

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTELGENX CORP.
Petitioner

v.

ICOS CORP.
Patent Owner

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

Inter Partes Review Case No. Unassigned

DECLARATION OF DOUGLAS REID PATTERSON, D.V.M, PH.D

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Inter Partes Review of USPN 6,943,166
Declaration of Douglas Reid Patterson, D.V.M., Ph.D. (INX1007)

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I, Douglas Reid Patterson, DVM, Ph.D, hereby declare as follows.

I. Introduction

1. I am over the age of eighteen and otherwise competent to make this declaration.

2. I have been retained as an expert witness on behalf of INTELGENX CORP. ("INTELGENX") for the above-captioned *inter partes* review (IPR). I am being compensated for my time in connection with this IPR at my standard consulting rate, which is \$350 per hour.

3. I understand that the petition for *inter partes* review involves U.S. Patent No. 6,943,166 ("the '166 patent"), INX1001, which resulted from U.S. Patent Application No. 10/031,556 ("the '556 application"), which is a national stage entry application of PCT Application Publication No. WO 00/66099 ("the '099 PCT application"), filed April 26, 2000. I also understand that the '166 patent's earliest possible priority date is April 30, 1999, the filing date of U.S. Provisional Patent Application No. 60/132,036. The '166 patent names William Ernest Pullman and John Steven Whitaker as the inventors. The '166 patent issued on September 13, 2005, from the '556 application. I understand that, according to the United States Patent and Trademark Office ("USPTO") records, the '166 patent is currently assigned to ICOS Corp. I also understand that ICOS Corp. is owned by Eli Lilly & Co. The patentee is referred to herein as "ICOS."

4. The '166 patent is directed generally to the field of phosphodiesterase (PDE) inhibitors, and more specifically to methods of using cyclic guanosine 3',5'-monophosphate specific phosphodiesterase type 5 (PDE-5) inhibitors for treating sexual dysfunction. INX1001, Abstract. The methods of the '166 patent utilize a unit dose containing from about 1 to about 20 mg of (6R,12aR)-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 ("tadalafil"). INX1001, 2:58-63, 14:65 to 15:17.

5. In preparing this Declaration, I have reviewed the '166 patent and each of the documents cited herein, in light of general knowledge in the art. In formulating my opinions, I have relied upon my experience, education, and knowledge in the relevant art. In formulating my opinions, I have also considered the viewpoint of a person of ordinary skill in the art ("POSA") (*i.e.*, a person of ordinary skill in the field of chemistry, pharmacology, or in a related field in the biological or chemical sciences defined further below in Section V) before April 30, 1999.

II. My background and qualifications

6. I am an expert in the fields of clinical pharmacology, preclinical drug development, and toxicology, and I have been an expert in these fields since before April 30, 1999. I am currently the President of Reid Patterson Consulting,

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