

**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.,

Petitioner

v.

HORIZON THERAPEUTICS, LLC,

Patent Owner

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Case IPR2017-01160  
Patent 9,326,966

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**PATENT OWNER'S UPDATED EXHIBIT LIST**

Pursuant to 37 C.F.R. § 42.63 (e), the Patent Owner hereby provides an updated exhibit list:

Ex. No.	Description
2001	Declaration of Dr. Gregory M. Enns, M.D., <i>Lupin Ltd. et al. v. Horizon Therapeutics, Inc.</i> , IPR2016-00829, Exhibit 2006, filed February 10, 2017.
2002	Statutory Disclaimer under 37 C.F.R. § 1.321(a) of claims 12, 14 and 15 of U.S. Patent 9,326,966, filed June 28, 2017.
2003	Simell, “Lysinuric Protein Intolerance and Other Cationic Aminoacidurias,” in <i>The Metabolic &amp; Molecular Bases of Inherited Disease</i> , Ch. 192, pp. 4933-4956 (Scriver <i>et al.</i> , eds., 8th ed. 2001). (“Simell 2001”).
2004	Singh <i>et al.</i> , “Nutritional Management of Urea Cycle Disorders,” <i>Crit. Care. Clin.</i> 21:S27-35 (2005). (“Singh”).
2005	U.S. Patent No. 9,095,559. (“559 Patent”).
2006	Declaration of Dr. Gregory M. Enns, M.D.
2007	Curriculum <i>vitae</i> of Dr. Gregory M. Enns, M.D.
2008	Ari Auron, Patrick D. Brophy, “Hyperammonemia in Review: Pathophysiology, Diagnosis, and Treatment,” <i>Pediatric Nephrology</i> , 27:207-22 (2012). (“Auron”).
2009	Mark L. Batshaw, <i>et al.</i> , “Alternative Pathway Therapy for Urea Cycle Disorders: Twenty Years Later,” <i>J. Pediatrics</i> , 38:S46-S55 (2001). (“Batshaw”).
2010	Nancy E. Maestri, <i>et al.</i> , “Prospective Treatment of Urea Cycle Disorders,” <i>J. of Pediatrics</i> , 119:923-28, no. 6 (1991). (“Maestri”).
2011	Nancy E. Maestri, <i>et al.</i> , “Plasma Glutamine Concentration: A Guide in the Management of Urea Cycle Disorders,” <i>J. Pediatrics</i> , 121:259–61, no. 2 (1992). (“Maestri 1992”).

<b>2012</b>	U.S. Patent Publication 2012/0022157 A1, filed August 27, 2009, published January 26, 2012. (“157 App”).
<b>2013</b>	Mendel Tuchman & Mark L. Batshaw, “Management of Inherited Disorders of Ureagenesis,” <i>The Endocrinologist</i> 12:99–109, no. 2 (2002). (“Tuchman”).
<b>2014</b>	Guoyao Wu, “Amino Acids: Metabolism, Functions, and Nutrition,” <i>Amino Acids</i> 37:1–17 (2009). (“Wu”).
<b>2015</b>	Alexander Broomfield & Stephen Grunewald, “How to use Serum Ammonia,” <i>Archives of Disease in Childhood—Education and Practice</i> 97:72–77 (2012). (“Broomfield”).
<b>2016</b>	Fumino Endo, <i>et al.</i> , “Clinical Manifestations of Inborn Errors of the Urea Cycle and Related Metabolic Disorders During Childhood,” <i>J. Nutrition</i> 134:1605S–09S (2004). (“Endo”).
<b>2017</b>	Gregory M. Enns, “Nitrogen Sparing Therapy Revisited 2009,” <i>Molecular Genetics and Metabolism</i> 100:S65–S71 (2010). (“Enns 2010”).
<b>2018</b>	Francois Feillet & J. V. Leonard, “Alternative Pathway Therapy for Urea Cycle Disorders,” <i>J. Inherited Metabolic Disease</i> , Supplement 1, 21:101–111 (1998). (“Feillet”).
<b>2019</b>	Johannes Haberle, <i>et al.</i> , “Suggested Guidelines for the Diagnosis and Management of Urea Cycle Disorders,” <i>Orphanet J. Rare Diseases</i> , 7:32, 1–30 (2012). (“Haberle”).
<b>2020</b>	Johannes Haberle, “Clinical Practice: The Management of Hyperammonemia,” <i>Eur. J. of Pediatrics</i> 170:21–34 (2011). (“Haberle Clinical”).
<b>2021</b>	J.V. Leonard & A. A. M. Morris, “Urea Cycle Disorders,” <i>Seminars in Neonatology</i> 7:27–35 (2002). (“Leonard”).
<b>2022</b>	Ann-Kaisa Niemi & Gregory M. Enns, “Sodium Phenylacetate and Sodium Benzoate in the Treatment of Neonatal Hyperammonemia,” <i>NeoReviews</i> , 7:e486–e95, no. 9 (2006). (“Niemi”).

