

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Apotex Inc. and Apotex Corp.,
Petitioners

v.

ABRAXIS BIOSCIENCE, LLC,
Patent Owner

Case IPR2018-00151
Patent 8,138,229 B2
Issued: March 20, 2012

Title: COMPOSITIONS AND METHODS OF
DELIVERY OF PHARMACOLOGICAL AGENTS

PETITIONERS' UPDATED EXHIBIT LIST

(as of January 10, 2018)

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 <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 [®] 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)
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”)
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” (“ <i>Remington’s</i> ”)
1028	Camden, U.S. Patent No. 6,177,460 B1, “Method of Treatment for Cancer or Viral Infections” (issued Jan. 23, 2001)
1029	E-mail chain between Petitioners’ and Patent Owner’s Counsel re additional discovery
1030	Panacea US Certificate of Dissolution
1031	Panacea Biotech Annual Report 2016-2017

Dated: January 10, 2018

STEPTOE & JOHNSON LLP
1114 Avenue of the Americas, 35th Floor
New York, NY 10036
Phone: 212-506-3900
Fax: 212-506-3950
Email: Abraxane@Steptoe.com

Respectfully submitted,

/John Josef Molenda/

John Josef Molenda
Reg. No. 47,804

Lead Counsel for Petitioners

Vishal Gupta
(Reg. No. 67,284)
Siew Yen Chong
(Reg. No. 62,108)
Fang Bu
(to seek *pro hac vice* admission)

Back-Up Counsel for Petitioners

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing **EXHIBIT LIST AND EXHIBIT NOS. 1029-1031**, 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:

Counsel for Petitioner Actavis **Counsel for Patent Owner Abraxis**

Samuel S. Park (lead counsel)
George C. Lombardi
Charles B. Klein
Kevin E. Warner
Eimeric Reig-Plessis
WINSTON & STRAWN LLP
AbraXaneIPR@winston.com

J. Patrick Elsevier (lead counsel)
Anthony M. Insogna
Cary Miller
Christopher J. Harnett
Lisamarie LoGiudice
JONES DAY
jpelsevier@jonesday.com
aminsogna@jonesday.com
cmiller@jonesday.com
llogiudice@jonesday.com
charnett@jonesday.com

F. Dominic Cerrito
Andrew S. Chalson
Daniel C. Wiesner
Frank C. Calvosa
QUINN EMANUEL URQUHART & SULLIVAN
nickcerrito@quinnemanuel.com
andrewchalson@quinnemanuel.com
danielwiesner@quinnemanuel.com
frankcalvosa@quinnemanuel.com

Date: January 10, 2018

/Siew Yen Chong/
Siew Yen Chong

Counsel for Apotex Inc. and Apotex Corp