IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALEXION PHARMACEUTICALS, INC. and ALEXION PHARMA INTERNATIONAL OPERATIONS LTD.,	)	C. A. No.: 24-005-GBW
Plaintiffs,	)	**JURY TRIAL DEMANDED**
v.	)	
SAMSUNG BIOEPIS CO. LTD.,	)	
Defendants.	)	

DEFENDANT SAMSUNG BIOEPIS CO. LTD.'S
ANSWER TO COMPLAINT AND COUNTERCLAIMS

Defendant Samsung Bioepis Co. Ltd. ("Samsung Bioepis" or "Defendant") hereby files its Answer and Counterclaims to Plaintiffs Alexion Pharmaceuticals, Inc.'s ("API") and Alexion Pharma International Operations Ltd.'s ("APIO") (collectively, "Alexion" or "Plaintiffs") Complaint for Patent Infringement ("Complaint", D.I. 1). Samsung Bioepis denies all allegations and characterizations in Plaintiffs' Complaint unless expressly admitted in the following Paragraphs.

ANSWER TO COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs in the Complaint. Samsung Bioepis denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Moreover, to the extent that any of Plaintiffs' allegations are vague or ambiguous, Samsung Bioepis denies said allegations. To the extent that any of the Complaint's headings or footnotes constitute allegations, Samsung Bioepis

specifically denies each and every one of them. Samsung Bioepis reserves the right to amend this Answer or to assert other defenses as this action proceeds. Samsung Bioepis denies that Plaintiffs are entitled to the relief requested or any other relief. Samsung Bioepis responds to the Complaint as follows:

NATURE OF THE ACTION

1. Upon information and belief, admitted.

2. The allegations set forth in Paragraph 2 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that SB12 is a biosimilar to SOLIRIS® (eculizumab). Samsung Bioepis also admits that Plaintiffs purport to allege infringement of United States Patent Nos. 9,732,149 ("the '149 patent"), 9,718,880 ("the '880 patent"), 9,725,504 ("the '504 patent"), 10,590,189 ("the '189 patent"), 10,703,809 ("the '809 patent"), and 9,447,176 ("the '176 patent") (collectively, "the Asserted Patents").

3. Samsung Bioepis admits that, on or before July 7, 2023, the FDA accepted for review its Biologics License Application ("BLA"), which seeks authorization from the FDA to make and sell SB12. Samsung Bioepis admits that its BLA was filed under Section 42 U.S.C. § 262(k), also known as 351(k) of the Public Health Service Act.

4. The allegations set forth in Paragraph 4 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

5. The allegations set forth in Paragraph 5 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

PARTIES

6. Samsung Bioepis admits, upon information and belief, based on the facts alleged in the Complaint, that API is a Delaware corporation with its principal place of business at 121 Seaport Boulevard, Boston, MA. Samsung Bioepis lacks knowledge or information sufficient to respond to the remaining allegations in Paragraph 6, and therefore, denies them.

7. Samsung Bioepis admits, upon information and belief, based on the facts alleged in the Complaint, that APIO is incorporated in Ireland with its principal place of business at College Business & Technology Park, Blanchardstown Road North, Dublin 15, Ireland. Samsung Bioepis lacks knowledge or information sufficient to respond to the allegations in Paragraph 7, and therefore, denies them.

8. Samsung Bioepis admits that it is a corporation organized and existing under the laws of South Korea. Samsung Bioepis denies the remaining allegations in Paragraph 8. Samsung's principal place of business is at 76 Songdogyoyuk-ro, Yeonsu-gu Incheon, 21987, Republic of Korea.

9. Samsung Bioepis admits that it develops biosimilar products. Samsung Bioepis further admits that it has sought regulatory approval for certain biosimilar products and has imported, marketed, distributed, offered to sell and/or sold some of those biosimilar products in the State of Delaware and throughout the United States. Samsung Bioepis denies the remaining allegations set forth in Paragraph 9 of the Complaint.

JURISDICTION AND VENUE

10. The allegations set forth in Paragraph 10 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis does not contest that this court has jurisdiction over the subject matter of this action

pursuant to 28 U.S.C. §§ 1331 and 1338(a) for the purposes of the instant action only, but only to the extent Plaintiffs have standing to bring the claims set forth in the Complaint. Samsung Bioepis denies the remaining allegations set forth in Paragraph 10 of the Complaint.

11. Samsung Bioepis admits that it submitted to the FDA BLA under Section 351(k) seeking approval of SB12. The remaining allegations set forth in Paragraph 11 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis does not contest personal jurisdiction for the purposes of the instant action only. Samsung Bioepis denies the remaining allegations set forth in Paragraph 11 of the Complaint.

12. Samsung Bioepis admits that, if SB12 is approved by the FDA, SB12 may be sold in the United States. The remaining allegations set forth in Paragraph 12 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

13. Samsung Bioepis admits that it has previously been sued in this District. Samsung Bioepis admits that it did not contest personal jurisdiction in *Genentech, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:18-cv-01363-CFC, D.I. 66 (D. Del. Jan. 31, 2019). The remaining allegations set forth in Paragraph 13 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis does not contest personal jurisdiction for the purposes of the instant action only. Samsung Bioepis denies the remaining allegations set forth in Paragraph 13 of the Complaint.

14. The allegations set forth in Paragraph 14 are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis does not contest personal jurisdiction over Samsung Bioepis for the purposes of the instant action only.

15. Samsung Bioepis admits that it is a corporation organized and existing under the laws of the Republic of Korea. The remaining allegations set forth in Paragraph 15 are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, denies the remaining allegations; however, Samsung Bioepis does not contest that venue is proper in this District for the purposes of the instant action only.

SOLIRIS®

16. Samsung Bioepis admits that SOLIRIS® contains a humanized antibody, eculizumab, which is an inhibitor of the complement pathway. Samsung also admits that SOLIRIS® is FDA-approved to treat paroxysmal nocturnal hemoglobinuria ("PNH"). Samsung Bioepis lacks knowledge or information sufficient to respond to the remaining allegations in Paragraph 16, and therefore, denies the remaining allegations.

17. Samsung Bioepis admits that SOLIRIS® first received FDA approval in 2007 for treatment of PNH. Samsung Bioepis also admits that SOLIRIS® is approved to treat aHUS, gMG, and NMOSD. Samsung Bioepis lacks knowledge or information sufficient to respond to the remaining allegations in Paragraph 17, and therefore, denies the remaining allegations.

18. Allegations set forth in Paragraph 18 are legal conclusions as to which no responsive pleading is necessary. To the extent a response is necessary, Samsung Bioepis lacks knowledge or information sufficient to respond to the allegations in Paragraph 18, and therefore, denies the remaining allegations.

SB12: SAMSUNG BIOEPIS'S ECULIZUMAB BIOSIMILAR PRODUCT

19. Admitted.

20. Samsung Bioepis admits Exhibit B to the Complaint refers to a clinical study entitled "A Phase III Randomised, Double-blind, Multicentre Study to Compare the Efficacy,

Safety, Pharmacokinetics, and Immunogenicity Between SB12 (Proposed Eculizumab Biosimilar) and Soliris® in Subjects With Paroxysmal Nocturnal Haemoglobinuria." Samsung Bioepis admits Exhibit B states that the "Study Start (Actual)" was "2019-08-07." Samsung Bioepis admits Exhibit A to the Complaint states, the study "demonstrated clinical equivalence in efficacy, safety, pharmacokinetics (PK), pharmacodynamics (PD), and immunogenicity of SB12 compared to reference eculizumab in paroxysmal nocturnal hemoglobinuria (PNH) patients."

SAMSUNG BIOEPIS'S BLA

21. Samsung Bioepis admits that, on or before July 7, 2023, it submitted to the FDA a BLA under Section 351(k) for SB12, for which SOLIRIS® is the reference product. Samsung Bioepis admits that SB12 is a biosimilar version of Alexion's SOLIRIS® product.

22. Samsung Bioepis admits that the FDA has not yet approved Samsung's BLA for its proposed SB12 biosimilar product.

23. Admitted.

24. To the extent Paragraph 24 implicates legal conclusions, no response is required. To the extent that a response is required, Samsung Bioepis admits that Exhibit C to the Complaint states "We write to provide Alexion notice of commercial marketing of Samsung's SB12 drug candidate pursuant to 42 U.S.C. § 262(*l*)(8)(A)," and that 42 U.S.C. § 262(*l*)(8)(A) reads "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing."

25. Denied. In its July 7, 2023 letter, Samsung Bioepis stated "Samsung does not intend to provide Alexion the application and manufacturing information under 42 U.S.C. § 262(l)(2)(A)." (D.I. 1-1 at 14.)

26. The allegations set forth in Paragraph 26 are legal conclusions as to which no

responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that it did not provide its BLA to Alexion and that Alexion has identified patents that it asserts are infringed by Samsung Bioepis. Samsung Bioepis lacks knowledge or information sufficient to respond to the remaining allegations in Paragraph 26, and therefore, denies them.

27. To the extent Paragraph 27 implicates legal conclusions, no response is required. To the extend a response is required, Samsung Bioepis admits that Plaintiffs' recitation of 42 U.S.C. § 262(*l*)(9)(C) is accurate.

SAMSUNG'S NOTICE OF COMMERCIAL MARKETING

28. Samsung Bioepis admits that Exhibit C to the Complaint (D.I. 1-1 at 14) refers to a July 7, 2023 letter, and that document speaks for itself. Samsung admits that the recitation of the contents of the communication is accurate with the exception that the citation at the end of the quote in the complaint contains a typographical error and should read "42 U.S.C. § 262(l)(2)(A)."

29. Samsung Bioepis admits that Exhibit C to the Complaint (D.I. 1-1 at 14) cited in Paragraph 29 refers to the July 7, 2023 letter, and that document speaks for itself. Exhibit C states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS)." Samsung Bioepis denies the remaining allegations set forth in Paragraph 29 of the Complaint.

30. Denied.

31. The allegations set forth in Paragraph 31 of the Complaint are conclusions of law as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits the documents cited in Paragraph 31, Exhibit D and Exhibit C, refer to FDA's Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years

2023 Through 2027 and the July 7, 2023 letter, respectively, and, that the documents speak for themselves. Samsung Bioepis does not have information sufficient to respond to the remaining allegations in Paragraph 31, and therefore, denies.

32. The allegations set forth in Paragraph 32 of the Complaint are conclusions of law as to which no responsive pleading is necessary. Samsung Bioepis denies the remaining allegations set forth in Paragraph 32 of the Complaint.

