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 25, 2019

EXPERT DECLARATION OF GEORGE M. GRASS, Ph.D.
IN SUPPORT OF GENENTECH'S EMERGENCY MOTION FOR
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

TABLE OF CONTENTS

Pages

I. Introduction

1. I have been retained as an expert in this matter by counsel for Genentech, Inc., and submit this declaration in support of Genentech's Emergency Motion for Temporary Restraining Order and Preliminary Injunction.

2. I have been asked for my opinion concerning various assertions made by Amgen in support of its contentions regarding the obviousness of claims 11 of U.S. Patent No. 6,627,196 (the "'196 patent"); 11of U.S. Patent No. 7,371,379 (the "'379 patent"); and 7 of U.S. Patent No. 10,160,811 (the "'811 patent"). I will refer herein to these three patents as the "dosing patents" and to the three claims as the "asserted claims."

3. For the reasons set forth in this declaration, it is my opinion that the prior art upon which Amgen relies does not contain sufficient information with respect to trastuzumab to reasonably predict that the three-week dosing regimen recited in the asserted claims would be effective to treat HER2-positive cancer. On the contrary, a skilled artisan considering the prior art would be concerned that extending the dosing interval from the weekly regimen approved by the Food and Drug Administration to a three-week regimen, even at higher doses, would not maintain adequate serum trough concentrations of trastuzumab.

II. Qualifications

4. I am President of G2 Research, Inc., a company I founded in August 2001 to provide consulting services to pharmaceutical and biotechnology companies in a variety of areas. Among other things, I have performed pharmacokinetic modeling to evaluate clinical regimens for antibodies and small molecules. I have also developed computer simulation software and models to predict drug pharmacokinetics.

5. I obtained a Ph.D. in Pharmaceutics at the University of Wisconsin, Madison in 1985. My Ph.D. thesis was entitled "Mechanisms of Corneal Drug Penetration." As a result of

this research, I was the co-recipient of the 1989 Ebert Prize, awarded by the American Pharmacists Association Academy of Pharmaceutical Research and Sciences, for a series of manuscripts published in the *Journal of Pharmaceutical Sciences* entitled "Mechanisms of Corneal Drug Penetration." I obtained a M.S. degree in Pharmaceutics at the University of Wisconsin, Madison in 1983. I obtained a Pharm. D. degree from the University of Nebraska in 1980, and was formerly licensed to practice pharmacy in the state of Nebraska.

6. I have spent more than thirty years working in the pharmaceutical industry. From 1985 to 1991, I worked as a Research Scientist at Syntex Research in Palo Alto, where I was responsible for formulation development and research in oral drug absorption, including methods to orally deliver peptides. Since 1991, I have been a pharmaceutical industry consultant. In 1991, I started my own company, Precision Instrument Design Inc., and, in 1997, another company, NaviCyte, Inc. In 1999, NaviCyte, Inc. was acquired by Trega Biosciences, and I served as Chief Technology Officer at Trega Biosciences, Inc. until 2001. In 2001, I founded G2 Research, Inc., and also founded RaptorGraphics, Inc., a computer graphics and simulation business. From 2005 to 2007, I was Vice President of Product Development and Chief Technology Officer for PDxRx, Inc., a specialty-focused pediatrics company. From 2007 to 2010, I was Senior Vice President of Research and Development for Sorbent Therapeutics, Inc., a company developing novel polymer therapeutics for sodium fluid removal. From January 2016 until May 2017, I was Senior Vice President of non-clinical development and founder for NeuroVia, Inc., a company developing a novel compound for childhood cerebral adrenoleukodystrophy.

7. I am the author or co-author of more than 30 published scientific articles, primarily in the areas of models to predict drug pharmacokinetics, corneal permeability and drug

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.