IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALEXION PHARMACEUTICALS, INC. and ALEXION PHARMA INTERNATIONAL OPERATIONS LTD., Plaintiffs, v. SAMSUNG BIOEPIS CO. LTD., Defendant.	)	C.A. No. _____

COMPLAINT

Plaintiffs Alexion Pharmaceuticals, Inc. and Alexion Pharma International Operations Ltd. (collectively, "Alexion"), for their Complaint against Defendant Samsung Bioepis Co. Ltd. ("Samsung"), hereby allege as follows:

NATURE OF THE ACTION

1. This civil action arises under the Patent Laws of the United States, 35 U.S.C. §§ 1, *et seq.*, including 35 U.S.C. § 271(a)-(c) & (e), the Biologics Price Competition and Innovation Action ("BPCIA"), including 42 U.S.C. § 262(*l*), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

2. This lawsuit results from Samsung's planned and/or ongoing manufacture, use, offer to sell, sale, and import/export of its biosimilar to SOLIRIS® (eculizumab), called SB12, which will infringe, either literally or under the doctrine of equivalents, 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. On information and belief, on or before July 7, 2023, the Food and Drug Administration ("FDA") accepted for review Samsung's abbreviated Biologics License Application ("aBLA"), which seeks authorization from the FDA to make and sell SB12. Samsung submitted that aBLA pursuant to the BPCIA, specifically 42 U.S.C. § 262(k) (also known as Section 351(k) of the Public Health Service Act).

4. As alleged herein, Samsung has infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(C)(ii) by submitting its aBLA seeking FDA approval to engage in the commercial manufacture, use, or sale of SB12 before the expiration of the Asserted Patents.

5. As alleged herein, Samsung would also infringe one or more claims of the Asserted Patents, under 35 U.S.C. § 271(a), (b), and/or (c), should it make, use, offer for sale, or sell within the United States, or import into the United States, Samsung's SB12 eculizumab biosimilar product, or actively induce another to do the same before the expiration of the Asserted Patents.

PARTIES

6. Alexion Pharmaceuticals, Inc. ("API") is a Delaware corporation with its principal place of business at 121 Seaport Boulevard, Boston, MA. API holds the legal title to the Asserted Patents.

7. Alexion Pharma International Operations Limited ("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. APIO is the sole beneficial owner of the economic rights to the Asserted Patents via an exclusive license to patents and applications owned by API.

8. Upon information and belief, Samsung is a corporation organized and existing under the laws of South Korea, with its principal place of business at 107, Cheomdan-daero Yeonsu-gu Incheon, 406-840 South Korea.

9. Upon information and belief, Samsung develops, manufactures, and seeks regulatory approval for biosimilar products, and imports, markets, distributes, offers to sell, and/or sells those biosimilar products in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

10. This action for patent infringement arises under the patent laws of the United States, Title 35 of the United States Code, Title 42 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. Accordingly, the Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Samsung because Samsung, through its aBLA, seeks FDA approval to sell SB12 throughout the United States, including in the State of Delaware.

12. On information and belief, Samsung, by itself or through others, intends to use, induce others to use, offer for sale, sell within the United States, and import into the United States, including the District of Delaware, SB12.

13. This Court also has personal jurisdiction over Samsung by virtue of Samsung's contacts with Delaware and the exercise of such personal jurisdiction is fair and reasonable. Litigating this suit in Delaware does not burden Samsung. For example, Samsung did not contest personal jurisdiction when sued by Genentech in another patent case in this district. *Genentech, Inc. v. Samsung Bioepis Co., Ltd.*, No. 18-1363-CFC (D. Del. 2018), D.I. 66 at ¶ 18.

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

15. Venue is proper in this District under 28 U.S.C. § 1391(c)(3). Samsung is a foreign corporation and is therefore subject to suit in any judicial district. *Brunette Machine Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706, 713-14 (1972); *In re HTC Corp.*, 889 F.3d 1349, 1357-58 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 1271 (2019). Further, on information and belief, Samsung has regularly and systematically transacted business in Delaware and through its intended launch will commit acts of patent infringement in Delaware.

SOLIRIS®

16. Alexion's branded biologic product, SOLIRIS®, contains a non-naturally occurring, uniquely-engineered humanized antibody, eculizumab, that works by binding with high "affinity" (*i.e.*, tightness) and "specificity" (*i.e.*, directed to a single antigen) to the human protein "C5," a key component of the complement pathway. Without SOLIRIS® treatment, the body naturally cleaves C5 into components "C5a" and "C5b," which lead to downstream effects of the complement pathway, including hemolysis in patients with paroxysmal nocturnal hemoglobinuria ("PNH"). When SOLIRIS® is administered it binds to a critical location ("epitope") on C5 with sufficient affinity and specificity to prevent cleavage of C5, thus blocking the effects of the complement pathway and sparing PNH patients' red blood cells from destruction.

