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BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG
Petitioner

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner

Case IPR: Unassigned

U.S. Patent No. 8,822,438

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,822,438
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.1-.80, 42.100-.123**

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U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, Virginia 22313-1450

LIST OF EXHIBITS

<i>Wockhardt Exhibit #</i>	<i>Description</i>
1001	Auerbauch, A. H. & Belldesgrum, A. S., U.S. Patent No. 8,822,438 (filed Feb. 24, 2011; issued Sep. 2, 2014) (“the ’438 patent”)
1002	Declaration of Paul A. Godley, MD, Ph.D., MPP
1003	Dr. Paul A. Godley’s <i>Curriculum Vitae</i>
1004	Gerber, G. S. & Chodak, G. W., “Prostate specific antigen for assessing response to ketoconazole and prednisone in patients with hormone refractory metastatic prostate cancer,” <i>J. of Urology</i> , 144(5): 1177-9 (1990) (“Gerber”)
1005	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 J. of Cancer</i> , 90: 2317-2325 (2004) (“O’Donnell”)
1006	Sartor, O. <i>et al.</i> , “Effect of prednisone on prostate-specific antigen in patients with hormone-refractory prostate cancer,” <i>Urology</i> , 52: 252-6 (1998) (“Sartor”)
1007	Tannock, I. F. <i>et al.</i> , “Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer,” <i>New Engl. J. Med.</i> , 351: 1502-1512 (2004)
1008	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>BJU Inter.</i> , 96:1241-1246 (2005)
1009	Kasper, D. L. <i>et al.</i> (Eds.). (2005). <i>Harrison’s Principles of Internal Medicine</i> , Vol. 1, 16 th ed. New York City, NY: The McGraw-Hill Companies, Inc.
1010	Tannock, I.F. <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>J. Clin. Oncol.</i> , 14: 1756-1764 (1996).

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1011	Harris, K.A. <i>et al.</i> , “Low dose ketoconazole with replacement doses of hydrocortisone in patients with progressive androgen independent prostate cancer,” <i>J. of Urology</i> , 168: 542-545 (2002)
1012	Hellerstedt, B. A. and Pienta, K. J., “The current state of hormonal therapy for prostate cancer,” <i>CA Cancer J. Clin.</i> , 52:154-179 (2002)
1013	Trump, D. L. <i>et al.</i> , “High-dose ketoconazole in advanced hormone-refractory prostate cancer: endocrinologic and clinical effects,” <i>J. Clin. Oncol.</i> , 7:1093-1098 (1989)
1014	Costa-Santos, M. <i>et al.</i> , “Two prevalent CYP17 mutations and geno-type-phenotype correlations in 24 Brazilian patients with 17-hydroxylyase deficiency,” <i>J. of Clin. Endocrin. & Metab.</i> , 89(1): 49-60 (2004)
1015	Oh, W.K., “Secondary hormonal therapies in the treatment of prostate cancer,” <i>Urology</i> , 60 (Suppl 3A): 87-93 (2002)
1016	Scholz, M. <i>et al.</i> , “Long-term outcome for men with androgen independent prostate cancer treated with ketoconazole and hydrocortisone,” <i>J. of Urology</i> , 173: 1947-1952 (2005)
1017	Fosså, S. D., <i>et al.</i> , “Flutamide versus prednisone in patients with prostate cancer symptomatically progressing after androgen-ablative therapy: a phase III study of the European Organization for Research and Treatment of Cancer Genitourinary Group,” <i>J. of Clin. Oncol.</i> , 19(1): 62-71 (2001)
1018	Brassel, S. A. <i>et al.</i> , “Prostate-specific antigen versus prostate-specific antigen density as predictor of tumor volume, margin status, pathologic stage, and biochemical recurrence of prostate cancer,” <i>Urology</i> , 66:1229-1233 (2005)
1019	Berry, W. <i>et al.</i> , “Phase III study of mitoxantrone plus low dose prednisone versus low dose prednisone alone in patients with asymptomatic hormone refractory prostate cancer,” <i>J. of Urology</i> , 168: 2439-2443 (2002)

