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.	Civil Action No. 17-1672-GMS

FIRST AMENDED COMPLAINT

Plaintiffs Genentech, Inc. ("Genentech") and City of Hope bring this First Amended Complaint for declaratory and injunctive relief against Defendant Pfizer Inc. to address Pfizer's infringement of 20 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.

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[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).

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 recognized that innovative work by granting Genentech numerous patents claiming Herceptin®, its manufacture, and its use. And as one of the pioneers in the biotechnology field, Genentech collaborated with scientists at research institutions such as the City of Hope to make foundational inventions, such as efficient techniques for making antibodies that can be used as drugs.

7. Seeking to profit from the success of Plaintiffs' innovations, Pfizer is seeking FDA approval of a biosimilar version of Herceptin® called PF-05280014. PF-05280014 is a copycat product for which Pfizer is seeking the same label indications and usage as Herceptin®. In fact, Pfizer is relying 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"). Pfizer initially purported to follow the process outlined in the BPCIA, which requires biosimilar applicants and innovator companies 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*). However, before completing the process required by the statute, Pfizer purported to provide Genentech with a notice pursuant to 42 U.S.C. § 262(*l*)(8)(A) on November 17, 2017, that it intends to market PF-05280014 in the United States. That notice of commercial marketing allows Plaintiffs to bring an immediate action for injunctive and declaratory relief concerning the patents that would be infringed by the manufacture and sale of Pfizer's biosimilar product.

9. Plaintiffs thus bring this action for infringement pursuant to 35 U.S.C. § 271(e)(2) based upon Pfizer's submission of its aBLA for PF-05280014. Plaintiffs also 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 described below. Pursuant to 42 U.S.C. § 262(*l*)(8)(B), Plaintiffs also seek a preliminary and/or permanent injunction barring Pfizer's manufacture, use, offer to sell, sale, or importation of its biosimilar product prior to the expiration of those patents. In the event that Pfizer imports or launches its biosimilar product and/or otherwise practice the patented inventions in the United States prior to the expiration of those patents, Plaintiffs also seek monetary damages, including lost profits, 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. Plaintiff City of Hope is a California not-for-profit organization, with its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

13. Founded in 1913, the City of Hope is a leading research hospital that incorporates cutting-edge research into patient care for cancer, diabetes, and other serious diseases.

14. Upon information and belief, Defendant Pfizer Inc. is a company organized and existing under the laws of the State of Delaware with its principal place of business located at 235 East 42nd Street, New York, NY 10017.

15. Pfizer Inc. is, among other things, engaged in the development of biologic drugs, including a proposed biosimilar version of Genentech's Herceptin® product, PF-05280014 ("Pfizer's aBLA product"). Upon information and belief, Pfizer's aBLA product will be distributed and sold in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

16. 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 and 1338.

17. Venue is proper with respect to Pfizer Inc. in this Court pursuant to 28 U.S.C. § 1400(b) because Pfizer is incorporated in Delaware.

18. This Court has personal jurisdiction over Pfizer because it is incorporated in Delaware. In addition, among other things, Pfizer has filed an Abbreviated Biologics License Application ("aBLA") No. 761081 with the FDA seeking approval to market its aBLA product, which reliably indicates that it will market its proposed biosimilar product in Delaware if approved.

THE PARTIES' EXCHANGES UNDER THE BPCIA

19. Pfizer submitted aBLA number 761081 to the FDA seeking approval for the commercial manufacture, use, offer for sale, or sale of the Pfizer aBLA product, a biosimilar version of trastuzumab, which is subject to BLA No. 103792 to Genentech, Inc.

20. The FDA accepted Pfizer's aBLA for review on August 21, 2017.

21. On August 28, 2017, Pfizer's outside counsel sent a letter to Genentech regarding the provision of a copy of Pfizer's aBLA for PF-05280014.

22. On September 5, 2017, Pfizer provided Genentech with a copy of Pfizer's aBLA, which included a small amount of manufacturing information.

