IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs, v. PFIZER INC., Defendant.	Case No. **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT

Plaintiffs Genentech, Inc. ("Genentech") and City of Hope (collectively, "Plaintiffs") bring this Complaint for monetary, declaratory, and injunctive relief against Defendant Pfizer Inc. ("Pfizer") to address Pfizer's infringement of 22 patents relating to Genentech's revolutionary cancer therapy, Avastin®.

NATURE OF THE CASE

1. Avastin® contains a genetically engineered antibody, bevacizumab, that inhibits the proliferation of blood vessels necessary for cancerous tumors to grow. The Food and Drug Administration ("FDA") first approved Avastin® in 2004. Based on extensive clinical testing by Genentech, Avastin® is now approved for use in treating metastatic colon cancer, lung cancer, glioblastoma, ovarian cancer, and cervical cancer. It is one of the top selling medicines in the United States and a critical source of research and development funding for Genentech.

2. Enacted in 2010 as part of the Affordable Care Act, the Biologics Price Competition and Innovation Act ("BPCIA") provides for abbreviated regulatory approval for biosimilars by letting applicants rely on the extensive clinical testing previously conducted by the innovator company that developed the medicine the applicant wants to copy.

3. Biologic medicines are complex and complicated to manufacture. As a result, biologics often have extensive patent portfolios associated with them. Avastin® is no exception. Genentech's innovative work in developing bevacizumab has been recognized by the United States Patent and Trademark Office ("USPTO") with dozens of patents covering the antibody itself, methods for its therapeutic use, and processes for the manufacture of therapeutic antibodies.

4. Recognizing the need to protect the patent rights of innovator companies like Genentech, Congress included provisions in the BPCIA to ensure that innovator companies have adequate opportunity to study the proposed biosimilars and the complex manufacturing

processes used to make them, and where appropriate, to assert infringement before competing biosimilars come to market. This process, often called the "patent dance," starts when the FDA accepts an application for review, and is supposed to run in parallel with the FDA's review process. The "patent dance" allows parties to narrow or eliminate disputes over infringement prior to approval and ensures the innovator has received enough information about the proposed biosimilar to determine if the proposed biosimilar infringes or will infringe any of the innovator's patents, as well as to seek a preliminary injunction should an applicant who receives approval attempt to launch at risk.

5. The statutory protections for Genentech in this case kicked in when the FDA notified Pfizer that its Abbreviated Biologic License Application, or "aBLA," had been accepted for review. That FDA notification gave Pfizer 20 days to provide Genentech with "a copy of the application submitted to [the FDA] under subsection (k), *and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application.*" 42 U.S.C. § 262(*l*)(2)(A) (emphasis added); *see also id*. § 262(*l*)(3)(A).

6. Pfizer's compliance with this requirement is critical to protecting Genentech's statutory rights. The BPCIA gives Genentech just 60 days after receiving this information to review it before serving Pfizer with a list of patents Genentech believes "could reasonably be asserted" against the manufacture, use, sale, offer for sale, or importation of Pfizer's proposed biosimilar. 42 U.S.C. § 262(*l*)(3)(A). The early disclosure requirements also serve to facilitate informed and orderly preliminary injunction proceedings, should that become necessary, after FDA licensure, but before the biosimilar product is commercialized.

7. On September 7, 2018, Genentech provided a list of "other information" that was relevant to its patent assessment, tying each request to the patents implicated. But Pfizer ignored

this targeted request and took the position that producing only portions of its aBLA alone was sufficient under the statute.

8. On September 14, 2018, Pfizer produced to Genentech what it later admitted to be only portions of the aBLA it submitted to the FDA. Pfizer did not produce any information or documents (other than what was contained in its incomplete aBLA production) Genentech had specifically requested in its September 7, 2018 letter.

9. On September 17, 2018, Genentech sent a letter documenting failures in Pfizer's purported 42 U.S.C. § 262(*l*)(2)(A) production, and offering to discuss a mutually agreed upon extension of Pfizer's deadline so that it could satisfy its obligations under the BPCIA.

10. On September 19, 2018, Pfizer responded by claiming its September 14, 2018 production satisfied its statutory obligations, and refused to provide a copy of its aBLA in the form it was provided to the FDA or to produce any of the "other information that describes the process or processes used to manufacture the biological product that is the subject of such application" required by 42 U.S.C. § 262(*l*)(2)(A).

11. Over the next two months, the parties exchanged correspondence regarding the deficiencies in Pfizer's production, but Pfizer did not agree to supplement its production or otherwise provide the information it was required to produce under the BPCIA prior to the deadline for Genentech to serve its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

12. Despite not having all the information to which it was entitled under the BPCIA to evaluate whether Pfizer's manufacture and sale of its proposed biosimilar Avastin® product ("Pfizer's aBLA product", "its aBLA Product")[1] would infringe Genentech's patents, on November 13, 2018, Genentech proceeded to serve a list of 31 patents pursuant to 42 U.S.C.

[1] References herein to Pfizer's aBLA product are to the drug substance and/or the drug product.

§ 262(*l*)(3)(A).

13. On December 21, 2018, Pfizer served disclosures purporting to comply with 42 U.S.C. § 262(*l*)(3)(B). On January 18, 2019, pursuant to 42 U.S.C. § 262(*l*)(8)(A), before Genentech's contentions pursuant to 42 U.S.C. § 262(*l*)(3)(C) would have been due, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019 (180 days from the date of the notice).

14. On February 19, 2019, and pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech provided Pfizer with its detailed statement asserting that the manufacture, use, sale, offer for sale, or importation of Pfizer's aBLA product would infringe 23 patents (its "(3)(C) Statement"). Genentech's statement included, with respect to 17 patents, the factual and legal basis of its opinion that those patents will be infringed by the commercial marketing of Pfizer's aBLA product, on a claim-by-claim basis, as well as providing a response to Pfizer's December 21, 2018 statement concerning validity and enforceability for those patents. Pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech was not obligated, and did not, provide infringement or validity contentions with respect to patents for which Pfizer did not provide non-infringement or invalidity contentions in its statement, pursuant to 42 U.S.C. § 262(*l*)(3)(B).

15. On March 6, 2019, Pfizer sent a letter to Genentech stating that Pfizer accepted and agreed that the 17 patents for which Genentech provided infringement contentions in its (3)(C) Statement would be the subject matter of an action for patent infringement pursuant to 42 U.S.C. § 262(*l*)(6), and thus the negotiations under 42 U.S.C. § 262(*l*)(4)(A) were concluded. The 17 patents listed in Pfizer's letter are: U.S. Patent Nos. 6,407,213; 6,610,516; 7,060,269; 7,169,901; 7,390,660; 7,485,704; 7,622,115; 7,807,799; 7,846,336; 8,314,225; 8,512,983; 8,574,869; 9,441,035; 9,714,293; 9,795,672; 9,884,904; and 10,010,611. Pfizer stated that 42

U.S.C. § 262(*l*)(6)(A) required Genentech to file an action for patent infringement within 30 days of Pfizer's March 6, 2019 letter.

16. Pursuant to the BPCIA, once the subsection (k) applicant and the reference product sponsor have agreed upon the patents that will be included in a patent infringement lawsuit, the reference product sponsor is to file an action for patent infringement of those patents in the appropriate venue of its choosing. 42 U.S.C. § 262(*l*)(6)(A). In addition, once the subsection (k) applicant has provided notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8), the reference product sponsor is permitted to file an action for declaratory judgment of patent infringement in the appropriate venue of its choosing. Plaintiffs therefore bring this action for infringement, declaratory judgment, an injunction, and any additional appropriate relief. Specifically, Plaintiffs seek an order declaring that Pfizer's actions are contrary to the BPCIA and that the manufacture, use, offer for sale, sale, and/or importation of Pfizer's proposed biologic product infringes Plaintiffs' intellectual property rights, and an order enjoining Pfizer from infringing the Asserted Patents (as listed below), including by offering to sell or selling its aBLA product until after the expiration of the last-to-expire of the Asserted Patents.

PARTIES

17. Plaintiff Genentech, Inc. is a corporation organized and existing under the laws of the State of Delaware with its corporate headquarters at 1 DNA Way, South San Francisco, California 94080.

18. Genentech was founded in 1976 and for four decades has been at the forefront of innovation in the field of therapeutic biotechnology. Today, Genentech employs a large number of researchers, scientists and post-doctoral staff members who routinely publish in top peer-reviewed journals and are among the leaders in total citations to their work by researchers.

Genentech currently markets numerous approved pharmaceutical and biologic drugs for a range of serious or life-threatening medical conditions, including various forms of cancer, heart attacks, strokes, rheumatoid arthritis, and respiratory diseases.

19. Plaintiff City of Hope is a California not-for-profit organization, with its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

20. Founded in 1913, City of Hope is a leading research hospital that incorporates cutting-edge research into patient care for cancer, diabetes, and other serious diseases.

21. Upon information and belief, Defendant Pfizer Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business at 235 East 42nd Street, New York, NY 10017.

22. Pfizer Inc. is, among other things, engaged in the development of biologic drugs, including Pfizer's aBLA product. Pfizer's aBLA product will be distributed and sold in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

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

24. Venue is proper with respect to Pfizer Inc. in this Court, pursuant to 28 U.S.C. § 1400(b) because Pfizer is incorporated in Delaware.

