UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF NEW YORK

NOVARTIS PHARMA AG, NOVARTIS PHARMACEUTICALS CORPORATION, and NOVARTIS TECHNOLOGY LLC, Plaintiffs, v. **REGENERON PHARMACEUTICALS, INC.,** Defendant.	Civil Action No.: 1:20-cv-00690 (TJM-CFH) **JURY TRIAL DEMANDED**

REGENERON PHARMACEUTICALS, INC.'S PARTIAL ANSWER TO NOVARTIS'S COMPLAINT FOR PATENT INFRINGEMENT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIM

Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Defendant"), by and through its attorneys, Barclay Damon LLP and Weil, Gotshal & Manges LLP, as and for its Partial Answer[1], Affirmative Defenses, and Counterclaim to the Complaint for Patent Infringement (the "Complaint") of plaintiff Novartis Pharma AG, Novartis Pharmaceuticals Corporation, and Novartis Technology LLC (collectively, "Plaintiffs" or "Novartis"), state as follows:

1. Regeneron admits Wet age-related macular degeneration ("Wet AMD") is the leading cause of vision loss in individuals over 50, drugs called vascular endothelial growth factor ("VEGF")-antagonists can be used to treat Wet AMD and other devastating ophthalmic conditions,

[1] Regeneron has filed a motion to dismiss concurrently with this Partial Answer directed to the allegations of paragraphs 33 and 34 of the Complaint, and has therefore not responded to those allegations in this Answer.

but must be injected into the eye by a physician, and that the injection itself carries a risk of complications including infection, inflammation, introduction of particles into the eye, and even potentially blindness. Regeneron denies the remaining allegations contained in paragraph 1 of the Complaint.

2. Regeneron admits it manufactures and markets in the United States a product called EYLEA® ("EYLEA"), which is provided in vial and pre-filled syringe ("PFS") presentations ("EYLEA PFS"), both of which contain the VEGF-antagonist aflibercept. Regeneron denies the remaining allegations contained in paragraph 2 of the Complaint.

3. Regeneron denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph # of the Complaint, and therefore, denies them.

4. Regeneron denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 4 of the Complaint, and therefore, denies them.

5. Regeneron denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 5 of the Complaint, and therefore, denies them.

6. Regeneron admits the allegations contained in paragraph 6 of the Complaint.

7. Regeneron admits the allegations contained in paragraph 7 of the Complaint.

8. Regeneron admits that the Complaint alleges a cause of action for patent infringement under 35 U.S.C. § 271, but denies the remaining allegations contained in paragraph 8 of the Complaint.

9. Regeneron admits the allegations contained in paragraph 9 of the Complaint.

10. Regeneron admits the allegations contained in paragraph 10 of the Complaint.

11. Regeneron admits it has a facility at 81 Columbia Turnpike, Rensselaer, New York 12144 and admits that venue is proper in this District. Regeneron denies the remaining allegations contained in paragraph 11 of the Complaint.

12. Regeneron admits that on December 29, 2015, the United States Patent and Trademark Office issued the '631 Patent[2], entitled "Syringe," and that the patent lists as inventors Juergen Sigg, Christophe Royer, Andrew M. Bryant, Heinrich M. Buettgen, and Marie Picci. Regeneron admits that what appears to be a true and correct copy of the '631 Patent is attached as Exhibit A to the Complaint. Regeneron denies the remaining allegations contained in paragraph 12 of the Complaint.

13. Regeneron admits that 35 U.S.C. § 282 states that a patent shall be presumed valid. Regeneron denies the remaining allegations contained in paragraph 13 of the Complaint.

14. Regeneron denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 14 of the Complaint, and therefore, denies them.

15. Regeneron admits Claim 1 of the '631 Patent reads as follows:

> 1. A pre-filled, terminally sterilized syringe for intravitreal injection, the syringe comprising a glass body forming a barrel, a stopper and a plunger and containing an ophthalmic solution which comprises a VEGF-antagonist, wherein:
>
> (a) the syringe has a nominal maximum fill volume of between about 0.5 ml and about 1 ml,
>
> (b) the syringe barrel comprises from about 1 µg to 100 [µ]g silicone oil,

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[2] The "'631 patent" refers to U.S. Patent No. 9,220,631.

(c) the VEGF antagonist solution comprises no more than 2 particles > 50 μm in diameter per ml and wherein the syringe has a stopper break loose force of less than about 11N.

Regeneron denies the remaining allegations contained in paragraph 15 of the Complaint.

16. Regeneron admits EYLEA PFS is a syringe pre-filled with the VEGF-antagonist aflibercept and approved for the treatment of, among other things, Wet AMD. Regeneron denies the remaining allegations contained in paragraph 16 of the Complaint.

17. Regeneron realleges and incorporates by reference its responses in the preceding paragraphs as though fully stated herein.

18. Regeneron denies that EYLEA PFS satisfies each and every element, either literally or under the doctrine of equivalents, of one or more claims of the '631 Patent and otherwise denies the allegations of paragraph 18.

19. Regeneron admits that EYLEA PFS is a pre-filled, terminally sterilized syringe for intravitreal injection.

20. Regeneron denies that the EYLEA PFS syringe comprises a glass body forming a barrel, a stopper, and a plunger to the extent Novartis maintains its assertion that the plunger and stopper of claim 1 of the '631 Patent requires a particular design that limits movement of the stopper and prevents ingress of gasses during sterilization, as Novartis asserted in International Trade Commission Investigation No. 337-TA-1207.

21. Regeneron admits that the EYLEA PFS contains an ophthalmic solution which comprises a VEGF-antagonist. Regeneron admits the drug product in the EYLEA PFS is a solution of the VEGF antagonist aflibercept provided at a strength of 40 mg/mL, and the approved indications for EYLEA PFS are ophthalmic.

22. Regeneron admits that the EYLEA PFS has a nominal maximum fill volume of between about 0.5 ml and about 1 ml.

23. Regeneron denies that the EYLEA PFS barrel comprises about 1 µg to 100 µg silicone oil to the extent Novartis maintains its assertion that silicone oil quantities measured via certain methods are not within the scope of claim 1 of the'631 Patent, as Novartis asserted in International Trade Commission Investigation No. 337-TA-1207.

24. Regeneron admits that the VEGF antagonist solution in the EYLEA PFS comprises no more than 2 particles >50 µm in diameter per ml.

25. Regeneron admits that, to the extent this claim limitation is not indefinite, the EYLEA PFS can have a stopper break loose force of less than 11N depending on the test conditions at which the stopper break loose force is measured. Regeneron otherwise denies the allegations in this paragraph.

26. Regeneron admits that the EYLEA PFS is presented in one blister pack containing one EYLEA 2 mg/0.05 mL sterile, single-dose pre-filled glass syringe.

27. Regeneron admits that the VEGF-antagonist aflibercept in the EYLEA PFS is administered by intravitreal injection.

28. Regeneron denies that it has made, used, offered for sale, sold, and or imported, and continues to make, use, offer for sale, sell, and/or import, the infringing EYLEA PFS product in the United States to the extent the EYLEA PFS does not infringe the '631 Patent as described above in paragraphs 18-27.

29. Regeneron denies that it has actively encouraged infringement of at least claim 24 of the '631 Patent by providing physicians with instructions to administer EYLEA PFS to treat patients suffering from choroidal neovascularization, wet age-related macular degeneration,

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