

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
Petitioner

v.

ALKERMES PHARMA IRELAND LIMITED,
Patent Owner

Case IPR2018-00943
Patent 7,919,499

DECLARATION OF CHARLES P. O'BRIEN, M.D., Ph.D.

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I, Charles P. O'Brien, M.D., Ph.D., declare:

INTRODUCTION

1. I am of legal age and am competent to make this Declaration.
2. I understand that the Patent Trial and Appeal Board has granted Amneal Pharmaceuticals LLC's ("Amneal") Petition for *Inter Partes* Review of claims 1–13 of U.S. Patent No. 7,919,499 ("the '499 patent").
3. I understand the '499 patent to be directed to Vivitrol, which was formerly known as "Vivitrex."

MY BACKGROUNDS AND QUALIFICATIONS

4. My qualifications, professional experience, education, and publications are set forth in my *curriculum vitae*, attached as Appendix A. Below is a brief summary.
5. I am a professor emeritus and have been a faculty member for the Department of Psychiatry at the University of Pennsylvania since 1971. I also recently served as its Vice-Chairman, a position I began in 1986. I first started teaching at the University of Pennsylvania in 1969 as an Instructor.
6. I received my B.S. from Tulane University in 1960 and my M.D. from Tulane Medical School in 1964. In 1964 I also received a M.S. in Physiology (Neurophysiology) from The Graduate School at Tulane University and then in 1966 I received a Ph.D. in Physiology (Neurophysiology) from The Graduate

School at Tulane University. I completed residencies at multiple hospitals, including the Massachusetts General Hospital in Boston and the National Hospital for Nervous Diseases in London.

7. After completing my education I served in the Navy from 1969-1971. I was a Lieutenant Commander at the Philadelphia Naval Hospital and worked at the Long Term Neuropsychiatric Unit.

8. I have held multiple positions at hospitals, including most recently the Director of Research, MIRECC at the VA Medical Center in Philadelphia, PA. Before this, I was the Chief of Psychiatry at the Philadelphia VA and I was responsible for over 9,000 psychiatric patients. I am also the Founding Director of the Center for Studies of Addiction at the University of Pennsylvania.

9. I have received numerous awards, honors, and membership opportunities in honorary societies for my work. Some of these include the 2003 Edward A. Strecker, M.D. Award for outstanding contributions to the field of Clinical Psychiatry, Pennsylvania Hospital and the Hospital of the University of Pennsylvania, the 2010 Gold Medal Award – Society of Biological Psychiatry, the 2012 Special Dean’s Award for outstanding achievements in medical education – University of Pennsylvania. I have also received an Honorary Doctorate from the University of Bordeaux, France for research collaborations with French scientists.

In addition, the National Institute on Drug Abuse presented me the 2015 Lifetime Science Award.

10. More recently, I accepted an award from the Clinical Research Forum for an article titled, *Extended-Release Naltrexone to Prevent Opioid Relapse in Criminal Justice Offenders*, of which I was the senior author and principal investigator. This article was published in the *New England Journal of Medicine*. This award was for the Top Ten Clinical Research Achievement Awards Ceremony and recognizes major research advances. I also had the honor of giving the keynote address at the National Academy of Medicine's Public Workshop of the Committee on Medication — Assisted Treatment for Opioid Use Disorder.

11. I am also involved in numerous professional and scientific societies, including national societies such as the American College of Neuropsychopharmacology (President, 2001), the American Psychiatric Association, and the American Society of Clinical Psychopharmacology. I have also held editorial positions on journals such as *Science*, *Journal of Pharmacology & Experimental Therapeutics*, *New England Journal of Medicine*, *Drug & Alcohol Dependence*, *Neuropsychopharmacology*, *Neuroscience*, *Life Science*, *American Journal of the Addictions*, *Biological Psychiatry*, and others.

12. I have authored or co-authored over 500 peer-reviewed articles, many of these on the treatment of addiction, including many on the topic of naltrexone

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