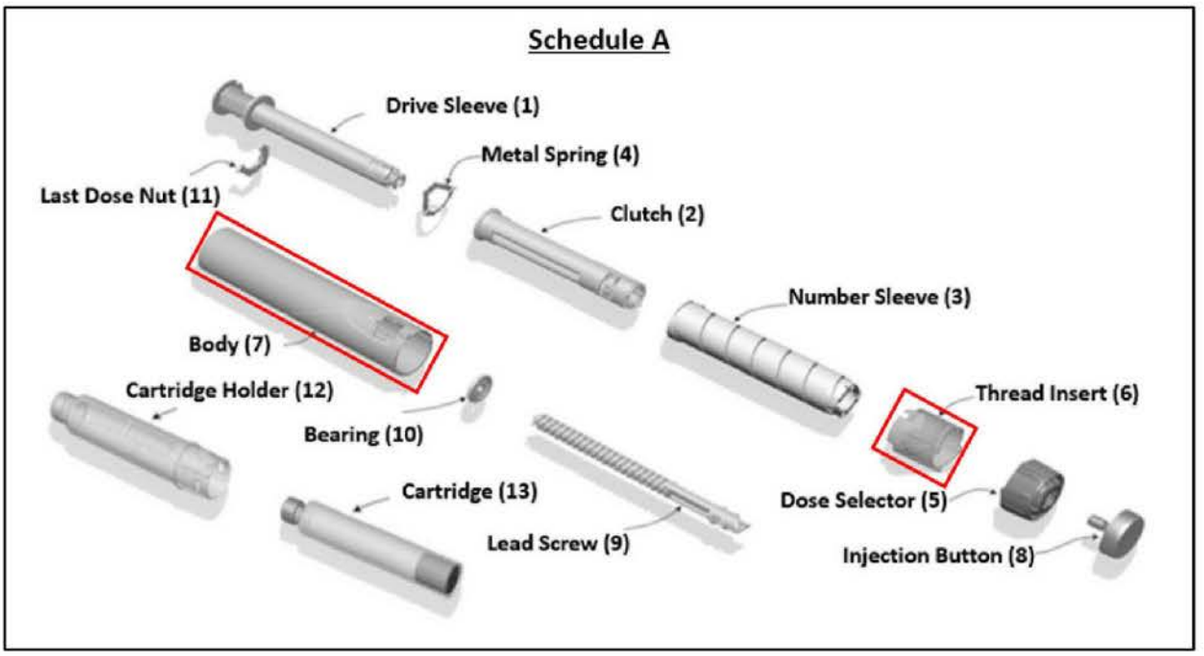
556. My physical inspection of the SoloSTAR product further reinforces my opinion.

557. Thus, to the extent the preamble of claim 21 is considered to be limiting, it is practiced by the SoloSTAR.

ii. [21b] a housing comprising a dose dispensing end and a first thread;

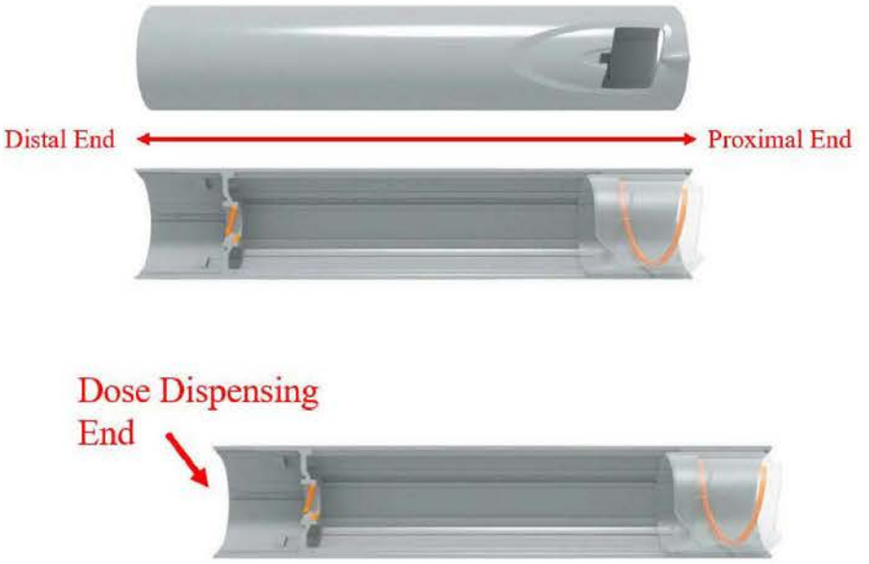
558. Claim 21 further recites "a housing comprising a dose dispensing end and a first thread." Ex. 1004, 8:17-18. It is my opinion that the SoloSTAR device practices this claim.

559. As depicted below, the SoloSTAR includes a housing.




560. The SoloSTAR includes a housing, which comprises the Thread Insert (6) and the Body (7), which snap-fit together and form a rigid, unitary structure.

561. The main housing extends from a distal end (i.e., dose dispensing end - the portion of the main housing that is closest to the medication dispensing end) to a proximal end (i.e., the portion of the main housing that is closest to the dose button).



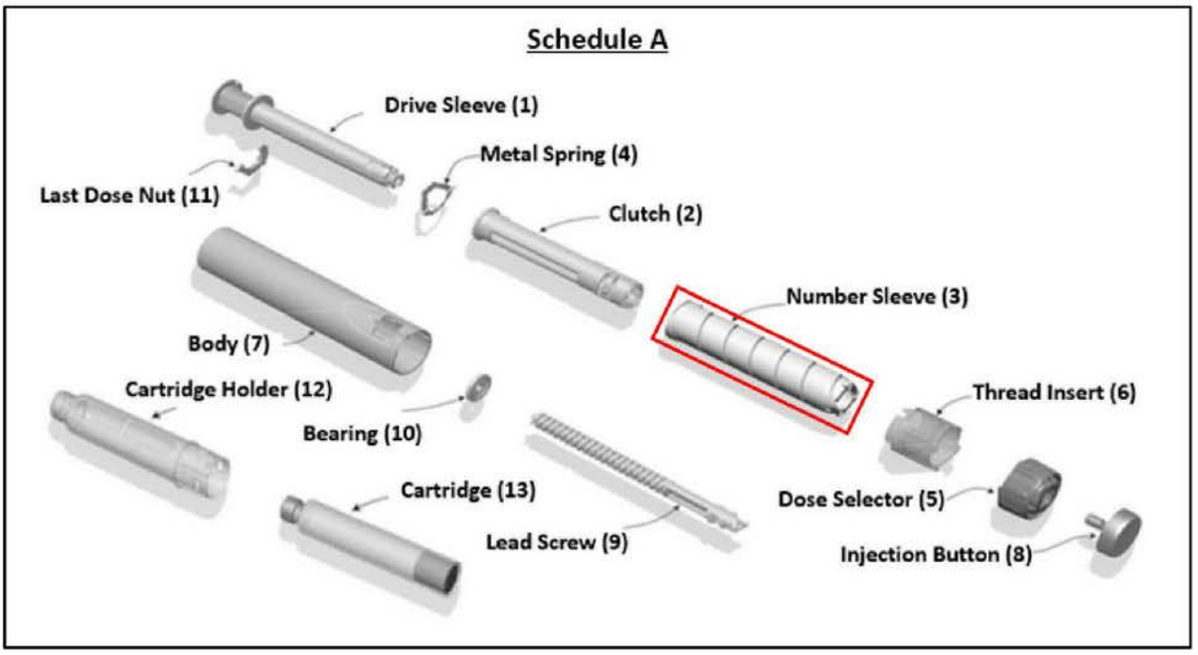

562. The Thread Insert (6) includes a threading (first thread) on its inner surface.


563. Thus, the SoloSTAR device has a housing comprising a dose dispensing end and a first thread.

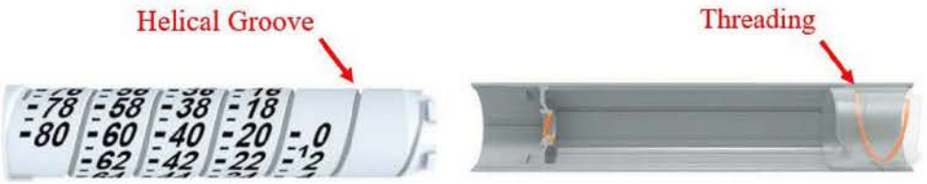
iii. [21c] a dose indicator comprising a second thread that engages with the first thread;

564. Claim 21 further recites "a dose indicator comprising a second thread that engages with the first thread" Ex. 1004, 8:19-20. It is my opinion that the SoloSTAR device practices this claim.

565. As depicted below, the SoloSTAR includes a dose indicator (Number Sleeve (3)).




566. The dose indicator (Number Sleeve (3)) is positioned within the housing (6, 7). The dose indicator (Number Sleeve (3)) includes a second thread (helical groove) on its outer surface that is configured to engage with the first thread (threading) provided by the housing (6, 7).

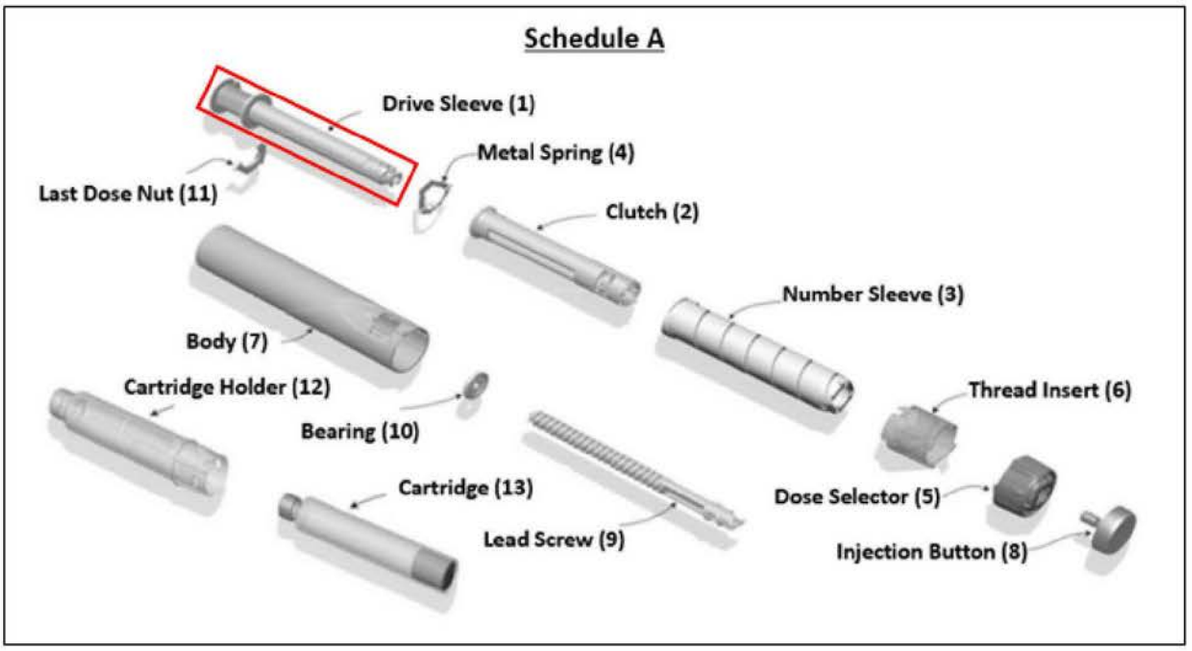



567. Thus, the SoloSTAR device has a dose indicator comprising a second thread that engages with the first thread.

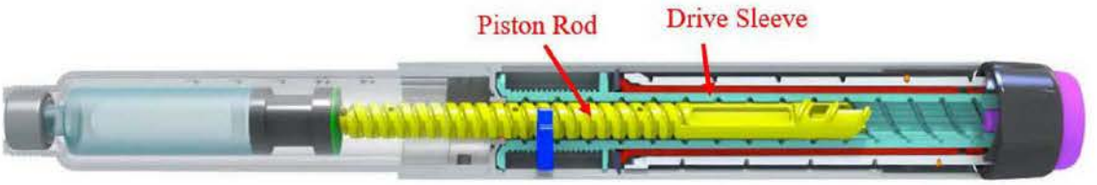
iv. [21d] a driving member comprising a third thread;

568. Claim 21 further recites "a driving member comprising a third thread." Ex. 1004, 8:21. It is my opinion that the SoloSTAR device practices this claim limitation.

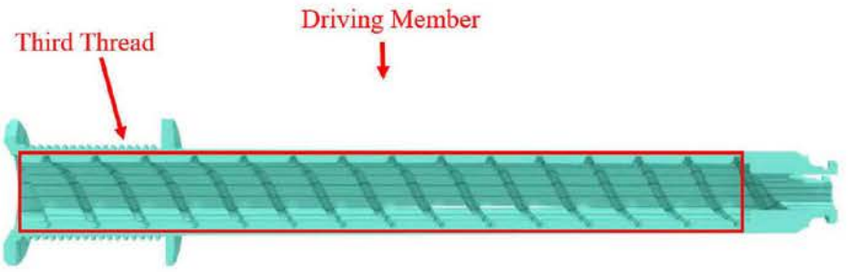
569. As depicted below, the SoloSTAR device includes a driving member (labeled as "Drive Sleeve (1)").



570. The drive sleeve (1) extends along a portion of the piston rod (lead screw (9)).




571. The driving member (1) comprises a third thread. In particular, the driving member includes an internal threading that extends the length of the component.

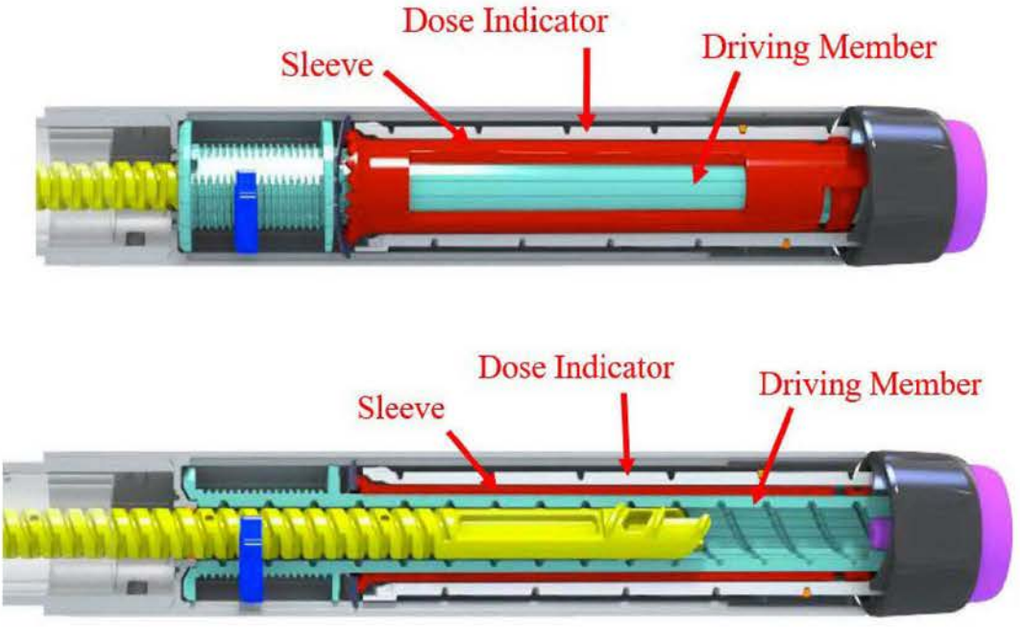



572. Thus, the SoloSTAR device has a driving member comprising a third thread.

v. [21e] a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;

573. Claim 21 further recites "a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator." Ex. 1004, 8:22-25. It is my opinion that the SoloSTAR device practices this claim limitation.

574. As depicted below, the sleeve is located radially inward of the dose indicator and radially outward of the driving member. Thus, the sleeve is disposed between the dose indicator and the driving member.




575. The *Principles of Operation of the SoloSTAR* document explains that the sleeve is releasably connected to the dose indicator: "The number sleeve is locked to the dosage selector and therefore turns as well , displaying increasing or decreasing numbers inside the thread insert (dose window). During the dose selection the clutch is engaged with the number sleeve and transfers the rotation of the number sleeve to the drive sleeve." Ex. 2161 at 8. This document further explains that "[d]uring the dose selection the clutch is engaged with the number sleeve and transfers the rotation to the drive sleeve." Ex. 2161 at 7. "The injection button is located next to the dosage selector and operates the clutch mechanism.

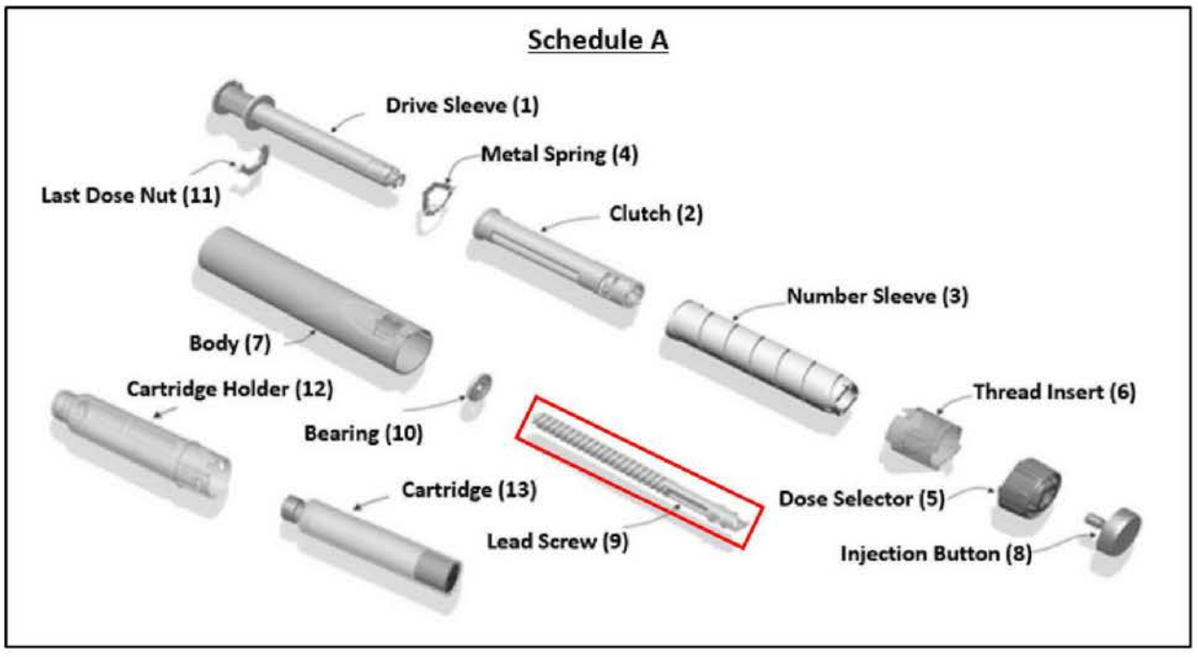
Pressing the button disengages clutch and number sleeve and thereby allows the number sleeve to rotate back into the body." Ex. 2161 at 7.

576. Thus, the SoloSTAR device has a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator.

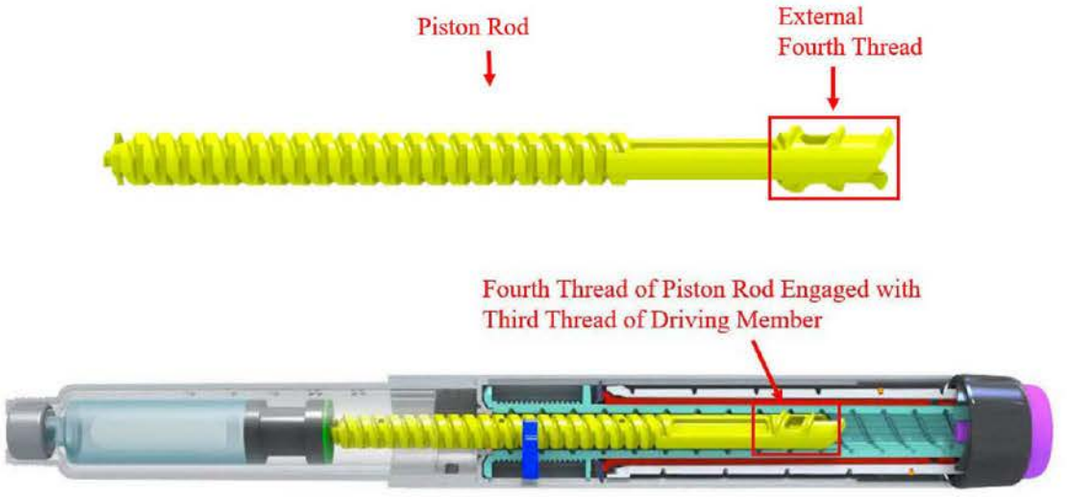
vi. [21f] a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread;

577. Claim 21 further recites "a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread." Ex. 1004, 8:25-26. It is my opinion that the SoloSTAR device practices this claim limitation.

578. As depicted below, the SoloSTAR device includes a piston rod (labeled as "Lead Screw (9)").



579. The piston rod (lead screw (9)) has an external fourth thread that is engaged with the third thread of the driving member (drive sleeve (1)).




580. Thus, the SoloSTAR device has a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread.

vii. [21g] a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing;

581. Claim 21 further recites "a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing." Ex. 1004, 8:27-31. It is my opinion that SoloSTAR device practices this claim limitation.

582. As depicted below, the SoloSTAR device includes a piston rod holder that is integrally formed in the housing, and therefore, is rotationally fixed relative to the housing.

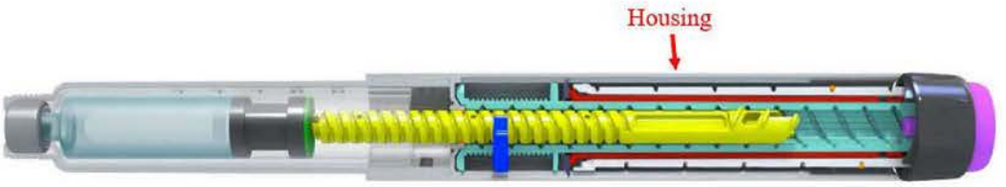

583. Due to the oppositely disposed threads of the piston rod, the piston rod is prevented from rotating during dose setting and permitted to rotate during dose dispensing. The *Principles of Operation of the SoloSTAR* document explains that piston rod (lead screw) rotates through threads in the insert (body thread) during dose dispensing: "The lead screw is located inside the drive sleeve and body and is connected to both via threaded interfaces. When the dose is being selected and the drive sleeve is rotating, the lead screw does not move. When the drive sleeve is then pushed in axially by the dispensing button without rotation, the lead screw is forced to rotate and as a result advances axially to exert force on the cartridge bung. . . The lead screw is forced to turn, since it is positioned inside the body thread that transfers the drive sleeve pushing force to it. As it turns inside the drive sleeve thread, the lead screw is also turning inside the body thread, advancing toward and applying pressure to the cartridge bung." Ex. 2161 at 9-10.

584. Thus, the SoloSTAR device has a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing.

viii. [21h] wherein: the housing is disposed at an outermost position of the drug delivery device;

585. Claim 21 further recites "wherein: the housing is disposed at an outermost position of the drug delivery device." Ex. 1004, 8:32-34. For the reasons set forth below, it is my opinion that the SoloSTAR device practices this claim limitation.

586. As depicted below, the housing is disposed at an outermost position of the drug delivery device.

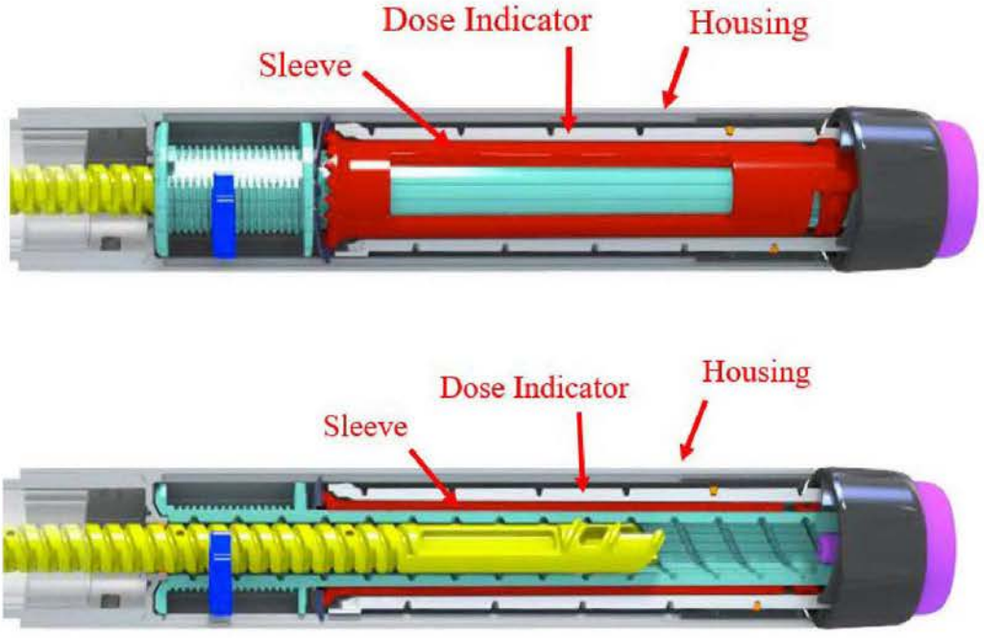



587. Thus, the SoloSTAR device has a housing disposed at an outermost position of the drug delivery device.

ix. [21i] the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing;

588. Claim 21 further recites "the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing" Ex. 1004, 8:35-39. For the reasons set forth below, it is my opinion that the SoloSTAR device practices this claim limitation.

589. As depicted below, the SoloSTAR dose indicator is located radially inward of the housing and radially outward of the sleeve. Thus, the dose indicator is disposed between the housing and the sleeve.




590. The *Principles of Operation of the SoloSTAR* document explains that the dose indicator (dosage selector) "has to be turned clockwise to increase and counter clockwise to decrease the dose" Ex. 2161 at 8. Due to the helically

threaded engagement between the dose indicator and the housing, the dose indicator rotates and traverses axially away from the dose dispensing end during dose setting when the dose is increased.

591. The *Principles of Operation of the SoloSTAR* document explains that the dose indicator (dosage selector / number sleeve) rotates back into the housing (body) when a dose is being dispensed: "To dispense the selected dose the injection button has to be pushed all the way in. The injection button is located behind the dosage selector and it operates the clutch mechanism. Pressing the button disengages clutch and number sleeve and therefore allows the number sleeve to rotate back into the body. As the clutch is disengaging from the number sleeve, it compresses the metal spring and by this action locks with the drive sleeve to prevent it from rotating relative to the number sleeve and body. As a result, by pressing the injection button, the drive sleeve moves in axially without rotation and the number sleeve rotates back into position for the next dose selection." Ex. 2161 at 9. Due to the helically threaded engagement between the dose indicator and the housing, the dose indicator rotates and traverses axially towards the dose dispensing end during dose dispensing.

592. Thus, the SoloSTAR device has a dose indicator disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away

from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing.

x. [21j] the driving member is configured to rotate relative to the piston rod;

593. Claim 21 further recites "the driving member is configured to rotate relative to the piston rod." Ex. 1004, 8:40-41. For the reasons set forth below, it is my opinion that the SoloSTAR device practices this claim limitation.

594. The *Principles of Operation of the SoloSTAR* document explains that during dose selection, the driving member (drive sleeve) rotates while the piston rod (lead screw) does not rotate: "During the dose selection the clutch is engaged with the number sleeve and transfers the rotation to the drive sleeve. . . The lead screw is not moving during the dose selection process." Ex. 2161 at 8.

595. Thus, the SoloSTAR device has a driving member configured to rotate relative to the piston rod.

xi. [21k] the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and

596. Claim 21 further recites "the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator." Ex. 1004, 8:42-44. For the reasons set forth below, it is my opinion that the SoloSTAR device practices this claim limitation.

597. The *Principles of Operation of the SoloSTAR* document explains that the sleeve (clutch) locks with the driving member (drive sleeve) and the the injection button is located behind the dosage selector and it operates the clutch mechanism. Pressing the button disengages clutch and number sleeve and therefore allows the number sleeve to rotate back into the body. As the clutch is disengaging from the number sleeve, it compresses the metal spring and by this action locks with the drive sleeve to prevent it from rotating relative to the number sleeve and body. As a result, by pressing the injection button, the drive sleeve moves in axially without rotation and the number sleeve rotates back into position for the next dose selection.

598. Thus, the SoloSTAR device has a sleeve rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator.

> xii. [21l] the piston rod and the driving member are configured to rotate relative to one another during dose dispensing; and

599. Claim 21 further recites "the piston rod and the driving member are configured to rotate relative to one another during dose dispensing." Ex. 1004, 8:45-46. For the reasons set forth below, it is my opinion that SoloSTAR device practices this claim limitation.

600. The *Principles of Operation of the SoloSTAR* document explains that during dose injection, the driving member (drive sleeve) moves axially while the

piston rod (lead screw) rotates: "When the drive sleeve is then pushed in axially by the dispensing button without rotation, the lead screw is forced to rotate and as a result advances axially to exert force on the cartridge bung." Ex. 2161 at 9-10.

601. Thus, the SoloSTAR device has a piston rod and driving member configured to rotate relative to one another during dose dispensing.

xiii. [21m] the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

602. Claim 21 further recites "the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing." Ex. 1004, 8:47-49. For the reasons set forth below, it is my opinion that the SoloSTAR device practices this claim limitation.

603. The *Principles of Operation of the SoloSTAR* document explains that during dose injection, the lead screw rotates and moves axially to exert force on the cartridge, which is towards the dose dispensing end: "When the drive sleeve is then pushed in axially by the dispensing button without rotation, the lead screw is forced to rotate and as a result advances axially to exert force on the cartridge bung." Ex. 2161 at 9-10.

