UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,

Petitioner

v.

HORIZON THERAPEUTICS, LLC,

Patent Owner

Case IPR2017-01767

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 initial exhibit list:

Exhibit No.	Description
2001	*RESERVED*.
2002	Notice of Allowance dated December 23, 2015, Prosecution History of U.S. Patent No. Patent 9,254,278.
2003	Dixon *et al*., "Intercurrent Illness in Inborn Errors of Intermediary Metabolism, 67 *Archives of Disease in Childhood*, 1387-1391 (1992) ("Dixon").
2004	Rani H. Singh, *et al*., "Nutritional Management of Urea Cycle Disorders," *Crit. Care. Clin*. 21:S27-35 (2005). ("Singh").
2005	Portion of Par Pharmaceutical, Inc.'s Initial Invalidity Contentions and Non-Infringement Contentions for U.S. Pat. Nos. 8,404,215 and 8,642,012 (pgs. 16-22), *Hyperion Therapeutics, Inc. v. Par Pharmaceutical, Inc*., C.A. No. 2:14-cv-00384 (JRG)(RSP) (E.D. Tex.)
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	Takhar Kasumov, *et al*., "New Secondary Metabolits of Phenylbutyrate in Humans and Rats," Drug Metabolim and Disposition, 32:10–19 (2004) ("Kasumov").
2019	Johannes Häberle, *et al*., "Suggested Guidelines for the Diagnosis and Management of Urea Cycle Disorders," *Orphanet J. Rare Diseases*, 7:32, 1–30 (2012). ("Häberle").
2020	Johannes Häberle, "Clinical Practice: The Management of Hyperammonemia," *Eur. J. of Pediatrics* 170:21–34 (2011). ("Häberle Clinical").
2021	J.V. Leonard & A. A. M. Morris, "Urea Cycle Disorders," *Seminars in Neonatology* 7:27–35 (2002). ("Leonard 2002").

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 Oct. 25, 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," in *Seminars in Oncology*, 27:560–77, no. 5 (John W. Yarbro, et al. eds., 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	Marshall Summar, "Current Strategies for the Management of Neonatal Urea Cycle Disorders," *J. Pediatrics* 138:S30–S39 (2001). ("Summar 2001").
2035	Marshall L. Summar, *et al*., "The Incidence of Urea Cycle Disorders," *Molecular Genetics and Metabolism* 110:179–180 (2013). ("Summar 2013").
2036	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").
2037	Bridget Wilcken, "Problems in the Management of Urea Cycle Disorders," *Molecular Genetics and Metabolism* 81:S86–S91 (2004). ("Wilcken").
2038	Information About FDA-Approved Drug, Buphenyl, http://www.accessdata.fda.gov/scripts/cder/daf/ (search Drug Name, Active Ingredient, or Application Number field for "020572", last accessed Feb. 9, 2017)
2039	Gregory M. Enns, "Neurologic Damage and Neurocognitive Dysfunction in Urea Cycle Disorders," *Seminars in Pediatric Neurology*, 15:132-139 (2008). ("Enns 2008").
2040	Ravicti® product insert, https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/203284s005lbl.pdf. ("Ravicti Label").
2041	Declaration of Robert F. Green In Response to Petitioner's Objections to Evidence.

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