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18 *Counsel's information continued on page i*

19 IN THE UNITED STATES DISTRICT COURT
20 FOR THE CENTRAL DISTRICT OF CALIFORNIA

22 REGENERON PHARMACEUTICALS,
INC., a New York corporation,

23 Plaintiff,

24 v.

26 AMGEN INC., a Delaware corporation,

27 Defendant.
28

Case No.

COMPLAINT

COMPLAINT

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

3 **INTRODUCTION**

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

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

22 3. EYLEA[®] has been administered millions of times to treat
23 certain ophthalmic disorders that, if left untreated, can lead to permanent blindness.
24 Its active ingredient is a genetically engineered fusion protein called aflibercept. It
25 works by blocking the overproduction of a naturally occurring protein in the eye
26 that can cause the formation of new blood vessels, leading to vision loss. Based on
27 extensive clinical testing by Regeneron, FDA approved EYLEA[®] in 2011 to treat
28 an ophthalmic disorder called neovascular (wet) age-related macular degeneration

1 (“wAMD”) and in 2014 to treat diabetic macular edema (“DME”). As a result of
2 Regeneron’s additional clinical testing, EYLEA® is now also approved for use in
3 treating other serious disorders of the eye: macular edema following retinal vein
4 occlusion and diabetic retinopathy. Most recently, FDA granted approval for
5 EYLEA® to treat retinopathy of prematurity in preterm infants, which is the leading
6 cause of childhood blindness worldwide. In addition to benefitting the many
7 patients it has been used to treat, EYLEA® is also a critical source of research and
8 development funding for Regeneron to develop other life-transforming medicines.

9 4. On October 31, 2023, Amgen publicly announced that the FDA
10 accepted its abbreviated Biologics Drug Application (“aBLA”) for ABP 938, a
11 biosimilar copy of EYLEA®. Enacted in 2010 as part of the Affordable Care Act,
12 the BPCIA provides for an abbreviated regulatory approval pathway for biosimilars
13 by letting applicants rely on the extensive clinical testing previously conducted, at
14 great expense, by the innovator company that developed the medicine the applicant
15 wants to copy. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1 (2017).

16 5. Amgen’s submission of its aBLA constitutes an act of patent
17 infringement under 35 U.S.C. § 271(e). Pursuant to 42 U.S.C. § 262(k)(7)(A),
18 Amgen’s aBLA may be approved as soon as EYLEA®’s regulatory exclusivity
19 expires on May 18, 2024. Regeneron files this action to obtain relief before Amgen
20 launches ABP 938 in the United States.

21 **PLAINTIFF**

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

	Patent	Issue Date	First Named Inventor
1			
2	9,222,106	December 29, 2015	Gang Chen
3	9,254,338	February 9, 2016	George D. Yancopoulos
4	9,315,281	April 19, 2016	Tikiri Jean Dissanayake
5	9,816,110	November 14, 2017	Ying Shen
6	10,130,681	November 20, 2018	George D. Yancopoulos
7	10,415,055	September 17, 2019	Gang Chen
8	10,464,992	November 5, 2019	Eric Furfine
9	10,669,594	June 2, 2020	Serge Monpoeho
10	10,828,345	November 10, 2020	George D. Yancopoulos
11	10,888,601	January 12, 2021	George D. Yancopoulos
12	10,905,786	February 2, 2021	Philip Shodder
13	10,918,754	February 16, 2021	Philip Shodder
14	11,066,458	July 20, 2021	Eric Furfine
15	11,084,865	August 10, 2021	Eric Furfine
16	11,104,715	August 31, 2021	Shawn Lawrence
17	11,160,918	November 2, 2021	Andrew Cook
18	11,253,572	February 22, 2022	George D. Yancopoulos
19	11,306,135	April 19, 2022	Shunhai Wang
20	11,459,374	October 4, 2022	Andrew Tustian
21	11,472,861	October 18, 2022	Shawn Lawrence
22	11,505,593	November 22, 2022	Shunhai Wang
23	11,535,663	December 27, 2022	Shawn Lawrence
24	11,542,317	January 3, 2023	Shunhai Wang
25	11,548,932	January 10, 2023	Shunhai Wang
26	11,555,176	January 17, 2023	Wei Xue
27	11,559,564	January 24, 2023	George D. Yancopoulos
28			

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

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

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

7 **JURISDICTION AND VENUE**

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

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

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

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

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

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

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

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

13 **FACTUAL ALLEGATIONS**

14 19. The BPCIA provides a mechanism to obtain FDA approval for
15 a biological product that is “biosimilar” to a previously licensed “reference
16 product” such as EYLEA®. 42 U.S.C. § 262(k). In order to be approved,
17 biosimilars must be “highly similar to the reference product notwithstanding minor
18 differences in clinically inactive components,” with “no clinically meaningful
19 differences between the biological product and the reference product in terms of
20 the safety, purity, and potency of the product.” *Id.* § 262(i)(2)(A)-(B).

