



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE PATENT TRIAL AND APPEAL BOARD  
In the *Inter Partes Review (IPR)* of  
U.S. Patent Nos. 8,822,438**

**DECLARATION OF DR. SCOTT R. SERELS, M.D.**

I, Scott R. Serels, M.D., do hereby declare:

1. I am making this declaration at the request of Amerigen Pharmaceuticals, Ltd., in the matter of the *Inter Partes Review (IPR)* of U.S. Patent No. 8,822,438 (the “438 Patent”), as set forth in the above caption.

2. I am being compensated for my work in this matter at the rate of \$500.00 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 practicing urologist and researcher, as well as the materials I have reviewed in connection with this case.

**A. Education and Professional Background**

3. I currently practice medicine at the Bladder Control Center of Norwalk, where I am the director of daily operations involving urodynamics, female urology and neurourology. I was board certified in urology in 2001, and American Board of Urology recertified in 2009. I became board certified in female pelvic medicine and reconstructive surgery in 2013.

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4. I received my bachelor of arts degrees in biology and economics *magna cum laude* from Brandeis University in 1988. I received my medical degree from New York University School of Medicine in 1992. I then completed two years of surgical residency, and four years of urologic residency at the Albert Einstein College of Medicine and Montefiore Medical Center. During my urologic residency, I completed rotations in urologic oncology and female urology at Memorial Sloan Kettering and UCLA, respectively. I then went to the Cleveland Clinic Foundation to serve as a clinical associate specializing in female urology, urodynamics and neurourology.

5. I am Associate Professor of Urology at the University of Vermont School of Medicine and a clinical faculty member at the Frank H. Netter School of Medicine at Quinnipiac University, where I also serve as a member of the faculty counsel. I am also the Urogynecology Section Head at Norwalk Hospital in Norwalk, Connecticut. I have authored approximately 100 peer reviewed publications, presentations and abstracts in the fields of urology and urogynecology.

6. Attached as Exhibit 1 is my curriculum vitae providing the details of my education, experience and training in medicine, including in the field of urology.

**B. Materials Considered**

7. The list of materials I considered in forming the opinions set forth in this declaration includes the following:

Exhibit	Description
AMG 1001	U.S. Patent No. 8,822,438 to Auerbach and Beldegrum, "Methods and Compositions for Treating Cancer" ("the '438 patent")
AMG 1003	O'Donnell, A. <i>et al.</i> , "Hormonal impact of the 17 $\alpha$ -hydroxylase/C <sub>17</sub> -20-lyase inhibitor abiraterone acetate (CB7630) in patients with prostate cancer," <i>British Journal of Cancer</i> , (90):2317-2325 (2004) ("O'Donnell")
AMG 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")
AMG 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")
AMG 1006	Tannock, I. <i>et al.</i> , "Chemotherapy with Mitoxantrone Plus Prednisone or Prednisone Alone for Symptomatic Hormone-Resistant Prostate Cancer," <i>Journal of Clin. Oncology</i> , 14(6):1756-1764 (1996)
AMG 1009	Ryan, C.J., <i>et al.</i> , "Abiraterone in Metastatic Prostate Cancer without Previous Chemotherapy," <i>New Engl. J. Med.</i> , 368: 138-148 (2012)
AMG 1011	March 4, 2013 Response (excerpt from prosecution history of '438 patent)



AMG 1012	June 4, 2013 Response (excerpt from prosecution history of '438 patent)
AMG 1018	Zytiga® Prescribing Information (2011)
AMG 1019	Zytiga® Prescribing Information and Co-administration Brochure (2015)
AMG 1020	Harris, K.A. <i>et al.</i> , "Low dose ketoconazole with replacement doses of hydrocortisone in patients with progressive androgen independent prostate cancer," <i>J. Urol.</i> , 168(2):542-5 (2002)
AMG 1021	William Oh, "Secondary hormonal therapies in the treatment of prostate cancer," <i>Urology</i> , volume 60:87-93 (Supplement 3A) (2002)
AMG 1022	Tannock, I. <i>et al.</i> , "Docetaxel plus Prednisone or Mitoxantrone plus Prednisone for Advanced Prostate Cancer," <i>N. Eng. J. Med.</i> , 351:1502-12 (2004)
AMG 1023	Attard, G. <i>et al.</i> , "Selective blockade of androgenic steroid synthesis by novel lyase inhibitors as a therapeutic strategy for treating metastatic prostate cancer," <i>Br. J. Urol.</i> 96(9): 1241-1246 (2005)
AMG 1024	Hellerstedt <i>et al.</i> , "The Current State of Hormonal Therapy for Prostate Cancer," <i>CA Cancer J. Clin.</i> , 52:154-179 (2002)
AMG 1025	Kasper, D.L. <i>et al.</i> (Eds.), <i>Harrison's Principles of Internal Medicine</i> , 16 <sup>th</sup> Edition (2005), p. 549
AMG 1026	Auchus, R.J. "The genetics, pathophysiology, and management of human deficiencies of P450c17," <i>Endocrinol. Metab. Clin. North Am.</i> (30)1:101-119 (2001)

AMG 1027	Costa-Santos, M. <i>et al.</i> , "Two Prevalent CYP17 Mutations and Genotype-Phenotype Correlations in 24 Brazilian Patients with 17-Hydroxylase Deficiency," <i>J. Clin. Endocrin. &amp; Metabol.</i> (89)1:49-60 (2004)
AMG 1028	Jubelirer, S.J., <i>et al.</i> , "High dose ketoconazole for the treatment of hormone refractory metastatic prostate carcinoma," <i>J. Urol.</i> , 142(1):89-901 (1989)
AMG 1029	U.S. Patent 5,688,977, Sisti, N.J. <i>et al.</i> , "Method for Docetaxel Synthesis"
AMG 1030	U.S. Food and Drug Administration ("FDA") FDA News Release dated May 19, 2004, "FDA Approves New Indication for Taxotere-Prostate Cancer"
AMG 1031	Tannock, I. <i>et al.</i> , "Treatment of metastatic prostatic cancer with low-dose prednisone: evaluation of pain and quality of life as pragmatic indices of response," <i>Journal of Clin. Oncology</i> , 7:590-7 (1989)
AMG 1032	Taxotere® Prescribing Information (2004)
AMG 1033	Scher, H.I. <i>et al.</i> , "Increased survival with Enzalutamide in Prostate Cancer after Chemotherapy," <i>New Eng. J. Med.</i> , 367:1187-97 (2012)
AMG 1034	de Bono, J.S. <i>et al.</i> , "Abiraterone and Increased Survival in Metastatic Prostate Cancer," <i>New Engl. J. Med.</i> , 364:1995-2005 (2011)
AMG 1035	Orange Book listing for Zytiga®

### C. Legal Standards

8. In my opinion, given the disclosure of the '438 Patent, I consider a

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