IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., and CITY OF HOPE	)	PUBLIC VERSION FILED: March 2, 2020
	)	
Plaintiffs,	)	[redacted]
	)	
v.	)	
	)	
AMGEN INC.	)	C.A. No. 17-1407-CFC
	)	
Defendant.	)	**JURY TRIAL DEMANDED**
	)	

SECOND AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT AND DECLARATORY JUDGMENT

Plaintiffs Genentech, Inc. and City of Hope, by their attorneys, for their Second Amended and Supplemental Complaint, allege as follows:

NATURE OF THE CASE

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

2. Last November, Amgen filed for FDA approval under the Biologics Price Competition and Innovation Act ("BPCIA"), 42 U.S.C. § 262, to commercialize a biosimilar copy of Avastin®. Enacted in 2010 as part of the Affordable Care Act, the BPCIA provides for abbreviated regulatory approval for biosimilars by letting applicants rely on the extensive clinical testing previously conducted by the innovator company that developed the medicine the applicant wants to copy.

3. Biologic medicines often have extensive patent portfolios associated with them. Avastin® is no exception. Genentech's innovative work in developing bevacizumab has been recognized by the Patent Office with dozens of patents covering the antibody itself, methods for its therapeutic use, and processes for the manufacture of therapeutic antibodies.

4. Recognizing the need to protect the patent rights of innovator companies like Genentech, Congress included provisions in the BPCIA to ensure that innovator companies have adequate opportunity to study the proposed biosimilars and the complex manufacturing processes used to make them, and where appropriate, to assert infringement before competing biosimilars come to market. This process, often called the "patent dance," starts when the FDA accepts an application for review, and is supposed to run in parallel with the FDA's review process. The "patent dance" allows parties to narrow or eliminate disputes over infringement prior to approval and ensures the innovator has received enough information about the proposed biosimilar to seek a preliminary injunction should an applicant who receives approval attempt to launch at risk.

5. The statutory protections for Genentech in this case kicked in on January 4, 2017, when the FDA notified Amgen that its Abbreviated Biologic License Application, or "aBLA," had been accepted for review. That gave Amgen twenty days to provide Genentech with "a copy of the application submitted to [FDA] under subsection (k), *and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application*." 42 U.S.C. § 262(*l*)(2)(A) (emphasis added); *see also id.* § 262(*l*)(3)(A).

6. Amgen's compliance with this requirement is critical to protecting Genentech's statutory rights. The BPCIA gives Genentech just sixty days after receiving this information to review it before serving Amgen with a list of patents Genentech believes "could reasonably be

asserted" against the manufacture, use, sale, offer for sale, or importation of Amgen's proposed biosimilar. 42 U.S.C. § 262(*l*)(3)(A). An extremely thorough review is critical, because patents not listed generally cannot be asserted in later litigation. 35 U.S.C. § 271(e)(6)(C). The early disclosure requirements also serve to facilitate informed and orderly preliminary injunction proceedings, should that become necessary, after FDA licensure but before the biosimilar product is commercialized.

7. Ignoring the express statutory language, Amgen refused to provide Genentech with anything except its aBLA. Ten days before Amgen's production was due, Genentech provided a list of "other information" that was relevant to its patent assessment, tying each request to the patents implicated. But Amgen ignored this targeted request and took the position that producing the aBLA alone was sufficient under the statute.

8. On February 15, 2017, Genentech sued Amgen for failing to comply with its statutory obligations under the BPCIA, thus hindering Genentech's ability to provide Amgen with a list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). This Court dismissed the action at Amgen's urging for want of subject matter jurisdiction. Genentech proceeded to serve a list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) despite Amgen's non-compliance with 42 U.S.C. § 262(*l*)(2).

9. On May 23, 2017, Amgen served disclosures purporting to comply with 42 U.S.C. § 262(*l*)(3)(B). [redacted]

[redacted]

10. Genentech relied on Amgen's representation, which Amgen made repeatedly. As detailed further below, Amgen violated this binding representation by asserting that the patents [redacted] were invalid and by asserting that it could begin marketing six months after October 6, 2017.

11. [redacted] Amgen has insisted that that such activities are non-infringing because of their relationship to regulatory activities, but in fact this conduct exceeds to scope of 35 U.S.C. § 271(e)(1) and is therefore actionable.

