

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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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,  
Petitioner,

v.

JANSSEN ONCOLOGY, INC.,  
Patent Owner.

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Case IPR2016-01332<sup>1</sup>  
Patent 8,822,438 B2

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**JANSSEN ONCOLOGY, INC.'S UPDATED EXHIBIT LIST**

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<sup>1</sup> Case IPR2017-00853 has been joined with this proceeding.

Pursuant to 37 C.F.R. § 42.63(e), Patent Owner, Janssen Oncology, Inc.

hereby submits a current list of its exhibits.

<b>Exhibit</b>	<b>Description</b>
JSN 2001	Notice of Termination of Preprocessing of <i>Ex Parte</i> Reexamination Request
JSN 2002	Declaration of David T. Pritikin in Support of Motion to Appear <i>Pro Hac Vice</i>
JSN 2003	Declaration of Bindu Donovan in Support of Motion to Appear <i>Pro Hac Vice</i>
JSN 2004	2016/11/10 (DI 239)-Opinion on Markman Patent Claim Construction (DNJ)
JSN 2005	2016-14-10 (DI 240) – Order on Markman Patent Claim Construction (DNJ)
JSN 2006	Hoffman Deposition Ex. 1 - J&J 2015 4 <sup>th</sup> Q results
JSN 2007	Hoffman Deposition Ex. 2 - J&J 2016 4 <sup>th</sup> Q results
JSN 2008	Hoffman Deposition Ex. 3 - <i>Concordia v. Method</i>

<b>Exhibit</b>	<b>Description</b>
JSN 2009	Garnick Deposition Ex. 1 – Bublely 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)
JSN 2010	Garnick Deposition Ex. 2 - 2015-12-04 Serels Declaration, <i>Amerigen Pharmaceuticals Ltd. v. Janssen Oncology, Inc.</i> , IPR2016-00286.
JSN 2011	Garnick Deposition Ex. 3 – Blackhard, Letter to Editor, <i>J. Urology</i> , 146(6):1621-1622 (1991)
JSN 2012	Duc et al., “In vitro and in vivo models for the evaluation of potent inhibitors of male rat 17 $\alpha$ -hydroxylase/C <sub>17,20</sub> -lyase,” <i>Journal of Steroid Biochemistry &amp; Molecular Biology</i> , 84:537-542 (2003)
JSN 2013	Boehringer-Ingelheim-BTG Press Release – “NEW TREATMENT FOR PROSTATE CANCER UNDER DEVELOPMENT,” dated May 22, 1996
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)

<b>Exhibit</b>	<b>Description</b>
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)
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)
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)
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)
JSN 2019	Public Citizen Press Room Release – “Antifungal Treatment Should Be Taken Off the Market, Public Citizen Tells FDAD,” dated February 24, 2015

<b>Exhibit</b>	<b>Description</b>
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)
JSN 2021	Boumpas et al., "Glucocorticoid Therapy for Immune-mediated Diseases: Basic and Clinical Correlates," <i>Ann. Internal Medicine</i> , 119:1198-1208 (1993)
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)
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)
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)
JSN 2025	Conde and Aronson, "Risk factors for male osteoporosis," <i>Urologic Oncology</i> , 21:380-383 (2003)

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