25. This Court has personal jurisdiction over Pfizer because it is incorporated in Delaware. In addition, among other things, Pfizer has filed aBLA No. 761099 with the FDA seeking approval to market its aBLA product, which reliably indicates that it will market its proposed biosimilar product in Delaware if approved.

FACTUAL BASIS FOR RELIEF

26. The BPCIA provides a mechanism to obtain FDA approval for a biological product that is "biosimilar" to a previously licensed "reference product" such as Avastin®. 42 U.S.C. § 262(k). Biosimilars must be "highly similar to the reference product notwithstanding minor differences in clinically inactive components," with "no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product." 42 U.S.C. § 262(i)(2)(A)-(B). In addition, a biosimilar must use the same mechanism of action as the reference product for the conditions of use prescribed, recommended, or suggested in the reference product's FDA approved label. *See* 42 U.S.C. § 262(k)(2)(A)(i)(II). The route of administration, dosage form, and strength of a biosimilar must also be the same as those of the reference product. *See* 42 U.S.C. § 262(k)(2)(A)(i)(I).

27. The BPCIA reduces the time and expense otherwise required to gain FDA approval by letting an applicant rely on most of the clinical testing used to establish the safety and efficacy of the reference product. The statute also includes extensive provisions to ensure the reference product sponsor (i.e., the innovator) has an opportunity to assess the proposed product and the manufacturing processes used to make it, to determine the extent to which there is threatened infringement of the innovator's patent rights, and if necessary, to vindicate those rights before the biosimilar product comes to market.

28. Genentech, the reference product sponsor of Avastin®, invested many years of effort into the design and development of Avastin® and received numerous patents rewarding this research. In addition, as an industry leader with many biologic products besides Avastin®, Genentech has an extensive patent portfolio covering various innovations generally applicable to the antibody manufacturing process.

THE ASSERTED PATENTS

29. As a result of Pfizer's conduct, Genentech has been forced to assess Pfizer's infringement based on incomplete information. Nevertheless, Genentech served on November 13, 2018 a list of 31 patents that Genentech believed could reasonably be asserted against the manufacture, use, sale, offer for sale, or import into the United States of Pfizer's aBLA product. *See* 42 U.S.C. § 262(*l*)(3)(A).

30. Pfizer notified Genentech of its contentions, pursuant to 42 U.S.C. § 262(*l*)(3)(B), with respect to these patents on December 21, 2018.

31. On January 18, 2019, before Genentech's contentions, pursuant to 42 U.S.C. § 262(*l*)(3)(C) would have been due, Pfizer provided Genentech notice pursuant to 42 U.S.C. § 262(*l*)(8)(A) of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019 (180 days from the date of the notice).

32. Genentech asserted through the "patent dance" that the following patents, among others, have been infringed and will be infringed by the manufacture, use, sale, or offer for sale of Pfizer's aBLA product. The patents-in-suit ("the Asserted Patents") on which Plaintiffs now bring claims are:

US Patent No.	Issue Date	First Named Inventor
EX A -- 6,054,297	Apr. 25, 2000	Carter
EX B -- 6,121,428	Sept. 19, 2000	Blank
EX C -- 6,331,415	Dec. 18, 2001	Cabilly
EX D -- 6,407,213	Jun. 18, 2002	Carter
EX E -- 6,610,516	Aug. 26, 2003	Andersen
EX F -- 6,884,879	Apr. 26, 2005	Baca
EX G – 7,060,269	Jun. 13, 2006	Baca
EX H -- 7,169,901	Jan. 30, 2007	Baca

US Patent No.	Issue Date	First Named Inventor
EX I -- 7,390,660	Jun. 24, 2008	Behrendt
EX J -- 7,485,704	Feb. 3, 2009	Fahrner
EX K -- 7,622,115	Nov. 24, 2009	Fyfe
EX L -- 7,807,799	Oct. 5, 2010	Fahrner
EX M -- 7,846,336	Dec. 7, 2010	Burg
EX N -- 7,923,221	Apr. 12, 2011	Cabilly
EX O -- 8,314,225	Nov. 20, 2012	Goepfert
EX P -- 8,512,983	Aug. 20, 2013	Gawlitzek
EX Q -- 8,574,869	Nov. 5, 2013	Kao
EX R -- 9,441,035	Sept. 13, 2016	Carvalhal
EX S -- 9,714,293	Jul. 25, 2017	Gawlitzek
EX T -- 9,795,672	Oct. 24, 2017	Fyfe
EX U -- 9,884,904	Feb. 6, 2018	Binder
EX V -- 10,010,611	Jul. 3, 2018	Gokarn

33. Genentech is the owner of all rights, title, and interest in the Asserted Patents, with the following exceptions: Genentech and City of Hope are co-owners of U.S. Patent Nos. 6,331,415 (Exhibit C) and 7,923,221 (Exhibit N). Hoffmann-La Roche, Inc. is the owner of U.S. Patent Nos. 7,390,660 (Exhibit I), 7,846,336 (Exhibit M), 8,314,225 (Exhibit O), and 9,884,904 (Exhibit U); Genentech is the exclusive licensee of these patents with the sole right to enforce these patents pursuant to a Patent Licensing Agreement between Genentech and Hoffmann-La Roche, Inc. dated January 13, 2017, as amended.

COUNT ONE
(Infringement of the ’297 Patent)

34. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

35. United States Patent No. 6,054,297 (“the ’297 patent”) (Exhibit A hereto) was duly and legally issued on April 25, 2000.

36. Although the ’297 patent expired on February 26, 2018, prior to expiry Pfizer infringed the ’297 patent in violation of 35 U.S.C. § 271(a) at least by making and/or using its aBLA product in the United States.

37. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s pre-expiration manufacture and/or use of its aBLA product infringed at least claim 1 of the ’297 patent.

38. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured before the expiration of the ’297 patent, Pfizer’s pre-expiration manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

39. If its aBLA is approved by the FDA, Pfizer intends to offer for sale or sell its aBLA product, some manufacture of which predated the expiry of the ’297 patent and infringed the ’297 patent.

40. Pfizer’s infringement of the ’297 patent was willful for reasons including the fact that Pfizer is and has been aware of the ’297 patent and its scope prior to making and/or using its aBLA product in the United States. Pfizer has knowledge of and is aware of the ’297 patent at least because the ’297 patent is cited in U.S. Patent No. 7,449,616 to which Pfizer is listed as an assignee. Additionally, Pfizer has had knowledge of and has been aware of the ’297 patent since at least as early as Genentech’s disclosure of this patent to Pfizer on November 3, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A) and related to Pfizer’s proposed biosimilar Herceptin® product.

41. As a consequence of Pfizer’s infringement of the ’297 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

42. Pfizer’s willful, wanton, and deliberate infringement of the ’297 patent justifies an

award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred, pursuant to 35 U.S.C. § 285.

43. Plaintiffs will suffer irreparable injury if Pfizer offers to sell or sells its aBLA product whose manufacture infringed the '297 patent. Unless Pfizer is enjoined from offering to sell or selling this product, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT TWO
(Infringement of the '428 Patent)

44. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

45. United States Patent No. 6,121,428 ("the '428 patent") (Exhibit B hereto) was duly and legally issued on September 19, 2000.

46. Although the '428 patent expired on June 12, 2018, prior to expiry Pfizer infringed the '428 patent in violation of 35 U.S.C. § 271(a) at least by making and/or using its aBLA product in the United States.

47. Based on Plaintiffs' current knowledge, which is informed by material Pfizer provided during the BPCIA "patent dance" to date, Pfizer's pre-expiration manufacture and/or use of its aBLA product infringed at least claim 16 of the '428 patent.

48. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured before the expiration of the '428 patent, Pfizer's pre-expiration manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

49. If its aBLA is approved by the FDA, Pfizer intends to offer for sale or sell its aBLA product, some manufacture of which predated the expiry of the '428 patent and infringed the '428 patent.

50. Pfizer's infringement of the '428 patent was willful for reasons including the fact that Pfizer is and has been aware of the '428 patent and its scope prior to making and/or using its aBLA product in the United States. Pfizer has had knowledge of and has been aware of the '428 patent since at least as early as Genentech's disclosure of this patent to Pfizer on November 3, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A) and related to Pfizer's proposed biosimilar Herceptin® product.

51. As a consequence of Pfizer's infringement of the '428 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

52. Pfizer's willful, wanton, and deliberate infringement of the '428 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred, pursuant to35 U.S.C. § 285.

53. Plaintiffs will suffer irreparable injury if Pfizer offers to sell or sells its aBLA product whose manufacture infringed the '428 patent. Unless Pfizer is enjoined from offering to sell or selling this product, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT THREE
(Infringement of the '415 Patent)

54. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

55. United States Patent No. 6,331,415 ("the '415 patent") (Exhibit C hereto) was duly and legally issued on December 18, 2001.

56. Although the '415 patent expired on December 18, 2018, prior to expiry Pfizer infringed the '415 patent in violation of 35 U.S.C. § 271(a) at least by making and/or using its aBLA product in the United States.

57. Based on Plaintiffs' current knowledge, which is informed by material Pfizer

provided during the BPCIA "patent dance" to date, Pfizer's pre-expiration manufacture and/or use of its aBLA product infringed at least claim 1 of the '415 patent.

58. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured before the expiration of the '415 patent, Pfizer's pre-expiration manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

59. If its aBLA is approved by the FDA, Pfizer intends to offer for sale or sell its aBLA product, some manufacture of which predated the expiry of the '415 patent and infringed the '415 patent.

60. Pfizer has knowledge of and is aware of the '415 patent at least because the '415 patent is cited in Pfizer's U.S. Patent No. 7,449,616 to which Pfizer is listed as an assignee. Additionally, Pfizer has had knowledge of and has been aware of the '415 patent since at least as early as Genentech's disclosure of this patent to Pfizer on November 3, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A) and related to Pfizer's proposed biosimilar Herceptin® product.

61. As a consequence of Pfizer's infringement of the '415 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

62. Pfizer's willful, wanton, and deliberate infringement of the '415 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs, pursuant to under 35 U.S.C. § 285.

63. Plaintiffs will suffer irreparable injury if Pfizer offers to sell or sells its aBLA product whose manufacture infringed the '415 patent. Unless Pfizer is enjoined from offering to sell or selling this product, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT FOUR
(Infringement of the ’213 Patent)

64. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

65. United States Patent No. 6,407,213 (“the ’213 patent”) (Exhibit D hereto) was duly and legally issued on June 18, 2002.

66. The ’213 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

67. Pfizer has infringed the ’213 patent in violation of 35 U.S.C. § 271(a) at least by making and/or using its aBLA product in the United States.

68. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s manufacture and/or use of its aBLA product infringed at least claim 65 of the ’213 patent.

69. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

70. Upon information and belief, Pfizer submitted aBLA No. 761099 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a biosimilar version of Avastin® before expiration of the ’213 patent. Pfizer knows and intends that its offer for sale and/or sale of its aBLA product in the United States will infringe the ’269 patent.

71. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer’s aBLA product before the expiration of the ’213 patent is an act of infringement of one or more claims of the ’213 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

72. Pfizer knew, understood, and believed that the ’213 patent was infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

73. Pfizer’s infringement of the ’213 patent was and is willful for reasons including the fact that Genentech listed the ’213 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A).

74. As a consequence of Pfizer’s infringement of the ’213 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

75. Pfizer’s willful, wanton, and deliberate infringement of the ’213 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred, pursuant to 35 U.S.C. § 285.

76. As a result of Pfizer’s infringement of the ’213 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the ’213 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT FIVE
(Declaratory Judgment of Infringement of the ’213 Patent)

77. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

78. Pfizer’s future manufacture of its aBLA product will infringe one or more claims of the ’213 patent, pursuant to 35 U.S.C. § 271(a).

79. Pfizer’s past manufacture of its aBLA product infringed one or more method claims of the ’213 patent.

80. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

81. Pfizer’s future sale of its aBLA product that was or will be manufactured using a

method or methods claimed by the ’213 patent will infringe one or more claims of the ’213 patent under 35 U.S.C. § 271(g).

82. Pfizer knows, understands, and believes that the ’213 patent is infringed by Pfizer’s aBLA product and by Pfizer’s submission of aBLA No. 761099 to the FDA.

83. Pfizer’s infringement of the ’213 patent was and will be willful, for reasons including the fact that Genentech listed the ’213 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A).

84. Unless Pfizer is enjoined from infringing the ’213 patent, including by selling its aBLA product made by processes patented by the ’213 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

85. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

86. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer’s past manufacture infringed the ’213 patents and whether its future manufacture and/or sale of its aBLA product will infringe the ’213 patent.

87. Genentech is entitled to a judgment that Pfizer’s past manufacture and its future manufacture and/or sale of its aBLA product will infringe the ’213 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT SIX
(Infringement of the ’516 Patent)

88. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

89. United States Patent No. 6,610,516 (“the ’516 patent”) (Exhibit E hereto) was duly and legally issued on August 26, 2003.

90. The ’516 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

91. Pfizer has infringed the ’516 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

92. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s manufacture of its aBLA product infringed at least claim 1 of the ’516 patent.

93. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

94. On information and belief based upon Pfizer’s notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the ’516 patent.

95. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer’s aBLA product before the expiration of the ’516 patent is an act of infringement of one or more claims of the ’516 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

96. Pfizer knew, understood, and believed that the ’516 patent was infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

97. Pfizer’s infringement of the ’516 patent was and is willful for reasons including the fact that Genentech listed the ’516 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A).

98. As a consequence of Pfizer's infringement of the '516 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

99. Pfizer's willful, wanton, and deliberate infringement of the '516 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred, pursuant to 35 U.S.C. § 285.

100. As a result of Pfizer's infringement of the '516 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the '516 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT SEVEN
(Declaratory Judgment of Infringement of the '516 Patent)

101. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

102. Pfizer's future manufacture of its aBLA product will infringe one or more claims of the '516 patent, pursuant to 35 U.S.C. § 271(a).

103. Pfizer's past manufacture of its aBLA product infringed one or more method claims of the '516 patent.

104. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

105. Pfizer's future sale of its aBLA product that was or will be manufactured using a method or methods claimed by the '516 patent will infringe one or more claims of the '516 patent, pursuant to 35 U.S.C. § 271(g).

106. Pfizer knows, understands, and believes that the '516 patent is infringed by Pfizer's aBLA product and by Pfizer's submission of aBLA No. 761099 to the FDA.

107. Pfizer's infringement of the '516 patent was and will be willful, for reasons

including the fact that Genentech listed the ’516 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

108. Unless Pfizer is enjoined from infringing the ’516 patent, including by selling its aBLA product made by processes patented by the ’516 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

109. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

110. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer’s past manufacture infringed the ’516 patent and whether its future manufacture and/or sale of its aBLA product will infringe the ’516 patent.

111. Genentech is entitled to a judgment that Pfizer’s past manufacture and its future manufacture and/or sale of its aBLA product will infringe the ’516 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT EIGHT
(Infringement of the ’879 Patent)

112. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

113. United States Patent No. 6,884,879 (“the ’879 patent”) (Exhibit F hereto) was duly and legally issued on April 26, 2005.

114. Although the ’879 patent expired on April 7, 2017, prior to expiry Pfizer infringed the ’879 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

115. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s pre-expiration manufacture of its

aBLA product infringed at least claim 4 of the ’879 patent.

116. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured before the expiration of the ’879 patent, Pfizer’s pre-expiration manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

117. If its aBLA is approved by the FDA, Pfizer intends to offer for sale or sell its aBLA product, some manufacture of which predated the expiry of the ’879 patent and infringed the ’879 patent.

118. Pfizer knew, understood, and believed that the ’879 patent was infringed by Pfizer’s aBLA product and by Pfizer’s submission of aBLA No. 761099 to the FDA.

119. Pfizer’s infringement of the ’879 patent was willful for reasons including the fact that Pfizer is and has been aware of the ’879 patent and its scope prior to making and/or using its aBLA product in the United States. The fact that Pfizer instituted an *inter partes* review before the USPTO to challenge claims of the ’672 patent shows that Pfizer was aware of Genentech’s patent portfolio specific to bevacizumab, which includes the ’879 patent.

120. As a consequence of Pfizer’s infringement of the ’879 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

121. Pfizer’s willful, wanton, and deliberate infringement of the ’879 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred, pursuant to 35 U.S.C. § 285.

122. Plaintiffs will suffer irreparable injury if Pfizer offers to sell or sells its aBLA product whose manufacture infringed the ’879 patent. Unless Pfizer is enjoined from offering to sell or selling this product, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate

remedy at law.

COUNT NINE
(Infringement of the ’269 Patent)

123. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

124. United States Patent No. 7,060,269 (“the ’269 patent”) (Exhibit G hereto) was duly and legally issued on June 13, 2006.

125. The ’269 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

126. Upon information and belief, Pfizer submitted aBLA No. 761099 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a biosimilar version of Avastin® before expiration of the ’269 patent. Pfizer knows and intends that its offer for sale and/or sale of its aBLA product in the United States will infringe the ’269 patent.

127. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer’s aBLA product before the expiration of the ’269 patent is an act of infringement of one or more claims of the ’269 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

128. Pfizer also will induce or contribute to infringement of the ’269 patent in violation of 35 U.S.C. § 271(b)–(c) by engaging in the commercial marketing, offering for sale, and/or selling its aBLA product in the United States.

129. Based upon Pfizer’s notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product.

130. On information and belief, Pfizer’s offer to sell and sale of its aBLA product will

encourage, suggest, teach, and/or induce the product's use as claimed in the '269 patent. The administration by, for example, physicians or patients would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '269 patent. Upon information and belief, this direct infringement would occur at Pfizer's behest, with Pfizer's intent, knowledge, and encouragement as a result of, for example, Pfizer's sales, marketing, and distribution of its proposed biosimilar product with its proposed prescribing information.

131. Based on Plaintiffs' current knowledge, which is informed by material Pfizer provided during the BPCIA "patent dance" to date, Pfizer's offer to sell or sale of its aBLA product in the United States would infringe at least claim 2 of the '269 patent.

132. On information and belief, Pfizer plans and intends to, and will, actively induce infringement of the '269 patent when it begins commercial marketing of its aBLA product.

