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Paper 13
Entered: November 4, 2015

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioner,

v.

HORIZON THERAPEUTICS, INC.,[1]
Patent Owner.

Case IPR2015-01117
Patent 8,642,012 B2

Before TONI R. SCHEINER, DEBORAH KATZ, and
GRACE KARAFFA OBERMANN, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

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

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[1] "[E]ffective May 7, 2015, the name of Hyperion Therapeutics, Inc., was changed to Horizon Therapeutics, Inc. . . . Accordingly, Horizon Therapeutics, Inc. . . . is the Patent Owner of U.S. Patent No. 8,642,012." Paper 5, 2.

I. INTRODUCTION

Par Pharmaceutical, Inc. ("Petitioner") filed a Petition (Paper 2, "Pet.") on April 29, 2015, requesting an *inter partes* review of claims 1–12 of U.S. Patent No. 8,642,012 B2 (Ex. 1001, "the '012 patent"). Horizon Therapeutics, Inc. ("Patent Owner") filed a Preliminary Response (Paper 8, "Prelim. Resp.") on August 5, 2015. We have jurisdiction under 35 U.S.C. § 314, 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."

Upon consideration of the information presented in the Petition and the Preliminary Response, we conclude that Petitioner has established a reasonable likelihood that it would prevail in its challenges to claims 1–12 of the '012 patent. Accordingly, we institute an *inter partes* review.

A. Related Proceedings

Patent Owner filed suit against Petitioner, alleging infringement of the '012 patent and U.S. Patent No. 8,404,215 B1 ("the '215 patent) in *Hyperion Therapeutics, Inc. v. Par Pharmaceutical, Inc.*, Case No. 2:14-CV-384-JRG-RSP (E.D. Tex.). Pet. 7; Paper 5, 3. In addition, concurrently with the Petition under consideration here, Petitioner filed a petition challenging the claims of the '215 patent (IPR2015-01127), but represents that that patent is not related to the '012 patent. Pet. 7.

B. The Asserted Grounds of Unpatentability

Petitioner asserts the challenged claims are unpatentable on the following grounds. Pet. 12–60:[2]

References	**Basis**	**Claims Challenged**
Brusilow '91,[3] Sherwin,[4] Comte,[5] and Shiple[6]	§ 103	1, 3, 4, 7, 8, 10, 12

[2] Petitioner supports its challenge with a Declaration, executed April 29, 2015, by Neal Sondheimer, M.D., Ph.D. ("Sondheimer Declaration") (Ex. 1002).

[3] Saul W. Brusilow, *Phenylacetylglutamine May Replace Urea as a Vehicle for Waste Nitrogen Excretion*, 29 PEDIATRIC RESEARCH 147–150 (1991) ("Brusilow '91") (Ex. 1012).

[4] Carl P. Sherwin at al., *The Maximum Production of Glutamine by the Human Body as Measured by the Output of Phenylacetylglutamine*, 37 J. BIOL. CHEM. 113–119 (1919) ("Sherwin") (Ex. 1016).

[5] Blandine Comte et al., *Identification of phenylbutyrylglutamine, a new metabolite of phenylbutyrate metabolism in humans*, 37 J. MASS SPECTROM. 581–590 (2002) ("Comte") (Ex. 1025).

[6] George J. Shiple & Carl P. Sherwin, *Synthesis of Amino Acids in Animal Organisms. I. Synthesis of Glycocoll and Glutamine in the Human Organism*, 44 J. AMER. CHEM. SOC. 618–624 (1922) ("Shiple") (Ex. 1017).

References	Basis	Claims Challenged
Brusilow '91 , Sherwin, Shiple, and Fernandes[7]	§ 103	5
Brusilow '91, Sherwin, Shiple, and the '647 patent[8]	§ 103	2, 9
Brusilow '91, Sherwin, Shiple, Kasumov,[9] and the '979 patent[10]	§ 103	6, 11
Brusilow '91and Simell[11]	§ 103	1, 3, 4, 7, 8, 10, 12
Brusilow '91, Simell, and Fernandes	§ 103	5
Brusilow '91, Simell, and the '647 patent	§ 103	2, 9
Brusilow '91, Simell, and Kasumov	§ 103	6, 11

[7] INBORN METABOLIC DISEASES: DIAGNOSIS AND TREATMENT 219–220 (John Fernandes et al. eds., Springer Verlag 3d ed. 2000) ("Fernandes") (Ex. 1011).

[8] U.S. Patent No. 4,284,647, issued August 18, 1981 to Brusilow et al. ("the '647 patent") (Ex. 1018).

[9] Takhar Kasumov et al., *New Secondary Metabolites of Phenylbutyrate in Humans and Rats*, 32 DRUG METABOLISM AND DISPOSITION 10–19 (2004) ("Kasumov") (Ex. 1015).

[10] U.S. Patent No. 5,968,979, issued October 19, 1999 to Brusilow ("the 979 patent") (Ex. 1026).

[11] Olly Simell et al., *Waste Nitrogen Excretion Via Amino Acid Acylation: Benzoate and Phenylacetate in Lysinuric Protein Intolerance*, 20 Pediatric Research 1117–1121 (1986) ("Simell") (Ex. 1005).

References	Basis	Claims Challenged
Brusilow '91	§ 103	1–4, 7, 9, 10, 12
Brusilow '91, Kasumov, and the '979 patent	§ 103	6, 11

C. The '012 Patent (Ex. 1001)

The '012 patent, titled "Methods of Treatment Using Ammonia-Scavenging Drugs," is directed to "treatment of patients with nitrogen retention states, in particular urea cycle disorders (UCDs) . . . [by] administer[ing] compounds that assist in elimination of waste nitrogen from the body." Ex. 1001, 1:18–25. These compounds—or "nitrogen scavenging drugs"[12]—include glyceryl tri-[4-phenylbutyrate] (HPN-100) and phenylbutyric acid (PBA)—both of which are prodrugs that are converted *in vivo* to phenylacetic acid (PAA). *Id.* at 3:61–66.

"For patients with nitrogen retention states such as UCD . . . the body's intrinsic capacity for waste nitrogen excretion is less than the body's waste nitrogen production based on a normal diet that contains significant amounts of protein." *Id.* at 2:22–25. "As a result, nitrogen builds up in the body . . . and usually results in excess ammonia in the blood . . . [which] has various toxic effects." *Id.* at 2:25–28.

[12] The terms "ammonia scavenger" and "nitrogen scavenger" are used interchangeably in the '012 patent. Ex. 1001, 4:6–7.

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