Filed On Behalf Of:

Alkermes Pharma Ireland Limited and
Alkermes Controlled Therapeutics, Inc.

By:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUYE PHARMA GROUP LTD., LUYE PHARMA (USA) LTD., SHANDONG LUYE PHARMACEUTICAL CO., LTD., and NANJING LUYE PHARMACEUTICAL CO., LTD.,
Petitioners,
v.
ALKERMES PHARMA IRELAND LTD and ALKERMES CONTROLLED THERAPEUTICS, INC.,
Patent Owners.

Case IPR2016-01096
U.S. Patent No. 6,667,061

DECLARATION OF DR. CORY J. BERKLAND

I, Cory J. Berkland, Ph.D., declare as follows:

I. Qualifications

1. I offer this declaration at the request of counsel for Alkermes Pharma Ireland Limited and Alkermes Controlled Therapeutics, Inc. (collectively, "Patent Owners"), and in response to the declaration submitted by Dr. Patrick P. DeLuca (Exh. 1002).

2. I am currently appointed as the Solon E. Summerfield Distinguished Professor in the Department of Pharmaceutical Chemistry and the Department of Chemical and Petroleum Engineering at the University of Kansas. I received a B.S. in Chemical Engineering from Iowa State University in December 1998, and an M.S. in Chemical Engineering from the University of Illinois in May 2001. I received a Ph.D. in Chemical and Biomolecular Engineering from the University of Illinois in May 2003. From 2004 to 2009, I was an Assistant Professor in the Department of Chemical and Petroleum Engineering and the Department of Pharmaceutical Chemistry at The University of Kansas. I was promoted to Associate Professor in 2009 and since 2012, I have been a Professor in these two departments with tenure.

3. My areas of expertise include parenteral injectable drug formulations using particulates and powders, microencapsulation of pharmaceuticals, and controlled-release drug delivery. Through collaborations with industrial and academic

partners, and close relationships with other experts in controlled release, I have developed considerable expertise in the formulation and characterization of polysaccharide-based injection vehicles, such as those that use carboxymethylcellulose ("CMC"), and microparticles.

4. The primary focus of my research has been the design and analysis of drug delivery approaches for improving the performance of therapeutic agents. I have worked on particles and aspects of pharmaceutical formulation and delivery, including injectable nanoparticle formulations, since 1997. Among other areas, I have conducted research aimed to formulate polysaccharide-based injection vehicles and designing controlled release microparticles.

5. My research group at the University of Kansas currently works on formulation approaches designed to modify drug dissolution kinetics and to control drug release rates. My work has encompassed designing appropriate injection vehicles for parenteral injectables, developing nanoparticle formulations, and formulating polymers for delivering small molecules, proteins, and DNA. I have expertise in analyzing the performance of such formulations and in applying mathematical models to elucidate the underlying phenomena controlling the injectability and dissolution rate of such drugs. I have also designed and taught classes on drug delivery that focus primarily on drug transport in pharmaceutical formulations and through different biological barriers in the human body.

6. I have been a member of various professional organizations, including the American Institute of Chemical Engineers, the American Chemical Society, the American Association of Pharmaceutical Scientists, and the Controlled Release Society. I am a Fellow of the American Institute of Medical and Biological Engineering, and have received honors and awards from various national and international organizations, including the Leading Light Award from the University of Kansas, the Nagai Foundation Distinguished Lectureship, and the Controlled Release Society Young Investigator Award. Other awards and honors I have received are listed in my CV (Exh. 2015).

7. I have sat on the editorial boards or advisory boards of scientific journals including Therapeutic Delivery, the Journal of Pharmaceutical Sciences, and the Journal of Pharmaceutical Innovation.

8. I have published on such topics as drug delivery, parenteral injectable nanoparticle formulation, surface modification, and biomaterials. I have published approximately 150 articles in peer-reviewed journals, three book chapters, and have been named as a co-inventor on more than 50 U.S. patents or applications.

9. I have served as a consultant for drug formulation and delivery for companies in the United States and internationally. I have been involved in the design and development of numerous pharmaceutical formulations, both in my capacity at the University of Kansas and as a company founder. For instance, I am

a co-founder of four companies: Orbis Biosciences, Inc., Savara Pharmaceuticals, Inc., Orion BioScience, Inc., and Bond Biosciences, Inc. I am the acting Chief Scientific Officer at Orbis Biosciences. Orbis develops controlled-release delivery systems, including parenteral injectable microsphere formulations. I was also a Member of the Scientific Advisory Board and the former Chief Technology Officer for Savara Pharmaceuticals, Inc. in Austin, Texas. Savara specializes in the development of pulmonary drug products. I am also the Chairperson of the Board of Directors of Orion BioScience, Inc., which develops injectable therapies for autoimmune diseases.

II. Scope of Assignment and Approach

10. I have been retained as an expert on behalf of Patent Owners to provide information and opinions to the Patent Trial and Appeal Board ("the Board") to assist in its analysis of the patentability of certain claims of U.S. Patent No. 6,667,061 ("the '061 patent") (Exh. 1001) under *inter partes* review ("IPR"). Specifically, counsel for Patent Owners asked me to provide opinions regarding the applicability of various prior art references to claims 1-13 and 17-23 of the '061 patent, in view of my knowledge of and experience with injectable formulations. These references include those raised by Petitioners, Luye Pharma Group, Limited, Shandong Luye Pharmaceutical Co., Limited, and Nanjing Luye Pharmaceutical Co., Limited (collectively, "Petitioners").

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