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.

11. 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.

12. 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.

13. 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).

14. On information and belief, Celltrion, Celltrion Healthcare Co. Ltd., 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.

15. On information and belief, Celltrion, Celltrion Healthcare Co. Ltd., 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.

16. This action arises under the BPCIA, 42 U.S.C. § 262(*l*), the Patent Laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, 1338, 2201(a), and 2202.

17. 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.

18. 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).

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

20. 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.*

FACTUAL BASIS FOR RELIEF

21. 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).

22. 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").

23. The ongoing 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).

24. 42 U.S.C. § 262(*l*)(9)(A) provides that, "[i]f a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B)."

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.

26. Celltrion's submission of its aBLA, combined with its Notice of Commercial Marketing, presents a controversy of sufficient immediacy to support declaratory judgment of patent infringement under 35 U.S.C. § (a)-(c) and (g).

27. On November 7, 2023, Regeneron served on Celltrion "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor" ("3A list") under § 262(*l*)(3)(A).

28. Regeneron therefore brings this action for a judgment of infringement and declaratory judgment of infringement of patents described in paragraph 8(B)(i) and (ii). 42 U.S.C. § 262(*l*)(9)(A).

CLAIMS FOR RELIEF

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

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

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

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

32. The '106 patent has not yet expired.

33. 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).

34. 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).

35. 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.

36. 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.

37. 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).

38. 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: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '106 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

40. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '106 patent.

41. 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.

42. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '106 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '106 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '106 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '106 patent. Celltrion has knowledge of and is aware of the '106 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '106 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents

since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '106 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '106 patent.

43. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '106 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '106 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

44. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '106 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '106 patent.

45. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '106 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '106 patent, before the expiration of the '106 patent.

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 9,254,338 UNDER 35 U.S.C. § 271(e)

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

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

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

49. The '338 patent has not yet expired.

50. 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).

51. 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).

52. 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.

53. 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.

54. 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).

55. 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 4: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '338 PATENT UNDER 35 U.S.C. § 271 (b) or (c)

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

57. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '338 patent.

58. 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.

59. Following FDA approval, Celltrion intends to and will immediately infringe the '338 patent under 35 U.S.C. § 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, offer for sale, sale, use, or promotion of use of CT-P42.

60. Celltrion has knowledge of and is aware of the '338 patent at least due to its filing of a petition for *inter partes* review of the '338 patent (IPR2022-00258) on December 9, 2021, Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '338 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that the use of CT-P42 will practice the methods prescribed in one or more claims of the '338 patent at least as of December 9, 2021.

61. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '338 patent at least because it filed an aBLA that includes a proposed label

with directions that instruct medical practitioners to administer and/or patients to use CT-P42 in a manner that infringes one or more claims of the ’338 patent.

62. Upon information and belief, Celltrion knows and/or is willfully blind to the fact that medical practitioners will administer and/or patients will use CT-P42 according to its proposed label, which will directly infringe one or more claims of the ’338 patent.

63. Upon information and belief, Celltrion knows or is willfully blind to the fact that it will aid and abet another’s direct infringement of at least one of the claims of the ’338 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in its proposed label for the Celltrion aBLA product.

64. In view of Celltrion’s submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the ’338 patent.

65. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’338 patent by actively inducing or contributing to the infringement of one or more claims of the ’338 patent, before the expiration of the ’338 patent.

66. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’338 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the ’338 patent, before the expiration of the ’338 patent.

COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 9,315,281 UNDER 35 U.S.C. § 271(e)

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

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

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

70. The '281 patent has not yet expired.

71. 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).

72. 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).

73. 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.

74. 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.

75. 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).

76. 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 6: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '281 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

78. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '281 patent.

79. 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.

80. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '281 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '281 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '281 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '281 patent. Celltrion has knowledge of and is aware of the

'281 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '281 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '281 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '281 patent.

81. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '281 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '281 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

82. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '281 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '281 patent.

83. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '281 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within

the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '281 patent, before the expiration of the '281 patent.

COUNT 7: INFRINGEMENT OF U.S. PATENT NO. 9,816,110 UNDER 35 U.S.C. § 271(e)

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

85. United States Patent No. 9,816,110 ("the '110 patent") (Exhibit 4 hereto), was duly and legally issued on November 14, 2017.

86. Regeneron is the owner of all right, title, and interest in the '110 patent.

87. The '110 patent has not yet expired.

88. 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).

89. 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).

90. 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.

91. 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.

92. 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).

93. 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 8: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '110 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

95. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '110 patent.

96. 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.

97. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '110 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '110 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '110 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '110 patent. Celltrion has knowledge of and is aware of the

'110 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '110 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '110 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '110 patent.

98. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '110 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '110 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

99. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '110 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '110 patent.

100. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '110 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within

the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '110 patent, before the expiration of the '110 patent.

COUNT 9: INFRINGEMENT OF U.S. PATENT NO. 10,130,681 UNDER 35 U.S.C. § 271(e)

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

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

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

104. The '681 patent has not yet expired.

105. 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).

106. 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).

107. 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.

108. 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.

109. 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).

110. 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 10: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '681 PATENT UNDER 35 U.S.C. § 271 (b) or (c)

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

112. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '681 patent.

113. 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.

114. Following FDA approval, Celltrion intends to and will immediately infringe the '681 patent under 35 U.S.C. § 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, offer for sale, sale, use, or promotion of use of CT-P42.

115. Celltrion has knowledge of and is aware of the '681 patent at least due to its filing of a petition for *inter partes* review of the '681 patent (IPR2023-00532) on February 10, 2023, Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '681 patent based

on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that the use of CT-P42 will practice the methods prescribed in one or more claims of the '681 patent at least as of February 10, 2023.

116. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '681 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to administer and/or patients to use CT-P42 in a manner that infringes one or more claims of the '681 patent.

117. Upon information and belief, Celltrion knows and/or is willfully blind to the fact that medical practitioners will administer and/or patients will use CT-P42 according to its proposed label, which will directly infringe one or more claims of the '681 patent.

118. Upon information and belief, Celltrion knows or is willfully blind to the fact that it will aid and abet another's direct infringement of at least one of the claims of the '681 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in its proposed label for the Celltrion aBLA product.

119. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '681 patent.

120. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '681 patent by actively inducing or contributing to the infringement of one or more claims of the '681 patent, before the expiration of the '681 patent.

121. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’681 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the ’681 patent, before the expiration of the ’681 patent.

COUNT 11: INFRINGEMENT OF U.S. PATENT NO. 10,415,055 UNDER 35 U.S.C. § 271(e)

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

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

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

125. The ’055 patent has not yet expired.

126. 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).

127. 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).

128. 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.

129. 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.

130. 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).

131. 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 12: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '055 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

133. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '055 patent.

134. 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.

135. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '055 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United

States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '055 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '055 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '055 patent. Celltrion has knowledge of and is aware of the '055 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '055 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '055 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '055 patent.

136. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '055 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '055 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

137. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’055 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion’s CT-P42, before the expiration of the ’055 patent.

138. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the ’055 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the ’055 patent, before the expiration of the ’055 patent.

COUNT 13: INFRINGEMENT OF U.S. PATENT NO. 10,464,992 UNDER 35 U.S.C. § 271(e)

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

140. United States Patent No. 10,464,992 (“the ’992 patent”) (Exhibit 7 hereto), was duly and legally issued on November 5, 2019.