33. The allegations set forth in Paragraph 33 are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

34. The allegations set forth in Paragraph 34 are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

ALEXION'S ASSERTED PATENTS

35. The allegations set forth in Paragraph 35 are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that Alexion obtained patents related to eculizumab but lacks knowledge or information sufficient to respond to the remaining allegations in Paragraph 35, and therefore, denies.

The '149 Patent

36. Samsung Bioepis admits the '149 patent is entitled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement" and bears the issue date August 15, 2017. Samsung Bioepis admits Exhibit E to the Complaint appears to be a copy of the '149 patent. The face of the '149 patent states the assignee of the patent is Alexion. To the extent the Complaint purports to generalize the content of the '149 patent, the content of the '149 patent

speaks for itself. Samsung Bioepis admits the '149 patent includes one claim that reads: "An antibody that binds C5 comprising a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4." The remaining allegations set forth in Paragraph 36 of the Complaint are legal conclusions as to which no responsive pleading is necessary.

The '880 Patent

37. Samsung Bioepis admits the '880 patent is entitled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement" and bears the issue date August 1, 2017. Samsung Bioepis admits Exhibit F to the Complaint appears to be a copy of the '880 patent. The face of the '880 patent states the assignee of the patent is Alexion. To the extent the Complaint purports to generalize the content of the '880 patent, the content of the '880 patent speaks for itself. The '880 patent includes three claims and Claim 1 reads: "A pharmaceutical composition for use in treating a patient afflicted with paroxysmal nocturnal hemoglobinuria (PNH), wherein the composition is a sterile, preservative free, 300 mg single-use dosage form comprising 30 ml of a 10 mg/ml antibody solution, wherein the antibody comprises a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4." The remaining allegations set forth in Paragraph 37 of the Complaint are legal conclusions as to which no responsive pleading is necessary.

The '504 Patent

38. Samsung Bioepis admits the '504 patent is entitled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement" and bears the issue date August 8, 2017. Samsung Bioepis admits Exhibit G to the Complaint appears to be a copy of the '504 patent. The face of the '504 patent states the assignee of the patent is Alexion. To the extent the Complaint purports to generalize the content of the '504 patent, the content of the '504 patent

speaks for itself. Samsung Bioepis admits the '504 patent includes ten claims and Claim 1 reads: "A method of treating a patient suffering from paroxysmal nocturnal hemoglobinuria (PNH) comprising administering to the patient a pharmaceutical composition comprising an antibody that binds C5, wherein the antibody comprises a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4." The remaining allegations set forth in Paragraph 38 of the Complaint are legal conclusions as to which no responsive pleading is necessary.

The '189 Patent

39. Samsung Bioepis admits the '189 patent is entitled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement" and bears the issue date March 17, 2020. Samsung Bioepis admits Exhibit H to the Complaint appears to be a copy of the '189 patent. The face of the '189 patent states the assignee of the patent is Alexion. To the extent the Complaint purports to generalize the content of the '189 patent, the content of the '189 patent speaks for itself. Samsung Bioepis admits the '189 patent includes eight claims and Claim 1 reads: "A method of treating a patient suffering from paroxysmal nocturnal hemoglobinuria (PNH) comprising administering to the patient a pharmaceutical composition comprising an antibody that binds C5, wherein the antibody comprises a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4, and wherein the composition comprises a single-unit dosage form comprising 300 mg of the antibody in 30 mL of a sterile, preservative-free solution." The remaining allegations set forth in Paragraph 39 of the Complaint are legal conclusions as to which no responsive pleading is necessary.

The '809 Patent

40. Samsung Bioepis admits the '809 patent is entitled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement" and bears the issue date July

7, 2020. Samsung Bioepis admits Exhibit I to the Complaint appears to be a copy of the '809 patent. The face of the '809 patent states the assignee of the patent is Alexion. To the extent the Complaint purports to generalize the content of the '809 patent, the content of the '809 patent speaks for itself. Samsung Bioepis admits the '809 patent includes 29 claims and Claim 1 reads: "A method of treating a patient having paroxysmal nocturnal hemoglobinuria (PNH), wherein the method comprises intravenously administering to the patient an antibody that binds C5, wherein the antibody comprises a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4." The remaining allegations set forth in Paragraph 40 of the Complaint are legal conclusions as to which no responsive pleading is necessary.

The '176 Patent

41. Samsung Bioepis admits the '176 patent is entitled "Methods and Compositions for Treating Complement-Associated Disorders" and bears the issue date September 20, 2016. Samsung Bioepis admits Exhibit J to the Complaint appears to be a copy of the '176 patent. The face of the '176 patent states the assignee of the patent is Alexion. To the extent the Complaint purports to generalize the contents of the '176 patent, the contents of the '176 patent speak for itself. Samsung Bioepis admits the '176 patent includes four claims and Claim 1 reads:

> A method for treating atypical hemolytic uremic syndrome (aHUS), the method comprising administering to a patient in need thereof eculizumab in an amount effective to treat aHUS in the patient; wherein the eculizumab is intravenously administered to the patient under the following schedule:
>
> at least 600 mg of eculizumab once per week for four consecutive weeks; and
>
> beginning at week five, maintenance doses of at least 900 mg eculizumab every two weeks thereafter.

The remaining allegations set forth in Paragraph 41 of the Complaint are legal conclusions as to which no responsive pleading is necessary.

COUNT I

Infringement of the '149 Patent Under 35 U.S.C. § 271(e)(2)(C)(ii)

42. Samsung Bioepis incorporates by reference its responses to each of the preceding Paragraphs of the Complaint as if fully set forth herein.

43. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

44. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

45. The allegations set forth in Paragraph 45 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®. Samsung Bioepis denies the remaining allegations of Paragraph 45.

46. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 46 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

47. Denied.

48. Denied.

49. Denied.

50. The allegations set forth in Paragraph 50 of the Complaint are legal conclusions to

which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that it filed an *inter partes* review petition related to the '149 patent with the United States Patent and Trademark Office on May 18, 2023. Samsung Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified the '149 patent.

51. Denied.

52. Denied.

53. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

COUNT II

Declaratory Judgment of Infringement of the '149 Patent

54. Samsung Bioepis incorporates by reference its responses to each of the preceding Paragraphs of the Complaint as if fully set forth herein.

55. The allegations set forth in Paragraph 55 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

56. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal

nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

57. Admitted.

58. Samsung Bioepis admits Exhibit C of the Complaint cited in Paragraph 58 refers to the July 7, 2023 letter, and that document speaks for itself. The remaining allegations set forth in Paragraph 58 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

59. Denied.

60. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

61. The allegations set forth in Paragraph 61 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®.

62. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 62 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

67. The allegations set forth in Paragraph 67 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that it filed an *inter partes* review petition related to the '149 patent with the United States

Patent and Trademark Office on May 18, 2023. Samsung Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified the '149 patent.

68. Denied.

69. Denied.

70. Samsung Bioepis admits that Plaintiffs purport to seek a declaratory judgment. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including declaratory judgment.

71. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

COUNT III

Infringement of the '880 Patent Under 35 U.S.C. § 271(e)(2)(C)(ii)

72. Samsung Bioepis incorporates by reference its responses to each of the preceding Paragraphs of the Complaint as if fully set forth herein.

73. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to

receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

74. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

75. The allegations set forth in Paragraph 75 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®. Samsung Bioepis denies the remaining allegations of Paragraph 75.

76. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 76 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

77. Denied.

78. Denied.

79. Denied.

80. The allegations set forth in Paragraph 80 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that it filed an *inter partes* review petition related to the '880 patent with the United States Patent and Trademark Office on May 31, 2023. Samsung Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified the '880 patent.

81. Denied.

82. Denied.

83. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument*

Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

COUNT IV

Declaratory Judgment of Infringement of the '880 Patent

84. Samsung Bioepis incorporates by reference its responses to each of the preceding Paragraphs of the Complaint as if fully set forth herein.

85. The allegations set forth in Paragraph 85 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

86. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

87. Admitted.

88. Samsung Bioepis admits Exhibit C to the Complaint cited in Paragraph 88 refers to the July 7, 2023 letter, and that document speaks for itself. The remaining allegations set forth in Paragraph 88 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

89. Denied.

90. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

91. The allegations set forth in Paragraph 91 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®.

92. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 92 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

93. Denied.

94. Denied.

95. Denied.

96. Denied.

97. The allegations set forth in Paragraph 97 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that it filed an *inter partes* review petition related to the '880 patent with the United States Patent and Trademark Office on May 31, 2023. Samsung Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified the '880 patent.

98. Denied.

99. Denied.

100. Samsung Bioepis admits that Plaintiffs purport to seek a declaratory judgment. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including declaratory judgment.

101. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive

relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

COUNT V

Infringement of the '504 Patent Under 35 U.S.C. § 271(e)(2)(C)(ii)

102. Samsung Bioepis incorporates by reference its responses to each of the preceding Paragraphs of the Complaint as if fully set forth herein.

103. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

104. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

105. The allegations set forth in Paragraph 105 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®. Samsung Bioepis denies the remaining allegations of Paragraph 105.

106. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 106 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

107. The allegations set forth in Paragraph 107 of the Complaint are legal conclusions

as to which no responsive pleading is necessary. Samsung Bioepis admits that, if SB12 is approved, SB12 may be advertised in the United States. Samsung Bioepis denies the remaining allegations set forth in Paragraph 107 of the Complaint.

108. Denied.

109. Denied.

110. Denied.

111. The allegations set forth in Paragraph 111 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that it filed an *inter partes* review petition related to the '504 patent with the United States Patent and Trademark Office on May 31, 2023. Samsung Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified the '504 patent.

112. Denied.

113. Denied.

114. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

COUNT VI

Declaratory Judgment of Infringement of the '504 Patent

115. Samsung Bioepis incorporates by reference its responses to each of the preceding Paragraphs of the Complaint as if fully set forth herein.

116. The allegations set forth in Paragraph 116 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

117. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

118. Admitted.

119. Samsung Bioepis admits that Exhibit C of the Complaint cited in Paragraph 119 refers to the July 7, 2023 letter, and that document speaks for itself. The remaining allegations set forth in Paragraph 119 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

120. Denied.

121. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

122. The allegations set forth in Paragraph 122 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®.

123. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 123 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

124. The allegations set forth in Paragraph 124 of the Complaint are legal conclusions as to which no responsive pleading is necessary. Samsung Bioepis admits that, if SB12 is approved, SB12 may be advertised in the United States. Samsung Bioepis denies the remaining allegations set forth in Paragraph 124 of the Complaint.

