IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., Plaintiff, v. AMGEN INC., Defendant.	C.A. No. 18-924-CFC JURY TRIAL DEMANDED

THIRD AMENDED COMPLAINT

Plaintiff Genentech, Inc. ("Genentech") brings this Third Amended Complaint against Defendant Amgen Inc. ("Amgen") to address Amgen's infringement of patents relating to Genentech's groundbreaking breast cancer drug Herceptin®.

NATURE OF THE CASE

1. Breast cancer is a serious disease affecting over 2.8 million women in the United States. Approximately 20-25% of those women suffer from "HER2-positive" breast cancer. This is a particularly aggressive form of the disease characterized by overexpression of human epidermal growth factor receptor 2 (i.e., "HER2") proteins due to excessive HER2 gene amplification.

2. In the early 1990s, a diagnosis of HER2-positive breast cancer was effectively a death sentence: patients had an average life expectancy of only 18 months. The quality of life for those patients was markedly poor—the disease rapidly metastasized (*i.e.*, spread to other parts of the body). The only available treatments were invasive and disfiguring surgery and chemotherapeutic drugs with harsh side effects, and those treatments added little to the patient's life span.

3. The treatment of HER2-positive breast cancer, and the lives of millions of women suffering from the disease, changed dramatically with Genentech's development of Herceptin®. Herceptin® was the first drug of its kind—an antibody called trastuzumab that specifically targeted the biological mechanism that makes HER2-positive breast cancer such an aggressive form of the disease.

4. Although the scientific community was initially skeptical that such an antibody-based therapy could work, Genentech's specific methods of using Herceptin® proved remarkably effective. Indeed, after Genentech revealed the results of its clinical studies, the scientific community hailed Herceptin® as "the beginning of a whole new wave of biological drugs that modulate the causes of cancer"[1] and a sign that "the whole field of cancer research has turned a corner."[2]

5. Since FDA approval of Herceptin® in 1998, Genentech has worked diligently to develop new methods of using Herceptin®—including improved dosing schedules and broader indications—to expand access to therapy and improve the quality of life for millions of patients worldwide. This research has greatly expanded the number of patients who are able to benefit from Herceptin®. To further expand access to this lifesaving drug, Genentech also provides Herceptin® free of charge to patients who are uninsured or cannot afford treatment and assists with out-of-pocket prescription-related expenses. All told, Genentech has spent over two decades, and billions of dollars, developing Herceptin® into the life-saving drug it is today.

6. Genentech's groundbreaking work developing Herceptin® was the result of years of research from a group of talented scientists. The United States Patent and Trademark Office

[1] Gina Kolata and Lawrence M. Fisher, *Drugs to Fight Breast Cancer Near Approval*, NEW YORK TIMES (FRONT PAGE) (Sept. 3, 1998).

[2] Robert Langreth, *Breast-Cancer Drug Is Backed by FDA Panel*, Wall Street J. (Sept. 3, 1998).

recognized that innovative work by granting Genentech numerous patents claiming Herceptin®, its manufacture, and its use.

7. Seeking to profit from the success of Genentech's innovations, Amgen sought FDA approval of a biosimilar version of Herceptin® called ABP 980 (trastuzumab-anns). The FDA approved ABP 980, which Amgen markets under the tradename Kanjinti, on June 13, 2019 for the same label indications and usage as Herceptin®. In fact, Amgen relied upon Genentech's own studies demonstrating the safety and efficacy of Herceptin® to obtain approval of its biosimilar product.

8. In 2010, Congress provided a pathway for resolving patent disputes relating to biosimilar products through the Biologics Price Competition and Innovation Act ("BPCIA"). Amgen initially purported to follow the process outlined in the BPCIA, which requires biosimilar applicants and innovator companies to exchange certain information concerning the biosimilar product and the patents that may be infringed by the manufacture and sale of the biosimilar product. *See* 42 U.S.C. § 262(*l*).

9. Genentech thus brings this action for infringement pursuant to 35 U.S.C. § 271(e)(2) based upon Amgen's submission of its Abbreviated Biologics License Application ("aBLA") for ABP 980. Genentech also seeks a judgment of infringement under 35 U.S.C. § 271(a), (b), and (g) that Amgen's manufacture, use, offer to sell, sale, or importation into the United States of Amgen's biosimilar product has infringed the patents described below. Genentech also seeks 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 Amgen's biosimilar product would infringe the patents described below. Pursuant to 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283,

Genentech also seeks a preliminary and/or permanent injunction barring Amgen's manufacture, use, offer to sell, sale, or importation of its biosimilar product prior to the expiration of those patents. Genentech also seeks monetary damages, including lost profits and/or a reasonable royalty, for Amgen's infringement of Genentech's patents, and any further relief as this Court may deem just and proper.

PARTIES

10. Plaintiff Genentech is a corporation organized and existing under the laws of the State of Delaware with its corporate headquarters at 1 DNA Way, South San Francisco, California 94080.

