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Dec 27 2023
U.S. DISTRICT COURT
Northern District of WV

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

REGENERON PHARMACEUTICALS, INC. Plaintiff, v. SAMSUNG BIOEPIS CO., LTD., Defendant.	CASE NO.: **1:23-CV-106 (Kleeh)** JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Plaintiff"), invented, developed, and sells EYLEA®, the market-leading treatment for several serious eye diseases. Defendant Samsung Bioepis Co., Ltd. ("Bioepis" or "Defendant") is seeking [redacted]

NATURE OF THE CASE

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

2. EYLEA® has been administered millions of times to treat certain ophthalmic disorders that, if left untreated, can lead to permanent blindness. Its active ingredient is a genetically engineered fusion protein called aflibercept. It works by blocking the overproduction of a naturally occurring protein in the eye that can cause the formation of new blood vessels, leading to vision loss. Based on extensive clinical testing by Regeneron, FDA approved EYLEA® in 2011 to treat an ophthalmic disorder called neovascular (wet) age-related macular degeneration ("wAMD") and in 2014 to treat diabetic macular edema ("DME"). As a result of Regeneron's additional clinical testing, EYLEA® is now also approved for use in treating other serious disorders

[1] As explained in its forthcoming memorandum in support of its motion to seal, Regeneron is bound by the provisions of 42 U.S.C. § 262(*l*)(1), which dictate that Bioepis determine, "in its sole discretion," what information constitutes Bioepis confidential information, that no such "confidential information shall be included in any publicly-available complaint or other pleading," and any violation of paragraph 1 could result in "irreparable harm for which there is no adequate legal remedy" and for which "the court shall consider immediate injunctive relief to be an appropriate and necessary remedy." Therefore, Regeneron initiates this case by filing a public version of this Complaint with redactions to any information that Bioepis has represented is Bioepis confidential information.

of the eye: macular edema following retinal vein occlusion and diabetic retinopathy. Most recently, FDA granted approval for EYLEA® to treat retinopathy of prematurity in preterm infants, which is the leading cause of childhood blindness worldwide. In addition to benefitting the many patients it has been used to treat, EYLEA® is also a critical source of research and development funding for Regeneron to develop other life-transforming medicines.

3. [redacted] Enacted in 2010 as part of the Affordable Care Act, the BPCIA provides for an abbreviated regulatory approval pathway for biosimilars by letting applicants rely on the extensive clinical testing previously conducted, at great expense, by the innovator company that developed the medicine the applicant wants to copy. *See Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1 (2017).

4. [redacted]

5. [redacted] This action is brought in addition to a related pending action before this Court. *See Regeneron Pharmaceuticals, Inc. v.*

Samsung Bioepis, Co., Ltd., No. 23-CV-00094-TSK (N.D.W. Va.).

THE PARTIES, JURISDICTION, AND VENUE

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

Patent	First Named Inventor
9,222,106	Gang Chen
9,254,338	George D. Yancopoulos
9,315,281	Tikiri Jean Dissanayake
9,562,238	Gang Chen
9,816,110	Ying Shen
10,130,681	George D. Yancopoulos
10,415,055	Gang Chen
10,464,992	Eric Furfine
10,669,594	Serge Monpoeho
10,828,345	George D. Yancopoulos
10,888,601	George D. Yancopoulos
10,905,786	Philip Stephen Shodder
10,918,754	Philip Stephen Shodder
10,927,342	Amy S. Johnson
11,053,280	Andrew Tustian
11,066,458	Eric Furfine
11,084,865	Eric Furfine
11,104,715	Shawn Lawrence
11,174,283	Andrew Tustian
11,253,572	George D. Yancopoulos
11,299,532	Andrew Tustian
11,306,135	Shunhai Wang
11,312,936	Amy S. Johnson
11,332,771	Shadia Abike Oshodi
11,472,861	Shawn Lawrence
11,485,770	Shunhai Wang
11,535,663	Shawn Lawrence
11,542,317	Shunhai Wang

11,548,932	Shunhai Wang
11,555,176	Wei Xue
11,559,564	George D. Yancopoulos
11,707,506	George D. Yancopoulos
11,732,024	Eric Furfine
11,753,459	Shunhai Wang
11,769,597	Lorah Perlee
11,788,102	Ying Shen
10,182,969*	Rachel Paige Arnott
11,103,552†	Kenneth S. Graham
11,160,918*	Andrew Cook
11,433,186*	Sibgat Ulla
11,439,758*	Trevor Langley
11,459,374*	Andrew Tustian
11,478,588*	Bryan Grygus
11,505,593*	Shunhai Wang
11,577,025*	Daniel B. Dix
11,793,926*	Andrew Cook
USD 858,754*	Bryan Grygus
USD 906,102*	Andrew Cook
USD 934,069*	Andrew Cook
USD 961,376*	Andrew Cook
USD 961,377*	Andrew Cook

7. On information and belief, Bioepis is a company organized and existing under the laws of the Republic of Korea with its principal place of business located at 76, Songdogyoyuk-ro, Yeonsu-gu, Incheon, Republic of Korea. Bioepis is a biopharmaceutical company that specializes in research and development of biosimilars and biopharmaceuticals.

