**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

| | | |
|---|---|---|
| GENENTECH, INC. | ) | |
| | ) | |
| Plaintiff, | ) | C. A. No. _____ |
| | ) | |
| v. | ) | **JURY TRIAL DEMANDED** |
| | ) | |
| SAMSUNG BIOEPIS CO. LTD., | ) | |
| | ) | |
| Defendant. | ) | |
| | ) | |
| | ) | |

**COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT**

Plaintiff Genentech, Inc. by its attorneys, for its Complaint, alleges as follows:

## I. THE PARTIES

1. Genentech, Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at 1 DNA Way, South San Francisco, California 94080. The company is dedicated to discovering, developing, and commercializing medicines to treat patients with debilitating and life-threatening diseases.

2. On information and belief, Samsung Bioepis Co. Ltd. ("Bioepis") is a corporation organized and existing under the laws of South Korea, with its principal place of business at 107, Cheomdan-daero Yeonsu-gu Incheon, 406-840 South Korea. Bioepis develops, manufactures, and seeks regulatory approval for biosimilar products, and imports, markets, distributes, offers to sell, and/or sells those biosimilar products in the State of Delaware and throughout the United States.

## II. NATURE OF THE ACTION

3. This action seeks relief under 35 U.S.C. § 271 for patent infringement and the Biologics Price Competition and Innovation Act ("BPCIA") against Bioepis in connection with its

manufacture and efforts to commercialize a biosimilar to Avastin®, Genentech's best-selling cancer therapy. Bioepis has infringed or threatens to infringe the following Asserted Patents:

| U.S. Patent No. | Issue Date | First Named Inventor |
|---|---|---|
| EX A – 6,586,206 | Jul. 1, 2003 | Dixit |
| EX B – 7,390,660 | Jun. 24, 2008 | Behrendt |
| EX C – 7,485,704 | Feb. 3, 2009 | Fahrner |
| EX D – 8,460,895 | Jun. 11, 2013 | Eisenkraetzer |
| EX E – 8,512,983 | Aug. 20, 2013 | Gawlitzek |
| EX F – 8,574,869 | Nov. 5, 2013 | Kao |
| EX G – 9,441,035 | Sep. 13, 2016 | Carvalhal |
| EX H – 9,487,809 | Nov. 8, 2016 | Zhou |
| EX I – 9,714,293 | Jul. 25, 2017 | Gawlitzek |
| EX J – 9,795,672 | Oct. 24, 2017 | Fyfe |
| EX K – 10,208,355 | Feb. 19, 2019 | Bais |
| EX L – 10,513,697 | Dec. 24, 2019 | da Silva Ribeiro |
| EX M – 10,662,237 | May 26, 2020 | Mehta |
| EX N – 10,676,710 | June 9, 2020 | Vijayasankaran |

4. Except for U.S. Patent Nos. 7,390,660 (Exhibit B); 8,460,895 (Exhibit D); and 10,513,697 (Exhibit L), Genentech owns all rights, title, and interest in the Patents-in-Suit. Genentech is the exclusive licensee of the other three patents and has an agreement with their owner, Hoffmann-La Roche, Inc., an affiliated company, granting Genentech the sole right to enforce these patents.

5. On information and belief, on November 18, 2019, the Food and Drug Administration accepted for review Bioepis' abbreviated Biologics License Application ("aBLA") No. 761159 seeking authorization to make and sell SB8, a biosimilar version of Avastin® ("Bioepis' bevacizumab biosimilar product"). Bioepis submitted that aBLA pursuant to the BPCIA, specifically 42 U.S.C. § 262(k) (also known as § 351(k) of the Public Health Service Act).

6. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. Subject to certain conditions, the abbreviated pathway permits an applicant to rely on the prior clinical tests, data, and results, and the prior licensure and approval status, of the innovative biological product, or "reference product." Here, Bioepis is seeking approval of SB8 based on the prior testing and related efforts Genentech, the "reference product sponsor," undertook in securing various approvals for Avastin®.

7. As alleged herein, Bioepis infringed one or more claims of the Patents-In-Suit under 35 U.S.C. § 271(e)(2)(C)(ii) when it submitted its aBLA seeking FDA approval to engage in the commercial manufacture, use or sale of SB8 before the expiration of the Asserted Patents.

8. As alleged herein, Bioepis would also infringe one or more claims of the Patents-In-Suit, under 35 U.S.C. § 271(b) and/or (g), should it make, use, offer for sale, or sell within the United States, or import into the United States, Bioepis' bevacizumab biosimilar product, or actively induce another to do the same before the expiration of the Patents-In-Suit.

## III. JURISDICTION AND VENUE

### A. Subject-Matter Jurisdiction

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

### B. Personal Jurisdiction

10. This Court has personal jurisdiction over Bioepis because Bioepis through its aBLA seeks FDA approval to sell SB8 throughout the United States, including the State of Delaware.

11. On information and belief, Bioepis, by itself or through others, intends to use, induce others to use, offer for sale, sell within the United States, and import into the United States, including the District of Delaware, its bevacizumab biosimilar product.

12. This Court also has personal jurisdiction over Bioepis by virtue of Bioepis' contacts with Delaware and the exercise of such personal jurisdiction is fair and reasonable. Litigating this suit in Delaware does not burden Bioepis. For example, Bioepis did not contest personal jurisdiction when sued by Genentech in another patent case in this district. *Genentech, Inc. v. Samsung Bioepis Co., Ltd.*, No. 1:18-cv-01363-CFC (D. Del. 2018), D.I. 66 ¶ 18.

