IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs and Counterclaim Defendants, v. PFIZER INC. Defendant and Counterclaim Plaintiff.	)	C.A. No. 17-1672-GMS

DEFENDANT PFIZER INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFFS' FIRST AMENDED COMPLAINT

Defendant and Counterclaim-Plaintiff Pfizer Inc. ("Pfizer"), by and through its attorneys, hereby submits this Answer, Affirmative Defenses, and Counterclaims to the First Amended Complaint filed by Plaintiffs Genentech, Inc. and City of Hope (collectively, "Genentech" or "Plaintiffs") on March 28, 2018 (the "First Amended Complaint"). (D.I. 23.)

ANSWER TO FIRST AMENDED COMPLAINT

Each of the paragraphs below corresponds to the same-numbered paragraphs (each a "Paragraph") in the First Amended Complaint. Pfizer denies all allegations in the First Amended Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Moreover, to the extent that any of Plaintiffs' allegations are vague and/or ambiguous, Pfizer denies said allegations. Pfizer denies that Genentech is entitled to the relief requested or any other relief. Pfizer responds to the First Amended Complaint as follows:

NATURE OF THE CASE

1. Admitted in part; denied in part. Pfizer admits that breast cancer is a disease affecting women in the United States. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 1 and, therefore, denies the same.

2. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2 and, therefore, denies the same.

3. Admitted in part; denied in part. Pfizer admits that Herceptin® contains trastuzumab, which is an antibody. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3 and, therefore, denies the same.

4. Pfizer admits that the sources cited in Paragraph 4 include the quoted language. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the other allegations of Paragraph 4 and, therefore, denies the same.

5. Pfizer admits that Herceptin® was approved by the FDA in 1998. Pfizer lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of Paragraph 5 and, therefore, denies the same.

6. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 6 and, therefore, denies the same.

7. Pfizer admits that it is seeking FDA approval of a biosimilar version of Herceptin® called PF-05280014. Pfizer admits that it is relying in part on data concerning Genentech's U.S.-licensed Herceptin® product. Also, Pfizer admits to proposing a draft label for PF-05280014 consistent with that of Genentech's U.S.-licensed Herceptin® product, including all

indications for which U.S.-licensed Herceptin® is currently approved. Pfizer otherwise denies the allegations of Paragraph 7.

8. Pfizer admits that in 2010, Congress passed the Biologics Price Competition and Innovation Act ("BPCIA"). Pfizer admits that pursuant to the BPCIA, biosimilar applicants and reference product sponsors exchange the biosimilar application submitted to the FDA for approval, and a list and description of patents that the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor. *See* 42 U.S.C. §262(*1*). Also, Pfizer admits that on November 17, 2017, consistent with the BPCIA and pursuant to 42 U.S.C. §262(*1*)(8)(A), Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. The remaining allegations of Paragraph 8 contain conclusions of law for which no response is required. To the extent an answer is required, Pfizer denies the remaining allegations of Paragraph 8.

9. Admitted in part; denied in part. Pfizer admits only that Plaintiffs brought this action for infringement pursuant to 35 U.S.C. § 271(e)(2). Pfizer admits only that Plaintiffs seek a declaratory judgment pursuant to 42 U.S.C. § 262(*l*)(9) and 28 U.S.C. § 2201 that the manufacture, use, offer to sell, sale, or importation into the United States of the Pfizer aBLA product would infringe the 20 patents in dispute in this case, to which they are not entitled. Pfizer also admits only that Plaintiffs seek a preliminary and/or permanent injunction pursuant to 42 U.S.C. § 262(*l*)(8)(B) barring Pfizer's manufacture, use, offer to sell, sale, or importation of its biosimilar product prior to the expiration of those patents, to which they are not entitled. Pfizer lacks sufficient knowledge or information to form a belief as to the truth of the last

sentence of paragraph 9 concerning Plaintiffs' future plans based on an event that has not occurred, and therefore denies the same.

THE PARTIES

10. On information and belief, admitted.

11. On information and belief, Pfizer admits that Genentech was founded in 1976. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 11 and, therefore, denies the same.

12. On information and belief, admitted.

13. On information and belief, Pfizer admits that City of Hope was founded in 1913. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 13 and, therefore, denies the same.

14. Admitted.

15. Pfizer admits that it is seeking licensure in the United States pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the drug product ("Pfizer Product") described in Pfizer's BLA No. 761081 ("Pfizer's BLA"), which is a biological drug. Pfizer admits that the BLA Product will be distributed in the United States, including the State of Delaware, but not before the date provided to Genentech in Pfizer's statement pursuant to 42 U.S.C. § 262(*l*)(3)(B). Pfizer otherwise denies the allegations of Paragraph 15.

JURISDICTION AND VENUE

16. Pfizer admits that the First Amended Complaint purports to bring an action under the BPCIA, 42 U.S.C. § 262(*l*) and the Patent Laws of the United States, Title 35, United State Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. Pfizer denies that Genentech

is entitled to any relief in this action. The remaining allegations of Paragraph 16 contain conclusions of law for which no response is required. To the extent an answer is required, Pfizer denies the remaining allegations of Paragraph 16.

17. Pfizer does not contest venue for purposes of this action only. Pfizer admits that Pfizer is incorporated in Delaware. The remaining allegations of Paragraph 17 contain conclusions of law for which no response is required. To the extent an answer is required, Pfizer denies the remaining allegations of Paragraph 17.

18. Pfizer admits that it is a corporation incorporated in Delaware. Pfizer admits that it has filed Biologics License Application No. 761081 with the FDA seeking approval to market the Pfizer product described therein. Pfizer does not contest personal jurisdiction for purposes of this action only. The remaining allegations of Paragraph 18 contain conclusions of law for which no response is required. To the extent an answer is required, Pfizer denies the remaining allegations of Paragraph 18.

THE PARTIES' EXCHANGES UNDER THE BPCIA

19. Pfizer admits that it submitted BLA No. 761081 to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the product described therein, a biosimilar version of Herceptin® called PF-05280014. Upon information and belief, Pfizer admits that trastuzumab is subject to BLA No. 103792 to Genentech.

20. Admitted.

21. Admitted.

22. Pfizer admits that on September 5, 2017, Pfizer provided Genentech with a complete copy of Pfizer's BLA, in compliance with § 262(*l*)(2)(A). Indeed, Pfizer's BLA contains over two-hundred and fifty thousand pages of information on Pfizer's Product and the

processes to manufacture it. The produced information completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA. Pfizer otherwise denies the allegations of Paragraph 22.

23. Pfizer admits that it received a letter from Genentech dated October 19, 2017, alleging that "the documents that Pfizer has produced so far do not appear to fully describe the PF-05280014 manufacturing processes." Pfizer admits that Genentech identified several categories of information for which it requested production of the information or identification of where the information may be found in Pfizer's BLA. Pfizer admits that it responded to Genentech in a letter dated November 1, 2017, which identified for each of Genentech's categories the sections of Pfizer's BLA that contain related information. Although the production of Pfizer's BLA satisfied 42 U.S.C. § 262(*l*)(2), Pfizer admits that it produced some additional documents in response to some of Genentech's categories in the spirit of cooperation. Pfizer admits that Genentech responded on November 3, 2017 with allegations that Pfizer's November 1, 2017 production was deficient in contravention of 42 U.S.C. § 262(*l*)(2). Pfizer otherwise denies the allegations of Paragraph 23.

24. The documents that Pfizer produced to Genentech demonstrate that Genentech had no reasonable basis to assert certain patents that it listed purportedly pursuant to 42 U.S.C. § 262(*l*)(3)(A). Pfizer admits that Genentech requested additional information purportedly pursuant to 42 U.S.C. § 262(*l*)(2)(A). Pfizer otherwise denies the allegations of Paragraph 24.

25. Pfizer admits that Genentech provided a list of patents purportedly pursuant to 42 U.S.C. 262(*l*)(3)(A) on November 3, 2017 ("Genentech's 3A List"). Pfizer otherwise denies the allegations of Paragraph 25.

26. Pfizer admits that on November 17, 2017, it notified Genentech pursuant to 42 U.S.C. § 262(*l*)(8)(A) that it intends to commence commercial marketing of PF-05280014 in the United States as early as 180 days from the date of the notice. Pfizer also admits that Genentech filed the original complaint in this action on November 17, 2017. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

27. Pfizer admits that on January 2, 2018, pursuant to and in compliance with 42 U.S.C. § 262(*l*)(3)(B), Pfizer provided its detailed statement, spanning over six hundred pages, that describes on a claim by claim basis, the factual and legal basis for its opinion that each of the patents listed by Genentech is invalid, unenforceable, and/or will not be infringed by the biological product that is the subject of Pfizer's BLA ("Pfizer's 3B Statement"). Pfizer otherwise denies the allegations of Paragraph 27.

28. Pfizer admits that on March 2, 2018, Genentech purported to provide its response to Pfizer's 3B Statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) ("Genentech's 3C Statement"). Pfizer also admits Genentech purported to include responses to Pfizer's non-infringement and invalidity statements for 18 of the 38 patents addressed in Pfizer's 3B Statement. Pfizer admits that Genentech proposed agreeing that all patents in Genentech's 3C Statement and two patents included on Genentech's 3A List be included in this infringement action. Pfizer otherwise denies the allegations of Paragraph 28.

PFIZER'S aBLA PRODUCT

29. Pfizer admits that the sources cited in Paragraph 29 include the quoted language. The remaining allegations of Paragraph 29 contain conclusions of law for which no response is required.

30. Admitted in part; denied in part. Pfizer admits that a justiciable case or controversy exists between the parties, but denies that any act of infringement has occurred.

GENENTECH'S ASSERTED PATENTS

31. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 31 and, therefore, denies the same.

32. Admitted in part; denied in part. Pfizer admits that Genentech has asserted that Pfizer's BLA product will infringe the patents cited in Paragraph 32. Pfizer denies the remaining allegations of Paragraph 32.

The Cabilly Patents

33. Pfizer admits that U.S. Patent Nos. 6,331,415 and 7,923,221 purport to relate to processes for producing an immunoglobulin. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 33 and, therefore, denies the same.