23. Genentech responded on October 19, 2017 to identify deficiencies in Pfizer's production of manufacturing information and request specific information concerning the manufacture of Pfizer's biosimilar product. Pfizer provided some additional manufacturing information on November 1, 2017, but did not satisfy its disclosure obligations. Genentech then responded on November 3, 2017 to explain that Pfizer's November 1, 2017 production was deficient in that it failed to provide all of the requested information in contravention of 42 U.S.C. § 262(*l*)(2).

24. Pfizer did not disclose all of the information relevant to establishing whether the manufacture of Pfizer'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 Pfizer provide "other information that describes the process or processes used to manufacture" as required by 42 U.S.C. § 262(*l*)(A). Pfizer's failure to provide sufficient information under those circumstances justifies Genentech's contention that manufacturing Pfizer's aBLA product will infringe such patents.

25. Despite Pfizer's non-compliance (and without waiving Genentech's objection to such non-compliance), Genentech provided its operative list of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A) on November 3, 2017 ("Genentech's 3A List").

26. 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. *See* Exhibit A. Genentech filed the original complaint in this action later that day.

27. On January 2, 2018, Pfizer purported to provide its detailed statement concerning non-infringement and invalidity pursuant to 42 U.S.C. § 262(*l*)(3)(B) for 38 of the 40 patents on Genentech's 3A List ("Pfizer's 3B Statement"). Pfizer's 3B Statement was deficient in numerous ways. For example, it—like Pfizer's document production—failed to fully describe Pfizer's manufacturing process, such that Genentech was unable to evaluate many of Pfizer's non-infringement arguments.

28. Nonetheless, and subject to its objections, Genentech provided its response to Pfizer's 3C Statement on March 2, 2018, pursuant to 42 U.S.C. § 262(*l*)(3)(C) ("Genentech's 3C Statement"). Genentech included responses to Pfizer's non-infringement and invalidity statements for 18 of the 38 patents addressed in Pfizer's 3B Statement. With its 3C Statement, Genentech proposed that Pfizer agree that all patents addressed in Genentech's 3C Statement and the two patents included on Genentech's 3A List but not include addressed on their merits in Pfizer's 3B Statement be included in this infringement action.

PFIZER'S aBLA PRODUCT

29. Pfizer has publicly states that its aBLA product is biosimilar to Herceptin®. For example, Pfizer has issued press releases claiming that PF-05280014 is "a potential biosimilar to

Herceptin®"[3] and an "investigational trastuzumab biosimilar,"[4] and it has announced the results of a Pfizer study that purports to conclude that "there were no clinically meaningful differences between PF-05280014 and Herceptin."[5] Given Pfizer's claim of biosimilarity, Pfizer's aBLA product must "utilize the same mechanism or mechanisms of action [as Herceptin®] for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling." 42 U.S.C. § 262(k)(2)(A)(i)(II).

30. Under 35 U.S.C. § 271(e)(2)(C), Pfizer 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 PF-05280014.

GENENTECH'S ASSERTED PATENTS

31. 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. These patents cover the antibody trastuzumab, along with its manufacture and use.

32. Upon information and belief, Pfizer's aBLA product will infringe at least the following patents, which Genentech has asserted in this lawsuit: U.S. Patent No. 6,331,415, U.S. Patent No. 7,923,221, U.S. Patent No. 6,407,213, U.S. Patent No. 7,846,441, U.S. Patent No. 7,892,549, U.S. Patent No. 6,627,196, U.S. Patent No. 7,371,379, U.S. Patent No. 6,339,142,

[3] https://www.pfizer.com/news/press-release/press-release-detail/pfizer_announces_positive_top_line_results_from_the_pivotal_comparative_reflections_b3271002_study_for_pf_05280014_a_potential_biosimilar_to_herceptin_1_trastuzumab

[4] https://investors.pfizer.com/investor-news/press-release-details/2017/Pfizer-Presents-Positive-Pivotal-Data-for-PF-05280014-an-Investigational-Biosimilar-to-Herceptin-trastuzumab-at-the-European-Society-for-Medical-Oncology-ESMO-2017-Congress/default.aspx