17. SOLIRIS® first received FDA approval in 2007 for use in treating PNH, and since then, based on extensive clinical testing by Alexion, it is now also approved to treat atypical hemolytic uremic syndrome (aHUS), generalized myasthenia gravis (gMG), and neuromyelitis optica spectrum disorder (NMOSD).

18. Alexion's innovative work in developing eculizumab has been rewarded with patents covering the antibody itself, pharmaceutical compositions of the antibody, and methods for its therapeutic use, among others.

SB12: SAMSUNG'S ECULIZUMAB BIOSIMILAR PRODUCT

19. On information and belief, Samsung has developed a proposed biosimilar to Alexion's SOLIRIS® product, called SB12. Samsung has publicly described SB12 as "a proposed biosimilar to Soliris (eculizumab)." Ex. A.

20. On August 7, 2019, Samsung initiated a Phase 3 study evaluating the efficacy and safety of SB12 compared with SOLIRIS®. *See* Ex. B. Samsung publicly stated that this Phase 3 study "demonstrated clinical equivalence in efficacy, safety, pharmacokinetics (PK), and immunogenicity of SB12 compared to reference eculizumab in paroxysmal nocturnal hemoglobinuria (PNH) patients." *See* Ex. A.

SAMSUNG'S aBLA

21. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval to market in the United States a biosimilar version of Alexion's SOLIRIS® product.

22. On information and belief, the FDA has not yet approved Samsung's aBLA for its proposed SB12 biosimilar product. *See* Ex. C.

23. On July 7, 2023, Samsung's counsel wrote to counsel for Alexion to provide notice of commercial marketing of Samsung's SB12 biosimilar product pursuant to 42 U.S.C. § 262(*l*)(8)(A).

24. Samsung's Notice of Commercial Marketing further supports that Samsung has submitted its aBLA to the FDA, since Samsung informed Alexion that it provided notice

"[p]ursuant to 42 U.S.C. § 262(*l*)(8)(A)." Ex. C. The cited statutory section, 42 U.S.C. § 262(*l*)(8)(A), provides that '[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…." (emphasis added). By providing notice "pursuant to" § 262(*l*)(8)(A), Samsung confirms it is a "subsection (k) applicant"—*i.e.*, an applicant that submitted an aBLA under 42 U.S.C. § 262(k).

25. In its July 7, 2023 letter, Samsung stated it "does not intend to provide Alexion Samsung's aBLA application and manufacturing information under 42 U.S.C. § 262(*l*)(2)(A)." *See* Ex. C.

26. Samsung's submission of an aBLA is an act of infringement under the BPCIA. 35 U.S.C. § 271(e)(2)(C)(ii). Because Samsung has refused to provide its aBLA, Alexion has identified patents that "could be identified pursuant to section 351(l)(3)(A)(i)." 35 U.S.C. § 271(e)(2)(C)(ii); *Sandoz Inc.* v. *Amgen Inc.*, 137 S. Ct. 1664, 1674–75 (2017) (clause (ii) of § 271(e)(2)(C) "provides that submission of the application represents an act of artificial infringement with respect to any patent that *could* have been included" had the parties proceeded through the clause (i) list exchange process).

27. Based on Samsung's statement of intent not to disclose its aBLA, the BPCIA also authorizes Alexion to "bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of *any patent that claims the biological product or a use of the biological product*." 42 U.S.C. § 262(*l*)(9)(C) (emphasis added).

SAMSUNG'S NOTICE OF COMMERCIAL MARKETING

28. On July 7, 2023, Samsung provided its 180-day notice of commercial marketing to Alexion, stating:

> 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).

> The SB12 drug product is a biosimilar of SOLIRIS®, which as you know is covered by Biologics License Application No. 125166. This notice is provided not later than 180 days before the date of the first commercial marketing Samsung's SB12 drug product. 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 does not intend to provide Alexion the application and manufacturing information under 42 U.S.C. § (l)(2)(A).

Ex. C.

29. This notice signals Samsung's intent to begin marketing and selling SB12 for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS) promptly upon receiving FDA approval to do so. *See* Ex. C.

30. Further, Samsung's intention to launch its SB12 biosimilar product presents a controversy of sufficient immediacy to support declaratory judgment of patent infringement under 35 U.S.C. § 271(a)-(c) and (e).