8. On information and belief, Bioepis, directly or indirectly, manufactures its drug products abroad. On information and belief, Bioepis directly, or via its subsidiaries, affiliates, or other agents, develops, distributes, or sells within the United States or imports into the United States Bioepis's drug products, including SB15, under the general direction and control of Bioepis. Non-limiting examples are provided below.

9. Bioepis is the holder of aBLA No. 761054 for RENFLEXIS, an approved biosimilar of Remicade. On information and belief, Bioepis manufactures and imports

RENFLEXIS, directly or indirectly, into the United States. For example, between April 2, 2020 and October 22, 2023, Bioepis imported 72 shipments of RENFLEXIS into the United States. As another example, between August 17, 2019 and October 25, 2023, Samsung Biologics Co. Ltd. ("Samsung Biologics")—the corporate parent of Bioepis—imported 57 shipments of RENFLEXIS into the United States.

10. [redacted] On information and belief, between August 29, 2021 and March 28, 2023, Bioepis imported or directed one or more of its subsidiaries, affiliates, or agents to import 17 shipments of SB15 into the United States. Each of these shipments contained product described as "AFLIBERCEPT (INHIBITOR (GROWTH FACTOR))." On information and belief, between July 2, 2019 and June 8, 2023, Samsung Biologics imported or directed one or more of its subsidiaries, affiliates, or agents to import 19 shipments of SB15 into the United States. Each of these shipments contained product described as "AFLIBERCEPT (INHIBITOR (GROWTH FACTOR))."

11. On information and belief, Bioepis and its respective subsidiaries, affiliates, and agents will function as an integrated organization and a single business enterprise in the manufacture of SB15, in the importation of SB15 into the United States, and in the sale or offer for sale of SB15 in the United States.

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

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

14. This Court has personal jurisdiction over Bioepis because [redacted] This conduct is "suit-related," has "substantial connection" with West Virginia, and therefore satisfies the minimum contacts requirement.

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

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

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

FACTUAL BASIS FOR RELIEF

18. 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).

19. The BPCIA reduces substantially the time and expense otherwise required to gain FDA approval, by allowing a biosimilar applicant like Bioepis to rely on most of the prior clinical testing that Regeneron conducted to establish the safety and efficacy of the reference product (EYLEA®). Regeneron, the reference product sponsor, invested many years of effort into its design and development of EYLEA® and received patents rewarding this research. In exchange for this accelerated and far less expensive application process, the BPCIA obligates a biosimilar applicant to address a reference product sponsor's relevant patents in a manner that permits adjudication of patent rights before commercialization of the biosimilar product. The BPCIA does so, *inter alia*, through a set of pre-litigation exchanges or steps outlined in 42 U.S.C. § 262(*l*) (herein referred to as the "patent dance").

20. [redacted]

21. [redacted]

[redacted]

22. [redacted]

23. [redacted]

24. [redacted]

25. [redacted]

[redacted]

26. [redacted]

27. [redacted]

[2] *Genentech, Inc. v. Immunex Rhode Island Corp.*, 964 F.3d 1109, 1111 (Fed. Cir. 2020).

[redacted]

28. [redacted]

29. [redacted]

30. [redacted]

[3] [redacted]

[redacted]

31. [redacted]

32. [redacted]

[4] [redacted]

[redacted]

33. [redacted]

34. [redacted]

CLAIMS FOR RELIEF

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

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

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

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

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[5] [redacted]

[6] [redacted]

38. The ’106 patent has not yet expired.

39. The ’106 patent claims methods of making biological products and [redacted]

40. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

41. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 20 of the ’106 patent.

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

43. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’106 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

44. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’106 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

set forth below.

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

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

48. The '338 patent has not yet expired.

49. The '338 patent claims methods of treatment using biological products and [redacted]

50. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

51. For example, the sale of SB15 [redacted] will contribute to and induce infringement of, *inter alia*, claim 1 of the '338 patent.

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

53. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '338 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

54. [redacted] the

commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’338 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

58. The ’281 patent has not yet expired.

59. The ’281 patent claims, *inter alia*, methods of making biological products and [redacted]

60. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’281 patent is an act of infringement of one or more claims of the ’281 patent under 35 U.S.C. § 271(e)(2)(C)(i).

61. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’281 patent.

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

63. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United

States, or importation into the United States, of SB15 before the expiration of the ’281 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

64. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’281 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 4: INFRINGEMENT OF U.S. PATENT NO. 9,562,238 UNDER 35 U.S.C. § 271(e)

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

66. United States Patent No. 9,562,238 (“the ’238 patent”) (Exhibit 4 hereto), was duly and legally issued on February 7, 2017.

