

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Apotex Inc. and Apotex Corp.,  
Petitioners

v.

ABRAXIS BIOSCIENCE, LLC,  
Patent Owner

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Case IPR2018-00153  
Patent 7,923,536 B2  
Issued: April 12, 2011

Title: COMPOSITIONS AND METHODS OF  
DELIVERY OF PHARMACOLOGICAL AGENTS

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**PETITIONERS' UPDATED EXHIBIT LIST**

**(as of January 10, 2018)**

## 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," Arch Ophthalmol. vol. 100, 484–87 (March 1982)
1008	Physicians' Desk Reference <sup>®</sup> 309, 881–887 (54th ed. 2000) "Taxol <sup>®</sup> (paclitaxel) Injection" ("Taxol <sup>®</sup> 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)
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")

<b>1015</b>	Patient Information Leaflet, “ABRAXANE <sup>®</sup> for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension) (albumin-bound)” (revised May 2007)
<b>1016</b>	Administrative Documents, New Drug Application No. 21-660
<b>1017</b>	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”)
<b>1018</b>	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”)
<b>1019</b>	U.S. Application No. 11/553,339, Non-Final Office Action (mailed Apr. 28, 2009)
<b>1020</b>	U.S. Application No. 11/553,339, Amendment in Response to Non-Final Office Action (dated Oct. 27, 2009)
<b>1021</b>	U.S. Application No. 11/553,339, Final Office Action (mailed Dec. 31, 2009)
<b>1022</b>	U.S. Application No. 11/553,339, Amendment After Final Action Under 37 C.F.R. §1.116 (dated Apr. 14, 2010)
<b>1023</b>	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”)
<b>1024</b>	U.S. Application No. 11/553,339, Notice of Allowance and Fee(s) Due (mailed June 1, 2010)
<b>1025</b>	FDA, <i>Approved Drug Products with Therapeutic Equivalence Evaluations</i> (33d ed. 2013) (“Orange Book”)
<b>1026</b>	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)
<b>1027</b>	E-mail chain between Petitioners’ and Patent Owner’s Counsel re additional discovery
<b>1028</b>	Panacea US Certificate of Dissolution
<b>1029</b>	Panacea Biotech Annual Report 2016-2017

Dated: January 10, 2018

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**CERTIFICATE OF SERVICE**

I hereby certify that a copy of the foregoing **EXHIBIT LIST AND EXHIBIT NOS. 1027-1029**, was served in its entirety on January 10, 2018 by filing this document through the Patent Trial Appeal Board End to End System as well as by delivering a copy via electronic mail, with Patent Owner's consent, to the following attorneys for Petitioner and Patent Owner in the Actavis IPR:

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