

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WOCKHARDT BIO AG
Petitioner

v.

JANSSEN ONCOLOGY, INC.
Patent Owner

Case IPR: Unassigned

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

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

*Inter Partes Review of U.S. Patent No. 8,822,438
Declaration of Paul A. Godley, M.D., Ph.D., MPP (Exhibit 1002)*

TABLE OF CONTENTS

I.	Overview.....	1
II.	My background and qualifications	3
III.	List of documents considered in formulating my opinion	5
IV.	Person of ordinary skill in the art	11
V.	State of the art before August 25, 2006	12
	A. The standard of care for prostate cancer, as of August 25, 2006.....	12
	B. PSA levels were known to be an indicator of prostate cancer progression and tumor burden.....	18
	C. Inhibiting adrenal androgen production was a focus of treating hormone refractory prostate cancer	18
	1. Ketoconazole was a known CYP17 inhibitor	22
	2. Abiraterone acetate was known to be a potent and more selective than ketoconazole and to effectively reduce testosterone levels	23
	3. Inhibiting cortisol production increased mineralocorticoids.....	24
	D. Glucocorticoids, such as prednisone, were part of the standard of care in treating mCRPC	24
VI.	The '438 patent and its claims	26
	A. Independent claim 1	27
	B. Dependent claims 2-20	27
	C. Claim construction	29
	1. “treat,” “treating,” and “treatment”	29
	2. “therapeutically effective amount of prednisone”	29

*Inter Partes Review of U.S. Patent No. 8,822,438
Declaration of Paul A. Godley, M.D., Ph.D., MPP (Exhibit 1002)*

VII.	The basis of my analysis with respect to obviousness	30
A.	A POSA reading Gerber, O’Donnell, and Sartor would have had the reason and the know-how to arrive at the methods of claims 1-20 with a reasonable expectation of success	31
1.	Independent claim 1	37
(a)	A POSA would have had reason to administer a CYP17 inhibitor and prednisone to treat prostate cancer	40
(b)	Abiraterone acetate was well-known to be a potent and more specific inhibitor of CYP17 than ketoconazole and to effectively reduce testosterone levels	41
(c)	A POSA would have had reason to administer a therapeutically effective amount of abiraterone acetate and prednisone to treat prostate cancer	43
(d)	A POSA would have had a reasonable expectation of successfully practicing the method of claim 1	47
2.	Dependent Claims 2-20.....	49
(a)	Claims 2 and 3	49
(b)	Claim 4.....	50
(c)	Claim 5.....	51
(d)	Claims 6 and 7	52
(e)	Claim 8.....	52
(f)	Claim 9.....	54
(g)	Claims 10 and 11	54
(h)	Claims 12 and 13	57
(i)	Claims 14-17.....	57
(j)	Claims 18-20.....	59

*Inter Partes Review of U.S. Patent No. 8,822,438
Declaration of Paul A. Godley, M.D., Ph.D., MPP (Exhibit 1002)*

B.	Objective indicia of non-obviousness	61
1.	No unexpectedly superior results.....	61
2.	No long-felt but unmet need or failure of others	67
3.	The commercial success of Zytiga [®] is not the result of unexpected results of the claimed invention.....	68
VIII.	Conclusion	69

*Inter Partes Review of U.S. Patent No. 8,822,438
Declaration of Paul A. Godley, M.D., Ph.D., MPP (Exhibit 1002)*

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

I. Overview

1. I am over the age of 18 and otherwise competent to make this declaration. This declaration is based on my personal knowledge as an expert in the diagnosis and treatment of genitourinary cancers. I understand this declaration is being submitted together with a petition for *Inter Partes* Review (“IPR”) of claims 1-20 of U.S. Patent No. 8,822,438 (“the ’438 patent”) (WCK1001).

2. I have been retained as an expert on behalf of Wockhardt Bio AG (“Wockhardt”), the Petitioner, for this IPR. I am being compensated for my time in connection with this IPR at my standard legal consultant rate of \$500/hr. I have no personal or financial interest in Wockhardt or in the outcome of this proceeding.

3. I understand that the ’438 patent issued on September 2, 2014, and resulted from U.S. Application No. 13/034,340, filed on February 24, 2011, which is a continuation of U.S. Application No. 11/844,440, filed on August 24, 2007, which claims the benefit of U.S. Provisional Application No. 60/921,506, filed on August 25, 2006. I also understand that the face page of the ’438 patent states that the ’438 patent is currently assigned to Janssen Oncology, Inc. (“Janssen”).

4. The face page of the ’438 patent cites several related U.S. patent applications including U.S. Application No. 13/034,340, filed on February 24, 2011, which is a continuation of U.S. Application No. 11/844,440, filed on August

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.