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Paper No. 10
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioners,

v.

HORIZON THERAPEUTICS, LLC,
Patent Owner.

Case IPR2017-01768
Patent 9,095,559 B2

Before TONI R. SCHEINER, LORA M. GREEN, and DEBORAH KATZ, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

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

I. Introduction

Par Pharmaceutical, Inc. ("Petitioner") filed a request for an *inter partes* review ("IPR") of claims 1–15 of U.S. Patent No. 9,095,559 B2 (Ex. 1001 ("the '559 patent") (Paper 3 ("Pet.")). Horizon Therapeutics, LLC ("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 challenges of at least claims 1 and 3. Therefore, we exercise our discretion to institute review of all the challenged claims.

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. The '559 Patent (Ex. 1001)

The claims of the '559 patent are directed to methods of using a drug, glyceryl tri-[4-phenylbutyrate] (also called "GPB" or "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. *See* Ex. 1002 ¶ 30. When the body functions normally, dietary amino acids are converted first to ammonia and then to urea in the urea cycle and, finally, excreted in urine. *See id.* ¶ 31.

In subjects with UCDs, the enzymes controlling the urea cycle are deficient, leading to high, toxic levels of ammonia in the blood and possibly brain damage, coma, or death. *See id.* ¶ 32; Ex. 2006 ¶¶ 36–37. To ameliorate the deficiency of enzymes, GPB and other so-called "nitrogen scavenging drugs" are administered and converted in the body to a compound that binds nitrogen and allows it to be excreted. Ex. 1002 ¶¶ 33–34; Ex. 2006 ¶¶ 42–43. Patent Owner does not dispute that GPB was a

known nitrogen scavenging drug before 2011, when the applications cited as priority documents for the '278 patent were filed.

The '559 patent claims methods related to treating a subject with a UCD, taking into consideration the level of ammonia in his or her blood (plasma) and comparing this level to the half of the "upper limit of normal" for plasma ammonia.

B. Related proceedings

The challenged '559 patent is part of a family of patents involved in litigations and other *inter partes* reviews. The parent of the application that became the '559 patent issued as patent 8,404,215. A continuation application filed from the application that became the '559 patent was issued as patent 9,254,278. Furthermore, a continuation of the application that became the '278 patent issued as patent 9,326,966. Each of these patents claims methods regarding dosing of GPB by comparison of plasma ammonia levels with the upper limit of normal. Each of these patents is or was the subject of a petition for *inter partes* reviews filed by either Par, the Petitioner in this case, or Lupin Ltd. and Lupin Pharmaceuticals Inc. ("Lupin"). A summary of these proceedings follows.

Patent	**Proceeding**	**Petitioner**	**Status**
9,095,559	IPR2016-00829	Lupin	Final Decision – all claims unpatentable (September 26, 2017, Paper 42); Notice of appeal to Federal Circuit filed (November 22, 2017, Paper 43)
9,254,278	IPR2017-01159 IPR2017-01767	Lupin Par	Trial instituted (September 28, 2017, Paper 10)

			Trial instituted (January 30, 2018, Paper 10)
8,404,215	IPR2015-01127 IPR2016-00284	Par Lupin	Final Decision – all claims unpatentable (September 29, 2016, Paper 49) Joined with IPR2015-01127
9,326,966	IPR2017-01160 IPR2017-01769	Lupin Par	Trial instituted (September 28, 2017, Paper 10) Trial instituted (January 30, 2018, Paper 10)

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. 1004)) 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. *See* IPR2015-01117 (PTAB November 3, 2016) (Paper 53). That decision has been appealed to the Court of Appeals for the Federal Circuit (App. No. 2017-1451).[1]

In addition, the following infringement suits in the District of New Jersey have been reported as related to this proceeding (*see* Pet. 11):

[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 was reportedly stayed pending the resolution Appeal No. 2017-1451 to the Federal Circuit. *See* IPR2017-01159, Paper 5 at 4.

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 is also related.

In addition, patent application 15/457,643, filed March 13, 2017, is related as a continuation of the application that issued as the '559 patent.

C. Asserted Grounds of Unpatentability

Petitioner challenges all of the claims of the '559 patent under four grounds as follows:

Ground	References	Claims
1	Fernandes (Ex. 1015)[2] in view of the '859 Publication (Ex. 1004)[3] optionally in view of Blau (Ex. 1006)[4], Simell (Ex. 1007)[5] and/or Lee (Ex. 1010)[6]	1, 2, 4, 7–10, 12, and 13

[2] INBORN METABOLIC DISEASES DIAGNOSIS AND TREATMENT, 214–22 (John Fernandes et al., eds., 3d ed. 2002) (Ex. 1015).
[3] U.S. Patent Publication 2010/0008859 A1, filed January 7, 2009, published January 14, 2010 (Ex. 1004).
[4] PHYSICIAN'S GUIDE TO THE LABORATORY DIAGNOSIS OF METABOLIC DISEASES, 261–76 (Nenad Blau et al. eds., 2d ed. 1996) (Ex. 1006).
[5] 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. 1007).
[6] Brendan Lee et al., *Phase 2 comparison of a novel ammonia scavenging agent with sodium phenylbutyrate in patients with urea cycle disorders: Safety, pharmacokinetics and ammonia control*, 100 MOLECULAR GENETICS AND METABOLISM, 221–228 (2010) (Ex. 1010).

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