

## **EXHIBIT A-2**

### **Invalidity Claim Chart of Boulange, alone or in combination with any of Sigg, Lam, Reuter, Scypinski, M Schoenknecht, Chacornac, Nema, D'Souza, Furfine, Badkar, Macugen, Eylea, Lucentis, Stewart, USP789 Hagen, Khandke, Wittland, Shams, Dixon, and/or Cormier against U.S. Patent No. 9,220,**

#### Charted Reference:

PCT Patent Publication No. WO 2009/030976 to Boulange *et al.* (“Boulange”), in view of Sigg, Lam, Reuter, Scypinski, M Schoenknecht, Chacornac, Nema, D'Souza, Furfine, Badkar, Macugen, Eylea, Lucentis, Stewart, USP789 Hagen, Khandke, Wittland, Shams, Dixon, and/or Cormier, render obvious claims 1-26 of U.S. Patent No. 9,220,000.

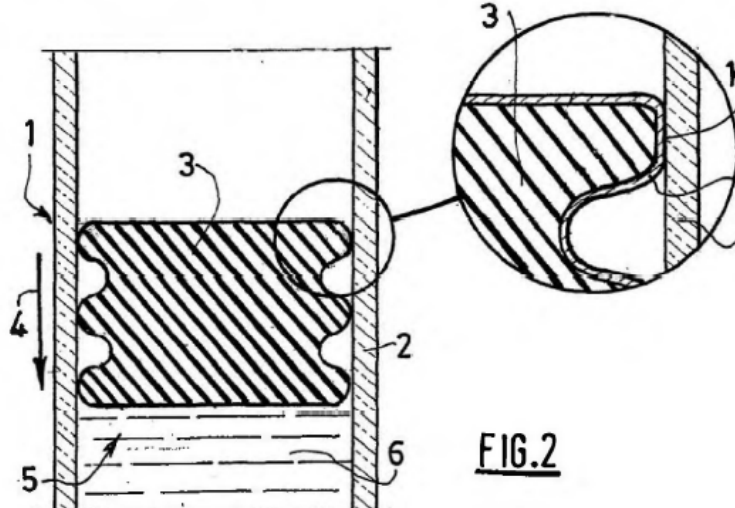
Boulange is an International Patent Application publication that was published on March 12, 2009, and therefore is prior art under 35 U.S.C. § 102(b).

This claim chart is based on Regeneron's current understanding of the asserted claims, and Regeneron's investigation of the prior art. Regeneron is not admitting to the accuracy of any particular construction. Regeneron reserves all rights to amend the claim chart in light of any claim construction developments or any amendments to Novartis's infringement contentions. Regeneron's contentions, should such developments occur or amendments be allowed. Further, as discovery is ongoing and Regeneron seeks discovery from third parties regarding the references identified in Regeneron's invalidity contentions as well as the prior art, Regeneron reserves the right to revise its invalidity contentions as appropriate in view of any ongoing developments.

The claim chart below identifies where each limitation of each asserted claim of the 631 Patent can be found in the prior art. The citations provided below are exemplary, rather than exhaustive, and Regeneron reserves the right to rely upon any other cited references. Where Regeneron identifies a portion of a reference's text, the identification should be understood to include the corresponding figure or diagram, and vice versa.

| Claim Language                              | Corresponding Disclosure  |
|---|---|
| <p>[1.a-pre] A pre-filled . . . syringe</p> | <p>Boulangé discloses a pre-filled syringe.</p> <p>For example, see the following passages and/or figures, as well as all related disclosures.</p> <p>The present invention relates in general to a medical device, for example a syringe, comprising at least one smooth coated part, , for example a container and/or a piston, the parts being able to move one relative to the other, for example translationally and/or rotationally, when the medical device is operated.</p> <p>In this application, the term distal means the part furthest from the user's hand and the term proximal means the part closest to the user's hand. Likewise, in this application, the term "distal direction" means the direction of administration, i.e., towards the patient and the term "proximal direction" means direction opposite to the direction of administration, i.e., away from the patient.</p> <p>Furthermore, the container is intended to accommodate a medical product in a gaseous, fluid, pasty or lyophilized phase, which may have a variable viscosity and is therefore able to flow, particularly because of the pressure exerted as a result of the movement of the piston relative to the container. The piston is preferably made at least partially from a viscoelastic material so as to ensure tightness in the region of contact between the container and the piston. At the same time, the volume of the medical product contained in the medical device varies, for example decreases, according to the relative movement between the two parts of the medical device.</p> <p><b>Boulangé at 1:3-22.</b></p> <p>With reference to figures 1 and 2, the medical device 1 comprises a first part 1 comprising parts 2 and 3, one being complementary to the other, for example a piston 3 and a container 2, the piston 3 and the internal surface of the container 2 being in contact with one another via a contact region 10. The piston 3 and the container 2 are able to move with respect to the other in a predetermined gliding movement 4, for example translationally and/or rotationally. The container 2 is intended to accommodate</p> |

