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

REGENERON PHARMACEUTICALS, INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Case No.: **1:22-CV-61 (Kleeh)**

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") invented, developed, and sells Eylea®, the market-leading treatment for certain serious eye diseases. Defendant Mylan Pharmaceuticals Inc. ("Mylan") is seeking FDA approval under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. §§ 262(k)-(*l*), to commercialize "M710," a proposed biosimilar of Eylea®. To vindicate its patent rights, Regeneron brings this Complaint seeking a judgment of patent infringement against Mylan under 35 U.S.C. § 271(e) and pursuant to the BPCIA.

NATURE OF THE CASE

1. Regeneron is a leading science-based American biotechnology company dedicated to improving human health and tackling the most urgent medical issues facing the Nation. Founded and led for over 30 years by physician-scientists, Regeneron has developed life-transforming medicines for people with serious diseases, including cancer, atopic dermatitis, asthma, eye diseases, cardiovascular and metabolic diseases, Ebola, and COVID-19, the latter of which has been used across the country, including by the former President. Regeneron's cutting-edge scientific advances were supported, in large part, by its ophthalmic product, Eylea®, which

FDA approved in 2011.

2. Eylea® has been administered millions of times to treat certain ophthalmic disorders that, if left untreated, can lead to permanent blindness. Its active ingredient is a genetically engineered fusion protein called aflibercept. It works by blocking the overproduction of a naturally occurring protein in the eye that can cause the formation of new blood vessels, leading to vision loss. Based on extensive clinical testing by Regeneron, FDA approved Eylea® in 2011 to treat an ophthalmic disorder called neovascular age-related macular degeneration. As a result of Regeneron's additional clinical testing, Eylea® is now also approved for use in treating other serious disorders of the eye: diabetic macular edema, macular edema following retinal vein occlusion, and diabetic retinopathy. And other clinical trials are ongoing, including to treat a retinal disease in premature babies called retinopathy of prematurity. 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.

3. Last October, Mylan filed for FDA approval under the BPCIA to commercialize a "biosimilar" copy of Eylea®. Enacted in 2010 as part of the Affordable Care Act, the BPCIA provides for a substantially 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.*, 137 S. Ct. 1664 (2017).

4. On December 28, 2021, FDA notified Mylan that its application—i.e., its abbreviated Biologic License Application, or "aBLA" No. 761274—for M710 had been accepted for review. Mylan's submission of its aBLA constitutes an act of patent infringement under 35 U.S.C. § 271(e).

5. By statute, Regeneron could not immediately file a lawsuit for Mylan's § 271(e) infringement. The BPCIA prohibits filing such a suit until certain requirements of 42 U.S.C. § 262(*l*), commonly called the "patent dance," are satisfied. In the patent dance, the BPCIA directs exchanges of certain information between the innovator company (or "reference product sponsor") and the biosimilar (or "subsection (k)") applicant. At the end of the patent dance, the reference product sponsor is authorized to initiate litigation against the biosimilar applicant within thirty days in a venue of its choosing. Mylan, the subsection (k) applicant, and Regeneron, the reference product sponsor, completed the final step of the patent dance—the exchange of lists of patents pursuant to § 262(*l*)(5)—on July 5. Regeneron then promptly brought this action as required by § 262(*l*)(6) to address Mylan's patent infringement under § 271(e).

THE PARTIES, JURISDICTION, AND VENUE

6. Regeneron Pharmaceuticals, Inc. is a corporation organized under the laws of the State of New York, with its principal place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591. The company 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: U.S. Patent Nos. 7,070,959; 9,222,106; 9,254,338; 9,669,069; 9,816,110; 10,130,681; 10,406,226; 10,415,055; 10,464,992; 10,669,594; 10,857,205; 10,888,601; 10,927,342; 10,973,879; 11,053,280; 11,066,458; 11,084,865; 11,104,715; 11,174,283; 11,186,625; 11,253,572; 11,299,532; 11,306,135; and 11,332,771 (collectively, the "asserted patents" or the "patents in suit").

