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

EXPERT DECLARATION OF SUSAN TANNENBAUM M.D. IN SUPPORT OF GENENTECH'S EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

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I. INTRODUCTION

1. I have been retained as an expert in this case by counsel for Genentech, Inc. ("Genentech") in connection with this matter.

2. I submit this declaration in support of Genentech's Emergency Motion for Temporary Restraining Order and Preliminary Injunction.

3. I have been asked for my opinion concerning infringement of claim 11 of U.S. Patent No. 6,627,196 (the "'196 patent"); claim 11 of U.S. Patent No. 7,371,379 (the "'379 patent"); and claim 7 of U.S. Patent No. 10,160,811 (the "'811 patent") (collectively, the "dosing patents"). For the reasons set forth in this report and accompanying Appendix A, it is my opinion that Amgen will direct infringement by physicians and intends for them to infringe the asserted claims of the dosing patents through its prescribing information, marketing, and sale of Kanjinti in the United States.

II. BACKGROUND AND QUALIFICATIONS

4. I received a B.S. in biology from Cornell University in 1974 and an M.D. from State University of New York at Downstate in 1974. From 1978-1982, I did my Residency and Chief Residency in Internal Medicine at Bronx Municipal Hospital Center/Albert Einstein College of Medicine, after which I was board certified in Internal Medicine. I then trained in Hematology-Oncology at the University of Pennsylvania, from 1982-1986, after which I was board certified in Hematology and Oncology.

5. From 1986-1995, I engaged in laboratory research and clinical care of patients at the Clinical Center at the National Institute of Health. During this time, I cared for patients receiving treatments for cancer and blood disorders, including treatment with novel biologics.

6. From 1995-1996, I worked as Medical Officer at the Indian Health Service where I helped establish an Oncology Clinic for follow-up of cancer patients.

7. I then joined Wilshire Oncology where I worked from late 1996 through 2003.

8. At Wilshire Oncology, which was part of the UCLA network, 70% of my clinical practice focused on women with breast cancer. While at Wilshire Oncology, I was also part of early clinical trials involving trastuzumab.

9. In 2003, I became the primary breast medical oncologist at the University of Connecticut Health Center, now known as UCONN Health. In 2012, I became the Medical Director of the Clinical and Translational Breast Program. In these roles, my practice involved both academic and clinical components.

10. In 2016, I became the Division Chair of Hematology-Oncology and the Clinical Director of the Cancer Center. My clinical responsibilities remain with added responsibilities of managing operations of our Cancer Center as well as developing our mission, recruiting faculty, and setting standards for the Division of Hematology-Oncology. I continue my clinical care and clinical research as well as administrative responsibilities in this setting.

11. For the past twenty-four years, I spend 60% of my time focusing on clinical care, with 80% of that time treating breast cancer patients.

12. My qualifications and credentials are set forth below and, in my *curriculum vitae*, attached as Appendix B.

III. BACKGROUND

A. Types of Cancer and Cancer Treatments

13. The term "cancer" refers to a collection of related diseases, all of which are characterized by the uncontrolled growth of cells in the body. The "biology" of each cancer, *i.e.*, how it grows and spreads, is dictated by the genes the cancer cells express and the cells' interactions with the surrounding environment.

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