[5] *Id.*

U.S. Patent No. 9,249,218, U.S. Patent No. 8,574,869, U.S. Patent No. 7,485,704, U.S. Patent No. 7,807,799, U.S. Patent No. 7,993,834, U.S. Patent No. 8,076,066, U.S. Patent No. 8,425,908, U.S. Patent No. 8,440,402, U.S. Patent No. 6,121,428, U.S. Patent No. 6,242,177, U.S. Patent No. 6,610,516, and U.S. Patent No. 8,314,225.

The Cabilly Patents

33. U.S. Patent Nos. 6,331,415 and 7,923,221 (collectively, the "Cabilly Patents") describe and claim a process for producing monoclonal antibodies, such as Herceptin®, from recombinant DNA. This effective and efficient process applies a novel co-expression technique to produce antibody heavy and light chains in a single host cell, and has given rise to an entire industry of therapeutic monoclonal antibodies.

34. U.S. Patent No. 6,331,415 ("the '415 patent"), titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," was duly and legally issued by the Patent Office on December 18, 2001. A true and correct copy of the '415 patent is attached as Exhibit B. Genentech and the City of Hope are the owners by assignment of the '415 patent.

35. U.S. Patent No. 7,923,221 ("the '221 patent"), titled "Methods of Making Antibody Heavy and Light Chains Having Specificity for a Desired Antigen," was duly and legally issued by the Patent Office on April 12, 2011. A true and correct copy of the '221 patent is attached as Exhibit C. Genentech and the City of Hope are the owners by assignment of the '221 patent.

The '213 Patent

36. U.S. Patent No. 6,407,213 ("the '213 patent") claims the Herceptin® antibody itself, along with other humanized monoclonal antibodies. The inventors of the '213 patent discovered that by grafting the key parts of a mouse antibody onto a human antibody consensus

sequence, they could create antibodies that were both tolerated by the immune system and effective to treat diseases like HER2-positive breast cancer. The techniques described in the '213 patent allowed scientists to efficiently design antibodies for specific disease targets by modifying mouse antibodies produced in the laboratory in specific ways so that they are compatible with a human immune system.

37. The '213 patent, titled "Method for Making Humanized Antibodies," was duly and legally issued by the Patent Office on June 18, 2002. A true and correct copy of the '213 patent is attached as Exhibit D. Genentech is the owner by assignment of the '213 patent.

The Combination Chemotherapy Patents

38. 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.

39. 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 E. Genentech is the owner by assignment of the '441 patent.

40. 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.

41. 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 F. Genentech is the owner by assignment of the ’549 patent.

42. U.S. Patent No. 8,425,908 (“the ’908 patent”), claims priority to the same provisional application as the ’441 and ’549 patents. The ’908 patent claims a method of treating a patient with HER2-positive gastric cancer by administering Herceptin® in combination with chemotherapy and in the absence of an anthracycline derivative.

43. The ’908 patent, titled “Treatment with Anti-ErbB2 Antibodies,” was duly and legally issued by the Patent Office on April 23, 2013. A true and correct copy of the ’908 patent is attached as Exhibit G. Genentech is the owner by assignment of the ’908 patent.

The Method of Administration Patents

44. U.S. Patent Nos. 6,627,196 and 7,371,379 (collectively, the “Method of Administration Patents”) 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.

45. U.S. Patent No. 6,627,196 (“the ’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 H. Genentech is the owner by assignment of the ’196 patent.

46. 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 I. Genentech is the owner by assignment of the '379 patent.

The Acidic Variants Patents

47. U.S. Patent Nos. 6,339,142 and 9,249,218 (collectively, the "Acidic Variants Patents") cover compositions with reduced amounts of more acidic structural variants of trastuzumab ("acidic variants") and chromatographic processes for removing these acidic variants during purification. Some trastuzumab acidic variants have lower potency than trastuzumab itself. The Acidic Variants Patents describe and claim chromatographic processes and compositions that ensure the Herceptin® drug product is uniformly pure and effective.