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

**C. Venue**

14. Venue is proper in this District under 28 U.S.C. § 1391(c)(3). Bioepis is a foreign corporation and is therefore subject to suit in any judicial district. *Brunette Machine Works, Ltd. v. Kockum Industries, Inc.*, 406 U.S. 706, 713-14 (1972); *In re HTC Corp.*, 889 F.3d 1349, 1357-58 (Fed. Cir. 2018), *cert. denied*, 139 S. Ct. 1271 (2019).

## IV. BACKGROUND

15. Avastin® contains a genetically engineered antibody, bevacizumab, that inhibits the proliferation of blood vessels necessary for cancerous tumors to grow. It first received FDA approval in 2004 for use in treating metastatic colon cancer, and since then, based on extensive clinical testing by Genentech, it is now approved also to treat 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.

16. Genentech's innovative work in developing bevacizumab has been rewarded with dozens of patents covering the antibody itself, methods for its therapeutic use, and processes for the manufacture of therapeutic antibodies.

17. 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.

18. In particular, the BPCIA provides that "[w]hen a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to [the reference product sponsor], subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the 'confidential information')." 42 U.S.C. § 262(*l*)(1)(B).

19. The referenced paragraph (2) provides that "[n]ot later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary 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; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor." 42 U.S.C. § 262(*l*)(2).

20. On December 6, 2019, Bioepis provided Genentech with "a copy of the application submitted to the Secretary under subsection (k)," but failed to provide Genentech with "such other information that describes the process or processes used to manufacture the biological product that is the subject of such application," as required by 42 U.S.C. § 262(*l*)(2)(A). Such failure removed any limits on Genentech's ability to bring an action for a declaration of infringement, validity, or enforceability of any patent that claims Bioepis' biosimilar bevacizumab or the use thereof. 42 U.S.C. § 262(*l*)(9)(C); 28 U.S.C. § 2201(b).

21. By a letter sent on December 10, 2019, Genentech reminded Bioepis of its obligation under 42 U.S.C. § 262(*l*)(2)(A) to provide Genentech with information describing Bioepis' manufacturing processes for SB8 in addition to the aBLA for SB8. In a response dated December 12, 2019, Bioepis insisted that the production of its aBLA alone had "fulfilled its obligations under 42 U.S.C. § 262(*l*)(2)(A)."

22. Genentech disputed the point. By letter dated January 6, 2020, Genentech notified Bioepis that its aBLA "lack[ed] information concerning aspects of the manufacture of SB8 that are relevant to ascertaining whether Bioepis infringes various patents." For example, the aBLA "contains little detail about the host cell line used to express SB8" (which was relevant to, for

example, infringement of U.S. Patent No. 9,487,809); lacks information regarding the content of the cell culture medium used in the manufacturing process for SB8 (which was relevant to, for example, infringement of U.S. Patent No. 8,512,983); and lacks information describing the dissolved oxygen levels during the harvest process for SB8 (which was relevant to infringement of U.S. Patent No. 8,574,869).

23. Bioepis dug in. In its response ten days later, Bioepis simply reasserted its position that "provid[ing] the complete copy of the BLA" for SB8 fulfilled its obligations under 42 U.S.C. § 262(*l*)(2)(A). Bioepis provided no additional information concerning the manufacturing process for SB8 in response to the specific deficiencies identified by counsel for Genentech.

24. On February 4, 2020, pursuant to its obligations under 42 U.S.C. § 262(*l*)(3)(A) (to the extent it had any), and based on its review of the limited materials Bioepis had provided, Genentech provided Bioepis with a list of patents "that it believes could reasonably be asserted against Bioepis' proposed SB8 product." Genentech informed Bioepis that it was not prepared to license any of these patents in connection with Bioepis' SB8 product.

25. Bioepis was required under 42 U.S.C. § 262(*l*)(3)(B) to respond within sixty days with a "detailed statement that describes, on a claim by claim basis, the factual and legal basis of [its] opinion . . . that [the patents identified by Genentech are] invalid, unenforceable, or will not be infringed by the commercial marketing" of Bioepis' SB8 product no later than April 6, 2020 (60 days following Genentech's provision of its list of patents). One month before it was due, Bioepis served a response denying infringement of all of the identified patents and providing only conclusory assertions that three of the patents identified by Genentech pursuant to 42 U.S.C. § 262(*l*)(3)(A) were invalid. Bioepis denied any obligation to provide its positions regarding the validity of the remaining patents on Genentech's list and, citing this Court's

decision in *Genentech, Inc. v. Amgen Inc.*, Civ. No. 17-1407-CFC, 2020 WL 636439, at *4–*5 (D. Del. Feb. 11, 2020), insisted that it retained the right to "adopt[] additional positions regarding noninfringement, invalidity, or unenforceability" at a later date.

26. Appended to its "Detailed Statement" Bioepis supplied Genentech with a redacted document purportedly identifying the ingredients of various components of the cell culture mediums used in the manufacturing process for SB8. This document was not provided by Bioepis in December 2019. It was not provided by Bioepis in response to Genentech's concerns that Bioepis had withheld "other information" about its manufacturing process. To the extent the document does disclose "other information" pertinent to the manufacture of SB8, Bioepis's reliance upon it in supporting its non-infringement contentions is an admission that Bioepis failed to timely provide the "other information" required by the BPCIA.

