

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA, LLC,
Petitioner

v.

SUMITOMO DAINIPPON PHARMA CO., LTD.,
Patent Owner

Case IPR2020-01053
Patent 9,815,827

DECLARATION OF DR. STEPHEN STAHL

TABLE OF CONTENTS

	PAGES
I. QUALIFICATIONS AND PROFESSIONAL EXPERIENCE.....	4
II. FEES AND PRIOR EXPERT TESTIMONY.....	7
III. INFORMATION CONSIDERED	8
IV. SUMMARY OF OPINIONS	8
V. PERSON OF ORDINARY SKILL IN THE ART.....	8
VI. CLAIM CONSTRUCTION.....	10
VII. LEGAL PRINCIPLES.....	10
VIII.BACKGROUND	13
A. Psychotic Disorders	13
1. Schizophrenia.....	13
2. Bipolar Disorder.....	14
B. Atypical Antipsychotics.....	16
C. The Mechanisms Underlying Weight Gain Are Complex and Poorly Understood.....	31
IX. U.S. PATENT NO. 9,815,827	36
X. OPINIONS REGARDING PRIORITY	38
XI. OPINIONS REGARDING OBVIOUSNESS.....	42
A. Claims 1-75 of the '827 Patent Are Not Obvious Over Saji '372.	44
B. Lack of Weight Gain Was Surprising and Unexpected.....	50
1. Horisawa Does Not Establish That Lack of Weight Gain Was Expected.	50
2. Ziprasidone's Lack of Weight Gain Does Not Establish That Lurasidone's Lack of Weight Gain Was Expected.	55
3. Lack of Weight Gain Was Not Expected Based on "Diversity of Humans."	59
C. Long Felt Need and Failure of Others Supports Non-Obviousness.....	60
D. Industry Skepticism Supports Non-Obviousness.....	63
E. The Prior Art Taught Away from Dosing Regimens in Which Lurasidone was the Sole Active Ingredient.	68
F. Lack of Weight Gain Is Not Inherent in the Prior Art.	69
XII. CONCLUSION	70

1. My name is Dr. Stephen Stahl. I am being offered as an expert to testify on behalf of Patent Owner Sumitomo Dainippon Pharma Co., Ltd. (“Sumitomo”) regarding the patentability of U.S. Patent No. 9,815,827 (“the ’827 patent”) in the above captioned case.

I. QUALIFICATIONS AND PROFESSIONAL EXPERIENCE

2. I have attached my curriculum vitae as Appendix A to this report. I have summarized my educational and professional background below.

3. I received my undergraduate and medical degrees from Northwestern University, Evanston, Illinois in 1973 and 1974, respectively. I received my Ph.D. in Neuropharmacology from the University of Chicago, Chicago, Illinois in 1976.

4. I have trained in three specialties: internal medicine at the University of Chicago; neurology at the University of California, San Francisco; and psychiatry at Stanford University. I am board certified in psychiatry and have been since 1981.

5. I have held faculty positions at Stanford University (1981-1985), the University of California, Los Angeles (1985-1988), the Institute of Psychiatry in London (1985-1988), the Institute of Neurology and the National Hospital for Nervous Disease in London (1987-1988). Currently, I am a Professor of Psychiatry at the University of California, San Diego and a Professor of Psychiatry and

Neuroscience at the University of California, Riverside. I am also an Honorary Visiting Senior Fellow in the Department of Psychiatry at the University of Cambridge in the United Kingdom.

6. I formerly served as the Assistant Director at the Stanford Mental Health Clinical Research Center at Stanford University Medical Center (1981-1985), a Guest Research Physician at the Donner Laboratory, Positron Emission Tomography Unity at Lawrence Berkeley Laboratories, University of California, Berkeley (1985-1985), and the Medical Director at the Institute for Psychopharmacology Research in San Diego and Carlsbad, California (1991-2001). I am currently the Director of Psychopharmacology for services and academic programs for the 5 facility, 6,500 patient California Department of State Hospital System.

7. I was formerly the Director of Clinical Sciences, Associate Medical Director and Principal Scientist at Alza Corporation in Palo Alto, California (1982-1984). I was also the Executive Director of Clinical Neuroscience and Director of the Laboratory of Clinical Neuropharmacology at the Merck Neuroscience Research Center in Harlow, Essex, United Kingdom (1985-1988). I currently serve as the Chairman of both the Neuroscience Education Institute and The Arbor Scientia Group located in Carlsbad, California.

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.