141. Regeneron is the owner of all right, title, and interest in the ’992 patent.

142. The ’992 patent has not yet expired.

143. The ’992 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).

144. 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 ’992 patent is an act of infringement of one or more claims of the ’992 patent under 35 U.S.C. § 271(e)(2)(C)(i).

145. 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 '992 patent.

146. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '992 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.

147. 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 '992 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

148. 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 '992 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 14: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '992 PATENT UNDER 35 U.S.C. § 271(a), (b), (c)

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

150. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '992 patent.

151. 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.

152. Following FDA approval, Celltrion intends to and will immediately begin—itself or through its subsidiaries, affiliates, or agents—to use, offer for sale, or sell within the United States, or import into the United States, Celltrion's CT-P42, which would constitute infringement of claims of the '992 patent under 35 U.S.C. § 271(a).

153. Following FDA approval, Celltrion intends to and will immediately begin to infringe the '992 patent under 35 U.S.C. § 271(b) and/or (c) by inducing others, including its subsidiaries, affiliates, agents, and physicians, to engage in the use, offer for sale, sale, marketing, distributing and/or importing of CT-P42.

154. Celltrion has knowledge of and is aware of the '992 patent at least due to its filing of a petition for *inter partes* review of the '992 patent (IPR2023-00462) on January 17, 2023, Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '992 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that CT-P42 comprises a formulation patented in one or more claims of the '992 patent at least as of January 17, 2023.

155. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '992 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to prescribe and/or use CT-P42. Celltrion also has an affirmative intent to actively induce infringement by others of one or more claims of the '992 patent at least because it will manufacture, directly or indirectly, CT-P42 that meets every limitation of one or more claims of the '992 patent, and will provide CT-P42 to its subsidiaries,

affiliates, agents, and/or physicians who will import, offer to sell, sell, and/or use CT-P42 in a manner that directly infringes one or more claims of the ’992 patent.

156. Upon information and belief, Celltrion knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’992 patent at least by providing its proposed label with instructions to use CT-P42.

157. In view of Celltrion’s submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion’s manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the ’992 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the ’992 patent.

158. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’992 patent by manufacturing, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing or contributing to the infringement of Celltrion’s CT-P42, before the expiration of the ’992 patent.

159. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the ’992 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the ’992 patent, before the expiration of the ’992 patent.

COUNT 15: INFRINGEMENT OF U.S. PATENT NO. 10,669,594 UNDER 35 U.S.C.

§ 271(e)

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

161. United States Patent No. 10,669,594 ("the '594 patent") (Exhibit 8 hereto), was duly and legally issued on June 2, 2020.

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

163. The '594 patent has not yet expired.

164. 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).

165. 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).

166. 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.

167. 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.

168. 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).

169. 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 16: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '594 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

171. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '594 patent.

172. 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.

173. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '594 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '594 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '594 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '594 patent. Celltrion has knowledge of and is aware of the '594 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of

the ’594 patent based on its active monitoring of Regeneron’s patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the ’594 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’594 patent.

174. In view of Celltrion’s submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion’s use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the ’594 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the ’594 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

175. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’594 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion’s CT-P42, before the expiration of the ’594 patent.

176. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the ’594 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the ’594 patent, before the expiration of the ’594 patent.

COUNT 17: INFRINGEMENT OF U.S. PATENT NO. 10,828,345 UNDER 35 U.S.C. § 271(e)

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

178. United States Patent No. 10,828,345 ("the '345 patent") (Exhibit 9 hereto), was duly and legally issued on November 10, 2020.

179. Regeneron is the owner of all right, title, and interest in the '345 patent.

180. The '345 patent has not yet expired.

181. 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).

182. 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).

183. 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.

184. 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.

185. 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).

186. 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 18: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '345 PATENT UNDER 35 U.S.C. § 271 (b) or (c)

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

188. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '345 patent.

189. 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.

190. Following FDA approval, Celltrion intends to and will immediately infringe the '345 patent under 35 U.S.C. § 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, offer for sale, sale, use, or promotion of use of CT-P42.

191. Celltrion has knowledge of and is aware of the '345 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '345 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that the use of CT-P42 will practice the

methods prescribed in one or more claims of the '345 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

192. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '345 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to administer and/or patients to use CT-P42 in a manner that infringes one or more claims of the '345 patent.

193. Upon information and belief, Celltrion knows and/or is willfully blind to the fact that medical practitioners will administer and/or patients will use CT-P42 according to its proposed label, which will directly infringe one or more claims of the '345 patent.

194. Upon information and belief, Celltrion knows or is willfully blind to the fact that it will aid and abet another's direct infringement of at least one of the claims of the '345 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in its proposed label for the Celltrion aBLA product.

195. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '345 patent.

196. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '345 patent by actively inducing or contributing to the infringement of one or more claims of the '345 patent, before the expiration of the '345 patent.

197. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '345 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling

within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the '345 patent, before the expiration of the '345 patent.

COUNT 19: INFRINGEMENT OF U.S. PATENT NO. 10,888,601 UNDER 35 U.S.C. § 271(e)

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

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

200. Regeneron is the owner of all right, title, and interest in the '601 patent.

201. The '601 patent has not yet expired.

202. 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).

203. 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).

204. 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.

205. 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.

206. 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).

207. 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 20: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '601 PATENT UNDER 35 U.S.C. § 271 (b) or (c)

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

209. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '601 patent.

210. 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.

211. Following FDA approval, Celltrion intends to and will immediately infringe the '601 patent under 35 U.S.C. § 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, offer for sale, sale, use, or promotion of use of CT-P42.

212. Celltrion has knowledge of and is aware of the '601 patent at least due to its filing of a petition for *inter partes* review of the '601 patent (IPR2023-00533) on February 10, 2023, Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '601 patent based

on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that the use of CT-P42 will practice the methods prescribed in one or more claims of the '601 patent at least as of February 10, 2023.

213. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '601 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to administer and/or patients to use CT-P42 in a manner that infringes one or more claims of the '601 patent.

214. Upon information and belief, Celltrion knows and/or is willfully blind to the fact that medical practitioners will administer and/or patients will use CT-P42 according to its proposed label, which will directly infringe one or more claims of the '601 patent.

215. Upon information and belief, Celltrion knows or is willfully blind to the fact that it will aid and abet another's direct infringement of at least one of the claims of the '601 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in its proposed label for the Celltrion aBLA product.

216. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '601 patent.

217. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '601 patent by actively inducing or contributing to the infringement of one or more claims of the '601 patent, before the expiration of the '601 patent.

218. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’601 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the ’601 patent, before the expiration of the ’601 patent.

COUNT 21: INFRINGEMENT OF U.S. PATENT NO. 10,927,342 UNDER 35 U.S.C. § 271(e)

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

220. United States Patent No. 10,927,342 (“the ’342 patent”) (Exhibit 11 hereto), was duly and legally issued on February 23, 2021.

221. Regeneron is the owner of all right, title, and interest in the ’342 patent.

222. The ’342 patent has not yet expired.

223. 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).

224. 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).

225. 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.

226. 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.

227. 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).

228. 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 22: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '342 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

230. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '342 patent.

231. 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.

232. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '342 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '342 patent. On information and belief, following FDA approval of its CT-P42, Celltrion

will induce infringement of one or more claims of the '342 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '342 patent. Celltrion has knowledge of and is aware of the '342 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '342 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '342 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '342 patent.

233. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '342 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '342 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

234. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '342 patent by using, offering to sell, and/or selling within the United

States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '342 patent.

235. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '342 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '342 patent, before the expiration of the '342 patent.