11. Genentech was founded in 1976 and for four decades has been at the forefront of innovation in the field of therapeutic biotechnology. Today, Genentech employs a large number of researchers, scientists, and post-doctoral staff members who routinely publish in top peer-reviewed journals and are among the leaders in total citations to their work by researchers. Genentech currently markets numerous approved pharmaceutical and biologic drugs for a range of serious or life-threatening medical conditions, including various forms of cancer, heart attacks, strokes, rheumatoid arthritis, and respiratory diseases.

12. Upon information and belief, Defendant Amgen is a company organized and existing under the laws of the State of Delaware with its principal place of business located at One Amgen Center Drive, Thousand Oaks, California 91320.

13. Amgen is, among other things, engaged in the development of biologic drugs, including a biosimilar version of Genentech's Herceptin® product, ABP 980 ("Amgen's aBLA product"). Upon information and belief, Amgen's aBLA product is or will be distributed and sold in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

14. This action arises under the BPCIA, 42 U.S.C. § 262(*l*) and the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, and 1338.

15. Venue is proper with respect to Amgen in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) because Amgen is incorporated in Delaware.

16. This Court has personal jurisdiction over Amgen because it is incorporated in Delaware. In addition, among other things, Amgen has been approved by the FDA to market its aBLA product and has announced that its aBLA product is now available to customers in the United States, including in Delaware.

THE PARTIES' EXCHANGES UNDER THE BPCIA

17. On July 31, 2017, Amgen announced that it had submitted an aBLA for ABP 980 to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Amgen aBLA product, a biosimilar version of trastuzumab, which is subject to BLA No. 103792 to Genentech.[3]

18. The FDA accepted Amgen's aBLA for review on September 26, 2017.

19. On October 16, 2017, Amgen provided Genentech with a copy of Amgen's aBLA, which included a small amount of manufacturing information.

20. On November 3, 2017, Amgen provided Genentech with additional manufacturing information regarding Amgen's aBLA product.

[3] http://www.amgen.com/media/news-releases/2017/07/amgen-and-allergan-submit-biosimilar-biologics-license-application-for-abp-980-to-us-food-and-drug-administration/

21. Genentech responded on November 20, 2017, to identify deficiencies in Amgen's production of manufacturing information and request specific information concerning the manufacture of Amgen's biosimilar product. Amgen provided additional manufacturing information on December 1, 2017, and December 4, 2017, but did not satisfy its disclosure obligations. Genentech then responded on December 15, 2017, to explain that Amgen's production was deficient in that it failed to provide all of the requested information in contravention of 42 U.S.C. § 262(*l*)(2).

22. Amgen did not disclose all of the information relevant to establishing whether the manufacture of Amgen's aBLA product will infringe each of the patents identified on Genentech's operative list pursuant to 42 U.S.C. § 262(*l*)(3)(A), despite Genentech's request that Amgen provide sufficient "other information that describes the process or processes used to manufacture" as required by 42 U.S.C. § 262(*l*)(A). Amgen's failure to provide sufficient information under those circumstances justifies Genentech's contention that manufacturing Amgen's aBLA product will infringe such patents.

23. Despite Amgen's non-compliance (and without waiving Genentech's objection to such non-compliance), Genentech provided its operative list of 36 patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) on December 15, 2017.

24. Amgen replied on December 20, 2017, to assert its position that it had complied with its disclosure obligations based on Amgen's earlier production of its aBLA and two manufacturing documents.

25. Genentech responded on December 27, 2017, to reiterate that Amgen's production was insufficient to provide Genentech with a complete understanding of Amgen's trastuzumab manufacturing process.

26. Amgen replied on February 1, 2018, with an additional supplemental production.

27. On February 6, 2018, Genentech supplemented its § 262(*l*)(3)(A) list to include a newly issued manufacturing patent: U.S. Patent No. 9,868,760.

28. On February 13, 2018, Amgen purported to provide its detailed statement concerning non-infringement and invalidity pursuant to 42 U.S.C. § 262(*l*)(3)(B) ("Amgen's 3B Statement"). Amgen's 3B Statement was deficient in numerous ways. For example, it—like Amgen's document productions—failed to fully describe Amgen's manufacturing process, such that Genentech was unable to evaluate many of Amgen's non-infringement arguments.

29. On February 27, 2018, March 12, 2018, and April 13, 2018, Amgen produced additional documents regarding Amgen's correspondence with the FDA regarding its aBLA submission. These supplemental productions still failed to fully describe Amgen's manufacturing process.

30. On April 13, 2018, and subject to its objections, Genentech provided its response to Amgen's 3C Statement pursuant to 42 U.S.C. § 262(*l*)(3)(C) ("Genentech's 3C Statement"). Genentech included responses to Amgen's non-infringement and invalidity statements for each of the patents addressed in Amgen's 3B Statement and maintained that ABP 980 will infringe at least 18 Genentech patents. With its 3C Statement, Genentech proposed that Amgen agree that all 18 of these patents be included in a first-phase infringement action under § 262(*l*)(6).