125. Denied.

126. Denied.

127. Denied.

128. The allegations set forth in Paragraph 128 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that it filed an *inter partes* review petition related to the '504 patent with the United States Patent and Trademark Office on May 31, 2023. Samsung Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified the '504 patent.

129. Denied.

130. Denied.

131. Samsung Bioepis admits that Plaintiffs purport to seek a declaratory judgment. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including declaratory judgment.

132. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

COUNT VII

Infringement of the '189 Patent Under 35 U.S.C. § 271(e)(2)(C)(ii)

133. Samsung Bioepis incorporates by reference its responses to each of the preceding Paragraphs of the Complaint as if fully set forth herein.

134. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

135. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

136. The allegations set forth in Paragraph 136 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®. Samsung Bioepis denies the remaining allegations of Paragraph 136.

137. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 137 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

138. The allegations set forth in Paragraph 138 of the Complaint are legal conclusions as to which no responsive pleading is necessary. Samsung Bioepis admits that, if SB12 is approved, SB12 may be advertised in the United States. Samsung Bioepis denies the remaining allegations set forth in Paragraph 138 of the Complaint.

139. Denied.

140. Denied.

141. Denied.

142. The allegations set forth in Paragraph 142 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that it filed an *inter partes* review petition related to the '189 patent with the United States Patent and Trademark Office on June 16, 2023. Samsung Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified the '189 patent.

143. Denied.

144. Denied.

145. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

COUNT VIII

Declaratory Judgment of Infringement of the '189 Patent

146. Samsung Bioepis incorporates by reference its responses to each of the preceding Paragraphs of the Complaint as if fully set forth herein.

147. The allegations set forth in Paragraph 147 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

148. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

149. Admitted.

150. Samsung Bioepis admits that Exhibit C of the Complaint cited in Paragraph 150 refers to the July 7, 2023 letter, and that document speaks for itself. The remaining allegations set forth in Paragraph 150 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

151. Denied.

152. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

153. The allegations set forth in Paragraph 153 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®.

154. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 154 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

155. The allegations set forth in Paragraph 155 of the Complaint are legal conclusions as to which no responsive pleading is necessary. Samsung Bioepis admits that, if SB12 is approved, SB12 may be advertised in the United States. Samsung Bioepis denies the remaining

allegations set forth in Paragraph 155 of the Complaint.

156. Denied.

157. Denied.

158. Denied.

159. The allegations set forth in Paragraph 159 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that it filed an *inter partes* review petition related to the '189 patent with the United States Patent and Trademark Office on June 16, 2023. Samsung Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified the '189 patent.

160. Denied.

161. Denied.

162. Samsung Bioepis admits that Plaintiffs purport to seek a declaratory judgment. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including declaratory judgment.

163. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

COUNT IX

Infringement of the '809 Patent Under 35 U.S.C. § 271(e)(2)(C)(ii)

164. Samsung Bioepis incorporates by reference its responses to each of the preceding

Paragraphs of the Complaint as if fully set forth herein.

165. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

166. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

167. The allegations set forth in Paragraph 167 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®. Samsung Bioepis denies the remaining allegations of Paragraph 167.

168. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 168 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

169. The allegations set forth in Paragraph 169 of the Complaint are legal conclusions as to which no responsive pleading is necessary. Samsung Bioepis admits that, if SB12 is approved, SB12 may be advertised in the United States. Samsung Bioepis denies the remaining allegations set forth in Paragraph 169 of the Complaint.

170. Denied.

171. Denied.

172. Denied.

173. The allegations set forth in Paragraph 173 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that it filed an *inter partes* review petition related to the '809 patent with the United States Patent and Trademark Office on June 16, 2023. Samsung Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified the '809 patent.

174. Denied.

175. Denied.

176. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

COUNT X

Declaratory Judgment of Infringement of the '809 Patent

177. Samsung Bioepis incorporates by reference its responses to each of the preceding Paragraphs of the Complaint as if fully set forth herein.

178. The allegations set forth in Paragraph 178 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

179. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA

seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

180. Admitted.

181. Samsung Bioepis admits Exhibit C of the Complaint cited in Paragraph 181 refers to the July 7, 2023 letter, and that document speaks for itself. The remaining allegations set forth in Paragraph 181 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

182. The allegations set forth in Paragraph 182 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

183. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

184. The allegations set forth in Paragraph 184 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®.

185. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 185 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

186. The allegations set forth in Paragraph 186 of the Complaint are legal conclusions as to which no responsive pleading is necessary. Samsung Bioepis admits that, if SB12 is approved, SB12 may be advertised in the United States. Samsung Bioepis denies the remaining allegations set forth in Paragraph 186 of the Complaint.

187. Denied.

188. Denied.

189. Denied.

190. The allegations set forth in Paragraph 190 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that it filed an *inter partes* review petition related to the '809 patent with the United States Patent and Trademark Office on June 16, 2023. Samsung Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified the '809 patent.

191. Denied.

192. Denied.

193. Samsung Bioepis admits that Plaintiffs purport to seek a declaratory judgment. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including declaratory judgment.

194. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

COUNT XI

Infringement of the '176 Patent Under 35 U.S.C. § 271(e)(2)(C)(ii)

195. Samsung Bioepis incorporates by reference its responses to each of the preceding Paragraphs of the Complaint as if fully set forth herein.

196. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

197. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

198. The allegations set forth in Paragraph 198 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®. Samsung Bioepis denies the remaining allegations of Paragraph 198.

199. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 199 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

200. The allegations set forth in Paragraph 200 of the Complaint are legal conclusions as to which no responsive pleading is necessary. Samsung Bioepis admits that, if SB12 is approved, SB12 may be advertised in the United States. Samsung Bioepis denies the remaining allegations set forth in Paragraph 200 of the Complaint.

201. Denied.

202. Denied.

203. Denied.

204. The allegations set forth in Paragraph 204 of the Complaint are legal conclusions

to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified the '176 patent.

205. Denied.

206. Denied.

207. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

COUNT XII

Declaratory Judgment of Infringement of the '176 Patent

208. Samsung Bioepis incorporates by reference its responses to each of the preceding Paragraphs of the Complaint as if fully set forth herein.

209. The allegations set forth in Paragraph 209 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

210. Samsung Bioepis admits that, on or before July 7, 2023, Samsung Bioepis submitted to the FDA a BLA under Section 351(k) for SB12 of which SOLIRIS® is the reference product. Exhibit C to the Complaint (D.I. 1-1 at 14) states "Samsung's application to the FDA seeks approval for its SB12 drug product with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). The BLA for the SB12 drug product has now been accepted for review by the FDA, and Samsung expects to

receive FDA approval in the first half of 2024." Samsung Bioepis, on information and belief, admits that Alexion is the holder of BLA No. 125166 which covers SOLIRIS® (eculizumab).

211. Admitted.

212. Samsung Bioepis admits that Exhibit C of the Complaint cited in Paragraph 212 refers to the July 7, 2023 letter, and that document speaks for itself. The remaining allegations set forth in Paragraph 212 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis denies the same.

213. Denied.

214. Samsung Bioepis admits that it has not provided Alexion a copy of its BLA.

215. The allegations set forth in Paragraph 215 of the Complaint are legal conclusions as to which no responsive pleading is necessary. To the extent a response is required, Samsung Bioepis admits that eculizumab is the active ingredient in SOLIRIS®.

216. Samsung Bioepis admits Exhibit K of the Complaint cited in Paragraph 216 refers to EMA's assessment report on eculizumab, and that the document speaks for itself.

217. The allegations set forth in Paragraph 217 of the Complaint are legal conclusions as to which no responsive pleading is necessary. Samsung Bioepis admits that, if SB12 is approved, SB12 may be advertised in the United States. Samsung Bioepis denies the remaining allegations set forth in Paragraph 217 of the Complaint.

218. Denied.

219. Denied.

220. Denied.

221. The allegations set forth in Paragraph 221 of the Complaint are legal conclusions to which no responsive pleading is necessary. To the extent a response is required, Samsung

Bioepis admits that counsel for Alexion sent counsel for Samsung Bioepis a letter dated September 5, 2023, in which Alexion's counsel identified U.S. Patent No. 9,447,176.

222. Denied.

223. Denied.

224. Samsung Bioepis admits that Plaintiffs purport to seek a declaratory judgment. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including declaratory judgment.

225. Samsung Bioepis admits that Plaintiffs purport to seek an injunction. Samsung Bioepis denies Plaintiffs are entitled to any relief pursuant to their claims including injunctive relief, in the least because one who seeks equity must do equity. *See, e.g., Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945) ("[H]e who comes into equity must come with clean hands.").

PRAYER FOR RELIEF

Samsung Bioepis denies that Plaintiffs are entitled to any relief whatsoever, including but not limited to the relief sought in paragraphs A through E of Plaintiffs' Prayer for Relief, and denies any allegations contained therein.

SAMSUNG'S AFFIRMATIVE DEFENSES

Further answering the Complaint, and as additional defenses there, Samsung Bioepis asserts the following Affirmative Defenses to Plaintiffs' Complaint without assuming any burden that is would not otherwise bear and without reducing or removing Plaintiffs' burdens of proof on its affirmative claims against Samsung Bioepis. Samsung Bioepis reserves the right to amend its currently pled Answer and Defenses as additional information becomes available and/or is otherwise discovered.

FIRST AFFIRMATIVE DEFENSE

The Complaint, and each and every purported claim for relief therein, fails to allege facts sufficient to state a claim.

SECOND AFFIRMATIVE DEFENSE

The manufacture, use, offer for sale, sale, and/or importation into the United States of SB12 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the Asserted Patents directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other matter.

THIRD AFFIRMATIVE DEFENSE

All claims of the Asserted Patents are invalid for failure to satisfy the requirements of 35 U.S.C. §§ 101 *et seq*., including without limitation §§ 101, 102, 103, 112, and/or 116; or under other judicially-created bases for invalidation.

FOURTH AFFIRMATIVE DEFENSE

All the claims of the PNH Patents (’149 patent, ’880 patent,’504 patent, ’189 patent, and ’809 patent) are unenforceable as a result of inequitable conduct during prosecution before the USPTO as particularly explained in Counts XIII-XVII of Samsung Bioepis’ counterclaims and the factual allegations incorporated therein.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs are barred from recovery, in whole or in part, by the doctrine of prosecution history estoppel.

