UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.
Petitioner,

v.

ICOS CORP.
Patent Owner.

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

DECLARATION OF FATEMEH AKHLAGHI, PHARM.D., PH.D.

DRL - EXHIBIT 1002

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I, Fatemeh Akhlaghi, declare as follows:

I. QUALIFICATIONS

1. My name is Fatemeh Akhlaghi. I am a Professor of Pharmacokinetics and Ernest Mario Distinguished Chair of Pharmaceutics in the College of Pharmacy, University of Rhode Island. I have over 18 years of experience in clinical pharmacology research and an extensive history of collaboration with academia and the pharmaceutical industry.

2. I received a Pharm. D. from the University of Mashhad, Iran, in 1990, and a Ph.D. in Pharmaceutical Sciences from the University of Sydney, Australia, in 1997.

3. My primary areas of technical expertise are drug development, drug delivery, and pharmacokinetics, including computational simulations and modeling of pharmacokinetic processes. I completed a post-doctoral fellowship at the University of Sydney in 1998 and another post-doctoral fellowship at the University of Cambridge, United Kingdom, in 2001 before joining the University of Rhode Island.

4. I joined the University of Rhode Island as a tenure track Assistant Professor in 2001. In 2006 I became an Associate Professor with tenure and in July 2011 was promoted to Full Professor. In July 2010, I also joined the faculty of Brown University Medical School as an Adjunct Associate Professor, and in

2014, I was promoted to Adjunct Professor.

5. My research interests include the general area of pharmaceutical sciences with a focus on pharmacokinetic/pharmacodynamics modeling, clinical pharmacology, translational sciences, drug metabolism, and pharmacogenomics. I have authored more than 70 full-length peer-reviewed articles and 100 abstracts in these areas. In addition, I have given more than 30 invited presentations and have consulted with multiple pharmaceutical companies involving clinical research, design of pharmacokinetic studies and pharmacokinetic/pharmacodynamics modeling.

6. A summary of my experience, education, publications and other qualifications is provided in my CV, a copy of which is submitted separately. EX1003.

II. SCOPE OF WORK

7. I understand 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 by Dr. Reddy's Laboratories, Inc. as a technical expert to provide analysis and opinions regarding the '166 patent. I have reviewed the '166 patent and sections of its prosecution history in the United States Patent and Trademark Office. EX1006. I have also reviewed and considered various other documents in arriving at my opinions, and I cite

them in this declaration. For convenience, documents cited in this declaration are listed in the Appendix in Section XIII.

8. I am compensated at the rate of $400/hour for my work. I have no financial interest in the outcome of this matter.

III. OVERVIEW OF THE '166 PATENT

9. The '166 patent issued on September 13, 2005. The '166 patent is titled "Compositions Comprising Phosphodiesterase Inhibitors for the Treatment of Sexual Dysfunction." The first page of the patent states that an application for the '166 patent (U.S. Application No. 10/031,556), was filed as a national stage entry application of PCT/US00/11129 and claims priority to provisional U.S. Application No. 60/132,036, filed on April 30, 1999.

10. The '166 patent is generally directed to the treatment of sexual dysfunction, including male erectile dysfunction and female arousal disorder using the compound (6*R*,12a*R*)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylenedioxyphenyl) pyrazino[2',1':6,1]pyrido[3,4-b]indole-1,4-dione, referred to herein for convenience as "tadalafil," and also referred to in the '166 patent as Compound I. EX1001, 2:58-63. Tadalafil is marketed under the trademark Cialis®. Cialis® Approved Label ("Cialis® Label," EX1010).The '166 patent states:

> 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

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