21 20. The BPCIA reduces substantially the time and expense
22 otherwise required to gain FDA approval, by allowing a biosimilar applicant like
23 Amgen to rely on most of the prior clinical testing that Regeneron conducted to
24 establish the safety and efficacy of the reference product (EYLEA®). Regeneron,
25 the reference product sponsor, invested many years of effort into its design and
26 development of EYLEA® and received patents rewarding this research. In
27 exchange for this accelerated and far less expensive application process, the BPCIA
28 obligates a biosimilar applicant to address a reference product sponsor's relevant

1 patents in a manner that permits adjudication of patent rights before
2 commercialization of the biosimilar product. The BPCIA does so, *inter alia*,
3 through a set of pre-litigation exchanges or steps outlined in 42 U.S.C. § 262(l)
4 (herein referred to as the “patent dance”).

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

14 22. 42 U.S.C. § 262(l)(9)(A) provides that, “[i]f a subsection (k)
15 applicant provides the application and information required under paragraph
16 (2)(A), neither the reference product sponsor nor the subsection (k) applicant may,
17 prior to the date notice is received under paragraph (8)(A), bring any action under
18 section 2201 of title 28 for a declaration of infringement, validity, or enforceability
19 of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).”
20 Regeneron later notified Amgen that its Production was deficient in several ways
21 that frustrated Regeneron’s review, and requested that Amgen produce specified
22 information.

23 23. Despite Amgen’s numerous deficiencies, Regeneron timely
24 served on Amgen “a list of patents for which the reference product sponsor believes
25 a claim of patent infringement could reasonably be asserted by the reference
26 product sponsor” (“3A List”) under § 262(l)(3)(A). Each of the Asserted Patents
27 identified below was included on Regeneron’s 3A List.

28

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

9 25. In response to Amgen’s purported 3(B) Statement, Regeneron
10 timely provided a detailed statement that described, with respect to each patent
11 described in Amgen’s purported 3(B) Statement, on a claim by claim basis, the
12 factual and legal basis for Regeneron’s opinion that such patent will be infringed
13 by the commercial marketing of ABP 938 and a response to Amgen’s purported
14 3(B) Statement concerning invalidity (“3(C) Contentions”). 42 U.S.C. §
15 262(l)(3)(C).

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

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

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

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

7 **CLAIMS FOR RELIEF**

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

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

12 30. United States Patent No. 9,222,106 (“the ’106 patent”) (Exhibit 1
13 hereto), was duly and legally issued on December 29, 2015.

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

15 32. The ’106 patent has not yet expired.

16 33. The ’106 patent claims methods of making biological products and was
17 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.
18 § 262(l)(3)(A).

19 34. The submission of Amgen’s aBLA to obtain FDA approval to engage in
20 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
21 States, of ABP 938 before the expiration of the ’106 patent is an act of infringement
22 of one or more claims of the ’106 patent under 35 U.S.C. § 271(e)(2)(C)(i).

23 35. For example, on information and belief, the manufacture, use, offer for
24 sale, and/or sale, or import into the United States, of ABP 938 will infringe, *inter alia*,
25 claim 20 of the ’106 patent.

26 36. Regeneron will be irreparably harmed if Amgen is not enjoined from
27 infringing one or more claims of the ’106 patent. Regeneron is entitled to injunctive

1 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
2 from any further infringement. Regeneron has no adequate remedy at law.

3 37. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
4 the United States, or importation into the United States, of ABP 938 before the
5 expiration of the ’106 patent will cause Regeneron injury, entitling Regeneron to
6 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

7 38. The submission of Amgen’s aBLA to obtain FDA approval to engage in
8 the commercial manufacture, use, offer for sale, and/or sale within the United States,
9 or importation into the United States, of ABP 938 before the expiration of the ’106
10 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

15 40. United States Patent No. 9,254,338 (“the ’338 patent”) (Exhibit 2
16 hereto), was duly and legally issued on February 9, 2016.

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

18 42. The ’338 patent has not yet expired.

19 43. The ’338 patent claims methods of treatment using biological products
20 and was included on the list of patents provided by Regeneron to Amgen pursuant to
21 42 U.S.C. § 262(l)(3)(A).

22 44. The submission of Amgen’s aBLA to obtain FDA approval to engage in
23 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
24 States, of ABP 938 before the expiration of the ’338 patent is an act of infringement
25 of one or more claims of the ’338 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

1 46. Regeneron will be irreparably harmed if Amgen is not enjoined from
2 infringing one or more claims of the '338 patent. Regeneron is entitled to injunctive
3 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
4 from any further infringement. Regeneron has no adequate remedy at law.