SIXTH AFFIRMATIVE DEFENSE

The filing of Samsung Bioepis’s BLA for SB12 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the Asserted Patents directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other matter.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs are not entitled to injunctive relief. Any injury to Plaintiffs is neither immediate nor irreparable. Plaintiffs have an adequate remedy at law for any claims it can prove. The balance of hardships does not warrant injunctive relief. The public interest would be disserved by an injunction.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs are barred from obtaining a finding of willfulness and receiving enhanced damages because the Complaint fails to allege that Samsung Bioepis's conduct rose to the level of intentional or deliberate behavior.

NINTH AFFIRMATIVE DEFENSE

Samsung Bioepis's actions in defending against this case do not give rise to an exceptional case under 35 U.S.C. § 271(e)(4) or § 285.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for damages and other relief are barred in whole or in part by the equitable doctrines of waiver, estoppel, and/or acquiescence due to actions and circumstances including, but not limited to, Plaintiffs' and/or Plaintiffs' predecessor-in-interest's unreasonable delay in asserting the '149, '880, '504, '189, '809, and '176 patents.

ELEVENTH AFFIRMATIVE DEFENSE

Samsung Bioepis's activities fall within the safe harbor provisions of 35 U.S.C. § 271(e)(1).

TWELFTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

RESERVATION OF RIGHTS

Samsung Bioepis expressly reserves the right to allege and assert additional defenses that

may be accorded to it under Rule 8(c) of the Federal Rules of Civil Procedure, the Patent Laws of the United States, and any other defenses, at law or in equity that now exist or in the future may be available based on discovery and further factual investigation in this case.

DEMAND FOR JURY TRIAL

Samsung Bioepis respectfully requests a trial by jury on all issues so triable.

COUNTERCLAIMS

For its Counterclaims against Plaintiff/Counterclaim Defendant Alexion Pharmaceuticals, Inc.'s ("API's") and Alexion Pharma International Operations Ltd.'s ("APIO's) (collectively, "Counterclaim Defendants"), Defendant/Counterclaim Plaintiff Samsung Bioepis Co., Ltd. ("Samsung Bioepis") states as follows:

NATURE OF THE ACTION

1. Samsung Bioepis seeks a declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that the claims of United States Patent Nos. 9,732,149 ("the '149 Patent"), 9,718,880 ("the '880 Patent"), 9,725,504 ("the '504 Patent"), 10,590,189 ("the '189 Patent"), 10,703,809 ("the '809 Patent"), and 9,447,176 ("the '176 Patent") (collectively, "the Asserted Patents") are invalid, are unenforceable, and have not been infringed, are not being infringed, and will not be infringed by the submission of Samsung Bioepis's BLA under Section 351(k) related to SB12 or the manufacture, use, sale, offer for sale, or importation of the product which is described in Samsung Bioepis's BLA under Section 351(k) related to SB12.

THE PARTIES

2. Samsung Bioepis is a corporation organized and existing under the laws of the Republic of Korea, having a principal place of business at 76 Songdogyoyuk-ro, Yeonsu-gu Incheon, 21987, Republic of Korea.

3. On information and belief, and based on information alleged in the Complaint, API is a Delaware corporation with its principal place of business at 121 Seaport Boulevard, Boston, MA.

4. On information and belief, and based on information alleged in the Complaint, APIO is a limited company incorporated in Ireland with its principal place of business at College Business & Technology Park, Blanchardstown Road North, Dublin 15, Ireland.

JURISDICTION & VENUE

5. These counterclaims are for declaratory judgment of noninfringement, invalidity, and unenforceability, which arise under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. § 262(l).

6. This Court has subject matter jurisdiction over these counterclaims pursuant to 42 U.S.C. §§ 262(*k*)–(*l*), 28 U.S.C. §§ 1331, 1338, 1367(a), 2201, and 2202, and 35 U.S.C. § 271(e)(2)(C).

7. Counterclaim Defendants have filed a Complaint in this District alleging infringement by Samsung Bioepis of one or more claims of each of the Asserted Patents. An actual controversy exists between Samsung Bioepis and Counterclaim Defendants as to the alleged infringement and validity of the Asserted Patents.

8. This Court has personal jurisdiction over Counterclaim Defendants because, *inter alia*, they have subjected themselves to the jurisdiction of this Court by filing the Complaint.

9. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b), and by virtue of Defendants' filing of this action in this District.

FACTUAL BACKGROUND

A. Samsung Bioepis's BLA and SB12

10. Samsung Bioepis is a pharmaceutical company that specializes in research and development of biosimilars and biopharmaceuticals. Since its inception in 2012, Samsung Bioepis has received approval for several biosimilar drugs in Europe, Asia, and the United States. Samsung Bioepis's biosimilar drugs are marketed and distributed throughout the world.

11. Samsung Bioepis is currently seeking licensure pursuant to 42 U.S.C. § 262(k) for the product referred to herein as "SB12" which is described in a Biologics License Application ("BLA") submitted to the FDA by Samsung Bioepis under Section 351(k).

12. The reference product for SB12 is SOLIRIS®, which was approved by the FDA in 2007. SOLIRIS® includes an antibody called eculizumab. Upon information and belief, SOLIRIS® is approved for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis (gMG), and neuromyelitis optica spectrum disorder (NMOSD).

13. Upon information and belief, Counterclaim Defendants first began marketing SOLIRIS® in the United States in 2007. At this time, there are no biosimilar versions of SOLIRIS® available on the market in the United States.

14. In 2009, Congress created a new pathway for FDA review and approval of "biosimilar" biological products, as well as new mechanisms to resolve patent disputes that may arise with respect to such products, known as the Biologics Price Competition and Innovation Act ("BPCIA").

15. The BPCIA sets forth an abbreviated pathway for FDA approval of biosimilars. 42 U.S.C. § 262(k). To obtain approval through the BPCIA's abbreviated process, an applicant must show that its biosimilar product is "highly similar" to the reference product and that there are no

"clinically meaningful differences" between the two products in terms of "safety, purity, and potency." *Id.* § 262(*i*)-(*k*)(2). Under the BPCIA, an applicant may not submit an application until four years after the reference product is first licensed, and the FDA may not license a biosimilar until 12 years after the reference product is first licensed. *Id.* § 262(*k*)(7).

16. Once an application for a biosimilar is submitted to the FDA, the BPCIA also states that an applicant "shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the [biosimilar]." *Id.* § 262(l)(8)(A).

17. On July 7, 2023, Samsung Bioepis's counsel sent counsel for Alexion a notice of commercial marketing for Samsung Bioepis's SB12 biosimilar product. (*See* D.I. 1-1 at 14).

B. The Asserted Patents

18. The '149 Patent, titled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement," issued on August 15, 2017, is assigned to API on its face. Upon information and belief and based on information alleged in the Complaint, Counterclaim Defendants own all rights, title, and interest in the '149 Patent.

19. The '880 Patent, titled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement," issued on August 1, 2017, is assigned to API on its face. Upon information and belief and based on information alleged in the Complaint, Counterclaim Defendants own all rights, title, and interest in the '880 Patent.

20. The '504 Patent, titled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement," issued on August 8, 2017, is assigned to API on its face. Upon information and belief and based on information alleged in the Complaint, Counterclaim Defendants own all rights, title, and interest in the '504 Patent.

21. The '189 Patent, titled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement," issued on March 17, 2020, is assigned to API on its face.

Upon information and belief and based on information alleged in the Complaint, Counterclaim Defendants own all rights, title, and interest in the '189 Patent.

22. The '809 Patent, titled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement," issued on July 7, 2020, is assigned to API on its face. Upon information and belief and based on information alleged in the Complaint, Counterclaim Defendants own all rights, title, and interest in the '809 Patent.

23. The '176 Patent, titled "Methods and Compositions for Treating Complement-Associated Disorders," issued on September 20, 2016, is assigned to API on its face. Upon information and belief and based on information alleged in the Complaint, Counterclaim Defendants own all rights, title, and interest in the '176 Patent.

Unenforceability of the PNH Patents

24. The '149 Patent, '880 Patent,'504 Patent, '189 Patent, and '809 Patent (hereinafter referred to collectively as the "PNH Patents") each are unenforceable due to inequitable conduct.

25. Each of the PNH Patents claims the sequence of eculizumab or the use of eculizumab to treat PNH (paroxysmal nocturnal hemoglobinuria), which is a disease of blood cells caused by a genetic mutation that renders cells more susceptible to destruction by what is known as the complement system.

26. The complement system can be inhibited at a later stage in the cascade which has been recognized to be useful for limiting PNH systems, while also retaining the upstream complement system activity necessary for immune system functions. In particular, the complement cascade can be inhibited at the step where C5 is converted to C5a and C5b with little effect on the immune system.

27. Before March 15, 2007, the antibody eculizumab was recognized as a known

inhibitor of C5 conversion.

28. As early as 1999, Alexion disclosed the sequence for eculizumab publicly, at least in a submission to Chemical Abstract Services ("CAS").

29. Indeed, in communications with the European Patent Office, Alexion represented that "the sequence for eculizumab was publicly available [before Feb. 3, 2004]," and the "sequence for eculizumab was submitted to [CAS] and entered into their STN database on 14 February 1999." Ex. A at 37 (Excerpt of European Patent Application No. 1 720 571 Opposition File History, Response to Official Communication of April 19, 2013 (Dec. 30, 2013) at 14).

30. In such correspondence, Alexion attached the following copy of the CAS entry to support that the sequence of eculizumab was publicly available in 1999:

```
L27  ANSWER 2 OF 2  REGISTRY  COPYRIGHT 2009 ACS on STN
RN   219685-50-4  REGISTRY  REGISTRY  COPYRIGHT 2009 ACS on STN
RN   219685-50-4  REGISTRY
ED   Entered STN:  14 Feb 1999
CN   Immunoglobulin, anti-(human complement C5 .alpha.-chain) (human-mouse
     monoclonal 5G1.1 heavy chain), disulfide with human-mouse monoclonal
     5G1.1 light chain, dimer (9CI)  (CA INDEX NAME)
OTHER NAMES:
CN   Eculizumab
CN   h5G1.1
CN   h5G1.1VHC+h5G1.1VLC
CN   Soliris
FS   PROTEIN SEQUENCE
MF   Unspecified
CI   MAN
SR   US Adopted Names Council (USAN)
LC   STN Files:   ADISINSIGHT, BIOSIS, CA, CAPLUS, CBNB, CHEMCATS, EMBASE,
       IMSDRUGNEWS, IMSPATENTS, IMSPRODUCT, IMSRESEARCH, IPA, MRCK*, PHAR,
       PROUSDDR, TOXCENTER, USAN, USPATFULL
         (*File contains numerically searchable property data)

*** STRUCTURE DIAGRAM IS NOT AVAILABLE ***
*** USE 'SQD' OR 'SQIDE' FORMATS TO DISPLAY SEQUENCE ***
59 REFERENCES IN FILE CA (1907 TO DATE)
2 REFERENCES TO NON-SPECIFIC DERIVATIVES IN FILE CA
59 REFERENCES IN FILE CAPLUS (1907 TO DATE)
```

Ex. A at 23 (Excerpt of European Patent Application No. 1 720 571 Opposition File History, Response to Official Communication of April 19, 2013 (Dec. 30, 2013) (attaching CAS entry No. 219685-560-4)).

