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

ELECTRONICALLY FILED
May 17 2024
U.S. DISTRICT COURT
Northern District of WV

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

CELLTRION, INC.,

Defendant.

CASE NO.: **1:24-CV-53 (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 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"). Regeneron and Celltrion completed the BPCIA patent resolution negotiation requirements of 42 U.S.C. § 262(*l*)(4) and thus Regeneron brings this Complaint pursuant to 42 U.S.C. § 262(*l*)(6)(A), seeking a judgment of patent infringement under 35 U.S.C. § 271(e) against the Defendant.

NATURE OF THE CASE

1. Regeneron is a leading science-based American biotechnology company. With a focus on patient access and fair drug pricing, Regeneron is dedicated to innovation, 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 29, 2023, Celltrion 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 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. On information and belief, on or around sixty days after filing for approval, FDA notified Celltrion that its application—*i.e.*, its abbreviated Biologics License Application or "aBLA" No. 761377—for CT-P42 had been accepted for review. Celltrion provided to Regeneron its Notice of Commercial Marketing, indicating its intent to begin marketing and selling CT-P42 immediately upon receiving approval from FDA. 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. Celltrion's submission of its aBLA constitutes an act of patent infringement under 35 U.S.C. § 271(e).

5. On April 19, 2024, during 42 U.S.C. § 262(*l*)(4)(A) negotiations, Regeneron and Celltrion reached an agreement on the patents to be litigated, completing the final step in the pre-litigation exchanges before litigation under 42 U.S.C. § 262(*l*)(6)(A). Accordingly, Regeneron files this action pursuant to 42 U.S.C. § 262(*l*)(6)(A) to obtain relief from Celltrion's 271(e) infringement. This action is brought in addition to a related pending action before this Court. *See Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, No. 23-CV-00089-TSK (N.D.W. Va.).

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
9,816,110	Ying Shen
10,130,681	George D. Yancopoulos
10,415,055	Gang Chen
10,669,594	Serge Monpoeho
10,828,345	George D. Yancopoulos
10,888,601	George D. Yancopoulos
10,927,342	Amy S. Johnson
11,066,458	Eric Furfine
11,084,865	Eric Furfine
11,253,572	George D. Yancopoulos
11,312,936	Amy S. Johnson
11,332,771	Shadia Abike Oshodi
11,505,593	Shunhai Wang
11,525,833	Yuetian Yan
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. On information and belief, 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.

8. On information and belief, Celltrion, directly or indirectly, manufactures its drug products abroad. On 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.

9. For example, Celltrion merged with Celltrion Healthcare Co. Ltd. on December 28, 2023, and it was announced that Celltrion (MergeCo) will merge with Celltrion Pharm Inc. by July 2024. 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 26 (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).

10. 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 27.

11. 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.

12. Celltrion is the holder of aBLA No. 125544 for Inflectra (infliximab), an approved biosimilar of Remicade. The Inflectra label indicates that Celltrion manufactures Inflectra for sale in the United States. Importation records identify Celltrion Healthcare Co. Ltd. on shipments of infliximab from March and July of 2022.

13. Celltrion is the holder of aBLA No. 761219 for Yuflyma, an approved biosimilar of Humira. The Yuflyma label identifies Celltrion USA, Inc., a subsidiary and/or affiliate of Celltrion, as the distributor of Yuflyma in the United States.

14. As stated above, Celltrion is the holder of aBLA No. 761377 for CT-P42. On information and belief, Celltrion itself imported or directed one or more of its subsidiaries, affiliates, or agents to import CT-P42 into the United States. For example, in April, June, and July 2022, shipments of "AFLIBERCEPT (INHIBITOR (GROWTH FACTOR))" were imported into the United States. In June 2023—the same month Celltrion publicly announced that it had filed its aBLA with FDA for CT-P42—an additional shipment of "AFLIBERCEPT (INHIBITOR (GROWTH FACTOR))" was imported into the United States. On information and belief, at least some of the importation of CT-P42 was done for commercial purposes and not "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1).