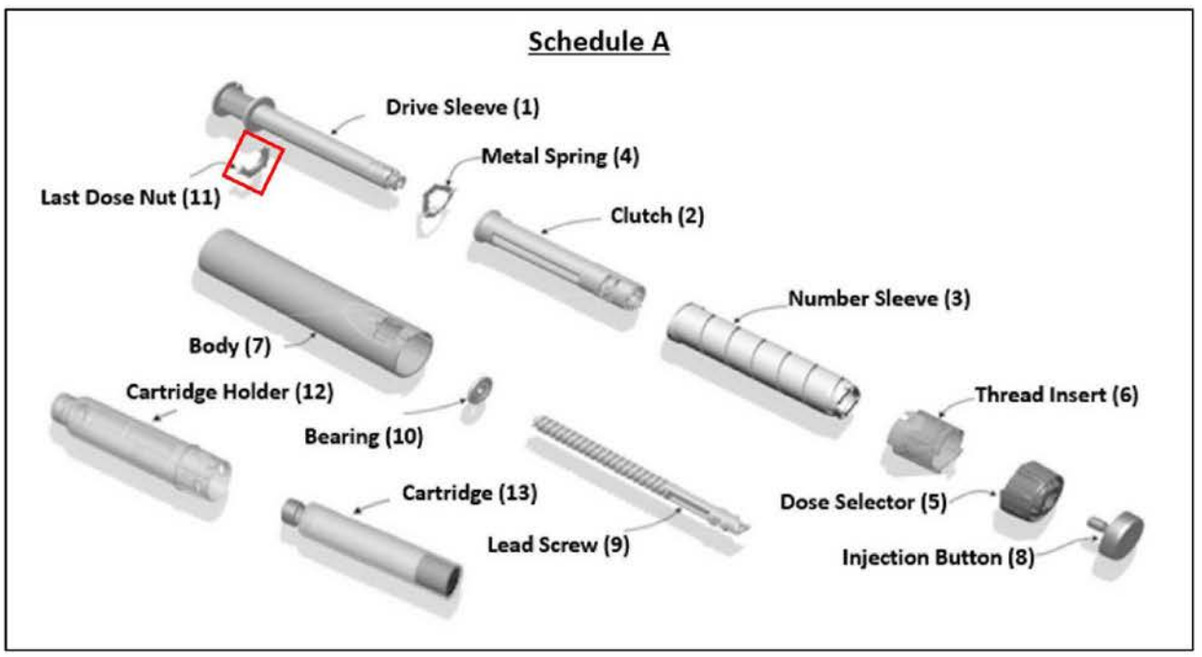
604. Thus, the SoloSTAR device has a piston rod configured to traverse axially towards the dose dispensing end during dose dispensing.

### b. Claim 30

i. The drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered.

605. Claim 30 recites "[t]he drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered." It is my opinion that the SoloSTAR device practices this claim.

606. As depicted below, the SoloSTAR device includes a last dose nut (11):




607. The *Principles of Operation of the SoloSTAR* document explains that the last dose nut advances axially on the drive sleeve with every unit expelled and eventually hits a stop which corresponds to 307 units:

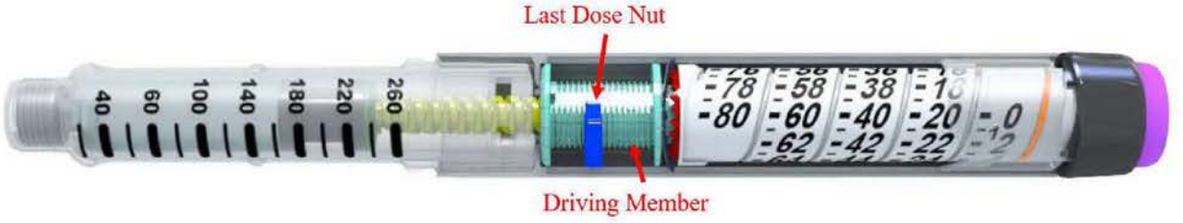
With every unit expelled the last dose nut (11) advances axially on the drive sleeve, to eventually hit a stop which corresponds to 307 units. This limits the amount of insulin to what can be accurately delivered from the cylindrical part of the cartridge. Since the labeled volume is 300 units the limitation to 307 units allows for removing air which maybe trapped inside the cartridge.

Ex. 2161 at 7.

The last dose nut is located between the middle flange and the end flange of the drive sleeve and is connected via threads. While the drive sleeve rotates the last dose nut moves axially as it is locked to the body with respect of rotation. The axial movement of the last dose nut corresponds to the selected dose.

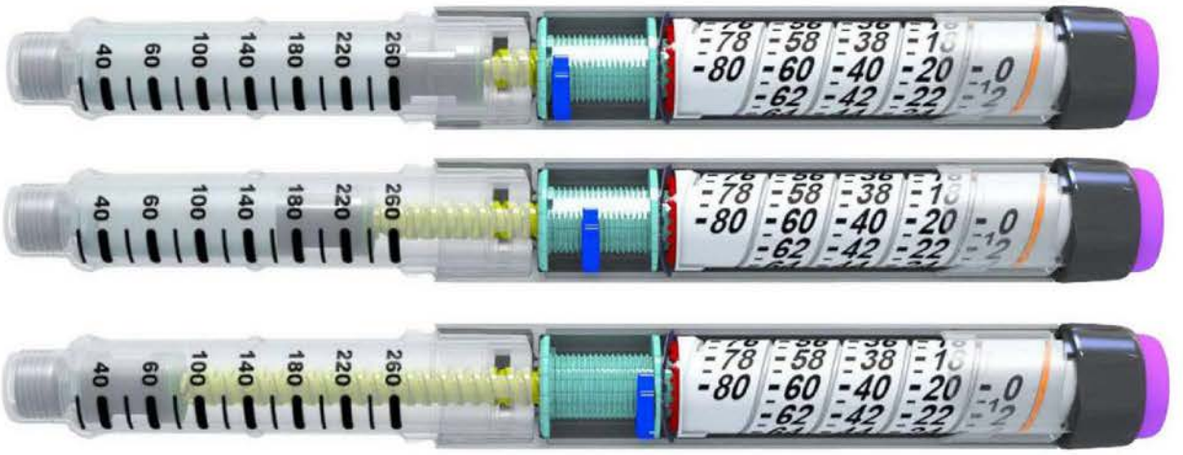
Ex. 2161 at 8.

608. As depicted below, the last dose is located between two flanges on the driving member (drive sleeve (1)):




609. When the cartridge is full, the last dose nut is located at the distal end of the threads located between the two flanges of the driving member. Because the last dose nut is rotatable fixed to the housing, when the user dials a dose of medication, thereby causing the driving member to rotate, the last dose nut moves axially in the proximal direction relative to the driving member. When the user dials up to the final dose in the cartridge, the last dose nut has reached the proximal

end of the threads between the driving member. As the user dials medication to dispense, dispenses medication, the last dose nut moves




610. Thus, the SoloSTAR device practices this claim.

### 6. The '008 Patent SoloSTAR® Analysis

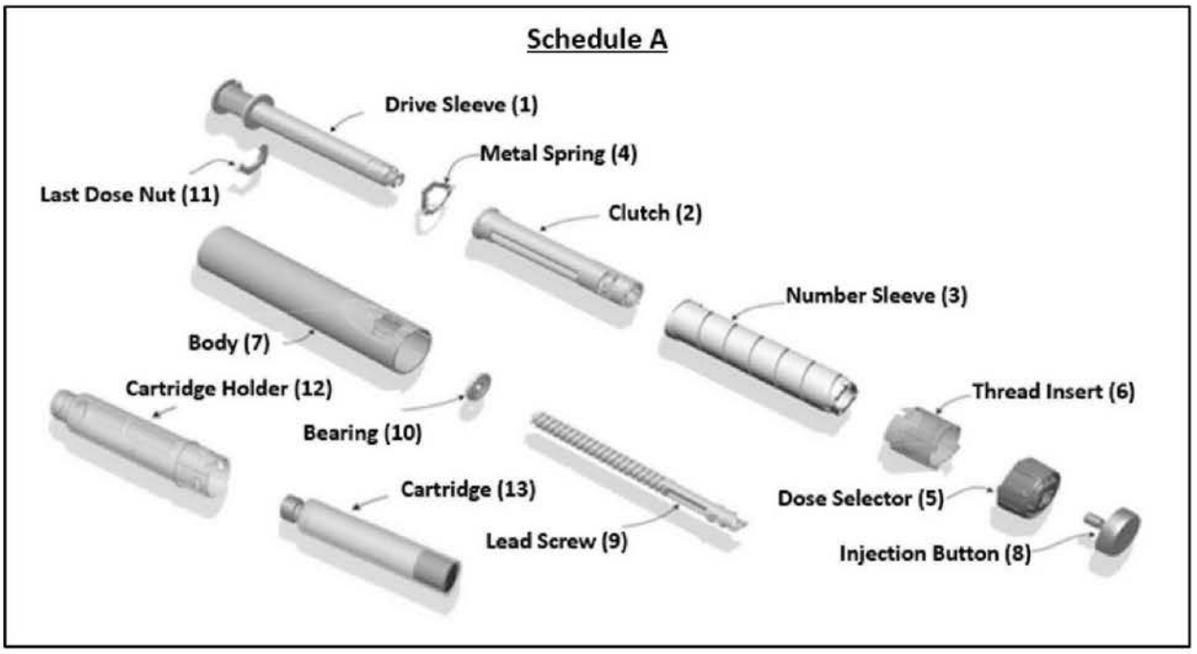
611. My opinion is that the SoloSTAR® device practices at least claim 1.

#### a. Claim 1

i. [1a – Preamble] A drive mechanism for use in a drug delivery device comprising:

612. The preamble of claim 1 recites "A drive mechanism for use in a drug delivery device comprising." Ex. 1005, 1:28-29. I understand that a claim preamble is generally not considered to be limiting. Thus, it may not be necessary to show that this language is met by the SoloSTAR in order to conclude that SoloSTAR practices the claim. Nevertheless, to the extent that the preamble to claim 1 is considered to be limiting, it is practiced by the SoloSTAR.

613. The SoloSTAR is shown in the Schedule A diagram below, which provides an exploded view showing each of the individual components of the device. As discussed below, because those components and their functions correspond to the components and functions recited in the rest of claim 1, this document further confirms that the SoloSTAR is a drug delivery device and has a drive mechanism as recited in the preamble of claim 1.

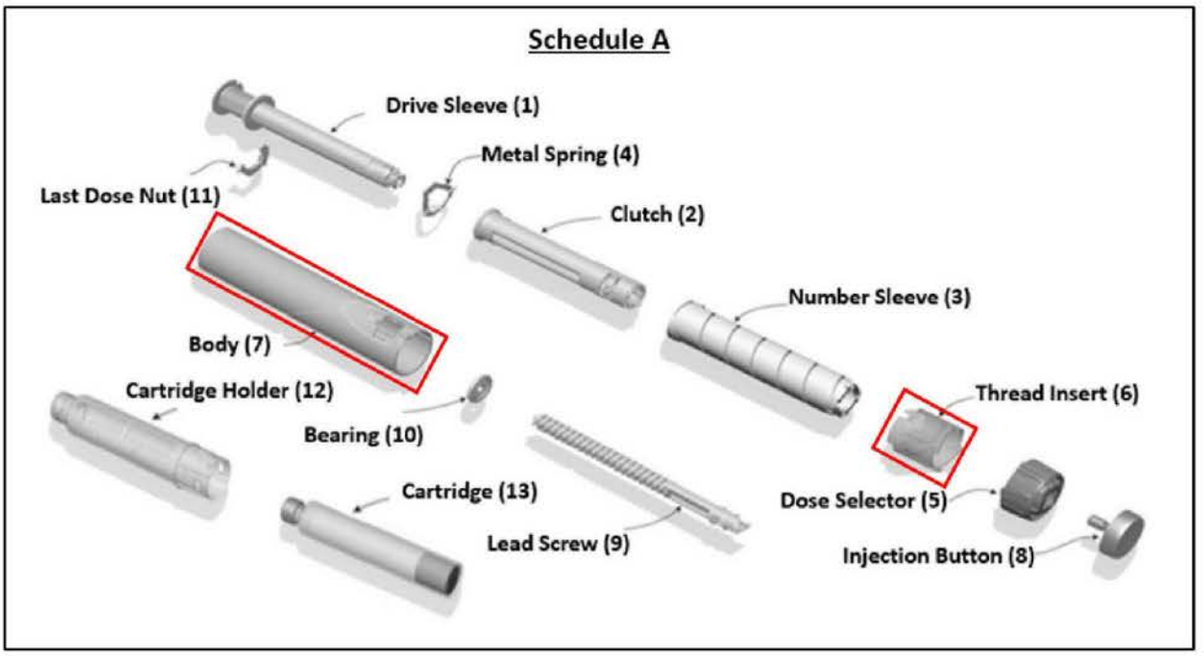



614. Thus, the SoloSTAR device has a drive mechanism for use in a drug delivery device.

ii. [1b] a housing comprising a helical thread;

615. Claim 1 further recites "a housing comprising a helical thread." Ex. 1005, 1:30. It is my opinion that the SoloSTAR device practices this claim limitation.

616. As depicted below, the SoloSTAR includes a housing.




617. The SoloSTAR housing comprises the Thread Insert (6) and the Body (7), which snap-fit together and form a rigid, unitary structure.

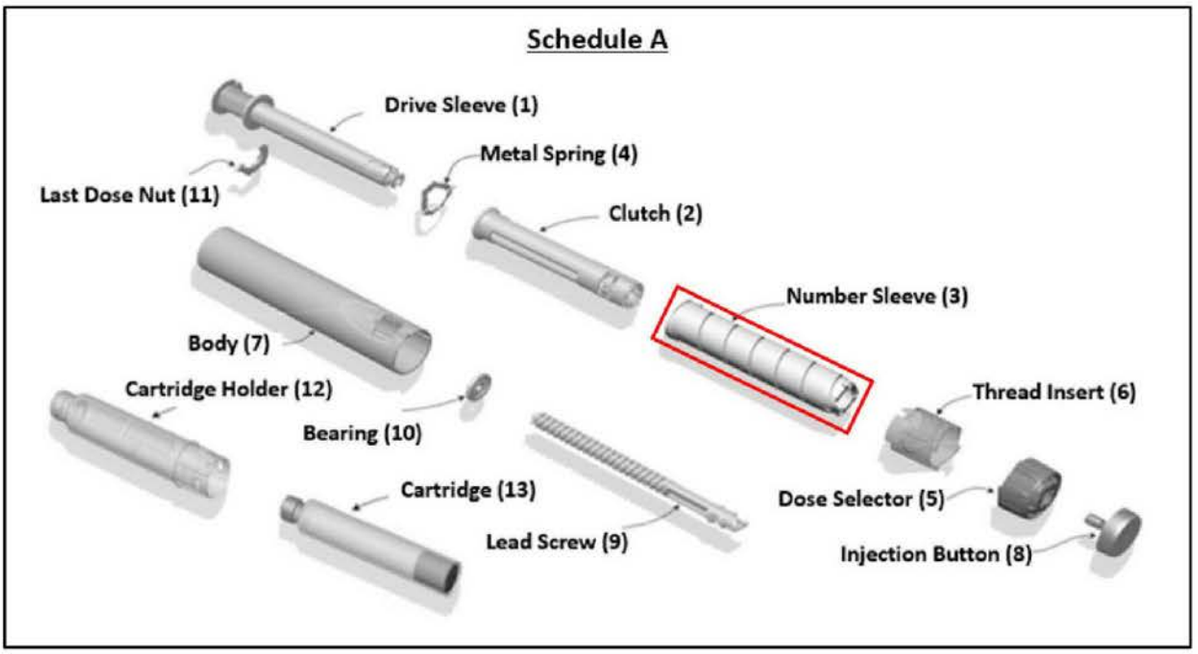
618. The Thread Insert (6) includes a helical thread on its inner surface.


619. Thus, the SoloSTAR device has a housing comprising a helical thread.

iii. [1c] a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing,

620. Claim 1 further recites "a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing." Ex. 1005, 1:31-32. It is my opinion that the SoloSTAR device practices this claim limitation.

621. As depicted below, the SoloSTAR includes a dose dial sleeve (3).




622. The dose dial sleeve (3) is positioned within the housing (6, 7). The dose dial sleeve (3) includes a helical thread (helical groove) on its outer surface that is configured to engage with the helical thread of the housing (6, 7).


623. Thus, the SoloSTAR device a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing.

iv. [1d] an insert provided in the housing, where the insert has a threaded circular opening;

624. Claim 1 further recites "an insert provided in the housing, where the insert has a threaded circular opening." Ex. 1005, 1:33-34. It is my opinion that the SoloSTAR device practices this claim limitation.

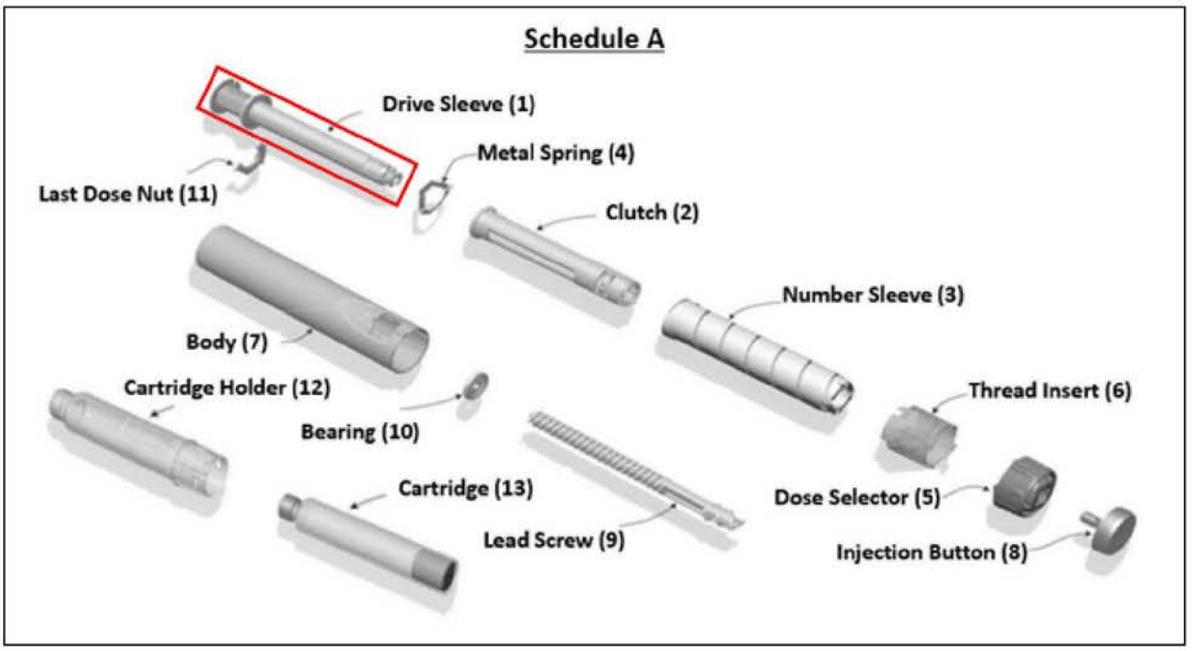
625. As depicted below, the SoloSTAR device includes an insert provided in the housing with a threaded circular opening. As described below, the threaded circular opening engages with a thread on the piston rod (Lead Screw (9)).


626. Thus, the SoloSTAR device has an insert provided in the housing, where the insert has a threaded circular opening.

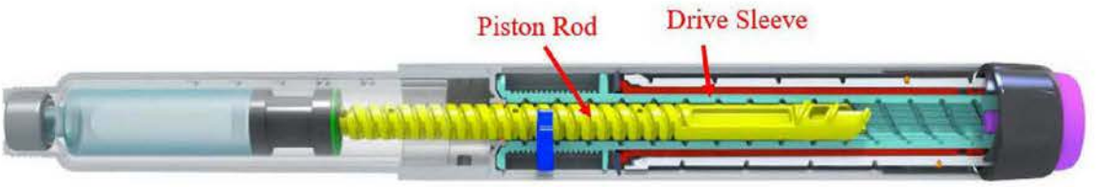
v. [1e] a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread;

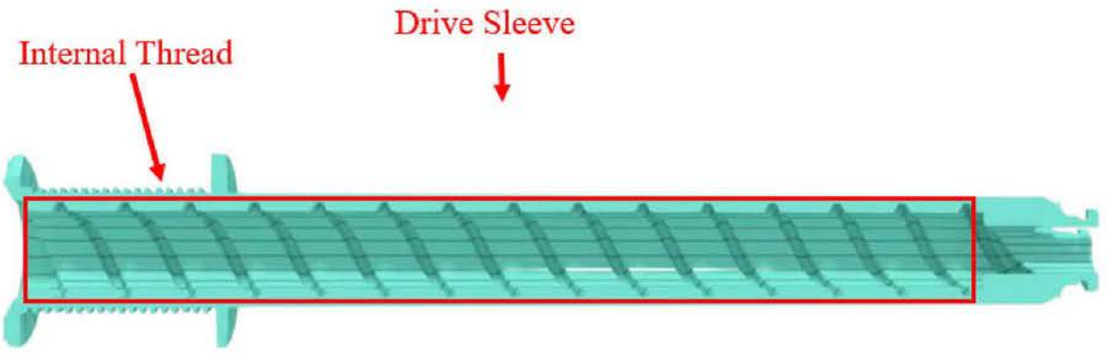
627. Claim 1 further recites "a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread." Ex. 1005, 1:35-36. It is my opinion that the SoloSTAR device practices this claim limitation.

628. As depicted below, the SoloSTAR device includes a drive sleeve (labeled as "Drive Sleeve (1)").




629. The drive sleeve (1) has an internal helical thread that is engaged with an external helical thread of the piston rod (lead screw (9)).





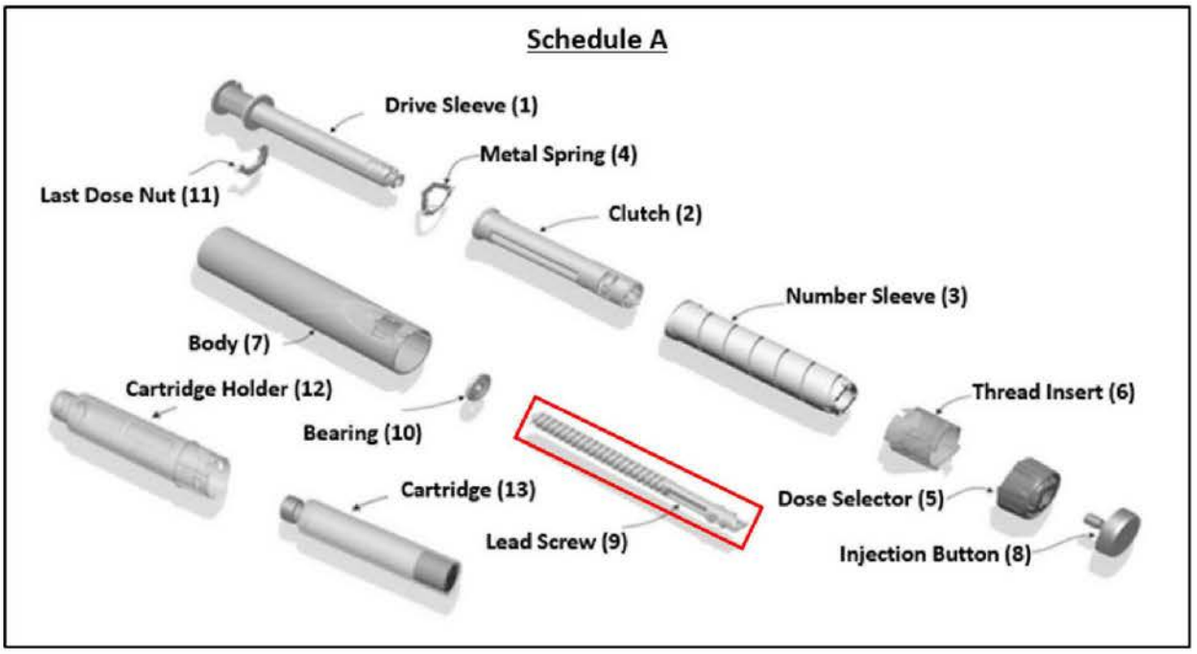

630. The *Principles of Operation of the SoloSTAR* document explains that the dose dial sleeve (number sleeve) is releasably connected to the drive sleeve via the tubular clutch: "The number sleeve is locked to the dosage selector and therefore turns as well, displaying increasing or decreasing numbers inside the thread insert (dose window). During the dose selection the clutch is engaged with the number sleeve and transfers the rotation of the number sleeve to the drive sleeve." Ex. 2161 at 8. This document further explains that "[d]uring the dose selection the clutch is engaged with the number sleeve and transfers the rotation to the drive sleeve." Ex. 2161 at 8. "The injection button is located next to the dosage selector and operates the clutch mechanism. Pressing the button disengages clutch and number sleeve and thereby allows the number sleeve to rotate back into the body." Ex. 2161 at 9.

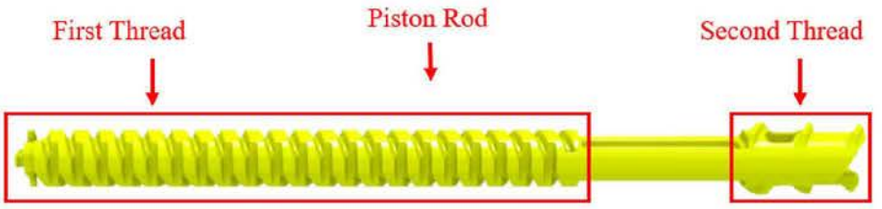
631. Thus, the SoloSTAR device has a drive sleeve releasably connected to the dose dial sleeve and having an internal helical thread.

vi. [1f] a piston rod having a first thread and a second thread, wherein the first thread is engaged with the threaded circular opening of the insert and the second thread is engaged with the internal helical thread of the drive sleeve; and

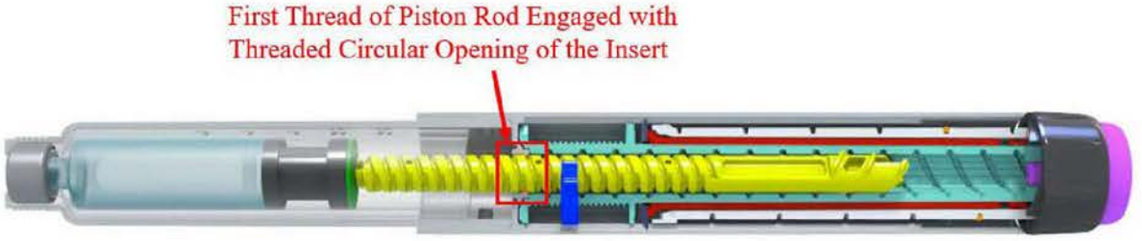
632. Claim 1 further recites "a piston rod having a first thread and a second thread, wherein the first thread is engaged with the threaded circular opening of the insert and the second thread is engaged with the internal helical thread of the drive sleeve." Ex. 1005, 1:36-41. It is my opinion that SoloSTAR device practices this claim limitation.

633. As depicted below, the SoloSTAR includes a piston rod (labeled as "Lead Screw (9)") having a first thread and a second thread.





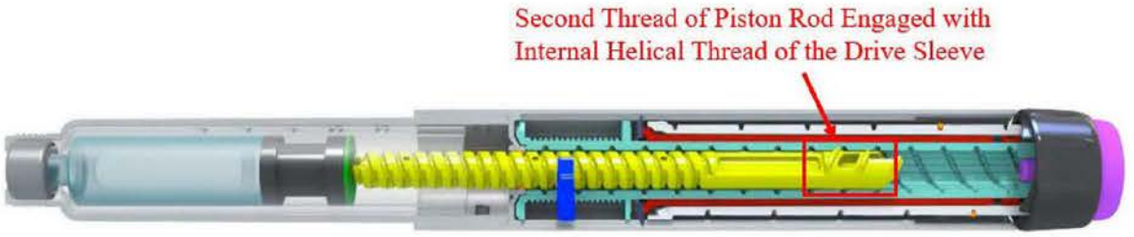

634. As depicted below, the first thread of the piston rod is engaged with the threaded circular opening of the insert.




635. The *Principles of Operation of the SoloSTAR* document explains that piston rod (lead screw) rotates through threads in the insert (body thread) during dose dispensing: "The lead screw is located inside the drive sleeve and body and is connected to both via threaded interfaces. When the dose is being selected and the drive sleeve is rotating, the lead screw does not move. When the drive sleeve is then pushed in axially by the dispensing button without rotation, the lead screw is forced to rotate and as a result advances axially to exert force on the cartridge bung. . . The lead screw is forced to turn, since it is positioned inside the body thread that transfers the drive sleeve pushing force to it. As it turns inside the drive

sleeve thread, the lead screw is also turning inside the body thread, advancing toward and applying pressure to the cartridge bung." Ex. 2161 at 9-10.

636. As depicted below, the second thread of the piston rod is engaged with the internal helical thread of the drive sleeve.




637. The *Principles of Operation of the SoloSTAR* document explains that the internal threading of the drive sleeve (1) is adapted to engage an external thread of the lead screw (9): "The lead screw (9) is located inside the drive sleeve and body and is connected to both via threaded interfaces." Ex. 2161.