48. U.S. Patent No. 6,339,142 ("the '142 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on January 15, 2002. A true and correct copy of the '142 patent is attached as Exhibit J. Genentech is the owner by assignment of the '142 patent.

49. U.S. Patent No. 9,249,218 ("the '218 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on February 2, 2016. A true and correct copy of the '218 patent is attached as Exhibit K. Genentech is the owner by assignment of the '218 patent.

HER2 Diagnostic Patents

50. 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.

51. 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 L. Genentech is the owner by assignment of the '834 patent.

52. 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 M. Genentech is the owner by assignment of the '066 patent.

53. 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 N. Genentech is the owner by assignment of the '402 patent.

Cell Culture, Purification, and Antibody Manufacturing Patents

54. 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, claim novel techniques developed by Genentech relating to various aspects of cell culture, purification, and antibody purification.

55. U.S. Patent No. 7,485,704 ("the '704 patent"), titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," was duly and legally issued by the Patent Office on February 3, 2009. A true and correct copy of the '704 patent is attached as Exhibit O. Genentech is the owner by assignment of the '704 patent.

56. U.S. Patent No. 7,807,799 ("the '799 patent"), titled "Reducing Protein A Leaching During Protein A Affinity Chromatography," was duly and legally issued by the Patent Office on October 5, 2010. A true and correct copy of the '799 patent is attached as Exhibit P. Genentech is the owner by assignment of the '799 patent.

57. U.S. Patent No. 6,242,177 ("the '177 patent"), titled "Methods and Compositions for Secretion of Heterologous Polypeptides," was duly and legally issued by the Patent Office on June 5, 2001. A true and correct copy of the '177 patent is attached as Exhibit Q. Genentech is the owner by assignment of the '177 patent.

58. U.S. Patent No. 6,610,516 ("the '516 patent"), titled "Cell Culture Process," was duly and legally issued by the Patent Office on August 26, 2003. A true and correct copy of the '516 patent is attached as Exhibit R. Genentech is the owner by assignment of the '516 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 S. Genentech is the owner by assignment of the '869 patent.

60. U.S. Patent No. 8,314,225 ("the '225 patent"), titled "Heavy Chain Mutant Leading to Improved Immunoglobulin Production," was duly and legally issued by the Patent Office on November 20, 2012. A true and correct copy of the '225 patent is attached as Exhibit T. The '225 patent is assigned to Hoffmann-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the '225 patent.

61. U.S. Patent No. 6,121,428 ("the '428 patent"), titled "Protein Recovery," was duly and legally issued by the Patent Office on September 19, 2000. A true and correct copy of the '428 patent is attached as Exhibit U. Genentech is the owner by assignment of the '428 patent.

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

62. Plaintiffs incorporate by reference paragraphs 1-61 as if fully set forth herein.

63. Genentech included the ’415 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

64. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the ’415 patent is a technical act of infringement of one or more claims of the ’415 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Celltrion pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

65. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Pfizer will infringe the ’415 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 PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, 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 Defendants’ proposed PF-05280014 drug product will infringe the ’415 patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (g).

66. Pfizer has knowledge of and is aware of the ’415 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. Pfizer’s infringement of the ’415 patent is willful.

67. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’415 patent. Plaintiffs have no adequate remedy at law.

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

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

69. Plaintiffs incorporate by reference paragraphs 1-68 as if fully set forth herein.

70. Genentech included the ’221 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

71. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the ’221 patent is a technical act of infringement of one or more claims of the ’221 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

72. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Plaintiffs reasonably believe that Pfizer will infringe the ’221 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 PF-

05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, 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).

73. Pfizer has knowledge of and is aware of the '221 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. Pfizer's infringement of the '221 patent is willful.

74. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '221 patent. Plaintiffs have no adequate remedy at law.