12. On July 22, 2017, Genentech served detailed infringement and validity contentions pursuant to 42 U.S.C. § 262(*l*)(3)(C) ("Genentech's (*l*)(3)(C) Contentions"). These contentions span 559 pages and provide particularized detail concerning Amgen's infringement of numerous patents. The contentions discuss information that Amgen alleges to be confidential. Accordingly, Genentech has not attached the contentions to this pleading but incorporates the contentions by reference.

13. Over the course of the ensuing months, Amgen refused to negotiate concerning the scope of litigation despite the requirements of 42 U.S.C. § 262(*l*)(4). Amgen purported to require additional time to review Genentech's (*l*)(3)(C) Contentions, thereby delaying the initiation of negotiations pursuant to 42 U.S.C. § 262(*l*)(4). Genentech sent multiple letters to Amgen during this period reiterating its willingness to begin the required negotiations. But,

[redacted] Genentech did not take other steps to accelerate the pace of negotiations, and it refrained from commencing litigation against Amgen.

14. Following the negotiations pursuant to 42 U.S.C. § 262(*l*)(4), Genentech—and not Amgen—would have had the opportunity to file an action for patent infringement in the appropriate venue of its choosing. Amgen sought to delay the initiation, and, by extension, the termination of those negotiations, in order to prevent Genentech from filing suit. Amgen's purported provision of notice pursuant to 42 U.S.C. § 262(*l*)(8) and filing of a lawsuit on the same day—before the conclusion of negotiations under 42 U.S.C. § 262(*l*)(4) that it had stalled unilaterally—constitutes an attempt to deprive Genentech of its statutory right to choose an appropriate venue to remediate Amgen's infringement.

15. Following a lengthy and unexplained delay, Amgen agreed to an in-person meeting to initiate 42 U.S.C. § 262(*l*)(4) negotiations that was held on September 14, 2017. At that meeting, Genentech proposed to Amgen that the litigation pursuant to 42 U.S.C. § 262(*l*)(6) encompass all of the patents asserted in this Complaint. Amgen disagreed, but suggested it would provide a counter-proposal concerning the scope of the litigation.

16. Amgen never sent such a proposal. Instead, on October 2, 2017, Amgen sent Genentech a letter stating that the 15-day window for "good-faith negotiations" had elapsed and that it would "be in touch regarding § 262(*l*)(5)."

17. On October 6, 2017, Amgen sent Genentech another letter "writing to ask if you are available to conduct § 262(*l*)(5) negotiations next week," Amgen offered to "provid[e] the number of patents pursuant to § 262(*l*)(5)(A) on Monday." Amgen's letter did not mention that

it had also purported to serve Genentech with a notice pursuant to § 262(*l*)(8) that it intended to begin commercial marketing. Nor did Amgen's letter indicate that it had, just hours earlier, filed a lawsuit against Genentech in the Central District of California, seeking a declaratory judgment with respect to all of the patents listed in Genentech's §262(*l*)(3)(A) list of patents.

18. The purpose of Amgen's behavior is manifest. It has deprived Genentech of its plain right under the BPCIA to thoroughly evaluate potential infringement before Amgen's proposed copy of Avastin® comes to market and it seeks to deprive Genentech of its right to select the forum for litigation pursuant to the BPCIA. As a result, Genentech has been forced to evaluate its rights based on an incomplete record and to file this lawsuit to preserve its rights in the face of Amgen's astonishing conduct.

19. Genentech therefore brings this action for infringement, declaratory judgment, and additional appropriate relief, specifically an order declaring that Amgen's actions are contrary to the BPCIA and that the manufacture, use, offer for sale, and/or sale of Amgen's proposed biologic product infringes Genentech's intellectual property rights.

THE PARTIES

20. 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.

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

22. Amgen Inc. is a corporation organized under the laws of the State of Delaware, with its principal place of business at One Amgen Center Drive, Thousand Oaks, California 91320.

23. Amgen is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling biologic drug products that are distributed and sold throughout the United States and in the State of Delaware. With respect to biologics, Amgen is both an innovator company with its own drugs and a biosimilar manufacturer hoping to copy drugs invented and developed by others.

JURISDICTION AND VENUE

24. 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. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

25. This Court has personal jurisdiction over Amgen because it is incorporated in the State of Delaware; because Amgen sought approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of ABP 215 in the United States, including in the State of Delaware; and because Amgen intends to market, distribute, offer for sale, and/or sell ABP 215 in the United States, including in the State of Delaware, deriving substantial revenue therefrom.

