IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

GENENTECH, INC., Plaintiff, v. CENTUS BIOTHERAPEUTICS LTD., FUJIFILM KYOWA KIRIN BIOLOGICS CO., LTD, FUJIFILM CORP., and KYOWA KIRIN CO., LTD., Defendants.	Case No. 2:20-cv-00361 **JURY TRIAL DEMANDED**

COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT

Plaintiff Genentech, Inc. by its attorneys, for its Complaint against Defendants Centus Biotherapeutics, Fujifilm Kyowa Kirin Biologics Co., Ltd., Fujifilm Corp., and Kyowa Kirin Co., Ltd. (collectively, "Defendants"), hereby alleges as follows:

PARTIES

1. Genentech, Inc. ("Genentech") 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, Defendant Centus Biotherapeutics Limited ("Centus") is a company organized and existing under the laws of the United Kingdom, with its principal place of business at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge, CB2 0AA, United Kingdom.

3. On information and belief, Defendant Fujifilm Kyowa Kirin Biologics Co., Ltd. ("FKKB") is a company organized and existing under the laws of Japan, with its principal place of business at Ohtemachi Building 9F, 1-6-1 Ohtemachi, Chiyoda-ku, Tokyo 100-0004 Japan. On information and belief, FKKB is a direct corporate parent of Centus.

4. On information and belief, Defendant Fujifilm Corp. ("Fujifilm") is a company organized and existing under the laws of Japan, with its principal place of business at Midtown West, 7-3, Akasaka 9-chome, Minato-ku, Tokyo 107-0052, Japan.

5. On information and belief, Defendant Kyowa Kirin Co., Ltd. ("KKC") is a company organized and existing under the laws of Japan, with its principal place of business at Ohtemachi Financial City Grand Cube, 1-9-2 Ohtemachi, Chiyoda-ku, Tokyo 100-0004, Japan.

6. On information and belief, FKKB is a joint venture between Fujifilm and KKC. On further information and belief, FKKB, Fujifilm, and KKC (collectively, the "Fujifilm

entities") exercise direct control over Centus,

7. On information and belief, Centus develops, manufactures, and seeks regulatory approval for biosimilar products, to import, market, distribute, offer to sell, and/or sell those biosimilar products in the State of Texas and throughout the United States.

NATURE OF THE ACTION

8. This is an action for patent infringement arising under 35 U.S.C. § 271, including § 271(e)(2)(C)(ii), which was enacted in 2010 as part of the Biologics Price Competition and Innovation Act ("the BPCIA"), and for relief under the BPCIA. This action involves patents that cover bevacizumab (the active ingredient of the biologic drug product, Avastin®), its method of manufacture, certain materials used in its manufacture, and certain approved therapeutic uses of bevacizumab. Genentech brings this suit to enjoin Defendants from infringing its patents and to secure any recoverable damages resulting from Defendants' infringement.

9. The asserted patents (collectively, "Patents-in-Suit") are as follows:

U.S. Patent No.	Issue Date	First Named Inventor
Ex. A – 6,586,206	July 1, 2003	Dixit
Ex. B – 7,390,660	Jun. 24, 2008	Behrendt
Ex. C – 8,574,869	Nov. 5, 2013	Kao
Ex. D – 9,441,035	Sept. 13, 2016	Carvalhal
Ex. E – 9,795,672	Oct. 24, 2017	Fyfe
Ex. F – 10,017,732	Jul. 10, 2018	Vijayasankaran
Ex. G – 10,208,355	Feb. 19, 2019	Bais
Ex. H – 10,336,983	Jul. 2, 2019	Popp
Ex. I – 10,662,237	May 26, 2020	Mehta
Ex. J – 10,676,710	Jun. 9, 2020	Vijayasankaran

10. Genentech is the owner of all rights, title, and interest in the Patents-in-Suit, with the following exceptions: Hoffmann-La Roche, Inc. is the owner of U.S Patent Nos. 7,390,660 (Exhibit B) and 10,336,983 (Exhibit H). 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, and as amended on June 2, 2018.

11. On information and belief, on November 18, 2019, the U.S. Food and Drug Administration ("FDA") accepted for review Centus's abbreviated Biologics License Application ("BLA") No. 761153 seeking authorization from the FDA to engage in the commercial manufacture, use, or sale of a biosimilar version of Avastin®, which Centus calls FKB238 ("Centus's bevacizumab biosimilar product"). On information and belief, Centus submitted that BLA pursuant to the BPCIA, specifically 42 U.S.C. § 262(k) (also known as § 351(k) of the Public Health Service Act ("PHSA")).

12. The BPCIA created an abbreviated pathway for the approval of biosimilar versions of approved biologic drugs. Subject to certain conditions, the abbreviated pathway (also known as "the (k) pathway") permits a biosimilar applicant (here, Centus) to rely on the prior clinical tests, data, and results, and the prior licensure and approval status, of the innovative biological product (here, Avastin®). Genentech is the sponsor of the reference product, Avastin®, which the FDA has approved for a number of different indications (*i.e.*, therapeutic uses).

13. As alleged herein, Centus, acting in concert with and at the direction of the Fujifilm entities, infringed one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(C)(ii) when it submitted its BLA seeking FDA approval to engage in the commercial manufacture, use or sale of Centus's bevacizumab biosimilar product.

