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

PETITIONER'S OBJECTIONS UNDER 37 C.F.R. § 42.64
TO EVIDENCE SUBMITTED BY PATENT OWNER

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Pursuant to 37 C.F.R. §42.64(b)(1), Petitioner Par Pharmaceutical, Inc. ("Petitioner") objects as follows to the admissibility of evidence submitted by Patent Owner Horizon Therapeutics, LLC ("Patent Owner") on May 9, 2018 in connection with Horizon Therapeutics, LLC's Response to Petition for *Inter Partes* Review (Paper No. 22, "Patent Owner's Response").

In this paper, a reference to "FRE" means the Federal Rules of Evidence, a reference to "CFR" means the Code of Federal Regulations, and "'278 patent" means U.S. Patent No. 9,254,278. All objections under FRE 802 (hearsay) apply to the extent Patent Owner relies on the exhibits identified in connection with that objection for the truth of the matter asserted therein.

Exhibit descriptions provided in this table are as listed in Patent Owner's Updated Exhibit List (Paper No. 23) and are used for identification purposes only. The use of the description does not indicate that Petitioner agrees with the descriptions or characterizations of the documents.

Exhibit	Description	Objection
2002	Notice of Allowance dated December 23, 2015, Prosecution History of U.S. Patent No. Patent 9,254,278.	A, B, G, K, L, M, N, O
2003	Dixon *et al.*, "Intercurrent Illness in Inborn Errors of Intermediary Metabolism, 67 *Archives of Disease in Childhood*, 1387-1391 (1992) ("Dixon").	A, B, K, L, N, O

2004	Rani H. Singh et al., "Nutritional Management of Urea Cycle Disorders," *Crit. Care. Clin.* 21:S27-35 (2005). ("Singh").	A, B, K, L, M, N, O
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.)	A, B, G, K, L, M, N, O
2006	Declaration of Dr. Gregory M. Enns, M.D.	A, B, K, L, N
2007	Curriculum *vitae* of Dr. Gregory M. Enns, M.D.	A, K, L, N
2008	Ari Auron, Patrick D. Brophy, "Hyperammonemia in Review: Pathophysiology, Diagnosis, and Treatment," *Pediatric Nephrology*, 27:207-22 (2012). ("Auron").	A, B, C, E, K, L, N, O
2009	Mark L. Batshaw, *et al*., "Alternative Pathway Therapy for Urea Cycle Disorders: Twenty Years Later," *J. Pediatrics,* 38:S46-S55 (2001). ("Batshaw").	A, B, K, L, N, O
2010	Nancy E. Maestri, *et al*., "Prospective Treatment of Urea Cycle Disorders," *J. of Pediatrics*, 119:923-28, no. 6 (1991). ("Maestri").	A, B, K, L, M, N, O
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").	A, B, K, L, M, N, O
2012	U.S. Patent Publication 2012/0022157 A1, filed August 27, 2009, published January 26, 2012. ("'157 App").	A, B, C, E, K, L, N, O
2013	Mendel Tuchman & Mark L. Batshaw, "Management of Inherited Disorders of Ureagenesis," *The Endocrinologist* 12:99–109, no. 2 (2002). ("Tuchman").	A, B, K, L, N, O

2014	Guoyao Wu, "Amino Acids: Metabolism, Functions, and Nutrition," *Amino Acids* 37:1–17 (2009). ("Wu").	A, B, C, E, K, L, M, N, O
2015	Alexander Broomfield & Stephen Grunewald, "How to use Serum Ammonia," *Archives of Disease in Childhood—Education and Practice* 97:72–77 (2012). ("Broomfield").	A, B, C, E, K, L, N, O
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").	A, B, K, L, N, O
2017	Gregory M. Enns, "Nitrogen Sparing Therapy Revisited 2009," *Molecular Genetics and Metabolism* 100:S65–S71 (2010). ("Enns 2010").	A, B, C, E, K, L, N, O
2018	Takhar Kasumov, *et al*., "New Secondary Metabolits of Phenylbutyrate in Humans and Rats," Drug Metabolim and Disposition, 32:10–19 (2004) ("Kasumov").	A, B, K, L, N, O
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").	A, B, C, E, K, L, N, O
2020	Johannes Häberle, "Clinical Practice: The Management of Hyperammonemia," *Eur. J. of Pediatrics* 170:21–34 (2011). ("Häberle Clinical").	A, B, C, E, K, L, N, O
2021	J.V. Leonard & A. A. M. Morris, "Urea Cycle Disorders," *Seminars in Neonatology* 7:27–35 (2002). ("Leonard 2002").	A, B, K, L, N, O
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").	A, B, K, L, M, N, O

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").	A, B, K, L, M, N, O
2024	Saul W. Brusilow & Nancy E. Maestri, "Urea Cycle Disorders: Diagnosis, Pathophysiology, and Therapy," *Advances in Pediatrics* 43:127–70 (1996). ("Brusilow 1996").	A, B, K, L, M, N, O
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").	A, B, K, L, N, O
2026	"Specialties of Genetics," *Am. Board of Medical Genetics and Genomics* (last accessed Jan. 17, 2017), http://abmgg.org/pages/training_specialties.shtml. ("ABMGG")	A, B, C, E, K, L, N, O
2027	"About Us," *Urea Cycle Disorders Consortium* (last accessed Oct. 25, 2017), https://www.rarediseasesnetwork.org/cms/ucdc/About-Us.	A, B, C, E, K, L, M, N, O
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").	A, B, K, L, M, N, O
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").	A, B, C, E, K, L, M, N, O
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").	A, B, K, L, M, N, O

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