

Paper No. ____
Filed: January 8, 2016

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

ASTRAZENECA AB,
Patent Owner.

Case IPR2015-01340
Patent RE44,186

**PETITIONER MYLAN PHARMACEUTICALS INC.'S
REQUEST FOR REHEARING PURSUANT TO 37 C.F.R. §42.71**

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I. INTRODUCTION

In response to the Decision Denying Institution of *Inter Partes* Review entered December 9, 2015, (Paper 12, hereinafter “Decision”) and pursuant to 37 C.F.R. § 42.71(d), Mylan Pharmaceuticals Inc. (“Petitioner”) hereby respectfully requests the Patent Trial and Appeal Board (“Board”) reconsider its decision denying institution for *inter partes* review of U.S. Patent No. RE44,186 E (“the ’186 patent”).

II. BASIS FOR REHEARING

A. Legal Standards

Pursuant to 37 C.F.R. § 42.71(d), a party may request rehearing of a decision by the Board whether to institute a trial. “The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, opposition, or reply.” *Id.* The Board will review the previous decision for an abuse of discretion. 37 C.F.R. § 42.71(c). “An abuse of discretion may be indicated if a decision is based on an erroneous interpretation of law, if a factual finding is not supported by substantial evidence, or if the decision represents an unreasonable judgment in weighing relevant factors.” IPR 2013-00369, Paper 39 at 2-3 (citing *Star Fruits S.N.C. v. United States*, 393 F.3d 1277, 1281 (Fed. Cir. 2005)).

The Petition asserted in Ground 1 that a combination of Ashworth I, Villhauer I, Raag and Hanessian rendered obvious the compound of claim 25 of the ’186 patent, and this compound was encompassed by each of the other

challenged claims. Decision, p. 5. According to the '186 patent, the compound of claim 25 (referred to for convenience in the Petition as saxagliptin) was said to be an inhibitor of the enzyme dipeptidyl peptidase IV (DP-IV) and therefore useful to ameliorate the diabetic condition. *Id.*, p. 3.

The Decision states that, “we accept Petitioner’s assertion that a person[] of ordinary skill would have chosen compound 25 as a lead compound . . . [and] focus on whether the evidence of record supports Petitioner’s contention that one of ordinary skill in the art would have been motivated to replace the 6-carbon cyclohexyl group at the 2-position of compound 25 with a 10-carbon adamantyl moiety.” Dec., pp. 7-8.

B. Erroneous Interpretation of Law

The Decision first found that there was insufficient motivation for one of ordinary skill to increase the stability of compound **25** by substituting a larger cycloalkane—in particular adamantyl—for the cyclohexyl group of compound **25**. The Decision concludes that Villhauer I, Ex. 1008, which discloses the adamantyl, “fails to cure the lack of rationale for substituting adamantyl at the 2-position of compound 25.” Dec., p. 11. The Decision bases its conclusion on the following statement, which contradicts the substantial evidence and errs as a matter of law: “[A]lthough Villhauer I identifies adamantyl as a possible moiety in ‘[e]ven more preferred compounds,’ *adamantyl groups are conspicuously absent from the preferred examples of Villhauer [I]*—‘Examples 1, 3, 5, 8, and 12 [, which] are

the preferred agents of the invention.’ Ex. 1008, 5, 21; *see* Pet. 26” (Dec., p. 11, emphasis added).

An obviousness analysis under § 103 does not require that a prior art reference, such as Villhauer I, identify a compound as a most preferred or exemplified agent of the invention. *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989). “In a section 103 inquiry, ‘the fact that a specific [embodiment] is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.’” (*Merck*, quoting *In re Lamberti*, 545 F.2d 747, 750 (C.C.P.A. 1976)); *see also Boston Sci. Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982, 991 (Fed. Cir. 2009) (citing *Merck* in holding that a prior art reference containing two separate embodiments that when combined taught the claimed invention, “need not have recognized the additional benefit of one embodiment to have rendered the claim obvious”).

Thus, it was legal error for the Board to observe as particularly noteworthy in its obviousness analysis that adamantyl groups were “conspicuously absent from the preferred examples of Villhauer [I].” Dec., p. 11. Not only does Villhauer I expressly state that an adamantylated compound is an “even more preferred compound of the invention,” but, in addition and contrary to the statement in the Decision, three different examples of adamantylated compounds are identified in Villhauer I, *see* Examples 47, 49 and 53 (Ex. 1008, p. 13) (*see* Pet., p. 9, pointing to the synthesis and characterization of an adamantyl-containing compound, Example 47, in Villhauer I). Patent Owner’s evidence corroborates Petitioner’s

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