

Case IPR2018-00943
Patent No. 7,919,499
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 1030)

**DECLARATION OF KINAM PARK, Ph.D. IN SUPPORT
OF *INTER PARTES* REVIEW OF U.S. PATENT NO. 7,919,499**

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I, KINAM PARK, declare and state as follows:

I. INTRODUCTION

1. I am a U.S. citizen and a resident of the State of Indiana.

2. I have been retained by Lerner, David, Littenberg, Krumholz & Mentlik, LLP (“counsel”) to provide my opinions in the field of pharmaceutical formulation for purposes of supporting a petition for *Inter Partes* Review (“IPR”). I have read and understand U.S. Patent No. 7,919,499 (“the ’499 Patent”) (Ex. 1001) as well as all other references discussed in this declaration. I am being compensated for my time in an amount consistent with my customary consulting fee, and my compensation is not contingent on my opinion or the outcome of this proceeding.

II. MY BACKGROUND AND QUALIFICATIONS

3. I am the Showalter Distinguished Professor of Biomedical Engineering, as well as a full Professor of Pharmaceutics at Purdue University. A copy of my CV is attached as Exhibit 1031. It contains a description of my education, academic appointments, professional activities, service on the editorial board of professional journals, books, referenced articles in scholarly journals, journal cover stories, patents, presentations, book reviews, teaching responsibilities, and thesis supervision.

4. I obtained my Ph.D. in Pharmaceutics from the University of Wisconsin in 1983, and completed a postdoctoral training in Chemical Engineering from the University of Wisconsin in 1985. I joined Purdue University as an Assistant Professor in 1986, and since 1994, I have been a Professor in the Department of Pharmaceutics at Purdue University. I also have been a Professor in the Department of Biomedical Engineering since 1998, and became the Showalter Distinguished Professor of Biomedical Engineering at Purdue University in 2006.

5. Since about 1986, I have been involved in the research, development, and manufacture of pharmaceutical formulations, and in particular controlled/sustained release drug delivery systems. I have conducted numerous research activities at Purdue University related to drug delivery technologies utilizing various polymers.

6. Since about 1994, one of my research interest has been developing long-acting microparticle formulations for oral administration. Since 2000, my research focused on injectable long-acting depot formulations based on biodegradable poly(lactide-co-glycolide) (PLGA), also known as poly(lactic-co-glycolic acid), using different manufacturing technologies, such as microenvironment-controlled encapsulation process, solvent exchange method, microfabrication, and double emulsion methods.

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