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

REGENERON PHARMACEUTICALS, INC.

Plaintiff,

v.

CELLTRION, INC.,

Defendant.

CASE NO.: **1:23-CV-89 (Kleeh)**

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Plaintiff"), invented, developed, and sells EYLEA®, the market-leading treatment for several serious eye diseases. Defendant Celltrion, Inc. ("Celltrion" or "Defendant") is seeking FDA approval under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. §§ 262(k)-(*l*), to commercialize "CT-P42," a proposed biosimilar of EYLEA®. Celltrion has served its notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A) ("Notice of Commercial Marketing"), indicating its intent to begin marketing and selling CT-P42 immediately upon receiving approval from the U.S. Food and Drug Administration ("FDA"). To vindicate its patent rights, Regeneron brings this Complaint pursuant to 28 U.S.C. §§ 2201-2202 and under 42 U.S.C. § 262(*l*)(9)(A) 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. On June 30, 2023, Celltrion publicly announced that it had filed abbreviated Biologics Drug Application ("aBLA") No. 761377 with FDA for CT-P42, a biosimilar copy of

EYLEA®. 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. Celltrion's submission of its aBLA constitutes an act of patent infringement under 35 U.S.C. § 271(e). Celltrion has also served its Notice of Commercial Marketing. Pursuant to 42 U.S.C. § 262(k)(7)(A), Celltrion's aBLA may be approved as soon as EYLEA®'s regulatory exclusivity expires on May 18, 2024. Regeneron files this action to obtain relief before Celltrion launches CT-P42 in the United States.

THE PARTIES, JURISDICTION, AND VENUE

5. 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
9,816,110	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

10,927,342	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
11,459,374	Andrew Tustian
11,472,861	Shawn Lawrence
11,485,770	Shunhai Wang
11,505,593	Shunhai Wang
11,525,833	Yuetian Yan
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
11,793,926	Andrew Cook
7,070,959	Nicholas J. Papadopoulos

6. Celltrion is a company organized and existing under the laws of the Republic of Korea with its principal place of business located at 23, Academy-ro, Yeonsu-gu, Incheon, Korea 22014. Celltrion is, among other things, engaged in the development of biologic drugs, including a proposed biosimilar version of Regeneron's EYLEA®, CT-P42.

7. Upon information and belief, Celltrion, directly or indirectly, manufactures its drug products abroad. Upon information and belief, Celltrion directly, or via its subsidiaries, affiliates, or other agents, develops, distributes, or sells within the United States or imports into the United States Celltrion's drug products, including CT-P42, under the general direction and control of Celltrion.

8. For example, it was announced in August 2023 that Celltrion will merge with Celltrion Healthcare Co. Ltd. by the end of 2023, and will merge with Celltrion Pharm Inc. six months later. A report from Celltrion's Board of Directors to its Shareholders states that, "[l]eading in the development and commercialization of the world's first antibody biosimilars in major markets like the U.S. and Europe, ***our companies*** have cemented themselves as top-tier players in the global biosimilars landscape." Exhibit 39 (emphasis added). "As we aim to leverage the accelerating market growth, merged Celltrion (MergeCo) will concentrate on optimizing operations to improve both agility and efficiency. This involves ***consolidating our existing subsidiaries***, which have until now operated independently with distinct focuses on development, production, and sales. The goal is to evolve into a ***fully integrated global life sciences company***." *Id.* (emphasis added).

9. A presentation on Celltrion's website regarding the Celltrion-Celltrion Healthcare Co. Ltd. merger states that the merger will simplify transactions and allow Celltrion to directly recognize revenue "vis-à-vis end-market product sales" with "[m]inimum related party transaction and working capital impact." Exhibit 40.

10. Celltrion's stated goal of evolving its affiliates and their respective subsidiaries into a fully integrated global life sciences company is supported by its past and current activities relating to its drug products. Non-limiting examples are described below.

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