Anthony R. Bisconti, State Bar No. 269230
tbisconti@bklwlaw.com
BIENERT KATZMAN LITTRELL WILLIAMS LLP
903 Calle Amanecer, Suite 350
San Clemente, California 92673
Telephone (949) 369-3700
Facsimile (949) 369-3701

WILLIAMS & CONNOLLY LLP (Of Counsel)
David I. Berl, State Bar No. 211761
Ellen E. Oberwetter (*pro hac vice* forthcoming)
Thomas S. Fletcher, State Bar No. 262693
Andrew V. Trask (*pro hac vice* forthcoming)
Teagan J. Gregory (*pro hac vice* forthcoming)
Shaun P. Mahaffy (*pro hac vice* forthcoming)
Kathryn S. Kayali (*pro hac vice* forthcoming)
Arthur J. Argall III (*pro hac vice* forthcoming)
Adam Pan (*pro hac vice* forthcoming)
Rebecca A. Carter (*pro hac vice* forthcoming)
Haylee N. Bernal Anderson (*pro hac vice* forthcoming)
Renee M. Griffin (*pro hac vice* forthcoming)
Jennalee Beazley* (*pro hac vice* forthcoming)
680 Maine Avenue, SW
Washington, DC 20024
Telephone (202) 434-5000

*Admitted only in Pennsylvania; practice supervised by D.C. Bar members

Attorneys for Plaintiff
Regeneron Pharmaceuticals, Inc.

Counsel's information continued on page i

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

REGENERON PHARMACEUTICALS, INC., a New York corporation, Plaintiff, v. AMGEN INC., a Delaware corporation, Defendant.	Case No. **COMPLAINT**

KELLOGG, HANSEN, TODD, FIGEL
& FREDERICK, P.L.L.C.
Andrew E. Goldsmith (*pro hac vice* forthcoming)
Jacob E. Hartman (*pro hac vice* forthcoming)
1615 M Street, NW, Suite 400
Washington, D.C. 20036
(202) 326-7992

WEIL GOTSHAL & MANGES LLP
Elizabeth S. Weiswasser (*pro hac vice* forthcoming)
Anish R. Desai (*pro hac vice* forthcoming)
Natalie C. Kennedy (*pro hac vice* forthcoming)
Tom Yu (*pro hac vice* forthcoming)
Yi Zhang (*pro hac vice* forthcoming)
Kathryn Leicht (*pro hac vice* forthcoming)
Rocco Recce (*pro hac vice* forthcoming)
Zhen Lin (*pro hac vice* forthcoming)
Kellie Van Beck (*pro hac vice* forthcoming)
767 5th Avenue
New York, NY 10153
(212) 310-8000

WEIL GOTSHAL & MANGES LLP
Christopher M. Pepe (*pro hac vice* forthcoming)
Priyata Y. Patel (*pro hac vice* forthcoming)
Matthew Sieger (*pro hac vice* forthcoming)
2001 M Street NW, Suite 600
Washington, DC 20036
(202) 682-7000

Attorneys for Plaintiff
Regeneron Pharmaceuticals, Inc.

Plaintiff Regeneron Pharmaceuticals, Inc. for its Complaint in this matter, alleges as follows:

INTRODUCTION

1. Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Plaintiff"), invented, developed, and sells EYLEA®, the market-leading treatment for several serious eye diseases. Defendant Amgen Inc. ("Amgen" or "Defendant") is seeking FDA approval under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. §§ 262(k)-(*l*), to commercialize "ABP 938," a proposed biosimilar of EYLEA®. To vindicate its patent rights, Regeneron brings this Complaint pursuant to 42 U.S.C. §§ 262(*l*)(6)(A), (9)(A) seeking a judgment of patent infringement against Amgen under 35 U.S.C. § 271(e).

2. Regeneron is a leading science-based American biotechnology company. With a focus on patient access and fair drug pricing, Regeneron is dedicated to innovation, improving human health, and tackling the most urgent medical issues facing the Nation. Founded and led for over 30 years by physician-scientists, Regeneron has developed life-transforming medicines for people with serious diseases, including cancer, atopic dermatitis, asthma, eye diseases, cardiovascular and metabolic diseases, Ebola, and COVID-19, which have been used across the country. Regeneron's cutting-edge scientific advances are supported, in large part, by its ophthalmic product, EYLEA®, which FDA approved in 2011.

