

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,
Petitioner

v.

JANSSEN ONCOLOGY, INC.,

Patent Owner

Case IPR2016-01332¹
Patent 8,822,438 B2

**REPLY DECLARATION OF MARC B. GARNICK, M.D.
IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S.
PATENT NO. 8,822,438**

¹ Case IPR2017-00853 has been joined with this proceedings.

JANSSEN EXHIBIT 2177



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1. I am the same Marc B. Garnick, M.D. who previously submitted a declarations dated June 30, 2016 and February 8, 2017. I submit this expert declaration to respond to certain opinions expressed in the expert declaration (Ex. 2038) submitted with Patent Owner's Response to the Petition.

2. In addition to my experience, education, and training, and the materials identified in my earlier declaration (Ex. 1002), I have also considered all materials identified in Exhibit A, as well as any materials cited herein not otherwise identified in Exhibit A, as well as any materials cited in Dr. Rettig's Declaration (Ex. 2038) not otherwise identified.

3. My *curriculum vitae* submitted with my original declaration remains accurate. *See* Ex. 1002, Ex. A.

4. The scope of my work and compensation remains the same since I submitted my original declarations in this proceeding. I was retained as a technical expert to provide opinions related to the patent at issue. My compensation is not dependent upon the outcome of the proceedings or my opinions given. I have no current affiliation with Janssen Oncology, Inc. or the inventors of the patent at issue.

I. SUMMARY OF OPINIONS

5. The administration of abiraterone acetate in combination with prednisone to treat advanced stage prostate cancer would have been obvious to

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aminoglutethimide. As detailed herein, his opinions are unsupported by the state of the art and the information well within a skilled artisan's knowledge.

II. LEGAL STANDARDS

7. In addition to the legal principles detailed in my previous declaration, I have been informed that to combine prior art teachings and render patent claims obvious, the prior art does not need to contain data that alters the standard of medical care. Instead, a skilled artisan must be motivated to and have a reasonable expectation of success in learning from the prior art.

III. PERSON OF ORDINARY SKILL IN THE ART

8. It continues to be my opinion, as expressed in my opening declaration (Ex. 1002), that a person of ordinary skill in the art ("POSA") at the time of filing of the '438 patent is someone who is a physician specializing in urology, endocrinology or oncology, or holds a Ph.D. in pharmacology, biochemistry or a related discipline (which may include, for example, pharmaceutical sciences). Additional experience could substitute for the advanced degree.

9. A person of ordinary skill in the art may also collaborate with one or more persons of skill in the art for one or more aspects in which the other person may have expertise, experience, and/or knowledge that was obtained through his or her education, industrial or academic experiences. A person of ordinary skill in the art may consult with an endocrinologist, oncologist or medical biochemist and thus

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