

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 ALLEN FRANCES, M.D. IN SUPPORT OF THE
PETITION FOR INTER PARTES REVIEW OF
U.S. PATENT NO. 9,125,939**

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G. Secondary Considerations Fail to Demonstrate the Non-Obviousness of
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XII. COMPENSATION51

XIII. SUPPLEMENTATION52

I, Allen Frances, M.D., submit this declaration on behalf of Petitioners Alkermes Pharma Ireland Ltd. and Alkermes, Inc. (collectively, “Alkermes”) to address the obviousness of claims 2, 6, 7, and 9 of U.S. Patent No. 9,125,939 to Kikuchi *et al.*, titled “Carbostyryl Derivatives and Mood Stabilizers for Treating Mood Disorders” (“the ’939 Patent”, Ex. 1001), and to provide technical background, scientific and clinical information that is relevant to that analysis.

I. ASSIGNMENT

1. I was asked to offer opinions on the level of ordinary skill in the field to which the ’939 patent pertains, that is, the qualifications of an individual to whom the alleged invention described in the ’939 patent would be directed to. I understand that the application that resulted in the issuance of the ’939 patent was filed on May 23, 2003. I understand that I have been asked to offer my opinions from the point of view of a person of ordinary skill prior to that date, that is, May 22, 2003 or earlier.

2. I was also asked to opine on whether the inventions of claims 2, 6, 7, and 9 of the ’939 patent would have been obvious to a person of ordinary skill as of May 22, 2003, in view of the knowledge and experience of that person as well as the prior art, that is, whether the above-referenced individual would have found the alleged invention of the ’939 patent to be a routine advancement in the

scientific field, requiring nothing more than a knowledge of scientific references that were available at the time, together with ordinary practice.

II. QUALIFICATIONS AND EXPERIENCE

3. I am a board certified clinical psychiatrist with nearly 50 years of experience treating patients for psychiatric and mood disorders. I received a B.A. from Columbia College (1963) and an M.D. from Downstate Medical Center (1967), and I completed my residency and fellowship in psychiatry and psychoanalytic medicine at Columbia University hospitals and the New York State Psychiatric Institute.

4. I am currently Professor Emeritus and former Chair of the Department of Psychiatry and Behavioral Sciences at Duke University, where I have been since 1991. Prior to that, I held professorial positions in psychiatry at the Columbia University College of Physicians and Surgeons and at the Cornell University Medical College.

5. I was Chair of the DSM-IV Task Force and also held leadership positions in the preparation of DSM-III and DSM-III-R. DSM refers to Diagnostic and Statistical Manual of Mental Disorders, a set of standards used by health professionals in the United States for the classification and diagnosis of mental disorders. My responsibilities as Chair of the DSM-IV Task Force included establishing the methods used in its preparation; recruiting the approximately one

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