

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.  
Petitioner,

v.

HORIZON THERAPEUTICS, INC.,  
Patent Owner.

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Case IPR2016-00284  
Patent 8,404,215 B1

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

KATZ, *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)*

*I. Introduction*

Petitioner, Lupin Ltd. and Lupin Pharmaceuticals, Inc. ("Lupin")  
requests *inter partes* review under 35 U.S.C. § 311 of claims 1–11 of U.S.

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Patent No. 8,404,215 B1 (Ex. 1001, “the ’215 patent”), owned by Horizon Therapeutics, Inc. (“Patent Owner”). Paper 1 (Lupin Pet.”). *Inter partes* review 2015-01127 was previously instituted regarding the same claims of the ’215 patent in light of the Petition filed by Par Pharmaceutical, Inc. (“Par”) and the Preliminary Response filed by Patent Owner. *See* IPR2015-01127 (“Par IPR”), Paper 13. In addition to institution of review, Lupin requests that the proceeding be joined with the IPR2015-01127 proceeding under 35 U.S.C. § 315(c). Paper 4 (“Mot.”).

Patent Owner did not file either a Preliminary Response or an opposition to Lupin’s Motion to Join.

## *II. Additional Related Matters*

Lupin represents that Patent Owner filed a complaint in the United States District Court for the District of New Jersey (Case No. 1:15-cv-07624-RBK-JS) alleging that Lupin infringes three United States patents, including the ’215 patent. Lupin represents that Patent Owner has also asserted the ’215 patent against Par in the United States District Court for the Eastern District of Texas (Case No. 14-cv-00384).

Lupin represents further that it is contemporaneously filing a second petition for *inter partes* review of the ’215 patent, although no other petition challenging the ’215 patent has been identified. (Pet. 7.) Lupin also filed a petition for *inter partes* review of U.S. Patent 9,095,559, which issued from an application that is a divisional of the application from which the ’215 patent issued. *See* IPR2016-00829.

Contemporaneous with this Petition, Lupin also filed a Petition and Motion for Joinder in IPR2016-00283, requesting review of Horizon’s U.S. Patent 8,642,012. The claims of that patent are to subject matter similar to

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the claims of the '215 patent, but the patents do not share prior applications. Like the Petition and Motion for Joinder in this proceeding, Lupin represents that the arguments and evidence presented in IPR2016-00283 are substantially identical to the grounds of challenge raised by Par against the same Horizon patent in IPR2015-01117. *See* IPR2016-00283, Paper 4, 4.

Patent Owner represents that on April 1, 2016, Lupin filed a Petition for *inter partes* review of U.S. Patent 9,095,559, which issued from U.S. Patent Application 13/775,000 as a divisional of the '215 patent. *See* Patent Owner's Updated Mandatory Notices, Paper 10, identifying IPR2016-00829.

### *III. Institution of Review*

Lupin seeks review of claims 1–11 of the '215 patent based on the following grounds:

Ground	References	Claim(s)
1	Fernandes <sup>1</sup> in view of Blau, <sup>2</sup> Simell, <sup>3</sup> and the '859 Publication <sup>4</sup>	1, 3–7, and 9

<sup>1</sup> INBORN METABOLIC DISEASES: DIAGNOSIS AND TREATMENT, 214–22 (J. Fernandes et al. eds., 3d ed. 2000).

<sup>2</sup> PHYSICIAN'S GUIDE TO THE LABORATORY DIAGNOSIS OF METABOLIC DISEASES, 261–76 (Nenad Blau et al. eds., 2d ed. 1996).

<sup>3</sup> Olli Simell et al., Waste Nitrogen Excretion Via Amino Acid Acylation: Benzoate and Phenylacetate in Lysinuric Protein Intolerance, 20 PEDIATRIC RESEARCH 1117–21 (1986).

<sup>4</sup> U.S. Patent Publication No. 2010/0008859 A1, filed January 7, 2009, published January 14, 2010.

2	Fernandes in view of Blau, Simell, and Brusilow '91 <sup>5</sup>	8
3	Fernandes in view of Blau, Simell, and the '859 Publication	10–11
4	Fernandes and Brusilow '84 <sup>6</sup> in view of Blau, and Simell	2, 4–7, 9, and 10

Lupin Pet. 10. These grounds are the same as Grounds 1–4 asserted by Par in the Petition in the Par IPR. *See* Par IPR, Paper 2, 10. Lupin does not assert the grounds for which review was not instituted in the Par IPR. *See* Mot. 4.

Lupin represents, and we find, that Lupin's petition regarding these grounds of review is substantially identical to the Petition filed by Par in the Par IPR. Mot. 4. Lupin also represents that it relies on the same exhibits and the same expert declaration (Declaration of Neal Sondheimer, M.D., Ph.D., Ex. 1002) relied upon by Par in the Par IPR to support its arguments for review. *Id.*

Patent Owner did not file a Preliminary Response regarding Lupin's Petition. Thus, Patent Owner raises no new arguments against institution of review.

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<sup>5</sup> Saul W. Brusilow, Phenylacetylglutamine May Replace Urea as a Vehicle for Waste Nitrogen Excretion, 29 PEDIATRIC RESEARCH 147–150 (1991).

<sup>6</sup> Saul W. Brusilow et al., Treatment of Episodic Hyperammonia in Children with Inborn Errors of Urea Synthesis, 310 THE NEW ENGLAND JOURNAL OF MEDICINE 1630–34 (1984).

For the same reasons that we determined the arguments and supporting evidence put forth in the Par IPR meet the threshold for institution of review of claims 1–11 of the '215 patent under Grounds 1–4 in the Par IPR, we also determine that the substantially identical arguments and evidence put forth by Lupin meet the threshold for institution of review of those same claims under the same grounds. Accordingly, we institute review of claims 1–11 of the '215 patent on the grounds asserted by Lupin.

#### *IV. Joinder*

Having determined that Lupin's Petition warrants institution, we must determine whether to exercise our discretion to join Lupin as a party to the Par IPR.

Under 35 U.S.C. § 315(c),

[i]f the Director institutes an inter partes review, the Director, in his or her discretion, may join as a party to that inter partes review any person who properly files a petition under section 311 that the Director, after receiving a preliminary response under section 313 or the expiration of the time for filing such a response, determines warrants the institution of an inter partes review under section 314.

By regulation, the Director's discretion has been delegated to the Board. 37 C.F.R. § 42.4(a). Therefore, we have discretion to join this proceeding to the instituted Par IPR if we determine that Lupin has met its burden of proving it is entitled to joinder. *See* 37 C.F.R. § 42.122(b); *see also* 37 C.F.R. § 42.20(c) ("The moving party has the burden of proof to establish that it is entitled to the requested relief.").

We note that Lupin represents that neither Patent Owner nor Par opposes joining the proceedings. Mot 1.

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