C. The PNH Patents Are Unenforceable Due to Alexion's Misrepresentations to the USPTO

31. The claims of the PNH Patents are unenforceable by reason of at least prosecuting attorney Jill Gorny Sloper's and co-inventor Leonard Bell's inequitable conduct during the prosecution of the applications that issued as the PNH Patents.

a. The '149 Patent – Inequitable Conduct by Prosecuting Attorney Sloper

32. Attorney Sloper filed U.S. Patent Application No. 15/284,105 on October 3, 2016, which issued as the '149 Patent. (D.I. 1-1 (the '149 Patent) at 53 (Complaint, Exhibit E)).

33. As a part of application No. 15/284,105, the examiner rejected the application as "the extensive number of both patent literature and NPL documents . . . indicates that eculizumab was wide-spread and well-known." Ex. B at 14 (Excerpt from the File History of U.S. Patent Application No. 15/284,105, Non-Final Rejection (Apr. 11, 2017) at 3).

34. Within this non-final rejection, the examiner reminded Attorney Sloper that "the reply to this requirement must be made with candor and good faith under 37 CFR 1.56." *Id.* at 17 (Non-Final Rejection (Apr. 11, 2017) at 6).

35. 37 C.F.R. § 1.56 states in part "[e]ach individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section."

36. 37 C.F.R. § 1.56 also states in part "no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct."

37. On June 13, 2017, Attorney Sloper owed a duty of candor and good faith to the United States Patent & Trademark Office ("USPTO"). Nevertheless, during the prosecution of the

application that issued as the '149 Patent, Attorney Sloper made misrepresentations to the USPTO contrary to both the facts and the previous representations made by Alexion during the European Opposition. Attorney Sloper represented that "neither eculizumab nor its complete sequence . . . was in the public domain prior to the March 15, 2007 effective filing date . . . ." as shown below:

> Exhibit H (Rother, US 2009/0028850). However, this is incorrect. Neither eculizumab nor its complete sequence, including the sequence of its unique, non-naturally occurring, protein-engineered heavy chain, was in the public domain prior to the March 15, 2007 effective filing date of the present application, as discussed in detail below. Accordingly, the presently claimed

Ex. B at 27 (Applicant Remarks (June 13, 2017) at 4).

CONCLUSION

If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at (617) 217-4630. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 12-0080, under Order No. AXJ-114BUSCN4.

Dated: June 13, 2017

Respectfully submitted,

Electronic signature: /Jill Gorny Sloper, Esq./
Jill Gorny Sloper, Esq.
Registration No.: 60,760
NELSON MULLINS RILEY & SCARBOROUGH LLP
One Post Office Square
Boston, Massachusetts 02109-2127
(617) 217-4630
(617) 217-4699 (Fax)
Attorney/Agent For Applicants

Id. at 34 (Applicant Remarks & Amendment (June 13, 2017) at 7).

38. Due in part to Attorne Sloper's affirmative misrepresentation of fact that neither eculizumab nor its complete sequence were in the public domain prior to March 15, 2007, the examiner issued a Notice of Allowance on July 3, 2017. *Id.* at 60-62 (Notice of Allowance (July 3, 2017)).

39. The foregoing material misrepresentations were material to, at least, claim 1 of the

'149 Patent, which expressly recites the amino acid sequence of the eculizumab antibody at issue during examination of the '149 Patent. (D.I. 1-1 at 80.)

b. The '880 Patent - Inequitable Conduct by Prosecuting Attorney Sloper

40. Similar to the '149 Patent discussed above, Attorney Sloper filed U.S. Patent Application No. 15/148,839 on May 6, 2016, which issued as the '880 Patent. (D.I. 1-1 (the '880 Patent) at 86 (Complaint, Exhibit F)).

41. As a part of application No. 15/148,839, the examiner rejected the claim within the application as obvious based in part on the Hillmen, Evans and Wang references, stating that "Evans teaches antibody 5G1.1, which is the same as eculizumab." Ex. C at 11-14 (Excerpt from the File History of U.S. Patent Application No. 15/148,839, Non-Final Rejection (August 16, 2016) at 1-4).

42. In response to the examiner's rejection, Attorney Sloper affirmatively represented to the USPTO that "the complete structure of eculizumab was not disclosed in the prior art, nor available to the public" prior to March 15, 2007:

> Specifically, prior to the March 15, 2007 effective filing date of the present application, the complete structure of eculizumab was not disclosed in the prior art; nor was it available to the public. Hillmen *et al.* fails to teach any part of the sequence of eculizumab.

Id. at 21-22 (Applicant Remarks (Feb. 15, 2017) at 6-7).

43. On April 4, 2017, the examiner rejected the application in part due to "the extensive number of patent literature and NPL documents . . . indicates that eculizumab was wide-spread and well-known." *Id.* at 26 (Non-Final Rejection (Apr. 4, 2017) at 3).

44. Attorney Sloper affirmatively stated multiple times in her response to this rejection that eculizumab and its sequence were not publicly available:

> and Exhibit H (Rother, US 2009/0028850). However, this is incorrect. Neither eculizumab nor its complete sequence, including the sequence of its unique, non-naturally occurring, protein-engineered heavy chain, was in the public domain prior to the March 15, 2007 effective filing date of the present application, as discussed in detail below. Accordingly, the presently claimed

> Applicants respectfully traverse the rejection. As discussed above, neither eculizumab nor its complete sequence were available to the public or in "public use" prior to the March 15, 2007 effective filing date of the present application. Therefore, the Examiner's underlying

Id. at 41, 45 (Applicant Remarks & Amendment (May 12, 2017) at 3, 8).

45. Due in part to Attorney Sloper's affirmative representation that neither eculizumab nor its complete sequence were in the public domain prior to March 15, 2007, the examiner issued a Notice of Allowance on June 7, 2017. Ex. C at 62-63 (Notice of Allowance (June 7, 2017)).

46. The foregoing material misrepresentations were material to, at least, claim 2 of the '880 Patent, which expressly recites the amino acid sequence of the eculizumab antibody at issue during examination of the '880 Patent. (D.I. 1-1 at 113.)

c. <u>The '504 Patent - Inequitable Conduct by Prosecuting Attorney Sloper and Named Co-Inventor Bell</u>

47. Attorney Sloper filed U.S. Patent Application No. 15/260,888 on September 9, 2016, which issued as the '504 Patent. (D.I. 1-1 (the '504 Patent) at 121 (Complaint, Exhibit G)).

48. As a part of the examination of application No. 15/260,888, the examiner rejected the claims as anticipated and obvious over various printed publications, including the Hillmen, Thomas, and Evans references, stating that "Hillmen and Thomas collectively teach that the 5G1.1 antibody can be used to treat PNH, and [Evans] provides the public with this antibody." Ex. D at 12-17 (Excerpt from the File History of U.S. Patent Application No. 15/260,888, Non-Final Rejection (Dec. 22, 2016) at 1-6).

49. In response to the examiner's rejections, Attorney Sloper responded by stating

"prior to the March 15, 2007 effective filing date of the present application, the complete structure of eculizumab was not disclosed in the prior art; nor was it available to the public":

> Applicants respectfully traverse the rejection. As described in the enclosed Declaration Pursuant to 37 C.F.R. § 1.132 by Dr. Leonard Bell (hereinafter "Declaration"), prior to the March 15, 2007 effective filing date of the present application, the complete structure of eculizumab was not disclosed in the prior art; nor was it available to the public. Specifically,

Id. at 21 (Applicant Remarks (Jan. 19, 2017) at 4). Attorney Sloper also represented:

> In sum, the complete structure of eculizumab was not disclosed prior to the March 15, 2007 effective filing date of the present application. Moreover, as described in the accompanying Declaration, eculizumab was not publicly available prior to March 15, 2007. Therefore, prior to the effective filing date of the present application, the complete structure of eculizumab was neither taught nor suggested in the cited prior art; nor was it obtainable by way of public availability.

Id. at 22 (Applicant Remarks (Jan. 19, 2017) at 5).

50. Attorney Sloper relied on a Declaration from named co-inventor Leonard Bell that bears the date January 18, 2017, which Attorney Sloper submitted to the USPTO during the prosecution of application No. 15/260,888:

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with 37 CFR § 1.6(a)(4).

Dated: January 19, 2017
Electronic Signature for Jill Gorny Sloper, Esq.: /Jill Gorny Sloper, Esq./

Docket No.: AXJ-114BUSCN3 (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Leonard Bell *et al.*

Application No.: 15/260,888

Confirmation No.: 2558

Filed: September 9, 2016

Art Unit: 1644

For: TREATMENT OF PAROXYSMAL NOCTURNAL HEMOGLOBINURIA PATIENTS BY AN INHIBITOR OF COMPLEMENT

Examiner: J. L. Rogers

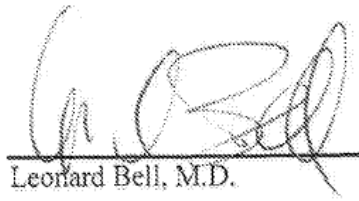
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION PURSUANT TO 37 CFR 1.132 BY DR. LEONARD BELL

Id. at 25-28 (Declaration Pursuant to 37 CFR 1.132 By Dr. Leonard Bell (Jan. 18, 2017)).

51. In this declaration, named co-inventor Bell states that the declaration was made under the penalty of perjury and that he understands "willful false statements may jeopardize the validity of the application or of any patent issued thereon":

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or of any patent issued thereon.



Leonard Bell, M.D.

1/18/2012
Date

Id. at 28.

52. Within the declaration, named co-inventor Bell asserted multiple times that prior to March 15, 2007 the complete structure of eculizumab was not disclosed to the public:

3. Moreover, prior to March 15, 2007, the complete structure of eculizumab was not disclosed to the public. For example, the Hillmen reference (Hillmen et al., N. ENGL. J.

* * *

9. In sum: the complete structure of eculizumab was not available to the public on or before March 15, 2007; eculizumab was not available to the public or being used by the public prior to that time; the unique protein-engineered heavy chain of eculizumab was

Id. at 26, 28.