14. As alleged herein, Defendants would also infringe one or more claims of the Patents-In-Suit, under 35 U.S.C. § 271(b) and/or (g), should they make, use, offer for sale, or sell

within the United States, or import into the United States, Centus's bevacizumab biosimilar product, or actively induce another to do the same, or contribute to the same, before the expiration of the Patents-In-Suit.

JURISDICTION AND VENUE

15. This action arises under the BPCIA, 42 U.S.C. § 262(*l*), the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and the Patent Laws of the United States, Title 35, United States Code. This Court has subject-matter jurisdiction over Genentech's claims under 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

16. This Court has personal jurisdiction over Defendants by virtue of the fact that, on information and belief, Centus, acting in concert with and at the direction of the Fujifilm entities, filed a BLA seeking approval from the FDA to engage in the commercial manufacture, use, or sale of Centus's biosimilar product in the Eastern District of Texas and throughout the United States, which directly gives rise to Genentech's claims of patent infringement. On information and belief, the FDA accepted that application for review on November 18, 2019.

17. On information and belief, Defendants, by themselves and through others, intend to use, induce others to use, offer to sell, sell within the United States, and import into the United States, including the Eastern District of Texas, Centus's bevacizumab biosimilar product.

18. This Court also has personal jurisdiction over Defendants by virtue of Defendants' contacts with Texas and the exercise of such personal jurisdiction is fair and reasonable. Litigating this suit in the Eastern District of Texas does not burden Defendants.

19. Venue is proper in this District pursuant to 28 U.S.C. § 1391(c)(3) and 28 U.S.C. § 1400(b). Defendants are foreign corporations and are therefore subject to suit in any judicial district.

FACTUAL BASIS FOR RELIEF

20. Avastin® contains a genetically engineered antibody, bevacizumab, which 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.

21. 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.

22. 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.

23. 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).

24. 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).

25. On December 5, 2019, Centus sent Genentech "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 Centus's biosimilar bevacizumab or the use thereof. 42 U.S.C. § 262(*l*)(9)(C); 28 U.S.C. § 2201(b).

26. By letter sent on December 13, 2019, counsel for Genentech indicated to counsel for Centus that Centus was required under 42 U.S.C. § 262(*l*)(2)(A) to provide Genentech with information describing Centus's manufacturing processes for FKB238 in addition to the BLA for FKB238. For example, Genentech included in this letter "a list of exemplary information concerning processes used to manufacture a biological product" along with exemplary citations to patents, and further explained that it "seek[s] this information to understand the process used in the production of Centus's bevacizumab product."

27. By letter sent on December 16, 2019, counsel for Centus responded to counsel for Genentech that Genentech's request for information "does not comport with the exchanges contemplated by 42 U.S.C. § 262(*l*)." With the exception of providing a replacement version of one document in its initial production, and three declarations with attached documents Centus provided in October, 2020 during negotiations pursuant to § 262(*l*)(4), Centus has not provided the additional information under 42 U.S.C. § 262(*l*)(2)(A) Genentech requested.

28. On February 4, 2020, pursuant to its obligations under 42 U.S.C. § 262(*l*)(3)(A), and based on its review of the limited materials Centus had provided concerning its FKB238 product, Genentech provided Centus with a list of patents "that it believes could reasonably be asserted against Centus's proposed FKB238 product." Genentech informed Centus that it was not prepared to license any of these patents in connection with Centus's FKB238 product.

29. Pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus was required to provide Genentech 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 Centus's FKB238 product no later than April 6, 2020 (*i.e.*, 60 days following Genentech's provision of its list of patents). On April 3, 2020,

purportedly pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus provided Genentech with sixteen documents each entitled "Detailed Statement" that purported to explain why each patent that Genentech listed under 42 U.S.C. § 262(*l*)(3)(A) "is invalid, unenforceable or will not be infringed by the commercial marketing of the biological product that is the subject of Centus's Biologics License Application No. 761153." Centus further asserted in these documents that it would not infringe any of the patents identified by Genentech by making, using, offering for sale, selling within the United States, or importing into the United States its FKB238 product, or inducing another to do the same, or contributing to the same.

30. In these documents, however, Centus provided only conclusory assertions that the patents identified by Genentech pursuant to 42 U.S.C. § 262(*l*)(3)(A) were invalid. For example, in many instances, Centus merely made formulaic assertions of obviousness, lack of written description, or lack of enablement, and simply reserved the right to further develop its position in the future. Centus cited no authority in support of its position that it may forego providing invalidity positions or may provide conclusory invalidity positions that it may later supplement during litigation.

31. The BPCIA also requires 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). On April 24, 2020, 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, Centus provided notice to Genentech of its intent to begin commercial manufacturing of its FKB238 product as early as October 21, 2020 (180 days from the date of this notice).

32. On June 2, 2020, and pursuant to 42 U.S.C. § 262(*l*)(3)(C), Genentech provided

Centus with its detailed statement asserting that the manufacture, use, sale, offer for sale, or importation of Centus's FKB238 product would infringe thirteen patents (its "(3)(C) Statement"). Genentech's statement included, with respect to each patent, the factual and legal basis of its opinion that those patents will be infringed by the commercial marketing of Centus's FKB238 product, on a claim-by-claim basis, as well as providing a response to Centus's April 3, 2020 statements concerning validity and enforceability for those patents.

