

Filed on behalf of: Corcept Therapeutics, Inc.

Entered: May 20, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NEPTUNE GENERICS, LLC,
Petitioner,

v.

CORCEPT THERAPEUTICS, INC.,
Patent Owner.

Case IPR2018-01494
U.S. Patent No. 8,921,348

**DECLARATION OF DR. NED H. KALIN, M.D. IN SUPPORT OF
PATENT OWNER'S RESPONSE**

<p>Corcept Therapeutics, Inc. Exhibit 2016 Neptune Generics, LLC v. Corcept Therapeutics, Inc. Case IPR2018-01494</p>

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I. INTRODUCTION AND QUALIFICATIONS

1. I have been retained by Corcept Therapeutics, Inc. ("Patent Owner" or "Corcept") to provide certain opinions related to U.S. Patent No. 8,921,348 ("the '348 Patent") in support of Patent Owner's Response in IPR2018-01494.

2. I am being compensated at my standard hourly rate of \$500 per hour, with reimbursement for reasonable expenses, for my work related to the IPR proceeding cited above. My compensation is not dependent on, and in no way affects, the substance of my statements in this Declaration.

3. I am the Hedberg Professor and Chairman of the Department of Psychiatry at the University of Wisconsin School of Medicine and Public Health. I am the Editor-in-Chief of the *American Journal of Psychiatry*, a premier scientific journal of the American Psychiatric Association. I am the Director of the HealthEmotions Research Institute and the Lane Neuroimaging Laboratory, a Professor in the Department of Psychology at the University of Wisconsin, and an affiliate scientist at the Wisconsin Regional Primate Center and the Harlow Primate Laboratory.

4. I serve as the principal investigator for several ongoing NIH funded research projects and have published over 200 peer-reviewed journal articles related to the adaptive and maladaptive expression of emotion and anxiety. My research focuses on uncovering basic mechanisms that relate stress to the

development of psychopathology and understanding the mechanisms that cause some children to be vulnerable for the development of anxiety and depression. In addition to my research activities, I treat patients who suffer from anxiety and depression who are refractory to standard treatment.

5. I earned my medical degree from Jefferson Medical School in Philadelphia, Pennsylvania. I did my residency in the Department of Psychiatry at the University of Wisconsin and my fellowship in Neuropsychopharmacology at the National Institute of Mental Health. I am board certified by the American Board of Psychiatry and Neurology. I am a fellow of the American College of Neuropsychopharmacology and the American College of Psychiatry.

6. I have been recognized for numerous awards including the 1985 A.E. Bennett Award for basic science research in biological psychiatry, the 2005 Edward A. Strecker Award, the 2007 American College of Psychiatrists Award for research in mood disorders, the 2007 Gerald Klerman Senior Investigator Award, and the 2015 Anna-Monika Prize of the European College of Neuropsychopharmacology. In 2013, I was inducted as a Fellow in the American Association for the Advancement of Science, and, in 2015, I was elected as a member of the National Academy of Medicine.

7. In 2017, I was inducted as a Distinguished Life Fellow of the American Psychiatric Association and was appointed to the Editorial Board of the

Journal of Psychiatric Research. I served as President of the International Society of Psychoneuroendocrinology, as President of the Society of Biological Psychiatry, and as a member of the National Advisory Mental Health Council. I was Co-Editor for the international journal, *Psychoneuroendocrinology*. I lecture regularly at national and international meetings.

8. From time to time, I have worked on various projects for Corcept. Over the past ten years, Corcept has paid me \$5,750 for my efforts. Corcept has also provided grant support to the University of Wisconsin. Those grants have been used in part to fund my research team, but I also receive funding from other sources, including, for example, from the National Institute of Mental Health.

9. A copy of my curriculum vitae is attached as Ex. 2017.

II. ASSIGNMENT

10. In forming my opinions in this Declaration, I have reviewed the materials cited in and listed in the Appendix to this Declaration. I have been asked to explain the tools and tests that clinicians and psychiatrists use to evaluate and monitor the efficacy of psychiatric drugs for treating various mental disorders such as depression, stress disorders, delirium, and others. I have based this on my academic pursuits, training, and experience as a practicing psychiatrist since 1979. I have prescribed various drugs for the treatment of various psychiatric diseases,

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