67. Regeneron is the owner of all right, title, and interest in the ’238 patent.

68. The ’238 patent has not yet expired.

69. The ’238 patent claims methods of making biological products and [redacted]

70. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’238 patent is an act of infringement of one or more claims of the ’238 patent under 35 U.S.C. § 271(e)(2)(C)(i).

71. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’238 patent.

72. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing

one or more claims of the ’238 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

73. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’238 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

74. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’238 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 9,816,110 UNDER 35 U.S.C. § 271(e)

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

76. United States Patent No. 9,816,110 (“the ’110 patent”) (Exhibit 5 hereto), was duly and legally issued on November 14, 2017.

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

78. The ’110 patent has not yet expired.

79. The ’110 patent claims methods of making biological products and [redacted]

80. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

81. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 18 of the ’110 patent.

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

83. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’110 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

84. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’110 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 6: INFRINGEMENT OF U.S. PATENT NO. 10,130,681 UNDER 35 U.S.C. § 271(e)

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

86. United States Patent No. 10,130,681 (“the ’681 patent”) (Exhibit 6 hereto), was duly and legally issued on November 20, 2018.

87. Regeneron is the owner of all right, title, and interest in the ’681 patent.

88. The ’681 patent has not yet expired.

89. The ’681 patent claims methods of treatment using biological products and [redacted]

[redacted]

90. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

91. For example, the sale of SB15 [redacted] will contribute to and induce infringement of, *inter alia*, claim 1 of the ’681 patent.

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

93. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’681 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

94. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’681 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 7: INFRINGEMENT OF U.S. PATENT NO. 10,415,055 UNDER 35 U.S.C. § 271(e)

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

96. United States Patent No. 10,415,055 ("the '055 patent") (Exhibit 7 hereto), was duly and legally issued on September 17, 2019.

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

98. The '055 patent has not yet expired.

99. The '055 patent claims methods of making biological products and [redacted]

100. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

101. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 23 of the '055 patent.

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

103. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '055 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

104. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation

into the United States, of SB15 before the expiration of the ’055 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 8: INFRINGEMENT OF U.S. PATENT NO. 10,464,992 UNDER 35 U.S.C. § 271(e)

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

106. United States Patent No. 10,464,992 (“the ’992 patent”) (Exhibit 8 hereto), was duly and legally issued on November 5, 2019.

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

108. The ’992 patent has not yet expired.

109. The ’992 patent claims biological products and [redacted]

110. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

111. For example, manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’992 patent.

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

113. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United

States, or importation into the United States, of SB15 before the expiration of the ’992 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

114. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’992 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 9: INFRINGEMENT OF U.S. PATENT NO. 10,669,594 UNDER 35 U.S.C. § 271(e)

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

116. United States Patent No. 10,669,594 (“the ’594 patent”) (Exhibit 9 hereto), was duly and legally issued on June 2, 2020.

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

118. The ’594 patent has not yet expired.

119. The ’594 patent claims methods of detecting biological contaminants and [redacted]

120. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

121. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’594 patent.

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

123. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’594 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

124. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’594 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

128. The ’345 patent has not yet expired.

129. The ’345 patent claims methods of treatment using biological products and [redacted]

130. [redacted] the

commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’345 patent is an act of infringement of one or more claims of the ’345 patent under 35 U.S.C. § 271(e)(2)(C)(i).

131. For example, the sale of SB15 [redacted] will contribute to and induce infringement of, *inter alia*, claim 1 of the ’345 patent.

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

133. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’345 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

134. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’345 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 11: INFRINGEMENT OF U.S. PATENT NO. 10,888,601 UNDER 35 U.S.C. § 271(e)

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

136. United States Patent No. 10,888,601 (“the ’601 patent”) (Exhibit 11 hereto), was duly and legally issued on January 12, 2021.

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

138. The ’601 patent has not yet expired.

139. The ’601 patent claims methods of treatment using biological products and [redacted]

140. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

141. For example, the sale of SB15 [redacted] will contribute to and induce infringement of, *inter alia*, claim 1 of the ’601 patent.

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

143. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’601 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

144. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’601 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 12: INFRINGEMENT OF U.S. PATENT NO. 10,905,786 UNDER 35 U.S.C. §

271(e)

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

146. United States Patent No. 10,905,786 ("the '786 patent") (Exhibit 12 hereto), was duly and legally issued on February 2, 2021.

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

148. The '786 patent has not yet expired.

149. The '786 patent claims, *inter alia*, methods of making biological products and [redacted]

150. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '786 patent is an act of infringement of one or more claims of the '786 patent under 35 U.S.C. § 271(e)(2)(C)(i).

151. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the '786 patent.

