UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX INC. and APOTEX CORP.,

Petitioners,

v.

NOVARTIS AG,

Patent Owner.

Case IPR2017-00854

U.S. Patent No. 9,187,405

DECLARATION OF FRED D. LUBLIN, M.D.

Mail Stop Patent Board
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Apotex v. Novartis

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

I, Fred D. Lublin, M.D., declare as follows:

I. Introduction

1. I am a Professor of Neurology and the Director of the Corinne Goldsmith Dickinson Center for Multiple Sclerosis at the Icahn School of Medicine at Mount Sinai, and Attending Neurologist at Mount Sinai Hospital in New York City. My full qualifications are below and in my CV (Ex. 2004).

2. Counsel for Novartis AG has asked for my view on issues related to the Apotex Petitioners' proposed challenges to U.S. Patent No. 9,187,405 in this proceeding. The '405 Patent claims a method of using fingolimod to treat relapsing-remitting multiple sclerosis (RRMS), a debilitating disease in which the immune system attacks the body's own central nervous system. The method involves administering 0.5 mg of fingolimod daily without any loading dose to a subject in need of reducing, preventing, or alleviating RRMS relapses; treating RRMS; and/or slowing progression of the disease. Fingolimod is the active ingredient in Novartis's Gilenya® RRMS medication, and Gilenya's label instructs doctors to use the method claimed in the '405 Patent. I understand Apotex argues that the '405 Patent's method would have been obvious to a person of skill in the art in June 2006, when Novartis filed the application for the Patent.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

3. Counsel has asked me two questions. First, who would be a "person of skill in the art" for purposes of the '405 Patent? Second, what would the differences among the Patent's claims mean to a person of skill?

4. I set out my full conclusions below. In summary, a "person of skill" here would be a team of people skilled in drug-dose development. That would include one or more people with skill in pharmacology, typically with biology degrees and expertise analyzing pharmacokinetic (PK) and pharmacodynamic (PD) data. I understand that Apotex and its expert Dr. Barbara Giesser contend that a person of skill would be solely a medical doctor. I disagree. A physician might be on the team, but, unless he or she had the necessary PK/PD skills, they would not develop initial dose strategies. They would lack the skills needed to interpret and extrapolate from data measuring how the drug behaves in the body.

5. As for the differences among the '405 Patent's claims, they would be important to a person of skill. Claims 1 and 2 describe a method for a subject in need of "reducing or preventing or alleviating relapses in" RRMS; claims 3 and 4 describe a method for a subject in need of "treating" RRMS; and claims 5 and 6 describe a method for a subject in need of "slowing progression" of RRMS. These different therapeutic claims describe different aspects of the disease. As a result, a person of skill would understand the inventors had patented methods that treat multiple dimensions of RRMS, unlike other therapies that might treat only one.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

Having a single medicine that could accomplish all of these goals was a significant advance in June 2006.

6. I understand that Apotex and Dr. Giesser argue that these differences among the Patent's claims do not matter because all RRMS patients need the benefits the claims describe. I disagree. The inventors here developed methods that would provide relief for different aspects of the disease at the same time, unlike other available treatments. I read the claims' use of these different terms to reflect that discovery.

7. My analysis here is based on the knowledge that I have acquired as a practicing neurologist for approximately 40 years; my research in the fields of neurology and MS; articles with which I am familiar; and the Exhibits I have cited within this declaration.

II. Qualifications

8. I am a licensed physician in both New York and Pennsylvania, and have been certified by the American Board of Medical Examiners and the American Board of Psychiatry and Neurology.

9. My professional interests relate primarily to neurology and neuroimmunology, and specifically the scientific and clinical aspects of MS, as well as the research and development of therapies for treating MS. I have authored or co-authored over 190 peer-reviewed academic publications in the field of neurology,

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

with an emphasis on MS. In addition, I co-wrote the textbook Multiple Sclerosis in Clinical Practice, Martin Dunitz, Ltd. (2003), and have written or co-written over 240 textbook chapters, editorials, abstracts, and letters in my areas of interest.

10. I received an A.B. from Temple University in 1968 (magna cum laude), and an M.D. from Jefferson Medical College in 1972 (summa cum laude). From 1972-1973, I interned at the Bronx Municipal Hospital-Albert Einstein Medical Center in New York City, specializing in internal medicine. Also in 1972, I completed an externship at the National Hospital for Nervous Disease in London. From 1973-1976, I was a resident in Neurology at New York Hospital-Cornell Medical Center in New York City, NY.

11. I have maintained an active neurology practice for the last 40 years, first as a resident at New York Hospital (1973-1976), and then as an attending physician at Thomas Jefferson University Hospital (1976-1996), Medical College of Pennsylvania Hospital and Hahnemann University Hospital (1996-2000), and Mount Sinai Hospital (2000-present).

12. From 1975-1976, I was an Instructor in Neurology at Cornell Medical College. From 1976-1978, I was an Instructor in Neurology and a Research Associate in Biochemistry (Immunology) at Jefferson Medical College of Thomas Jefferson University. In 1978, I was promoted to Assistant Professor of Neurology and Assistant Professor of Biochemistry. In 1982, I was further promoted to

DOCKET
ALARM
Find authenticated court documents without watermarks at docketalarm.com.

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.

WHAT WILL YOU BUILD? | **sales@docketalarm.com** | **1-866-77-FASTCASE**

fastcase®
Smarter legal research.