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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.,
Petitioners,

v.

HORIZON THERAPEUTICS, LLC,
Patent Owner.

Case IPR2017-01159
Patent 9,254,278 B2

Before GRACE KARAFFA OBERMANN, DEBORAH KATZ, and RAMA G. ELLURU, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

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

I. BACKGROUND

Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Petitioner") filed a request for an *inter partes* review ("IPR") of claims 1–15 of U.S. Patent No. 9,254,278 B2 (Ex. 1001 ("the '278 patent") (Paper 3 ("Pet.")). Horizon

Therapeutics, Inc. ("Patent Owner") filed a Preliminary Response (Paper 7 ("Prelim. Resp.")).

Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted unless Petitioner shows that there is "a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Petitioner makes that showing with respect to the grounds for unpatentability of claims 1–15. Therefore, we institute review as to claims 1–15.

Our findings of fact and conclusions of law are based on the record developed thus far, prior to Patent Owner's Response under 37 C.F.R. § 42.120. This is not a final decision as to the patentability of any challenged claim. If a final decision is issued in this case, it will be based on the full record developed during trial.

A. Related proceedings

The challenged '278 patent is part of a family of patents involved in litigations and other *inter partes* reviews. The grandparent of the application that became the '278 patent issued as patent 8,404,215 ("the '215 patent"). The parent of the application that became the '278 patent issued as patent 9,095,559 ("the '559 patent"). The application that became the '278 patent is the parent of the application that issued as patent 9,326,966 ("the '966 patent"). Each of these patents is or was the subject of a petition for *inter partes* review.

Specifically, the '215 patent was the subject of IPR2015-01127, filed by Par Pharmaceutical, Inc. ("Par"). IPR2016-00284 filed by Petitioner, was instituted and joined with the IPR2015-01127 proceeding. The claims challenged in that review are similar to the claims challenged in the present

review, wherein fasting blood ammonia levels are measured, compared to the upper limited of normal, and an adjusted dose of drug is administered if "the fasting blood ammonia level is greater than half the upper limit of normal for blood ammonia level." *See Par Pharm., Inc. v. Horizon Therapeutics, LLC*, Case IPR2015-01127, slip op. at 6–7 (PTAB September 29, 2016) (Paper 49). Those claims were held to be unpatentable.

The '559 patent was the subject of IPR2016-00829, filed by Petitioner. The claims challenged in that review also are similar to the claims challenged in the present review, wherein fasting blood ammonia levels are measured and compared to the upper limit of normal, and an adjusted dose of drug is administered relative to the upper limit of normal for fasting plasma ammonia levels. *See* Prelim. Resp. 5. Those claims were held to be unpatentable. *See Lupin, Ltd. v. Horizon Therapeutics, LLC*, Case IPR2016-00829 (PTAB September 26, 2017) (Paper 42).

Petitioner also filed a petition for review of the claims of the '966 patent (IPR2017-01160) on the same day the instant petition was filed. That review is instituted concurrently with this review. *See Lupin Ltd. v. Horizon Therapeutics, LLC*, Case IPR2017-01160 (PTAB September 28, 2017) (Paper 10).

In addition, on July 13, 2017, Par filed petitions for review of the '559 patent, the '278 patent, and the '966 patent (IPR2017-01768, IPR2017-01767, and IPR2017-01769, respectively). A decision on whether to institute trial based on these pending petitions has not yet been made.

We note that patent 8,642,012 is not related by lineage to the currently challenged '278 patent, but the publication of the application from which it issued (publication 2010/0008859 (Ex. 1007)) is cited by Petitioner as prior

art in the current challenges. The claims of patent 8,642,012 were challenged in IPR2015-01117, though it was determined that Petitioner failed to show that the claims were unpatentable. That decision has been appealed to the Court of Appeals for the Federal Circuit (App. No. 2017-1451).[1]

In addition, the parties report the following infringement suits in the District of New Jersey:

Horizon Therapeutics Inc. v. Par Pharmaceutical Inc., Case No. 1:16-cv-3910-RBK-JS (D.N.J.) filed on June 30, 2016, asserting infringement of the '559 patent, the '278 patent, and the '966 patent;

Horizon Therapeutics Inc. v. Lupin Ltd. and Lupin Pharmaceuticals Inc., Case No. 1:15-cv-07624-RBK-JS (D.N.J. filed Oct. 19, 2015), asserting infringement of the '559 patent;

Horizon Therapeutics Inc. v. Lupin Ltd. and Lupin Pharmaceuticals Inc., Civil Action No. 1:16-cv-4438-RBK-JS (D.N.J.) filed on July 21, 2016, asserting infringement of the '278 patent and the '966 patent.

Patent Owner reports the following related patent applications:

application 15/074,625, filed March 18, 2016;
application 15/074,666, filed March 18, 2016;
application 15/074,691, filed March 18, 2016; and
application 15/457,643, filed March 13, 2017.

(*See* Paper 6.)

[1] Infringement of patent 8,642,012 was asserted in the Eastern District of Texas in *Hyperion Therapeutics Inc. v. Par Pharmaceutical, Inc.*, Case No. 2:14-cv-00384-JRG-RSP (E.D. Tex.) filed on April 23, 2014. That case reportedly has been stayed pending the resolution Appeal No. 2017-1451 to the Federal Circuit. Paper 5 at 4.

B. The '278 Patent (Ex. 1001)

The claims of the '278 patent are directed to methods of using a drug, glyceryl tri-[4-phenylbutryate] (also called "HPN-100"), to treat subjects with urea cycle disorders. Patients suffering from urea cycle disorders ("UCDs") are unable to remove excess nitrogen waste, which is normally excreted in the urine. Ex. 1002 ¶ 30. When the body functions properly dietary amino acids are converted first to ammonia and then to urea in the urea cycle and, finally, excreted in the urine. *Id.* ¶ 28. In those with UCDs, the enzymes controlling the urea cycle are deficient, leading to high, toxic levels of ammonia in the blood and possibly brain damage, comma, or death. *Id.* ¶ 29; Ex. 2006 ¶¶ 35–36.

C. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of '278 patent claims 1–15 under 35 U.S.C. § 103 over the following references:

Ground	References	Claims
1	'859 Publication[2]	1–3
2	Blau[3], Simell[4], and the '859 Publication	4–7 and 12–15
3	Blau, Simell, the '859 publication, and Brusilow '979 patent[5]	8–11

[2] U.S. Patent Publication 2010/0008859 A1, was filed on January 7, 2009, and published on January 14, 2010 (Ex. 1007).
[3] PHYSICIAN'S GUIDE TO THE LABORATORY DIAGNOSIS OF METABOLIC DISEASES, 261–76 (Nenad Blau et al. eds., 2d ed. 1996) (Ex. 1006).
[4] Olli Simell et al., *Waste Nitrogen Excretion Via Amino Acid Acylation: Benzoate and Phenylacetate in Lysinuric Protein Intolerance*, 20 PEDIATRIC RESEARCH 1117–21 (1986) (Ex. 1005).
[5] U.S. Patent 5,968,979, issued October 19, 1999 (Ex. 1024).

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