UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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**MONOSOL RX, LLC**
Petitioner

v.

**ICOS CORPORATION,**
Patent Owner

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**Case: IPR2017-00412**
**Patent 6,943,166 B1**

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# PETITIONER MONOSOL RX, LLC'S REQUEST FOR REHEARING
***37 C.F.R.* § *42.71***

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## INTRODUCTION

MonoSol Rx, LLC ("Petitioner"), by this motion under 37 C.F.R. § 42.71(d), respectfully requests rehearing of the Board's *Decision Denying Institution of Inter Partes Review 37 C.F.R. § 42.108* (Paper No. 11, Entered July 3, 2017) (hereinafter "Decision"). Claims 1-12 of the patent at issue, U.S. Patent No. 6,943,166 ("the '166 patent"), relate to methods of administering a known compound, tadalafil, in a dose range that was taught in the prior art. Claim 1, the only independent claim, includes the dose limitations of "about 1 to about 20 mg, up to a maximum total dose of 20 mg per day."

In denying institution of the IPR, the Board stated that even though in the pharmaceutical field an ordinary artisan would strive to optimize a drug dose to minimize adverse side effects while maintaining efficacy, "a claimed invention is not shown to be unpatentable where 'the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.'" Decision, p. 9 (internal citations omitted). However, as explained below, the Decision not to institute this IPR should be modified because: (I) the Board overlooked the Expert Declaration of Dr. Roger Williams (Ex. 1010), which provides clear guidance as to the form of the claimed invention and how a person of ordinary skill would achieve the claimed dose; (II) the Board's factual findings with respect to the FDA petition and admitted prior art were not supported by substantial evidence; and (III)

institution would be consistent with the Board's prior decision in IPR2017-00323, which relied on the same evidence that Dr. Williams analyzed and that Petitioner had submitted in this Request. For these reasons, as explained below, Petitioner asks that the Board revisit its decision not to institute trial.

## STANDARD OF REVIEW

Requests for rehearing are governed by 37 C.F.R. § 42.71(d), which provides in pertinent part:

> A party dissatisfied with a decision may file a single request for re-hearing without prior authorization from the Board. The burden of showing a decision should be modified lies with the party challenging the decision. The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, or a reply.

*Id.* When rehearing a decision on petition, a panel reviews the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion occurs when the Board has misapprehended or overlooked a significant fact. *See Merial Ltd. v. Virbac*, IPR2014-01279, Paper 18 at 8 (P.T.A.B. Apr. 15, 2015) ("[W]hen we recognize that we have misapprehended or overlooked a significant fact, the necessary abuse of discretion required by Rule 42.71(c) has been established.") A request for rehearing is granted when a Petitioner demonstrates a reasonable likelihood of prevailing on its challenge. *See Blue Coat Systems, Inc. v. Finjan Inc.*, IPR2016-01444, Paper 11 (P.T.A.B. July 18, 2017) (granting request for

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