REDACTED VERSION

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., 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

Case IPR2016-01332[1]
Patent 8,822,438 B2

REPLY DECLARATION OF IVAN T. HOFMANN

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[1] Case IPR2017-00853 has been joined with this proceeding.

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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 Petitioners for the above-captioned *inter partes* review ("IPR"). I previously prepared and issued the Declaration of Ivan T. Hofmann, CPA/CFF, CLP dated June 30, 2016 (the "Hofmann Declaration"). Ex. 1017 (Hofmann Decl.). I submitted a substantially similar declaration in IPR2017-00853.

3. I have been asked to prepare this declaration (the "Hofmann Reply Declaration") in response to the declaration of Christopher A. Vellturo, Ph.D. dated March 8, 2017 (the "Vellturo Declaration" (Ex. 2044)), relating to the alleged commercial success of Zytiga (abiraterone acetate) and U.S. Patent No. 8,822,438 (the "'438 Patent") on behalf of Janssen Oncology, Inc. ("Janssen" or "Patent Owner"). I understand that the sole independent claim of the '438 Patent claims "[a] method for the treatment of a prostate cancer in a human comprising administering to said human a therapeutically effective amount of abiraterone

acetate[2] or a pharmaceutically acceptable salt thereof and a therapeutically effective amount of prednisone." Ex. 1002 (Garnick Decl.) at ¶ 34; Ex. 1001 ('438 Patent).

4. In formulating my opinions, I have considered the documents cited in the Hofmann Declaration and the additional documents listed in **Attachment A-1** cited within this Hofmann Reply Declaration. In formulating my opinions expressed in this declaration, I have relied upon my education, experience, and knowledge of the subjects discussed.

5. 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.

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[2] I understand that from a technical perspective, abiraterone acetate and abiraterone are distinct compounds. I also understand that abiraterone acetate metabolizes into abiraterone in the body and abiraterone is the active pharmaceutical ingredient. *See, e.g.*, Ex. 1097 (Bantle Reply Decl.) at p. 51, footnote 11. For the purposes of this declaration, I treat the references to abiraterone acetate and abiraterone as interchangeable.

II. Qualifications, Case Background, and Definitions of Commercial Success and Nexus Relative to Objective Indicia of Nonobviousness

6. My qualifications are generally described in Section II of the Hofmann Declaration. Ex. 1017 (Hofmann Decl.). I incorporate those qualifications by reference here. I have also provided an updated *curriculum vitae* in **Attachment A-2** to this declaration, which contains additional details on my background, experience, and prior testimony.

7. My understanding of certain topics related to the background of this matter and the definitions of commercial success and nexus are generally described in in Sections III and IV of the Hofmann Declaration, respectively. Ex. 1017 (Hofmann Decl.). I incorporate those qualifications by reference here.

III. Lack of Objective Indicia of Nonobviousness

8. In my opinion, the performance of Zytiga fails to provide objective indicia of nonobviousness of the asserted claims of the ’438 Patent, because no other company had the ability to commercialize a product containing abiraterone acetate in the U.S. as a result of the “blocking” nature of U.S. Patent No. 5,604,213 (the “’213 Patent” (Ex. 1005)).

9. As discussed in the Hofmann Declaration, I understand that the ’213 Patent claims both the abiraterone acetate compound and methods for treating an

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