

Filed on behalf of: Abraxis Bioscience, LLC

Filed: November 7, 2017

### UPDATED EXHIBIT LIST – IPR2017-01101

<b>EX</b>	<b>Description</b>
<b>2001</b>	Declaration of Nicholas A. Peppas, Sc.D. In Support of Patent Owner’s Preliminary Response
<b>2002</b>	Frye, D. K., Taxane Chemotherapy–Advances in Treatment for Breast Cancer. US Oncological Disease. 2006; 1(1):40–41
<b>2003</b>	Paclitaxel (Taxol®) Formulation and Prodrugs: The Chemistry and Pharmacology of Taxol® and its Derivatives, Elsevier B.V. 1995; 103–130
<b>2004</b>	Gelderblom <i>et al.</i> , Cremophor EL: the drawbacks and advantages of vehicle selection for drug formulation. Eur J Cancer 2001; 37:1590–1598
<b>2005</b>	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)
<b>2006</b>	FDA News. “Phase III Trial of Tocosol Paclitaxel Does Not Meet Primary Endpoint” (published 2017)
<b>2007</b>	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
<b>2008</b>	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
<b>2009</b>	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
<b>2010</b>	FirstWord Pharma, “Results of Phase III study of NK105, a novel macromolecular micelle encapsulating an anticancer drug” (created July 12, 2016)
<b>2011</b>	Full Prescribing Information, Abraxane® , revised July 2015
<b>2012</b>	Schnitzer <i>et al.</i> , Albondin-mediated Capillary Permeability to Albumin. J Biol Chem. 1994; 269(8):6072–6082
<b>2013</b>	Schnitzer J.E., gp60 is an albumin-binding glycoprotein expressed by continuous endothelium involved in albumin transcytosis. Am J Physiol.

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	1992; 262:H246–H254
<b>2014</b>	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
<b>2015</b>	Laino, C., June 3, 2009, “Abraxane Beats Standard Breast Cancer Treatment” <a href="http://www.webmd.com/breast-cancer/news/20090609/breast-cancer-drug-abraxane-is-effective">www.webmd.com/breast-cancer/news/20090609/breast-cancer-drug-abraxane-is-effective</a>
<b>2016</b>	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
<b>2017</b>	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
<b>2018</b>	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
<b>2019</b>	Irizarry <i>et al.</i> , Cremophor EL-containing paclitaxel-induced anaphylaxis: a call to action. <i>Community Oncology.</i> 2009; 6(3):132–134
<b>2020</b>	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
<b>2021</b>	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
<b>2022</b>	<i>Intentionally Left Blank</i>
<b>2023</b>	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
<b>2024</b>	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
<b>2025</b>	The Application of HPLC for Proteins, High Performance Liquid Chromatography: Principles and Methods in Biotechnology. John Wiley & Sons, Chichester, UK, 1996, 411–467
<b>2026</b>	Sparreboom <i>et al.</i> , Determination of paclitaxel in human plasma using single solvent extraction prior to isocratic reversed-phase high-

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	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
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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” <a href="http://blogs.sciencemag.org/pipeline/archives/2008/08/29/sticky_containers_vanishing_drugs">http://blogs.sciencemag.org/pipeline/archives/2008/08/29/sticky_containers_vanishing_drugs</a> (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
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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

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<b>2039</b>	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
<b>2040</b>	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
<b>2041</b>	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
<b>2042</b>	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
<b>2043</b>	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
<b>2044</b>	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
<b>2045</b>	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
<b>2046</b>	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
<b>2047</b>	Yuan, F., Transvascular Drug Delivery in Solid Tumors. <i>Semin in Radiat Oncol.</i> 1998; 8(3):164–175
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<b>2050</b>	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
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<b>2053</b>	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
<b>2054</b>	Surapaneni <i>et al.</i> , Designing Paclitaxel Drug Delivery Systems Aimed at Improved Patient Outcomes: Current Status and Challenges. ISRN Pharmacol. 2012; 1–15
<b>2055</b>	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
<b>2056</b>	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
<b>2057</b>	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
<b>2058</b>	U.S. Application No. 12/910,693, Notice of Allowance (mailed Dec. 27, 2011)
<b>2059</b>	Diaz <i>et al.</i> , Molecular Recognition of Taxol by Microtubules. J Biol Chem. 2002; 275(34):26265–26276
<b>2060</b>	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
<b>2061</b>	Evangelio <i>et al.</i> , Fluorescent Taxoids as Probes of the Microtubule Cytoskeleton. Cell Motil Cytoskel. 1998; 39:73–90
<b>2062</b>	<i>Intentionally Left Blank</i>
<b>2063</b>	Declaration of Lisamarie LoGiudice

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