33. On June 8, 2020, pursuant to 42 U.S.C. § 262(*l*)(7), Genentech wrote Centus to supplement its 42 U.S.C. § 262(*l*)(3)(A) list to include U.S. Patent No. 10,662,237. By letter dated June 15, 2020, it further supplemented this list to include U.S. Patent No. 10,676,710.

34. Centus responded on July 8, 2020 and July 15, 2020, purportedly pursuant to 42 U.S.C. § 262(*l*)(3)(B), providing Genentech with two documents purporting to explain why the additional patents identified by Genentech pursuant to 42 U.S.C. § 262(*l*)(7) are invalid. Centus further asserted in these documents that it would not infringe any of the patents identified by Genentech by making, using, offering for sale, selling within the United States, or importing into the United States its FKB238 product, or inducing another to do the same, or contributing to the same.

35. Like Centus's previous detailed statements, these documents provided only conclusory assertions that the patents identified by Genentech pursuant to 42 U.S.C. § 262(*l*)(3)(A) were invalid and Centus cited no authority in support of its position that it may forego providing invalidity positions or may provide conclusory invalidity positions that it may later supplement during litigation.

36. On July 10, 2020, Genentech contacted Centus to engage in good-faith negotiation pursuant to 42 U.S.C. § 262(*l*)(4)(A) to attempt to "agree on which, if any, patents

. . . shall be the subject of an action for patent infringement under [42 U.S.C. § 262(*l*)(6)]." Centus did not respond to Genentech's request until August 20, 2020, and at that point stated it needed additional time to gather documents it believed would assist in the parties' negotiation.

37. Following a lengthy and unexplained delay, Centus agreed on September 11, 2020 to initiate 42 U.S.C. § 262(*l*)(4) negotiations by teleconference on September 25, 2020. During this meeting, Genentech identified information it had requested from Centus in its December 13, 2019 letter and that Centus had failed to provide. Centus again refused to provide certain categories of information, and maintained that it had complied with the BPCIA's obligation to produce information to Genentech, but agreed to supplement its disclosure with respect to others.

38. After additional communications among counsel, the Genentech and Centus concluded their negotiations on Tuesday, October 13, 2020. Genentech and Centus agreed that the ten patents identified in Paragraph 4 above would be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6).

39. 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. Genentech therefore brings this action for infringement, declaratory judgment, an injunction, and any additional appropriate relief. Specifically, Genentech seeks an order declaring that Centus's actions are contrary to the

BPCIA and that the manufacture, use, offer for sale, sale, and/or importation of Centus's proposed biologic product infringes Genentech's intellectual property rights, and an order enjoining Centus from infringing the Patents-in-Suit (as listed below), including by offering to sell or selling its BLA product until after the expiration of the last-to-expire of the Patents-in-Suit.

40. On November 9, 2020, Genentech asked Centus whether it would agree to delay the commercial launch of its FKB238 product in the United States pending the resolution of this patent infringement litigation. On November 10, 2020, Centus responded that it could not commit to any such delay, and did not provide any additional update regarding its plans to launch FKB238 in the United States.

COUNT ONE AGAINST ALL DEFENDANTS
(Infringement of the '206 Patent Under 35 U.S.C. § 271(e))

41. Paragraphs 1–40 are incorporated by reference as if fully set forth herein.

42. United States Patent No. 6,586,206 ("the '206 patent") (Exhibit A hereto) was duly and legally issued on July 1, 2003. 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).

43. On information and belief, including based on the contents of Centus's BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus, in concert with and at the direction of the Fujifilm entities, infringed claims of the '206 patent under 35 U.S.C. § 271(e)(2) by submitting its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '206 patent.

44. On information and belief, Defendants have known of or have been willfully

blind to the existence and contents of the ’206 patent since Centus’s founding. Despite such knowledge, Centus, in concert with and at the direction of the Fujifilm entities, nonetheless filed its BLA with the FDA and/or continued to pursue such BLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Centus’s bevacizumab biosimilar product before the expiration of the ’206 patent and in violation of Genentech’s patent rights.

45. Genentech is entitled to a judgment that the Defendants have infringed one or more claims of the ’206 patent by submitting a BLA 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 Centus’s bevacizumab biosimilar product before the expiration of the ’206 patent.

46. Genentech would be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Centus’s bevacizumab biosimilar product once it is approved by the FDA. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such actions.

COUNT TWO AGAINST ALL DEFENDANTS
(Declaratory Judgment of Infringement of the ’206 Patent Under 35 U.S.C. § 271(g))

47. Paragraphs 1–46 are incorporated by reference as if fully set forth herein.

48. On information and belief, Centus submitted a BLA 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 Centus’s bevacizumab biosimilar product before the expiration of the ’206 patent.

49. On information and belief, including based on the contents of Centus’s BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), following FDA approval of its

bevacizumab biosimilar product, Centus—acting in concert with and at the direction of the Fujifilm entities—intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Centus's bevacizumab biosimilar product, which would constitute infringement of one or more claims of the '206 patent under 35 U.S.C. § 271(g) because Centus's 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.

50. An actual controversy has arisen and now exists between the parties concerning whether Defendants' 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 Centus's bevacizumab biosimilar product, has infringed and/or will infringe one or more claims of the '206 patent.

