

II. CLAIM CONSTRUCTION

A. '833 Patent

1. **"About:"**³ when used in connection with pH, means "+ or – 0.1 pH units from [the stated number]."⁴

2. **"Replacing the isotonicity agent previously utilized in said formulation with propylene glycol,"**⁵ **"the propylene glycol-containing formulation relative to that observed for the formulation containing the previously utilized isotonicity agent,"**⁶ and **"the isotonicity agent to be replaced by propylene glycol:"**⁷ "Having a first formulation that utilized an isotonicity agent other than propylene glycol and having a second formulation wherein the isotonicity agent used in the first formulation is substituted or replaced with propylene glycol[.]"⁸ Independent claim 23 of the '833 patent recites:

23. A method for reducing deposits on production equipment during production of a GLP-1 agonist formulation, said method comprising **replacing the isotonicity agent previously utilized in said formulation with propylene glycol** at a concentration of between 1-100 mg/ml, and wherein said GLP-1 agonist formulation comprises a disodium phosphate dihydrate buffer.⁹

Claims 23–31 are process claims.¹⁰ The specification is clear that, for the intended application, propylene glycol is superior to mannitol and related substances, because

³ Found in claims 1, 5, 6, 7, 16, 20, 21, and 22 of the '833 patent.

⁴ The parties agree to this construction. D.I. 52 at 4.

⁵ Found in claims 23, 26, and 29 of the '833 patent.

⁶ Found in claims 24, 27, and 30 of the '833 patent.

⁷ Found in claims 25, 28, and 31 of the '833 patent.

⁸ The court adopts defendant's proposal. Plaintiff had proposed "utilizing propylene glycol in lieu of another isotonicity agent evaluated for use in a GLP-1 agonist pharmaceutical formulation." D.I. 39 at 3 of 11–4 of 11; D.I. 52 at 6.

⁹ '833 patent, 24:7–13 (emphasis added).

¹⁰ *Id.*, 24:7–59.

“mannitol results in clogging of injection devices[.]”¹¹ Moreover, in describing various embodiments, the specification explains, for example, that “during production of a peptide formulation, [] the method comprises replacing the isotonicity agent previously utilized in said formulation with propylene glycol[.]”¹²

The claimed process requires that “during production of a . . . formulation[.]”¹³ there is an “isotonicity agent [that was] previously utilized in said formulation[.]”¹⁴ that is replaced “with propylene glycol[.]”¹⁵ The specification does not discuss (or claim) a process for removing the previously used isotonicity agent from the formulation and then replacing the isotonicity agent with propylene glycol.¹⁶ In fact, the parties agree that the formulation containing propylene glycol is separate and distinct from the formulation in which another isotonicity agent was “previously utilized[.]”¹⁷ Therefore, in order for the method to comprise “replacing the isotonicity agent previously utilized in said formulation with propylene glycol[.]”¹⁸ there must be a separate prior formulation containing this other isotonicity agent.¹⁹

¹¹ *Id.*, 1:30–49.

¹² *Id.*, 14:16–19.

¹³ *Id.*, 24:8.

¹⁴ *Id.*, 24:9–10.

¹⁵ *Id.*, 24:11.

¹⁶ *E.g.*, *id.* at 24:7–13.

¹⁷ See D.I. 52 at 6 (defendant proposing the “first-second” formulation construction); *cf id.* at 7 (emphasis added) (plaintiff proposing “utilizing propylene glycol **in lieu of** another isotonicity agent[.]”)

¹⁸ ‘833 patent, 24:9–10.

¹⁹ Plaintiff argues that “the ‘833 patent’s focus is not chronology; it does not describe a sequential process of formulation development, one made after the other, but instead a broad evaluation of multiple formulations, leading to use of propylene glycol over the others they made and tested because it had the best properties. This is the ‘replacement’ they made to reduce the unwanted deposits and clogs.” D.I. 52 at 8. In essence, in the context of the claims, plaintiff contends that “replacing the isotonicity agent previously utilized in said formulation with propylene glycol[.]” ‘833 patent, 24:9–10), has the same meaning as “utilizing propylene glycol in lieu of another isotonicity agent[.]” D.I. 52 at 6–8). Plaintiff’s proposed construction reads the “isotonicity agent previously utilized” limitation from the claims and is, therefore, not appropriate.