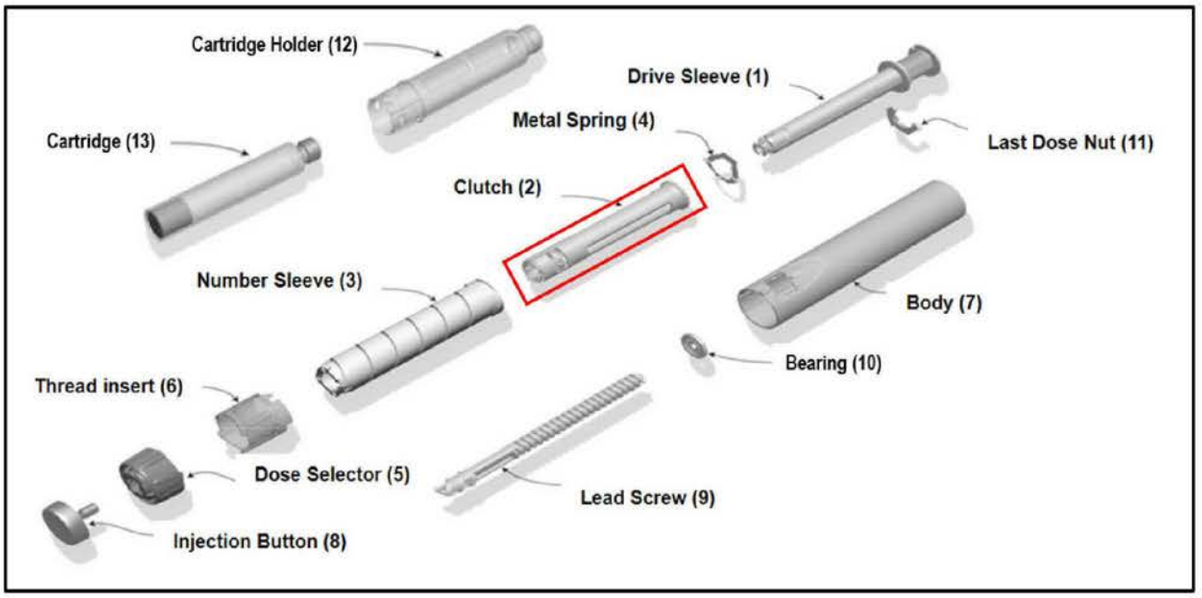
638. Thus, the SoloSTAR device has a piston rod having a first thread and a second thread, wherein the first thread is engaged with the threaded circular opening of the insert and the second thread is engaged with the internal helical thread of the drive sleeve.

vii. [1g] a clutch located between the dose dial sleeve and the drive sleeve, wherein the clutch is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve.

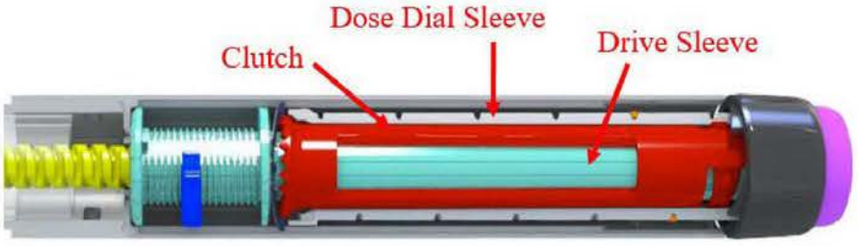
639. Claim 1 further recites "a clutch located between the dose dial sleeve and the drive sleeve." Ex. 1005, 1:42-45. As explained in Section VIII, I

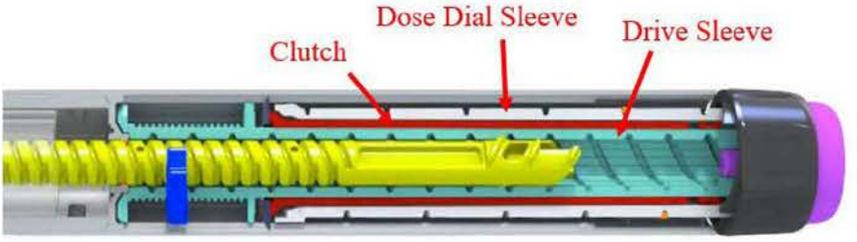
understand that the Court in the Mylan DNJ Action construed "clutch" according to its plain and ordinary meaning, which is "a component that can operate to reversibly lock two components in rotation." Under this construction of "clutch," and for the reasons set forth below, it is my opinion that the SoloSTAR device practices this claim limitation.

640. As depicted below, the SoloSTAR device includes a clutch (2).




641. The clutch (2) is located radially outward of the drive sleeve and radially inward of the dose dial sleeve.






642. The *Principles of Operation of the SoloSTAR* document explains that during dose selection, the clutch (2) is engaged with the dose dial sleeve (number sleeve) and transfer rotation to the drive sleeve: "The number sleeve is locked to the dosage selector and therefore turns as well, displaying increasing or decreasing numbers inside the thread insert (dose window). During the dose selection the clutch is engaged with the number sleeve and transfers the rotation of the number sleeve to the drive sleeve." Ex. 2161 at 8. This document further explains that the clutch (2) couples and declouples the number sleeve (3) and the drive sleeve (1), which are both moveable components, and that the clutch (2) is operatively coupled to the dose knob (5): "During the dose selection the clutch is engaged with the number sleeve and transfers the rotation to the drive sleeve. . . The injection button is located next to the dosage selector and operates the clutch mechanism. Pressing the button disengages clutch and number sleeve and thereby allows the number sleeve to rotate back into the body." Ex. 2161 at 9.

643. Thus, the SoloSTAR device has a clutch located between the dose dial sleeve and the drive sleeve, wherein the clutch is located (i) radially outward of the drive sleeve and (ii) radially inward of the dose dial sleeve.

### B. The OptiClik Does Not Practice the Challenged Claims

644. I have been asked to consider whether Sanofi's OptiClik pen injector, developed by Ypsomed ("OptiClick"), practices any of the challenged claims. For the reasons set forth below, it is my opinion that Opticlik does not practice the claims of the Challenged Patents.

645. In forming my opinion, I conducted a physical examination of the OptiClik. I have also reviewed and considered materials relating to the OptiClik device.

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

647. With the exception of claim 51 of the 486 Patent, each challenged independent claim requires a threaded engagement between a housing and a dose dial sleeve/dose indicator. *See* Ex. 1001, 6:41-45 ("a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured

to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve"); Ex. 1002 8:12-16 ("a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing, said helical groove provided along an outer surface of said dose dial sleeve"); Ex. 1003, 6:63-65 ("a dose dial sleeve positioned within said housing, said dose dial sleeve comprising a helical groove configured to engage a threading provided by said main housing"); Ex. 1004, 8:17-20 ("a housing comprising a dose dispensing end and a first thread; a dose indicator comprising a second thread that engages with the first thread"); Ex. 1005, ("a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing." Ex. 1005, 17:31-32 ("a dose dial sleeve having a threaded surface that is engaged with the helical thread of the housing").

648. The OptiClik is an electronic direct drive pen injector and does not have a dose dial sleeve or dose indicator engaged with a threading of the housing. Thus, the Opticlik does not practice claim 1 of the 069 Patent, claim 11 of the 044 Patent, claim 1 of the 486 Patent, or Claim 1 of the 008 Patent.

649. Claim 51 of the 486 patent requires a "clutch comprising. . . a tubular body [] having a diameter sized such that said distal end of said tubular body may be positioned within a proximal end of a dial member." Ex. 1003, 10:32-37. As

discussed above, the OptiClik did not have a dial member (or dose dial sleeve), and thus, does not practice claim 51 of the 486 Patent.

### C. Benefits of the Claims of the Challenged Patents

650. In my opinion, the claimed components and interfaces, such as the threaded engagements, piston rod, drive sleeves/driving members, dose stops, and clutch enable an injection device with (i) low injection force, (ii) short or long injection stroke length for low or high dose per injection, and (iii) a relatively small number of components that decrease the complexity and cost of the device. The arrangement of components limits the frictional losses in the mechanism, thereby providing an efficient force transmission from the user's hand to the injection piston in the ampoule that contains the medicament. The challenged claims also enable a device without a "resetting" operation, thereby making the injection pen easier to use. The challenged claims further enabled an injection device with a shorter dial extension, providing additional benefits for patients lacking dexterity. Specifically, the SoloSTAR has a maximum of 80 units, while the FlexPen only has a maximum of 60 units. While the SoloSTAR's dial would extend to 25.5mm to inject 60 units, the FlexPen must extend to 33mm to inject 60 units. All of these features are evidenced in the SoloSTAR injector pen which practices the inventions of the challenged claims. The embodiments described in the challenged patents also show that these advantages can be realized by a small number of

components, thereby enabling a device that can be manufactured at lower cost. Also, because the pen is disposable, the components can be made of inexpensive materials, thereby further reducing the production costs.

## XIII. CONCLUSION AND JURAT

651. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Dated: June 24, 2019

By: 

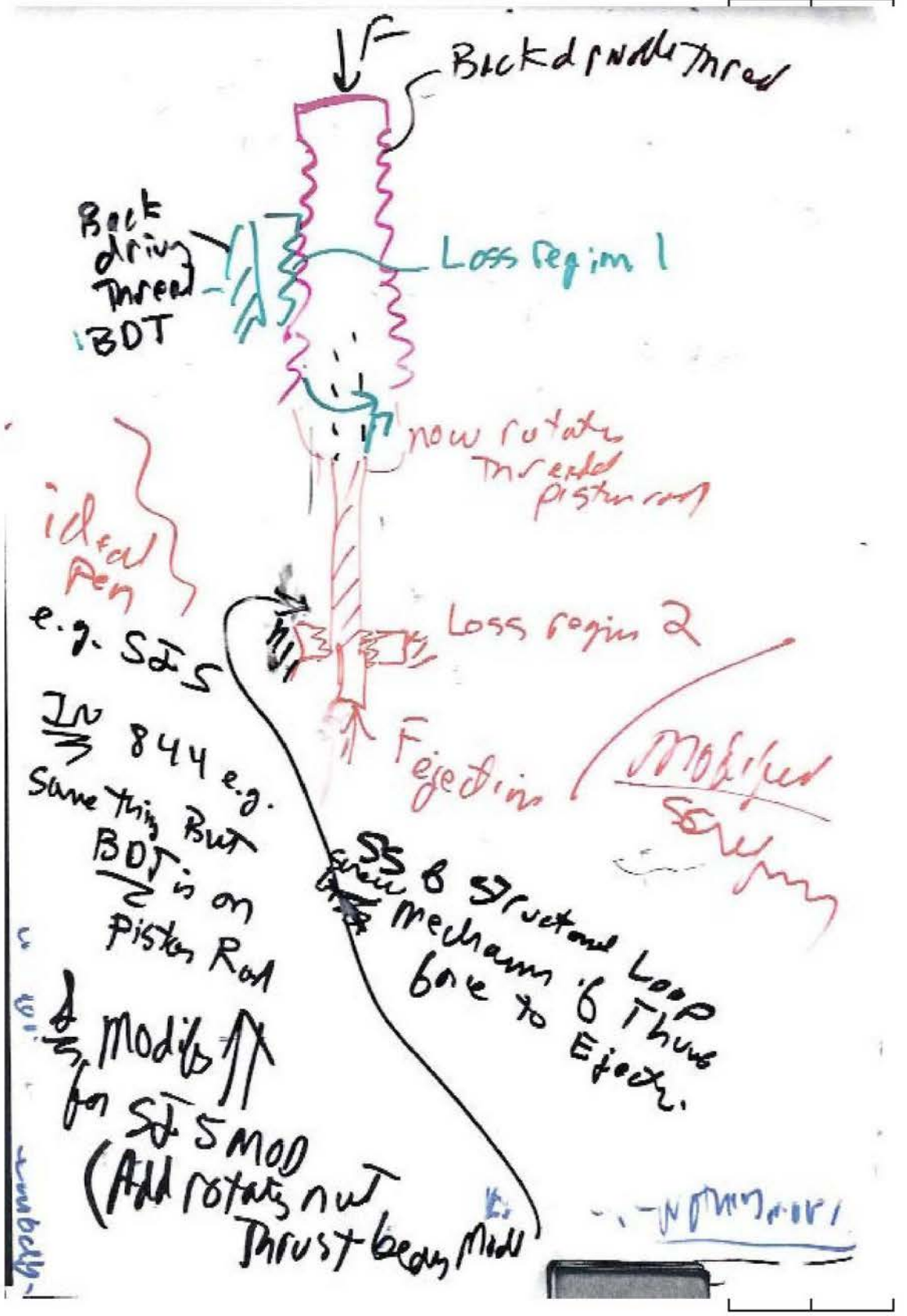
Dr. Alexander Slocum

Table of Appendices

| Appendix No. | Description |
|---|---|
| A | **Screwthread_Analysis.xls is the spreadsheet** |
| B | **Analytical models of injector pen characteristics** contains the description of models for leadscrew cross section and pen mechanism. In particular, the latter is applied to Steenfeldt-Jensen's fifth embodiment and the fifth embodiment as modified by petitioner. |
| C | **Steenfeldt-Jensen '004 Analysis** describes using the patent figures for creation of a 3D CAD model of the fifth embodiment using Fig 15, 16, and 17 as the foundation. The CAD is used to illustrate the operation of the device and the motion of the elements with respect to each other during the operation. Also included is a closer evaluation of petitioner's suggested modification and limitations. |
| D | **Burroughs '046 Analysis reviews the** patent illustrations showing the impact of adding a second tooth, beam bending analysis and FEA created using the model as presented in the patent. |
| E | **DCA Test Rig Force Measurements** has the test data and analysis from the DCA test rig |
| F | **Analysis_of_Leinsing_new_tooth** are the spreadsheets with scanned-analysis of formulas developed to model the additional tooth. |
| G | **List of Materials Considered** |

| | | | | |
|---|---|---|---|---|
| **Screwthread_Analysis.xls** | | | | |
| To determine forces and torques in Steenfeldt-Jensen pen injector | | | | |
| By Alex Slocum, 6/20/2019 | | | | |
| Enter numbers in **BOLD,** results in **RED** | | | | |
| Be consistant with units! (in, lb or N, m or N, mm) | | | | |
| **Stage 1: User applies force to button creating torque input to actuate threaded piston rod** | | | | |
| **User thumb force input** | **10** | | Fuser | N |
| **Thread to be backdriven to create rotation** | | | | |
| Pitch diameter | **12.0** | | Dpbd | mm |
| Root diameter | **11.5** | | Drbd | mm |
| Lead (distance traveled with one complete rotation) | **11.0** | | Leadbd | mm |
| Reference: Helix angle (degrees, radians) | **16.3** | **0.284** | | |
| Flank angle alpha, cos(alpha) | **6** | **0.995** | cosalphabd | degrees |
| ***Friction properties of backdriven thread*** | | | | |
| Coefficient of friction between backdriven screw threads | **0.1** | | mutbd | |
| Actual Beta | **1.09** | | betabd | |
| Actual screwthread efficiency (Slocum PMD page 709 Eq. 10.8.18) | **72%** | | etabd | |
| Reference: efficiency for lowering a load (>100% if backdriveable) | **157%** | | etaLL | |
| Backdriveable? | **YES** | | | |
| ***Resulting torque generated that gets applied to piston rod thread*** | **12.64** | | Torquepr | N-mm |
| **Stage 2: Torque generated is input to actuate actuate threaded piston rod** | | | | |
| **Thurst surface between rotating drive thread and housing (for Petitioner's modifed 5th embodiement, not present in 5th)** | | | | |
| Outside Diameter | **9.4** | | ODpr | mm |
| Inside Diameter | **5.7** | | IDpr | mm |
| Average diameter for torque calculation | **7.70** | | Dtbavg | mm |
| **Non-circular piston rod sliding drive spline (for 5th embodiement, not present in modified 5th)** | | | | |
| % reduction in root diameter to form flats | **20%** | | wof | |
| Width of flat | **1.98** | | wofmm | |
| Distance between flats | **2.64** | | Dfpr | mm |
| Force couple magnitude | **6.38** | | Fcspline | |
| Coefficient of friction of between spline components | **0.1** | | muspline | |
| Drag force from the force couple | **1.28** | | Fdragspline | |
| **Piston Rod Thread** | | | | |
| Pitch diameter | **3.9** | | Dppr | mm |
| Root diameter | **3.3** | | Drpr | mm |
| Lead (distance traveled with one complete rotation) | **3.98** | | Leadpr | mm |
| Reference: Helix angle (degrees, radians) | **17.9** | **0.313** | | |
| Flank angle alpha, cos(alpha) | **6** | **0.995** | cosalphapr | degrees |
| ***Friction properties*** | | | | |
| Coefficient of friction between moving thrust surfaces (if present, else enter 0) | **0.1** | | mutbpr | |
| Coefficient of friction of piston rod screw threads | **0.1** | | mutpr | |
| Actual Beta | **0.98** | | betapr | |
| Actual screwthread efficiency | **74%** | | etapr | |
| Backdriveable? | **YES** | | | |
| **Resulting ampoule piston force** | | | | |
| *With spline and without rotating thrust surface (e.g., Steenfeldt-Jensen 5th Embodiment)* | | | | |
| Ampoule piston force (output) | **13.4** | | Finwtb | N |
| Amplification of user thumb force (Force user pushes/resulting ampoule piston force) | **134%** | | Awtb | |
| Ideal amplification based only on thread pitch ratio | **276%** | | | |
| *With spline and rotating thrust surface (i.e., Steenfeldt-Jensen's 5th as Modified by Petitioner)* | | | | |
| Ampoule piston force (output) | **8.9** | | Fintb | N |
| Amplification of user thumb force (Force user pushes/resulting ampoule piston force) | **89%** | | Atb | |
| ***Percent increase in injection force for modified 5th embodiement*** | **51%** | | | |
| **Leadscrew stresses and buckling load** | | | | |
| Length | **30.0** | | Lpr | |
| Material | **Delrin** | | | |
| Young's Modulus | **2800** | | Epr | MPa |
| Yield stress | **69** | | sigmaxpr | MPa |
| Root diameter area for full round shaft | **8.55** | | Ardpr | mm^2 |
| Root diameter area for shaft with flats | **7.66** | | Ardprwf | mm^2 |
| Itwist for full round shaft | **11.64** | | Ippr | mm^4 |
| Itwist for shaft with flats | **9.58** | | Ipprwf | mm^4 |
| Ibuckle for full round shaft | **5.82** | | Ipr | mm^4 |
| Ibuckle for shaft with flats | **3.93** | | Iprwf | mm^4 |

| | | | | |
|---|---|---|---|---|
| ***Maximum allowable ampoule piston force to not buckle piston rod (assume fixed-free)*** | | | | |
| Full round shaft | **49** | | Finmax | N |
| Shaft with flats | **33** | | Finmaxwf | N |
| ***Load induced stresses*** | | | | |
| Full round shaft | | | | |
| Torsional shear stress | **2.1** | | taupr | MPa |
| Axial stress | **1.6** | | sigpr | MPa |
| Von Mises equivelant stress | **4.0** | | sigeqpr | MPa |
| Shaft with flats | | | | |
| Torsional shear stress | **2.6** | | tauprwf | MPa |
| Axial stress | **1.8** | | sigprwf | MPa |
| Von Mises equivelant stress | **4.8** | | sigeqprwf | MPa |
| **Safety Factors** | | | | |
| Stress Safety Factor | | | | |
| Full round shaft | **17.2** | | | |
| Shaft with flats | **14.3** | | | |
| *Buckling Load Safety Factor* | | **Buckle?** | | |
| *Shaft with flats* | **2.5** | **NO** | | |
| *Shaft without flats* | **3.6** | **NO** | | |



Analaysis based on leadscrew equations in Shigley 4th Edition "Mechanical Engineering Design"

| **Parameters** | | | | |
|---|---|---|---|---|
| | with friction | without friction | | |
| **Pitch diameter** | **12.0** | 12.0 | | |
| **Lead (aka also known as pitch)** | **11.0** | 11.0 | | |
| **Friction coeff** | **0.1** | 0 | | |
| **Alpha Thread angle (radians)** | **0.105** | **0.105** | | |
| **Force multiplied by this to get required torque** | | | | |
| Raising a load: T=F*D/2* (this number) | **0.404194** | **0.291784** | Shigley 4th edition Eq. 8-5 | |
| **Efficiency from Shigley** | **72%** | | | |
| **Efficiency from Slocum PMD text** | **72%** | | | |
| **Difference** | **0.0000%** | | | |
| Lowering a load: T=F*D/2* (this number) | **0.185783** | **0.291784** | | |
| **Efficiency from Shigley** | **157%** | | | |
| **Efficiency from Slocum PMD text** | **157%** | | | |
| **Difference** | **0.0000%** | | | |

Based on spreadsheet:

| | | | |
|---|---|---|---|
| **Circular and noncircular shafts.xls** | | | |
| To determine area moments of inertia of circular and noncircular shafts | | | |
| By Alex Slocum 6/19/2019 | | | |
| Enter numbers in **BOLD,** results in **RED** | | | |
| Be consistant with units! (e.g., in or mm) | | | |
| | | variable | units |
| **Piston rod thread root diameter** | **3.30** | D | mm |
| **Circular section** | | | |
| Ipolar (for twist strength) | **11.64** | Ipc | mm^4 |
| Ixx=Iyy (for buckling strength) | **5.82** | Ixxc | mm^4 |
| Cross sectional area | **8.55** | Ac | mm^2 |
| **Non-circular section** | | | |
| Width between flats | **2.64** | df | mm |
| Shaft diameter reduction | **20%** | sdr | |
| Ipolar (for twist strength) | **9.58** | Ipnc | mm^4 |
| width of flats | **1.98** | wf | mm |
| percent of root diameter | **60%** | prd | |
| Iyy (for buckling strength) | **3.93** | Iyync | mm^4 |
| Cross sectional area | **7.66** | Acnc | mm^2 |
| **Comparison non-circular / circular** | | | |
| Twist strength reduction | **18%** | tsr | |
| Buckling strength redution | **32%** | bsr | |
| | | | |
| Ip and Ixx calculation variables | | | |
| thetamax | 0.64 | thetamaxXX | |
| tan(theta) | 0.75 | tanthetaXX | |
| sec(theta) | 1.25 | secthetaXX | |
| sin(theta) | 0.60 | sinthetaXX | |
| Iyy calculation variables | | | |
| thetamax | 0.93 | thetamaxYY | |
| tan(theta) | 0.75 | tanthetaYY | |
| sec(theta) | 1.25 | secthetaYY | |
| sin(theta) | 0.60 | sinthetaYY | |

**Appendix B: Analytical models of injector pen characteristics**

A POSA will know that pen injectors need to apply significant force through a very small diameter leadscrew to push out the medicament. A POSA will also understand the design of machine elements including shafts such as leadscrews including that overall an efficient leadscrew driven pen injector system will have smaller diameter leadscrew threads near the output to reduce frictional losses; and also, however, a smaller diameter leadscrew means the shaft is more prone to buckling under load. Furthermore, a POSA will also know that for a leadscrew, the buckling strength is based on the cross section of the leadscrew shaft at the root diameter of the thread along its length. These functional requirements are in opposition to each other and thus a POSA would create an analytical model to optimize the system before reaching a conclusion on what performance might be. Such a model was not presented by Petitioner or its expert to accompany their opinions, and thus I have done it as part of my unbiased consideration of their opinions to determine if they have any merit in these matters.

**Pen injector threads**

Petitioner and its expert admitted that low injection force (the force the user exerts with their thumb) is an important design consideration. The force that must be applied to the ampoule piston will be relatively constant across devices (it does depend on the viscosity of the insulin and the piston design to some extent), so what matters greatly is the efficiency of the mechanical design of the pen. For the patents in suit and the alleged prior art that rely only on screw threads for their internal mechanisms to achieve force amplification of the user's thumb force, selecting the proper thread geometry (and materials to have a low coefficient of friction) is of paramount importance. It is the shape of the threads and their diameters that is critical. In addition to creating an efficient mechanism to minimize the injection force, the pen injector must also be low cost to manufacture and ergonomic to operate. This is where the inventiveness of the various patents comes into play: how are components selected and packaged together.

Regardless of the arrangement of internal components in a pen injector, the flow of force will be from the user's thumb through the mechanism and into the ampoule piston. This flow of force for these types of mechanisms will be:

1) Applied thumb force flows into a threaded shaft that reacts against a mating thread so relative rotation occurs between the two. *This is the backdriven thread portion of the pen injector, where user thumb force (injection force) is transformed into rotary motion and torque.*
2) The rotation generated is applied to a threaded interface between the piston rod and a mating thread to cause the piston rod to advance. *This is the threaded piston rod portion of the pen injector, where torque and rotation are transformed into linear motion and force on the ampoule piston.*

Note that it does not matter which thread is internal or external, or which thread is fixed or rotating: the analysis is the same. All that matters is there is a planar rotating thrust surface

(e.g., a thrust bearing supporting a rotating threaded drive tube according to Petitioner's proposed modification). In addition, the way the rotation generated by the backdriven thread is transferred to the threaded rod is of importance as it can be either directly (so no additional frictional losses) or indirectly through a coupling (e.g., a spline) which may induce some additional frictional losses to be accounted for.

To this end, a spreadsheet was created to model pen injectors generically and then it was applied as Screwthread_Analysis.xls to compare Steenfeldt-Jensen's fifth embodiment to Petitioner's proposed modification. The result of now having a rotating thrust surface--*i.e.*, the driver tube's collar—is that the net output force applied to the ampoule piston is reduced by over half: The ratio force generated on ampoule piston with thrust bearing / without thrust bearing is 51%. This is such a large reduction in force, which means that a user would have to push twice as hard to generate the same force on the ampoule, that a POSA would never choose to use such a design as suggested by the Petitioner. .

The spreadsheet inputs and outputs are well labeled and should be self-explanatory. In general, inputs include the user's injection force (selected here to be 10N) and the properties of the first threaded portion (the threads that are backdriven) including geometry and friction coefficient. Inputs also include the properties of the second threaded portion (the threaded piston rod) including geometry and friction coefficient for the threaded rod and for the rotating thrust surface. Material properties are also input for strength calculations. The spreadsheet calculates the response of the system with and without collar friction and also with and without flats on the leadscrew shaft.

Below are screenshots from the spreadsheet with values entered to represent Steenfeldt-Jensen's fifth embodiment and Petitioner's proposed modification, where the internal thread on the end of the drive tube now advances the threaded piston rod so the drive tube now needs a thrust interface to the housing. Input values were provided by Mr. Robert Veasey of DCA Engineering.

| | A | B | C | D | E |
|---|---|---|---|---|---|
| 1 | **Screwthread_Analysis.xls** | | | | |
| 2 | To determine forces and torques in Steenfeldt-Jensen pen injector | | | | |
| 3 | By Alex Slocum, 6/20/2019 | | | | |
| 4 | Enter numbers in **BOLD**, results in **RED** | | | | |
| 5 | Be consistant with units! (in, lb or N, m or N, mm) | | | | |

*Stage 1 inputs and calculations*

| | A | B | C | D | E |
|---|---|---|---|---|---|
| 6 | **Stage 1: User applies force to button creating torque input to actuate threaded piston rod** | | | | |
| 7 | **User thumb force input** | **10** | | Fuser | N |
| 8 | **Thread to be backdriven to create rotation** | | | | |
| 9 | Pitch diameter | **12.0** | | Dpbd | mm |
| 10 | Root diameter | **11.5** | | Drbd | mm |
| 11 | Lead (distance traveled with one complete rotation) | **11.0** | | Leadbd | mm |
| 12 | Reference: Helix angle (degrees, radians) | **16.3** | **0.284** | | |
| 13 | Flank angle alpha, cos(alpha) | **6** | **0.995** | cosalphabd | degrees |
| 14 | ***Friction properties of backdriven thread*** | | | | |
| 15 | Coefficient of friction between backdriven screw threads | **0.1** | | mutbd | |
| 16 | Actual Beta | **1.09** | | betabd | |
| 17 | Actual screwthread efficiency (Slocum PMD page 709 Eq. 10.8.18) | **72%** | | etabd | |
| 18 | Reference: efficiency for lowering a load (>100% if backdriveable) | **157%** | | etaLL | |
| 19 | Backdriveable? | **YES** | | | |
| 20 | ***Resulting torque generated that gets applied to piston rod thread*** | **12.64** | | Torquepr | N-mm |

The output of the first stage is the torque generated by the backdriven thread that will be applied to the second stage: the driving of the leadscrew thread either through a spline connection (the fifth embodiment) or via the modified drive tube being rotated, where the leadscrew still must slide through a spline that keeps the leadscrew from rotating.

*Stage 2 inputs and calculations*

| | A | B | C | D | E |
|---|---|---|---|---|---|
| 21 | **Stage 2: Torque generated is input to actuate actuate threaded piston rod** | | | | |
| 22 | **Thurst surface between rotating drive thread and housing (for Petitioner's modifed 5th embodiement, not present in 5th)** | | | | |
| 23 | Outside Diameter | **9.4** | | ODpr | mm |
| 24 | Inside Diameter | **5.7** | | IDpr | mm |
| 25 | Average diameter for torque calculation | **7.70** | | Dtbavg | mm |
| 26 | **Non-circular piston rod sliding drive spline (for 5th embodiement, not present in modified 5th)** | | | | |
| 27 | % reduction in root diameter to form flats | **20%** | | wof | |
| 28 | Width of flat | **1.98** | | wofmm | |
| 29 | Distance between flats | **2.64** | | Dfpr | mm |
| 30 | Force couple magnitude | **6.38** | | Fcspline | |
| 31 | Coefficient of friction of between spline components | **0.1** | | muspline | |
| 32 | Drag force from the force couple | **1.28** | | Fdragspline | |
| 33 | **Piston Rod Thread** | | | | |
| 34 | Pitch diameter | **3.9** | | Dppr | mm |
| 35 | Root diameter | **3.3** | | Drpr | mm |
| 36 | Lead (distance traveled with one complete rotation) | **3.98** | | Leadpr | mm |
| 37 | Reference: Helix angle (degrees, radians) | **17.9** | **0.313** | | |
| 38 | Flank angle alpha, cos(alpha) | **6** | **0.995** | cosalphapr | degrees |
| 39 | ***Friction properties*** | | | | |
| 40 | Coefficient of friction between moving thrust surfaces (if present, else enter 0) | **0.1** | | mutbpr | |
| 41 | Coefficient of friction of piston rod screw threads | **0.1** | | mutpr | |
| 42 | Actual Beta | **0.98** | | betapr | |
| 43 | Actual screwthread efficiency | **74%** | | etapr | |
| 44 | Backdriveable? | **YES** | | | |
| 45 | **Resulting ampoule piston force** | | | | |
| 46 | *With spline and without rotating thrust surface (e.g., Steenfeldt-Jensen 5th Embodiment)* | | | | |
| 47 | Ampoule piston force (output) | **13.4** | | Finwtb | N |
| 48 | Amplification of user thumb force (Force user pushes/resulting ampoule piston force) | **134%** | | Awtb | |
| 49 | Ideal amplification based only on thread pitch ratio | **276%** | | | |
| 50 | *With spline and rotating thrust surface (i.e., Steenfeldt-Jensen's 5th as Modified by Petitioner)* | | | | |
| 51 | Ampoule piston force (output) | **8.9** | | Fintb | N |
| 52 | Amplification of user thumb force (Force user pushes/resulting ampoule piston force) | **89%** | | Atb | |
| 53 | ***Percent increase in injection force for modified 5th embodiement*** | **51%** | | | |

The output of the second stage is the force on the ampoule from the fifth embodiment and from Petitioner's proposed modification. The result clearly shows that if a POSA were to advocate the change to the fifth embodiment suggested by the Petitioner, the pen injector would require ~50% more force to be applied by the user, which runs counter to a POSA's design objectives in this field. The second stage force results are also useful for then assessing the structural integrity of the design.