133. On information and belief, Pfizer knows that its aBLA product and its proposed labeling are especially made or adapted for use in infringing the '269 patent, and that Pfizer's aBLA product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Pfizer plans and intends to, and will, contribute to infringement of the '269 patent when it begins commercial marketing of its aBLA product.

134. Pfizer knew, understood, and believed that the '269 patent was infringed by at least its submission of aBLA No. 761099 to the FDA.

135. Pfizer's infringement of the '269 patent was and will be willful for reasons including the fact that Genentech listed the '269 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(l)(3)(A).

136. Unless Pfizer is enjoined from infringing the '269 patent, Plaintiffs will suffer

irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT TEN
(Declaratory Judgment of Infringement of the ’269 Patent)

137. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

138. Pfizer knows and intends that its offer for sale and/or sale of its aBLA product in the United States will infringe the ’269 patent.

139. Pfizer’s aBLA product is adapted for infringement of the ’269 patent and is not a staple article of commerce.

140. Pfizer will induce or contribute to infringement of the ’269 patent in violation of 35 U.S.C. § 271(b)–(c) by offering for sale, and/or selling its aBLA product in the United States.

141. On information and belief, Pfizer’s offer to sell and sale of its aBLA product will encourage, suggest, teach, and/or induce the product’s use as claimed in the ’269 patent.

142. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s offer to sell or sale of its aBLA product in the United States would infringe at least claim 2 of the ’269 patent.

143. Pfizer plans and intends to, and will, actively induce infringement of the ’269 patent when it begins commercial marketing of its aBLA product.

144. Pfizer knows that its aBLA product and its proposed labeling are especially made or adapted for use in infringing the ’269 patent, and that Pfizer’s aBLA product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Pfizer plans and intends to, and will, contribute to infringement of the ’269 patent when it begins commercial marketing of its aBLA product.

145. Pfizer knows, understands, and believes that the ’269 patent is infringed by at least its submission of aBLA No. 761099 to the FDA.

146. Pfizer's infringement of the '269 patent was and will be willful, for reasons including the fact that Genentech listed the '269 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

147. Unless Pfizer is enjoined from infringing the '269 patent, including being enjoined from inducing or contributing to infringement of the '269 patent in violation of 35 U.S.C. § 271(b)-(c) by offering for sale, and/or selling its aBLA product in the United States, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

148. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

149. Accordingly, there is real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer's future offer to sell and sale of its aBLA product will encourage, suggest, teach, and/or induce the product's use will infringe the '269 patent.

150. Genentech is entitled to a judgment that Pfizer's future offer to sell and sale of its aBLA product will encourage, suggest, teach, and/or induce the product's use will infringe the '269 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT ELEVEN
(Infringement of the '901 Patent)

151. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

152. United States Patent No. 7,169,901 ("the '901 patent") (Exhibit H hereto) was duly and legally issued on January 30, 2007.

153. The '901 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

154. Pfizer has infringed the '901 patent in violation of 35 U.S.C. § 271(a) at least by

making and/or using its aBLA product in the United States.

155. Based on Plaintiffs' current knowledge, which is informed by material Pfizer provided during the BPCIA "patent dance" to date, Pfizer's pre-expiration manufacture and/or use of its aBLA product infringed at least claim 1 of the '901 patent.

156. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured before the expiration of the '901 patent, Pfizer's pre-expiration manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

157. Pfizer knew, understood, and believed that the '901 patent was infringed by Pfizer's aBLA product and by Pfizer's submission of aBLA No. 761099 to the FDA.

158. Pfizer's infringement of the '901 patent was willful, for reasons including the fact that Genentech listed the '901 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

159. As a consequence of Pfizer's infringement of the '901 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

160. Pfizer's willful, wanton, and deliberate infringement of the '901 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred, pursuant to 35 U.S.C. § 285.

161. As a result of Pfizer's infringement of the '901 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the '901 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs will also suffer irreparable injury if Pfizer offers to sell or sells its aBLA product whose manufacture infringed the '901 patent. Unless Pfizer is enjoined from offering to sell or selling this product, Plaintiffs will suffer irreparable injury. Plaintiffs

have no adequate remedy at law.

COUNT TWELVE
(Infringement of the ’660 Patent)

162. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

163. United States Patent No. 7,390,660 (“the ’660 patent”) (Exhibit I hereto) was duly and legally issued on June 24, 2008.

164. The ’660 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

165. Pfizer has infringed the ’660 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

166. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s manufacture of its aBLA product infringed at least claim 1 of the ’660 patent.

167. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s -manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

168. On information and belief based upon Pfizer’s notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the ’660 patent.

169. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer’s aBLA product before the expiration of the ’660 patent is an act of infringement of one or more claims of the ’660 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

170. Pfizer knew, understood, and believed that the ’660 patent was infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

171. Pfizer’s infringement of the ’660 patent was and is willful for reasons including the fact that Genentech listed the ’660 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

172. As a consequence of Pfizer’s infringement of the ’660 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

173. Pfizer’s willful, wanton, and deliberate infringement of the ’660 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred, pursuant to 35 U.S.C. § 285.

174. As a result of Pfizer’s infringement of the ’660 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the ’660 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT THIRTEEN
(Declaratory Judgment of Infringement of the ’660 Patent)

175. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

176. Pfizer’s future manufacture of its aBLA product will infringe one or more claims of the ’660 patent, pursuant to 35 U.S.C. § 271(a).

177. Pfizer’s past manufacture of its aBLA product infringed one or more method claims of the ’660 patent.

178. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

179. Pfizer’s future sale of its aBLA product that was or will be manufactured using a

method or methods claimed by the ’660 patent will infringe one or more claims of the ’660 patent, pursuant to 35 U.S.C. § 271(g).

180. Pfizer knows, understands, and believes that the ’660 patent is infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

181. Pfizer’s infringement of the ’660 patent was and will be willful, for reasons including the fact that Genentech listed the ’660 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

182. Unless Pfizer is enjoined from infringing the ’660 patent, including by selling its aBLA product made by processes patented by the ’660 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

183. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

184. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer’s past manufacture infringed the ’660 patent and whether its future manufacture and/or sale of its aBLA product will infringe the ’660 patent.

185. Genentech is entitled to a judgment that Pfizer’s past manufacture and its future manufacture and/or sale of its aBLA product will infringe the ’660 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT FOURTEEN
(Infringement of the ’704 Patent)

186. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

187. United States Patent No. 7,485,704 (“the ’704 patent”) (Exhibit J hereto) was duly and legally issued on February 3, 2009.

188. The ’704 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

189. Pfizer has infringed the ’704 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

190. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s manufacture of its aBLA product infringed at least claim 1 of the ’704 patent.

191. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

192. On information and belief based upon Pfizer’s notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the ’704 patent.

193. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer’s aBLA product before the expiration of the ’704 patent is an act of infringement of one or more claims of the ’704 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

194. Pfizer knew, understood, and believed that the ’704 patent was infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

195. Pfizer’s infringement of the ’704 patent was and is willful for reasons including the fact that Genentech listed the ’704 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A).

196. As a consequence of Pfizer's infringement of the '704 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

197. Pfizer's willful, wanton, and deliberate infringement of the '704 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred, pursuant to 35 U.S.C. § 285.

198. As a result of Pfizer's infringement of the '704 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the '704 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT FIFTEEN
(Declaratory Judgment of Infringement of the '704 Patent)

199. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

200. Pfizer's future manufacture of its aBLA product will infringe one or more claims of the '704 patent, pursuant to 35 U.S.C. § 271(a).

201. Pfizer's past manufacture of its aBLA product infringed one or more method claims of the '704 patent.

202. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

203. Pfizer's future sale of its aBLA product that was or will be manufactured using a method or methods claimed by the '704 patent will infringe one or more claims of the '704 patent, pursuant to 35 U.S.C. § 271(g).

204. Pfizer knows, understands, and believes that the '704 patent is infringed by Pfizer's aBLA product and by its submission of aBLA No. 761099 to the FDA.

205. Pfizer's infringement of the '704 patent was and will be willful, for reasons

including the fact that Genentech listed the ’704 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A).

206. Unless Pfizer is enjoined from infringing the ’704 patent, including by selling its aBLA product made by processes patented by the ’704 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

207. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

208. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer’s past manufacture infringed the ’704 patent and that its future manufacture and/or sale of its aBLA product will infringe the ’704 patent.

209. Genentech is entitled to a judgment that Pfizer’s past manufacture and its future manufacture and/or sale of its aBLA product will infringe the ’704 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT SIXTEEN
(Infringement of the ’115 Patent)

210. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

211. United States Patent No. 7,622,115 (“the ’115 patent”) (Exhibit K hereto) was duly and legally issued on November 24, 2009.

212. The ’115 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

213. Upon information and belief, Pfizer submitted aBLA No. 761099 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a biosimilar version of Avastin® before expiration of the ’115 patent. Pfizer knows and intends

that its offer for sale and/or sale of its aBLA product in the United States will infringe the ’115 patent.

214. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer’s aBLA product before the expiration of the ’115 patent is an act of infringement of one or more claims of the ’115 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

215. Pfizer will also induce or contribute to infringement of the ’115 patent in violation of 35 U.S.C. § 271(b)-(c) by engaging in the commercial marketing, offering for sale, and/or selling its aBLA product in the United States.

