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 IPR2017-01159
Patent 9,254,278

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	*RESERVED*.
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").

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.