*Structural integrity results:*

| | A | B | C | D | E |
|---|---|---|---|---|---|
| 54 | **Leadscrew stresses and buckling load** | | | | |
| 55 | Length | **30.0** | | Lpr | |
| 56 | Material | **Delrin** | | | |
| 57 | Young's Modulus | **2800** | | Epr | MPa |
| 58 | Yield stress | **69** | | sigmaxpr | MPa |
| 59 | Root diameter area for full round shaft | **8.55** | | Ardpr | mm^2 |
| 60 | Root diameter area for shaft with flats | **7.66** | | Ardprwf | mm^2 |
| 61 | Itwist for full round shaft | **11.64** | | Ippr | mm^4 |
| 62 | Itwist for shaft with flats | **9.58** | | Ipprwf | mm^4 |
| 63 | Ibuckle for full round shaft | **5.82** | | Ipr | mm^4 |
| 64 | Ibuckle for shaft with flats | **3.93** | | Iprwf | mm^4 |
| 65 | ***Maximum allowable ampoule piston force to not buckle piston rod (assume fixed-free)*** | | | | |
| 66 | Full round shaft | **49** | | Finmax | N |
| 67 | Shaft with flats | **33** | | Finmaxwf | N |
| 68 | ***Load induced stresses*** | | | | |
| 69 | Full round shaft | | | | |
| 70 | Torsional shear stress | **2.1** | | taupr | MPa |
| 71 | Axial stress | **1.6** | | sigpr | MPa |
| 72 | Von Mises equivelant stress | **4.0** | | sigeqpr | MPa |
| 73 | Shaft with flats | | | | |
| 74 | Torsional shear stress | **2.6** | | tauprwf | MPa |
| 75 | Axial stress | **1.8** | | sigprwf | MPa |
| 76 | Von Mises equivelant stress | **4.8** | | sigeqprwf | MPa |
| 77 | **Safety Factors** | | | | |
| 78 | Stress Safety Factor | | | | |
| 79 | Full round shaft | **17.2** | | | |
| 80 | Shaft with flats | **14.3** | | | |
| 81 | *Buckling Load Safety Factor* | | **Buckle?** | | |
| 82 | *Shaft with flats* | **2.5** | **NO** | | |
| 83 | *Shaft without flats* | **3.6** | **NO** | | |

The Structural integrity results indicate that the elements are not in danger of failing, but the buckling safety margins are modest considering that the buckling load limit is affected by the length of the leadscrew shaft squared, and the root diameter to the fourth power. Flats machined on the leadscrew shaft reduce the buckling load capacity by 30%.

**Coefficient of friction is independent of load**

With the coefficient of friction between two materials constant, regardless of load or pressure, when a force is applied to a rotating thrust surface, the larger the diameter of the thrust surface, the lower the contact pressure will be, which decreases wear. However, the drag

torque will increase linearly with diameter of the thrust surface. This is the simple physics of how disc brakes work.

# Appendix C: Steenfeldt-Jensen ‘004 Analysis

Embodiment 5: Original and evaluation of Petitioner’s suggested design modification

# Steenfeldt-Jensen '004 Cross Section

***Figure 16 Cross Section***

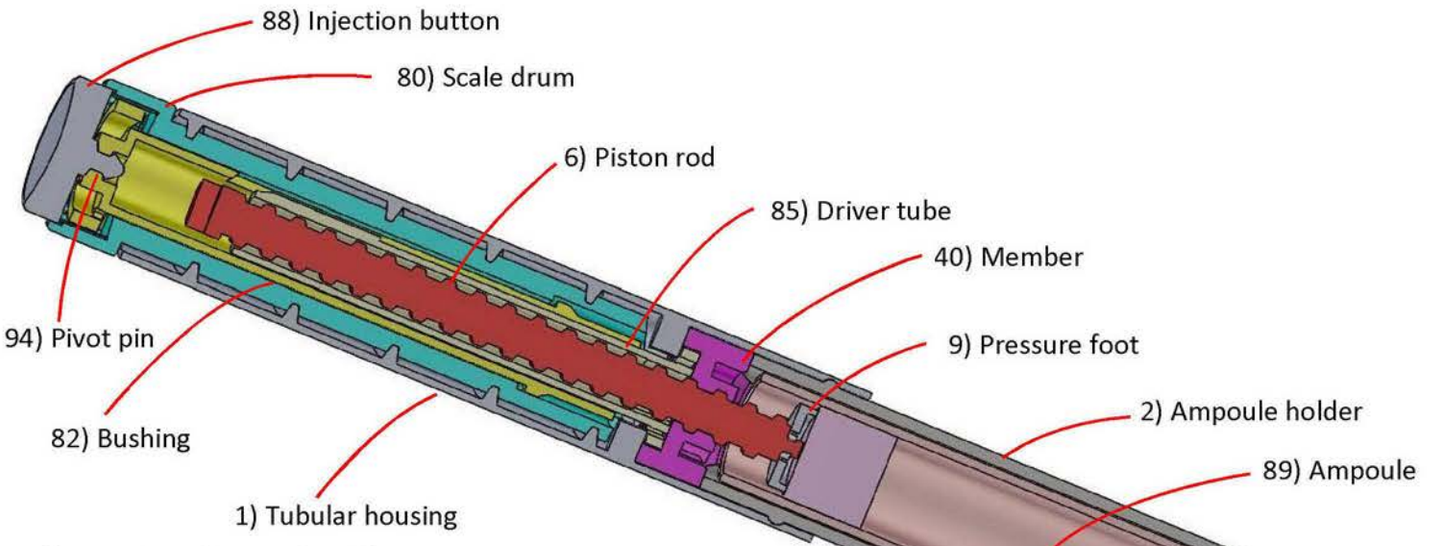
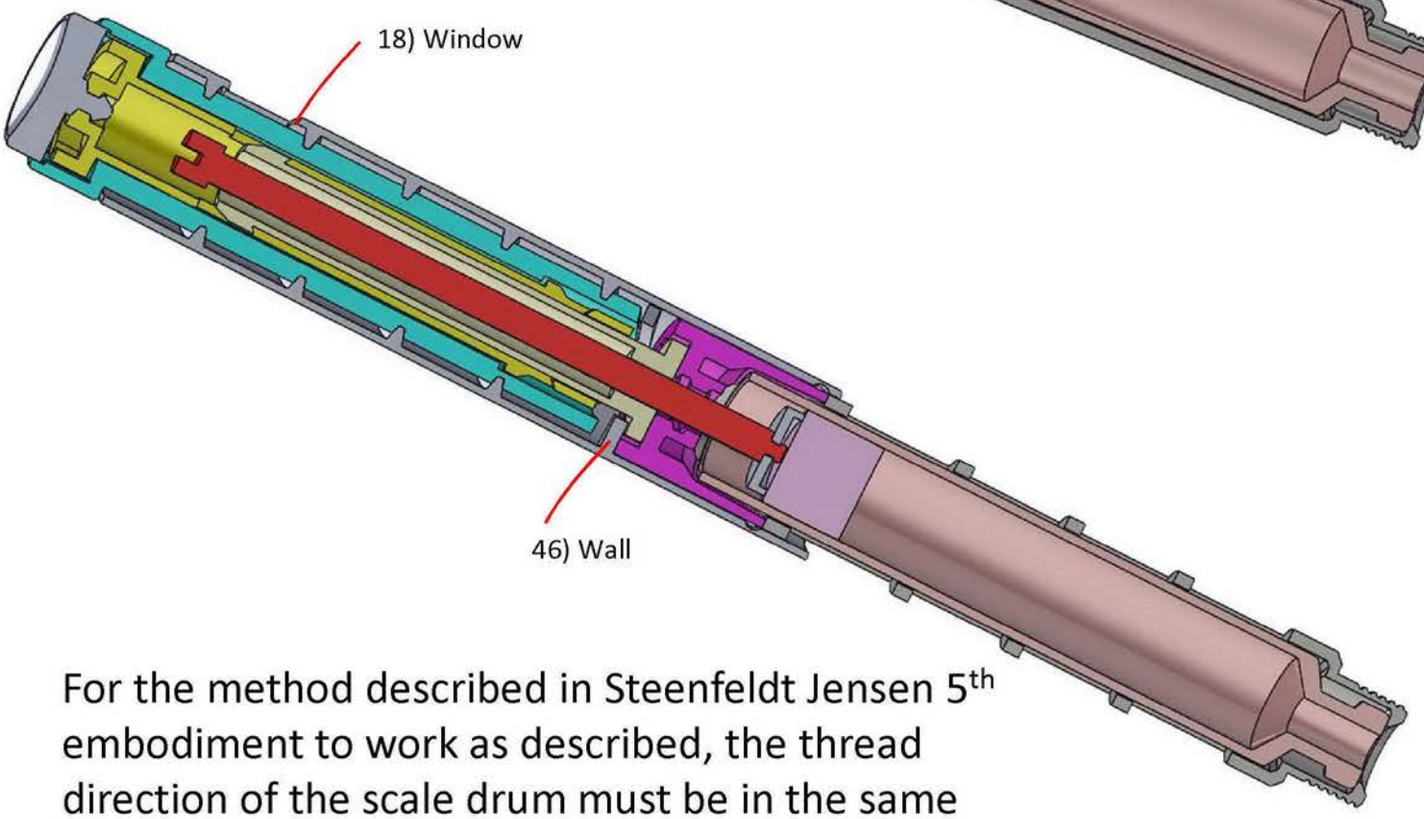
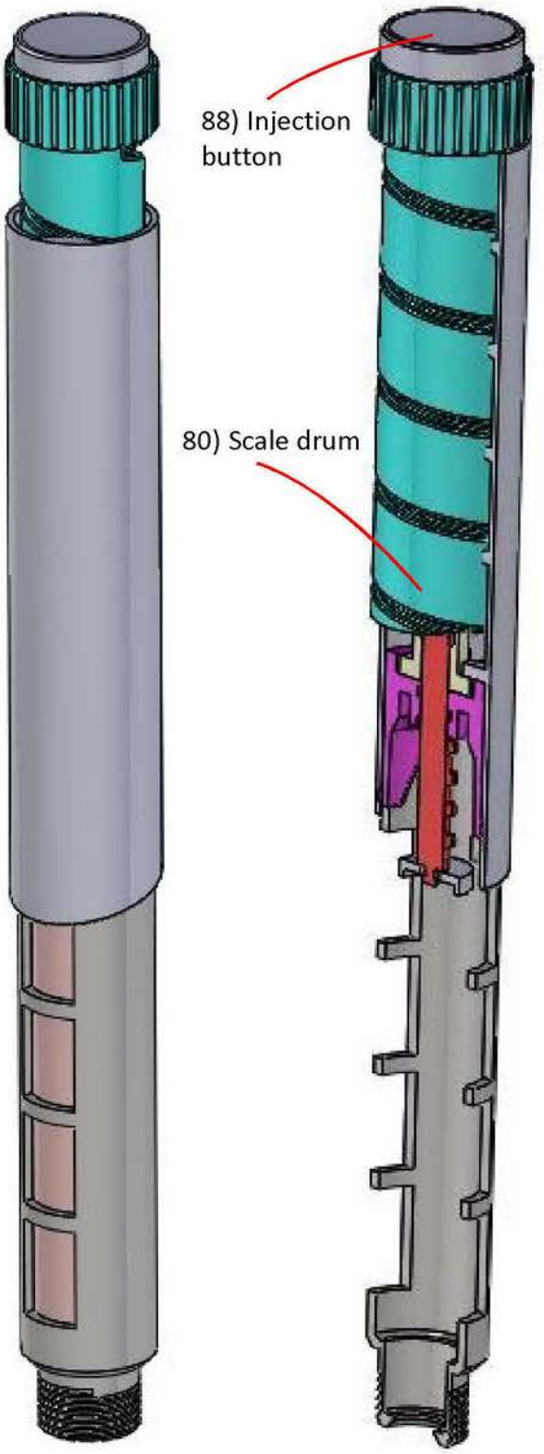



***Figure 15 Cross Section***

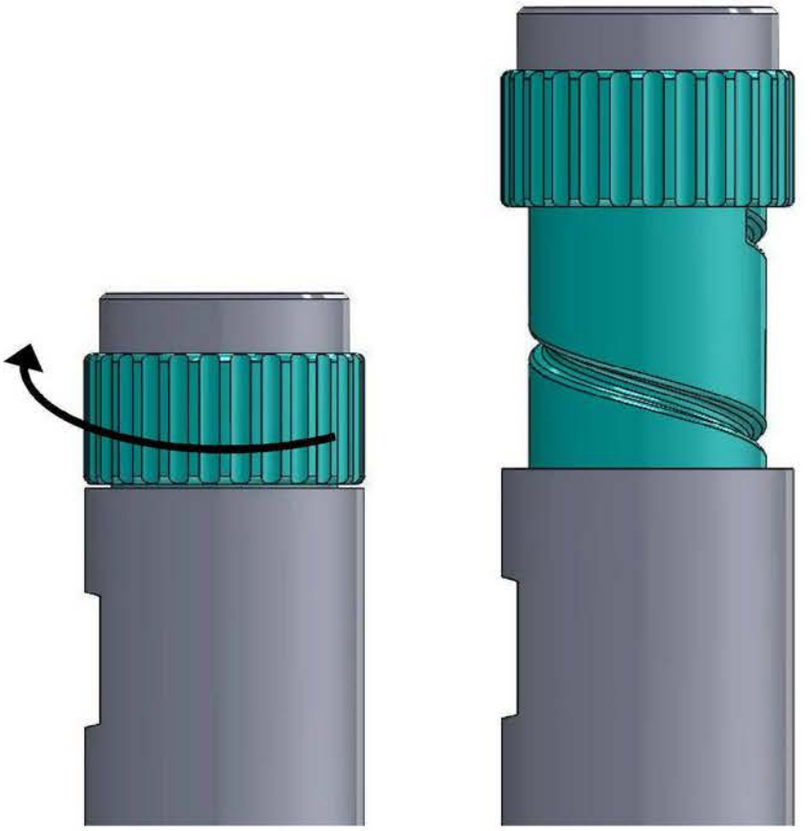



For the method described in Steenfeldt Jensen 5th embodiment to work as described, the thread direction of the scale drum must be in the same direction as the driver tube 85. So that on the down stroke (dispensing) the piston rod 6 moves towards the ampoule.

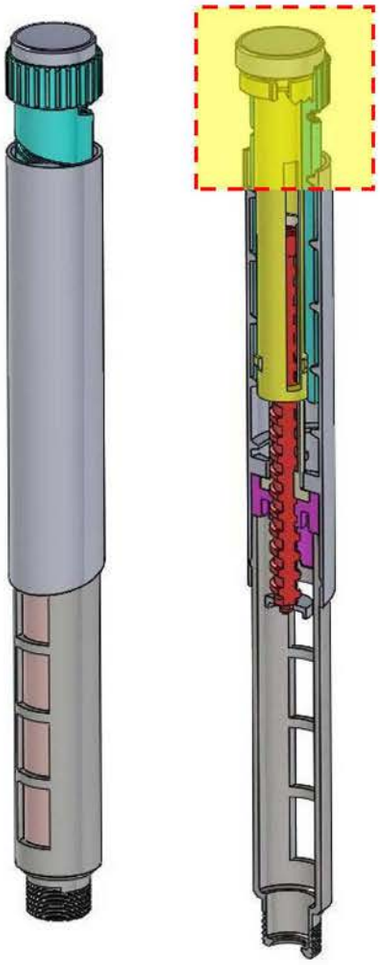
# Steenfeldt-Jensen
# Dose setting



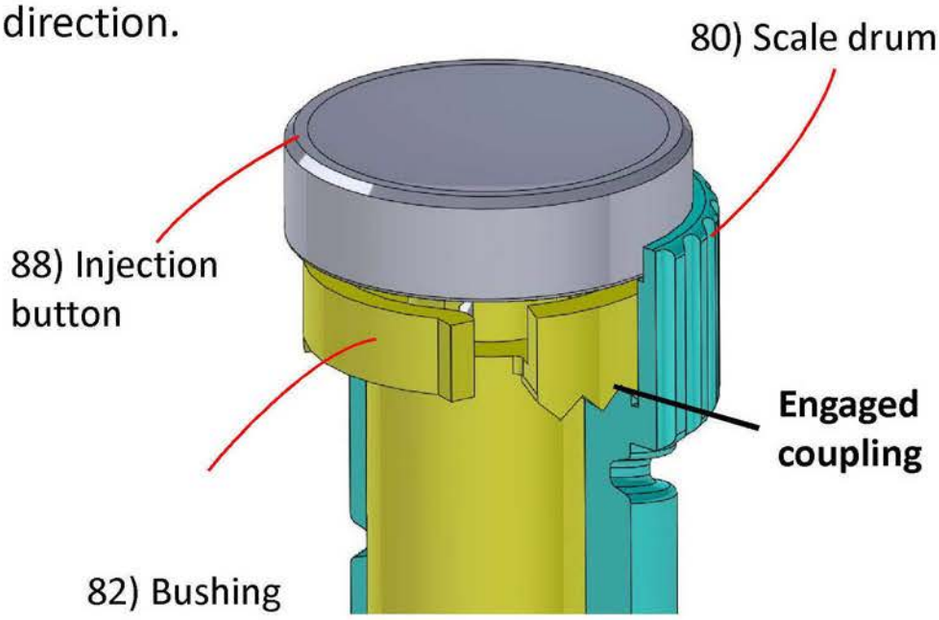

During dose setting the scale drum 80 rotates, creating a separation between the tubular housing 1 and the scale drum 80. The embodiment shown in figures 15, 16, and 17 of the '004 patent does not have a biasing element that keeps the rosette 93 (coupling) in the disengaged position.

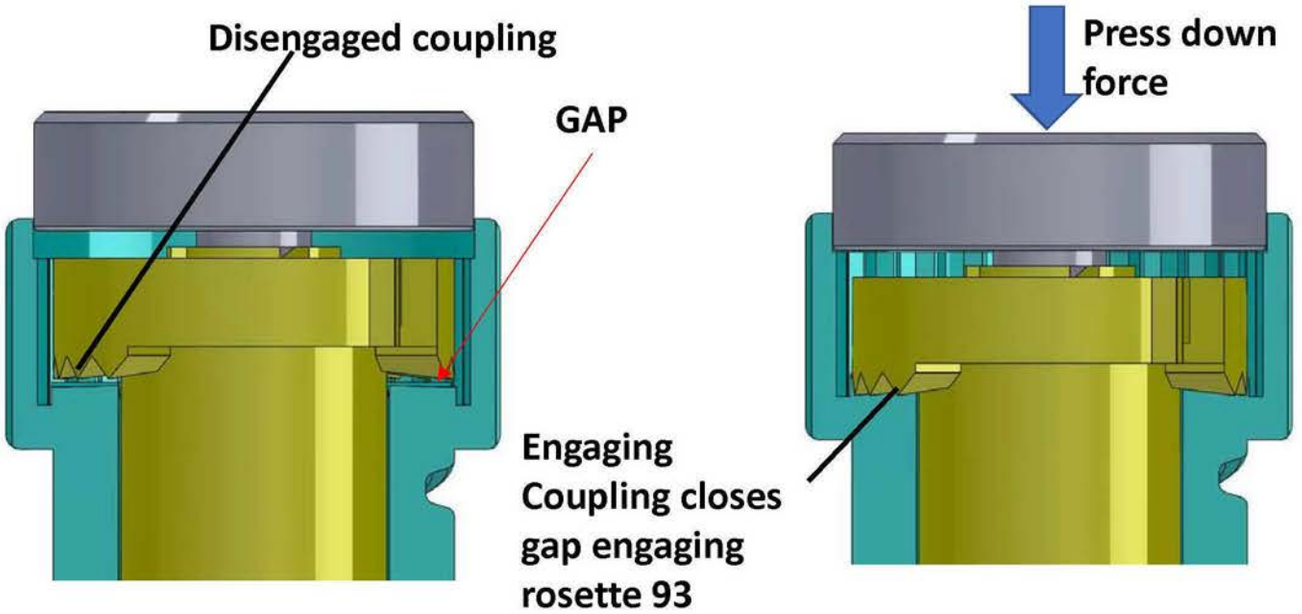


# Steenfeldt-Jensen Actuation

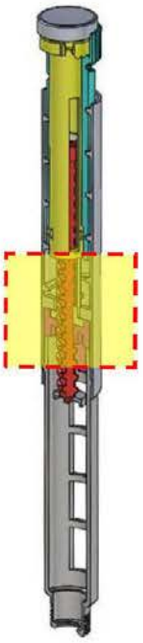


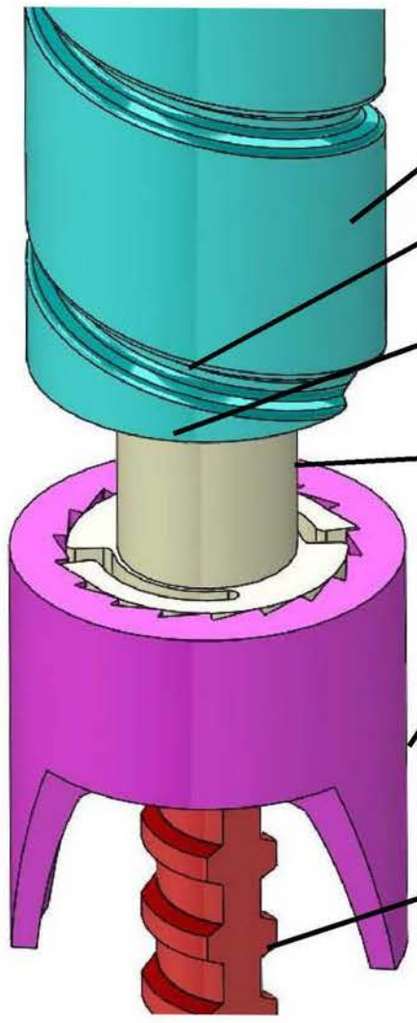
To dispense, the injection button 88 is pressed down and the rosette 93 (coupling) is engaged, at this state the rotation of the scale drum 80 will rotate the bushing 82 as well as the driver tube 85. The patent describes the engagement between the bushing 82, scale drum 80, and driver tube 85 at 11:26-33. When the driver tube 85 rotates during dispensing, the flexure arms of the driver tube 85 allow for rotation in one direction.



# Steenfeldt-Jensen Component: Assembly





80) Scale drum

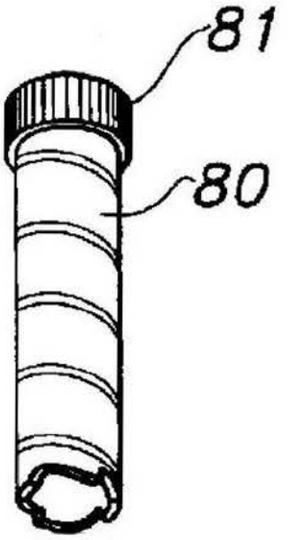
Left hand thread

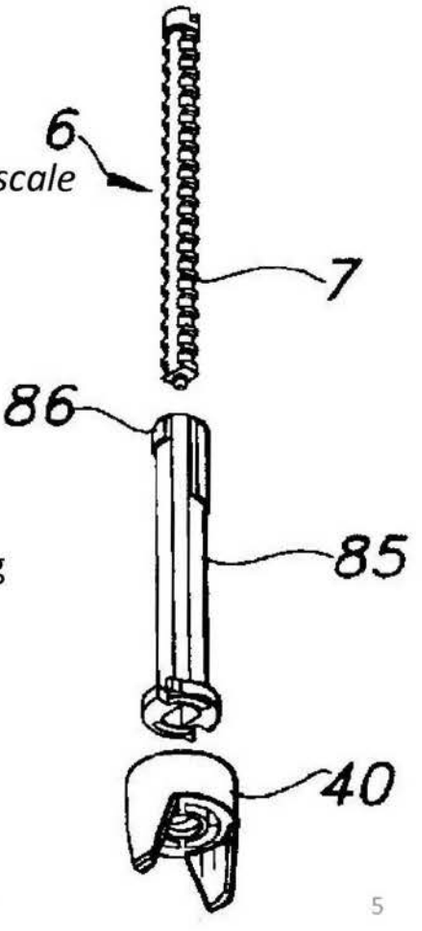
*Simplification of the scale drum end*

85) Driver tube
Slotted

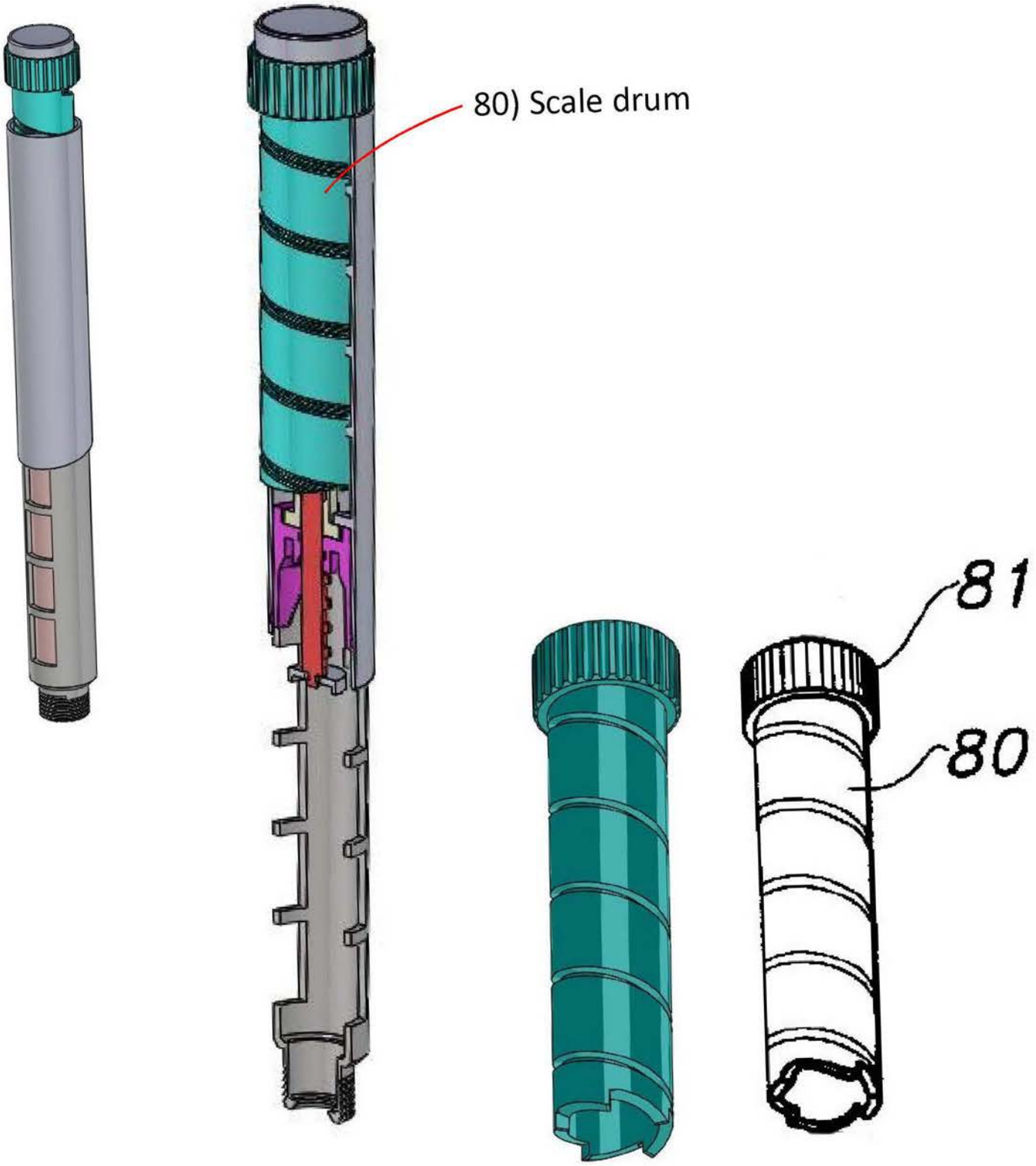
The member 40 that is fixed relative to the housing