B. '893 Patent

3. “Driving part:”²⁰ “a part that transfers force from the push button.”²¹ Claim 1 recites:

1. A push button connection for an injection device comprising:

a push button mountable on a driving part being rotatable relatively to the push button and which push button further comprises a bore with a bottom surface and which bore surrounds a protrusion on the driving part which protrusion has a top surface and wherein a pivot bearing is formed between the bottom surface and the top surface, wherein when a user presses on the push button the force is directed toward the driving part and wherein the driving part rotates relative to the push button.²²

In the context of this “push button connection[,]”²³ when “the user pushes the push button 10[,]”²⁴ this action “moves the driving part 20 axially forward in the injection device.”²⁵ “During this forward movement of the driving part 20 it also rotates.”²⁶ Thus, the “driving part” transfers force from the push button.

4. Meanwhile, defendant’s proposal of “component with a protrusion that inserts into the push button that is used to transfer axial force from the push button to the

²⁰ Found in claims 1, 2, and 5 of the ‘893 patent.

²¹ The court adopts plaintiff’s construction, which relies on the plain meaning. D.I. 39 at 5 of 11.

²² ‘893 patent, 4:40–51.

²³ *Id.*, 4:40.

²⁴ *Id.*, 3:38; *see also* Fig. 1.

²⁵ ‘893 patent, 3:38–39.

²⁶ *Id.*, 3:40–41; *see also id.*, 3:42–43 (“Such injection device is described in details in EP 1.003.581.”); *id.*, 1:24–26 (“U.S. Pat. No. 6,235,004 [(“the ‘004 patent”)] discloses an injection device in which according to FIG. 15-16 a dose is set by rotating the scale drum out of the housing in a threaded connection.”). Figures 15–16 of European Patent No. 1003581 (the “EP ‘581”) show the entirety of an injection device, (EP ‘581 patent at 17), as do similar figures in the ‘004 patent, ‘004 patent, figs. 15–16). The elements corresponding to the “driving part” of the ‘893 patent are described in the ‘004 patent according to various names that include: “a tubular injector element ‘70[,]” ‘004 patent, 10:24; Fig. 14), and a “bushing 82[,]” *id.*, 11:26; Fig. 16).

injector[.]”²⁷ is not supported by the specification. First, the court agrees with plaintiff that defendant’s proposed “component with a protrusion” is redundant with limitations present in the claim.²⁸ Second, as to defendant’s proposed “transfer axial force” limitation, defendant argues that, in view of Figure 2, “the only force that the driving part transfers from the push button is an axial force.”²⁹ The specification says otherwise:

When the user applies an injection force A at the peripheral area of the push button **10**, a vertical reaction force B will appear at the pivot point **22, 18**, at the same time a radial force C will occur at the upper radial bearing **13, 23**. Since the upper radial bearing **13, 23** are located at the top part **23** having the smaller diameter, the resulting torque is relatively small. Further, a radial force D will occur at the lower radial bearing **14, 25**, however due to the distance between the upper radial bearing **13, 23** and the lower radial bearing **14, 25**, the force resulting on the lower radial bearing **14, 25** is relatively small.³⁰

Although these forces are relatively small, the “force pair” of “C” and “D” in Figure 2 is something the inventors sought to minimize.³¹ Nonetheless, the specification recognizes that “the offset applied push button forces[.]” result in a “bending force” applied to the protrusion of the driving part.³² Therefore, to limit the driving part to solely transmitting axial forces would read the Figure 2 embodiment, which is discussed extensively in the specification, from the claim.

²⁷ D.I. 39 at 5 of 11.

²⁸ D.I. 52 at 50–51. The “push button connection” in claim 1 is limited as follows: “which push button further comprises a bore with a bottom surface and which bore surrounds a protrusion on the driving part[.]” ‘893 patent, 4:43–45.

²⁹ D.I. 52 at 50.

³⁰ ‘893 patent, 4:23–32.

³¹ *Id.*, 2:4.