3. 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.

4. On October 31, 2023, Amgen publicly announced that the FDA accepted its abbreviated Biologics Drug Application ("aBLA") for ABP 938, 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).

5. Amgen's submission of its aBLA constitutes an act of patent infringement under 35 U.S.C. § 271(e). Pursuant to 42 U.S.C. § 262(k)(7)(A), Amgen'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 Amgen launches ABP 938 in the United States.

PLAINTIFF

6. Plaintiff Regeneron is a corporation organized and existing under the laws of the State of New York with its principal place of business located at 777 Old Saw Mill River Road, Tarrytown, New York 10591. Regeneron is dedicated to discovering, developing, and commercializing medicines to treat patients with debilitating and life-threatening diseases. Regeneron owns each of the patents asserted in this Complaint (collectively, the "asserted patents" or the "patents in suit"):

Patent	Issue Date	First Named Inventor
9,222,106	December 29, 2015	Gang Chen
9,254,338	February 9, 2016	George D. Yancopoulos
9,315,281	April 19, 2016	Tikiri Jean Dissanayake
9,816,110	November 14, 2017	Ying Shen
10,130,681	November 20, 2018	George D. Yancopoulos
10,415,055	September 17, 2019	Gang Chen
10,464,992	November 5, 2019	Eric Furfine
10,669,594	June 2, 2020	Serge Monpoeho
10,828,345	November 10, 2020	George D. Yancopoulos
10,888,601	January 12, 2021	George D. Yancopoulos
10,905,786	February 2, 2021	Philip Shodder
10,918,754	February 16, 2021	Philip Shodder
11,066,458	July 20, 2021	Eric Furfine
11,084,865	August 10, 2021	Eric Furfine
11,104,715	August 31, 2021	Shawn Lawrence
11,160,918	November 2, 2021	Andrew Cook
11,253,572	February 22, 2022	George D. Yancopoulos
11,306,135	April 19, 2022	Shunhai Wang
11,459,374	October 4, 2022	Andrew Tustian
11,472,861	October 18, 2022	Shawn Lawrence
11,505,593	November 22, 2022	Shunhai Wang
11,535,663	December 27, 2022	Shawn Lawrence
11,542,317	January 3, 2023	Shunhai Wang
11,548,932	January 10, 2023	Shunhai Wang
11,555,176	January 17, 2023	Wei Xue
11,559,564	January 24, 2023	George D. Yancopoulos

Patent	Issue Date	First Named Inventor
11,680,930	June 20, 2023	Nathan Mao
11,707,506	July 25, 2023	George D. Yancopoulos
11,753,459	September 12, 2023	Shunhai Wang
11,769,597	September 26, 2023	Lorah Perlee
11,788,102	October 17, 2023	Ying Shen
11,793,926	October 24, 2023	Andrew Cook

DEFENDANT

7. Amgen Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320. Amgen is, among other things, engaged in the development of biosimilar drugs, including a proposed biosimilar version of Regeneron's EYLEA®, ABP 938.

8. Upon information and belief, Amgen, directly or indirectly, manufactures its drug products within the United States and abroad. Upon information and belief, Amgen directly, or via its subsidiaries, affiliates, or other agents, develops, distributes, or sells within the United States or imports into the United States Amgen's drug products, including ABP 938, under the general direction and control of Amgen.

9. Amgen already has biosimilars that have been introduced into the United States market. For example, Amgen is the holder of a Biologics License Application for Amjevita, an approved biosimilar of Humira. Amgen Inc. also manufactures Amjevita.

10. On information and belief, Amgen and its subsidiaries, affiliates, and agents will function as an integrated organization and a single business enterprise in the manufacture of ABP 938, in the importation of ABP 938

into the United States, and in the sale or offer for sale of ABP 938 in the United States.