31. On April 25, 2018, and April 30, 2018, Amgen produced additional documents regarding Amgen's correspondence with the FDA regarding its aBLA submission. These supplemental productions still failed to fully describe Amgen's manufacturing process.

32. After Genentech served its 3C Statement, the parties initiated negotiations under § 262(*l*)(4). On May 23, 2018, Genentech and Amgen agreed that the 37 patents addressed in the

exhibits to Genentech's 3C Statement shall be the subject of an action for patent infringement under § 262(*l*)(6).

33. In light of the parties' agreement, § 262(*l*)(6)(A) required Genentech to bring an action for patent infringement with respect to each of the 37 patents that were part of the parties' agreement. This action is Genentech's action pursuant to § 262(*l*)(6)(A).

34. On May 15, 2018, while the parties' negotiations pursuant to § 262(*l*)(4) were underway, Amgen purported to notify Genentech pursuant to 42 U.S.C. § 262(*l*)(8)(A) that it intends to commence commercial marketing of ABP 980 in the United States no earlier than 180 from May 15, 2018 (i.e., October 28, 2018).

35. On June 21, 2018, Genentech and City of Hope (collectively, "Plaintiffs") sued Amgen for infringement of all 37 patents that the parties agreed to litigate during their § 262(*l*)(4) negotiations. On July 19, 2018, Plaintiffs and Amgen stipulated to dismiss with prejudice all claims for infringement of U.S. Patent Nos. 6,242,177, 6,489,447, 6,586,206, 6,870,034, 7,449,184, 7,501,122, 8,044,017, 8,314,225, 8,357,301, 8,460,895, 8,691,232, 8,710,196, 8,771,988, 9,047,438, 9,080,183, 9,428,766, 9,487,809, 9,493,744, and 9,868,760 relating to ABP 980, subject to certain conditions.

36. In a letter dated November 7, 2018, pursuant to the Court's scheduling order (D.I. 44), Genentech identified to Amgen a narrowed list of 10 patents which it intended to assert against Amgen in this litigation. In the same letter, Genentech notified Amgen that it intended to assert infringement of claims 10 and 11 of U.S. App. No. 14/073,659 ("the '659 application") once issued by the U.S. Patent Office. On December 25, 2018, the '659 application issued as U.S. Patent No. 10,160,811 ("the '811 patent"). Claims 6 and 7 of the '811 patent as issued

correspond to claims 10 and 11 of the '659 application. Genentech further supplemented its § 262(*l*)(3)(A) list to include the '811 patent.

37. On July 23, 2019, Plaintiffs and Amgen stipulated to dismiss with prejudice all claims for infringement of U.S. Patent Nos. 6,331,415, 7,923,221, 6,407,213, 6,417,335, 9,249,218, 6,121,428, and 6,620,918 relating to ABP 980. City of Hope was dismissed as a plaintiff to this case through that stipulation. That stipulation was so-ordered by the Court on July 24, 2019. D.I. 325

38. On August 2, 2019, Genentech and Amgen stipulated to a judgment of non-infringement of U.S. Patent Nos. 8,512,983 and 9,714,293 under the Court's claim construction of "a glutamine-free production culture medium," while preserving Genentech's ability to challenge that claim construction on appeal. That stipulation was so-ordered by the Court on August 20, 2019. D.I. 340.

AMGEN'S aBLA PRODUCT

39. Amgen has publicly stated that its aBLA product is biosimilar to Herceptin®. For example, Amgen has issued press releases claiming that ABP 980 is "a biosimilar candidate to Herceptin®" and "ABP 980 is a biosimilar candidate to trastuzumab,"[4] and it has announced the results of an Amgen study that purports to conclude that "[e]fficacy, safety and immunogenicity data support ABP 980 as a trastuzumab biosimilar."[5]

40. Given Amgen's claim of biosimilarity, Amgen's aBLA product must "utilize the same mechanism or mechanisms of action [as Herceptin®] for the condition or conditions of use

[4] http://www.amgen.com/media/news-releases/2017/07/amgen-and-allergan-submit-biosimilar-biologics-license-application-for-abp-980-to-us-food-and-drug-administration/

[5] https://www.amgen.com/media/news-releases/2017/09/amgen-and-allergan-present-phase-3-data-on-biosimilar-trastuzumab-candidate-abp-980-at-the-european-society-for-medical-oncology-2017-congress/

prescribed, recommended, or suggested in the proposed labeling." 42 U.S.C. § 262(k)(2)(A)(i)(II).

41. Under 35 U.S.C. § 271(e)(2)(C), Amgen has committed a statutory act of patent infringement with respect to patents identified by Genentech under 42 U.S.C. § 262(*l*)(3), through the submission of its aBLA application for ABP 980.