27. On March 30, 2020, counsel for Bioepis sent a letter to counsel for Genentech "pursuant to 42 U.S.C. § 262(*l*)(8)(A) of Samsung Bioepis's intent to begin commercial marketing for its bevacizumab biosimilar in the United States as early as 180 days" from the date of the letter.

28. On May 5, 2020, Genentech served infringement and validity contentions pursuant to 42 U.S.C. § 262(*l*)(3)(C). This document exceeds 300 pages. It is referenced in subsequent paragraphs as providing the factual basis for Genentech's infringement allegations. It is not attached to this Complaint in view of its length and the fact that it refers to information designated by Bioepis as confidential.

29. Following service of those contentions, counsel for Genentech and Bioepis engaged in several conversations pursuant to 42 U.S.C. § 262(*l*)(4). Those discussions concluded on May 29, 2020 with the agreement that Genentech would file suit pursuant to 42 U.S.C. § 262(*l*)(6) asserting the patents identified above as Exhibit A through Exhibit L.

30. On June 15, 2020, Genentech served a supplement to its list of patents pursuant to 42 U.S.C. § 262(*l*)(7), identifying the patents identified above as Exhibit M and Exhibit N.

**COUNT 1: INJUNCTION BARRING COMMERCIAL MARKETING UNTIL NOTICE PERIOD UNDER 42 U.S.C. § 262(*l*)(8)(A) ELAPSES**

31. Paragraphs 1-30 are incorporated by reference as if fully set forth herein.

32. The BPCIA provides that "[t]he subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k)." 42 U.S.C. § 262(*l*)(8)(A).

33. Bioepis purported to provide notice to Genentech pursuant to 42 U.S.C. § 262(*l*)(8)(A) on March 30, 2020; by its terms, that subsection operates to bar Bioepis from commercial marketing pending, at a minimum, 180 days following such notice.

34. On information and belief, following FDA approval of its SB8 product, Bioepis will imminently begin to use, offer, for sale, and sell in the United States, and import into the United States, its bevacizumab biosimilar product. In light of its willful failure to comply with other provisions of the BPCIA, it is reasonable to infer that Bioepis might begin to market its bevacizumab biosimilar product prior to the 180 day period following its purported notice pursuant to § 262(*l*)(8)(A).

35. Genentech is entitled to injunctive relief preventing Bioepis from commercial marketing consistent with the notice period provided by that statute.

**COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 6,586,206 ("THE '206 PATENT") UNDER 35 U.S.C. § 271(e)**

36. Paragraphs 1-35 are incorporated by reference as if fully set forth herein.

37. Claims of the '206 patent cover methods of making recombinant proteins like bevacizumab. The '206 patent was identified in Genentech's list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

38. On information and belief, as described in Genentech's (*l*)(3)(C) contentions, Bioepis infringed claims of the '206 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '206 patent.

39. On information and belief, Bioepis has known of the '206 patent since Bioepis was founded or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '206 patent and in violation of Genentech's patent rights.

40. Genentech is entitled to a judgment that Bioepis has infringed claims of the '206 patent by submitting an aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '206 patent.

41. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis' FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the '206 patent.

**COUNT 3: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '206 PATENT UNDER 35 U.S.C. § 271(g)**

42. Paragraphs 1–41 are incorporated by reference as if fully set forth herein.

43. On information and belief, Bioepis submitted its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '206 patent.

44. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis' bevacizumab biosimilar product, which would constitute infringement of claims of the '206 patent under 35 U.S.C. § 271(g), as explained in Genentech's (*l*)(3)(C) Contentions. Bioepis' bevacizumab biosimilar product is made by the claimed process(es) and is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

45. An actual controversy has arisen and now exists between the parties concerning whether Bioepis' manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, has infringed and/or will infringe claims of the '206 patent.

46. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the '206 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '206 patent.

47. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the '206 patent. Genentech does not have an adequate remedy at law and is entitled to

injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '206 patent.

**COUNT 4: INFRINGEMENT OF U.S. PATENT NO. 7,390,660 ("THE '660 PATENT") UNDER 35 U.S.C. § 271(e)**

48. Paragraphs 1–47 are incorporated by reference as if fully set forth herein.

49. Claims of the '660 patent cover methods of cultivating Chinese Hamster Ovary ("CHO") cells, which can be used in the manufacturing processes for recombinant proteins like bevacizumab. The '660 patent was identified in Genentech's list pursuant to 42 U.S.C. § 262(l)(3)(A).

50. On information and belief, as described in Genentech's (*l*)(3)(C) contentions, Bioepis infringed claims of the '660 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '660 patent.

51. On information and belief, Bioepis has known of the '660 patent since Bioepis was founded or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '660 patent and in violation of Genentech's patent rights.

52. Genentech is entitled to a judgment that Bioepis has infringed one or more claims of the '660 patent by submitting an aBLA referencing Genentech's Avastin® and seeking FDA

approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '660 patent.

53. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis' FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the '660 patent.

**COUNT 5: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '660 PATENT UNDER 35 U.S.C. § 271(g)**

54. Paragraphs 1–53 are incorporated by reference as if fully set forth herein.

55. On information and belief, Bioepis submitted its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '660 patent.

56. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis' bevacizumab biosimilar product, which would constitute infringement of claims of the '660 patent under 35 U.S.C. § 271(g), as explained in Genentech's (*l*)(3)(C) Contentions. Bioepis' bevacizumab biosimilar product is made by the claimed process(es) and is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

57. An actual controversy has arisen and now exists between the parties concerning whether Bioepis' manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or

contributing to the manufacture of Bioepis' bevacizumab biosimilar product, has infringed and/or will infringe one or more claims of the '660 patent.

58. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the '660 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '660 patent.

59. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the '660 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '660 patent.

**COUNT 6: INFRINGEMENT OF U.S. PATENT NO. 7,485,704 ("THE '704 PATENT") UNDER 35 U.S.C. § 271(e)**

60. Paragraphs 1–59 are incorporated by reference as if fully set forth herein.

61. Claims of the '704 patent cover methods of purifying recombinant proteins, like bevacizumab. The '704 patent was identified in Genentech's list pursuant to 42 U.S.C. § 262(l)(3)(A).

62. On information and belief, as described in Genentech's (*l*)(3)(C) Contentions, Bioepis infringed claims of the '704 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '704 patent.

63. On information and belief, Bioepis has known of the ’704 patent since Bioepis was founded or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’704 patent and in violation of Genentech’s patent rights.

64. Genentech is entitled to a judgment that Bioepis has infringed claims of the ’704 patent by submitting an aBLA referencing Genentech’s Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’704 patent.

65. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis’ FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the ’704 patent.

## COUNT 7: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’704 PATENT UNDER 35 U.S.C. § 271(g)

66. Paragraphs 1–65 are incorporated by reference as if fully set forth herein.

67. On information and belief, Bioepis submitted its aBLA referencing Genentech’s Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’704 patent.

68. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the

United States, or import into the United States, Bioepis' bevacizumab biosimilar product, which would constitute infringement of claims of the '704 patent under 35 U.S.C. § 271(g), as described in Genentech's (*l*)(3)(C) Contentions. Bioepis' bevacizumab biosimilar product is made by the claimed process(es) and is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

69. An actual controversy has arisen and now exists between the parties concerning whether Bioepis' manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, has infringed and/or will infringe claims of the '704 patent.

70. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the '704 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '704 patent.

71. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the '704 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '704 patent.

**COUNT 8: INFRINGEMENT OF U.S. PATENT NO. 8,460,895 ("THE '895 PATENT") UNDER 35 U.S.C. § 271(e)**

72. Paragraphs 1–71 are incorporated by reference as if fully set forth herein.

73. Claims of the ’895 patent cover methods of making recombinant polypeptides like bevacizumab. The ’895 patent was identified in Genentech’s list pursuant to 42 U.S.C. § 262(l)(3)(A).

74. On information and belief, as described in Genentech’s (*l*)(3)(C) contentions, Bioepis infringed claims of the ’895 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech’s Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’895 patent.

75. On information and belief, Bioepis has known of the ’895 patent since the patent issued or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’895 patent and in violation of Genentech’s patent rights.

76. Genentech is entitled to a judgment that Bioepis has infringed claims of the ’895 patent by submitting an aBLA referencing Genentech’s Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’895 patent.

77. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis’ FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the ’895 patent.

**COUNT 9: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’895 PATENT UNDER 35 U.S.C. § 271(g)**

78. Paragraphs 1–77 are incorporated by reference as if fully set forth herein.

79. On information and belief, Bioepis submitted its aBLA referencing Genentech’s Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’895 patent.

80. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis’ bevacizumab biosimilar product, which would constitute infringement of claims of the ’895 patent under 35 U.S.C. § 271(g), as explained in Genentech’s (*l*)(3)(C) Contentions. Bioepis’ bevacizumab biosimilar product is made by the claimed process(es) and is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

81. An actual controversy has arisen and now exists between the parties concerning whether Bioepis’ manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis’ bevacizumab biosimilar product, has infringed and/or will infringe claims of the ’895 patent.

82. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the ’895 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis’ bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis’ bevacizumab biosimilar product, before the expiration of the ’895 patent.

83. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the ’895 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis’ bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis’ bevacizumab biosimilar product, before the expiration of the ’895 patent.

**COUNT 10: INFRINGEMENT OF U.S. PATENT NO. 8,512,983 (“THE ’983 PATENT”) UNDER 35 U.S.C. § 271(e)**

84. Paragraphs 1–83 are incorporated by reference as if fully set forth herein.

85. Claims of the ’983 patent cover methods of making recombinant proteins, like bevacizumab. The ’983 patent was identified in Genentech’s list pursuant to 42 U.S.C. § 262(l)(3)(A).

86. On information and belief, as described in Genentech’s (*l*)(3)(C) Contentions, Bioepis infringed claims of the ’983 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech’s Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’983 patent.

87. On information and belief, Bioepis has known of the ’983 patent since the patent issued or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’983 patent and in violation of Genentech’s patent rights.

88. Genentech is entitled to a judgment that Bioepis has infringed claims of the ’983 patent by submitting an aBLA referencing Genentech’s Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’983 patent.

89. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis’ FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the ’983 patent.

**COUNT 11: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’983 PATENT UNDER 35 U.S.C. § 271(g)**

90. Paragraphs 1–89 are incorporated by reference as if fully set forth herein.

91. On information and belief, Bioepis submitted its aBLA referencing Genentech’s Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’983 patent.

92. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis’ bevacizumab biosimilar product, which would constitute infringement of claims of the ’983 patent under 35 U.S.C. § 271(g), as described in Genentech’s (l)(3)(C) Contentions. Bioepis’ bevacizumab biosimilar product is made by the claimed process(es) and is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

93. An actual controversy has arisen and now exists between the parties concerning whether Bioepis' manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, has infringed and/or will infringe claims of the '983 patent.

94. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the '983 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '983 patent.

95. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the '983 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '983 patent.

**COUNT 12: INFRINGEMENT OF U.S. PATENT NO. 8,574,869 ("THE '869 PATENT") UNDER 35 U.S.C. § 271(e)**

96. Paragraphs 1–95 are incorporated by reference as if fully set forth herein.

97. Claims of the '869 patent cover methods of making recombinant proteins, like bevacizumab. The '869 patent was identified in Genentech's list pursuant to 42 U.S.C. § 262(l)(3)(A).

98. On information and belief, as described in Genentech's (*l*)(3)(C) Contentions, Bioepis infringed claims of the '869 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA

referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '869 patent.

99. On information and belief, Bioepis has known of the '869 patent since the patent issued or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '869 patent and in violation of Genentech's patent rights.

100. Genentech is entitled to a judgment that Bioepis has infringed claims of the '869 patent by submitting an aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '869 patent.

101. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis' FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the '869 patent.

**COUNT 13: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '869 PATENT UNDER 35 U.S.C. § 271(g)**

102. Paragraphs 1–101 are incorporated by reference as if fully set forth herein.

103. On information and belief, Bioepis submitted its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial

manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '869 patent.

104. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis' bevacizumab biosimilar product, which would constitute infringement of claims of the '869 patent under 35 U.S.C. § 271(g), as described in Genentech's (*l*)(3)(C) Contentions. Bioepis' bevacizumab biosimilar product is made by the claimed process(es) and is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

105. An actual controversy has arisen and now exists between the parties concerning whether Bioepis' manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, has infringed and/or will infringe claims of the '869 patent.

106. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the '869 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '869 patent.

107. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the '869 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or

actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '869 patent.

**COUNT 14: INFRINGEMENT OF U.S. PATENT NO. 9,441,035 ("THE '035 PATENT") UNDER 35 U.S.C. § 271(e)**

108. Paragraphs 1–107 are incorporated by reference as if fully set forth herein.

109. Claims of the '035 patent cover methods of producing bevacizumab. The '035 patent was identified in Genentech's list pursuant to 42 U.S.C. § 262(l)(3)(A).

110. On information and belief, as described in Genentech's (*l*)(3)(C) contentions, Bioepis infringed claims of the '035 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '035 patent.

111. On information and belief, Bioepis has known of the '035 patent since the patent issued or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '035 patent and in violation of Genentech's patent rights.

112. Genentech is entitled to a judgment that Bioepis has infringed claims of the '035 patent by submitting an aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '035 patent.

113. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into

the United States of Bioepis' FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the '035 patent.

**COUNT 15: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '035 PATENT UNDER 35 U.S.C. § 271(g)**

114. Paragraphs 1–113 are incorporated by reference as if fully set forth herein.

115. On information and belief, Bioepis submitted its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '035 patent.

116. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis' bevacizumab biosimilar product, which would constitute infringement of claims of the '035 patent under 35 U.S.C. § 271(g), as explained in Genentech's (*l*)(3)(C) Contentions. Bioepis' bevacizumab biosimilar product is made by the claimed process(es) and is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

117. An actual controversy has arisen and now exists between the parties concerning whether Bioepis' manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, has infringed and/or will infringe claims of the '035 patent.

118. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the '035 patent by manufacturing, using, offering to sell, or selling within

the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '035 patent.

119. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the '035 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '035 patent.

**COUNT 16: INFRINGEMENT OF U.S. PATENT NO. 9,487,809 ("THE '809 PATENT") UNDER 35 U.S.C. § 271(e)**

120. Paragraphs 1–119 are incorporated by reference as if fully set forth herein.

121. Claims of the '809 patent cover methods of decreasing lactate production in cultured cells producing a polypeptide, like bevacizumab. The '809 patent was identified in Genentech's list pursuant to 42 U.S.C. § 262(l)(3)(A).

122. On information and belief, as described in Genentech's (*l*)(3)(C) contentions, Bioepis infringed claims of the '809 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '809 patent.

123. On information and belief, Bioepis has known of the '809 patent since the patent issued or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of

Bioepis' bevacizumab biosimilar product before the expiration of the '809 patent and in violation of Genentech's patent rights.

124. Genentech is entitled to a judgment that Bioepis has infringed claims of the '809 patent by submitting an aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '809 patent.

125. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis' FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the '809 patent.

**COUNT 17: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '809 PATENT UNDER 35 U.S.C. § 271(g)**

126. Paragraphs 1–125 are incorporated by reference as if fully set forth herein.

127. On information and belief, Bioepis submitted its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '809 patent.

128. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis' bevacizumab biosimilar product, which would constitute infringement of claims of the '809 patent under 35 U.S.C. § 271(g), as explained in Genentech's (*l*)(3)(C) Contentions. Bioepis' bevacizumab biosimilar product is made by the

claimed process(es) and is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

129. An actual controversy has arisen and now exists between the parties concerning whether Bioepis' manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, has infringed and/or will infringe claims of the '809 patent.

130. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the '809 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '809 patent.

131. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the '809 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '809 patent.

**COUNT 18: INFRINGEMENT OF U.S. PATENT NO. 9,714,293 ("THE '293 PATENT") UNDER 35 U.S.C. § 271(e)**

132. Paragraphs 1–131 are incorporated by reference as if fully set forth herein.

133. Claims of the '293 patent cover methods of making recombinant proteins, like bevacizumab. The '293 patent was identified in Genentech's list pursuant to 42 U.S.C. § 262(l)(3)(A).

