IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioner,

v.

HORIZON THERAPEUTICS, LLC,
Patent Owner.

Case IPR: Unassigned
U.S. Patent No. 9,561,197

PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 9,561,197 UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. §§ 42.1-.80, 42.100-.123

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Exhibit No.	Description
1001	Scharschmidt, B. and Mokhtarani, M., U.S. Patent No. 9,561,197 (filed Sept. 11, 2012; issued Feb. 7, 2017) ("the '197 patent")
1002	Declaration of Neal Sondheimer, M.D., Ph.D.
1003	*Curriculum Vitae* of Neal Sondheimer, M.D., Ph.D.
1004	Lee, B., *et al.*, *Phase 2 Comparison of a Novel Ammonia Scavenging Agent with Sodium Phenylbutyrate in Patients with Urea Cycle Disorders: Safety, Pharmacokinetics and Ammonia Control*, MOLECULAR GENETICS METABOLISM, 100: 221-28 (2010) ("Lee")
1005	Praphanphoj, V., *et al.*, *Three Cases of Intravenous Sodium Benzoate and Sodium Phenylacetate Toxicity Occurring in the Treatment in the Treatment of Acute Hyperammonaemia*, J. INHERIT. METAB. DIS., 23: 129-36 (2000) ("Praphanphoj")
1006	Thibault, A., *et al.*, *A Phase I and Pharmacokinetic Study of Intravenous Phenylacetate in Patients with Cancer*, CANCER RESEARCH, 54: 1690-94 (1994) ("Thibault")
1007	Carducci, M.A., *et al.*, *A Phase I Clinical and Pharmacological Evaluation of Sodium Phenylbutyrate on an 120-h Infusion Schedule*, CLINICAL CANCER RESEARCH, 7: 3047-55 (2001) ("Carducci")
1008	Msall, M., *et al.*, *Neurologic Outcome in Children with Inborn Errors of Urea Synthesis — Outcome of Urea-Cycle Enzymopathies*, NEW ENGLAND JOURNAL OF MEDICINE, 310: 1500-05 (1984)
1009	File History for U.S. Patent No. 9,561,197
1010	MacArthur, R.B., *et al.*, *Pharmacokinetics of Sodium Phenylacetate and Sodium Benzoate Following Intravenous Administration As Both a Bolus and Continuous Infusion to Healthy Adult Volunteers*, MOLECULAR GENETICS AND METABOLISM, 81: S67-S73 (2004)
1011	McGuire, B.M., *et al.*, *Pharmacology and Safety of Glycerol Phenylbutyrate in Healthy Adults and Adults with Cirrhosis*, HEPATOLOGY, 51: 2077-85 (2010)
1012	Buxton, I.L.O., *Goodman & Gilman's: The Pharmacological Basis of Therapeutics*, 1-39 (L. Brunton et al., eds., 11th ed. 2006)

Exhibit No.	Description
1013	Ravicti Product Label, Revised: Apr. 2017
1014	Buphenyl Label, Revised: Apr. 2008
1015	Ammonul Label, Revised: Feb. 2005
1016	Center for Drug Evaluation and Research, NDA No. 203284, Summary Review
1017	Feillet, F. and Leonard, J.V., *Alternative Pathway Therapy for Urea Cycle Disorders*, J. INHER. METAB. DIS., 21: 101-11 (1998).
1018	Fernandes, J., *et al.*, *Inborn Metabolic Diseases Diagnosis and Treatment*, 214-222 (J. Fernandes et al., eds., 3d ed. 2000)
1019	Scientific Discussion for Ammonaps, EMEA, 1-12 (2005)
1020	Scharschmidt, B., U.S. Patent Appl. Pub. No. 2010/0008859 (filed Jan. 7, 2009; published Jan. 14, 2010)
1021	Scharschmidt, B., U.S. Patent Appl. Pub. No. 2012/0022157 (filed Aug. 27, 2009; published Jan. 26, 2012)
1022	Brusilow, *Phenylacetylglutamine May Replace Urea as a Vehicle for Waste Nitrogen Excretion*, PEDIATRIC RESEARCH, 29: 147-50 (1991)
1023	Brusilow, S.W., U.S. Patent No. 5,968,979 (filed Jan. 13, 1998; issued Oct. 19, 1999)
1024	Yang, D., *et al.*, *Assay of the Human Liver Citric Acid Cycle Probe Phenylacetylglutamine and of Phenylacetate in Plasma by Gas Chromatography-Mass Spectrometry*, ANALYTICAL BIOCHEMISTRY, 212: 277-82 (1993)
1025	Yamaguchi, M. and Nakamura, M., *Determination of Free and Total Phenylacetic Acid in Human and Rat Plasma by High-Performance Liquid Chromatography with Fluorescence Detection*, CHEM. PHARM. BULL., 35: 3740-45 (1987)
1026	Laryea, M.D., *et al.*, *Simultaneous LC-MS/MS Determination of Phenylbutyrate, Phenylacetate Benzoate and their Corresponding Metabolites Phenylacetylglutamine and Hippurate in Blood and Urine*, J. INHERITED METABOLIC DISEASES, 33: S321-S328 (2010)

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