

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

SLAYBACK PHARMA LLC

Petitioner

v.

SUMITOMO DAINIPPON PHARMA CO., LTD

Patent Owner

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Patent No. 9,815,827

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*Inter Partes* Review No. Unassigned

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**DECLARATION OF DR. THOMAS R. KOSTEN, M.D.**

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1. I, Thomas R. Kosten, M.D., have been retained by counsel for Petitioner Slayback Pharma LLC (Petitioner or Slayback). I understand that Petitioner seeks *inter partes* review (“IPR”) of U.S. Patent 9,815,827 (EX-1001, ‘827 Patent), assigned to Sumitomo Dainippon Pharma Co., Ltd. (Patent Owner) to request that the United States Patent and Trademark Office cancel claims 1-75 of the ‘827 patent as unpatentable. I submit this expert declaration in support of Petitioner’s IPR Petition for the ‘827 patent.

## **I. QUALIFICATIONS AND BACKGROUND**

### **A. Education and Experience**

2. My education and experience includes training as a medical doctor with board certification in Psychiatry from the American Board of Psychiatry and Neurology.

3. I am presently a professor in the Departments of Psychiatry, Pharmacology and Neuroscience at Baylor College of Medicine, Vice-Chair of Psychiatry and founding Director of the Division of Addictive Disorders and Alcoholism. I have directed psychiatric treatment programs for over 25 years including the Yale University and Veterans Administration (VA) programs in Connecticut and now in Houston, Texas. I am also the past national Director for the VA substance use disorders Quality Enhancement Research Initiative Center, which monitors and sets standards for the quality of VA substance abuse care.

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4. In my practice, I have had numerous opportunities to determine when individuals are treated appropriately with a full range of psychotropic medications including antipsychotics such as Latuda® (lurasidone HCl) and complications of these treatments. Because of my education, training and experience, I can provide an expert opinion on this class of antipsychotic medications, their development and their application to a range of psychiatric disorders including, but not limited to, schizophrenia and non-schizophrenic disorders such as and including bipolar disorders.

5. I have treated hundreds of patients with antipsychotic medications such as lurasidone.

6. Since 2001, based on an annual ranking by U.S. News & World Report, I have retained the distinction of “Top Doc” in the field of psychiatry; rated in the top 10% of Addictions Medicine, and top 1%, of United States physicians nationwide. I am an editor for the *American Journal on Addictions* and was on the editorial boards of the American Journal of Psychiatry and major journals in the field of psychiatry.

7. I am a Distinguished Life Fellow in the American Psychiatric Association and the American College of Neuropsychopharmacology (ACNP), the organization responsible for the journal *Neuropsychopharmacology*.

8. I received a Bachelor of Science in Biophysics from Rensselaer

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Polytechnic Institute/Troy, NY in 1973 and a Medical Degree from Cornell University Medical College/New York, NY in 1977.

9. A copy of my *curriculum vitae* is attached as Exhibit A and provides all 750 of my publications. In it are detailed my internationally recognized credentials as an expert in psychiatric disorders including schizophrenic, substance use, anxiety and affective disorders, which includes bipolar disorders.

**B. Materials Considered**

10. In forming my opinions set forth in this declaration, I considered and relied upon my education, background, and years of experience in the practice of medicine in the field of psychiatry, as well as the materials identified in this Declaration. The materials considered are listed in Exhibit C.

**C. Scope of Work, Compensation, Other Matters**

11. I have been retained by counsel for Petitioner in connection with this matter. I am being compensated for my consulting work at the rate of \$450 per hour. My compensation in this case is in no way dependent on the outcome of this matter. A list of the cases since 2014 where I have testified as an expert is attached as Exhibit B.

## II. SUMMARY OF OPINIONS

12. As discussed in this Declaration:

a) It is my opinion that the methods of treatment claimed in the manic depressive claims of the '827 Patent are disclosed in Latuda® Information (EX-1007), and therefore, each manic depressive claim of the '827 Patent is anticipated by Latuda® Information.

b) It is my opinion that the manic depressive claims were obvious to a POSA when Latuda® Information (EX-1007) and Loebel (EX-1008) are viewed in light of the state of the art prior to August 27, 2013.

c) It is my opinion that claims 1-75 of the '827 Patent are invalid for obviousness over the Saji Patent (EX-1009) in light of the prior art.

13. The claims of the '827 Patent (EX-1001) relate to methods of using lurasidone or its salts to treat psychiatric disorders. Some issued claims of the '827 Patent are limited to treating schizophrenia. Other issued claims of the '827 Patent, referred to herein as the “manic depressive claims” comprise treating “manic depressive psychosis.”

14. The manic depressive claims of the '827 Patent all require:

- a) treating manic depressive psychosis;
- b) by administering lurasidone or its salts;
- c) orally;

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