31. On information and belief, the FDA's approval of Samsung's aBLA is imminent. Unlike the Hatch-Waxman Act, filing a lawsuit under the BPCIA does not trigger an automatic 30-month stay of FDA approval for the biosimilar. Instead, the FDA approval process continues regardless of any patent infringement. The FDA has expressed its intention to "[r]eview and act on 90 percent of original biosimilar biological product application submissions within 10 months of the 60 day filing date." Ex. D at 4. Although Samsung has refused to disclose its aBLA filing date, "Samsung expects to receive FDA approval in the first half of 2024." Ex. C.

32. Samsung's submission of its aBLA, combined with its stated intention to begin commercial manufacture, use, sale, offers for sale, and/or importation of SB12 promptly upon receiving FDA approval to do so, creates an actual, immediate, and real controversy within the

Declaratory Judgment Act that Samsung will infringe one or more claims of the Asserted Patents, literally or under the doctrine of equivalents.

33. As set forth below, Samsung's SB12 biosimilar product will infringe Alexion's patents, including at least the Asserted Patents, either literally or under the doctrine of equivalents. *See* 35 U.S.C. §§ 271 (a)-(c) & (e).

34. These facts show that there is substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

ALEXION'S ASSERTED PATENTS

35. In the course of developing SOLIRIS®, Alexion obtained patents related to eculizumab (the non-naturally occurring, uniquely-engineered humanized antibody that is the active compound in SOLIRIS®), compositions containing eculizumab, and methods for its therapeutic use.

The '149 Patent

36. The '149 patent is titled "Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement," and was duly and legally issued on August 15, 2017. A true and correct copy of the '149 patent is attached hereto as Ex. E. Alexion is the legal title holder by assignment of the '149 patent. Broadly speaking, the '149 patent is directed to and claims the non-naturally occurring, uniquely-engineered humanized antibody, eculizumab, the active ingredient in SOLIRIS®. The '149 patent includes one claim. Claim 1 recites:

> 1. 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 ’880 Patent

37. The ’880 patent is titled “Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement,” and was duly and legally issued on August 1, 2017. A true and correct copy of the ’880 patent is attached hereto as Ex. F. Alexion is the legal title holder by assignment of the ’880 patent. In general, the ’880 patent is directed to and claims pharmaceutical compositions of eculizumab, the antibody that is the active ingredient in SOLIRIS®. The ’880 patent includes three claims, two of which are independent. Claim 1 recites:

> 1. A pharmaceutical composition for use in treating a patient afflicted with paroxysmal nocturnal hemoglobinuria (PNH), wherein the composition is 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 ’504 Patent

38. The ’504 patent is titled “Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement,” and was duly and legally issued on August 8, 2017. A true and correct copy of the ’504 patent is attached hereto as Ex. G. Alexion is the legal title holder by assignment of the ’504 patent. Generally, the ’504 patent is directed to and claims methods of treating patients using eculizumab, the antibody that is the active ingredient in SOLIRIS®. The ’504 patent includes ten claims, one of which is independent. Claim 1 recites:

> 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.

The ’189 Patent

39. The ’189 patent is titled “Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement,” and was duly and legally issued on March 17, 2020. A true and correct copy of the ’189 patent is attached hereto as Ex. H. Alexion is the legal title holder by assignment of the ’189 patent. Broadly, the ’189 patent is directed to and claims methods of treating patients using eculizumab, the antibody that is the active ingredient in SOLIRIS®. The ’189 patent includes eight claims, two of which are independent. Claim 1 recites:

> 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.

The ’809 Patent

40. The ’809 patent is titled “Treatment of Paroxysmal Nocturnal Hemoglobinuria Patients by an Inhibitor of Complement,” and was duly and legally issued on July 7, 2020. A true and correct copy of the ’809 patent is attached hereto as Ex. I. Alexion is the legal title holder by assignment of the ’809 patent. In general, the ’809 patent is directed to and claims methods of treating patients using eculizumab, the antibody that is the active ingredient in SOLIRIS®. The ’809 patent includes 29 claims, one of which is independent. Claim 1 recites:

> 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.

The ’176 Patent

41. The ’176 patent is titled “Methods and Compositions for Treating Complement-Associated Disorders,” and was duly and legally issued on September 20, 2016. A true and correct copy of the ’176 patent is attached hereto as Ex. J. Alexion is the legal title holder by assignment of the ’176 patent. In general, the ’176 patent is directed to and claims methods of treating patients using eculizumab, the antibody that is the active ingredient in SOLIRIS®. The ’176 patent includes four claims, one of which is independent. Claim 1 recites:

> 1. 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.

