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 IPR2016-01332[1]
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.

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

TABLE OF CONTENTS

DOCKET ALARM

Find authenticated court documents without watermarks at docketalarm.com.

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

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

skilled artisans as of the priority date of the ’438 patent. First, skilled artisans would have known that the state of the prior art included administration of ketoconazole and other steroid synthesis inhibitors, such as aminoglutethimide, in combination with glucocorticoid replacement. These were well-known and accepted treatments for advanced prostate cancer. Second, skilled artisans would have known that abiraterone acetate was a next-generation steroid synthesis inhibitor, and an obvious choice for administration in advanced stage prostate cancer—a point that Dr. Rettig does not dispute. Third, skilled artisans would have expected to need to administer abiraterone acetate with glucocorticoids because it was known to inhibit the steroid synthesis pathway, like other agents in its class. In particular, abiraterone acetate was known to be a strong, potent inhibitor of the CYP17 enzyme, similar to ketoconazole. Fourth, prednisone was a commonly used glucocorticoid and its characteristics made it an obvious choice for co-administration with abiraterone acetate.

6. Dr. Rettig attempts to undercut the obviousness of the claims of the ’438 patent by nitpicking at a number of ancillary issues such as the mechanism of steroid synthesis inhibition of ketoconazole, and the data supporting expected disruptions in the synthesis of adrenal steroids when administering abiraterone acetate. His arguments largely ignore the wealth of art supporting administration of glucocorticoids, in particular prednisone, with ketoconazole as well as

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

DOCKET ALARM

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.