IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENENTECH, INC., CITY OF HOPE, and HOFFMANN-LA ROCHE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
CELLTRION, INC., CELLTRION HEALTHCARE, CO. LTD., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICALS INTERNATIONAL GMBH,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Genentech, Inc. ("Genentech"), City of Hope, and Hoffmann-La Roche Inc. ("HLR"; collectively, "Plaintiffs") bring this Complaint for declaratory and injunctive relief against Defendants Celltrion, Inc. and Celltrion Healthcare Co., Ltd. (collectively, "Celltrion") and Defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals International GmbH (collectively, "Teva") to address Defendants' 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

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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).

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 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, Celltrion is seeking FDA approval of a biosimilar version of Herceptin® called CT-P6. CT-P6 is a copycat product for which Celltrion is seeking the same label indications and usage as Herceptin®. In fact, Celltrion is relying upon Genentech's own studies demonstrating the safety and efficacy of Herceptin® to obtain approval of its biosimilar product. Upon information and belief, Teva will be engaged in the marketing and distribution of Celltrion's CT-P6 product in the United States upon FDA approval.

8. In 2010, Congress provided a pathway for resolving patent disputes relating to biosimilar products through the Biologics Price Competition and Innovation Act ("BPCIA"). Celltrion 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*). However, before completing the process required by the statute, Celltrion has purported to provide Genentech with a notice pursuant to 42 U.S.C. § 262(*l*)(8)(A) that they intend to market CT-P6 in the United States. That notice of commercial

marketing allows Plaintiffs to bring an immediate action for injunctive and declaratory relief concerning the patents that would be infringed by the manufacture and sale of Celltrion's biosimilar product.

9. Plaintiffs thus bring this action for infringement pursuant to 35 U.S.C. § 271(e)(2) based upon Celltrion's submission of its aBLA for CT-P6. 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 Celltrion's biosimilar product would infringe the 40 patents described below. Pursuant to 42 U.S.C. § 262(*l*)(8)(B), Plaintiffs also seek a preliminary and/or permanent injunction barring Defendants' manufacture, use, offer to sell, sale, or importation of its biosimilar product prior to the expiration of those patents. In the event that Defendants import or launch their biosimilar product and/or otherwise practice the patented inventions in the United States prior to the expiration of those patents, Plaintiffs also seek monetary damages, including lost profits, and any further relief as this Court may deem just and proper.

PARTIES

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

11. Genentech was founded in 1976 and for four decades has been at the forefront of innovation in the field of therapeutic biotechnology. Today, Genentech employs a large number of researchers, scientists, and post-doctoral staff members who routinely publish in top peer-reviewed journals and are among the leaders in total citations to their work by researchers. Genentech currently markets numerous approved pharmaceutical and biologic drugs for a range

of serious or life-threatening medical conditions, including various forms of cancer, heart attacks, strokes, rheumatoid arthritis, and respiratory diseases.

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

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

14. Plaintiff Hoffmann La-Roche Inc. is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 150 Clove Road, Suite 8, Little Falls, New Jersey 07424.

15. Upon information and belief, Defendant Celltrion, Inc. is a company organized and existing under the laws of the Republic of Korea with its principal place of business located at 19, Academy-ro, 51beon-gil, Yeonsu-gu, Incheon, Korea.

16. Celltrion, Inc. is, among other things, engaged in the development of biologic drugs, including a proposed biosimilar version of Genentech's Herceptin® product, CT-P6 ("Celltrion's aBLA product"). Upon information and belief, Celltrion's aBLA product will be distributed and sold in the State of Delaware and throughout the United States.

17. Upon information and belief, Defendant Celltrion Healthcare Co., Ltd. is a company organized and existing under the laws of the Republic of Korea with its principal place of business located at 19, Academy-ro, 51beon-gil, Yeonsu-gu, Incheon, Korea.

18. Celltrion Healthcare Co., Ltd. is, among other things, engaged in the marketing and distribution of Celltrion's biologic products in the United States, including Celltrion's aBLA product.

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