6) Piston rod
Left hand thread

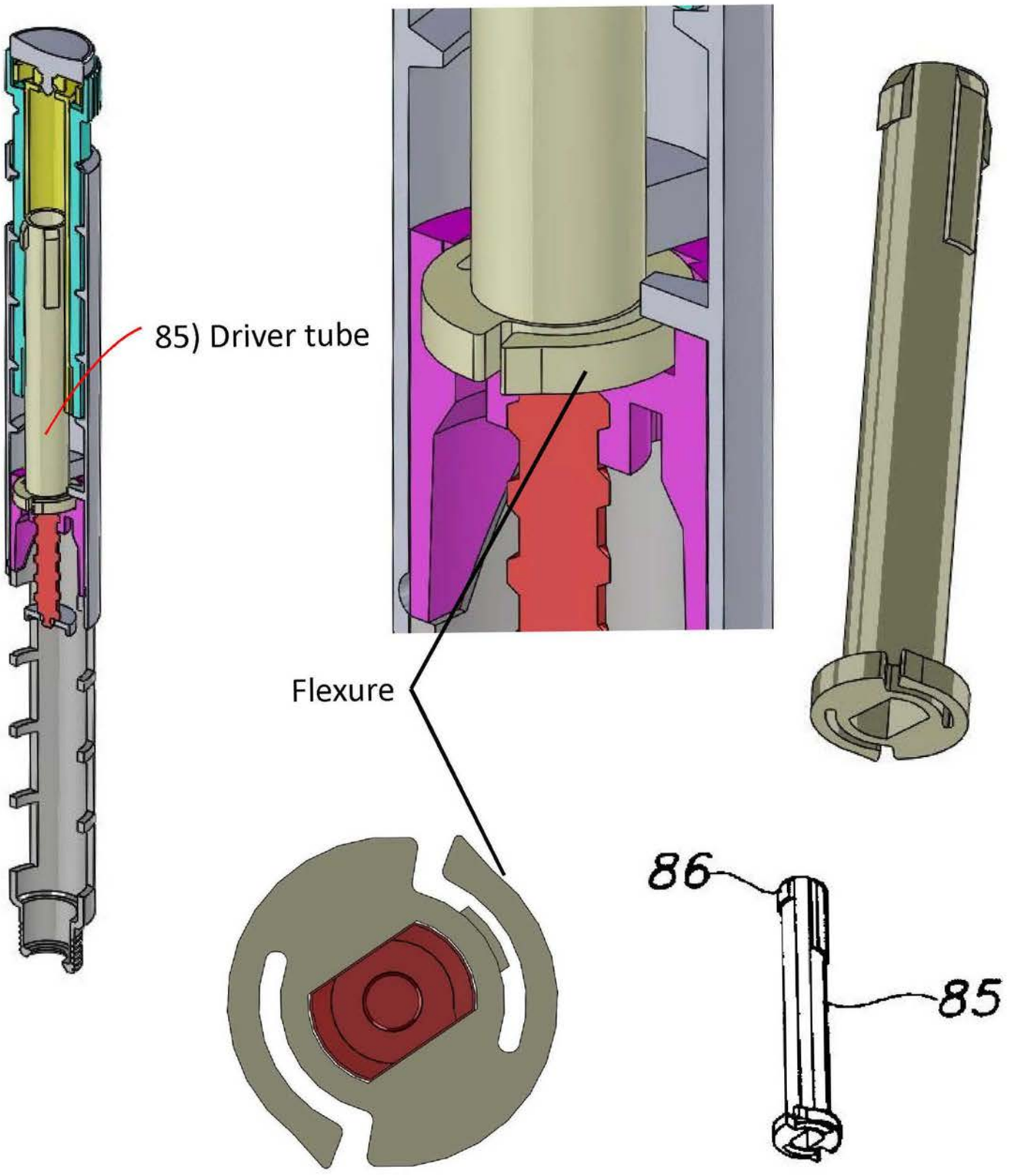


# Steenfeldt-Jensen
# Component: scale drum



# Steenfeldt-Jensen
# Component: driver tube



# Steenfeldt-Jensen '004 – 5th Embodiment Configuration

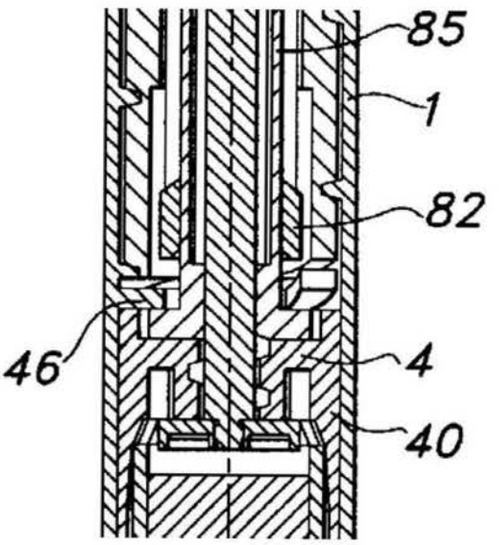
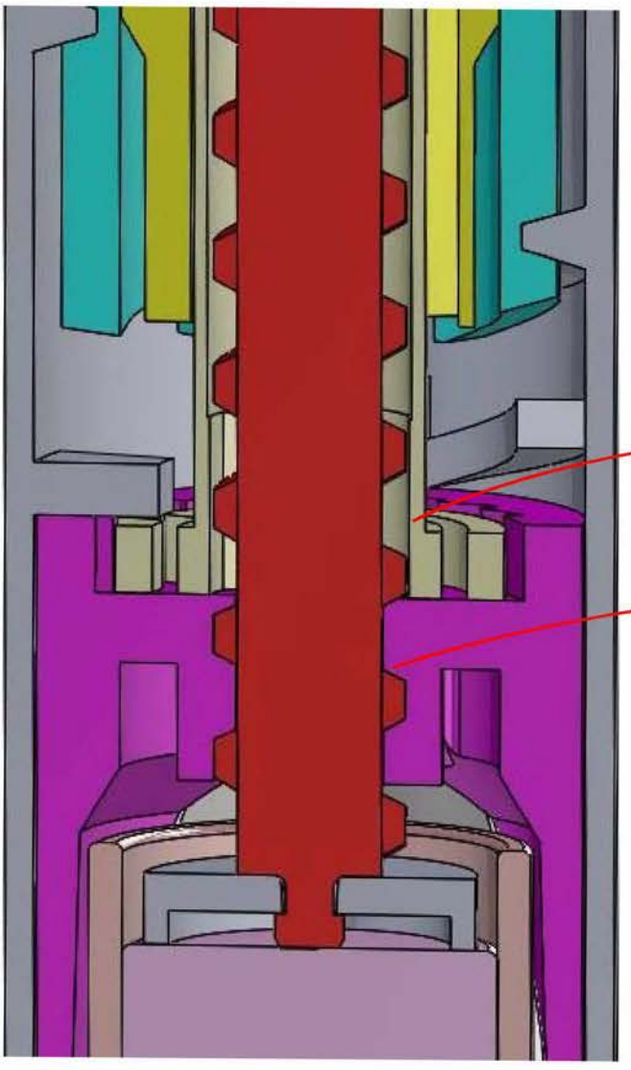
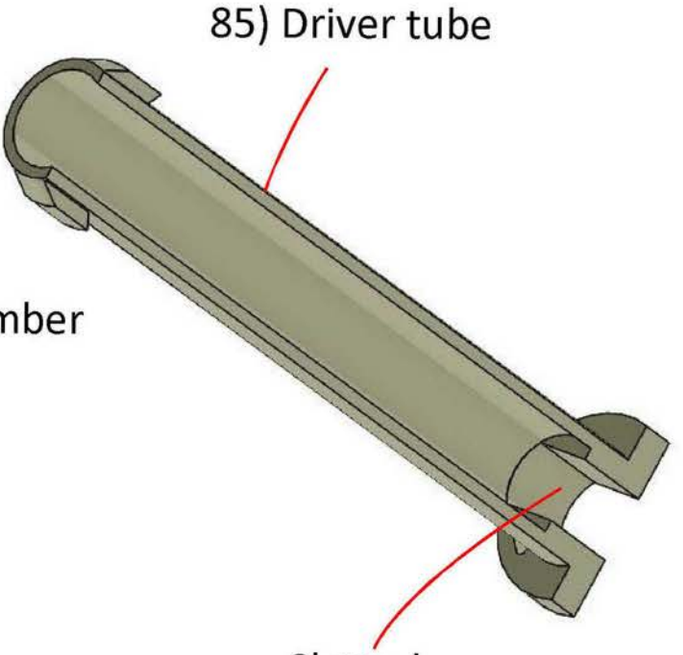
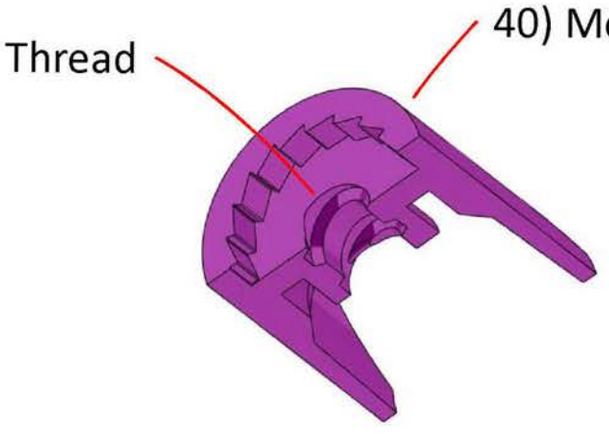


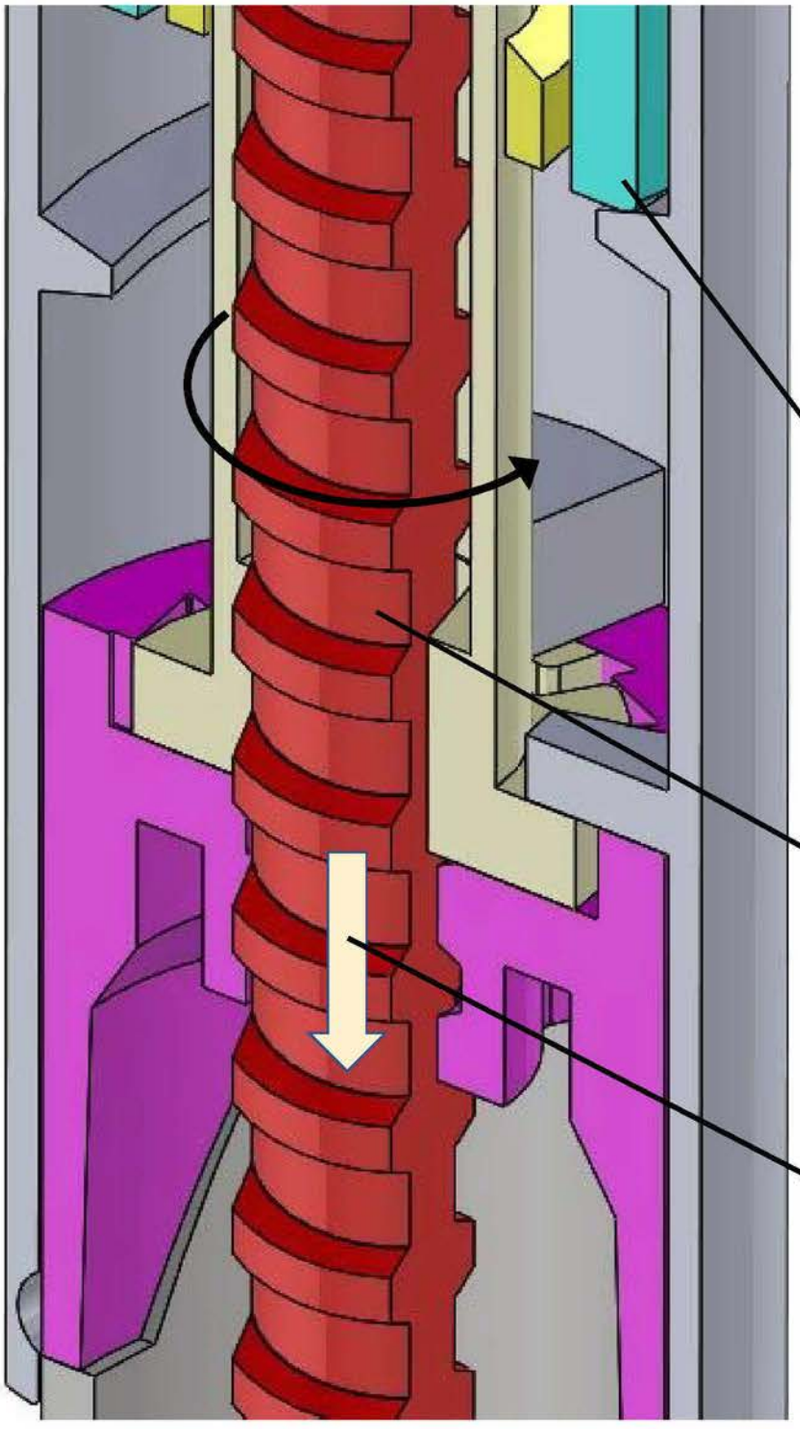

Figure 15



# Steenfeldt-Jensen
# Rotation of piston rod motion



Steenfeldt Jensen 5th embodiment thread components function as follows: Given that the rotation of scale drum 80 is left handed and the driver tube 85 is slotted, the left handed piston rod 6 thread moves downwards towards the ampoule 2 because member 40 is fixed.

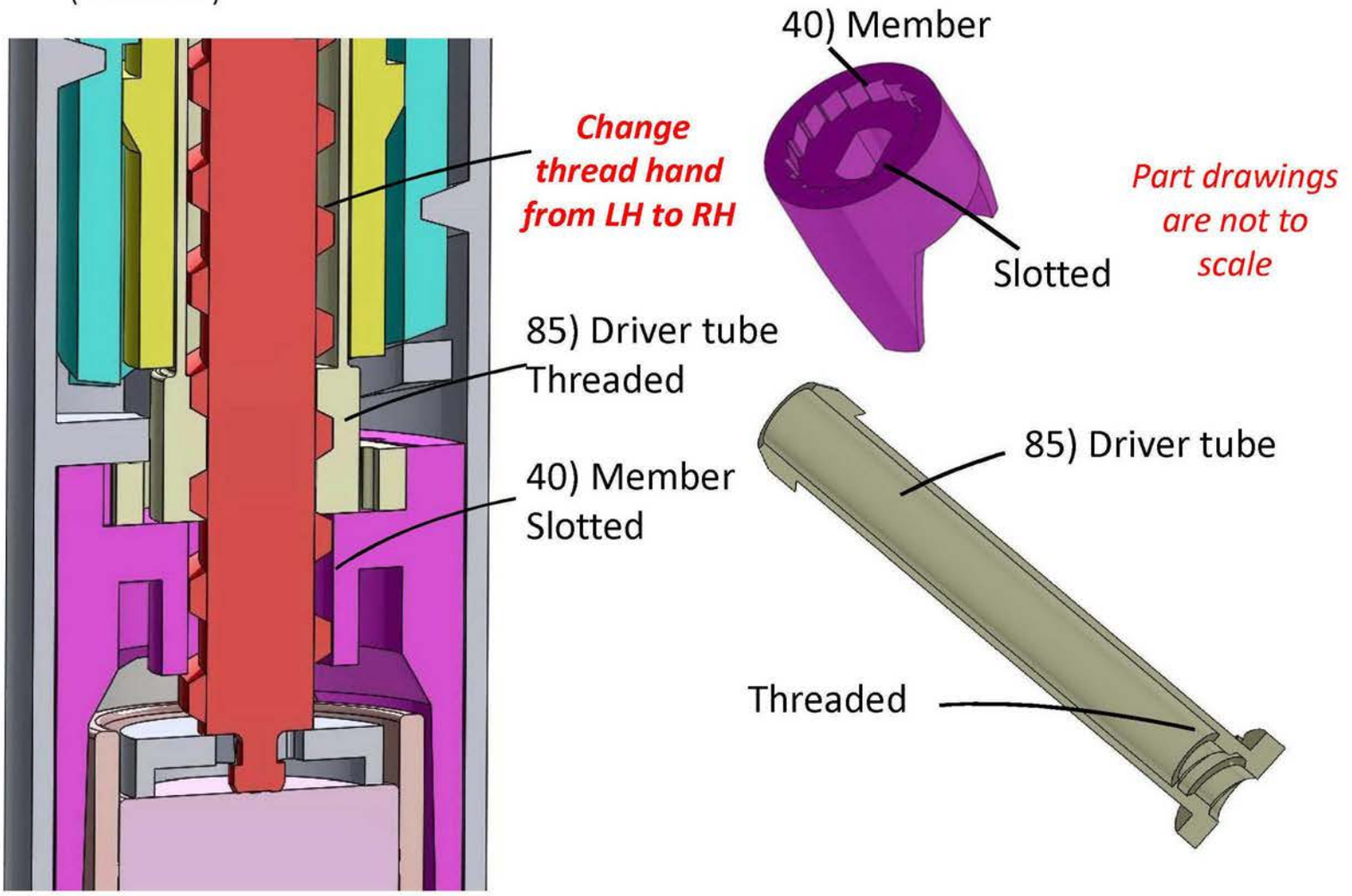
80) Scale drum

6) Piston rod is allowed to rotate and move axially

Axial direction of travel of the piston rod that is left hand threaded in the Steenfeldt Jensen 5th embodiment

# Investigation of Petitioner's modification to Steenfeldt-Jensen 5th embodiment

Steenfeldt-Jensen '004
Petitioner's modification to the 5th embodiment requires at a minimum the handedness of the thread to be reversed, else when dose knob is pushed, the piston rod will retract and no medicant will be injected whatsoever.
(minimum)



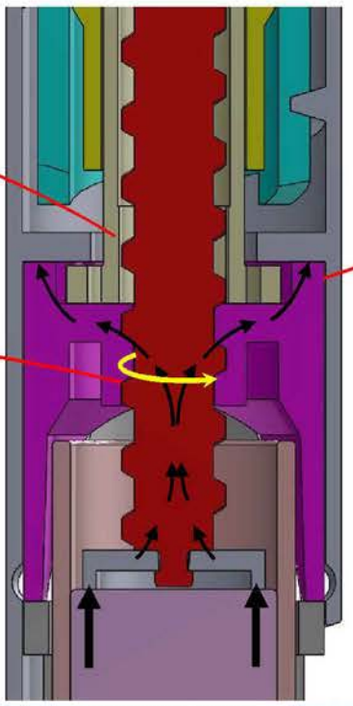

The modification proposed by the Petitioner to only slot member 40 and thread the driver would result in the motion of the left handed piston rod 6 thread to move upwards toward the injection button 88 instead of the ampoule. By making member 40 with a slot geometry the piston rod 6 will no longer rotate relative to the tubular housing 1, the piston rod 6 will only move axially. Thus, to even make the proposed modification work the thread handedness of the driver tube 85 must be changed to a right handed thread, and thus the piston rod thread direction must also be changed to a right handed thread to have the axial motion of the piston rod move towards the ampoule during the dispensing phase.

# Steenfeldt-Jensen ‘004
# Structural loop comparison

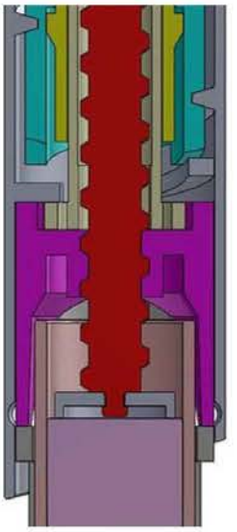
***Original Embodiment 5***

85) Driver tube slotted

40) Member threaded



40) Member rotation fixed

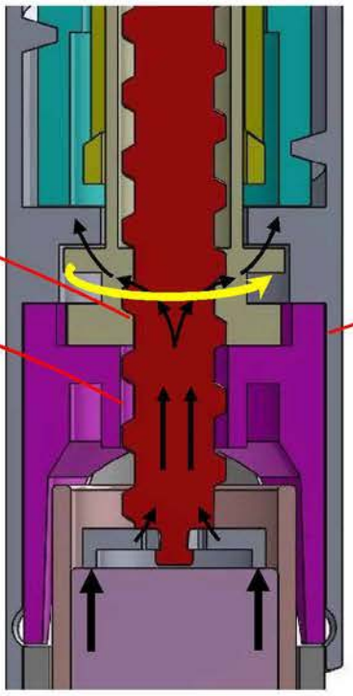


*Model strict to Fig 15*

***Petitioner’s Modified Embodiment***

85) Driver tube threaded

40) Member slotted



Yellow arrow size represents the diameter where the frictional thrust motion occurs.

40) Member rotation fixed

# Appendix D:Burroughs ‘004 Patent Analysis

Beam bending analysis and finite element analysis

# Burroughs et al '046 Cross Section

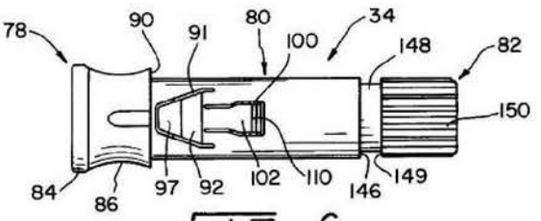



FIG. 6

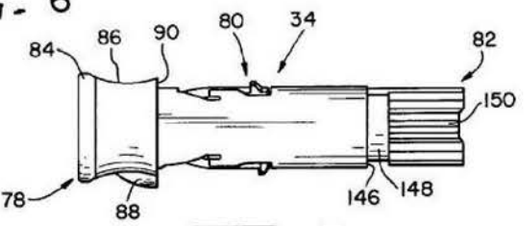



FIG. 7

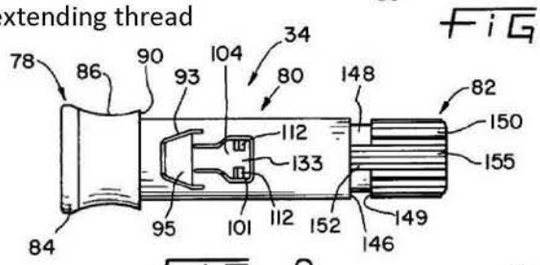



FIG. 8

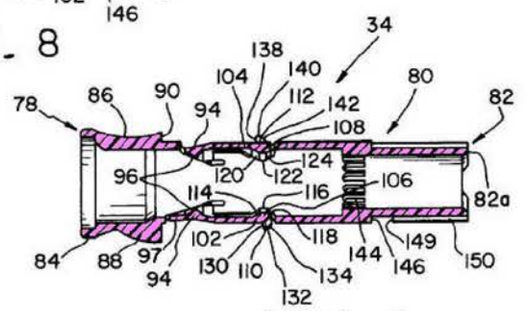
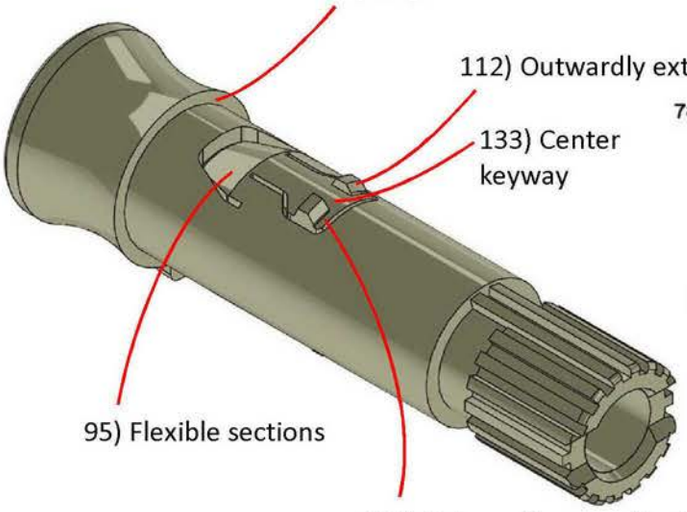
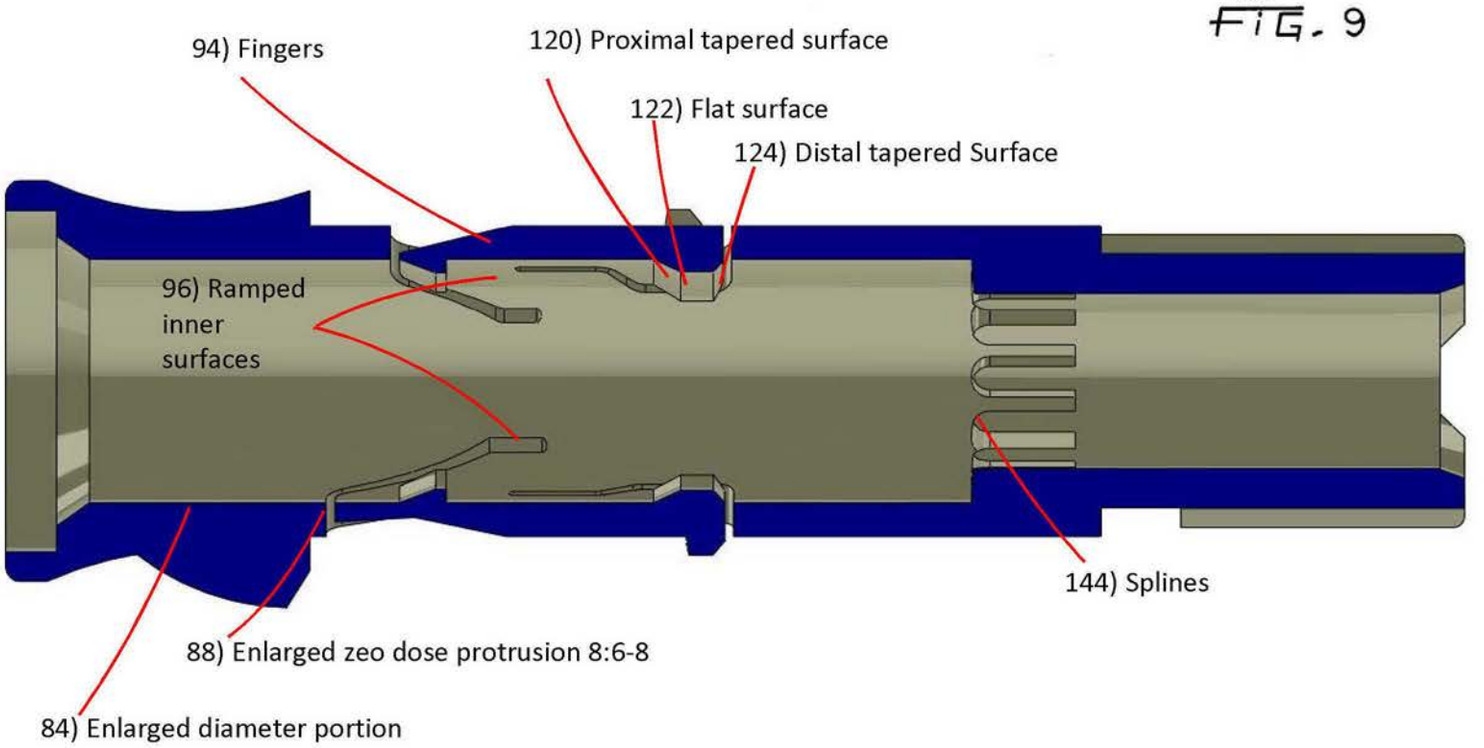
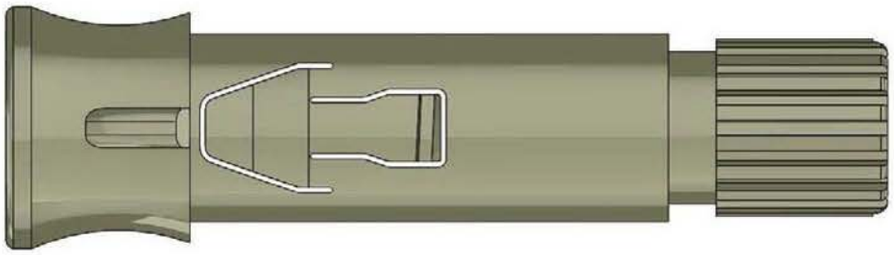



FIG. 9



# Burroughs et al ‘046 Cross Section



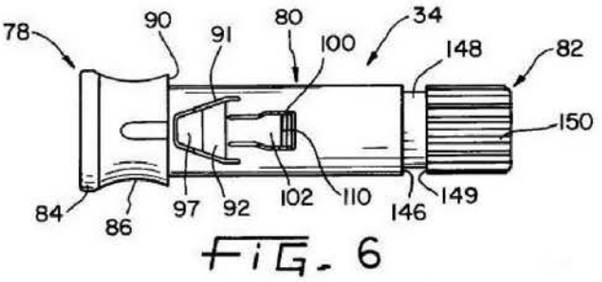
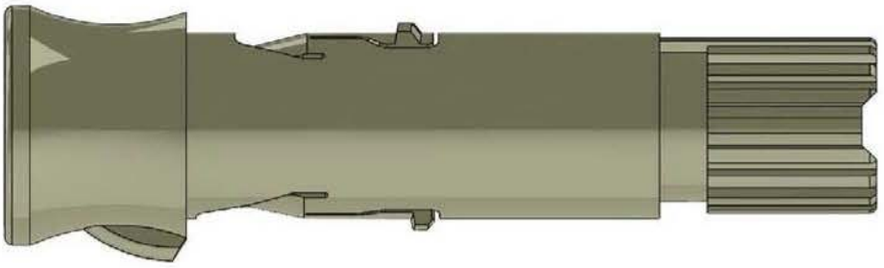