5 47. Amgen's commercial manufacture, use, offer for sale, and/or sale within
6 the United States, or importation into the United States, of ABP 938 before the
7 expiration of the '338 patent will cause Regeneron injury, entitling Regeneron to
8 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

9 48. The submission of Amgen's aBLA to obtain FDA approval to engage in
10 the commercial manufacture, use, offer for sale, and/or sale within the United States,
11 or importation into the United States, of ABP 938 before the expiration of the '338
12 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

20 52. The '281 patent has not yet expired.

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

24 54. The submission of Amgen's aBLA to obtain FDA approval to engage in
25 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
26 States, of ABP 938 before the expiration of the '281 patent is an act of infringement
27 of one or more claims of the '281 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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1 States, of ABP 938 before the expiration of the '110 patent is an act of infringement
2 of one or more claims of the '110 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

10 67. Amgen's commercial manufacture, use, offer for sale, and/or sale within
11 the United States, or importation into the United States, of ABP 938 before the
12 expiration of the '110 patent will cause Regeneron injury, entitling Regeneron to
13 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

14 68. The submission of Amgen's aBLA to obtain FDA approval to engage in
15 the commercial manufacture, use, offer for sale, and/or sale within the United States,
16 or importation into the United States, of ABP 938 before the expiration of the '110
17 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

25 72. The '681 patent has not yet expired.

26 73. The '681 patent claims methods of treatment using biological products
27 and was included on the list of patents provided by Regeneron to Amgen pursuant to
28 42 U.S.C. § 262(l)(3)(A).

1 74. The submission of Amgen's aBLA to obtain FDA approval to engage in
2 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
3 States, of ABP 938 before the expiration of the '681 patent is an act of infringement
4 of one or more claims of the '681 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

12 77. Amgen's commercial manufacture, use, offer for sale, and/or sale within
13 the United States, or importation into the United States, of ABP 938 before the
14 expiration of the '681 patent will cause Regeneron injury, entitling Regeneron to
15 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

16 78. The submission of Amgen's aBLA to obtain FDA approval to engage in
17 the commercial manufacture, use, offer for sale, and/or sale within the United States,
18 or importation into the United States, of ABP 938 before the expiration of the '681
19 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

27 82. The '055 patent has not yet expired.

28

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

4 84. The submission of Amgen's aBLA to obtain FDA approval to engage in
5 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
6 States, of ABP 938 before the expiration of the '055 patent is an act of infringement
7 of one or more claims of the '055 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

15 87. Amgen's commercial manufacture, use, offer for sale, and/or sale within
16 the United States, or importation into the United States, of ABP 938 before the
17 expiration of the '055 patent will cause Regeneron injury, entitling Regeneron to
18 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

19 88. The submission of Amgen's aBLA to obtain FDA approval to engage in
20 the commercial manufacture, use, offer for sale, and/or sale within the United States,
21 or importation into the United States, of ABP 938 before the expiration of the '055
22 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

27 90. United States Patent No. 10,464,992 ("the '992 patent") (Exhibit 7
28 hereto), was duly and legally issued on November 5, 2019.

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

2 92. The '992 patent has not yet expired.

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

5 94. The submission of Amgen's aBLA to obtain FDA approval to engage in
6 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
7 States, of ABP 938 before the expiration of the '992 patent is an act of infringement
8 of one or more claims of the '992 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

12 96. Regeneron will be irreparably harmed if Amgen is not enjoined from
13 infringing one or more claims of the '992 patent. Regeneron is entitled to injunctive
14 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
15 from any further infringement. Regeneron has no adequate remedy at law.

16 97. Amgen's commercial manufacture, use, offer for sale, and/or sale within
17 the United States, or importation into the United States, of ABP 938 before the
18 expiration of the '992 patent will cause Regeneron injury, entitling Regeneron to
19 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

20 98. The submission of Amgen's aBLA to obtain FDA approval to engage in
21 the commercial manufacture, use, offer for sale, and/or sale within the United States,
22 or importation into the United States, of ABP 938 before the expiration of the '992
23 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

4 102. The ’594 patent has not yet expired.

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

8 104. The submission of Amgen’s aBLA to obtain FDA approval to engage in
9 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
10 States, of ABP 938 before the expiration of the ’594 patent is an act of infringement
11 of one or more claims of the ’594 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

19 107. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
20 the United States, or importation into the United States, of ABP 938 before the
21 expiration of the ’594 patent will cause Regeneron injury, entitling Regeneron to
22 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

23 108. The submission of Amgen’s aBLA to obtain FDA approval to engage in
24 the commercial manufacture, use, offer for sale, and/or sale within the United States,
25 or importation into the United States, of ABP 938 before the expiration of the ’594
26 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

5 110. United States Patent No. 10,828,345 (“the ’345 patent”) (Exhibit 9
 6 hereto), was duly and legally issued on November 10, 2020.

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

8 112. The ’345 patent has not yet expired.