42. On June 13, 2019, Amgen's aBLA product was approved by the FDA.

43. On July 18, 2019, Amgen issued a press release announcing that "KANJINTI™ (trastuzumab-anns), a biosimilar to Herceptin® (trastuzumab), [is] now available in the United States (U.S.)."[6]

44. Since making its aBLA product available to customers in the United States, Amgen has stated that it "has received confirmation from its customers that they have begun administering Kanjinti® to cancer patients."[7]

GENENTECH'S ASSERTED PATENTS

45. Genentech has spent over two decades and significant resources developing Herceptin®, and the USPTO has awarded to Genentech numerous patents on innovations resulting from this massive undertaking.

46. Upon information and belief, Amgen's aBLA product infringes or will infringe at least the following patents, which Genentech has asserted in this lawsuit: U.S. Patent No. 7,846,441, U.S. Patent No. 7,892,549, U.S. Patent No. 6,627,196, U.S. Patent No. 7,371,379,

[6] http://investors.amgen.com/news-releases/news-release-details/amgen-and-allergans-mvasitm-bevacizumab-awwb-and-kanjintitm

[7] Second Declaration of Robert Jacobson in Support of Amgen Inc.'s Opposition to Genentech, Inc.'s Emergency Motion for an Injunction Pending Appeal, *Genentech, Inc. v. Amgen Inc.*, No. 19-2156 (Fed. Cir.), ECF No. 28 (July 29, 2019).

U.S. Patent No. 10,160,811, U.S. Patent No. 8,574,869, U.S. Patent No. 7,993,834, U.S. Patent No. 8,076,066, and U.S. Patent No. 8,440,402.

The Combination Chemotherapy Patents

47. U.S. Patent No. 7,846,441 ("the '441 patent"), claims the administration of Herceptin® in combination with a chemotherapy agent known as a taxoid, in the absence of an anthracycline derivative (another chemotherapy agent) in an amount effective to extend time to disease progression without overall increase in severe adverse events. This specific method of treatment unexpectedly resulted in a significant improvement in patient outcomes. It nearly doubled the time until disease progression compared to treatment using a taxoid alone, and it also avoided the serious cardiotoxicity associated with Herceptin® in combination with anthracycline derivatives that unexpectedly presented during the Herceptin® clinical trials.

48. The '441 patent, titled "Treatment with Anti-ErbB2 Antibodies," was duly and legally issued by the Patent Office on December 7, 2010. A true and correct copy of the '441 patent is attached as Exhibit A. Genentech is the owner by assignment of the '441 patent.

49. U.S. Patent No. 7,892,549 ("the '549 patent") is a continuation to the '441 patent that claims a method of treating a patient with HER2-positive breast cancer by administering Herceptin® in combination with a taxoid and a further growth inhibitory agent or further therapeutic agent.

50. The '549 patent, titled "Treatment with Anti-ErbB2 Antibodies," was duly and legally issued by the Patent Office on February 22, 2011. A true and correct copy of the '549 patent is attached as Exhibit B. Genentech is the owner by assignment of the '549 patent.

The Method of Administration Patents

51. U.S. Patent Nos. 6,627,196, 7,371,379, and 10,160,811 (collectively, the "Method of Administration Patents") generally cover the most common administration method for Herceptin®: an initial dose of 8 mg/kg, followed by 6 mg/kg doses once every three weeks. Herceptin® was initially approved for administration on a weekly regimen, but Genentech discovered that the drug could be dosed only once every three weeks without reducing safety or effectiveness. The discovery of three-weekly dosing has had a marked impact on patients' quality of life by providing the same life-saving effects of Herceptin® while allowing patients to receive treatment less frequently.

52. U.S. Patent No. 6,627,196 ("'196 patent"), titled "Dosages for Treatment with Anti-ErbB2 Antibodies," was duly and legally issued by the Patent Office on September 30, 2003. A true and correct copy of the '196 patent is attached as Exhibit C. Genentech is the owner by assignment of the '196 patent.

53. U.S. Patent No. 7,371,379 ("the '379 patent"), titled "Dosages for Treatment with Anti-ErbB2 Antibodies," was duly and legally issued by the Patent Office on May 13, 2008. A true and correct copy of the '379 patent is attached as Exhibit D. Genentech is the owner by assignment of the '379 patent.

54. U.S. Patent No. 10,160,811 ("the '811 patent"), titled "Treatment with Anti-ErbB2 Antibodies," was duly and legally issued by the Patent Office on December 25, 2018. A true and correct copy of the '811 patent is attached as Exhibit E. Genentech is the owner by assignment of the '811 patent.

HER2 Diagnostic Patents

55. U.S. Patent Nos. 7,993,834, 8,076,066, and 8,440,402 claim novel techniques for identifying patients who might benefit from trastuzumab therapy using gene amplification techniques even where immunohistochemistry techniques suggest that the patient may not overexpress HER2.

56. U.S. Patent No. 7,993,834 ("the '834 patent"), titled "Detection of ErbB2 Gene Amplification to Increase the Likelihood of the Effectiveness of ErbB2 Antibody Breast Cancer Therapy," was duly and legally issued by the Patent Office on August 9, 2011. A true and correct copy of the '834 patent is attached as Exhibit F. Genentech is the owner by assignment of the '834 patent.