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

153. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '786 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

154. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’786 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 13: INFRINGEMENT OF U.S. PATENT NO. 10,918,754 UNDER 35 U.S.C. § 271(e)

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

156. United States Patent No. 10,918,754 (“the ’754 patent”) (Exhibit 13 hereto), was duly and legally issued on February 16, 2021.

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

158. The ’754 patent has not yet expired.

159. The ’754 patent claims, *inter alia*, methods of making biological products and [redacted]

160. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’754 patent is an act of infringement of one or more claims of the ’754 patent under 35 U.S.C. § 271(e)(2)(C)(i).

161. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’754 patent.

162. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing one or more claims of the ’754 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement.

Regeneron has no adequate remedy at law.

163. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '754 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

164. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '754 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 14: INFRINGEMENT OF U.S. PATENT NO. 10,927,342 UNDER 35 U.S.C. § 271(e)

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

166. United States Patent No. 10,927,342 ("the '342 patent") (Exhibit 14 hereto), was duly and legally issued on February 23, 2021.

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

168. The '342 patent has not yet expired.

169. The '342 patent claims methods of making biological products and [redacted]

170. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

171. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’342 patent.

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

173. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’342 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

174. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’342 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 15: INFRINGEMENT OF U.S. PATENT NO. 11,053,280 UNDER 35 U.S.C. § 271(e)

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

176. United States Patent No. 11,053,280 (“the ’280 patent”) (Exhibit 15 hereto), was duly and legally issued on July 6, 2021.

177. Regeneron is the owner of all right, title, and interest in the ’280 patent.

178. The ’280 patent has not yet expired.

179. The ’280 patent claims methods of making biological products and [redacted]

[redacted]

180. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

181. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 5 of the ’280 patent.

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

183. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’280 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

184. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’280 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 16: INFRINGEMENT OF U.S. PATENT NO. 11,066,458 UNDER 35 U.S.C. § 271(e)

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

186. United States Patent No. 11,066,458 (“the ’458 patent”) (Exhibit 16 hereto), was

duly and legally issued on July 20, 2021.

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

188. The ’458 patent has not yet expired.

189. The ’458 patent claims biological products and [redacted]

190. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

191. For example, manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’458 patent.

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

193. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’458 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

194. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’458 patent entitles Regeneron to fees

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

COUNT 17: INFRINGEMENT OF U.S. PATENT NO. 11,084,865 UNDER 35 U.S.C. § 271(e)

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

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

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

198. The '865 patent has not yet expired.

199. The '865 patent claims biological products and [redacted]

200. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

201. For example, manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 will infringe, *inter alia*, claim 51 of the '865 patent.

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

203. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '865 patent will

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

204. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '865 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 18: INFRINGEMENT OF U.S. PATENT NO. 11,104,715 UNDER 35 U.S.C. § 271(e)

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

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

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

208. The '715 patent has not yet expired.

209. The '715 patent claims methods of making biological products [redacted]

210. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

211. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the '715 patent.

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

213. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’715 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

214. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’715 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 19: INFRINGEMENT OF U.S. PATENT NO. 11,174,283 UNDER 35 U.S.C. § 271(e)

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

216. United States Patent No. 11,174,283 (“the ’283 patent”) (Exhibit 19 hereto), was duly and legally issued on November 16, 2021.

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

218. The ’283 patent has not yet expired.

219. The ’283 patent claims methods of making biological products [redacted]

220. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15

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).

221. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’283 patent.

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

223. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’283 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

224. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’283 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 20: INFRINGEMENT OF U.S. PATENT NO. 11,253,572 UNDER 35 U.S.C. § 271(e)

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

226. United States Patent No. 11,253,572 (“the ’572 patent”) (Exhibit 20 hereto), was duly and legally issued on February 22, 2022.

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

228. The ’572 patent has not yet expired.

229. The ’572 patent claims methods of treatment using biological products and was [redacted]

230. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

231. For example, the sale of SB15 [redacted] will contribute to and induce infringement of, *inter alia*, claim 1 of the ’572 patent.

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

233. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’572 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

234. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’572 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 21: INFRINGEMENT OF U.S. PATENT NO. 11,299,532 UNDER 35 U.S.C. § 271(e)

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

set forth below.

236. United States Patent No. 11,299,532 ("the '532 patent") (Exhibit 21 hereto), was duly and legally issued on April 12, 2022.

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

238. The '532 patent has not yet expired.

239. The '532 patent claims methods of making biological products [redacted]

240. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

241. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 19 of the '532 patent.

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

243. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '532 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

244. [redacted] the

commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’532 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 22: INFRINGEMENT OF U.S. PATENT NO. 11,306,135 UNDER 35 U.S.C. § 271(e)

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

246. United States Patent No. 11,306,135 (“the ’135 patent”) (Exhibit 22 hereto), was duly and legally issued on April 19, 2022.

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

248. The ’135 patent has not yet expired.

249. The ’135 patent claims biological products and [redacted]

250. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

251. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 14 of the ’135 patent.