³² *Id.*, 2:9–14. In at least one embodiment, the bending force applied to the “driving part” would, in turn, transmit those forces to other elements within the injection device. Compare ‘893 patent, Fig. 2 (showing forces “C” and “D” on the “driving part”), with EP ‘531, Fig. 16 (showing “bushing 82” (which is equivalent to the “driving part” in the ‘893 patent) in contact with “scale drum 80”).

5. **“Pivot bearing.”**³³ “a bearing that supports an end of a rotating shaft subject to an axial load.”³⁴ The specification does not define the structure of “pivot bearing” and instead provides functional descriptions of the structure. For example, the specification explains:

When a user pushes on the injection button, the force applied is directed to the forward movement of the driving part, however, since the push button and the driving part rotate relatively to each other a friction between these rotating parts will occur. The user therefore also has to apply a force large enough to overcome this friction. One way of minimizing the force a user must apply in order to perform an injection is therefore to minimize this friction. By forming a pivot bearing between the two parts, the surface area of interaction between the two objects can be minimized and the radius of the resulting friction force can be kept at a minimum.³⁵

In this description, the “pivot bearing” somehow minimizes “the surface area of interaction” and, therefore, keeps “the resulting friction force . . . at a minimum.”³⁶

Confusingly, the specification describes an embodiment in which a “pivot bearing” is formed with a “pivot” element in the bearing,³⁷ which seems to suggest a meaning of “pivot bearing” that deviates from the plain meaning.³⁸ However, other than this

³³ Found in claim 1 of the ‘893 patent.

³⁴ Plaintiff proposed a plain meaning definition. D.I. 52 at 24. The court agrees that a plain meaning definition is appropriate. For the reasons discussed herein, the court relies on extrinsic evidence for a plain meaning definition of “pivot bearing” in light of the specification.

³⁵ ‘893 patent, 1:46–56.

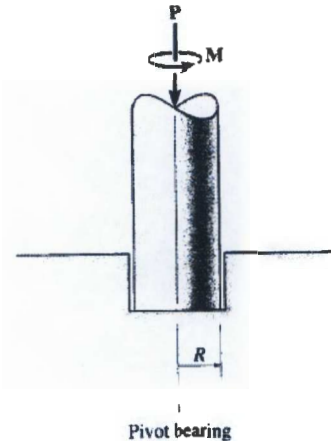
³⁶ *Id.* The court addresses the question of minimizing forces herein.

³⁷ *Id.*, 2:27–31 (emphasis added) (“[t]he push button used in the connection has a central bore dedicated to engage the protrusion provided on the driving part. The bottom of the bore is preferable [sic] **formed with a pivot**. This pivot bears on a surface of the protrusion thus forming a pivot bearing.”); see also *id.*, 4:11–14 (“In this position, the pivot **18** formed in the most proximal bottom surface **17** of the bore **12** bears on the top surface **22** of the protrusion **21** thus forming a pivot bearing **22, 18**.”).

³⁸ As is discussed herein, the **extrinsic evidence** demonstrates that the plain meaning of pivot bearing refers to the rotating shaft as the “pivot” and the surface supporting the shaft as the bearing—there appears to be no requirement that the pivot (i.e., the rotating shaft) be able to pivot around the surface of the bearing as is

preferred embodiment nothing else in the intrinsic record³⁹ suggests that the applicant intended a different definition.⁴⁰ The definitions proposed by the parties share two common elements: (1) a definition of the bearing, including its shape, and (2) a reference to friction reduction.⁴¹ The court addresses these two components of the definition in sequence.

6. First, the bearing surface can take any number of shapes. The specification does not describe these shapes, and claim 1 does not limit the pivot bearing to a specific shape.⁴² The court, therefore, turns to extrinsic evidence.⁴³ A textbook on the subject of statics explains that “[p]ivot and collar bearings are commonly used in machines to support an



discussed with respect to the embodiment disclosed in Figures 1 and 2 of the '893 patent. See D.I. 52-1, ex. E at 38 of 208, 40 of 208 (referring to the rotating shaft as the “pivot”); see also *id.*, ex. A at 4 of 208 & Fig. 8-21(a) (“Pivot . . . bearings are commonly used in machines to support an axial load on a rotating shaft.”).

