

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

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EXHIBITS CITED

Exhibit	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”)
1003	Desai et al., U.S. Patent No. 5,439,686, “Methods for <i>In Vivo</i> 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	<i>Remington’s Pharmaceutical Sciences</i> (18th ed. 1990), Chapt. 19, “Disperse Systems,” and Chapt. 78, “Sterilization” (“ <i>Remington’s</i> ”)
1009	FDA Guideline on Sterile Drug Products Produced by Aseptic Processing (June 1987, reprinted June 1991 and Feb. 1997)
1010	EMA Guidance on Manufacture of the Finished Dosage Form (April 1996)
1011	<i>Elan Pharma Int’l Ltd. v. Abraxis BioScience, Inc.</i> , Judgment and Verdict Form, No. 06-438-GMS, Dkt. 614 (D. Del. June 16, 2008)
1021	U.S. Application No. 11/520,479, Declaration of Neil P. Desai Pursuant to 37 C.F.R. § 1.132 (dated Jan. 27, 2012) (“First Inventor Declaration”)
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”)
1026	U.S. Pharmacopoeia 23 (1995 ed.) (excerpted)
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”)

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