7. On information and belief, Mylan Pharmaceuticals Inc. is a corporation organized under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan

Pharmaceuticals Inc. is a wholly owned subsidiary of Viatris Inc. ("Viatris").

8. On information and belief, Mylan develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state, including West Virginia, either directly or indirectly.

9. Regeneron's claims for patent infringement arise under the patent laws of the United States, Titles 35 and 42 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. Mylan and its development partners have publicly announced their intention to ignore Regeneron's patent rights and launch an aflibercept biosimilar product before the expiration of the patents asserted in this action.

11. On information and belief, Momenta Pharmaceuticals Inc. is or was Mylan's development partner for its proposed aflibercept biosimilar product. In August 2020, Momenta publicly announced that it "believe[d]" its collaboration with Mylan to market an aflibercept biosimilar product "has the potential to launch in the 2023 time frame,"[1] before the expiry of the asserted patents.

12. Viatris later announced its intention to become the "first to market" an aflibercept biosimilar product. Rajiv Malik, the president of Viatris, explained that becoming "the first to market [an aflibercept biosimilar product] is becoming [sic] decisive advantage. And that's where we're going to focus on that how can we be the first to market."[2]

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[1] Momenta Pharmaceuticals Inc., Form 10-Q, at 26 (Aug. 10, 2020), https://seekingalpha.com/filings/pdf/14323380.

[2] Goldman Sachs 42nd Annual Global Healthcare Conference, Viatris Inc. Presentation (June 10, 2021), https://seekingalpha.com/article/4434224-viatris-inc-vtrs-management-presents-goldman-sachs-42nd-annual-global-healthcare-conference.

13. This Court has personal jurisdiction over Mylan because it is incorporated in the State of West Virginia; because Mylan is seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of M710 in the United States, including in the State of West Virginia; and because, if its product receives FDA approval, Mylan intends to market, distribute, offer for sale, and/or sell it in the United States, including in the State of West Virginia, deriving substantial revenue therefrom.

14. In addition, Mylan has consented to jurisdiction in the State of West Virginia in one or more prior cases arising out of its manufacture, use, offer for sale, sale, and/or importation of Mylan pharmaceutical products in the United States, including in the State of West Virginia.

15. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and § 1400(b). Venue is proper because Mylan Pharmaceuticals Inc. is incorporated in the State of West Virginia and resides in this judicial district.

FACTUAL BASIS FOR RELIEF

16. 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).

17. The BPCIA reduces substantially the time and expense otherwise required to gain FDA approval, by allowing a biosimilar applicant like Mylan 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 numerous 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 its patent dance.

18. The patent dance between Regeneron and Mylan proceeded substantially as follows within the timeframes specified in the BPCIA. Mylan informed Regeneron that its aBLA for M710 was accepted for FDA review on December 28, 2021. Mylan provided Regeneron access to Mylan's aBLA through an online review platform. Under § 262(*l*)(3)(A), Regeneron next provided Mylan with a list of patents for which "a claim of patent infringement could reasonably be asserted" if Mylan commercialized its product. Under § 262(*l*)(7), Regeneron also provided to Mylan a "supplement to the list" for several additional patents that issued following Regeneron's service of its original patent list provided under § 262(*l*)(3)(A).

19. Upon receiving Regeneron's patent lists, Mylan served "detailed statements" for the patents on the original or supplemental list. By statute, a biosimilar applicant's detailed statements must either represent that it will not begin commercial marketing of its biosimilar product before the patent expires (under § 262(*l*)(3)(B)(ii)(II)) or allege that the patent is invalid, unenforceable, or not infringed (under § 262(*l*)(3)(B)(ii)(I)). Remarkably, Mylan's "detailed statements" respected not one of Regeneron's patents; rather, according to Mylan, every one of Regeneron's listed patents is not infringed, invalid, and unenforceable.

