

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LLC,
Petitioner

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner

Case IPR2017-01103
Patent 7,923,536 B2

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

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PO Box 1450
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. 7,923,536 B2, “Compositions and Methods of Delivery of Pharmacological Agents” (issued Apr. 12, 2011) (the “’536 patent”) |
| 1002 | Declaration of Cory J. Berkland, Ph.D. in Support of Petition for <i>Inter Partes</i> Review |
| 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) (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,” <i>Arch Ophthalmol.</i> 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 | <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) |
| 1012 | <i>Elan Pharma Int’l Ltd. v. Abraxis BioScience, Inc.</i> , Sixth Day of Trial, No. 06-438-GMS, Dkt. 624 (D. Del. June 9, 2008) |

| EX. | Description |
|-------------|--|
| 1013 | <i>Elan Pharma Int'l Ltd. v. Abraxis BioScience, Inc.</i> , 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 <i>In Vivo</i> 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)," <i>Cancer</i> 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," <i>Clin Cancer Res.</i> 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, <i>Approved Drug Products with Therapeutic Equivalence Evaluations</i> (33d ed. 2013) ("Orange Book") |

| EX. | Description |
|-------------|---|
| 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 | Declaration of George C. Lombardi In support of Motion for Pro Hac Vice Admission |
| 1028 | Declaration of Charles B. Klein. In support of Motion for Pro Hac Vice Admission |
| 1029 | Declaration of Kevin E. Warner In support of Motion for Pro Hac Vice Admission |
| 1030 | 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. 1027-1030”** was served by electronic mail upon the following counsel for

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