

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.,

Petitioner

v.

HORIZON THERAPEUTICS, INC.,

Patent Owner

Case IPR 2016-00829

Patent 9,095,559

PATENT OWNER'S EXHIBIT LIST
(as of February 10, 2017)

Exhibit No.	Description
2001	Complaint for Patent Infringement, <i>Horizon Therapeutics, Inc. v. Lupin Ltd. et al.</i> , Civil Action No. 15-cv-07624-RBK-JS (D.N.J. filed Oct. 19, 2015).
2002	Amended Complaint for Patent Infringement, <i>Horizon Therapeutics, Inc. v. Lupin Ltd. et al.</i> , Civil Action No. 15-cv-07624-RBK-JS (D.N.J. filed Apr. 6, 2016).
2003	Olli Simell, <i>Lysinuric Protein Intolerance and Other Cationic Aminoacidurias</i> , in <i>THE METABOLIC & MOLECULAR BASES OF INHERITED DISEASE</i> at 4949 (Charles R. Scriver et al. eds., 8 th ed. 2001).
2004	Rani H. Singh et al., <i>Nutritional Management of Urea Cycle Disorders</i> , 21 <i>CRITICAL CARE CLINICS</i> , no. 4S, S27-S35 (2005). (“Singh”).
2005	Portion of Invalidity Contentions (pages 16-22), served Nov. 13, 2014 in <i>Hyperion Therapeutics, Inc. v. Par Pharma., Inc.</i> , 2:14-cv-00384-JRG-RSP (E.D. Tex.)
2006	Declaration of Gregory M. Enns, M.D.
2007	Curriculum vitae of Gregory M. Enns, M.D.
2008	Ari Auron, Patrick D. Brophy, <i>Hyperammonemia in Review: Pathophysiology, Diagnosis, and Treatment</i> , 27 <i>PEDIATRIC NEPHROLOGY</i> , Issue 2, 207–22 (2012). (“Auron”).
2009	Mark L. Batshaw, et al., <i>Alternative Pathway Therapy for Urea Cycle Disorders: Twenty Years Later</i> , 38 <i>THE JOURNAL OF PEDIATRICS</i> , no. 1, S46–S55 (2001). (“Batshaw”).
2010	Nancy E. Maestri, et al., <i>Prospective Treatment of Urea Cycle Disorders</i> , 119 <i>THE JOURNAL OF PEDIATRICS</i> , no. 6, 923–28 (1991). (“Maestri”).

2011	Nancy E. Maestri, et al., <i>Plasma Glutamine Concentration: A Guide in the Management of Urea Cycle Disorders</i> , 121 THE JOURNAL OF PEDIATRICS, no. 2, 259–61 (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, <i>Management of Inherited Disorders of Ureagenesis</i> , 12 THE ENDOCRINOLOGIST 99–109 (2002). (“Tuchman”).
2014	Guoyao Wu, <i>Amino Acids: Metabolism, Functions, and Nutrition</i> , 37 AMINO ACIDS 1–17 (2009). (“Wu”).
2015	Alexander Broomfield & Stephen Grunewald, <i>How to use Serum Ammonia</i> , 97 ARCHIVES OF DISEASE IN CHILDHOOD—EDUCATION AND PRACTICE 72–77 (2012). (“Broomfield”).
2016	Fumino Endo, et al., <i>Clinical Manifestations of Inborn Errors of the Urea Cycle and Related Metabolic Disorders During Childhood</i> , 134 THE JOURNAL OF NUTRITION 1605S–09S (2004). (“Endo”)
2017	Gregory M. Enns, <i>Nitrogen Sparing Therapy Revisited 2009</i> , 100 MOLECULAR GENETICS AND METABOLISM S65–S71 (2010). (“Enns 2010”).
2018	Francois Feillet & J. V. Leonard, <i>Alternative Pathway Therapy for Urea Cycle Disorders</i> , 21 Journal of Inherited Metabolic Disease, Supplement 1, 101–111 (1998). (“Feillet”).
2019	Johannes Haberle, et al., <i>Suggested Guidelines for the Diagnosis and Management of Urea Cycle Disorders</i> , 7 ORPHANET JOURNAL OF RARE DISEASES, no. 32, 1–30 (2012). (“Haberle”).
2020	Johannes Haberle, <i>Clinical Practice: The Management of Hyperammonemia</i> , 170 EUROPEAN JOURNAL OF PEDIATRICS 21–34 (2011). (“Haberle Clinical”).

