

Filed on behalf of: Abraxis Bioscience, LLC

Filed: November 7, 2017

UPDATED EXHIBIT LIST – IPR2017-01104

EX	Description
2001	Declaration of Nicholas A. Peppas, Sc.D. In Support of Patent Owner’s Preliminary Response
2002	Frye, D. K., Taxane Chemotherapy–Advances in Treatment for Breast Cancer. US Oncological Disease. 2006; 1(1):40–41
2003	Paclitaxel (Taxol®) Formulation and Prodrugs: The Chemistry and Pharmacology of Taxol® and its Derivatives, Elsevier B.V. 1995; 103–130
2004	Gelderblom <i>et al.</i> , Cremophor EL: the drawbacks and advantages of vehicle selection for drug formulation. Eur J Cancer 2001; 37:1590–1598
2005	Desai <i>et al.</i> , US 5,916,596, “Protein Stabilized Pharmacologically Active Agents, Methods for the Preparation Thereof and Methods for the Use Thereof” (issued Jun. 29,1999)
2006	FDA News. “Phase III Trial of Tocosol Paclitaxel Does Not Meet Primary Endpoint” (published 2017)
2007	Paz-Ares <i>et al.</i> , Phase III trial comparing paclitaxel poliglumex vs docetaxel in the second-line treatment of non-small-cell lung cancer. Brit J Cancer. 2008; 98:1608–1613
2008	Langer <i>et al.</i> , Phase III Trial Comparing Paclitaxel Poliglumex (CT-2103, PPX) in Combination with Carboplatin Versus Standard Paclitaxel and Carboplatin in the Treatment of PS 2 Patients with Chemotherapy-Naïve Advanced Non-small Cell Lung Cancer. J Thorac Oncol. 2008; 3:623–630
2009	Hamaguchi <i>et al.</i> , NK105, a paclitaxel-incorporating micellar nanoparticle formulation, can extend in vivo antitumour activity and reduce the neurotoxicity of paclitaxel, Brit J Cancer. 2005; 92:1240–1246
2010	FirstWord Pharma, “Results of Phase III study of NK105, a novel macromolecular micelle encapsulating an anticancer drug” (created July 12, 2016)
2011	Full Prescribing Information, Abraxane® , revised July 2015
2012	Schnitzer <i>et al.</i> , Albondin-mediated Capillary Permeability to Albumin. J Biol Chem. 1994; 269(8):6072–6082
2013	Schnitzer J.E., gp60 is an albumin-binding glycoprotein expressed by continuous endothelium involved in albumin transcytosis. Am J Physiol.

Filed on behalf of: Abraxis Bioscience, LLC

Filed: November 7, 2017

	1992; 262:H246–H254
2014	John <i>et al.</i> , Quantitative analysis of albumin uptake and transport in the rat microvessel endothelial monolayer. <i>Am J Physiol-Lung C.</i> 2003; 284:L187–L196
2015	Laino, C., June 3, 2009, “Abraxane Beats Standard Breast Cancer Treatment” www.webmd.com/breast-cancer/news/20090609/breast-cancer-drug-abraxane-is-effective
2016	Blum <i>et al.</i> , Phase II Study of Weekly Albumin-Bound Paclitaxel for Patients with Metastatic Breast Cancer Heavily Pretreated with Taxanes. <i>Clin Breast Cancer.</i> 2007; 7(11):850–856
2017	Gradishar <i>et al.</i> , Phase III Trial of Nanoparticle Albumin-Bound Paclitaxel Compared with Polyethylated Castor Oil-Based Paclitaxel in Women with Breast Cancer. <i>J Clin Oncol.</i> 2005; 23(31):7794–7803
2018	Zhang <i>et al.</i> , Nab-Paclitaxel is an Active Drug in Preclinical Model of Pediatric Solid Tumors. <i>Clin Cancer Res.</i> 2013; 19(21):5972–5983
2019	Irizarry <i>et al.</i> , Cremophor EL-containing paclitaxel-induced anaphylaxis: a call to action. <i>Community Oncology.</i> 2009; 6(3):132–134
2020	Rajeshkumar <i>et al.</i> , Superior Therapeutic Efficacy of nab-Paclitaxel over Cremophor-based paclitaxel in locally advanced and metastatic models of human pancreatic cancer. <i>Brit J Cancer.</i> 2016; 115:442–453
2021	Wani, <i>et al.</i> , Plant antitumor agents. VI. The isolation and structure of taxol, a novel antileukemic and antitumor agent from <i>Taxus brevifolia</i> . <i>J Am Chem Soc.</i> 1971; 93(9):2325–7
2022	<i>Intentionally Left Blank</i>
2023	Chromatographic Techniques for the Characterization of Proteins: Physical Methods to Characterize Pharmaceutical Proteins, Springer Science and Business Media, New York, NY, 1995, Vol. 7:243–299
2024	Girard <i>et al.</i> , Separation of Human Serum Albumin Components by RP-HPLC and CZE and their Characterization by ESI-MS. <i>Chromatographia.</i> 1999; 49: S21–S27
2025	The Application of HPLC for Proteins, High Performance Liquid Chromatography: Principles and Methods in Biotechnology. John Wiley & Sons, Chichester, UK, 1996, 411–467
2026	Sparreboom <i>et al.</i> , Determination of paclitaxel in human plasma using single solvent extraction prior to isocratic reversed-phase high-