15. On information and belief, Celltrion (a company resulting from the recent merger of Celltrion, Celltrion Healthcare Co. Ltd.) and Celltrion Pharm. Inc., and their respective subsidiaries, affiliates, and agents, including Celltrion USA, Inc., will function as an integrated organization and a single business enterprise in the manufacture of CT-P42, in the importation of CT-P42 into the United States, and in the sale or offer for sale of CT-P42 in the United States.

16. On information and belief, Celltrion (a company resulting from the recent merger of Celltrion and Celltrion Healthcare Co. Ltd.) and Celltrion Pharm. Inc. and their respective subsidiaries, affiliates, and agents, including Celltrion USA, Inc., develop, manufacture, distribute,

sell, and/or import drug products for the entire United States market and do business in every state, including West Virginia, either directly or indirectly.

17. This action arises under the BPCIA, 42 U.S.C. § 262(*l*), the Patent Laws of the United States, and Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, and 1338.

18. This Court has personal jurisdiction over Celltrion because Celltrion has filed its aBLA for CT-P42 with FDA, seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of CT-P42 in the United States, including in the State of West Virginia; and because, if its product receives FDA approval, Celltrion intends to—by itself or through others—market, distribute, offer for sale, and/or sell it in the United States, including in the State of West Virginia, deriving substantial revenue therefrom. This conduct is "suit-related," has "substantial connection" with West Virginia, and therefore satisfies the minimum contacts requirement.

19. Alternatively, this Court has personal jurisdiction over Celltrion because Celltrion develops, manufactures, distributes, sells, and/or imports drug products for the West Virginia market, including other biosimilar products such as Yuflyma, and because it does business in West Virginia, either directly or indirectly. These activities are so continuous and systematic as to render Celltrion essentially at home in West Virginia. *Daimler AG v. Bauman*, 571 U.S. 117, 127 (2014).

20. Alternatively, this Court has personal jurisdiction over Celltrion pursuant to Federal Rule of Civil Procedure 4(k)(2).

21. Venue is proper in this District under 28 U.S.C. §§ 1391(c)(3), 1400(b). Celltrion is a foreign corporation and is therefore subject to suit in any judicial district. *Id.* Further, Celltrion does business, either directly or indirectly, in Braxton, Calhoun, Doddridge, Gilmer, Harrison,

Marion, Monongalia, Pleasants, Preston, Ritchie, and Taylor Counties.

FACTUAL BASIS FOR RELIEF

22. 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).

23. The BPCIA reduces substantially the time and expense otherwise required to gain FDA approval, by allowing a biosimilar applicant like Celltrion 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 patents rewarding this research. In exchange for this accelerated and far less expensive application process, the BPCIA obligates a biosimilar applicant to address a reference product sponsor's relevant patents in a manner that permits adjudication of patent rights before commercialization of the biosimilar product. The BPCIA does so, *inter alia*, through a set of pre-litigation exchanges or steps outlined in 42 U.S.C. § 262(*l*) (herein referred to as the "patent dance").

24. The patent dance between Regeneron and Celltrion has proceeded substantially as follows. On September 1, 2023, Celltrion contacted outside counsel for Regeneron and indicated its intent to participate in the patent dance procedure. On September 13, 2023, Celltrion served a copy of its Biologics License Application for CT-P42 ("Celltrion aBLA") under 42 U.S.C. § 262(l)(2)(A).

25. Celltrion served to Regeneron its Notice of Commercial Marketing, indicating its intent to begin marketing and selling CT-P42 immediately upon receiving approval from the FDA. Pursuant to 42 U.S.C. § 262(k)(7)(A), approval of Celltrion's aBLA may be made effective as soon as EYLEA®'s regulatory exclusivity expires on May 18, 2024. Accordingly, Regeneron filed an action in this Court on November 8, 2023 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 Celltrion under 35 U.S.C. §§ 271(a)-(c) and (g), and a judgment of patent infringement under 35 U.S.C. § 271(e). *See Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, No. 23-CV-00089-TSK D.I. 1 (N.D.W. Va.).