34. Pfizer admits that U.S. Patent No. 6,331,415 is titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," and was issued on December 18, 2001 by the Patent Office. Pfizer admits that what purports to be a copy of the '415 patent is attached to the First Amended Complaint as Exhibit B. Pfizer admits that U.S. Patent No. 6,331,415, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 34 and, therefore, denies the same.

35. Pfizer admits that U.S. Patent No. 7,923,221 is titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," and was issued on April 12, 2011 by the Patent Office. Pfizer admits that what purports to be a copy of the '221 patent is attached to the First Amended Complaint as Exhibit C. Pfizer admits that U.S. Patent

No. 7,923,221, on its face, is assigned to Genentech, Inc. and City of Hope. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 35 and, therefore, denies the same.

The ’213 Patent

36. Pfizer admits that U.S. Patent No. 6,407,213 purports to relate to methods for the preparation and use of variant antibodies. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 36 and, therefore, denies the same.

37. Pfizer admits that U.S. Patent No. 6,407,213 is titled “Method for Making Humanized Antibodies,” and was issued on June 18, 2002 by the Patent Office. Pfizer admits that what purports to be a copy of the ’213 patent is attached to the First Amended Complaint as Exhibit D. Pfizer admits that U.S. Patent No. 6,407,213 is assigned on its face to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 37 and, therefore, denies the same.

The Combination Chemotherapy Patents

38. Pfizer admits that U.S. Patent No. 7,846,441 purports to relate to the treatment of disorders characterized by the overexpression of ErbB2. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 38 and, therefore, denies the same.

39. Pfizer admits that U.S. Patent No. 7,846,441 is titled “Treatment with Anti-ErbB2 Antibodies,” and was issued on December 7, 2010 by the Patent Office. Pfizer admits that what purports to be a copy of the ’441 patent is attached to the First Amended Complaint as Exhibit E. Pfizer admits that U.S. Patent No. 7,846,441, on its face, is assigned to Genentech, Inc. Pfizer

lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 39 and, therefore, denies the same.

40. Pfizer admits that U.S. Patent No. 7,892,549 is a continuation of U.S. Patent No. 7,846,441 and purports to relate to the treatment of disorders characterized by the overexpression of ErbB2. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 40 and, therefore, denies the same.

41. Pfizer admits that U.S. Patent No. 7,892,549 is titled "Treatment with Anti-ErbB2 Antibodies," and was issued on February 22, 2011 by the Patent Office. Pfizer admits that what purports to be a copy of the '549 patent is attached to the First Amended Complaint as Exhibit F. Pfizer admits that U.S. Patent No. 7,892,549, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 41 and, therefore, denies the same.

42. Pfizer admits that U.S. Patent Nos. 8,425,908, 7,846,441, and 7,892,549 identify Provisional Application No. 60/069,346 on the face of the patent as a related U.S. application. Pfizer admits that U.S. Patent No. 8,425,908 purports to relate to the treatment of disorders characterized by the overexpression of ErbB2. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 42 and, therefore, denies the same.

43. Pfizer admits that U.S. Patent No. 8,425,908 is titled "Treatment with Anti-ErbB2 Antibodies," and was issued on April 23, 2013 by the Patent Office. Pfizer admits that what purports to be a copy of the '908 patent is attached to the First Amended Complaint as Exhibit G. Pfizer admits that U.S. Patent No. 8,425,908, on its face, is assigned to Genentech, Inc. Pfizer

lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 43 and, therefore, denies the same.

The Method of Administration Patents

44. Pfizer admits that U.S. Patent Nos. 6,627,196 and 7,371,379 purport to relate to the treatment of disorders characterized by the overexpression of ErbB2. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 44 and, therefore, denies the same.

45. Pfizer admits that U.S. Patent No. 6,627,196 is titled "Dosages for Treatment with Anti-ErbB2 Antibodies," and was issued on September 30, 2003 by the Patent Office. Pfizer admits that what purports to be a copy of the '196 patent is attached to the First Amended Complaint as Exhibit H. Pfizer admits that U.S. Patent No. 6,627,196, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 45 and, therefore, denies the same.

46. Pfizer admits that U.S. Patent No. 7,371,379 is titled "Dosages for Treatment with Anti-ErbB2 Antibodies," and was issued on May 13, 2008 by the Patent Office. Pfizer admits that what purports to be a copy of the '379 patent is attached to the First Amended Complaint as Exhibit I. Pfizer admits that U.S. Patent No. 7,371,379, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 46 and, therefore, denies the same.

The Acidic Variants Patents

47. Pfizer admits that U.S. Patent Nos. 6,339,142 and 9,249,218 purport to relate to methods for purifying a polypeptide by ion exchange chromatography. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 47 and, therefore, denies the same.

48. Pfizer admits that U.S. Patent No. 6,339,142 is titled "Protein Purification," and was issued on January 15, 2002 by the Patent Office. Pfizer admits that what purports to be a copy of the '142 patent is attached to the First Amended Complaint as Exhibit J. Pfizer admits that U.S. Patent No. 6,339,142, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 48 and, therefore, denies the same.

49. Pfizer admits that U.S. Patent No. 9,249,218 is titled "Protein Purification," and was issued on February 2, 2016 by the Patent Office. Pfizer admits that what purports to be a copy of the '218 patent is attached to the First Amended Complaint as Exhibit K. Pfizer admits that U.S. Patent No. 9,249,218, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 49 and, therefore, denies the same.

HER2 Diagnostic Patents

50. Pfizer admits that U.S. Patent Nos. 7,993,834, 8,076,066, and 8,440,402 purport to relate to the treatment of cancers characterized by the overexpression of a tumor antigen. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 50 and, therefore, denies the same.

51. Pfizer admits that U.S. Patent No. 7,993,834 is titled "Detection of ErbB2 Gene Amplification to Increase the Likelihood of the Effectiveness of ErbB2 Antibody Breast Cancer Therapy," and was issued on August 9, 2011 by the Patent Office. Pfizer admits that what purports to be a copy of the '834 patent is attached to the First Amended Complaint as Exhibit L. Pfizer admits that U.S. Patent No. 7,993,834, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 51 and, therefore, denies the same.

52. Pfizer admits that U.S. Patent No. 8,076,066 is titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," and was issued on December 13, 2011 by the Patent Office. Pfizer admits that what purports to be a copy of the '066 patent is attached to the First Amended Complaint as Exhibit M. Pfizer admits that U.S. Patent No. 8,076,066, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 52 and, therefore, denies the same.

53. Pfizer admits that U.S. Patent No. 8,440,402 is titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," and was issued on May 14, 2013 by the Patent Office. Pfizer admits that what purports to be a copy of the '402 patent is attached to the First Amended Complaint as Exhibit N. Pfizer admits that U.S. Patent No. 8,440,402, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 53 and, therefore, denies the same.

Cell Culture, Purification, and Antibody Manufacturing Patents

54. Pfizer admits only that U.S. Patent Nos. 6,242,177, 6,610,516, 8,574,869, 6,121,428, 7,485,704, 7,807,799 and 8,314,225 purport to relate to various subject matter. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 54 and, therefore, denies the same.

55. Pfizer admits that U.S. Patent No. 7,485,704 is titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," and was issued on February 3, 2009 by the Patent Office. Pfizer admits that what purports to be a copy of the '704 patent is attached to the First Amended Complaint as Exhibit O. Pfizer admits that U.S. Patent No. 7,485,704, on its

face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 55 and, therefore, denies the same.

56. Pfizer admits that U.S. Patent No. 7,807,799 is titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," and was issued on October 5, 2010 by the Patent Office. Pfizer admits that what purports to be a copy of the '799 patent is attached to the First Amended Complaint as Exhibit P. Pfizer admits that U.S. Patent No. 7,807,799, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 56 and, therefore, denies the same.

57. Pfizer admits that U.S. Patent No. 6,242,177 is titled "Methods and Compositions for Secretion of Heterologous Polypeptides," and was issued on June 5, 2001 by the Patent Office. Pfizer admits that what purports to be a copy of the '177 patent is attached to the First Amended Complaint as Exhibit Q. Pfizer admits that U.S. Patent No. 6,242,177, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 57 and, therefore, denies the same.

58. Pfizer admits that U.S. Patent No. 6,610,516 is titled "Cell Culture Process," and was issued on August 26, 2003 by the Patent Office. Pfizer admits that what purports to be a copy of the '516 patent is attached to the First Amended Complaint as Exhibit R. Pfizer admits that U.S. Patent No. 6,610,516, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 58 and, therefore, denies the same.

59. Pfizer admits that U.S. Patent No. 8,574,869 titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," and was issued on November 5, 2013 by the Patent Office. Pfizer admits that what purports to be a copy of the '869 patent is

attached to the First Amended Complaint as Exhibit S. Pfizer admits that U.S. Patent No. 8,574,869, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 59 and, therefore, denies the same.

60. Pfizer admits that U.S. Patent No. 8,314,225 titled "Heavy Chain Mutant Leading to Improved Immunoglobulin Production," and was issued on November 20, 2012 by the Patent Office. Pfizer admits that what purports to be a copy of the '225 patent is attached to the First Amended Complaint as Exhibit T. Pfizer admits that U.S. Patent No. 8,314,225 is assigned on its face to Hoffmann-La Roche Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 60 and, therefore, denies the same.

61. Pfizer admits that U.S. Patent No. 6,121,428 titled "Protein Recovery," and was issued on September 19, 2000 by the Patent Office. Pfizer admits that what purports to be a copy of the '428 patent is attached to the First Amended Complaint as Exhibit U. Pfizer admits that U.S. Patent No. 6,121,428, on its face, is assigned to Genentech, Inc. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 61 and, therefore, denies the same.

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

62. Pfizer incorporates by reference its answers to Paragraphs 1-61 as if fully set forth herein.

63. Pfizer admits that Genentech included the '415 patent in the list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar,

PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

64. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 64 and, therefore, denies the same.

65. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '415 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 65 and, therefore, denies the same.