216. Based upon Pfizer’s notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product.

217. On information and belief, Pfizer’s offer to sell and sale of its aBLA product will encourage, suggest, teach, and/or induce the product’s use as claimed in the ’115 patent. The administration by, for example, physicians or patients would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the ’115 patent. Upon information and belief, this direct infringement would occur at Pfizer’s behest, with Pfizer’s intent, knowledge, and encouragement as a result of, for example, Pfizer’s sales, marketing, and distribution of its proposed biosimilar product with its proposed prescribing information.

218. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s offer to sell or sale of its aBLA product in the United States would infringe at least claim 1 of the ’115 patent.

219. On information and belief Pfizer plans and intends to, and will, actively induce infringement of the ’115 patent when it begins commercial marketing of its aBLA product.

220. Pfizer’s aBLA product is adapted for infringement of the ’115 patent and is not a staple article of commerce.

221. On information and belief, Pfizer knows that its aBLA product and its proposed labeling are especially made or adapted for use in infringing the ’115 patent, and that Pfizer’s aBLA product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Pfizer plans and intends to, and will, contribute to infringement of the ’115 patent when it begins commercial marketing of its aBLA product.

222. Pfizer knew, understood, and believed that the ’115 patent was infringed by at least its submission of aBLA No. 761099 to the FDA.

223. Pfizer’s infringement of the ’115 patent was and will be willful for reasons including the fact that Pfizer’s subsidiary Hospira, Inc. filed a petition for an *inter partes* review of the ’115 patent (IPR2016-01771). Additionally, Genentech listed the ’115 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(l)(3)(A).

224. Unless Pfizer is enjoined from infringing the ’115 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT SEVENTEEN
(Declaratory Judgment of Infringement of the ’115 Patent)

225. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

226. Pfizer knows and intends that its offer for sale and/or sale of its aBLA product in the United States will infringe the ’115 patent.

227. Pfizer’s aBLA product is adapted for infringement of the ’115 patent and is not a staple article of commerce.

228. Pfizer will induce or contribute to infringement of the ’115 patent in violation of 35 U.S.C. § 271(b)–(c) by offering for sale, and/or selling its aBLA product in the United States.

229. On information and belief, Pfizer’s offer to sell and sale of its aBLA product will encourage, suggest, teach, and/or induce the product’s use as claimed in the ’115 patent.

230. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s offer to sell or sale of its aBLA product in the United States would infringe at least claim 1 of the ’115 patent.

231. Pfizer plans and intends to, and will, actively induce infringement of the ’115 patent when it begins commercial marketing of its aBLA product.

232. Pfizer knows that its aBLA product and its proposed labeling are especially made or adapted for use in infringing the ’115 patent, and that Pfizer’s aBLA product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Pfizer plans and intends to, and will, contribute to infringement of the ’115 patent when it begins commercial marketing of its aBLA product.

233. Pfizer knows, understands, and believes that the ’115 patent is infringed by at least its submission of aBLA No. 761099 to the FDA.

234. Pfizer’s infringement of the ’115 patent was and will be willful, for reasons including the fact that Pfizer’s subsidiary, Hospira, Inc., filed a petition for an *inter partes* review of the ’115 patent in (IPR2016-01771). Additionally, Genentech listed the ’115 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A).

235. Unless Pfizer is enjoined from infringing the ’115 patent, including being enjoined from inducing or contributing to infringement of the ’115 patent in violation of 35 U.S.C. § 271(b)-(c) by offering for sale, and/or selling its aBLA product in the United States,

Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

236. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

237. Accordingly, there is real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer's future offer to sell and sale of its aBLA product will encourage, suggest, teach, and/or induce the product's use will infringe the '115 patent.

238. Genentech is entitled to a judgment that Pfizer's future offer to sell and sale of its aBLA product will encourage, suggest, teach, and/or induce the product's use will infringe the '115 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT EIGHTEEN
(Infringement of the '799 Patent)

239. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

240. United States Patent No. 7,807,799 ("the '799 patent") (Exhibit L hereto) was duly and legally issued on October 5, 2010.

241. The '799 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

242. Pfizer has infringed the '799 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

243. Based on Plaintiffs' current knowledge, which is informed by material Pfizer provided during the BPCIA "patent dance" to date, Pfizer's manufacture of its aBLA product infringed at least claim 1 of the '799 patent.

244. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA

product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

245. On information and belief based upon Pfizer's notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the '799 patent.

246. The submission of Pfizer's aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer's aBLA product before the expiration of the '799 patent is an act of infringement of one or more claims of the '799 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

247. Pfizer knew, understood, and believed that the '799 patent was infringed by Pfizer's aBLA product and by its submission of aBLA No. 761099 to the FDA.

248. Pfizer's infringement of the '799 patent was and is willful for reasons including the fact that Genentech listed the '799 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the '799 patent at least as early as January, 2018.

249. As a consequence of Pfizer's infringement of the '799 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

250. Pfizer's willful, wanton, and deliberate infringement of the '799 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred, pursuant to 35 U.S.C. § 285.

251. As a result of Pfizer's infringement of the '799 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the '799 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT NINETEEN
(Declaratory Judgment of Infringement of the '799 Patent)

252. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

253. Pfizer's future manufacture of its aBLA product will infringe one or more claims of the '799 patent, pursuant to 35 U.S.C. § 271(a).

254. Pfizer's past manufacture of its aBLA product infringed one or more method claims of the '799 patent.

255. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

256. Pfizer's future sale of its aBLA product that was or will be manufactured using a method or methods claimed by the '799 patent will infringe one or more claims of the '799 patent, pursuant to 35 U.S.C. § 271(g).

257. Pfizer knows, understands, and believes that the '799 patent is infringed by Pfizer's aBLA product and by its submission of aBLA No. 761099 to the FDA.

258. Pfizer's infringement of the '799 patent was and will be willful, for reasons including the fact that Genentech listed the '799 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the '799 patent no later than January, 2018.

259. Unless Pfizer is enjoined from infringing the '799 patent, including by selling its aBLA product made by processes patented by the '799 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

260. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

261. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer's past manufacture infringed the '799 patent and whether its future manufacture and/or sale of its aBLA product will infringe the '799 patent.

262. Genentech is entitled to a judgment that Pfizer's past manufacture and its future manufacture and/or sale of its aBLA product will infringe the '799 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT TWENTY
(Infringement of the '336 Patent)

263. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

264. United States Patent No. 7,846,336 ("the '336 patent") (Exhibit M hereto) was duly and legally issued on December 7, 2010.

265. The '336 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

266. Pfizer has infringed the '336 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

267. Based on Plaintiffs' current knowledge, which is informed by material Pfizer provided during the BPCIA "patent dance" to date, Pfizer's manufacture of its aBLA product infringed at least claim 1 of the '336 patent.

268. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

269. On information and belief based upon Pfizer's notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within

the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the ’336 patent.

270. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer’s aBLA product before the expiration of the ’336 patent is an act of infringement of one or more claims of the ’336 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

271. Pfizer knew, understood, and believed that the ’336 patent was infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

272. Pfizer’s infringement of the ’336 patent was and is willful for reasons including the fact that Genentech listed the ’336 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

273. As a consequence of Pfizer’s infringement of the ’336 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

274. Pfizer’s willful, wanton, and deliberate infringement of the ’336 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred, pursuant to 35 U.S.C. § 285.

275. As a result of Pfizer’s infringement of the ’336 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the ’336 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT TWENTY-ONE
(Declaratory Judgment of Infringement of the ’336 Patent)

276. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

277. Pfizer’s future manufacture of its aBLA product will infringe one or more claims of the ’336 patent, pursuant to 35 U.S.C. § 271(a).

278. Pfizer's past manufacture of its aBLA product infringed one or more method claims of the '336 patent.

279. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

280. Pfizer's future sale of its aBLA product that was or will be manufactured using a method or methods claimed by the '336 patent will infringe one or more claims of the '336 patent, pursuant to 35 U.S.C. § 271(g).

281. Pfizer knows, understands, and believes that the '336 patent is infringed by Pfizer's aBLA product and by its submission of aBLA No. 761099 to the FDA.

282. Pfizer's infringement of the '336 patent was and will be willful, for reasons including the fact that Genentech listed the '336 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

283. Unless Pfizer is enjoined from infringing the '336 patent, including by selling its aBLA product made by processes patented by the '336 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

284. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

285. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer's past manufacture infringed the '336 patent and whether its future manufacture and/or sale of its aBLA product will infringe the '336 patent.

286. Genentech is entitled to a judgment that Pfizer's past manufacture and its future

manufacture and/or sale of its aBLA product will infringe the ’336 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT TWENTY-TWO
(Infringement of the ’221 Patent)

287. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

288. United States Patent No. 7,923,221 (“the ’221 patent”) (Exhibit N hereto) was duly and legally issued on April 12, 2011.

289. Although the ’221 patent expired on December 18, 2018, prior to expiry Pfizer infringed the ’221 patent in violation of 35 U.S.C. § 271(a) at least by making and/or using its aBLA product in the United States.

290. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s pre-expiration manufacture and/or use of its aBLA product infringed at least claim 1 of the ’221 patent.

291. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured before the expiration of the ’221 patent, Pfizer’s pre-expiration manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

292. If its aBLA is approved by the FDA, Pfizer intends to offer for sale or sell its aBLA product, some manufacture of which predated the expiry of the ’221 patent and infringed the ’221 patent.

