Trials@uspto.gov
571-272-7822

Paper No. 17
Entered: January 31, 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 IPR2016-01564
Patent 8,846,695 B2

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

YANG, *Administrative Patent Judge*.

DECISION
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 1–4 of U.S. Patent No. 8,846,695 B2 ("the '695 patent," Ex. 1001). Paper 2 ("Pet."). Boehringer Ingelheim International GmbH ("Patent Owner") timely filed a Preliminary Response. Paper 11 ("Prelim. Resp."). We review the Petition under 35 U.S.C. § 314.

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Because Petitioner has established a reasonable likelihood that it would prevail in showing the unpatentability of claims 1–4, we institute an *inter partes* review of the challenged claims.

Related Proceedings

Patent Owner informs us that it has asserted the '695 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 7, 3.

According to the parties, the '695 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 7, 2–3. In that case, Patent Owner also asserted U.S. Patent Nos. 8,673,927, 8,853,156, and 9,173,859. Pet. 5. Petitioner has concurrently filed IPR2016-01563, IPR2016-01565, and IPR2016-01566, challenging those patents respectively. *Id.*

The '695 Patent

The '695 patent is directed to "certain DPP-4 [dipeptidyl peptidase 4] inhibitors for improving glycemic control, such as e.g. improving hemoglobin A1c (HbA1c) and/or fasting plasma glucose (FPG), in type 2 diabetes patients with inadequate glycemic control despite therapy with metformin, as well as to the use of these DPP-4 inhibitors in antidiabetic therapy." Ex. 1001, 1:6–11.

The '695 patent states that metformin is the drug of choice for beginning or first-line antidiabetic therapy. *Id.* at 2:1–7. It is, however, associated with a high secondary failure rate, that is, some diabetic patients may fail to achieve or maintain glycemic control over time. *Id.* at 1:26, 2:10–12.

"DPP-4 inhibitors interfere with the plasma level of bioactive peptides including the peptide GLP-1 and are considered to be promising drugs for the treatment of diabetes mellitus." *Id.* at 3:67–4:3. According to the '695 patent, the inventor surprisingly found that certain DPP-4 inhibitors had "unexpected and particularly advantageous properties, which make them particularly suitable for improving glycemic control in patients with type 2 diabetes mellitus inadequately controlled on metformin alone." *Id.* at 9:9–14. Specifically, the '695 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 17:33–37, 21:4–7.

Illustrative Claims

Among the challenged claims, claims 1 and 2 are independent. Claim 1 is representative and it reads as follows:

> 1. A method for treating type 2 diabetes mellitus in a patient with inadequate glycemic control despite therapy with metformin, said method comprising orally administering 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine to said patient in an amount of 5 mg per day in combination with metformin.

Claim 2 is similar to claim 1, except it recites administering linagliptin "as add-on combination with metformin."

Asserted Grounds of Unpatentability

Petitioner asserts the following grounds, each of which challenges the patentability of claims 1–4:

Ground	Basis	References
1	§ 103	Charbonnel[1] or Hughes[2] in view of the '940 Publication[3]

[1] Charbonnel et al., *Efficacy and Safety of the Dipeptidyl Peptidase-4 Inhibitor Sitagliptin Added to Ongoing Metformin Therapy in Patients With Type 2 Diabetes Inadequately Controlled with Metformin Alone*, 29 DIABETES CARE 2638–43 (2006) (Ex. 1004).
[2] Hughes, Int'l Pub. No. WO 2005/117861, published December 15, 2005 (Ex. 1005).
[3] Dugi et al., U.S. Patent Publication No. 2007/0281940, published December 6, 2007 (Ex. 1003).

Ground	Basis	References
2	§ 103	Janumet,[4] Nauck,[5] or Ahrén 2008[6] in view of the '940 Publication

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).

---

[4] Janumet™ (sitagliptin/metformin HCL) tablets Prescribing Information (Ex. 1007).

[5] Nauck et al., *Efficacy and Safety of the Dipeptidyl Peptidase-4 Inhibitor, Sitagliptin, Compared with the Sulfonylurea, Glipizide, in Patients with Type 2 Diabetes Inadequately Controlled on Metformin Alone: A Randomized, Double-Blind, Non-Inferiority Trial*, 9 DIABETES, OBESITY AND METABOLISM 194–205 (2007) (Ex. 1006).

[6] Ahrén, Novel Combination Treatment of Type 2 Diabetes DPP-4 Inhibition + Metformin, 4 VASCULAR HEALTH AND RISK MANAGEMENT 383–94 (2008) (Ex. 1022).

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.