66. Pfizer has knowledge of and is aware of U.S. Patent No. 6,331,415. Pfizer otherwise denies the allegations of Paragraph 66.

67. Denied.

68. Denied.

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

69. Pfizer incorporates by reference its answers to Paragraphs 1-68 as if fully set forth herein.

70. Pfizer admits that Genentech included the '221 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar,

PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

71. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 71 and, therefore, denies the same.

72. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '221 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 72 and, therefore, denies the same.

73. Pfizer has knowledge of and is aware of U.S. Patent No. 7,923,221. Pfizer otherwise denies the allegations of Paragraph 73.

74. Denied.

75. Denied.

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

76. Pfizer incorporates by reference its answers to Paragraphs 1-75 as if fully set forth herein.

77. Pfizer admits that Genentech included the '213 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided

notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

78. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 78 and, therefore, denies the same.

79. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '213 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 79 and, therefore, denies the same.

80. Pfizer has knowledge of and is aware of U.S. Patent No. 6,407,213. Pfizer otherwise denies the allegations of Paragraph 80.

81. Denied.

82. Denied.

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

83. Pfizer incorporates by reference its answers to Paragraphs 1-82 as if fully set forth herein.

84. Pfizer admits that Genentech included the ’441 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer’s notice of commercial marketing.

85. Pfizer denies any allegation of infringement based on the submission of Pfizer’s BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 85 and, therefore, denies the same.

86. Pfizer denies any allegation of infringement based on Pfizer’s activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer’s proposed PF-05280014 drug product will infringe the ’441 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 86 and, therefore, denies the same.

87. Pfizer has knowledge of and is aware of U.S. Patent No. 7,846,441. Pfizer otherwise denies the allegations of Paragraph 87.

88. Denied.

89. Denied.

90. Denied.

91. Denied.

92. Denied.

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

93. Pfizer incorporates by reference its answers to Paragraphs 1-92 as if fully set forth herein.

94. Pfizer admits that Genentech included the ’549 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer’s notice of commercial marketing.

95. Pfizer denies any allegation of infringement based on the submission of Pfizer’s BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 95 and, therefore, denies the same.

96. Pfizer denies any allegation of infringement based on Pfizer’s activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer’s proposed PF-05280014 drug product will infringe the ’549 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 96 and, therefore, denies the same.

97. Pfizer has knowledge of and is aware of U.S. Patent No. 7,892,549. Pfizer otherwise denies the allegations of Paragraph 97.

98. Denied.

99. Denied.

100. Denied.

101. Denied.

102. Denied.

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

103. Pfizer incorporates by reference its answers to Paragraphs 1-102 as if fully set forth herein.

104. Pfizer admits that Genentech included the ’196 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer’s notice of commercial marketing.

105. Pfizer denies any allegation of infringement based on the submission of Pfizer’s BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 105 and, therefore, denies the same.

106. Pfizer denies any allegation of infringement based on Pfizer’s activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer’s proposed

PF-05280014 drug product will infringe the ’196 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 106 and, therefore, denies the same.

107. Pfizer has knowledge of and is aware of U.S. Patent No. 6,627,196. Pfizer otherwise denies the allegations of Paragraph 107.

108. Denied.

109. Denied.

110. Denied.

111. Denied.

112. Denied.

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

113. Pfizer incorporates by reference its answers to Paragraphs 1-112 as if fully set forth herein.

114. Pfizer admits that Genentech included the ’379 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer’s notice of commercial marketing.

115. Pfizer denies any allegation of infringement based on the submission of Pfizer’s BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 115 and, therefore, denies the same.

116. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '379 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 116 and, therefore, denies the same.

117. Pfizer has knowledge of and is aware of U.S. Patent No. 7,371,379. Pfizer otherwise denies the allegations of Paragraph 117.

118. Denied.

119. Denied.

120. Denied.

121. Denied.

122. Denied.

COUNT VIII
INFRINGEMENT OF U.S. PATENT NO. 6,339,142

123. Pfizer incorporates by reference its answers to Paragraphs 1-122 as if fully set forth herein.

124. Pfizer admits that Genentech included the '142 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

125. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 125 and, therefore, denies the same.

126. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '142 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 126 and, therefore, denies the same.

127. Pfizer has knowledge of and is aware of U.S. Patent No. 6,339,142. Pfizer otherwise denies the allegations of Paragraph 127.

128. Denied.

129. Denied.

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

130. Pfizer incorporates by reference its answers to Paragraphs 1-129 as if fully set forth herein.

131. Pfizer admits that Genentech included the '218 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar,

PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

132. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 132 and, therefore, denies the same.

133. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '218 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 133 and, therefore, denies the same.

134. Pfizer has knowledge of and is aware of U.S. Patent No. 9,249,218. Pfizer otherwise denies the allegations of Paragraph 134.

135. Denied.

136. Denied.

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

137. Pfizer incorporates by reference its answers to Paragraphs 1-136 as if fully set forth herein.

138. Pfizer admits that Genentech included the ’869 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer’s notice of commercial marketing.

139. Pfizer denies any allegation of infringement based on the submission of Pfizer’s BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 139 and, therefore, denies the same.

140. Pfizer denies any allegation of infringement based on Pfizer’s activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer’s proposed PF-05280014 drug product will infringe the ’869 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 140 and, therefore, denies the same.

141. Pfizer has knowledge of and is aware of U.S. Patent No. 8,574,869. Pfizer otherwise denies the allegations of Paragraph 141.

142. Denied.

143. Denied.

COUNT XI
INFRINGEMENT OF U.S. PATENT NO. 7,485,704

144. Pfizer incorporates by reference its answers to Paragraphs 1-143 as if fully set forth herein.

145. Pfizer admits that Genentech included the '704 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

146. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 146 and, therefore, denies the same.

147. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '704 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 147 and, therefore, denies the same.

148. Pfizer has knowledge of and is aware of U.S. Patent No. 7,485,704. Pfizer otherwise denies the allegations of Paragraph 148.

149. Denied.

150. Denied.

COUNT XII
INFRINGEMENT OF U.S. PATENT NO. 7,807,799

151. Pfizer incorporates by reference its answers to Paragraphs 1-150 as if fully set forth herein.

152. Pfizer admits that Genentech included the ’799 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer’s notice of commercial marketing.

153. Pfizer denies any allegation of infringement based on the submission of Pfizer’s BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 153 and, therefore, denies the same.

154. Pfizer denies any allegation of infringement based on Pfizer’s activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer’s proposed PF-05280014 drug product will infringe the ’799 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 154 and, therefore, denies the same.

155. Pfizer has knowledge of and is aware of U.S. Patent No. 7,807,799. Pfizer otherwise denies the allegations of Paragraph 155.

156. Denied.

157. Denied.

COUNT XIII
INFRINGEMENT OF U.S. PATENT NO. 8,314,225

158. Pfizer incorporates by reference its answers to Paragraphs 1-157 as if fully set forth herein.

159. Pfizer admits that Genentech included the ’225 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer’s notice of commercial marketing.

160. Pfizer denies any allegation of infringement based on the submission of Pfizer’s BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 160 and, therefore, denies the same.

161. Pfizer denies any allegation of infringement based on Pfizer’s activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer’s proposed PF-05280014 drug product will infringe the ’225 patent pursuant to 35 U.S.C. §§ 271(a), (b),

and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 161 and, therefore, denies the same.

162. Pfizer has knowledge of and is aware of U.S. Patent No. 8,314,225. Pfizer otherwise denies the allegations of Paragraph 162.

163. Denied.

164. Denied.

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

165. Pfizer incorporates by reference its answers to Paragraphs 1-164 as if fully set forth herein.

166. Pfizer admits that Genentech included the ’834 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer’s notice of commercial marketing.

167. Pfizer denies any allegation of infringement based on the submission of Pfizer’s BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 167 and, therefore, denies the same.

168. Pfizer denies any allegation of infringement based on Pfizer’s activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer’s manufacture, importation, sale, offer

for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '834 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 168 and, therefore, denies the same.

169. Pfizer has knowledge of and is aware of U.S. Patent No. 7,993,834. Pfizer otherwise denies the allegations of Paragraph 169.

170. Denied.

171. Denied.

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

172. Pfizer incorporates by reference its answers to Paragraphs 1-171 as if fully set forth herein.

173. Pfizer admits that Genentech included the '066 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

174. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 174 and, therefore, denies the same.

175. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-

05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '066 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 175 and, therefore, denies the same.

176. Pfizer has knowledge of and is aware of U.S. Patent No. 8,076,066. Pfizer otherwise denies the allegations of Paragraph 176.

177. Denied.

178. Denied.

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

179. Pfizer incorporates by reference its answers to Paragraphs 1-178 as if fully set forth herein.

180. Pfizer admits that Genentech included the '908 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

181. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 181 and, therefore, denies the same.

182. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '908 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 182 and, therefore, denies the same.

183. Pfizer has knowledge of and is aware of U.S. Patent No. 8,425,908. Pfizer otherwise denies the allegations of Paragraph 183.

184. Denied.

185. Denied.

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

186. Pfizer incorporates by reference its answers to Paragraphs 1-185 as if fully set forth herein.

187. Pfizer admits that Genentech included the '402 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

188. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a

belief as to the truth of the remaining allegations of Paragraph 188 and, therefore, denies the same.

189. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '402 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 189 and, therefore, denies the same.

190. Pfizer has knowledge of and is aware of U.S. Patent No. 8,440,402. Pfizer otherwise denies the allegations of Paragraph 190.

191. Denied.

192. Denied.

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

193. Pfizer incorporates by reference its answers to Paragraphs 1-192 as if fully set forth herein.

194. Pfizer admits that Genentech included the '428 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar, PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

195. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer admits that on March 2, 2018, Genentech provided to Pfizer its 3C Statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 195 and, therefore, denies the same.

196. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '428 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 196 and, therefore, denies the same.

197. Pfizer has knowledge of and is aware of U.S. Patent No. 6,121,428. Pfizer otherwise denies the allegations of Paragraph 197.

