

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.
Petitioner

v.

SUMITOMO DAINIPPON PHARMA CO., LTD.
Patent Owner

U.S. Patent No. 9,555,027

Title: Pharmaceutical Composition

Inter Partes Review Case No. Unassigned

DECLARATION OF DR. ADAM KAPLIN
17 April, 2017

CONTENTS

	Page
I. INTRODUCTION	1
II. BACKGROUND AND QUALIFICATIONS	2
III. LEVEL OF ORDINARY SKILL IN THE ART	4
IV. SUMMARY OF OPINIONS	5
V. OPTIMAL LURASIDONE DOSAGE RANGE	6
VI. OPTIMAL DELIVERY OF LURASIDONE USING A SINGLE TABLET	8
VII. IMMEDIATE RELEASE PREPARATIONS	10
VIII. CONCLUSION	12

I, Dr. Adam Kaplin, hereby declare as follows.

I. INTRODUCTION

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of Par Pharmaceutical, Inc. (“Par”) for the above-captioned *Inter Partes* Review (“IPR”). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$400 per hour for my work on this matter. I also am reimbursed for travel and other direct expenses. I have no personal or financial interest in the outcome of this proceeding.

3. I understand that this declaration is being submitted in support of a petition for IPR of U.S. Patent No. 9,555,027 (Ex. 1001, “the ’027 Patent”), which issued from U.S. Application No. 14/512,189 on January 31, 2017. The ’027 Patent names Kazuyuki Fujihara as inventor. I further understand that, according to USPTO records, the ’027 Patent is currently assigned to Sumitomo Dainippon Pharma Co., Ltd.

4. In preparing this declaration, I have reviewed the ’027 Patent, as well as each of the documents cited herein, in light of the general knowledge in the field as of May 26, 2005. In forming my opinions, I have relied upon my experience, education, and knowledge in the relevant art.

II. BACKGROUND AND QUALIFICATIONS

5. I am the Chief Neuropsychiatric Consultant at the Johns Hopkins Multiple Sclerosis and Transverse Myelitis Centers, where my research focuses on the biological bases of the effects of the immune system on mood regulation and cognition, the biological bases of depression and dementia, and discovering new ways to diagnose and treat such diseases. I also provide a weekly Neuropsychiatric Consultation Clinic for patients around the world to receive ongoing care for such conditions.

6. I received my B.S. in Biology from Yale University in 1988 and my M.D. and Ph.D. from Johns Hopkins School of Medicine in 1996. While completing my undergraduate research thesis, I trained in the laboratory of Nobel Laureate Sidney Altman, Ph.D. As an assistant researcher at the Yale School of Medicine, I also trained in the laboratory of Nobel Laureate George Palade, M.D. I then completed my Ph.D. and postdoctoral training in the laboratory of Solomon Snyder, M.D., a recipient of the National Medal of Science.

7. More recently, I have helped develop and apply technological innovations to improve patient care and clinical research, including inventing and developing an automated mood-tracking technology that functions as a personalized, electronic health diary for clinical patients.

8. I am on the board of medical advisors to the Montel Williams MS Foundation, Cody Unser First Step Foundation, Nancy Davis MS Foundation and Center Without Walls, and Johns Hopkins Multiple Sclerosis and Transverse Myelitis Center's Project RESTORE. I am also a medical advisor to Remedy Health Media, Anthrotonix Inc., and My Counterpane.

9. At Johns Hopkins School of Medicine, I have taught post-doctoral courses on bioethics and psychiatry courses for medical students. I continue to teach seminars on ethics in psychiatry.

10. I have published over 40 peer-reviewed research articles in the areas of spinal cord disorders, depression, and other neurologic disorders. I have also authored books and book chapters on diseases of the nervous system and other neurological and psychiatric disorders, including contributions to the Oxford Textbook of Psychiatry. In addition, I am a named inventor on 10 patents and patent applications, including several for the treatments of neurological autoimmune diseases.

11. In more recent years, I have received Baltimore Magazine's Top Psychiatrist award for 2012, the inaugural Elsevier Clinical Keys Innovator Award in 2013, and the inaugural PM360 award as ELITE Tech Know Geek for excellence and innovation in Health Information Technology in 2015.

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