Filed on behalf of: Abraxis Bioscience, LLC

Filed: November 7, 2017

	performance liquid chromatography with ultraviolet detection. J. Chromatogr B. 1998; 705:159–164
2027	Martin <i>et al.</i> , Assay of paclitaxel (Taxol) in plasma and urine by high-performance liquid chromatography. J. Chromatogr B. 1998; 709:281–288
2028	Tian <i>et al.</i> , Degradation of Paclitaxel and Related Compounds in Aqueous Solutions I: Epimerization. J Pharm Sci. 2008; 97(3):1224–1235
2029	Tian <i>et al.</i> , Degradation of Paclitaxel and Related Compounds in Aqueous Solutions II: Nonepimerization Degradation Under Neutral to Basic pH Conditions. J Pharm Sci. 2008; 97(8):3100–3108
2030	Tian <i>et al.</i> , Degradation of Paclitaxel and Related Compounds in Aqueous Solutions III: Degradation Under Acidic pH Conditions and Overall Kinetics. J Pharm Sci. 2010; 99(3):1288–1298
2031	Pillai <i>et al.</i> , Pharmaceutical Glass Interactions: A Review of Possibilities. J Pharm Sci & Res. 2016; Vol. 8(2):103–111
2032	“Sticky Containers, Vanishing Drugs” http://blogs.sciencemag.org/pipeline/archives/2008/08/29/sticky_containers_vanishing_drugs (August 29, 2008)
2033	Mani <i>et al.</i> , Delivery of paclitaxel from cobalt–chromium alloy surfaces without polymeric carriers. Biomaterials. 2010; 31(20):5372–5384
2034	Green <i>et al.</i> , Measurement of paclitaxel and its metabolites in human plasma using liquid chromatography/ion trap mass spectrometry with a sonic spray ionization interface. Rapid Commun Mass Sp. 2006; 20(14):2183–2189
2035	Heldman <i>et al.</i> , Paclitaxel Stent Coating Inhibits Neointimal Hyperplasia at 4 Weeks in a Porcine Model of Coronary Restenosis. Circulation. 2001; 103:2289–2295
2036	Fukazawa <i>et al.</i> , Reduction of non-specific adsorption of drugs to plastic containers used in bioassays or analyses. J Pharmacol Tox Met. 2010; 61:329–333
2037	Hunz <i>et al.</i> , Plasma And Tissue Pharmacokinetics Of Epirubicin And Paclitaxel In Patients Receiving Neoadjuvant Chemotherapy For Locally Advanced Primary Breast Cancer. Clin Pharmacol Ther. 2007; 81(5):659–668
2038	Pfeifer <i>et al.</i> , Precipitation of paclitaxel during infusion by pump. Am J Hosp Pharm. 1993; 50:2518–2521

