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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v. **CIVIL NO. 1:22-CV-61 (KLEEH)**

MYLAN PHARMACEUTICALS INC., and BIOCON BIOLOGICS, INC.,

Defendants.

****SEALED****

MEMORANDUM OPINION AND ORDER FOLLOWING BENCH TRIAL

I. INTRODUCTION

In this patent infringement action, the plaintiff, Regeneron Pharmaceuticals, Inc., ("Regeneron"), and the Defendants, Mylan Pharmaceuticals Inc. and Biocon Biologics, Inc. (collectively, "the Defendants"),[1] dispute whether the Defendants have infringed claims 6 and 25 of Regeneron's U.S. Patent No. 11,253,572 ("the '572 Patent"); Claims 11 and 19 of Regeneron's U.S. Patent No. 10,888,601 ("the '601 Patent"); and claims 4, 7, 9, 11, 14, 15, 16, and 17 of Regeneron's U.S. Patent No. 11,084,865 ("the '865 Patent"). They also dispute whether each of these asserted claims is valid and enforceable.

[1] Regeneron initially brought this lawsuit against only Defendant Mylan Pharmaceuticals Inc. ("Mylan"). (ECF No. 1). Defendant Biocon Biologics, Inc. was added later by stipulation (ECF No. 523).

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Regeneron has sued the Defendants under the Biologics Price Competition and Innovation Act ("BPCIA"), which "governs a type of drug called a biosimilar, which is a biologic product that is highly similar to a biologic product that has already been approved by the Food and Drug Administration (FDA)." Sandoz Inc. v. Amgen Inc., 582 U.S. 1, 5 (2017). The BPCIA provides an abbreviated route for FDA approval of biosimilars.

The patents-in-suit are associated with Regeneron's FDA approved Eylea® product, which contains a biological product known as aflibercept. The Defendants filed a Biologics License Application ("BLA") seeking FDA approval to market a biosimilar aflibercept product under the trade name Yesafili™ prior to the expiration of the patents in suit.[2] The Court is tasked with deciding the following:

(1) whether the Defendants' BLA products infringe claims 4, 7, 9, 11, 14, 15, 16, and 17 of the '865 Patent;

(2) whether the Defendants' proposed label induces infringement of claims 6 and 25 of the '572 Patent and claims 11 and 19 of the '601 Patent;

[2] Mylan filed BLA No. 761274 with the FDA on October 29, 2021. It transferred ownership of that BLA to Biocon effective March 31, 2023. (ECF No. 523).

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(3) whether claims 4, 7, 9, 11, 14, 15, 16, and 17 of the '865 Patent are invalid as anticipated or obvious or invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, or indefiniteness;

(4) whether claims 6 and 25 of the '572 Patent are invalid as anticipated or obvious or invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, or indefiniteness; and

(5) whether claims 11 and 19 of the '601 Patent are invalid as anticipated or obvious or invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, or indefiniteness.

Following a nine-day bench trial, the parties submitted their memoranda of law of these issues, and the case is ripe for the Court's decision.

II. FINDINGS OF FACT

A. Parties, Jurisdiction, and Venue

Regeneron 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. Mylan is a company organized under the laws of the State of West Virginia with its principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505. Mylan is an indirect wholly-owned subsidiary

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of Viatris Inc. Biocon is a company based in India. The Court has subject matter and personal jurisdiction, and venue in this District is proper.

B. The BPCIA

Under the Public Health Service Act ("PHSA"), a sponsor seeking to market a biologic drug must file a BLA with the Food and Drug Administration ("FDA") that details the biologic's chemistry, pharmacology, manufacturing process, and medical effects. Sandoz, 582 U.S. at 6. Through the BPCIA, Congress amended the Public Health Service Act and the Patent Act in an effort to balance the goals of competition and innovation. BPCIA § 7001(b), Pub. L. No. 111-148. To expedite getting competing "biosimilars" to market, Congress created an abbreviated regulatory approval pathway so that the biosimilar applicant does not have to regenerate early preclinical and clinical studies; rather, the applicant can instead rely, in part, on the data supporting the previous approval of a reference biologic product. 42 U.S.C. § 262(i)(2), (k); Sandoz, 582 U.S. at 7. A biosimilar "is a biologic product that is highly similar to a biologic product that has already been approved." Sandoz, 582 U.S. at 5.

The Defendants' BLA for its biosimilar product, Yesafili, relies on the Eylea BLA data as the reference biologic product

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under the statute. (ECF No. 1, ¶ 3; ECF No. 435, Answer to ¶ 3). To compensate the reference product sponsor ("RPS"), here Regeneron, for the use of these data, Congress grants the RPS a valuable twelve (12) years of marketing exclusivity, independent of any patent protection to which it is entitled. Sandoz, 582 U.S. at 7 ("the manufacturer of a new biologic enjoys a 12-year period when its biologic may be marketed without competition from biosimilars"). Regeneron's marketing exclusivity period (which includes an additional extension for performing a pediatric study) is set to expire on May 18, 2024. ECF Nos. 5, 7.

C. Procedural Background

By letter dated January 5, 2022, Mylan notified Regeneron that "FDA has received a BLA from Mylan for M710, a proposed biosimilar to aflibercept, which was submitted under 42 U.S.C. § 62(k)." By letter dated February 22, 2022, Regeneron served on Mylan a list of patents pursuant to 42 U.S.C. § 262(l)(3)(A), that Regeneron believed "could reasonably be asserted against a person 'engaged in the making, using, offering to sell, selling or importing into the United States of the biological product that is the subject of' Mylan's BLA No. 761274." Regeneron's list of patents pursuant to 42 U.S.C. § 262(l)(3)(A) included each patent-in-suit as well as additional patents. Mylan subsequently served

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