UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTELGENX CORP.
Petitioner

v.

ICOS CORP.
Patent Owner

Patent No. 6,943,166
Issued: September 13, 2005
Filed: April 26, 2000
Inventors: Pullman and Whitaker

Title: COMPOSITIONS COMPRISING PHOSPHODIESTERASE INHIBITORS FOR THE TREATMENT OF SEXUAL DYSFUNCTION

Inter Partes Review No. - *not yet assigned*

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 6,943,166 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.1-.80, 42.100-.1

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I. INTRODUCTION

INTELGENX CORP. (Petitioner) petitions for *inter partes* review, seeking cancellation of claims 1-12 of U.S. Patent No. 6,943,166 ("the '166 patent") (INX1001), as unpatentable for obviousness. According to USPTO records, the '166 patent is assigned to ICOS CORP. On information and belief, ICOS CORP. is owned by ELI LILLY AND CO. (collectively, "Patent Owner").

II. OVERVIEW

The '166 patent claims would have been obvious over the prior art—Daugan '675 (INX1002). Like every claim of the ’166 patent, Daugan '675 is directed toward treating sexual dysfunction with a potent, highly-selective phosphodiesterase type 5 (PDE5) inhibitor known as tadalafil. INX1002, 1-5. Daugan '675 explicitly describes that tadalafil can be administered through a variety of dosage forms, across a range of doses, once or more a day to treat both male and female sexual dysfunction. INX1002, 1-5; 12-17. The only purported difference between Daugan '675 and the '166 patent claims is that Daugan '675 discloses a dosing range of 0.2–400 mg whereas the '166 patent more narrowly claims 1–20 mg. When "there is a range disclosed in the prior art, and the claimed invention falls within that range, there is a presumption of obviousness." *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004).

Patent Owner argued during prosecution that the range claimed by the '166

patent is non-obvious due to the "unexpected result" that administering a lower dose of tadalafil resulted in lower side effects without a loss of efficacy. INX1024, 536-538, 612-614. But Patent Owner's argument should be rejected for several reasons. First, there is no evidence of record that a person skilled in the art ("POSA") would have been surprised to discover that a lower dose of tadalafil would be associated with reduced side effects. To the contrary, these are merely differences in degree of results (rather than differences in kind), which would be very much expected by a pharmacologist or similar skilled artisan. INX1007, ¶47. Indeed, the Examiner rejected this argument for the same reasons. INX1024, 628. Second, identifying the optimum dosing regimen for a drug such as tadalafil would have required only routine experimentation and optimization. INX1007, ¶¶16–17, 27–33; INX1005, ¶¶60, 84–89. Indeed, before 1999 and even today, it is commonplace when seeking approval for a new drug to conduct a dose-ranging study to establish a safe and effective dosing regimen. A POSA following the teachings of Daugan '675 and accepted industry practices would have quickly and easily arrived at the range of 1–20 mg as set forth in Ground 1. INX1007, ¶47. Third, even if Patent Owner's evidence of alleged unexpected results is given any weight, the evidence is not commensurate with the full scope of the claims. INX1007, ¶¶51-53; INX1005, ¶¶ 156-158. The broadest claim of the '166 patent covers doses as low as one twentieth of the 20 mg dose, covers administration

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