198. Denied.

199. Denied.

COUNT XIX
INFRINGEMENT OF U.S. PATENT NO. 6,242,177

200. Pfizer incorporates by reference its answers to Paragraphs 1-199 as if fully set forth herein.

201. Pfizer admits that Genentech included the '177 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar,

PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

202. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 202 and, therefore, denies the same.

203. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '117 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 203 and, therefore, denies the same.

204. Pfizer has knowledge of and is aware of U.S. Patent No. 6,242,177. Pfizer otherwise denies the allegations of Paragraph 204.

205. Denied.

206. Denied.

COUNT XX
INFRINGEMENT OF U.S. PATENT NO. 6,610,516

207. Pfizer incorporates by reference its answers to Paragraphs 1-206 as if fully set forth herein.

208. Pfizer admits that Genentech included the '516 patent in its list of patents provided on November 3, 2017. Pfizer admits that on November 17, 2017, Pfizer provided notice to Genentech of its intent to begin commercial marketing of its trastuzumab biosimilar,

PF-05280014, as described in BLA No. 761081, as early as 180 days from the date of the notice. Pfizer admits that Exhibit A purports to be a copy of Pfizer's notice of commercial marketing.

209. Pfizer denies any allegation of infringement based on the submission of Pfizer's BLA. Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 209 and, therefore, denies the same.

210. Pfizer denies any allegation of infringement based on Pfizer's activities relating to the manufacture, importation, sale, offer for sale, use, and/or promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product. Pfizer also denies that Plaintiffs are entitled to a declaratory judgment that Pfizer's manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and Pfizer's proposed PF-05280014 drug product will infringe the '516 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g). Pfizer lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 210 and, therefore, denies the same.

211. Pfizer has knowledge of and is aware of U.S. Patent No. 6,610,516. Pfizer otherwise denies the allegations of Paragraph 211.

212. Denied.

213. Denied.

PRAYER FOR RELIEF

The remainder of the First Amended Complaint recites a prayer for relief for which no response is required. To the extent any response is required, Pfizer denies that Genentech is entitled to any remedy or relief.

ADDITIONAL DENIAL

To the extent that there are any allegations in the First Amended Complaint directed to

Pfizer to which Pfizer did not respond specifically, such omission was inadvertent, and Pfizer hereby denies any such allegations.

AFFIRMATIVE AND OTHER DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or truth of any allegation in the First Amended Complaint, Pfizer relies upon the following defenses:

FIRST DEFENSE

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

SECOND DEFENSE

Pfizer has complied with the provisions of the BPCIA, including specifically 42 U.S.C. § 262(*l*)(2)(A).

THIRD DEFENSE

All claims of the asserted patents are invalid for failure to meet the requirements of patentability under 35 U.S.C. § 101 *et seq.*, including without limitation §§ 101, 102, 103, 112, and/or any judicially-created doctrine of invalidity including obviousness-type double patenting.

FOURTH DEFENSE

The manufacture, use, offer for sale, sale and/or importation into the United States of product described in BLA No. 761081 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of any asserted patent directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

FIFTH DEFENSE

The filing of BLA No. 761081 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of any asserted patent directly or indirectly, by inducement, contributorily, literally or under the doctrine of equivalents, or in any other manner.

SIXTH DEFENSE

Genentech is not entitled to preliminary and/or permanent equitable relief, including but not limited to a preliminary and/or permanent injunction that enjoins Pfizer, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with Pfizer and/or its successors or assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any product that purportedly infringes, or the use or manufacture of which purportedly infringes any of the asserted patents.

SEVENTH DEFENSE

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

EIGHT DEFENSE

Pfizer has not willfully infringed any claim of the asserted patents.

NINTH DEFENSE

Pfizer's activities fall within the safe harbor provisions of 35 U.S.C. § 271(e)(1).

TENTH DEFENSE

Plaintiffs cannot maintain a cause of action for any of the asserted patents because they have not complied with the BPCIA.

ELEVENTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

RESERVATION OF DEFENSES

Pfizer reserves its right to assert any additional defenses or counterclaims, at law or equity, which may exist.

PFIZER'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Counterclaim Plaintiff Pfizer Inc. ("Pfizer") by and through its attorneys, hereby submits these Counterclaims against Counterclaim Defendants Genentech, Inc. and City of Hope (collectively, "Genentech").

1. These are Pfizer's Counterclaims for declaratory judgment of non-infringement and invalidity of one or more claims of the asserted patents under 35 U.S.C. § 271(e)(2)(C)(i), 28 U.S.C. §§ 2201 and 2202.

2. Pfizer repeats and incorporates by reference each of the foregoing Paragraphs of Pfizer's Answer and Affirmative Defenses to the First Amended Complaint.

THE PARTIES

3. Pfizer is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 235 East 42nd Street, New York, NY 10017.

4. On information and belief, Genentech, Inc. is a corporation existing under the laws of the State of Delaware, with its principal place of business at 1 DNA Way, South San Francisco, California 94080.

5. On information and belief, City of Hope is not-for-profit organization existing under the laws of California with its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

JURISDICTION AND VENUE

6. These counterclaims are for declaratory judgment of invalidity and non-infringement, which arise under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, pursuant to 28 U.S.C. §§ 2201 and 2202 for determining questions of actual controversy between

the parties regarding the rights and other legal relations of the parties with respect to the Biosimilars Price Competition and Innovation Act (the "BPCIA").

7. This Court has subject matter jurisdiction over these counterclaims pursuant to 42 U.S.C. § 262(k)-(*l*), 28 U.S.C. §§ 1331, 1338(a) and 1367(a), and 35 U.S.C. § 271(e)(2)(C).

8. This Court has personal jurisdiction over each of Genentech, Inc. and City of Hope at least because they have subjected themselves to the jurisdiction of this Court in this case by filing the First Amended Complaint.

9. Venue in this case is proper in this judicial district pursuant to 28 U.S.C. § 1391 and by virtue of Genentech's filing of this action in this Court.

THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT

10. In 2010, as part of the Patient Protection and Affordable Care Act, Congress enacted the Biologics Price Competition and Innovation Act of 2009.

11. The BPCIA established an abbreviated pathway for regulatory approval of follow-on biological products that are "highly similar" to a previously approved product (the "reference product"). The purpose of this law was to create a "biosimilars pathway balancing innovation and consumer interests."

12. The U.S. Food and Drug Administration ("FDA") traditionally approves a biological product for commercial marketing by granting a biologics license under 42 U.S.C. § 262(a).

13. The BPCIA, by contrast and design, allows an applicant to file an abbreviated biologics license application to demonstrate that its product is "biosimilar" to or "interchangeable" with a previously approved reference product, together with "publicly-available information regarding the [FDA]'s previous determination that the reference product is

safe, pure, and potent." Thus, the BPCIA authorizes a biosimilar applicant to rely in part on the approved license of a reference product.

14. To balance innovation and price competition, Congress enacted the BPCIA to provide a four-year and a 12-year exclusivity period to a reference product, both beginning on the date of first licensure of the reference product. Specifically, approval of a subsection (k) application "may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a)." Thus, a sponsor of an approved reference product (the "reference product sponsor" or "RPS") receives up to 12 years of exclusivity against follow-on products, regardless of patent protection.

15. In addition to the biosimilars pathway of 42 U.S.C. § 262(k), the BPCIA sets forth a procedure by which the biosimilar applicant and reference product sponsor may exchange information relating to potential patent disputes. *See* 42 U.S. C. § 262(*l*). These exchanges occur after the biosimilar BLA has been submitted to the FDA but before any court-enforced confidentiality protections are in place.

16. First, within 20 days after the FDA publishes a notice of acceptance for a 262(k) application, the applicant may provide a copy of the application to the reference product sponsor. 42 U.S.C. § 262(*l*)(2)(A). The BPCIA gives a biosimilar applicant the option either to share its biosimilar application with the reference product sponsor promptly after acceptance of the BLA by the FDA or to face the consequences provided by the BPCIA, specifically 42 U.S.C. § 262(*l*)(9)(C).

17. The BPCIA does not provide for injunctive relief, declaratory judgment of non-compliance or damages for failing to provide the disclosures pursuant to subsection (*l*)(2)(A).

Instead, the BPCIA and/or 35 U.S.C. § 271(e)(4) precludes and preempts any and all such claims and remedies.

18. If the subsection (k) applicant chooses to provide its subsection (k) application to the reference product sponsor, the reference product sponsor may provide "a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted . . ." not later than 60 days after receipt of the application. 42 U.S.C. § 262(*l*)(3)(A). The reference product sponsor may also identify which of the listed patents it would be willing to license to the subsection (k) applicant.

19. The subsection (k) applicant then has 60 days after receipt of the list pursuant to § 262(*l*)(3)(A) 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). The subsection (k) applicant may also provide a response regarding any patents that the reference product sponsor would be willing to license.

20. The reference product sponsor then has 60 days after receipt of the list pursuant to § 262(*l*)(3)(B) to provide "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)."

21. After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant engage in "good faith negotiations" to agree on which, if any, patents listed under paragraph (3) to litigate. If the parties reach agreement, the reference product sponsor has 30 days to bring suit.

22. In addition, under certain circumstances, the subsection (k) applicant may provide notice of commercial marketing to the reference product sponsor.

FACTUAL BACKGROUND

A. Genentech's BLA for Herceptin®

23. According to the FDA's "Purple Book," Genentech obtained a license from the FDA for Herceptin® (trastuzumab) on September 25, 1998.

24. According to the current product label, Herceptin® is indicated for the treatment of HER2 overexpressing breast cancer and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

25. Genentech has marketed and sold Herceptin® since 1998. Therefore, under 42 U.S.C. § 262(k)(7), Amgen's 12-year exclusivity period for Herceptin® has long since expired.

B. Pfizer's BLA No. 761081

26. Pfizer is one of the world's premier biopharmaceutical companies. Pfizer applies science and global resources to bring therapies to people that extend and significantly improve their lives through the discovery, development and manufacture of healthcare products. Pfizer's global portfolio includes medicines, vaccines and medical devices, as well as many of the world's best-known consumer healthcare products. Pfizer works across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Pfizer collaborates with healthcare providers, governments and local communities to support and expand access to reliable, affordable healthcare around the world.

