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, Sc Shah, Fries, Schoenknecht, Chacornac, Nema, D'Souza, Furfine, Badkar, Macugen, Eylea, Lucentis, Stewart, US DC365, Hagen, Khandke, Wittland, Shams, Dixon, and/or Cormier, render obvious claims 1-26 of U.S. Patent N

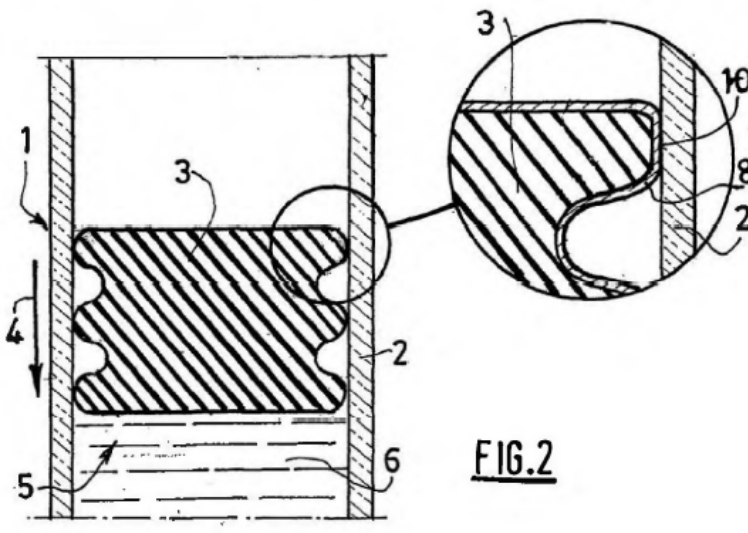
Boulange is an International Patent Application publication that was published on March 12, 2009, and therefore at least under pre-AIA § 102(b).

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

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

Claim Language	Corresponding Disclosure
[1.a-pre] A pre-filled . . . syringe	Boulange discloses a pre-filled syringe. For example, see the following passages and/or figures, as well as all related d The present invention relates in general to a medical device, for example a comprising at least one smooth coated part, , for example a container and/ parts being able to move one relative to the other, for example translationa rotationally, when the medical device is operated. In this application, the term distal means the part furthest from the user's h term proximal means the part closest to the user's hand. Likewise, in this a term "distal direction" means the direction of administration, i.e., towards the term "proximal direction" means direction opposite to the direction of i.e., away from the patient. Furthermore, the container is intended to accommodate a medical product gaseous, fluid, pasty or lyophilized phase, which may have a variable visc therefore able to flow, particularly because of the pressure exerted as a res movement of the piston relative to the container. The piston is preferably partially from a viscoelastic material so as to ensure tightness in the regio between the container and the piston. At the same time, the volume of the contained in the medical device varies, for example decreases, according t movement between the two parts of the medical device. **Boulange at 1:3-22.** With reference to figures 1 and 2, the medical device 1 comprises a first a parts 2 and 3, one being complementary to the other, for example a piston container 2, the piston 3 and the internal surface of the container 2 being i one another via a contact region 10. The piston 3 and the container 2 are a with respect to the other in a predetermined gliding movement 4, for exam translationally and/or rotationally. The container 2 is intended to accomm

Claim Language	Corresponding Disclosure
	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 alo 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 reg provided with a coating 8 which is continuous, intrinsically elastic and firr the piston 3. **Boulange at 9:21-35.** The following test protocol is performed on a medical device 1 of the syri according to the second embodiment depicted in Figure 2 of the present ap The container 2 is a glass syringe body accommodating a piston 3 able to translationally along arrow 4 of figure 2 inside the container 2. The piston 3 is made of a viscoelastic material such as bromobutyl rubber available at West Company, or chlorobutyl rubber commercially available Company. **Boulange at 13:8-15.**

Claim Language	Corresponding Disclosure
	 FIG.2 **Boulange at Figure 2; *see also* Boulange at Figure 1.** tests were applied on containers filled with 1 mL of demineralised water a with one piston to be tested (coated or uncoated)") **Boulange at 14:19-21.** To the extent Novartis alleges this limitation is not met by any of the disclosur 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.
terminally sterilized syringe	It would have been obvious to terminally sterilize the prefilled syringe disclose 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
	Boulange alone or in view of Lam, Sigg, Nema, Metzner, Wittland, Hagen, Sc D'Souza, disclose a terminally sterilized syringe. A POSITA would have had a expectation of success combining Boulange and Lam, Sigg, Nema, Metzner, W Scypinski, and/or D'Souza in a way that would satisfy this limitation. To the extent this limitation is not expressly and/or inherently disclosed by Bo limitation would have been obvious, even without resorting to the disclosures reference, because it was within the common knowledge of persons of ordinary was used according to known methods, to achieve predictable results. In addition, the 631 Patent fails to disclose a new process for terminal sterilizat explains "a careful balancing act is required to ensure that while a suitable leve carried out, the syringe remains suitably sealed, such that the therapeutic is not Patent at 1:31-36. The 631 Patent says that the sterilization it discloses may be methods, such as by using VHP or EtO, but no details are provided regarding t process itself. 631 Patent at 9:49-54 ("As noted above, a terminal sterilisation p to sterilise the syringe and such a process may use a known process such as an (EtO) or a hydrogen peroxide (H2O2) sterilisation process. Needles to be used may be sterilised by the same method, as may kits according to the invention." description in the 631 Patent only sets forth desired results – how long the syri the Sterility Assurance Level, the alkylation of the product, and the amount of remaining – but does not detail the steps to achieving them. *See e.g.*, *id.* at 9:55 631 Patent does not provide any details regarding the known sterilization meth those methods were known in the art and thus render this claim limitation obvi A POSITA would have known that terminal sterilization of prefilled containers packaging is one way to sterilize the device and maintain a low bio-burden and contaminants. A POSITA also would have known that terminal sterilization is range of solutions, including those that are temperature, oxidation, or radiation

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.