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Paper 16
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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 E

Before MICHAEL P. TIERNEY, RAMA G. ELLURU, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges.*

ELLURU, *Administrative Patent Judge*.

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

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition to institute an *inter partes* review of claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 (Paper 3, 1 "Pet.") of RE44,186 E (Ex. 1001, "the '186 patent"). Astrazeneca AB ("Patent Owner") filed a Patent Owner Preliminary Response. Paper 7 ("Prelim. Resp."). We subsequently ordered Petitioner to respond to certain arguments raised in the preliminary response. Paper 10. Petitioner filed the authorized Reply to Patent Owner's Preliminary Response. Paper 11 ("Reply").

We denied institution of an *inter partes* review of all the challenged claims. Paper 12, 14. Petitioner subsequently filed a Request for Rehearing (Paper 13), which we granted in an Order concurrently issued with this Decision. Paper 15.

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted "unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314(a). Upon considering the current record, we conclude that Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of challenged claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 of the '186 patent. Therefore, we institute an *inter partes* review of the challenged claims of the '186 patent.

A. Related Matters

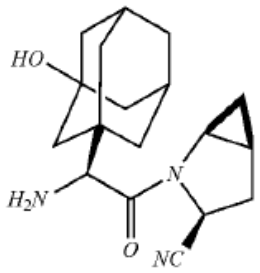
According to Petitioner, the '186 patent is at issue in numerous district court actions. Pet. 16; Papers 2, 5.

B. The '186 patent (Ex. 1001)

The '186 patent is directed to "cyclopropyl-fused pyrrolidine-based inhibitors of dipeptidyl peptidase IV" ("DP-IV"). Ex. 1001, 1:19–20. DP-IV is responsible for the metabolic cleavage of certain endogenous peptides including glucagon. *Id*. at 1:34–42. Glucagon is a peptide with multiple physiologic roles, including the stimulation of insulin secretion, the promotion of satiety, and the slowing of gastric emptying. *Id*. at 1:44–48. Glucagon is rapidly degraded in the body, primarily by DP-IV-mediated enzymatic cleavage. *Id*. at 1:55–64. Inhibitors of DP-IV *in vivo* may, therefore, increase endogenous levels of glucagon, and serve to ameliorate the diabetic condition. *Id*. at 1:64–67.

C. Illustrative Claim

For the purposes of this Decision, claim 25[1] is illustrative of the challenged claims and is drawn to the compound shown below, or a pharmaceutically acceptable salt thereof.



This compound is known as (1S,3S,5S)-2-[(2S)-2-amino-2-(3-hydroxy-1-adamantyl) acetyl]-2-azabicyclo[3.1.0]hexane-3-carbonitrile or

[1] All the challenged claims are directed to compounds, compositions, and methods relating to the specific compound recited in claim 25.

"saxagliptin." *See* Pet. 3; Prelim. Resp. 22–23; Ex. 1003 ¶ 15; Ex. 2047, 9.

D. Prior Art Asserted by Petitioner

Pursuant to 37 C.F.R. § 42.104(b), Petitioner identifies the following prior art as the basis for challenging claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 of the '186 patent. S*ee* Pet. 5–6.

Ashworth et al., *2-Cyanopyrrolidides as Potent, Stable Inhibitors of Dipeptidyl Peptidase IV,* 6(10) BIOORGANIC & MED. CHEM. LETT. 1163–66 (1996). Ex. 1007 ("Ashworth I").

Villhauer, WO 98/19998, published May 14, 1998. Ex. 1008 ("Villhauer").

Raag, et al., *Crystal Structures of Cytochrome P-450$_{CAM}$ Complexed with Camphane, Thiocamphor, and Adamantane: Factors Controlling P-450 Substrate Hydroxylation*, 30 BIOCHEM. 2647–84 (1991). Ex. 1009 ("Raag").

Hanessian et al., *The Synthesis of Enantiopure w-Methanoprolines and w-Methanopipecolic Acids by a Novel Cyclopropanation Reaction: The "Flattening" of Proline*, 36(17) ANGEW. CHEM. INT. ED. ENGL. 1881–84 (1997). Ex. 1010 ("Hanessian I").

Bachovchin et al., WO/99/38501, published Aug. 5, 1999. Ex. 1011 ("Bachovchin").

Center for Drug Evaluation and Research, Application Number: NDA 20-357, Revised Package Insert, available by FOIA Jan. 8, 1998. Ex. 1012 ("GLUCOPHAGE Label").

Center for Drug Evaluation and Research, Application Number: NDA 20-766, Package Insert, available by FOIA Aug. 9, 1999. Ex. 1013 ("XENICAL Label").

Center for Drug Evaluation and Research, Application Number: NDA 19-643/S-033, Package Insert, available by FOIA Sept. 15, 1994. Ex. 1014 ("MEVACOR Label").

Petitioner also refers to the Declaration of David P. Rotella, Ph.D. ("Dr. Rotella"). Ex. 1003.

E. Asserted Grounds

Petitioner challenges claims 1, 2, 4, 6–22, 25–30, 32–37, and 39–42 of the '186 patent on the following grounds. Pet. 2–3, 22, 46, 50, 53.

References	Basis	Claims challenged
Ashworth I, Villhauer, Raag, and Hanessian I	§ 103(a)	1, 2, 4, 6–11, 25–28, 32–35, 39, and 40
Ashworth I, Villhauer, Raag, Hanessian I, Bachovchin, and GLUCOPHAGE Label	§ 103(a)	12–16, 29, 30, 36, 37, 41, and 42
Ashworth I, Villhauer, Raag, Hanessian I, Bachovchin ,and XENICAL Label	§ 103(a)	12, 17, 18, and 22
Ashworth I, Villhauer, Raag, Hanessian I, Bachovchin, and MEVACOR Label	§ 103(a)	12, 19, 20, and 21

II. ANALYSIS

A. Claim Interpretation

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); *In re Cuozzo Speed Techs., LLC*, 793 F.3d 1268, 1278–79 (Fed. Cir. 2015), *cert. granted sub nom. Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 890 (mem.) (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).

Petitioner contends that the claims use conventional terminology. Pet. 18–19. Patent Owner does not contest the construction of any claim term.

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