27. Pfizer is seeking licensure pursuant to 42 U.S.C. § 262(k) for the importation, commercial manufacture, offer to sell, sale and/or use of the drug product PF-05280014 described in Pfizer's BLA No. 761081 ("Pfizer's BLA") submitted on June 22, 2017.

28. The reference product to Pfizer's BLA is Herceptin® (trastuzumab). The drug product PF-05280017 is a proposed biosimilar for Herceptin® seeking approval for the following indications: the treatment of HER2 overexpressing breast cancer and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

29. Now, Genentech seeks to delay Pfizer from marketing Pfizer's trastuzumab biosimilar, to extend Genentech's exclusivity even further beyond that contemplated by Congress in the BPCIA, and delay patient access to a more affordable version of this drug.

C. Pfizer Complied with Requirements of the BPCIA

30. On August 21, 2017, the FDA accepted Pfizer's BLA for review. Pfizer notified Genentech on August 28, 2017 that Pfizer's BLA had been accepted by the FDA, and on September 5, 2017, within 20 days of the FDA's notice and in full compliance with 42 U.S.C. § 262(*l*)(2)(A), Pfizer provided Genentech with Pfizer's complete BLA. Pfizer's BLA contains over two-hundred and fifty thousand pages of information on Pfizer's Product and the processes to manufacture it. The produced information completely "describe[d] the process or processes used to manufacture the biological product that is the subject of such application" as contemplated by the BPCIA.

31. On October 19, 2017, Pfizer received a letter from Genentech alleging that "the documents that Pfizer has produced so far do not appear to fully describe the PF-05280014 manufacturing processes." Genentech identified several categories of information for which it requested production of the information or identification of where the information may be found in Pfizer's BLA.

32. On November 1, 2017, Pfizer responded to Genentech in a letter identifying for each of Genentech's categories the sections of Pfizer's BLA that contain related information. Furthermore, although Pfizer fully complied with 42 U.S.C. § 262(*l*)(2) when Pfizer provided to Genentech its complete BLA, in the spirit of cooperation, Pfizer produced additional documents in response to Genentech's request.

33. Contrary to Genentech's assertions that Pfizer's November 1, 2017 production was deficient, Pfizer not only fully complied with the requirements of 42 U.S.C. § 262(*l*)(2), but also went beyond what was required to comply with the patent exchange contemplated by the BPCIA in the spirit of cooperation. The documents that Pfizer produced to Genentech as of November 1, 2017 provided additional information to the already-complete BLA that Pfizer had initially provided, and further demonstrate that Genentech had no reasonable basis for listing numerous patents pursuant to 42 U.S.C. § 262(*l*)(3)(A).

D. Genentech Brought This Action Prior To Completion of the Patent Exchange Contemplated by the BPCIA

34. On November 3, 2017, Genentech provided to Pfizer its list of patents purportedly pursuant to 42 U.S.C. 262(*l*)(3)(A) ("Genentech's 3(A) List").

35. On November 17, 2017, Pfizer notified Genentech pursuant to 42 U.S.C. § 262(*l*)(8)(A) that it intends to commence commercial marketing of PF-05280014 in the United States 180 days from the date of the notice. On that same day—***over six weeks*** before Pfizer's response pursuant to 42 U.S.C. § 262(*l*)(3)(B) was due, prior to the completion of the exchange of information pursuant to the BPCIA, and without making any attempt to contact counsel for Pfizer with regards thereto—Genentech prematurely filed the original complaint in this action.

36. Genentech did not wait until Pfizer had presented its position on each of the asserted patents and, thus, deprived Pfizer of its ability to control the number of patents in the patent litigation contemplated by the BPCIA.

37. Genentech's actions violate both the letter and the spirit of the BPCIA.

E. Pursuant to the BPCIA, the Parties Must Engage in "Good Faith Negotiations" to Agree on which Patents, If Any, to Litigate

38. Despite Genentech's decision to commence this action prematurely, Pfizer complied and continues to comply with the patent exchange provisions of the BPCIA. On January 2, 2018, Pfizer provided its detailed statement, spanning over six hundred pages, that describes on a claim by claim basis, the factual and legal basis for its opinion that each of the patents listed in Genentech's 3A List is invalid, unenforceable, and/or will not be infringed by the biological product that is the subject of Pfizer's BLA pursuant to 42 U.S.C. § 262(*l*)(3)(B) ("Pfizer's 3(B) Statement"). Thus, Pfizer fully complied with the BPCIA patent information exchange provisions.

39. On March 2, 2018, Genentech purported to provide to Pfizer a statement pursuant to 42 U.S.C.§ 262(*l*)(3)(C). Genentech's 3C Statement purported to include responses to Pfizer's non-infringement and invalidity statements for 18 patents addressed in Pfizer's 3B Statement and a proposal that the patents in Genentech's 3C Statement and two additional patents included on Genentech's 3A List continue to be litigated and that claims relating to the remaining patents-in-suit be voluntarily dismissed without prejudice.

40. On March 23, 2018, Pfizer and Genentech stipulated and agreed that all claims for infringement of U.S. Patent Nos. 6,417,335, 6,489,447, 6,586,206, 6,620,918, 6,716,602, 7,390,660, 7,449,184, 7,501,122, 8,044,017, 8,460,895, 8,512,983, 8,633,302, 8,691,232, 8,710,196, 8,771,988, 8,822,655, 9,428,766, 9,487,809, 9,493,744, and 9,714,293 against Pfizer

are dismissed with prejudice and all counterclaims for judgment of non-infringement and invalidity of the Patents are dismissed without prejudice. (D.I. 18.) The aforementioned stipulation was so ordered by the Court on March 28, 2018. (D.I. 22.)

THE PATENTS-IN-SUIT

41. U.S. Patent No. 6,121,428 is titled "Protein Recovery" and lists Gregory S. Blank, Daljit S. Narindray, and Gerardo A. Zapata as the inventors. U.S. Patent No. 6,121,428, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the '428 Patent.

42. U.S. Patent No. 6,242,177 is titled "Methods and Compositions for Secretion of Heterologous Polypeptides" and lists Laura C. Simmons and Daniel G. Yansura as the inventors. U.S. Patent No. 6,242,177, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the '177 Patent.

43. U.S. Patent No. 6,331,415 is titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein" and lists Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel as the inventors. U.S. Patent No. 6,331,415, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech and City of Hope are the owners by assignment of the '415 Patent.

44. U.S. Patent No. 6,339,142 is titled "Protein Purification" and lists Carol D. Basey and Greg S. Blank as the inventors. U.S. Patent No. 6,339,142, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the '142 Patent.

45. U.S. Patent No. 6,407,213 is titled "Method for Making Humanized Antibodies" and lists Paul J. Carter and Leonard G. Presta as the inventors. U.S. Patent No. 6,407,213, on its

face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’213 Patent.

46. U.S. Patent No. 6,610,516 is titled “Cell Culture Process” and lists Dana C. Andersen, Tiffany M. Bridges, Martin Gawlitzek, and Cynthia A. Hoy as the inventors. U.S. Patent No. 6,610,516, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’516 Patent.

47. U.S. Patent No. 6,627,196 is titled “Dosages for Treatment with Anti-ErbB2 Antibodies” and lists Sharon A. Baughman and Steven Shak as the inventors. U.S. Patent No. 6,627,196, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’196 Patent.

48. U.S. Patent No. 7,371,379 is titled “Dosages for Treatment with Anti-ErbB2 Antibodies” and lists Sharon A. Baughman and Steven Shak as the inventors. U.S. Patent No. 7,371,379, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’379 Patent.

49. U.S. Patent No. 7,485,704 is titled “Reducing Protein A Leaching During Protein A Affinity Chromatography” and lists Robert L. Fahrner, Amy Laverdiere, Paul J. McDonald, and Rhona M. O'Leary as the inventors. U.S. Patent No. 7,485,704, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’704 Patent.

50. U.S. Patent No. 7,807,799 is titled “Reducing Protein A Leaching During Protein A Affinity Chromatography” and lists Robert L. Fahrner, Amy Laverdiere, Paul J. McDonald, and Rhona M. O'Leary as the inventors. U.S. Patent No. 7,807,799, on its face, is assigned to

Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’799 Patent.

51. U.S. Patent No. 7,846,441 is titled “Treatment with Anti-ErbB2 Antibodies” and lists Susan D. Hellmann as the inventor. U.S. Patent No. 7,846,441, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’441 Patent.

52. U.S. Patent No. 7,892,549 is titled “Treatment with Anti-ErbB2 Antibodies” and lists Virginia E. Paton, Steven Shak, and Susan D. Hellmann as the inventors. U.S. Patent No. 7,892,549, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’549 Patent.

53. U.S. Patent No. 7,923,221 is titled “Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen” and lists Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel as the inventors. U.S. Patent No. 7,923,221, on its face, is assigned to Genentech, Inc. and City of Hope. According to the First Amended Complaint, Genentech and City of Hope are the owners by assignment of the ’221 Patent.

54. U.S. Patent No. 7,993,834 is titled “Detection of ErbB2 Gene Amplification to Increase the Likelihood of the Effectiveness of ErbB2 Antibody Breast Cancer Therapy” and lists Robert D. Mass as the inventor. U.S. Patent No. 7,993,834, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’834 Patent.

55. U.S. Patent No. 8,076,066 is titled “Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy” and lists Robert D.

Mass as the inventor. U.S. Patent No. 8,076,066, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’066 Patent.

56. U.S. Patent No. 8,314,225 is titled “Heavy Chain Mutant Leading to Improved Immunoglobulin Production” and lists Ulrich Goepfert, Silke Hansen, Hendrik Knoetgen, Erhard Kopetzki, and Oliver Ploettner as the inventors. U.S. Patent No. 8,314,225 is assigned on its face to Hoffmann-La Roche Inc. According to the First Amended Complaint, the ’225 patent is assigned to Hoffmann-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the ’225 patent.

