

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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**DECLARATION OF PAUL A. GODLEY, M.D., Ph.D., MPP**

WCK1104

Wockhardt Bio AG v. Janssen Oncology, Inc.

*Inter Partes Review of U.S. Patent No. 8,822,438*  
*Reply Declaration of Paul A. Godley, M.D., Ph.D., MPP (Exhibit 1104)*

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***Inter Partes Review of U.S. Patent No. 8,822,438  
Reply Declaration of Paul A. Godley, M.D., Ph.D., MPP (Exhibit 1104)***

I, Paul A. Godley, do hereby declare as follows:

**I. Introduction**

**A. Qualifications**

1. My background and qualifications are generally described in Section II of my initial declaration submitted in the proceeding on August 10, 2016 (“Initial Declaration”) (WCK1002, ¶¶9-15). I incorporate those qualifications by reference here. I have also provided an updated *curriculum vitae*, attached as WCK1105, which contains more details on my background, experience, and publications. I am being compensated as set forth in my previous Declaration (WCK1002, ¶2), and I continue to have no personal or financial interest in Wockhardt or in the outcome of this proceeding.

**B. Scope of work**

2. For this declaration, I was asked to review and discuss the declaration of Dr. Matthew Rettig (“the Rettig Declaration”). (JSN2038). I have also reviewed the declaration of Dr. Richard Auchus (“the Auchus Declaration”) (JSN2040), Dr. Rettig’s deposition transcript (WCK1097), and Janssen’s Patent Owner Response (“Janssen’s POR”) (Paper 43). 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

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knowledge of the subject matter discussed. I have also reviewed, considered, or relied upon documents and other materials, which are cited in the table below:

<b><i>Wockhardt/Janssen Exhibit #</i></b>	<b><i>Description</i></b>
<b>WCK1002</b>	Declaration of Paul A. Godley, M.D., Ph.D., MPP
<b>WCK1004</b>	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")
<b>WCK1005</b>	O'Donnell, A. <i>et al.</i> , "Hormonal impact of the 17 $\alpha$ -hydroxylase/C <sub>17,20</sub> lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer," <i>British J. of Cancer</i> , 90: 2317-2325 (2004) ("O'Donnell")
<b>WCK1006</b>	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")
<b>WCK1009</b>	Kasper, D. L. <i>et al.</i> (Eds.). (2005). <i>Harrison's Principles of Internal Medicine</i> , Vol. 1, 16 <sup>th</sup> ed., Ch. 81:543-550 & Ch. 321:2127-2148, New York City, NY: The McGraw-Hill Companies, Inc.
<b>WCK1010</b>	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).
<b>WCK1011</b>	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)

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