293. Pfizer knew, understood, and believed that the ’221 patent was infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

294. Pfizer’s infringement of the ’221 patent was willful for reasons including the fact that Pfizer is and has been aware of the ’221 patent and its scope prior to making and/or using its

aBLA product in the United States. Pfizer has had knowledge of and has been aware of the ’221 patent since at least as early as Genentech’s disclosure of this patent to Pfizer on November 3, 2017, pursuant to 42 U.S.C. § 262(*l*)(3)(A) and related to Pfizer’s proposed biosimilar Herceptin® product.

295. As a consequence of Pfizer’s infringement of the ’221 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

296. Pfizer’s willful, wanton, and deliberate infringement of the ’221 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred, pursuant to 35 U.S.C. § 285.

297. Plaintiffs will suffer irreparable injury if Pfizer offers to sell or sells its aBLA product whose manufacture infringed the ’221 patent. Unless Pfizer is enjoined from offering to sell or selling this product, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT TWENTY-THREE
(Infringement of the ’225 Patent)

298. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

299. United States Patent No. 8,314,225 (“the ’225 patent”) (Exhibit O hereto) was duly and legally issued on November 20, 2012.

300. The ’225 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

301. Pfizer has infringed the ’225 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

302. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s manufacture of its aBLA product

infringed at least claim 20 of the ’225 patent.

303. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

304. On information and belief based upon Pfizer’s notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the ’225 patent.

305. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer’s aBLA product before the expiration of the ’225 patent is an act of infringement of one or more claims of the ’225 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

306. Pfizer knew, understood, and believed that the ’225 patent was infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

307. Pfizer’s infringement of the ’225 patent was and is willful for reasons including the fact that Genentech listed the ’225 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the ’225 patent at least as early as January 2018.

308. As a consequence of Pfizer’s infringement of the ’225 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

309. Pfizer’s willful, wanton, and deliberate infringement of the ’225 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred, pursuant to 35 U.S.C. § 285.

310. As a result of Pfizer's infringement of the '225 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the '225 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT TWENTY-FOUR
(Declaratory Judgment of Infringement of the '225 Patent)

311. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

312. Pfizer's future manufacture of its aBLA product will infringe one or more claims of the '225 patent, pursuant to 35 U.S.C. § 271(a).

313. Pfizer's past manufacture of its aBLA product infringed one or more method claims of the '225 patent.

314. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

315. Pfizer's future sale of its aBLA product that was or will be manufactured using a method or methods claimed by the '225 patent will infringe one or more claims of the '225 patent, pursuant to 35 U.S.C. § 271(g).

316. Pfizer knows, understands, and believes that the '225 patent is infringed by Pfizer's aBLA product and by its submission of aBLA No. 761099 to the FDA.

317. Pfizer's infringement of the '225 patent was and will be willful, for reasons including the fact that Genentech listed the '225 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the '225 patent no later than January, 2018.

318. Unless Pfizer is enjoined from infringing the '225 patent, including by selling its aBLA product made by processes patented by the '225 patent, Plaintiffs will suffer irreparable

injury. Plaintiffs have no adequate remedy at law.

319. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

320. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer's past manufacture infringed the '225 patent and whether its future manufacture and/or sale of its aBLA product will infringe the '225 patent.

321. Genentech is entitled to a judgment that Pfizer's past manufacture and its future manufacture and/or sale of its aBLA product will infringe the '225 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT TWENTY-FIVE
(Infringement of the '983 Patent)

322. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

323. United States Patent No. 8,512,983 ("the '983 patent") (Exhibit P hereto) was duly and legally issued on August 20, 2013.

324. The '983 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

325. Pfizer has infringed the '983 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

326. Based on Plaintiffs' current knowledge, which is informed by material Pfizer provided during the BPCIA "patent dance" to date, Pfizer's manufacture of its aBLA product infringed at least claim 1 of the '983 patent.

327. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA

product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

328. On information and belief based upon Pfizer's notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the '983 patent.

329. The submission of Pfizer's aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer's aBLA product before the expiration of the '983 patent is an act of infringement of one or more claims of the '983 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

330. Pfizer knew, understood, and believed that the '983 patent was infringed by Pfizer's aBLA product and by its submission of aBLA No. 761099 to the FDA.

331. Pfizer's infringement of the '983 patent was and is willful for reasons including the fact that Genentech listed the '983 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the '983 patent at least as early as January, 2018.

332. As a consequence of Pfizer's infringement of the '983 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

333. Pfizer's willful, wanton, and deliberate infringement of the '983 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred, pursuant to 35 U.S.C. § 285.

334. As a result of Pfizer's infringement of the '983 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the '983 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT TWENTY-SIX
(Declaratory Judgment of Infringement of the '983 Patent)

335. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

336. Pfizer's future manufacture of its aBLA product will infringe one or more claims of the '983 patent, pursuant to 35 U.S.C. § 271(a).

337. Pfizer's past manufacture of its aBLA product infringed one or more method claims of the '983 patent.

338. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

339. Pfizer's future sale of its aBLA product that was or will be manufactured using a method or methods claimed by the '983 patent will infringe one or more claims of the '983 patent under 35 U.S.C. § 271(g).

340. Pfizer knows, understands, and believes that the '983 patent is infringed by Pfizer's aBLA product and by its submission of aBLA No. 761099 to the FDA.

341. Pfizer's infringement of the '983 patent was and will be willful, for reasons including the fact that Genentech listed the '983 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the '983 patent no later than January, 2018.

342. Unless Pfizer is enjoined from infringing the '983 patent, including by selling its aBLA product made by processes patented by the '983 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

343. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

344. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer's past manufacture infringed the '983 patent and whether its future manufacture and/or sale of its aBLA product will infringe the '983 patent.

345. Genentech is entitled to a judgment that Pfizer's past manufacture and its future manufacture and/or sale of its aBLA product will infringe the '983 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT TWENTY-SEVEN
(Infringement of the '869 Patent)

346. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

347. United States Patent No. 8,574,869 ("the '869 patent") (Exhibit Q hereto) was duly and legally issued on November 5, 2013.

348. The '869 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

349. Pfizer has infringed the '869 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

350. Based on Plaintiffs' current knowledge, which is informed by material Pfizer provided during the BPCIA "patent dance" to date, Pfizer's manufacture of its aBLA product infringed at least claim 1 of the '869 patent.

351. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

352. On information and belief based upon Pfizer's notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within

the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the '869 patent.

353. The submission of Pfizer's aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer's aBLA product before the expiration of the '869 patent is an act of infringement of one or more claims of the '869 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

354. Pfizer knew, understood, and believed that the '869 patent was infringed by Pfizer's aBLA product and by its submission of aBLA No. 761099 to the FDA.

355. Pfizer's infringement of the '869 patent was and is willful for reasons including the fact that Genentech listed the '869 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the '869 patent at least as early as January, 2018.

356. As a consequence of Pfizer's infringement of the '869 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

357. Pfizer's willful, wanton, and deliberate infringement of the '869 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred, pursuant to 35 U.S.C. § 285.

358. As a result of Pfizer's infringement of the '869 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the '869 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT TWENTY-EIGHT
(Declaratory Judgment of Infringement of the '869 Patent)

359. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

360. Pfizer's future manufacture of its aBLA product will infringe one or more claims

of the ’869 patent, pursuant to 35 U.S.C. § 271(a).

361. Pfizer’s past manufacture of its aBLA product infringed one or more method claims of the ’869 patent.

362. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

363. Pfizer’s future sale of its aBLA product that was or will be manufactured using a method or methods claimed by the ’869 patent will infringe one or more claims of the ’869 patent, pursuant to 35 U.S.C. § 271(g).

364. Pfizer knows, understands, and believes that the ’869 patent is infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

365. Pfizer’s infringement of the ’869 patent was and will be willful, for reasons including the fact that Genentech listed the ’869 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the ’869 patent no later than January, 2018.

366. Unless Pfizer is enjoined from infringing the ’869 patent, including by selling its aBLA product made by processes patented by the ’869 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

367. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

368. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer’s past manufacture infringed the ’869 patent and whether its future manufacture and/or sale of its aBLA product will

infringe the ’869 patent.

369. Genentech is entitled to a judgment that Pfizer’s past manufacture and its future manufacture and/or sale of its aBLA product will infringe the ’869 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT TWENTY-NINE
(Infringement of the ’035 Patent)

370. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

371. United States Patent No. 9,441,035 (“the ’035 patent”) (Exhibit R hereto) was duly and legally issued on September 13, 2016.

372. The ’035 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

373. Pfizer has infringed the ’035 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

374. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s manufacture of its aBLA product infringed at least claim 1 of the ’035 patent.

375. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured , Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

376. On information and belief based upon Pfizer’s notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the ’035 patent.

377. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the

commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer's aBLA product before the expiration of the '035 patent is an act of infringement of one or more claims of the '035 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

378. Pfizer knew, understood, and believed that the '035 patent was infringed by Pfizer's aBLA product and by its submission of aBLA No, 761099 to the FDA.

379. Pfizer's infringement of the '035 patent was and is willful for reasons including the fact that Genentech listed the '035 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the '035 patent at least as early as January, 2018.