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

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

76. Genentech incorporates by reference paragraphs 1-75 as if fully set forth herein.

77. Genentech included the '213 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

78. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer's submission of the

aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the '213 patent is a technical act of infringement of one or more claims of the '213 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

79. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '213 patent in violation of 35 U.S.C. §§ 271(a), (b), and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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 (c).

80. Pfizer has knowledge of and is aware of the '213 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. Pfizer's infringement of the '213 patent is willful.

81. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '213 patent. Genentech has no adequate remedy at law.

82. 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), and/or 35 U.S.C. §§ 271(a), (b), and/or (c) preventing

Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

83. Genentech incorporates by reference paragraphs 1-82 as if fully set forth herein.

84. Genentech included the '441 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

85. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the '441 patent is a technical act of infringement of one or more claims of the '441 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

86. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '441 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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(b) and/or (c).

87. Pfizer 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. Pfizer’s infringement of the ’441 patent is willful.

88. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Pfizer aBLA product, Pfizer 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.

89. Upon information and belief, Pfizer 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 Pfizer aBLA product according to Pfizer’s proposed package insert and, therefore, will directly infringe at least one claim of the ’441 patent, either literally or under the doctrine of equivalents.

90. Upon information and belief, Pfizer 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 Pfizer’s proposed package insert for the Pfizer aBLA product.

91. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’441 patent. Genentech has no adequate remedy at law.

92. 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), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

93. Genentech incorporates by reference paragraphs 1-92 as if fully set forth herein.

94. Genentech included the '549 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

95. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the '549 patent is a technical act of infringement of one or more claims of the '549 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

96. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '549 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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(b) and/or (c).

97. Pfizer 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. Pfizer's infringement of the '549 patent is willful.

98. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Pfizer aBLA product, Pfizer 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.

99. Upon information and belief, Pfizer 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 Pfizer aBLA product according to Pfizer's proposed package insert and, therefore, will directly infringe at least one claim of the '549 patent, either literally or under the doctrine of equivalents.

100. Upon information and belief, Pfizer 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 Pfizer's proposed package insert for the Pfizer aBLA product.

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

102. 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), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

103. Genentech incorporates by reference paragraphs 1-102 as if fully set forth herein.

104. Genentech included the '196 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

105. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the '196 patent is a technical act of infringement of one or more claims of the '196 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

106. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '196 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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(b) and/or (c).

107. Pfizer 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. Pfizer's infringement of the '196 patent is willful.

108. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Pfizer aBLA product, Pfizer 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.

109. Upon information and belief, Pfizer 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 Pfizer aBLA product according to Pfizer's proposed package insert and, therefore, will directly infringe at least one claim of the '196 patent, either literally or under the doctrine of equivalents.

110. Upon information and belief, Pfizer 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 Pfizer's proposed package insert for the Pfizer aBLA product.

111. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '196 patent. Genentech has no adequate remedy at law.

112. 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), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

113. Genentech incorporates by reference paragraphs 1-112 as if fully set forth herein.

114. Genentech included the '379 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

115. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the '379 patent is a technical act of infringement of one or more claims of the '379 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

116. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '379 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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(b) and/or (c).

117. Pfizer 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. Pfizer's infringement of the '379 patent is willful.

118. By the filing of an aBLA that, on information and belief, includes a proposed package insert having directions that instruct patients to administer and/or use and medical practitioners to prescribe and/or administer the Pfizer aBLA product, Pfizer 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.

119. Upon information and belief, Pfizer 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 Pfizer aBLA product according to Pfizer's proposed package insert and, therefore, will directly infringe at least one claim of the '379 patent, either literally or under the doctrine of equivalents.

120. Upon information and belief, Pfizer 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 Pfizer's proposed package insert for the Pfizer aBLA product.

121. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '379 patent. Genentech has no adequate remedy at law.

122. 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), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

123. Genentech incorporates by reference paragraphs 1-122 as if fully set forth herein.

124. Genentech included the '142 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

125. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the '142 patent is a technical act of infringement of one or more claims of the '142 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

126. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '142 patent in violation of 35 U.S.C. §§ 271(a), (b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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 (c).

