

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PAR PHARMACEUTICAL, INC.,  
Petitioners,

v.

HORIZON THERAPEUTICS, LLC,  
Patent Owner.

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Case IPR2017-01767  
Patent 9,254,278 B2

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Before DEBORAH KATZ, GRACE KARAFFA OBERMANN, 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

Par Pharmaceutical, Inc. (“Petitioner” or “Par”) 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,

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 grounds for unpatentability for at least claim 1. We institute review of 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 ’278 Patent (Ex. 1001)*

The claims of the ’278 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. Ex. 1002 ¶ 28. When the body functions normally, dietary amino acids are converted to ammonia and then to urea in the urea cycle and, finally, excreted in urine. *Id.* ¶ 29.

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. *Id.* ¶ 30; Ex. 2006 ¶¶ 37–38. GPB and other so-called “nitrogen scavenging drugs” are used to treat UCDs because these drugs are converted in the body to a compound that binds nitrogen and

allows nitrogen to be excreted. Ex. 1002 ¶¶ 31–32; Ex. 2006 ¶ 43–44.

Patent Owner does not dispute that GPB was a known nitrogen scavenging drug before 2011, when the applications cited as priority for the '278 patent were filed. *See* Ex. 1004.

The '278 patent claims methods of treating a subject with urea cycle disorders by administering GPB. In claim 1 of the '278 patent, the amount of GPB administered is sufficient to produce an amount of ammonia in the plasma, called a “plasma ammonia level,” that is within a recited target range. In the other claims of the '278 patent, GPB is administered on the condition that the plasma ammonia level is within a certain range.

*B. 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 parent of the application that became the '278 patent issued as patent 9,095,559. The application that became the '278 patent is the parent of the application that 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
9,254,278	IPR2017-01159	Lupin	Trial instituted (September 28, 2017, Paper 10)

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8,404,215	IPR2015-01127	Par	Final Decision – all claims unpatentable (September 29, 2016, Paper 49)
	IPR2016-00284	Lupin	Joined with IPR2015-01127
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)
	IPR2016-01768	Par	Trial instituted (January 30, 2018, Paper 10)
9,326,966	IPR2017-01160	Lupin	Trial instituted (September 28, 2017, Paper 10)
	IPR2017-01769	Par	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, and 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).<sup>1</sup>

The following infringement suits in the District of New Jersey have been reported as related to this proceeding because they involved the '278 patent or the patents related to it:

*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; and

*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.

*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, 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 '278 patent.

### C. Asserted Grounds of Unpatentability

Petitioner challenges the patentability of '278 patent claims 1–15 under the following grounds:

Ground	Basis	References	Claims
1	35 U.S.C. § 102(b)	'859 Publication (Ex. 1004) <sup>2</sup>	1–3

<sup>1</sup> 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.

<sup>2</sup> U.S. Patent Publication 2010/0008859 A1, was filed on January 7, 2009, and published on January 14, 2010 (Ex. 1004).

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