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

253. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '135 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

254. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '135 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 23: INFRINGEMENT OF U.S. PATENT NO. 11,312,936 UNDER 35 U.S.C. § 271(e)

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

256. United States Patent No. 11,312,936 ("the '936 patent") (Exhibit 23 hereto), was duly and legally issued on April 26, 2022.

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

258. The '936 patent has not yet expired.

259. The '936 patent claims methods of making biological products [redacted]

260. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '936 patent is an act of infringement of one or more claims of the '936 patent under 35 U.S.C. § 271(e)(2)(C)(i).

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

sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’936 patent.

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

263. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’936 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

264. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’936 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 24: INFRINGEMENT OF U.S. PATENT NO. 11,332,771 UNDER 35 U.S.C. § 271(e)

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

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

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

268. The ’771 patent has not yet expired.

269. The ’771 patent claims methods of making biological products [redacted]

270. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 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).

271. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’771 patent.

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

273. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’771 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

274. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’771 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 25: INFRINGEMENT OF U.S. PATENT NO. 11,472,861 UNDER 35 U.S.C. § 271(e)

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

276. United States Patent No. 11,472,861 (“the ’861 patent”) (Exhibit 25 hereto), was duly and legally issued on October 18, 2022.

277. Regeneron is the owner of all right, title, and interest in the ’861 patent.

278. The ’861 patent has not yet expired.

279. The ’861 patent claims methods of making biological products [redacted]

280. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’861 patent is an act of infringement of one or more claims of the ’861 patent under 35 U.S.C. § 271(e)(2)(C)(i).

281. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’861 patent.

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

283. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’861 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

284. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’861 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 26: INFRINGEMENT OF U.S. PATENT NO. 11,485,770 UNDER 35 U.S.C. § 271(e)

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

286. United States Patent No. 11,485,770 ("the '770 patent") (Exhibit 26 hereto), was duly and legally issued on November 1, 2022.

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

288. The '770 patent has not yet expired.

289. The '770 patent claims biological products and [redacted]

290. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '770 patent is an act of infringement of one or more claims of the '770 patent under 35 U.S.C. § 271(e)(2)(C)(i).

291. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the '770 patent.

292. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing one or more claims of the '770 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

293. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '770 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35

U.S.C. § 271(e)(4)(C).

294. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’770 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 27: INFRINGEMENT OF U.S. PATENT NO. 11,535,663 UNDER 35 U.S.C. § 271(e)

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

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

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

298. The ’663 patent has not yet expired.

299. The ’663 patent claims methods of making biological products and [redacted]

300. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’663 patent is an act of infringement of one or more claims of the ’663 patent under 35 U.S.C. § 271(e)(2)(C)(i).

301. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’663 patent.

302. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing one or more claims of the ’663 patent. Regeneron is entitled to injunctive relief at least under 35

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

303. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '663 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

304. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '663 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 28: INFRINGEMENT OF U.S. PATENT NO. 11,542,317 UNDER 35 U.S.C. § 271(e)

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

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

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

308. The '317 patent has not yet expired.

309. The '317 patent claims biological products and methods of treatment using biological products and [redacted]

310. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '317 patent is an act of infringement of one or more claims of the '317

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

311. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’317 patent.

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

313. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’317 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

314. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’317 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 29: INFRINGEMENT OF U.S. PATENT NO. 11,548,932 UNDER 35 U.S.C. § 271(e)

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

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

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

318. The ’932 patent has not yet expired.

319. The ’932 patent claims methods of making biological products and [redacted]

[redacted]

320. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’932 patent is an act of infringement of one or more claims of the ’932 patent under 35 U.S.C. § 271(e)(2)(C)(i).

321. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 22 of the ’932 patent.

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

323. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’932 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

324. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’932 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 30: INFRINGEMENT OF U.S. PATENT NO. 11,555,176 UNDER 35 U.S.C. § 271(e)

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

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

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

328. The '176 patent has not yet expired.

329. The '176 patent claims methods of making biological products and [redacted]

330. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '176 patent is an act of infringement of one or more claims of the '176 patent under 35 U.S.C. § 271(e)(2)(C)(i).

331. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 20 of the '176 patent.

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

333. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '176 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

334. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation

into the United States, of SB15 before the expiration of the ’176 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 31: INFRINGEMENT OF U.S. PATENT NO. 11,559,564 UNDER 35 U.S.C. § 271(e)

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

336. United States Patent No. 11,559,564 (“the ’564 patent”) (Exhibit 31 hereto), was duly and legally issued on January 24, 2023.

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

338. The ’564 patent has not yet expired.

339. The ’564 patent claims methods of treatment using biological products and [redacted]

340. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’564 patent is an act of infringement of one or more claims of the ’564 patent under 35 U.S.C. § 271(e)(2)(C)(i).

341. For example, the sale of SB15 [redacted] will contribute to and induce infringement of, *inter alia*, claim 1 of the ’564 patent.

