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

Paper No. 11
Entered: July 3, 2017

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 Institution of *Inter Partes* Review
37 C.F.R. § 42.108

INTRODUCTION

MonoSol Rx, LLC ("Petitioner") filed a Corrected Petition (Paper 4, "Pet.") to institute an *inter partes* review of claims 1–12 of U.S. Patent No. 6,943,166 B1 (Ex. 1001, "the '166 patent"). ICOS Corporation ("Patent Owner") timely filed a Preliminary Response. Paper 9 ("Prelim. Resp.").

Based on this record, we determine Petitioner has not established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. *See* 35 U.S.C. § 314(a). Therefore, we deny institution of an *inter partes* review.

Related Proceedings

According to the parties, Patent Owner asserted the '166 patent against numerous entities, but not Petitioner, in the United States District Court for the Eastern District of Virginia. Pet. 45; Paper 8, 2–4.

We previously denied a petition for *inter partes* review of the same challenged claims filed by IntelGenX Corp. *IntelGenX Corp. v. ICOS Corp.*, IPR2016-00678 (PTAB Sept. 1, 2016) (Paper 13). Thereafter, IntelGenX filed a request for rehearing, and we authorized Patent Owner to file a responsive brief. IPR2016-00678, Papers 14, 15. Before Patent Owner filed any responsive briefing, Petitioner withdrew its request. IPR2016-00678, Paper 16. We, thus, terminated that proceeding. IPR2016-00678, Paper 17.

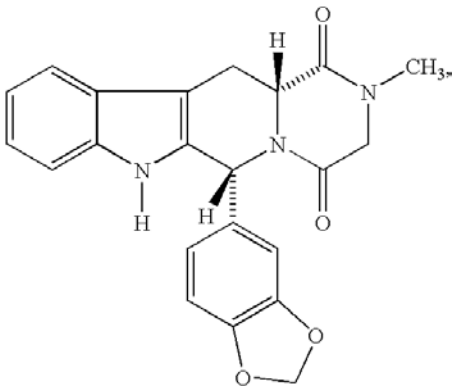
The '166 patent is also the subject of IPR2017-00323, filed by Mylan Pharmaceuticals Inc. We instituted an *inter partes* review in that case. *Mylan Pharmaceuticals Inc. v. ICOS Corp.*, IPR2017-00323 (PTAB June 12, 2017) (Paper 12).

The '166 Patent

The '166 patent relates to a highly selective phosphodiesterase (PDE) enzyme inhibitor, and its use in a pharmaceutical unit dosage form. Ex. 1001, Abstract, 1:14–16.

Type 5 cGMP-specific PDE (PDE5) is an attractive target in the treatment of sexual dysfunction. *Id.* at 1:34–39. Before the '166 patent invention, a pharmaceutical product, which provides a PDE5 inhibitor, was available and marketed for treating male erectile dysfunction ("ED") under the trademark VIAGRA®. *Id.* at 1:41–43. The active ingredient in VIAGRA® is sildenafil. *Id.* at 1:43–44. According to the '166 patent, however, "[w]hile sildenafil has obtained significant commercial success, it has fallen short due to its significant adverse side effects." *Id.* at 1:58–60.

The '166 patent discloses a pharmaceutical unit dosage composition comprising about 1 to about 20 mg of compound tadalafil, which has the following structure:



Id. at 3:11–28. The '166 patent discloses that the pharmaceutical unit dosage is suitable for oral administration, and is useful for treating sexual dysfunction. *Id.* at 3:29–31.

Illustrative Claim

Claim 1 is the sole independent claim challenged in the Petition. It reads:

> 1. A method of treating sexual dysfunction in a patient in need thereof 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 a compound having the structure [of formula (I)].

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds, each of which challenges the patentability of claims 1–12:

Basis	Reference(s)
§ 103	Daugan[1] and the Guideline for Industry[2]
§ 103	Daugan and the FDA Petition[3]
§ 103	Daugan

In support of its patentability challenges, Petitioner relies on the Declaration of Dr. Roger Williams (Ex. 1010).

ANALYSIS

Claim Construction

In an *inter partes* review, the Board interprets a claim term in an unexpired patent according to its broadest reasonable construction in light of the specification of the patent in which it appears. 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144–46 (2016). Under that standard, and absent any special definitions, we assign claim terms their

[1] Daugan, WO 97/03675, published Feb. 6, 1997 (Ex. 1005).
[2] The Guideline for Industry, Dose Response Information to Support Drug Registration, published November 9, 1994 (Ex. 1014).
[3] Petition To Add Information About Sildenafil's Danger's To The Drug Label, Dated July 1, 1998 (Ex. 1015).

ordinary and customary meaning, as would be understood by one of ordinary skill in the art at the time of the invention, in the context of the entire patent disclosure. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). Any special definitions for claim terms must be set forth with reasonable clarity, deliberateness, and precision. *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994).

Claim terms need only be construed to the extent necessary to resolve the controversy. *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011). On this record and for purposes of this Decision, we see no need to construe any term expressly in order to determine whether to institute an *inter partes* proceeding.

Prior Art Disclosures

Daugan

Daugan identifies (6R,12aR)-2,3,6,7,12,12a-hexahydro-2-methyl-6-(3,4-methylene-dioxyphenyl)pyrazino[2',1':6.1] pyrido[3,4-b]indole-1,4-dione, also known as compound (A), as a compound of the invention. Ex. 1007, 3:24–25. Compound (A) is the same as the compound of the formula in the '166 patent set forth above, i.e., tadalafil.

Daugan teaches that tadalafil is useful for treating male or female sexual dysfunction. *Id.* at 4:25–28. According to Daugan, tadalafil may be administered orally to treat ED. *Id.* at 3:30–32. It also teaches that "for a typical adult patient, individual tablets or capsules contain from 0.2-400mg of active compound, in a suitable pharmaceutically acceptable vehicle or carrier, for administration in single or multiple doses, once or several times per day," and that generally, the dosage is "in the range of from 0.5-800mg

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.