53. The examiner followed up with a Non-Final Rejection stating in part:

> Applicant's arguments submitted on 1/19/2017 were fully considered but were not considered persuasive.
>
> Applicant has submitted a declaration by Dr. Leonard Bell that prior to March 15, 2007 effective filing date of the present application, the complete structure of eculizumab was not disclosed in the prior art; nor was it available to the public and that Hillmen fails to teach any part of the sequence of eculizumab (p. 4 of the Response).
>
> This argument was not considered persuasive for the following reasons:
>
> The Bell declaration submitted on 1/19/2017 states that clinical trials were conducted "but only under strict control and conditions of confidentiality". However the declaration does not provide any evidence that the experiments conducted in the HILLMEN reference were under any condition of confidentiality, nor does it provide any evidence that the authors of that study were working under the direction of the present inventors.
>
> It remains the examiner's position that there is substantial evidence that eculizumab was in use more than a year before applicant filed for the patent.

Id. at 35 (Non-Final Rejection (Apr. 11, 2017) at 3).

54. Within this non-final rejection, the examiner reminded Attorney Sloper and the named inventors that "the reply to this requirement must be made with candor and good faith under 37 CFR 1.56":

> 9. The applicant is reminded that the reply to this requirement must be made with candor and good faith under 37 CFR 1.56. Where the applicant does not have or cannot readily obtain an item of required information, a statement that the item is unknown or cannot be readily obtained may be accepted as a complete reply to the requirement for that item.

Id. at 40 (Non-Final Rejection (Apr. 11, 2017) at 8).

55. In response to this Office Action, Attorney Sloper again reiterated that "neither eculizumab nor its complete sequence were available to the public of in 'public use' prior to the March 16, 2007 effective filing date of the present application," calling the examiner's reasoning "factually incorrect":

> Applicants respectfully traverse the rejection. As discussed above, neither eculizumab nor its complete sequence were available to the public or in "public use" prior to the March 15, 2007 effective filing date of the present application. Therefore, the Examiner's underlying premise supporting the present obviousness rejection (*i.e.*, that eculizumab was publicly known or used prior to March 15, 2007) is factually incorrect. Moreover, none of Hillmen *et al.*, Thomas *et al.*, Evans *et*

Id. at 53-54 (Applicant Remarks & Amendment (June 13, 2017) at 8-9.)

56. Due in part to Attorney Sloper's and named co-inventor Bell's affirmative representations that neither eculizumab nor its complete sequence were in the public domain prior to March 15, 2007, the examiner issued a Notice of Allowance on June 28, 2017. *Id.* at 57-63 (Notice of Allowance (June 28, 2017)).

57. The foregoing material misrepresentations were material to, at least, claim 1 of the '504 Patent, which expressly recites the amino acid sequence of the eculizumab antibody at issue during examination of the '504 Patent. (D.I. 1-1 at 148.)

d. <u>The '189 Patent- Inequitable Conduct by Prosecuting Attorney Sloper</u>

58. Attorney Sloper filed U.S. Patent Application No. 15/642,096 on July 5, 2017, which issued as the '189 Patent. (D.I. 1-1 (the '189 Patent) at 156 (Complaint, Exhibit H)).

59. As a part of the examination of application No. 15/642,096, the examiner rejected the claims as obvious over various printed publications, including the Hillman, Evans, and Bowdish references, contending that one of ordinary skill in the art would have found it obvious to produce "an antibody identical to currently claimed SEQ ID NO:2 and 4." Ex. E at 13-19 (Excerpt from the File History of U.S. Patent Application No. 15/642,096, Non-Final Rejection (May 31, 2019) at 2-8); Ex. E at 27-34 (Non-Final Rejection (June 11, 2019) at 2-8).

60. In response to the examiner's rejections, Attorney Sloper responded by stating that prior to the March 15, 2007, the sequence of eculizumab was not publicly known or disclosed in

the prior art:

> Prior to March 15, 2007, the priority date of the present application, the unique amino acid sequence of the antibody in Soliris® (eculizumab) recited in the pending claims was not publicly known or disclosed in the prior art. In particular, while a person of ordinary skill in the

Id. at 44 (Applicant Remarks & Amendment (Dec. 11, 2019) at 6); *see id.* at 54 (Applicant Remarks & Amendment (Dec. 11, 2019) at 16).

61. Attorney Sloper also misleadingly pointed the USPTO to look at the Thomas reference to determine the structure of eculizumab, even though the Thomas reference discloses an IgG4 antibody, when eculizumab is an IgG2/IgG4 antibody as disclosed in other prior art references, such as Tacken (see Ex. H). Ex. E at 44 (Applicant Remarks & Amendment (Dec. 11, 2019) at 6).

62. Due in part to Attorney Sloper's affirmative representation that neither eculizumab nor its complete sequence were in the public domain prior to March 15, 2007, the examiner issued a Notice of Allowance on January 22, 2020. *Id.* at 71-73 (Notice of Allowance (Jan. 22, 2020)).

63. The foregoing material misrepresentations were material to, at least, claim 1 of the '189 Patent, which expressly recites the amino acid sequence of the eculizumab antibody at issue during examination of the '189 Patent. (D.I. 1-1 at 187.)

e. <u>The '809 Patent - Inequitable Conduct by Prosecuting Attorney Sloper</u>

64. Attorney Sloper filed U.S. Patent Application No. 16/804,567 on February 28, 2020, which issued as the '809 Patent. (D.I. 1-1 (the '809 Patent) at 189 (Complaint, Exhibit I)).

65. The examiner rejected the application on the basis of non-statutory double patenting over applications that issued as the remaining PNH Patents, including the '149 Patent, '880 Patent, '504 Patent, and '189 Patent, as well as various other Alexion patents and patent applications. Ex.

F at 14-19 (Excerpt from the File History of U.S. Patent Application No. 16/804,567, Non-Final Rejection (Apr. 20, 2020) at 3-8).

66. In response, Attorney Sloper filed a request for a terminal disclaimer over the '149 Patent, '880 Patent, '504 Patent, and '189 Patent, as well as the other related patents and patent applications discussed in the examiner's Non-Final Rejection. *Id.* at 48-50 (Terminal Disclaimer (Apr. 27, 2020)); *id.* at 59 (Applicant Remarks & Amendment (Apr. 27, 2020) at 6).

67. Attorney Sloper's terminal disclaimer was accepted by the USPTO on May 5, 2020 and filed on May 5, 2020. *Id.* at 73 (Terminal Disclaimer Review Decision (May 5, 2020)).

68. The '809 Patent is a continuation stemming from the '149 Patent, '504 Patent, '880 Patent, and the '189 Patent, as shown on the face of the '809 Patent below:

Related U.S. Application Data

Continuation of application No. 16/750,978, filed on Jan. 23, 2020, which is a continuation of application No. 15/642,096, filed on Jul. 5, 2017, now Pat. No. 10,590,189, which is a continuation of application No. 15/284,015, filed on Oct. 3, 2016, now Pat. No. 9,732,149, which is a continuation of application No. 15/260,888, filed on Sep. 9, 2016, now Pat. No. 9,725,504, which is a continuation of application No. 15/148,839, filed on May 6, 2016, now Pat. No. 9,718,880, which is a continuation of application No. 13/426,973, filed on Mar. 22, 2012, now abandoned, which is a continuation of application No. 12/225,040, filed as application No. PCT/US2007/006606 on Mar. 15, 2007, now abandoned.

(D.I. 1-1 at 189.)

69. The '809 Patent's specification is substantively identical to that of the '149 Patent, '504 Patent, '880 Patent, and the '189 Patent. (*See generally* D.I. 1-1 at 86-221.)

70. All of the PNH Patents include claims that recite the amino acid sequence of the eculizumab antibody. (*See id.*)

71. For example, the '809 Patent, claim 1 states:

> 1. A method of treating a patient having paroxysmal nocturnal hemoglobinuria (PNH), wherein the method comprises intravenously administering to the patient an antibody that binds C5, wherein the antibody comprises a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4.

(D.I. 1-1 at 221 (claim 1)). Claim 1 of the '189 Patent similarly covers the method of treating PNH with an antibody of the same sequence:

> 1. A method of treating a patient suffering from paroxysmal nocturnal hemoglobinuria (PNH) comprising administering to the patient a pharmaceutical composition comprising an antibody that binds C5, wherein the antibody comprises a heavy chain consisting of SEQ ID NO: 2 and a light chain consisting of SEQ ID NO: 4, and wherein the composition comprises a single-unit dosage form comprising 300 mg of the antibody in 30 mL of a sterile, preservative-free solution.

(D.I. 1-1 at 187 (claim 1).)

72. And each of the PNH Patents were examined by the same two Examiners, primary examiner, Daniel E. Kolker, and assistant examiner, James Rogers. (D.I. 1-1 at 53, 86, 121, 156, 189.)

73. Thus, Attorney Sloper's affirmative representations in the related PNH Patents are of an immediate and necessary relation to the claims of the '809 Patent.

74. Due in part to Attorney Sloper's affirmative representations in the related PNH Patents that neither eculizumab nor its complete sequence were in the public domain prior to March 15, 2007, the examiner issued a Notice of Allowance on January 22, 2020. Ex. F at 74-80 (Notice of Allowance (Jan. 22, 2020)).

75. The material misrepresentations within the prosecution of the remaining PNH Patents were material to, at least, claim 1 of the '809 Patent, which expressly recites the amino acid sequence of the eculizumab antibody at issue during examination of the '809 Patent. (D.I. 1-1 at 221).

f. Allegations Pertaining to All PNH Patents

76. On information and belief, Attorney Sloper and named co-inventor Bell knowingly and willingly made false and misleading statements and misrepresented material facts to secure the PNH Patents, as set forth above.

77. Inequitable conduct by Attorney Sloper and named co-inventor Bell during the prosecution of each of the PNH Patents was directly material to patentability, as shown in part by the Examiner's rejections and notice of Allowance, and directly led to issuance of each of the PNH Patents.

78. The materiality of misrepresentations by Attorney Sloper and named co-inventor Bell is further shown by the decision of the European Patent Office ("EPO") regarding a counterpart European patent application to the PNH Patents, in which the EPO refused to grant the application, in part based on its conclusion that "[e]culizumab is considered to have been available to the public before the filing date of the present application." Ex. G at 13 (Excerpt of File History for European Patent No. 3 167 888 at 1444).

