

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Amerigen Pharmaceuticals Limited and Argentum Pharmaceuticals LLC

Petitioners

v.

Janssen Oncology, Inc.

Patent Owner

U.S. Patent No. 8,822,438 to Auerbach et al.

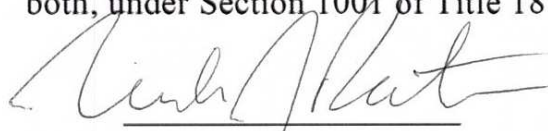
Issue Date: September 2, 2014

Title: Methods and Compositions for Treating Cancer


Inter Partes Review No. 2016-00286¹

Declaration of Dr. Mark J. Ratain

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.



Mark J. Ratain, M.D.



Date

¹ Case IPR2016-01317 has been joined with this proceeding.

Contents

I. Introduction	1
II. Education and Professional Background	1
III. Legal Standards	7
IV. Summary of Opinions.....	9
V. Analysis.....	10
A. There Was A Basis in the Prior Art to Add Prednisone to Abiraterone Acetate for Purposes of Glucocorticoid Replacement	10
B. There Was a Clinical Basis for Believing That the Combination of Abiraterone Acetate and Prednisone Would Be Successful in Achieving the Results Claimed in the ‘438 Patent	20
C. There is No Evidence of Unexpected Results Supporting the Non-Obviousness of the Claims of the ‘438 Patent	22
1. There Is No Unexpected Difference in Results In Comparison to the Closest Prior Art	22
2. There is no evidence that AA plus prednisone is superior to AA alone....	25
3. Unexpected results for prednisone and abiraterone cannot be inferred from any results for dexamethasone in combination with abiraterone	30
4. There is No Evidence that Use of Abiraterone in Combination with Prednisone in Patients with mCRPC Results in Increased Efficacy by Avoiding Clinical Resistance to Abiraterone	33
D. The ‘438 Patent Claims Did Not Fulfil A Long-Felt But Unsolved Need	36
E. The commercial success of abiraterone was expected based on the disclosures in O’Donnell and Barrie, as well as other prior art.....	37

F. Other Secondary Considerations Are Not Relevant Because There is No
Nexus Between the Attributes of the '438 Patent Claims and the Cited
Considerations 38

I, Mark J. Ratain, M.D., do hereby declare:

I. Introduction

1. At the request of Petitioners Amerigen Pharmaceuticals, Ltd. and Argentum Pharmaceuticals, LLC (“Petitioners”) in the matter of the *inter partes* review of U.S. Patent No. 8,822,438 (the “438 Patent” (AMG 1001), requested by Petitioners and instituted by the Patent Trial and Appeal Board (“PTAB”) of the United States Patent and Trademark Office in Case No. IPR2016-00286 and Case No. IPR2016-01317, I have been asked to respond to certain opinions expressed in the expert declaration and deposition testimony of Matthew B. Rettig, M.D. (JSN 2038) submitted on behalf of Patent Owner Janssen Oncology, Inc. (“Janssen”).

2. I am being compensated for my work in this matter at the rate of \$800.00 per hour. My compensation in no way depends on the outcome of this proceeding. The opinions I set forth herein are my own, and are based on the education, experience, training and skill that I have accumulated in the course of my career as a physician and researcher, as well as the materials I have reviewed in connection with this case.

II. Education and Professional Background

3. I graduated from Harvard University *magna cum laude* in 1976 with an A.B. in Biochemical Sciences. I obtained my M.D. from Yale University

School of Medicine in 1980. I completed my internship and residency at the Johns Hopkins Hospital in Baltimore, MD from 1980-1983. I completed a fellowship in Hematology/Oncology at the Department of Medicine at the University of Chicago from 1986-1988.

4. In 1986, I joined the Department of Medicine, Section of Hematology/Oncology and Committee on Clinical Pharmacology at the University of Chicago as an Instructor and became a Professor in that department in 1995. In 2002, I was appointed as the inaugural Leon O. Jacobson Professor in the Department of Medicine at The University of Chicago.

5. I have had a number of leadership roles in the University of Chicago's Cancer Center, dating back to 1991 when I became the Director of the Developmental Therapeutics Program. Since 1999, I have been the Associate Director for Clinical Sciences, with responsibility for strategic oversight of all oncology clinical trials.

6. I have also had a number of leadership roles in clinical pharmacology at the University of Chicago. In 1992, I was appointed Chairman of the University's interdepartmental unit in clinical pharmacology, then known as the Committee on Clinical Pharmacology, whose main purpose was postdoctoral training in clinical pharmacology, primarily supported by a training grant from the National Institutes of Health ("NIH"). In 2010, my role changed, as I founded a

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.