FIG. 6



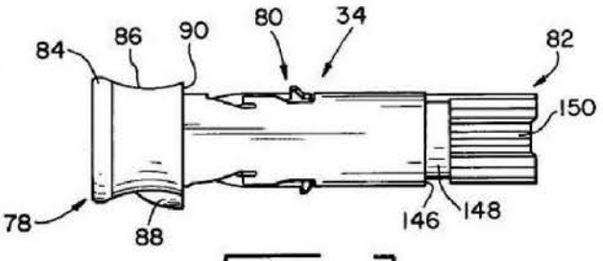
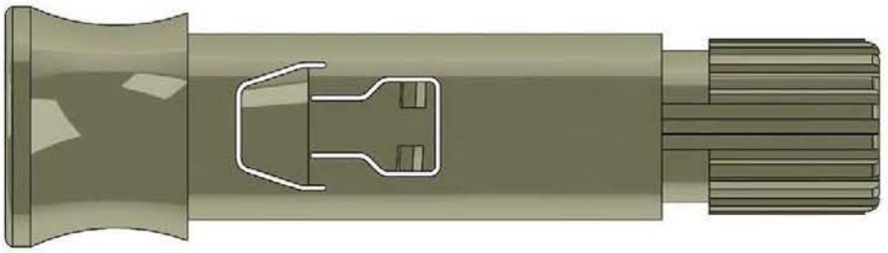



FIG. 7



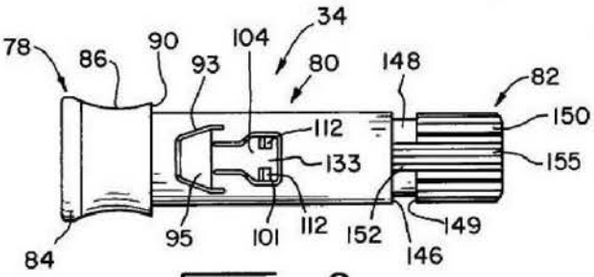
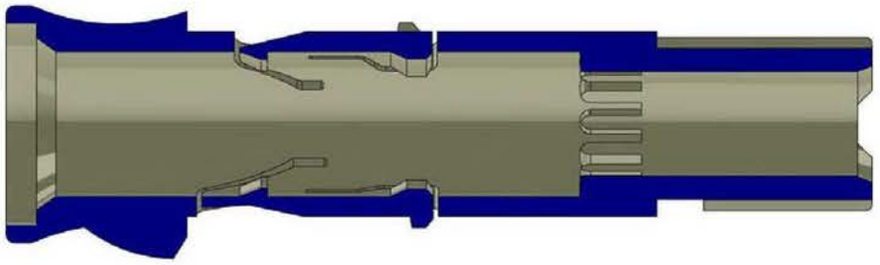



FIG. 8



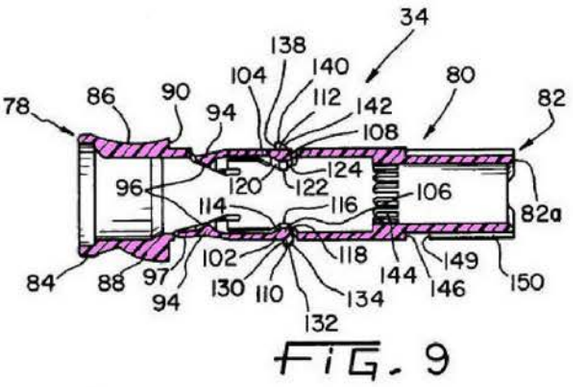
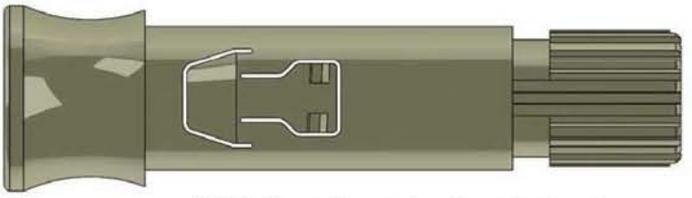
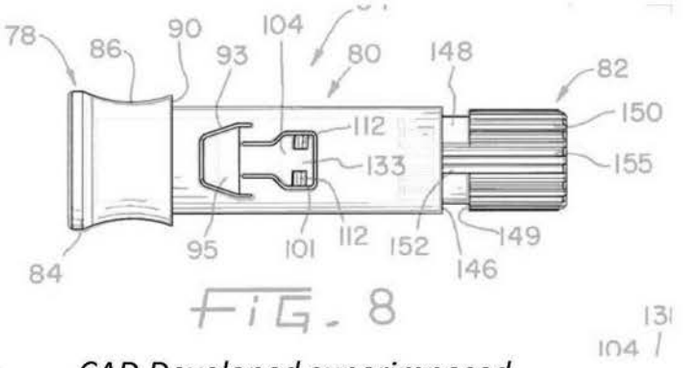



FIG. 9

# Burroughs et al '046 Beam Bending Setup

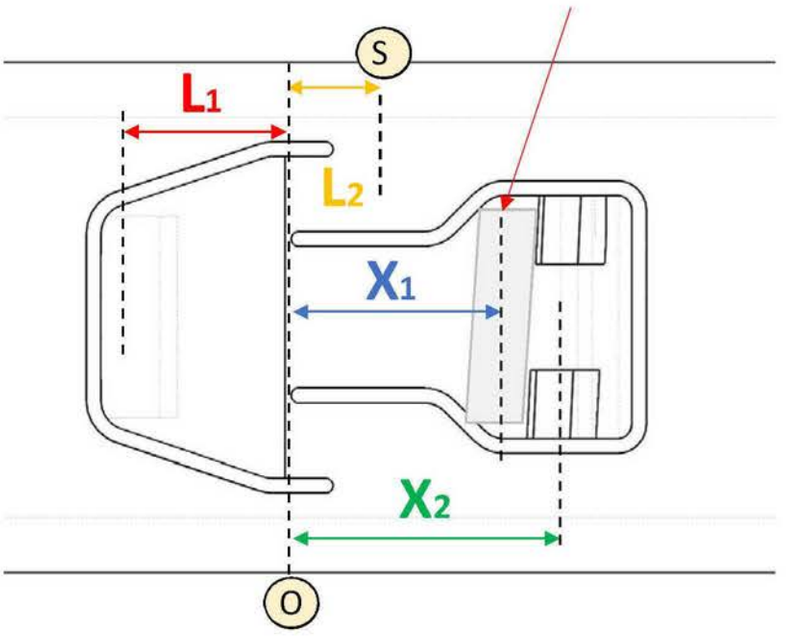


*CAD Developed using Patent Figures 6-9*



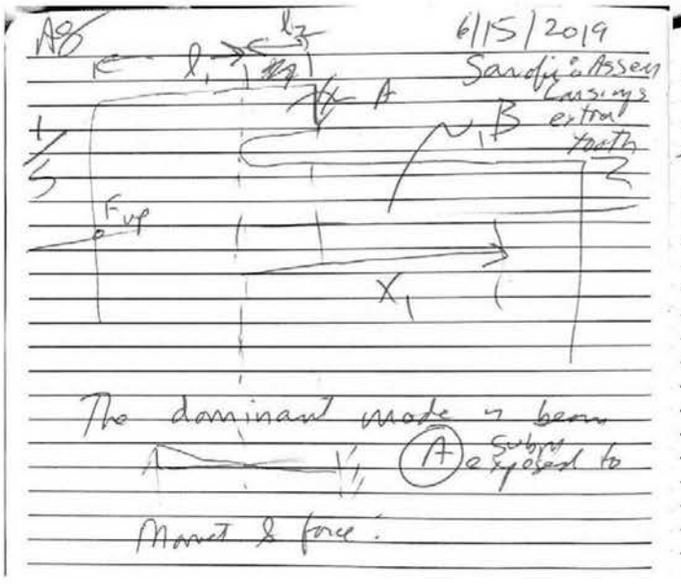

*CAD Developed superimposed with Figure 8 of Patent*

Proposed New Tooth

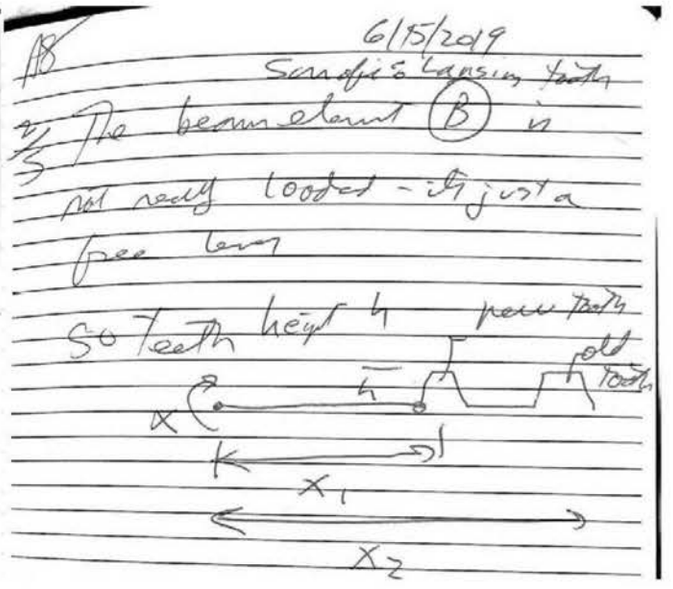



S = Support
O = Interface

*Derivation excerpt*

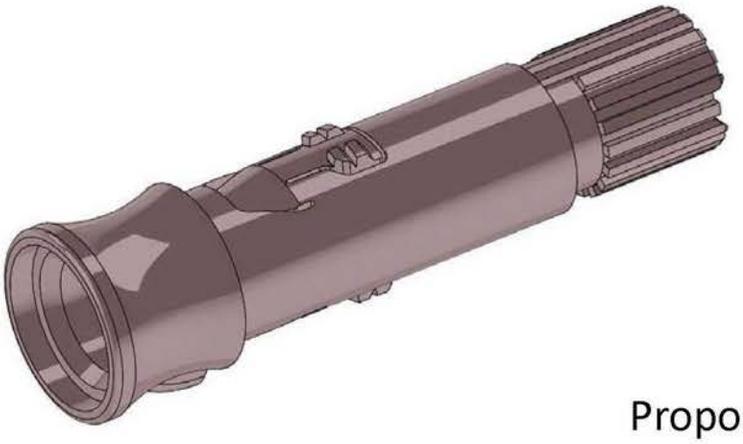



*The dominant mode is beam A exposed to moment & force.*



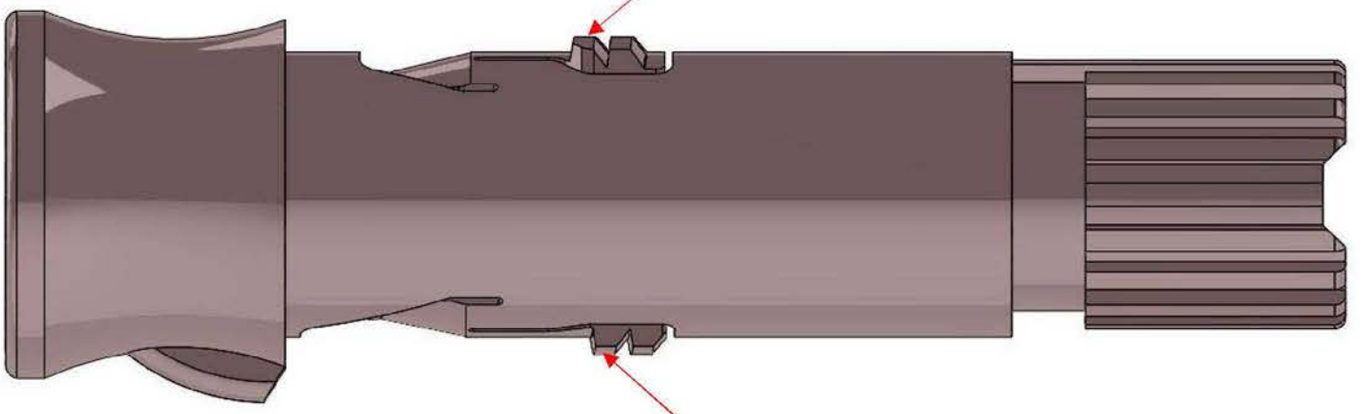

*The beam element B is not really loaded – its just a free beam. So teeth height h.*

# Burroughs et al '046 Leinsing New Tooth



**When the new tooth is added now the edge will have to deflect more below, thus there must be clearance.**

Proposed New Tooth



Proposed New Tooth

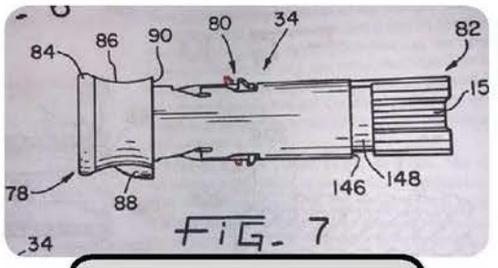
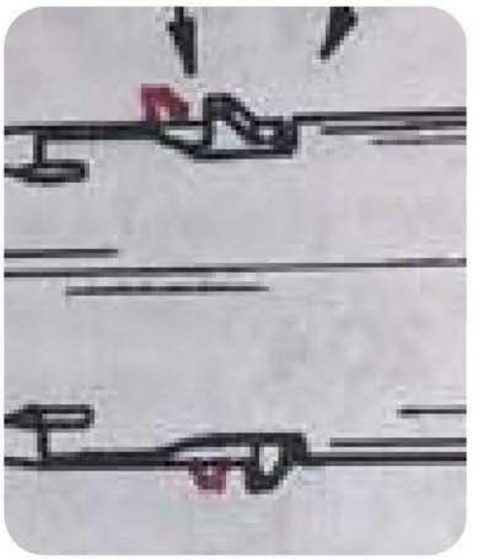


FIG. 7

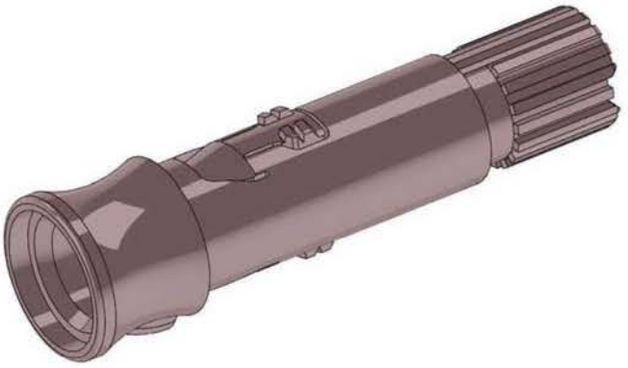
Leinsing modification

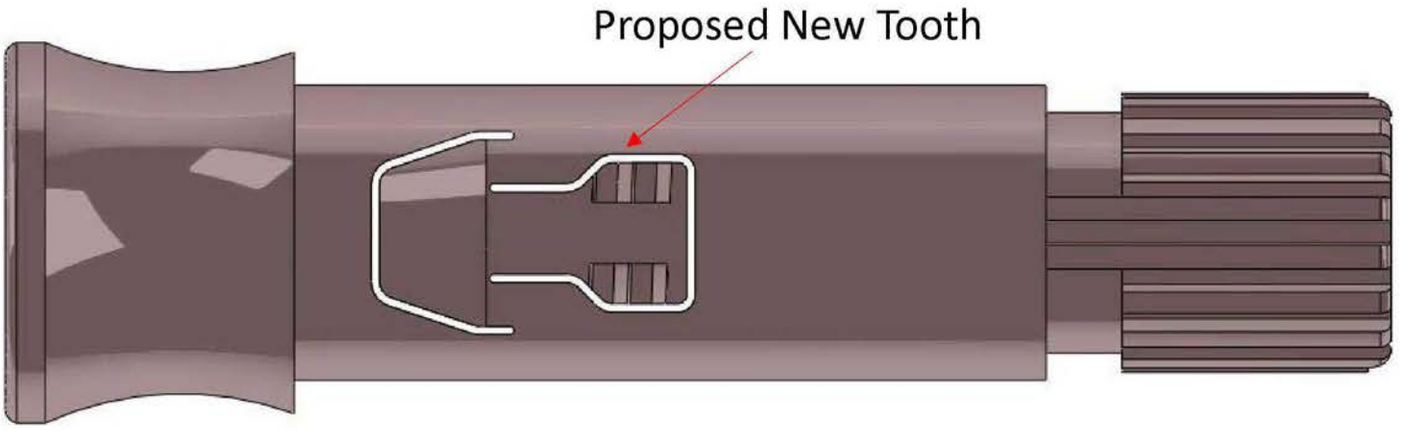


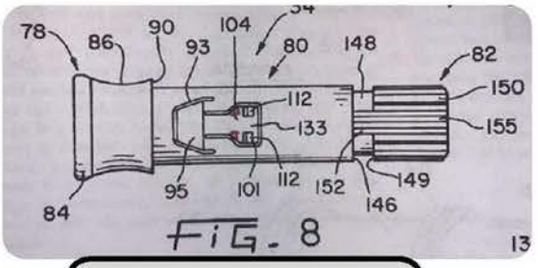


**Sanofi Exhibit 2107.381**
**Mylan v. Sanofi**
**IPR2018-01675**

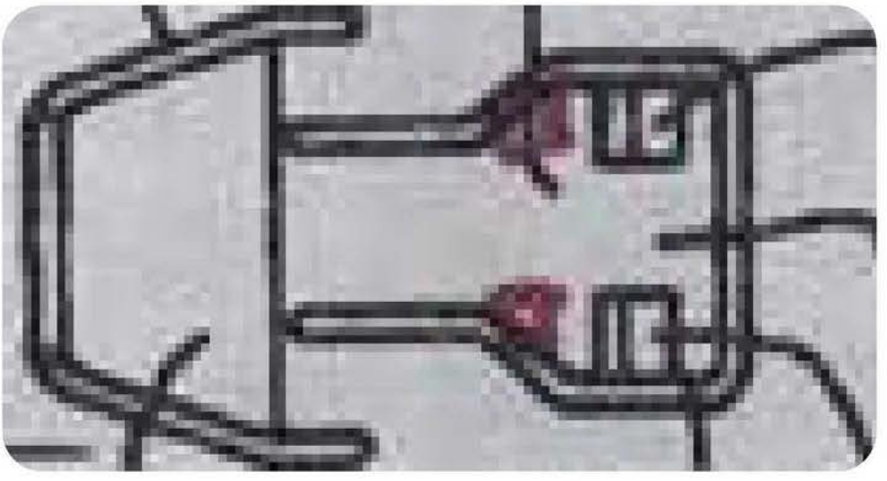
# Burroughs et al ‘046
# Leinsing New Tooth Rendering



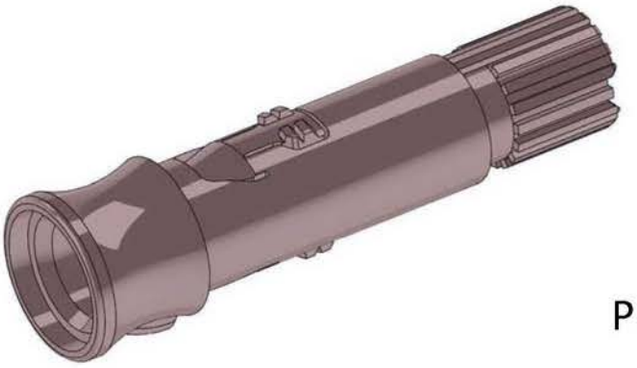


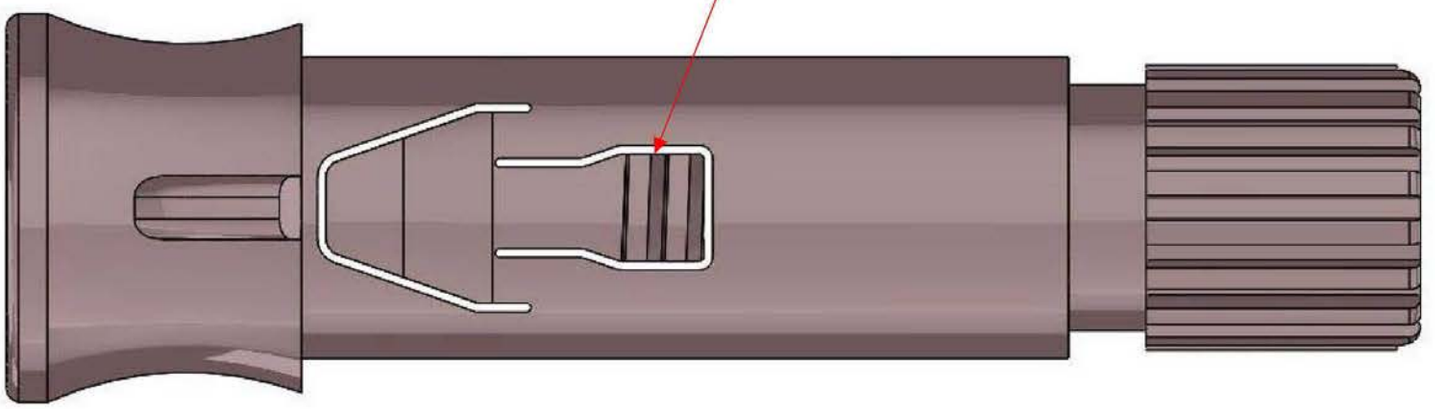

Leinsing modification

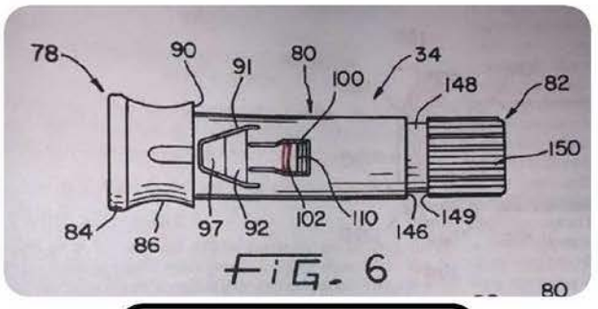


# Burroughs et al ‘046
# Leinsing New Tooth Rendering

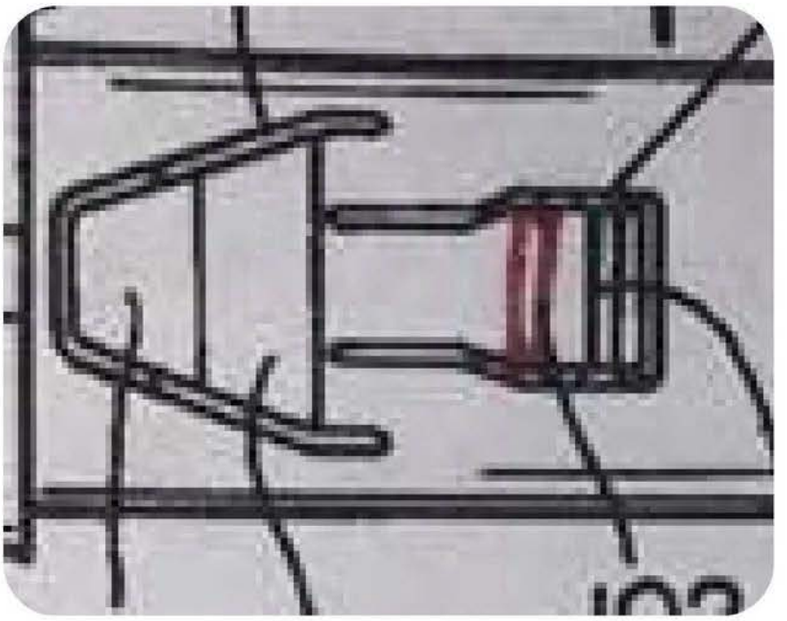


Proposed New Tooth





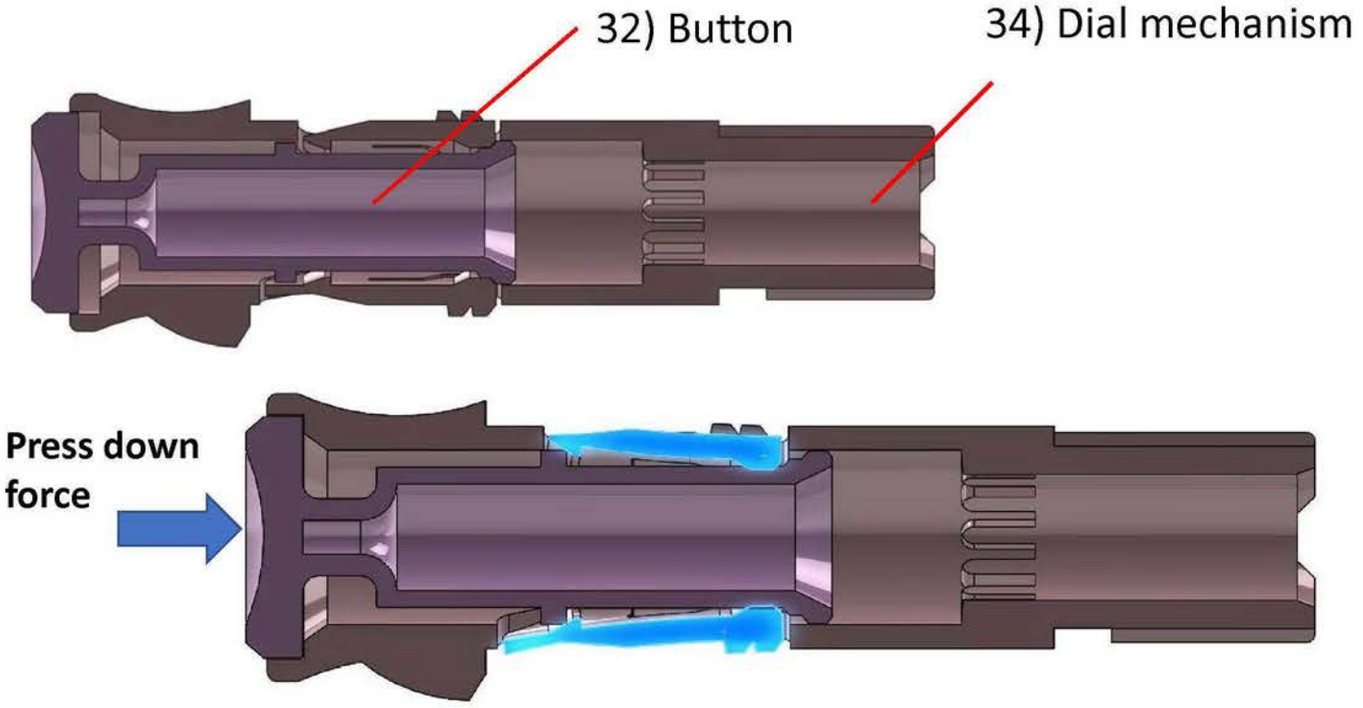

Leinsing modification





**Sanofi Exhibit 2107.383**
**Mylan v. Sanofi**
**IPR2018-01675**

# Burroughs et al '046
# Impact second tooth on button




Pressing the button allows for the double stepped distal end 52 to move out of the way in order to allow the dial tabs 102 & 104 to move when the button 32 enlarged diameter portion 54 "pushes against ramped surfaces 96" (per 8:11-18). The addition of the second tooth for the same geometry will create an interference section when the second tooth clears the thread region given that it is closer to the pivot of the flexure

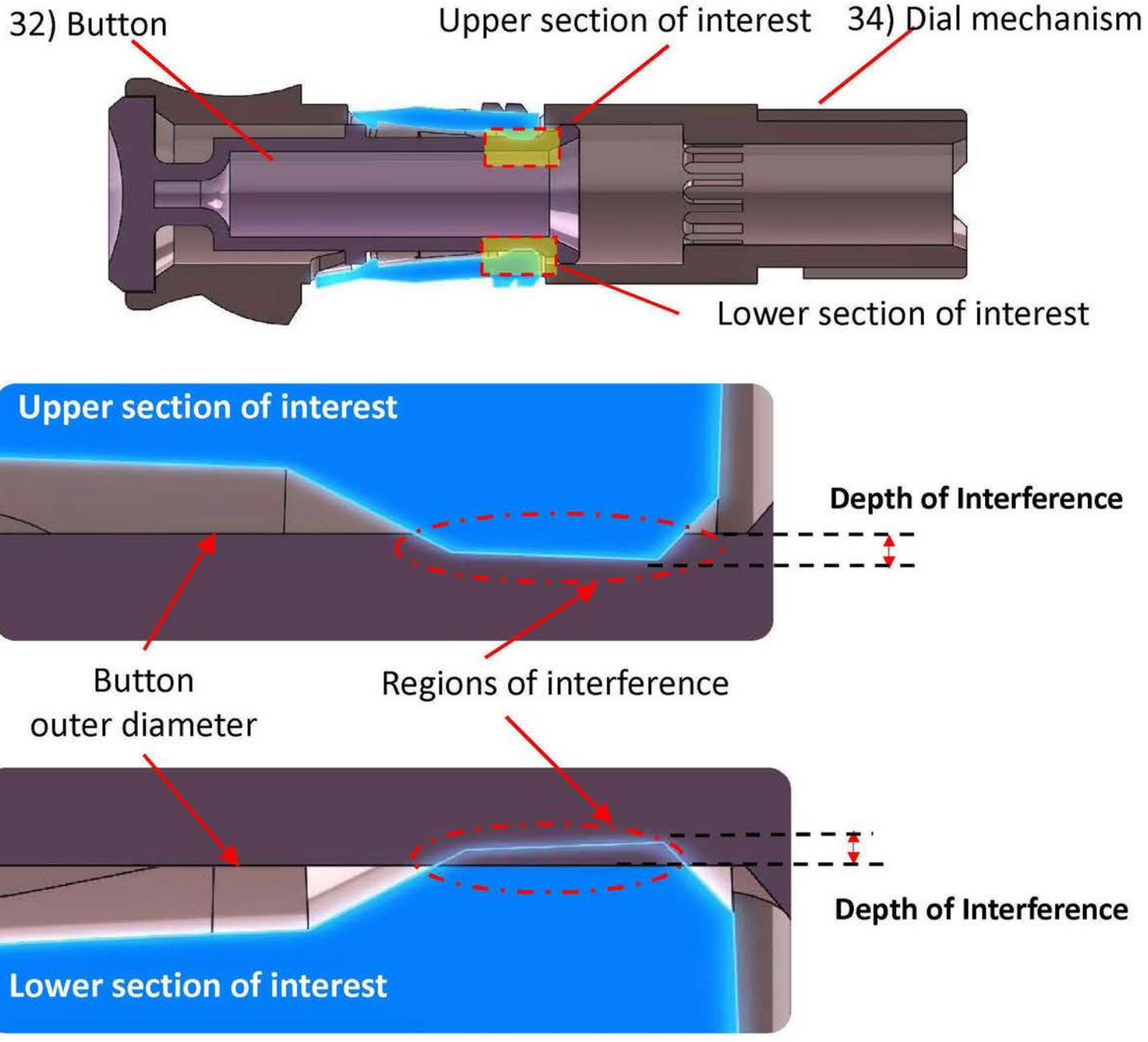
*7:47-63*

Generally U-shaped grooves **91** and **93** (FIGS. **6**, **8**) are formed in intermediate portion **80** to form a flexible sections **92** and **95**, respectively. As best shown in FIG. **9**, the proximal ends of flexible sections **92** and **95** each include fingers **94** having ramped inner surfaces **96** adapted for engagement with enlarged diameter portion **54** of button **32**. When button **32** is depressed, enlarged diameter portion **54** is also depressed and thereby pushes against ramped surfaces **96**, which in turn forces fingers **94** outward and legs **102** and **104** inward. Dial mechanism **34** is then able to

*7:47-63*

Referring to FIG. **14** and FIG. **15**, button **32** comprises a hollow cylindrical portion **48** having a proximal end **50**. Cylindrical portion **48** includes a distal end **52** in the form of a double-stepped annular bead and further includes an enlarged diameter ring **54** comprising a ledge surface **56** and an enlarged diameter flat surface **58**. The double-stepped distal end **52** includes a first step **57** and a second step **59**. As shown in FIG. **1**, first step **57** is used to prevent dial tabs **102** and **104** from collapsing inward, and second step **59** is used both to keep button **32** centered within dial mechanism **34** and also prevent button **32** from inadvertently falling or being removed from dial **34**. Proximal end **50** of button **32** further includes a finger-engageable end **68** having a recessed surface **70**. End **68** is integrally connected to hollow cylindrical portion **48** by connection portion **72** (FIG. **15**). In the exemplary embodiment, end **68** protrudes 1.5 millimeters beyond the end of dial mechanism **34** to enable the user to easily depress the button during injection.

