

Paper No. _____
Filed: March 15, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

Petitioner

v.

JANSSEN ONCOLOGY, INC.

Patent Owner

Case No. IPR2016-01332
U.S. Patent No. 8,822,438

PETITIONER'S OBJECTIONS TO PATENT OWNER'S EXHIBITS

Pursuant to 37 C.F.R. § 42.64(b)(1), Petitioner Mylan Pharmaceuticals Inc. (“Petitioner”) objects to the admissibility of the following exhibits filed by Patent Owner Janssen Oncology, Inc. (“Janssen”) in the Patent Owner’s Response in the above-captioned *inter partes* review.

Petitioner’s objections are timely under 37 C.F.R. § 42.64(b)(1) because they are being filed and served within five (5) business days of the filing of Patent Owner’s Response on March 8, 2017, Paper No. 35. Petitioner’s objections provide notice to Janssen that Petitioner may move to exclude these exhibits under 37 C.F.R. § 42.64(c).

In this paper, a reference to “FRE” means the Federal Rules of Evidence, a reference to “CFR” means the Code of Federal Regulations, and “’438 patent” means U.S. Patent No. 8,822,438. All objections under FRE 801-803 (hearsay) apply to the extent Patent Owner relies on the exhibits identified in connection with that objection for the truth of the matter asserted therein.

Exhibit descriptions provided in this table are from Patent Owner’s exhibit list and are used for identification purposes only. The use of the description does not indicate that Petitioner agrees with the descriptions or characterizations of the documents.

Exhibit	Description	Objection
JSN 2004	2016/11/10 (DI 239)-Opinion on Markman Patent Claim Construction (DNJ)	A, I, N, O, U, V

Exhibit	Description	Objection
JSN 2005	2016-14-10 (DI 240)-Order on Markman Patent Claim Construction (DNJ)	A, I, N, O, U, V
JSN 2006	Hoffman Deposition Ex. 1 - J&J 2015 4th Q results	A, B, D, F, L, T
JSN 2007	Hoffman Deposition Ex. 2 - J&J 2016 4th Q results	A, B, D, F, L, T
JSN 2008	Hoffman Deposition Ex. 3 - <i>Concordia v. Method</i>	A, B, I, K, L, N, O ¹
JSN 2009	Garnick Deposition Ex. 1 – Bubley et al., “Eligibility and Response Guidelines for Phase II Clinical Trials in Androgen-Independent Prostate Cancer: Recommendations From the Prostate-Specific Antigen Working Group,” <i>J. Clin. Oncology</i> , 17:3461-3467 (1999)	A, J, K, M
JSN 2010	Garnick Deposition Ex. 2 - 2015-12-04 Serels Declaration, <i>Amerigen Pharmaceuticals Ltd. v. Janssen Oncology, Inc.</i> , IPR2016-00286.	A, C, D, E, F, G, H, I, M, N, O, W, X, Y
JSN 2011	Garnick Deposition Ex. 3 – Blackhard, Letter to Editor, <i>J. Urology</i> , 146(6):1621-1622 (1991)	A, B, K, L, M ²
JSN 2012	Duc et al., “In vitro and in vivo models for the evaluation of potent inhibitors of male rat 17 α -hydroxylase/C _{17,20} -lyase,” <i>Journal of Steroid Biochemistry & Molecular Biology</i> , 84:537-542 (2003)	A, M, N, O

¹ Petitioner objects to JSN 2008 because it is not an accurate representation of Hofmann Deposition Ex. 3, as demonstrated by the Hofmann deposition transcript. JSN 2128 at 3, 103–04.

² Petitioner objects to JSN 2011 because it is not an accurate representation of Garnick Deposition Ex. 3, as demonstrated by the Garnick deposition transcript. JSN 2126 at 4, 184–88.