26. In addition, Amgen has consented to jurisdiction in the State of Delaware in one or more prior cases arising out of its manufacture, use, offer for sale, sale, and/or importation of Amgen pharmaceutical products in the United States, including in the State of Delaware. This includes cases Amgen has initiated as the plaintiff.

27. Venue is proper in this district pursuant to 28 U.S.C. § 1400(b) because Amgen is incorporated in Delaware. In addition, Amgen has consented to venue in this district repeatedly, including in connection with litigation under the BPCIA. In particular, Amgen has consented to venue in this district with respect to an action that, like the instant suit, seeks a declaration that Amgen has violated the BPCIA with respect to its bevacizumab aBLA.

FACTUAL BASIS FOR RELIEF

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

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

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

THE GENENTECH PATENTS

31. As a result of Amgen's conduct, Genentech has been forced to assess Amgen's infringement based on incomplete information. Nevertheless, faced with the risk of being forever barred from asserting patents should a court later find Amgen's production compliant with the statute, Genentech served on March 24, 2017 a list of 27 patents that Genentech believed could reasonably be asserted against the manufacture, use, sale, offer for sale, or import into the United States of ABP 215. *See* 42 U.S.C. § 262(*l*)(3)(A). In response to Amgen's (*l*)(3)(B) contentions, Genentech declined to serve infringement contentions pursuant to § 262(*l*)(3)(C) as to two patents.

32. Subsequent to the service of Genentech's list of patents it believed could reasonably be asserted against ABP 215 pursuant to 42 U.S.C. § 262(*l*)(3)(A), United States Patent No. 9,795,672 ("the '672 patent") (Exhibit M hereto) was duly and legally issued on Oct. 24, 2017.

33. Pursuant to 42 U.S.C. § 262(*l*)(7), on November 2, 2017 Genentech provided to Amgen a supplement to its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) to include the '672 patent. Amgen notified Genentech of its contentions pursuant to 42 U.S.C. § 262(*l*)(3)(B), with respect to this patent by email dated December 1, 2017. Genentech asserted through the patent dance that the following patents have been infringed and will be infringed by the

manufacture, use, sale, or offer for sale of ABP 215. After certain discovery, the patents-in-suit ("the Asserted Patents") are:

US Patent No.	Issue Date	First Named Inventor
EX A -- 6,054,297	April 25, 2000	Carter
EX B -- 6,331,415	Dec. 18, 2001	Cabilly
EX C -- 6,407,213	June 18, 2002	Carter
EX D -- 6,417,335	July 9, 2002	Basey
EX E -- 6,884,879	April 26, 2005	Baca
EX F -- 7,060,269	June 13, 2006	Baca
EX G -- 7,169,901	Jan. 30, 2007	Baca
EX H -- 7,375,193	May 20, 2008	Baca
EX I -- 7,923,221	April 12, 2011	Cabilly
EX J -- 8,512,983	Aug. 20, 2013	Gawlitzek
EX K -- 8,574,869	Nov. 5, 2013	Kao
EX L -- 9,441,035	Sept. 13, 2016	Carvalhal
EX M – 9,795,672	Oct. 24, 2017	Fyfe

34. Genentech is the owner of all right, title, and interest in the Asserted Patents, with the following exceptions. Genentech and City of Hope are co-owners of U.S. Patent No. 6,331,415 (Exhibit B) and U.S. Patent No. 7,923,221 (Exhibit I).

35. Case No. 17-cv-1471 has been consolidated with this action. This second amended and supplemental complaint does not alter the operative complaint in Case No. No. 17-cv-1471.

Count 1
(Infringement and Declaration of Infringement of the '297 Patent)

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

37. United States Patent No. 6,054,297 ("the '297 patent") (Exhibit A hereto), was duly and legally issued on April 25, 2000.

38. Amgen has infringed claims 9 and 10 of the '297 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Plaintiffs' First Supplemental Objections and Responses to Amgen's First Set of Interrogatories to Plaintiffs (Nos. 1-7).

39. [redacted] Amgen believed, [redacted] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42 U.S.C. § 262(*l*)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by Amgen's ABP 215. [redacted]

40. Amgen's infringement of the '297 patent was willful.

41. As a result of Amgen's infringement of the '297 patent, Genentech has suffered irreparable injury. Unless Amgen is enjoined from further use of material made by infringing the '297 patent, Genentech will suffer additional irreparable injury. Genentech has no adequate remedy at law.

