

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Alkermes Pharma Ireland, Ltd.
and Alkermes, Inc.
Petitioners,

v.

Otsuka Pharmaceutical Co., Ltd.
Patent Owner
Patent No. 9,125,939 B2
Issued: September 8, 2015
Filed: August 2, 2006
Inventors: Tetsuro Kikuchi, Taro Iwamoto, Tsuyoshi Hirose

Title: CARBOSTYRIL DERIVATIVES AND MOOD STABILIZERS FOR
TREATING MOOD DISORDERS

Inter Partes Review No. IPR2017-00287

**DECLARATION OF JESSIE AU, PHARM.D., PH.D., IN SUPPORT OF
THE PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 9,125,939**

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1. I, Jessie Au, Pharm. D., Ph.D., declare as follows:

I. INTRODUCTION

2. I have been retained by Alkermes, Inc. and Alkermes Pharma Ireland Limited (collectively, “Alkermes”) in connection with its petition for *inter partes* review of U.S. Patent No. 9,125,939 (“the ’939 patent”). I am being compensated for the time spent preparing this declaration, at my customary consulting rate of \$750 per hour. My compensation is not contingent on the outcome of any matter or on any of the opinions provided below. I have no financial interest in the outcome of this proceeding.

3. The opinions set forth in this declaration are my own. My opinions are based on many years of experience in the fields of pharmacology and therapy development. In forming my opinions, I also relied on the documents cited herein and in my appendices.

II. BACKGROUND AND QUALIFICATIONS

4. I received my Doctor of Pharmacy (in clinical pharmacy) and Doctor of Philosophy (in pharmaceutical chemistry) degrees from the University of California San Francisco, in 1972 and 1980, respectively. I joined the faculty of The Ohio State University in 1983 as an assistant professor, rose to the rank of Full Professor in 1992, and received the life-time honorific title of Distinguished University Professor in 1998. I took early retirement from The Ohio State

University in 2013 and currently hold the title of Distinguished University Professor Emeritus.

5. I am a co-founder and Chief Scientific Officer of Optimum Therapeutics LLC, a research and development company that has been in operation since 2003 and is located in Carlsbad, San Diego County, CA.

6. I have additional appointments at several academic institutions in the United States and abroad. I am Research Professor and Mosier Endowed Chair in Pharmaceutical Sciences at the University of Oklahoma Health Sciences Center, Adjunct Professor of Surgery at Medical University of South Carolina, Chair Professor in Systems Pharmacology at Taipei Medical University (Taipei, Taiwan, Republic of China), and Distinguished Scholar at Chinese University of Hong Kong in Hong Kong (SAR, China).

7. In April 2016, I co-founded Institute of Quantitative Systems Pharmacology (QSP). The goal of this institute is to develop a multi-institutional QSP training program on drug development. This program is designed to (a) stimulate collaborative QSP research projects among participating faculty members, (b) provide cross-laboratory training to students (*i.e.*, QSP students are mandated to work in two or more laboratories for their dissertation research), and (c) provide internship to QSP students at end-user institutions (*e.g.*, regulatory agencies, pharmaceutical companies).

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