UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LLC
Petitioner,

v.

ABRAXIS BIOSCIENCE, LLC
Patent Owner

IPR2017-001101; IPR2017-01103; IPR2017-01104
U.S. Patent Nos. 7,820,788; 7,923,536; and 8,138,229

DECLARATION OF NICHOLAS A. PEPPAS, SC.D.

I, Nicholas A. Peppas, Sc.D., hereby declare and state as follows:

1. I submit this declaration on behalf of Abraxis Bioscience, LLC ("Abraxis" or "Patent Owner"), Patent Owner of U.S. Pat. Nos. 7,820,788 ("the '788 patent"), 7,923,536 ("the '536 patent"), and 8,138,229 ("the '229 patent") (collectively, "the Abraxis Patents") in connection with the petitions for *inter partes* reviews filed by Actavis LLC ("Actavis" or "Petitioner") in case nos. IPR2017-01101, IPR2017-01103, and IPR2017-01104 (collectively, the "Actavis IPR Petitions").

I. Qualifications

2. I am the Cockrell Family Regents Chair (*i.e.*, Chaired Professor) in Engineering at The University of Texas at Austin with appointments in the Departments of Chemical Engineering, Biomedical Engineering of the Cockrell College of Engineering, and the Division of Pharmaceutics of the College of Pharmacy of the University of Texas at Austin since January 1, 2003. I am also a tenured full professor with joint appointment in the Department of Pediatrics at the Dell Medical School of the same University. From September 2009 to August 2015, I was also the Chairman of the Biomedical Engineering Department in the same University.

3. Previously, I was the Showalter Distinguished Professor of Chemical and Biomedical Engineering at Purdue University, in West Lafayette, Indiana, with joint

appointments in the School of Chemical Engineering and in the Department of Biomedical Engineering. I joined Purdue University in 1976. I have degrees in chemical engineering from the National Technical University of Athens, Greece (Dipl. Eng., 1971) and the Massachusetts Institute of Technology - MIT (Sc.D., 1973). I did one year of postdoctoral work with Professors Clark Colton, Kenneth Smith and Robert Lees at the Arteriosclerosis Center of the Massachusetts Institute of Technology (1975–76).

4. I am an elected member of the (US) National Academy of Engineering, the (US) National Academy of Medicine, the American Academy of Arts and Sciences, the National Academy of Inventors, the Academy of Engineering, Medicine and Sciences of Texas, the National Academy of Pharmacy of France, the Royal Academy of Pharmacy of Spain and the Academy of Athens, Greece.

5. I have received honorary doctorate degrees from the University of Ghent, Belgium (1999), the University of Parma, Italy (1999), the University of Athens (2000), and the University of Ljubljana, Slovenia (2012), granted by their respective Faculties of Pharmacy. The doctorate from the University of Parma also carries the title "Doctor of Pharmacy". I have also received an honorary doctorate (in Chemical Engineering) from the University of Patras (2015).

6. I have served as a Visiting Professor at the Faculty of Pharmacy of the University of Geneva, Switzerland (Fall 1982), the Department of Chemical Engineering of the California Institute of Technology (Spring 1983), the Faculty of Pharmacy of the University of Paris-Sud (Fall 1986), the Department of Pharmacy of the University of Parma, Italy (Fall 1987), the School of Pharmacy of the Hoshi University of Tokyo, Japan (Spring 1994), the School of Pharmacy of the Hebrew University of Jerusalem, Israel (Spring 1994), the Departments of Pharmacy and Materials Science of the University of Naples, Italy (May 1996), the Department of Pharmacy of the Free University of Berlin, Germany (January-March 2001), the Department of Pharmacy of the Complutense University of Madrid, Spain (March-May 2001) and the Department of Materials Science of the Nanyang Technological Institute of Singapore (2006).

7. My teaching assignments at the University of Texas in the past ten years have been courses on "Introduction to Polymer Science and Engineering", Advances in Biomedical Engineering", "Advances in Biomaterials Science and Engineering", "Bionanotechnology", and "Kinetics and Reaction Engineering".

8. Starting in 1979, I have developed and taught, along with Professors Robert Langer of MIT, Frank Szoka of the University of California at San Francisco and

others, the course "Advances in Controlled Release Technology" offered every summer at MIT. This is a five-day course offered to industrial and university researchers who do not have a sufficient background in the field. In my lectures, I teach the theory of diffusion of polymers and liquids, the utilization of polymer micro- and nanoparticles as carriers in drug delivery, as well as the preparation and characterization of drug delivery systems such as tablets, films, capsules, microspheres, nanospheres and related pharmaceutical systems. The past summer (2017) was the 39th year I taught this course.

9. My research contributions have been in several areas of drug and protein delivery including therapeutic agents for treatment of diabetes, cancer, autoimmune diseases and cardiovascular problems, biomaterials, bionanotechnology, mass transfer, kinetics and reaction engineering, polymers and biomedical engineering.

10. Since 1979, I have also worked on the design, development and investigation of the pharmaceutical and medical applications of micro- and nanoparticulate polymers and drug delivery formulations. I have published numerous papers on the design and use of polymers as micro- and nanoparticles and I have participated in the development of a number of products that incorporated micro- and nanoparticles in order to achieve desirable release properties.

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