

Filed: May 10, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE PATENT TRIAL AND APPEAL BOARD

---

MYLAN PHARMACEUTICALS INC., ACTAVIS  
LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC,  
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S  
LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD.,  
SUN PHARMACEUTICALS INDUSTRIES, LTD.,  
SUN PHARMACEUTICALS INDUSTRIES, INC.,  
TEVA PHARMACEUTICALS USA, INC., WEST-WARD  
PHARMACEUTICAL CORP., and HIKMA PHARMACEUTICALS, LLC,

Petitioners

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

---

Case IPR2016-01332<sup>1</sup>  
Patent 8,822,438 B2

---

**FIFTH UPDATED LIST OF PETITIONER'S EXHIBITS**

---

<sup>1</sup> Case IPR2017-00853 has been joined with this proceeding.

Pursuant to 37 C.F.R. § 42.63(e), Petitioner submits the following current exhibit list.

Exhibit	Description
MYL 1001	U.S. Patent No. 8,822,438, Auerbach and Beldegrun, “Methods and Compositions for Treating Cancer” (“the ’438 patent”)
MYL 1002	Declaration of Marc B. Garnick, MD (“Garnick Decl.”)
MYL 1003	O’Donnell, A. et al., “Hormonal impact of the 17 $\alpha$ -hydroxylase/C17,20-lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer,” Br. J. Cancer, (90):2317–2325 (2004) (“O’Donnell”)
MYL 1004	Gerber, G.S. et al., “Prostate specific antigen for assessing response to ketoconazole and prednisone in patients with hormone refractory metastatic cancer,” J. Urology, 144(5):1177–9 (1990) (“Gerber”)
MYL 1005	U.S. Patent No. 5,604,213, Barrie S.E. et al., “17-Substituted Steroids Useful In Cancer Treatment” (“the ’213 patent”)
MYL 1006	Tannock, I. et al., “Chemotherapy with mitoxantrone plus prednisone or prednisone alone for symptomatic hormone-resistant prostate cancer: a Canadian randomized trial with palliative end points,” J. Clinical Oncology, 14:1756–1764 (1996) (“Tannock”)
MYL 1007	February 3, 2012 Office Action (excerpt from prosecution history of ’438 patent)
MYL 1008	July 3, 2012 Response (excerpt from prosecution history of ’438 patent)
MYL 1009	Ryan, C.J. et al., “Abiraterone in metastatic prostate cancer without previous chemotherapy,” New Eng. J. Med., 368:138–148 (2013).
MYL 1010	January 11, 2013 Response (excerpt from prosecution history of ’438 patent)
MYL 1011	March 4, 2013 Office Action (excerpt from prosecution history of ’438 patent)

<b>Exhibit</b>	<b>Description</b>
MYL 1012	June 4, 2013 Response (excerpt from prosecution history of '438 patent)
MYL 1013	July 3, 2013 Notice of Allowance (excerpt from prosecution history of '438 patent)
MYL 1014	October 25, 2013 Notice of Allowance (excerpt from prosecution history of '438 patent)
MYL 1015	February 11, 2014 Notice of Allowance (excerpt from prosecution history of '438 patent)
MYL 1016	June 2, 2014 Notice of Allowance (excerpt from prosecution history of '438 patent)
MYL 1017	Confidential Declaration of Ivan T. Hofmann ("Hofmann Declaration")
MYL 1018	2011 Zytiga® Approval Prescribing Information
MYL 1019	2015 Zytiga® Prescribing Information, Co-administration Brochure
MYL 1020	Harris, K.A. et al., "Low dose ketoconazole with replacement doses of hydrocortisone in patients with progressive androgen independent prostate cancer," J. Urology, 168:542–545 (August 2002)
MYL 1021	Oh, W.K. "Secondary hormonal therapies in the treatment of prostate cancer," Urology, 60(Supp. 3A):87–93 (2002)
MYL 1022	Tannock, I. et al., "Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer," N. Eng. J. Med., 351:1502–12 (2004)
MYL 1023	Attard, G. et al., "Selective blockade of androgenic steroid synthesis by novel lyase inhibitors as a therapeutic strategy for treating metastatic prostate cancer," Br. J. Urol., 96(9): 1241–1246 (2005)
MYL 1024	Hellerstedt, B.A. et al., "The current state of hormonal therapy for prostate cancer," CA Cancer J. Clin., 52:154–179 (2002).