Filed on behalf of: Abraxis Bioscience, LLC

Filed: November 7, 2017

2039	Xu <i>et al.</i> , Stability of paclitaxel in 5% dextrose injection or 0.9% sodium chloride injection at 4, 22, or 32 °C. <i>Am J Hosp Pharm.</i> 1994;51:3058–3060
2040	Trissel <i>et al.</i> , Pharmaceutical properties of paclitaxel and their effects on preparation and administration. <i>Pharmacotherapy.</i> 1997; 17(5 Part 2):133S–139S
2041	Kattige, Long-term physical and chemical stability of a generic paclitaxel infusion under simulated storage and clinical-use conditions. <i>Eur J Hosp Pharm-S P.</i> 2006; 12(6):129–134
2042	Lee <i>et al.</i> , Hydrotropic solubilization of paclitaxel: analysis of chemical structures for hydrotropic property. <i>Pharmacol Res.</i> 2003; 20(7):1022–1030
2043	Feng, <i>et al.</i> , Effects of emulsifiers on the controlled release of paclitaxel (Taxol®) from nanospheres of biodegradable polymers. <i>J Control Release.</i> 2001; 71(1):53–69
2044	Vilker <i>et al.</i> , The Osmotic Pressure of Concentrated Protein Solutions: Effect of Concentration and pH in Saline Solutions of Bovine Serum Albumin. <i>J Colloid Interf Sci.</i> 1981; 79(2):548–566
2045	Fogh-Andersen <i>et al.</i> , Ionic Binding, Net Charge, and Donnan Effect of Human Serum Albumin as a Function of pH. <i>Clin Chem.</i> 1993; 39(1):48–52
2046	Curnis <i>et al.</i> , Improving Chemotherapeutic Drug Penetration in Tumors by Vascular Targeting and Barrier Alteration. <i>J Clin Invest.</i> 2002; 110(4):475–482
2047	Yuan, F., Transvascular Drug Delivery in Solid Tumors. <i>Semin in Radiat Oncol.</i> 1998; 8(3):164–175
2048	<i>Intentionally Left Blank</i>
2049	<i>Intentionally Left Blank</i>
2050	Ziller <i>et al.</i> , Control of Crystal Growth in Drug Suspension: 1) Design of a Control Unit and Application to Acetaminophen Suspensions). <i>Drug Dev Ind Pharm.</i> 1988; 14(15–17):2341–2370
2051	USP Monograph, Paclitaxel. 30(40):1279 http://www.pharmacopeia.cn/v29240/usp29nf24s0_m60190.html
2052	Garnett <i>et al.</i> , The effects of serum and human albumin on calcium hydroxyapatite crystal growth. <i>Biochem J.</i> 1990; 266:863–868

Filed on behalf of: Abraxis Bioscience, LLC

Filed: November 7, 2017

2053	Kommanaboyina <i>et al.</i> , Trends in Stability Testing, with Emphasis on Stability During Distribution and Storage. Drug Dev Ind Pharm. 1999; 25(7):857–868
2054	Surapaneni <i>et al.</i> , Designing Paclitaxel Drug Delivery Systems Aimed at Improved Patient Outcomes: Current Status and Challenges. ISRN Pharmacol. 2012; 1–15
2055	Flynn, G.L., Solubility Concepts and Their Applications to the Formulation of Pharmaceutical Systems: Part I. Theoretical Foundations. PDA J Pharm Sci Tech. 1984; 38:202–209
2056	Pyo <i>et al.</i> , Preparation and Dissolution Profiles of the Amorphous, Dihydrated Crystalline, and Anhydrous Crystalline Forms of Paclitaxel. Drying Technol. 2007; 25(10):1759–1767
2057	Steinhardt <i>et al.</i> , Differences between Bovine and Human Serum Albumins: Binding Isotherms, Optical Rotatory Dispersion, Viscosity, Hydrogen Ion Titration, and Fluorescence Effects. Biochemistry-US. 1971; 10(22):4005–4015
2058	U.S. Application No. 12/910,693, Notice of Allowance (mailed Dec. 27, 2011)
2059	Diaz <i>et al.</i> , Molecular Recognition of Taxol by Microtubules. J Biol Chem. 2002; 275(34):26265–26276
2060	Chen <i>et al.</i> , Albumin-bound nanoparticle (nab) paclitaxel exhibits enhanced paclitaxel tissue distribution and tumor penetration. Cancer Chemoth Pharm. 2015; 76:699–712
2061	Evangelio <i>et al.</i> , Fluorescent Taxoids as Probes of the Microtubule Cytoskeleton. Cell Motil Cytoskel. 1998; 39:73–90
2062	<i>Intentionally Left Blank</i>
2063	Declaration of Lisamarie LoGiudice

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.