UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CIPLA LTD.,
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner

Case IPR2018-00162
Patent 7,820,788 B2

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

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a. Albumin-paclitaxel combination 38

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c. Albumin-paclitaxel ratio of about 1:1 to 9:1 40

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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")

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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)

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