Exhibit	Description	Objection
JSN 2013	Boehringer-Ingelheim-BTG Press Release – “NEW TREATMENT FOR PROSTATE CANCER UNDER DEVELOPMENT,” dated May 22, 1996	A, B, C, D, E, F, K, N, O
JSN 2014	Attard et al., “Phase I Clinical Trial of a Selective Inhibitor of CYP17, Abiraterone Acetate, Confirms That Castration-Resistant Prostate Cancer Commonly Remains Hormone Driven,” <i>Journal of Clinical Oncology</i> , 26(28):4563-4571 (2008)	A, C, D, E, F
JSN 2015	Attard et al., “Selective Inhibition of CYP17 With Abiraterone Acetate Is Highly Active in the Treatment of Castration-Resistant Prostate Cancer,” <i>Journal of Clinical Oncology</i> , 27(23):3742-3748 (2009)	A, C, D, E, F
JSN 2016	Danila et al., “Phase II Multicenter Study of Abiraterone Acetate Plus Prednisone Therapy in Patients With Docetaxel-Treated Castration-Resistant Prostate Cancer,” <i>Journal of Clinical Oncology</i> , 28(9):1496-1501 (2010)	A, C, D, E, F
JSN 2017	Ryan et al., “Phase II Study of Abiraterone in Chemotherapy-Naïve Flare Discordant with Serologic Response Metastatic Castration-Resistant Prostate Cancer Displaying Bone,” <i>Clinical Cancer Research</i> , 17:4854-4861 (2011)	A, C, D, E, F
JSN 2018	Jubelirer and Hogan, “High Dose Ketoconazole For The Treatment Of Hormone Refractory Metastatic Prostate Carcinoma: 16 Cases And Review Of The Literature,” <i>The Journal of Urology</i> , 142:89- 91 (1989)	A
JSN 2019	Public Citizen Press Room Release – “Antifungal Treatment Should Be Taken Off the Market, Public Citizen Tells FDAD,” dated February 24, 2015	A, B, C, E, K, N, O

Exhibit	Description	Objection
JSN 2020	Williams et al., "Objective Responses to Ketoconazole Therapy in Patients with Relapsed Progressive Prostatic Cancer," <i>British Journal of Urology</i> , 58:45-51 (1986)	A, N, O
JSN 2021	Boumpas et al., "Glucocorticoid Therapy for Immune-mediated Diseases: Basic and Clinical Correlates," <i>Ann. Internal Medicine</i> , 119:1198-1208 (1993)	A, N, O
JSN 2022	Debruyne and Witjes, "Ketoconazole High Dose (H.D.) In The Management Of Metastatic Prostatic Carcinoma," <i>The Journal of Urology</i> , 135(4, pt.2):203A, Abstract 397 (1986)	A, I, N, O
JSN 2023	Herr and Pfitzenmaier, "Glucocorticoid use in prostate cancer and other solid tumours: implications for effectiveness of cytotoxic treatment and metastases," <i>The Lancet</i> , 7:425-430 (2006)	A, N, O
JSN 2024	Krishnan et al., "A Glucocorticoid-Responsive Mutant Androgen Receptor Exhibits Unique Ligand Specificity: Therapeutic Implications for Androgen-Independent Prostate Cancer," <i>Endocrinology</i> , 145:1889-1900 (2002)	A, N, O
JSN 2025	Conde and Aronson, "Risk factors for male osteoporosis," <i>Urologic Oncology</i> , 21:380-383 (2003)	A, N, O
JSN 2026	Remington – The Science and Practice of Pharmacy, 20th ed., pp. 1363-1370 (2000)	A, I, K, M, N, O
JSN 2027	Rumohr and Chang, "Current chemotherapeutic approaches for androgen-independent prostate cancer," <i>Current Opinion in Investigational Drugs</i> , 7(6):529-533 (2006)	A, C, E, K, M, N, O
JSN 2028	Declaration of Professor Ian Judson, M.D.	A, D, F, G, H, I, J, N, O, Q, S, T, U
JSN 2029	Judson CV	A, L, I, N, O
JSN 2030	Clinical Cancer Research Peer Review letter to Judson, dated May 12, 2003	A, B, C, D, E, F, N, O

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