42. As a consequence of Amgen's infringement of the '297 patent, Genentech has suffered damages in an amount not yet determined, but no less than a reasonable royalty.

43. Amgen's willful, wanton, and deliberate infringement of the '297 patent justifies an award to Genentech of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

44. Genentech is entitled to a declaration that Amgen infringed the '297 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Plaintiffs' First Supplemental Objections and Responses to Amgen's First Set of Interrogatories to Plaintiffs (Nos. 1-7).

45. Genentech is entitled to a declaration that Amgen's infringement of the '297 patent was willful.

Count 2
(Infringement and Declaration of Infringement of the '415 Patent)

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

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

48. Amgen has infringed claims 1, 2, 11, 18, 19, 20, and 33 of the '415 patent in violation of 35 U.S.C. § 271(a) and (g) by making and/or using ABP 215 in the United States, as explained in Plaintiffs' First Supplemental Objections and Responses to Amgen's First Set of Interrogatories to Plaintiffs (Nos. 1-7).

49. [redacted] Amgen believed, [redacted] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42 U.S.C. § 262(*l*)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by Amgen's ABP 215. [redacted]

50. Amgen's infringement of the '415 patent was willful.

51. As a result of Amgen's infringement of the '415 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from further use of material made by infringing the '415 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

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

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

54. Genentech is entitled to a declaration that Amgen infringed the '415 patent in violation of 35 U.S.C. § 271(a) and (g) by making and/or using ABP 215 in the United States, as explained in Plaintiffs' First Supplemental Objections and Responses to Amgen's First Set of Interrogatories to Plaintiffs (Nos. 1-7).

55. Genentech is entitled to a declaration that Amgen's infringement of the '415 patent was willful.

Count 3
(Infringement and Declaration of Infringement of the '213 Patent)

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

57. United States Patent No. 6,407,213 ("the '213 patent") (Exhibit C hereto), was duly and legally issued on June 18, 2002.

58. Amgen has infringed claims 25, 63, 65-67, 69, 71-73, and 75-78 of the '213 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (*l*)(3)(C) contentions.

59. [redacted] Amgen believed, [redacted] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement in their 42 U.S.C. § 262(*l*)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was infringed by Amgen's ABP 215.

60. Amgen's infringement of the '213 patent was willful.

61. As a result of Amgen's infringement of the '213 patent, Genentech has suffered irreparable injury. Unless Amgen is enjoined from infringing the '213 patent, Genentech will suffer additional irreparable injury. Genentech has no adequate remedy at law.

62. As a consequence of Amgen's infringement of the '213 patent, Genentech has suffered damages in an amount not yet determined, but no less than a reasonable royalty.

63. Amgen's willful, wanton, and deliberate infringement of the '213 patent justifies an award to Genentech of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

64. Genentech is entitled to a declaration that Amgen infringed and will infringe claims 25, 63, 65-67, 69, 71-73, and 75-78 of the '213 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (*l*)(3)(c) contentions.

65. Genentech is entitled to a declaration that Amgen's infringement of the '213 patent was and will be willful.

Count 4
(Infringement and Declaration of Infringement of the '335 Patent)

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

67. United States Patent No. 6,417,335 ("the '335 patent") (Exhibit D hereto), was duly and legally issued on July 9, 2002.

68. Amgen has infringed claims 1, 3, and 7 of the '335 patent in violation of 35 U.S.C. § 271(a) and (g) by making and/or using ABP 215 in the United States, as explained in Genentech's (*l*)(3)(c) contentions.

69. [redacted] Amgen believed, [redacted] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement in their 42 U.S.C. § 262(*l*)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was infringed by Amgen's ABP 215.

70. Amgen's infringement of the '335 patent was willful.

71. As a result of Amgen's infringement of the '335 patent, Genentech has suffered irreparable injury. Unless Amgen is enjoined from infringing the '335 patent, Genentech will suffer additional irreparable injury. Genentech has no adequate remedy at law.

72. As a consequence of Amgen's infringement of the '335 patent, Genentech has suffered damages in an amount not yet determined, but no less than a reasonable royalty.

73. Amgen's willful, wanton, and deliberate infringement of the '335 patent justifies an award to Genentech of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

74. Genentech is entitled to a declaration that Amgen infringed and will infringe claims 1, 3, and 7 of the '335 patent in violation of 35 U.S.C. § 271(a) and (g) by making, using,

offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (*l*)(3)(c) contentions.

