

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG
Petitioner

v.

JANSSEN ONCOLOGY, INC.
Patent Owner.

Case IPR2016-01582
Patent 8,822,438

WOCKHARDT BIO AG'S UPDATED EXHIBIT LIST

Mail Stop "PATENT BOARD"
Patent Trial and Appeal Board
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Wockhardt Bio AG's Updated Exhibit List
IPR of USPN 8,822,438

Wockhardt Exhibit #	Description
1001	Auerbauch, A. H. & Belldegrum, 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, M.D., 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.

**Wockhardt Bio AG's Updated Exhibit List
IPR of USPN 8,822,438**

Wockhardt Exhibit #	Description
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).
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-hydroxylase 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)

**Wockhardt Bio AG's Updated Exhibit List
IPR of USPN 8,822,438**

Wockhardt Exhibit #	Description
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)
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)

**Wockhardt Bio AG's Updated Exhibit List
IPR of USPN 8,822,438**

Wockhardt Exhibit #	Description
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)
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")

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.