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Paper 17
Entered: February 9, 2017

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACUTICALS INC.,
Petitioner,

v.

BOEHRINGER INGELHEIM INTERNATIONAL GMBH,
Patent Owner.

Case IPR2016-01565
Patent 8,853,156 B2

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

SCHEINER, *Administrative Patent Judge*.

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

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner" or "Mylan") filed a Petition (Paper 2, "Pet.") requesting an *inter partes* review of claims 1, 2, 4–8, 10–18, and 23–25 of U.S. Patent No. 8,853,156 B2 (Ex. 1001, "the '156 patent"). Boehringer Ingelheim International GmbH ("Patent Owner" or "Boehringer") filed a Preliminary Response to the Petition (Paper 11, "Prelim. Resp."). We have statutory authority 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."

Upon consideration of the arguments and evidence presented in the Petition and the Preliminary Response, we are persuaded that Petitioner has established a reasonable likelihood that it would prevail in its challenge to claims 1, 2, 4, 5, and 23 of the '156 patent. Accordingly, we institute an *inter partes* review of claims 1, 2, 4, 5, and 23.

A. Related Proceedings

The '156 patent has been asserted in *Boehringer Ingelheim Pharm. Inc. v. Mylan Pharmaceuticals*, Case No. 1:15-cv-00145-JPB (N.D.W.Va.) (inactive), and *Boehringer Ingelheim Pharm. Inc. v. HEC Pharm Group*, Case No. 3:15-cv-05982 (D.N.J.) (consolidated). Pet. 3; Paper 7, 3.

U.S. Patent Nos. 8,673,927, 8,846,695, and 9,173,859 also have been asserted in the consolidated litigation, and Petitioner has filed IPR2016-

01563, IPR2016-01564, and IPR2016-1566, requesting *inter partes* review of those patents, respectively. Pet. 3.

B. The Asserted Grounds of Unpatentability

Petitioner asserts that the challenged claims are unpatentable on the following grounds:

References	**Basis**	**Claims Challenged**
Mikhail[1]	§ 102(a)	1, 2, 4, 5, and 23
The Januvia Label,[2] Huettner,[3] and Mikhail or the Knowledge of a POSA	§ 103(a)	1, 2, 4–8, 10–18, and 23–25

Petitioner supports its challenges with the Declaration of Mayer B. Davidson, M.D, dated August 10, 2016 (Ex. 1002, "Davidson Declaration").

[1] Nasser Mikhail, *Incretin mimetics and dipeptidyl peptidase 4 inhibitors in clinical trials for the treatment of type 2 diabetes*, 17 EXPERT OPIN. INVESTIG. DRUGS 845–853 (2008) (Ex. 1003, "Mikhail").

[2] Januvia™ (sitagliptin phosphate tablets) Prescribing Information (2006) (Ex. 1006, "the Januvia Label").

[3] Silke Huettner et al., *BI 1356, a Novel and Selective Xanthine Based DPP-4 Inhibitor, Demonstrates Good Safety and Tolerability with a Wide Therapeutic Window*, Poster No. 0586P, ADA (June 22–25, 2007) (Ex. 1004, "Huettner").

C. The '156 Patent (Ex. 1001)

The '156 patent, titled "Treatment for Diabetes in Patients Inappropriate for Metformin Therapy," issued October 7, 2014, names inventors Klaus Dugi, Eva Ulrike Graefe-Mody, Ruth Harper, and Hans-Juergen Woerle. Ex. 1001 (54), (75).

"One of the typical long-term complications of diabetes is diabetic neuropathy," which can lead to renal impairment, and "can progress to renal failure in some cases." *Id.* at 1:17–25. The '156 patent teaches that "[m]etformin is an antihyperglycemic agent which improves glucose tolerance in patients with type 2 diabetes mellitus," but "treatment with metformin can be associated with adverse symptoms, such as e.g. gastrointestinal symptoms or, occasionally, as a severe adverse effect, lactic acidosis (which can be fatal), for which one putative risk factor is decreased renal function." *Id.* at 1:51–62. "Further, since metformin is largely eliminated unchanged by the kidneys via glomerular filtration and tubular secretion, it is contraindicated in patients with renal disease or kidney impairment." *Id.* at 1:62–65. "Thus, conventional metformin therapy can be inappropriate for certain patients, e.g. due to intolerability or contraindication against metformin." *Id.* at 1:65–67.

The '156 patent discloses another class of drugs, DPP-IV inhibitors, which "are considered to be promising drugs for the treatment of diabetes mellitus." Ex. 1001, 4:12–13. DPP-IV inhibitors act through a different mechanism than metformin. Ex. 1002 ¶ 29. A highly simplified explanation

of the mechanism is as follows: the enzyme DPP-IV (dipeptidyl peptidase IV) breaks down certain bioactive peptides, including glucagon-like peptide (GLP-1) (Ex. 1001, 4:6–11), a naturally occurring peptide "that helps reduce blood glucose by stimulating the pancreas to produce insulin and by inhibiting the release of glucagon, a substance that causes the liver to release glucose" (Ex. 1002 ¶ 29), but DPP-IV inhibitors block the activity of the DPP-IV enzyme, thereby preventing the breakdown of GLP-1 and helping to lower blood glucose levels (*id.*).

The '156 patent discloses a number of DPP-IV inhibitors (Ex. 1001, 16:35–19:28), including a particularly preferred species, 1-[(4 -methyl-quinazolin-2 -yl)methyl]-3-methy1-7-(2-butyn-1-y1)-8-(3-(R)-amino-piperidin-l-y1)-xanthine—also known as "BI 1356" or "linagliptin" (Ex. 1001, 16:39–40; Ex. 1002 ¶ 17). According to the '156 patent, DPP-IV inhibitors are "particularly suitable for treating and/or preventing (including preventing or slowing the progression) of metabolic diseases, particularly diabetes (especially type 2 diabetes mellitus) and conditions related thereto (e.g. diabetic complications), particularly in patients for whom metformin therapy is inappropriate due to intolerability or contraindication against metformin." Ex. 1001, 9:33–39. Such patients include those ineligible for metformin therapy due to renal disease, renal impairment or renal dysfunction, unstable or acute congestive heart failure, acute or chronic metabolic acidosis, or hereditary galactose intolerance. *Id.* at 27:51–60.

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