9 113. The ’345 patent claims methods of treatment using biological products
 10 and was included on the list of patents provided by Regeneron to Amgen pursuant to
 11 42 U.S.C. § 262(*I*)(3)(A).

12 114. The submission of Amgen’s aBLA to obtain FDA approval to engage in
 13 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
 14 States, of ABP 938 before the expiration of the ’345 patent is an act of infringement
 15 of one or more claims of the ’345 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

23 117. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
 24 the United States, or importation into the United States, of ABP 938 before the
 25 expiration of the ’345 patent will cause Regeneron injury, entitling Regeneron to
 26 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

27 118. The submission of Amgen’s aBLA to obtain FDA approval to engage in
 28 the commercial manufacture, use, offer for sale, and/or sale within the United States,

1 or importation into the United States, of ABP 938 before the expiration of the '345
2 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

10 122. The '601 patent has not yet expired.

11 123. The '601 patent claims methods of treatment using biological products
12 and was included on the list of patents provided by Regeneron to Amgen pursuant to
13 42 U.S.C. § 262(l)(3)(A).

14 124. The submission of Amgen’s aBLA to obtain FDA approval to engage in
15 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
16 States, of ABP 938 before the expiration of the '601 patent is an act of infringement
17 of one or more claims of the '601 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

25 127. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
26 the United States, or importation into the United States, of ABP 938 before the
27 expiration of the '601 patent will cause Regeneron injury, entitling Regeneron to
28 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

1 128. The submission of Amgen’s aBLA to obtain FDA approval to engage in
2 the commercial manufacture, use, offer for sale, and/or sale within the United States,
3 or importation into the United States, of ABP 938 before the expiration of the ’601
4 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

12 132. The ’786 patent has not yet expired.

13 133. The ’786 patent claims methods of making biological products and was
14 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.
15 § 262(l)(3)(A).

16 134. The submission of Amgen’s aBLA to obtain FDA approval to engage in
17 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
18 States, of ABP 938 before the expiration of the ’786 patent is an act of infringement
19 of one or more claims of the ’786 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

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

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

3 138. The submission of Amgen's aBLA to obtain FDA approval to engage in
4 the commercial manufacture, use, offer for sale, and/or sale within the United States,
5 or importation into the United States, of ABP 938 before the expiration of the '786
6 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

7 **COUNT 12: INFRINGEMENT OF U.S. PATENT NO. 10,918,754 UNDER 35**
8 **U.S.C. § 271(e)**

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

11 140. United States Patent No. 10,918,754 ("the '754 patent") (Exhibit 12
12 hereto), was duly and legally issued on February 16, 2021.

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

14 142. The '754 patent has not yet expired.

15 143. The '754 patent claims methods of making biological products and was
16 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.
17 § 262(l)(3)(A).

18 144. The submission of Amgen's aBLA to obtain FDA approval to engage in
19 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
20 States, of ABP 938 before the expiration of the '754 patent is an act of infringement
21 of one or more claims of the '754 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

1 147. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
2 the United States, or importation into the United States, of ABP 938 before the
3 expiration of the ’754 patent will cause Regeneron injury, entitling Regeneron to
4 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

5 148. The submission of Amgen’s aBLA to obtain FDA approval to engage in
6 the commercial manufacture, use, offer for sale, and/or sale within the United States,
7 or importation into the United States, of ABP 938 before the expiration of the ’754
8 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

16 152. The ’458 patent has not yet expired.

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

19 154. The submission of Amgen’s aBLA to obtain FDA approval to engage in
20 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
21 States, of ABP 938 before the expiration of the ’458 patent is an act of infringement
22 of one or more claims of the ’458 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

26 156. Regeneron will be irreparably harmed if Amgen is not enjoined from
27 infringing one or more claims of the ’458 patent. Regeneron is entitled to injunctive
28

1 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
2 from any further infringement. Regeneron has no adequate remedy at law.

3 157. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
4 the United States, or importation into the United States, of ABP 938 before the
5 expiration of the ’458 patent will cause Regeneron injury, entitling Regeneron to
6 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

7 158. The submission of Amgen’s aBLA to obtain FDA approval to engage in
8 the commercial manufacture, use, offer for sale, and/or sale within the United States,
9 or importation into the United States, of ABP 938 before the expiration of the ’458
10 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

15 160. United States Patent No. 11,084,865 (“the ’865 patent”) (Exhibit 14
16 hereto), was duly and legally issued on August 10, 2021.

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

18 162. The ’865 patent has not yet expired.

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

21 164. The submission of Amgen’s aBLA to obtain FDA approval to engage in
22 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
23 States, of ABP 938 before the expiration of the ’865 patent is an act of infringement
24 of one or more claims of the ’865 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

28

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

5 167. Amgen's commercial manufacture, use, offer for sale, and/or sale within
6 the United States, or importation into the United States, of ABP 938 before the
7 expiration of the '865 patent will cause Regeneron injury, entitling Regeneron to
8 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

9 168. The submission of Amgen's aBLA to obtain FDA approval to engage in
10 the commercial manufacture, use, offer for sale, and/or sale within the United States,
11 or importation into the United States, of ABP 938 before the expiration of the '865
12 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

20 172. The '715 patent has not yet expired.

