

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ICOS CORPORATION,
Patent Owner.

Case IPR2017-00323
Patent 6,943,166 B1

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

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

Mylan Pharmaceuticals Inc. (“Petitioner”) filed a Petition (Paper 2, “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”) filed a Preliminary Response. Paper 9 (“Prelim. Resp.”). We review the Petition under 35 U.S.C. § 314.

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim, we institute an *inter partes* review of claims 1–12.

Related Proceedings

According to the parties, Patent Owner asserted the ’166 patent against Petitioner in *Eli Lilly and Company et al. v. Mylan Pharmaceuticals Inc.*, No. 1:16-cv-01122 (E.D. Va.). Pet. 25; Paper 8, 2. Patent Owner also asserted the ’166 patent against numerous other entities in the same district court. Pet. 25–26; 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.

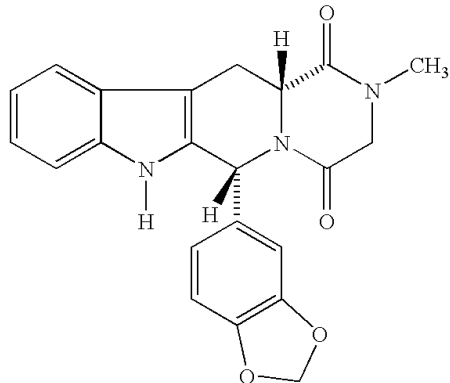
The '166 Patent

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. The '166 patent acknowledges a prior-art 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 Ground of Unpatentability

Petitioner challenges the patentability of claims 1–12 based on a single ground—obviousness over the combination of Daugan,¹ SNDA,² and the FDA Guideline.³

In support of its patentability challenges, Petitioner relies on the Declaration of Drs. George Grass (Ex. 1002) and Muta M. Issa (Ex. 1004).

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 ordinary and customary meaning, as would be understood by one of ordinary

¹ Daugan, International Publication No. WO 97/03675, published Feb. 6, 1997 (Ex. 1007, “Daugan”).

² Center for Drug Evaluation and Research, Approval Package for VIAGRA®, Approval Date March 27, 1998 (Ex. 1008, “SNDA”).

³ Dose-Response Information to Support Drug Registration, 59 Fed. Reg. 55972 (Nov. 9, 1994) (Ex. 1009, “the FDA Guideline”).

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.

Disclosures of Asserted Prior Art

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 daily.” *Id.* at 5:1–7. Further, Daugan teaches preparing tablets with 50 mg active compound. *Id.* at 12:15–14:16.

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