Trials@uspto.gov
Tel. 571-272-7822

Paper 18
Entered: March 5, 2018

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

Before SHERIDAN K. SNEDDEN, SUSAN L. C. MITCHELL, and ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

DECISION
Denying Petitioner's Request for Rehearing
37 C.F.R. § 42.71(d)

I. INTRODUCTION

MonoSol Rx, LLC ("Petitioner") filed a Petition for an *inter partes* review of claims 1–12 of U.S. Patent No. 6,943,166 B1 (Ex. 1001, "the '166 patent"). Paper 4 ("Pet."). We denied the Petition. Paper 11 ("Dec."). Petitioner filed a request for rehearing of the Decision. Paper 12 ("Reh'g Req."). With our authorization, ICOS Corporation ("Patent Owner") filed an opposition to the request for rehearing (Paper 14), and Petitioner filed a reply (Paper 15 ("Reply")).

For the following reasons, we deny Petitioner's request.

II. STANDARD OF REVIEW

When rehearing a decision on institution, the Board reviews the decision for an abuse of discretion. 37 C.F.R. § 42.71(c). An abuse of discretion occurs when a "decision was based on an erroneous conclusion of law or clearly erroneous factual findings, or . . . a clear error of judgment." *PPG Indus. Inc. v. Celanese Polymer Specialties Co.*, 840 F.2d 1565, 1567 (Fed. Cir. 1988) (citations omitted). The request must identify, specifically, all matters the party believes the Board misapprehended or overlooked. 37 C.F.R. § 42.71(d).

III. DISCUSSION

Claim 1 of the '166 patent is directed to a method of treating sexual dysfunction comprising "orally administering one or more unit dose containing about 1 to about 20 mg, up to a maximum total dose of 20 mg per day," of tadalafil. In our Decision denying the Petition, we declined to institute *inter partes* review of the challenged claims as obvious over the teachings of Daugan, (1) alone, (2) in combination with the Guideline for Industry, or (3) in combination with the FDA Petition. Dec. 7–11.

In its rehearing request, Petitioner argues that (1) we overlooked the 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;" (2) our "factual findings with respect to the FDA petition and admitted prior art were not supported by substantial evidence;" and (3) "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." Reh'g Req. 1–2. We are not persuaded.

As a preliminary matter, we note the Petition improperly incorporates by reference a large amount of the Williams Declaration. For example, Petitioner argues that "a POSA would only need routine optimization to find that 1 to about 20 mg, up to a maximum total dose of 20 mg per day would be obvious even in view of Daugan '675 alone." Pet. 9. As support, the Petition cites to 26 paragraphs and over 20 pages of the Williams Declaration. *Id.* (citing Ex. 1010, ¶¶ 105, 131–155). Merely a paragraph later, still on page 9 of the Petition, Petitioner contends that "[t]o the extent it was not obvious based on Daugan '675 alone, it would have been obvious to a POSA to optimize the dose range to minimize adverse side effects while maintaining pharmaceutical efficacy, as was typical for the pharmaceutical industry." *Id.* As support, the Petition cites to another over 30 paragraphs of the Williams Declaration. *Id.* (citing Ex. 1010, ¶¶ 158–188). By incorporating nearly 60 paragraphs of the Williams Declaration into one page of the Petition, Petitioner circumvents the page/word number limits. Our Rules do not permit this practice. *See* 37 C.F.R. § 42. 6(3) ("Arguments

must not be incorporated by reference from one document into another document."); § 42.24 (providing page/word number limits for the papers).

Nevertheless, we did not, as Petitioner asserts, overlook the Williams Declaration. After all, Petitioner presents the Williams Declaration to support its arguments, which we addressed. *See* Dec. 8 (discussing the "routine optimization" argument), 9 (discussing the argument regarding optimizing the dose range to minimize adverse side effects while maintaining pharmaceutical efficacy). If we had not considered nearly 60 paragraphs of the Williams Declaration as supporting evidence, we would have dismissed those contentions as unsupported attorney arguments. In other words, not explicitly citing the Williams Declaration at every turn in the Decision does not suggest we overlooked it.[1]

Petitioner, in its rehearing request, also alleges that we overlooked the FDA Petition in view of admitted prior art. Reh'g Req. 10–11. According to Petitioner, we failed to account for the similarities between tadalafil and sildenafil, and tadalafil's higher potency than sildenafil. *Id.* at 10–12. We disagree. In the Decision, we cited, in length, the disclosures of the FDA Petition (Dec. 7), and summarized it as addressing the side effects of

[1] In our Decision, we stated that "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.'" Dec. 9 (citing *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)). Petitioner appears to contend that it is erroneous, or at least improper, that we cited *In re O'Farrell* because that case was from "***1988***, when [obvious to try] was still 'improper grounds for a § 103 rejection.'" *See* Reply 1. We disagree. As discussed in a 2009, a post-*KSR* decision, *In re O'Farrell* clarifies the meaning of obvious to try and differentiates between proper and improper applications of obvious to try. *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (stating *KSR* "actually resurrects [the Federal Circuit]'s own wisdom in *In re O'Farrell*").

sildenafil (*id.* at 9). We addressed Petitioner's argument that "in view of the FDA Petition, an ordinary artisan 'would have known that based on the market pressure to compete with sildenafil, a drug manufacturer would have to market a drug that had the same or *better efficacy*, and in a dose that maintained efficacy but that also minimized adverse effects.'" *Id.* (citing Pet. 25) (emphasis added). We, however, found Petitioner's argument unpersuasive because the FDA Petition only provided "general guidance" to identify a maximum daily dosage of tadalafil. *Id.* Petitioner may disagree with our analysis; that, however, does not mean we overlooked the evidence.

Petitioner is correct that we previously instituted trial in IPR2017-00323. *Mylan Pharmaceuticals Inc. v. ICOS Corp.*, IPR2017-00323 ("Mylan IPR") (PTAB June 12, 2017) (Paper 12). Petitioner is also correct that Dr. Williams analyzed the prior art asserted in Mylan IPR.[2] Reh'g Req. 12–13. Evidence of the record in the two cases, however, is not the same. As we explained in Mylan IPR,

> Petitioner points to SNDA for teaching that sildenafil is therapeutically effective in treating ED at doses as low as 5 mg and as high as 100 mg. *Id.* at 36 (citing Ex. 1008, 126–28). Citing the testimony of Dr. Grass, Petitioner argues that "these doses, adjusted for the increased potency of tadalafil, are expected to be approximately equivalent to tadalafil doses of 2.8 mg and 57 mg, respectively." *Id.* (citing Ex. 1002 ¶ 79); *see also* Ex. 1002 ¶ 77 (calculating the predicted doses of tadalafil based on the doses of sildenafil and the ratio of IC_{50} values).
>
> Petitioner emphasizes the teaching of SNDA that a dose of 25 mg sildenafil "is already fairly high on the dose-response curve." Pet. 37 (citing Ex. 1008, 70). According to Petitioner, 25 mg of

[2] Petitioner in this case, however, challenges claims 1–12 of the '166 based on grounds different from the one asserted in the Mylan IPR. *Compare* Pet. 6–7 *with* Mylan IPR, Paper 2, 27.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.