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

343. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United

States, or importation into the United States, of SB15 before the expiration of the ’564 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

344. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’564 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 32: INFRINGEMENT OF U.S. PATENT NO. 11,707,506 UNDER 35 U.S.C. § 271(e)

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

346. United States Patent No. 11,707,506 (“the ’506 patent”) (Exhibit 32 hereto), was duly and legally issued on July 25, 2023.

347. Regeneron is the owner of all right, title, and interest in the ’506 patent.

348. The ’506 patent has not yet expired.

349. The ’506 patent claims methods of treatment using biological products, [redacted]

350. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’506 patent is an act of infringement of one or more claims of the ’506 patent under 35 U.S.C. § 271(e)(2)(C)(i).

351. For example, the sale of SB15 [redacted]

will contribute to and induce infringement of, *inter alia*, claim 1 of the ’506 patent.

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

353. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’506 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

354. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’506 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 33: INFRINGEMENT OF U.S. PATENT NO. 11,732,024 UNDER 35 U.S.C. § 271(e)

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

356. United States Patent No. 11,732,024 (“the ’024 patent”) (Exhibit 33 hereto), was duly and legally issued on August 22, 2023.

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

358. The ’024 patent has not yet expired.

359. The ’024 patent claims biological products, [redacted]

360. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’024 patent is an act of infringement of one or more claims of the ’024 patent under 35 U.S.C. § 271(e)(2)(C)(i).

361. For example, manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’024 patent.

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

363. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’024 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

364. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’024 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 34: INFRINGEMENT OF U.S. PATENT NO. 11,753,459 UNDER 35 U.S.C. § 271(e)

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

366. United States Patent No. 11,753,459 (“the ’459 patent”) (Exhibit 34 hereto), was duly and legally issued on September 12, 2023.

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

368. The ’459 patent has not yet expired.

369. The ’459 patent claims biological products, [redacted]

370. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’459 patent is an act of infringement of one or more claims of the ’459 patent under 35 U.S.C. § 271(e)(2)(C)(i).

371. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the ’459 patent.

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

373. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’459 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

374. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’459 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

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

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

378. The '597 patent has not yet expired.

379. The '597 patent claims methods of treatment using biological products, [redacted]

380. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '597 patent is an act of infringement of one or more claims of the '597 patent under 35 U.S.C. § 271(e)(2)(C)(i).

381. For example, the sale of SB15 [redacted] will contribute to and induce infringement of, *inter alia*, claim 1 of the '597 patent.

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

383. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '597 patent will

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

384. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the '597 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 36: INFRINGEMENT OF U.S. PATENT NO. 11,788,102 UNDER 35 U.S.C. § 271(e)

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

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

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

388. The '102 patent has not yet expired.

389. The '102 patent claims methods of making biological products, [redacted]

390. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '102 patent is an act of infringement of one or more claims of the '102 patent under 35 U.S.C. § 271(e)(2)(C)(i).

391. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 will infringe, *inter alia*, claim 1 of the '102 patent.

392. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing

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

393. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’102 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

394. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’102 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 37: INFRINGEMENT OF U.S. PATENT NO. 10,182,969* UNDER 35 U.S.C. § 271(e)

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

396. United States Patent No. 10,182,969 (“the ’969 patent”) (Exhibit 37 hereto), was duly and legally issued on January 22, 2019.

397. Regeneron is the owner of all right, title, and interest in the ’969 patent.

398. The ’969 patent has not yet expired.

399. The ’969 patent claims delivery devices for biological products, and it [redacted]

[redacted]

400. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’969 patent is an act of infringement of one or more claims of the ’969 patent under 35 U.S.C. § 271(e)(2)(C)(i).

401. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the ’969 patent.

402. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing one or more claims of the ’969 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

403. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the ’969 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

404. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’969 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 38: INFRINGEMENT OF U.S. PATENT NO. 11,103,552† UNDER 35 U.S.C. § 271(e)

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

406. United States Patent No. 11,103,552 ("the '552 patent") (Exhibit 38 hereto), was duly and legally issued on August, 31, 2021.

407. Regeneron is the owner of all right, title, and interest in the '552 patent.

408. The '552 patent has not yet expired.

409. The '552 patent claims biological products, and it [redacted]

410. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '552 patent is an act of infringement of one or more claims of the '552 patent under 35 U.S.C. § 271(e)(2)(C)(i).

411. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the '552 patent.

412. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing

one or more claims of the ’552 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

413. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the ’552 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

414. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’552 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 39: INFRINGEMENT OF U.S. PATENT NO. 11,160,918* UNDER 35 U.S.C. § 271(e)

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

416. United States Patent No. 11,160,918 (“the ’918 patent”) (Exhibit 39 hereto), was duly and legally issued on November 2, 2021.