75. Genentech is entitled to a declaration that Amgen's infringement of the '335 patent was and will be willful.

Count 5
(Infringement and Declaration of Infringement of the '879 Patent)

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

77. United States Patent No. 6,884,879 ("the '879 patent") (Exhibit E hereto), was duly and legally issued on April 26, 2005.

78. Amgen has infringed claims 1-7, 9-11, and 13 of the '879 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Plaintiffs' First Supplemental Objections and Responses to Amgen's First Set of Interrogatories to Plaintiffs (Nos. 1-7).

79. [redacted] Amgen believed, [redacted] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42 U.S.C. § 262(*l*)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by Amgen's ABP 215. [redacted]

80. Amgen's infringement of the '879 patent was willful.

81. As a result of Amgen's infringement of the '879 patent, Genentech has suffered irreparable injury. Unless Amgen is enjoined from further use of material made by infringing the

’879 patent, Genentech will suffer additional irreparable injury. Genentech has no adequate remedy at law.

82. As a consequence of Amgen’s infringement of the ’879 patent, Genentech has suffered damages in an amount not yet determined, but no less than a reasonable royalty.

83. Amgen’s willful, wanton, and deliberate infringement of the ’879 patent justifies an award to Genentech of increased damages under 35 U.S.C. § 284, and attorneys’ fees and costs incurred under 35 U.S.C. § 285.

84. Genentech is entitled to a declaration that Amgen infringed the ’879 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Plaintiffs’ First Supplemental Objections and Responses to Amgen’s First Set of Interrogatories to Plaintiffs (Nos. 1-7).

85. Genentech is entitled to a declaration that Amgen’s infringement of the ’879 patent was willful.

Count 6
(Infringement and Declaration of Infringement of the ’269 Patent)

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

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

88. Amgen has used ABP 215 in the United States.

89. ABP 215 is adapted for infringement of the ’269 patent and is not a staple article of commerce.

90. Amgen knew and intended that its use of ABP 215 in the United States would infringe claim 2 of the ’269 patent.

91. Amgen’s infringement of the ’269 patent was willful.

92. Amgen's willful, wanton, and deliberate infringement of the '269 patent justifies an award to Genentech of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

93. Genentech is entitled to a declaration that Amgen has induced or contributed to infringement of the '269 patent in violation of 35 U.S.C. § 271(b)-(c) by using ABP 215 in the United States.

94. Genentech is entitled to a declaration that Amgen's infringement of the '269 patent in violation of 35 U.S.C. § 271(b)-(c) was willful.

95. [redacted] Amgen believed, [redacted] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement in their 42 U.S.C. § 262(*l*)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was infringed by Amgen's ABP 215.

Count 7
(Infringement and Declaration of Infringement of the '901 Patent)

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

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

98. Amgen has infringed claims 1-8 and 11 of the '901 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (*l*)(3)(c) contentions.

99. [redacted] Amgen believed, [redacted]

[redacted] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement in their 42 U.S.C. § 262(*l*)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was infringed by Amgen's ABP 215.

100. Amgen's infringement of the '901 patent was willful.

101. As a result of Amgen's infringement of the '901 patent, Genentech has suffered irreparable injury. Unless Amgen is enjoined from further use of material made by infringing the '901 patent, Genentech will suffer additional irreparable injury. Genentech has no adequate remedy at law.

102. As a consequence of Amgen's infringement of the '901 patent, Genentech has suffered damages in an amount not yet determined, but no less than a reasonable royalty.

103. Amgen's willful, wanton, and deliberate infringement of the '901 patent justifies an award to Genentech of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

104. Genentech is entitled to a declaration that Amgen infringed and will infringe claims 1-8 and 11 of the '901 patent in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (*l*)(3)(c) contentions.

105. Genentech is entitled to a declaration that Amgen's infringement of the '901 patent was willful.

Count 8
(Infringement and Declaration of Infringement of the '193 Patent)

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

107. United States Patent No. 7,375,193 ("the '193 patent") (Exhibit H hereto), was duly and legally issued on May 20, 2008.

108. Amgen has infringed claims 1-22 of the '193 patent in violation of 35 U.S.C. § 271(a) by making and/or using MVASI in the United States, as explained in Plaintiffs' First Supplemental Objections and Responses to Amgen's First Set of Interrogatories to Plaintiffs (Nos. 1-7).

