IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs and Counterclaims Defendants, v. AMGEN INC., Defendant and Counterclaim Plaintiff.	Case No. 18-00924-GMS **PUBLIC VERSION**

AMGEN INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Amgen Inc. ("Amgen"), by and through its undersigned attorneys, hereby submits its Answer, Affirmative Defenses, and Counterclaims to the First Amended Complaint for declaratory and injunctive relief ("Complaint"), filed by Plaintiffs Genentech, Inc. ("Genentech") and City of Hope ("City of Hope," collectively, "Plaintiffs") on July 19, 2018.

Pursuant to Fed. R. Civ. P. 8(b)(3), Amgen denies each and every allegation in the Complaint, whether express or implied, except those specifically and expressly admitted below. Any factual allegation admitted below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that may arguably follow from the admitted facts. To the extent any allegation in the Complaint is vague and/or ambiguous, Amgen denies such allegations. Amgen denies that Plaintiffs are entitled to the relief requested or any other relief.

The headings and subheadings in Amgen's Answer are used solely for purposes of convenience and organization to mirror those appearing in the Complaint; to the extent that any

headings or other non-numbered statements in the Complaint contain or imply any allegations, Amgen denies each and every allegation therein. Each of the numbered paragraphs in the Answer below corresponds to the same-numbered paragraphs in the Complaint.

NATURE OF THE CASE

1. Amgen admits that breast cancer is a serious disease affecting women in the United States. Amgen further admits that overexpression of HER2 has been found in about 25% to 30% of human breast cancers and overexpression correlates with poor prognosis in patients with such cancers. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 1, and on that basis denies them.

2. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 2, and on that basis denies them.

3. Amgen admits that Herceptin® (hereinafter "Herceptin") contains the antibody trastuzumab. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 3, and on that basis denies them.

4. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the allegations of paragraph 4, and on that basis denies them.

5. Amgen admits that the FDA initially approved Herceptin in 1998. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 5, and on that basis denies them.

6. Amgen admits that the Patent Office has issued patents relating to trastuzumab. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 6, and on that basis denies them.

7. Amgen admits that pursuant to the Biologics Price Competition and Innovation Act ("BPCIA"), it is seeking FDA approval of a trastuzumab biosimilar called ABP 980. Amgen

further admits that it has included in its application for FDA approval of ABP 980 publicly available information regarding the FDA's previous determination that Genentech's trastuzumab product is safe, pure, and potent. Amgen also admits that it has submitted to FDA a proposed draft label that contains the same indications for which Herceptin is also approved. Amgen denies the remaining allegations of paragraph 7.

8. Amgen admits that Congress enacted the BPCIA in 2010. Amgen further admits that it has complied with 42 U.S.C. § 262(l). The remaining allegations of paragraph 8 are legal conclusions that require no response, and on that basis Amgen denies them.

9. Amgen admits that Plaintiffs have brought an action alleging patent infringement seeking relief against Amgen. Amgen denies Plaintiffs are entitled to any such relief, requested or otherwise. Amgen denies the remaining allegations of paragraph 9.

PARTIES

10. Upon information and belief, Amgen admits the allegations of paragraph 10.

11. Upon information and belief, Amgen admits that Genentech was founded in 1976 and that Genentech is the sponsor for a number of products that have received FDA approval. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 11, and on that basis denies them.

12. Upon information and belief, Amgen admits the allegations of paragraph 12.

13. Upon information and belief, Amgen admits that City of Hope was founded in 1913. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 13, and on that basis denies them.

14. Amgen admits the allegations of paragraph 14.

15. Amgen admits the allegations of paragraph 15.

JURISDICTION AND VENUE

16. The allegations of paragraph 16 are legal conclusions that require no response, and on that basis Amgen denies them.

17. Amgen admits that it is incorporated in the State of Delaware. The remaining allegations of paragraph 17 contain legal conclusions that require no response, and on that basis Amgen denies them.

18. Amgen admits that it is incorporated in the State of Delaware. Amgen admits that it has submitted a Biologics License Application (hereinafter "Amgen's BLA") seeking FDA approval of ABP 980. The remaining allegations of paragraph 18 contain legal conclusions that require no response, and on that basis Amgen denies them.

THE PARTIES' EXCHANGES UNDER THE BPCIA

19. Amgen admits that on July 31, 2017, it announced the submission of Amgen's BLA to the FDA for ABP 980, which is being developed as a biosimilar to trastuzumab. Upon information and belief, Amgen admits that Genentech's trastuzumab is subject to BLA No. 103792. Amgen denies the remaining allegations of paragraph 19.

20. Amgen admits the allegations of paragraph 20.

21. Amgen admits that on October 16, 2017, Amgen provided Genentech a copy of Amgen's BLA. Amgen denies the remaining allegations of paragraph 21.

22. Amgen admits the allegations of paragraph 22.

23. Amgen admits that on November 20, 2017, Genentech requested specific information concerning the manufacture of Amgen's biosimilar product and that Amgen provided additional manufacturing information to Genentech on December 1, 2017, and December 4, 2017. Amgen further admits that Genentech responded on December 15, 2017. Amgen denies the remaining allegations of paragraph 23.

24. Amgen denies the allegations of paragraph 24.

25. Amgen admits that on December 15, 2017, Amgen received a list of 36 patents from Genentech purporting to comply with Genentech's statutory obligations pursuant to 42 U.S.C. § 262(*l*)(3)(A) ("Genentech's 3A Statement"). Amgen denies the remaining allegations of paragraph 25.

26. Amgen admits the allegations of paragraph 26.

27. Amgen admits that Genentech responded on December 27, 2017. Amgen denies the remaining allegations of paragraph 27.

28. Amgen admits the allegations of paragraph 28.

29. Amgen admits that on February 6, 2018, Genentech supplemented its § 262(*l*)(3)(A) list to include U.S. Patent No. 9,868,760. Amgen denies the remaining allegations of paragraph 29.

30. Amgen admits that on February 13, 2018, pursuant to 42 U.S.C. § 262(*l*)(3)(B), Amgen provided Genentech with its detailed statement concerning non-infringement and invalidity of the 36 patents identified in Genentech's December 15, 2017 disclosure ("Amgen's 3B Statement"). On March 3, 2018, Amgen supplemented its February 13, 2018 disclosure with its § 262(*l*)(3)(B) disclosure for U.S. Patent No. 9,868,760. Genentech's allegation regarding the sufficiency of Amgen's 3B statement contains legal conclusions that require no response, and on that basis Amgen denies them. Amgen denies the remaining allegations of paragraph 30.

31. Amgen admits that on [redacted], Amgen produced additional documents regarding [redacted]. Amgen denies the remaining allegations of paragraph 31.

32. Amgen admits that on April 13, 2018, Amgen received Genentech's responses to Amgen's 3B Statement purporting to comply with Genentech's statutory obligations pursuant to 42 U.S.C. § 262(*l*)(3)(C) ("Genentech's 3C Statement"). Amgen admits that Genentech maintained that ABP 980 will infringe 18 of the 37 Genentech patents identified in Genentech's 3A Statement, and that Genentech proposed that all 18 of these patents be included in a first-phase infringement action. Amgen denies the merits of Genentech's allegations of infringement. Amgen denies the remaining allegations of paragraph 32.

33. Amgen admits that on [redacted], Amgen provided additional documents regarding [redacted]. Amgen denies the remaining allegations of paragraph 33.

34. Amgen admits that after Genentech served its 3C Statement, the parties initiated negotiations under § 262(*l*)(4). Amgen further admits that Genentech and Amgen agreed that the 37 patents addressed in Genentech's 3A Statement shall be the subject of an action for patent infringement under § 262(*l*)(6)(A). Amgen denies the merits of Genentech's allegations of infringement. Amgen denies the remaining allegations of paragraph 34.

35. Amgen denies the merits of Genentech's allegations of infringement. The remaining allegations of paragraph 35 are legal conclusions that require no response, and on that basis Amgen denies them.

36. Amgen admits that on [redacted], Amgen notified Genentech pursuant to 42 U.S.C. § 262(*l*)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations of paragraph 36.

