

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 GERALD WALTER CHODAK, MD
IN SUPPORT OF JANSSEN ONCOLOGY, INC.'S
PATENT OWNER RESPONSE**

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

I, Gerald W. Chodak, M.D., hereby declare as follows:

I. INTRODUCTION

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. (“Amerigen”) 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 \$325 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.

II. QUALIFICATIONS AND EXPERIENCE

3. I am a Board Certified physician in Urology and have been in clinical practice since 1982 . I received my M.D. degree from the State University of New York at Buffalo in 1975 and completed my training in Urology at the University of Chicago in 1981. I received my Bachelor’s degree in Chemistry from the

University of Rochester in 1969, and my Master's degree in Chemistry from the State University of New York at Buffalo in 1971. My *curriculum vitae* can be found at Exhibit 2043.

4. From 1982-1999, I was a full time faculty member in the Department of Surgery/Urology at the University of Chicago, reaching the rank of Professor in 1989. In 1999, I formed the Midwest Prostate and Urology Health Center in Chicago, and remained its director until 2008 when I closed my clinical practice. Currently, I conduct online consultations for patients with prostate cancer.

5. I am credited with performing the first laparoscopic lymph node operation for prostate cancer in Japan, Sweden, Finland and Norway and also the first continent urinary diversion for bladder cancer in Illinois. In addition, I was part of the team that performed the first laparoscopic retroperitoneal lymph node dissection ("RPLND") for testes cancer and bilateral nephrectomy.

6. I am a named author on over 161 original peer-reviewed medical articles, over 40 published abstracts, and 24 book chapters, mostly on prostate cancer. I have been invited to speak in over 120 engagements, throughout the United States and in more than 14 countries to both physicians and the public.

7. I have received numerous awards over the course of my career and served on numerous professional committees. I have also served as an expert

speaker for a number of pharmaceutical companies, including Johnson and Johnson, and have served on numerous pharmaceutical advisory boards.

8. My primary area of research over the last 33 years has been in the field of prostate cancer. I have been a principal or co-investigator on numerous prostate cancer clinical trials sponsored by the NIH, the American Cancer Society, and pharmaceutical companies.

9. My opinions are based on my education, research, and medical practice and experience in the field of oncology, including my specific experience studying and treating prostate cancer, as well as my investigation and study of the relevant materials. A list of the documents that I relied on in connection with the development of my opinions set forth in this declaration is attached as Appendix A.

III. GERBER (1990)

A. BACKGROUND

10. I am a co-author of Gerber, G.S. *et al.*, “Prostate Specific Antigen for Assessing Response to Ketoconazole and Prednisone in Patients with Hormone Refractory Metastatic Prostate Cancer,” *J. of Urology*, 144(5):1177-9 (1990) (“Gerber”). My co-author, Dr. Glenn S. Gerber, was then a resident at the University of Chicago, working under my supervision. It is my understanding that a copy of Gerber (1990) has been previously submitted in this proceeding as Amerigen Ex. 1004 (“Ex. 1004”).

11. I understand that Petitioners’ expert, Dr. Scott Serels, has stated in his declaration that “[k]etoconazole ... was commonly used off-label in combination with prednisone to treat metastatic refractory prostate cancer.” (Ex. 1002 at ¶23). I also understand that Dr. Serels has stated that “[k]etoconazole ... was known to be effective as a second-line treatment for metastatic hormone-refractory prostate cancer.” (*Id.* at ¶ 33). In addition, I understand that Dr. Serels has stated that “Gerber teaches that the combination of ketoconazole and prednisone is safe and effective in treating human patients with hormone-refractory advanced prostate cancer.” (*Id.* at ¶ 48). I disagree with all three of his statements.

12. Gerber is a retrospective chart review of clinical observations, including prostate-specific antigen (“PSA”) levels, in 15 men with metastatic

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