COUNT 23: INFRINGEMENT OF U.S. PATENT NO. 11,053,280 UNDER 35 U.S.C. § 271(e)

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

237. United States Patent No. 11,053,280 ("the '280 patent") (Exhibit 12 hereto), was duly and legally issued on July 6, 2021.

238. Regeneron is the owner of all right, title, and interest in the '280 patent.

239. The '280 patent has not yet expired.

240. The '280 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).

241. 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 '280 patent is an act of infringement of one or more claims of the '280 patent under 35 U.S.C. § 271(e)(2)(C)(i).

242. 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 5 of the '280 patent.

243. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’280 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.

244. 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 ’280 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

245. 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 ’280 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 24: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’280 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

247. On information and belief, Celltrion submitted its aBLA referencing Regeneron’s EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the ’280 patent.

248. 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.

249. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the ’280 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United

States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '280 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '280 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '280 patent. Celltrion has knowledge of and is aware of the '280 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '280 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '280 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '280 patent.

250. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '280 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '280 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

251. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’280 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion’s CT-P42, before the expiration of the ’280 patent.

252. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the ’280 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the ’280 patent, before the expiration of the ’280 patent.

COUNT 25: INFRINGEMENT OF U.S. PATENT NO. 11,066,458 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. 11,066,458 (“the ’458 patent”) (Exhibit 13 hereto), was duly and legally issued on July 20, 2021.

255. Regeneron is the owner of all right, title, and interest in the ’458 patent.

256. The ’458 patent has not yet expired.

257. 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).

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 ’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).

259. 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.

260. 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.

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 '458 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 '458 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 26: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '458 PATENT UNDER 35 U.S.C. § 271(a), (b), (c)

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

264. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '458 patent.

265. 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.

266. Following FDA approval, Celltrion intends to and will immediately begin—itself or through its subsidiaries, affiliates, or agents—to use, offer for sale, or sell within the United States, or import into the United States, Celltrion's CT-P42, which would constitute infringement of claims of the '458 patent under 35 U.S.C. § 271(a).

267. Following FDA approval, Celltrion intends to and will immediately begin to infringe the '458 patent under 35 U.S.C. § 271(b) and/or (c) by inducing others, including its subsidiaries, affiliates, agents, and physicians, to engage in the use, offer for sale, sale, marketing, distributing and/or importing of CT-P42.

268. Celltrion has knowledge of and is aware of the '458 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '458 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that CT-P42 comprises a formulation patented in one or more claims of the '458 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(l)(3)(A) and the filing of this Complaint.

269. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '458 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to prescribe and/or use CT-P42. Celltrion also has an affirmative intent to actively induce infringement by others of one or more claims of the '458 patent at least because it will manufacture, directly or indirectly, CT-P42 that meets every limitation of one or more claims of the '458 patent, and will provide CT-P42 to its subsidiaries,

affiliates, agents, and/or physicians who will import, offer to sell, sell, and/or use CT-P42 in a manner that directly infringes one or more claims of the '458 patent.

270. Upon information and belief, Celltrion knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '458 patent at least by providing its proposed label with instructions to use CT-P42.

271. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '458 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '458 patent.

272. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '458 patent by manufacturing, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing or contributing to the infringement of Celltrion's CT-P42, before the expiration of the '458 patent.

273. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '458 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the '458 patent, before the expiration of the '458 patent.

COUNT 27: INFRINGEMENT OF U.S. PATENT NO. 11,084,865 UNDER 35 U.S.C. § 271(e)

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

275. United States Patent No. 11,084,865 ("the '865 patent") (Exhibit 14 hereto), was duly and legally issued on August 10, 2021.

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

277. The '865 patent has not yet expired.

278. 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).

279. 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).

280. 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 '865 patent.

281. 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.

282. 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).

283. 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 28: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '865 PATENT UNDER 35 U.S.C. § 271(a), (b), (c)

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

285. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '865 patent.

286. 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.

287. Following FDA approval, Celltrion intends to and will immediately begin—itself or through its subsidiaries, affiliates, or agents—to use, offer for sale, or sell within the United States, or import into the United States, Celltrion's CT-P42, which would constitute infringement of claims of the '865 patent under 35 U.S.C. § 271(a).

288. Following FDA approval, Celltrion intends to and will immediately begin to infringe the '865 patent under 35 U.S.C. § 271(b) and/or (c) by inducing others, including its subsidiaries, affiliates, agents, and physicians, to engage in the use, offer for sale, sale, marketing, distributing and/or importing of CT-P42.

289. Celltrion has knowledge of and is aware of the '865 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '865 patent based

on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that CT-P42 comprises a formulation patented in one or more claims of the '865 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(l)(3)(A) and the filing of this Complaint.

290. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '865 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to prescribe and/or use CT-P42. Celltrion also has an affirmative intent to actively induce infringement by others of one or more claims of the '865 patent at least because it will manufacture, directly or indirectly, CT-P42 that meets every limitation of one or more claims of the '865 patent, and will provide CT-P42 to its subsidiaries, affiliates, agents, and/or physicians who will import, offer to sell, sell, and/or use CT-P42 in a manner that directly infringes one or more claims of the '865 patent.

291. Upon information and belief, Celltrion knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '865 patent at least by providing its proposed label with instructions to use CT-P42.

292. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '865 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '865 patent.

293. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’865 patent by manufacturing, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing or contributing to the infringement of Celltrion’s CT-P42, before the expiration of the ’865 patent.

294. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the ’865 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the ’865 patent, before the expiration of the ’865 patent.

COUNT 29: INFRINGEMENT OF U.S. PATENT NO. 11,104,715 UNDER 35 U.S.C. § 271(e)

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

296. United States Patent No. 11,104,715 (“the ’715 patent”) (Exhibit 15 hereto), was duly and legally issued on August 31, 2021.

297. Regeneron is the owner of all right, title, and interest in the ’715 patent.

298. The ’715 patent has not yet expired.

299. The ’715 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).

300. 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 ’715 patent is an act of infringement of one or more claims of the ’715 patent under 35 U.S.C. § 271(e)(2)(C)(i).

301. 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 '715 patent.

302. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '715 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.

303. 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 '715 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

304. 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 '715 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 30: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '715 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

306. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '715 patent.

307. 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.

308. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '715 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '715 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '715 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '715 patent. Celltrion has knowledge of and is aware of the '715 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '715 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '715 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '715 patent.

309. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '715 patent. An actual controversy has also arisen and now exists between the parties

concerning whether Celltrion has infringed and/or will infringe one or more claims of the ’715 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

310. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’715 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion’s CT-P42, before the expiration of the ’715 patent.

311. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the ’715 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the ’715 patent, before the expiration of the ’715 patent.

COUNT 31: INFRINGEMENT OF U.S. PATENT NO. 11,174,283 UNDER 35 U.S.C. § 271(e)

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

313. United States Patent No. 11,174,283 (“the ’283 patent”) (Exhibit 16 hereto), was duly and legally issued on November 16, 2021.

314. Regeneron is the owner of all right, title, and interest in the ’283 patent.

315. The ’283 patent has not yet expired.

316. The ’283 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).

317. 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 '283 patent is an act of infringement of one or more claims of the '283 patent under 35 U.S.C. § 271(e)(2)(C)(i).

318. 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 '283 patent.

319. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '283 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.

320. 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 '283 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

321. 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 '283 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 32: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '283 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

323. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '283 patent.

324. 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.

325. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '283 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '283 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '283 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '283 patent. Celltrion has knowledge of and is aware of the '283 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '283 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '283 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '283 patent.

326. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or

importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the ’283 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the ’283 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

327. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’283 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion’s CT-P42, before the expiration of the ’283 patent.

328. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the ’283 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the ’283 patent, before the expiration of the ’283 patent.

COUNT 33: INFRINGEMENT OF U.S. PATENT NO. 11,253,572 UNDER 35 U.S.C. § 271(e)

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

330. United States Patent No. 11,253,572 (“the ’572 patent”) (Exhibit 17 hereto), was duly and legally issued on February 22, 2022.

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

332. The ’572 patent has not yet expired.

333. 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).

334. 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).

335. 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.

336. 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.

337. 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).

338. 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 34: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '572 PATENT UNDER 35 U.S.C. § 271 (b) or (c)

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

340. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '572 patent.

341. 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.

342. Following FDA approval, Celltrion intends to and will immediately infringe the '572 patent under 35 U.S.C. § 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, offer for sale, sale, use, or promotion of use of CT-P42.

343. Celltrion has knowledge of and is aware of the '572 patent at least due Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '572 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that the use of CT-P42 will practice the methods prescribed in one or more claims of the '572 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

344. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '572 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to administer and/or patients to use CT-P42 in a manner that infringes one or more claims of the '572 patent.

345. Upon information and belief, Celltrion knows and/or is willfully blind to the fact that medical practitioners will administer and/or patients will use CT-P42 according to its proposed label, which will directly infringe one or more claims of the '572 patent.

346. Upon information and belief, Celltrion knows or is willfully blind to the fact that it will aid and abet another's direct infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in its proposed label for the Celltrion aBLA product.

347. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '572 patent.

348. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '572 patent by actively inducing or contributing to the infringement of one or more claims of the '572 patent, before the expiration of the '572 patent.

349. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '572 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the '572 patent, before the expiration of the '572 patent.

COUNT 35: INFRINGEMENT OF U.S. PATENT NO. 11,299,532 UNDER 35 U.S.C. § 271(e)

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

351. United States Patent No. 11,299,532 ("the '532 patent") (Exhibit 18 hereto), was duly and legally issued on April 12, 2022.

352. Regeneron is the owner of all right, title, and interest in the '532 patent.

353. The ’532 patent has not yet expired.

354. The ’532 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).

355. 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 ’532 patent is an act of infringement of one or more claims of the ’532 patent under 35 U.S.C. § 271(e)(2)(C)(i).

356. 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 19 of the ’532 patent.

357. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’532 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.

358. 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 ’532 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

359. 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 ’532 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 36: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '532 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

361. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '532 patent.

362. 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.

363. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '532 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '532 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '532 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '532 patent. Celltrion has knowledge of and is aware of the '532 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '532 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '532 patent. On information and belief,

Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '532 patent.

364. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '532 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '532 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

365. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '532 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '532 patent.

366. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '532 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '532 patent, before the expiration of the '532 patent.

COUNT 37: INFRINGEMENT OF U.S. PATENT NO. 11,306,135 UNDER 35 U.S.C. § 271(e)

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

368. United States Patent No. 11,306,135 ("the '135 patent") (Exhibit 19 hereto), was duly and legally issued on April 19, 2022.

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

370. The '135 patent has not yet expired.

371. The '135 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).

372. 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 '135 patent is an act of infringement of one or more claims of the '135 patent under 35 U.S.C. § 271(e)(2)(C)(i).

373. 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 14 of the '135 patent.

374. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '135 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.

375. 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 '135 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

376. 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 '135 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 38: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '135 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

378. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '135 patent.

379. 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.

380. Following FDA approval, Celltrion intends to and will immediately begin—itself or through its subsidiaries, affiliates, or agents—to use, offer for sale, or sell within the United States, or import into the United States, Celltrion's CT-P42, which would constitute infringement of claims of the '135 patent under 35 U.S.C. § 271(a).

381. Following FDA approval, Celltrion intends to and will immediately begin to infringe the '135 patent under 35 U.S.C. § 271(b) and/or (c) by inducing others, including its subsidiaries, affiliates, agents, and physicians, to engage in the use, offer for sale, sale, marketing, distributing and/or importing of CT-P42.

382. Celltrion has knowledge of and is aware of the '135 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '135 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since

2021. Celltrion knows and/or is willfully blind to the fact that CT-P42 comprises a composition patented in one or more claims of the '135 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(l)(3)(A) and the filing of this Complaint.

383. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '135 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to prescribe and/or use CT-P42. Celltrion also has an affirmative intent to actively induce infringement by others of one or more claims of the '135 patent at least because it will manufacture, directly or indirectly, CT-P42 that meets every limitation of one or more claims of the '135 patent, and will provide CT-P42 to its subsidiaries, affiliates, agents, and/or physicians who will import, offer to sell, sell, and/or use CT-P42 in a manner that directly infringes one or more claims of the '135 patent.

384. Upon information and belief, Celltrion knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '135 patent at least by providing its proposed label with instructions to use CT-P42.

385. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '135 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '135 patent.

386. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '135 patent by manufacturing, using, offering to sell, and/or selling

within the United States, or importing into the United States, CT-P42, or by actively inducing or contributing to the infringement of Celltrion's CT-P42, before the expiration of the '135 patent.

387. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '135 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the '135 patent, before the expiration of the '135 patent.

COUNT 39: INFRINGEMENT OF U.S. PATENT NO. 11,312,936 UNDER 35 U.S.C. § 271(e)

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

389. United States Patent No. 11,312,936 ("the '936 patent") (Exhibit 20 hereto), was duly and legally issued on April 26, 2022.

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

391. The '936 patent has not yet expired.

392. 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).

393. 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).

394. 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.

395. 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.

396. 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).

397. 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 40: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’936 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

399. On information and belief, Celltrion submitted its aBLA referencing Regeneron’s EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the ’936 patent.

400. 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.

401. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the ’936 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United

States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '936 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '936 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '936 patent. Celltrion has knowledge of and is aware of the '936 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '936 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '936 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '936 patent.

402. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '936 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '936 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

403. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’936 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion’s CT-P42, before the expiration of the ’936 patent.

404. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the ’936 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the ’936 patent, before the expiration of the ’936 patent.

COUNT 41: INFRINGEMENT OF U.S. PATENT NO. 11,332,771 UNDER 35 U.S.C. § 271(e)

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

406. United States Patent No. 11,332,771 (“the ’771 patent”) (Exhibit 21 hereto), was duly and legally issued on May 17, 2022.

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

408. The ’771 patent has not yet expired.

409. The ’771 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).

410. 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).

411. 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.

412. 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.

413. 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).

414. 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 42: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '771 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

416. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '771 patent.

417. 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.

418. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '771 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '771 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '771 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '771 patent. Celltrion has knowledge of and is aware of the '771 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '771 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '771 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '771 patent.

419. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '771 patent. An actual controversy has also arisen and now exists between the parties

concerning whether Celltrion has infringed and/or will infringe one or more claims of the '771 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

420. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '771 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '771 patent.

421. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '771 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '771 patent, before the expiration of the '771 patent.

COUNT 43: INFRINGEMENT OF U.S. PATENT NO. 11,459,374 UNDER 35 U.S.C. § 271(e)

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

423. United States Patent No. 11,459,374 ("the '374 patent") (Exhibit 22 hereto), was duly and legally issued on October 4, 2022.

424. Regeneron is the owner of all right, title, and interest in the '374 patent.

425. The '374 patent has not yet expired.

426. The '374 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).

427. 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 '374 patent is an act of infringement of one or more claims of the '374 patent under 35 U.S.C. § 271(e)(2)(C)(i).