³⁹ Defendant argues that during prosecution, the applicant “distinguished the term ‘pivot bearing’ from prior art on the basis of this [pivoting-element-in-the-pivot bearing] embodiment. D.I. 52 at 36; see also *supra* note 37. Specifically, defendant contends that plaintiff “distinguished the ‘893 patent [application] from [the Gallay] prior art on the basis of this particular spherical ‘raised pointer’ pivot bearing embodiment.” *Id.* at 37. Upon review of the record, the applicant cited the embodiment discussed in the specification and argued that “Gallay is directed to a completely different application and therefor [sic] lacks a pivot bearing as recited in claim 1.” D.I. 39-1, ex. D at 55 of 118. The applicant did not distinguish between one pivot bearing in the application and a second pivot bearing in the prior art; rather the applicant averred that “[t]here is no corresponding bearing in Gallay[.]” *Id.* at 58 of 118.

⁴⁰ For example, the pivoting-element-in-the-pivot bearing embodiment is not claimed, or discussed, in claim 1. ‘893 patent, 4:43–48.

⁴¹ Compare D.I. 39 at 4 (Plaintiff proposing the “plain meaning, which is ‘a machine part in which another part turns, where friction along the axis of rotation is reduced at the contacting surfaces of the two parts[.]’”), with *id.* (Defendant proposing “a conical or spherical surface in contact with another surface to reduce friction between two parts that are subjected to axial thrust and rotation[.]”).

⁴² ‘893 patent, 4:40–51.

⁴³ The applicant relied on a dictionary definition of “bearing” during prosecution of the ‘893 patent. D.I. 39-1, ex. D at 68 of 118. Plaintiff contends that this definition “is

axial load on a rotating shaft[.]”⁴⁴ which is depicted in an accompanying figure.⁴⁵ In comparison to collar bearings, which support an axial load in *the middle* of a rotating shaft, it is plain that pivot bearings support an *end* of the rotating shaft.⁴⁶ The textbooks and journal articles provided by the parties refer to the rotating shaft as the “pivot” and the surface supporting the shaft as the bearing.⁴⁷ In claim 1, the pivot bearing is formed from the “top surface” of the “protrusion on the driving part” and the “bottom surface” of the “bore” in the “push button.”⁴⁸ Therefore, the court concludes that the pivot bearing in the “push button connection” consists of a pivot, which is the “protrusion on the driving part” (which rotates) and a receiving bearing, which is the “bore” in the “push button” (which does not rotate).⁴⁹ Thus, the extrinsic evidence suggests a definition of pivot bearing as *a bearing*⁵⁰ *that supports an end of a rotating shaft subject to an axial load.*

the clearest indication of what the applicants understood pivot bearing to mean[.]” D.I. 52 at 30 (citation omitted)), because “‘prior art cited in a patent or cited in the prosecution history of the patent constitutes **intrinsic evidence**’ for purposes of claim construction.” *Id.* (emphasis added) (citing *Kumar v. Ovonic Battery Co.*, 351 F.3d 1364 (Fed. Cir. 2003)). In *Kumar*, the Federal Circuit explained that “[o]ur cases have recognized that although the dictionary can be an important tool in claim construction by providing a starting point for determining the ordinary meaning of a term to a person of skill in the art, ‘the intrinsic record’ can resolve ambiguity in claim language or, where clear, trump an inconsistent dictionary definition.” *Kumar*, 351 F.3d 1367–68 (citation omitted). The dictionary definition is not prior art discussed by the applicant or the examiner during prosecution. Therefore, it is not part of the intrinsic record, and for purposes of claim construction, the court will consider it along with the other extrinsic evidence provided by the parties.

⁴⁴ D.I. 52-1, ex. A at 4 of 208.

⁴⁵ *Id.* at Fig. 8-21.

⁴⁶ *Id.*

⁴⁷ (*E.g.*, D.I. 52-1, ex. E at 38 of 208 (“The bearing area is, therefore, the area of the end of the pivot[.]”); *id.* at 40 of 208 (“The end of the pivot should be of steel, and it may be flat on the end or slightly cup shaped.”)).

⁴⁸ ‘893 patent, 4:43–48.

⁴⁹ *Id.*, 4:40–51.