<b>2023</b>	Marshall Summar & Mendel Tuchman, “Proceedings of a Consensus Conference for the Management of Patients with Urea Cycle Disorders,” <i>J. Pediatrics</i> , 138:S6–S10 (2001). (“Summar”).
<b>2024</b>	Saul W. Brusilow & Nancy E. Maestri, “Urea Cycle Disorders: Diagnosis, Pathophysiology, and Therapy,” <i>Advances in Pediatrics</i> 43:127–70 (1996). (“Brusilow 1996”).
<b>2025</b>	Colloquium, “Consensus Statement from a Conference for the Management of Patients with Urea Cycle Disorders,” <i>J. Pediatrics</i> , Supplement 1, 138:S1–S5 (2001). (“Consensus”).
<b>2026</b>	“Specialties of Genetics,” <i>Am. Board of Medical Genetics and Genomics</i> (last accessed Jan. 17, 2017), <a href="http://abmgg.org/pages/training_specialties.shtml">http://abmgg.org/pages/training_specialties.shtml</a> . (“ABMGG”).
<b>2027</b>	“About Us,” <i>Urea Cycle Disorders Consortium</i> (last accessed Jan. 17, 2017), <a href="https://www.rarediseasesnetwork.org/cms/ucdc/About-Us">https://www.rarediseasesnetwork.org/cms/ucdc/About-Us</a> .
<b>2028</b>	Gregory M. Enns, <i>et al.</i> , “Survival After Treatment with Phenylacetate and Benzoate for Urea-Cycle Disorders,” <i>The New England Journal of Medicine</i> 356:2282–92 (2007). (“Enns”).
<b>2029</b>	Gregory M. Enns & Tina M. Cowan, “Hyperammonemia,” in <i>Signs and Symptoms of Genetic Conditions: A Handbook</i> , ch. 18, 261–279 (Louanne Hudgins <i>et al.</i> , eds., 2014). (“Enns 2014”).
<b>2030</b>	Michael Msall, <i>et al.</i> , “Neurologic Outcome in Children with Inborn Errors of Urea Synthesis,” <i>The New England Journal of Medicine</i> 310:1500–1505 (1984). (“Msall”).
<b>2031</b>	B.D. Cheson, <i>et al.</i> , “Novel Therapeutic Agents for the Treatment of Myelodysplastic Syndromes,” <i>Seminars in Oncology</i> , 27:560–77, no. 5 (2000). (“Cheson”).
<b>2032</b>	Fernando Scaglia, <i>et al.</i> , “Effect of Alternative Pathway Therapy on Branched Chain Amino Acid Metabolism in Urea Cycle Disorder Patients,” <i>Molecular Genetics and Metabolism, Supplement 1</i> , 81:S79-S85 (2004). (“Scaglia”).

<b>2033</b>	Saul W. Brusilow & Arthur L. Horwich, “Urea Cycle Enzymes,” in <i>The Online Metabolic and Molecular Bases of Inherited Disease</i> , Ch. 85, pp. 1–89 (David Valle et al. eds., 2015). (“Brusilow Online”).
<b>2034</b>	Transcript of January 31, 2017 Deposition of Dr. Keith Vaux, <i>Lupin Ltd. et al. v. Horizon Therapeutics, Inc.</i> , IPR2016-00829.
<b>2035</b>	Jennifer Seminara, <i>et al.</i> , “Establishing a consortium for the study of rare diseases: The Urea Cycle Disorders Consortium,” <i>Molecular Genetics and Metabolism</i> 100:S97-S105 (2010). (“Seminara”).
<b>2036</b>	<i>RESERVED.</i>
<b>2037</b>	Keith K. Vaux, “Book Reviews: A Clinical Guide to Inherited Metabolic Diseases, 2nd ed.,” <i>J. Heredity</i> 94:195 (2) (2003). (“Vaux Book Review”).
<b>2038</b>	<i>RESERVED.</i>
<b>2039</b>	<i>RESERVED.</i>
<b>2040</b>	Marshall Summar, “Current Strategies for the Management of Neonatal Urea Cycle Disorders,” <i>J. Pediatrics</i> 138:S30–S39 (2001). (“Summar 2001”).
<b>2041</b>	RAVICTI® product insert, <a href="http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/203284s004lbl.pdf">http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/203284s004lbl.pdf</a> . (“Ravicti”).
<b>2042</b>	Marshall L. Summar, <i>et al.</i> , “The Incidence of Urea Cycle Disorders,” <i>Molecular Genetics and Metabolism</i> 110:179–180 (2013). (“Summar 2013”).
<b>2043</b>	Marshall L. Summar, <i>et al.</i> , “Diagnosis, Symptoms, Frequency and Mortality of 260 Patients with Urea Cycle Disorders from a 21-Year, Multicentre Study of Acute Hyperammonaemic Episodes,” <i>Acta Paediatrica</i> 97:1420–25 (2008). (“Summar 2008”).
<b>2044</b>	Bridget Wilcken, “Problems in the Management of Urea Cycle Disorders,” <i>Molecular Genetics and Metabolism</i> 81:S86–S91 (2004). (“Wilcken”).

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