26. On November 8, 2023, Regeneron timely served a list pursuant to § 262(*l*)(3)(A) ("3(A) List") identifying patents for which it believed a claim of patent infringement could reasonably be asserted if Celltrion engaged in the making, using, offering to sell, selling, or importing into the United States of CT-P42 based on the information and analysis available to Regeneron at that time.

27. On January 8, 2024, Celltrion purported to provide a statement pursuant to 42 U.S.C. § 262(*l*)(3)(B)(ii)(I) ("3(B) Statement"). Celltrion's purported 3(B) Statement failed to provide a detailed statement describing, on a claim by claim basis, the factual and legal basis for its opinion that the patents on Regeneron's 3(A) List are invalid or will not be infringed as required under § 262(*l*)(3)(B)(ii) and by the Federal Circuit's decision in *Amgen Inc. v. Hospira, Inc.*, 866 F.3d 1355, 1362 (Fed. Cir. 2017). Rather, the contentions in Celltrion's 3(B) Statement were often conclusory or lacking supporting citation.

28. In letters dated October 6, 2023, March 3, 2024, and March 8, 2024, Regeneron requested that Celltrion correct the deficiencies in Celltrion's production under 42 U.S.C.

§ 262(*l*)(2)(A) and (B) and subsequent productions under this Court's Scheduling Order in *Regeneron Pharmaceuticals, Inc. v. Celltrion, Inc.*, No. 23-CV-00089-TSK (N.D.W. Va.) by providing specific documents. Celltrion has provided only a subset of the requested information thus far.

29. On March 8, 2024, Regeneron timely provided a detailed statement that described, with respect to each patent described in Celltrion's purported 3(B) Statement, on a claim by claim basis, the factual and legal basis for Regeneron's opinion that such patent will be infringed by the commercial marketing of CT-P42 and a response to Celltrion's purported 3(B) Statement concerning invalidity ("3(C) Contentions"). 42 U.S.C. § 262(*l*)(3)(C).

30. In Regeneron's letter attaching its 3(C) Contentions, Regeneron asked Celltrion to provide its availability to begin negotiations under § 262(*l*)(4)(A) over which patents on Regeneron's 3(A) list should be litigated under § 262(*l*)(6). After receipt of Regeneron's 3(C) Contentions, Celltrion initiated good faith negotiations under paragraph 4. In response, among other things, Regeneron proposed to litigate 25 patents under § 262(*l*)(6). In correspondence dated April 19, 2024 Celltrion agreed to Regeneron's proposed 25 patents.

31. 42 U.S.C. § 262(*l*)(6)(A) provides that, if there is an agreement on the paragraph 4 patents, "the reference product sponsor shall bring an action for patent infringement with respect to each such patent" no later than 30 days after such agreement. As such, Regeneron is required to assert the 25 patents agreed upon under 42 U.S.C. § 262(*l*)(6)(A).[1]

32. Accordingly, Regeneron brings this action pursuant to 42 U.S.C. § 262(*l*)(6)(A) for a judgment of infringement under 35 U.S.C. 271(e) with respect to 25 patents.

[1] Regeneron reserves its rights under 35 U.S.C. § 271(e)(6)(C), should Celltrion make any amendments, modifications, or supplements to Celltrion's BLA that would result in infringement of the patents that were included on Regeneron's 3(A) List that were not also on the parties' list of agreed upon patents under paragraph 4.

CLAIMS FOR RELIEF

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 9,222,106 UNDER 35 U.S.C. § 271(e)

33. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

34. United States Patent No. 9,222,106 ("the '106 patent") (Exhibit 1 hereto), was duly and legally issued on December 29, 2015.

35. Regeneron is the owner of all right, title, and interest in the '106 patent.

36. The '106 patent has not yet expired.

37. The '106 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

38. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '106 patent is an act of infringement of one or more claims of the '106 patent under 35 U.S.C. § 271(e)(2)(C)(i).

39. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 will infringe, *inter alia*, claim 20 of the '106 patent.

40. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '106 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

41. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '106

patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

42. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '106 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 9,254,338 UNDER 35 U.S.C. § 271(e)

43. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

44. United States Patent No. 9,254,338 ("the '338 patent") (Exhibit 2 hereto), was duly and legally issued on February 9, 2016.

45. Regeneron is the owner of all right, title, and interest in the '338 patent.

46. The '338 patent has not yet expired.

47. The '338 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

48. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '338 patent is an act of infringement of one or more claims of the '338 patent under 35 U.S.C. § 271(e)(2)(C)(i).

49. For example, the sale of CT-P42 pursuant to the label proposed in Celltrion's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '338 patent.

50. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '338 patent. Regeneron is entitled to injunctive relief at least under 35

U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

51. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '338 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

52. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '338 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 9,315,281 UNDER 35 U.S.C. § 271(e)

53. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

54. United States Patent No. 9,315,281 ("the '281 patent") (Exhibit 3 hereto), was duly and legally issued on April 19, 2016.

55. Regeneron is the owner of all right, title, and interest in the '281 patent.

56. The '281 patent has not yet expired.

57. The '281 patent claims, *inter alia*, methods of making biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

58. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '281 patent is an act of infringement of one or more claims of the '281 patent under 35 U.S.C. § 271(e)(2)(C)(i).

59. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 will infringe, *inter alia*, claim 13 of the ’281 patent.

60. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’281 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

61. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’281 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

62. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’281 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 4: INFRINGEMENT OF U.S. PATENT NO. 9,816,110 UNDER 35 U.S.C. § 271(e)

63. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

64. United States Patent No. 9,816,110 (“the ’110 patent”) (Exhibit 4 hereto), was duly and legally issued on November 14, 2017.

65. Regeneron is the owner of all right, title, and interest in the ’110 patent.

66. The ’110 patent has not yet expired.

67. The ’110 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and

on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

68. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '110 patent is an act of infringement of one or more claims of the '110 patent under 35 U.S.C. § 271(e)(2)(C)(i).

69. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 will infringe, *inter alia*, claim 18 of the '110 patent.

70. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '110 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

71. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '110 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

72. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '110 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 10,130,681 UNDER 35 U.S.C. § 271(e)

73. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

74. United States Patent No. 10,130,681 ("the '681 patent") (Exhibit 5 hereto), was duly and legally issued on November 20, 2018.

75. Regeneron is the owner of all right, title, and interest in the '681 patent.

76. The '681 patent has not yet expired.

77. The '681 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

78. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '681 patent is an act of infringement of one or more claims of the '681 patent under 35 U.S.C. § 271(e)(2)(C)(i).

79. For example, the sale of CT-P42 pursuant to the label proposed in Celltrion's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '681 patent.

80. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '681 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

81. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '681 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

82. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation

into the United States, of CT-P42 before the expiration of the ’681 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 6: INFRINGEMENT OF U.S. PATENT NO. 10,415,055 UNDER 35 U.S.C. § 271(e)

83. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

84. United States Patent No. 10,415,055 (“the ’055 patent”) (Exhibit 6 hereto), was duly and legally issued on September 17, 2019.

85. Regeneron is the owner of all right, title, and interest in the ’055 patent.

86. The ’055 patent has not yet expired.

87. The ’055 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

88. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the ’055 patent is an act of infringement of one or more claims of the ’055 patent under 35 U.S.C. § 271(e)(2)(C)(i).

89. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 will infringe, *inter alia*, claim 23 of the ’055 patent.

90. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’055 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

91. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '055 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

92. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '055 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 7: INFRINGEMENT OF U.S. PATENT NO. 10,669,594 UNDER 35 U.S.C. § 271(e)

93. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

94. United States Patent No. 10,669,594 ("the '594 patent") (Exhibit 7 hereto), was duly and legally issued on June 2, 2020.

95. Regeneron is the owner of all right, title, and interest in the '594 patent.

96. The '594 patent has not yet expired.

97. The '594 patent claims methods of detecting biological contaminants and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

98. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '594 patent is an act of infringement of one or more claims of the '594 patent under 35 U.S.C. § 271(e)(2)(C)(i).