51. Genentech is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that Defendants have infringed and/or would infringe one or more claims of the '206 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Centus's bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '206 patent.

52. Genentech would be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '206 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Centus's bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of

Centus's bevacizumab biosimilar product, before the expiration of the '206 patent. Both the balance of the hardships as between Genentech and Defendants and the public interest further support this Court enjoining Defendants' infringing activities.

COUNT THREE AGAINST ALL DEFENDANTS
(Infringement of the '660 Patent Under 35 U.S.C. § 271(e))

53. Paragraphs 1–52 are incorporated by reference as if fully set forth herein.

54. United States Patent No. 7,390,660 ("the '660 patent") (Exhibit B hereto) was duly and legally issued on June 24, 2008. 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).

55. On information and belief, including based on the contents of Centus's BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus, in concert with and at the direction of the Fujifilm entities, infringed claims of the '660 patent under 35 U.S.C. § 271(e)(2) by submitting its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '660 patent.

56. On information and belief, Defendants have known of or have been willfully blind to the existence and contents of the '660 patent since Centus's founding. Despite such knowledge, Centus, in concert with and at the direction of the Fujifilm entities, nonetheless filed its BLA with the FDA and/or continued to pursue such BLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Centus's bevacizumab biosimilar product before the expiration of the '660 patent and in violation of Genentech's patent rights.

57. Genentech is entitled to a judgment that the Defendants have infringed one or more claims of the ’660 patent by submitting a BLA 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 Centus’s bevacizumab biosimilar product before the expiration of the ’660 patent.

58. Genentech would be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Centus’s bevacizumab biosimilar product once it is approved by the FDA. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such actions.

COUNT FOUR AGAINST ALL DEFENDANTS
(Declaratory Judgment of Infringement of the ’660 Patent Under 35 U.S.C. § 271(g))

59. Paragraphs 1–58 are incorporated by reference as if fully set forth herein.

60. On information and belief, Centus submitted its BLA 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 Centus’s bevacizumab biosimilar product before the expiration of the ’660 patent.

61. On information and belief, including based on the contents of Centus’s BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), following FDA approval of its bevacizumab biosimilar product, Centus—acting in concert with and at the direction of the Fujifilm entities—intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Centus’s bevacizumab biosimilar product, which would constitute infringement of one or more claims of the ’660 patent under 35 U.S.C. § 271(g) because Centus’s 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.

62. An actual controversy has arisen and now exists between the parties concerning whether Defendants' 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 Centus's bevacizumab biosimilar product, has infringed and/or will infringe one or more claims of the '660 patent.

63. Genentech is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that Defendants have infringed and/or would infringe one or more claims of the '660 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Centus's bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '660 patent.

64. Genentech would be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '660 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Centus's bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '660 patent. Both the balance of the hardships as between Genentech and Defendants and the public interest further support this Court enjoining Defendants' infringing activities.

COUNT FIVE AGAINST ALL DEFENDANTS
(Infringement of the '869 Patent Under 35 U.S.C. § 271(e))

65. Paragraphs 1–64 are incorporated by reference as if fully set forth herein.

66. United States Patent No. 8,574,869 ("the '869 patent") (Exhibit C hereto) was

duly and legally issued on November 5, 2013. 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).

67. On information and belief, including based on the contents of Centus's BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus, in concert with and at the direction of the Fujifilm entities, infringed claims of the '869 patent under 35 U.S.C. § 271(e)(2) by submitting its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '869 patent.

68. On information and belief, Defendants have known of or have been willfully blind to the existence and contents of the '869 patent since Centus's founding. Despite such knowledge, Centus, in concert with and at the direction of the Fujifilm entities, nonetheless filed its BLA with the FDA and/or continued to pursue such BLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Centus's bevacizumab biosimilar product before the expiration of the '869 patent and in violation of Genentech's patent rights.

69. Genentech is entitled to a judgment that the Defendants have infringed one or more claims of the '869 patent by submitting a BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '869 patent.

70. Genentech would be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Centus's bevacizumab biosimilar product once it is approved by the FDA.

Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such actions.

COUNT SIX AGAINST ALL DEFENDANTS
(Declaratory Judgment of Infringement of the '869 Patent Under 35 U.S.C. § 271(g))

71. Paragraphs 1–70 are incorporated by reference as if fully set forth herein.

72. On information and belief, Centus submitted its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '869 patent.

73. On information and belief, including based on the contents of Centus's BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), following FDA approval of its bevacizumab biosimilar product, Centus—acting in concert with and at the direction of the Fujifilm entities—intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Centus's bevacizumab biosimilar product, which would constitute infringement of one or more claims of the '869 patent under 35 U.S.C. § 271(g) because Centus's 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.

74. An actual controversy has arisen and now exists between the parties concerning whether Defendants' 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 Centus's bevacizumab biosimilar product, has infringed and/or will infringe one or more claims of the '869 patent.

75. Genentech is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that

Defendants have infringed and/or would infringe one or more claims of the ’869 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Centus’s bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Centus’s bevacizumab biosimilar product, before the expiration of the ’869 patent.

76. Genentech would be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the ’869 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Centus’s bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Centus’s bevacizumab biosimilar product, before the expiration of the ’869 patent. Both the balance of the hardships as between Genentech and Defendants and the public interest further support this Court enjoining Defendants’ infringing activities.

