## 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 CORY J. BERKLAND, Ph.D.

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I, Cory J. Berkland, 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").

#### **MY QUALIFICATIONS**

3. My qualifications, professional experience, education, and publications are set forth in my curriculum vitae, attached as Appendix A. I provide a brief summary below.

4. I completed my undergraduate training in Chemical Engineering from Iowa State University, Ames, IA in 1998. I completed my post-graduate training from the University of Illinois, Urbana, IL and received my M.S. (in Chemical Engineering) and my Ph.D. (in Chemical and Bimolecular Engineering) in 2001 and 2003, respectively.

5. I am currently the Solon E. Summerfield Distinguished Professor at The University of Kansas. I am appointed as a Distinguished Professor in the Department of Pharmaceutical Chemistry in the School of Pharmacy and in the Department of Chemical & Petroleum Engineering in the School of Engineering. Since 2009, I have been a tenured professor in both the Department of Pharmaceutical Chemistry and the Department of Chemical & Petroleum Engineering at The University of Kansas.

6. I have received numerous awards for my work in the field of nanoparticles and drug delivery, including recently being inducted into the American Institute for Medical and Biological Engineering (AIMBE) based, in part, for my work in controlled release drug delivery systems. I was also elected to the National Academy of Inventors as a result of my work in the pharmaceutical sciences.

7. I have been a thesis advisor and postgraduate-scholar sponsor for numerous students in the fields of Pharmaceutical Chemistry, Bioengineering, Chemistry, and Chemical Engineering.

8. I have taught a variety of classes on both the undergraduate and graduate level including classes titled, Emerging Trends in Pharmaceutical Chemistry, Drug Delivery, and Biopharmaceutics and Drug Delivery.

9. I have received recognition for my teaching including being awarded the W.T. Kemper Fellowship for Teaching Excellence (2010) and a Teaching Achievement Award (2007).

10. I am currently on, or have served on, multiple advisory boards for journals, including the Journal of Pharmaceutical Sciences, the Journal of Pharmaceutical Innovation, and the Journal of Therapeutic Delivery.

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