Paper No. 2
Filed: July 10, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

DR. REDDY'S LABORATORIES, INC.
Petitioner,

v.

ICOS CORPORATION
Patent Owner.

Case No. IPR2017-01757
U.S. Patent No. 6,943,166

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,943,166

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I. INTRODUCTION

Pursuant to the provisions of 35 U.S.C. § 311 and § 6 of the Leahy-Smith America Invents Act ("AIA"), and to 37 C.F.R. Part 42, Dr. Reddy's Laboratories, Inc., ("Petitioner") hereby requests *inter partes* review of United States Patent No. 6,943,166 to Pullman ("the '166 patent," EX1001), which issued on September 13, 2005, and is currently assigned to ICOS Corp., which is owned by Eli Lilly and Co. (collectively "Patent Owner").

The '166 patent is directed to a dosing regimen for treating sexual dysfunction using a prior art compound now known as tadalafil, a phosphodiesterase type 5 (PDE5) inhibitor with previously reported and previously claimed utility for treating sexual dysfunction. The dosing regimen claimed in the '166 is the administration of about 1 to about 20 mg of tadalafil, where the total maximum daily dose is no larger than 20 mg. The art taught not only the compound tadalafil itself, but that (i) orally administered tadalafil was useful in treating sexual dysfunction at daily dosages as low as 0.5 mg (EX1007); and (ii) tadalafil was nearly twice as potent as sildenafil citrate (Viagra®), another inhibitor of the same PDE5 enzyme that gained FDA approval in March 1998. EX1008.

Sildenafil (25 mg, 50 mg, and 100mg) was approved, as a once-daily treatment for male erectile dysfunction, and it was known to produce only minor adverse events at the approved once-daily doses of 25 and 50 mg. As tadalafil was

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nearly twice as potent as sildenafil for the same PDE5 enzyme, the person of ordinary skill in the art would have been motivated to adjust the dosing of tadalafil proportionately based on known data regarding the approved doses of sildenafil.

Dose response analyses of sildenafil for treatment of sexual dysfunction were documented in the prior art. *See, e.g.*, EX1008 at 0070. Skilled artisans routinely produced these dose-response curves to inform dosage decisions and, following FDA Guidelines (*e.g.*, EX1009), routinely selected doses below a dose-response plateau as a preferred daily dosage. In accordance with this, and as discussed in detail below, a 25 mg daily dose of sildenafil falls near the top of the dose-response curve but below its plateau. EX1008 at 0070. In other words, the dose response curve generated for sildenafil identified that daily dose as within the optimal dose range with respect to efficacy and adverse events.

As explained by Dr. Fatemeh Akhlaghi, a professor and pharmacokineticist with over 18 years of experience in clinical pharmacology research and an extensive history of collaboration with academia and the pharmaceutical industry, to determine an appropriate daily dose of tadalafil a person of ordinary skill would have compared the potency data for tadalafil and sildenafil (consisting of IC_{50} values for the PDE5 enzyme) that were reported in the prior art. Based on this comparison (3.5 nM to 2.0 nM), tadalafil would have been expected to be nearly twice as potent as sildenafil, and the dose response for tadalafil would have been

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