

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.

IPR2016-00283

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,642,012
PURSUANT TO §§ 35 U.S.C. 311-319 AND 37 C.F.R. § 42**

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List of Exhibits

- Ex. 1001: U.S. Patent No. 8,642,012 to Scharschmidt (“the ‘012 patent), filed January 7, 2009, issued February 4, 2014.
- Ex. 1002: Declaration of Dr. Neal Sondheimer.
- Ex. 1003: *Curriculum vitae* of Dr. Neal Sondheimer.
- Ex. 1004: Reserved.
- Ex. 1005: 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. 1006: Reserved.
- Ex. 1007: Reserved.
- Ex. 1008: Reserved.
- Ex. 1009: Reserved.
- Ex. 1010: Reserved.
- Ex. 1011: Fernandes, Saudubray Berghe (editors), *Inborn Metabolic Diseases Diagnosis and Treatment*, 219-220 (3d ed. 2000). (“*Fernandes*”).
- Ex. 1012: Brusilow, *Phenylacetylglutamine May Replace Urea as a Vehicle for Waste Nitrogen Excretion*, 29 *Pediatric Research*, 147-150 (1991). (“*Brusilow ‘91*”).
- Ex. 1013: Reserved.
- Ex. 1014: Reserved.
- Ex. 1015: Kasumov, et al., *New Secondary Metabolites of Phenylbutyrate in Humans and Rats*, 32 *Drug Metabolism and Disposition*, 10-19 (2004). (“*Kasumov*”).
- Ex. 1016: 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*”).

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- Ex. 1017: 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*”).
- Ex. 1018: U.S. Patent No. 4,284,647 to Brusilow *et al.*, filed March 31, 1980, issued August 18, 1981 (“the ‘647 patent”).
- Ex. 1019: Reserved.
- Ex. 1020: Reserved.
- Ex. 1021: Prosecution History of the ‘012 patent.
- Ex. 1022: Joint Claim Construction filed March 13, 2015 in Eastern District of Texas District Court, Case 2:14-cv-00384.
- Ex. 1023: Piscitelli, *et al.*, *Disposition of Phenylbutyrate and its Metabolites, Phenylacetate and Phenylacetylglutamine*, 35 J. Clin. Pharmacol., 368-373 (1995). (“*Piscitelli*”).
- Ex. 1025: Comte, *et al.*, *Identification of phenylbutyrylglutamine, a new metabolite of phenylbutyrate metabolism in humans*, J. Mass. Spectrom. 2002:37:581-90. (“*Comte*”).
- Ex. 1026: U.S. Patent No. 5,968,979 to Brusilow, filed Feb. 7, 1995, issued Oct. 19, 1999 (“the ‘979 patent”).
- Ex. 1027: Collins *et al.*, *Oral Sodium Phenylbutyrate Therapy in Homozygous (3 Thalassemia: A Clinical Trial*, 85 Blood 43 (1995). (“*Collins*”).

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