COUNT SEVEN AGAINST ALL DEFENDANTS
(Infringement of the ’035 Patent Under 35 U.S.C. § 271(e))

77. Paragraphs 1–76 are incorporated by reference as if fully set forth herein.

78. United States Patent No. 9,441,035 (“the ’035 patent”) (Exhibit D hereto) was duly and legally issued on September 13, 2016. Claims of the ’035 patent cover methods of making bevacizumab. The ’035 patent was identified in Genentech’s list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

79. On information and belief, including based on the contents of Centus’s BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus, in concert with and at the direction of the Fujifilm entities, infringed claims of the ’035 patent under 35 U.S.C. § 271(e)(2) by submitting its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '035 patent.

80. On information and belief, Defendants have known of or have been willfully blind to the existence and contents of the '035 patent since its issuance. Despite such knowledge, Centus, in concert with and at the direction of the Fujifilm entities, nonetheless filed its BLA with the FDA and/or continued to pursue such BLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Centus's bevacizumab biosimilar product before the expiration of the '035 patent and in violation of Genentech's patent rights.

81. Genentech is entitled to a judgment that the Defendants have infringed one or more claims of the '035 patent by submitting a BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '035 patent.

82. Genentech would be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Centus's bevacizumab biosimilar product once it is approved by the FDA. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such actions.

COUNT EIGHT AGAINST ALL DEFENDANTS
(Declaratory Judgment of Infringement of the '035 Patent Under 35 U.S.C. § 271(g))

83. Paragraphs 1–82 are incorporated by reference as if fully set forth herein.

84. On information and belief, Centus submitted its BLA 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 Centus's bevacizumab biosimilar product before the expiration of

the ’035 patent.

85. On information and belief, including based on the contents of Centus’s BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), following FDA approval of its bevacizumab biosimilar product, Centus—acting in concert with and at the direction of the Fujifilm entities—intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Centus’s bevacizumab biosimilar product, which would constitute infringement of one or more claims of the ’035 patent under 35 U.S.C. § 271(g) because Centus’s 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.

86. An actual controversy has arisen and now exists between the parties concerning whether Defendants’ 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 Centus’s bevacizumab biosimilar product, has infringed and/or will infringe one or more claims of the ’035 patent.

87. Genentech is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that Defendants have infringed and/or would infringe one or more claims of the ’035 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Centus’s bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Centus’s bevacizumab biosimilar product, before the expiration of the ’035 patent.

88. Genentech would be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the ’035 patent. Genentech does not have an adequate remedy

at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Centus's bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '035 patent. Both the balance of the hardships as between Genentech and Defendants and the public interest further support this Court enjoining Defendants' infringing activities.

COUNT NINE AGAINST ALL DEFENDANTS
(Infringement of the '672 Patent Under 35 U.S.C. § 271(e))

89. Paragraphs 1–88 are incorporated by reference as if fully set forth herein.

90. United States Patent No. 9,795,672 ("the '672 patent") (Exhibit E hereto) was duly and legally issued on October 24, 2017. 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).

91. On information and belief, including based on the contents of Centus's BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus, in concert with and at the direction of the Fujifilm entities, infringed claims of the '672 patent under 35 U.S.C. § 271(e)(2) by submitting its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '672 patent.

92. On information and belief, Defendants have known of or have been willfully blind to the existence and contents of the '672 patent since its issuance. Despite such knowledge, Centus, in concert with and at the direction of the Fujifilm entities, nonetheless filed its BLA with the FDA and/or continued to pursue such BLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Centus's bevacizumab

biosimilar product before the expiration of the ’672 patent and in violation of Genentech’s patent rights.

93. Genentech is entitled to a judgment that the Defendants have infringed one or more claims of the ’672 patent by submitting a BLA 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 Centus’s bevacizumab biosimilar product with its proposed label before the expiration of the ’672 patent.

94. Genentech would be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Centus’s bevacizumab biosimilar product and label once it is approved by the FDA. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such actions.

COUNT TEN AGAINST ALL DEFENDANTS
(Declaratory Judgment of Infringement of the ’672 Patent Under 35 U.S.C. § 271(b))

95. Paragraphs 1–94 are incorporated by reference as if fully set forth herein.

96. On information and belief, Centus submitted its BLA 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 Centus’s bevacizumab biosimilar product before the expiration of the ’672 patent.

97. If a doctor were to administer to a patient, or a patient were to self-administer, Centus’s bevacizumab biosimilar product for treating cancer pursuant to regimens, *i.e.*, methods, in Centus’s prescribing information for that product, performing such methods would directly infringe one or more claims of the ’672 patent, as described in Genentech’s (*l*)(3)(c) contentions.

98. As alleged herein, Centus—acting in concert with and at the direction of the

Fujifilm entities—has taken or will take actions that it intended, or will intend, to cause doctors to administer to patients, or patients to self-administer, Centus's 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, Centus—acting in concert with and at the direction of the Fujifilm entities—intends to advertise and otherwise inform doctors and patients that its bevacizumab biosimilar product is available to treat cancer using those claimed treatment methods.

99. As alleged herein, Defendants were aware of the '672 patent and knew that, if Centus's 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.

