

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner

v.

JANSSEN ONCOLOGY, INC.,
Patent Owner

Patent No. 8,822,438
Case No. Unassigned

Declaration of Devalingam Mahalingam, M.D., Ph.D.

TABLE OF CONTENTS

I.	Qualifications	2
II.	Scope of Work.....	3
III.	Legal Standards	7
IV.	Background and the '438 Patent	9
V.	Claim Construction	22
VI.	Claim 1 is Unpatentable as Obvious over O'Donnell in view of Gerber or the '213 patent in view of Gerber	23
VII.	Claims 2-20 are unpatentable as obvious over O'Donnell and/or the '213 patent in view of Gerber.....	27
VIII.	Secondary Considerations Do Not Indicate that the Claims of the '438 Patent Are Non-Obvious	36
IX.	The Prior Art Taught That Prednisone was “Effective for Treating Prostate Cancer” as Construed by the Board	47
X.	Conclusion.....	50

I, Devalingam Mahalingam, M.D., Ph.D., do declare and state as follows.

I. QUALIFICATIONS

1. I am over the age of eighteen (18) and otherwise competent to make this declaration.

2. My name is Devalingam Mahalingam. I am currently an Associate Professor in the Division of Hematology/Oncology, Department of Medicine in the University of Texas Health Science Center, San Antonio, Texas. In 2011, I was appointed co-Leader of the Genitourinary and Gastrointestinal Malignancies Program of the Cancer Therapy and Research Center, San Antonio, Texas, which is a position that I continue to hold to this day. I have been a staff physician at the University Health Care system since 2009 and also a staff physician at St. Luke's Baptist Health System since 2014. I have published at least 50 peer-reviewed journal articles and at least three book chapters in the field of gastrointestinal and genitourinary cancers.

3. In 2009, I earned a Ph.D. in Cancer Research from the Department of Medicine of the National University of Ireland and completed my Higher Specialty in Medical Oncology at the Royal College of Physicians Ireland. I also completed an Oncology Fellowship at the Institute of Drug Development University of Texas Health Science Center in 2009.

4. A summary of my education, experience, publications, awards and honors, patents, publications, and presentations is provided in my CV, a copy of which is submitted separately. Ex. 1074. In view of my professional experience and expertise outlined above and provided in my curriculum vitae, I am considered an expert in the field of gastrointestinal and genitourinary cancers, including prostate cancer.

II. SCOPE OF WORK

5. I have been retained as an expert witness on behalf of Argentum Pharmaceuticals LLC ("Petitioner") for a *inter partes* review ("IPR") of U.S. Patent No. 8,822,438 (hereinafter, "the '438 patent," Ex. 1001). I am being compensated for my time in connection with this IPR at a rate of \$500 per hour. My compensation is not contingent on the conclusions I reach herein or on the specifics of my testimony. I have no financial stake in the outcome of this proceeding.

6. I understand that the '438 patent is currently subject to a previous IPR, *Amerigen Pharmaceuticals, Ltd. v. Janssen Oncology, Inc.*, IPR2016- 00286 (the "Amerigen IPR"). I understand that Petitioner Argentum seeks to become a party to the Amerigen IPR. I have reviewed the materials submitted in the Amerigen IPR, including the Declaration of Dr. Scott R. Serels (Ex. 1002). In formulating my opinion, I considered the following documents:

Exhibit	Description
1001	U.S. Patent No. 8,822,438, Auerbach and Belldegrum, "Methods and Compositions for Treating Cancer" ("the '438 patent")
1002	Declaration of Dr. Scott Serels, MD ("Serels Decl.")
1003	O'Donnell, A. <i>et al.</i> , "Hormonal impact of the 17 α -hydroxylase/C ₁₇ -20-lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer," <i>British Journal of Cancer</i> , (90):2317-2325 (2004) ("O'Donnell")
1004	Gerber, G.S. <i>et al.</i> , "Prostate specific antigen for assessing response to ketoconazole and prednisone in patients with hormone refractory metastatic cancer," <i>The Journal of Urology</i> , 144(5):1177-9 (1990) ("Gerber")
1005	U.S. Patent No. 5,604,213, Barrie S.E. <i>et al.</i> , "17-Substituted Steroids Useful In Cancer Treatment" ("the '213 patent")
1006	Tannock <i>et al.</i> , "Chemotherapy with mitoxantrone plus prednisone or prednisone alone for symptomatic hormone-resistant prostate cancer: a Canadian randomized trial with palliative end points," <i>The Journal of Clinical Oncology</i> , 14:1756-1764 (1996) ("Tannock")
1007	February 3, 2012 Office Action (excerpt from prosecution history of '438 patent)
1008	July 3, 2012 Response (excerpt from prosecution history of '438 patent)
1009	Ryan <i>et al.</i> , "Abiraterone in metastatic prostate cancer without previous chemotherapy," <i>The New England Journal of Medicine</i> , 368:138-148 (2012).
1010	January 11, 2013 Response (excerpt from prosecution history of '438 patent)
1011	March 4, 2013 Office Action (excerpt from prosecution history of '438 patent)

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