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.

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