⁵⁰ The parties had sought to further define “bearing” as either “a machine part in which another part turns” (Plaintiff) or “a conical or spherical surface in contact with another surface” (Defendant). D.I. 39 at 4. Plaintiff acknowledges that its definition “could apply to both the pivot bearing and the radial bearing” claimed in the ‘893 patent.

7. Second, with respect to reducing friction, the specification explains that the reason for using a pivot bearing between the “push button” and the “driving part” is to minimize the friction between these two parts so that, in the injection device, “the force a user must apply [to the push button] in order to perform an injection” is as small as possible.⁵¹ Both parties seek to translate the stated design objective of minimizing friction into a definitional requirement that the pivot bearing “reduce[s]” friction.⁵² The court notes that bearings reduce friction between moving parts, and an inclusion of friction reduction in the definition of “bearing” is redundant. Moreover, it is unclear what the reference point is for friction reduction as proposed by the parties. For example, the specification is clear that, in comparison with designs in the prior art,⁵³ the pivot bearing itself is the design choice that minimizes the friction between these two parts, because

D.I. 52 at 25. Since the applicant sought to differentiate between these two machine elements by giving them different names and using them in different claim limitations, a common definition blurs the necessary distinction in the claims between the “pivot bearing” and the “radial bearing.” As to defendant’s “conical or spherical surface” construction, this appears to be based entirely on attorney argument, without any citation to the specification. *Id.* at 28 (emphasis in original) (“[A] flat bearing surface would actually *maximize* the surface of interaction and could be further *minimized* by creating a curved or pointed bearing at the surface of interaction. Therefore, a POSA would understand that the pivot bearing in the ‘893 Patent could not be a flat bearing and must either be curved (i.e. spherical) or pointed (i.e. conical)[.]”). Plaintiff’s opposing attorney argument, including citation to extrinsic evidence, is not especially persuasive, either. *Id.* at 27, 30–34. Absent clear direction from the specification or the extrinsic evidence, the court declines to read a limitation on the shape of either the pivot surface or the bearing surface.

⁵¹ ‘893 patent, 1:46–56.

⁵² Compare D.I. 39 at 4 (Plaintiff proposing the “where friction along the axis of rotation is reduced at the contacting surfaces of the two parts[.]”), with *id.* (Defendant proposing “to reduce friction between two parts that are subjected to axial thrust and rotation[.]”).

⁵³ A reference point for the friction involved is discussed in the specification in relation to the ‘004 patent. ‘893 patent, 1:29–34 (citing Figs. 15–16 of the ‘004 patent) (“[T]he push button and the bushing rotates relatively to each other. The friction occurring between these relatively rotatable parts contributes to the force a user needs to apply in order to push back the bushing and the scale drum in order to inject the set dose.”). The ‘004 patent disclosed “an injection button **88** is rotatably mounted with a pivot pin **94** journaled [with a collar bearing] in an end wall of the bushing **82**.” ‘004 patent, 11:49–51, Figs. 15–16. For a rotating shaft of a given radius, in comparison to the collar bearing disclosed in the ‘004 patent, a pivot bearing would result in less friction. *E.g.*, D.I. 52-1, ex. A at 5 of 208, equations 8-7 and 8-8.

“the radius of the resulting friction force can be kept at a minimum.”⁵⁴ According to the extrinsic evidence, “in the case of a pivot bearing” with a flat end, the moment (turning force) required to overcome the static friction in the bearing is directly proportional to the axial force and the radius⁵⁵ of the bearing.⁵⁶ Therefore, minimizing the radius (and hence the diameter) of the “protrusion” of the “driving part” minimizes “the radius of the resulting friction force,” which, in turn, minimizes friction between the “push button” and the “driving part.” Claim 1 recites a limitation that includes a pivot bearing, and the specification explains that, in this “injection device” application, a pivot bearing is superior to other design choices, because in comparison to those other designs it reduces the amount of force required to inject the medication. However, were the court to employ the term “bearing” in the definition of “pivot bearing,” nothing in the intrinsic record⁵⁷ suggests that the proposed reductions in friction would further distinguish a “pivot bearing” from any other bearing. Therefore, the court defines pivot bearing as a *bearing that supports an end of a rotating shaft subject to an axial load.*

8. **“Radial bearing:”**⁵⁸ “a bearing that supports a load on a shaft that is perpendicular to the axis of rotation.”⁵⁹ Claim 2 recites “[a] push button connection

⁵⁴ ‘893 patent, 1:55–56. Defendant contends that while “[t]he parties agree that a pivot bearing is used to reduce rotational friction between parts, . . . this is simply an inherent property of a ‘pivot bearing’ in mechanical engineering.” D.I. 52 at 27. Based upon the specification, and the extrinsic evidence, the court agrees.