21 173. The '715 patent claims methods of making biological products and was
22 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.
23 § 262(l)(3)(A).

24 174. The submission of Amgen's aBLA to obtain FDA approval to engage in
25 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
26 States, of ABP 938 before the expiration of the '715 patent is an act of infringement
27 of one or more claims of the '715 patent under 35 U.S.C. § 271(e)(2)(C)(i).

28

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

3 176. Regeneron will be irreparably harmed if Amgen is not enjoined from
4 infringing one or more claims of the '715 patent. Regeneron is entitled to injunctive
5 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
6 from any further infringement. Regeneron has no adequate remedy at law.

7 177. Amgen's commercial manufacture, use, offer for sale, and/or sale within
8 the United States, or importation into the United States, of ABP 938 before the
9 expiration of the '715 patent will cause Regeneron injury, entitling Regeneron to
10 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

11 178. The submission of Amgen's aBLA to obtain FDA approval to engage in
12 the commercial manufacture, use, offer for sale, and/or sale within the United States,
13 or importation into the United States, of ABP 938 before the expiration of the '715
14 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

22 182. The '918 patent has not yet expired.

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

25 184. The submission of Amgen's aBLA to obtain FDA approval to engage in
26 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
27 States, of ABP 938 before the expiration of the '918 patent is an act of infringement
28 of one or more claims of the '918 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

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

12 188. The submission of Amgen's aBLA to obtain FDA approval to engage in
13 the commercial manufacture, use, offer for sale, and/or sale within the United States,
14 or importation into the United States, of ABP 938 before the expiration of the '918
15 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

23 192. The '572 patent has not yet expired.

24 193. The '572 patent claims methods of treatment using biological products
25 and was included on the list of patents provided by Regeneron to Amgen pursuant to
26 42 U.S.C. § 262(l)(3)(A).

27 194. The submission of Amgen's aBLA to obtain FDA approval to engage in
28 the commercial manufacture, use, offer for sale, and/or sale, or import into the United

1 States, of ABP 938 before the expiration of the '572 patent is an act of infringement
2 of one or more claims of the '572 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

10 197. Amgen's commercial manufacture, use, offer for sale, and/or sale within
11 the United States, or importation into the United States, of ABP 938 before the
12 expiration of the '572 patent will cause Regeneron injury, entitling Regeneron to
13 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

14 198. The submission of Amgen's aBLA to obtain FDA approval to engage in
15 the commercial manufacture, use, offer for sale, and/or sale within the United States,
16 or importation into the United States, of ABP 938 before the expiration of the '572
17 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

25 202. The '135 patent has not yet expired.

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

28

1 204. The submission of Amgen's aBLA to obtain FDA approval to engage in
2 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
3 States, of ABP 938 before the expiration of the '135 patent is an act of infringement
4 of one or more claims of the '135 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

7 206. Regeneron will be irreparably harmed if Amgen is not enjoined from
8 infringing one or more claims of the '135 patent. Regeneron is entitled to injunctive
9 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
10 from any further infringement. Regeneron has no adequate remedy at law.

11 207. Amgen's commercial manufacture, use, offer for sale, and/or sale within
12 the United States, or importation into the United States, of ABP 938 before the
13 expiration of the '135 patent will cause Regeneron injury, entitling Regeneron to
14 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

15 208. The submission of Amgen's aBLA to obtain FDA approval to engage in
16 the commercial manufacture, use, offer for sale, and/or sale within the United States,
17 or importation into the United States, of ABP 938 before the expiration of the '135
18 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

26 212. The '374 patent has not yet expired.
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1 213. The '374 patent claims methods of making biological products and was
2 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.
3 § 262(l)(3)(A).

4 214. The submission of Amgen's aBLA to obtain FDA approval to engage in
5 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
6 States, of ABP 938 before the expiration of the '374 patent is an act of infringement
7 of one or more claims of the '374 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

11 216. Regeneron will be irreparably harmed if Amgen is not enjoined from
12 infringing one or more claims of the '374 patent. Regeneron is entitled to injunctive
13 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
14 from any further infringement. Regeneron has no adequate remedy at law.

15 217. Amgen's commercial manufacture, use, offer for sale, and/or sale within
16 the United States, or importation into the United States, of ABP 938 before the
17 expiration of the '374 patent will cause Regeneron injury, entitling Regeneron to
18 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

19 218. The submission of Amgen's aBLA to obtain FDA approval to engage in
20 the commercial manufacture, use, offer for sale, and/or sale within the United States,
21 or importation into the United States, of ABP 938 before the expiration of the '374
22 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

23 **COUNT 20: INFRINGEMENT OF U.S. PATENT NO. 11,472,861 UNDER 35**
24 **U.S.C. § 271(e)**

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

27 220. United States Patent No. 11,472,861 ("the '861 patent") (Exhibit 20
28 hereto), was duly and legally issued on October 18, 2022.

