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Paper 7
Entered: August 4, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACTELION PHARMACEUTICALS LTD,
Petitioner,

v.

ICOS CORPORATION,
Patent Owner.

Case IPR2015-00562
Patent 6,821,975

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

SNEDDEN, *Administrative Patent Judge*.

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

I. INTRODUCTION

Actelion Pharmaceuticals Ltd ("Petitioner") filed a Petition (Paper 1; "Pet.") to institute an *inter partes* review of claims 1–11 of US 6,821,975 B2 (Ex. 1001; "the '975 patent"). ICOS Corporation ("Patent Owner") filed a Patent Owner Preliminary Response. Paper 6 ("Prelim. Resp.").

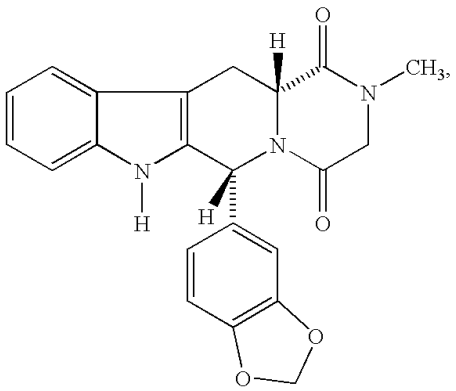
Upon consideration of the above-mentioned Petition and Preliminary Response, we conclude that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of at least one challenged claim. 35 U.S.C. § 314(a). We authorize institution of an *inter partes* review as to claims 1–11.

A. Related Proceedings

The parties inform us of no related litigation between them. Pet. 1; Paper 4. Concurrent with the present *inter partes* review, Petitioner also requested review of claims in U.S. Patent No. 7,182,958 ("the'958 patent") (Case IPR2015-00561). *Id.*

B. The '975 patent (Ex. 1001)

The '975 patent discloses particulate preparations of a free drug form of a β-carboline compound having the following formula:



and pharmaceutically acceptable salts and solvates thereof. The compound of the above formula, referred to as "compound (I)" in the '975 patent, is alternatively known as:

1) tadalafil;

2) (6R-trans)-6-(1,3-benzodioxol-5-yl)-2,3,6,7,12,12a-hexahydro-2-methylpyrazino[1′,2′:1,6]pyrido[3,4-b]indole-1,4-dione; or

3) (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.

Prelim. Resp. 14–15; Ex. 1006, 3:24–25.

"The term 'free drug' refers to solid particles of compound (I) not intimately embedded in a polymeric coprecipitate." Ex. 1001, 4:5–6. The free drug may be crystalline. *Id.* at 5:8.

The '975 patent discloses compound (I) as a free drug in particulate form, wherein at least 90% of the particles have a particle size of less than about 40 microns. *Id.* at 4:61–5:7. Particles less than 10 microns in size are also disclosed. *Id.* The particulate form of the free drug may be achieved using a milling process. *Id.* at 5:12–20, 10:6–17.

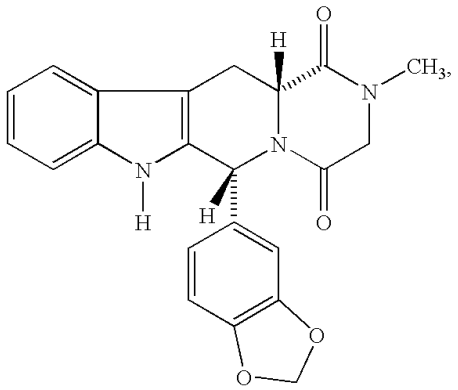
The '975 patent discloses that "the use of compound (I) and pharmaceutical compositions for treatment of sexual dysfunction, e.g., male erectile dysfunction and female sexual arousal disorder." *Id.* at 2:50–53.

The '975 patent discloses pharmaceutical compositions comprising particulate compound (I) and one or more pharmaceutically acceptable excipients, diluents, or carriers. *Id.* at 3:1–42, 7:9–55.

C. Challenged Claims

Claims 1, 6, 9, and 11 are the independent claims among the challenged claims, and are reproduced below: [1]

1. A free drug particulate form of a compound having a formula



or pharmaceutically acceptable salts and solvates thereof, comprising particles of the compound wherein at least 90% of the particles have a particle size of less than about 40 microns.

6. A method of treating sexual dysfunction in a patient in need thereof, which comprises administering to the patient a therapeutically effective amount of a solid composition comprising the free drug particulate form as in any one of claims 1-4 and one or more pharmaceutically-acceptable carriers, diluents, or excipients.

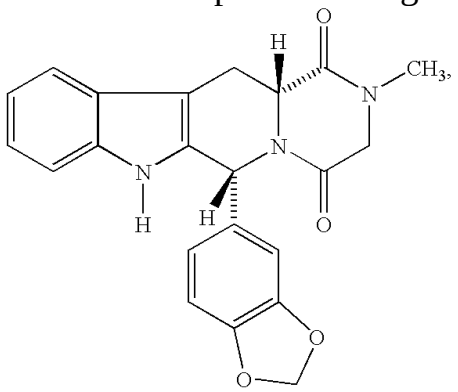
9. A method of manufacturing the free drug particulate form of claim 1 comprising:

(a) providing a solid, free form of the compound, and

(b) comminuting the solid free form of the compound to provide particles of the compound wherein at least 90% of the particles have a particle size of less than about 40 microns.

[1] We consider claims 6 and 9 as independent claims as these claims are directed to a different statutory class of invention, methods, rather than compositions of matter recited in claim 1.

11. A pharmaceutical solid composition prepared by admixing particles of a compound having a formula



or a pharmaceutically acceptable salt or solvate thereof, with one or more pharmaceutically acceptable carrier, diluent, or excipient, wherein the particles of the compound have a d90=40 or less.

Claims 2–5 depend from claim 1, either directly or indirectly. Claims 7 and 8 depend from claim 6. Claim 10 depends from claim 9.

D. Prior Art and Supporting Evidence

Petitioner relies on the following prior art:

Daugan et al., WO 97/03675, published Feb. 6, 1997. Ex. 1006 ("Daugan").

Butler et al., WO 96/38131, published Dec. 5, 1996. Ex. 1008 ("Butler").

U.S. Patent No. 4,344,934, issued Aug. 17, 1982. Ex. 1010 ("Martin").

Seth et al., U.S. Patent No. 4,721,709, issued Jan. 26, 1988. Ex. 1011 ("Seth").

Deodatt A. Wadke, Abu T. M. Serajuddin, and Harold Jacobson, *Preformulation Testing* in PHARMACEUTICAL DOSAGE FORMS: TABLETS, VOL. 1, Chpt. 1, pp. 1-73, Marcel Decker (Herbert A. Lieberman, Leon Lachman and Joseph B. Schwartz, Eds., 2nd ed.,

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