20. Under § 262(*l*)(3)(C), Regeneron provided its detailed responses to Mylan's contentions, setting forth particular grounds for infringement based on the confidential information in Mylan's aBLA and rebutting Mylan's noninfringement, invalidity and unenforceability allegations. Regeneron did not contend infringement on one of the patents on

its list and informed Mylan it did not plan to assert that patent.

21. Next, under § 262(*l*)(4)(A), Regeneron initiated negotiations over which patents on Regeneron's list should be litigated in a § 271(e) infringement action. Regeneron proposed litigating a targeted subset of the listed patents, in order to facilitate the Court's adjudication of the parties' primary disputes on a full record before approval of Mylan's product. Mylan refused to do so. Instead, it proposed to litigate twenty-five of the listed patents. Next, under § 262(*l*)(5)(B), the parties exchanged the lists of patents that each believed should be part of the infringement action under § 271(e). Mylan listed twenty-five patents, whereas Regeneron listed twelve (each of which was also on Mylan's list).

22. If the parties disagree on the patents that should be part of the litigation, § 262(*l*)(6)(B) requires the innovator company to bring suit on every patent selected by either party. Thus, despite Regeneron's efforts to focus this case on a targeted subset of asserted patents, Mylan's expansive listing of patents requires Regeneron by statute to include each one of those patents in this Complaint. Regeneron therefore brings this action for infringement of twenty-four patents,[3] while remaining amenable to approaches for streamlining this proceeding in conformity with the BPCIA's goal of adjudicating patent disputes before approval or commercialization of the proposed biosimilar product.[4]

[3] The twenty-four patents include each of Mylan's listed patents minus the one patent for which Regeneron did not serve contentions and no longer asserts against Mylan.

[4] The infringement allegations in this Complaint do not reference any specific content of Mylan's aBLA, which Mylan has designated as confidential under an agreement pursuant to 42 U.S.C. § 262(*l*)(1)(A). To be clear, Regeneron has already served upon Mylan hundreds of pages of detailed contentions setting forth and putting Mylan on notice of the factual and legal basis for the allegations made in this lawsuit.

FIRST CAUSE OF ACTION
(INFRINGEMENT OF THE '959 PATENT)

23. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

24. United States Patent No. 7,070,959 (the "'959 patent") (Exhibit 1 hereto), was duly and legally issued on July 4, 2006.

25. Regeneron is the owner of all right, title, and interest in the '959 patent.

26. The '959 patent has not yet expired.

27. The '959 patent claims a method of producing aflibercept and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

28. The submission of Mylan'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 M710 before the expiration of the '959 patent is an act of infringement of one or more claims of the '959 patent under 35 U.S.C. § 271(e)(2)(C)(i).

29. For example, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 11 of the '959 patent.

30. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '959 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

31. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '959 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief

under 35 U.S.C. § 271(e)(4)(C).

32. The submission of Mylan'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 M710 before the expiration of the '959 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

SECOND CAUSE OF ACTION
(INFRINGEMENT OF THE '106 PATENT)

33. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

34. United States Patent No. 9,222,106 (the "'106 patent") (Exhibit 2 hereto), was duly and legally issued on December 29, 2015.

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

36. The '106 patent has not yet expired.

37. The '106 patent claims methods of making biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

38. The submission of Mylan'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 M710 before the expiration of the '106 patent is an act of infringement of one or more claims of the '106 patent under 35 U.S.C. § 271(e)(2)(C)(i).

39. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 20 of the '106 patent.

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

41. Mylan’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the ’106 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

42. The submission of Mylan’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 M710 before the expiration of the ’106 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

THIRD CAUSE OF ACTION
(INFRINGEMENT OF THE ’338 PATENT)

43. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

44. United States Patent No. 9,254,338 (the “’338 patent”) (Exhibit 3 hereto), was duly and legally issued on February 9, 2016.

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

46. The ’338 patent has not yet expired.

47. The ’338 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

48. The submission of Mylan’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

M710 before the expiration of the ’338 patent is an act of infringement of one or more claims of the ’338 patent under 35 U.S.C. § 271(e)(2)(C)(i).