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1020	U.S. Food and Drug Administration (“FDA”) News Release dated May 19, 2004, “FDA Approves New Indication for Taxotere—Prostate Cancer,” http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108301.htm (last accessed 8/8/2016)
1021	Ryan, C. J. <i>et al.</i> , “Phase II study of abiraterone acetate in chemotherapy-naïve metastatic castration-resistant prostate cancer displaying bone flare discordant with serologic response,” <i>Clin. Cancer Res.</i> , 17:4854-4861 (2011) (“Ryan 2011”)
1022	Attard, F. <i>et al.</i> , “Selective inhibition of CYP17 with abiraterone acetate is highly active in the treatment of castration-resistant prostate cancer,” <i>J. of Clin. Oncol.</i> , 27:3742-3748 (2009) (“Attard 2009”)
1023	Ryan, C. J. <i>et al.</i> , “Abiraterone in metastatic prostate cancer without previous chemotherapy,” <i>N Engl J Med</i> , 368:138-148 (2013) (“Ryan 2013”)
1024	Danila, D. C. <i>et al.</i> , “Phase II multicenter study of abiraterone acetate plus prednisone therapy in patients with docetaxel-treated castration-resistant prostate cancer,” <i>J. of Clin. Oncol.</i> , 28:1496-1501 (2010) (“Danila”)
1025	Kelly, W. K. <i>et al.</i> , “Prostate-specific antigen as a measure of disease outcome in metastatic hormone-refractory prostate cancer,” <i>J. of Clin. Oncol.</i> , 11:607-615 (1993)
1026	Small, E. J. <i>et al.</i> , “Serum prostate-specific antigen decline as a marker of clinical outcome in hormone-refractory prostate cancer patients: association with progression-free survival, pain end points, and survival,” <i>J. of Clin. Oncol.</i> , 19:1304-1311 (2001)
1027	Miller, G. M. & Hinman, Jr., F., “Cortisone treatment in advanced carcinoma of the prostate,” <i>J. of Urology</i> , 72(3): 485-496 (1954)

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Wockhardt Exhibit #	Description
1028	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>J. of Clin. Oncol.</i> , 7(5): 590-597 (1989)
1029	Scher, H. I. & Sawyers, C. L., “Biology of progressive, castration-resistant prostate cancer: directed therapies targeting the androgen-receptor signaling axis,” <i>J Clin Oncol</i> , 23:8253-8261 (2005)
1030	Barrie, S. E. <i>et al</i> , U.S. Patent No. 5,604,213 (filed Sep. 30, 1994; issued Feb. 18, 1997)
1031	File History for U.S. Patent No. 8,822,438
1032	Gilman, A. <i>et al.</i> (Eds.). (1990). <i>The Pharmacological Basis of Therapeutics</i> , 8 th ed. Elmsford, NY: Pergamon Press, Inc., 62-83, 1431-1462
1033	Ganong, W. F. (1979). <i>Review of Medical Physiology</i> . Los Altos, CA: Lange Medical Publications, 277-300
1034	Taxotere Prescribing Information (2004), http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/020449s028lbl.pdf (last accessed 8/8/2016)
1035	Potter, G. A. <i>et al</i> , “Novel steroidal inhibitors of human cytochrome P45017 α (17 α -hydroxylase-C17,20-lyase): potential agents for the treatment of prostate cancer,” <i>J. Med. Chem.</i> , 38:2463-2471 (1995) (“Potter”)
1036	Fakih, M. <i>et al.</i> , “Glucocorticoids and Treatment of Prostate Cancer: A Preclinical and Clinical Reivew,” <i>Urology</i> , 60:553-561 (2002) (“Fakih”)
1037	MacAdams, M. R. <i>et al</i> , “Reduction of serum testosterone levels during chronic glucocorticoid therapy,” <i>Ann Int Med</i> , 104:648-651 (1986)

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