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, LLC

Patent Owner.

IPR2017-01160

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,326,966 <u>PURSUANT TO §§ 35 U.S.C. 311-319 AND 37 C.F.R. § 42</u>

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Dr. Gregory Enns
April 23, 2018
Exhibit No. 1027
Megan F. Alvarez
RPR, CSR No. 12470



LUPIN EX. 1027

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List of Exhibits

Ex. No.	Description
Ex. 1001	U.S. Patent No. 9,254,278 to Scharschmidt et al. ("'278 Patent")
Ex. 1002	Declaration of Keith Vaux, M.D.
Ex. 1003	U.S. Patent No. 9,326,966 to Scharschmidt et al. ("'966 Patent")
Ex. 1004	Brusilow, et al., Treatment of Episodic Hyperammonemia in Children with Inborn Errors of Urea Synthesis, 310 The New England Journal of Medicine, 1630-1634 (1984). ("Brusilow '84").
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	Blau, Duran, Blaskovics, Gibson (editors), <i>Physician's Guide to the Laboratory Diagnosis of Metabolic Diseases</i> , 261-276 (2d ed. 1996). ("Blau").
Ex. 1007	U.S. Patent Publication No. 2010/0008859, filed January 7, 2009, published January 14, 2010. (the "'859 Publication").
Ex. 1008	Scientific Discussion for Ammonaps, EMEA 2005, available at http://www.ema.europa.eu/docs/en_GB/document_library/EPARScientific_Discussion/human/000219/WC500024748.pdf. ("Scientific Discussion").
Ex. 1009	Dixon, et al., Intercurrent Illness in Inborn Errors of Intermediary Metabolism, 67 Archives of Disease in Childhood, 1387-1391 (1992). ("Dixon").
Ex. 1010	UMass Memorial Laboratories, Lab Updates, February 2007, Measurement of Ammonia in Blood
Ex. 1011	Brusilow, Phenylacetylglutamine May Replace Urea as a Vehicle for Waste Nitrogen Excretion, 29 Pediatric Research, 147-150 (1991). ("Brusilow '91").



Ex. 1012	Yajima, et al., Diurnal Fluctuation of Blood Ammonia Levels in Adult-Type Citrullinemia, 137 Tohoku J. Exp. Med., 213-220 (1982). ("Yajima").
Ex. 1013	Batshaw, et al., Treatment of Carbamyl Phosphate Synthetase Deficiency with Keto Analogues of Essential Amino Acids, 292 The New England J. Medicine, 1085-1090 (1975). ("Batshaw").
Ex. 1014	Kasumov, et al., New Secondary Metabolites of Phenylbutyrate in Humans and Rats, 32 Drug Metabolism and Disposition, 10-19 (2004). ("Kasumov").
Ex. 1015	Barsotti, Measurement of Ammonia in Blood, 138 J Pediatrics, S11- S20 (2001). ("Barsotti").
Ex. 1016	Berry, et al., Long-term management of patients with urea cycle disorders, Journal of Pediatrics, Vol. 138, No. 1, S56–S61 (2001). ("Berry").
Ex. 1017	Levin, et al., <i>Hyperammonaemia A Variant Type of Deficiency of Liver Ornithine Transcarbamylase</i> , Arch. Dis. Childh., 1964, 44. 162 (1968).
Ex. 1018	Prosecution History of U.S. Patent No. 8,404,215.
Ex. 1019	Excerpt from Stedman's Medical Dictionary (Lippincott Williams & Wilkins 2006).
Ex. 1020	Buphenyl [®] label, Physician's Desk Reference, 60 th ed. (2006) at 3327-28.
Ex. 1021	Ammonul [®] label, Physician's Desk Reference, 60 th ed. (2006) at 3323-26.
Ex. 1022	Prosecution History of U.S. Patent No. 9,254,278.
Ex. 1023	Curriculum vitae of Keith Vaux, M.D.
Ex. 1024	U.S. Patent No. 5,968,979 ("Brusilow '979 Patent").
Ex. 1025	Prosecution History of U.S. Patent No. 9,326,966.



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