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

42. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

43. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

44. Samsung has not provided Alexion a copy of its aBLA.

45. To be marketed as a biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

46. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product, SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

47. Thus, Samsung's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of SB12 prior to the expiration of the '149 patent is an act of infringement of one or more claims of the '149 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

48. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the '149 patent, either literally or under the doctrine of equivalents.

49. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another's direct infringement of at least one claim of the '149 patent, either literally or under the doctrine of equivalents.

50. Samsung has knowledge of and is aware of the '149 patent, including due to the filing on May 18, 2023 of an inter partes review ("IPR") petition with the United States Patent

and Trademark Office ("USPTO") to invalidate the '149 patent, correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023, and the filing of this Complaint.

51. Samsung's infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

52. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the '149 patent.

53. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

COUNT II
Declaratory Judgment of Infringement of the '149 Patent

54. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

55. This declaratory judgment action is authorized by, *inter alia*, the BPCIA due to Samsung's provision of a notice of commercial marketing, and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(*l*)(8)(A-B), 262(*l*)(9)(C); 35 U.S.C. § 271(e); 28 U.S.C. §§ 2201, 2202. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

56. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

57. On July 7, 2023, Samsung provided Alexion a notice of commercial marketing pursuant to 42 U.S.C. § 262(*l*)(8)(A). Ex. C.

58. On information and belief, Samsung has made substantial preparations and intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of SB12 promptly upon receiving FDA approval to do so. Samsung informed Alexion it intends to market SB12 "with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic syndrome (aHUS)." Ex. C. Samsung's stated intention to launch its SB12 biosimilar product presents a controversy of sufficient immediacy to support declaratory judgment of patent infringement under 35 U.S.C. § 271(a)-(c) and (e).

59. Samsung's submission of its aBLA, combined with its stated intention in its Notice of Commercial Marketing to begin commercial manufacture, use, sale, offers for sale, and/or importation of SB12 prior to the expiration of the '149 patent creates an actual, immediate, and real controversy within the Declaratory Judgment Act that Samsung will infringe one or more of the claims of the '149 patent, literally or under the doctrine of equivalents.

60. Samsung has not provided Alexion a copy of its aBLA.

61. To be marketed as biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

62. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product,

SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

63. On information and belief, Samsung has directly infringed or will directly infringe at least one claim of the '149 patent by making, using, offering for sale, selling within and/or importing into the United States SB12, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a).

64. On information and belief, Samsung has affirmative intent to actively induce or contribute to infringement by others of at least one claim of the '149 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b)-(c).

65. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the '149 patent, either literally or under the doctrine of equivalents.

66. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another's direct infringement of at least one claim of the '149 patent, either literally or under the doctrine of equivalents.

67. Samsung has knowledge of and is aware of the '149 patent, including due to the filing on May 18, 2023 of an IPR petition with the USPTO to invalidate the '149 patent, correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023 and the filing of this Complaint.

68. Samsung's infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung's

wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

69. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the ’149 patent.

70. Alexion seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of SB12 will infringe the ’149 patent.

71. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

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

72. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

73. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

74. Samsung has not provided Alexion a copy of its aBLA.

75. To be marketed as a biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

76. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product, SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

77. Thus, Samsung's submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of SB12 prior to the expiration of the '880 patent is an act of infringement of one or more claims of the '880 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

78. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the '880 patent, either literally or under the doctrine of equivalents.

79. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another's direct infringement of at least one claim of the '880 patent, either literally or under the doctrine of equivalents.

80. Samsung has knowledge of and is aware of the '880 patent, including due to the filing on May 31, 2023 of an IPR petition with the USPTO to invalidate the '880 patent, correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023, and the filing of this Complaint.

81. Samsung's infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung's wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

82. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the ’880 patent.

83. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

COUNT IV
Declaratory Judgment of Infringement of the ’880 Patent

84. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

85. This declaratory judgment action is authorized by, inter alia, the BPCIA due to Samsung’s provision of a notice of commercial marketing, and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(l)(8)(A-B), 262(l)(9)(C); 35 U.S.C. § 271(e); 28 U.S.C. §§ 2201, 2202. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

86. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

87. On July 7, 2023, Samsung provided Alexion a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A). Ex. C.

88. On information and belief, Samsung has made substantial preparations and intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of SB12 promptly upon receiving FDA approval to do so. Samsung informed Alexion it intends to market SB12 “with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic syndrome (aHUS).” Ex. C. Samsung’s stated intention to launch

its SB12 biosimilar product presents a controversy of sufficient immediacy to support declaratory judgment of patent infringement under 35 U.S.C. § 271(a)-(c) and (e).