2021	J.V. Leonard & A. A. M. Morris, <i>Urea Cycle Disorders</i> , 7 SEMINARS IN NEONATOLOGY 27–35 (2002). (“Leonard”).
2022	Ann-Kaisa Niemi & Gregory M. Enns, <i>Sodium Phenylacetate and Sodium Benzoate in the Treatment of Neonatal Hyperammonemia</i> , 7 NEOREVIEWS, no. 9, e486–e95 (2006). (“Niemi”).
2023	Marshall Summar & Mendel Tuchman, <i>Proceedings of a Consensus Conference for the Management of Patients with Urea Cycle Disorders</i> , 138 THE JOURNAL OF PEDIATRICS, no. 1, S6–S10 (2001). (“Summar”).
2024	Saul W. Brusilow & Nancy E. Maestri, <i>Urea Cycle Disorders: Diagnosis, Pathophysiology, and Therapy</i> , 43 ADVANCES IN PEDIATRICS 127–70 (1996). (“Brusilow 1996”).
2025	Colloquium, <i>Consensus Statement from a Conference for the Management of Patients with Urea Cycle Disorders</i> , 138 THE JOURNAL OF PEDIATRICS, Supplement 1, S1–S5 (2001). (“Consensus”).
2026	<i>Specialties of Genetics</i> , AMERICAN BOARD OF MEDICAL GENETICS AND GENOMICS (last accessed Jan. 17, 2017), http://abmagg.org/pages/training_specialties.shtml .
2027	<i>About Us</i> , UREA CYCLE DISORDERS CONSORTIUM (last accessed Jan. 17, 2017), https://www.rarediseasesnetwork.org/cms/ucdc/About-Us .
2028	Gregory M. Enns, et al., <i>Survival After Treatment with Phenylacetate and Benzoate for Urea-Cycle Disorders</i> , 356 THE NEW ENGLAND JOURNAL OF MEDICINE 2282–92 (2007). (“Enns”).
2029	Gregory M. Enns & Tina M. Cowan, <i>Hyperammonemia</i> , in SIGNS AND SYMPTOMS OF GENETIC CONDITIONS: A HAND BOOK 18 261–279 (Louanne Hudgins et al., eds., 2014). (“Enns 2014”).

2030	Michael Msall, et al., <i>Neurologic Outcome in Children with Inborn Errors of Urea Synthesis</i> , 310 THE NEW ENGLAND JOURNAL OF MEDICINE 1500–1505 (1984). (“Msall”).
2031	B.D. Cheson, et al., <i>Novel Therapeutic Agents for the Treatment of Myelodysplastic Syndromes</i> , 27 SEMINARS IN ONCOLOGY, no. 5, 560–77 (2000). (“Cheson”).
2032	Fernando Scaglia, et al., <i>Effect of Alternative Pathway Therapy on Branched Chain Amino Acid Metabolism in Urea Cycle Disorder Patients</i> , 81 MOLECULAR GENETICS AND METABOLISM, Supplement 1, S79–S85 (2004). (“Scaglia”).
2033	Saul W. Brusilow & Arthur L. Horwich, <i>Urea Cycle Enzymes</i> , in THE ONLINE METABOLIC AND MOLECULAR BASES OF INHERITED DISEASE ch. 85 1–89 (David Valle et al. eds., 2015). (“Brusilow Online”).
2034	Deposition of Dr. Keith Vaux
2035	Dr. Vaux’s University of California San Diego online biography. (“Vaux UCSD”).
2036	Ephrem Chin, et al., <i>Novel Human Pathological Mutations</i> , 126 HUMAN GENETICS 329–352 (2009). (“Chin”).
2037	Keith K. Vaux, <i>Book Reviews: A Clinical Guide to Inherited Metabolic Diseases, 2nd ed.</i> , 94 Journal of Heredity, no. 2, 196 (2003). (“Vaux Book Review”).

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