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 ROBERT D. STONER, Ph.D.



Inter Partes Review of U.S. Patent No. 8,822,438 Declaration of Robert D. Stoner, Ph.D. (Exhibit 1077)

TABLE OF CONTENTS

I.	Intro	Introduction		
	A.	Background and Qualifications	1	
	B.	Scope of Work	2	
II.	Sum	mary of Opinions	7	
III.	Background		12	
	A.	Prostate cancer	12	
	B.	Zytiga® (abiraterone acetate)	13	
	C.	The '438 Patent	14	
	D.	Prosecution of the '438 Patent	15	
	E.	The '213 "blocking" Patent	15	
IV.	Analysis of Commercial Success		16	
	A.	Economic relevance and the definitions of commercial success and nexus relative to objective indicia of nonobviousness	16	
	B.	Lack of nexus between the performance of Zytiga® and the '438 Patent claims	20	
		1. J&J's '213 Patent serves as a "blocking patent," and undermines the relevance of commercial success at to the '438 patent	22	
		2. Any features of the '438 Patent arguably driving Zytiga®'s sales already existed in the prior art and are not relevant	28	
	C.	Xtandi® has taken Zytiga®'s market share	32	
	D.	"Unexpected" commercial success of Zytiga® is neither economically nor legally relevant to objective indicia of		



Inter Partes Review of U.S. Patent No. 8,822,438 Declaration of Robert D. Stoner, Ph.D. (Exhibit 1077)

		nonobviousness of the '438 Patent, and the performance metrics for Zytiga® presented during the prosecution of the '438 Patent are misleading and incomplete	38
	E.	Janssen has not shown that Zytiga® is a commercial success	40
V	Con	clusion	46



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

I. Introduction

A. Background and Qualifications

- 1. I am over the age of eighteen and otherwise competent to make this declaration. I have personal knowledge of the facts set forth in this Declaration and am competent to testify to the same.
- 2. I am a Principal at Economists Incorporated, and an expert in industrial organization, with more than twenty five years of experience in consulting, antitrust, and economic research. I provide expert witness testimony and consulting in a variety of areas, including reasonable royalties, commercial success, damages estimation, and business strategy.
- 3. My expertise and experience encompass a variety of topics, including intellectual property, competition, antitrust, utility regulation, international trade, commercial litigation, and class action. My work in intellectual property spans the life sciences (with specific industry expertise in pharmaceuticals, medical devices and drug wholesaling) as well as electronics (including computer memory, digital music, smart phones, text messaging and telecommunications). I have worked on projects in a diverse range of other industries (such as pharmaceutical data, electric utilities, grocery stores, casinos, hospital beds, automobiles and oil refining and marketing). I frequently provide expertise and analysis in evaluating commercial



Inter Partes Review of U.S. Patent No. 8,822,438 Declaration of Robert D. Stoner, Ph.D. (Exhibit 1077)

success in the pharmaceutical industry.

- 4. I earned my Ph.D. and M.A. in Economics from Berkeley, University of California in 1978 and 1976, respectively, and my B.A. in Economics from Santa Cruz, University of California in 1970. At Santa Cruz, I received both General Honors and Honors in Economics. I have also published research in several peer-reviewed academic journals.
- 5. I am educated and experienced in economics, as detailed in this Declaration. My qualifications and credentials are also fully set forth in my *curriculum vitae*, provided as WCK1078. I understand that my declaration will be included in Petitioner's Exhibit List as WCK1077. I have examined and am familiar with the contents of WCK1048-1080. Each of these Exhibits is publicly available, or derived from documents that are publicly available, and is a true and correct copy of the documents cited, including but not limited to the following: WCK1048, WCK1052, WCK1054, WCK1057, WCK1059, WCK1060, WCK1061, WCK1063, WCK1065, WCK1067, WCK1068, WCK1069, WCK1070, WCK1071, WCK1073 and WCK1080.

B. Scope of Work

6. 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



DOCKET

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.

