UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LLC,
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner

Case IPR2017-01101
Patent 7,820,788 B2

DECLARATION OF CORY J. BERKLAND, Ph.D.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW

TABLE OF CONTENTS

EXHIBITS CITED

EX	Description
1001	Desai et al., U.S. Patent No. 7,820,788 B2, "Compositions and Methods of Delivery of Pharmacological Agents" (issued Oct. 26, 2010) (the "'788 patent")
1004	Kadima et al., WO 00/06152, "Pharmaceutically Acceptable Composition Comprising an Aqueous Solution of Paclitaxel and Albumin" (published Feb. 10, 2000) ("Kadima")
1005	Liversidge et al., U.S. Patent No. 5,399,363, "Surface Modified Anticancer Nanoparticles" (issued Mar. 21, 1995) ("Liversidge")
1006	Desai et al., WO 1999/000113, "Novel Formulations of Pharmacological Agents, Methods for the Preparation thereof and Methods for the Use thereof" (published Jan. 7, 1999) ("Desai")
1007	Li et al., "Fluorescein Binding to Normal Human Serum Proteins Demonstrated by Equilibrium Dialysis," Arch Ophalmol. vol. 100, 484–87 (March 1982)
1009	FDA Guideline on Sterile Drug Products Produced by Aseptic Processing (June 1987, reprinted June 1991 and Feb. 1997)
1010	EMEA Guidance on Manufacture of the Finished Dosage Form (April 1996)
1011	*Elan Pharma Int'l Ltd. v. Abraxis BioScience, Inc.*, Judgment and Verdict Form, No. 06-438-GMS, Dkt. 614 (D. Del. June 16, 2008)
1017	Damascelli, B et al. "Intraarterial chemotherapy with polyoxyethylated castor oil free paclitaxel, incorporated in albumin nanoparticles (ABI-007)," Cancer 2001 Nov; 92(10):2592–2602 ("Damascelli")
1018	Ibrahim et al., "Phase I and pharmacokinetic study of ABI-007, a Cremophor-free, protein-stabilized, nanoparticle formulation of paclitaxel," Clin Cancer Res. 2002 May; 8:1038–44 ("Ibrahim")
1023	U.S. Application No. 11/553,339, Declaration of Neil P. Desai Pursuant to 37 C.F.R. § 1.132 (dated Apr. 14, 2010)

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

I. INTRODUCTION

1. 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 have been retained by Petitioner Actavis LLC in connection with its request for *inter partes* review of U.S. Patent No. 7,820,788 ("the '788 patent"). A copy of the '788 patent has been marked EX1001. I have reviewed and am familiar with the '788 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 opinions regarding the patentability of claims 1–12 of the '788 patent (the "challenged claims"). This declaration includes a discussion of my background and qualifications, the legal standards used in my analysis, an overview of the '788 patent from the perspective of a person of ordinary skill in the art at the time that the patent was filed (a "skilled artisan"), and my opinions regarding the patentability of the challenged claims.

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.

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