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-CFC [redacted] PUBLIC VERSION FILED: July 19, 2019

DECLARATION OF CHRISTY OLIGER IN SUPPORT OF GENENTECH'S MOTION FOR PRELIMINARY INJUNCTION

I. PERSONAL BACKGROUND

1. My name is Christy Oliger. I have been employed at Genentech, Inc. since 2000 in a variety of positions.

2. In my current role as Senior Vice President of BioOncology, which I began in 2017, I manage the company's United States commercial operations for its oncology products.

II. BACKGROUND REGARDING HERCEPTIN

A. History of Herceptin[1]

3. Genentech has a long history of developing innovative therapies to solve some of the most difficult problems in medicine. The development of Herceptin was one of Genentech's early successes in the field of biooncology, and it remains one of the Company's most important medicines.

4. In the 1980s, scientists observed that approximately 25% of breast tumors had an excess of human epidermal growth factor receptor 2 (i.e., "HER2") proteins. Breast cancer characterized by overexpression of HER2—now referred to as "HER2-positive" or "HER2+"—is particularly aggressive. Genentech scientists exploring the role of HER2 overexpression then created specific "monoclonal antibodies"—man-made versions of proteins created by the immune system for use against bacteria and viruses—that limited the effect of HER2 by binding to the HER2 receptors on breast cancer cells. The early clinical trials of the monoclonal antibody known as trastuzumab were so successful that the FDA approved an unusual expanded access program under which certain patients could receive treatment even though they were not eligible for the trials.

5. Herceptin, Genentech's brand name for trastuzumab, was initially approved by the FDA in 1998 for the treatment of HER2+ metastatic (or late stage) breast cancer. At the time, Herceptin was unique—it was the first biological or antibody treatment targeted to solid cancer tumors. As described below, Genentech has invested significantly in research to expand the use of Herceptin to early stage breast cancer, making a cure available to many patients for the first time.

B. Importance of Herceptin to Patients

6. In the early 1990s, before Herceptin became available, HER2+ breast cancer was one of the worst diagnoses a patient could receive. HER2+ breast cancer responded particularly poorly to the treatments that were then available, and patients diagnosed with HER2+ breast cancer had an average life expectancy of only 18 months, and 50% of those diagnosed with the disease died within two years. Herceptin improved response rates and duration, time to progression (i.e., the time between the date of diagnosis or treatment to the time the disease begins to worsen or spread), and overall survival compared with

[1] *See, e.g.*, Ex. 33, Genentech.com, Her2 (https://www.gene.com/stories/her2/).

treatment with chemotherapy alone, resulting in improved overall survival of roughly 25% and reduced risk of death of 50% for metastatic HER2+ breast cancer.

7. Since Herceptin was first approved, Genentech has spent billions of dollars expanding its use. For example, Genentech's research has greatly expanded the number of patients who are able to benefit from treatment with Herceptin by identifying, through clinical trials, patient populations who benefit from the therapy, securing approval for additional indications, and by developing new methods of identifying and treating HER2+ breast cancer patients using new methods and combinations.

8. Herceptin's benefits have been demonstrated through numerous successful clinical trials.[2] For example, Herceptin was initially approved for use in treatment of metastatic HER2+ breast cancer, Genentech later demonstrated the effectiveness of Herceptin in adjuvant treatment of early HER2+ breast cancer through clinical trials involving nearly ten thousand patients at a cost of nearly one billion dollars.

9. Genentech's work developing treatments using Herceptin in the adjuvant (post-surgery) setting has made a cure possible for the first time. In fact, HER2+ breast cancer is now one of the most treatable types of breast cancer, and HER2+ breast cancer patients are now more likely to die of some other cause than from their breast cancer.

10. As a result of Herceptin's success and Genentech's post-approval efforts to identify additional patient populations Herceptin could help, Herceptin is now FDA-approved for (1) adjuvant treatment of HER2+ breast cancer, including as part of first-line treatment and as a single agent following certain other treatments; (2) treatment of metastatic HER2+ breast cancer, including as part of first-line treatment and as a single agent for certain patients; and (3) treatment of HER2+ metastatic gastric cancer and HER2+ gastroesophageal junction adenocarcinoma.[3]

11. In addition, Genentech developed a treatment using the combination of Herceptin and Perjeta (pertuzumab), another anti-HER2 antibody developed by Genentech, which achieved even higher survival benefits in the curative setting than Herceptin alone. Kadcyla, another Genentech antibody which is comprised of trastuzumab and the chemotherapy medicine emtansine linked together, reduced the risk of recurrence by half as compared to treatment with Herceptin among HER2+ breast cancer patients with residual disease after completion of preoperative treatment.