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

2 222. The '861 patent has not yet expired.

3 223. The '861 patent claims methods of making biological products and was
4 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.
5 § 262(l)(3)(A).

6 224. The submission of Amgen's aBLA to obtain FDA approval to engage in
7 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
8 States, of ABP 938 before the expiration of the '861 patent is an act of infringement
9 of one or more claims of the '861 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

12 226. Regeneron will be irreparably harmed if Amgen is not enjoined from
13 infringing one or more claims of the '861 patent. Regeneron is entitled to injunctive
14 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
15 from any further infringement. Regeneron has no adequate remedy at law.

16 227. Amgen's commercial manufacture, use, offer for sale, and/or sale within
17 the United States, or importation into the United States, of ABP 938 before the
18 expiration of the '861 patent will cause Regeneron injury, entitling Regeneron to
19 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

20 228. The submission of Amgen's aBLA to obtain FDA approval to engage in
21 the commercial manufacture, use, offer for sale, and/or sale within the United States,
22 or importation into the United States, of ABP 938 before the expiration of the '861
23 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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1 230. United States Patent No. 11,505,593 (“the ’593 patent”) (Exhibit 21
2 hereto), was duly and legally issued on November 22, 2022.

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

4 232. The ’593 patent has not yet expired.

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

7 234. The submission of Amgen’s aBLA to obtain FDA approval to engage in
8 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
9 States, of ABP 938 before the expiration of the ’593 patent is an act of infringement
10 of one or more claims of the ’593 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

17 237. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
18 the United States, or importation into the United States, of ABP 938 before the
19 expiration of the ’593 patent will cause Regeneron injury, entitling Regeneron to
20 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

21 238. The submission of Amgen’s aBLA to obtain FDA approval to engage in
22 the commercial manufacture, use, offer for sale, and/or sale within the United States,
23 or importation into the United States, of ABP 938 before the expiration of the ’593
24 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

5 240. United States Patent No. 11,535,663 (“the ’663 patent”) (Exhibit 22
6 hereto), was duly and legally issued on December 27, 2022.

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

8 242. The ’663 patent has not yet expired.

9 243. The ’663 patent claims methods of making biological products and was
10 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.
11 § 262(l)(3)(A).

12 244. The submission of Amgen’s aBLA to obtain FDA approval to engage in
13 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
14 States, of ABP 938 before the expiration of the ’663 patent is an act of infringement
15 of one or more claims of the ’663 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

18 246. Regeneron will be irreparably harmed if Amgen is not enjoined from
19 infringing one or more claims of the ’663 patent. Regeneron is entitled to injunctive
20 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
21 from any further infringement. Regeneron has no adequate remedy at law.

22 247. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
23 the United States, or importation into the United States, of ABP 938 before the
24 expiration of the ’663 patent will cause Regeneron injury, entitling Regeneron to
25 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

26 248. The submission of Amgen’s aBLA to obtain FDA approval to engage in
27 the commercial manufacture, use, offer for sale, and/or sale within the United States,
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1 or importation into the United States, of ABP 938 before the expiration of the '663
2 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

10 252. The '317 patent has not yet expired.

11 253. The '317 patent claims biological products and methods of treatment
12 using biological products and was included on the list of patents provided by
13 Regeneron to Amgen pursuant to 42 U.S.C. § 262(D)(3)(A).

14 254. The submission of Amgen’s aBLA to obtain FDA approval to engage in
15 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
16 States, of ABP 938 before the expiration of the '317 patent is an act of infringement
17 of one or more claims of the '317 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

20 256. Regeneron will be irreparably harmed if Amgen is not enjoined from
21 infringing one or more claims of the '317 patent. Regeneron is entitled to injunctive
22 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
23 from any further infringement. Regeneron has no adequate remedy at law.

24 257. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
25 the United States, or importation into the United States, of ABP 938 before the
26 expiration of the '317 patent will cause Regeneron injury, entitling Regeneron to
27 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

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1 258. The submission of Amgen’s aBLA to obtain FDA approval to engage in
2 the commercial manufacture, use, offer for sale, and/or sale within the United States,
3 or importation into the United States, of ABP 938 before the expiration of the ’317
4 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

12 262. The ’932 patent has not yet expired.

13 263. The ’932 patent claims methods of making biological products and was
14 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.
15 § 262(l)(3)(A).

