

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.
Petitioner,

v.

ICOS CORP.
Patent Owner.

Patent No. 6,943,166

DECLARATION OF MUTA M. ISSA, M.D., M.B.A

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I, Muta M. Issa, declare as follows:

I. QUALIFICATIONS

1. My name is Muta M. Issa. I am currently a tenured Professor of Urology in the School of Medicine at Emory University. I am also Chief of Urology at the Atlanta Veterans Affairs Medical Center and a Senior Faculty Member at the Emory Clinic and Emory University Hospital. Before I joined Emory as an Assistant Professor in 1997, I was an Assistant Professor of Urology at Stanford University School of Medicine.

2. I received an M.D. *Magna Cum Laude* from the Royal College of Surgeons in Ireland in 1983. I completed an internship in Medicine (1983-1984), instructorship in Physiology (1984-1985) and surgical training (1985-1987), which included general surgery, accident and emergency medicine and cardiothoracic surgery at the Royal College of Surgeons in Ireland. I received my urological training from Johns Hopkins University Hospital (1987-1988) and Stanford University Medical Center (1988-1993).

3. During my career I have served on numerous committees and panels, including President of the Atlanta Urological Association, Member of a Special Task Force commission by the National Pharmacy Benefit Management and Strategic Healthcare, Department of Veterans Affairs the VA Policy Guidelines on

Erectile Dysfunction “The Primary Care Management of Erectile Dysfunction” (USA Publication), Consultant (ad hoc) to Agency of Healthcare Research and Quality (AHRQ), US Health & Human Services, President Elect of the Urological Society for American Veterans, as a member of the Advisory/Steering Committee and Chair of the Organizing Committee of the VA Forum of the American Urological Association, and a member of the Scientific Committee of the International Scientific Committee of Radionuclides in Nephro-urology. Among other things, I have served on the editorial boards of the journals *The Scientific World Journal of Urology* and *Urologists in Cancer Care*. I have also served as a manuscript reviewer for many journals, including *The Journal of Urology*, *Investigative Urology*, *Urology*, *Journal of Endourology*, *British Journal of Urology International*, *European Urology*, *Prostate Cancer and Prostatic Diseases*, and *International Journal of Urology*.

4. I am an inventor on ten issued U.S. Patents describing a resectoscope electrode assembly, the treatment of urinary strictures, a method and instrument for effecting anastomosis, as well as a catheter assembly and anchors for anastomosis. I have authored or co-authored more than 100 peer-reviewed journal articles pertaining to the field of urology. I have taught undergraduate, graduate and medical school courses in urology including topics on the development and uses of therapeutic agents for urological applications.

5. I have 24-years of experience as an academic urologist in the field of academic urology that includes such areas as research design, methodology, data analysis, reporting and publishing. In parallel, I have experience as a practicing urologist in the field of clinical urology that includes areas such as male sexual and erectile dysfunction, diagnostic ultrasonography, potency preserving surgical procedures and reconstructive genito-urinary surgery.

6. A summary of my experience, education, publications and other qualifications is provided in my CV, a copy of which is submitted separately. EX1005.

II. SCOPE OF WORK

7. I am informed that a petition is being filed with the United States Patent and Trademark Office for *Inter Partes Review* of U.S. Patent No. 6,943,166 (“the ’166 patent,” EX1001). I have been retained as a technical expert to provide analysis and opinions regarding the ’166 patent. I have reviewed the ’166 patent and portions of its prosecution history at the U.S. Patent Office. EX1006. I have also considered other documents cited in this declaration, which are listed in the Appendix in Section XIII.

8. I am being compensated at the rate of \$600/hour for my time. I have no financial interest in the outcome of this matter.

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