

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMERIGEN PHARMACEUTICALS LIMITED

and

ARGENTUM PHARMACEUTICALS LLC

Petitioners

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

Case IPR2016-00286¹

Patent No. 8,822,438 B2

PETITIONERS' UPDATED EXHIBIT LIST

¹Case IPR2016-01317 has been joined with this proceeding.

LISTING OF EXHIBITS PURSUANT TO 37 C.F.R. § 42.63(e)

Pursuant to 37 C.F.R. 42.63(e), Petitioner, Amerigen Pharmaceuticals, Ltd. hereby submits a current list of its exhibits:

Exhibit	Description
AMG 1001	U.S. Patent No. 8,822,438, Auerbach and Belldegrum, “Methods and Compositions for Treating Cancer” (“the ‘438 patent”)
AMG 1002	Declaration of Dr. Scott Serels, MD, dated December 4, 2015
AMG 1003	O’Donnell, A. <i>et al.</i> , “Hormonal impact of the 17 α -hydroxylase/C ₁₇ -20-lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer,” <i>British Journal of Cancer</i> , (90):2317-2325 (2004) (“O’Donnell”)
AMG 1004	Gerber, G.S. <i>et al.</i> , “Prostate specific antigen for assessing response to ketoconazole and prednisone in patients with hormone refractory metastatic cancer,” <i>The Journal of Urology</i> , 144(5):1177-9 (1990) (“Gerber”)
AMG 1005	U.S. Patent No. 5,604,213, Barrie S.E. <i>et al.</i> , “17-Substituted Steroids Useful In Cancer Treatment” (“the ‘213 patent”)
AMG 1006	Tannock <i>et al.</i> , “Chemotherapy with mitoxantrone plus prednisone or prednisone alone for symptomatic hormone-resistant prostate cancer: a Canadian randomized trial with palliative end points,” <i>The Journal of Clinical Oncology</i> , 14:1756-1764 (1996) (“Tannock 1996”)
AMG 1007	February 3, 2012 Office Action (excerpt from prosecution history of ‘438 patent)
AMG 1008	July 3, 2012 Response (excerpt from prosecution history of ‘438 patent)

AMG 1009	Ryan <i>et al.</i> , “Abiraterone in metastatic prostate cancer without previous chemotherapy,” <i>The New England Journal of Medicine</i> , 368:138-148 (2012).
AMG 1010	January 11, 2013 Response (excerpt from prosecution history of '438 patent)
AMG 1011	March 4, 2013 Office Action (excerpt from prosecution history of '438 patent)
AMG 1012	June 4, 2013 Response (excerpt from prosecution history of '438 patent)
AMG 1013	July 3, 2013 Notice of Allowance (excerpt from prosecution history of '438 patent)
AMG 1014	October 25, 2013 Notice of Allowance (excerpt from prosecution history of '438 patent)
AMG 1015	February 11, 2014 Notice of Allowance (excerpt from prosecution history of '438 patent)
AMG 1016	June 2, 2014 Notice of Allowance (excerpt from prosecution history of '438 patent)
AMG 1017	Declaration of Dr. DeForest McDuff, Ph.D., dated December 4, 2015
AMG 1018	2011 Zytiga® Approval Prescribing Information
AMG 1019	2015 Zytiga® Prescribing Information, Co-administration Brochure
AMG 1020	Harris <i>et al.</i> , “Low dose Ketoconazole with replacement doses of hydrocortisone in patients with progressive androgen independent prostate cancer,” <i>The Journal of Urology</i> , volume 168:542-545 (August 2002)
AMG 1021	William Oh, “Secondary hormonal therapies in the treatment of prostate cancer,” <i>Urology</i> , volume 60:87-93 (Supplement 3A) (September 2002)

AMG 1022	Tannock, I. <i>et al.</i> , “Docetaxel plus Prednisone or Mitoxantrone plus Prednisone for Advanced Prostate Cancer,” <i>N. Eng. J. Med.</i> , 351:1502-12 (2004)
AMG 1023	Attard, G. <i>et al.</i> , “Selective blockade of androgenic steroid synthesis by novel lyase inhibitors as a therapeutic strategy for treating metastatic prostate cancer,” <i>Br. J. Urol.</i> 96(9): 1241-1246 (2005)
AMG 1024	Hellerstedt <i>et al.</i> , “The Current State of Hormonal Therapy for Prostate Cancer,” <i>CA Cancer J. Clin.</i> , 52:154-179 (2002).
AMG 1025	Kasper, D.L. <i>et al.</i> (Eds.), <i>Harrison's Principles of Internal Medicine</i> , 16 th Edition (2005), p. 549.
AMG 1026	Auchus, R.J. “The genetics, pathophysiology, and management of human deficiencies of P450c17,” <i>Endocrinol. Metab. Clin. North Am.</i> (30)1:101-119 (2001)
AMG 1027	Costa-Santos, M. <i>et al.</i> , “Two Prevalent CYP17 Mutations and Genotype-Phenotype Correlations in 24 Brazilian Patients with 17-Hydroxylase Deficiency,” <i>J. Clin. Endocrin. & Metabol.</i> (89)1:49-
AMG 1028	Jubelirer, S.J., <i>et al.</i> , “High dose ketoconazole for the treatment of hormone refractory metastatic prostate carcinoma,” <i>J. Urol.</i> , 142(1):89-901 (1989)
AMG 1029	U.S. Patent 5,688,977, Sisti, N.J. <i>et al.</i> , “Method for Docetaxel Synthesis”
AMG 1030	U.S. Food and Drug Administration (“FDA”) FDA News Release dated May 19, 2004, “FDA Approves New Indication for Taxotere-Prostate Cancer”

AMG 1031	Tannock, I. <i>et al.</i> , "Treatment of metastatic prostatic cancer with low-dose prednisone: evaluation of pain and quality of life as pragmatic indices of response," <i>Journal of Clin. Oncology</i> , 7:590-7 (1989)
AMG 1032	Taxotere® Prescribing Information (2004)
AMG 1033	Scher, H.I. <i>et al.</i> , "Increased survival with Enzalutamide in Prostate Cancer after Chemotherapy," <i>New Eng. J. Med.</i> , 367:1187-97 (2012)
AMG 1034	de Bono, J.S. <i>et al.</i> , "Abiraterone and Increased Survival in Metastatic Prostate Cancer," <i>New Engl. J. Med.</i> , 364:1995-2005 (2011)
AMG 1035	Orange Book listing for Zytiga®
AMG 1036	Initial Application (excerpt from prosecution history of '438 patent)
AMG 1037	November 25, 2011 Office Action (excerpt from prosecution history of '438 patent)
AMG 1038	December 21, 2011 Response (excerpt from prosecution history of '438 patent)
AMG 1039	September 11, 2012 Office Action (excerpt from prosecution history of '438 patent)
AMG 1040	Cancer.net (ASCO Patient Website), Treatment of Metastatic Castration-Resistant Prostate Cancer, http://www.cancer.net/research-and-advocacy/asco-careand-treatment-recommendations-patients/treatment-metastatic-castrationresistant-prostate-cancer (accessed 7/24/2015).

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