

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.

IPR2017-01159

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,254,278
PURSUANT TO §§ 35 U.S.C. 311-319 AND 37 C.F.R. § 42**

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LUPIN EX. 1026

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Ex. 1002	Declaration of Keith Vaux, M.D.
Ex. 1003	U.S. Patent No. 9,326,966 to Scharschmidt <i>et al.</i> (“’966 Patent”)
Ex. 1004	Brusilow, <i>et al.</i> , <i>Treatment of Episodic Hyperammonemia in Children with Inborn Errors of Urea Synthesis</i> , 310 <i>The New England Journal of Medicine</i> , 1630-1634 (1984). (“ <i>Brusilow ’84</i> ”).
Ex. 1005	Simell, <i>et al.</i> , <i>Waste Nitrogen Excretion Via Amino Acid Acylation: Benzoate and Phenylacetate in Lysinuric Protein Intolerance</i> , 20 <i>Pediatric Research</i> , 1117-1121 (1986). (“ <i>Simell</i> ”).
Ex. 1006	Blau, Duran, Blaskovics, Gibson (editors), <i>Physician’s Guide to the Laboratory Diagnosis of Metabolic Diseases</i> , 261-276 (2d ed. 1996). (“ <i>Blau</i> ”).
Ex. 1007	U.S. Patent Publication No. 2010/0008859, filed January 7, 2009, published January 14, 2010. (<i>the “’859 Publication”</i>).
Ex. 1008	Scientific Discussion for Ammonaps, EMEA 2005, available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Scientific_Discussion/human/000219/WC500024748.pdf . (“ <i>Scientific Discussion</i> ”).
Ex. 1009	Dixon, <i>et al.</i> , <i>Intercurrent Illness in Inborn Errors of Intermediary Metabolism</i> , 67 <i>Archives of Disease in Childhood</i> , 1387-1391 (1992). (“ <i>Dixon</i> ”).
Ex. 1010	UMass Memorial Laboratories, Lab Updates, February 2007, Measurement of Ammonia in Blood
Ex. 1011	Brusilow, <i>Phenylacetylglutamine May Replace Urea as a Vehicle for Waste Nitrogen Excretion</i> , 29 <i>Pediatric Research</i> , 147-150 (1991). (“ <i>Brusilow ’91</i> ”).

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

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