16 264. The submission of Amgen’s aBLA to obtain FDA approval to engage in
17 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
18 States, of ABP 938 before the expiration of the ’932 patent is an act of infringement
19 of one or more claims of the ’932 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

22 266. Regeneron will be irreparably harmed if Amgen is not enjoined from
23 infringing one or more claims of the ’932 patent. Regeneron is entitled to injunctive
24 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
25 from any further infringement. Regeneron has no adequate remedy at law.

26 267. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
27 the United States, or importation into the United States, of ABP 938 before the
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1 expiration of the '932 patent will cause Regeneron injury, entitling Regeneron to
2 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

3 268. The submission of Amgen's aBLA to obtain FDA approval to engage in
4 the commercial manufacture, use, offer for sale, and/or sale within the United States,
5 or importation into the United States, of ABP 938 before the expiration of the '932
6 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

14 272. The '176 patent has not yet expired.

15 273. The '176 patent claims methods of making biological products and was
16 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.
17 § 262(l)(3)(A).

18 274. The submission of Amgen's aBLA to obtain FDA approval to engage in
19 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
20 States, of ABP 938 before the expiration of the '176 patent is an act of infringement
21 of one or more claims of the '176 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

1 277. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
2 the United States, or importation into the United States, of ABP 938 before the
3 expiration of the ’176 patent will cause Regeneron injury, entitling Regeneron to
4 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

5 278. The submission of Amgen’s aBLA to obtain FDA approval to engage in
6 the commercial manufacture, use, offer for sale, and/or sale within the United States,
7 or importation into the United States, of ABP 938 before the expiration of the ’176
8 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

13 280. United States Patent No. 11,559,564 (“the ’564 patent”) (Exhibit 26
14 hereto), was duly and legally issued on January 24, 2023.

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

16 282. The ’564 patent has not yet expired.

17 283. The ’564 patent claims methods of treatment using biological products
18 and was included on the list of patents provided by Regeneron to Amgen pursuant to
19 42 U.S.C. § 262(l)(3)(A).

20 284. The submission of Amgen’s aBLA to obtain FDA approval to engage in
21 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
22 States, of ABP 938 before the expiration of the ’564 patent is an act of infringement
23 of one or more claims of the ’564 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

27 286. Regeneron will be irreparably harmed if Amgen is not enjoined from
28 infringing one or more claims of the ’564 patent. Regeneron is entitled to injunctive

1 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
2 from any further infringement. Regeneron has no adequate remedy at law.

3 287. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
4 the United States, or importation into the United States, of ABP 938 before the
5 expiration of the ’564 patent will cause Regeneron injury, entitling Regeneron to
6 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

7 288. The submission of Amgen’s aBLA to obtain FDA approval to engage in
8 the commercial manufacture, use, offer for sale, and/or sale within the United States,
9 or importation into the United States, of ABP 938 before the expiration of the ’564
10 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

15 290. United States Patent No. 11,680,930 (“the ’930 patent”) (Exhibit 27
16 hereto), was duly and legally issued on June 20, 2023.

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

18 292. The ’930 patent has not yet expired.

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

22 294. The submission of Amgen’s aBLA to obtain FDA approval to engage in
23 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
24 States, of ABP 938 before the expiration of the ’930 patent is an act of infringement
25 of one or more claims of the ’930 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

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

9 298. The submission of Amgen's aBLA to obtain FDA approval to engage in
10 the commercial manufacture, use, offer for sale, and/or sale within the United States,
11 or importation into the United States, of ABP 938 before the expiration of the '930
12 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

20 302. The '506 patent has not yet expired.

21 303. The '506 patent claims methods of treatment using biological products
22 and was included on the list of patents provided by Regeneron to Amgen pursuant to
23 42 U.S.C. § 262(l)(3)(A).

24 304. The submission of Amgen's aBLA to obtain FDA approval to engage in
25 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
26 States, of ABP 938 before the expiration of the '506 patent is an act of infringement
27 of one or more claims of the '506 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

4 306. Regeneron will be irreparably harmed if Amgen is not enjoined from
5 infringing one or more claims of the '506 patent. Regeneron is entitled to injunctive
6 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
7 from any further infringement. Regeneron has no adequate remedy at law.

8 307. Amgen's commercial manufacture, use, offer for sale, and/or sale within
9 the United States, or importation into the United States, of ABP 938 before the
10 expiration of the '506 patent will cause Regeneron injury, entitling Regeneron to
11 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

12 308. The submission of Amgen's aBLA to obtain FDA approval to engage in
13 the commercial manufacture, use, offer for sale, and/or sale within the United States,
14 or importation into the United States, of ABP 938 before the expiration of the '506
15 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

23 312. The '459 patent has not yet expired.

