UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LLC,
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner

Case IPR2017-01100
Patent 8,853,260 B2

DECLARATION OF EDMUND J. ELDER, Jr., Ph.D., R.Ph.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW

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EXHIBITS CITED

EX	Description
1001	Desai et al., U.S. Patent No. 8,853,260 B2, "Formulations of Pharmacological Agents, Methods for the Preparation thereof and Methods for the Use thereof" (issued Oct. 7, 2014) (the "'260 patent")
1002	Declaration of Cory J. Berkland, Ph.D. in Support of Petition for *Inter Partes* Review
1003	Desai et al., U.S. Patent No. 5,439,686, "Methods for *In Vivo* Delivery of Substantially Water Insoluble Pharmacologically Active Agents and Compositions Useful therefor" (issued Aug. 8, 1995) ("Desai")
1004	Shively, U.S. Patent No. 5,407,683, "Pharmaceutical Solutions and Emulsions Containing Taxol" (issued Apr. 18, 1995) ("Shively")
1005	Liversidge et al., U.S. Patent No. 5,399,363, "Surface Modified Anticancer Nanoparticles" (issued Mar. 21, 1995) ("Liversidge")
1006	*Remington's Pharmaceutical Sciences* (18th ed. 1990), Chapt. 19, "Disperse Systems," and Chapt. 78, "Sterilization" ("*Remington's*")
1024	U.S. Application No. 11/520,479, Supplemental Declaration of Neil P. Desai Pursuant to 37 C.F.R. § 1.132 (dated Nov. 1, 2013) ("Second Inventor Declaration")
1027	List et al., U.S. Patent No. 5,389,382, "Hydrosols of Pharmacologically Active Agents and their Pharmaceutical Compositions Comprising Them" (issued Feb. 14, 1995) ("List")

I, Edmund J. Elder, Jr., Ph.D., R.Ph., hereby declare as follows:

I. INTRODUCTION

1. I am the Director of the Zeeh Pharmaceutical Experiment Station at the School of Pharmacy at the University of Wisconsin-Madison. I have been retained by Petitioner Actavis LLC in connection with its request for *inter partes* review of U.S. Patent No. 8,853,260 ("the '260 patent"). A copy of the '260 patent has been marked EX1001. I have reviewed and am familiar with the '260 patent. Generally, it describes and claims pharmaceutical compositions comprising the anticancer drug paclitaxel bound to the protein albumin and formulated as nanoparticles, and methods of using such compositions to treat diseases including cancer.

2. I have been asked to provide my independent opinions regarding the patentability of claims 1–27 of the '260 patent (the "challenged claims") and to review the Declaration of Cory J. Berkland in Support of Petition for *Inter Partes* Review, which has been marked EX1002. This declaration includes a discussion of my background and qualifications, the legal standards used in my analysis, and my opinions and relevant experiences as a person of ordinary skill in the art as of June 1997 (a "skilled artisan") regarding the subject matter of the '260 patent.

3. I am being compensated for my work in this proceeding at my standard hourly consulting rate of $500.00 per hour. My compensation is in no way contingent on the substance of my opinions or the outcome of this proceeding.

4. As set forth more fully below, it is my opinion that the challenged claims are unpatentable because they would have been obvious to a skilled artisan as of June 1997 in view of U.S. Patent No. 5,439,686 to Desai et al. ("Desai") (EX1003), U.S. Patent No. 5,407,683 to Shively ("Shively") (EX1004), U.S. Patent No. 5,399,363 to Liversidge et al. ("Liversidge") (EX1005), and *Remington's Pharmaceutical Sciences* (18th ed. 1990) ("*Remington's*") (EX1006). The bases for my opinions are set forth in this declaration.

II. BACKGROUND AND QUALIFICATIONS

5. I obtained my Bachelor of Science degree in Pharmacy, and my Doctor of Philosophy (Ph.D.) degree in Pharmaceutical Sciences, from the Medical University of South Carolina in 1985 and 1989, respectively. I have over 30 years of experience characterizing materials used in the preparation of pharmaceutical products, formulating pharmaceutical products, and testing such formulations.

6. My current responsibilities as Director of the Zeeh Pharmaceutical Experiment Station at the University of Wisconsin-Madison ("the Station") include overseeing all aspects of our services, including providing pharmaceutical pre-formulation and formulation expertise to support pharmaceutical and biopharmaceutical development collaborations across the University of Wisconsin system campuses and for clients outside the University. The Station works for both academia and pharmaceutical industry clients in developing and characterizing drugs and

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