

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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WOCKHARDT BIO AG,

Petitioner

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

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Case IPR: 2016-01582

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

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**REPLY DECLARATION OF ROBERT D. STONER, Ph.D.**

WCK1122

Wockhardt Bio AG v. Janssen Oncology, Inc.

*Inter Partes Review of U.S. Patent No. 8,822,438  
Reply Declaration of Robert D. Stoner, Ph.D. (Exhibit 1122)*

I, Robert D. Stoner, Ph.D., declare as follows:

**I. Introduction**

**A. Qualifications**

1. My background and qualifications are generally described in Section I.A. of my initial declaration submitted in the proceeding on August 10, 2016 (“initial declaration”) (WCK1077.) I incorporate those qualifications by reference here. I have also provided an updated curriculum vitae with this declaration (WCK1098), which contains more details on my background, experience, publications, and prior testimony.

**B. Scope of Work**

2. I have been retained on behalf of Wockhardt Bio AG (“Wockhardt” or “Petitioner”) in connection with the above-captioned *inter partes* review (“IPR”). I am being compensated at a rate of \$595 per hour for my work. My compensation is not dependent on the substance of my testimony or the outcome of this matter.

3. For this declaration, I was asked to review and discuss the declaration of Dr. Christopher Velluro in Support of Patent Owner Response (“Velluro Declaration”) (JSN2115) relating to the alleged commercial success of Zytiga® (abiraterone acetate) and U.S. Patent No. 8,822,438 (“the ’438 patent”) (WCK1001). This declaration is a statement of my opinions in this matter and the basis and reasons for those opinions. In forming the opinions expressed in this declaration, I have relied upon my education, experience, and knowledge of the

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subject matter discussed. For this declaration, I have also reviewed, considered, or relied upon documents and other materials which are cited herein as well as in the table below<sup>1</sup>:

<b><i>Wockhardt/Janssen Exhibit #</i></b>	<b><i>Description</i></b>
<b>WCK1001</b>	Auerbauch, A. H. & Beldegrum, A. S., U.S. Patent No. 8,822,438 (filed Feb. 24, 2011; issued Sep. 2, 2014) ("the '438 patent")
<b>WCK1002</b>	Declaration of Paul A. Godley, MD, Ph.D., MPP
<b>WCK1030</b>	Barrie, S. E. <i>et al</i> , U.S. Patent No. 5,604,213 (filed Sep. 30, 1994; issued Feb. 18, 1997)
<b>WCK1034</b>	Taxotere Prescribing Information (2004), <a href="http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/020449s0281bl.pdf">http://www.accessdata.fda.gov/drugsatfda_docs/label/2004/020449s0281bl.pdf</a> (last accessed 8/8/2016)
<b>WCK1063</b>	Jevtana Website, Dosing and Administration, <a href="http://www.jevtana.com/hcp/dosing/default.aspx">http://www.jevtana.com/hcp/dosing/default.aspx</a> (accessed Aug. 8, 2016)
<b>WCK1077</b>	Declaration of Robert D. Stoner, Ph.D.
<b>WCK1087</b>	"BTG Licenses New Prostate Cancer Drug to Cougar Biotechnology," April 20, 2004, 2 pages (last accessed on April 3, 2017)
<b>WCK1088</b>	Deposition Transcript of Ian Judson, M.D., Friday, April 7, 2017
<b>WCK1099</b>	Deposition Transcript of Christopher A. Vellturo, Ph.D., Wednesday, April 5, 2017

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<sup>1</sup> This table includes materials considered in my initial declaration only if they are specifically cited in my reply declaration.