37. Amgen admits the allegations of paragraph 37.

AMGEN'S BLA PRODUCT

38. Amgen admits that it has publicly stated that its BLA product is a biosimilar candidate to trastuzumab. Amgen admits the remaining allegations of paragraph 38.

39. Amgen admits that Amgen's BLA for trastuzumab included "information demonstrating that Amgen's BLA product and trastuzumab utilize the same mechanism of action . . . for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling" submitted in Amgen's BLA pursuant to 42 U.S.C. § 262(k)(2)(A)(i)(II). Amgen denies the remaining allegations of paragraph 39.

40. The allegations of paragraph 40 are legal conclusions that require no response, and on that basis Amgen denies them.

GENENTECH'S ASSERTED PATENTS

41. Amgen admits that the United States Patent and Trademark Office has issued patents relating to trastuzumab, its manufacture, and its use. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 41, and on that basis denies them.

42. Amgen admits that Genentech has asserted the following patents in this lawsuit: U.S. Patent No. 6,331,415, U.S. Patent No. 7,923,221, U.S. Patent No. 6,407,213, U.S. Patent No. 7,846,441, U.S. Patent No. 7,892,549, U.S. Patent No. 6,627,196, U.S. Patent No. 7,371,379, U.S. Patent No. 6,417,335, , U.S. Patent No. 9,249,218, U.S. Patent No. 8,574,869, U.S. Patent No. 6,620,918, U.S. Patent No. 7,993,834, U.S. Patent No. 8,076,066, U.S. Patent No. 8,425,908, U.S. Patent No. 8,440,402, U.S. Patent No. 6,121,428, U.S. Patent No. 8,512,983, and U.S. Patent No. 9,714,293. Amgen denies the remaining allegations of paragraph 42, and denies the merits of Genentech's allegations of infringement.

The Cabilly Patents

43. Amgen admits that U.S. Patent Nos. 6,331,415 and 7,923,221 purport to relate to a process for producing monoclonal antibodies from recombinant DNA. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 43, and on that basis denies them.

44. Amgen admits that U.S. Patent No. 6,331,415 ("the '415 patent") is titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein." Amgen further admits that the face of the '415 patent reflects (1) an issue date of December 18, 2001 and (2) that the patent was assigned to Genentech and City of Hope. Amgen admits that Exhibit A to the Complaint purports to be a copy of the '415 patent. Amgen denies that the '415 patent was "duly and legally" issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 44, and on that basis denies them.

45. Amgen admits that U.S. Patent No. 7,923,221 ("the '221 patent") is titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen." Amgen further admits that the face of the '221 patent reflects (1) an issue date of April 12, 2011 and (2) that the patent was assigned to Genentech and City of Hope. Amgen admits that Exhibit B to the Complaint purports to be a copy of the '221 patent. Amgen denies that the '221 patent was "duly and legally" issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 45, and on that basis denies them.

The '213 Patent

46. Amgen admits that U.S. Patent No. 6,407,213 ("the '213 patent") purports to relate to a humanized antibody and/or a humanized antibody variable domain. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 46, and on that basis denies them.

47. Amgen admits that the ’213 patent is titled “Methods of Making Humanized Antibodies.” Amgen further admits that the face of the ’213 patent reflects (1) an issue date of June 18, 2002 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit C to the Complaint purports to be a copy of the ’213 patent. Amgen denies that the ’213 patent was “duly and legally” issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 47, and on that basis denies them.

The Combination Chemotherapy Patents

48. Amgen admits that U.S. Patent No. 7,846,441 (“the ’441 patent”) purports to relate to a method of administering anti-ErbB2 antibodies. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 48, and on that basis denies them.

49. Amgen admits that the ’441 patent is titled “Treatment with Anti-ErbB2 Antibodies.” Amgen further admits that the face of the ’441 patent reflects (1) an issue date of December 7, 2010 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit D to the Complaint purports to be a copy of the ’441 patent. Amgen denies that the ’441 patent was “duly and legally” issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 49, and on that basis denies them.

50. Amgen admits that U.S. Patent No. 7,892,549 (“the ’549 patent”) purports to be a continuation of the ’441 patent, and purports to relate to a method of treating a patient with HER2-positive breast cancer using anti-ErbB2 antibodies. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 50, and on that basis denies them.

51. Amgen admits that the ’549 patent is titled “Treatment with Anti-ErbB2 Antibodies.” Amgen further admits that the face of the ’549 patent reflects (1) an issue date of

February 22, 2011 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit E to the Complaint purports to be a copy of the ’549 patent. Amgen denies that the ’549 patent was “duly and legally” issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 51, and on that basis denies them.

52. Amgen admits that U.S. Patent No. 8,425,908 (“the ’908 patent”) purports to claim priority to the same provisional application as the’441 and ’549 patents. Amgen admits that the ’908 patent purports to relate to a method of treating a patient with HER2-positive gastric cancer using anti-ErbB2 antibodies. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 52, and on that basis denies them.

53. Amgen admits that the ’908 patent is titled “Treatment with Anti-ErbB2 Antibodies.” Amgen further admits that the face of the ’908 patent reflects (1) an issue date of April 23, 2013 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit F to the Complaint purports to be a copy of the ’908 patent. Amgen denies that the ’908 patent was “duly and legally” issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 53, and on that basis denies them.

The Method of Administration Patents

54. Amgen admits that U.S. Patent Nos. 6,627,196 and 7,371,379 purport to relate to a method of administering anti-ErbB2 antibodies. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 54, and on that basis denies them.

55. Amgen admits that U.S. Patent No. 6,627,196 (“the ’196 patent”) is titled “Dosages for Treatment with Anti-ErbB2 Antibodies.” Amgen further admits that the face of the’196 patent reflects (1) an issue date of September 30, 2003 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit G to the Complaint purports to be a copy of the’196 patent. Amgen

denies that the ’196 patent was “duly and legally” issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 55, and on that basis denies them.

56. Amgen admits that U.S. Patent No. 7,371,379 (“the ’379 patent”) is titled “Dosages for Treatment with Anti-ErbB2 Antibodies.” Amgen further admits that the face of the ’379 patent reflects (1) an issue date of May 13, 2008 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit H to the Complaint purports to be a copy of the ’379 patent. Amgen denies that the ’379 patent was “duly and legally” issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 56, and on that basis denies them.

The Acidic Variants Patents

57. Amgen admits that U.S. Patent Nos. 6,417,335 and 9,249,218 purport to relate to a method for purifying a polypeptide by ion exchange chromatography. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 57, and on that basis denies them.

58. Amgen admits that U.S. Patent No. 6,417,335 (“the ’335 patent”) is titled “Protein Purification.” Amgen further admits that the face of the ’335 patent indicates (1) an issue date of July 9, 2002 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit I to the Complaint purports to be a copy of the ’335 patent. Amgen denies that the ’335 patent was “duly and legally” issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 58, and on that basis denies them.

59. Amgen admits that U.S. Patent No. 9,249,218 (“the ’218 patent”) is titled “Protein Purification.” Amgen further admits that the face of the ’218 patent indicates (1) an issue date of February 2, 2016 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit J

to the Complaint purports to be a copy of the ’218 patent. Amgen denies that the ’218 patent was “duly and legally” issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 59, and on that basis denies them.

HER2 Diagnostic Patents

60. Amgen admits that U.S. Patent Nos. 7,993,834, 8,076,066, and 8,440,402 purport to relate to techniques for identifying patients who might benefit from ErbB2 antibody therapy using gene amplification. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 60, and on that basis denies them.

61. Amgen admits that U.S. Patent No. 7,993,834 (“the ’834 patent”) is titled “Detection of ErbB2 Gene Amplification to Increase the Likelihood of the Effectiveness of ErbB2 Antibody Breast Cancer Therapy.” Amgen further admits that the face of the ’834 patent indicates (1) an issue date of August 9, 2011 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit K to the Complaint purports to be a copy of the ’834 patent. Amgen denies that the ’834 patent was “duly and legally” issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 61, and on that basis denies them.