49. For example, the sale of M710 pursuant to the label proposed in Mylan’s aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the ’338 patent.

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

51. Mylan’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the ’338 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

52. The submission of Mylan’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 M710 before the expiration of the ’338 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

FOURTH CAUSE OF ACTION
(INFRINGEMENT OF THE ’069 PATENT)

53. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

54. United States Patent No. 9,669,069 (the “’069 patent”) (Exhibit 4 hereto), was duly and legally issued on June 6, 2017.

55. Regeneron is the owner of all right, title, and interest in the ’069 patent.

56. The ’069 patent has not yet expired.

57. The ’069 patent claims uses of a biological product and was included on the list of

patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

58. The submission of Mylan'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 M710 before the expiration of the '069 patent is an act of infringement of one or more claims of the '069 patent under 35 U.S.C. § 271(e)(2)(C)(i).

59. For example, the sale of M710 pursuant to the label proposed in Mylan's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '069 patent.

60. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '069 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

61. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '069 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

62. The submission of Mylan'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 M710 before the expiration of the '069 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

FIFTH CAUSE OF ACTION
(INFRINGEMENT OF THE '110 PATENT)

63. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

64. United States Patent No. 9,816,110 (the "'110 patent") (Exhibit 5 hereto), was duly and legally issued on November 14, 2017.

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

66. The '110 patent has not yet expired.

67. The '110 patent claims methods related to manufacturing a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

68. The submission of Mylan'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 M710 before the expiration of the '110 patent is an act of infringement of one or more claims of the '110 patent under 35 U.S.C. § 271(e)(2)(C)(i).

69. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 18 of the '110 patent.

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

71. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '110 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

72. The submission of Mylan'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 M710 before the expiration of the '110 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

SIXTH CAUSE OF ACTION
(INFRINGEMENT OF THE '681 PATENT)

73. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

74. United States Patent No. 10,130,681 (the "'681 patent") (Exhibit 6 hereto), was duly and legally issued on November 20, 2018.

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

76. The '681 patent has not yet expired.

77. The '681 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

78. The submission of Mylan'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 M710 before the expiration of the '681 patent is an act of infringement of one or more claims of the '681 patent under 35 U.S.C. § 271(e)(2)(C)(i).

79. For example, the sale of M710 pursuant to the label proposed in Mylan's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '681 patent.

80. Regeneron will be irreparably harmed if Mylan 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 Mylan from any further infringement.

Regeneron has no adequate remedy at law.

81. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '681 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

82. The submission of Mylan'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 M710 before the expiration of the '681 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

SEVENTH CAUSE OF ACTION
(INFRINGEMENT OF THE '226 PATENT)

83. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

84. United States Patent No. 10,406,226 (the "'226 patent") (Exhibit 7 hereto), was duly and legally issued on September 10, 2019.

85. Regeneron is the owner of all right, title, and interest in the '226 patent.

86. The '226 patent has not yet expired.

87. The '226 patent claims methods of manufacturing biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

88. The submission of Mylan'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 M710 before the expiration of the '226 patent is an act of infringement of one or more claims of the '226 patent under 35 U.S.C. § 271(e)(2)(C)(i).

89. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 3 of the ’226 patent.

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

91. Mylan’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the ’226 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

92. The submission of Mylan’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 M710 before the expiration of the ’226 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

EIGHTH CAUSE OF ACTION
(INFRINGEMENT OF THE ’055 PATENT)

93. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

94. United States Patent No. 10,415,055 (the “’055 patent”) (Exhibit 8 hereto), was duly and legally issued on September 17, 2019.

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

96. The ’055 patent has not yet expired.

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

also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

98. The submission of Mylan'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 M710 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).

99. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 23 of the '055 patent.

