

**IN THE 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.**

**Petitioners,**

**v.**

**HORIZON THERAPEUTICS, INC.**

**Patent Owner.**

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**IPR2016-00829**

**PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,095,559  
PURSUANT TO §§ 35 U.S.C. 311-319 AND 37 C.F.R. § 42**

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<b>Ex. No.</b>	<b>Description</b>
Ex. 1001	U.S. Patent No. 9,095,559 to Scharschmidt <i>et al.</i> (“’559 patent”)
Ex. 1002	Declaration of Keith Vaux, M.D.
Ex. 1003	<i>Curriculum vitae</i> of Keith Vaux, M.D.
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 <a href="http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-">http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-</a>

	<p>_Scientific_Discussion/human/000219/WC500024748.pdf.</p> <p>(<i>“Scientific Discussion”</i>).</p>
Ex. 1009	<p>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>).</p>
Ex. 1010	<p>UMass Memorial Laboratories, Lab Updates, February 2007, Measurement of Ammonia in Blood</p>
Ex. 1011	<p>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>).</p>
Ex. 1012	<p>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). (<i>“Yajima”</i>).</p>
Ex. 1013	<p>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). (<i>“Batshaw”</i>).</p>
Ex. 1014	<p>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). (<i>“Kasumov”</i>).</p>

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