99. For example, on information and belief, manufacture, use, offer for sale, and/or

sale, or import into the United States, of CT-P42 will infringe, *inter alia*, claim 1 of the ’594 patent.

100. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’594 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

101. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’594 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

102. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’594 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 8: INFRINGEMENT OF U.S. PATENT NO. 10,828,345 UNDER 35 U.S.C. § 271(e)

103. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

104. United States Patent No. 10,828,345 (“the ’345 patent”) (Exhibit 8 hereto), was duly and legally issued on November 10, 2020.

105. Regeneron is the owner of all right, title, and interest in the ’345 patent.

106. The ’345 patent has not yet expired.

107. The ’345 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

108. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '345 patent is an act of infringement of one or more claims of the '345 patent under 35 U.S.C. § 271(e)(2)(C)(i).

109. For example, the sale of CT-P42 pursuant to the label proposed in Celltrion's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '345 patent.

110. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '345 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

111. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '345 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

112. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '345 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 9: INFRINGEMENT OF U.S. PATENT NO. 10,888,601 UNDER 35 U.S.C. § 271(e)

113. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

114. United States Patent No. 10,888,601 ("the '601 patent") (Exhibit 9 hereto), was duly and legally issued on January 12, 2021.

115. Regeneron is the owner of all right, title, and interest in the ’601 patent.

116. The ’601 patent has not yet expired.

117. The ’601 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

118. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the ’601 patent is an act of infringement of one or more claims of the ’601 patent under 35 U.S.C. § 271(e)(2)(C)(i).

119. For example, the sale of CT-P42 pursuant to the label proposed in Celltrion’s aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the ’601 patent.

120. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’601 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

121. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’601 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

122. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’601 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 10: INFRINGEMENT OF U.S. PATENT NO. 10,927,342 UNDER 35 U.S.C. § 271(e)

123. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

124. United States Patent No. 10,927,342 ("the '342 patent") (Exhibit 10 hereto), was duly and legally issued on February 23, 2021.

125. Regeneron is the owner of all right, title, and interest in the '342 patent.

126. The '342 patent has not yet expired.

127. The '342 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

128. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '342 patent is an act of infringement of one or more claims of the '342 patent under 35 U.S.C. § 271(e)(2)(C)(i).

129. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 will infringe, *inter alia*, claim 1 of the '342 patent.

130. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '342 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

131. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '342 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief

under 35 U.S.C. § 271(e)(4)(C).

132. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '342 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 11: INFRINGEMENT OF U.S. PATENT NO. 11,066,458 UNDER 35 U.S.C. § 271(e)

133. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

134. United States Patent No. 11,066,458 ("the '458 patent") (Exhibit 11 hereto), was duly and legally issued on July 20, 2021.

135. Regeneron is the owner of all right, title, and interest in the '458 patent.

136. The '458 patent has not yet expired.

137. The '458 patent claims biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

138. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '458 patent is an act of infringement of one or more claims of the '458 patent under 35 U.S.C. § 271(e)(2)(C)(i).

139. For example, manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 will infringe, *inter alia*, claim 1 of the '458 patent.

140. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '458 patent. Regeneron is entitled to injunctive relief at least under 35

U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

141. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '458 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

142. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '458 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 12: INFRINGEMENT OF U.S. PATENT NO. 11,084,865 UNDER 35 U.S.C. § 271(e)

143. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

144. United States Patent No. 11,084,865 ("the '865 patent") (Exhibit 12 hereto), was duly and legally issued on August 10, 2021.

145. Regeneron is the owner of all right, title, and interest in the '865 patent.

146. The '865 patent has not yet expired.

147. The '865 patent claims biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

148. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '865 patent is an act of infringement of one or more claims of the

’865 patent under 35 U.S.C. § 271(e)(2)(C)(i).

149. For example, manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 will infringe, *inter alia*, claim 4 of the ’865 patent.

150. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’865 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

151. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’865 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

152. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’865 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 13: INFRINGEMENT OF U.S. PATENT NO. 11,253,572 UNDER 35 U.S.C. § 271(e)

153. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

154. United States Patent No. 11,253,572 (“the ’572 patent”) (Exhibit 13 hereto), was duly and legally issued on February 22, 2022.

155. Regeneron is the owner of all right, title, and interest in the ’572 patent.

156. The ’572 patent has not yet expired.

157. The ’572 patent claims methods of treatment using biological products and was

included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

158. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '572 patent is an act of infringement of one or more claims of the '572 patent under 35 U.S.C. § 271(e)(2)(C)(i).

159. For example, the sale of CT-P42 pursuant to the label proposed in Celltrion's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '572 patent.

160. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '572 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

161. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '572 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

162. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '572 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 14: INFRINGEMENT OF U.S. PATENT NO. 11,312,936 UNDER 35 U.S.C. § 271(e)

163. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

164. United States Patent No. 11,312,936 ("the '936 patent") (Exhibit 14 hereto), was duly and legally issued on April 26, 2022.

165. Regeneron is the owner of all right, title, and interest in the '936 patent.

166. The '936 patent has not yet expired.

167. The '936 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

168. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '936 patent is an act of infringement of one or more claims of the '936 patent under 35 U.S.C. § 271(e)(2)(C)(i).

169. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 will infringe, *inter alia*, claim 1 of the '936 patent.

170. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '936 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

171. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '936 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

172. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation

into the United States, of CT-P42 before the expiration of the ’936 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 15: INFRINGEMENT OF U.S. PATENT NO. 11,332,771 UNDER 35 U.S.C. § 271(e)

173. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

174. United States Patent No. 11,332,771 (“the ’771 patent”) (Exhibit 15 hereto), was duly and legally issued on May 17, 2022.

175. Regeneron is the owner of all right, title, and interest in the ’771 patent.

176. The ’771 patent has not yet expired.

177. The ’771 patent claims methods of making biological products and it was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

178. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the ’771 patent is an act of infringement of one or more claims of the ’771 patent under 35 U.S.C. § 271(e)(2)(C)(i).

179. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 will infringe, *inter alia*, claim 1 of the ’771 patent.

180. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’771 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

181. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the

United States, or importation into the United States, of CT-P42 before the expiration of the ’771 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

182. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’771 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 16: INFRINGEMENT OF U.S. PATENT NO. 11,505,593 UNDER 35 U.S.C. § 271(e)

183. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

184. United States Patent No. 11,505,593 (“the ’593 patent”) (Exhibit 16 hereto), was duly and legally issued on November 22, 2022.

185. Regeneron is the owner of all right, title, and interest in the ’593 patent.

186. The ’593 patent has not yet expired.

187. The ’593 patent claims biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

188. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the ’593 patent is an act of infringement of one or more claims of the ’593 patent under 35 U.S.C. § 271(e)(2)(C)(i).

189. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 as provided in such an amended or supplemented

BLA will infringe, *inter alia*, claim 1 of the ’593 patent.

190. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’593 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

191. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’593 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

192. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’593 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 17: INFRINGEMENT OF U.S. PATENT NO. 11,525,833 UNDER 35 U.S.C. § 271(e)

193. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

194. United States Patent No. 11,525,833 (“the ’833 patent”) (Exhibit 17 hereto), was duly and legally issued on December 13, 2022.

195. Regeneron is the owner of all right, title, and interest in the ’833 patent.

196. The ’833 patent has not yet expired.

197. The ’833 patent claims methods of identifying biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

198. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '833 patent is an act of infringement of one or more claims of the '833 patent under 35 U.S.C. § 271(e)(2)(C)(i).

199. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 as provided in such an amended or supplemented BLA will infringe, *inter alia*, claim 1 of the '833 patent.

200. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '833 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

201. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '833 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

202. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '833 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 18: INFRINGEMENT OF U.S. PATENT NO. 11,555,176 UNDER 35 U.S.C. § 271(e)

203. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

204. United States Patent No. 11,555,176 ("the '176 patent") (Exhibit 18 hereto), was

duly and legally issued on January 17, 2023.

205. Regeneron is the owner of all right, title, and interest in the ’176 patent.

206. The ’176 patent has not yet expired.

207. The ’176 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

208. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the ’176 patent is an act of infringement of one or more claims of the ’176 patent under 35 U.S.C. § 271(e)(2)(C)(i).

209. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 will infringe, *inter alia*, claim 1 of the ’176 patent.

210. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’176 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

211. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’176 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

212. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’176 patent entitles Regeneron to

fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 19: INFRINGEMENT OF U.S. PATENT NO. 11,559,564 UNDER 35 U.S.C. § 271(e)

213. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

214. United States Patent No. 11,559,564 ("the '564 patent") (Exhibit 19 hereto), was duly and legally issued on January 24, 2023.

215. Regeneron is the owner of all right, title, and interest in the '564 patent.

216. The '564 patent has not yet expired.

217. The '564 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

218. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '564 patent is an act of infringement of one or more claims of the '564 patent under 35 U.S.C. § 271(e)(2)(C)(i).

219. For example, the sale of CT-P42 pursuant to the label proposed in Celltrion's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '564 patent.

220. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '564 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

221. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '564

patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

222. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '564 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 20: INFRINGEMENT OF U.S. PATENT NO. 11,707,506 UNDER 35 U.S.C. § 271(e)

223. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

224. United States Patent No. 11,707,506 ("the '506 patent") (Exhibit 20 hereto), was duly and legally issued on July 25, 2023.

225. Regeneron is the owner of all right, title, and interest in the '506 patent.

226. The '506 patent has not yet expired.

227. The '506 patent claims methods of treatment using biological products, was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

228. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '506 patent is an act of infringement of one or more claims of the '506 patent under 35 U.S.C. § 271(e)(2)(C)(i).

229. For example, the sale of CT-P42 pursuant to the label proposed in Celltrion's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '506 patent.

230. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing

one or more claims of the ’506 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

231. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’506 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

232. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’506 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 21: INFRINGEMENT OF U.S. PATENT NO. 11,732,024 UNDER 35 U.S.C. § 271(e)

233. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

234. United States Patent No. 11,732,024 (“the ’024 patent”) (Exhibit 21 hereto), was duly and legally issued on August 22, 2023.

235. Regeneron is the owner of all right, title, and interest in the ’024 patent.

236. The ’024 patent has not yet expired.

237. The ’024 patent claims biological products, was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

238. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-

P42 before the expiration of the ’024 patent is an act of infringement of one or more claims of the ’024 patent under 35 U.S.C. § 271(e)(2)(C)(i).

239. For example, manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 will infringe, *inter alia*, claim 41 of the ’024 patent.

240. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’024 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

241. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’024 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

242. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’024 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 22: INFRINGEMENT OF U.S. PATENT NO. 11,753,459 UNDER 35 U.S.C. § 271(e)

243. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

244. United States Patent No. 11,753,459 (“the ’459 patent”) (Exhibit 22 hereto), was duly and legally issued on September 12, 2023.

245. Regeneron is the owner of all right, title, and interest in the ’459 patent.

246. The ’459 patent has not yet expired.

247. The ’459 patent claims biological products, was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

248. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the ’459 patent is an act of infringement of one or more claims of the ’459 patent under 35 U.S.C. § 271(e)(2)(C)(i).

249. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 will infringe, *inter alia*, claim 1 of the ’459 patent.

250. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’459 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

251. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’459 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

252. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’459 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 23: INFRINGEMENT OF U.S. PATENT NO. 11,769,597 UNDER 35 U.S.C. § 271(e)

253. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

254. United States Patent No. 11,769,597 ("the '597 patent") (Exhibit 23 hereto), was duly and legally issued on September 26, 2023.