100. An actual controversy has arisen and now exists between the parties concerning whether Defendants 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.

101. Genentech is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that Defendants 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.

102. Genentech does not have an adequate remedy at law and is entitled to injunctive

relief prohibiting Defendants from using, inducing others to use, offering to sell, or selling within the United States Centus's bevacizumab biosimilar product for treating cancer according to the methods claimed by the '672 patent before the expiration of the '672 patent. Both the balance of the hardships as between Genentech and Defendants and the public interest further support this Court enjoining Defendants' infringing activities.

COUNT ELEVEN AGAINST ALL DEFENDANTS
(Infringement of the '732 Patent Under 35 U.S.C. § 271(e))

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

104. United States Patent No. 10,017,732 ("the '732 patent") (Exhibit F hereto) was duly and legally issued on July 10, 2018. Claims of the '732 patent cover methods of making recombinant antibodies, like bevacizumab. The '732 patent was identified in Genentech's list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

105. On information and belief, including based on the contents of Centus's BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus, in concert with and at the direction of the Fujifilm entities, infringed claims of the '732 patent under 35 U.S.C. § 271(e)(2) by submitting its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '732 patent.

106. On information and belief, Defendants have known of or have been willfully blind to the existence and contents of the '732 patent since its issuance. Despite such knowledge, Centus, in concert with and at the direction of the Fujifilm entities, nonetheless filed its BLA with the FDA and/or continued to pursue such BLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Centus's bevacizumab biosimilar product before the expiration of the '732 patent and in violation of Genentech's patent

rights.

107. Genentech is entitled to a judgment that the Defendants have infringed one or more claims of the ’732 patent by submitting a BLA 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 Centus’s bevacizumab biosimilar product before the expiration of the ’732 patent.

108. Genentech would be irreparably harmed if the Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Centus’s bevacizumab biosimilar product once it is approved by the FDA. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such actions.

COUNT TWELVE AGAINST ALL DEFENDANTS
(Declaratory Judgment of Infringement of the ’732 Patent Under 35 U.S.C. § 271(g))

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

110. On information and belief, Centus submitted its BLA 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 Centus’s bevacizumab biosimilar product before the expiration of the ’732 patent.

111. On information and belief, including based on the contents of Centus’s BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), following FDA approval of its bevacizumab biosimilar product, Centus—acting in concert with and at the direction of the Fujifilm entities—intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Centus’s bevacizumab biosimilar product, which would constitute infringement of one or more claims of the ’732 patent under 35 U.S.C. § 271(g) because Centus’s 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.

112. An actual controversy has arisen and now exists between the parties concerning whether Defendants' 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 Centus's bevacizumab biosimilar product, has infringed and/or will infringe one or more claims of the '732 patent.

113. Genentech is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that Defendants have infringed and/or would infringe one or more claims of the '732 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Centus's bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '732 patent.

114. Genentech would be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '732 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Centus's bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '732 patent. Both the balance of the hardships as between Genentech and Defendants and the public interest further support this Court enjoining Defendants' infringing activities.

COUNT THIRTEEN AGAINST ALL DEFENDANTS
(Infringement of the '355 Patent Under 35 U.S.C. § 271(e))

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

116. United States Patent No. 10,208,355 ("the '355 patent") (Exhibit G hereto) was duly and legally issued on February 19, 2019. Claims of the '355 patent cover methods of treating a patient having glioblastoma with a VEGF antagonist, like bevacizumab. The '355 patent was identified in Genentech's list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

117. On information and belief, including based on the contents of Centus's BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus, in concert with and at the direction of the Fujifilm entities, infringed claims of the '355 patent under 35 U.S.C. § 271(e)(2) by submitting its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '355 patent.

118. On information and belief, Defendants have known of or have been willfully blind to the existence and contents of the '355 patent since its issuance. Despite such knowledge, Centus, in concert with and at the direction of the Fujifilm entities, nonetheless filed its BLA with the FDA and/or continued to pursue such BLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Centus's bevacizumab biosimilar product before the expiration of the '355 patent and in violation of Genentech's patent rights.

119. Genentech is entitled to a judgment that the Defendants have infringed one or more claims of the '355 patent by submitting a BLA 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 Centus's bevacizumab biosimilar product with its proposed label before the expiration of the '355 patent.

120. Genentech would be irreparably harmed if Defendants are not enjoined from the

commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Centus's bevacizumab biosimilar product and label once it is approved by the FDA. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such actions.

COUNT FOURTEEN AGAINST ALL DEFENDANTS
(Declaratory Judgment of Infringement of the '355 Patent Under 35 U.S.C. § 271(b))

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

122. On information and belief, Centus submitted its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '355 patent.

123. If a doctor were to administer to a patient, or a patient were to self-administer, Centus's bevacizumab biosimilar product for treating a patient with a glioblastoma pursuant to regimens, *i.e.*, methods, in Centus's prescribing information for that product, performing such methods would directly infringe one or more claims of the '355 patent.

124. As alleged herein, Centus—acting in concert with and at the direction of the Fujifilm entities—took or will take actions that it intended, or will intend, to cause doctors to administer to patients, or patients to self-administer, Centus's 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 for patients having a glioblastoma, would infringe the '355 patent. On information and belief, following FDA approval of its bevacizumab biosimilar product, Centus—acting in concert with and at the direction of the Fujifilm entities—intends to advertise and otherwise inform doctors and patients that its bevacizumab biosimilar product is available to treat patients having a glioblastoma using those

claimed treatment methods.

