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Paper No. 15
Entered: February 3, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.,
Petitioner,

v.

BOEHRINGER INGELHEIM INTERNATIONAL GMBH,
Patent Owner.

Case IPR2016-01566
Patent 9,173,859 B2

Before TONI R. SCHEINER, BRIAN P.MURPHY, and ZHENYU YANG, *Administrative Patent Judges*.

YANG, *Administrative Patent Judge*.

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

INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition for an *inter partes* review of claims 1–22 of U.S. Patent No. 9,173,859 B2 ("the '859 patent," Ex. 1001). Paper 2 ("Pet."). Boehringer Ingelheim International GmbH ("Patent Owner") timely filed a Preliminary Response. Paper 9 ("Prelim. Resp."). We review the Petition under 35 U.S.C. § 314.

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. Therefore, we decline to institute an *inter partes* review of claims 1–22 of the '859 patent. *See* 35 U.S.C. § 314(a).

Related Proceedings

Patent Owner informs us that it has asserted the '859 patent against Petitioner in *Boehringer Ingelheim Pharm. Inc. v. Mylan Pharm. Inc.*, Case No. 1:15-cv-00145 (N.D.W.Va.), which is currently inactive. Paper 6, 3.

According to the parties, the '859 patent is the subject of several other cases in district courts, which have been consolidated into *Boehringer Ingelheim Pharm. Inc. v. HEC Pharm Group*, Case No. 3:15-cv-05982 (D.N.J.). Pet. 5; Paper 6, 2. In that case, Patent Owner also asserted U.S. Patent Nos. 8,673,927, 8,846,695, and 8,853,156. Pet. 5. Petitioner has concurrently filed IPR2016-01563, IPR2016-01564, and IPR2016-01565, challenging those patents respectively. *Id.*

The '859 Patent

The '859 patent describes selected DPP-4 inhibitors that are useful for treating various diseases, including type 2 diabetes. Ex. 1001, 3:66–4:20, 16:45–17:2. Specifically, the '859 patent identifies DPP-4 inhibitor 1-[(4-

methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, also known as BI 1356 or linagliptin, as "particularly preferred." *Id.* at 5:20–35.

DPP-4 inhibitors "influence the plasma level of bioactive peptides including the peptide GLP-1 and are highly promising molecules for the treatment of diabetes mellitus." *Id.* at 1:21–23. The '859 patent states that the DPP-4 inhibitors disclosed therein may be used in conjunction with other antidiabetic agents, such as metformin, "either in a free combination or in a fixed combination in a tablet." *Id.* at 8:60–9:11, 20:25–51. According to the '859 patent:

> A particularly preferred example of an antidiabetic combination partner is metformin in doses of about 100 mg to 500 mg or 200 mg to 850 mg (1-3 times a day), or about 300 mg to 1000 mg once or twice a day, or delayed-release metformin in doses of about 100 mg to 1000 mg or preferably 500 mg to 1000 mg once or twice a day or about 500 mg to 2000 mg once a day.

Id. at 14:6–12.

Illustrative Claims

Among the challenged claims, claims 1, 13, 14, and 16–18 are independent. Claims 1 and 14 are representative and are reproduced below:

> 1. A method of treating type 2 diabetes comprising
>
> administering to a patient in need thereof (a) 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, or a therapeutically active salt thereof, in an oral dosage of 2.5 mg or 5 mg, and (b) metformin
>
> wherein the dose of metformin is 100 mg to 500 mg or 200 mg to 850 mg (1-3 times a day), or 300 mg to 1000 mg once or twice a day, or as delayed-release metformin in a dose of 500 mg to

1000 mg once or twice a day, or 500 mg to 2000 mg once a day, or

wherein the dose of metformin is 500 mg, 850 mg or 1000 mg as a single dose with a total daily dose of metformin of 500-2850 mg, or 500 mg, 1000 mg, 1500 mg or 2000 mg metformin in delayed release form, or

wherein the dose of metformin is 500 mg to 1000 mg.

14. An oral tablet formulation comprising 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine in an amount of 2.5 mg or 5 mg optionally in combination with metformin, and a pharmaceutically acceptable carrier or diluent.

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds of unpatentability:

Claims	Basis	Reference(s)
14–20	§ 103	The '510 publication[1]
1–22	§ 103	The '510 publication and Glucophage® Label[2]
1–22	§ 103	The '510 Publication and Ahrén,[3] Hughes,[4] and/or Brazg[5]

[1] Himmelsbach et al., U.S. Patent Publication No. 2004/0097510, published May 20, 2004 (Ex. 1003).
[2] Glucophage® and Glucophage® XR Label (Ex. 1004).
[3] Ahrén et al., *Twelve and 52-Week Efficacy of the Dipeptidase IV Inhibitor LAF237 in Metformin-Treated Patients with Type 2 Diabetes*, DIABETES CARE 27:2874–80 (2004) (Ex. 1005).
[4] Hughes, Int'l Pub. No. WO 2005/117861, published December 15, 2005 (Ex. 1006).
[5] Brazg, et al., *Effect of Adding MK-0431 to On-going Metformin Therapy in Type 2 Diabetic Patients Who Have Inadequate Glycemic Control on Metformin*, DIABETES 54 (Suppl. 1):A3 (2005) (Ex. 1007).

In support of its patentability challenge, Petitioner relies on the Declaration of Dr. Mayer B. Davidson. Ex. 1002.

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.

Anticipation by the '510 Publication

Petitioner asserts that the '510 publication anticipates claims 14 and 20. Pet. 30–31. Based on the current record, we determine Petitioner has not established a reasonable likelihood that it would prevail in this assertion.

The '510 publication discloses a genus of substituted xanthine compounds that act as DPP-IV inhibitors, particularly for the prevention and treatment of type 2 diabetes. Ex. 1003, Abstract, ¶¶ 3, 4. It discloses linagliptin as one in a series of 30 "[m]ost particularly preferred" substituted

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