89. Samsung's submission of its aBLA, combined with its stated intention in its Notice of Commercial Marketing to begin commercial manufacture, use, sale, offers for sale, and/or importation of SB12 prior to the expiration of the '880 patent creates an actual, immediate, and real controversy within the Declaratory Judgment Act that Samsung will infringe one or more of the claims of the '880 patent, literally or under the doctrine of equivalents.

90. Samsung has not provided Alexion a copy of its aBLA.

91. To be marketed as biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

92. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product, SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

93. On information and belief, Samsung has directly infringed or will directly infringe at least one claim of the '880 patent by making, using, offering for sale, selling within and/or importing into the United States SB12, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a).

94. On information and belief, Samsung has affirmative intent to actively induce or contribute to infringement by others of at least one claim of the ’880 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b)-(c).

95. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the ’880 patent, either literally or under the doctrine of equivalents.

96. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another’s direct infringement of at least one claim of the ’880 patent, either literally or under the doctrine of equivalents.

97. Samsung has knowledge of and is aware of the ’880 patent, including due to the filing on May 31, 2023 of an IPR petition with the USPTO to invalidate the ’880 patent, correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023 and the filing of this Complaint.

98. Samsung’s infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

99. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the ’880 patent.

100. Alexion seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of SB12 will infringe the ’880 patent.

101. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

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

102. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

103. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

104. Samsung has not provided Alexion a copy of its aBLA.

105. To be marketed as a biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

106. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product, SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

107. As a biosimilar to SOLIRIS®, and on information and belief, Samsung seeks FDA approval for a label that specifies treatment methods that, if followed as expected, will infringe

the methods of treatment claimed by the ’504 patent. On information and belief, following FDA approval of SB12, Samsung intends to advertise and otherwise inform doctors and patients that SB12 is available to treat PNH using those claimed treatment methods.

108. Thus, Samsung’s submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of SB12 prior to the expiration of the ’504 patent is an act of infringement of one or more claims of the ’504 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

109. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the ’504 patent, either literally or under the doctrine of equivalents.

110. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another’s direct infringement of at least one claim of the ’504 patent, either literally or under the doctrine of equivalents.

111. Samsung has knowledge of and is aware of the ’504 patent, including due to the filing on May 31, 2023 of an IPR petition with the USPTO to invalidate the ’504 patent, correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023 and the filing of this Complaint.

112. Samsung’s infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

113. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the ’504 patent.

114. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

COUNT VI
Declaratory Judgment of Infringement of the ’504 Patent

115. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

116. This declaratory judgment action is authorized by, inter alia, the BPCIA due to Samsung’s provision of a notice of commercial marketing, and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(l)(8)(A-B), 262(l)(9)(C); 35 U.S.C. § 271(e); 28 U.S.C. §§ 2201, 2202. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

117. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

118. On July 7, 2023, Samsung provided Alexion a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A). Ex. C.

119. On information and belief, Samsung has made substantial preparations and intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of SB12 promptly upon receiving FDA approval to do so. Samsung informed Alexion it intends to market SB12 “with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic syndrome (aHUS).” Ex. C. Samsung’s stated intention to launch

its SB12 biosimilar product presents a controversy of sufficient immediacy to support declaratory judgment of patent infringement under 35 U.S.C. § 271(a)-(c) and (e).

120. Samsung's submission of its aBLA, combined with its stated intention in its Notice of Commercial Marketing to begin commercial manufacture, use, sale, offers for sale, and/or importation of SB12 prior to the expiration of the '504 patent creates an actual, immediate, and real controversy within the Declaratory Judgment Act that Samsung will infringe one or more of the claims of the '504 patent, literally or under the doctrine of equivalents.

121. Samsung has not provided Alexion a copy of its aBLA.

122. To be marketed as biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

123. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product, SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

124. As a biosimilar to SOLIRIS®, and on information and belief, Samsung seeks FDA approval for a label that specifies treatment methods that, if followed as expected, will infringe the methods of treatment claimed by the '504 patent. On information and belief, following FDA approval of SB12, Samsung intends to advertise and otherwise inform doctors and patients that SB12 is available to treat PNH using those claimed treatment methods.

125. On information and belief, Samsung has affirmative intent to actively induce or contribute to infringement by others of at least one claim of the ’504 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b)-(c).

126. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the ’504 patent, either literally or under the doctrine of equivalents.

127. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another’s direct infringement of at least one claim of the ’504 patent, either literally or under the doctrine of equivalents.

