

Filed: May 3, 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 IPR2016-01332¹
Patent 8,822,438 B2

FOURTH UPDATED LIST OF PETITIONER'S EXHIBITS

¹ 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 α -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) |

| Exhibit | Description |
|----------|--|
| 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, http://www.cancer.net/research-and-advocacy/asco-care-and-treatment-recommendations-patients/treatment-metastatic-castration-resistant-prostate-cancer (accessed 6/28/2016). |
| MYL 1041 | Cancer.org (ACS), "What are the key statistics about prostate cancer?" http://www.cancer.org/cancer/prostatecancer/detailedguide/prostate-cancer-key-statistics (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 http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm331492.htm (access 6/30/2016). |
| MYL 1046 | FDA Website, Drugs@FDA – Zytiga, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails (accessed 6/28/2016). |
| MYL 1047 | FDA Website, Orange Book, Zytiga (NDA 202379), http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=202379&Product_No=001&table1=OB_Rx (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, http://www.jevtana.com/hcp/dosing/default.aspx (accessed 6/28/2016). |

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