134. On information and belief, as described in Genentech's (*l*)(3)(C) Contentions, Bioepis infringed claims of the '293 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '293 patent.

135. On information and belief, Bioepis has known of the '293 patent since the patent issued or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '293 patent and in violation of Genentech's patent rights.

136. Genentech is entitled to a judgment that Bioepis has infringed claims of the '293 patent by submitting an aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '293 patent.

137. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis' FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the '293 patent.

**COUNT 19: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '293 PATENT UNDER 35 U.S.C. § 271(g)**

138. Paragraphs 1–137 are incorporated by reference as if fully set forth herein.

139. On information and belief, Bioepis submitted its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '293 patent.

140. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis' bevacizumab biosimilar product, which would constitute infringement of claims of the '293 patent under 35 U.S.C. § 271(g), as explained in Genentech's (*l*)(3)(C) Contentions. Bioepis' bevacizumab biosimilar product is made by the claimed process(es) and is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

141. An actual controversy has arisen and now exists between the parties concerning whether Bioepis' manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, has infringed and/or will infringe claims of the '293 patent.

142. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the '293 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '293 patent.

143. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the '293 patent. Genentech does not have an adequate remedy at law and is entitled to

injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '293 patent.

**COUNT 20: INFRINGEMENT OF U.S. PATENT NO. 9,795,672 ("THE '672 PATENT") UNDER 35 U.S.C. § 271(e)**

144. Paragraphs 1–143 are incorporated by reference as if fully set forth herein.

145. Claims of the '672 patent cover methods of treating cancer with bevacizumab. The '672 patent was identified in Genentech's list pursuant to 42 U.S.C. § 262(l)(3)(A).

146. On information and belief, as described in Genentech's (*l*)(3)(C) Contentions, Bioepis infringed claims of the '672 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '672 patent.

147. On information and belief, Bioepis has known of the '672 patent since the patent issued or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '672 patent and in violation of Genentech's patent rights.

148. Genentech is entitled to a judgment that Bioepis has infringed one or more claims of the '672 patent by submitting an aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '672 patent.

149. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis' FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the '672 patent.

**COUNT 21: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '672 PATENT UNDER 35 U.S.C. § 271(b)**

150. Paragraphs 1–149 are incorporated by reference as if fully set forth herein.

151. On information and belief, Bioepis submitted its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '672 patent.

152. If a doctor were to administer to a patient, or a patient were to self-administer, Bioepis' bevacizumab biosimilar product for treating cancer pursuant to regimens, *i.e.*, methods, in Bioepis' prescribing information for that product, performing such methods would directly infringe claims of the '672 patent, as described in Genentech's (*l*)(3)(C) Contentions.

153. As alleged herein, Bioepis took actions that it intended to cause doctors to administer to patients, or patients to self-administer, Bioepis' bevacizumab biosimilar product pursuant to those methods. Those actions included seeking FDA approval for a label that specified treatment methods that, if followed as expected, would infringe the '672 patent. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to advertise and otherwise inform doctors and patients that its bevacizumab biosimilar product is available to treat cancer using those claimed treatment methods.

154. As alleged herein, Bioepis was aware of the ’672 patent and knew that, if its bevacizumab biosimilar product were administered as specified in the prescribing information for its bevacizumab biosimilar product, such administration would constitute direct infringement of the ’672 patent.

155. An actual controversy has arisen and now exists between the parties concerning whether Bioepis would induce infringement of the ’672 patent by offering to sell or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, the prescribing information for which instructs doctors and patients to follow regimens claimed in the ’672 patent for treating patients with bevacizumab.

156. Genentech is entitled to a declaratory judgment that Bioepis would induce infringement of the ’672 patent under 35 U.S.C. § 271(b) by offering to sell or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, the prescribing information for which instructs doctors and patients to follow regimens claimed in the ’672 patent for treating patients with bevacizumab.

157. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from using, inducing others to use, offering to sell, or selling within the United States Bioepis’ bevacizumab biosimilar product for treating cancer according to the methods claimed by the ’672 patent before the expiration of the ’672 patent.

**COUNT 22: INFRINGEMENT OF U.S. PATENT NO. 10,208,355 (“THE ’355 PATENT”) UNDER 35 U.S.C. § 271(e)**

158. Paragraphs 1–157 are incorporated by reference as if fully set forth herein.

159. Claims of the ’355 patent cover methods of treating a patient having a glioblastoma by administering a VEGF antagonist, like bevacizumab. The ’355 patent was identified in Genentech’s list pursuant to 42 U.S.C. § 262(l)(3)(A).

160. On information and belief, as described in Genentech's (*l*)(3)(C) Contentions, Bioepis infringed claims of the '355 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '355 patent.

161. On information and belief, Bioepis has known of the '355 patent since the patent issued or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '355 patent and in violation of Genentech's patent rights.

162. Genentech is entitled to a judgment that Bioepis has infringed one or more claims of the '355 patent by submitting an aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '355 patent.

163. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis' FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the '355 patent.

**COUNT 23: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '355 PATENT UNDER 35 U.S.C. § 271(b)**

164. Paragraphs 1–163 are incorporated by reference as if fully set forth herein.

165. On information and belief, Bioepis submitted its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '355 patent.

166. If a doctor were to administer to a patient, or a patient were to self-administer, Bioepis' bevacizumab biosimilar product for treating cancer pursuant to regimens, *i.e.*, methods, in Bioepis' prescribing information for that product, performing such methods would directly infringe claims of the '355 patent, as described in Genentech's (*l*)(3)(C) Contentions.