⁵⁵ By “radius,” the court refers to the geometric property that is one half of the diameter of the protrusion on the driving shaft.

⁵⁶ D.I. 52-1, ex. A at 5 of 208, equation 8-8 (“ $M = 2/3 \mu_s PR$ ” where μ_s is the coefficient of static friction for the material, P is the axial force, and R is the radius of the pivot).

⁵⁷ Both parties seek to include statements made by the applicant during prosecution, specifically in an appeal to the Board of Patent Appeals and Interferences. D.I. 39-1, ex. D. The court has reviewed these materials and finds the layers of attorney argument contained in in the BPAI appeal briefs and in the parties claim construction briefing referencing these materials unpersuasive in narrowing the definition of “pivot bearing” to specific embodiments or to dictionary definitions discussed by the applicant.

⁵⁸ Found in claims 2, 3, 4 of the ‘893 patent.

⁵⁹ The court agrees with plaintiff and adopts a plain meaning definition.

according to claim 1, in which at least one radial bearing between the push button and the driving part is provided.⁶⁰ The specification discusses, but does not define, the radial bearing term.⁶¹ For example, the specification states: “[i]n order to secure the fit between the push button and the driving part and on the same time direct forces applied on the periphery of the push button to the driving part at least one radial bearing between the push button and the protrusion is formed.”⁶² As with the “pivot bearing” term, the court declines to engage in defining “radial bearing” according to “reducing” friction objectives associated with bearings and instead uses the term “bearing” in its construction.⁶³

9. According to the extrinsic evidence, “[a] bearing can [] be classified as a radial bearing or a thrust bearing, depending on whether the bearing load is in the radial or axial direction, respectively, of the shaft.”⁶⁴ “The load on the shaft can be divided into radial and axial components. . . . [and] the radial load component is in the direction normal [or perpendicular] to the shaft axis.”⁶⁵ “Certain bearings . . . can support radial as well as thrust forces. [But c]ertain other bearings . . . are applied only for radial

⁶⁰ ‘893 patent, 4:53–55.

⁶¹ See *id.*, 4:14–16 (“the push button **10** is radially supported by the protrusion **21** at the top part **23** forming a radial top bearing **23**, **13**.”); *id.*, 4:22–25 (“When the user applies an injection force A at the peripheral area of the push button **10** a vertical reaction force B will appear at the pivot point **22**, **18**, at the same time a radial force C will occur at the upper radial bearing **13**, **23**.”).

⁶² *Id.*, 1:57–61.

⁶³ For example, plaintiff argues that “[t]he radial bearings ‘have the least possible radius of friction[.]’” D.I. 52 at 38 (quoting ‘893 patent, 1:62–67). This is a preferred embodiment, ‘893 patent, 1:62 (introducing embodiment with “[p]referably”), and plaintiff does not explain why the claim should be limited to this embodiment. As with “pivot bearing,” defendant argues that all bearings function “in part to reduce friction between two parts.” D.I. 52 at 39.

⁶⁴ D.I. 52-1, ex. F at 3.

⁶⁵ *Id.*

loads.”⁶⁶ Therefore, the court defines radial bearing according to the plain meaning as a *bearing that supports a load on a shaft that is perpendicular to the axis of rotation.*

C. ‘956 Patent

10. Claims 1 and 2 of the ‘956 patent recite:

1. A limiting mechanism that prevents setting of a dose that exceeds the injectable amount of liquid left in a cartridge of an injection device wherein a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device, and the dose is injected by pressing an injection button which rotates back the dose setting member which during this rotation carries the driver with it to rotate this driver which moves the piston rod forward, wherein the driver is provided with a track having a length which is related to the total injectable amount of medicament in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of this dose setting member and wherein the driver is disk shaped and the track has a spiral shape which is engaged by the track follower which is flexibly coupled to the dose setting member so that the track follower can be moved radially when it follows the track of the driver element.

