

Paper No. \_\_\_\_  
Date Served: February 23, 2017

Filed on behalf of: Aventis Pharma S.A.

By:

Dominick A. Conde  
dconde@fchs.com  
(212) 218-2100

**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 8**

## EXHIBIT LIST 8

<b>Aventis Exhibit No.</b>	<b>Description</b>
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).
2006	Beer <i>et al.</i> , <i>Double-Blinded Randomized Study of High-Dose Calcitriol plus Docetaxel Compared with Placebo plus Docetaxel</i>

	<i>in Androgen-Independent Prostate Cancer: A Report from the ASCENT Investigators</i> , 25(6) J. Clin. Oncol. 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) J. Urol. 2439-43 (2002).
2008	<i>Bristol-Myers Squibb Reports Results for Phase 3 Trial of Yervoy<sup>®</sup> (Ipilimumab) in Previously-Treated Castration Resistant Prostate Cancer</i> , Business Wire News HQ Press Release (September 12, 2013), available at <a href="http://news.bms.com/press-release/rd-news/Bristol-myers-squibb-reports-results-Phase-3-trial-yervoy-ipilimumab-previousl">http://news.bms.com/press-release/rd-news/Bristol-myers-squibb-reports-results-Phase-3-trial-yervoy-ipilimumab-previousl</a> .
2009	Cabral, <i>Factors Determining Cellular Mechanisms of Resistance to Antimitotic Drugs</i> , 4(1) Drug Resistance Updates 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) Cancer 1959-66 (2007).
2011	D'Amico, <i>US Food and Drug Administration Approval of Drugs for the Treatment of Prostate Cancer: A New Era Has Begun</i> , 32(4) J. Clin. Oncol. 362-64 (2014).

2012	December 2013 Yervoy <sup>®</sup> 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-Secreting, Allogeneic, Cellular Immunotherapy for Metastatic Hormone-Refractory Prostate Cancer</i> , 113(5) Cancer 975-84 (2008).

2019	July 2009 Avastin <sup>®</sup> Label.
2020	Kaur <i>et al.</i> , <i>Suramin 's Development: What Did We Learn?</i> , 20(2) Investigational New Drugs 209-19 (2002).
2021	Kola & Landis, <i>Can the Pharmaceutical Industry Reduce Attrition Rates?</i> , 3(8) Nature Revs. Drug Discovery 711-15 (2004).
2022	Larotaxel Every 3 Weeks vs. Capecitabine in Patients with Metastatic Breast Cancer Progressing After Taxanes and Anthracycline Therapy, available at <a href="https://clinicaltrials.gov/ct2/show/NCT00081796?term=larotaxel&amp;rank=7">https://clinicaltrials.gov/ct2/show/NCT00081796?term=larotaxel&amp;rank=7</a> .
2023	Larotaxel plus Cisplatin vs. Gemcitabine plus Cisplatin in First Line Treatment of Patients with Locally Advanced/Metastatic Bladder Cancer, available at <a href="https://clinicaltrials.gov/ct2/show/NCT00625664?term=larotaxel&amp;rank=4">https://clinicaltrials.gov/ct2/show/NCT00625664?term=larotaxel&amp;rank=4</a> .
2024	Larotaxel vs. 5-FU in Patients with Pancreatic Cancer Previously Treated with Gemcitabine, available at <a href="https://clinicaltrials.gov/ct2/show/NCT00417209?term=larotaxel&amp;rank=2">https://clinicaltrials.gov/ct2/show/NCT00417209?term=larotaxel&amp;rank=2</a>
2025	Mackinnon <i>et al.</i> , <i>Molecular Biology Underlying the Clinical</i>

# 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.