167. As alleged herein, Bioepis took actions that it intended to cause doctors to administer to patients, or patients to self-administer, Bioepis' bevacizumab biosimilar product pursuant to those methods. Those actions included seeking FDA approval for a label that specified treatment methods that, if followed as expected, would infringe the '355 patent. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to advertise and otherwise inform doctors and patients that its bevacizumab biosimilar product is available to treat cancer using those claimed treatment methods.

168. As alleged herein, Bioepis was aware of the '355 patent and knew that, if its bevacizumab biosimilar product were administered as specified in the prescribing information for its bevacizumab biosimilar product, such administration would constitute direct infringement of the '355 patent.

169. An actual controversy has arisen and now exists between the parties concerning whether Bioepis would induce infringement of the '355 patent by offering to sell or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, the

prescribing information for which instructs doctors and patients to follow regimens claimed in the ’355 patent for treating patients with bevacizumab.

170. Genentech is entitled to a declaratory judgment that Bioepis would induce infringement of the ’355 patent under 35 U.S.C. § 271(b) by offering to sell or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, the prescribing information for which instructs doctors and patients to follow regimens claimed in the ’355 patent for treating patients with bevacizumab.

171. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from using, inducing others to use, offering to sell, or selling within the United States Bioepis’ bevacizumab biosimilar product for treating cancer according to the methods claimed by the ’355 patent before the expiration of the ’355 patent.

**COUNT 24: INFRINGEMENT OF U.S. PATENT NO. 10,513,697 (“THE ’697 PATENT”) UNDER 35 U.S.C. § 271(e)**

172. Paragraphs 1–171 are incorporated by reference as if fully set forth herein.

173. Claims of the ’697 patent cover methods of making recombinant polypeptides like bevacizumab. The ’697 patent was identified in Genentech’s list pursuant to 42 U.S.C. § 262(l)(3)(A).

174. On information and belief, as described in Genentech’s (*l*)(3)(C) contentions, Bioepis infringed claims of the ’697 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech’s Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’697 patent.

175. On information and belief, Bioepis has known of the ’697 patent since the patent issued or has been willfully blind to its existence and contents since then. Despite such knowledge,

Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '697 patent and in violation of Genentech's patent rights.

176. Genentech is entitled to a judgment that Bioepis has infringed claims of the '697 patent by submitting an aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '697 patent.

177. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis' FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the '697 patent.

**COUNT 25: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '697 PATENT UNDER 35 U.S.C. § 271(g)**

178. Paragraphs 1–177 are incorporated by reference as if fully set forth herein.

179. On information and belief, Bioepis submitted its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '697 patent.

180. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis' bevacizumab biosimilar product, which would constitute infringement of claims of the '697 patent under 35 U.S.C. § 271(g), as explained

in Genentech's (*l*)(3)(C) Contentions. Bioepis' bevacizumab biosimilar product is made by the claimed process(es) and is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

181. An actual controversy has arisen and now exists between the parties concerning whether Bioepis' manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, has infringed and/or will infringe claims of the '697 patent.

182. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the '697 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '697 patent.

183. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the '697 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '697 patent.

**COUNT 26: INFRINGEMENT OF U.S. PATENT NO. 10,662,237 ("THE '237 PATENT") UNDER 35 U.S.C. § 271(e)**

184. Paragraphs 1–183 are incorporated by reference as if fully set forth herein.

185. Claims of the '237 patent cover methods of making recombinant proteins like bevacizumab. The '237 Patent issued on May 26, 2020. Pursuant to 42 U.S.C. § 262(*l*)(7), on

June 15, 2020 Genentech provided to Bioepis a supplement to its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) to include the ’237 Patent. At that time, Genentech provided Bioepis with a copy of the ’237 Patent. Bioepis has knowledge of the ’237 Patent.

186. On information and belief, Bioepis infringed one or more claims (e.g., claim 1) of the ’237 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech’s Avastin® and/or continuing to seek FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’237 patent.

187. On information and belief, Bioepis has known of the ’237 patent since the patent issued or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’237 patent and in violation of Genentech’s patent rights.

188. Genentech is entitled to a judgment that Bioepis has infringed claims of the ’237 patent by submitting an aBLA referencing Genentech’s Avastin® and continuing to seek FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’237 patent.

189. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis’ FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the ’237 patent.

**COUNT 27: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’237 PATENT UNDER 35 U.S.C. § 271(g)**

190. Paragraphs 1–189 are incorporated by reference as if fully set forth herein.

191. On information and belief, Bioepis submitted its aBLA referencing Genentech’s Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’237 patent.

192. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis’ bevacizumab biosimilar product, which would constitute infringement of one or more claims (e.g., claim 1) of the ’237 patent under 35 U.S.C. § 271(g). Bioepis’ bevacizumab biosimilar product is made by the claimed process(es) and is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

193. An actual controversy has arisen and now exists between the parties concerning whether Bioepis’ manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis’ bevacizumab biosimilar product, has infringed and/or will infringe claims of the ’237 patent.

194. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the ’237 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis’ bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis’ bevacizumab biosimilar product, before the expiration of the ’237 patent.

195. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the ’237 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis’ bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis’ bevacizumab biosimilar product, before the expiration of the ’237 patent.

