

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.
Petitioner,

v.

ICOS CORPORATION
Patent Owner.

U.S. Patent No. 6,943,166

DECLARATION OF ANTHONY SLIWINSKI, M.D.

DBL EXHIBIT 1004

TABLE OF CONTENTS

	<u>Page</u>
I. QUALIFICATIONS.....	1
II. SCOPE OF WORK	2
III. OVERVIEW OF THE '166 PATENT.....	2
IV. BRIEF SUMMARY OF THE FILE HISTORY OF THE '166 PATENT.....	5
V. LEGAL STANDARDS.....	5
VI. LEVEL OF ORDINARY SKILL AND RELEVANT TIME	8
VII. CLAIM CONSTRUCTION	9
VIII. THE STATE OF THE ART	10
IX. THE ASSERTED REFERENCES DISCLOSE OR SUGGEST EACH OF THE CLAIMED FEATURES OF THE '166 PATENT	14
A. Brief Overview of the Asserted References	14
1. The '675 PCT.....	14
2. Sildenafil NDA.	15
3. FDA Guideline.....	15
B. Detailed Analysis of the Claims.....	16
1. The Teachings of the '675 PCT in view of Sildenafil NDA and FDA Guideline Make the Therapeutic Indications of Claims 1-3 Obvious.	16
X. THERE WAS NO LONG-FELT NEED FOR THE CLAIMED DOSING REGIMEN.....	21
XI. CONCLUDING STATEMENTS	23
XII. APPENDIX – LIST OF EXHIBITS.....	24

I, Anthony Sliwinski, declare as follows:

I. QUALIFICATIONS

1. My name is Anthony Sliwinski. I am a Board certified urologist with over 30 years of experience. I am currently the co-director of Men's Wellness at Virginia Urology, where I have been practicing since 1994. Before I joined Virginia Urology Center, I was employed at the McGuire Clinic from 1991 to 1994.

2. I received an M.D. from Georgetown University School of Medicine in Washington D.C. in 1986. I completed an Internship in Surgery (1986-1987), and was Junior Assistant Resident in Surgery (1987-1988) at the Medical College of Virginia in Richmond, Virginia. I also received my urological training from the Medical College of Virginia as Assistant Resident in Urology (1988-1989), Senior Assistant Resident in Urology (1989-1990), and Chief Resident in Urology (1990-1991).

3. During my career I have given numerous presentations in the field of urology, which include multiple presentations regarding sexual/erectile dysfunction.

4. I have extensive experience as a principal investigator involving research in the urological field, which include multiple studies concerning sexual/erectile dysfunction.

5. I have over 26-years of experience as a practicing urologist, which

includes treating over 4000 patients with sexual/erectile dysfunction, and prescribing both Viagra[®] and Cialis[®]. In addition, I have broad knowledge concerning the development in the treatment of sexual/erectile dysfunction and pharmaceutical products, as I have stayed current with publications concerning the same, and have incorporated such knowledge into my practice.

6. A summary of my experience, education, 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 \$500/hour for my time. I have no financial interest in the outcome of this matter.

III. OVERVIEW OF THE ’166 PATENT

9. The ’166 patent, entitled “Compositions Comprising Phosphodiesterase Inh[i]bitors for the Treatment of Sexual D[y]sfunction” issued on September 13,

2005. I understand that the earliest claimed priority date of the '166 patent is April 30, 1999.

10. The '166 patent discusses treatment of sexual dysfunction, including male erectile dysfunction and female arousal disorder. Specifically, the '166 patent discusses such treatment by administration of (6*R*,12*aR*)-2,3,6,7,12,12*a*-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl)pyrazino[2',1':6,1]-pyrido[3,4-*b*]indole-1,4-dione, which I understand is the chemical name for "tadalafil." EX1001, 2:58-63; *see also, e.g.*, EX1001, abstract. I am familiar with tadalafil, which can be sold under the trade name Cialis[®], through my clinical practice.

11. Tadalafil belongs to a class of compounds called PDE5 inhibitors.

The '166 patent provides a description of the role of PDE5 inhibitors in the body:

The biochemical, physiological, and clinical effects of cyclic guanosine 3',5'-monophosphate specific phosphodiesterase (cGMP-specific PDE) inhibitors suggest their utility in a variety of disease states in which modulation of smooth muscle, renal, hemostatic, inflammatory, and/or endocrine function is desired. Type 5 cGMP-specific phosphodiesterase (PDE5) is the major cGMP hydrolyzing enzyme in vascular smooth muscle, and its expression in penile corpus cavernosum has been reported. Thus, PDE5 is an attractive target in the treatment of sexual dysfunction.

Id. at 1:29-40 (citations omitted).

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