

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.

Case IPR2016-00286¹
Patent 8,822,438 B2

**DECLARATION OF RICHARD AUCHUS, M.D., Ph.D.
IN SUPPORT OF JANSSEN ONCOLOGY, INC.'S
PATENT OWNER RESPONSE**

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

I, Richard Auchus, M.D., Ph.D. hereby declare as follows:

I. ENGAGEMENT

1. I have been retained by counsel for Patent Owner Janssen Oncology, Inc. (“Janssen”) to provide expert testimony as background for the panel of Administrative Patent Judges of the Patent Trial and Appeal Board of the United States Patent and Trademark Office (“Panel”) as it considers issues relating to the patentability of U.S. Patent No. 8,822,438 (the ’438 Patent) (Ex. 1001) in an *inter partes* review requested by Amerigen Pharmaceuticals Ltd. and Argentum Pharmaceuticals LLC (collectively “Petitioners”) in Case No. IPR2016-00286 and Case No. IPR2016-01317.

2. I am being compensated at my customary rate of \$350 per hour for work in connection with this proceeding. I am also being reimbursed for reasonable and customary expenses associated with my work in this proceeding. My compensation is in no way contingent upon the outcome of this proceeding or the specifics of my testimony.

3. I understand that a person of ordinary skill (“POSA”) is a hypothetical person who has the characteristics of an ordinary practitioner, including ordinary creativity. For purposes of my analysis in this case, I have considered the issues in the context of a POSA, which would have been a physician specializing in urology or medical oncology who has significant practical experience in the treatment of

patients with prostate cancer. A POSA would have worked in a team or setting that includes access to one or more individuals who have expertise in endocrinology, biochemistry, pharmacology, and/or molecular biology or a related field of science, and who has experience in prostate cancer treatments or androgen synthesis and action. I have been informed that Petitioners define a POSA as someone who is a physician specializing in urology or oncology, or holds a Ph.D. in pharmacology, biochemistry, or a related discipline. My analysis and the opinions set forth herein would remain unchanged under Petitioners' proposed definition.

II. QUALIFICATIONS AND EXPERIENCE

4. I am a physician, Board Certified in endocrinology, diabetes, and metabolism. I am currently Professor of Internal Medicine, Division of Metabolism, Endocrinology and Diabetes ("MEND") at the University of Michigan Medical School. I am also Program Director of the MEND Fellowship Program, which provides training in clinical endocrinology and offers specialized clinics in pituitary diseases, endocrine tumors and genetics, endocrinopathies in pregnancy, intensive diabetes care, bariatrics, and metabolic bone diseases. I am also Professor in the Department of Pharmacology, University of Michigan.

5. I received my Bachelor's degree in Chemistry at the Massachusetts Institute of Technology in 1982, and my M.D./Ph.D. in Pharmacology at

Washington University School of Medicine in St. Louis in 1988. I completed my residency in internal medicine at the University of Iowa in 1991, and my fellowship in endocrinology at Wilford Hall U.S. Air Force Medical Center/UTHSC San Antonio in 1993, where I also served in the U.S. Air Force's medical corps. My *curriculum vitae* can be found at Ex. 2041.

6. From 1996-1999, I conducted postdoctoral research and served on the faculty in pediatrics and internal medicine at the University of California, San Francisco. Prior to joining the University of Michigan, I held the positions of Assistant Professor (1999-2005), Associate Professor (2005-2008), and Full Professor (2008-2011) at the University of Texas Southwestern Medical Center in Dallas, where I was also Acting Chief of the Division of Endocrinology and Metabolism and the Division of Translational Research.

7. My research interests include investigation of the basic mechanisms underlying steroid hormone biosynthesis, as well as the clinical and translational investigation of disorders of the pituitary, adrenals, ovaries, and testes that cause hypertension, infertility, and obesity. The common theme of my work is steroid and sterol biosynthesis and action with an emphasis on human diseases. In my clinical practice I also focus on diseases involving changes in steroid hormone production.

8. I have been a principal or co-investigator on several clinical trials and studies sponsored by the National Institutes of Health, March of Dimes, Robert A. Welch Foundation, and pharmaceutical companies. I am active in physician training and education, as well as efforts to improve the health of patients with endocrine diseases.

9. I am a named author on over 208 original peer-reviewed medical journal articles and book chapters, and have presented at a diverse range of national and international conferences. I am a Council Member of the American Professors of Diabetes, Endocrinology, and Metabolism organization as well as a member of the American Heart Association, American Association of Clinical Endocrinologists, and the Endocrine Society. I am on the editorial board of several professional journals. I have also served as an ad hoc referee for the *New England Journal of Medicine* and the *Proceedings of the National Academy of Sciences* (PNAS), among others. I have been the recipient of numerous awards including the CARES Foundation's Pioneer Award, The Charles A. and Elizabeth Ann Sanders Chair in Translational Research, and the Burroughs Wellcome Clinical Scientist Award in Translational Research.

10. My opinions are based on my education, research, and medical practice and experience in the field of endocrinology as well as my investigation and study of the relevant materials. A list of the documents that I relied on in

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