**COUNT 28: INFRINGEMENT OF U.S. PATENT NO. 10,676,710 (“THE ’710 PATENT”) UNDER 35 U.S.C. § 271(e)**

196. Paragraphs 1–195 are incorporated by reference as if fully set forth herein.

197. Claims of the ’710 patent cover methods of making recombinant proteins like bevacizumab. The ’710 Patent issued on June 9, 2020. Pursuant to 42 U.S.C. § 262(*l*)(7), on June 15, 2020 Genentech provided to Bioepis a supplement to its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) to include the ’710 Patent. At that time, Genentech provided Bioepis with a copy of the ’710 Patent. Bioepis has knowledge of the ’710 Patent.

198. On information and belief, Bioepis infringed one or more claims (e.g., claim 1) of the ’710 patent under 35 U.S.C. § 271(e)(2) by submitting its aBLA referencing Genentech’s Avastin® and/or continuing to seek FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis’ bevacizumab biosimilar product before the expiration of the ’710 patent.

199. On information and belief, Bioepis has known of the ’710 patent since the patent issued or has been willfully blind to its existence and contents since then. Despite such knowledge, Bioepis nonetheless filed its aBLA with the FDA and/or continued to pursue such aBLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of

Bioepis' bevacizumab biosimilar product before the expiration of the '710 patent and in violation of Genentech's patent rights.

200. Genentech is entitled to a judgment that Bioepis has infringed claims of the '710 patent by submitting an aBLA referencing Genentech's Avastin® and continuing to seek FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '710 patent.

201. Genentech would be irreparably harmed if Bioepis is not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Bioepis' FDA approved bevacizumab biosimilar product. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Bioepis from such infringement of claims of the '710 patent.

**COUNT 29: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '710 PATENT UNDER 35 U.S.C. § 271(g)**

202. Paragraphs 1–201 are incorporated by reference as if fully set forth herein.

203. On information and belief, Bioepis submitted its aBLA referencing Genentech's Avastin® and seeking FDA approval under 42 U.S.C. § 262(k) to engage in the commercial manufacture, use, or sale of Bioepis' bevacizumab biosimilar product before the expiration of the '710 patent.

204. On information and belief, following FDA approval of its bevacizumab biosimilar product, Bioepis intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Bioepis' bevacizumab biosimilar product, which would constitute infringement of one or more claims (e.g., claim 1) of the '710 patent under 35 U.S.C. § 271(g). Bioepis' bevacizumab biosimilar product is made by the claimed process(es) and

is not materially changed by subsequent processes and does not become a trivial and nonessential component of another product.

205. An actual controversy has arisen and now exists between the parties concerning whether Bioepis' manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, its bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, has infringed and/or will infringe claims of the '710 patent.

206. Genentech is entitled to a declaratory judgment that Bioepis has infringed and/or would infringe claims of the '710 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '710 patent.

207. Genentech would be irreparably harmed if Bioepis is not enjoined from infringing claims of the '710 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Bioepis from making, using, offering to sell, or selling within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Bioepis' bevacizumab biosimilar product, before the expiration of the '710 patent.

**PRAYER FOR RELIEF**

WHEREFORE, Genentech respectfully requests that this Court enter judgment in its favor against Bioepis and grant the following relief:

A. An injunction enjoining the commercial making, using, offering for sale, and selling in the United States, or importing into the United States, of Bioepis' bevacizumab biosimilar

product until no less than 180 days after Bioepis' purported notice of commercial marketing on March 30, 2020; and

B. A preliminary injunction enjoining the commercial making, using, offering for sale, and selling in the United States, or importing into the United States, of Bioepis' bevacizumab biosimilar product pending a final determination in this matter as to infringement, validity, and enforceability of the asserted claims of each of the Patents-in-Suit.

C. A judgment that Bioepis has infringed each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2) by submitting to the FDA its aBLA to obtain approval of Bioepis' bevacizumab biosimilar product;

D. A judgment that Bioepis has infringed or will infringe each of the Patents-in-Suit under 35 U.S.C. § 271(b) and/or (g) by making, offering to sell, selling, or using within the United States, or importing into the United States, Bioepis' bevacizumab biosimilar product, or actively inducing someone to do the same, or contributing to the same, during the term of each of the Patents-in-Suit, respectively;

E. Damages in the form of lost profits but in no event less than a reasonable royalty on any infringing sales;

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

G. Permanent equitable relief, including but not limited to a permanent injunction that enjoins Bioepis, its officers, employees, parents, subsidiaries, affiliate corporations, and other related business entities and/or their successors or assigns from infringing the Patents-in-Suit, or actively inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use

or manufacturing of which infringes the Patents-in-Suit, or inducing any other person acting in concert with Bioepis to do any of the foregoing;

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

I. An award of Genentech's costs and expenses in this action; and

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

**JURY DEMAND**

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

Dated: June 28, 2020

MCCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*
Michael P. Kelly (# 2295)
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
Tel.: (302) 984-6300
Fax: (302) 984-6399
mkelly@mccarter.com
dsilver@mccarter.com
ajoyce@mccarter.com

*Attorneys for Plaintiff Genentech, Inc.*

OF COUNSEL:

Paul B. Gaffney
David I. Berl
Thomas S. Fletcher
Teagan J. Gregory
Sumeet P. Dang
Williams & Connolly LLP
725 Twelfth St. NW
Washington, DC 20005
(202) 434-5000