57. U.S. Patent No. 8,076,066 ("the '066 patent"), titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," was duly and legally issued by the Patent Office on December 13, 2011. A true and correct copy of the '066 patent is attached as Exhibit G. Genentech is the owner by assignment of the '066 patent.

58. U.S. Patent No. 8,440,402 ("the '402 patent"), titled "Gene Detection Assay for Improving the Likelihood of an Effective Response to a HER2 Antibody Cancer Therapy," was duly and legally issued by the Patent Office on May 14, 2013. A true and correct copy of the '402 patent is attached as Exhibit H. Genentech is the owner by assignment of the '402 patent.

The Kao Patent

59. U.S. Patent No. 8,574,869 ("the '869 patent"), titled "Prevention of Disulfide Bond Reduction During Recombinant Production of Polypeptides," was duly and legally issued

by the Patent Office on November 5, 2013. A true and correct copy of the ’869 patent is attached as Exhibit I. Genentech is the owner by assignment of the ’869 patent.

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

60. Genentech incorporates by reference paragraphs 1-59 as if fully set forth herein.

61. Upon review of publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent infringement, either literally or under the doctrine of equivalents, could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of ABP 980 prior to the expiration of the ’441 patent. Genentech included the ’441 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech also provided Amgen with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its opinion that the ’441 patent will be infringed by the commercial marketing of ABP 980, pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

62. Amgen submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of ABP 980 before the expiration of the ’441 patent. Amgen has therefore committed a technical act of infringement of one or more claims of the ’441 patent under 35 U.S.C. § 271(e)(2)(C)(i).

63. Likewise, based on publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Amgen has infringed or will infringe the ’441 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and its ABP 980 drug product, as explained in Genentech’s 3C Statement. Such

infringement either has occurred or is imminent because, among other things, Amgen has announced that its aBLA product is now available in the United States.

64. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Amgen's manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and Amgen's ABP 980 drug product has infringed or will infringe the '441 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

65. Amgen has knowledge of and is aware of the '441 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. Amgen's infringement of the '441 patent is willful.

66. By obtaining FDA approval of a package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Amgen aBLA product, Amgen has an affirmative intent to actively induce infringement by others of one or more claims of the '441 patent, either literally or under the doctrine of equivalents.

67. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Amgen aBLA product according to Amgen's package insert and, therefore, will directly infringe at least one claim of the '441 patent, either literally or under the doctrine of equivalents.

68. Upon information and belief, Amgen knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '441 patent, either literally or under the doctrine of equivalents, by at least Amgen's package insert for the Amgen aBLA product.

69. Pursuant to 35 U.S.C. § 284, Genentech is entitled to damages, including lost profits and/or a reasonable royalty, for Amgen's infringement of the '441 patent.

70. Genentech has suffered or will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '441 patent. Genentech has no adequate remedy at law.

71. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA product.

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

72. Genentech incorporates by reference paragraphs 1-59 as if fully set forth herein.

73. Upon review of publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent infringement, either literally or under the doctrine of equivalents, could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of ABP 980 prior to the expiration of the '549 patent. Genentech included the '549 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech also provided Amgen with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its opinion that the '549 patent will be infringed by the commercial marketing of ABP 980, pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

74. Amgen submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of ABP 980 before the expiration of the '549 patent. Amgen has

therefore committed a technical act of infringement of one or more claims of the ’549 patent under 35 U.S.C. § 271(e)(2)(C)(i).

75. Likewise, based on publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Amgen has infringed or will infringe the ’549 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and its ABP 980 drug product, as explained in Genentech’s 3C Statement. Such infringement either has occurred or is imminent because, among other things, Amgen has announced that its aBLA product is now available in the United States.

76. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Amgen’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and Amgen’s ABP 980 drug product has infringed or will infringe the ’549 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

77. Amgen has knowledge of and is aware of the ’549 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. Amgen’s infringement of the ’549 patent is willful.

78. By obtaining FDA approval of a package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Amgen aBLA product, Amgen has an affirmative intent to actively induce infringement by others of one or more claims of the ’549 patent, either literally or under the doctrine of equivalents.

79. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe

and/or administer the Amgen aBLA product according to Amgen's package insert and, therefore, will directly infringe at least one claim of the '549 patent, either literally or under the doctrine of equivalents.

80. Upon information and belief, Amgen knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '549 patent, either literally or under the doctrine of equivalents, by at least Amgen's package insert for the Amgen aBLA product.

81. Pursuant to 35 U.S.C. § 284, Genentech is entitled to damages, including lost profits and/or a reasonable royalty, for Amgen's infringement of the '549 patent.

82. Genentech has suffered or will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '549 patent. Genentech has no adequate remedy at law.

83. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA product.