417. Regeneron is the owner of all right, title, and interest in the ’918 patent.

418. The ’918 patent has not yet expired.

419. The ’918 patent claims packaging for biological products, and it [redacted]

[redacted]

420. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’918 patent is an act of infringement of one or more claims of the ’918 patent under 35 U.S.C. § 271(e)(2)(C)(i).

421. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the ’918 patent.

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

423. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the ’918 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

424. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’918 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 40: INFRINGEMENT OF U.S. PATENT NO. 11,793,926* UNDER 35 U.S.C. § 271(e)

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

426. United States Patent No. 11,793,926 ("the '926 patent") (Exhibit 40 hereto), was duly and legally issued on October 24, 2023.

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

428. The '926 patent has not yet expired.

429. The '926 patent claims packaging for biological products and methods for sterilizing packaging for biological products, and it [redacted]

430. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '926 patent is an act of infringement of one or more claims of the '926 patent under 35 U.S.C. § 271(e)(2)(C)(i).

431. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 11 of the '926 patent.

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

433. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the ’926 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

434. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’926 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 41: INFRINGEMENT OF U.S. PATENT NO. 11,433,186* UNDER 35 U.S.C. § 271(e)

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

436. United States Patent No. 11,433,186 (“the ’186 patent”) (Exhibit 41 hereto), was duly and legally issued on September 6, 2022.

437. Regeneron is the owner of all right, title, and interest in the ’186 patent.

438. The ’186 patent has not yet expired.

439. The ’186 patent claims delivery devices for biological products, and it [redacted]

[redacted]

440. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’186 patent is an act of infringement of one or more claims of the ’186 patent under 35 U.S.C. § 271(e)(2)(C)(i).

441. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the ’186 patent.

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

443. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the ’186 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

444. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’186 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 42: INFRINGEMENT OF U.S. PATENT NO. 11,439,758* UNDER 35 U.S.C. § 271(e)

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

446. United States Patent No. 11,439,758 ("the '758 patent") (Exhibit 42 hereto), was duly and legally issued on September 13, 2022.

447. Regeneron is the owner of all right, title, and interest in the '758 patent.

448. The '758 patent has not yet expired.

449. The '758 patent claims delivery devices for biological products, and it [redacted]

450. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '758 patent is an act of infringement of one or more claims of the '758 patent under 35 U.S.C. § 271(e)(2)(C)(i).

451. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the '758 patent.

452. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing

one or more claims of the ’758 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

453. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the ’758 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

454. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’758 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

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

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

456. United States Patent No. 11,459,374 (“the ’374 patent”) (Exhibit 43 hereto), was duly and legally issued on October 4, 2022.

457. Regeneron is the owner of all right, title, and interest in the ’374 patent.

458. The ’374 patent has not yet expired.

459. The ’374 patent claims methods of making biological products, and it [redacted]

[redacted]

460. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’374 patent is an act of infringement of one or more claims of the ’374 patent under 35 U.S.C. § 271(e)(2)(C)(i).

461. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 20 of the ’374 patent.

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

463. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the ’374 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

464. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’374 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 44: INFRINGEMENT OF U.S. PATENT NO. 11,478,588* UNDER 35 U.S.C. § 271(e)

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

466. United States Patent No. 11,478,588 ("the '588 patent") (Exhibit 44 hereto), was duly and legally issued on October 25, 2022.

467. Regeneron is the owner of all right, title, and interest in the '588 patent.

468. The '588 patent has not yet expired.

469. The '588 patent claims components of delivery devices of biological products, and it [redacted]

470. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '588 patent is an act of infringement of one or more claims of the '588 patent under 35 U.S.C. § 271(e)(2)(C)(i).

471. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the '588 patent.

472. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing

one or more claims of the ’588 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

473. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the ’588 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

474. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’588 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 45: INFRINGEMENT OF U.S. PATENT NO. 11,505,593* UNDER 35 U.S.C. § 271(e)

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

476. United States Patent No. 11,505,593 (“the ’593 patent”) (Exhibit 45 hereto), was duly and legally issued on November 22, 2022.

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

478. The ’593 patent has not yet expired.

479. The ’593 patent claims biological products, and it [redacted]

[redacted]

480. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the ’593 patent is an act of infringement of one or more claims of the ’593 patent under 35 U.S.C. § 271(e)(2)(C)(i).

481. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the ’593 patent.

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

483. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the ’593 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

484. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’593 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 46: INFRINGEMENT OF U.S. PATENT NO. 11,577,025* UNDER 35 U.S.C. § 271(e)

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

486. United States Patent No. 11,577,025 ("the '025 patent") (Exhibit 46 hereto), was duly and legally issued on February 14, 2023.

487. Regeneron is the owner of all right, title, and interest in the '025 patent.

488. The '025 patent has not yet expired.

489. The '025 patent claims methods of packaging biological products, and it [redacted]

490. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the '025 patent is an act of infringement of one or more claims of the '025 patent under 35 U.S.C. § 271(e)(2)(C)(i).

491. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the '025 patent.

492. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing

one or more claims of the ’025 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

493. Bioepis’s commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the ’025 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

494. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the ’025 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 47: INFRINGEMENT OF U.S. PATENT NO. USD 858,754* UNDER 35 U.S.C. § 271(e)

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

496. United States Patent No. USD 858,754 (“the D754 patent”) (Exhibit 47 hereto), was duly and legally issued on September 3, 2019.

497. Regeneron is the owner of all right, title, and interest in the D754 patent.

498. The D754 patent has not yet expired.

499. The D754 patent claims the design of a syringe cap, and it [redacted]

[redacted]

500. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the D754 patent is an act of infringement of the claim of the D754 patent under 35 U.S.C. § 271(e)(2)(C)(i).

501. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the D754 patent.

502. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing the claim of the D754 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

503. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the D754 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

504. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the D754 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 48: INFRINGEMENT OF U.S. PATENT NO. USD 906,102* UNDER 35 U.S.C. § 271(e)

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

506. United States Patent No. USD 906,102 ("the D102 patent") (Exhibit 48 hereto), was duly and legally issued on December 29, 2020.

507. Regeneron is the owner of all right, title, and interest in the D102 patent.

508. The D102 patent has not yet expired.

509. The D102 patent claims the design of packaging, and it [redacted]

510. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the D102 patent is an act of infringement of the claim of the D102 patent under 35 U.S.C. § 271(e)(2)(C)(i).

511. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the D102 patent.

512. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing the

claim of the D102 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

513. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the D102 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

514. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the D102 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 49: INFRINGEMENT OF U.S. PATENT NO. USD 934,069* UNDER 35 U.S.C. § 271(e)

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

516. United States Patent No. USD 934,069 ("the D069 patent") (Exhibit 49 hereto), was duly and legally issued on October 26, 2021.

517. Regeneron is the owner of all right, title, and interest in the D069 patent.

518. The D069 patent has not yet expired.

519. The D069 patent claims the design of packaging, and it [redacted]

[redacted]

520. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the D069 patent is an act of infringement of the claim of the D069 patent under 35 U.S.C. § 271(e)(2)(C)(i).

521. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the D069 patent.

522. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing the claim of the D069 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

523. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the D069 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

524. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the D069 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 50: INFRINGEMENT OF U.S. PATENT NO. USD 961,376* UNDER 35 U.S.C. § 271(e)

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

526. United States Patent No. USD 961,376 ("the D376 patent") (Exhibit 50 hereto), was duly and legally issued on August 23, 2022.

527. Regeneron is the owner of all right, title, and interest in the D376 patent.

528. The D376 patent has not yet expired.

529. The D376 patent claims the design of packaging, and it [redacted]

530. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the D376 patent is an act of infringement of the claim of the D376 patent under 35 U.S.C. § 271(e)(2)(C)(i).

531. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the D376 patent.

532. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing the

claim of the D376 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

533. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the D376 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

534. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the D376 patent entitles Regeneron to fees under 35 U.S.C. § 271(e)(4) and § 285.

COUNT 51: INFRINGEMENT OF U.S. PATENT NO. USD 961,377* UNDER 35 U.S.C. § 271(e)

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

536. United States Design Patent No. USD 961,377 ("the D377 patent") (Exhibit 51 hereto), was duly and legally issued on August 23, 2022.

537. Regeneron is the owner of all right, title, and interest in the D377 patent.

538. The D377 patent has not yet expired.

539. The D377 patent claims the design of packaging, and it [redacted]

[redacted]

540. [redacted] the commercial manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 before the expiration of the D377 patent is an act of infringement of the claim of the D377 patent under 35 U.S.C. § 271(e)(2)(C)(i).

541. For example, on information and belief, manufacture, use, offer for sale, and/or sale, or import into the United States, of SB15 [redacted] will infringe, *inter alia*, claim 1 of the D377 patent.

542. Regeneron will be irreparably harmed if Bioepis is not enjoined from infringing the claim of the D377 patent. Regeneron is entitled to injunctive relief at least under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(D) preventing Bioepis from any further infringement. Regeneron has no adequate remedy at law.

543. Bioepis's commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 [redacted] before the expiration of the D377 patent will cause Regeneron injury, entitling Regeneron to damages and/or other monetary relief under 35 U.S.C. § 271(e)(4)(C).

544. [redacted] the commercial manufacture, use, offer for sale, and/or sale within the United States, or importation into the United States, of SB15 before the expiration of the D377 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 Bioepis has infringed the patents in suit;

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

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

(d) Statutory relief under 35 U.S.C. § 271(e)(4)(D), including but not limited to a permanent injunction prohibiting Bioepis, its officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns from

infringing the patents in suit, or contributing to the same, or actively inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacturing of which infringes, the patents in suit;

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

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

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

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

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

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

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