2. A limiting mechanism that prevents setting of a dose that exceeds the amount of liquid left in a cartridge of an injection device wherein a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device, and the dose is injected by rotating back the dose setting member which during this rotation carries the driver with it to rotate this driver which moves the piston rod forward, wherein the driver is provided with a track having a length which is related to the total amount of medicament in the cartridge and which track is engaged by a track follower coupled to the dose setting member to follow rotation of this dose setting member and wherein the driver is cylindrical and the track has a helical shape which is engaged by the track follower which is coupled to the dose setting member so that the track follower can be moved rotationally when it follows the track of the driver element.⁶⁷

⁶⁶ *Id.*

⁶⁷ ‘956 patent, 4:61–5:27.

11. **“Driver:”**⁶⁸ “a part that transfers force from the injection button.”⁶⁹ The specification explains that:

An object of the invention is to provide a limiting mechanism which prevents setting of a dose that exceeds the amount of liquid left in a cartridge of an injection device of the geared type wherein a dose is set by rotating a dose setting member relative to a driver and away from a fixed stop in the injection device, and the dose is injected by rotating back the dose setting member which during this rotation carries the driver element with it to rotate this driver element which moves the piston rod forward.⁷⁰

Therefore, the driver moves the piston rod forward to inject the medication. In the two embodiments disclosed, this process is initiated “when the injection button is pressed[.]”⁷¹

12. **“Track:”**⁷² “a path along which a part moves.”⁷³ Claim 1 describes that “the driver is provided with a track . . . which track is engaged by a track follower . . . [which] can be moved radially when it follows the track of the driver element.”⁷⁴ In claim 2, “the driver is provided with a track . . . which track is engaged by a track follower . . . [which] can be moved rotationally when it follows the track of the driver element”⁷⁵ Claim 5

⁶⁸ Found in claims 1, 2, 3, 4 of the ‘956 patent.

⁶⁹ The court adopts plaintiff’s construction. D.I. 39 at 6. Defendant had proposed “a disk-shaped or cylindrical component with a helical track on its outer surface[.]” *id.*, which is redundant with limitations already present in the claims, ‘956 patent, 5:6–7, 5:23–24.

⁷⁰ *Id.*, 2:14–22.

⁷¹ *Id.*, 3:56–65; see also *id.*, 4:38–50 (“When the dose is injected by pressing a[n] . . . injection button . . . rotation will be transmitted to the driver.”).

⁷² Found in claims 1, 2, 5 of the ‘956 patent.

⁷³ The court adopts plaintiff’s construction. D.I. 39 at 7. The court declines to follow defendant’s proposal of “a helical groove on the outer surface of the driver,” *id.*, which is limited to an embodiment in the specification, because “a POSA would understand that [both spiral and helical] shapes may [] be described as ‘helical.’” D.I. 52 at 58 (citing D.I. 39-1, ex. E at 100 of 118 (arguing that “by definition a thread is helical.”)). This argument is not persuasive.

⁷⁴ ‘956 patent, 5:2–11.

⁷⁵ *Id.*, 5:19–27.

recites an “assembly [that] comprises: (a) a helical track . . . and (b) a follower that engages the helical track; wherein the follower moves along the helical track[.]”⁷⁶

13. **“Track follower:”**⁷⁷ “a part that moves along a path.”⁷⁸ As discussed above in relation to the “track” term, it is apparent in claims 1, 2, and 5, that the “track follower” moves along the track, which the court has defined as “a path along which a part moves.”⁷⁹

14. **“Track having a length:”**⁸⁰ “the length of the track that the track follower can move along.”⁸¹ Claim 1 states that “the driver is provided with a track having a length which is related to the total injectable amount of medicament in the cartridge[.]”⁸² The motion of the track follower along the track is critical to setting the dosage, and if there is insufficient medication in the cartridge, the dosage cannot be set.⁸³ Moreover, during prosecution, the applicant argued that “[a]s the follower moves along the track . . . only during dose setting, it acts as a summation machine for the set and injected doses. Thus, the length which the follower can move along the track (or the track along

⁷⁶ *Id.*, 5:48–53.