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

26 314. The submission of Amgen's aBLA to obtain FDA approval to engage in
27 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
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1 States, of ABP 938 before the expiration of the '459 patent is an act of infringement
2 of one or more claims of the '459 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

10 317. Amgen's commercial manufacture, use, offer for sale, and/or sale within
11 the United States, or importation into the United States, of ABP 938 before the
12 expiration of the '459 patent will cause Regeneron injury, entitling Regeneron to
13 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

14 318. The submission of Amgen's aBLA to obtain FDA approval to engage in
15 the commercial manufacture, use, offer for sale, and/or sale within the United States,
16 or importation into the United States, of ABP 938 before the expiration of the '459
17 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

25 322. The '597 patent has not yet expired.

26 323. The '597 patent claims methods of treatment using biological products
27 and was included on the list of patents provided by Regeneron to Amgen pursuant to
28 42 U.S.C. § 262(l)(3)(A).

1 324. The submission of Amgen’s aBLA to obtain FDA approval to engage in
2 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
3 States, of ABP 938 before the expiration of the ’597 patent is an act of infringement
4 of one or more claims of the ’597 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

12 327. Amgen’s commercial manufacture, use, offer for sale, and/or sale within
13 the United States, or importation into the United States, of ABP 938 before the
14 expiration of the ’597 patent will cause Regeneron injury, entitling Regeneron to
15 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

16 328. The submission of Amgen’s aBLA to obtain FDA approval to engage in
17 the commercial manufacture, use, offer for sale, and/or sale within the United States,
18 or importation into the United States, of ABP 938 before the expiration of the ’597
19 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

20 **COUNT 31: INFRINGEMENT OF U.S. PATENT NO. 11,788,102 UNDER 35**
21 **U.S.C. § 271(e)**

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

24 330. United States Patent No. 11,788,102 (“the ’102 patent”) (Exhibit 31
25 hereto), was duly and legally issued on October 17, 2023.

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

27 332. The ’102 patent has not yet expired.

28

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

4 334. The submission of Amgen's aBLA to obtain FDA approval to engage in
5 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
6 States, of ABP 938 before the expiration of the '102 patent is an act of infringement
7 of one or more claims of the '102 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

11 336. Regeneron will be irreparably harmed if Amgen is not enjoined from
12 infringing one or more claims of the '102 patent. Regeneron is entitled to injunctive
13 relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Amgen
14 from any further infringement. Regeneron has no adequate remedy at law.

15 337. Amgen's commercial manufacture, use, offer for sale, and/or sale within
16 the United States, or importation into the United States, of ABP 938 before the
17 expiration of the '102 patent will cause Regeneron injury, entitling Regeneron to
18 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

19 338. The submission of Amgen's aBLA to obtain FDA approval to engage in
20 the commercial manufacture, use, offer for sale, and/or sale within the United States,
21 or importation into the United States, of ABP 938 before the expiration of the '102
22 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

23 **COUNT 32: INFRINGEMENT OF U.S. PATENT NO. 11,793,926**

24 **UNDER 35 U.S.C. § 271(e)**

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

27 340. United States Patent No. 11,793,926 ("the '926 patent") (Exhibit 32
28 hereto), was duly and legally issued on October 24, 2023.

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

2 342. The '926 patent has not yet expired.

3 343. The '926 patent claims packaging for biological products and was
4 included on the list of patents provided by Regeneron to Amgen pursuant to 42 U.S.C.
5 § 262(l)(3)(A).

6 344. The submission of Amgen's aBLA to obtain FDA approval to engage in
7 the commercial manufacture, use, offer for sale, and/or sale, or import into the United
8 States, of ABP 938 before the expiration of the '926 patent is an act of infringement
9 of one or more claims of the '926 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

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

17 347. Amgen's commercial manufacture, use, offer for sale, and/or sale within
18 the United States, or importation into the United States, of ABP 938 before the
19 expiration of the '926 patent will cause Regeneron injury, entitling Regeneron to
20 damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

21 348. The submission of Amgen's aBLA to obtain FDA approval to engage in
22 the commercial manufacture, use, offer for sale, and/or sale within the United States,
23 or importation into the United States, of ABP 938 before the expiration of the '926
24 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

25 **PRAYER FOR RELIEF**

26 WHEREFORE, Regeneron requests the following relief:

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

28

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

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

19 (d) Statutory relief under 35 U.S.C. § 271(e)(4)(D), including but not
20 limited to a permanent injunction prohibiting Amgen, its officers, partners, agents,
21 servants, employees, parents, subsidiaries, affiliate corporations, other related
22 business entities, and all other persons acting in concert, participation, or in privity
23 with them and/or their successors or assigns from infringing the patents in suit, or
24 contributing to the same, or actively inducing anyone to do the same, by acts including
25 the manufacture, use, offer to sell, sale, distribution, or importation of any current or
26 future versions of a product that infringes, or the use or manufacturing of which
27 infringes, the patents in suit;
28

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

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

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

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

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

9 (j) Such further relief as this court may deem just and proper.
10

11
12 Respectfully submitted,

13
14 Dated: January 10, 2024

**BIENERT KATZMAN
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/s/ Anthony R. Bisconti

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