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Paper 13
Entered: September 1, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTELGENX CORPORATION,
Petitioner,

v.

ICOS CORPORATION,
Patent Owner.

Case IPR2016-00678
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

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INTRODUCTION

IntelGenX Corporation ("Petitioner") filed a Petition (Paper 1, "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 11 ("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, there are no related matters that would affect or be affected by this proceeding. Pet. 59; Paper 8, 2.

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

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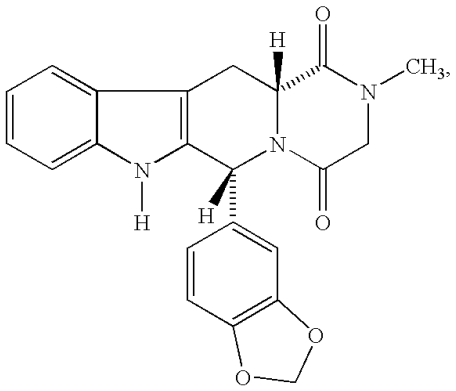
following structure:



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	References
§ 103	Daugan[1]
§ 103	Daugan and SNDA[2]

[1] Daugan, WO 97/03675, published Feb. 6, 1997 (Ex. 1002, "Daugan").

[2] Center for Drug Evaluation and Research, Approval Package for VIAGRA®, Approval Date March 27, 1998 (Ex. 1003, "SNDA").

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In support of its patentability challenges, Petitioner relies on the Declaration of Drs. Wayne J.G. Hellstrom (Ex. 1005) and Douglas Reid Patterson (Ex. 1007).

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 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).

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.

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. 1002, 3:24–25. Compound (A) is the same as the compound of formula (I) in the '166 patent, i.e., tadalafil.

Daugan teaches that tadalafil is useful for treating male or female

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sexual dysfunction. *Id.* at 4:25–28. According to Daugan, tadalafil may be administered orally to treat erectile dysfunction. *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." *Id.* at 5:4–7. Specifically, Daugan teaches preparing tablets with 50 mg active compound. *Id.* at 12:15–14:16.

SNDA

SNDA teaches sildenafil is a potent PDE5 inhibitor and is useful for treating ED. Ex. 1003, 35. Sildenafil is therapeutically effective for treating ED at doses of 25, 50, and 100 mg. *Id.* at 127–28, 215, 217–19. According to SNDA, in some patients, doses as low as 5 and 10 mg are therapeutically effective over placebo. *Id.* SNDA states that the "maximum recommended dosing frequency is once per day." *Id.* at 50.

Obviousness Grounds

Petitioner contends that claims 1–12 would have been obvious over the teachings of Daugan, either alone or in combination with SNDA. Pet. 20–46. In both obviousness grounds, Petitioner relies on both Daugan and SNDA for suggesting tadalafil dose recited in claim 1. Based on the current record, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

Specifically, Petitioner points to Daugan for teaching tadalafil formulations comprising individual tablets or capsules containing "from 0.2-400mg of active compound." *Id.* at 22, 25 (citing Ex. 1002, 5). According to Petitioner, while Daugan provides examples of 50 mg dosage forms for oral administration, it teaches that "other strengths" and "other doses" may

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