# UNITED STATES PATENT AND TRADEMARK OFFICE

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# BEFORE THE PATENT TRIAL AND APPEAL BOARD

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PAR PHARMACEUTICAL, INC.,

Petitioner

v.

HORIZON THERAPEUTICS, LLC,

Patent Owner

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Case IPR2017-01768

Patent 9,095,559

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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:

| Exhibit No. | Description |
|---|---|
| 2001 | *RESERVED.* |
| 2002 | Notice of Allowance dated June 18, 2015, Prosecution History of U.S. Patent No. 9,095,559. |
| 2003 | Dixon *et al.*, "Intercurrent Illness in Inborn Errors of Intermediary Metabolism," *Archives of Disease in Childhood*, 67:1387-1391 (1992) ("Dixon"). |
| 2004 | Rani H. Singh *et al.*, "Nutritional Management of Urea Cycle Disorders," *Crit. Care. Clin.* 21:S27-S35 (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. |
| 2007 | Curriculum *vitae* of Dr. Gregory M. Enns. |
| 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*, 138:S46-S55, no. 1 (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"). |
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| 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 & Stephanie Grunewald, "How to use Serum Ammonia," *Archives of Disease in Childhood—Education and Practice* 97:72–77 (2012). ("Broomfield"). |
| 2016 | Fumio 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 Metabolites of Phenylbutyrate in Humans and Rats," *Drug Metabolism and Disposition*, 32:10–19, no. 1 (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"). |
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| 2023 | Marshall Summar & Mendel Tuchman, "Proceedings of a Consensus Conference for the Management of Patients with Urea Cycle Disorders," *J. Pediatrics*, 138:S6–S10, no. 1 (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, no. 1 (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 J. 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 J. 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"). |
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| 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, no. 1 (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/2017/203284s 005lbl.pdf. ("Ravicti Label"). |
| 2041 | *RESERVED for* Declaration of Robert F. Green In Response to Petitioner's Objections to Evidence. |

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