57. U.S. Patent No. 8,425,908 is titled “Treatment with Anti-ErbB2 Antibodies” and lists Susan D. Hellmann as the inventor. U.S. Patent No. 8,425,908, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’908 Patent.

58. U.S. Patent No. 8,440,402 is titled “Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy” and lists Robert D. Mass as the inventor. U.S. Patent No. 8,440,402, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’402 Patent.

59. U.S. Patent No. 8,574,869 is titled “Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides” and lists Yung-Hsiang Kao, Michael W. Laird, Melody Trexler Schmidt, Rita L. Wong, and Daniel P. Hewitt as the inventors. U.S. Patent No. 8,574,869, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the ’869 Patent.

60. U.S. Patent No. 9,249,218 is titled "Protein Purification" and lists Carol D. Basey and Greg S. Blank as the inventors. U.S. Patent No. 9,249,218, on its face, is assigned to Genentech, Inc. According to the First Amended Complaint, Genentech is the owner by assignment of the '218 Patent.

COUNT I
Declaratory Judgment of Non-infringement of U.S. Patent No. 6,121,428

61. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 60 of the Counterclaims above.

62. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,121,428 either directly or indirectly, and either literally or under the doctrine of equivalents.

63. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,121,428 either literally or under the doctrine of equivalents and is not liable for such infringement.

64. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,121,428 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,121,428.

65. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT II
Declaratory Judgment of Non-infringement of U.S. Patent No. 6,242,177

66. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 65 of the Counterclaims above.

67. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,242,177 either directly or indirectly, and either literally or under the doctrine of equivalents.

68. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,242,177 either literally or under the doctrine of equivalents and is not liable for such infringement.

69. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,242,177 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,242,177.

70. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT III
Declaratory Judgment of Invalidity of U.S. Patent No. 6,331,415

71. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 70 of the Counterclaims above.

72. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 6,331,415, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 6,331,415.

73. The claims of U.S. Patent No. 6,331,415 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

74. The alleged invention of U.S. Patent No. 6,331,415 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

75. The alleged invention of U.S. Patent No. 6,331,415 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

76. U.S. Patent No. 6,331,415 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

77. The alleged invention of U.S. Patent No. 6,331,415 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 6,331,415 is no more than the

predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 6,331,415 and would have had a reasonable expectation of success in doing so.

78. The subject matter claimed in U.S. Patent No. 6,331,415 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

79. U.S. Patent No. 6,331,415 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

80. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 6,331,415 are invalid.

81. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT IV
Declaratory Judgment of Non-infringement of U.S. Patent No. 6,331,415

82. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 81 of the Counterclaims above.

83. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,331,415 either directly or indirectly, and either literally or under the doctrine of equivalents.

84. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,331,415 either literally or under the doctrine of equivalents and is not liable for such infringement.

85. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,331,415 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,331,415.

86. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT V
Declaratory Judgment of Invalidity of U.S. Patent No. 6,339,142

87. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 86 of the Counterclaims above.

88. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 6,339,142, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 6,339,142.

89. The claims of U.S. Patent No. 6,339,142 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

90. The alleged invention of U.S. Patent No. 6,339,142 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

91. The alleged invention of U.S. Patent No. 6,339,142 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

92. U.S. Patent No. 6,339,142 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

93. The alleged invention of U.S. Patent No. 6,339,142 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 6,339,142 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 6,339,142 and would have had a reasonable expectation of success in doing so.

94. The subject matter claimed in U.S. Patent No. 6,339,142 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the

prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

95. U.S. Patent No. 6,339,142 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

96. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 6,339,142 are invalid.

97. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT VI
Declaratory Judgment of Non-infringement of U.S. Patent No. 6,339,142

98. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 97 of the Counterclaims above.

99. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,339,142 either directly or indirectly, and either literally or under the doctrine of equivalents.

100. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,339,142 either literally or under the doctrine of equivalents and is not liable for such infringement.

101. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,339,142 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,339,142.

102. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT VII
Declaratory Judgment of Invalidity of U.S. Patent No. 6,407,213

103. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 102 of the Counterclaims above.

104. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 6,407,213, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 6,407,213.

105. The claims of U.S. Patent No. 6,407,213 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112, and/or under the doctrine of obviousness-type double patenting.

106. The alleged invention of U.S. Patent No. 6,407,213 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

107. The alleged invention of U.S. Patent No. 6,407,213 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

108. U.S. Patent No. 6,407,213 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

109. The alleged invention of U.S. Patent No. 6,407,213 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 6,407,213 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 6,407,213 and would have had a reasonable expectation of success in doing so.

110. The subject matter claimed in U.S. Patent No. 6,407,213 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

111. U.S. Patent No. 6,407,213 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms

as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

112. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 6,407,213 are invalid.

113. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT VIII
Declaratory Judgment of Unenforceability of U.S. Patent No. 6,407,213

114. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 113 of the Counterclaims above.

115. During the prosecution of the U.S. Patent No. 6,407,213 ("'213 patent"), Genentech made misrepresentations and omissions in filings with the U.S. Patent and Trademark Office[1] ("Patent Office") material to patentability and did so with the specific intent to mislead or deceive the Patent Office.

116. Genentech deliberately misrepresented the teachings of U.S. Patent No. 5,530,101 ("'101 patent") to the Patent Office to overcome a rejection based on that reference. Genentech told the Examiner that the '101 Patent does not use the Kabat numbering system, despite the fact that the '101 Patent expressly states that the Kabat numbering system is used for certain disclosed sequences.

[1] The filings are signed by patent counsel for Genentech, Ms. Wendy M. Lee (Reg. No. 40,378).

117. On November 17, 1993, Genentech filed its patent application with claims requiring substitutions at specific locations, including "93H." (*See* November 17, 1993 Claims at 109-110.)

118. On December 9, 1994, the Examiner issued a Non-Final Rejection, rejecting various pending claims as obvious under § 103 over EP 0239400, Queen 1989, and Riechmann 1988. (*See* December 9, 1994 Non-Final Rejection at 4.)

119. On June 12, 1995, Genentech amended the pending claims and deleted references to various substitutions, including a substitution at amino acid position "93H." (*See* June 12, 1995 Amendment at 3-4.)

120. On December 19, 1996, the Examiner issued a Non-Final Rejection, rejecting various pending claims as anticipated by the '101 Patent. (*See* December 19, 1996 Non-Final Rejection at 7-8.)

121. In a Supplemental Amendment dated October 6, 1997, signed by Ms. Wendy M. Lee, Genentech argued 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." (October 6, 1997 Supplemental Amendment at 6.)

122. In a Supplemental Amendment dated January 15, 1999, Genentech included a substitution at residue 93H in new claim 115 and claims dependent therefrom. (*See* January 15, 1999 Supplemental Amendment at 8.)

123. On October 25, 2000, the Examiner issued a Non-Final Rejection, rejecting claims 115-117, 123, and 127, which included the 93H substitution, as anticipated by the '101

Patent because the Examiner understood the '101 Patent to disclose a substitution at 93H according to the Kabat numbering system. (*See* October 25, 2000 Non-Final Rejection at 7.)

124. In an Amendment dated April 25, 2001, signed by Ms. Lee, Genentech distinguished the '101 patent, arguing that the '101 patent uses a different numbering system and, in particular, does not disclose a substitution at 93H using the Kabat system:

> 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.

(April 25, 2001 Amendment at 7.)

125. On December 11, 2001, the Examiner indicated during an interview that the pending claims, including claims 115-117, 123 and 127, were allowable. (*See* December 11, 2001 Examiner Interview Summary Record at 1.)

126. Contrary to Genentech's representations to the Patent Office that the '101 patent does not use the Kabat numbering system, the '101 patent expressly 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 8:15-18.) The '101 patent also expressly refers to "numbering according to Kabat, op. cit." with specific reference to position 93H. (*Id.* at 15:17-37.) Moreover, Table 5 of the '101 patent identifies residue "H93," and expressly states that "[t]he amino acids residues are numbered according to the Kabat system":

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.

127. Additionally, the sequence in Figure 30A of the ’101 Patent, which shows a substitution at 93H, is numbered according to the Kabat system:

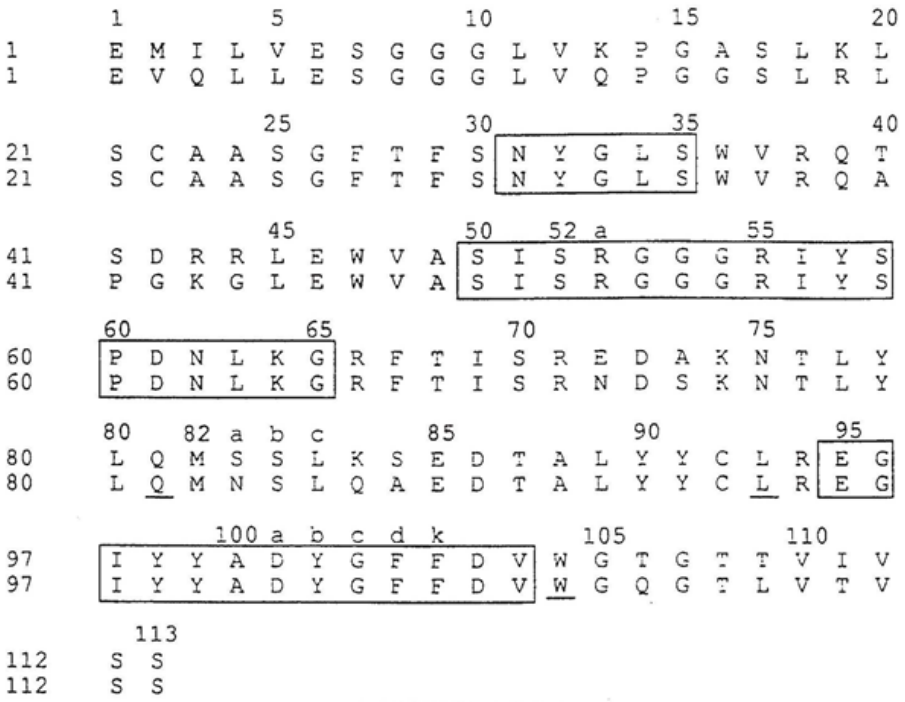

FIGURE 30A

And the sequences in Figures 2B, 6B, and 40 B, which use sequential numbering, show a substitution at 97H that corresponds to 93H in the Kabat numbering system.

