IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

IN RE: AFLIBERCEPT PATENT LITIGATION

MDL NO. 1:24-MD-3103-TSK

THIS DOCUMENT RELATES TO CASE NO. 1:23-CV-89

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ORDER GRANTING MOTION FOR PRELIMINARY INJUNCTION

Pending before the Court is Plaintiff Regeneron's Motion for Preliminary Injunction [ECF Nos. 108, 131[1]]. The motion is fully briefed and ripe for decision. For the reasons set forth herein, the motion is **GRANTED**.

I. PRELIMINARY STATEMENT

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") filed this patent infringement action. Therein, at issue in the preliminary injunction is one of those patents: U.S. Patent No. 11,084,865 (the "Product Patent"). The asserted patent claims are associated with Regeneron's product Eylea® and Celltrion's filing of an abbreviated Biologics License Application ("aBLA") seeking to commercially manufacture, use, import, offer to sell, and/or sell "CT-P42," a biosimilar version of Eylea.

[1] All docket references are to member case 1:23-CV-89 unless otherwise indicated.

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II. FACTUAL BACKGROUND

1. Regeneron's Eylea Product

Regeneron invented and developed Eylea, which the U.S. Food and Drug Administration ("FDA") approved on November 18, 2011. The Court has previously addressed the pertinent background and development of Eylea. See Regeneron Pharm., Inc. v. Mylan Pharm. Inc., --- F. Supp. 3d ---, 2024 WL 382495, at *13-14 (N.D.W. Va. Jan. 31, 2024) ("Mylan") (discussing relevant background of Eylea). "Eylea is an ophthalmic drug product invented by Regeneron scientists that has been used to treat millions of patients suffering from diseases that can cause vision loss or even blindness." Id. at *13. The active ingredient in Eylea is the fusion protein now referred to as aflibercept. Aflibercept was initially developed as a cancer therapeutic and Regeneron later discovered that aflibercept could be used to treat angiogenic eye diseases—eye diseases caused by uncontrolled blood vessel growth in the retina—through intravitreal injections (injection into the vitreous of the eye). Id. at *13-14.

After more than a decade of development and multiple clinical trials, Regeneron achieved an Eylea formulation that improved on the leading treatment for one angiogenic disease—wet Age-Related Macular Degeneration ("AMD"). Id. at *13 (quoting Trial Tr.

172:16-24 (Yancopoulos)). The Eylea formulation contains 40 mg/ml aflibercept, 10 mM sodium phosphate, 40 mM sodium chloride, 0.03% polysorbate 20, and 5% sucrose, pH 6.2. Id. at *14. Following its initial FDA approval, Regeneron tested Eylea effectiveness in patients with other angiogenic eye disorders, ultimately obtaining approval for Eylea's use to treat those conditions as well. Id. Soon, Eylea "became the new gold standard of care" for treating such eye disorders. Mylan Trial Tr. at 172:19-20 (ECF No. 108-27, Sheridan Ex. 51).

Following the success of Regeneron's Eylea vial formulation, Regeneron developed and obtained approval in November 2011 for Eylea in a pre-filled syringe ("PFS"). See Sheridan Decl. ¶ 48 (ECF No. 108-21). Then in August 2023, Regeneron received approval to sell Eylea HD, an 8 mg formulation that requires less frequent injections and provides improved anatomical outcomes in the form of drier retinas. Id.; Clark Decl. ¶ 3 (ECF No. 108-34). Eylea HD is currently approved to treat wet AMD, Diabetic Macular Edema ("DME"), and Diabetic Retinopathy ("DR"). Clark Decl. ¶ 3.

2. Other Anti-VEGF Treatments

For the past five years, Eylea has maintained its place as the "category leader" in anti-VEGF treatments, [redacted]

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[redacted] The second most popular anti-VEGF agent, Avastin (bevacizumab), [redacted] Avastin is an oncology drug for metastatic colorectal cancer (among other cancers), but ophthalmologists sometimes use it off-label (i.e., for diseases for which it does not have FDA approval) to treat angiogenic eye disorders. Sheridan Decl. ¶ 55 (ECF No. 108-21). The third- and fourth-most popular anti-VEGF agents, Vabysmo (faricimab) and Lucentis (ranibizumab), are approved to treat angiogenic eye disorders. Id. ¶¶ 57-59. Genentech manufactures all three drugs. Id. ¶¶ 55, 57-59.

Eylea, Avastin, Vabysmo, and Lucentis make up more than [redacted] of anti-VEGF ophthalmic sales. Clark Decl. ¶ 6; Clark Ex. 1 at 3-4. Other products on the market—such as Beovu are prescribed less frequently. Regeneron Pharms., Inc. v. Mylan Pharms., Inc., C.A. No. 1:22-cv-61, ECF No. 571 (Trial Tr.) at 861:6-862:4 (Albini). Overall, Eylea has maintained its category leadership due to its safety, efficacy, and dosing regimen advantage. Clark Decl. ¶ 7.

3. Aflibercept Biosimilars

At least nine pharmaceutical companies are developing and seeking FDA approval for aflibercept biosimilars, each of which contains the same active ingredient as Eylea, also in a 2 mg vial

and in some cases PFS formulation. Sheridan Decl. ¶ 49. Absent injunctive relief, Regeneron expects [redacted]

4. Celltrion's aBLA and Proposed Biosimilar Product

Celltrion is a Korean biopharmaceutical company headquartered in Incheon, South Korea and is focused on the development of biosimilars to previously licensed "reference products" like Regeneron's Eylea® product. Shin Decl. ¶¶ 2-3 (ECF No. 68-1). On June 30, 2023, Celltrion filed aBLA No. 761377 ("Celltrion's aBLA") with FDA seeking approval under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. §§ 262(k)-(l), to market and distribute its biosimilar of Eylea, "CT-P42," throughout the United States, including in West Virginia. Shin Decl. ¶¶ 4, 9. [redacted]

Celltrion's aBLA specifies [redacted]

[2] CT-P42 is supplied in two presentations: a vial as part of a vial kit and a pre-filled syringe. Trout Decl. App. A ¶¶ 1, 10, 109 (ECF No. 108-4).

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