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

REGENERON PHARMACEUTICALS, INC. Plaintiff, v. SAMSUNG BIOEPIS, CO., LTD., Defendant.	CASE NO.: 1:23-cv-94 Kleeh JURY TRIAL DEMANDED ELECTRONICALLY FILED 11/21/2023 U.S. DISTRICT COURT Northern District of WV

COMPLAINT

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Plaintiff"), invented, developed, and sells EYLEA®, the market-leading treatment for several serious eye diseases. Defendant Samsung Bioepis Co., Ltd. ("Bioepis" or "Defendant") is seeking [redacted] To vindicate its patent rights, Regeneron brings this Complaint[1] pursuant to 28 U.S.C. §§ 2201-2202 and under 42 U.S.C. § 262(*l*)(9)(A)

[1] As explained in its forthcoming memorandum in support of its motion to seal, Regeneron is bound by the provisions of 42 U.S.C. § 262(*l*)(1), which dictate that Bioepis determine, "in its sole discretion," what information constitutes Bioepis confidential information, that no such "confidential information shall be included in any publicly-available complaint or other pleading," and any violation of paragraph 1 could result in "irreparable harm for which there is no adequate legal remedy" and for which "the court shall consider immediate injunctive relief to be an appropriate and necessary remedy." Therefore, Regeneron initiates this case by filing a public version of this Complaint with redactions to any information that Bioepis has represented is Bioepis confidential information.

seeking declaratory judgment of patent infringement against the Defendant under 35 U.S.C. §§ 271(a)-(c) and (g), and a judgment of patent infringement against the Defendant under 35 U.S.C. § 271(e).

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, which have been used across the country. Regeneron's cutting-edge scientific advances are 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 (wet) age-related macular degeneration ("wAMD") and in 2014 to treat diabetic macular edema ("DME"). As a result of Regeneron's additional clinical testing, EYLEA® is now also approved for use in treating other serious disorders of the eye: macular edema following retinal vein occlusion and diabetic retinopathy. Most recently, FDA granted approval for EYLEA® to treat retinopathy of prematurity in preterm infants, which is the leading cause of childhood blindness worldwide. 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 to develop other life-transforming medicines.

3. [redacted] Enacted in 2010 as part of the Affordable Care Act, the BPCIA provides for an 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.*, 582 U.S. 1 (2017).

4. [redacted]

5. [redacted] Regeneron files this action to obtain relief before Bioepis launches SB15 in the United States.

THE PARTIES, JURISDICTION, AND VENUE

6. Plaintiff Regeneron is a corporation organized and existing under the laws of the State of New York with its principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591. Regeneron 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 (collectively, the "asserted patents"

or the "patents in suit"):

Patent	First Named Inventor
9,222,106	Gang Chen
9,254,338	George D. Yancopoulos
9,315,281	Tikiri Jean Dissanayake
9,562,238	Gang Chen
9,816,110	Ying Shen
10,130,681	George D. Yancopoulos
10,415,055	Gang Chen
10,464,992	Eric Furfine
10,669,594	Serge Monpoeho
10,828,345	George D. Yancopoulos
10,888,601	George D. Yancopoulos
10,905,786	Philip Stephen Shodder
10,918,754	Philip Stephen Shodder
10,927,342	Amy S. Johnson
11,053,280	Andrew Tustian
11,066,458	Eric Furfine
11,084,865	Eric Furfine
11,104,715	Shawn Lawrence
11,174,283	Andrew Tustian
11,253,572	George D. Yancopoulos
11,299,532	Andrew Tustian
11,306,135	Shunhai Wang
11,312,936	Amy S. Johnson
11,332,771	Shadia Abike Oshodi
11,472,861	Shawn Lawrence
11,485,770	Shunhai Wang
11,535,663	Shawn Lawrence
11,542,317	Shunhai Wang
11,548,932	Shunhai Wang
11,555,176	Wei Xue
11,559,564	George D. Yancopoulos
11,707,506	George D. Yancopoulos
11,732,024	Eric Furfine
11,753,459	Shunhai Wang
11,769,597	Lorah Perlee
11,788,102	Ying Shen
7,070,959	Nicholas J. Papadopoulos

7. On information and belief, Bioepis is a company organized and existing under the laws of the Republic of Korea with its principal place of business located at 76, Songdogyoyuk-

ro, Yeonsu-gu, Incheon, Republic of Korea. Bioepis is a biopharmaceutical company that specializes in research and development of biosimilars and biopharmaceuticals.

8. On information and belief, Bioepis, directly or indirectly, manufactures its drug products abroad. On information and belief, Bioepis directly, or via its subsidiaries, affiliates, or other agents, develops, distributes, or sells within the United States or imports into the United States Bioepis's drug products, including SB15, under the general direction and control of Bioepis. Non-limiting examples are provided below.

9. Bioepis is the holder of aBLA No. 761054 for RENFLEXIS, an approved biosimilar of Remicade. On information and belief, Bioepis manufactures and imports RENFLEXIS, directly or indirectly, into the United States. For example, between April 2, 2020 and October 22, 2023, Bioepis imported 72 shipments of RENFLEXIS into the United States. As another example, between August 17, 2019 and October 25, 2023, Samsung Biologics Co. Ltd. ("Samsung Biologics")—the corporate parent of Bioepis—imported 57 shipments of RENFLEXIS into the United States.

10. [redacted] On information and belief, between August 29, 2021 and March 28, 2023, Bioepis imported or directed one or more of its subsidiaries, affiliates, or agents to import 17 shipments of SB15 into the United States. Each of these shipments contained product described as "AFLIBERCEPT (INHIBITOR (GROWTH FACTOR))." On information and belief, between July 2, 2019 and June 8, 2023, Samsung Biologics imported or directed one or more of its subsidiaries, affiliates, or agents to import 19 shipments of SB15 into the United States. Each of these shipments contained product described as "AFLIBERCEPT (INHIBITOR (GROWTH FACTOR))."

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