

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC
Petitioner

v.

MERCK PATENTGESELLSCHAFT
Patent Owner

Patent No. 8,673,921

Issue Date: March 18, 2014

Title: POLYMORPHIC FORMS OF
1-[4-(5-CYANOINDOL-3-YL)BUTYL]-4-
(2-CARBAMOYLBENZOFURAN-5-YL)
PIPERAZINE HYDROCHLORIDE

Inter Partes Review No.: Unassigned

DECLARATION OF DR. SANJAY J. MATHEW, M.D.

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I, Sanjay Mathew, do declare as follows:

I. Introduction

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of Argentum Pharmaceuticals LLC for a *inter partes* review (IPR) for U.S. Patent No. 8,673,921 (“’921 patent”) (Ex. 1001). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$700 per hour. I understand that my declaration accompanies a petition for *inter partes* review involving the above-mentioned U.S. Patent.

I. My Background and Qualifications

3. I am currently Professor of Psychiatry with Tenure at the Menninger Department of Psychiatry at Baylor College of Medicine. In addition, I am also Staff Physician at the Michael E. DeBakey VA Medical Center since 2010. Since 2010, I have also been the Director of the Mood and Anxiety Disorders Program. As of 2014, I am also the Johnson Family Chair for Research in Psychiatry. I have authored numerous original research articles, reviews, book chapters, and abstracts for meetings.

4. I received a B.A. in Biology in 1991 from Dartmouth College in

Hanover, New Hampshire and a M.D. in 1997 from Baylor College of Medicine in Houston, Texas. From 1997-1998, I was an intern at Columbia-Presbyterian Hospital in New York. During the period of 1998–2001, I completed my Residency at New York State Psychiatric Institute (NYSPI). I also completed a National Institute of Mental Health (NIMH)-funded T32 Research Fellowship in Mood/Anxiety Disorders at Columbia University from 2001-2004.

5. I was re-certified to the American Board of Psychiatry and Neurology in 2012.

6. I am a member of the American Psychiatric Association, the American Medical Association, Anxiety and Depression Association of America, International Society of Magnetic Resonance in Medicine, Society of Biological Psychiatry, Society for Neuroscience, American College of Neuropsychopharmacology, European College of Neuropsychopharmacology, American Society of Clinical Psychopharmacology, and the National Network of Depression Centers.

7. My area of expertise is in the psychopharmacological management of adult patients with difficult-to-treat depressive and anxiety disorders. Accordingly, I believe that I am more than competent to express the opinions set forth below.

8. My *curriculum vitae* is attached as an appendix to this document.

II. The Basis for My Opinion

9. In formulating my opinion, I considered the documents listed in

Appendix A.

II. Legal Principles

A. Anticipation

10. I understand from counsel that a patent claim is “anticipated” if all elements of the claim are disclosed in a single prior art reference in the same way the elements are arranged in the claim. I further understand that where a reference provides broad disclosure of a larger group of, *e.g.*, combinations, as well as specific preferences for the combinations, the reference still anticipates so long as all claim elements are disclosed as arranged in the claim. I am also told that the prior art reference must be enabling (*i.e.*, allowing a Person of Ordinary Skill in the Art (“POSA”) to make and use the claimed invention without undue experimentation) in order to anticipate the claim.

B. Obviousness

11. I understand that an obviousness analysis involves comparing a claim to the prior art to determine whether the claimed invention would have been obvious to a POSA in view of the prior art, and in light of the general knowledge in the art. I also understand that when a POSA would have reached the claimed invention through routine experimentation, the invention may be deemed obvious. I understand that a finding of obviousness for a specific range or ratio in a patent can be overcome

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