127. Pfizer has knowledge of and is aware of the '142 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. Pfizer's infringement of the '142 patent is willful.

128. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '142 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), and/or 35 U.S.C. §§ 271(a), (b), and/or (c) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

130. Genentech incorporates by reference paragraphs 1-129 as if fully set forth herein.

131. Genentech included the '218 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

132. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the '218 patent is a technical act of infringement of one or more claims of the '218 patent under 35 U.S.C. § 271(e)(2)(C)(i), either

literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

133. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '218 patent in violation of 35 U.S.C. §§ 271(a), (b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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 (c).

134. Pfizer has knowledge of and is aware of the '218 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. Pfizer's infringement of the '218 patent is willful.

135. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '218 patent. Genentech has no adequate remedy at law.

136. 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), and/or 35 U.S.C. §§ 271(a), (b), and/or (c) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

137. Genentech incorporates by reference paragraphs 1-136 as if fully set forth herein

138. Genentech included the '869 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

139. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the '869 patent is a technical act of infringement of one or more claims of the '869 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

140. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer 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 PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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).

141. Pfizer 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. Pfizer's infringement of the '869 patent is willful.

142. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '869 patent. Genentech has no adequate remedy at law.

143. 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), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

144. Genentech incorporates by reference paragraphs 1-143 as if fully set forth herein.

145. Genentech included the '704 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

146. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the '704 patent is a technical act of infringement of one or more claims of the '704 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

147. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '704 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 PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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).

148. Pfizer has knowledge of and is aware of the '704 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. Pfizer's infringement of the '704 patent is willful.

149. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '704 patent. Genentech has no adequate remedy at law.

150. 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), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

151. Genentech incorporates by reference paragraphs 1-150 as if fully set forth herein.

152. Genentech included the ’799 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

153. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the ’799 patent is a technical act of infringement of one or more claims of the ’799 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

154. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the ’799 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 PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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).

155. Pfizer has knowledge of and is aware of the ’799 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. Pfizer’s infringement of the ’799 patent is willful.

156. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’799 patent. Genentech has no adequate remedy at law.

157. 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), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

158. Genentech incorporates by reference paragraphs 1-157 as if fully set forth herein.

159. Genentech included the ’225 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

160. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the ’225 patent is a technical act of infringement of one or more claims of the ’225 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

161. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the ’225 patent in violation of 35 U.S.C. §§ 271(a) and/or (b) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-

05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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) and/or (b).

162. Pfizer has knowledge of and is aware of the '225 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. Pfizer's infringement of the '225 patent is willful.

163. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '225 patent. Genentech has no adequate remedy at law.

164. 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), and/or 35 U.S.C. § 271(a) and/or (b) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

165. Genentech incorporates by reference paragraphs 1-164 as if fully set forth herein.

166. Genentech included the '834 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

167. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer's submission of the

aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the '834 patent is a technical act of infringement of one or more claims of the '834 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

168. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '834 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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(b) and/or (c).

169. Pfizer 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. Pfizer's infringement of the '834 patent is willful.

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

171. 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), and/or 35 U.S.C. § 271(b) and/or (c) preventing Pfizer

from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

172. Genentech incorporates by reference paragraphs 1-171 as if fully set forth herein.

173. Genentech included the ’066 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

174. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the ’066 patent is a technical act of infringement of one or more claims of the ’066 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

175. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the ’066 patent in violation of 35 U.S.C. §§ 271 (b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech’s 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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 (b) and/or (c).

176. Pfizer 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. Pfizer’s infringement of the ’066 patent is willful.

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

178. 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), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

179. Genentech incorporates by reference paragraphs 1-178 as if fully set forth herein.

180. Genentech included the ’908 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

181. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the ’908 patent is a technical act of infringement of one or more claims of the ’908 patent under 35 U.S.C. § 271(e)(2)(C)(i), either

literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

182. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '908 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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(b) and/or (c).