428. 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 '374 patent.

429. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '374 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.

430. 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 '374 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

431. 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 '374 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 44: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '374 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

433. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '374 patent.

434. 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.

435. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '374 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '374 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '374 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '374 patent. Celltrion has knowledge of and is aware of the '374 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '374 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '374 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '374 patent.

436. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or

importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '374 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '374 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

437. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '374 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '374 patent.

438. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '374 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '374 patent, before the expiration of the '374 patent.

COUNT 45: INFRINGEMENT OF U.S. PATENT NO. 11,472,861 UNDER 35 U.S.C. § 271(e)

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

440. United States Patent No. 11,472,861 ("the '861 patent") (Exhibit 23 hereto), was duly and legally issued on October 18, 2022.

441. Regeneron is the owner of all right, title, and interest in the '861 patent.

442. The '861 patent has not yet expired.

443. The '861 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).

444. 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 '861 patent is an act of infringement of one or more claims of the '861 patent under 35 U.S.C. § 271(e)(2)(C)(i).

445. 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 '861 patent.

446. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '861 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.

447. 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 '861 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

448. 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 '861 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 46: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '861 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

450. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '861 patent.

451. 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.

452. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '861 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '861 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '861 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '861 patent. Celltrion has knowledge of and is aware of the '861 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '861 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '861 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '861 patent.

453. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '861 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '861 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

454. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '861 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '861 patent.

455. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '861 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '861 patent, before the expiration of the '861 patent.

COUNT 47: INFRINGEMENT OF U.S. PATENT NO. 11,485,770 UNDER 35 U.S.C. § 271(e)

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

457. United States Patent No. 11,485,770 ("the '770 patent") (Exhibit 24 hereto), was duly and legally issued on November 1, 2022.

458. Regeneron is the owner of all right, title, and interest in the '770 patent.

459. The '770 patent has not yet expired.

460. The ’770 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).

461. 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 ’770 patent is an act of infringement of one or more claims of the ’770 patent under 35 U.S.C. § 271(e)(2)(C)(i).

462. 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 ’770 patent.

463. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’770 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.

464. 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 ’770 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

465. 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 ’770 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 48: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’770 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

467. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '770 patent.

468. 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.

469. Following FDA approval, Celltrion intends to and will immediately begin—itself or through its subsidiaries, affiliates, or agents—to use, offer for sale, or sell within the United States, or import into the United States, Celltrion's CT-P42, which would constitute infringement of claims of the '770 patent under 35 U.S.C. § 271(a).

470. Following FDA approval, Celltrion intends to and will immediately begin to infringe the '770 patent under 35 U.S.C. § 271(b) and/or (c) by inducing others, including its subsidiaries, affiliates, agents, and physicians, to engage in the use, offer for sale, sale, marketing, distributing and/or importing of CT-P42.

471. Celltrion has knowledge of and is aware of the '770 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '770 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that CT-P42 comprises a composition patented in one or more claims of the '770 patent at least as of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

472. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '770 patent at least because it filed an aBLA that includes a proposed label

having directions that instruct medical practitioners to prescribe and/or use CT-P42. Celltrion also has an affirmative intent to actively induce infringement by others of one or more claims of the '770 patent at least because it will manufacture, directly or indirectly, CT-P42 that meets every limitation of one or more claims of the '770 patent, and will provide CT-P42 to its subsidiaries, affiliates, agents, and/or physicians who will import, offer to sell, sell, and/or use CT-P42 in a manner that directly infringes one or more claims of the '770 patent.

473. Upon information and belief, Celltrion knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '770 patent at least by providing its proposed label with instructions to use CT-P42.

474. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '770 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '770 patent.

475. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '770 patent by manufacturing, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing or contributing to the infringement of Celltrion's CT-P42, before the expiration of the '770 patent.

476. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '770 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within

the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the '770 patent, before the expiration of the '770 patent.

COUNT 49: INFRINGEMENT OF U.S. PATENT NO. 11,505,593 UNDER 35 U.S.C. § 271(e)

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

478. United States Patent No. 11,505,593 ("the '593 patent") (Exhibit 25 hereto), was duly and legally issued on November 22, 2022.

479. Regeneron is the owner of all right, title, and interest in the '593 patent.

480. The '593 patent has not yet expired.

481. 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).

482. 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).

483. 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 '593 patent.

484. 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.

485. 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).

486. 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 50: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '593 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

488. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '593 patent.

489. 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.

490. Following FDA approval, Celltrion intends to and will immediately begin—itself or through its subsidiaries, affiliates, or agents—to use, offer for sale, or sell within the United States, or import into the United States, Celltrion's CT-P42, which would constitute infringement of claims of the '593 patent under 35 U.S.C. § 271(a).

491. Following FDA approval, Celltrion intends to and will immediately begin to infringe the '593 patent under 35 U.S.C. § 271(b) and/or (c) by inducing others, including its

subsidiaries, affiliates, agents, and physicians, to engage in the use, offer for sale, sale, marketing, distributing and/or importing of CT-P42.

492. Celltrion has knowledge of and is aware of the '593 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '593 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that CT-P42 comprises a composition patented in one or more claims of the '593 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(l)(3)(A) and the filing of this Complaint.

493. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '593 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to prescribe and/or use CT-P42. Celltrion also has an affirmative intent to actively induce infringement by others of one or more claims of the '593 patent at least because it will manufacture, directly or indirectly, CT-P42 that meets every limitation of one or more claims of the '593 patent, and will provide CT-P42 to its subsidiaries, affiliates, agents, and/or physicians who will import, offer to sell, sell, and/or use CT-P42 in a manner that directly infringes one or more claims of the '593 patent.

494. Upon information and belief, Celltrion knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '593 patent at least by providing its proposed label with instructions to use CT-P42.

495. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties

concerning whether Celltrion's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '593 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '593 patent.

496. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '593 patent by manufacturing, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing or contributing to the infringement of Celltrion's CT-P42, before the expiration of the '593 patent.

497. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '593 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the '593 patent, before the expiration of the '593 patent.

COUNT 51: INFRINGEMENT OF U.S. PATENT NO. 11,525,833 UNDER 35 U.S.C. § 271(e)

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

499. United States Patent No. 11,525,833 ("the '833 patent") (Exhibit 26 hereto), was duly and legally issued on December 13, 2022.

500. Regeneron is the owner of all right, title, and interest in the '833 patent.

501. The '833 patent has not yet expired.

502. 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).

503. 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).

504. 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 ’833 patent.

505. 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.

506. 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).

507. 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 52: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’833 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

509. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '833 patent.

510. 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.

511. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '833 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '833 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '833 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '833 patent. Celltrion has knowledge of and is aware of the '833 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '833 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '833 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '833 patent.

512. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '833 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '833 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

513. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '833 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '833 patent.

514. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '833 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '833 patent, before the expiration of the '833 patent.

COUNT 53: INFRINGEMENT OF U.S. PATENT NO. 11,535,663 UNDER 35 U.S.C. § 271(e)

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

516. United States Patent No. 11,535,663 ("the '663 patent") (Exhibit 27 hereto), was duly and legally issued on December 27, 2022.

517. Regeneron is the owner of all right, title, and interest in the '663 patent.

518. The '663 patent has not yet expired.

519. The ’663 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).

520. 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 ’663 patent is an act of infringement of one or more claims of the ’663 patent under 35 U.S.C. § 271(e)(2)(C)(i).

521. 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 ’663 patent.

522. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’663 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.

