IN THE 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) **DEMAND FOR JURY TRIAL**

FIRST AMENDED COMPLAINT AND ANSWER TO COUNTERCLAIM

Plaintiffs Novartis Pharma AG ("NPAG"), Novartis Pharmaceuticals Corporation ("NPC") and Novartis Technology LLC ("NT") (collectively, "Plaintiffs" or "Novartis") bring this action against Defendant Regeneron Pharmaceuticals, Inc. ("Regeneron") for infringement of U.S. Patent No. 9,220,631 ("the '631 patent").

INTRODUCTION

1. 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, but must be injected into the eye by a physician. The injection itself carries a risk of complications including infection, inflammation, introduction of particles into the eye, and even potentially blindness. To address the problems associated with injection of VEGF-antagonists into the eye, Novartis scientists invented groundbreaking pre-filled, sterilized syringes that permit more safe, effective and

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efficient injections of VEGF-antagonists into the eye. These inventions are disclosed and claimed in the '631 patent.

2. Regeneron 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. EYLEA® PFS unlawfully uses Novartis's patented syringe technology and infringes the '631 patent.

THE PARTIES

3. Plaintiff Novartis Pharma AG is a company organized and existing under the laws of Switzerland, with a principal place of business at Forum 1 Novartis Campus, CH-4056 Basel, Switzerland.

4. Plaintiff Novartis Pharmaceuticals Corporation is a Delaware corporation with a principal place of business at One Health Plaza, East Hanover, New Jersey, 07936.

5. Plaintiff Novartis Technology LLC is a Delaware corporation with a principal place of business at One Health Plaza, East Hanover, New Jersey, 07936.

6. On information and belief, Regeneron is a New York corporation with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, New York 10591.

7. On information and belief, Regeneron has an established facility in this District at 81 Columbia Turnpike, Rensselaer, New York 12144.

JURISDICTION AND VENUE

8. This is an action for patent infringement arising under 35 U.S.C. § 271.

9. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. The Court has personal jurisdiction over Regeneron because it is domiciled in New York.

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11. Venue is proper in this District under 28 U.S.C. §§ 1400(b) and 1391. On information and belief, Regeneron has a regular and established place of business in Rensselaer, New York, which is within this District, and Regeneron has committed acts of infringement within the District.

BACKGROUND

12. On December 29, 2015, the United States Patent and Trademark Office duly and legally issued the '631 patent, entitled "Syringe," to inventors Juergen Sigg, Christophe Royer, Andrew M. Bryant, Heinrich M. Buettgen, and Marie Picci. A true and correct copy of the '631 patent is attached as Exhibit A.

13. The '631 patent is valid and presumed valid under 35 U.S.C. § 282. The '631 patent is also enforceable.

14. Novartis owns the right, title and interest in the '631 patent necessary to bring this action, including the exclusive right to enforce the patent in the United States.

15. The '631 patent discloses and claims certain novel terminally sterilized, pre-filled syringes that include VEGF-antagonists. Claim 1, for example, 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,
>
> (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.

(the '631 patent (Exhibit A) at cl. 1).

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16. EYLEA® PFS is a syringe pre-filled with the VEGF-antagonist aflibercept and approved for the treatment of, among other things, Wet AMD. On information and belief, EYLEA® PFS is covered by one or more claims of the '631 patent.

COUNT I: INFRINGEMENT OF THE '631 PATENT

17. Novartis realleges and incorporates by reference the allegations in the preceding paragraphs as though fully stated herein.

18. Regeneron was found by an administrative law judge of the International Trade Commission ("ITC") in a Section 337 Investigation captioned *Certain Pre-filled Syringes for Intravitreal Injection and Components Thereof*, Inv. No. 337-TA-1207 (U.S. ITC Jun. 19, 2020) (the "ITC Investigation") to infringe several claims of the '631 patent.

19. Regeneron's EYLEA® PFS satisfies each and every element, either literally or under the doctrine of equivalents, of one or more claims of the '631 patent, including at least claim 1 as follows.

20. EYLEA® PFS is a pre-filled, terminally sterilized syringe for intravitreal injection.

21. The EYLEA® PFS syringe comprises a glass body forming a barrel, a stopper, and a plunger.

22. The EYLEA® PFS contains an ophthalmic solution which comprises a VEGF-antagonist. 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.

23. The EYLEA® PFS has a nominal maximum fill volume of between about 0.5 mL and about 1 mL.

24. The EYLEA® PFS barrel comprises about 1 µg to 100 µg silicone oil.

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25. The VEGF antagonist solution in the EYLEA® PFS comprises no more than 2 particles >50 μm in diameter per mL.

26. The EYLEA® PFS has a stopper break loose force of less than about 11N.

27. The EYLEA® PFS is presented in one blister pack containing one EYLEA® 2 mg/0.05 mL sterile, single-dose pre-filled glass syringe.

28. The VEGF-antagonist aflibercept in the EYLEA® PFS is administered by intravitreal injection.

29. Since at least December 2019, Regeneron 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. Such conduct constitutes direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '631 patent under 35 U.S.C. § 271(a).

30. Regeneron 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, macular edema secondary to retinal vein occlusion, choroidal neovascularization secondary to pathologic myopia, diabetic macular edema, diabetic retinopathy, and/or proliferative retinopathy. On information and belief, the physicians have infringed and will continue to infringe at least claim 24 by treating such patients in this manner.

31. Regeneron has actively induced infringement of one or more claims of the '631 patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(b).

32. Regeneron's unlawful infringement activities have caused and will continue to cause Novartis substantial harm.

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