183. Pfizer has knowledge of and is aware of the '908 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. Pfizer's infringement of the '908 patent is willful.

184. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '908 patent. Genentech has no adequate remedy at law.

185. 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), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

186. Genentech incorporates by reference paragraphs 1-185 as if fully set forth herein.

187. Genentech included the '402 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

188. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer's submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the '402 patent is a technical act of infringement of one or more claims of the '402 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

189. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '402 patent in violation of 35 U.S.C. §§ 271(b) and/or (c) as a result of its activities relating to the manufacture, importation, sale, offer for sale, use, and promotion of the use of the PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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(b) and/or (c).

190. Pfizer 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. Pfizer’s infringement of the ’402 patent is willful.

191. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’402 patent. Genentech has no adequate remedy at law.

192. 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), and/or 35 U.S.C. §§ 271(b) and/or (c) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

193. Genentech incorporates by reference paragraphs 1-192 as if fully set forth herein.

194. Genentech included the ’428 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

195. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the ’428 patent is a technical act of infringement of one or more claims of the ’428 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents. Genentech has provided detailed, claim-by-claim infringement contentions to Pfizer pursuant to 42 U.S.C.§ 262(*l*)(3)(C).

196. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the '428 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 PF-05280014 drug substance and its proposed PF-05280014 drug product, as explained in Genentech's 3C Statement. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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).

197. Pfizer has knowledge of and is aware of the '428 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. Pfizer's infringement of the '428 patent is willful.

198. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '428 patent. Genentech has no adequate remedy at law.

199. 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), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

200. Genentech incorporates by reference paragraphs 1-199 as if fully set forth herein.

201. Genentech included the ’177 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

202. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the ’177 patent is a technical act of infringement of one or more claims of the ’177 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

203. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the ’177 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 PF-05280014 drug substance and its proposed PF-05280014 drug product. Pursuant to 42 U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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 ’177 patent pursuant to 35 U.S.C. §§ 271(a), (b) and/or (g).

204. Pfizer has knowledge of and is aware of the ’177 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. Pfizer’s infringement of the ’177 patent is willful.

205. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’177 patent. Genentech has no adequate remedy at law.

206. 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), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

207. Genentech incorporates by reference paragraphs 1-206 as if fully set forth herein.

208. Genentech included the ’516 patent in its disclosure of patents pursuant to 42 U.S.C. § 262(*l*)(3)(A). On November 17, 2017, Pfizer chose to file a notice of commercial marketing. *See* Exhibit A.

209. Based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer’s submission of the aBLA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Pfizer aBLA product prior to the expiration of the ’516 patent is a technical act of infringement of one or more claims of the ’516 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

210. Likewise, based on publicly available information and/or information provided by Pfizer pursuant to 42 U.S.C. § 262(*l*)(2), Genentech reasonably believes that Pfizer will infringe the ’516 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 PF-05280014 drug substance and its proposed PF-05280014 drug product. Pursuant to 42

U.S.C. § 262(*l*)(9)(A) and 28 U.S.C. § 2201, Genentech is 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).

211. Pfizer has knowledge of and is aware of the '516 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. Pfizer's infringement of the '516 patent is willful.

212. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '516 patent. Genentech has no adequate remedy at law.

213. 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), and/or 35 U.S.C. §§ 271(a), (b), and/or (g) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor against Pfizer and grant the following relief:

a. a judgment that Pfizer 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 Pfizer 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 Pfizer aBLA product before the expirations of the asserted patents;

c. preliminary and/or permanent equitable relief, including but not limited to a preliminary and permanent injunction that enjoins Pfizer, 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 Pfizer 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 in the event that Pfizer imports or launches its biosimilar product and/or otherwise practice the patented inventions in the United States prior to the expiration of the asserted patents, including lost profits and/or a reasonable royalty, and an accounting and/or ongoing royalty for any post-judgment infringement;

e. a judgment that Pfizer'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.

/s/ Frederick L. Cottrell, III

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