11. On information and belief, Amgen and its subsidiaries, affiliates, and agents develop, manufacture, distribute, sell, and/or import drug products for the entire United States market and do business in every state, including California, either directly or indirectly.

JURISDICTION AND VENUE

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

13. Amgen is a corporation organized and existing under the laws of the State of Delaware and has its corporate headquarters located at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen's office located at this address is a regular and established place of business within the forum.

14. Amgen is listed with the Office of the California Secretary of State as an entity that is currently doing business in the State of California, and the office of the California Secretary of State has assigned Amgen the following business entity number: C1579467. The Office of the California Secretary of State business listing for Defendant states the physical address of Amgen is One Amgen Center Drive, Thousand Oaks, CA 91320.

15. Amgen is a corporate entity currently doing business in the State of California and having a regular established place of business within the forum, Amgen purposefully engaged in activities that are directed at the forum, the action arises out of or relates to those activities, and the assertion of personal jurisdiction in the forum comports with traditional notions of fair play and substantial justice. For at least this reason, the Court has jurisdiction over Amgen in this action.

16. This Court also has personal jurisdiction over Amgen because Amgen is seeking approval to engage in the commercial manufacture, use, offer for

sale, sale, and/or importation of ABP 938 in the United States, including in the State of California; and because, if its product receives FDA approval, Amgen intends to market, distribute, offer for sale, and/or sell it in the United States, including in the State of California, deriving substantial revenue therefrom.

17. In addition, Amgen has consented to jurisdiction in the Central District of California in one or more prior cases arising out of its manufacture, use, offer for sale, sale, and/or importation of Amgen pharmaceutical products in the United States, including in the State of California. This includes cases Amgen has initiated as the plaintiff.

18. Venue is proper in this district under 28 U.S.C. § 1391(b) because Amgen Inc. resides in this District and a substantial part of the events and injury giving rise to Plaintiff's claims has and continues to occur in this District.

FACTUAL ALLEGATIONS

19. 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).

20. The BPCIA reduces substantially the time and expense otherwise required to gain FDA approval, by allowing a biosimilar applicant like Amgen 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").

21. Amgen initiated the Patent Dance by serving Regeneron with its aBLA pursuant to 42 U.S.C. § 262(*l*)(2)(A) ("Amgen's Production"). Amgen's Production failed to satisfy § 262(*l*)(2)(A) because, for example, Amgen's Production did not contain "other information that describes the process or processes used to manufacture the biological product that is the subject of such application," as required by 42 U.S.C. § 262(*l*)(2)(A). Additionally, a number of documents in Amgen's Production included inactive hyperlinks to underlying documents. These deficiencies impaired Regeneron's review of Amgen's Production and its ability to engage in the patent dance.

22. 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)." Regeneron later notified Amgen that its Production was deficient in several ways that frustrated Regeneron's review, and requested that Amgen produce specified information.

23. Despite Amgen's numerous deficiencies, Regeneron timely served on Amgen "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). Each of the Asserted Patents identified below was included on Regeneron's 3A List.

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

25. In response to Amgen's purported 3(B) Statement, Regeneron timely provided a detailed statement that described, with respect to each patent described in Amgen's purported 3(B) Statement, on a claim by claim basis, the factual and legal basis for Regeneron's opinion that such patent will be infringed by the commercial marketing of ABP 938 and a response to Amgen's purported 3(B) Statement concerning invalidity ("3(C) Contentions"). 42 U.S.C. § 262(*l*)(3)(C).

26. In Regeneron's letter attaching its 3(C) Contentions, Regeneron began the negotiations specified under 42 U.S.C. § 262(*l*)(4)(A) and offered to confer with Amgen. Amgen's counsel responded to say that they were not immediately available. Two weeks later, Regeneron followed up on its earlier proposal pursuant to 42 U.S.C. § 262(*l*)(4)(A), and offered to confer with Amgen on any day that week. Amgen did not respond. Three days later, Regeneron wrote to Amgen again by email, following up on its earlier messages and asking for Amgen's position.