128. Samsung has knowledge of and is aware of the ’504 patent, including due to the filing on May 31, 2023 of an IPR petition with the USPTO to invalidate the ’504 patent, correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023 and the filing of this Complaint.

129. Samsung’s infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

130. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the ’504 patent.

131. Alexion seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of SB12 will infringe the ’504 patent.

132. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

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

133. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

134. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

135. Samsung has not provided Alexion a copy of its aBLA.

136. To be marketed as a biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

137. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product, SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

138. As a biosimilar to SOLIRIS®, and on information and belief, Samsung seeks FDA approval for a label that specifies treatment methods that, if followed as expected, will infringe

the methods of treatment claimed by the ’189 patent. On information and belief, following FDA approval of SB12, Samsung intends to advertise and otherwise inform doctors and patients that SB12 is available to treat PNH using those claimed treatment methods.

139. Thus, Samsung’s submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of SB12 prior to the expiration of the ’189 patent is an act of infringement of one or more claims of the ’189 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

140. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the ’189 patent, either literally or under the doctrine of equivalents.

141. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another’s direct infringement of at least one claim of the ’189 patent, either literally or under the doctrine of equivalents.

142. Samsung has knowledge of and is aware of the ’189 patent, including due to the filing on June 16, 2023 of an IPR petition with the USPTO to invalidate the ’189 patent, correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023 and the filing of this Complaint.

143. Samsung’s infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

144. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the ’189 patent.

145. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

COUNT VIII
Declaratory Judgment of Infringement of the ’189 Patent

146. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

147. This declaratory judgment action is authorized by, inter alia, the BPCIA due to Samsung’s provision of a notice of commercial marketing, and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(l)(8)(A-B), 262(l)(9)(C); 35 U.S.C. § 271(e); 28 U.S.C. §§ 2201, 2202. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

148. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

149. On July 7, 2023, Samsung provided Alexion a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A). Ex. C.

150. On information and belief, Samsung has made substantial preparations and intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of SB12 promptly upon receiving FDA approval to do so. Samsung informed Alexion it intends to market SB12 “with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic syndrome (aHUS).” Ex. C. Samsung’s stated intention to launch

its SB12 biosimilar product presents a controversy of sufficient immediacy to support declaratory judgment of patent infringement under 35 U.S.C. § 271(a)-(c) and (e).

151. Samsung's submission of its aBLA, combined with its stated intention in its Notice of Commercial Marketing to begin commercial manufacture, use, sale, offers for sale, and/or importation of SB12 prior to the expiration of the '189 patent creates an actual, immediate, and real controversy within the Declaratory Judgment Act that Samsung will infringe one or more of the claims of the '189 patent, literally or under the doctrine of equivalents.

152. Samsung has not provided Alexion a copy of its aBLA.

153. To be marketed as biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

154. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product, SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

155. As a biosimilar to SOLIRIS®, and on information and belief, Samsung seeks FDA approval for a label that specifies treatment methods that, if followed as expected, will infringe the methods of treatment claimed by the '189 patent. On information and belief, following FDA approval of SB12, Samsung intends to advertise and otherwise inform doctors and patients that SB12 is available to treat PNH using those claimed treatment methods.

156. On information and belief, Samsung has affirmative intent to actively induce or contribute to infringement by others of at least one claim of the ’189 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b)-(c).

157. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the ’189 patent, either literally or under the doctrine of equivalents.

158. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another’s direct infringement of at least one claim of the ’189 patent, either literally or under the doctrine of equivalents.

159. Samsung has knowledge of and is aware of the ’189 patent, including due to the filing on June 16, 2023 of an IPR petition with the USPTO to invalidate the ’189 patent, correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023 and the filing of this Complaint.

160. Samsung’s infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

161. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the ’189 patent.

162. Alexion seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of SB12 will infringe the ’189 patent.

163. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

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

164. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

165. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

166. Samsung has not provided Alexion a copy of its aBLA.

167. To be marketed as a biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

168. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product, SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

169. As a biosimilar to SOLIRIS®, and on information and belief, Samsung seeks FDA approval for a label that specifies treatment methods that, if followed as expected, will infringe

the methods of treatment claimed by the ’809 patent. On information and belief, following FDA approval of SB12, Samsung intends to advertise and otherwise inform doctors and patients that SB12 is available to treat PNH using those claimed treatment methods.

170. Thus, Samsung’s submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of SB12 prior to the expiration of the ’809 patent is an act of infringement of one or more claims of the ’809 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

171. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the ’809 patent, either literally or under the doctrine of equivalents.

172. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another’s direct infringement of at least one claim of the ’809 patent, either literally or under the doctrine of equivalents.