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

101. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '055 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

102. The submission of Mylan'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 M710 before the expiration of the '055 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

NINTH CAUSE OF ACTION
(INFRINGEMENT OF THE '992 PATENT)

103. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

104. United States Patent No. 10,464,992 (the "'992 patent") (Exhibit 9 hereto), was duly and legally issued on November 5, 2019.

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

106. The '992 patent has not yet expired.

107. The '992 patent claims biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

108. The submission of Mylan'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 M710 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).

109. For example, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '992 patent.

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

111. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '992 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

112. The submission of Mylan'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 M710 before the expiration of the ’992 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

TENTH CAUSE OF ACTION
(INFRINGEMENT OF THE ’594 PATENT)

113. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

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

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

116. The ’594 patent has not yet expired.

117. The ’594 patent claims methods of detecting biological contaminants and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

118. The submission of Mylan’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 M710 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).

119. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the ’594 patent.

120. Regeneron will be irreparably harmed if Mylan 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 Mylan from any further infringement.

Regeneron has no adequate remedy at law.

121. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '594 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

122. The submission of Mylan'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 M710 before the expiration of the '594 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

ELEVENTH CAUSE OF ACTION
(INFRINGEMENT OF THE '205 PATENT)

123. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

124. United States Patent No. 10,857,205 (the "'205 patent") (Exhibit 11 hereto), was duly and legally issued on December 8, 2020.

125. Regeneron is the owner of all right, title, and interest in the '205 patent.

126. The '205 patent has not yet expired.

127. The '205 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

128. The submission of Mylan'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 M710 before the expiration of the '205 patent is an act of infringement of one or more claims of the '205 patent under 35 U.S.C. § 271(e)(2)(C)(i).

129. For example, the sale of M710 pursuant to the label proposed in Mylan's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '205 patent.

130. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '205 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

131. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '205 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

132. The submission of Mylan'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 M710 before the expiration of the '205 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

TWELFTH CAUSE OF ACTION
(INFRINGEMENT OF THE '601 PATENT)

133. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

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

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

136. The '601 patent has not yet expired.

137. The '601 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C.

§ 262(*l*)(5).

138. The submission of Mylan'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 M710 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).

139. For example, the sale of M710 pursuant to the label proposed in Mylan's aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the '601 patent.

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

141. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '601 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

142. The submission of Mylan'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 M710 before the expiration of the '601 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

THIRTEENTH CAUSE OF ACTION
(INFRINGEMENT OF THE '342 PATENT)

143. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

144. United States Patent No. 10,927,342 (the "'342 patent") (Exhibit 13 hereto), was duly and legally issued on February 23, 2021.

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

146. The ’342 patent has not yet expired.

147. The ’342 patent claims methods of cultivating biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

148. The submission of Mylan’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 M710 before the expiration of the ’342 patent is an act of infringement of one or more claims of the ’342 patent under 35 U.S.C. § 271(e)(2)(C)(i).

149. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the ’342 patent.

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

151. Mylan’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the ’342 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

152. The submission of Mylan’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

M710 before the expiration of the ’342 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

FOURTEENTH CAUSE OF ACTION
(INFRINGEMENT OF THE ’879 PATENT)

153. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

154. United States Patent No. 10,973,879 (the “’879 patent”) (Exhibit 14 hereto), was duly and legally issued on April 13, 2021.

155. Regeneron is the owner of all right, title, and interest in the ’879 patent.

156. The ’879 patent has not yet expired.

157. The ’879 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

158. The submission of Mylan’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 M710 before the expiration of the ’879 patent is an act of infringement of one or more claims of the ’879 patent under 35 U.S.C. § 271(e)(2)(C)(i).

159. For example, the sale of M710 while the reference product is approved for the uses patented in the ’879 patent will contribute to and induce infringement of, *inter alia*, claim 1 of the ’879 patent.

160. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the ’879 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

161. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '879 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

162. The submission of Mylan'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 M710 before the expiration of the '879 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

FIFTEENTH CAUSE OF ACTION
(INFRINGEMENT OF THE '280 PATENT)

163. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

164. United States Patent No. 11,053,280 (the "'280 patent") (Exhibit 15 hereto), was duly and legally issued on July 6, 2021.