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<i>Wockhardt/Janssen Exhibit #</i>	<i>Description</i>
<b>WCK1100</b>	Cancer Research UK, "Our milestones: the birth of a new prostate cancer drug," September 21, 2015 (last accessed April 17, 2017)
<b>WCK1101</b>	Mohler, J.L., <i>et al.</i> , "The Androgen Axis in Recurrent Prostate Cancer," <i>Clin Can Res</i> 10:440-447 (2004)
<b>WCK1102</b>	The Institute of Cancer Research, "Abiraterone: a story of scientific innovation and commercial partnership," May 11, 2014 (last accessed April 17, 2017)
<b>WCK1104</b>	Second Declaration of Paul A. Godley, MD, Ph.D., MPP
<b>WCK1107</b>	Mestre-Ferrandiz, J., <i>et al.</i> , "The R&D Cost of a New Medicine," <i>Office of Health Economics</i> , London UK, 1–86 (2012)
<b>WCK1108</b>	DiMasi, J.A., <i>et al.</i> , "Innovation in the pharmaceutical industry: New estimates of R&D costs," <i>Journal of Health Economics</i> 47: 20–33 (2016)
<b>WCK1109</b>	NCT0205010, Phase II Clinical Trial of Abiraterone Acetate Without Exogenous Glucocorticoids in Men with Castration-resistant Prostate Cancer with Correlative Assessment of Hormone Intermediates, Clinicaltrials.gov
<b>WCK1110</b>	Zytiga <sup>®</sup> Approved in the EU for Use in the Treatment of Metastatic Castration-Resistant Prostate Cancer Before Chemotherapy, <a href="https://www.jnj.com/media-center/press-releases/zytiga-approved-in-the-eu-for-use-in-the-treatment-of-metastatic-castration-resistant-prostate-cancer-before-chemotherapy">https://www.jnj.com/media-center/press-releases/zytiga-approved-in-the-eu-for-use-in-the-treatment-of-metastatic-castration-resistant-prostate-cancer-before-chemotherapy</a> (last accessed 4/18/17)
<b>WCK1111</b>	Dizdar, O., "Is Dexamethasone a Better Partner for Abiraterone than Prednisolone?," <i>The Oncologist</i> 20: e13 (2015)
<b>WCK1112</b>	EMA – Zytiga Product Information, <a href="http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_Product_Information/human/002321/WC500112858.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_Product_Information/human/002321/WC500112858.pdf</a> (last accessed 4/18/17)

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<b><i>Wockhardt/Janssen Exhibit #</i></b>	<b><i>Description</i></b>
<b>WCK1113</b>	Storlie, J.A., <i>et al.</i> , "Prostate Specific Antigen Levels and Clinical Response to Low Dose Dexamethasone for Hormone-Refractory Metastatic Prostate Carcinoma," <i>Cancer</i> 76:96-100 (1995)
<b>WCK1114</b>	David, Jesse and Stewart (2005), "Commercial Success: Economic Principles Applied to Patent Litigation," in Gregory K. Leonard and Lauren J. Stiroh, ed., <i>Economic Approaches to Intellectual Property Policy, Litigation, and Management</i> , White Plains, NY: National Economic Research Associates, Inc.
<b>WCK1117</b>	Auerbauch, A. H. & Beldegrum, A. S., U.S. Pat. Appl. Publ. No. 2015/0005268 (filed September 12, 2014; issued January 1, 2015)
<b>WCK1120</b>	Deposition Transcript of Christopher A. Vellturo, Ph.D., Tuesday, December 20, 2016 (IPR2016-00286)
<b>JSN2028</b>	Declaration of Professor Ian Judson, M.D.
<b>JSN2038</b>	Declaration of Matthew Rettig, M.D.
<b>JSN2115</b>	Declaration of Christopher A. Vellturo, Ph.D.
<b>[REDACTED]</b>	[REDACTED]
<b>JSN2095</b>	Zytiga Usage – prednisone information
<b>JSN2109</b>	Hotte and Saad, "Current Management of castrate-resistant prostate cancer," <i>Current Oncology</i> , 17(2):S72-S79 (2010)
<b>JSN2134</b>	Zytiga Market Share data
<b>JSN2135</b>	Truven Commercial and Medicare data
<b>JSN2160</b>	Deposition Transcript of Robert D. Stoner, taken by Patent Owner on February 10, 2017
<b>JSN2162</b>	Deposition Transcript of Paul A. Godley, taken by Patent Owner on March 7, 2017
	All Exhibits listed in Appendix A to the Declaration of Christopher A. Vellturo, Ph.D. in Support of Patent Owner Response

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