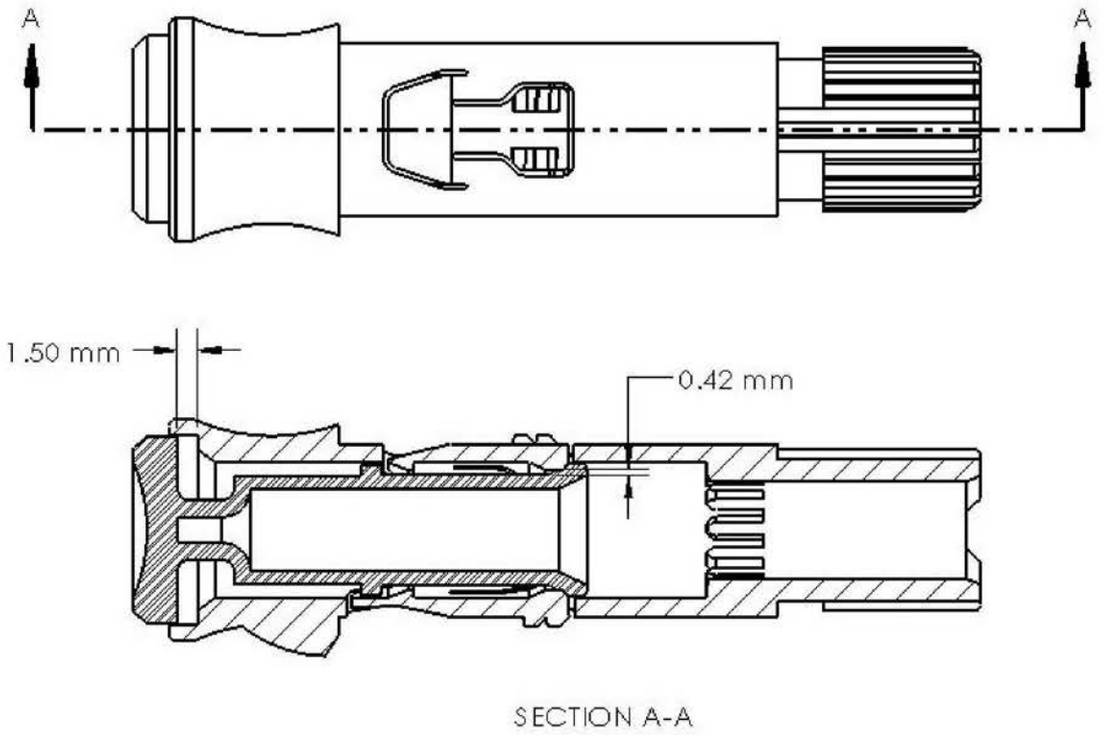
# Burroughs et al '046
# Impact second tooth on button




Note: Images show representation of the interference, do not scale. Refer to the finite element analysis (FEA) section below to determine the magnitude of the interference which is on the order of 0.14 mm at the points of interest. See FEA section.

# Burroughs et al '046
# Beam Bending Setup for sizing

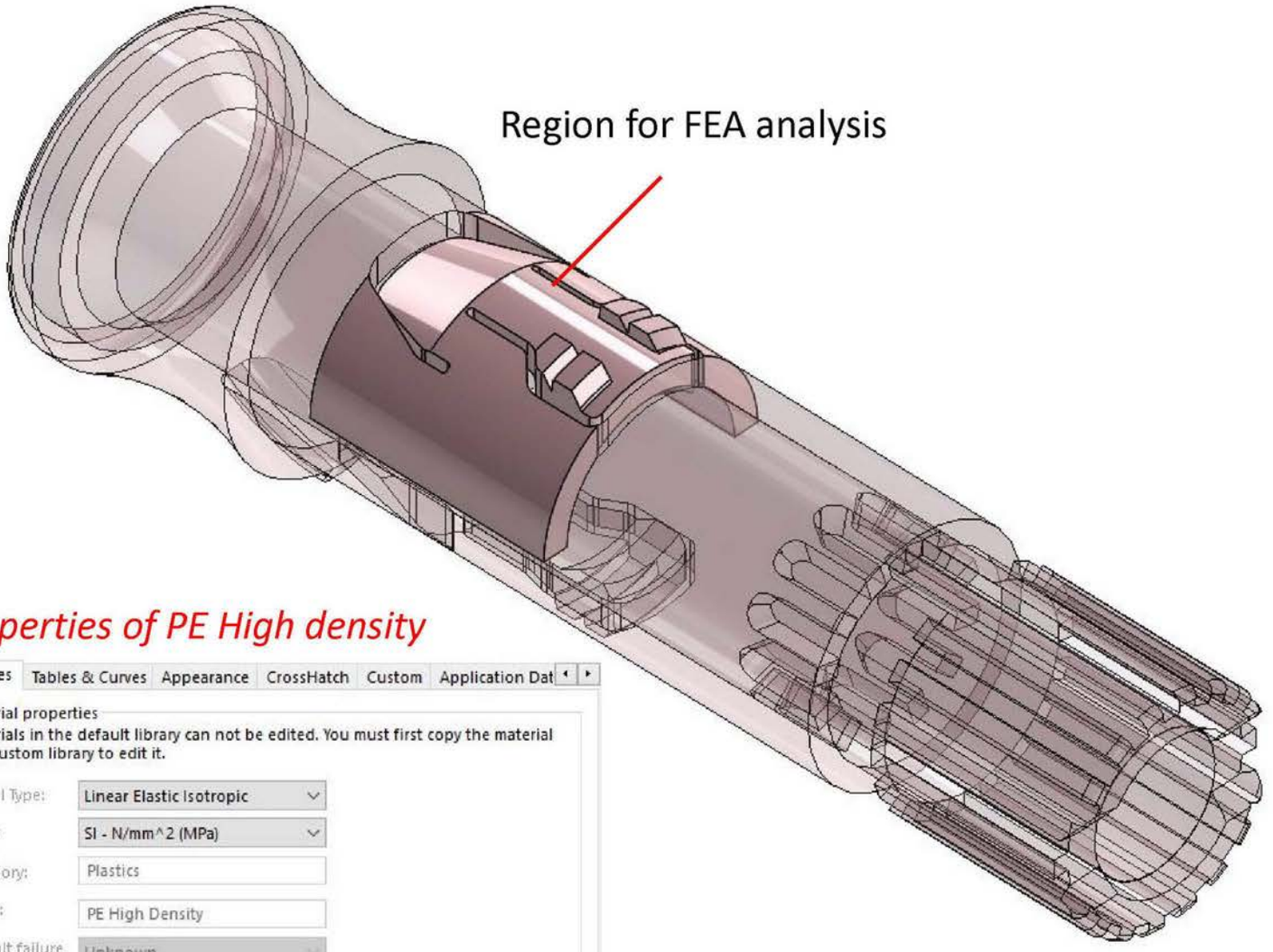
Burroughs provides the dimension of 1.5 mm to enable the user to depress the button 7:62-64. Using the reference value provided by Burroughs the order of magnitude size of the flexure can be established.




*7:42-64*

used both to keep button **32** centered within dial mechanism **34** and also prevent button **32** from inadvertently falling or being removed from dial **34**. Proximal end **50** of button **32** further includes a finger-engageable end **68** having a recessed surface **70**. End **68** is integrally connected to hollow cylindrical portion **48** by connection portion **72** (FIG. **15**). In the exemplary embodiment, end **68** protrudes 1.5 millimeters beyond the end of dial mechanism **34** to enable the user to easily depress the button during injection.

# Burroughs et al ‘046
# FEA model section & materials




*Properties of PE High density*

Properties | Tables & Curves | Appearance | CrossHatch | Custom | Application Dat

Material properties

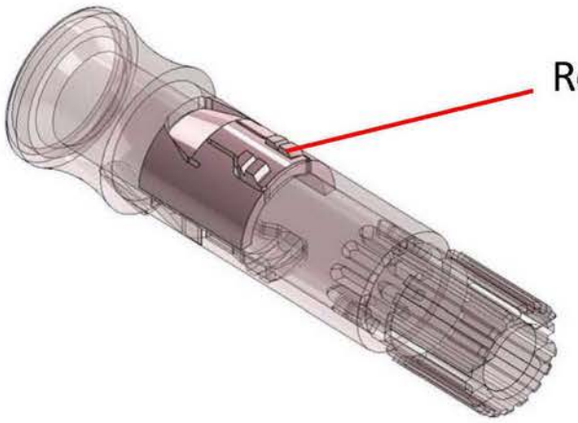
Materials in the default library can not be edited. You must first copy the material to a custom library to edit it.

| | |
|---|---|
| Model Type: | Linear Elastic Isotropic |
| Units: | SI - N/mm^2 (MPa) |
| Category: | Plastics |
| Name: | PE High Density |
| Default failure criterion: | Unknown |
| Description: | |
| Source: | |
| Sustainability: | Defined |

| Property | Value | Units |
|---|---|---|
| Elastic Modulus | 1070 | N/mm^2 |
| Poisson's Ratio | 0.4101 | N/A |
| Shear Modulus | 377.2 | N/mm^2 |
| Mass Density | 952 | kg/m^3 |
| Tensile Strength | 22.1 | N/mm^2 |
| Compressive Strength | | N/mm^2 |
| Yield Strength | | N/mm^2 |
| Thermal Expansion Coefficient | | /K |
| Thermal Conductivity | 0.461 | W/(m·K) |

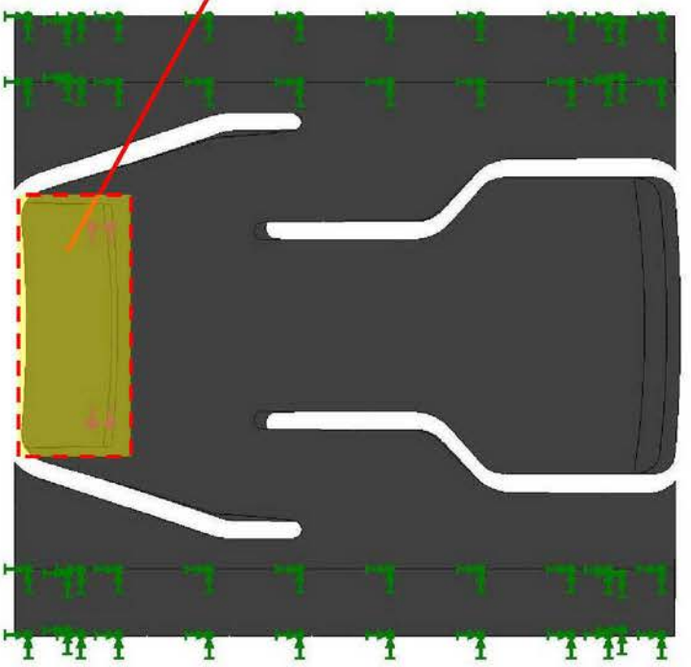
The region of interest was isolated for a FEA modeling using Solidworks 2018 with high density polyethylene.

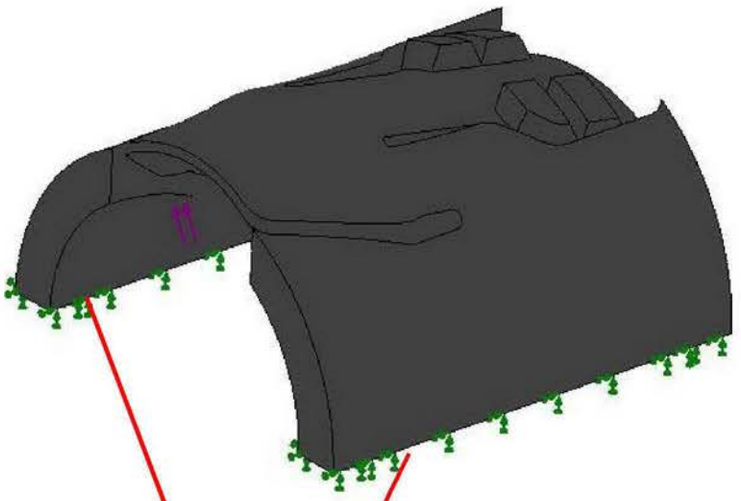
# Burroughs et al '046 FEA model loading



Region for FEA analysis

Region where an outwardly force is applied



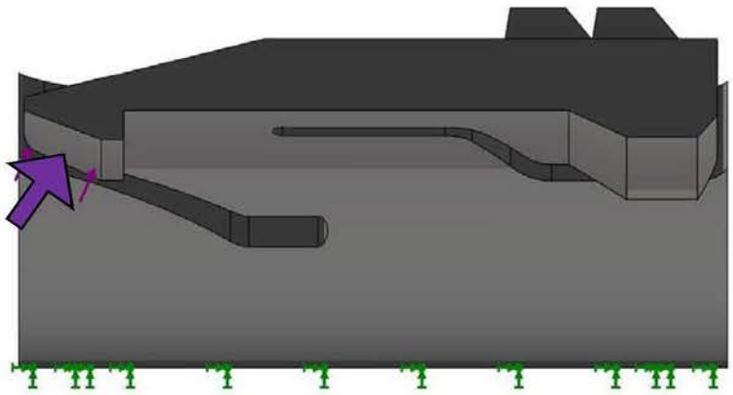


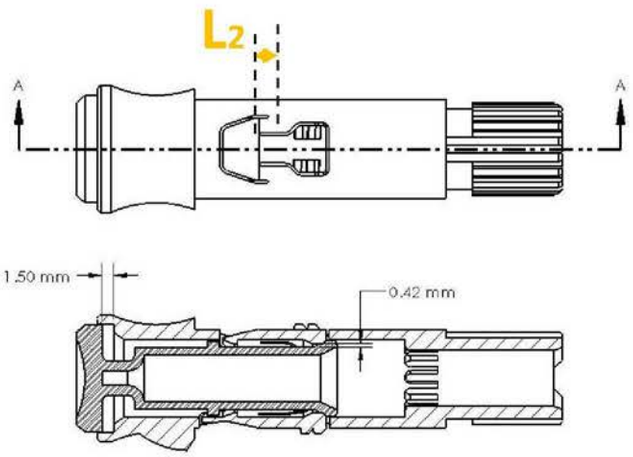
Bottom view of the region of interest showing the inner lip where the force is applied at the ramped surface faces 96

The faces where the hemisphere is sliced in the axial direction are modeled as fixed.

# Burroughs et al '046
# Quantify loading

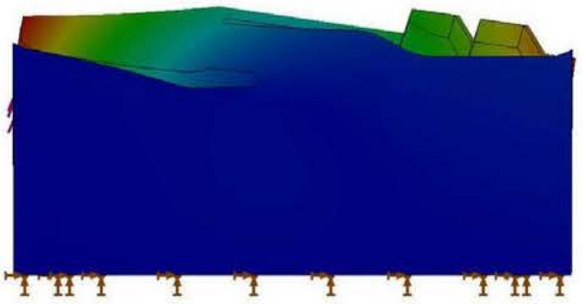
After establishing the geometry using the CAD developed, and the fixturing from basic construction of the part, the next part is to quantify the load. Since the maximum clearance between the button 32 and the dial mechanism 34 is on the order of 0.42 mm. The load at L1 from the reference position 0, is increased until the displacement of point M is between 0.4 mm and 0.42 mm. Applying 8.5 Newtons of force results in a displacement 0.42 mm at point M, and the vertical displacement of point N for that 8.5 N of applied force is 0.341 mm.



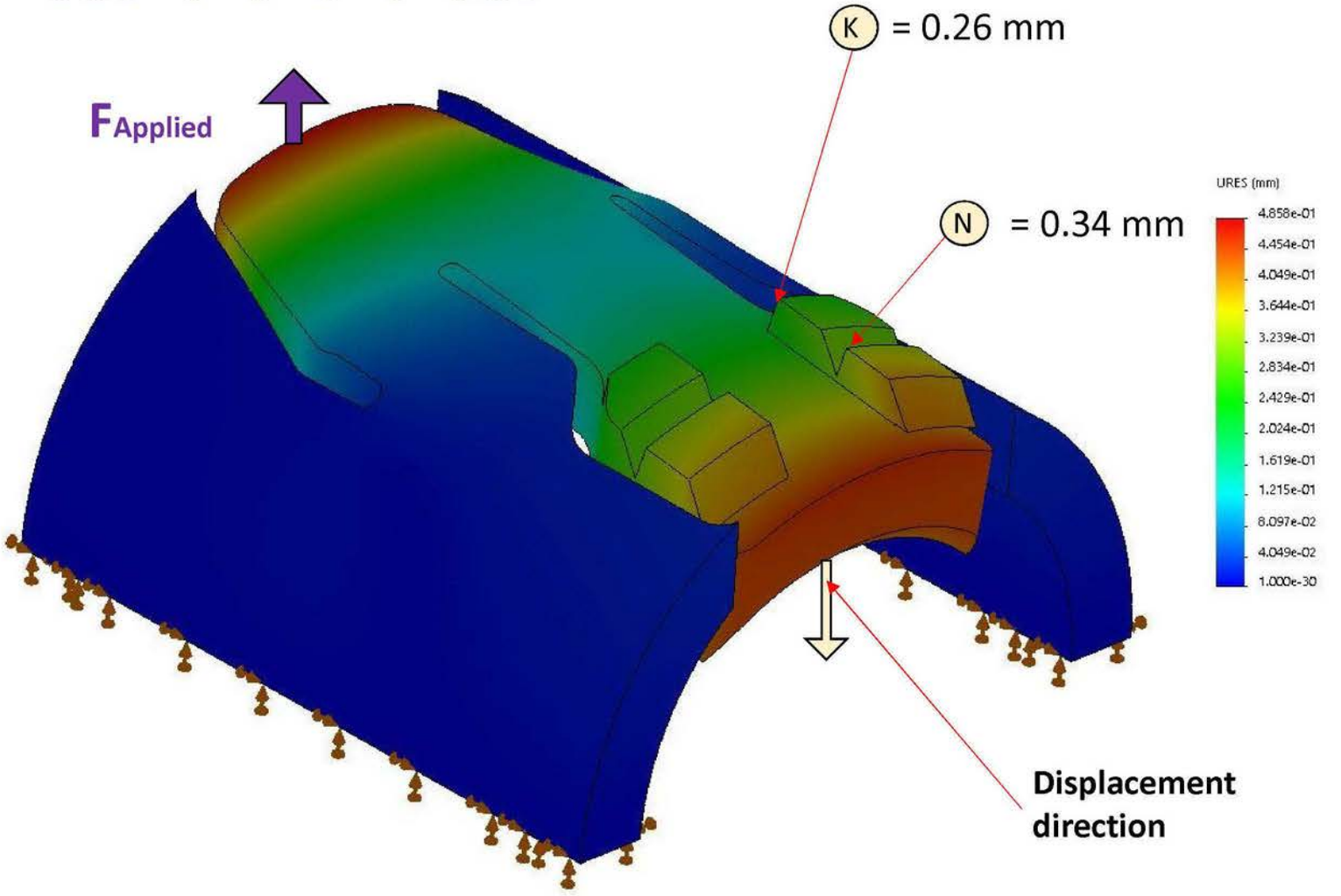


# Burroughs et al '046
# FEA model: Displacement Analysis for 8.5 N

A 8.5 N load in the in results in a an approximate displacement of 0.42 mm displacement in the internal surface between the flat surface 122 and the distal tapered surface 124.

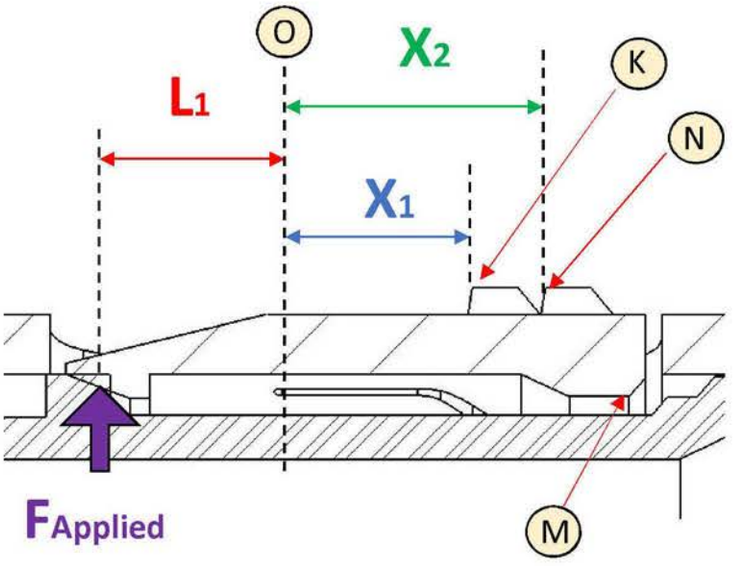


*Side view of displacement shown with a 2X magnification on displacement*



# Burroughs et al '046
# FEA model: Displacement Comparison

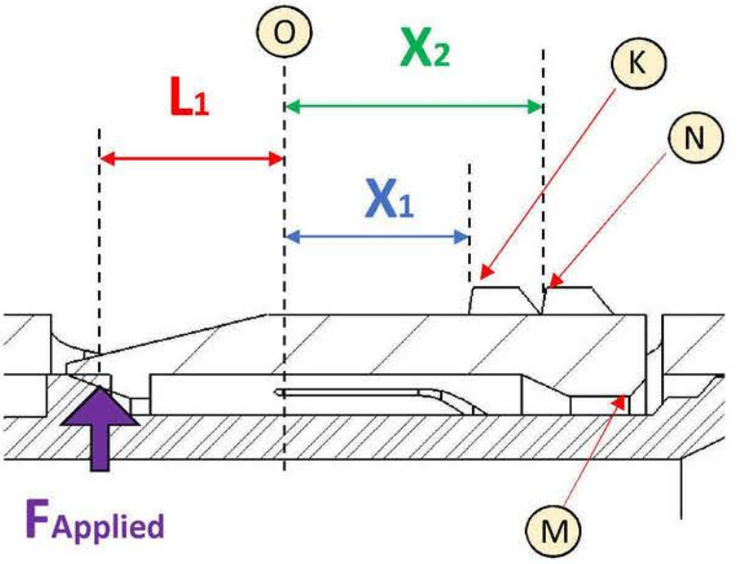
Now to find the load that generates the same tip displacement at the second tooth added by Leinsing. The load is incrementally increased and a displacement measurement is taken at point K until the displacement at point K approximately equals the 0.34 mm. The resulting F applied is 11.25 Newtons.

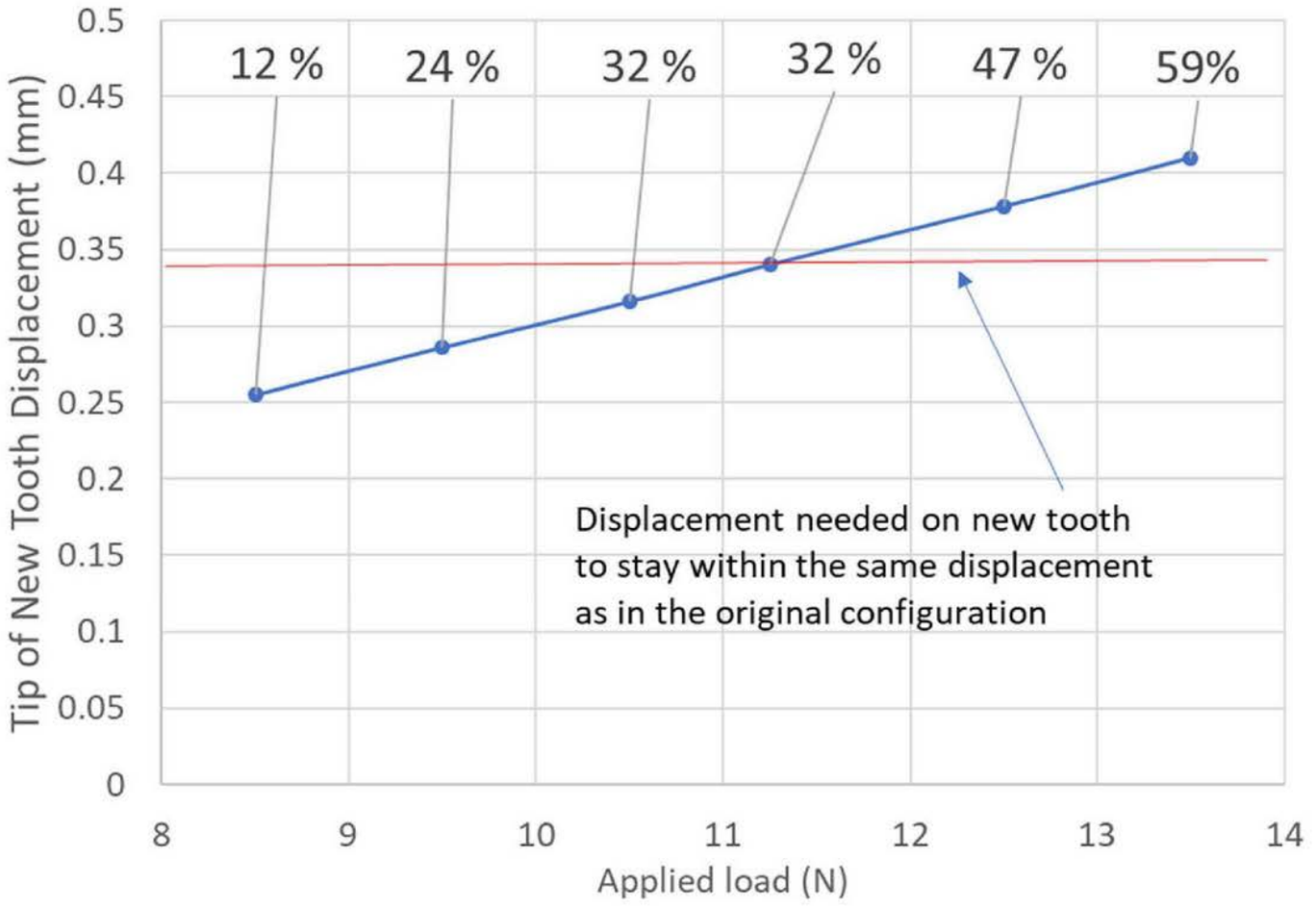



| Load (Newtons) | Point K (4025 Node) | Point N (4006 Node) | Point M (5333 Node) |
|---|---|---|---|
| 8.5 | 0.255 | 0.341 | 0.42 |
| 9.5 | 0.286 | 0.382 | 0.469 |
| 10.5 | 0.316 | 0.424 | 0.52 |
| 11.25 | 0.34 | 0.455 | 0.558 |
| 12.5 | 0.378 | 0.507 | 0.623 |
| 13.5 | 0.41 | 0.549 | 0.674 |

# Burroughs et al '046
# FEA model: data visualization

The FEA analysis shows that 11.25 N would be required to create a 0.34 mm tip displacement of the second tooth suggested by Leinsing. This is an increase of 32% in loading over Burroughs original embodiment, which agrees with the excel spreadsheet.