79. On information and belief, Attorney Sloper during the prosecution of each of the PNH Patents, and named co-inventor Bell during prosecution of the '504 patent, knowingly and intentionally misrepresented to the USPTO that eculizumab and its complete sequence were not in the public domain prior to the March 15, 2007 effective filing date.

80. On information and belief, Attorney Sloper, as a patent attorney representing Alexion and Alexion's agent, would have been aware of the ongoing prosecution of Alexion's patent portfolio pertaining to equivalent subject matter to the PNH patents in other patent jurisdictions, such as the EPO.

81. Indeed, Attorney Sloper was aware of the EP 1 720 571 application as well as of there being opposition proceedings related to EP 1 720 571 (which subsequently issued as

European Patent No. 3 167 888). This is evidenced by the PNH Patents, each of which contain one or more references to the EP 1 720 571 application or an opposition thereof on their face. (D.I. 1-1 at 55, 87, 89, 122-124, 157-58, 160-61, 190, 194-96.).

82. The submission of knowingly false and misleading statements, like those contained in remarks by Attorney Sloper and named co-inventor Bell in response to rejections from the USPTO, is, on its own, inherently material to the patent prosecution process and constitutes egregious misconduct.

83. Further, deceptive intent is the single most reasonable inference to be drawn in light of the foregoing allegations, because of the intent to counter the Examiner's rejections and falsely represent that the sequence of eculizumab was not in the public domain as of March 15, 2007.

84. The PNH Patents are unenforceable because Attorney Sloper and named co-inventor Bell breached their duty of candor and good faith to the USPTO during the prosecution of the PNH Patents by submitting false and misleading statements and misrepresenting material facts with an intent to deceive the USPTO, thereby committing inequitable conduct.

D. The '149 Patent, '880 Patent, and '504 Patent Are Unenforceable Due to Failure to Disclose the Tacken and Mueller PCT Prior Art References

85. The claims of the '149 Patent, '880 Patent, and '504 Patent are unenforceable by reason of at least prosecuting attorney Jill Gorny Sloper and named co-inventors Russell P. Rother's and Mark Evans' inequitable conduct by failing to disclose material prior art references, Tacken and Mueller PCT, during the prosecution of the applications that issued as the '149 Patent, '880 Patent, and '504 Patent.

86. As described above, Attorney Sloper filed each of the applications that issued as the '149 Patent, '880 Patent, and '504 Patent.

87. 37 C.F.R. § 1.56 states in part "[e]ach individual associated with the filing and

prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section."

88. Attorney Sloper and co-inventors Mark J. Evans and Russell P. Rother had a duty to disclose to the USPTO all information known to that individual to be material to patentability, including prior art references, during the prosecution of the '149 Patent, '880 Patent, and '504 Patent.

89. Tacken is an article entitled *Effective induction of naïve and recall T-cell responses by targeting antigen to human dendritic cells via a humanized anti-DC-SIGN antibody* that was published online in *Blood* as a first edition paper on May 5, 2005. Ex. H. Therefore, Tacken is undisputed prior art to the '149 Patent, '880 Patent, and '504 Patent that Alexion asserts have an effective filing date of March 15, 2007.

90. The listed authors of the Tacken reference include Russell P. Rother, a named co-inventor on the '149 Patent, '880 Patent, and '504 Patent. Accordingly, named co-inventor Rother had knowledge of the Tacken reference at least as of the date of its publication in 2005.

91. The Mueller PCT is PCT Application No. WO 97/11,971 assigned to Alexion Pharmaceuticals Inc. Ex. I.

92. The listed co-inventors of the Mueller PCT reference include Mark J. Evans and Russell P. Rother, named co-inventors of the '149 Patent, '880 Patent, and '504 Patent. *Id.* Accordingly, named co-inventors Rother and Evans had knowledge of the Mueller PCT reference at least as of the date of its publication in 1997.

93. Neither Tacken nor the Mueller PCT were disclosed to the USPTO during the prosecution of the applications that issued as the '149 Patent, '880 Patent, and '504 Patent. (*See*

D.I. 1-1 at 53-56, 86-89, 121-24.)

94. Tacken and the Mueller PCT are both but-for material to the patentability of the applications that issued as the '149 Patent, '880 Patent, and '504 Patent. Neither reference is cumulative to the prior art of record in each of those patents.

95. For example, Tacken discloses that "h5G1.1-mAb" is "eculizamab [sic]" and that h5G1.1-mAb contains the "human hybrid IgG2/IgG4 constant domain." Ex. H at 3. This is directly material to the constant regions of SEQ ID NOS:2 and 4 that are recited in, at least, Claim 1 of the '149 Patent, Claim 2 of the '880 Patent, and Claim 1 of the '504 Patent.

96. For example, Mueller PCT refers to antibodies with this IgG2/G4 constant region as "HuG2/G4 mAb" and describes using "h5G1.1 CO12 HuG2/G4 mAb." Ex. H at 15-16. Mueller PCT discloses the exact amino acid sequences for the constant regions of SEQ ID NOS: 2 and 4 that are recited in, at least, Claim 1 of the '149 Patent, Claim 2 of the '880 Patent, and Claim 1 of the '504 Patent, and thus Mueller PCT is directly material to the patentability of those claims.

97. Further, the Patent Trademark and Appeal Board's decisions to institute *inter partes* review petitions challenging the '149 Patent, '880 Patent, and '504 Patent, each based in part on the Tacken and Mueller PCT references, are evidence of the but-for materiality of Tacken and the Mueller PCT. Ex. J (IPR2023-00933 ('149 Patent) Institution Decision); Ex. K (IPR2023-00998 ('880 Patent) Institution Decision); Ex. L (IPR2023-00999 ('504 Patent) Institution Decision).

98. Materiality of the disclosures of the Tacken and Mueller PCT references is further shown by the contradictory statements made by prosecuting attorneys on behalf of Alexion in other proceedings for the USPTO. For example, attorneys representing Alexion in other USPTO proceedings stated "it was well-known to one of ordinary skill in the art [as of 2002] that eculizumab has a G2/G4 Fc portion, i.e., a mutated Fc portion" and that "h5G1.1 … [was] well-

known to one of ordinary skill in the art as eculizumab." Ex. M at 11-12 (Excerpt from the File History for U.S. Patent Application No. 11/127,438, Applicant Remarks & Amendment (Aug. 2, 2011) at 10-11).

99. Yet, in contradiction to this, Attorney Sloper falsely contended during prosecution of the PNH Patents that "[T]he literature as of March 15, 2007 . . . consistently identified 'eculizumab' as the antibody described in the 'Thomas' publication, … which has a naturally-occurring 'IgG4' heavy chain constant region. Accordingly, a person of ordinary skill in the art as of March 15, 2007 would have had no doubt that 'eculizumab' was Thomas's IgG4-isotype humanized antibody, because the pertinent literature consistently and unambiguously said so." Ex. E at 44 (Excerpt from the File History of U.S. Patent Application No. 15/642,096, Applicant Remarks & Amendment (Dec. 11, 2019) at 6).

100. On information and belief, co-inventors Evans and Rother as well as Attorney Sloper's failure to disclose the Tacken and Mueller PCT applications was deliberate and intentional.

101. Deceptive intent is the single most reasonable inference to be drawn in light of the foregoing allegations, at least in part as shown by the contradictory statements made regarding the sequence identity of the eculizumab heavy chain constant region during patent prosecution in which the issue of public knowledge of the sequence of eculizumab was the primary issue as discussed above.

COUNT I: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF PATENT NO. 9,732,149

102. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

103. There is an actual, substantial, and continuing justiciable case or controversy

between Samsung Bioepis and Counterclaim Defendants regarding whether the filing of Samsung Bioepis's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of SB12 infringes, has infringed, or will infringe any valid and enforceable claim of the '149 patent either directly, indirectly, literally, or under the doctrine of equivalents.

104. Samsung Bioepis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '149 patent either literally or under the doctrine of equivalents.

105. Additionally, the claims of the '149 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112. By way of non-limiting example, the claims of the '149 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least the following references, alone and/or in combination: Bowdish, Evans, Bell, Tacken, and/or Mueller PCT. Because one cannot infringe an invalid claim, the claims of the '149 patent are not infringed directly, indirectly, literally, or under the doctrine of equivalents.

106. Samsung Bioepis is entitled to a declaratory judgment that the submission of Samsung Bioepis's BLA and the making, using, offering to sell, selling, and/or importing of SB12 has not, does not, and will not infringe any valid and enforceable claim of the '149 patent.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF PATENT NO. 9,732,149

107. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

108. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding the invalidity of the '149 patent, based on Counterclaim Defendants' allegation in its Complaint that Samsung Bioepis has

infringed or will infringe the ’149 patent.

109. The claims of the ’149 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112. By way of non-limiting example, the claims of the ’149 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least the following references, alone and/or in combination: Bowdish, Evans, Bell, Tacken, and/or Mueller PCT.

110. Samsung Bioepis is entitled to a judicial declaration that all claims of the ’149 patent are invalid.

COUNT III: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF PATENT NO. 9,718,880

111. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

112. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding whether the filing of Samsung Bioepis’s BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of SB12 infringes, has infringed, or will infringe any valid and enforceable claim of the ’880 patent either directly, indirectly, literally, or under the doctrine of equivalents.

113. Samsung Bioepis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’880 patent either literally or under the doctrine of equivalents.

114. Additionally, the claims of the ’880 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112. By way of non-limiting example, the claims of the ’880 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least the

following references, alone and/or in combination: Bowdish, Evans, Bell, Tacken, Wang, and/or Mueller PCT. Because one cannot infringe an invalid claim, the claims of the '880 patent are not infringed directly, indirectly, literally, or under the doctrine of equivalents.

115. Samsung Bioepis is entitled to a declaratory judgment that the submission of Samsung Bioepis's BLA and the making, using, offering to sell, selling, and/or importing of SB12 has not, does not, and will not infringe any valid and enforceable claim of the '880 patent.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF PATENT NO. 9,718,880

116. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

117. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding the invalidity of the '880 patent, based on Counterclaim Defendants' allegation in its Complaint that Samsung Bioepis has infringed or will infringe the '880 patent.

118. The claims of the '880 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112. By way of non-limiting example, the claims of the '880 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least the following references, alone and/or in combination: Bowdish, Evans, Bell, Tacken, Wang, and/or Mueller PCT.

119. Samsung Bioepis is entitled to a judicial declaration that all claims of the '880 patent are invalid.

COUNT V: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF PATENT NO. 9,725,504

120. Samsung Bioepis incorporates by reference and realleges the allegations set forth

in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

121. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding whether the filing of Samsung Bioepis's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of SB12 infringes, has infringed, or will infringe any valid and enforceable claim of the '504 patent either directly, indirectly, literally, or under the doctrine of equivalents.

