

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTAVIS LABORATORIES FL, INC., AMNEAL PHARMACEUTICALS LLC,
AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, DR. REDDY'S
LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SUN
PHARMACEUTICALS INDUSTRIES, LTD., SUN PHARMACEUTICALS
INDUSTRIES, INC., TEVA PHARMACEUTICALS USA, INC., WEST-WARD
PHARMACEUTICAL CORP., and HIKMA PHARMACEUTICALS, LLC

Petitioners

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. IPR2017-00853

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

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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 Actavis Laboratories FL, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Of New York, LLC, Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Sun Pharmaceuticals Industries, Ltd., Sun Pharmaceuticals Industries, Inc., Teva Pharmaceuticals USA, Inc., West-Ward Pharmaceutical Corp., And Hikma Pharmaceuticals, LLC for the above-captioned *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 Ex. 1001. I understand that Alan H. Auerbach and Arie S. Bellegrun are the named inventors and that, according to the United States

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.

Patent and Trademark Office (“USPTO”) records, the ’438 Patent is currently assigned to JANSSEN ONCOLOGY, INC. (“Janssen” or “Patent Owner”). Ex. 1001.

4. My company, Gleason IP, a division of Gleason & Associates, P.C. (“Gleason”), has been retained by Winston & Strawn, LLP on behalf of Actavis Laboratories FL, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Of New York, LLC, Dr. Reddy’s Laboratories, Inc., Dr. Reddy’s Laboratories, Ltd., Sun Pharmaceuticals Industries, Ltd., Sun Pharmaceuticals Industries, Inc., Teva Pharmaceuticals USA, Inc., West-Ward Pharmaceutical Corp., And Hikma Pharmaceuticals, LLC 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 \$450 per hour and by other Gleason personnel, working at my direction and under my supervision, at rates ranging from \$110 to \$295 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

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