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

166. The '280 patent has not yet expired.

167. The '280 patent claims methods of producing biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

168. The submission of Mylan'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 M710 before the expiration of the '280 patent is an act of infringement of one or more claims of the '280 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the ’280 patent.

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

171. Mylan’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the ’280 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

172. The submission of Mylan’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 M710 before the expiration of the ’280 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

SIXTEENTH CAUSE OF ACTION
(INFRINGEMENT OF THE ’458 PATENT)

173. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

174. United States Patent No. 11,066,458 (the “’458 patent”) (Exhibit 16 hereto), was duly and legally issued on July 20, 2021.

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

176. The ’458 patent has not yet expired.

177. The ’458 patent claims biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C.

§ 262(*l*)(5).

178. The submission of Mylan'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 M710 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).

179. For example, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '458 patent.

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

181. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '458 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

182. The submission of Mylan'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 M710 before the expiration of the '458 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

SEVENTEENTH CAUSE OF ACTION
(INFRINGEMENT OF THE '865 PATENT)

183. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

184. United States Patent No. 11,084,865 (the "'865 patent") (Exhibit 17 hereto), was duly and legally issued on August 10, 2021.

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

186. The ’865 patent has not yet expired.

187. The ’865 patent claims biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

188. The submission of Mylan’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 M710 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).

189. For example, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the ’865 patent.

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

191. Mylan’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the ’865 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

192. The submission of Mylan’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 M710 before the expiration of the ’865 patent entitles Regeneron to fees under 35 U.S.C.

§ 271(e)(4) and § 285.

EIGHTEENTH CAUSE OF ACTION
(INFRINGEMENT OF THE '715 PATENT)

193. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

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

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

196. The '715 patent has not yet expired.

197. The '715 patent claims methods of producing biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

198. The submission of Mylan'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 M710 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).

199. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '715 patent.

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

201. Mylan's commercial manufacture, use, offer for sale, and/or sale within the

United States, or importation into the United States, of M710 before the expiration of the '715 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

202. The submission of Mylan'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 M710 before the expiration of the '715 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

NINETEENTH CAUSE OF ACTION
(INFRINGEMENT OF THE '283 PATENT)

203. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

204. United States Patent No. 11,174,283 (the "'283 patent") (Exhibit 19 hereto), was duly and legally issued on November 16, 2021.

205. Regeneron is the owner of all right, title, and interest in the '283 patent.

206. The '283 patent has not yet expired.

207. The '283 patent claims methods of producing biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

208. The submission of Mylan'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 M710 before the expiration of the '283 patent is an act of infringement of one or more claims of the '283 patent under 35 U.S.C. § 271(e)(2)(C)(i).

209. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '283

patent.

210. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the ’283 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

211. Mylan’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the ’283 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

212. The submission of Mylan’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 M710 before the expiration of the ’283 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

TWENTIETH CAUSE OF ACTION
(INFRINGEMENT OF THE ’625 PATENT)

213. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

214. United States Patent No. 11,186,625 (the “’625 patent”) (Exhibit 20 hereto), was duly and legally issued on November 30, 2021.

215. Regeneron is the owner of all right, title, and interest in the ’625 patent.

216. The ’625 patent has not yet expired.

217. The ’625 patent claims biological products and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

218. The submission of Mylan'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 M710 before the expiration of the '625 patent is an act of infringement of one or more claims of the '625 patent under 35 U.S.C. § 271(e)(2)(C)(i).

219. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 and/or M710 drug substance will infringe, *inter alia*, claim 1 of the '625 patent.

220. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '625 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

221. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '625 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

222. The submission of Mylan'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 M710 before the expiration of the '625 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

TWENTY-FIRST CAUSE OF ACTION
(INFRINGEMENT OF THE '572 PATENT)

223. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

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

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

226. The ’572 patent has not yet expired.

227. The ’572 patent claims uses of a biological product and was included on the list of patents provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(3)(A). The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

228. The submission of Mylan’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 M710 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).