173. Samsung has knowledge of and is aware of the ’809 patent, including due to the filing on June 16, 2023 of an IPR petition with the USPTO to invalidate the ’809 patent, correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023 and the filing of this Complaint.

174. Samsung’s infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

175. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the ’809 patent.

176. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

COUNT X
Declaratory Judgment of Infringement of the ’809 Patent

177. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

178. This declaratory judgment action is authorized by, inter alia, the BPCIA due to Samsung’s provision of a notice of commercial marketing, and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(l)(8)(A-B), 262(l)(9)(C); 35 U.S.C. § 271(e); 28 U.S.C. §§ 2201, 2202. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

179. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

180. On July 7, 2023, Samsung provided Alexion a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A). Ex. C.

181. On information and belief, Samsung has made substantial preparations and intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of SB12 promptly upon receiving FDA approval to do so. Samsung informed Alexion it intends to market SB12 “with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic syndrome (aHUS).” Ex. C. Samsung’s stated intention to launch

its SB12 biosimilar product presents a controversy of sufficient immediacy to support declaratory judgment of patent infringement under 35 U.S.C. § 271(a)-(c) and (e).

182. Samsung's submission of its aBLA, combined with its stated intention in its Notice of Commercial Marketing to begin commercial manufacture, use, sale, offers for sale, and/or importation of SB12 prior to the expiration of the '809 patent creates an actual, immediate, and real controversy within the Declaratory Judgment Act that Samsung will infringe one or more of the claims of the '809 patent, literally or under the doctrine of equivalents.

183. Samsung has not provided Alexion a copy of its aBLA.

184. To be marketed as biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

185. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product, SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

186. As a biosimilar to SOLIRIS®, and on information and belief, Samsung seeks FDA approval for a label that specifies treatment methods that, if followed as expected, will infringe the methods of treatment claimed by the '809 patent. On information and belief, following FDA approval of SB12, Samsung intends to advertise and otherwise inform doctors and patients that SB12 is available to treat PNH using those claimed treatment methods.

187. On information and belief, Samsung has affirmative intent to actively induce or contribute to infringement by others of at least one claim of the ’809 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b)-(c).

188. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the ’809 patent, either literally or under the doctrine of equivalents.

189. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another’s direct infringement of at least one claim of the ’809 patent, either literally or under the doctrine of equivalents.

190. Samsung has knowledge of and is aware of the ’809 patent, including due to the filing on June 16, 2023 of an IPR petition with the USPTO to invalidate the ’809 patent, correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023 and the filing of this Complaint.

191. Samsung’s infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

192. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the ’809 patent.

193. Alexion seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of SB12 will infringe the ’809 patent.

194. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

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

195. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

196. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

197. Samsung has not provided Alexion a copy of its aBLA.

198. To be marketed as a biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

199. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product, SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

200. As a biosimilar to SOLIRIS®, and on information and belief, Samsung seeks FDA approval for a label that specifies treatment methods that, if followed as expected, will infringe

the methods of treatment claimed by the ’176 patent. On information and belief, following FDA approval of SB12, Samsung intends to advertise and otherwise inform doctors and patients that SB12 is available to treat aHUS using those claimed treatment methods.

201. Thus, Samsung’s submission of its aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of SB12 prior to the expiration of the ’176 patent is an act of infringement of one or more claims of the ’176 patent under 35 U.S.C. § 271(e)(2)(C), either literally or under the doctrine of equivalents.

202. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the ’176 patent, either literally or under the doctrine of equivalents.

203. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another’s direct infringement of at least one claim of the ’176 patent, either literally or under the doctrine of equivalents.

204. Samsung has knowledge of and is aware of the ’176 patent, including due to correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023, and the filing of this Complaint.

205. Samsung’s infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

206. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the ’176 patent.

207. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

COUNT XII
Declaratory Judgment of Infringement of the '176 Patent

208. Alexion incorporates by reference each of the preceding paragraphs as if fully set forth herein.

209. This declaratory judgment action is authorized by, inter alia, the BPCIA due to Samsung's provision of a notice of commercial marketing, and by the Declaratory Judgment Act. *See* 42 U.S.C. §§ 262(l)(8)(A-B), 262(l)(9)(C); 35 U.S.C. § 271(e); 28 U.S.C. §§ 2201, 2202. A judicial determination of infringement is necessary and appropriate to resolve this controversy.

210. On information and belief, on or before July 7, 2023, Samsung submitted an aBLA to the FDA seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of SB12, its biosimilar version of SOLIRIS® (eculizumab), in treating PNH and aHUS. Ex. C. The reference product for eculizumab is BLA No. 125166. Alexion is the holder of BLA No. 125166.