109. [redacted] Amgen believed, [redacted] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42 U.S.C. § 262(*l*)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by Amgen's MVASI. [redacted]

110. Amgen's infringement of the '193 patent was willful.

111. As a result of Amgen's infringement of the '193 patent, Genentech has suffered irreparable injury. Unless Amgen is enjoined from further use of material made by infringing the '193 patent, Genentech will suffer additional irreparable injury. Genentech has no adequate remedy at law.

112. As a consequence of Amgen's infringement of the '193 patent, Genentech has suffered damages in an amount not yet determined, but no less than a reasonable royalty.

113. Amgen's willful, wanton, and deliberate infringement of the '193 patent justifies an award to Genentech of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

114. Genentech is entitled to a declaration that Amgen infringed the '193 patent in violation of 35 U.S.C. § 271(a) by making and/or using MVASI in the United States, as explained in Plaintiffs' First Supplemental Objections and Responses to Amgen's First Set of Interrogatories to Plaintiffs (Nos. 1-7).

115. Genentech is entitled to a declaration that Amgen's infringement of the '193 patent was willful.

Count 9
(Infringement and Declaration of Infringement of the '221 Patent)

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

117. United States Patent No. 7,923,221 ("the '221 patent") (Exhibit I hereto), was duly and legally issued on April 12, 2011.

118. Amgen has infringed claims 1, 2, 4, 5, 8, 9, 10, 11, 15, 16, 20, 21, 24, 25, 26, 31, 32, 34, 38, 39, 43, 44 and 47 of the '221 patent in violation of 35 U.S.C. § 271(a) and (g) by making and/or using ABP 215 in the United States, as explained in Plaintiffs' First Supplemental Objections and Responses to Amgen's First Set of Interrogatories to Plaintiffs (Nos. 1-7).

119. [redacted] Amgen believed, [redacted] that biosimilar applicants like Amgen must include all bases for its contentions of non-infringement and invalidity in their 42 U.S.C. § 262(*l*)(3)(B) contentions and cannot legally change those contentions in subsequent litigation. Amgen knew, understood, and believed that this patent was valid and infringed by

Amgen's ABP 215. [redacted]

120. Amgen's infringement of the '221 patent was willful.

121. As a result of Amgen's infringement of the '221 patent, Plaintiffs have suffered irreparable injury. Unless Amgen is enjoined from further use of material made by infringing the '221 patent, Plaintiffs will suffer additional irreparable injury. Plaintiffs have no adequate remedy at law.

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

123. Amgen's willful, wanton, and deliberate infringement of the '221 patent justifies an award to Plaintiffs of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

124. Genentech is entitled to a declaration that Amgen infringed the '221 patent in violation of 35 U.S.C. § 271(a) and (g) by making and/or using ABP 215 in the United States, as explained in Plaintiffs' First Supplemental Objections and Responses to Amgen's First Set of Interrogatories to Plaintiffs (Nos. 1-7).

125. Genentech is entitled to a declaration that Amgen's infringement of the '221 patent was be willful.

Count 10[1]
(Infringement and Declaration of Infringement of the '983 Patent)

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

[1] This Count originally was numbered Count 12 in Genentech's proposed Second Amended Complaint. It is encompassed by the Stipulation and Order Regarding Judgment of Non-Infringement, D.I. 578 ¶ 1.

127. United States Patent No. 8,512,983 ("the '983 patent") (Exhibit J hereto), was duly and legally issued on Aug. 20, 2013. Amgen has infringed claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 16, 17, 18, 19, and 23 of the '983 patent in violation of 35 U.S.C. § 271(a) and (g) by making and/or using ABP 215 in the United States, as explained in Genentech's (*l*)(3)(c) contentions.

128. Amgen's infringement of the '983 patent was willful.

129. As a result of Amgen's infringement of the '983 patent, Genentech has suffered irreparable injury. Unless Amgen is enjoined from infringing the '983 patent, Genentech will suffer additional irreparable injury. Genentech has no adequate remedy at law.

130. As a consequence of Amgen's infringement of the '983 patent, Genentech has suffered damages in an amount not yet determined, but no less than a reasonable royalty.

