IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE, Plaintiffs, v. AMGEN INC., Defendant.	C.A. No. 18-924-GMS REDACTED PUBLIC VERSION FILED: JULY 2, 2018

COMPLAINT

Plaintiffs Genentech, Inc. ("Genentech") and City of Hope (collectively, "Plaintiffs") bring this Complaint for declaratory and injunctive relief against Defendant Amgen Inc. ("Amgen") to address Amgen's infringement of patents relating to Genentech's groundbreaking breast cancer drug Herceptin®.

NATURE OF THE CASE

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

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

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chemotherapeutic drugs with harsh side effects, and those treatments added little to the patient's life span.

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

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

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

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

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

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6. Genentech's groundbreaking work developing Herceptin® was the result of years of research from a group of talented scientists. The United States Patent and Trademark Office recognized that innovative work by granting Genentech numerous patents claiming Herceptin®, its manufacture, and its use. And as one of the pioneers in the biotechnology field, Genentech collaborated with scientists at research institutions such as the City of Hope to make foundational inventions, such as efficient techniques for making antibodies that can be used as drugs.

7. Seeking to profit from the success of Plaintiffs' innovations, Amgen is seeking FDA approval of a biosimilar version of Herceptin® called ABP 980. ABP 980 is a copycat product for which Amgen is seeking the same label indications and usage as Herceptin®. In fact, Amgen 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"). Amgen initially purported to follow the process outlined in the BPCIA, which requires biosimilar applicants and innovator companies to exchange certain information concerning the biosimilar product and the patents that may be infringed by the manufacture and sale of the biosimilar product. *See* 42 U.S.C. § 262(*l*).

9. Plaintiffs thus bring this action for infringement pursuant to 35 U.S.C. § 271(e)(2) based upon Amgen's submission of its aBLA for ABP 980. Plaintiffs also seek a declaratory judgment pursuant to 42 U.S.C. § 262(*l*)(9) and 28 U.S.C. § 2201 that the manufacture, use, offer to sell, sale, or importation into the United States of Amgen's biosimilar product would infringe the patents described below. Pursuant to 35 U.S.C. § 271(e)(4)(B), 42 U.S.C. § 262(*l*)(8)(B), 35 U.S.C. § 271(a), (b), and/or 35 U.S.C. § 283, Plaintiffs also seek a preliminary and/or permanent

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injunction barring Amgen's manufacture, use, offer to sell, sale, or importation of its biosimilar product prior to the expiration of those patents. In the event that Amgen imports, manufactures, or launches its biosimilar product, and/or otherwise practices the patented inventions in the United States prior to the expiration of those patents, Plaintiffs also seek monetary damages, including lost profits, and any further relief as this Court may deem just and proper.

PARTIES

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

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

12. Plaintiff City of Hope is a California not-for-profit organization, with its principal place of business at 1500 East Duarte Road, Duarte, California 91010.

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

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

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

JURISDICTION AND VENUE

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

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

18. This Court has personal jurisdiction over Amgen because it is incorporated in Delaware. In addition, among other things, Amgen has filed an Abbreviated Biologics License Application ("aBLA") for ABP 980 with the FDA seeking approval to market it, which reliably indicates that it will market its proposed biosimilar product in Delaware if approved.

THE PARTIES' EXCHANGES UNDER THE BPCIA

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

20. The FDA accepted Amgen's aBLA for review [redacted]

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

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