229. For example, the sale of M710 pursuant to the label proposed in Mylan’s aBLA will contribute to and induce infringement of, *inter alia*, claim 1 of the ’572 patent.

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

231. Mylan’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the ’572 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

232. The submission of Mylan’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 M710 before the expiration of the ’572 patent entitles Regeneron to fees under 35 U.S.C.

§ 271(e)(4) and § 285.

TWENTY-SECOND CAUSE OF ACTION
(INFRINGEMENT OF THE '532 PATENT)

233. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

234. United States Patent No. 11,299,532 (the "'532 patent") (Exhibit 22 hereto), was duly and legally issued on April 12, 2022.

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

236. The '532 patent has not yet expired.

237. The '532 patent claims methods of manufacturing biological products and was included in a supplemental notice provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(7) on May 5, 2022. The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

238. The submission of Mylan'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 M710 before the expiration of the '532 patent is an act of infringement of one or more claims of the '532 patent under 35 U.S.C. § 271(e)(2)(C)(i).

239. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '532 patent.

240. Regeneron will be irreparably harmed if Mylan is not enjoined from infringing one or more claims of the '532 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Mylan from any further infringement. Regeneron has no adequate remedy at law.

241. Mylan's commercial manufacture, use, offer for sale, and/or sale within the

United States, or importation into the United States, of M710 before the expiration of the ’532 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

242. The submission of Mylan’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 M710 before the expiration of the ’532 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

TWENTY-THIRD CAUSE OF ACTION
(INFRINGEMENT OF THE ’135 PATENT)

243. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

244. United States Patent No. 11,306,135 (the “’135 patent”) (Exhibit 23 hereto), was duly and legally issued on April 19, 2022.

245. Regeneron is the owner of all right, title, and interest in the ’135 patent.

246. The ’135 patent has not yet expired.

247. The ’135 patent claims biological products and was included in a supplemental notice provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(7) on May 5, 2022. The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

248. The submission of Mylan’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 M710 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).

249. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the ’135

patent.

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

251. Mylan’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the ’135 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

252. The submission of Mylan’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 M710 before the expiration of the ’135 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

TWENTY-FOURTH CAUSE OF ACTION
(INFRINGEMENT OF THE ’771 PATENT)

253. Regeneron incorporates paragraphs 1-22 as if fully set forth herein.

254. United States Patent No. 11,332,771 (the “’771 patent”) (Exhibit 24 hereto), was duly and legally issued on May 17, 2022.

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

256. The ’771 patent has not yet expired.

257. The ’771 patent claims methods of producing biological products and was included in a supplemental notice provided by Regeneron to Mylan pursuant to 42 U.S.C. § 262(*l*)(7) on June 16, 2022. The patent also was included on the lists of patents exchanged by Regeneron and Mylan pursuant to 42 U.S.C. § 262(*l*)(5).

258. The submission of Mylan'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 M710 before the expiration of the '771 patent is an act of infringement of one or more claims of the '771 patent under 35 U.S.C. § 271(e)(2)(C)(i).

259. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of M710 will infringe, *inter alia*, claim 1 of the '771 patent.

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

261. Mylan's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of M710 before the expiration of the '771 patent will cause Regeneron injury, entitling Regeneron to damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

262. The submission of Mylan'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 M710 before the expiration of the '771 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 Mylan has infringed the patents in suit;

(b) Statutory relief under 35 U.S.C. § 271(e)(4)(D), including but not limited to a permanent injunction prohibiting Mylan, 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) 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;

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

(e) An award for an accounting of damages from Mylan's infringement;

(f) Preliminary and/or permanent equitable relief, including pursuant to 35 U.S.C. § 271(e)(4)(B), including but not limited to a preliminary and permanent injunction that enjoins Mylan, 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;

(g) 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);

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

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

Date: August 2, 2022

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