125. As alleged herein, Defendants were 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.

126. An actual controversy has arisen and now exists between the parties concerning whether Defendants 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 having a glioblastoma with bevacizumab.

127. Genentech is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that Defendants 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 having a glioblastoma with bevacizumab.

128. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from using, inducing others to use, offering to sell, or selling within the United States Centus’s bevacizumab biosimilar product for treating patients having a glioblastoma according to the methods claimed by the ’355 patent before the expiration of the ’355 patent. Both the balance of the hardships as between Genentech and Defendants and the public interest further support this Court enjoining Defendants’ infringing activities.

COUNT FIFTEEN AGAINST ALL DEFENDANTS
(Infringement of the '983 Patent Under 35 U.S.C. § 271(e))

129. Paragraphs 1–128 are incorporated by reference as if fully set forth herein.

130. United States Patent No. 10,336,983 ("the '983 patent") (Exhibit H hereto) was duly and legally issued on July 2, 2019. Claims of the '983 patent cover methods for increasing the specific productivity of CHO cells that produce exogenous polypeptides, like bevacizumab. The '983 patent was identified in Genentech's list pursuant to 42 U.S.C. § 262(*l*)(3)(A).

131. On information and belief, including based on the contents of Centus's BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus, in concert with and at the direction of the Fujifilm entities, infringed claims of the '983 patent under 35 U.S.C. § 271(e)(2) by submitting its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '983 patent.

132. On information and belief, Defendants have known of or have been willfully blind to the existence and contents of the '983 patent since its issuance. Despite such knowledge, Centus, in concert with and at the direction of the Fujifilm entities, nonetheless filed its BLA with the FDA and/or continued to pursue such BLA with the FDA, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Centus's bevacizumab biosimilar product before the expiration of the '983 patent and in violation of Genentech's patent rights.

133. Genentech is entitled to a judgment that the Defendants have infringed one or more claims of the '983 patent by submitting a BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '983 patent.

134. Genentech would be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Centus's bevacizumab biosimilar product once it is approved by the FDA. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such actions.

COUNT SIXTEEN AGAINST ALL DEFENDANTS
(Declaratory Judgment of Infringement of the '983 Patent Under 35 U.S.C. § 271(g))

135. Paragraphs 1–134 are incorporated by reference as if fully set forth herein.

136. On information and belief, Centus submitted its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '983 patent.

137. On information and belief, including based on the contents of Centus's BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), following FDA approval of its bevacizumab biosimilar product, Centus—acting in concert with and at the direction of the Fujifilm entities—intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Centus's bevacizumab biosimilar product, which would constitute infringement of one or more claims of the '983 patent under 35 U.S.C. § 271(g) because Centus's 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.

138. An actual controversy has arisen and now exists between the parties concerning whether Defendants' 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 Centus's bevacizumab biosimilar product, has infringed and/or will infringe one or more claims of the '983 patent.

139. Genentech is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that Defendants have infringed and/or would infringe one or more claims of the '983 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Centus's bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '983 patent.

140. Genentech would be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '983 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Centus's bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '983 patent. Both the balance of the hardships as between Genentech and Defendants and the public interest further support this Court enjoining Defendants' infringing activities.

COUNT SEVENTEEN AGAINST ALL DEFENDANTS
(Infringement of the '237 Patent Under 35 U.S.C. § 271(e))

141. Paragraphs 1–140 are incorporated by reference as if fully set forth herein.

142. United States Patent No. 10,662,237 ("the '237 patent") (Exhibit I hereto) was duly and legally issued on May 26, 2020. Claims of the '237 patent cover methods for filtrating viruses from compositions comprising recombinant proteins, like bevacizumab. The '237 patent was identified in Genentech's 42 U.S.C. § 262(*l*)(3)(A) list pursuant to the provisions of 42 U.S.C. § 262(*l*)(7).

143. On information and belief, including based on the contents of Centus's BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus, in concert with and at the direction of the Fujifilm entities, infringed claims of the '237 patent under 35 U.S.C. § 271(e)(2) by submitting its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '237 patent.

144. On information and belief, Defendants have has known of or has been willfully blind to the existence and contents of the '237 patent since its issuance. Despite such knowledge, on information and belief, Centus, in concert with and at the direction of the Fujifilm entities, nonetheless has continued to seek approval of its bevacizumab product based on its previously filed, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Centus's bevacizumab biosimilar product before the expiration of the '237 patent and in violation of Genentech's patent rights.

145. Genentech is entitled to a judgment that the Defendants have infringed one or more claims of the '237 patent by submitting a BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '237 patent.

146. Genentech would be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Centus's bevacizumab biosimilar product once it is approved by the FDA. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such actions.

COUNT EIGHTEEN AGAINST ALL DEFENDANTS
(Declaratory Judgment of Infringement of the ’237 Patent Under 35 U.S.C. § 271(g))

147. Paragraphs 1–146 are incorporated by reference as if fully set forth herein.

148. On information and belief, Centus submitted its BLA 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 Centus’s bevacizumab biosimilar product before the expiration of the ’237 patent.

