

Case IPR2018-00943
Patent No. 7,919,499
Supplemental Declaration of Kinam Park, Ph.D.
Attorney Docket No. AMNEAL 7.1R-005

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC,
Petitioner,

v.

ALKERMES PHARMA IRELAND LIMITED,
Patent Owner.

Patent No. 7,919,499 to Elliot Ehrich
Issue Date: May 19, 2015
Title: NALTREXONE LONG ACTING
FORMULATIONS AND METHODS OF USE

Inter Partes Review No. IPR2018-00943

(Exhibit 1061)

**SUPPLEMENTAL DECLARATION OF
KINAM PARK, Ph.D. IN SUPPORT OF
PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE**

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I, KINAM PARK, declare and state as follows:

I. INTRODUCTION

1. I am the same Kinam Park, Ph.D., who submitted a declaration in support of Petitioner's Petition for *Inter Partes* Review ("Prior Declaration," Ex. 1030) on April 19, 2018.

2. My background, education, training, compensation, and professional experiences are set forth in my Prior Declaration and are incorporated herein by reference.

3. I have reviewed the Declarations of Cory J. Berkland, Ph.D., and Charles P. O'Brien, M.D., Ph.D. submitted by Alkermes in support of its Response as well as the Patent Owner's Response ("Response"), Patent Owner's Preliminary Response, and the various exhibits submitted to date and those cited herein.

II. SUMMARY OF OPINIONS

4. I have been asked to provide my opinions on the '499 Patent and state of the art around April 2004, which is the priority date of the '499 Patent. In addition, I have been asked to respond to the opinions set forth in Dr. Berkland's and Dr. O'Brien's declarations.

5. Here, I address issues raised in the Patent Owner's Preliminary Response (Paper No. 7), by the Board's Institution Decision (Paper No. 8), and the

Patent Owner's Response ("Response") (Paper No. 14), and I provide supplemental evidence in support of my opinions that the claims of the '499 Patent are anticipated and obvious to a person of ordinary skill in the art at the time of the invention.

6. I maintain my opinions that claims 1, 3-5, and 10-12 were taught by Comer and Nuwayser and that all of the challenged claims would be readily apparent to a person of skill in the art for the reasons explained in the various grounds identified in the Petition. I disagree with many of the opinions expressed by Dr. Berkland and Dr. O'Brien, and I will address some of these herein. My silence on a particular opinion does not mean I agree with that opinion.

III. A PERSON OF ORDINARY SKILL IN THE ART

7. I understand Dr. Berkland's definition of POSA is someone with a Master's degree and two or three years' experience, or a Ph.D. or M.D. with at least one or two years' experience. As I stated in my Prior Declaration, I believe the treatment steps of the claimed method are very well known and should not be the central focus of the discussion of patentability. Most of the central issues are formulation related, and medical doctors often do not have sufficient formulation knowledge and experience. However, my opinions do not change if Dr. Berkland's definition is adopted.

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