27. Later that day, Amgen responded with a letter accepting Regeneron's original proposal pursuant to 42 U.S.C. § 262(*l*)(4)(A), thereby concluding the parties' negotiations. 42 U.S.C. § 262(*l*)(6)(A) provides that "[i]f the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the

reference product sponsor shall bring an action for patent infringement with respect to each such patent." Amgen's letter accepting Regeneron's proposal was sent not more than 30 days from the filing of this complaint.

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

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 Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

34. The submission of Amgen'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 ABP 938 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, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 20 of the '106 patent.

36. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

37. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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 Amgen'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 ABP 938 before the expiration of the '106 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

42. The '338 patent has not yet expired.

43. The '338 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

44. The submission of Amgen'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 ABP 938 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).

45. For example, the sale of ABP 938 pursuant to the label proposed in Amgen's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '338 patent.

46. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

47. Amgen’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

48. The submission of Amgen’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 ABP 938 before the expiration of the ’338 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

50. United States Patent No. 9,315,281 (“the ’281 patent”) (Exhibit 3 hereto), was duly and legally issued on April 19, 2016.

51. Regeneron is the owner of all right, title, and interest in the ’281 patent.

52. The ’281 patent has not yet expired.

53. The ’281 patent claims, *inter alia*, methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

54. The submission of Amgen’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 ABP 938 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).

55. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 13 of the ’281 patent.

56. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

57. Amgen’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

58. The submission of Amgen’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 ABP 938 before the expiration of the ’281 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

62. The ’110 patent has not yet expired.

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

64. The submission of Amgen’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 ABP 938 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).

65. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 18 of the '110 patent.

66. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

67. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

68. The submission of Amgen'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 ABP 938 before the expiration of the '110 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

72. The '681 patent has not yet expired.

73. The '681 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

74. The submission of Amgen'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 ABP 938 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).

75. For example, the sale of ABP 938 pursuant to the label proposed in Amgen's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '681 patent.

76. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

77. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

78. The submission of Amgen'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 ABP 938 before the expiration of the '681 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

80. United States Patent No. 10,415,055 ("the '055 patent") (Exhibit 6 hereto), was duly and legally issued on September 17, 2019.

81. Regeneron is the owner of all right, title, and interest in the '055 patent.

82. The '055 patent has not yet expired.

83. The ’055 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

84. The submission of Amgen’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 ABP 938 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).

85. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 23 of the ’055 patent.

86. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

87. Amgen’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

88. The submission of Amgen’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 ABP 938 before the expiration of the ’055 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 7: INFRINGEMENT OF U.S. PATENT NO. 10,464,992 UNDER 35 U.S.C. § 271(e)

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

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

91. Regeneron is the owner of all right, title, and interest in the '992 patent.

92. The '992 patent has not yet expired.

93. The '992 patent claims biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

94. The submission of Amgen'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 ABP 938 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).

95. For example, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '992 patent.

96. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

97. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

98. The submission of Amgen'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 ABP 938 before the expiration of the '992 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 8: INFRINGEMENT OF U.S. PATENT NO. 10,669,594 UNDER 35 U.S.C. § 271(e)

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

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

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

102. The '594 patent has not yet expired.

103. The '594 patent claims methods of detecting biological contaminants and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

104. The submission of Amgen'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 ABP 938 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).

105. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '594 patent.

106. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

107. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

108. The submission of Amgen'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 ABP 938 before the expiration of the '594 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 9: INFRINGEMENT OF U.S. PATENT NO. 10,828,345 UNDER 35 U.S.C. § 271(e)

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

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

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

112. The '345 patent has not yet expired.

113. The '345 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

114. The submission of Amgen'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 ABP 938 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).

115. For example, the sale of ABP 938 pursuant to the label proposed in Amgen's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '345 patent.

116. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

117. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

118. The submission of Amgen'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 ABP 938 before the expiration of the '345 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

122. The '601 patent has not yet expired.

123. The '601 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

124. The submission of Amgen'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 ABP 938 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).

125. For example, the sale of ABP 938 pursuant to the label proposed in Amgen's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '601 patent.

126. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

127. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

128. The submission of Amgen'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 ABP 938 before the expiration of the '601 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 11: INFRINGEMENT OF U.S. PATENT NO. 10,905,786 UNDER 35 U.S.C. § 271(e)

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

130. United States Patent No. 10,905,786 ("the '786 patent") (Exhibit 11 hereto), was duly and legally issued on February 2, 2021.

131. Regeneron is the owner of all right, title, and interest in the '786 patent.

132. The '786 patent has not yet expired.

133. The '786 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

134. The submission of Amgen'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 ABP 938 before the expiration of the '786 patent is an act of infringement of one or more claims of the '786 patent under 35 U.S.C. § 271(e)(2)(C)(i).

135. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, inter alia, claim 15 of the '786 patent.

136. Regeneron will be irreparably harmed if Amgen is not enjoined from infringing one or more claims of the '786 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen from any further infringement. Regeneron has no adequate remedy at law.

137. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the

expiration of the ’786 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

138. The submission of Amgen’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 ABP 938 before the expiration of the ’786 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 12: INFRINGEMENT OF U.S. PATENT NO. 10,918,754 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. 10,918,754 (“the ’754 patent”) (Exhibit 12 hereto), was duly and legally issued on February 16, 2021.

141. Regeneron is the owner of all right, title, and interest in the ’754 patent.

142. The ’754 patent has not yet expired.

143. The ’754 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

144. The submission of Amgen’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 ABP 938 before the expiration of the ’754 patent is an act of infringement of one or more claims of the ’754 patent under 35 U.S.C. § 271(e)(2)(C)(i).

145. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, inter alia, claim 1 of the ’754 patent.

146. Regeneron will be irreparably harmed if Amgen is not enjoined from infringing one or more claims of the ’754 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen from any further infringement. Regeneron has no adequate remedy at law.

147. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the '754 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 Amgen'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 ABP 938 before the expiration of the '754 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 13: INFRINGEMENT OF U.S. PATENT NO. 11,066,458 UNDER 35 U.S.C. § 271(e)

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

150. United States Patent No. 11,066,458 ("the '458 patent") (Exhibit 13 hereto), was duly and legally issued on July 20, 2021.

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

152. The '458 patent has not yet expired.

153. The '458 patent claims biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

154. The submission of Amgen'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 ABP 938 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).

155. For example, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '458 patent.

156. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

157. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

158. The submission of Amgen'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 ABP 938 before the expiration of the '458 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 14: INFRINGEMENT OF U.S. PATENT NO. 11,084,865 UNDER 35 U.S.C. § 271(e)

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

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

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

162. The '865 patent has not yet expired.

163. The '865 patent claims biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

164. The submission of Amgen'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 ABP 938 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).

165. For example, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '865 patent.

166. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

167. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

168. The submission of Amgen'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 ABP 938 before the expiration of the '865 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 15: INFRINGEMENT OF U.S. PATENT NO. 11,104,715 UNDER 35 U.S.C. § 271(e)

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

170. United States Patent No. 11,104,715 ("the '715 patent") (Exhibit 15 hereto), was duly and legally issued on August 31, 2021.

171. Regeneron is the owner of all right, title, and interest in the '715 patent.

172. The '715 patent has not yet expired.

173. The '715 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

174. The submission of Amgen'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 ABP 938 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).

175. For example, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '715 patent.

176. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

177. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

178. The submission of Amgen'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 ABP 938 before the expiration of the '715 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 16: INFRINGEMENT OF U.S. PATENT NO. 11,160,918 UNDER 35 U.S.C. § 271(e)

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

180. United States Patent No. 11,160,918 ("the '918 patent") (Exhibit 16 hereto), was duly and legally issued on November 2, 2021.

181. Regeneron is the owner of all right, title, and interest in the '918 patent.

182. The '918 patent has not yet expired.

183. The '918 patent claims biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

184. The submission of Amgen'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 ABP 938 before the expiration of the '918 patent is an act of infringement of one or more claims of the '918 patent under 35 U.S.C. § 271(e)(2)(C)(i).

185. For example, on information and belief, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '918 patent.

186. Regeneron will be irreparably harmed if Amgen is not enjoined from infringing one or more claims of the '918 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen from any further infringement. Regeneron has no adequate remedy at law.

187. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the '918 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

188. The submission of Amgen'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 ABP 938 before the expiration of the '918 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 17: INFRINGEMENT OF U.S. PATENT NO. 11,253,572 UNDER 35 U.S.C. § 271(e)

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

190. United States Patent No. 11,253,572 ("the '572 patent") (Exhibit 17 hereto), was duly and legally issued on February 22, 2022.

191. Regeneron is the owner of all right, title, and interest in the '572 patent.

192. The '572 patent has not yet expired.

193. The '572 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

194. The submission of Amgen'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 ABP 938 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).

195. For example, the sale of ABP 938 pursuant to the label proposed in Amgen's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '572 patent.

196. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

197. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

198. The submission of Amgen'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 ABP 938 before the expiration of the '572 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 18: INFRINGEMENT OF U.S. PATENT NO. 11,306,135 UNDER 35 U.S.C. § 271(e)

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

200. United States Patent No. 11,306,135 ("the '135 patent") (Exhibit 18 hereto), was duly and legally issued on April 19, 2022.

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

202. The '135 patent has not yet expired.

203. The '135 patent claims biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

204. The submission of Amgen'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 ABP 938 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).

205. For example, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 14 of the '135 patent.

206. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

207. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

208. The submission of Amgen'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 ABP 938 before the expiration of the '135 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 19: INFRINGEMENT OF U.S. PATENT NO. 11,459,374 UNDER 35 U.S.C. § 271(e)

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

210. United States Patent No. 11,459,374 ("the '374 patent") (Exhibit 19 hereto), was duly and legally issued on October 4, 2022.

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

212. The '374 patent has not yet expired.

213. The ’374 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

214. The submission of Amgen’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 ABP 938 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).

215. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 20 of the ’374 patent.

216. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

217. Amgen’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

218. The submission of Amgen’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 ABP 938 before the expiration of the ’374 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 20: INFRINGEMENT OF U.S. PATENT NO. 11,472,861 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. 11,472,861 (“the ’861 patent”) (Exhibit 20 hereto), was duly and legally issued on October 18, 2022.

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

222. The '861 patent has not yet expired.

223. The '861 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

224. The submission of Amgen'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 ABP 938 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).

225. For example, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '861 patent.

226. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

227. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

228. The submission of Amgen'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 ABP 938 before the expiration of the '861 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 21: INFRINGEMENT OF U.S. PATENT NO. 11,505,593 UNDER 35 U.S.C. § 271(e)

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

230. United States Patent No. 11,505,593 ("the '593 patent") (Exhibit 21 hereto), was duly and legally issued on November 22, 2022.

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

232. The '593 patent has not yet expired.

233. The '593 patent claims biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

234. The submission of Amgen'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 ABP 938 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).

235. For example, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '593 patent.

236. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

237. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

238. The submission of Amgen'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 ABP 938 before the expiration of the '593 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 22: INFRINGEMENT OF U.S. PATENT NO. 11,535,663 UNDER 35 U.S.C. § 271(e)

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

240. United States Patent No. 11,535,663 ("the '663 patent") (Exhibit 22 hereto), was duly and legally issued on December 27, 2022.

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

242. The '663 patent has not yet expired.

243. The '663 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

244. The submission of Amgen'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 ABP 938 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).

245. For example, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '663 patent.

246. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

247. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

248. The submission of Amgen'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 ABP 938 before the expiration of the '663 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 23: INFRINGEMENT OF U.S. PATENT NO. 11,542,317 UNDER 35 U.S.C. § 271(e)

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

250. United States Patent No. 11,542,317 ("the '317 patent") (Exhibit 23 hereto), was duly and legally issued on January 3, 2023.

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

252. The '317 patent has not yet expired.

253. 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 Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

254. The submission of Amgen'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 ABP 938 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).

255. For example, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '317 patent.

256. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

257. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

258. The submission of Amgen'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 ABP 938 before the expiration of the '317 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 24: INFRINGEMENT OF U.S. PATENT NO. 11,548,932 UNDER 35 U.S.C. § 271(e)

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

260. United States Patent No. 11,548,932 ("the '932 patent") (Exhibit 24 hereto), was duly and legally issued on January 10, 2023.