# Appendix E:
## DCA Test Rig Force Measurements

| Right side rig | Force (N) | |
|---|---|---|
| | Static | Dynamic |
| Modified 5th element/5th element | 150% | 152% |
| Additional torque required by modified 5th element | 50% | 52% |

Config. A: 5th embodiement modified (rotating member)

| | Force (N) | |
|---|---|---|
| test # | static | dynamic |
| 1 | 2 | 1.75 |
| 2 | 2.18 | 1.76 |
| 3 | 1.98 | 1.83 |
| 4 | 2.08 | 1.72 |
| 5 | 1.94 | 1.74 |
| 6 | 2.07 | 1.8 |
| 7 | 1.92 | 1.72 |
| 8 | 2.05 | 1.75 |
| 9 | 2.02 | 1.7 |
| 10 | 1.92 | 1.71 |
| Average | 2.02 | 1.75 |
| standard deviation | 0.078 | 0.039 |
| Ratio static to dynamic | 1.15 | |

Config. B: 5th embodiement (rotating spline)

| | Force (N) | |
|---|---|---|
| test # | static | dynamic |
| 1 | 1.4 | 1.15 |
| 2 | 1.34 | 1.14 |
| 3 | 1.35 | 1.14 |
| 4 | 1.36 | 1.14 |
| 5 | 1.34 | 1.15 |
| 6 | 1.33 | 1.11 |
| 7 | 1.36 | 1.14 |
| 8 | 1.33 | 1.15 |
| 9 | 1.34 | 1.17 |
| 10 | 1.3 | 1.19 |
| Average | 1.35 | 1.15 |
| standard deviation | 0.025 | 0.020 |
| Ratio static to dynamic | 1.17 | |

| Left side rig | Force (N) | |
|---|---|---|
| | Static | Dynamic |
| Modified 5th element/5th element | 154% | 142% |
| Additional torque required by modified 5th element | 54% | 42% |

Config. A: 5th embodiement modified (rotating member)

| | Force (N) | |
|---|---|---|
| test # | static | dynamic |
| 1 | 2.29 | 2 |
| 2 | 2.18 | 1.95 |
| 3 | 2.22 | 1.95 |
| 4 | 2.27 | 1.9 |
| 5 | 2.14 | 1.84 |
| 6 | 2.35 | 1.87 |
| 7 | 2.27 | 1.85 |
| 8 | 2.32 | 1.9 |
| 9 | 2.18 | 1.87 |
| 10 | 2.37 | 1.88 |
| Average | 2.26 | 1.90 |
| standard deviation | 0.070 | 0.046 |
| Ratio static to dynamic | 1.19 | |

Config. B: 5th embodiement (rotating spline)

| | Force (N) | |
|---|---|---|
| test # | static | dynamic |
| 1 | 1.42 | 1.31 |
| 2 | 1.44 | 1.36 |
| 3 | 1.56 | 1.35 |
| 4 | 1.51 | 1.35 |
| 5 | 1.44 | 1.31 |
| 6 | 1.5 | 1.36 |
| 7 | 1.52 | 1.31 |
| 8 | 1.49 | 1.36 |
| 9 | 1.39 | 1.33 |
| 10 | 1.43 | 1.33 |
| Average | 1.47 | 1.34 |
| standard deviation | 0.048 | 0.020 |
| Ratio static to dynamic | 1.10 | |

# Appendix F:
## Analysis_of_Leinsing_new_tooth

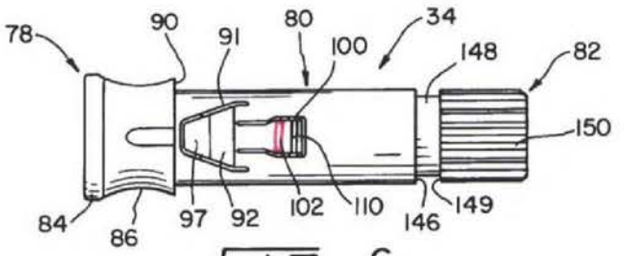



FIG. 6

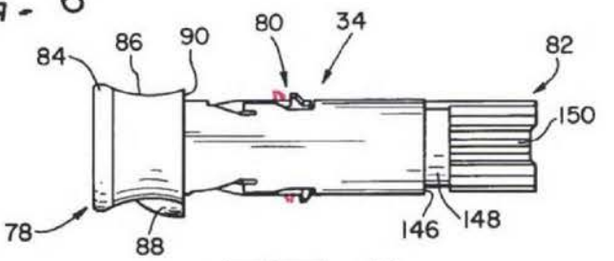



FIG. 7

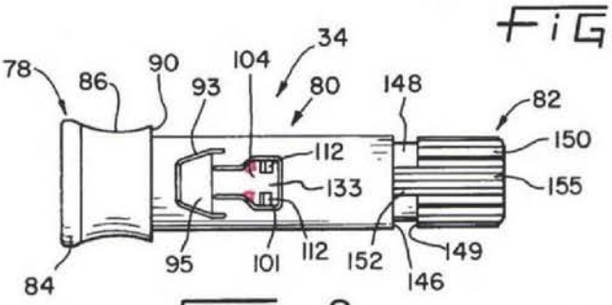



FIG. 8

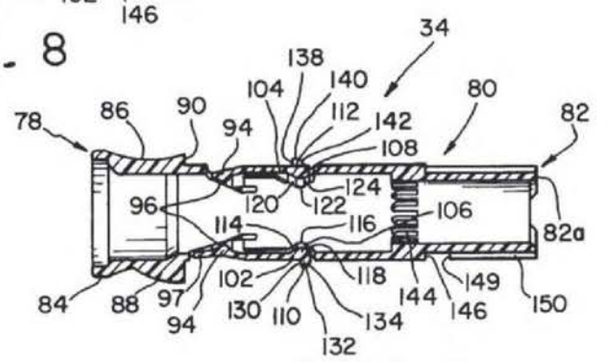



FIG. 9

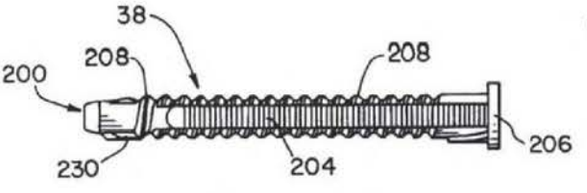
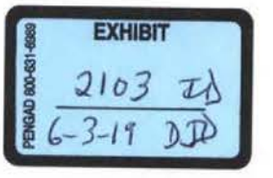



FIG. 12




Mylan Exhibit - 1013
Mylan v. Sanofi

| | |
|---|---|
| **Analysis of Leinsing's new tooth added to Burroughs** | |
| Alex Slocum June 14, 2019 | |
| Design requirement: keep the force at end of beam and stress in beam the same, just change relative lengths of beam elements to enable new proposed tooth to be moved to clear engaging thread | |
| Note, dimensions relative to drawing (so unitless) | |
| **Original distances** | |
| distance to new tooth, X_1 | **0.55** |
| distance to original tooth, X_2 | **0.72** |
| X_2/X_1 | **1.309** |
| Increase in force and stress IF no change is done to beam lengths and new tooth is to clear | **31%** |
| Distance of force (displacement) application, L_1 | **0.4** |
| Length of beam segment A, L_2 | **0.29** |
| constant C = L_1+L_2 initial | **0.69** |
| Constant C_3 for quadratic | **0.207** |
| **From the quadratic equation, terms a, b, c** | |
| aq | **1** |
| bq | **-1.38** |
| cq | **0.414** |
| New L_2 diemsion required: | |
| solution 1 | **0.94** |
| solution 2 | **0.44** |
| **Modified dimensions** | |
| L_2 new | **0.44** |
| L_1 new | **0.25** |
| Check: (L_2^2/2+L_1*L_2) new/old = X_2/X_1, ? | **TRUE** |
| L_2 new / L_2 original | **1.52** |
| L_1 new / L_1 original | **0.62** |
| **Change in deflection at end of beam (L_1) to get the tooth deflection** | |
| New design deflection/original design deflection | **1.08** |
| NOTE the force and stress is the same (original design criteria) | |
| | |
| **2nd order effects** | |
| height of tooth relative to length scale, Htooth | **0.14** |
| Slope at deflection (degrees) | **14.58** |
| cosine error ignoring tilt when calculating required slope (but this counters the fact deflection ignored and only slope used for lever calcs, see notes) | **3.2%** |
| IF < 5%, ignoring tilt insignificant? | **TRUE** |

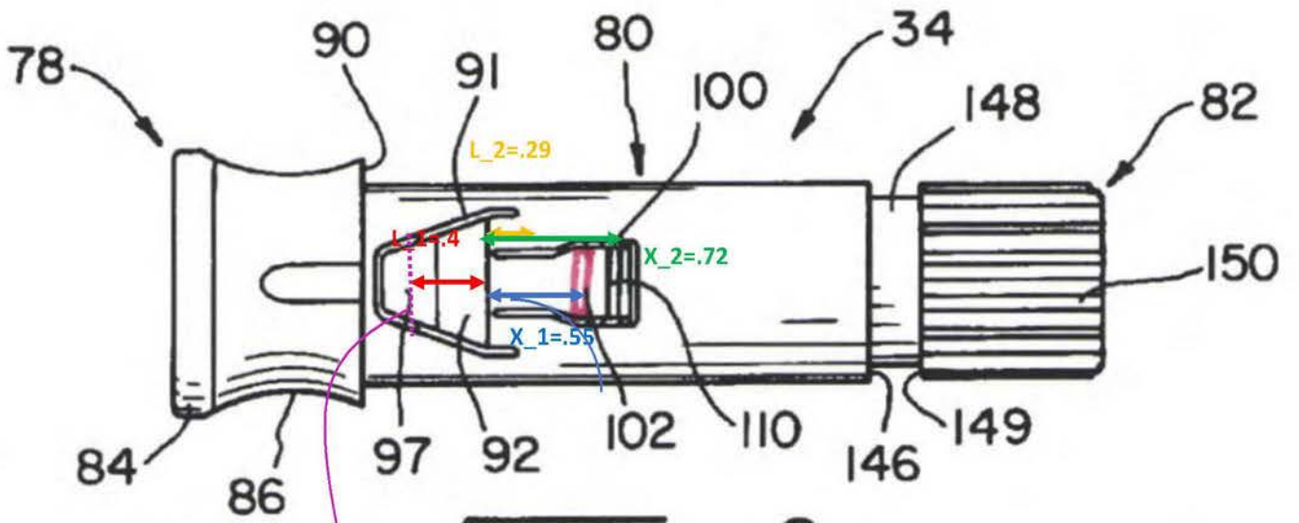
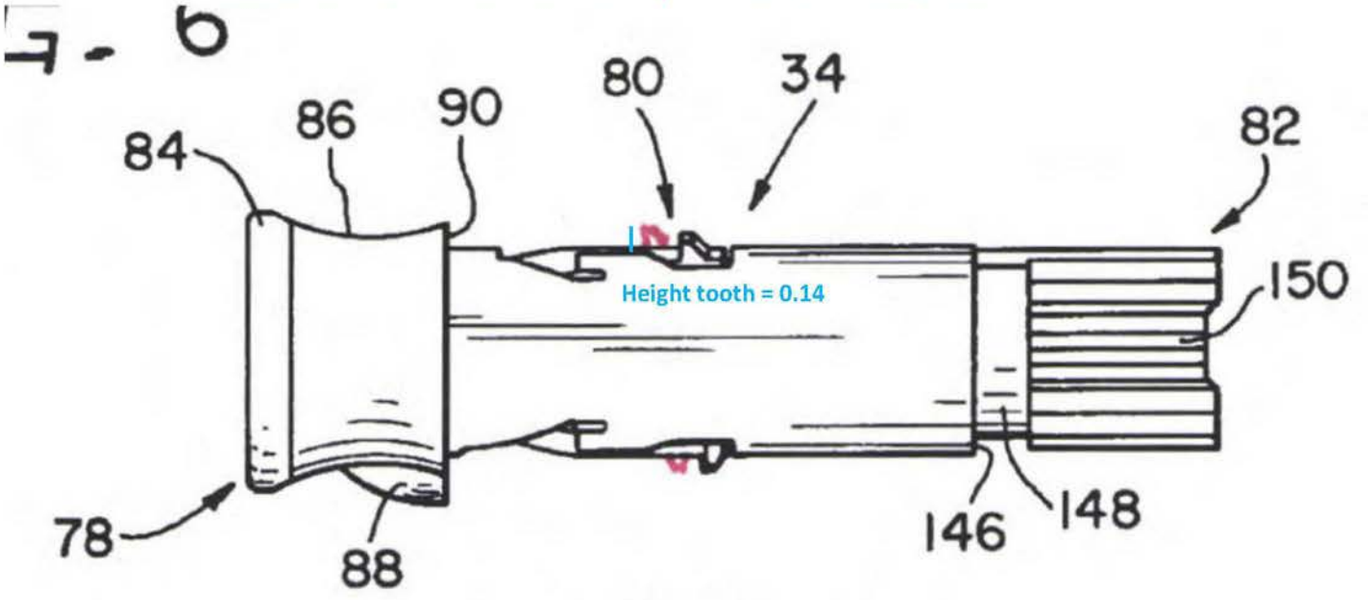



FIG. 6

Location of internal ramp inner surface 96

80



| | |
|---|---|
| **Analysis of Leinsing's new tooth added to Burroughs** | |
| Alex Slocum June 14, 2019 | |
| Design requirement: keep the force at end of beam and stress in beam the same, just change relative lengths of beam elements to enable new proposed tooth to be moved to clear engaging thread | |
| Note, dimensions relative to drawing (so unitless) | |
| **Original distances** | |
| distance to new tooth, X_1 | **0.46** |
| distance to original tooth, X_2 | **0.65** |
| X_2/X_1 | **1.413** |
| Increase in force and stress IF no change is done to beam lengths and new tooth is to clear | **41%** |
| Distance of force (displacement) application, L_1 | **0.4** |
| Length of beam segment A, L_2 | **0.29** |
| constant C = L_1+L_2 initial | **0.69** |
| Constant C_3 for quadratic | **0.223** |
| **From the quadratic equation, terms a, b, c** | |
| aq | **1** |
| bq | **-1.38** |
| cq | **0.447** |
| New L_2 diemsion required: | |
| solution 1 | **0.86** |
| solution 2 | **0.52** |
| **Modified dimensions** | |
| L_2 new | **0.52** |
| L_1 new | **0.17** |
| Check: (L_2^2/2+L_1*L_2) new/old = X_2/X_1, ? | **TRUE** |
| L_2 new / L_2 original | **1.79** |
| L_1 new / L_1 original | **0.43** |
| **Change in deflection at end of beam (L_1) to get the tooth deflection** | |
| New design deflection/original design deflection | **1.10** |
| NOTE the force and stress is the same (original design criteria) | |
| | |
| **2nd order effects** | |
| height of tooth relative to length scale, Htooth | **0.14** |
| Slope at deflection (degrees) | **17.44** |
| cosine error ignoring tilt when calculating required slope (but this counters the fact deflection ignored and only slope used for lever calcs, see notes) | **4.6%** |
| IF < 5%, ignoring tilt insignificant? | **TRUE** |

Appendix G – List of Materials Considered

| Exhibit # | Description |
|---|---|
| 2100 | Leinsing Deposition Exhibit 2100: Thomas van der Burg, *Injection Force of SoloSTAR® Compared with Other Disposable Insulin Pen Devices at Constant Volume Flow Rates,* J. of Diabetes Sci. and Tech., Vol. 5, Issue 1, 150-155 (Jan. 2001) |
| 2101 | Leinsing Deposition Exhibit 2101: Estelle Davis, et. al., *An evaluation of prefilled insulin pens: a focuse on the Next Generation FlexPen®,* Med. Devices: Evidence & Research, 41-50 (2010:3) |
| 2102 | Leinsing Deposition Exhibit 2102: Hand drawings |
| 2103 | Leinsing Deposition Exhibit 2103: Annotations of Figures 6-15 of Burroughs |
| 2104 | Leinsing Deposition Exhibit 2104: Annotations of Figures 5-8 of the 486 Patent |
| 2105 | Leinsing Deposition Exhibit 2105: Hand drawings |
| 2106 | Leinsing Deposition exhibit 2106: Annotations of Figures 11 and 12 of Giambattista |
| 2107 | Declaration of Alexander Slocum, Ph.D. |
| 2108 | Curriculum Vitae of Alexander Slocum, Ph.D. |
| 2109 | Expert Report of Henry R. Grabowski, Ph.D. |
| 2110 | Curriculum Vitae of Henry R. Grabowski, Ph.D. |
| 2111 | Declaration of Dr. Robin S. Goland |
| 2112 | Curriculum Vitae of Dr. Robin S. Goland |
| 2113 | Bradley M. Wright et al., *A Review Of Insulin Pen Devices And Use In The Elderly Diabetic Population*, 3 Clinical Medicine Insights: Endocrinology & Diabetes 54-63 (2010) |
| 2114 | Teresa L. Pearson, *A-Practical-Review-of-Insulin-Pen-Devices*, EMJ Diabet., 58-64 (2014:2) |
| 2115 | Arthritis & Diabetes, *What do diabetes and arthritis have in common? Plenty.*, https://www.arthritis.org/living-with-arthritis/comorbidities/diabetes-and-arthritis/ |
| 2116 | Andreas Bode, *Development of the SoloSTAR insulin pen device design verification and validation*, 6 Expert Opinion on Drug Delivery 103-112 (2008) |
| 2117 | Sanofi's Patented Pen animation |

| Exhibit # | Description |
|---|---|
| 2118 | John Carter, *Usability, Paticipant Acceptance, and Safety of a Prefilled Insulin Injection Device in a 3-Month Observational Survey in Everyday Clinical Practice in Australia, J. Diabetes Sci & Tech., Vol. 3, Issue 6, 1425-1438 (Nov. 2009)* |
| 2119 | Sherwyn Schwartz, *Correct Use of a New Reusable Insulin Injection Pen by Patients with Diabetes: A Design Validation Study*, 4 J. Diabetes Sci. and Tech. 1229-1235 (2010) |
| 2120 | *Reserved* |
| 2121 | DBA Design Effectiveness Awards 2009 |
| 2122 | SoloSTAR Disposable Pen Injector (The Grand Prix Oct. 22, 2009) |
| 2123 | Arnd Friedrichs et al., *Dose Accuracy and Injection Force of Different Insulin Glargine Pens*, 7 J. Diabetes Sci. and Tech. 1346-1353 (2013) |
| 2124 | Stacey A. Seggelke et al., *Effect of Glargine Insulin Delivery Method (Pen Device Versus Vial/Syringe) on Glycemic Control and Patient Preferences in Patients with Type 1 and Type 2 Diabetes*, 20 ENDOCRINE PRACTICE, 536, 536, 538–539 (2014) |
| 2125 | Julia Pfutzner et al., *Evaluation of Dexterity in Insulin-Treated Patients with Type 1 and Type 2 Diabetes Mellitus*, 5 J. Diabetes Sci. and Tech. 158-165 (2011) |
| 2126 | Jerome S. Fischer et al., *United States Patient Preference and Usability for the New Disposable Insulin Device Solostar® versus Other Disposable Pens*, 2 JOURNAL OF DIABETES SCIENCE AND TECHNOLOGY 1157-1160 (2008) |
| 2127 | U.S. Provisional Patent Application 60/073820 |
| 2128 | Samita Garg et al., *Insulin glargine and glulisine SoloSTAR pens for the treatment of diabetes*, 5 Expert Rev. Med. Devices 113-123 (2008) |
| 2129 | Nicolae Hancu et al., *A Pan-European and Canadian Prospective Survey to Evaluate Patient Satisfaction with the SoloSTAR Insulin Injection Device in Type 1 and Type 2 Diabetes*, 5 J. Diabetes Sci. and Tech. 1224-1234 (2011) |
| 2130 | Norbert Hermanns, Bernhard Kulzer & Thomas Haak, *Dosing Accuracy with a Novel Pen Device (SoloSTAR) as Performed by Patients with Diabetes in a Clinical Setting*, 10 Diabetes Tech. & Threapeutics 322-327 (2008) |

| Exhibit # | Description |
|---|---|
| 2131 | ISO 11608-1, Pen-injectors for medical use (1st Ed. Dec. 15, 2000) |
| 2132 | Meike Krzywon et al., *Study on the Dosing Accuracy of Commonly Used Disposable Insulin Pens*, 14 Diabetes Tech. & Therapeutics 804-809 (2012) |
| 2133 | Lantus SoloSTAR Pen Guide |
| 2134 | Arlan L. Rosenbloom, *Limitation of Finger Joint Mobility in Diabetes Mellitus*, 3 J. Diabetic Complications 77-87 (1989) |
| 2135 | Douglas Merritt et al., *Dose Accuracy and Injection Force of Disposable Pens Delivering Pramlintide for the Treatment of Diabetes*, 4 J. Diabetes Sci. and Tech. 1438-1446 (2010) |
| 2136 | Novo Nordisk Form 6-K (Feb. 9, 2009) |
| 2137 | Novo Nordisk History |
| 2138 | W. Schady et al, *Observations on Severe Ulnar Neuropathy in Diabetes*, 12 J Diabetes and Its Complications 128-132 (1998) |
| 2139 | Alfred Penfornis & Kristian Horvat, *Dose Accuracy Compariosn Between SoloSTAR and FlexPen at Three Different Dose Levels*, 10 Diabetes Tech. & Therapeutics 359-362 (2008) |
| 2140 | Riccardo Perfetti, *Reusable and Disposable Insulin Pens for the Treatment of Diabetes: Understanding the Global Differences in User Preference and an Evaluation of Inpatient Insulin Pen Use*, 12 Diabetes Tech. & Therapeutics 79-85 (2010) |
| 2141 | John Shelmet et al., *Preference and resource utilization in elderly patients: InnoLet versus vial/syringe*, 63 Diabetes Res. and Clinical Prac. 27-35 (2004) |
| 2142 | *Prix Galien USA Announces 2009 Final Candidates* (Prix Galien USA, August 7, 2009) |
| 2143 | Thomas Haak et al., *Comparison of Usability and Patient Preference for the New Disposable Insulin Device SoloStar Versus FlexPen, Lilly Disposable Pen, and a Prototype Pen: An Open-Label Study*, 29 CLINICAL THERAPEUTICS, 650-660 (2007) |
| 2144 | Alastair Clarke & Geralyn Spollett, *Dose accuracy and injection force dynamics of a novel disposable insulin pen*, 4 EXPERT OPINION ON DRUG DELIVERY 165-174 (2007) |

| Exhibit # | Description |
|---|---|
| 2145 | US Lantus SoloSTAR Launch Book, 2007, PTX-0705, Document bates stamped SANOFI_00232909-45 |
| 2146 | Lantus COMPASS Study Report (Nov. 29, 2007), PTX-0739, Document bates stamped SANOFI3_90330807-1025 |
| 2147 | Steenfeldt-Jensen 5th Embodiment Animation |
| 2148 | Steenfeldt-Jensen 1st Embodiment Animation |
| 2149 | Steenfeldt-Jensen 2nd Embodiment Animation |
| 2150 | Steenfeldt-Jensen 5th Embodiment Thread and Slot Animation |
| 2151 | Steenfeldt-Jensen 5th Embodiment vs. Proposed Modification Animation |
| 2152 | Steenfeldt-Jensen 5th Embodiment vs. Proposed Modification Collar Friction Animation |
| 2153 | International Patent Application WO999038554A1 |
| 2154 | *Reserved* |
| 2155 | *Reserved* |
| 2156 | *Reserved* |
| 2157 | Declaration of Chris Langley |
| 2158 | Geralyn Spollett, *Insulin Devices, Addressing Barriers to Insulin Therapy With the Ideal Pen, 957-967 (The Diabetes EDUCATOR)* |
| 2159 | Serpil Savas et al., *The effects of the diabetes related soft tissue hand lesions and the reduced hand strength on functional disability of hand in type 2 diabetic patients*, 77 Diabetes Res. and Clinical Prac. 77-83 (2007) |
| 2160 | Jean-Louis Selam, *Evolution of Diabetes Insulin Delivery Devices*, 4 J. Diabetes Sci. and Tech. 505-513 (2010) |
| 2161 | SoloSTAR Principles of Operation, PTX-0553, Document bates stamped SANOFI_00406383-94 |
| 2162 | Sanofi Patent Drive Sleeve and Piston Rod Animation |
| 2163 | Deposition of Karl R. Leinsing, dated June 3, 2019 for IPR2018-01675, -01676, -01678, -01680 |
| 2164 | Deposition of Karl R. Leinsing, dated June 4, 2019 for IPR2018-01675, -01676, -01678, -01680 |

| Exhibit # | Description |
|---|---|
| 2165 | Opinion and Order regarding Claim Construction, *Sanofi-Aventis U.S. LLC v. Mylan, N.V.*, Civil Action No. 17-9105-SRC-SLW (D.N.J. May 9, 2019), Dkt. No. 319 |
| 2166 | Memorandum and Order regarding Claim Construction, *Sanofi-Aventis U.S. LLC v. Merck*, No. 16-812-RGA (D. Del. Jan. 12, 2018), Dkt. No. 192 |
| 2167 | Giambattista Animation (1) |
| 2168 | Giambattista Animation (2) |
| 2169 | U.S. Patent No. 4,648,872 |
| 2170 | U.S. Patent No. 4,747,824 |
| 2171 | U.S. Patent No. 6,248,093 |
| 2172 | Karl R. Leinsing Declaration in *Hologic, Inc. v. Minerva Surgical, Inc., No. 15-1031* (D. Del. Jan. 26, 2018), Dkt. No. 309 |
| 2173 | Bruce A. Perkins, David Olaleye & Vera Bril, *Carpal Tunnel Syndrome in Patients With Diabetic Polyneuropathy*, 25 Diabetes Care 565-569 (2002) |
| 2174 | Jefferson Becker et al., *An evaluation of gender, obesity, age and diabetes mellitus as risk factors for carpal tunnel syndrome*, 113 Clinical Neurophysiology 1429-1434 (2002) |
| 2175 | A. Pfutzner et al., *Prefilled insulin device with reduced injection force: patient perception and accuracy*, 24 Current Med. Res. and Opinion 2545-2549 (2008) |
| 2176 | Ercan Cetinus et al., *Hand grip strength in patients with type 2 diabetes mellitus*, Diabetes Res. and Clinical Prac. 1-9 (2005) |
| 2177 | Ragnhild I. Cederlund et al., *Hand disorders, hand function, and activities of daily living in elderly men with type 2 diabetes*, 23 J. Diabetes and Its Complications 32-99 (2009) |
| 2178 | Shubha Gundmi et al., *Hand dysfunction in type 2 diabetes mellitus: Systematic review with meta-analysis*, 61 Annals of Physical and Rehabilitation Med. 99-104 (2018) |
| 2179 | Joule J. Li et al., *Muscle grip strength predicts incident type 2 diabetes: Population-based cohort study*, 65 Metabolism Clinical and Experimental 883-892 (2016) |
| 2180 | Considering Insulin Pens for Routine Hospital Use - Consider This... (ISMP article), https://www.ismp.org/resources/considering-insulin-pens-routine-hospital-use-consider |

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| 2181 | Trigger Finger Overview (Mayo Clinic), https://www.mayoclinic.org/diseases-conditions/trigger-finger/symptoms-causes/syc-20365100 |
| 2182 | Bone and joint problems associated with diabetes (Mayo Clinic), https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/diabetes/art-20049314 |
| 2183 | Peripheral Neuropathy (Mayo Clinic), https://www.mayoclinic.org/diseases-conditions/peripheral-neuropathy/symptoms-causes/syc-20352061 |
| 2184 | Charles E. Buban, *A pen that seeks to improve diabetes care*, INQUIRER.NET (2008), Document Bates stamped SANOFI_00006282-84 |
| 2185 | "*Sanofi-aventis' SoloSTAR(R) Insulin Pen for Lantus and Apidra Receives the Prestigious GOOD DESIGN Award*", (PR Newswire Feb. 14), Document Bates stamped SANOFI_00006299-301 |
| 2186 | Select Injectable Insulin Drugs Approved by the FDA in the U.S. |
| 2187 | U.S. Dollar Sales of Lantus SoloSTAR |
| 2188 | U.S. New Prescriptions of Lantus SoloSTAR |
| 2189 | U.S. Total Prescriptions of Lantus SoloSTAR |
| 2190 | U.S. Share of Sales by Drugs in the Lantus Franchise |
| 2191 | Formulary Placement of Long-Acting Insulin Pen Products: Commercial Plans |
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| 2195 | U.S. Share of Long-Acting Pens Among All Pens |
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| 2197 | U.S. New Prescriptions of Long-Acting Pens |
| 2198 | U.S. Total Prescriptions of Long-Acting Pens |
| 2199 | U.S. Share of Long-Acting Pen Products |
| 2200 | Yuzu Sato et al., *Clinical Aspects of physical exercise for diabetes/metabolic syndrome*, 77S Diabetes Research and Clinical Practice S87 (2007) |

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|---|---|
| 2201 | 2007 Good Design Award from The Chicago Athenaeum: Museum of Architecture and Design |
| 2202 | *Reserved* |
| 2203 | U.S. Total Marketing Expenditure of Long Acting Insulin Franchises |
| 2204 | U.S. Total Marketing Expenditures of Long-Acting Insulin Pens |
| 2205 | U.S. Marketing-to-Sales Ratios of Select Injectable Insulin Drugs |
| 2206 | Møller First Embodiment Animation |
| 2207 | Møller Second Embodiment Animation |
| 2208 | Press Release, *Lantus / Apdira SoloSTAR help to improve patient satisfaction* (June 27, 2011), Document bates stamped SANOFI_00179886-88 |
| 2209 | Henry Grabowski, John Vernon & Joseph A. DiMasi, *Returns on Research and Development for 1990s New Drug Introductions*, 20 Pharmacoeconomics 15 (2002) |
| 2210 | Julie M. Donohue, Marisa Cevasco & Meredith B. Rosenthal, *A Decade of Direct-to-Consumer Advertising of Prescription Drugs,* 357 N. Engl. J. Med. 673 (2007) |
| 2211 | Collar Friction Model Demonstrator Animation |
| 2212 | Excerpts from Ernest Rabinowicz, Friction And Wear of Materials, 2nd Edition, 68-70 (John Wiley & Sons, Inc. 1995) |
| 2213 | *Reserved* |
| 2214 | Excerpts from Alexander H. Slocum, *Precision Machine Design,* 706-709 (Prentice-Hall, Inc. 1992) |
| 2215 | Collar Friction Model Demonstration 1 |
| 2216 | Collar Friction Model Demonstration 2 |
| 2217 | Collar Friction Model Demonstration 3 |
| 2218 | SoloSTAR Dial Inject Video |