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

84. Genentech incorporates by reference paragraphs 1-59 as if fully set forth herein.

85. Upon review of publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent infringement, either literally or under the doctrine of equivalents, could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of ABP 980 prior to the expiration of the '196

patent. Genentech included the ’196 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech also provided Amgen with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its opinion that the ’196 patent will be infringed by the commercial marketing of ABP 980, pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

86. Amgen submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of ABP 980 before the expiration of the ’196 patent. Amgen has therefore committed a technical act of infringement of one or more claims of the ’196 patent under 35 U.S.C. § 271(e)(2)(C)(i).

87. Likewise, based on publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Amgen has infringed or will infringe the ’196 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and its ABP 980 drug product, as explained in Genentech’s 3C Statement and Genentech’s infringement contentions served in this case. Such infringement either has occurred or is imminent because, among other things, Amgen has announced that its aBLA product is now available in the United States.

88. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Amgen’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and Amgen’s ABP 980 drug product has infringed or will infringe the ’196 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

89. Amgen has knowledge of and is aware of the ’196 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. Amgen’s infringement of the ’196 patent is willful.

90. By obtaining FDA approval of a package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Amgen aBLA product, Amgen has an affirmative intent to actively induce infringement by others of one or more claims of the ’196 patent, either literally or under the doctrine of equivalents.

91. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Amgen aBLA product according to Amgen’s package insert and, therefore, will directly infringe at least one claim of the ’196 patent, either literally or under the doctrine of equivalents.

92. Upon information and belief, Amgen knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’196 patent, either literally or under the doctrine of equivalents, by at least Amgen’s package insert for the Amgen aBLA product.

93. Pursuant to 35 U.S.C. § 284, Genentech is entitled to damages, including lost profits and/or a reasonable royalty, for Amgen’s infringement of the ’196 patent.

94. Genentech has suffered or will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the ’196 patent. Genentech has no adequate remedy at law.

95. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA product.

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

96. Genentech incorporates by reference paragraphs 1-59 as if fully set forth herein.

97. Upon review of publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent infringement, either literally or under the doctrine of equivalents, could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of ABP 980 prior to the expiration of the '379 patent. Genentech included the '379 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech also provided Amgen with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its opinion that the '379 patent will be infringed by the commercial marketing of ABP 980, pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

98. Amgen submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of ABP 980 before the expiration of the '379 patent. Amgen has therefore committed a technical act of infringement of one or more claims of the '379 patent under 35 U.S.C. § 271(e)(2)(C)(i).

99. Likewise, based on publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Amgen has infringed or will infringe the '379 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and its ABP 980 drug product, as explained in Genentech's 3C Statement and Genentech's infringement contentions served in this case. Such infringement either has occurred or is imminent because, among other things, Amgen has announced that its aBLA product is now available in the United States.

100. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Amgen's manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and Amgen's ABP 980 drug product has infringed or will infringe the '379 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

101. Amgen has knowledge of and is aware of the '379 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. Amgen's infringement of the '379 patent is willful.

102. By obtaining FDA approval of a package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Amgen aBLA product, Amgen has an affirmative intent to actively induce infringement by others of one or more claims of the '379 patent, either literally or under the doctrine of equivalents.

103. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Amgen aBLA product according to Amgen's package insert and, therefore, will directly infringe at least one claim of the '379 patent, either literally or under the doctrine of equivalents.

104. Upon information and belief, Amgen knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '379 patent, either literally or under the doctrine of equivalents, by at least Amgen's package insert for the Amgen aBLA product.

105. Pursuant to 35 U.S.C. § 284, Genentech is entitled to damages, including lost profits and/or a reasonable royalty, for Amgen's infringement of the '379 patent.

106. Genentech has suffered or will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the ’379 patent. Genentech has no adequate remedy at law.

107. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA product.

COUNT V
INFRINGEMENT OF U.S. PATENT NO. 10,160,811

108. Genentech incorporates by reference paragraphs 1-59 as if fully set forth herein.

109. Upon review of publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent infringement, either literally or under the doctrine of equivalents, could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of ABP 980 prior to the expiration of the ’811 patent. Genentech included the ’811 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) as supplemented.

110. Amgen submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of ABP 980 before the expiration of the ’811 patent. Amgen has therefore committed a technical act of infringement of one or more claims of the ’811 patent under 35 U.S.C. § 271(e)(2)(C)(i).

111. Likewise, based on publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Amgen has infringed or will infringe the ’811 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the

manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and its ABP 980 drug product as explained in Genentech's infringement contentions served in this case. Such infringement either has occurred or is imminent because, among other things, Amgen has announced that its aBLA product is now available in the United States.

112. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Amgen's manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and Amgen's ABP 980 drug product has infringed or will infringe the '811 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

113. Amgen has knowledge of and is aware of the '811 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) as supplemented and the filing of this Complaint. Amgen's infringement of the '811 patent is willful.

114. By obtaining FDA approval of a package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Amgen aBLA product, Amgen has an affirmative intent to actively induce infringement by others of one or more claims of the '811 patent, either literally or under the doctrine of equivalents.