261. Regeneron is the owner of all right, title, and interest in the '932 patent.

262. The '932 patent has not yet expired.

263. The '932 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

264. The submission of Amgen'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 ABP 938 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).

265. For example, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 22 of the '932 patent.

266. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

267. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

268. The submission of Amgen’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 ABP 938 before the expiration of the ’932 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 25: INFRINGEMENT OF U.S. PATENT NO. 11,555,176 UNDER 35 U.S.C. § 271(e)

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

270. United States Patent No. 11,555,176 (“the ’176 patent”) (Exhibit 25 hereto), was duly and legally issued on January 17, 2023.

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

272. The ’176 patent has not yet expired.

273. The ’176 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

274. The submission of Amgen’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 ABP 938 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).

275. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 20 of the ’176 patent.

276. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

277. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

278. The submission of Amgen'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 ABP 938 before the expiration of the '176 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 26: INFRINGEMENT OF U.S. PATENT NO. 11,559,564 UNDER 35 U.S.C. § 271(e)

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

280. United States Patent No. 11,559,564 ("the '564 patent") (Exhibit 26 hereto), was duly and legally issued on January 24, 2023.

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

282. The '564 patent has not yet expired.

283. The '564 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

284. The submission of Amgen'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 ABP 938 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).

285. For example, the sale of ABP 938 pursuant to the label proposed in Amgen's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '564 patent.

286. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

287. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

288. The submission of Amgen'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 ABP 938 before the expiration of the '564 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 27: INFRINGEMENT OF U.S. PATENT NO. 11,680,930 UNDER 35 U.S.C. § 271(e)

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

290. United States Patent No. 11,680,930 ("the '930 patent") (Exhibit 27 hereto), was duly and legally issued on June 20, 2023.

291. Regeneron is the owner of all right, title, and interest in the '930 patent.

292. The '930 patent has not yet expired.

293. The '930 patent claims methods used in making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

294. The submission of Amgen'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 ABP 938 before the expiration of the '930 patent is an act of infringement of one or more claims of the '930 patent under 35 U.S.C. § 271(e)(2)(C)(i).

295. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '930 patent.

296. Regeneron will be irreparably harmed if Amgen is not enjoined from infringing one or more claims of the '930 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen from any further infringement. Regeneron has no adequate remedy at law.

297. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 before the expiration of the '930 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

298. The submission of Amgen'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 ABP 938 before the expiration of the '930 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 28: INFRINGEMENT OF U.S. PATENT NO. 11,707,506 UNDER 35 U.S.C. § 271(e)

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

300. United States Patent No. 11,707,506 ("the '506 patent") (Exhibit 28 hereto), was duly and legally issued on July 25, 2023.

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

302. The '506 patent has not yet expired.

303. The '506 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

304. The submission of Amgen'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 ABP 938 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).

305. For example, the sale of ABP 938 pursuant to the label proposed in Amgen's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '506 patent.

306. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

307. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

308. The submission of Amgen'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 ABP 938 before the expiration of the '506 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 29: INFRINGEMENT OF U.S. PATENT NO. 11,753,459 UNDER 35 U.S.C. § 271(e)

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

310. United States Patent No. 11,753,459 ("the '459 patent") (Exhibit 29 hereto), was duly and legally issued on September 12, 2023.

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

312. The '459 patent has not yet expired.

313. The '459 patent claims biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

314. The submission of Amgen'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 ABP 938 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).

315. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 1 of the '459 patent.

316. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

317. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

318. The submission of Amgen'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 ABP 938 before the expiration of the '459 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 30: INFRINGEMENT OF U.S. PATENT NO. 11,769,597 UNDER 35 U.S.C. § 271(e)

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

320. United States Patent No. 11,769,597 ("the '597 patent") (Exhibit 30 hereto), was duly and legally issued on September 26, 2023.

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

322. The '597 patent has not yet expired.

323. The '597 patent claims methods of treatment using biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

324. The submission of Amgen'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 ABP 938 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).

