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Paper 16
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 IPR2016-01563
Patent 8,673,927 B2

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

MURPHY, *Administrative Patent Judge*.

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

I. INTRODUCTION

Mylan Pharmaceuticals Inc. ("Petitioner") filed a Petition requesting an *inter partes* review of claims 1–26 of U.S. Patent No. 8,673,927 B2 (Ex. 1001, "the '927 patent"). Paper 2 ("Pet."). Boehringer Ingelheim International GmbH ("Patent Owner") filed a Preliminary Response to the Petition. Paper 10 ("Prelim. Resp."). We have statutory authority under 35 U.S.C. § 314(a), 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."

Based on the arguments and evidence presented in the Petition and Preliminary Response, we determine there is a reasonable likelihood Petitioner would prevail with respect to claims 1 and 10 of the '927 patent challenged in the Petition. Therefore, we institute an *inter partes* review.

A. Related Proceedings

Petitioner and Patent Owner identify the following as related district court proceedings in the District of New Jersey regarding the '927 patent: *Boehringer Ingelheim Pharmaceuticals Inc. v. HEC Pharm. Group*, Civ. Action No. 3:15-cv-05982-PGS-TJB (consolidated); *Boehringer Ingelheim Pharmaceuticals Inc., v. Accord Healthcare, Inc.*, Case No. 3:16-cv- 00852-PGS-TJB; *Boehringer Ingelheim Pharmaceuticals Inc. v. Dr. Reddy's Laboratories, Ltd.*, Case No. 3:16-cv-02394-PGS-TJB; *Boehringer Ingelheim Pharmaceuticals Inc. v. Prinston Pharmaceutical Inc.*, Case No. 3:16- cv-00851-PGS-TJB; *Boehringer Ingelheim Pharmaceuticals Inc. v. Sun Pharmaceutical Industries Ltd.*, Case No. 3:16-cv-01727-PGS-TJB. Pet. 3; Paper 7, 2–3.

Patent Owner identifies the following inactive district court cases: in the U.S. District Court for the Middle District of North Carolina, *Boehringer Ingelheim Pharmaceuticals Inc. v. Intas Pharmaceuticals Ltd.*, Case No. 1:15-cv-00664-CCE-LPA; in the U.S. District Court for the Northern District of West Virginia, *Boehringer Ingelheim Pharmaceuticals Inc. v. Mylan Pharmaceuticals Inc.*, Case No. 1:15-cv-00145-JPB. Paper 7, 3.

Petitioner identifies requests for *inter partes* review of related U.S. Patent Nos. 8,846,695 (IPR2016-01564), 8,853,156 (IPR2016-01565), and 9,173,859 (IPR2016-01566), which also are asserted in *Boehringer Ingelheim Pharmaceuticals Inc. v. HEC Pharm. Group*, Civ. Action No. 3:15-cv-05982-PGS-TJB (D.N.J.) (consolidated). Pet. 3.

B. Proposed Grounds of Unpatentability

Petitioner advances three grounds of unpatentability under 35 U.S.C. §§ 102 and 103 in relation to the challenged claims in the '927 patent:

Reference[s]	Statutory Basis	Challenged Claims
'510 Publication (Ex. 1003)[1]	§ 102	18–26
'510 Publication and Glucophage Label (Ex. 1004)[2]	§ 103	1–26

[1] Himmelsbach et al., U.S. Patent Publication No. 2004/0097510, published May 20, 2004 ("the '510 Publication"). Ex. 1003.

[2] Glucophage® (metformin hydrochloride tablets) and Glucophage® XR (metformin hydrochloride extended-release tablets) prescribing information ("Glucophage Label"). Ex. 1004.

Reference[s]	Statutory Basis	Challenged Claims
'510 Publication, Ahrén (Ex. 1005),[3] Hughes (1006),[4] and/or Brazg (1007)[5]	§ 103	1–26

Pet. 9. Petitioner supports its challenge with a Declaration by Dr. Mayer B. Davidson ("Davidson Declaration"). Ex. 1002.

C. The '927 Patent

The '927 patent, titled "Uses of DPP-IV Inhibitors," issued March 18, 2014, from an application filed November 15, 2010. Ex. 1001. The '927 claims priority, through a continuation application, to EP application 06009203, filed May 4, 2006. *Id.* at (30), 1:3–4. The '927 patent is assigned to Patent Owner. *Id.* at (73).

The Dipeptidyl Peptidase ("DPP")-IV enzyme breaks down bioactive peptides, including the peptide GLP-1. *Id.* at 1:18–23. GLP-1 is 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 ¶ 28 (citing Ex. 1011, 149–150; Ex. 1014, 708); *see also* Prelim. Resp. 10. DPP-IV enzymes deactivate GLP-1 (and related hormones), thereby depressing the level of insulin in the body. *Id.* DPP-IV inhibitors are used to inhibit the DPP-IV enzyme, thereby preventing the breakdown of GLP-1 and helping to regulate blood glucose levels. *Id.* The '927

[3] Ahrén et al., *Twelve and 52-Week Efficacy of the Dipeptidase IV Inhibitor LAF237 in Metformin-Treated Patients with Type 2 Diabetes*, 27 DIABETES CARE 2874–880 (2004) ("Ahrén"). Ex. 1005.
[4] Hughes, International Patent No. WO 2005/117861, published December 15, 2005 ("Hughes"). 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*, 54 DIABETES (Suppl. 1):A3 (2005) ("Brazg"). Ex. 1007.

patent states that DPP-IV inhibitors "are highly promising molecules for the treatment of diabetes mellitus." Ex. 1001, 1:21–23.

The '927 patent describes a genus of DPPV-IV inhibitor compounds according to formula I (*id.* at 4:54–5:22), but the claims at issue are directed to methods of treating type II diabetes using one species of DPP-IV inhibitor known as "linagliptin."[6] *Id.* at 5:25–35 ("1-[(4 -methyl-quinazolin-2 -yl)methyl]-3-methy1-7-(2-butyn-1-y1)-8-(3-(R)-amino-piperidin-l-y1)-xanthine (cf. WO2004/018468, Example 2 (142)"). The '927 patent identifies linagliptin as one of twelve "particularly preferred DPP-IV inhibitors" that may "bring about unexpected therapeutic advantages or improvements when combined with other pharmaceutical active substances." *Id.* at 5:23–27, 8:15–17. Metformin is identified as a "particularly preferred example of an antidiabetic combination partner" for the DPP-IV inhibitors. *Id.* at 14:32–33. The '927 patent describes an orally administered dose of "the DPP IV inhibitors" as "0.5 mg to 100 mg, preferably 2.5 mg to 50 mg, in each case 1 to 4 times a day" *(id.* at 8:32–33), and it further describes oral tablet dosage forms containing 0.5, 1.0, 2.5, 5.0, and 10.0 mg of DPP-IV inhibitor (*id.* at 20:4–24).

The '927 patent includes a series of prophetic treatment examples. *Id.* at 16:20–23:44. Prophetic Example 13 describes a "Combined Treatment with DPP IV Inhibitor–Metformin" used for treating type II diabetes or pre-diabetes. *Id.* at 20:52–57. The combined treatment method is described as follows: "a DPP IV inhibitor according to the invention may be combined with the anti-diabetically active substance metformin . . . in a tablet." *Id.* at 20:57–60. The '927 patent further states:

[6] "Type 2 diabetes mellitus . . . manifests itself in a fasting blood sugar level exceeding 125 mg of glucose per dl of plasma." Ex. 1001, 1:30–32.

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