Exhibit	Description
MYL 1025	Kasper, D.L. et al. (Eds.), Harrison's Principles of Internal Medicine, 16th Edition (2005), 549.
MYL 1026	Auchus, R.J. "The genetics, pathophysiology, and management of human deficiencies of P450c17," Endocrinol. Metab. Clin. North Am. 30(1):101-119 (2001)
MYL 1027	Costa-Santos, M. et al., "Two prevalent CYP17 mutations and genotype-phenotype correlations in 24 Brazilian patients with 17-hydroxylase deficiency," J. Clin. Endocrin. & Metabol., 89(1):49-60 (2004)
MYL 1028	Jubelirer, S.J., et al., "High dose ketoconazole for the treatment of hormone refractory metastatic prostate carcinoma," J. Urol., 142(1):89-91 (1989)
MYL 1029	U.S. Patent 5,688,977, Sisti, N.J. et al., "Method for Docetaxel Synthesis"
MYL 1030	U.S. Food and Drug Administration ("FDA") FDA News Release dated May 19, 2004, "FDA Approves New Indication for Taxotere-Prostate Cancer"
MYL 1031	Tannock, I. et al., "Treatment of metastatic prostatic cancer with low-dose prednisone: evaluation of pain and quality of life as pragmatic indices of response," J. Clin. Oncology, 7:590-7 (1989)
MYL 1032	Intentionally left blank
MYL 1033	Scher, H.I. et al., "Increased survival with enzalutamide in prostate cancer after chemotherapy," New Eng. J. Med., 367:1187-97 (2012)
MYL 1034	de Bono, J.S. et al., "Abiraterone and increased survival in metastatic prostate cancer," New Engl. J. Med., 364:1995-2005 (2011)
MYL 1035	Orange Book listing for Zytiga®
MYL 1036	Initial Application (excerpt from prosecution history of '438 patent)
MYL 1037	Intentionally left blank

Exhibit	Description
MYL 1038	Intentionally left blank
MYL 1039	September 11, 2012 Office Action (excerpt from prosecution history of '438 patent)
MYL 1040	Cancer.net (ASCO Patient Website), Treatment of Metastatic Castration-Resistant Prostate Cancer, <a href="http://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/treatment-metastatic-castration-resistant-prostate-cancer">http://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/treatment-metastatic-castration-resistant-prostate-cancer</a> (accessed 6/28/2016).
MYL 1041	Cancer.org (ACS), "What are the key statistics about prostate cancer?" <a href="http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-key-statistics">http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-key-statistics</a> (accessed 6/28/2016).
MYL 1042	Intentionally left blank
MYL 1043	Intentionally left blank
MYL 1044	Intentionally left blank
MYL 1045	FDA News Release, "FDA expands Zytiga's use for late-stage prostate cancer," 12/10/2012 <a href="http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm331492.htm">http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm331492.htm</a> (access 6/30/2016).
MYL 1046	FDA Website, Drugs@FDA – Zytiga, <a href="http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails">http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails</a> (accessed 6/28/2016).
MYL 1047	FDA Website, Orange Book, Zytiga (NDA 202379), <a href="http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=202379&amp;Product_No=001&amp;table1=OB_Rx">http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=202379&amp;Product_No=001&amp;table1=OB_Rx</a> (accessed 6/30/2016).
MYL 1048	<i>Galderma Labs., L.P. v. Tolmar, Inc.</i> , 737 F.3d 731, 740–41 (Fed. Cir. 2013).
MYL 1049	Jevtana Website, Dosing and Administration, <a href="http://www.jevtana.com/hcp/dosing/default.aspx">http://www.jevtana.com/hcp/dosing/default.aspx</a> (accessed 6/28/2016).

# 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.