523. 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 ’663 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

524. 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 ’663 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 54: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’663 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

526. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '663 patent.

527. 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.

528. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '663 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '663 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '663 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '663 patent. Celltrion has knowledge of and is aware of the '663 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '663 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '663 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '663 patent.

529. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '663 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '663 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

530. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '663 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '663 patent.

531. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '663 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '663 patent, before the expiration of the '663 patent.

COUNT 55: INFRINGEMENT OF U.S. PATENT NO. 11,542,317 UNDER 35 U.S.C. § 271(e)

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

533. United States Patent No. 11,542,317 ("the '317 patent") (Exhibit 28 hereto), was duly and legally issued on January 3, 2023.

534. Regeneron is the owner of all right, title, and interest in the '317 patent.

535. The '317 patent has not yet expired.

536. The ’317 patent claims biological products and 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).

537. 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 ’317 patent is an act of infringement of one or more claims of the ’317 patent under 35 U.S.C. § 271(e)(2)(C)(i).

538. 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 ’317 patent.

539. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’317 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.

540. 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 ’317 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

541. 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 ’317 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 56: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '317 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

543. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '317 patent.

544. 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.

545. Following FDA approval, Celltrion intends to and will immediately begin—itself or through its subsidiaries, affiliates, or agents—to use, offer for sale, or sell within the United States, or import into the United States, Celltrion's CT-P42, which would constitute infringement of claims of the '317 patent under 35 U.S.C. § 271(a).

546. Following FDA approval, Celltrion intends to and will immediately begin to infringe the '317 patent under 35 U.S.C. § 271(b) and/or (c) by inducing others, including its subsidiaries, affiliates, agents, and physicians, to engage in the use, offer for sale, sale, marketing, distributing and/or importing of CT-P42.

547. Celltrion has knowledge of and is aware of the '317 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A), and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '317 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that CT-P42 comprises a formulation

patented in one or more claims of the '317 patent at least as of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

548. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '317 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to prescribe and/or use CT-P42. Celltrion also has an affirmative intent to actively induce infringement by others of one or more claims of the '317 patent at least because it will manufacture, directly or indirectly, CT-P42 that meets every limitation of one or more claims of the '317 patent, and will provide CT-P42 to its subsidiaries, affiliates, agents, and/or physicians who will import, offer to sell, sell, and/or use CT-P42 in a manner that directly infringes one or more claims of the '317 patent.

549. Upon information and belief, Celltrion knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '317 patent at least by providing its proposed label with instructions to use CT-P42.

550. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '317 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '317 patent.

551. Upon information and belief, Celltrion knows and/or is willfully blind to the fact that medical practitioners will administer and/or patients will use CT-P42 according to its proposed label, which will directly infringe one or more claims of the '317 patent.

552. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’317 patent by manufacturing, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing or contributing to the infringement of Celltrion’s CT-P42, before the expiration of the ’317 patent.

553. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the ’317 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the ’317 patent, before the expiration of the ’317 patent.

COUNT 57: INFRINGEMENT OF U.S. PATENT NO. 11,548,932 UNDER 35 U.S.C. § 271(e)

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

555. United States Patent No. 11,548,932 (“the ’932 patent”) (Exhibit 29 hereto), was duly and legally issued on January 10, 2023.

556. Regeneron is the owner of all right, title, and interest in the ’932 patent.

557. The ’932 patent has not yet expired.

558. The ’932 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).

559. 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 ’932 patent is an act of infringement of one or more claims of the ’932 patent under 35 U.S.C. § 271(e)(2)(C)(i).

560. 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 '932 patent.

561. Regeneron will be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '932 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.

562. 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 '932 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

563. 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 '932 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 58: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '932 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

565. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '932 patent.

566. 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.

567. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '932 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '932 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '932 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '932 patent. Celltrion has knowledge of and is aware of the '932 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '932 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '932 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '932 patent.

568. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '932 patent. An actual controversy has also arisen and now exists between the parties

concerning whether Celltrion has infringed and/or will infringe one or more claims of the '932 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

569. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '932 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '932 patent.

570. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '932 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '932 patent, before the expiration of the '932 patent.

COUNT 59: INFRINGEMENT OF U.S. PATENT NO. 11,555,176 UNDER 35 U.S.C. § 271(e)

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

572. United States Patent No. 11,555,176 ("the '176 patent") (Exhibit 30 hereto), was duly and legally issued on January 17, 2023.

573. Regeneron is the owner of all right, title, and interest in the '176 patent.

574. The '176 patent has not yet expired.

575. 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).

576. 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).

577. 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.

578. 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.

579. 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).

580. 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 60: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '176 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

582. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '176 patent.

583. 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.

584. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '176 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '176 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '176 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '176 patent. Celltrion has knowledge of and is aware of the '176 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '176 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the '176 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the '176 patent.

585. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's use, offer to sell, and/or sale within the United States, or

importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '176 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the '176 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

586. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '176 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion's CT-P42, before the expiration of the '176 patent.

587. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '176 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the '176 patent, before the expiration of the '176 patent.

COUNT 61: INFRINGEMENT OF U.S. PATENT NO. 11,559,564 UNDER 35 U.S.C. § 271(e)

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

589. United States Patent No. 11,559,564 ("the '564 patent") (Exhibit 31 hereto), was duly and legally issued on January 24, 2023.

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

591. The '564 patent has not yet expired.

592. 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).

593. 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).

594. 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.

595. 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.

596. 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).

597. 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 62: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '564 PATENT UNDER 35 U.S.C. § 271 (b) or (c)

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

599. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '564 patent.

600. 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.

601. Following FDA approval, Celltrion intends to and will immediately infringe the '564 patent under 35 U.S.C. § 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, offer for sale, sale, use, or promotion of use of CT-P42.

602. Celltrion has knowledge of and is aware of the '564 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '564 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that the use of CT-P42 will practice the methods prescribed in one or more claims of the '564 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

603. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '564 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to administer and/or patients to use CT-P42 in a manner that infringes one or more claims of the '564 patent.

604. Upon information and belief, Celltrion knows and/or is willfully blind to the fact that medical practitioners will administer and/or patients will use CT-P42 according to its proposed label, which will directly infringe one or more claims of the '564 patent.

605. Upon information and belief, Celltrion knows or is willfully blind to the fact that it will aid and abet another's direct infringement of at least one of the claims of the '564 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in its proposed label for the Celltrion aBLA product.

606. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '564 patent.

607. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '564 patent by actively inducing or contributing to the infringement of one or more claims of the '564 patent, before the expiration of the '564 patent.

608. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '564 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the '564 patent, before the expiration of the '564 patent.

COUNT 63: INFRINGEMENT OF U.S. PATENT NO. 11,707,506 UNDER 35 U.S.C. § 271(e)

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

610. United States Patent No. 11,707,506 ("the '506 patent") (Exhibit 32 hereto), was duly and legally issued on July 25, 2023.

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

612. The ’506 patent has not yet expired.

613. The ’506 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).

614. 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).

615. 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.

616. 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.

617. 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).

618. 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 64: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '506 PATENT UNDER 35 U.S.C. § 271 (b) or (c)

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

620. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '506 patent.

621. 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.

622. Following FDA approval, Celltrion intends to and will immediately infringe the '506 patent under 35 U.S.C. § 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, offer for sale, sale, use, or promotion of use of CT-P42.

623. Celltrion has knowledge of and is aware of the '506 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '506 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that the use of CT-P42 will practice the methods prescribed in one or more claims of the '506 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

624. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '506 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to administer and/or patients to use CT-P42 in a manner that infringes one or more claims of the '506 patent.

