

Filed on behalf of: Aventis Pharma S.A.

By:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN LABORATORIES LIMITED

Petitioner,

v.

AVENTIS PHARMA S.A.

Patent Owner.

Case IPR2016-00712
U.S. Patent No. 8,927,592

PATENT OWNER'S EXHIBIT LIST 3

EXHIBIT LIST 3¹

Aventis Exhibit No.	Description
2001	June 23, 2016 Declaration of Dr. Oliver Sartor.
2002	Curriculum Vitae of Dr. Oliver Sartor.
2003	A Randomized, Open Label, Phase 3 Study of Larotaxel IV every 3 Weeks Versus Capecitabine (Xeloda) Tablets Twice Daily for 2 Weeks in 3-Week Cycles in Patients with Metastatic Cancer (MBC) Progressing After Taxanes and Anthracycline Therapy (EFC6089), available at EFC6089_summary.pdf.
2004	Antonarakis & Eisenberger, <i>Phase III Trials with Docetaxel-Based Combinations for Metastatic Castration-Resistant Prostate Cancer: Time to Learn From Past Experiences</i> , 31(14) J. Clin. Oncol. 1709-12 (2013).
2005	Armstrong & George, <i>New Drug Development in Metastatic Prostate Cancer</i> , 26(4) Urologic Oncol.: Seminars & Original Investigations 430-37 (2008).

¹ Patent Owner's Exhibit List 2 was served, but not filed on October 20, 2016 with Patent Owner's supplemental evidence.

2006	Beer <i>et al.</i> , <i>Double-Blinded Randomized Study of High-Dose Calcitriol plus Docetaxel Compared with Placebo plus Docetaxel in Androgen-Independent Prostate Cancer: A Report from the ASCENT Investigators</i> , 25(6) <i>J. Clin. Oncol.</i> 669-74 (2007).
2007	Berry <i>et al.</i> , <i>Phase III Study of Mitoxantrone plus Low Dose Prednisone Versus Low Dose Prednisone Alone in Patients with Asymptomatic Hormone Refractory Prostate Cancer</i> , 168(6) <i>J. Urol.</i> 2439-43 (2002).
2008	Bristol-Myers Squibb Reports Results for Phase 3 Trial of Yervoy [®] (Ipilimumab) in Previously-Treated Castration Resistant Prostate Cancer, Business Wire News HQ Press Release (September 12, 2013), available at http://news.bms.com/press-release/rd-news/Bristol-myers-squibb-reports-results-Phase-3-trial-yervoy-ipilimumab-previousl .
2009	Cabral, <i>Factors Determining Cellular Mechanisms of Resistance to Antimitotic Drugs</i> , 4(1) <i>Drug Resistance Updates</i> 3-8 (2001).
2010	Carducci <i>et al.</i> , <i>A Phase 3 Randomized Controlled Trial of the Efficacy and Safety of Atrasentan in Men with Metastatic Hormone-Refractory Prostate Cancer</i> , 110(9) <i>Cancer</i> 1959-66 (2007).
2011	D'Amico, <i>US Food and Drug Administration Approval of Drugs for</i>

	<i>the Treatment of Prostate Cancer: A New Era Has Begun</i> , 32(4) J. Clin. Oncol. 362-64 (2014).
2012	December 2013 Yervoy [®] Label.
2013	Didier, US Patent Application Publication No. 2005/0065138.
2014	Di Lorenzo <i>et al.</i> , <i>Combination of Bevacizumab and Docetaxel in Docetaxel-Pretreated Hormone-Refractory Prostate Cancer: A Phase 2 Study</i> , 54(5) Eur. Urol. 1089-96 (2008).
2015	Dieras <i>et al.</i> , <i>Phase II Multicenter Study of Larotaxel (XRP9881), a Novel Taxoid, in Patients with Metastatic Breast Cancer Who Previously Received Taxane-Based Therapy</i> , 19(7) Annals of Oncol. 1255-60 (2008).
2016	Dumontet & Sikic, <i>Mechanisms of Action of and Resistance to Antitubulin Agents: Microtubule Dynamics, Drug Transport, and Cell Death</i> , 17(3) J. Clin. Oncol. 1061-70 (1999).
2017	Halabi <i>et al.</i> , <i>Prostate-Specific Antigen Changes as Surrogate for Overall Survival in Men with Metastatic Castration-Resistant Prostate Cancer Treated with Second-Line Chemotherapy</i> , 31(31) J. Clin. Oncol. 1-9 (2013).
2018	Higano <i>et al.</i> , <i>Phase I/2 Dose-Escalation Study of a GM-CSF-</i>

	<i>Secreting, Allogeneic, Cellular Immunotherapy for Metastatic Hormone-Refractory Prostate Cancer</i> , 113(5) <i>Cancer</i> 975-84 (2008).
2019	July 2009 Avastin [®] Label.
2020	Kaur <i>et al.</i> , <i>Suramin 's Development: What Did We Learn?</i> , 20(2) <i>Investigational New Drugs</i> 209-19 (2002).
2021	Kola & Landis, <i>Can the Pharmaceutical Industry Reduce Attrition Rates?</i> , 3(8) <i>Nature Reviews Drug Discovery</i> 711-15 (2004).
2022	Larotaxel Every 3 Weeks vs. Capecitabine in Patients with Metastatic Breast Cancer Progressing After Taxanes and Anthracycline Therapy, available at https://clinicaltrials.gov/ct2/show/NCT00081796?term=larotaxel&rank=7 .
2023	Larotaxel plus Cisplatin vs. Gemcitabine plus Cisplatin in First Line Treatment of Patients with Locally Advanced/Metastatic Bladder Cancer, available at https://clinicaltrials.gov/ct2/show/NCT00625664?term=larotaxel&rank=4 .
2024	Larotaxel vs. 5-FU in Patients with Pancreatic Cancer Previously Treated with Gemcitabine, available at

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