115. Upon information and belief, Amgen is aware, has knowledge, and/or is willfully blind to the fact that patients will administer and/or use and medical practitioners will prescribe and/or administer the Amgen aBLA product according to Amgen's package insert and, therefore, will directly infringe at least one claim of the '811 patent, either literally or under the doctrine of equivalents.

116. Upon information and belief, Amgen knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '811 patent, either literally

or under the doctrine of equivalents, by at least Amgen's package insert for the Amgen aBLA product.

117. Pursuant to 35 U.S.C. § 284, Genentech is entitled to damages, including lost profits and/or a reasonable royalty, for Amgen's infringement of the '811 patent.

118. Genentech has suffered or will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '811 patent. Genentech has no adequate remedy at law.

119. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA product.

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

120. Genentech incorporates by reference paragraphs 1-59 as if fully set forth herein.

121. Upon review of publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent infringement, either literally or under the doctrine of equivalents, could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of ABP 980 prior to the expiration of the '834 patent. Genentech included the '834 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech also provided Amgen with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its opinion that the '834 patent will be infringed by the commercial marketing of ABP 980, pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

122. Amgen submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of ABP 980 before the expiration of the ’834 patent. Amgen has therefore committed a technical act of infringement of one or more claims of the ’834 patent under 35 U.S.C. § 271(e)(2)(C)(i).

123. Likewise, based on publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Amgen has infringed or will infringe the ’834 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and its ABP 980 drug product, as explained in Genentech’s 3C Statement and Genentech’s infringement contentions served in this case. Such infringement either has occurred or is imminent because, among other things, Amgen has announced that its aBLA product is now available in the United States.

124. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Amgen’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and Amgen’s ABP 980 drug product has infringed or will infringe the ’834 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

125. Amgen has knowledge of and is aware of the ’834 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. Amgen’s infringement of the ’834 patent is willful.

126. By obtaining FDA approval of a package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Amgen aBLA product, Amgen has an affirmative intent to actively induce infringement by others of one or more claims of the ’834 patent, either literally or under the doctrine of

equivalents.

127. Pursuant to 35 U.S.C. § 284, Genentech is entitled to damages, including lost profits and/or a reasonable royalty, for Amgen's infringement of the '834 patent.

128. Genentech has suffered or will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '834 patent. Genentech has no adequate remedy at law.

129. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA product.

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

130. Genentech incorporates by reference paragraphs 1-59 as if fully set forth herein.

131. Upon review of publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent infringement, either literally or under the doctrine of equivalents, could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of ABP 980 prior to the expiration of the '066 patent. Genentech included the '066 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech also provided Amgen with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its opinion that the '066 patent will be infringed by the commercial marketing of ABP 980, pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

132. Amgen submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of ABP 980 before the expiration of the '066 patent. Amgen has

therefore committed a technical act of infringement of one or more claims of the ’066 patent under 35 U.S.C. § 271(e)(2)(C)(i).

133. Likewise, based on publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Amgen has infringed or will infringe the ’066 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and its ABP 980 drug product, as explained in Genentech’s 3C Statement and Genentech’s infringement contentions served in this case. Such infringement either has occurred or is imminent because, among other things, Amgen has announced that its aBLA product is now available in the United States.

134. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Amgen’s manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and Amgen’s ABP 980 drug product has infringed or will infringe the ’066 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

135. Amgen has knowledge of and is aware of the ’066 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. Amgen’s infringement of the ’066 patent is willful.

136. Pursuant to 35 U.S.C. § 284, Genentech is entitled to damages, including lost profits and/or a reasonable royalty, for Amgen’s infringement of the ’066 patent.

137. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the ’066 patent. Genentech has no adequate remedy at law.

138. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA product.

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

139. Genentech incorporates by reference paragraphs 1-59 as if fully set forth herein.

140. Upon review of publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent infringement, either literally or under the doctrine of equivalents, could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of ABP 980 prior to the expiration of the ’402 patent. Genentech included the ’402 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech also provided Amgen with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its opinion that the ’402 patent will be infringed by the commercial marketing of ABP 980, pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

141. Amgen submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of ABP 980 before the expiration of the ’402 patent. Amgen has therefore committed a technical act of infringement of one or more claims of the ’402 patent under 35 U.S.C. § 271(e)(2)(C)(i).

142. Likewise, based on publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Amgen has infringed or will infringe the ’402 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug

substance and its ABP 980 drug product, as explained in Genentech's 3C Statement. Such infringement either has occurred or is imminent because, among other things, Amgen has announced that its aBLA product is now available in the United States.

143. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Amgen's manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and Amgen's ABP 980 drug product has infringed or will infringe the '402 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

144. Amgen has knowledge of and is aware of the '402 patent, including due to Genentech's disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. Amgen's infringement of the '402 patent is willful.

145. Pursuant to 35 U.S.C. § 284, Genentech is entitled to damages, including lost profits and/or a reasonable royalty, for Amgen's infringement of the '402 patent.