122. Samsung Bioepis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '504 patent either literally or under the doctrine of equivalents.

123. Additionally, the claims of the '504 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112. By way of non-limiting example, the claims of the '504 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least the following references, alone and/or in combination: Bowdish, Evans, Bell, Tacken, Wang, and/or Mueller PCT. Because one cannot infringe an invalid claim, the claims of the '504 patent are not infringed directly, indirectly, literally, or under the doctrine of equivalents.

124. Samsung Bioepis is entitled to a declaratory judgment that the submission of Samsung Bioepis's BLA and the making, using, offering to sell, selling, and/or importing of SB12 has not, does not, and will not infringe any valid and enforceable claim of the '504 patent.

COUNT VI: DECLARATORY JUDGMENT OF INVALIDITY OF PATENT NO. 9,725,504

125. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

126. There is an actual, substantial, and continuing justiciable case or controversy

between Samsung Bioepis and Counterclaim Defendants regarding the invalidity of the '504 patent, based on Counterclaim Defendants' allegation in its Complaint that Samsung Bioepis has infringed or will infringe the '504 patent.

127. The claims of the '504 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112. By way of non-limiting example, the claims of the '504 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least the following references, alone and/or in combination: Bowdish, Evans, Bell, Tacken, Wang, and/or Mueller PCT.

128. Samsung Bioepis is entitled to a judicial declaration that all claims of the '504 patent are invalid.

COUNT VII: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF PATENT NO. 10,590,189

129. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

130. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding whether the filing of Samsung Bioepis's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of SB12 infringes, has infringed, or will infringe any valid and enforceable claim of the '189 patent either directly, indirectly, literally, or under the doctrine of equivalents.

131. Samsung Bioepis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '189 patent either literally or under the doctrine of equivalents.

132. Additionally, the claims of the '189 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code,

including but not limited to §§ 101, 102, 103, and/or 112. By way of non-limiting example, the claims of the '189 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least the following references, alone and/or in combination: Bowdish, Evans, Bell, Tacken, Wang, and/or Mueller PCT. Because one cannot infringe an invalid claim, the claims of the '189 patent are not infringed directly, indirectly, literally, or under the doctrine of equivalents.

133. Samsung Bioepis is entitled to a declaratory judgment that the submission of Samsung Bioepis's BLA and the making, using, offering to sell, selling, and/or importing of SB12 has not, does not, and will not infringe any valid and enforceable claim of the '189 patent.

COUNT VIII: DECLARATORY JUDGMENT OF INVALIDITY OF PATENT NO. 10,590,189

134. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

135. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding the invalidity of the '189 patent, based on Counterclaim Defendants' allegation in its Complaint that Samsung Bioepis has infringed or will infringe the '189 patent.

136. The claims of the '189 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112. By way of non-limiting example, the claims of the '189 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least the following references, alone and/or in combination: Bowdish, Evans, Bell, Tacken, Wang, and/or Mueller PCT.

137. Samsung Bioepis is entitled to a judicial declaration that all claims of the '189 patent are invalid.

COUNT IX: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF PATENT NO. 10,703,809

138. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

139. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding whether the filing of Samsung Bioepis's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of SB12 infringes, has infringed, or will infringe any valid and enforceable claim of the '809 patent either directly, indirectly, literally, or under the doctrine of equivalents.

140. Samsung Bioepis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '809 patent either literally or under the doctrine of equivalents.

141. Additionally, the claims of the '809 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112. By way of non-limiting example, the claims of the '809 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least the following references, alone and/or in combination: Bowdish, Evans, Bell, Tacken, Wang, Mueller PCT, Hillmen, Hill, and/or Brown. Because one cannot infringe an invalid claim, the claims of the '809 patent are not infringed directly, indirectly, literally, or under the doctrine of equivalents.

142. Samsung Bioepis is entitled to a declaratory judgment that the submission of Samsung Bioepis's BLA and the making, using, offering to sell, selling, and/or importing of SB12 has not, does not, and will not infringe any valid and enforceable claim of the '809 patent.

COUNT X: DECLARATORY JUDGMENT OF INVALIDITY OF PATENT NO. 10,703,809

143. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

144. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding the invalidity of the '809 patent, based on Counterclaim Defendants' allegation in its Complaint that Samsung Bioepis has infringed or will infringe the '809 patent.

145. The claims of the '809 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112. By way of non-limiting example, the claims of the '809 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of at least the following references, alone and/or in combination: Bowdish, Evans, Bell, Tacken, Wang, Mueller PCT, Hillmen, Hill, and/or Brown.

146. Samsung Bioepis is entitled to a judicial declaration that all claims of the '809 patent are invalid.

COUNT XI: DECLARATORY JUDGMENT OF NONINFRINGEMENT OF PATENT NO. 9,447,176

147. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

148. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding whether the filing of Samsung Bioepis's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of SB12 infringes, has infringed, or will infringe any valid and enforceable claim of the '176

patent either directly, indirectly, literally, or under the doctrine of equivalents.

149. Samsung Bioepis has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '176 patent either literally or under the doctrine of equivalents.

150. Additionally, the claims of the '176 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112. Because one cannot infringe an invalid claim, the claims of the '176 patent are not infringed directly, indirectly, literally, or under the doctrine of equivalents.

151. Samsung Bioepis is entitled to a declaratory judgment that the submission of Samsung Bioepis's BLA and the making, using, offering to sell, selling, and/or importing of SB12 has not, does not, and will not infringe any valid and enforceable claim of the '176 patent.

COUNT XII: DECLARATORY JUDGMENT OF INVALIDITY OF PATENT NO. 9,447,176

152. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

153. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding the invalidity of the '176 patent, based on Counterclaim Defendants' allegation in its Complaint that Samsung Bioepis has infringed or will infringe the '176 patent.

154. The claims of the '176 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, and/or 112.

155. Samsung Bioepis is entitled to a judicial declaration that all claims of the '176

patent are invalid.

COUNT XIII: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF PATENT NO. 9,732,149

156. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

157. The '149 patent is unenforceable due to the inequitable conduct during the prosecution of the '149 patent with the intent to deceive the USPTO, as detailed in paragraphs 24-101, inclusive, above.

158. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding the unenforceability of the '149 patent based on Counterclaim Defendants' allegation in its Complaint that Samsung Bioepis has infringed or will infringe the '149 patent.

159. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*, Samsung Bioepis requests a declaration from the Court that the '149 patent is unenforceable due to inequitable conduct.

COUNT XIV: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF PATENT NO. 9,718,880

160. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

161. The '880 patent is unenforceable due to the inequitable conduct during the prosecution of the '880 patent and '149 patent with the intent to deceive the USPTO, as detailed in paragraphs 24-101, inclusive, above.

162. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding the unenforceability of the '880 patent based on Counterclaim Defendants' allegation in its Complaint that Samsung Bioepis

has infringed or will infringe the ’149 patent, ’880 patent, and ’504 patent.

163. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*, Samsung Bioepis requests a declaration from the Court that the ’880 patent is unenforceable due to inequitable conduct.

COUNT XV: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF PATENT NO. 9,725,504

164. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

165. The ’504 patent is unenforceable due to the inequitable conduct during the prosecution of the ’504 patent, ’880 patent, and ’149 patent with the intent to deceive the USPTO, as detailed in paragraphs 24-101, inclusive, above.

166. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding the unenforceability of the ’504 patent, based on Counterclaim Defendants’ allegation in its Complaint that Samsung Bioepis has infringed or will infringe the ’504 patent.

167. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*, Samsung Bioepis requests a declaration from the Court that the ’504 patent is unenforceable due to inequitable conduct.

COUNT XVI: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF PATENT NO. 10,590,189

168. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

169. The ’189 patent is unenforceable due to the inequitable conduct during the prosecution of the ’189 patent, ’504 patent, ’880 patent, and ’149 patent with the intent to deceive the USPTO, as detailed in paragraphs 24-101, inclusive, above.

170. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding the unenforceability of the '189 patent, based on Counterclaim Defendants' allegation in its Complaint that Samsung Bioepis has infringed or will infringe the '189 patent.

171. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*, Samsung Bioepis requests a declaration from the Court that the '189 patent is unenforceable due to inequitable conduct.

COUNT XVII: DECLARATORY JUDGMENT OF UNENFORCEABILITY OF PATENT NO. 10,703,809

172. Samsung Bioepis incorporates by reference and realleges the allegations set forth in the preceding Paragraphs of its Counterclaims as if fully set forth herein.

173. The '189 patent is unenforceable due to the inequitable conduct during the prosecution of the '189 patent, '504 patent, '880 patent, and '149 patent with the intent to deceive the USPTO, as detailed in paragraphs 24-101, inclusive, above.

174. There is an actual, substantial, and continuing justiciable case or controversy between Samsung Bioepis and Counterclaim Defendants regarding the unenforceability of the '809 patent based on Counterclaim Defendants' allegation in its Complaint that Samsung Bioepis has infringed or will infringe the'809 patent.

175. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*, Samsung Bioepis requests a declaration from the Court that the '809 patent is unenforceable due to inequitable conduct.

PRAYER FOR RELIEF

WHEREFORE, Samsung Bioepis respectfully requests that this Court enter a Judgment and Order against Counterclaim Defendants as follows:

A. Dismissing Counterclaim Defendants' Complaint with prejudice;

B. Entering a judgment and declaration that Samsung Bioepis has not, does not, and will not infringe any valid and enforceable claim of United States Patent Nos. 9,732,149; 9,718,880; 9,725,504; 10,590,189; 10,703,809; and 9,447,176;

C. Entering a judgment and declaration that one or more claims of United States Patent Nos. 9,732,149; 9,718,880; 9,725,504; 10,590,189; 10,703,809; and 9,447,176 are invalid;

D. Entering a judgment and declaration that one or more claims of United States Patent Nos. 9,732,149; 9,718,880; 9,725,504; 10,590,189; and 10,703,809 are unenforceable;

E. Entering a judgment that this is an exceptional case and an award of reasonable attorney's fees pursuant to 35 U.S.C. § 285;

F. Awarding Samsung Bioepis its costs and expenses; and

G. Granting such other relief as the Court deems just and proper.

JURY DEMAND

Samsung Bioepis, by and through its undersigned counsel, hereby demands, pursuant to Fed. R. Civ. P. 38, a trial by jury on all claims so triable in this action.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ James L. Higgins

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**Pro hac vice* admission to be filed

Dated: February 8, 2024

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