62. Amgen admits that U.S. Patent No. 8,076,066 (“the ’066 patent”) is titled “Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy.” Amgen further admits that the face of the ’066 patent indicates (1) an issue date of December 13, 2011 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit L to the Complaint purports to be a copy of the ’066 patent. Amgen denies that the ’066 patent was “duly and legally” issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 62, and on that basis denies them.

63. Amgen admits that U.S. Patent No. 8,440,402 ("the '402 patent") is titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy." Amgen further admits that the face of the '402 patent indicates (1) an issue date of May 14, 2013 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit M to the Complaint purports to be a copy of the '402 patent. Amgen denies that the '402 patent was "duly and legally" issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 63, and on that basis denies them.

Cell Culture, Purification, and Antibody Manufacturing Patents

64. Amgen admits that U.S. Patent Nos. 6,121,428, 6,620,918, 8,512,983, 8,574,869, and 9,714,293 purport to relate to various subject matter including cell culture, purification, and antibody purification. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 64, and on that basis denies them.

65. Amgen admits that U.S. Patent No. 6,121,428 ("the '428 patent") is titled "Protein Recovery." Amgen further admits that the face of the '428 patent indicates (1) an issue date of September 19, 2000 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit N to the Complaint purports to be a copy of the '428 patent. Amgen denies that the '428 patent was "duly and legally" issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 65, and on that basis denies them.

66. Amgen admits that U.S. Patent No. 6,620,918 ("the '918 patent") is titled "Separation of Polypeptide Monomers." Amgen further admits that the face of the '918 patent indicates (1) an issue date of September 16, 2003 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit O to the Complaint purports to be a copy of the '918 patent. Amgen denies that the '918 patent was "duly and legally" issued. Amgen lacks sufficient knowledge or

information to form a belief as to the truth of the remaining allegations of paragraph 66, and on that basis denies them.

67. Amgen admits that U.S. Patent No. 8,512,983 ("the '983 patent") is titled "Production of Proteins in Glutamine-Free Cell Culture Media." Amgen further admits that the face of the '983 patent indicates (1) an issue date of August 20, 2013 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit P to the Complaint purports to be a copy of the '983 patent. Amgen denies that the '983 patent was "duly and legally" issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 67, and on that basis denies them.

68. Amgen admits that U.S. Patent No. 8,574,869 ("the '869 patent") is titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides." Amgen further admits that the face of the '869 patent indicates (1) an issue date of November 5, 2013 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit Q to the Complaint purports to be a copy of the '869 patent. Amgen denies that the '869 patent was "duly and legally" issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 68, and on that basis denies them.

69. Amgen admits that U.S. Patent No. 9,714,293 ("the '293 patent") is titled "Production of Proteins in Glutamine-Free Cell Culture Media." Amgen further admits that the face of the '293 patent indicates (1) an issue date of July 25, 2017 and (2) that the patent was assigned to Genentech. Amgen admits that Exhibit R to the Complaint purports to be a copy of the '293 patent. Amgen denies that the '293 patent was "duly and legally" issued. Amgen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations of paragraph 69, and on that basis denies them.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 6,331,415

70. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

71. Amgen admits that Genentech included the '415 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 71.

72. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 72.

73. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 73.

74. Amgen denies the allegations of paragraph 74.

75. Amgen admits that Genentech included the '415 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 75.

76. Amgen denies the allegations of paragraph 76.

77. Amgen denies the allegations of paragraph 77.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 7,923,221

78. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

79. Amgen admits that Genentech included the '221 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 79.

80. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 80.

81. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 81.

82. Amgen denies the allegations of paragraph 82.

83. Amgen admits that Genentech included the '221 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 83.

84. Amgen denies the allegations of paragraph 84.

85. Amgen denies the allegations of paragraph 85.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 6,407,213

86. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

87. Amgen admits that Genentech included the '213 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 87.

88. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 88.

89. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 89.

90. Amgen denies the allegations of paragraph 90.

91. Amgen admits that Genentech included the '213 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 91.

92. Amgen denies the allegations of paragraph 92.

93. Amgen denies the allegations of paragraph 93.

COUNT IV
INFRINGEMENT OF U.S. PATENT NO. 7,846,441

94. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

95. Amgen admits that Genentech included the '441 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 95.

96. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 96.

97. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 97.

98. Amgen denies the allegations of paragraph 98.

99. Amgen admits that Genentech included the '441 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 99.

100. Amgen denies the allegations of paragraph 100.

101. Amgen denies the allegations of paragraph 101.

102. Amgen denies the allegations of paragraph 102.

103. Amgen denies the allegations of paragraph 103.

104. Amgen denies the allegations of paragraph 104.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 7,892,549

105. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

106. Amgen admits that Genentech included the '549 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 106.

107. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 107.

108. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 108.

109. Amgen denies the allegations of paragraph 109.

110. Amgen admits that Genentech included the '549 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 110.

111. Amgen denies the allegations of paragraph 111.

112. Amgen denies the allegations of paragraph 112.

113. Amgen denies the allegations of paragraph 113.

114. Amgen denies the allegations of paragraph 114.

115. Amgen denies the allegations of paragraph 115.

COUNT VI
INFRINGEMENT OF U.S. PATENT NO. 8,425,908

116. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

117. Amgen admits that Genentech included the ’908 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 117.

118. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 118.

119. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 119.

120. Amgen denies the allegations of paragraph 120.

121. Amgen admits that Genentech included the ’908 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 121.

122. Amgen denies the allegations of paragraph 122.

123. Amgen denies the allegations of paragraph 123.

124. Amgen denies the allegations of paragraph 124.

125. Amgen denies the allegations of paragraph 125.

126. Amgen denies the allegations of paragraph 126.

COUNT VII
INFRINGEMENT OF U.S. PATENT NO. 6,627,196

127. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

128. Amgen admits that Genentech included the’196 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 128.

129. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 129.

130. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 130.

131. Amgen denies the allegations of paragraph 131.

132. Amgen admits that Genentech included the'196 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 132.

133. Amgen denies the allegations of paragraph 133.

134. Amgen denies the allegations of paragraph 134.

135. Amgen denies the allegations of paragraph 135.

136. Amgen denies the allegations of paragraph 136.

137. Amgen denies the allegations of paragraph 137.

COUNT VIII
INFRINGEMENT OF U.S. PATENT NO. 7,371,379

138. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

139. Amgen admits that Genentech included the '379 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 139.

140. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 140.

141. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 141.

142. Amgen denies the allegations of paragraph 142.

143. Amgen admits that Genentech included the ’379 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 143.

144. Amgen denies the allegations of paragraph 144.

145. Amgen denies the allegations of paragraph 145.

146. Amgen denies the allegations of paragraph 146.

147. Amgen denies the allegations of paragraph 147.

148. Amgen denies the allegations of paragraph 148.

COUNT IX
INFRINGEMENT OF U.S. PATENT NO. 6,417,335

149. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

150. Amgen admits that Genentech included the ’335 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 150.

151. Amgen admits that it submitted its BLA to the FDA on [redacted] Amgen denies the remaining allegations of paragraph 151.

152. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 152.

153. Amgen denies the allegations of paragraph 153.

154. Amgen admits that Genentech included the ’335 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 154.

155. Amgen denies the allegations of paragraph 155.

156. Amgen denies the allegations of paragraph 156.

COUNT X
INFRINGEMENT OF U.S. PATENT NO. 9,249,218

157. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

158. Amgen admits that Genentech included the '218 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 158.

159. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 159.

160. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 160.

161. Amgen denies the allegations of paragraph 161.

162. Amgen admits that Genentech included the '218 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 162.

163. Amgen denies the allegations of paragraph 163.

164. Amgen denies the allegations of paragraph 164.

COUNT XI
INFRINGEMENT OF U.S. PATENT NO. 7,993,834

165. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

166. Amgen admits that Genentech included the '834 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 166.

167. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 167.

168. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 168.

169. Amgen denies the allegations of paragraph 169.

170. Amgen admits that Genentech included the '834 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 170.

171. Amgen denies the allegations of paragraph 171.

172. Amgen denies the allegations of paragraph 172.

COUNT XII
INFRINGEMENT OF U.S. PATENT NO. 8,076,066

173. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

174. Amgen admits that Genentech included the '066 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 174.

175. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 175.

176. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 176.

177. Amgen denies the allegations of paragraph 177.

178. Amgen admits that Genentech included the ’066 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 178.

179. Amgen denies the allegations of paragraph 179.

180. Amgen denies the allegations of paragraph 180.

COUNT XIII
INFRINGEMENT OF U.S. PATENT NO. 8,440,402

181. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

182. Amgen admits that Genentech included the ’402 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 182.

183. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 183.

184. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 184.

185. Amgen denies the allegations of paragraph 185.

186. Amgen admits that Genentech included the ’402 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 186.

187. Amgen denies the allegations of paragraph 187.

188. Amgen denies the allegations of paragraph 188.

COUNT XIV
INFRINGEMENT OF U.S. PATENT NO. 6,121,428

189. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

190. Amgen admits that Genentech included the ’428 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 190.

191. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 191.

192. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 192.

193. Amgen admits that Genentech included the ’428 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 193.

COUNT XV
INFRINGEMENT OF U.S. PATENT NO. 6,620,918

194. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

195. Amgen admits that Genentech included the ’918 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 195.

196. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 196.

197. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 197.

198. Amgen denies the allegations of paragraph 198.

199. Amgen admits that Genentech included the ’918 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 199.

200. Amgen denies the allegations of paragraph 200.

201. Amgen denies the allegations of paragraph 201.

COUNT XVI
INFRINGEMENT OF U.S. PATENT NO. 8,512,983

202. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

203. Amgen admits that Genentech included the ’983 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 203.

204. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 204.

205. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 205.

206. Amgen denies the allegations of paragraph 206.

207. Amgen admits that Genentech included the ’983 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 207.

208. Amgen denies the allegations of paragraph 208.

209. Amgen denies the allegations of paragraph 209.

COUNT XVII
INFRINGEMENT OF U.S. PATENT NO. 8,574,869

210. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

211. Amgen admits that Genentech included the ’869 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 211.

212. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 212.

213. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than 180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 213.

214. Amgen denies the allegations of paragraph 214.

215. Amgen admits that Genentech included the ’869 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 215.

216. Amgen denies the allegations of paragraph 216.

217. Amgen denies the allegations of paragraph 217.

COUNT XVIII
INFRINGEMENT OF U.S. PATENT NO. 9,714,293

218. Amgen incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

219. Amgen admits that Genentech included the ’293 patent in its 3A and 3C Statements. Amgen denies the remaining allegations in paragraph 219.

220. Amgen admits that it submitted its BLA to the FDA on [redacted]. Amgen denies the remaining allegations of paragraph 220.

221. Amgen admits that it notified Genentech pursuant to 42 U.S.C. § 262(l)(8)(A) that it intends to commence first commercial marketing of ABP 980 in the United States no earlier than

180 days from [redacted] (i.e., [redacted]). Amgen denies the remaining allegations in paragraph 221.

222. Amgen denies the allegations of paragraph 222.

223. Amgen admits that Genentech included the '293 patent on its 3A and 3C Statements. Amgen denies the remaining allegations of paragraph 223.

224. Amgen denies the allegations of paragraph 224.

225. Amgen denies the allegations of paragraph 225.

ANSWER TO PRAYER FOR RELIEF

Plaintiffs' prayer for relief does not require a response. To the extent a response is required, Amgen denies that Plaintiffs are entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Without admitting or implying that Amgen bears the burden of proof or burden of persuasion as to any of them, Amgen, on information and belief, asserts the following defenses:

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

1. Plaintiffs' Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE
(Invalidity)

2. The patents-in-suit, and each of the claims thereof, are invalid for failure to comply with one or more conditions of patentability set forth in 35 U.S.C. § 1, et. seq., including one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), which are incorporated by reference as if fully set forth herein.

THIRD AFFIRMATIVE DEFENSE

(No Infringement)

3. Amgen has not, does not, and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the patents-in-suit, for at least the reasons set forth in Amgen's detailed statement pursuant to 42 U.S.C. § 262(*l*)(3)(B), which are incorporated by reference as if fully set forth herein.

FOURTH AFFIRMATIVE DEFENSE
(Safe Harbor)

4. Amgen is exempt from liability under the safe harbor of 35 U.S.C. § 271(e)(1), including to the extent Plaintiffs claim that the manufacture and clinical use of ABP 980 is an act of infringement.

FIFTH AFFIRMATIVE DEFENSE
(No Willfulness)

5. Amgen has not willfully infringed any claim of the patents-in-suit.

SIXTH AFFIRMATIVE DEFENSE
(No Recovery of Costs)

6. Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this action.

SEVENTH AFFIRMATIVE DEFENSE
(No Exceptional Case)

7. Amgen's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285 or 35 U.S.C. § 271(e)(4).

EIGHTH AFFIRMATIVE DEFENSE
(No Equitable Relief)

8. Plaintiffs are not entitled to any preliminary or permanent equitable relief.

NINTH AFFIRMATIVE DEFENSE
(Waiver, Estoppel)

9. Plaintiffs' Complaint, and each of its purported causes of action, is barred in whole or in part by the doctrines of waiver and/or estoppel.

TENTH AFFIRMATIVE DEFENSE
(Failure to Mitigate)

10. Plaintiffs have failed to mitigate the harm they claim to have sustained, if any.

ELEVENTH AFFIRMATIVE DEFENSE
(Unclean Hands/ Inequitable Conduct)

11. Plaintiffs' Complaint, and each of its purported causes of action, is barred by Plaintiffs' unclean hands, in view of at least the reasons relating to Genentech's inequitable conduct.

12. During the prosecution of the '213 patent, Genentech made misrepresentations and omissions material to patentability and did so with the specific intent to mislead or deceive the Patent Office.

13. Genentech deliberately misrepresented the teachings of U.S. Patent No. 5,530,101 ("the '101 patent") to the Patent Office in order to overcome a rejection based on that reference. Specifically, Genentech told the Examiner that the '101 patent does not use the Kabat numbering system, despite its repeated references to "numbering according to Kabat" and "the Kabat system."

14. Genentech also made deliberate misrepresentations and omissions regarding Queen 1989, including (i) falsely distinguishing Queen 1989 on the ground that it used "sequential numbering," as opposed to the Kabat numbering system; and (ii) providing information at the request of the Examiner that conspicuously omitted a key residue ("62L") disclosed in the prior art. Deceptive intent by Genentech is the single most reasonable inference to be drawn from the prosecution history and all other available evidence.

15. On November 17, 1993, Genentech filed its patent application with claims requiring substitutions at specific locations, including positions "62L" and "93H." On December 9, 1994,

the Examiner issued a Non-Final Rejection, rejecting the claims as obvious under § 103 over EP 0239400, Queen 1989, Riechmann 1988.

16. On June 12, 1995, Genentech amended the pending claims and deleted references to amino acid position "62L."

17. Following a final rejection and an Examiner interview, the case was transferred to a different Examiner and a new non-final rejection issued on December 23, 1996. The new Examiner maintained all prior rejections and further rejected the pending claims as anticipated by the '101 patent.

18. In response to the non-final rejection, Genentech once again amended the pending claims on June 27, 1997, adding amino acid position "62L" back into the claims.

19. On October 7, 1997, Genentech argued in its remarks to the Patent Office that Queen 1989 and the '101 patent were distinguishable because they "use sequential numbering for the variable domain residues of the antibodies described in these references, whereas the claims of the instant application use Kabat numbering for the framework region residues." Genentech repeated the same argument later in the prosecution of the '213 patent to distinguish Queen 1989 and the '101 patent with specific reference to residue "93H":

> Applicants point out that – as explained earlier in prosecution – the substituted 93 FR residue in the cited references [Queen 1989 and the '101 patent] is not 93H 'utilizing the numbering system set forth in Kabat' (see page 13, line 33 through to line 22 on page 14 of the present application) as required by claims 115-117, 123 and 127 of the present application. In particular, as noted on page 6 of the amendment hand carried to the Office on 10/7/97, residue no. 93 in the heavy chain of the anti-Tac antibody in the cited references, is actually 89H utilizing the numbering system set forth in Kabat. The cited references use a sequential numbering system, rather than the Kabat numbering system claimed herein.

