UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE PATENT TRIAL AND APPEAL BOARD

_____

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BIOGEN MA INC.,
Patent Owner.

Case IPR2018-01403
Patent 8,399,514 B2

DECLARATION OF MATVEY LUKASHEV, PH.D.

Table of Contents

I, Matvey Lukashev, have personal knowledge of the facts stated herein and provide the following testimony:

I. Personal Background and Introduction

1. I am the Senior Director of Translational Research at the ALS Therapy Development Institute in Boston, Massachusetts. I received my Ph.D. from the Russian Academy of Medical Sciences and did my postdoctoral training at Johns Hopkins and the University of California, San Francisco. My career has focused on drug development in the fields of neurology, oncology, immunology, and fibrosis.

2. Prior to working at the ALS Therapy Development Institute, I was employed as a scientist by Biogen for nearly 15 years, from 1998 through 2012. During that time, I worked on a drug candidate called BG-12, now known as Tecfidera® and prescribed for the treatment of multiple sclerosis. As a result of my work on BG-12 and described in more detail below, I am a named co-inventor, together with Dr. Gilmore O'Neill, on Biogen's U.S. Patent No. 8,399,514 ("the '514 patent").

3. I understand that the U.S. Patent and Trademark Office has instituted an *Inter Partes* Review, IPR2018-01403, involving the '514 patent.

4. I provide this declaration based on my personal knowledge and my role in the subject matter of the '514 patent.

II. Inventorship of the '514 Patent Claims

5. My work at Biogen on the BG-12 project related to mechanism of action analysis and biomarker discovery, for which I was a research lead. Through this work, I discovered that dimethyl fumarate interacts with Keap1, the key regulator of the Nrf2 pathway. Examples 1-3 in the '514 patent describe some of the work that I supervised in understanding this mechanism of action.

6. I am not a clinician and was not involved in the clinical aspects of the BG-12 MS program. I was not involved in the selection of doses to be used in clinical trials, which is not my expertise, nor was I involved in the portions of the '514 patent dealing with clinical treatment of disease. My focus and expertise is on the research and discovery side of pharmaceutical drug development rather than the clinical side.

7. I have reviewed the claims of the '514 patent. Dr. O'Neill is solely responsible for discovering the subject matter of claims 1-16 and 20, which are directed to methods of treating MS by administering about 480 mg per day of dimethyl fumarate, monomethyl fumarate, or a combination thereof. Both Dr. O'Neill and I are jointly responsible for the subject matter of claims 17-19, which are directed to those methods, as well as the increased expression level of NQO1 when dimethyl fumarate is administered to a patient, the latter part of which was my contribution.

III. Conclusion

8. I declare that all statements made herein of my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

9. In signing this declaration, I understand that the declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I acknowledge that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the time allotted for cross examination.

DATE: 05.28.2019

By: M. Lukashev
Matvey Lukashev

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.