UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,

Petitioner

V.

JANSSEN ONCOLOGY, INC.,

Patent Owner

U.S. Patent No. 8,822,438 to Auerbach *et al.* Issue Date: September 2, 2014 Title: Methods and Compositions for Treating Cancer

Inter Partes Review No. IPR2016-01332

DECLARATION OF IVAN T. HOFMANN, CPA/CFF, CLP

I.	Introduction
II.	Qualifications
III.	Case Background
	A. Prostate Cancer
	B. Zytiga (abiraterone acetate)10
	C. The '438 Patent
	D. Prosecution of the '438 Patent
IV.	The Definitions of Commercial Success and Nexus Relative to Objective Indicia of Nonobviousness
V.	The Performance of Zytiga Does Not Provide Objective Indicia of Nonobviousness of the '438 Patent Due to the Existence of a Blocking Patent
VI.	The Performance of Zytiga Does Not Provide Objective Indicia of Nonobviousness of the '438 Patent because There is No Nexus between the Performance of Zytiga and the Claims of the '438 Patent
VII.	The Performance Metrics for Zytiga Presented During the Prosecution of the '438 Patent are Misleading and Incomplete

I, Ivan T. Hofmann, hereby declare as follows.

I. Introduction

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. I have been retained as an independent expert on behalf of MYLAN PHARMACEUTICALS INCORPORATED ("Mylan" or "Petitioner") for the abovecaptioned *inter partes* review ("IPR").

3. I understand that this IPR involves U.S. Patent No. 8,822,438 (the "'438 Patent" or the "Patent-at-Issue").¹ MYL Ex. 1001. I understand that Alan H. Auerbach and Arie S. Belldegrun are the named inventors and that, according to the United States Patent and Trademark Office ("USPTO") records, the '438 Patent is currently assigned to JANSSEN ONCOLOGY, INC. ("Janssen" or "Patent Owner"). MYL Ex. 1001.

¹ I understand that the Patent Trial and Appeal Board instituted trial in IPR2016-00286, captioned *Amerigen Pharms. Ltd. (Petitioner) v. Janssen Oncology, Inc. (Patent Owner)*, on May 31, 2016. I also understand that in conjunction with the petition, Amerigen filed the declaration of DeForest McDuff dated December 4, 2015 (the "McDuff Declaration"). I reviewed the McDuff Declaration in forming my opinions.

4. My company, Gleason IP, a division of Gleason & Associates, P.C. ("Gleason"), has been retained by Perkins Coie LLP on behalf of Mylan to evaluate aspects of commercial success, from an economic perspective, as it pertains to Zytiga (abiraterone acetate) and the '438 Patent. Gleason is being compensated for the work performed on this engagement based on the time incurred by me at a rate of \$435 per hour and by other Gleason personnel, working at my direction and under my supervision, at rates ranging from \$95 to \$275 per hour. Our compensation is not affected by the outcome of this case.

5. In formulating my opinions, I have considered all documents cited in this declaration. I have included a list of these documents in **Attachment A-1** to this declaration. This declaration summarizes my current opinions, which are subject to change depending upon additional information and/or analysis. I reserve the right to supplement this declaration in response to any opinions of experts on behalf of the Patent Owner and/or as additional information becomes available.

II. Qualifications

6. I am a Managing Director at Gleason, which is an economic, accounting, and financial consulting firm that provides services primarily in the areas of Valuation, Litigation Support, Intellectual Property, Forensic Accounting and Financial Reorganization. I am the leader of the Intellectual Property Practice. Prior to joining Gleason, I worked for the global firm of Deloitte & Touche, LLP.

7. I graduated *magna cum laude* from the University of Notre Dame in 1994 with a Bachelor of Business Administration degree and a double major in Economics and Accounting. I am a Certified Public Accountant ("CPA"). I am also Certified in Financial Forensics ("CFF"). I am a member of the Licensing Executives Society ("LES") and have received my Certified Licensing Professional ("CLP") designation, which is granted by the LES to professionals with demonstrated knowledge and experience in the areas of intellectual property and licensing. I have attended and instructed numerous continuing education seminars since the completion of my formal education and have been a speaker on numerous occasions on a variety of financial, economic, accounting, and valuation topics. I have presented to various bar associations and organizations on the issues of intellectual property, financial damages, valuation, financial statement analysis, and other topics.

8. I have extensive knowledge and experience in the areas of economic and market analysis as it relates to litigation matters. My experience in intellectual property matters includes the valuation of intellectual property, analysis of objective indicia of nonobviousness, market analysis involving product performance, the determination of damages associated with patent infringement and other intellectual property (including

DOCKET A L A R M



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.