(*See* Applicant Remarks, dated Apr. 26, 2001, at 7.)

20. On December 11, 2001, the Examiner indicated during an interview that the pending claims were allowable.

21. Contrary to Genentech's representations to the Patent Office—namely, that the '101 patent does not use the Kabat numbering system—the '101 patent states: "Residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest (National Institutes of Health, Bethesda, Md.) (1987)." ('101 patent at 9:13–18.) In addition, the '101 patent expressly refers to "numbering according to Kabat, op. cit." with specific reference to position 93 in the heavy chain. (*See id.* at 15:17–37.) Moreover, Table 5 of the '101 patent refers to residue "H93," with explicit reference to numbering "according to the Kabat system," as shown below:

TABLE 5

Residues in the framework sequence showing contacts with residues in the hypervariable regions.

Residue No.[1]	Amino Acid	Contacting CDR residues[2]
Fd79		
L49	Lys	L50Y, L53N, L55E, H99D, H100Y
H93	Leu	H35S, H37V, H100CF
Fd138-80		
L36	His	L34V, L89Q
H27	Tyr	H32H, H34I
H30	Tyr	H32H, H53R
H48	Phe	H63F
H66	Lys	H63F
H67	Ala	H63F

1. The amino acid residues are numbered according to the Kabat system (E. A. Kabat et al., Sequences of Proteins of Immunological Interest, National Institutes of Health, Bethesda, MD (1987)): the first letter (H or L) stands for the heavy chain or light chain. The following number is the residue number. The last letter is the amino acid one letter code.
2. The hypervariable regions are defined according to Kabat: Light chain CDR1: residue 24–34; CDR2: 50–56; CDR3: 89–97. Heavy chain CDR1: 31–35; CDR2: 50–65; CDR3: 95–102.

22. In order to overcome the § 102 rejection based on the '101 patent, Genentech falsely represented to the Patent Office that the '101 patent used sequential numbering, while arguing that the "claims of the instant application use Kabat numbering for the framework region residues." Genentech misrepresented the teachings of the '101 patent, despite clear and repeated references in the '101 patent to the Kabat numbering system. Absent Genentech's false and

misleading distinction, the Examiner had no reason to withdraw the § 102 rejection based on the '101 patent.

23. Genentech also made deliberate and material misrepresentations and omissions regarding Queen 1989 during the prosecution of the '213 patent. Genentech distinguished Queen 1989 on the ground that it used "sequential numbering," as opposed to the Kabat numbering system. At the Examiner's request, Genentech submitted a comparison of the different numbering systems purportedly utilized in Queen 1989 and the pending claims.[1] The alignments provided by Genentech to the Examiner conspicuously omitted the "62L" residue in both numbering systems. As noted above, residue "62L" was recited in then-pending claims of the '213 patent, and Queen 1989 expressly discloses "residues at positions corresponding to . . . 47 and 62 of the light chain (Fig. 2)." (*See* Queen 1989 at 10032.) Importantly, Queen 1989 discloses residues in the Kabat numbering system and, in particular, residue "62 of the light chain."

TWELFTH AFFIRMATIVE DEFENSE
(Failure to Mark)

25. Plaintiffs are barred from recovering damages for any alleged patent infringement because Plaintiffs have made, offered for sale, or sold within the United States a patented article—Herceptin—without giving proper notice to the public that the same is patented. 35 U.S.C. § 287.

THIRTEENTH AFFIRMATIVE DEFENSE
(No Standing)

26. Plaintiffs lack standing to assert one or more patents-in-suit.

OTHER AFFIRMATIVE DEFENSES RESERVED

As Amgen's investigation is ongoing and discovery has not yet been completed, Amgen is

[1] *See* 10/7/97 Applicant Remarks at 6–10 ("As requested by the Examiner in the interview, alignments of heavy chain variable domain (Exhibit A) and light chain variable domain (Exhibit B) sequences of the 101 patent (including the sequences for the murine and humanized anti-Tac antibody of Queen *et al.*) with sequential and Kabat residue numbering is attached.").

without complete information regarding the existence or non-existence of other facts or acts that would constitute a defense to the purported causes of action in Plaintiffs' Complaint. Accordingly, Amgen reserves the right to assert any other defenses that discovery may reveal.

COUNTERCLAIMS

Amgen submits these counterclaims against Plaintiffs Genentech, Inc. and City of Hope:

THE PARTIES

1. Counterclaim-Plaintiff Amgen is a company organized and existing under the laws of the State of Delaware with its corporate headquarters at One Amgen Center Drive, Thousand Oaks, CA 91320.

2. As alleged in Plaintiffs' Complaint, 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, CA 94080.

3. As alleged in Plaintiffs' Complaint, City of Hope is a California not-for-profit organization, with its principal place of business at 1500 East Duarte Road, Duarte, CA 91010.

JURISDICTION AND VENUE

4. Amgen's Counterclaims arise under the patent laws of the United States, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction over Amgen's Counterclaims under 28 U.S.C. §§ 1331 and 1338.

5. Venue in this case is proper in this District because Genentech, Inc. is a Delaware corporation, and by virtue of Plaintiffs' filing of the Complaint in this District, which gave rise to these Counterclaims. Plaintiffs contend in their Complaint that venue is proper in this District.

FACTUAL BACKGROUND

6. Amgen has been a biotechnology pioneer since the 1980s, discovering, developing,

manufacturing, and delivering innovative and important human therapeutic products. Since its inception, Amgen has focused on the development of biologic drugs. Unlike most traditional drugs that are synthesized chemically and have a known structure, biologic drugs are "complex mixtures that are not easily identified or characterized" and represent "the cutting-edge of biomedical research." FDA, What are "Biologics" Questions and Answers (Aug. 5, 2015), http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm. Because of their complexity, biologic drugs require substantially more effort, monetary resources and technical expertise to develop than traditional drugs that are synthesized chemically.

7. Over the last nearly 40 years and still today, Amgen's unparalleled experience and expertise in biologics research, development and manufacture has enabled it to develop biologic drugs to treat serious illnesses where there has previously been unmet medical needs and limited treatment options. These medicines have dramatically changed the treatment of disease and the lives of patients with these life-altering and life-threatening diseases. Since its inception, Amgen has developed a number of biologic medicines that have changed the standard of care, two of which have been named Product of the Year by Fortune Magazine and many of which have received scientific and industry awards in recognition of Amgen's innovation. Over the last twenty years alone, Amgen received FDA approval of at least thirteen drugs that have addressed serious illnesses of patients.

8. In 2011, Amgen announced that it would develop and commercialize several oncology antibody biosimilar drugs, including biosimilar versions of Genentech's Avastin®, Herceptin, and Rituxan®. In the announcement, Amgen recognized that "the development and commercialization of biosimilar products will not follow a pure brand or generic model, and will require significant expertise, infrastructure, and investment to ensure safe, reliably supplied

therapies for patients." Amgen and Watson Announce Collaboration to Develop and Commercialize Oncology Biosimilars, Media Release (Dec. 19, 2011), http://www.amgenbiosimilars.com/media/media-releases/2011/12/amgen-and-watson-announce-collaboration-to-develop-and-commercialize-oncology-biosimilars/.

9. Since its original announcement regarding biosimilars, Amgen has devoted significant time, effort, and substantial monetary resources to the development of ABP 980. With its deep experience in biologics development and manufacture, Amgen developed materials that have been and will be used to make ABP 980, including its proprietary cell line and cell culture used to produce the antibody that is the active ingredient of ABP 980 ("ABP 980 antibody"). Amgen also designed the manufacturing process and process controls that have been and will be used to make ABP 980, including, among other things, developing the cell culture, harvest, and numerous purification steps to manufacture and purify the ABP 980 antibody. Amgen also conducted numerous clinical studies in which it successfully tested ABP 980 in humans. In the end, Amgen generated comprehensive analytical, pharmacokinetic, pharmacodynamic and clinical data that was submitted to the FDA as part of the FDA-approval process.

