

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 injection 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”).

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