255. Regeneron is the owner of all right, title, and interest in the '597 patent.

256. The '597 patent has not yet expired.

257. The '597 patent claims methods of treatment using biological products, was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

258. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '597 patent is an act of infringement of one or more claims of the '597 patent under 35 U.S.C. § 271(e)(2)(C)(i).

259. For example, the sale of CT-P42 pursuant to the label proposed in Celltrion's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '597 patent.

260. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '597 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

261. Celltrion's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '597 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief

under 35 U.S.C. § 271(e)(4)(C).

262. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the '597 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 24: INFRINGEMENT OF U.S. PATENT NO. 11,788,102 UNDER 35 U.S.C. § 271(e)

263. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

264. United States Patent No. 11,788,102 ("the '102 patent") (Exhibit 24 hereto), was duly and legally issued on October 17, 2023.

265. Regeneron is the owner of all right, title, and interest in the '102 patent.

266. The '102 patent has not yet expired.

267. The '102 patent claims methods of making biological products, was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

268. The submission of Celltrion's aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the '102 patent is an act of infringement of one or more claims of the '102 patent under 35 U.S.C. § 271(e)(2)(C)(i).

269. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 will infringe, *inter alia*, claim 21 of the '102 patent.

270. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing

one or more claims of the ’102 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

271. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’102 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

272. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’102 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 25: INFRINGEMENT OF U.S. PATENT NO. 11,793,926 UNDER 35 U.S.C. § 271(e)

273. Regeneron incorporates by reference all of the allegations set forth above as if fully set forth below.

274. United States Patent No. 11,793,926 (“the ’926 patent”) (Exhibit 25 hereto), was duly and legally issued on October 24, 2023.

275. Regeneron is the owner of all right, title, and interest in the ’926 patent.

276. The ’926 patent has not yet expired.

277. The ’926 patent claims packaging for biological products and methods for sterilizing packaging for biological products and was included on the list of patents provided by Regeneron to Celltrion pursuant to 42 U.S.C. § 262(*l*)(3)(A) and on the list agreed upon by both parties under 42 U.S.C. § 262(*l*)(4)(A).

278. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the

commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 before the expiration of the ’926 patent is an act of infringement of one or more claims of the ’926 patent under 35 U.S.C. § 271(e)(2)(C)(i).

279. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of CT-P42 as provided in such an amended or supplemented BLA will infringe, *inter alia*, claim 11 of the ’926 patent.

280. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’926 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Celltrion from any further infringement. Regeneron has no adequate remedy at law.

281. Celltrion’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’926 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

282. The submission of Celltrion’s aBLA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of CT-P42 before the expiration of the ’926 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

PRAYER FOR RELIEF

WHEREFORE, Regeneron requests the following relief:

(a) A judgment that Celltrion has infringed the patents in suit;

(b) Permanent equitable relief, pursuant to 35 U.S.C. § 271(e)(4)(B), including but not limited to a permanent injunction that enjoins Celltrion, its officers, partners, agents, servants,

employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns from infringing the patents in suit, or contributing to the same, or actively inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacturing of which infringes, the patents in suit;

(c) Preliminary equitable relief, pursuant to 35 U.S.C. § 271(e)(4)(B), including but not limited to a preliminary injunction that enjoins Celltrion, its officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns from infringing the patents in suit, or contributing to the same, or actively inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacturing of which infringes, the patents in suit;

(d) Statutory relief under 35 U.S.C. § 271(e)(4)(D), including but not limited to a permanent injunction prohibiting Celltrion, its officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns from infringing the patents in suit, or contributing to the same, or actively inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacturing of which infringes, the patents in suit;

(e) Damages pursuant to 35 U.S.C. § 271(e)(4)(C), if applicable, in the form of lost profits but in no event less than a reasonable royalty;

(f) A judgment that the infringement has been willful and an enhancement of damages;

(g) An award for an accounting of damages from Celltrion's infringement;

(h) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285 and 35 U.S.C. § 271(e)(4);

(i) An award of Regeneron's costs and expenses in this action; and

(j) Such further relief as this court may deem just and proper.

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