131. Amgen's willful, wanton, and deliberate infringement of the '983 patent justifies an award to Genentech of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

132. Genentech is entitled to a declaration that Amgen infringed and will infringe claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 16, 17, 18, 19, and 23 of the '983 patent in violation of 35 U.S.C. § 271(a) and (g) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (*l*)(3)(c) contentions.

133. Genentech is entitled to a declaration that Amgen's infringement of the '983 patent was willful.

Count 11
(Infringement and Declaration of Infringement of the '869 Patent)

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

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

136. Amgen has infringed at least[2] claims 1, 5, 7, and 8 of the '869 patent in violation of 35 U.S.C. § 271(a) and (g) by making and/or using ABP 215 in the United States, as explained in Genentech's (*l*)(3)(c) contentions.

137. Amgen's infringement of the '869 patent was willful.

138. As a result of Amgen's infringement of the '869 patent, Genentech has suffered irreparable injury. Unless Amgen is enjoined from infringing the '869 patent, Genentech will suffer additional irreparable injury. Genentech has no adequate remedy at law.

139. As a consequence of Amgen's infringement of the '869 patent, Genentech has suffered damages in an amount not yet determined, but no less than a reasonable royalty.

140. Amgen's willful, wanton, and deliberate infringement of the '869 patent justifies an award to Genentech of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285. Genentech is entitled to a declaration that Amgen infringed and will infringe at least claims 1, 5, 7, and 8 of the '869 patent in violation of 35 U.S.C. § 271(a) and (g) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (*l*)(3)(c) contentions.

Count 12[3]
(Infringement and Declaration of Infringement of the '035 Patent)

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

[2] Genentech understands that the Court denied Genentech's motion to amend relating to claim 4 pending further consideration at the Status Conference scheduled for March 5, 2020.

[3] This Count originally was numbered Count 15 in Genentech's proposed Second Amended Complaint. It is encompassed by the Stipulation and Order Regarding Judgment of Non-Infringement, D.I. 484 ¶ 1.

142. United States Patent No. 9,441,035 ("the '035 patent") (Exhibit L hereto), was duly and legally issued on Sept. 13, 20035 patent in violation of 35 U.S.C. § 271(a) by making and/or using ABP 215 in the United States, as explained in Genentech's (l)(3)(c) contentions.

143. Amgen has infringed claims 1, 2, 3, 4, 5, 6, 7, 9, 14, 33, 34, 35, 36, 37, 39, 40, 41, 42, 43, 44, 45, 46, 47, 49, 54, 73, 74, 75, 76, 77, and 79 of the '035 patent in violation of 35 U.S.C. § 271(a) and (g) by making and/or using ABP 215 in the United States, as explained in Genentech's (*l*)(3)(c) contentions.

144. Amgen's infringement of the '035 patent was willful.

145. As a result of Amgen's infringement of the '035 patent, Genentech has suffered irreparable injury. Unless Amgen is enjoined from infringing the '035 patent, Genentech will suffer additional irreparable injury. Genentech has no adequate remedy at law.

146. As a consequence of Amgen's infringement of the '035 patent, Genentech has suffered damages in an amount not yet determined, but no less than a reasonable royalty.

147. Amgen's willful, wanton, and deliberate infringement of the '035 patent justifies an award to Genentech of increased damages under 35 U.S.C. § 284, and attorneys' fees and costs incurred under 35 U.S.C. § 285.

148. Genentech is entitled to a declaration that Amgen infringed and will infringe claims 1, 2, 3, 4, 5, 6, 7, 9, 14, 33, 34, 35, 36, 37, 39, 40, 41, 42, 43, 44, 45, 46, 47, 49, 54, 73, 74, 75, 76, 77, and 79 of the '035 patent in violation of 35 U.S.C. § 271(a) and (g) by making, using, offering for sale, and/or selling ABP 215 in the United States, as explained in Genentech's (*l*)(3)(c) contentions.

Count 13
(Infringement and Declaration of Infringement of the '672 Patent)

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

150. The ’672 patent (Exhibit M hereto) was duly and legally issued on Oct. 24, 2017.

151. Genentech is the owner of all right, title, and interest in the ’672 patent.

152. The ’672 patent has not yet expired.

153. Pursuant to 42 U.S.C. § 262(*l*)(7), on November 2, 2017 Genentech provided to Amgen a supplement to its list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) to include the ’672 patent. At that time, Genentech provided Amgen with a copy of the ’672 patent. Amgen notified Genentech of its contentions pursuant to 42 U.S.C. § 262(*l*)(3)(B), with respect to this patent by email dated December 1, 2017. Amgen has knowledge of the ’672 patent.

