IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs, v. PFIZER, INC., Defendant.	Civil Action No. _____

COMPLAINT

Plaintiffs Genentech, Inc. ("Genentech") and City of Hope bring this Complaint for declaratory and injunctive relief against Defendant Pfizer, Inc. to address Pfizer's infringement of 40 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. 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"). Pursuant to the process outlined in the BPCIA, 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*). On November 17, 2017 Pfizer purported to provide Genentech with a notice pursuant to 42 U.S.C. § 262(*l*)(8)(A) that it intends to market PF-05280014 in the United States.

9. Plaintiffs thus seek a judgment 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 Genentech patents described below infringes those patents under 35 U.S.C. § 271(e)(2)(C)(i). Plaintiffs also seek a 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 launches its biosimilar product prior to the

expiration of those patents, Plaintiffs also seek monetary damages, including its lost profits, and any further relief as this Court may deem just and proper.

PARTIES

10. Plaintiff Genentech, Inc. 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. 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.

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. To date, Pfizer has not provided its detailed statement concerning non-infringement and invalidity pursuant to 42 U.S.C. § 262(*l*)(3)(B) for the patents on Genentech's patent list.

PFIZER'S aBLA PRODUCT

27. 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).

28. 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

29. 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.

30. 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.

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[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.*

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, U.S. Patent No. 6,417,335, U.S. Patent No. 6,489,447, U.S. Patent No. 9,249,218, U.S. Patent No. 8,574,869, U.S. Patent No. 6,620,918, U.S. Patent No. 7,485,704, U.S. Patent No. 7,807,799, U.S. Patent No. 8,633,302, U.S. Patent No. 8,691,232, U.S. Patent No. 8,771,988, U.S. Patent No. 8,822,655, U.S. Patent No. 9,428,766, U.S. Patent No. 9,487,809, U.S. Patent No. 9,714,293, U.S. Patent No. 7,449,184, U.S. Patent No. 7,501,122, 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. 8,460,895, U.S. Patent No. 8,512,983, U.S. Patent No. 6,121,428, U.S. Patent No. 6,242,177, U.S. Patent No. 6,586,206, U.S. Patent No. 6,610,516, U.S. Patent No. 6,716,602, U.S. Patent No. 7,390,660, U.S. Patent No. 8,044,017, U.S. Patent No. 8,314,225, U.S. Patent No. 8,710,196, and U.S. Patent No. 9,493,744.

The Cabilly Patents

31. 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.

32. 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.

33. 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

34. 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.

35. 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

36. 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.

37. 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.

38. 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.

39. 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.

40. 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.

41. 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

42. 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.

43. 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.

44. 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

45. U.S. Patent Nos. 6,339,142; 6,417,335; 6,489,447; 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.

46. 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.

47. U.S. Patent No. 6,417,335 ("the '335 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on July 9, 2002. A true and correct copy of the '335 patent is attached as Exhibit K. Genentech is the owner by assignment of the '335 patent.

48. U.S. Patent No. 6,489,447 ("the '447 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on December 3, 2002. A true and correct copy of the '447 patent is attached as Exhibit L. Genentech is the owner by assignment of the '447 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 M. Genentech is the owner by assignment of the '218 patent.

Combination Therapy with Perjeta

50. U.S. Patent Nos. 7,501,122, 7,449,184, and 8,691,232 claim novel therapies combining trastuzumab with another anti-HER2 antibody developed by Genentech called pertuzumab. That combination therapy is a common method of treatment for HER2-positive breast cancer patients involving Herceptin®.

51. U.S. Patent No. 7,501,122 ("the '122 patent"), titled "Treatment with Anti-ErbB2 Antibody Combinations," was duly and legally issued by the Patent Office on March 10, 2009. A true and correct copy of the '122 patent is attached as Exhibit N. Genentech is the owner by assignment of the '122 patent.