128. Genentech misrepresented to the Examiner that the ’101 patent used sequential numbering, while arguing that the “claims of the instant application use Kabat numbering for the framework region residues,” to overcome the pending § 102 rejection based on the ’101 patent. In particular, Genentech misrepresented to the Examiner that “the substituted 93 FR residue in the [’101 patent] is not 93H ‘utilizing the numbering system set forth in Kabat,’” despite the express teaching in the ’101 Patent of a substitution at 93H using the Kabat system. Deceptive intent by Genentech is the single most reasonable inference to be drawn in light of the fact that the ’101 patent discloses sequences numbered according to the Kabat system and expressly describes a substitution at 93H using the Kabat system.

129. The Examiner had no reason to withdraw the § 102 rejection over the ’101 patent of claims reciting the 93H substitution, absent Genentech’s false and misleading representations. Genentech provided no other arguments to distinguish the ’101 patent from the claimed subject matter of claims 115-117, 123, and 127 in its April 26, 2001 Amendment. (*See* April 26, 2001 Amendment at 7-8.)

130. There is a real, substantial, and justiciable controversy between Pfizer and Genentech concerning whether the claims of the ’213 patent are enforceable in view of Genentech’s inequitable conduct before the Patent Office.

131. Pfizer is entitled to a judicial declaration that all claims of the ’213 patent are unenforceable.

COUNT IX
Declaratory Judgment of Non-infringement of U.S. Patent No. 6,407,213

132. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 131 of the Counterclaims above.

133. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,407,213 either directly or indirectly, and either literally or under the doctrine of equivalents.

134. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,407,213 either literally or under the doctrine of equivalents and is not liable for such infringement.

135. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,407,213 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,407,213.

136. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT X
Declaratory Judgment of Invalidity of U.S. Patent No. 6,610,516

137. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 136 of the Counterclaims above.

138. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 6,610,516, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 6,610,516.

139. The claims of U.S. Patent No. 6,610,516 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

140. The alleged invention of U.S. Patent No. 6,610,516 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

141. The alleged invention of U.S. Patent No. 6,610,516 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

142. U.S. Patent No. 6,610,516 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

143. The alleged invention of U.S. Patent No. 6,610,516 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 6,610,516 is no more than the

predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 6,610,516 and would have had a reasonable expectation of success in doing so.

144. The subject matter claimed in U.S. Patent No. 6,610,516 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

145. U.S. Patent No. 6,610,516 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

146. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 6,610,516 are invalid.

147. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XI
Declaratory Judgment of Non-infringement of U.S. Patent No. 6,610,516

148. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 147 of the Counterclaims above.

149. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 6,610,516 either directly or indirectly, and either literally or under the doctrine of equivalents.

150. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,610,516 either literally or under the doctrine of equivalents and is not liable for such infringement.

151. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 6,610,516 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 6,610,516.

152. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

153. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 6,610,516. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,710,196

154. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 153 of the Counterclaims above.

155. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 8,710,196, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 8,710,196.

156. The claims of U.S. Patent No. 8,710,196 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 103 and/or 112.

157. U.S. Patent No. 8,710,196 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

158. The alleged invention of U.S. Patent No. 8,710,196 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 8,710,196 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 8,710,196 and would have had a reasonable expectation of success in doing so.

159. The subject matter claimed in U.S. Patent No. 8,710,196 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the

prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

160. U.S. Patent No. 8,710,196 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

161. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 8,710,196 are invalid.

162. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XIII
Declaratory Judgment of Non-infringement of U.S. Patent No. 8,710,196

163. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 162 of the Counterclaims above.

164. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 8,710,196 either directly or indirectly, and either literally or under the doctrine of equivalents.

165. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,710,196 either literally or under the doctrine of equivalents and is not liable for such infringement.

166. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,710,196 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 8,710,196.

167. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XIV
Declaratory Judgment of Invalidity of U.S. Patent No. 7,371,379

168. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 167 of the Counterclaims above.

169. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,371,379, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,371,379.

170. The claims of U.S. Patent No. 7,371,379 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 103 and/or 112, and/or under the doctrine of obviousness-type double patenting.

171. U.S. Patent No. 7,371,379 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

172. The alleged invention of U.S. Patent No. 7,371,379 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,371,379 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,371,379 and would have had a reasonable expectation of success in doing so.

173. The subject matter claimed in U.S. Patent No. 7,371,379 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

174. U.S. Patent No. 7,371,379 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

175. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,371,379 are invalid.

176. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XV
Declaratory Judgment of Non-infringement of U.S. Patent No. 7,371,379

177. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 176 of the Counterclaims above.

178. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,371,379 either directly or indirectly, and either literally or under the doctrine of equivalents.

179. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,371,379 either literally or under the doctrine of equivalents and is not liable for such infringement.

180. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,371,379 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,371,379.

181. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

182. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 7,371,379.

Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XVI
Declaratory Judgment of Invalidity of U.S. Patent No. 7,485,704

183. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 182 of the Counterclaims above.

184. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,485,704, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,485,704.

185. The claims of U.S. Patent No. 7,485,704 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. § 103.

186. U.S. Patent No. 7,485,704 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

187. The alleged invention of U.S. Patent No. 7,485,704 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,485,704 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,485,704 and would have had a reasonable expectation of success in doing so.

188. The subject matter claimed in U.S. Patent No. 7,485,704 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

189. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,485,704 are invalid.

190. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XVII
Declaratory Judgment of Non-infringement of U.S. Patent No. 7,485,704

191. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 190 of the Counterclaims above.

192. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,485,704 either directly or indirectly, and either literally or under the doctrine of equivalents.

193. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,485,704 either literally or under the doctrine of equivalents and is not liable for such infringement.

194. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent

No. 7,485,704 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,485,704.

195. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

196. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 7,485,704. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XVIII
Declaratory Judgment of Invalidity of U.S. Patent No. 7,807,799

197. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 196 of the Counterclaims above.

198. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,807,799, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,807,799.

199. The claims of U.S. Patent No. 7,807,799 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102 and/or 103.

200. The alleged invention of U.S. Patent No. 7,807,799 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

201. The alleged invention of U.S. Patent No. 7,807,799 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

202. U.S. Patent No. 7,807,799 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

203. The alleged invention of U.S. Patent No. 7,807,799 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,807,799 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,807,799 and would have had a reasonable expectation of success in doing so.

204. The subject matter claimed in U.S. Patent No. 7,807,799 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

205. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,807,799 are invalid.

206. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XIX
Declaratory Judgment of Non-infringement of U.S. Patent No. 7,807,799

207. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 206 of the Counterclaims above.

208. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,807,799 either directly or indirectly, and either literally or under the doctrine of equivalents.

209. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,807,799 either literally or under the doctrine of equivalents and is not liable for such infringement.

210. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,807,799 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,807,799.

211. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

212. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 7,807,799. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XX
Declaratory Judgment of Invalidity of U.S. Patent No. 7,846,441

213. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 212 of the Counterclaims above.

214. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,846,441, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,846,441.

215. The claims of U.S. Patent No. 7,846,441 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 103 and/or 112.

216. U.S. Patent No. 7,846,441 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

217. The alleged invention of U.S. Patent No. 7,846,441 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,846,441 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the

alleged invention of U.S. Patent No. 7,846,441 and would have had a reasonable expectation of success in doing so.

218. The subject matter claimed in U.S. Patent No. 7,846,441 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

219. U.S. Patent No. 7,846,441 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

220. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,846,441 are invalid.

221. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXI
Declaratory Judgment of Non-infringement of U.S. Patent No. 7,846,441

222. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 221 of the Counterclaims above.

223. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will

infringe any valid and enforceable claim of U.S. Patent No. 7,846,441 either directly or indirectly, and either literally or under the doctrine of equivalents.

224. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,846,441 either literally or under the doctrine of equivalents and is not liable for such infringement.

225. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,846,441 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,846,441.

226. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

227. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 7,846,441. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XXII
Declaratory Judgment of Invalidity of U.S. Patent No. 7,892,549

228. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 227 of the Counterclaims above.

229. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,892,549, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,892,549.

230. The claims of U.S. Patent No. 7,892,549 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

231. The alleged invention of U.S. Patent No. 7,892,549 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

232. The alleged invention of U.S. Patent No. 7,892,549 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

233. U.S. Patent No. 7,892,549 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

234. The alleged invention of U.S. Patent No. 7,892,549 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,892,549 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,892,549 and would have had a reasonable expectation of success in doing so.

235. The subject matter claimed in U.S. Patent No. 7,892,549 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

236. U.S. Patent No. 7,892,549 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

237. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,892,549 are invalid.

238. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXIII
Declaratory Judgment of Non-infringement of U.S. Patent No. 7,892,549

239. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 238 of the Counterclaims above.

240. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,892,549 either directly or indirectly, and either literally or under the doctrine of equivalents.

241. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,892,549 either literally or under the doctrine of equivalents and is not liable for such infringement.

242. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,892,549 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,892,549.

243. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

244. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 7,892,549. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XXIV
Declaratory Judgment of Invalidity of U.S. Patent No. 7,923,221

245. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 244 of the Counterclaims above.

246. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,923,221, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,923,221.

247. The claims of U.S. Patent No. 7,923,221 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

248. The alleged invention of U.S. Patent No. 7,923,221 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

249. The alleged invention of U.S. Patent No. 7,923,221 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

250. U.S. Patent No. 7,923,221 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

251. The alleged invention of U.S. Patent No. 7,923,221 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,923,221 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,923,221 and would have had a reasonable expectation of success in doing so.

252. The subject matter claimed in U.S. Patent No. 7,923,221 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the

prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

253. U.S. Patent No. 7,923,221 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

254. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,923,221 are invalid.

255. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXV
Declaratory Judgment of Non-infringement of U.S. Patent No. 7,923,221

256. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 255 of the Counterclaims above.

257. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,923,221 either directly or indirectly, and either literally or under the doctrine of equivalents.

258. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,923,221 either literally or under the doctrine of equivalents and is not liable for such infringement.

259. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,923,221 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,923,221.

260. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXVI
Declaratory Judgment of Invalidity of U.S. Patent No. 7,993,834

261. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 260 of the Counterclaims above.

262. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 7,993,834, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 7,993,834.

263. The claims of U.S. Patent No. 7,993,834 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 103 and/or 112, and/or under the doctrine of obviousness-type double patenting.

264. U.S. Patent No. 7,993,834 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

265. The alleged invention of U.S. Patent No. 7,993,834 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 7,993,834 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 7,993,834 and would have had a reasonable expectation of success in doing so.

266. The subject matter claimed in U.S. Patent No. 7,993,834 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

267. U.S. Patent No. 7,993,834 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

268. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 7,993,834 are invalid.

269. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXVII
Declaratory Judgment of Non-infringement of U.S. Patent No. 7,993,834

270. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 269 of the Counterclaims above.

271. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 7,993,834 either directly or indirectly, and either literally or under the doctrine of equivalents.

272. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,993,834 either literally or under the doctrine of equivalents and is not liable for such infringement.

273. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 7,993,834 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 7,993,834.

274. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

275. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 7,993,834.

Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XXVIII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,076,066

276. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 275 of the Counterclaims above.

277. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 8,076,066, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 8,076,066.

278. The claims of U.S. Patent No. 8,076,066 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 103 and/or 112.

279. U.S. Patent No. 8,076,066 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

280. The alleged invention of U.S. Patent No. 8,076,066 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 8,076,066 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 8,076,066 and would have had a reasonable expectation of success in doing so.

281. The subject matter claimed in U.S. Patent No. 8,076,066 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

282. U.S. Patent No. 8,076,066 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

283. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 8,076,066 are invalid.

284. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXIX
Declaratory Judgment of Non-infringement of U.S. Patent No. 8,076,066

285. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 284 of the Counterclaims above.

286. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 8,076,066 either directly or indirectly, and either literally or under the doctrine of equivalents.

287. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,076,066 either literally or under the doctrine of equivalents and is not liable for such infringement.

288. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,076,066 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 8,076,066.

289. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

290. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 8,076,066. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XXX
Declaratory Judgment of Invalidity of U.S. Patent No. 8,314,225

291. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 290 of the Counterclaims above.

292. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 8,314,225, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 8,314,225.

293. The claims of U.S. Patent No. 8,314,225 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103 and/or 112.

294. The alleged invention of U.S. Patent No. 8,314,225 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

295. The alleged invention of U.S. Patent No. 8,314,225 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

296. U.S. Patent No. 8,314,225 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

297. The alleged invention of U.S. Patent No. 8,314,225 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 8,314,225 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 8,314,225 and would have had a reasonable expectation of success in doing so.

298. The subject matter claimed in U.S. Patent No. 8,314,225 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the

prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

299. U.S. Patent No. 8,314,225 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

300. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 8,314,225 are invalid.

301. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXXI
Declaratory Judgment of Non-infringement of U.S. Patent No. 8,314,225

302. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 301 of the Counterclaims above.

303. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 8,314,225 either directly or indirectly, and either literally or under the doctrine of equivalents.

304. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,314,225 either literally or under the doctrine of equivalents and is not liable for such infringement.

305. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,314,225 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 8,314,225.

306. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXXII
Declaratory Judgment of Invalidity of U.S. Patent No. 8,425,908

307. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 306 of the Counterclaims above.

308. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 8,425,908, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 8,425,908.

309. The claims of U.S. Patent No. 8,425,908 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 103 and/or 112.

310. U.S. Patent No. 8,425,908 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

311. The alleged invention of U.S. Patent No. 8,425,908 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 8,425,908 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 8,425,908 and would have had a reasonable expectation of success in doing so.

312. The subject matter claimed in U.S. Patent No. 8,425,908 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

313. U.S. Patent No. 8,425,908 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

314. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 8,425,908 are invalid.

315. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXXIII
Declaratory Judgment of Non-infringement of U.S. Patent No. 8,425,908

316. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 315 of the Counterclaims above.

317. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 8,425,908 either directly or indirectly, and either literally or under the doctrine of equivalents.

318. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,425,908 either literally or under the doctrine of equivalents and is not liable for such infringement.

319. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,425,908 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 8,425,908.

320. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

321. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 8,425,908.

Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XXXIV
Declaratory Judgment of Invalidity of U.S. Patent No. 8,440,402

322. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 321 of the Counterclaims above.

323. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 8,440,402, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 8,440,402.

324. The claims of U.S. Patent No. 8,440,402 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 103 and/or 112.

325. U.S. Patent No. 8,440,402 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

326. The alleged invention of U.S. Patent No. 8,440,402 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 8,440,402 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 8,440,402 and would have had a reasonable expectation of success in doing so.

327. The subject matter claimed in U.S. Patent No. 8,440,402 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

328. U.S. Patent No. 8,440,402 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

329. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 8,440,402 are invalid.

330. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXXV
Declaratory Judgment of Non-infringement of U.S. Patent No. 8,440,402

331. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 330 of the Counterclaims above.

332. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 8,440,402 either directly or indirectly, and either literally or under the doctrine of equivalents.

333. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,440,402 either literally or under the doctrine of equivalents and is not liable for such infringement.

334. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,440,402 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 8,440,402.

335. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

336. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 8,440,402. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XXXVI
Declaratory Judgment of Invalidity of U.S. Patent No. 8,574,869

337. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 336 of the Counterclaims above.

338. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 8,574,869, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 8,574,869.

339. The claims of U.S. Patent No. 8,574,869 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 103 and/or 112.

340. U.S. Patent No. 8,574,869 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

341. The alleged invention of U.S. Patent No. 8,574,869 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 8,574,869 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 8,574,869 and would have had a reasonable expectation of success in doing so.

342. The subject matter claimed in U.S. Patent No. 8,574,869 fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

343. U.S. Patent No. 8,574,869 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

344. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 8,574,869 are invalid.

345. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXXVII
Declaratory Judgment of Non-infringement of U.S. Patent No. 8,574,869

346. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 345 of the Counterclaims above.

347. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 8,574,869 either directly or indirectly, and either literally or under the doctrine of equivalents.

348. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,574,869 either literally or under the doctrine of equivalents and is not liable for such infringement.

349. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 8,574,869 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 8,574,869.

350. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

351. Pfizer's BLA and the additional documents provided to Genentech clearly establish that Genentech does not have a reasonable basis to assert U.S. Patent No. 8,574,869. Therefore, Pfizer is entitled to an award of reasonable attorney fees under 35 U.S.C. § 285 because this case is exceptional.

COUNT XXXVIII
Declaratory Judgment of Invalidity of U.S. Patent No. 9,249,218

352. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 351 of the Counterclaims above.

353. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of U.S. Patent No. 9,249,218, based on Genentech's allegation in its First Amended Complaint that Pfizer has infringed or will infringe U.S. Patent No. 9,249,218.

354. The claims of U.S. Patent No. 9,249,218 are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and/or 112.

355. The alleged invention of U.S. Patent No. 9,249,218 was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

356. The alleged invention of U.S. Patent No. 9,249,218 was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

357. U.S. Patent No. 9,249,218 describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

358. The alleged invention of U.S. Patent No. 9,249,218 does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in U.S. Patent No. 9,249,218 is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of U.S. Patent No. 9,249,218 and would have had a reasonable expectation of success in doing so.

359. The subject matter claimed in U.S. Patent No. 9,249,218 fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

360. U.S. Patent No. 9,249,218 does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

361. The claims of U.S. Patent No. 9,249,218 are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they

do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

362. Pfizer is entitled to a judicial declaration that all claims of U.S. Patent No. 9,249,218 are invalid.

363. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

COUNT XXXIX
Declaratory Judgment of Non-infringement of U.S. Patent No. 9,249,218

364. Pfizer hereby incorporates by reference each and every allegation set forth in its Answer and Affirmative Defenses to the First Amended Complaint and Paragraphs 1 to 363 of the Counterclaims above.

365. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Pfizer's BLA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Pfizer's Product infringes, has infringed, or will infringe any valid and enforceable claim of U.S. Patent No. 9,249,218 either directly or indirectly, and either literally or under the doctrine of equivalents.

366. Pfizer has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 9,249,218 either literally or under the doctrine of equivalents and is not liable for such infringement.

367. Pfizer is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of U.S. Patent No. 9,249,218 either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, or importation of Pfizer's Product that is the subject of Pfizer's BLA has not

infringed, does not infringe, and will not infringe any valid and enforceable claims of U.S. Patent No. 9,249,218.

368. Such a declaration is necessary and appropriate at this time to determine the rights and obligations of the parties.

PRAYER FOR RELIEF

WHEREFORE, Pfizer prays that the Court enter judgment in its favor and against Plaintiffs as follows:

A. Adjudging and decreeing that Plaintiffs be denied all relief requested under their First Amended Complaint;

B. Declaring that Pfizer has not and will not infringe any valid and enforceable claim of any asserted patent;

C. Declaring that the patents described in Paragraphs 41 to 60 of Pfizer's Counterclaims are invalid;

D. Enjoining Plaintiffs and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice hereof from threatening or initiating infringement litigation against Pfizer or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Pfizer, or charging them either orally or in writing with infringement of any patent asserted herein against Pfizer;

E. Granting Pfizer Judgment in its favor on Plaintiffs' First Amended Complaint;

F. Denying Plaintiffs' request for injunctive relief;

G. Denying Plaintiffs' request for any monetary damages;

H. Finding that Plaintiffs did not have a good-faith basis for bringing this action;

I. Finding this case to be exceptional under 35 U.S.C. § 285 and awarding Pfizer its

costs and reasonable attorneys' fees;

J. An award of costs, expenses, and attorney fees pursuant to 28 U.S.C. § 1927;

K. An award of taxable costs;

L. An award of interest; and

M. Awarding any other such relief as is just and proper.

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