

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ACTAVIS LLC,  
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC,  
Patent Owner

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Case IPR2017-01100  
Patent 8,853,260 B2

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

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## EXHIBITS CITED

| Exhibit     | Description  |
|-------------|--|
| <b>1001</b> | 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”)              |
| <b>1003</b> | 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”) |
| <b>1004</b> | Shively, U.S. Patent No. 5,407,683, “Pharmaceutical Solutions and Emulsions Containing Taxol” (issued Apr. 18, 1995) (“Shively”)   |
| <b>1005</b> | Liversidge et al., U.S. Patent No. 5,399,363, “Surface Modified Anticancer Nanoparticles” (issued Mar. 21, 1995) (“Liversidge”)  |
| <b>1006</b> | <i>Remington’s Pharmaceutical Sciences</i> (18th ed. 1990), Chapt. 19, “Disperse Systems,” and Chapt. 78, “Sterilization” (“ <i>Remington’s</i> ”)   |
| <b>1009</b> | FDA Guideline on Sterile Drug Products Produced by Aseptic Processing (June 1987, reprinted June 1991 and Feb. 1997)   |
| <b>1010</b> | EMA Guidance on Manufacture of the Finished Dosage Form (April 1996)   |
| <b>1011</b> | <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)  |
| <b>1021</b> | 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”)   |
| <b>1024</b> | 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”)  |
| <b>1026</b> | U.S. Pharmacopoeia 23 (1995 ed.) (excerpted)   |
| <b>1027</b> | 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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