| Claim Language | Corresponding Disclosure   |
|----------------|--|
|                | <p>product 6 in the liquid, gaseous or fluid phase, the volume of said product according to the movement of the piston 3 with respect to the container 2. for administering the product 6, the piston 3 is caused to move distally along figure 1 in order to push the product 6 out of the container 2. The piston 3 deform in order to tighten the contact region 10. For example on figure 2, the developed surface of the piston 3, which corresponds to the contact region provided with a coating 8 which is continuous, intrinsically elastic and firm the piston 3.</p> <p><b>Boulange at 9:21-35.</b></p> <p>The following test protocol is performed on a medical device 1 of the syringe according to the second embodiment depicted in Figure 2 of the present application.</p> <p>The container 2 is a glass syringe body accommodating a piston 3 able to move translationally along arrow 4 of figure 2 inside the container 2.</p> <p>The piston 3 is made of a viscoelastic material such as bromobutyl rubber commercially available at West Company, or chlorobutyl rubber commercially available at West Company.</p> <p><b>Boulange at 13:8-15.</b></p> |

| Claim Language                | Corresponding Disclosure  |
|-------------------------------|---|
|                               |  <p><b>FIG. 2</b></p> <p><b>Boulangé at Figure 2; see also Boulangé at Figure 1.</b></p> <p>tests were applied on containers filled with 1 mL of demineralised water a with one piston to be tested ( coated or uncoated)"</p> <p><b>Boulangé at 14:19-21.</b></p> <p>To the extent Novartis alleges this limitation is not met by any of the disclosures have been obvious in view of Sigg, Lam, Reuter, Scypinski, Metzner, Shah, Fr Chacornac, Nema, D'Souza, Furfine, Badkar, Macugen, Eylea, Lucentis, Stew Hioki, DC365, Hagen, Khandke, Wittland, Shams, Dixon, and/or Cormier. See A-13, B-1–B-3 and all references cited therein.</p> |
| terminally sterilized syringe | It would have been obvious to terminally sterilize the prefilled syringe disclosure POSITA would have understood and appreciated the benefits of terminal steril or EtO and would have found it obvious to sterilize the syringe in such manner claim limitation.   |

| Claim Language | Corresponding Disclosure   |
|----------------|--|
|                | <p>Boulangé alone or in view of Lam, Sigg, Nema, Metzner, Wittland, Hagen, Scypinski, and/or D’Souza, disclose a terminally sterilized syringe. A POSITA would have had a reasonable expectation of success combining Boulangé and Lam, Sigg, Nema, Metzner, Wittland, Hagen, Scypinski, and/or D’Souza in a way that would satisfy this limitation.</p> <p>To the extent this limitation is not expressly and/or inherently disclosed by Boulangé, this limitation would have been obvious, even without resorting to the disclosures of Lam, Sigg, Nema, Metzner, Wittland, Hagen, Scypinski, and/or D’Souza, because it was within the common knowledge of persons of ordinary skill in the art, and a POSITA would have used according to known methods, to achieve predictable results.</p> <p>In addition, the 631 Patent fails to disclose a new process for terminal sterilization. Boulangé explains “a careful balancing act is required to ensure that while a suitable level of sterilization is carried out, the syringe remains suitably sealed, such that the therapeutic is not lost.” 631 Patent at 1:31-36. The 631 Patent says that the sterilization it discloses may be carried out by various methods, such as by using VHP or EtO, but no details are provided regarding the specific process itself. 631 Patent at 9:49-54 (“As noted above, a terminal sterilisation process is required to sterilise the syringe and such a process may use a known process such as an ethylene oxide (EtO) or a hydrogen peroxide (H2O2) sterilisation process. Needles to be used in the syringe may be sterilised by the same method, as may kits according to the invention.”). The description in the 631 Patent only sets forth desired results – how long the syringe should be sterilized, the Sterility Assurance Level, the alkylation of the product, and the amount of residual sterilant remaining – but does not detail the steps to achieving them. <i>See e.g., id.</i> at 9:55-56. The 631 Patent does not provide any details regarding the known sterilization methods used in the art, and those methods were known in the art and thus render this claim limitation obvious.</p> <p>A POSITA would have known that terminal sterilization of prefilled containers and syringes in their packaging is one way to sterilize the device and maintain a low bio-burden and low level of contaminants. A POSITA also would have known that terminal sterilization is achieved through a range of solutions, including those that are temperature, oxidation, or radiation based.</p> |

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