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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Case No.: **1:22-CV-61 (Kleeh)**

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") invented, developed, and sells Eylea®, the market-leading treatment for certain serious eye diseases. Defendant Mylan Pharmaceuticals Inc. ("Mylan") is seeking FDA approval under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. §§ 262(k)-(*l*), to commercialize "M710," a proposed biosimilar of Eylea®. To vindicate its patent rights, Regeneron brings this Complaint seeking a judgment of patent infringement against Mylan under 35 U.S.C. § 271(e) and pursuant to the BPCIA.

NATURE OF THE CASE

1. Regeneron is a leading science-based American biotechnology company dedicated to improving human health and tackling the most urgent medical issues facing the Nation. Founded and led for over 30 years by physician-scientists, Regeneron has developed life-transforming medicines for people with serious diseases, including cancer, atopic dermatitis, asthma, eye diseases, cardiovascular and metabolic diseases, Ebola, and COVID-19, the latter of which has been used across the country, including by the former President. Regeneron's cutting-edge scientific advances were supported, in large part, by its ophthalmic product, Eylea®, which

FDA approved in 2011.

2. Eylea® has been administered millions of times to treat certain ophthalmic disorders that, if left untreated, can lead to permanent blindness. Its active ingredient is a genetically engineered fusion protein called aflibercept. It works by blocking the overproduction of a naturally occurring protein in the eye that can cause the formation of new blood vessels, leading to vision loss. Based on extensive clinical testing by Regeneron, FDA approved Eylea® in 2011 to treat an ophthalmic disorder called neovascular age-related macular degeneration. As a result of Regeneron's additional clinical testing, Eylea® is now also approved for use in treating other serious disorders of the eye: diabetic macular edema, macular edema following retinal vein occlusion, and diabetic retinopathy. And other clinical trials are ongoing, including to treat a retinal disease in premature babies called retinopathy of prematurity. In addition to benefitting the many patients it has been used to treat, Eylea® is also a critical source of research and development funding for Regeneron.

3. Last October, Mylan filed for FDA approval under the BPCIA to commercialize a "biosimilar" copy of Eylea®. Enacted in 2010 as part of the Affordable Care Act, the BPCIA provides for a substantially abbreviated regulatory approval pathway for biosimilars by letting applicants rely on the extensive clinical testing previously conducted, at great expense, by the innovator company that developed the medicine the applicant wants to copy. *See Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664 (2017).

4. On December 28, 2021, FDA notified Mylan that its application—i.e., its abbreviated Biologic License Application, or "aBLA" No. 761274—for M710 had been accepted for review. Mylan's submission of its aBLA constitutes an act of patent infringement under 35 U.S.C. § 271(e).

5. By statute, Regeneron could not immediately file a lawsuit for Mylan's § 271(e) infringement. The BPCIA prohibits filing such a suit until certain requirements of 42 U.S.C. § 262(*l*), commonly called the "patent dance," are satisfied. In the patent dance, the BPCIA directs exchanges of certain information between the innovator company (or "reference product sponsor") and the biosimilar (or "subsection (k)") applicant. At the end of the patent dance, the reference product sponsor is authorized to initiate litigation against the biosimilar applicant within thirty days in a venue of its choosing. Mylan, the subsection (k) applicant, and Regeneron, the reference product sponsor, completed the final step of the patent dance—the exchange of lists of patents pursuant to § 262(*l*)(5)—on July 5. Regeneron then promptly brought this action as required by § 262(*l*)(6) to address Mylan's patent infringement under § 271(e).

THE PARTIES, JURISDICTION, AND VENUE

6. Regeneron Pharmaceuticals, Inc. is a corporation organized under the laws of the State of New York, with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591. The company is dedicated to discovering, developing, and commercializing medicines to treat patients with debilitating and life-threatening diseases. Regeneron owns each of the patents asserted in this Complaint: U.S. Patent Nos. 7,070,959; 9,222,106; 9,254,338; 9,669,069; 9,816,110; 10,130,681; 10,406,226; 10,415,055; 10,464,992; 10,669,594; 10,857,205; 10,888,601; 10,927,342; 10,973,879; 11,053,280; 11,066,458; 11,084,865; 11,104,715; 11,174,283; 11,186,625; 11,253,572; 11,299,532; 11,306,135; and 11,332,771 (collectively, the "asserted patents" or the "patents in suit").

7. On information and belief, Mylan Pharmaceuticals Inc. is a corporation organized under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan

Pharmaceuticals Inc. is a wholly owned subsidiary of Viatris Inc. ("Viatris").

8. On information and belief, Mylan develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state, including West Virginia, either directly or indirectly.

9. Regeneron's claims for patent infringement arise under the patent laws of the United States, Titles 35 and 42 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. Mylan and its development partners have publicly announced their intention to ignore Regeneron's patent rights and launch an aflibercept biosimilar product before the expiration of the patents asserted in this action.

11. On information and belief, Momenta Pharmaceuticals Inc. is or was Mylan's development partner for its proposed aflibercept biosimilar product. In August 2020, Momenta publicly announced that it "believe[d]" its collaboration with Mylan to market an aflibercept biosimilar product "has the potential to launch in the 2023 time frame,"[1] before the expiry of the asserted patents.

12. Viatris later announced its intention to become the "first to market" an aflibercept biosimilar product. Rajiv Malik, the president of Viatris, explained that becoming "the first to market [an aflibercept biosimilar product] is becoming [sic] decisive advantage. And that's where we're going to focus on that how can we be the first to market."[2]

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[1] Momenta Pharmaceuticals Inc., Form 10-Q, at 26 (Aug. 10, 2020), https://seekingalpha.com/filings/pdf/14323380.

[2] Goldman Sachs 42nd Annual Global Healthcare Conference, Viatris Inc. Presentation (June 10, 2021), https://seekingalpha.com/article/4434224-viatris-inc-vtrs-management-presents-goldman-sachs-42nd-annual-global-healthcare-conference.

13. This Court has personal jurisdiction over Mylan because it is incorporated in the State of West Virginia; because Mylan is seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of M710 in the United States, including in the State of West Virginia; and because, if its product receives FDA approval, Mylan intends to market, distribute, offer for sale, and/or sell it in the United States, including in the State of West Virginia, deriving substantial revenue therefrom.

14. In addition, Mylan has consented to jurisdiction in the State of West Virginia in one or more prior cases arising out of its manufacture, use, offer for sale, sale, and/or importation of Mylan pharmaceutical products in the United States, including in the State of West Virginia.

15. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and § 1400(b). Venue is proper because Mylan Pharmaceuticals Inc. is incorporated in the State of West Virginia and resides in this judicial district.

FACTUAL BASIS FOR RELIEF

16. The BPCIA provides a mechanism to obtain FDA approval for a biological product that is "biosimilar" to a previously licensed "reference product" such as Eylea®. 42 U.S.C. § 262(k). In order to be approved, biosimilars must be "highly similar to the reference product notwithstanding minor differences in clinically inactive components," with "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." *Id.* § 262(i)(2)(A)-(B).

17. The BPCIA reduces substantially the time and expense otherwise required to gain FDA approval, by allowing a biosimilar applicant like Mylan to rely on most of the prior clinical testing that Regeneron conducted to establish the safety and efficacy of the reference product (Eylea®). Regeneron, the reference product sponsor, invested many years of effort into its design and development of Eylea® and received numerous patents rewarding this research. In exchange

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