UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner,

v.

ICOS CORPORATION,
Patent Owner.

Case No. IPR2017-01762
Patent No. 6,943,166 B1

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, Argentum Pharmaceuticals LLC, ("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"). *Inter partes* review of Claims 1-12 of the '166 patent was instituted in IPR2017-00323 on June 12, 2017, based on a petition filed by Mylan Pharmaceuticals Inc. ("Mylan IPR"). Argentum hereby files its own Petition on the same ground instituted in the Mylan IPR and concurrently seeks to join the instituted Mylan IPR. A motion for joinder with IPR2017-00323 is being filed concurrently with this Petition. This petition is accompanied by declarations from Dr. Culley C. Carson III, M.D. (Ex. 1037) and Dr. Jackie Corbin, Ph.D. (Ex. 1038) indicating that they have reviewed the declarations of Dr. George Grass, Pharm.D., Ph.D. and Dr. Muta M. Issa, M.D., M.B.A., which are Exs. 1002, 1004 in IPR2017-00323 and in this IPR. Additionally, Drs. Carson and Corbin indicated in their declarations that they agree with the opinions and reasoning in the declarations of Drs. Grass and Issa and have adopted the same opinions and reasoning.

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 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,

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