625. Upon information and belief, Celltrion knows and/or is willfully blind to the fact that medical practitioners will administer and/or patients will use CT-P42 according to its proposed label, which will directly infringe one or more claims of the '506 patent.

626. Upon information and belief, Celltrion knows or is willfully blind to the fact that it will aid and abet another's direct infringement of at least one of the claims of the '506 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in its proposed label for the Celltrion aBLA product.

627. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '506 patent.

628. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '506 patent by actively inducing or contributing to the infringement of one or more claims of the '506 patent, before the expiration of the '506 patent.

629. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the '506 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the '506 patent, before the expiration of the '506 patent.

COUNT 65: INFRINGEMENT OF U.S. PATENT NO. 11,732,024 UNDER 35 U.S.C. § 271(e)

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

631. United States Patent No. 11,732,024 ("the '024 patent") (Exhibit 33 hereto), was duly and legally issued on August 22, 2023.

632. Regeneron is the owner of all right, title, and interest in the '024 patent.

633. The '024 patent has not yet expired.

634. The '024 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).

635. 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).

636. 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.

637. 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.

638. 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).

639. 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 66: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '024 PATENT UNDER 35 U.S.C. § 271(a), (b), (c)

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

641. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '024 patent.

642. 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.

643. Following FDA approval, Celltrion intends to and will immediately begin—itself or through its subsidiaries, affiliates, or agents—to use, offer for sale, or sell within the United States, or import into the United States, Celltrion's CT-P42, which would constitute infringement of claims of the '024 patent under 35 U.S.C. § 271(a).

644. Following FDA approval, Celltrion intends to and will immediately begin to infringe the '024 patent under 35 U.S.C. § 271(b) and/or (c) by inducing others, including its subsidiaries, affiliates, agents, and physicians, to engage in the use, offer for sale, sale, marketing, distributing and/or importing of CT-P42.

645. Celltrion has knowledge of and is aware of the '024 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '024 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since

2021. Celltrion knows and/or is willfully blind to the fact that CT-P42 comprises a formulation patented in one or more claims of the '024 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(l)(3)(A) and the filing of this Complaint.

646. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '024 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to prescribe and/or use CT-P42. Celltrion also has an affirmative intent to actively induce infringement by others of one or more claims of the '024 patent at least because it will manufacture, directly or indirectly, CT-P42 that meets every limitation of one or more claims of the '024 patent, and will provide CT-P42 to its subsidiaries, affiliates, agents, and/or physicians who will import, offer to sell, sell, and/or use CT-P42 in a manner that directly infringes one or more claims of the '024 patent.

647. Upon information and belief, Celltrion knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '024 patent at least by providing its proposed label with instructions to use CT-P42.

648. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '024 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '024 patent.

649. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '024 patent by manufacturing, using, offering to sell, and/or selling

within the United States, or importing into the United States, CT-P42, or by actively inducing or contributing to the infringement of Celltrion's CT-P42, before the expiration of the '024 patent.

650. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '024 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the '024 patent, before the expiration of the '024 patent.

COUNT 67: INFRINGEMENT OF U.S. PATENT NO. 11,753,459 UNDER 35 U.S.C. § 271(e)

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

652. United States Patent No. 11,753,459 ("the '459 patent") (Exhibit 34 hereto), was duly and legally issued on September 12, 2023.

653. Regeneron is the owner of all right, title, and interest in the '459 patent.

654. The '459 patent has not yet expired.

655. The '459 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).

656. 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).

657. 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.

658. 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.

659. 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).

660. 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 68: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '459 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

662. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '459 patent.

663. 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.

664. Following FDA approval, Celltrion intends to and will immediately begin—itself or through its subsidiaries, affiliates, or agents—to use, offer for sale, or sell within the United

States, or import into the United States, Celltrion's CT-P42, which would constitute infringement of claims of the '459 patent under 35 U.S.C. § 271(a).

665. Following FDA approval, Celltrion intends to and will immediately begin to infringe the '459 patent under 35 U.S.C. § 271(b) and/or (c) by inducing others, including its subsidiaries, affiliates, agents, and physicians, to engage in the use, offer for sale, sale, marketing, distributing and/or importing of CT-P42.

666. Celltrion has knowledge of and is aware of the '459 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '459 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that CT-P42 comprises a composition patented in one or more claims of the '459 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(l)(3)(A) and the filing of this Complaint.

667. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '459 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to prescribe and/or use CT-P42. Celltrion also has an affirmative intent to actively induce infringement by others of one or more claims of the '459 patent at least because it will manufacture, directly or indirectly, CT-P42 that meets every limitation of one or more claims of the '459 patent, and will provide CT-P42 to its subsidiaries, affiliates, agents, and/or physicians who will import, offer to sell, sell, and/or use CT-P42 in a manner that directly infringes one or more claims of the '459 patent.

668. Upon information and belief, Celltrion knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '459 patent at least by providing its proposed label with instructions to use CT-P42.

669. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the '459 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the '459 patent.

670. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the '459 patent by manufacturing, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing or contributing to the infringement of Celltrion's CT-P42, before the expiration of the '459 patent.

671. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the '459 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the '459 patent, before the expiration of the '459 patent.

COUNT 69: INFRINGEMENT OF U.S. PATENT NO. 11,769,597 UNDER 35 U.S.C. § 271(e)

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

673. United States Patent No. 11,769,597 ("the '597 patent") (Exhibit 35 hereto), was duly and legally issued on September 26, 2023.

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

675. The '597 patent has not yet expired.

676. The '597 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).

677. 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).

678. 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.

679. 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.

680. 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).

681. 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 70: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '597 PATENT UNDER 35 U.S.C. § 271 (b) or (c)

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

683. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '597 patent.

684. 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.

685. Following FDA approval, Celltrion intends to and will immediately infringe the '597 patent under 35 U.S.C. § 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, offer for sale, sale, use, or promotion of use of CT-P42.

686. Celltrion has knowledge of and is aware of the '597 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '597 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that the use of CT-P42 will practice the methods prescribed in one or more claims of the '597 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint.

687. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '597 patent at least because it filed an aBLA that includes a proposed label

having directions that instruct medical practitioners to administer and/or patients to use CT-P42 in a manner that infringes one or more claims of the ’597 patent.

688. Upon information and belief, Celltrion knows and/or is willfully blind to the fact that medical practitioners will administer and/or patients will use CT-P42 according to its proposed label, which will directly infringe one or more claims of the ’597 patent.

689. Upon information and belief, Celltrion knows or is willfully blind to the fact that it will aid and abet another’s direct infringement of at least one of the claims of the ’597 patent, either literally or under the doctrine of equivalents, at least by recommending such infringing acts in its proposed label for the Celltrion aBLA product.

690. In view of Celltrion’s submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the ’597 patent.

691. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’597 patent by actively inducing or contributing to the infringement of one or more claims of the ’597 patent, before the expiration of the ’597 patent.

692. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing one or more claims of the ’597 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the ’597 patent, before the expiration of the ’597 patent.

COUNT 71: INFRINGEMENT OF U.S. PATENT NO. 11,788,102 UNDER 35 U.S.C.

§ 271(e)

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

694. United States Patent No. 11,788,102 ("the '102 patent") (Exhibit 36 hereto), was duly and legally issued on October 17, 2023.

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

696. The '102 patent has not yet expired.

697. The '102 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).

698. 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).

699. 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 '102 patent.

700. 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.

