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Paper 32
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,
Petitioner,

v.

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

Case IPR2016-00283
Patent 8,642,012 B2

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

SCHEINER, *Administrative Patent Judge*.

DECISION
Instituting *Inter Partes* Review and
Granting Petitioner's Unopposed Motion for Joinder
37 C.F.R. § 42.108
37 C.F.R. § 42.122(b)

[1] Formerly known as Hyperion Therapeutics, Inc. Paper 9, 1.

I. INTRODUCTION

Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, "Lupin" or "Petitioner") filed a Petition (Paper 1, "Pet.") on December 4, 2015, requesting an *inter partes* review of claims 1–12 of U.S. Patent No. 8,642,012 B2 (Ex. 1001, "the '012 patent"). With its Petition, Lupin timely filed a Motion for Joinder (Paper 4, "Mot."), pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. §§ 42.22 and 42.122(b), seeking to join this proceeding with *Par Pharmaceutical, Inc. v. Horizon Therapeutics, Inc.*, Case IPR2015-01117 ("the Par IPR"), which was instituted on November 4, 2015. Horizon Therapeutics, Inc. ("Patent Owner") did not file a Preliminary Response or an opposition to the Motion for Joinder.

In the Motion for Joinder, Lupin confirms that it seeks review of the same claims at issue in the Par IPR, based solely on the grounds of unpatentability authorized by the Board in the Par IPR. Mot. 4. The petitioner in the Par IPR has not filed an opposition to Lupin's request for joinder.

For the reasons that follow, we institute an *inter partes* review of claims 1–12 of the '012 patent based on the same grounds instituted in the Par IPR. We also grant the Motion for Joinder subject to the conditions discussed below.

The Scheduling Order in place in the Par IPR shall govern the joined proceedings. Par IPR, Paper 14.

A. Additional Related Proceedings

Patent Owner filed suit against Petitioner, alleging infringement of the '012 patent, in *Horizon Therapeutics, Inc. v. Lupin Ltd.*, Case No. 1:15-cv-07624-RBK-JS (D. N.J. filed Oct. 19, 2015). Pet. 7; Paper 9, 2. In addition, concurrently with the Petition under consideration here, Lupin filed a petition challenging the claims of Horizon's U.S. Patent 8,404,215 B1 (IPR2016-00284), but represents that that patent is not related to the '012 patent. Pet. 8.

Patent Owner also filed suit against Par, alleging infringement of the '012 patent in *Hyperion Therapeutics Inc. v. Par Pharmaceutical, Inc.*, Case No. 14-cv-00384-JRG-RSP (E.D. Tex. Filed April 23, 2014)."[2] Pet. 7; Paper 9, 2.

II. ANALYSIS

A. Instituting Review of Claims 1–12 of the '012 Patent

We first address whether the Petition warrants review—only then do we address whether joinder is appropriate. *See* 35 U.S.C. § 315(c) (joinder provision, relating to *inter partes* reviews, requires, as an initial matter, a determination that the petition accompanying the joinder motion warrants institution of review). We have jurisdiction under 35 U.S.C. § 314, which provides that review may be authorized only if "the information presented in

[2] Patent Owner represents that "the district court stayed that case pending resolution of IPR2015-01117 and IPR2015-01127." Paper 9, 2.

the petition . . . and any [preliminary] response . . . 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." 35 U.S.C. § 314(a).

In the Par IPR, we instituted review of claims 1–12 of the '012 patent on the following grounds.

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

[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

The Instant Petition challenges the same claims of the '012 patent as those we instituted on in the Par IPR, based on the same asserted prior art, and four proposed grounds of unpatentability that are substantially identical to the four grounds instituted in the Par IPR. *Compare* Pet. 15–36, *with* the Par IPR, Paper 2 (the "Par Pet."), 15–36.

Moreover, the present Petition involves the same arguments and evidence—including the same witness declaration—that supported our

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[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).

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