52. U.S. Patent No. 7,449,184 ("the '184 patent"), titled "Fixed Dosing of HER Antibodies," was duly and legally issued by the Patent Office on November 11, 2008. A true and correct copy of the '184 patent is attached as Exhibit O. Genentech is the owner by assignment of the '184 patent.

53. U.S. Patent No. 8,691,232 ("the '232 patent"), titled "Extending Time to Disease Progression or Survival in Cancer Patients," was duly and legally issued by the Patent Office on April 8, 2014. A true and correct copy of the '232 patent is attached as Exhibit P. Genentech is the owner by assignment of the '232 patent.

HER2 Diagnostic Patents

54. 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.

55. 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 Q. Genentech is the owner by assignment of the '834 patent.

56. 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 R. Genentech is the owner by assignment of the '066 patent.

57. 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 S. Genentech is the owner by assignment of the '402 patent.

Cell Culture, Purification, and Antibody Manufacturing Patents

58. U.S. Patent Nos. 6,242,177, 6,586,206, 6,610,516, 6,716,602, 7,390,660, 8,460,895, 8,512,983, 8,574,869, 8,771,988, 9,428,766, 9,487,809, 9,714,293, 6,121,428, 6,620,918, 7,485,704, 7,807,799, 8,633,302, 8,822,655, 8,044,017, 8,314,225, 8,710,196, and 9,493,744 claim novel techniques developed by Genentech relating to various aspects of cell culture, purification, and antibody purification.

59. U.S. Patent No. 6,620,918 ("the '918 patent"), titled "Separation of Polypeptide Monomers," was duly and legally issued by the Patent Office on September 16, 2003. A true and correct copy of the '918 patent is attached as Exhibit T. Genentech is the owner by assignment of the '918 patent.

60. 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 U. Genentech is the owner by assignment of the '704 patent.

61. 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 V. Genentech is the owner by assignment of the '799 patent.

62. U.S. Patent No. 8,044,017 ("the '017 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on October 25, 2011. A true and correct copy of the '017 patent is attached as Exhibit W. Genentech is the owner by assignment of the '017 patent.

63. 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 X. Genentech is the owner by assignment of the '177 patent.

64. U.S. Patent No. 6,586,206 ("the '206 patent"), titled "Methods for Making Recombinant Proteins Using Apoptosis Inhibitors," was duly and legally issued by the Patent Office on July 1, 2003. A true and correct copy of the '206 patent is attached as Exhibit Y. Genentech is the owner by assignment of the '206 patent.

65. 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 Z. Genentech is the owner by assignment of the '516 patent.

66. U.S. Patent No. 6,716,602 ("the '602 patent"), titled "Metabolic Rate Shifts in Fermentations Expressing Recombinant Proteins," was duly and legally issued by the Patent Office on April 6, 2004. A true and correct copy of the '602 patent is attached as Exhibit AA. Genentech is the owner by assignment of the '602 patent.

67. U.S. Patent No. 7,390,660 ("the '660 patent"), titled "Methods for Growing Mammalian Cells In Vitro," was duly and legally issued by the Patent Office on June 24, 2008. A true and correct copy of the '660 patent is attached as Exhibit BB. The '660 patent is assigned to Hoffmann-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the '660 patent.

68. U.S. Patent No. 8,460,895 ("the '895 patent"), titled "Method for Producing Recombinant Proteins with a Constant Content of pCO.sub.2 in the Medium," was duly and legally issued by the Patent Office on June 11, 2013. A true and correct copy of the '895 patent is attached as Exhibit CC. The '895 patent is assigned to Hoffmann-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the '895 patent.

69. U.S. Patent No. 8,512,983 ("the '983 patent"), titled "Production of Proteins in Glutamine-Free Cell Culture Media," was duly and legally issued by the Patent Office on August 20, 2013. A true and correct copy of the '983 patent is attached as Exhibit DD. Genentech is the owner by assignment of the '983 patent.

70. 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 EE. Genentech is the owner by assignment of the '869 patent.