Congress Enacts Legislation Creating a Regulatory Pathway for Biosimilar Biological Products

10. By amending the Public Health Service Act, the Patent Act, and the Declaratory Judgment Act, and through the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA"), Congress created a new pathway for FDA review and approval of "biosimilar" biological products, as well as new mechanisms to resolve patent disputes that may arise with respect to such products.

11. "The BPCIA governs a type of drug called a biosimilar, which is a biologic product that is highly similar to a biologic product that has already been approved by the Food and Drug

Administration (FDA)." *Sandoz Inc. v. Amgen Inc.*, 137 S. Ct. 1664, 1669 (2017).

12. The BPCIA sets forth an abbreviated pathway for FDA approval of biosimilars. 42 U.S.C. § 262(k). To obtain approval through the BPCIA's abbreviated process, an applicant must show that its biosimilar product is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the two products in terms of "safety, purity, and potency." 42 U.S.C. § 262(k)(2). Under the BPCIA, an applicant may not submit an application until 4 years after the reference product is first licensed, and the FDA may not license a biosimilar until 12 years after the reference product is first licensed. 42 U.S.C. § 262(k)(7).

13. The reference product sponsor may have patents relating to the biological product, as well as therapeutic uses for and/or processes used to manufacture the biological product that it believes may be relevant to the biosimilar product. In recognition that there may be patent disputes between the reference product sponsor and the biosimilar applicant, "[t]he BPCIA sets forth a carefully calibrated scheme for preparing to adjudicate, and then adjudicating, claims of [patent] infringement." *Sandoz*, 137 S. Ct. at 1671 (citing 42 U.S.C. § 262(l)).

14. The BPCIA describes a process whereby the reference product sponsor and the biosimilar applicant exchange information in advance of a specific and statutorily prescribed action for patent infringement. First, the process begins when the applicant provides "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." 42 U.S.C. § 262(l)(2)(A). In addition, the applicant "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)(B). Second, the BPCIA states that the reference product sponsor shall provide "a list of patents for which the reference product sponsor believes a claim of

patent infringement could reasonably be asserted by the reference product sponsor . . . if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(l)(3)(A). Third, the BPCIA requires the applicant to provide a "detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application." 42 U.S.C. § 262(l)(3)(B)(ii)(I). Alternatively, the applicant can provide "a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires." 42 U.S.C. § 262(l)(3)(B)(ii)(II). Last, the BPCIA states that the reference product sponsor "shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I)." 42 U.S.C. § 262(l)(3)(C).

15. Following the information exchange, the BPCIA requires the reference product sponsor and the applicant to engage in "good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6) [of the statute]." 42 U.S.C. § 262(l)(4). If agreement cannot be reached, the statute provides for a mechanism of further exchanges to determine which patent(s) will be the subject of a paragraph (6) patent litigation. 42

U.S.C. § 262(l)(4)(B)-(5). While the procedure and timing depend on whether the reference product sponsor and the applicant can reach agreement, the process may result in a statutorily defined action for patent infringement. 42 U.S.C. § 262(l)(6).

16. Paragraph (l)(8) of the BPCIA states 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). Once the applicant's notice of commercial marketing is received by the reference product sponsor, any limitation under the BPCIA on bringing an action under section 2201 of title 28 for a declaration of rights concerning patent infringement, validity and/or enforceability is lifted. 42 U.S.C. § 262(l)(9).

The Parties' Exchanges Following the Filing of Amgen's Subsection (k) Application for Approval of Its Biosimilar Product

17. On [redacted], Amgen submitted its Biologics License Application ("BLA") for ABP 980 under 42 U.S.C. § 262(k). Amgen's BLA was submitted after the expiration of the 4-year and 12-year statutory periods provided by 42 U.S.C. § 262(k)(7). Amgen received notification from the FDA that its BLA had been accepted for review on [redacted].

18. On October 16, 2017, Amgen timely sent to Genentech its disclosure under 42 U.S.C. § 262(*l*)(2)(A). Amgen's § 262(*l*)(2)(A) disclosure contained, among other things, extensive information regarding the manufacturing processes used to make ABP 980. In fact, Amgen provided Genentech the complete BLA that contains extensive technical details and batch records describing, among other things, (i) the source, history, and generation of the cell substrate, (ii) the cell culture and harvest process, (iii) each and every purification process step, and (iv) the raw materials used during the manufacture of ABP 980. Amgen's production contained sufficiently detailed information regarding its biosimilar product and manufacturing processes,

which complied with 42 U.S.C. § 262(*l*)(2)(A)-(B) and enabled Genentech to undertake its obligations under 42 U.S.C. § 262(*l*)(3)(A). In addition to the complete BLA, Amgen also provided on [redacted] that included further information describing [redacted].

19. Thereafter, Genentech wrote a letter to Amgen alleging that Amgen's § 262(*l*)(2)(A) disclosures were insufficient because they did not "fully describe the ABP 980 manufacturing processes." In this letter, dated November 20, 2017, Genentech listed several overly broad and vaguely defined categories of information for which it requested production of additional documents or identification of where the information could be found in the documents Amgen had produced.

20. In reply, on December 1, 2017, Amgen timely sent a letter to Genentech communicating Amgen's good-faith belief that its disclosures, including its complete BLA, contained sufficiently detailed information regarding its biosimilar product and manufacturing processes, which satisfied Amgen's production obligations under 42 U.S.C. § 262(*l*)(2)(A). Nonetheless, Amgen communicated its willingness to cooperate with Genentech to identify the information sought in Amgen's BLA, and to provide additional information within a reasonable time. Amgen then identified sections in its BLA that contained detailed information relevant to Genentech's specific requests. In addition, on [redacted] and [redacted], Amgen provided supplemental disclosures that included [redacted], as well as two detailed internal manufacturing documents.

21. On December 15, 2017, Genentech provided Amgen with its list of patents purporting to comply with 42 U.S.C. § 262(*l*)(3)(A) ("the (3)(A) list") that Genentech "believe[d] could be asserted against Amgen's proposed ABP 980 product based upon a review of the

product's aBLA filing." Thereafter, on February 6, 2018, Genentech sent a letter to Amgen supplementing its (3)(A) list with a newly issued patent, U.S. Patent No. 9,868,760 (the "'760 patent"). Together with this supplement, Genentech's (3)(A) list included a total of 37 patents. Despite providing this list and without identifying any particular deficiency, Genentech maintained that Amgen had not complied with its disclosure obligations under § 262(*l*)(2)(A).

22. Amgen continued to provide supplemental disclosures [redacted]. Specifically, supplemental disclosures were sent to Genentech on [redacted]

23. Amgen responded to Genentech's (3)(A) list by providing Genentech a statement under 42 U.S.C. § 262(*l*)(3)(B)(ii)(I) that describes on a claim-by-claim basis the factual and legal bases for Amgen's opinion that the patents on Genentech's (3)(A) list are not infringed and/or are invalid or unenforceable (Amgen's "(3)(B) statement"). Amgen annotated its non-infringement positions with detailed citations to its BLA. Amgen timely provided its detailed statement to Genentech on February 13, 2018. Amgen timely provided its detailed statement regarding the '760 patent on March 8, 2018.

24. On April 13, 2018, Amgen received Genentech's alleged statement pursuant to § 262(*l*)(3)(C) (Genentech's "(3)(C) statement"). Even though the BPCIA required Genentech to provide, among other things, "on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that [each] patent [identified in Amgen's (3)(B) statement] will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application," Genentech did not address all of the patents identified in Amgen's (3)(B) statement. Specifically, Genentech did not provide any response to Amgen's detailed

statement for 19 of the 37 patents, including the following patents: 6,242,177, 6,489,447, 6,586,206, 6,870,034, 7,449,194, 7,501,122, 8,044,017, 8,314,225, 8,357,301, 8,460,895, 8,691,232, 8,710,196, 8,771,988, 9,047,438, 9,080,183, 9,428,766, 9,487,809, 9,493,744, and 9,868,760. In addition, for the 18 patents for which Genentech purported to provide a response to Amgen's (3)(B) statement, Genentech provided no factual or legal basis to support a claim of infringement for 11 patents, and 2 claims of a twelfth patent, on its (3)(A) list, relying instead on its own unsupported assertion that Amgen violated § 262(*l*)(2)(A) to "justify" its position that Amgen's commercial marketing of ABP 980 under the trade name KANJINTI™ would somehow infringe Genentech's patents. In addition, Genentech proposed moving forward with the first-phase infringement action under 42 U.S.C. § 262(*l*)(6) on the 18 patents for which they did purport to provide a written response to Amgen's (3)(B) statement.

