UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MONOSOL RX, LLC
Petitioner

v.

ICOS CORPORATION,
Patent Owner

Case: IPR2017-00412
Patent 6,943,166

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

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Pursuant to 35 U.S.C. § 311, MonoSol Rx, LLC ("Petitioner") respectfully petitions for Inter Partes Review, seeking cancellation of claims 1-12 of U.S. Patent No. **6,943,166** (the '166 Patent). According to USPTO records, the '166 patent is assigned to ICOS CORP c/o Eli Lilly and Co. ("Patent Owner"). A copy of the '166 Patent is attached as Exh. 1001. As demonstrated by the grounds presented below, the alleged invention of the challenged claims are obvious and should be canceled under 35 U.S.C. § 103.

I. PAYMENT OF FEES

Pursuant to 37 C.F.R. section 42.103, $23,000 is being paid at the time of filing this petition, charged to Deposit Account 19-4293. Should any further fees be required by the present Petition, the Patent Trial and Appeal Board ("PTAB") is hereby authorized to charge the above referenced Deposit Account.

II. REQUEST FOR *INTER PARTES* REVIEW OF CLAIMS 1-12 OF THE '166 PATENT

Pursuant to 37 C.F.R. §42.104(b), Petitioner requests that the PTAB find unpatentable Claims 1-12 of the '166 patent. Such relief is justified as the alleged invention of the '166 patent was described by others prior to the filing date of the '166 patent and obvious to one of skill in the art.

Petitioner is aware that the '166 patent was previously challenged by IntelGenx Corp. in a request for Inter Partes Review, and that this Petition was

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denied institution on September 1, 2016. IPR2016-00678, Paper 13. That Petition raised two grounds of unpatentability: (1) Daugan and (2) Daugan and SNDA (the Viagra® Approval Package). However, in that case, the PTAB found that the Petitioner "ignored the maximum-total dose requirement" in failing to "point to the asserted prior art or otherwise explain why an ordinary artisan would limit the tadalafil dose to 20 mg per day." *Id*. at 7. The PTAB therefore concluded that the Petitioner had "not established a reasonable likelihood it would prevail in showing that claim 1 would have been obvious over Daugan, either alone or in combination with SNDA." *Id*.

A. The Alleged Invention of the '166 Patent

The '166 patent relates generally to a method of treating sexual dysfunction by orally administering tadalafil in a specific dose range that is encompassed by the prior art. The '166 patent acknowledges that tadalafil was already known to be administered in doses of 0.2-400 mg without apparent "significant side effects" Ex. 1001, col. 2, lines 12-21. The '166 patent therefore sought to claim a method of administering a specific dose of tadalafil, namely "about 1 to about 20 mg, up to a maximum total dose of 20 mg per day." *Id*. at claim 1.

During prosecution, there was no dispute that the prior art taught methods of treating sexual dysfunction by orally administering to a patient in need thereof one or more unit dose of tadalafil, in 0.2 to 400 mg, once or several times per day and

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