154. Amgen has obtained FDA approval under 42 U.S.C. § 262(k) to manufacture, use, offer for sale, and/or sell within the United States, or import into the United States, ABP 215, a biosimilar version of Genentech’s Avastin® (bevacizumab) product.

155. For example, the sale of MVASI pursuant to its label will contribute to and induce infringement of, *inter alia*, claim 1 of the ’672 patent.

156. Claim 1 recites “a method of treating cancer in a patient comprising administering to the patient an effective amount of bevacizumab.” For example, Amgen’s product is indicated for the treatment of cancer, as set forth in Section 1 of the MVASI Label. For example, Amgen’s MVASI Label instructs physicians on the dosage and administration necessary to administer an effective amount, as set forth in Section 2 of the MVASI Label.

157. Claim 1 further recites, “wherein the patient has a grade III hypertensive event resulting from the bevacizumab administration.” For example, Amgen’s MVASI Label warns physicians in Section 5.7 about the relationship between administration of MVASI and hypertension. Administration of MVASI will result in patients having a grade III hypertensive event resulting from the bevacizumab administration.

158. Claim 1 further recites, "the method further comprising administering to the patient an antihypertensive agent in an amount sufficient to manage the grade III hypertensive event." For example, Amgen's MVASI Label instructs physicians in Section 5.7 in the management of hypertension. Amgen's MVASI Label instructs and encourages physicians to administer to the patient an antihypertensive agent in an amount sufficient to manage the grade III hypertensive event.

159. Claim 1 further recites, "while continuing to treat the patient with bevacizumab, the treatment being carried out without altering the dosing regimen." For example, Amgen's MVASI Label instructs physicians in Sections 2.4 and 5.7 concerning how to administer MVASI while managing hypertension. Amgen's MVASI Label instructs and encourages physicians to administer to the patient an antihypertensive while continuing to treat the patient with bevacizumab and without altering the dosing regimen.

160. As illustrated above, Genentech is entitled to a declaration that the use of Amgen's MVASI as described in the MVASI Label will infringe claim 1 of the '672 patent.

161. Genentech is also entitled to a declaration that the use of Amgen's MVASI pursuant to the MVASI Label will infringe claims 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, and 18. Amgen's December 1, 2017 contentions do not contest that administration of ABP 215 pursuant to the MVASI Label would infringe the additional limitations of these dependent claims.

162. On information and belief, the use of MVASI as described in Amgen's MVASI Label will encourage, suggest, teach, and/or induce the product's use in connection with antihypertensive therapy as claimed in the '672 patent.

163. On information and belief, Amgen plans and intends to, and will, actively induce infringement of the ’672 patent when it begins commercial marketing of MVASI.

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

165. ABP 215 is adapted for infringement of the ’672 patent and is not a staple article of commerce.

166. Amgen will induce or contribute to infringement of the ’672 patent in violation of 35 U.S.C. § 271(b)-(c) by offering for sale, and/or selling ABP 215 in the United States.

167. Amgen’s inducement or contribution to infringement of the ’672 patent in violation of 35 U.S.C. § 271(b)-(c) by offering for sale, and/or selling ABP 215 in the United States will be willful.

168. Unless Amgen is enjoined from infringing the ’672 patent, Genentech will suffer irreparable injury. Genentech has no adequate remedy at law.

WHEREFORE, Genentech requests the following relief:

(a) A judgment that Amgen has infringed the Asserted Patents;

(b) Damages in the form of lost profits but in no event less than a reasonable royalty on past and future infringing conduct and/or sales;

(c) A judgment that the infringement has been willful and an enhancement of damages;

(d) An award for an accounting of damages from Amgen’s infringement;

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

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

(g) An award of Plaintiffs' costs and expenses in this action; and

(h) Such further relief as this court may deem just and proper.

JURY DEMAND

Plaintiffs Genentech, Inc. and City of Hope, by and through their undersigned counsel, hereby demand, pursuant to Fed. R. Civ. P. 38, a trial by jury on all claims so triable in this action.

Dated: February 19, 2020

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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CERTIFICATE OF SERVICE

The undersigned counsel hereby certifies that true and correct copies of the foregoing document were caused to be served on February 19, 2020 on the following counsel in the manner indicated:

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Dated: February 19, 2020

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