149. On information and belief, including based on the contents of Centus’s BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), following FDA approval of its bevacizumab biosimilar product, Centus—acting in concert with and at the direction of the Fujifilm entities—intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Centus’s bevacizumab biosimilar product, which would constitute infringement of one or more claims of the ’237 patent under 35 U.S.C. § 271(g) because Centus’s 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.

150. An actual controversy has arisen and now exists between the parties concerning whether Defendants’ 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 Centus’s bevacizumab biosimilar product, has infringed and/or will infringe one or more claims of the ’237 patent.

151. Genentech is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that Defendants have infringed and/or would infringe one or more claims of the ’237 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the

United States, Centus's bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '237 patent.

152. Genentech would be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '237 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Centus's bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '237 patent. Both the balance of the hardships as between Genentech and Defendants and the public interest further support this Court enjoining Defendants' infringing activities.

COUNT NINETEEN AGAINST ALL DEFENDANTS
(Infringement of the '710 Patent Under 35 U.S.C. § 271(e))

153. Paragraphs 1–152 are incorporated by reference as if fully set forth herein.

154. United States Patent No. 10,676,710 ("the '710 patent") (Exhibit J hereto) was duly and legally issued on June 9, 2020. Claims of the '710 patent cover methods of making recombinant antibodies, like bevacizumab. The '710 patent was identified in Genentech's 42 U.S.C. § 262(*l*)(3)(A) list pursuant to the provisions of 42 U.S.C. § 262(*l*)(7).

155. On information and belief, including based on the contents of Centus's BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus, in concert with and at the direction of the Fujifilm entities, infringed claims of the '710 patent under 35 U.S.C. § 271(e)(2) by submitting its BLA 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 Centus's bevacizumab biosimilar product before the expiration of the '710 patent.

156. On information and belief, Defendants have known of or have been willfully blind to the existence and contents of the ’710 patent since its issuance. Despite such knowledge, on information and belief, Centus, in concert with and at the direction of the Fujifilm entities, nonetheless has continued to seek approval of its bevacizumab product based on its previously filed, seeking approval from the FDA to engage in the commercial manufacture, use or sale of Centus’s bevacizumab biosimilar product before the expiration of the ’710 patent and in violation of Genentech’s patent rights.

157. Genentech is entitled to a judgment that the Defendants have infringed one or more claims of the ’710 patent by submitting a BLA 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 Centus’s bevacizumab biosimilar product before the expiration of the ’710 patent.

158. Genentech would be irreparably harmed if Defendants are not enjoined from the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Centus’s bevacizumab biosimilar product once it is approved by the FDA. Genentech does not have an adequate remedy at law and is entitled to injunctive relief preventing Defendants from such actions.

COUNT TWENTY AGAINST ALL DEFENDANTS
(Declaratory Judgment of Infringement of the ’710 Patent Under 35 U.S.C. § 271(g))

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

160. On information and belief, including based on the contents of Centus’s BLA and its detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), Centus submitted its BLA 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 Centus’s bevacizumab biosimilar product before the expiration of the ’710 patent.

161. On information and belief, following FDA approval of its bevacizumab biosimilar product, Centus—acting in concert with and at the direction of the Fujifilm entities—intends to and will immediately begin to use, offer for sale, or sell within the United States, or import into the United States, Centus's bevacizumab biosimilar product, which would constitute infringement of one or more claims of the '710 patent under 35 U.S.C. § 271(g) because Centus's 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.

162. An actual controversy has arisen and now exists between the parties concerning whether Defendants' 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 Centus's bevacizumab biosimilar product, has infringed and/or will infringe one or more claims of the '710 patent.

163. Genentech is entitled to a declaratory judgment pursuant to 28 U.S.C. § 2201 that Defendants have infringed and/or would infringe one or more claims of the '710 patent by manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, Centus's bevacizumab biosimilar product, or by actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '710 patent.

164. Genentech would be irreparably harmed if Defendants are not enjoined from infringing one or more claims of the '710 patent. Genentech does not have an adequate remedy at law and is entitled to injunctive relief prohibiting Defendants from making, using, offering to sell, or selling within the United States, or importing into the United States, Centus's

bevacizumab biosimilar product, or actively inducing or contributing to the manufacture of Centus's bevacizumab biosimilar product, before the expiration of the '710 patent. Both the balance of the hardships as between Genentech and Defendants and the public interest further support this Court enjoining Defendants' infringing activities.

JURY TRIAL DEMANDED

Plaintiff requests a trial by jury on all claims so triable.

PRAYER FOR RELIEF

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

a. An injunction enjoining any Defendant, or any entity in privity with any Defendant, from making, using, offering for sale, and selling in the United States, or importing into the United States, of Centus's bevacizumab biosimilar product;

b. A preliminary injunction enjoining any Defendant, or any entity in privity with any Defendant, from making, using, offering for sale, and selling in the United States, or importing into the United States, of any Centus 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 Defendants have infringed the Patents-in-Suit;

d. A declaration that Defendants' future manufacture, use, sale, offer to sell, or importation of its bevacizumab biosimilar product will infringe the Patents-in-Suit;

e. Damages in the form of lost profits but in no event less than a reasonable royalty;

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

g. An award for an accounting of damages from Defendants' infringement;

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.

Dated: November 12, 2020

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