701. 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).

702. 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 72: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '102 PATENT UNDER 35 U.S.C. § 271 (b) and (g)

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

704. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '102 patent.

705. 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.

706. On information and belief, following FDA approval of its CT-P42, Celltrion intends to and will immediately infringe one or more claims of the '102 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States, directly or indirectly, CT-P42 manufactured by the process patented in one or more claims of the '102 patent. On information and belief, following FDA approval of its CT-P42, Celltrion will induce infringement of one or more claims of the '102 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States CT-P42 manufactured by the process patented in one or more claims of the '102 patent. Celltrion has knowledge of and is aware of the '102 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of

the ’102 patent based on its active monitoring of Regeneron’s patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion will manufacture, directly or indirectly, CT-P42 by using a process patented in one or more claims of the ’102 patent. On information and belief, Celltrion will provide this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe one or more claims of the ’102 patent.

707. In view of Celltrion’s submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion’s use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more claims of the ’102 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe one or more claims of the ’102 patent by actively inducing the importation, use, offer to sell, and/or sale of CT-P42.

708. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’102 patent by using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing the infringement of Celltrion’s CT-P42, before the expiration of the ’102 patent.

709. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the ’102 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing the infringement of one or more claims of the ’102 patent, before the expiration of the ’102 patent.

COUNT 73: INFRINGEMENT OF U.S. PATENT NO. 11,793,926 UNDER 35 U.S.C. § 271(e)

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

711. United States Patent No. 11,793,926 ("the '926 patent") (Exhibit 37 hereto), was duly and legally issued on October 24, 2023.

712. Regeneron is the owner of all right, title, and interest in the '926 patent.

713. The '926 patent has not yet expired.

714. The '926 patent claims 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).

715. 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).

716. 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 11 of the '926 patent.

717. 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.

718. 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).

719. 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.

COUNT 74: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '926 PATENT UNDER 35 U.S.C. § 271(a), (b), (c)

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

721. On information and belief, Celltrion submitted its aBLA referencing Regeneron's EYLEA® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, and/or sale of CT-P42 before the expiration of the '926 patent.

722. 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.

723. Following FDA approval, Celltrion intends to and will immediately begin—itself or through its subsidiaries, affiliates, or agents—to use, offer for sale, or sell within the United States, or import into the United States, Celltrion's CT-P42, which would constitute infringement of claims of the '926 patent under 35 U.S.C. § 271(a).

724. Following FDA approval, Celltrion intends to and will immediately begin to infringe the '926 patent under 35 U.S.C. § 271(b) and/or (c) by inducing others, including its subsidiaries, affiliates, agents, and physicians, to engage in the use, offer for sale, sale, marketing, distributing and/or importing of CT-P42.

725. Celltrion has knowledge of and is aware of the '926 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '926 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. Celltrion knows and/or is willfully blind to the fact that CT-P42 comprises a formulation patented in one or more claims of the '926 patent at least as of the date of Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(l)(3)(A) and the filing of this Complaint.

726. Celltrion has an affirmative intent to actively induce infringement by others of one or more claims of the '926 patent at least because it filed an aBLA that includes a proposed label having directions that instruct medical practitioners to prescribe and/or use CT-P42. Celltrion also has an affirmative intent to actively induce infringement by others of one or more claims of the '926 patent at least because it will manufacture, directly or indirectly, CT-P42 that meets every limitation of one or more claims of the '926 patent, and will provide CT-P42 to its subsidiaries, affiliates, agents, and/or physicians who will import, offer to sell, sell, and/or use CT-P42 in a manner that directly infringes one or more claims of the '926 patent.

727. Upon information and belief, Celltrion knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '926 patent at least by providing its proposed label with instructions to use CT-P42.

728. In view of Celltrion's submission of its aBLA and service of its Notice of Commercial Marketing, an actual controversy has arisen and now exists between the parties concerning whether Celltrion's manufacture, use, offer to sell, and/or sale within the United States, or importation into the United States, of CT-P42 has infringed and/or will infringe one or more

claims of the ’926 patent. An actual controversy has also arisen and now exists between the parties concerning whether Celltrion has infringed and/or will infringe by actively inducing and/or contributing to the infringement of one or more claims of the ’926 patent.

729. Regeneron is entitled to a declaratory judgment that Celltrion has infringed and/or would infringe claims of the ’926 patent by manufacturing, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or by actively inducing or contributing to the infringement of Celltrion’s CT-P42, before the expiration of the ’926 patent.

730. Regeneron would be irreparably harmed if Celltrion is not enjoined from infringing claims of the ’926 patent. Regeneron does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Celltrion from making, using, offering to sell, and/or selling within the United States, or importing into the United States, CT-P42, or actively inducing or contributing to the infringement of one or more claims of the ’926 patent, before the expiration of the ’926 patent.

COUNT 75: INFRINGEMENT OF U.S. PATENT NO. 7,070,959 UNDER 35 U.S.C. § 271(b), (g)

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

732. United States Patent No. 7,070,959 (“the ’959 patent”) (Exhibit 38 hereto), was duly and legally issued on July 4, 2006.

733. Regeneron is the owner of all right, title, and interest in the ’959 patent.

734. The ’959 patent expired on June 16, 2023.

735. The ’959 patent claims a system for producing 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).

736. On information and belief, Celltrion infringed, inter alia, claim 11 of the '959 patent under 35 U.S.C. § 271(g) by importing into the United States or offering to sell, selling, or using within the United States commercial batches of CT-P42 that were made by an infringing process. On information and belief, these activities fall outside of the activities protected under 35 U.S.C. § 271(e)(1) because they amount to stockpiling CT-P42 for commercial use upon approval of Celltrion's aBLA.

737. On information and belief, Celltrion induced infringement of, *inter alia*, claim 11 of the '959 patent under 35 U.S.C. § 271(b) by actively inducing one or more of its subsidiaries, affiliates, or agents to import into the United States or to sell, offer to sell, or use within the United States commercial batches of CT-P42 manufactured by the process patented in, *inter alia*, claim 11 of the '959 patent. Celltrion has knowledge of and is aware of the '959 patent at least due to Regeneron's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. On information and belief, Celltrion has also had knowledge of the '959 patent based on its active monitoring of Regeneron's patents. For example, Celltrion has filed seven petitions for *inter partes* review or post grant review against various Regeneron patents since 2021. On information and belief, Celltrion manufactured, directly or indirectly, CT-P42 by using a process patented in, *inter alia*, claim 11 of the '959 patent. On information and belief, Celltrion provided this CT-P42 to one or more of its subsidiaries, affiliates, or agents knowing or willfully blind to the fact that one or more of its subsidiaries, affiliates, or agents will directly infringe, *inter alia*, claim 11 of the '959 patent.

738. Celltrion's commercial 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 '959 patent have caused

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

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) and 42 U.S.C. § (*l*)(8)(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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JS 44 (Rev. 04/21) **CIVIL COVER SHEET** 1:23-CV-89 Received: 11/8/2023

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

REGENERON PHARMACEUTICALS, INC.

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Carey Douglas Kessler & Ruby, PLLC, 707 Virginia Street East, 901 Chase Tower, Charleston, WV 25301

DEFENDANTS

CELLTRION, INC.

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
35 U.S.C. §§ 100 et seq.

Brief description of cause:
Patent infringement.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE Thomas S. Kleeh DOCKET NUMBER 1:22-cv-00061

DATE
November 8, 2023

SIGNATURE OF ATTORNEY OF RECORD
/s/ Steven R. Ruby

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.