12. Today, tens of thousands of patients receive Herceptin annually, and Herceptin is the market leader for each approved indication. [redacted]

[2] *See, e.g.*, Ex. 34, Genentech.com, Press Release, "Herceptin Plus Chemotherapy Improved Disease-Free Survival and Overall Survival in Adjuvant Setting for Early-Stage Her2-Positive Breast Cancer Patients," May 13, 2005 (http://www.gene.com/media/press-releases/8429/2005-05-13/herceptin-plus-chemotherapy-improved-dis).

[3] Ex. 7, at GNE-HER_002466538 [Herceptin Prescribing Information].

[redacted]

C. Importance of Herceptin to Genentech

13. Herceptin is one of Genentech's most important products, and one of its highest-grossing. Herceptin has played a key role in the development of Genentech's reputation as a leader in oncology drugs generally and humanized monoclonal antibodies in particular.

14. Herceptin is typically sold to healthcare providers such as hospitals and oncology clinics. Many hospitals and clinics contract with group purchasing organizations ("GPOs"), which in turn contract with Genentech [redacted]. By volume, clinic GPO accounts are responsible for approximately [redacted] of Herceptin sales.[5] Other Herceptin providers include 340B hospitals, which comprise approximately [redacted] of the Herceptin market,[6] non-340B hospitals, which comprise approximately [redacted] of the market, about a third of which ([redacted] of the market) are part of the National Comprehensive Cancer Network ("NCCN")[7], and non-GPO Clinics, which comprise approximately [redacted] of the market.

15. The term wholesale acquisition cost ("WAC") refers to the manufacturer's list price for a drug to wholesalers or direct purchasers without accounting for discounts or rebates. The current WAC for Herceptin is [redacted] per 150mg vial.[8]

16. Without biosimilar competition, Genentech has historically increased the price of Herceptin annually, in part to account for inflation.[9]

17. Herceptin sales have steadily increased over time. The gross/net sales of Herceptin in the United States in the last four years were as follows:

- 2015: [redacted];
- 2016: [redacted];

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[4] Ex. 35, at GNE-HER_002993635, GNE-HER_002993637, GNE-HER_002993648-3650 [redacted] (all patients shown as receiving Perjeta also received Herceptin).

[5] Ex. 36, at GNE-HER_002948939 [redacted].

[6] "340B" refers to 340B of the Public Health Services Act, which was enacted pursuant to the Veterans Health Care Act of 1992, and which requires pharmaceutical manufacturers to provide large discounts on outpatient drugs purchased by certain covered entities. *See* 42 U.S.C. § 256b.

[7] NCCN is a not-for-profit alliance of 27 leading cancer centers. *See* NCCN.org, About NCCN (https://www.nccn.org/about/).

[8] Ex. 37, at GNE-HER_002952195 [redacted].

[9] Ex. 38, at GNE-HER_002230692 [redacted].

- 2017: [redacted];
- 2018: [redacted].[10]

18. Through May 2019, Genentech recorded gross sales in the United States of [redacted] for Herceptin, and net sales of [redacted] during that time.[11]

19. Much of the revenue Genentech derives from sales of Herceptin and other drugs is reinvested. For example, as discussed below, Genentech provides extensive patient access programs with the goal of ensuring that no patient who would benefit from therapies such as Herceptin is forced to go without for financial reasons.

20. In addition, Genentech has invested billions in research and development ("R&D") related to its breast cancer therapies alone. That reinvestment in the breast cancer research has resulted in the development of additional therapies such as Perjeta and Kadcyla, discussed below.

21. Patent protection is a key incentive underlying Genentech's commitment to R&D. Genentech submitted its first patent application in 1979, and since then has secured patents worldwide covering its innovations. All told, Genentech is one of the leading innovators in the field of biotechnology. Without the exclusivity afforded by patents, Genentech could not rely on the financial success of its products, no matter how innovative its work, to fund its R&D efforts. And without expectation of financial success for its products, Genentech could not justify its commitment to the large-scale R&D spending that has led to life-changing advances such as Herceptin, Perjeta, and Kadcyla.

III. BACKGROUND REGARDING RELATED PRODUCTS

A. Other Anti-HER2 Products

22. In April 2019, Genentech launched Herceptin Hylecta, a combination of trastuzumab and recombinant human hyaluronidase-oysk approved for certain HER2+ early breast cancer and metastatic breast cancer patients.[12] Herceptin Hylecta can be administered via subcutaneous rather than intravenous injection.[13] Subcutaneous administration can be preferable because it is typically faster, simpler, more convenient, and less uncomfortable.

23. Perjeta is approved for use in combination with Herceptin and chemotherapy for adjuvant treatment of certain HER2+ breast cancer patients as well as treatment of HER2+

[10] Ex. 39, at GNE-HER_002995964 [redacted].

[11] *Id.*

[12] Ex. 40, https://www.gene.com/media/press-releases/14779/2019-02-28/fda-approves-herceptin-hylecta-for-subcu

[13] *Id.*

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