IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. and LUPIN PHARMACEUTICALS INC.
Petitioners,

v.

HORIZON THERAPEUTICS, INC.

Patent Owner.

U.S. Patent No. 8,642,012 B2 to Scharschmidt, *et al*.
Issue Date: February 4, 2014
Title: Methods of Treatment Using Ammonia-Scavenging Drugs

Inter Partes Review No. IPR2016-00283

MOTION FOR JOINDER
Pursuant to 35 U.S.C. § 315(c), 37 C.F.R. §§ 42.22 and 42.122(b)

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I. STATEMENT OF THE PRECISE RELIEF REQUESTED

Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively "Lupin") respectfully submit this Motion for Joinder, together with a Petition for *Inter Partes* Review of U.S. Patent No. 8,642,012. Pursuant to 35 U.S.C. § 315(c) and 37 C.F.R. § 42.122(b), Lupin requests institution of *inter partes* review (IPR) and joinder with the IPR concerning the same patent in *Par Pharmaceutical, Inc. v. Horizon Therapeutics, Inc.*, Case IPR2015-01117 (the "Par IPR"), which was instituted on November 4, 2015. Joinder is appropriate because it will promote the efficient and consistent resolution of the validity of a single patent, and will not delay the Par IPR trial schedule or prejudice the parties to that IPR. Par and Patent Owner have advised Lupin that they do not oppose Lupin's motion for joinder. Further, as detailed below, Par and Lupin have entered into a cooperation agreement in the event of the joinder of this IPR and the Par IPR.

Lupin's request for joinder is timely, as it is submitted within one month of the November 4, 2015 institution of the Par IPR. 37 C.F.R. §§ 42.22, 42.122(b).

II. STATEMENT OF MATERIAL FACTS

Horizon Therapeutics, Inc. ("Patent Owner") owns U.S. Patent 8,642,012 ("the '012 patent").[1] On November 4, 2015, the Board instituted Par's IPR on the '012 patent on the following four grounds of unpatentability:

> (1) obviousness of claims 1, 3, 4, 7, 8, 10 and 12 over Brusilow, *Phenylacetylglutamine May replace Urea as a Vehicle for Waste Nitrogen Excretion*, 29 Pediatric Research 147–150 (1991) ("*Brusilow '91*") in view of Sherwin, et 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*"), Comte, et al., *Identification of phenylbutyrylglutamine, a new metabolite of phenylbutyrate metabolism in humans,* J. Mass. Spectrom. 2002:37:581-90 ("Comte"), and Shiple, *et al*., *Synthesis of Amino Acids in Animal Organisms. I. Synthesis of Glycocoll and Glutamine in the Human Organism*, 44 J. American Chem. Society, 618–624 (1922) ("*Shiple*");

[1] At the time of issuance, the '012 patent was assigned to Hyperion Therapeutics, Inc., which changed its name to Horizon Therapeutics, Inc. effective on May 7, 2015.

(2) obviousness of claim 5 over *Brusilow '91* in view of *Sherwin*, *Shiple*, and Fernandes, Saudubray Berghe (editors), *Inborn Metabolic Diseases Diagnosis and Treatment,* 219-220 (3d ed. 2000) ("*Fernandes*");

(3) obviousness of claims 2 and 9 over *Brusilow '91* in view of *Sherwin*, *Shiple*, and U.S. Patent No. 4,284,647 to Brusilow et al. ("the '647 Patent"); and

(4) obviousness of claims 6 and 11 over *Brusilow '91* in view of *Sherwin*, *Shiple*, Kasumov, *et al., New Secondary Metabolites of Phenylbutyrate in Humans and Rats,* 32 Drug Metabolism and Disposition, 10–19 (2004) ("*Kasumov*"), and U.S. Patent No. 5,968,979 to Brusilow ("the '979 Patent").

See Institution of *Inter Partes* Review, Par IPR Paper No. 13, November 4, 2015.

III. STATEMENT OF REASONS FOR RELIEF REQUESTED

A. Legal Standard

The Leahy-Smith America Invents Act (AIA) permits joinder of like review proceedings, *e.g.* an IPR may be joined with another IPR. 37 C.F.R. § 42.122(a). The Board has discretion to join parties to an existing IPR. 35 U.S.C. § 315(c). In deciding whether to exercise its discretion, the Board considers factors including: (1) the movant's reasons why joinder is appropriate; (2) whether the new petition

presents any new grounds of unpatentability; (3) what impact (if any) joinder would have on the trial schedule for the existing review; and (4) how briefing and discovery may be simplified. *Dell Inc. v. Network-1 Security Solutions, Inc*., Decision on Motion for Joinder, IPR2013-00385, Paper No. 17 at 4 (July 29, 2013). The Board should consider "the policy preference for joining a party that does not present new issues that might complicate or delay an existing proceeding." *Id.* at 10. Under this framework, joinder of the present Lupin Petition for IPR with the Par IPR is appropriate.

B. Joinder is Appropriate Because Lupin's Petition Contains No New Grounds of Unpatentability and Joinder Will Not Impact the Trial Schedule

Joinder will not impact the Board's ability to complete its review of the '012 patent in a timely manner, as Lupin raises no issues that are not already before the Board in the Par IPR. Lupin's Petition seeks review of the same claims at issue in the Par IPR (claims 1–12 of the '012 patent), based on the same grounds and combinations of prior art. Indeed, Lupin's Petition is substantively identical to Par's petition (Par IPR, Paper No. 1), except that Lupin updated the Mandatory Notices and omitted prior art combinations not instituted by the Board in the Par IPR. There are no other substantive differences. Further, Lupin relies on the same exhibits and same expert declaration of Dr. Sondheimer that Par submitted in

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