380. As a consequence of Pfizer's infringement of the '035 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

381. Pfizer's willful, wanton, and deliberate infringement of the '035 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred, pursuant to 35 U.S.C. § 285.

382. As a result of Pfizer's infringement of the '035 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the '035 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT THIRTY
(Declaratory Judgment of Infringement of the '035 Patent)

383. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

384. Pfizer's future manufacture of its aBLA product will infringe one or more claims of the '035 patent, pursuant to 35 U.S.C. § 271(a).

385. Pfizer's past manufacture of its aBLA product infringed one or more method claims of the '035 patent.

386. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

387. Pfizer's future sale of its aBLA product that was or will be manufactured using a method or methods claimed by the '035 patent will infringe one or more claims of the '035 patent, pursuant to 35 U.S.C. § 271(g).

388. Pfizer knows, understands, and believes that the '035 patent is infringed by Pfizer's aBLA product and by its submission of aBLA No. 761099 to the FDA.

389. Pfizer's infringement of the '035 patent was and will be willful, for reasons including the fact that Genentech listed the '035 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the '035 patent no later than January, 2018.

390. Unless Pfizer is enjoined from infringing the '035 patent, including by selling its aBLA product made by processes patented by the '035 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

391. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

392. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer's past manufacture infringed the '035 patent and whether its future manufacture and/or sale of its aBLA product will infringe the '035 patent.

393. Genentech is entitled to a judgment that Pfizer's past manufacture and its future manufacture and/or sale of its aBLA product will infringe the '035 patent, and that that

infringement will cause Plaintiffs to suffer irreparable injury.

COUNT THIRTY-ONE
(Infringement of the ’293 Patent)

394. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

395. United States Patent No. 9,714,293 (“the ’293 patent”) (Exhibit S hereto) was duly and legally issued on July 25, 2017.

396. The ’293 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

397. Pfizer has infringed the ’293 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

398. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s manufacture of its aBLA product infringed at least claim 1 of the ’293 patent.

399. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

400. On information and belief based upon Pfizer’s notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the ’293 patent.

401. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer’s aBLA product before the expiration of the ’293 patent is an act of infringement of one or more claims of the ’293 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

402. Pfizer knew, understood, and believed that the ’293 patent was infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

403. Pfizer’s infringement of the ’293 patent was and is willful for reasons including the fact that Genentech listed the ’293 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the ’293 patent at least as early as January, 2018.

404. As a consequence of Pfizer’s infringement of the ’293 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

405. Pfizer’s willful, wanton, and deliberate infringement of the ’293 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred, pursuant to 35 U.S.C. § 285.

406. As a result of Pfizer’s infringement of the ’293 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the ’293 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT THIRTY-TWO
(Declaratory Judgment of Infringement of the ’293 Patent)

407. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

408. Pfizer’s future manufacture of its aBLA product will infringe one or more claims of the ’293 patent, pursuant to 35 U.S.C. § 271(a).

409. Pfizer’s past manufacture of its aBLA product infringed one or more method claims of the ’293 patent.

410. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

411. Pfizer's future sale of its aBLA product that was or will be manufactured using a method or methods claimed by the '293 patent will infringe one or more claims of the '293 patent, pursuant to 35 U.S.C. § 271(g).

412. Pfizer knows, understands, and believes that the '293 patent is infringed by Pfizer's aBLA product and by its submission of aBLA No. 761099 to the FDA.

413. Pfizer's infringement of the '293 patent was and will be willful, for reasons including the fact that Genentech listed the '293 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A). Additionally, based on correspondence between the parties, Pfizer was aware of the '293 patent no later than January, 2018.

414. Unless Pfizer is enjoined from infringing the '293 patent, including by selling its aBLA product made by processes patented by the '293 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

415. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

416. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer's past manufacture infringed the '293 patent and whether its future manufacture and/or sale of its aBLA product will infringe the '293 patent.

417. Genentech is entitled to a judgment that Pfizer's past manufacture and its future manufacture and/or sale of its aBLA product will infringe the '293 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT THIRTY-THREE
(Infringement of the '672 Patent)

418. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

419. United States Patent No. 9,795,672 ("the '672 patent") (Exhibit T hereto) was duly and legally issued on October 24, 2017.

420. The '672 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

421. Upon information and belief, Pfizer submitted aBLA No. 761099 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of a biosimilar version of Avastin® before expiration of the '672 patent. Pfizer knows and intends that its offer for sale and/or sale of its aBLA product in the United States will infringe the '672 patent.

422. The submission of Pfizer's aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer's aBLA product before the expiration of the '672 patent is an act of infringement of one or more claims of the '672 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

423. Pfizer will also induce or contribute to infringement of the '672 patent in violation of 35 U.S.C. § 271(b)-(c) by engaging in the commercial marketing, offering for sale, and/or selling its aBLA product in the United States.

424. Based upon Pfizer's notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product.

425. On information and belief, Pfizer's offering to sell and sale of its aBLA product will encourage, suggest, teach, and/or induce the product's use as claimed in the '672 patent. The administration by, for example, physicians or patients would constitute direct infringement, either literally or under the doctrine of equivalents, of one or more claims of the '672 patent.

Upon information and belief, this direct infringement would occur at Pfizer's behest, with Pfizer's intent, knowledge, and encouragement as a result of, for example, Pfizer's sales, marketing, and distribution of its proposed biosimilar product with its proposed prescribing information.

426. Based on Plaintiffs' current knowledge, which is informed by material Pfizer provided during the BPCIA "patent dance" to date, Pfizer's offer to sell or sale of its aBLA product in the United States would infringe at least claim 2 of the '672 patent.

427. On information and belief, Pfizer plans and intends to, and will, actively induce infringement of the '672 patent when it begins commercial marketing of its aBLA product.

428. Pfizer's aBLA product is adapted for infringement of the '672 patent and is not a staple article of commerce.

429. On information and belief, Pfizer knows that its aBLA product and its proposed labeling are especially made or adapted for use in infringing the '672 patent, and that Pfizer's aBLA product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Pfizer plans and intends to, and will, contribute to infringement of the '672 patent when it begins commercial marketing of its aBLA product.

430. Pfizer knew, understood, and believed that the '672 patent was infringed by at least its submission of aBLA No. 761099 to the FDA.

431. Pfizer's infringement of the '672 patent was and will be willful for reasons including the fact that Pfizer filed a petition for *inter partes* review of the '672 patent (IPR2018-00373).Additionally, Genentech listed the '672 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(l)(3)(A).

432. Unless Pfizer is enjoined from infringing the '672 patent, Plaintiffs will suffer

irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT THIRTY-FOUR
(Declaratory Judgment of Infringement of the ’672 Patent)

433. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

434. Pfizer knows and intends that its offer for sale and/or sale of its aBLA product in the United States will infringe the ’672 patent.

435. Pfizer’s aBLA product is adapted for infringement of the ’672 patent and is not a staple article of commerce.

436. Pfizer will induce or contribute to infringement of the ’672 patent in violation of 35 U.S.C. § 271(b)–(c) by offering for sale, and/or selling its aBLA product in the United States.

437. On information and belief, Pfizer’s offer to sell and sale of its aBLA product will encourage, suggest, teach, and/or induce the product’s use as claimed in the ’672 patent.

438. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s offer to sell or sale of its aBLA product in the United States would infringe at least claim 1 of the ’672 patent.

439. If its aBLA is approved by the FDA, Pfizer plans and intends to, and will, actively induce infringement of the ’672 patent when it begins commercial marketing of its aBLA product.

440. Pfizer knows that its aBLA product and its proposed labeling are especially made or adapted for use in infringing the ’672 patent, and that Pfizer’s aBLA product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Pfizer plans and intends to, and will, contribute to infringement of the ’672 patent when it begins commercial marketing of its aBLA product.

441. Pfizer knows, understands, and believes that the ’672 patent is infringed by at

least its submission of aBLA No. 761099 to the FDA.

442. Pfizer's infringement of the '672 patent was and will be willful, for reasons including the fact that Pfizer filed a petition for *inter partes* review of the '672 patent (IPR2018-00373)). Additionally, Genentech listed the '672 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

443. Unless Pfizer is enjoined from infringing the '672 patent, including being enjoined from inducing or contributing to infringement of the '672 patent in violation of 35 U.S.C. § 271(b)-(c) by offering for sale, and/or selling its aBLA product in the United States, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

444. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

445. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer's future offer to sell and sale of its aBLA product will encourage, suggest, teach, and/or induce the product's use will infringe the '672 patent.

446. Genentech is entitled to a judgment that Pfizer's future offer to sell and sale of its aBLA product will encourage, suggest, teach, and/or induce the product's use will infringe the '672 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT THIRTY-FIVE
(Infringement of the '904 Patent)

447. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

448. United States Patent No. 9,884,904 ("the '904 patent") (Exhibit U hereto) was duly and legally issued on February 6, 2018.

449. The '904 patent was among the patents Pfizer agreed on March 6, 2019 should be

included in a suit for patent infringement under the BPCIA.

450. Pfizer has infringed the ’904 patent in violation of 35 U.S.C. § 271(a) at least by making its aBLA product in the United States.

451. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s manufacture of its aBLA product infringed at least claim 1 of the ’904 patent.

452. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

453. On information and belief based upon Pfizer’s notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the ’904 patent.

454. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer’s aBLA product before the expiration of the ’904 patent is an act of infringement of one or more claims of the ’904 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

455. Pfizer knew, understood, and believed that the ’904 patent was infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

456. Pfizer’s infringement of the ’904 patent was and is willful for reasons including the fact that Genentech listed the ’904 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

457. As a consequence of Pfizer’s infringement of the ’904 patent, Plaintiffs have

suffered damages in an amount not yet determined, but no less than a reasonable royalty.

458. Pfizer's willful, wanton, and deliberate infringement of the '904 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys' fees and costs incurred, pursuant to 35 U.S.C. § 285.

459. As a result of Pfizer's infringement of the '904 patent, Plaintiffs will suffer irreparable injury. Unless Pfizer is enjoined from infringing the '904 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT THIRTY-SIX
(Declaratory Judgment of Infringement of the '904 Patent)

460. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

461. Pfizer's future manufacture of its aBLA product will infringe one or more claims of the '904 patent, pursuant to 35 U.S.C. § 271(a).

462. Pfizer's past manufacture of its aBLA product infringed one or more method claims of the '904 patent.

463. Based on information and belief, including information about the amount of Pfizer's aBLA product Pfizer manufactured, Pfizer's manufacture and/or use of its aBLA product was not protected by the "safe harbor" provision of 35 U.S.C. § 271(e)(1).

464. Pfizer's future sale of its aBLA product that was or will be manufactured using a method or methods claimed by the '904 patent will infringe one or more claims of the '904 patent, pursuant to 35 U.S.C. § 271(g).

465. Pfizer knows, understands, and believes that the '213 patent is infringed by at least its submission of aBLA No. 761099 to the FDA.

466. Pfizer's infringement of the '904 patent was and will be willful, for reasons including the fact that Genentech listed the '904 patent on its November 13, 2018 list pursuant to

42 U.S.C. § 262(*l*)(3)(A).

467. Unless Pfizer is enjoined from infringing the ’904 patent, including by selling its aBLA product made by processes patented by the ’904 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

468. Pfizer provided notice to Genentech of its intent to begin commercial marketing of its aBLA product as early as July 17, 2019.

469. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer’s past manufacture infringed the ’904 patent and whether its future manufacture and/or sale of its aBLA product will infringe the ’904 patent.

470. Genentech is entitled to a judgment that Pfizer’s past manufacture and its future manufacture and/or sale of its aBLA product will infringe the ’904 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT THIRTY-SEVEN
(Infringement of the ’611 Patent)

471. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

472. United States Patent No. 10,010,611 (“the ’611 patent”) (Exhibit V hereto) was duly and legally issued on July 3, 2018.

473. The ’611 patent was among the patents Pfizer agreed on March 6, 2019 should be included in a suit for patent infringement under the BPCIA.

474. Pfizer has infringed the ’611 patent in violation of 35 U.S.C. § 271(a) at least by making and/or using its aBLA product in the United States.

475. Based on Plaintiffs’ current knowledge, which is informed by material Pfizer provided during the BPCIA “patent dance” to date, Pfizer’s manufacture or use of its aBLA

product infringed at least claim 1 of the ’611 patent.

476. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

477. On information and belief based upon Pfizer’s notice of commercial marketing, pursuant to 42 U.S.C. § 262(*l*)(8)(A), Pfizer intends to, and will, offer for sale and/or sell within the United States, or import into the United States, its aBLA product as early as July 17, 2019, which is before the expiration of the ’611 patent.

478. The submission of Pfizer’s aBLA to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, and/or sale, or import into the United States of Pfizer’s aBLA product before the expiration of the ’611 patent is an act of infringement of one or more claims of the ’611 patent, pursuant to 35 U.S.C. § 271(e)(2)(C).

479. Pfizer knew, understood, and believed that the ’611 patent was infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

480. Pfizer’s infringement of the ’611 patent was and is willful for reasons including the fact that Genentech listed the ’611 patent on its November 13, 2018 list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

481. As a consequence of Pfizer’s infringement of the ’611 patent, Plaintiffs have suffered damages in an amount not yet determined, but no less than a reasonable royalty.

482. Pfizer’s willful, wanton, and deliberate infringement of the ’611 patent justifies an award to Plaintiffs of increased damages, pursuant to 35 U.S.C. § 284, and attorneys’ fees and costs incurred, pursuant to 35 U.S.C. § 285.

483. As a result of Pfizer’s infringement of the ’611 patent, Plaintiffs will suffer

irreparable injury. Unless Pfizer is enjoined from infringing the ’611 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT THIRTY-EIGHT
(Declaratory Judgment of Infringement of the ’611 Patent)

484. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

485. Pfizer’s future manufacture of its aBLA product will infringe one or more claims of the ’611 patent, pursuant to 35 U.S.C. § 271(a).

486. Pfizer’s past manufacture of its aBLA product infringed one or more method claims of the ’611 patent.

487. Based on information and belief, including information about the amount of Pfizer’s aBLA product Pfizer manufactured, Pfizer’s manufacture and/or use of its aBLA product was not protected by the “safe harbor” provision of 35 U.S.C. § 271(e)(1).

488. Pfizer’s future sale of its aBLA product that was or will be manufactured using a method or methods claimed by the ’611 patent will infringe one or more claims of the ’611 patent, pursuant to 35 U.S.C. § 271(g).

489. Pfizer knows, understands, and believes that the ’611 patent is infringed by Pfizer’s aBLA product and by its submission of aBLA No. 761099 to the FDA.

490. Pfizer’s infringement of the ’611 patent was and will be willful, for reasons including the fact that Genentech listed the ’611 patent on its November 13, 2018 list, pursuant to 42 U.S.C. § 262(*l*)(3)(A).

491. Unless Pfizer is enjoined from infringing the ’611 patent, including by selling its aBLA product made by processes patented by the ’611 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

492. Pfizer provided notice to Genentech of its intent to begin commercial marketing

of its aBLA product as early as July 17, 2019.

493. Accordingly, there is a real, immediate, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer's past manufacture infringed the '611 patent and whether its future manufacture and/or sale of its aBLA product will infringe the '611 patent.

494. Genentech is entitled to a judgment that Pfizer's past manufacture and its future manufacture and/or sale of its aBLA product will infringe the '611 patent, and that that infringement will cause Plaintiffs to suffer irreparable injury.

COUNT THIRTY-NINE
(Declaratory Judgment as to 42 U.S.C. § 262(*l*)(9)(C))

495. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

496. This claim arises pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

497. Pfizer's aBLA for Pfizer's aBLA product was submitted to the FDA, pursuant to 42 U.S.C. § 262(k), the subsection of the BPCIA governing licensure of biologic products as biosimilar or interchangeable to licensed products.

498. On September 14, 2018, Genentech received what Pfizer represented to be its production, pursuant to 42 U.S.C. § 262(*l*)(2)(A). Both before and after receiving this production, Genentech asked Pfizer to provide certain information in addition to its aBLA, as required by 42 U.S.C. § 262(*l*)(2)(A), relating to the manufacturing process for Pfizer's aBLA product. Upon information and belief, Pfizer had in its possession such information. Pfizer refused to produce this information.

499. In fact, and as Pfizer later admitted, the September 14, 2018 production did not include every portion of the aBLA Pfizer submitted to the FDA for Pfizer's aBLA product

(bevacizumab).

500. Nevertheless, Pfizer took the position that its September 14, 2018 production satisfied its obligations under 42 U.S.C. § 262(*l*)(2)(A).

501. Genentech disputes, and continues to dispute, that Pfizer's production of portions of its aBLA satisfied its obligations under 42 U.S.C. § 262(*l*)(2)(A).

502. Accordingly, there is a real, substantial, and continuing case or controversy between Genentech and Pfizer regarding whether Pfizer complied with 42 U.S.C. § 262(*l*)(2)(A).

503. Genentech is entitled to a judgment that Pfizer failed to provide the application and information required, pursuant to 42 U.S.C. § 262(*l*)(2)(A), and that 42 U.S.C. § 262(*l*)(9)(C) therefore prohibits Pfizer from bringing "an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product [bevacizumab] or use of the biological product [bevacizumab]."

JURY TRIAL DEMANDED

Plaintiffs request a trial by jury on all claims so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

a. A judgment that Pfizer has infringed the Asserted Patents;

b. A declaration that Pfizer's future manufacture, use, sale, or offer to sell its aBLA product will infringe the Asserted Patents;

c. A judgment that Pfizer failed to provide the application and information required, pursuant to 42 U.S.C. § 262(*l*)(2)(A) and that 42 U.S.C. § 262(*l*)(9)(C) therefore prohibits Pfizer from filing a declaratory judgment action with respect to "any patent that claims the biological product [bevacizumab] or use of the biological product [bevacizumab]."

d. Damages in the form of lost profits but in no event less than a reasonable

royalty;

e. A judgment that the infringement has been willful and an enhancement of damages;

f. An award for an accounting of damages from Pfizer's infringement;

g. A declaration that this is an exceptional case and an award of attorneys' fees, pursuant to 35 U.S.C. § 285;

h. An award of Plaintiffs' costs and expenses in this action;

i. Preliminary and/or permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins Pfizer, 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 the same, or actively inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacturing of which infringes the Asserted Patents; and

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

Dated: April 5, 2019

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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