325. For example, the sale of ABP 938 pursuant to the label proposed in Amgen's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '597 patent.

326. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

327. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

328. The submission of Amgen'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 ABP 938 before the expiration of the '597 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 31: INFRINGEMENT OF U.S. PATENT NO. 11,788,102 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. 11,788,102 ("the '102 patent") (Exhibit 31 hereto), was duly and legally issued on October 17, 2023.

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

332. The '102 patent has not yet expired.

333. The ’102 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

334. The submission of Amgen’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 ABP 938 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).

335. For example, on information and belief, the manufacture, use, offer for sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*, claim 21 of the ’102 patent.

336. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

337. Amgen’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

338. The submission of Amgen’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 ABP 938 before the expiration of the ’102 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 32: INFRINGEMENT OF U.S. PATENT NO. 11,793,926 UNDER 35 U.S.C. § 271(e)

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

340. United States Patent No. 11,793,926 (“the ’926 patent”) (Exhibit 32 hereto), was duly and legally issued on October 24, 2023.

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

342. The '926 patent has not yet expired.

343. The '926 patent claims packaging for biological products and was included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C. § 262(*l*)(3)(A).

344. The submission of Amgen'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 ABP 938 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).

345. For example, on information and belief, the manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 will infringe, *inter alia*, claim 11 of the '926 patent.

346. Regeneron will be irreparably harmed if Amgen 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 Amgen from any further infringement. Regeneron has no adequate remedy at law.

347. Amgen's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of ABP 938 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).

348. The submission of Amgen'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 ABP 938 before the expiration of the '926 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

PRAYER FOR RELIEF

WHEREFORE, Regeneron requests the following relief:

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

(c) Preliminary equitable relief, pursuant to 35 U.S.C. § 271(e)(4)(B), including but not limited to a preliminary injunction that enjoins Amgen, 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 Amgen, 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 Amgen'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.

Respectfully submitted,

Dated: January 10, 2024

BIENERT KATZMAN LITTRELL WILLIAMS LLP

/s/ Anthony R. Bisconti
Anthony R. Bisconti

WILLIAMS & CONNOLLY LLP
David I. Berl
Ellen E. Oberwetter (*pro hac vice* forthcoming)
Thomas S. Fletcher
Andrew V. Trask (*pro hac vice* forthcoming)
Teagan J. Gregory (*pro hac vice* forthcoming)
Shaun P. Mahaffy (*pro hac vice* forthcoming)
Kathryn S. Kayali (*pro hac vice* forthcoming)
Arthur J. Argall III (*pro hac vice* forthcoming)
Adam Pan (*pro hac vice* forthcoming)
Rebecca A. Carter (*pro hac vice* forthcoming)
Haylee N. Bernal Anderson (*pro hac vice* forthcoming)
Renee M. Griffin (*pro hac vice* forthcoming)
Jennalee Beazley* (*pro hac vice* forthcoming)

KELLOGG, HANSEN, TODD, FIGEL & FREDERICK, P.L.L.C.
Andrew E. Goldsmith (*pro hac vice* forthcoming)
Jacob E. Hartman (*pro hac vice* forthcoming)

WEIL GOTSHAL & MANGES LLP
Elizabeth S. Weiswasser (*pro hac vice* forthcoming)
Anish R. Desai (*pro hac vice* forthcoming)
Natalie C. Kennedy (*pro hac vice* forthcoming)
Tom Yu (*pro hac vice* forthcoming)
Yi Zhang (*pro hac vice* forthcoming)
Kathryn Leicht (*pro hac vice* forthcoming)
Rocco Recce (*pro hac vice* forthcoming)
Zhen Lin (*pro hac vice* forthcoming)
Kellie Van Beck (*pro hac vice* forthcoming)

WEIL GOTSHAL & MANGES LLP
Christopher M. Pepe (*pro hac vice* forthcoming)
Priyata Y. Patel (*pro hac vice* forthcoming)
Matthew Sieger (*pro hac vice* forthcoming)

Attorneys for Regeneron Pharmaceuticals, Inc