25. Amgen and Genentech participated in negotiations under 42 U.S.C. § 262(*l*)(4) on May 15, 2018, regarding which patents on Genentech's (3)(A) list should be the subject of an action for patent infringement under 42 U.S.C. § 262(*l*)(6). After these initial discussions, and several other exchanges, the parties agreed to proceed with litigation under 42 U.S.C. § 262(*l*)(6) on all patents identified in Genentech's (3)(A) list, and to work in good faith to stipulate to dismissal of the 19 patents for which Genentech did not provide a response to Amgen's (3)(B) statement.

26. In addition, on [redacted], Amgen wrote to Genentech providing notice under 42 U.S.C. § 262(*l*)(8)(A) that "first commercial marketing of the biological product licensed under Amgen's 42 U.S.C. § 262(k) Biologics License Application [redacted] will commence no earlier than 180 from the date of the notice."

27. On June 21, 2018, Genentech filed a lawsuit against Amgen in the District of

Delaware alleging infringement of all of the patents identified on Genentech's (3)(A) list. Genentech served Amgen with the complaint on June 29, 2018.

28. On July 19, 2018 Plaintiffs and Amgen stipulated to dismiss with prejudice all claims for infringement of U.S. Patent Nos. 6,242,177, 6,489,447, 6,586,206, 6,870,034, 7,449,184, 7,501,122, 8,044,017, 8,314,225, 8,357,301, 8,460,895, 8,691,232, 8,710,196, 8,771,988, 9,047,438, 9,080,183, 9,428,766, 9,487,809, 9,493,744, and 9,868,760 relating to ABP 980.

29. On July 19, 2018, Genentech filed a First Amended Complaint alleging infringement of all of the eighteen patents identified on Genentech's (3)(C) list.

THE PATENTS-IN-SUIT

30. U.S. Patent No. 6,331,415, titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," issued on December 18, 2001. Genentech alleges that Genentech and City of Hope co-own the '415 patent. The earliest possible priority date for the '415 patent is April 8, 1983. Upon information and belief, the '415 patent expires on December 18, 2018.

31. U.S. Patent No. 7,923,221, titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," issued on April 12, 2011. Genentech alleges that Genentech and City of Hope co-own the '221 patent. The earliest possible priority date of the '221 patent is April 8, 1983. Upon information and belief, the '221 patent expires on December 18, 2018.

32. U.S. Patent No. 6,407,213, titled "Method for Making Humanized Antibodies," issued on June 18, 2002. Genentech alleges that it owns the '213 patent. The earliest possible priority date for the '213 patent is June 14, 1991. Upon information and belief, the '213 patent expires on June 18, 2019.

33. U.S. Patent No. 7,846,441, titled "Treatment with Anti-ErbB2 Antibodies," issued on December 7, 2010. Genentech alleges that it owns the '441 patent. The earliest possible priority date for the '441 patent is December 12, 1997. Upon information and belief, the '441 patent expires on May 6, 2021.

34. U.S. Patent No. 7,892,549, titled "Treatment with Anti-ErbB2 Antibodies," issued on February 22, 2011. Genentech alleges that it owns the '549 patent. On its face, the '549 patent references a priority date of December 12, 1997, but the earliest possible priority date for the '549 patent is February 3, 2003. Upon information and belief, the '549 patent expires on May 6, 2021.

35. U.S. Patent No. 8,425,908, titled "Treatment with Anti-ErbB2 Antibodies" issued on April 23, 2013. Genentech alleges that it owns the '908 patent. The earliest possible priority date for the '908 patent is December 12, 1997. Upon information and belief, the '908 patent expires on December 10, 2018.

36. U.S. Patent No. 6,627,196, titled "Dosages for Treatment with Anti-ErbB2 Antibodies," issued on September 30, 2003. Genentech alleges that it owns the Baughman '196 patent. The earliest possible priority date for the Baughman '196 patent is August 27, 1999. Upon information and belief, the Baughman '196 patent expires on August 25, 2020.

37. U.S. Patent No. 7,371,379, titled "Dosages for Treatment with Anti-ErbB2 Antibodies," issued on May 13, 2008. Genentech alleges that it owns the '379 patent. The earliest possible priority date for the '379 patent is August 27, 1999. Upon information and belief, the '379 patent expires on February 16, 2022.

38. U.S. Patent No. 6,417,335, titled "Protein Purification," issued on July 9, 2002. Genentech alleges that it owns the '335 patent. The earliest possible priority date for the '335 patent is May 6, 1998. Upon information and belief, the '335 patent expires on May 3, 2019.

39. U.S. Patent No. 9,249,218, titled "Protein Purification," issued on February 2, 2016. Genentech alleges that it owns the '218 patent. The earliest possible priority date for the '218 patent is May 6, 1998. Upon information and belief, the '218 patent expires on May 3, 2019.

40. U.S. Patent No. 7,993,834, titled "Detection of ErbB2 Gene Amplification to Increase the Likelihood of the Effectiveness of ErbB2 Antibody Breast Cancer Therapy," issued on August 9, 2011. Genentech alleges that it owns the '834 patent. The earliest possible priority date for the '834 patent is May 19, 2000. Upon information and belief, the '834 patent expires on February 18, 2022.

41. U.S. Patent No. 8,076,066, titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," issued on December 13, 2011. Genentech alleges that it owns the '066 patent. The earliest possible priority date for the '066 patent is May 19, 2000. Upon information and belief, the '066 patent expires on May 18, 2021.

42. U.S. Patent No. 8,440,402, titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," issued on May 14, 2013. Genentech alleges that it owns the '402 patent. The earliest possible priority date for the '402 patent is May 19, 2000. Upon information and belief, the '402 patent expires on May 18, 2021.

43. U.S. Patent No. 6,121,428, titled "Protein Recovery," issued on September 19, 2000. Genentech alleges that it owns the '428 patent. The earliest possible priority date for the '428 patent is June 13, 1997. Upon information and belief, the '428 patent expired on June 12, 2018.

44. U.S. Patent No. 6,620,918, titled "Separation of Polypeptide Monomers," issued on

September 16, 2003. Genentech alleges that it owns the ’918 patent. The earliest possible priority date for the ’918 patent is June 1, 1998. Upon information and belief, the ’918 patent expires on May 26, 2019.

45. U.S. Patent No. 8,512,983, titled “Production of Proteins in Glutamine-Free Cell Culture Media,” issued on August 20, 2013. Genentech alleges that it owns the ’983 patent. The earliest possible priority date for the ’983 patent is August 11, 2009. Upon information and belief, the ’983 patent expires on January 4, 2031.

46. U.S. Patent No. 8,574,869, titled “Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides,” issued on November 5, 2013. Genentech alleges that it owns the ’869 patent. The earliest possible priority date for the ’869 patent is July 9, 2007. Upon information and belief, the ’869 patent expires on July 8, 2028.

47. U.S. Patent No. 9,714,293, titled “Production of Proteins in Glutamine-Free Cell Culture Media,” issued on July 25, 2017. Genentech alleges that it owns the ’293 patent. The earliest possible priority date for the ’293 patent is August 11, 2009. Upon information and belief, the ’293 patent expires on January 4, 2031.

Count 1
Non-Infringement and Invalidity of U.S. Patent No. 6,331,415

48. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

49. Plaintiffs have alleged that Genentech and City of Hope co-own U.S. Patent No. 6,331,415 (“the ’415 patent”).

50. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the ’415 patent, as set forth in Plaintiffs’ disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

51. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the ’415 patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

52. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’415 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

53. The claims of the ’415 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons and/or based on the references set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

54. Amgen is entitled to a judgment that the claims of the ’415 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons and/or based on the references set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 2
Non-Infringement and Invalidity of U.S. Patent No. 7,923,221

55. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

56. Plaintiffs have alleged that Genentech and City of Hope are co-owners of U.S. Patent No. 7,923,221 (“the ’221 patent”).

57. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the ’221 patent, as set forth in Plaintiffs’ disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

58. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the ’221 patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

59. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’221 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

60. The claims of the ’221 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons and/or based on the references set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

61. Amgen is entitled to a judgment that the claims of the ’221 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons and/or based on the references set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 3
Non-Infringement and Invalidity of U.S. Patent No. 6,407,213

62. Amgen restates and incorporates by reference the allegations in the preceding

paragraphs as if fully set forth herein.

63. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 6,407,213 ("the '213 patent").

64. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '213 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

65. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '213 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

66. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '213 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

67. The claims of the '213 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

68. Amgen is entitled to a judgment that the claims of the '213 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 4
Non-Infringement and Invalidity of U.S. Patent No. 7,846,441

69. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

70. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 7,846,441 ("the '441 patent").

71. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '441 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

72. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '441 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

73. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '441 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

74. The claims of the '441 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

75. Amgen is entitled to a judgment that the claims of the '441 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C.

§ 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 5
Non-Infringement and Invalidity of U.S. Patent No. 7,892,549

76. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

77. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 7,892,549 ("the '549 patent").

78. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '549 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

79. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '549 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

80. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '549 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

81. The claims of the '549 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

82. Amgen is entitled to a judgment that the claims of the '549 patent are invalid and/or

unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 6
Non-Infringement and Invalidity of U.S. Patent No. 8,425,908

83. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

84. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 8,425,908 ("the '908 patent").

85. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '908 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

86. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '908 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

87. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '908 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

88. The claims of the '908 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least

the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

89. Amgen is entitled to a judgment that the claims of the '908 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 7
Non-Infringement and Invalidity of U.S. Patent No. 6,627,196

90. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

91. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 6,627,196 ("the'196 patent").

92. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the'196 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

93. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the'196 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

94. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the'196 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

95. The claims of the'196 patent are invalid for failure to comply with one or more

conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

96. Amgen is entitled to a judgment that the claims of the'196 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 8
Non-Infringement and Invalidity of U.S. Patent No. 7,371,379

97. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

98. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 7,371,379 ("the '379 patent").

99. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '379 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

100. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '379 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

101. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '379 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of

information under a federal law that regulates the manufacture, use, or sale of drugs.

102. The claims of the ’379 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

103. Amgen is entitled to a judgment that the claims of the ’379 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 9
Non-Infringement and Invalidity of U.S. Patent No. 6,417,335

104. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

105. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 6,417,335 (“the ’335 patent”).

106. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the ’335 patent, as set forth in Plaintiffs’ disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

107. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the ’335 patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

108. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’335 patent because particular activities

related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

109. The claims of the ’335 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

110. Amgen is entitled to a judgment that the claims of the ’335 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 10
Non-Infringement and Invalidity of U.S. Patent No. 9,249,218

111. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

112. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 9,249,218 (“the ’218 patent”).

113. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the ’218 patent, as set forth in Plaintiffs’ disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

114. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the ’218 patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

115. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’218 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

116. The claims of the ’218 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

117. Amgen is entitled to a judgment that the claims of the ’218 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 11
Non-Infringement and Invalidity of U.S. Patent No. 7,993,834

118. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

119. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 7,993,834 (“the ’834 patent”).

120. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the ’834 patent, as set forth in Plaintiffs’ disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

121. Amgen has not directly or indirectly infringed, and will not directly or indirectly

infringe, any valid and enforceable claim of the ’834 patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

122. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’834 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

123. The claims of the ’834 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

124. Amgen is entitled to a judgment that the claims of the ’834 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 12
Non-Infringement and Invalidity of U.S. Patent No. 8,076,066

125. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

126. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 8,076,066 (“the ’066 patent”).

127. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the ’066 patent, as set forth in Plaintiffs’

disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

128. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the ’066 patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

129. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the ’066 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

130. The claims of the ’066 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

131.

132. Amgen is entitled to a judgment that the claims of the ’066 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 13
Non-Infringement and Invalidity of U.S. Patent No. 8,440,402

133. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

134. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in

U.S. Patent No. 8,440,402 ("the '402 patent").

135. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '402 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

136. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '402 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

137. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '402 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

138. The claims of the '402 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

139.

140. Amgen is entitled to a judgment that the claims of the '402 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 14

Non-Infringement and Invalidity of U.S. Patent No. 6,121,428

141. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

142. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 6,121,428 ("the '428 patent").

143. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '428 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

144. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '428 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

145. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '428 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

146. The claims of the '428 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons and/or based on the references set forth herein and in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

147. Amgen is entitled to a judgment that the claims of the '428 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons and/or based on the references set forth herein and in Amgen's

disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 15

Non-Infringement and Invalidity of U.S. Patent No. 6,620,918

148. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

149. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 6,620,918 ("the '918 patent").

150. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '918 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

151. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '918 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

152. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '918 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

153. The claims of the '918 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

154. Amgen is entitled to a judgment that the claims of the '918 patent are invalid and/or

unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 16

Non-Infringement and Invalidity of U.S. Patent No. 8,512,983

155. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

156. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 8,512,983 ("the '983 patent").

157. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '983 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

158. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '983 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

159. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '983 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

160. The claims of the '983 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least

the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

161. Amgen is entitled to a judgment that the claims of the '983 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 17
Non-Infringement and Invalidity of U.S. Patent No. 8,574,869

162. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

163. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 8,574,869 ("the '869 patent").

164. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '869 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

165. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '869 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

166. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '869 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of information under a federal law that regulates the manufacture, use, or sale of drugs.

167. The claims of the '869 patent are invalid for failure to comply with one or more

conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

168. Amgen is entitled to a judgment that the claims of the '869 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

Count 18
Non-Infringement and Invalidity of U.S. Patent No. 9,714,293

169. Amgen restates and incorporates by reference the allegations in the preceding paragraphs as if fully set forth herein.

170. Plaintiffs have alleged that Genentech is the owner of all right, title, and interest in U.S. Patent No. 9,714,293 ("the '293 patent").

171. A case or controversy exists because Plaintiffs have alleged that Amgen has infringed and will infringe one or more claims of the '293 patent, as set forth in Plaintiffs' disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(C).

172. Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any valid and enforceable claim of the '293 patent, for at least the reasons set forth in Amgen's disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

173. Under 35 U.S.C. § 271(e)(1), Amgen has not directly or indirectly infringed, and will not directly or indirectly infringe, any claim of the '293 patent because particular activities related to ABP 980, such as the manufacture or testing of ABP 980 related to submission of the BLA, were and will be solely for uses reasonably related to the development and submission of

information under a federal law that regulates the manufacture, use, or sale of drugs.

174. The claims of the ’293 patent are invalid for failure to comply with one or more conditions of patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation and/or unenforceability, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B).

175. Amgen is entitled to a judgment that the claims of the ’293 patent are invalid and/or unenforceable, and that Amgen has not and will not infringe any valid and enforceable claim of that patent, for at least the reasons set forth in Amgen’s disclosure pursuant to 42 U.S.C. § 262(*l*)(3)(B). Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

PRAYER FOR RELIEF

WHEREFORE, Amgen respectfully requests that the Court enter judgment:

A. adjudging and decreeing that Plaintiffs be denied all forms of relief requested in their Complaint;

B. dismissing the Complaint in its entirety with prejudice;

C. declaring that the claims of the patents-in-suit have not been and will not be infringed by Amgen;

D. declaring that the claims of the patents-in-suit are invalid;

E. declaring that the claims of the patents-in-suit are unenforceable;

F. finding that this is an exceptional case under 35 U.S.C. § 285;

G. awarding attorneys’ fees, costs, and expenses to Amgen; and

H. granting such other and further relief as this Court deems just and proper.

Dated: August 2, 2018

SMITH, KATZENSTEIN & JENKINS, LLP

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CERTIFICATE OF SERVICE

I certify that on August 2, 2018, a copy of Amgen Inc.'s Answer, Affirmative Defenses, and Counterclaims were caused to be served by email on the following counsel:

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