UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.,

Petitioner

v.

HORIZON THERAPEUTICS, LLC,

Patent Owner

Case IPR2017-01160
Patent 9,326,966

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., *Lupin Ltd. et al. v. Horizon Therapeutics, Inc.*, 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 *The Metabolic & Molecular Bases of Inherited Disease*, Ch. 192, pp. 4933-4956 (Scriver *et al.*, eds., 8th ed. 2001). ("Simell 2001").
2004	Singh *et al.*, "Nutritional Management of Urea Cycle Disorders," *Crit. Care. Clin*. 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 *vitae* of Dr. Gregory M. Enns, M.D.
2008	Ari Auron, Patrick D. Brophy, "Hyperammonemia in Review: Pathophysiology, Diagnosis, and Treatment," *Pediatric Nephrology*, 27:207-22 (2012). ("Auron").
2009	Mark L. Batshaw, *et al.*, "Alternative Pathway Therapy for Urea Cycle Disorders: Twenty Years Later," *J. Pediatrics*, 38:S46-S55 (2001). ("Batshaw").
2010	Nancy E. Maestri, *et al.*, "Prospective Treatment of Urea Cycle Disorders," *J. of Pediatrics*, 119:923-28, no. 6 (1991). ("Maestri").
2011	Nancy E. Maestri, *et al.*, "Plasma Glutamine Concentration: A Guide in the Management of Urea Cycle Disorders," *J. Pediatrics*, 121:259–61, no. 2 (1992). ("Maestri 1992").

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

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

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

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