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 B1

PETITIONER MONOSOL RX, LLC'S REPLY TO PATENT OWNER'S OPPOSITION TO REQUEST FOR REHEARING

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

Petitioner's Request for Rehearing ("Request") was premised on a proper factual and legal basis. Thus, Patent Owner's Opposition to the Request fails.

Petitioner ***did*** identify where its arguments were previously raised in the Petition. See, e.g., Req. at 5, 8, 12 (citing Pet. 33-34, 44, and 22-24); Ex. 1010.[1]

The Opposition mistakenly argues that the Williams Declaration[2] was addressed by the Board. This is wrong. The only cite to this declaration (see Opp. 1, citing Dec., p. 4, 8) refers to *Petitioner's* arguments – not the Board's Analysis:

- Decision at p. 4: "In support of its patentability challenges, Petitioner relies on the Declaration of Dr. Roger Williams (Ex. 1010)."
- Decision at p. 8. "Pet. 15, 22, 27, 38"

The first cite is a background statement, *before* the Board's Analysis begins. The second cite does not list or cite the Williams Declaration. Indeed, there is no reference to the Declaration anywhere on p. 8 of the Board's Decision.[3]

Patent Owner inaccurately contends that Petitioner's obvious to try position was addressed. But Petitioner submitted that the Board overlooked its obvious to try position ***under currently applicable law***. Req. at 10-11. The case cited by the Board and by Patent Owner, *In re O'Farrell*, referred to the "obvious to try" standard ***in 1988,*** when it was still "improper grounds for a § 103 rejection." 853

---

[1] The Cutler reference was cited in Ex. 1010 and in p. 11 of the Petition.
[2] Patent Owner argues "improper incorporation" by reference (Opp. 3), but cites no legal authority – just its own Preliminary Response ("Paper 9").
[3] The *Velander* and *Daicel* cases are inapposite because the Williams Declaration was not conclusory and may be evaluated with other factual evidence at trial.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

F.2d 894, 902 (Fed. Cir. 1988). Under post-*KSR* law, "obvious to try" is no longer "improper" when there is a "finite number of identified, predictable solutions." *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007). Such is the case here. Ex. 1010, ¶¶ 158-167; Pet. at 22 (finite dose range to optimize). Moreover, the Petition did address "reasonable expectation of success." (e.g., Pet. at 12), contrary to Patent Owner's assertions (Opp. at 2).

Patent Owner suggests that Petitioner's reliance in common sense was insufficient. Opp. at 3. But Petitioner relied on the prior art, a POSA's ability to optimize based on the prior art, market pressure, design need, ***and*** common sense.

Patent Owner argues that Dr. Williams is distinct from a POSA. Opp. at 3 ¶6. But Dr. Williams is a POSA, and ¶175 of Declaration shows what he believed to be public FDA correspondence. Finally, the Patent Owner mistakenly argues that the "admitted prior art" is a ground "never raised." This is not true. Dr. Williams specifically discussed the admitted prior art as acknowledged in '166 patent. Ex. 1010, ¶¶45-51 (known problems of sildenafil including side effects) (referring to Ex. 1001, col. 2, lines 58- 65), and Daugan, which is in cited in Grounds 1-3 (Pet. 6-7), is referred to as "admitted prior art" in Ex. 1010, ¶ 131.

CONCLUSION

Petitioner respectfully requests rehearing and reconsideration of the decision not to institute the IPR and institution of the IPR as requested.

DOCKET ALARM Find authenticated court documents without watermarks at docketalarm.com.

Respectfully Submitted,

Date: August 16, 2017

By: /*Harold H. Fox/*

Harold H. Fox
Reg. No. 41,498

Customer Number: 27890
Steptoe & Johnson LLP
1330 Connecticut Avenue, N.W.
Washington, DC 20036-1795
Telephone: (202) 429-3000
Facsimile: (202) 429-3902

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing PETITIONER MONOSOL RX, LLC'S REPLY TO PATENT OWNER'S OPPOSITION TO REQUEST FOR REHEARING was served on August 16, 2017 by filing this document through the Patent Trial and Appeal Board End to End system as well as by delivering a copy via electronic email to the attorneys of record for the Patent Owner's as follows:

Mark J. Feldstein
mark.feldstein@finnegan.com

Joshua L. Goldberg
joshua.goldberg@finnegan.com

Yieyie Yang
yieyie.yang@finnegan.com

Maureen D. Queler
maureen.queler@finnegan.com

Mark J. Stewart
stewart_mark@lilly.com

Dan L. Wood
wood_dan_l@lilly.com

Gerald P. Keleher
keleher_gerald@lilly.com

Date: August 16, 2017

By: /Harold H. Fox/
Harold H. Fox
Reg. No. 41,498
Counsel for MonoSol Rx, LLC

DOCKET ALARM
Find authenticated court documents without watermarks at docketalarm.com.