211. On July 7, 2023, Samsung provided Alexion a notice of commercial marketing pursuant to 42 U.S.C. § 262(l)(8)(A). Ex. C.

212. On information and belief, Samsung has made substantial preparations and intends to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of SB12 promptly upon receiving FDA approval to do so. Samsung informed Alexion it intends to market SB12 "with a label directed to indications for paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic syndrome (aHUS)." Ex. C. Samsung's stated intention to launch its SB12 biosimilar product presents a controversy of sufficient immediacy to support declaratory judgment of patent infringement under 35 U.S.C. § 271(a)-(c) and (e).

213. Samsung's submission of its aBLA, combined with its stated intention in its Notice of Commercial Marketing to begin commercial manufacture, use, sale, offers for sale, and/or importation of SB12 prior to the expiration of the '176 patent creates an actual, immediate, and real controversy within the Declaratory Judgment Act that Samsung will infringe one or more of the claims of the '176 patent, literally or under the doctrine of equivalents.

214. Samsung has not provided Alexion a copy of its aBLA.

215. To be marketed as biosimilar to SOLIRIS® pursuant to 42 U.S.C. § 262(i)(2) & (k)(2)(A)(i), SB12 must be highly similar to SOLIRIS® with only minor differences in clinically inactive components, and with no clinically meaningful difference between SB12 and SOLIRIS® in terms of safety, purity, and potency. Eculizumab is the active ingredient in SOLIRIS®. Accordingly, SB12 must contain either eculizumab or a human monoclonal antibody identical or highly similar in amino acid sequence to eculizumab.

216. Further, the European Medicines Agency (EMA) conducted a similarity assessment between Epysqli (Samsung's SB12 biosimilar in Europe) and the reference product, SOLIRIS®. The EMA concluded that the two products share an "identical primary [amino acid] sequence." Ex. K at 23.

217. As a biosimilar to SOLIRIS®, and on information and belief, Samsung seeks FDA approval for a label that specifies treatment methods that, if followed as expected, will infringe the methods of treatment claimed by the '176 patent. On information and belief, following FDA approval of SB12, Samsung intends to advertise and otherwise inform doctors and patients that SB12 is available to treat aHUS using those claimed treatment methods.

218. On information and belief, Samsung has affirmative intent to actively induce or contribute to infringement by others of at least one claim of the ’176 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b)-(c).

219. On information and belief, Samsung is aware, has knowledge, and/or is willfully blind to the fact that the commercial manufacture, use, sale, offer to sell, and/or importation of SB12 directly infringes at least one claim of the ’176 patent, either literally or under the doctrine of equivalents.

220. On information and belief, Samsung will knowingly or with willful blindness induce or contribute to another’s direct infringement of at least one claim of the ’176 patent, either literally or under the doctrine of equivalents.

221. Samsung has knowledge of and is aware of the ’176 patent, including due to correspondence between counsel for Alexion and counsel for Samsung dated September 5, 2023, and the filing of this Complaint.

222. Samsung’s infringement has and will continue to damage Alexion, who is entitled to recover from Samsung under 35 U.S.C. § 284 the damages resulting from Samsung’s wrongful acts in an amount to be determined at trial, and in any event no less than a reasonable royalty.

223. Moreover, Alexion will suffer irreparable injury for which damages are an inadequate remedy unless Samsung is enjoined from infringing the claims of the ’176 patent.

224. Alexion seeks a declaratory judgment that future commercial manufacture, use, sale, offer for sale, and/or importation of SB12 will infringe the ’176 patent.

225. Alexion seeks an injunction preventing Samsung from the commercial manufacture, use, sale, offer for sale within and/or importation into the United States of SB12.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

A. A judgment and declaration that Samsung has or will infringe or has or will induce or contribute to infringement of one or more claims of the Asserted Patents by engaging in the manufacture, import, offer for sale, sale, or use within the United States of the Samsung aBLA Product before the expirations of the Asserted Patents;

B. Preliminary and permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins Samsung, its officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them and/or their successors or assigns from infringing the Asserted Patents, or contributing to or inducing anyone to do the same, by acts including manufacture, use, offer to sell, sale, or distribution within the United States, or importation into the United States, of any current or future versions of the Samsung aBLA Product, the use or manufacturing of which infringes the Asserted Patents;

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

D. Any available damages pursuant to 35 U.S.C. § 284; and

E. Such other relief as this Court may deem just and proper.

Date: January 3, 2024

MCCARTER & ENGLISH, LLP

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