⁷⁷ Found in claims 1, 2, 4 of the ‘956 patent.

⁷⁸ The court adopts plaintiff’s proposal. D.I. 39 at 8. Defendant had proposed “movable lever that follows a pre-determined path and is coupled to the dose setting member.” *Id.* Claim 1 states that the “track is engaged by a track follower coupled to the dose setting member[.]” ‘956 patent, 5:4–5; *see also id.*, 5:25–26 (“the track follower [] is coupled to the dose setting member.”). In light of the claim language, defendant’s construction is redundant.

⁷⁹ *Id.*, 5:2–11; 5:19–27; 5:48–53.

⁸⁰ Found in claims 1, 2 of the ‘956 patent.

⁸¹ The court adopts plaintiff’s proposal. D.I. 39 at 9. Defendant had proposed a plain meaning, which it contends is the total length of the track. *Id.*; D.I. 52 at 64–65.

⁸² ‘956 patent, 5:2–4.

⁸³ *Id.*, 4:10-16 (“[T]he position of the cam in the track reflects the total amount of medicine administered. When the cam **21** abuts the end wall **24** of the track **20** the set dose cannot be increased and by adapting the length of the track to the total amount of medicine in the cartridge it is ensured that a dose larger than the amount of medicine remaining in the cartridge cannot be set.”).

the follower) defines the volume of the drug that remains in the pen syringe that is available to be injected.”⁸⁴

ORDER: THE COURT’S CLAIM CONSTRUCTION

At Wilmington this 25th day of June, 2018, having heard oral argument, having reviewed the papers submitted with the parties’ proposed claim constructions, and having considered all of the parties’ arguments (whether or not explicitly discussed herein);

IT IS ORDERED that the disputed claim language of U.S. Patent Nos. 8,114,833 (“the ‘833 patent”); 9,265,893 (“the ‘893 patent”); and RE41,956 (“the ‘956 patent”) shall be construed consistent with the tenets of claim construction set forth by the United States Court of Appeals for the Federal Circuit in *Phillips v. AWH Corp.*,⁸⁵ as follows:

Claim Term	Construction
about (‘833 patent, cls. 1, 5, 6, 7, 16, 20, 21, 22)	+ or – 0.1 pH units from [the stated number]

⁸⁴ D.I. 39-1 at 93–94 of 118 & r.6.

⁸⁵ 415 F.3d 1303 (Fed. Cir. 2005) (en banc).

Claim Term	Construction
replacing the isotonicity agent previously utilized in said formulation with propylene glycol ('833 patent, cls. 23, 26, 29) the propylene glycol-containing formulation relative to that observed for the formulation containing the previously utilized isotonicity agent ('833 patent, cls. 24, 27, 30) the isotonicity agent to be replaced by propylene glycol ('833 patent, cls. 25, 28, 31)	having a first formulation that utilized an isotonicity agent other than propylene glycol and having a second formulation wherein the isotonicity agent used in the first formulation is substituted or replaced with propylene glycol
driving part ('893 patent, cls. 1, 2, 5)	a part that transfers force from the push button
pivot bearing ('893 patent, cl. 1)	a bearing that supports an end of a rotating shaft subject to an axial load
radial bearing ('893 patent, cls. 2, 3, 4)	a bearing that supports a load on a shaft that is perpendicular to the axis of rotation
driver ('956 patent, cls. 1, 2, 3, 4)	a part that transfers force from the injection button
track ('956 patent, cls. 1, 2, 4)	a path along which a part moves
track follower ('956 patent, cls. 1, 2, 4)	a part that moves along a path
track having a length ('956 patent, cls. 1, 2)	the length of the track that the track follower can move along

Pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72 (b)(1), and D. Del. LR 72.1, any objections to the Report and Recommendation shall be filed within fourteen

(14) days limited to ten (10) pages after being served with the same. Any response shall be limited to ten (10) pages.

The parties are directed to the Court's Standing Order in Non-Pro Se Matters for Objections Filed under Fed. R. Civ. P. 72 dated October 9, 2013, a copy of which is found on the Court's website (www.ded.uscourts.gov.)

Dated: June 26, 2018

/s/ Mary Pat Thyng
Chief U.S. Magistrate Judge