146. Genentech has suffered or will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the '402 patent. Genentech has no adequate remedy at law.

147. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA product.

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

148. Genentech incorporates by reference paragraphs 1-59 as if fully set forth herein.

149. Upon review of publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Genentech believes that a claim of patent

infringement, either literally or under the doctrine of equivalents, could reasonably be asserted by Genentech if a person not licensed by Genentech engaged in the making, using, offering to sell, selling, or importing into the United States of ABP 980 prior to the expiration of the '869 patent. Genentech included the '869 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). Genentech also provided Amgen with a detailed statement that describes, on a claim-by-claim basis, the factual and legal basis of its opinion that the '869 patent will be infringed by the commercial marketing of ABP 980, pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

150. Amgen submitted its aBLA to obtain approval to engage in the commercial manufacture, use, or sale of ABP 980 before the expiration of the '869 patent. Amgen has therefore committed a technical act of infringement of one or more claims of the '869 patent under 35 U.S.C. § 271(e)(2)(C)(i).

151. Likewise, based on publicly available information and/or information provided by Amgen pursuant to 42 U.S.C. § 262(*l*)(2), Amgen has infringed or will infringe the '869 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (g) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and its ABP 980 drug product, as explained in Genentech's 3C Statement and Genentech's infringement contentions served in this case. Such infringement either has occurred or is imminent because, among other things, Amgen has announced that its aBLA product is now available in the United States.

152. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is entitled to a declaratory judgment that Amgen's manufacture, importation, sale, offer for sale, use, and promotion of the use of the ABP 980 drug substance and Amgen's ABP 980 drug product has infringed or will infringe the '869 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

153. Amgen has knowledge of and is aware of the ’869 patent, including due to Genentech’s disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) and the filing of this Complaint. Amgen’s infringement of the ’869 patent is willful.

154. Pursuant to 35 U.S.C. § 284, Genentech is entitled to damages, including lost profits and/or a reasonable royalty, for Amgen’s infringement of the ’869 patent.

155. Genentech has suffered or will suffer irreparable injury for which damages are an inadequate remedy unless Amgen is enjoined from infringing the claims of the ’869 patent. Genentech has no adequate remedy at law.

156. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), 35 U.S.C. § 271(a), (b), (g), and/or 35 U.S.C. § 283 preventing Amgen from the commercial manufacture, use, offer to sell, or sale within the United States of the Amgen aBLA product.

PRAYER FOR RELIEF

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

a. a judgment that Amgen has infringed or induced infringement of one or more claims of the asserted patents under 35 U.S.C. § 271(e)(2)(C);

b. a judgment that Amgen has infringed or will infringe, or has induced or will induce infringement, of one or more claims of the asserted patents by engaging in the manufacture, import, offer for sale, sale, or use within the United States of the Amgen aBLA product before the expirations of the asserted patents under 35 U.S.C. § 271(a), (b), and/or (g);

c. preliminary and/or permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins Amgen, its officers, partners, agents, servants,

employees, parents, subsidiaries, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with Amgen and/or its successors or assigns from infringing the asserted patents, or contributing to or inducing anyone to do the same, by acts including the manufacture, use, offer to sell, sale, distribution, or importation of any current or future versions of a product that infringes, or the use or manufacturing of which infringes the asserted patents;

d. monetary damages, including lost profits and/or a reasonable royalty, and an accounting and/or ongoing royalty for any post-judgment infringement;

e. a judgment that Amgen's infringement was willful and enhancement of any monetary damages pursuant to 35 U.S.C. § 284;

f. a declaration that this is an exceptional case and an award to Plaintiffs of their attorneys' fees, costs, and expenses pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

g. such other relief as this Court may deem just and proper.

JURY DEMAND

Plaintiff Genentech, Inc., by and through its undersigned counsel, hereby demand, pursuant to Federal Rule of Civil Procedure 38, a trial by jury on all claims so triable in this action.

Dated: August 27, 2019

Respectfully submitted,

/s/ Daniel M. Silver

Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
McCARTER & ENGLISH, LLP
Renaissance Centre
405 North King Street, 8th Floor
Wilmington, DE 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
ajoyce@mccarter.com

Counsel for Plaintiff Genentech, Inc.

Of Counsel:

William F. Lee
Lisa J. Pirozzolo
Emily R. Whelan
Kevin S. Prussia
Andrew J. Danford
WILMER CUTLER PICKERING
HALE AND DORR LLP
60 State Street
Boston, MA 02109
william.lee@wilmerhale.com
lisa.pirozzolo@wilmerhale.com
emily.whelan@wilmerhale.com
kevin.prussia@wilmerhale.com
andrew.danford@wilmerhale.com

Robert J. Gunther Jr.
WILMER CUTLER PICKERING
HALE AND DORR LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
robert.gunther@wilmerhale.com

Daralyn J. Durie
Adam R. Brausa
DURIE TANGRI LLP
217 Leidesdorff St.
San Francisco, CA 94111
ddurie@durietangri.com
abrausa@durietangri.com