

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
Petitioner,

v.

BRISTOL-MYERS SQUIBB COMPANY and PFIZER INC. ,
Patent Owners.

U.S. Patent No. 9,326,945 to Patel *et al.*

Inter Partes Review IPR2018-00892

DECLARATION OF KINAM PARK, PH.D.

MYLAN EXHIBIT 1002

1. I, Kinam Park, Ph.D., have been retained by counsel for Petitioner Mylan Pharmaceuticals Inc. (“Mylan”). I understand that Mylan is petitioning for *inter partes* review (“IPR”) of U.S. Patent No. 9,326,945 to Patel *et al.* (the ’945 patent”) (Ex. 1001), which is assigned to Bristol Myers Squibb Company and Pfizer Inc. (“Patent Owners”), to request that the United States Patent and Trademark Office cancel certain claims of the ’945 patent as unpatentable. I submit this expert declaration in support of Mylan’s IPR petition for the ’945 patent.

I. QUALIFICATIONS AND BACKGROUND

A. Education and Experience

2. I am the Showalter Distinguished Professor of Biomedical Engineering and Professor of Pharmaceutics at Purdue University. I am also President of Akina, Inc., a research company located in West Lafayette that I founded in 2001, and that focuses on polymers for drug delivery and biomedical applications as well as developing new drug delivery technologies.

3. My research, training, and experience are all in the areas of pharmaceutical sciences, specifically in the areas of pharmaceutics, biopharmaceutics, and biomedical engineering. My research has focused on drug delivery, including delivery of poorly soluble drugs through use of particle size reduction to nano/micro drug crystals, and oral formulations of fast-dissolving

tablets and gastric retention devices, localized drug delivery using drug-device combination products, and injectable long-acting depot formulations using biodegradable polymers. My extensive research in these areas includes *in vitro* experimentation and *in situ* and *in vivo* studies in animals, including evaluating and analyzing the dissolution and absorption of immediate-release and extended-release solid oral dosage forms. I have also conducted theoretical analyses and simulations of drug behavior in the body.

4. I received a B.S. degree in Pharmacy from Seoul National University in Seoul, Korea in 1975. I received a Ph.D. degree in Pharmaceutics from the University of Wisconsin, Madison in 1983. In 1985, I completed my postdoctoral training in Chemical Engineering at the University of Wisconsin, Madison.

5. I began working at Purdue University in February 1986. From February 1986 through June 1994, I was an Associate Professor in the Department of Pharmaceutics. In July 1994, I became a Professor in the Department of Pharmaceutics and became a Professor in the Department of Biomedical Engineering in July 1998. In 2006, I was named the Showalter Distinguished Professor of Biomedical Engineering at the Weldon School of Biomedical Engineering, Purdue University, while maintaining a Professor position at the College of Pharmacy.

6. As noted above, in 2001, I founded Akina, Inc., which provides a

variety of research products and services with a focus on controlled release and biomedical applications. Akina, Inc. includes two divisions: PolySciTech, its products division, and Akinalytics, its laboratory services division. The PolySciTech division focuses on providing research reagents and products, including biodegradable/biocompatible polymers, fluorescent products, chemical intermediates, assay kits, and other products used in biomedical research and development. Leveraging the developed experience with synthesis and characterization of novel polymer formulation, as well as in-house research and development, the Akinalytics division provides an array of services that range from simple analysis of a single sample to multi-year contracted research.

7. I have authored or co-authored over 560 publications, comprising books, book chapters, cover stories, and referred articles in the area of pharmaceuticals, including reducing the particle size of compounds in order to improve solubility and bioavailability. I have given almost 300 invited lectures. I hold 22 patents.

8. I have served on the editorial board of numerous journals in the area of drug delivery, including, for example, *Advanced Drug Delivery Reviews*, *Drug Delivery Technology*, *Encyclopedia of Pharmaceutical Technology*, *Journal of Drug Delivery Science and Technology*, *Nano Reviews*, and *Drug Delivery and Translational Research*, to name a few. I served as associate editor and book

review editor for *Pharmaceutical Research*, guest editor for *Colloids and Surfaces B: Biointerfaces*, and guest editor for *Advanced Drug Delivery Reviews*.

Currently, I have been serving as the Editor-in-Chief of the *Journal of Controlled Release* since 2005.

9. I am a member of numerous professional societies, including the American Association of Pharmaceutical Scientists, American Chemical Society, Controlled Release Society, the Society for Biomaterials, and Biomedical Engineering Society.

10. I have also served on scientific advisory boards for numerous symposiums, including the International Symposium on Recent Advances in Drug Delivery System, the Advisory Panel on Excipients: Substance and Characterization Expert Committee for the United States Pharmacopeia (or USP), the European Symposium on Controlled Drug Delivery, and the International Symposium on Microencapsulation.

11. A copy of my *curriculum vitae*, which lists my publications, patents, invited lectures, and professional activities and describes my qualifications in detail, is attached as Exhibit A.

B. Bases for Opinions

12. In forming my opinions set forth in this declaration, I have considered and relied upon my education, background, and decades of experience in the field

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