71. U.S. Patent No. 8,771,988 ("the '988 patent"), titled "Protein Expression From Multiple Nucleic Acids," was duly and legally issued by the Patent Office on July 8, 2014. A true and correct copy of the '988 patent is attached as Exhibit FF. The '988 patent is assigned to Hoffmann-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the '988 patent.

72. 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 GG. The '225 patent is assigned to Hoffmann-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the '225 patent.

73. U.S. Patent No. 9,428,766 ("the '766 patent"), titled "Protein Expression From Multiple Nucleic Acids," was duly and legally issued by the Patent Office on August 30, 2016. A true and correct copy of the '766 patent is attached as Exhibit HH. The '766 patent is assigned to Hoffmann-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the '766 patent.

74. U.S. Patent No. 9,487,809 ("the '809 patent"), titled "Decreasing Lactate Level and Increasing Polypeptide Production by Downregulating the Expression of Lactate Dehydrogenase and Pyruvate Dehydrogenase Kinase," was duly and legally issued by the Patent Office on November 8, 2016. A true and correct copy of the '809 patent is attached as Exhibit II. Genentech is the owner by assignment of the '809 patent.

75. U.S. Patent No. 9,714,293 ("the '293 patent"), titled "Production of Proteins in Glutamine-Free Cell Culture Media," was duly and legally issued by the Patent Office on July 25, 2017. A true and correct copy of the '293 patent is attached as Exhibit JJ. Genentech is the owner by assignment of the '293 patent.

76. 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 KK. Genentech is the owner by assignment of the '428 patent.

77. U.S. Patent No. 8,710,196 ("the cell culture '196 patent"), titled "Protein Purification," was duly and legally issued by the Patent Office on April 29, 2014. A true and correct copy of the cell culture '196 patent is attached as Exhibit LL. Genentech is the owner by assignment of the cell culture '196 patent.

78. U.S. Patent No. 8,633,302 ("the '302 patent"), titled "Variable Tangential Flow Filtration," was duly and legally issued by the Patent Office on January 21, 2014. A true and correct copy of the '302 patent is attached as Exhibit MM. The '302 patent is assigned to Hoffmann-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the '302 patent.

79. U.S. Patent No. 8,822,655 ("the '655 patent"), titled "Pre-filtration Adjustment of Buffer Solutes," was duly and legally issued by the Patent Office on September 2, 2014. A true and correct copy of the '655 patent is attached as Exhibit NN. The '655 patent is assigned to Hoffmann-La Roche, Inc., and Genentech is the exclusive licensee with the right to enforce the '655 patent.

80. U.S. Patent No. 9,493,744 ("the '744 patent"), titled "Methods for Viral Inactivation and Other Adventitious Agents," was duly and legally issued by the Patent Office on November 15, 2016. A true and correct copy of the '744 patent is attached as Exhibit OO. Genentech is the owner by assignment of the '744 patent.

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

81. Plaintiffs incorporate by reference paragraphs 1-80 as if fully set forth herein.

82. 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.

83. 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.

84. 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.

85. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’415 patent.

86. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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

87. Plaintiffs incorporate by reference paragraphs 1-80 as if fully set forth herein.

88. 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.

89. 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.

90. 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.

91. Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '221 patent.

92. Plaintiffs are entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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

93. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

94. 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.

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 '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.

96. 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.

97. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '213 patent.

98. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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

99. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

100. 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.

101. 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.

102. 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.

103. 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.

104. 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.

105. 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.

106. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '441 patent.

107. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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

108. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

109. 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.

110. 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.

111. 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.

112. 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.

113. 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.

114. 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.

115. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’549 patent.

116. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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

117. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

118. 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.

119. 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.

120. 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.

121. 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.

122. 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.

123. 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.

124. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '196 patent.

125. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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

126. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

127. 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.

128. 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.

129. 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.

130. 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.

131. 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.

132. 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.

133. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’379 patent.

134. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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

135. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

136. 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.

137. 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.

138. 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.

139. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '142 patent.

140. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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. 6,417,335

141. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

142. Genentech included the '335 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.

143. 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 '335 patent is a technical act of infringement of one or more claims of the '335 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

144. Pfizer has knowledge of and is aware of the '335 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 '335 patent is willful.

145. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '335 patent.

146. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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. 6,489,447

147. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

148. Genentech included the ’447 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.

149. 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 ’447 patent is a technical act of infringement of one or more claims of the ’447 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

150. Pfizer has knowledge of and is aware of the ’447 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 ’447 patent is willful.

151. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’447 patent.

152. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

153.

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

154. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

155. 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.

156. 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.

157. 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.

158. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '218 patent.

159. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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. 8,574,869

160. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein

161. 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.

162. 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.

163. 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.

164. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '869 patent.

165. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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. 6,620,918

166. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

167. Genentech included the '918 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.

168. 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 '918 patent is a technical act of infringement of one or more claims of the '918 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

169. Pfizer has knowledge of and is aware of the '918 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 '918 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 '918 patent.

171. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(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. 7,485,704

172. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

173. 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.

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 '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.

175. 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.

176. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’704 patent.

177. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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. 7,807,799

178. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

179. 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.

180. 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.

181. 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.

182. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’799 patent.

183. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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. 8,044,017

184. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

185. Genentech included the ’017 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.

186. 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 ’017 patent is a technical act of infringement of one or more claims of the ’017 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

187. Pfizer has knowledge of and is aware of the ’017 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 ’017 patent is willful.

188. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’017 patent.

189. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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. 8,633,302

190. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

191. Genentech included the '302 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.

192. 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 '302 patent is a technical act of infringement of one or more claims of the '302 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

193. Pfizer has knowledge of and is aware of the '302 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 '302 patent is willful.

194. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '302 patent.

195. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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. 8,691,232

196. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

197. Genentech included the ’232 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.

198. 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 ’232 patent is a technical act of infringement of one or more claims of the ’232 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

199. Pfizer has knowledge of and is aware of the ’232 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 ’232 patent is willful.

200. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’232 patent.

201. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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. 8,771,988

202. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

203. Genentech included the ’988 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.

204. 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 '988 patent is a technical act of infringement of one or more claims of the '988 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

205. Pfizer has knowledge of and is aware of the '988 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 '988 patent is willful.

206. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '988 patent.

207. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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. 8,822,655

208. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

209. Genentech included the '655 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.

210. 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 '655 patent is a technical act of

infringement of one or more claims of the ’655 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

211. Pfizer has knowledge of and is aware of the ’655 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 ’655 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 ’655 patent.

213. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

214. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

215. 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.

216. 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.

217. 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.

218. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '225 patent.

219. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

COUNT XXII
INFRINGEMENT OF U.S. PATENT NO. 8,710,196

220. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

221. Genentech included the cell culture '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.

222. 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 cell culture '196 patent is a technical act of infringement of one or more claims of the cell culture '196 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

223. Pfizer has knowledge of and is aware of the cell culture '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 cell culture '196 patent is willful.

224. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the cell culture '196 patent.

225. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

COUNT XXIII
INFRINGEMENT OF U.S. PATENT NO. 9,428,766

226. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

227. Genentech included the '766 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.

228. 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 '766 patent is a technical act of infringement of one or more claims of the '766 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

229. Pfizer has knowledge of and is aware of the '766 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 '766 patent is willful.

230. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '766 patent.

231. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

COUNT XXIV
INFRINGEMENT OF U.S. PATENT NO. 9,487,809

232. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

233. Genentech included the '809 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.

234. 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 '809 patent is a technical act of infringement of one or more claims of the '809 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

235. Pfizer has knowledge of and is aware of the '809 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 '809 patent is willful.

236. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '809 patent.

237. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

238. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

239. Genentech included the ’293 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.

240. 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 ’293 patent is a technical act of infringement of one or more claims of the ’293 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

241. Pfizer has knowledge of and is aware of the ’293 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 ’293 patent is willful.

242. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’293 patent.

243. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

COUNT XXVI
INFRINGEMENT OF U.S. PATENT NO. 7,449,184

244. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

245. Genentech included the ’184 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.

246. 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 ’184 patent is a technical act of infringement of one or more claims of the ’184 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

247. Pfizer has knowledge of and is aware of the ’184 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 ’184 patent is willful.

248. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’184 patent.

249. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

COUNT XXVII
INFRINGEMENT OF U.S. PATENT NO. 7,501,122

250. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

251. Genentech included the ’122 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.

252. 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 '122 patent is a technical act of infringement of one or more claims of the '122 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

253. Pfizer has knowledge of and is aware of the '122 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 '122 patent is willful.

254. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '122 patent.

255. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

256. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

257. 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.

258. 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.

259. 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.

260. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’834 patent.

261. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

262. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

263. 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.

264. 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.

265. 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.

266. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’066 patent.

267. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

COUNT XXX
INFRINGEMENT OF U.S. PATENT NO. 9,493,744

268. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

269. Genentech included the ’744 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.

270. 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 ’744 patent is a technical act of infringement of one or more claims of the ’744 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

271. Pfizer has knowledge of and is aware of the ’744 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 ’744 patent is willful.

272. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’744 patent.

273. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

274. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

275. 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.

276. 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.

277. 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.

278. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’908 patent.

279. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

280. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

281. 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.

282. 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.

283. 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.

284. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’402 patent.

285. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

COUNT XXXIII
INFRINGEMENT OF U.S. PATENT NO. 8,460,895

286. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

287. Genentech included the '895 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.

288. 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 '895 patent is a technical act of infringement of one or more claims of the '895 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

289. Pfizer has knowledge of and is aware of the '895 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 '895 patent is willful.

290. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '895 patent.

291. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

292. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

293. Genentech included the ’983 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.

294. 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 ’983 patent is a technical act of infringement of one or more claims of the ’983 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

295. Pfizer has knowledge of and is aware of the ’983 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 ’983 patent is willful.

296. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’983 patent.

297. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

298. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

299. 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.

300. 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.

301. 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.

302. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the '428 patent.

303. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

304. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

305. 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.

306. 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.

307. 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.

308. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’177 patent.

309. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

COUNT XXXVII
INFRINGEMENT OF U.S. PATENT NO. 6,586,206

310. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

311. Genentech included the ’206 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.

312. 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 ’206 patent is a technical act of infringement of one or more claims of the ’206 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

313. Pfizer has knowledge of and is aware of the ’206 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 ’206 patent is willful.

314. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’206 patent.

315. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

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

316. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

317. 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.

318. 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.

319. 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.

320. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’516 patent.

321. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

COUNT XXXIX
INFRINGEMENT OF U.S. PATENT NO. 6,716,602

322. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

323. Genentech included the ’602 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.

324. 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 ’602 patent is a technical act of infringement of one or more claims of the ’602 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

325. Pfizer has knowledge of and is aware of the ’602 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 ’602 patent is willful.

326. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’602 patent.

327. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) preventing Pfizer from the commercial manufacture, use, offer to sell, or sale within the United States of the Pfizer aBLA product.

COUNT XL
INFRINGEMENT OF U.S. PATENT NO. 7,390,660

328. Genentech incorporates by reference paragraphs 1-80 as if fully set forth herein.

329. Genentech included the ’660 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.

330. 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 ’660 patent is a technical act of infringement of one or more claims of the ’660 patent under 35 U.S.C. § 271(e)(2)(C)(i), either literally or under the doctrine of equivalents.

331. Pfizer has knowledge of and is aware of the ’660 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 ’660 patent is willful.

332. Genentech will suffer irreparable injury for which damages are an inadequate remedy unless Pfizer is enjoined from infringing the claims of the ’660 patent.

333. Genentech is entitled to an injunction pursuant to at least 35 U.S.C. § 271(e)(4)(B) 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 brings its biosimilar product to market 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 Plaintiff of its 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.

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Dated: November 17, 2017

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