

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LLC,
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner

Case IPR2017-01104
Patent 8,138,229 B2

PETITIONERS' UPDATED EXHIBIT LIST
(as of November 3, 2017)

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
Submitted Electronically via the Patent Review Processing System

LIST OF EXHIBITS

EX.	Description
1001	Desai et al., U.S. Patent No. 8,138,229 B2, “Compositions and Methods of Delivery of Pharmacological Agents” (issued Mar. 20, 2012) (the “’229 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) (the “’686 patent”)
1004	Kadima et al., WO 2000/006152, “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 Ophthalmol. vol. 100, 484–87 (March 1982)
1008	Physicians’ Desk Reference® 309, 881–887 (54th ed. 2000) “Taxol® (paclitaxel) Injection” (“Taxol® label”)
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	Elan Pharma Int’l Ltd. v. Abraxis BioScience, Inc., Judgment and Verdict Form, No. 06-438-GMS, Dkt. 614 (D. Del. June 16, 2008)
1012	Elan Pharma Int’l Ltd. v. Abraxis BioScience, Inc., Sixth Day of Trial, No. 06-438-GMS, Dkt. 624 (D. Del. June 9, 2008)

1013	Elan Pharma Int'l Ltd. v. Abraxis BioScience, Inc., Seventh Day of Trial, No. 06-438-GMS, Dkt. 625 (D. Del. June 10, 2008)
1014	Grinstaff et al., U.S. Patent No. 5,498,421, "Composition Useful for In Vivo Delivery of Biologics and Methods Employing Same (issued Mar. 12, 1996) (the "421 patent")
1015	Patient Information Leaflet, "ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)" (revised May 2007)
1016	Administrative Documents, New Drug Application No. 21-660
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")
1019	U.S. Application No. 11/553,339, Non-Final Office Action (mailed Apr. 28, 2009)
1020	U.S. Application No. 11/553,339, Amendment in Response to Non-Final Office Action (dated Oct. 27, 2009)
1021	U.S. Application No. 11/553,339, Final Office Action (mailed Dec. 31, 2009)
1022	U.S. Application No. 11/553,339, Amendment After Final Action Under 37 C.F.R. §1.116 (dated Apr. 14, 2010)
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) (the "Inventor Declaration")
1024	U.S. Application No. 11/553,339, Notice of Allowance and Fee(s) Due (mailed June 1, 2010)
1025	FDA, Approved Drug Products with Therapeutic Equivalence Evaluations (33d ed. 2013) ("Orange Book")
1026	Desai et al., "Protein Stabilized Pharmacologically Active Agents, Methods for the Preparation Thereof and Methods for the Use Thereof," U.S. Patent No. 5,916,596 (issued Jun. 29, 1999)

1027	Remington's Pharmaceutical Sciences (18th ed. 1990), Chapt. 85, "Intravenous Admixtures" ("Remington's")
1028	Camden, U.S. Patent No. 6,177,460 B1, "Method of Treatment for Cancer or Viral Infections" (issued Jan. 23, 2001)
1029	Declaration of George C. Lombardi In support of Motion for <i>Pro Hac Vice</i> Admission
1030	Declaration of Charles B. Klein. In support of Motion for Pro Hac Vice Admission
1031	Declaration of Kevin E. Warner In support of Motion for Pro Hac Vice Admission
1032	Declaration of Eimeric Reig-Plessis In support of Motion for Pro Hac Vice Admission

Dated: November 3, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e) and 42.105(a), this is to certify that on November 3, 2017, I caused to be served a true and correct copy of the foregoing **“PETITIONERS’ UPDATED EXHIBIT LIST As Of November 3, 2017 and Exs. 1029-1032”** was served by electronic mail upon the following counsel for

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