

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.,
Petitioner

v.

HORIZON THERAPEUTICS, LLC,
Patent Owner

Case IPR2018-00459
Patent 9,561,197

PATENT OWNER'S INITIAL EXHIBIT LIST

Pursuant to 37 C.F.R. § 42.63 (e), the Patent Owner hereby provides an

initial exhibit list:

Exhibit No.	Description
2001	Declaration of Vernon Reid Sutton, M.D.
2002	Curriculum vitae of Vernon Reid Sutton, M.D. (“Sutton CV”)
2003	Marshall Summar et al., “The Incidence of Urea Cycle Disorders,” <i>Mol. Gen. Metab.</i> 110, 179-180, 180 (2013) (“Summar 2013”)
2004	Johannes Haberle et al., “Suggested Guidelines for the Diagnosis and Management of Urea Cycle Disorders,” <i>Orphanet J. Rare Dis.</i> , 7:32, 1-30 at 1-2 (2012) (“Haberle 2012”)
2005	Marshall Summar et al., “Current Strategies for the Management of Neonatal Urea Cycle Disorders,” <i>J. Pediatrics</i> , 138(1), S30-S39, S30 (2001) (“Summar 2001”)
2006	Ari Auron et al., “Hyperammonemia in Review: Pathophysiology, Diagnosis, and Treatment,” <i>Pediatr. Nephrol.</i> , Feb. 27(2), 207-222, 207 (2012) (“Auron”)
2007	Johannes Haberle, “Clinical Practice: The Management of Hyperammonemia,” <i>Eur. J. Pediatr.</i> 170:21-34, 21 (2011) (“Haberle 2011”)
2008	Marshall Summar et al., “Diagnosis, Symptoms, Frequency and Mortality of 260 Patients with Urea Cycle Disorders from a 21-year, Multicenter Study of Acute Hyperammonaemic Episodes,” <i>Acta Paediatr.</i> , 97:1420-1425, 1423, Fig. 3 (2008) (“Summar 2008”)
2009	Gregory Enns, “Nitrogen Sparing Therapy Revisited 2009,” <i>Mol. Gen. Metab.</i> 100:S65-S71, S65 (2010) (“Enns 2009”)
2010	Fumio Endo et al., “Clinical Manifestations of Inborn Errors of the Urea Cycle and Related Metabolic Disorders During Childhood,” <i>J. Nutrition</i> , 134(6):1605S-1609S, 1605S-1606S, 1608S (2004) (“Endo”)

Exhibit No.	Description
2011	Michael Msall et al., “Neurologic Outcome in Children with Inborn Errors of Urea Synthesis: Outcome of Urea Cycle Enzymopathies,” <i>New Engl. J. Med.</i> , 310(23):1500-1505, 1502 (1984) (“Msall”)
2012	J.V. Leonard et al., “Urea Cycle Disorders,” <i>Semin. Neonatol.</i> 7:27-35, 33-34 (2002) (“Leonard”)
2013	F. Feillet et al., “Alternative Pathway Therapy for Urea Cycle Disorders,” <i>J. Inher. Metab. Dis.</i> 21:101-111, 101, 109 (1998) (“Feillet”)
2014	Gerard Berry et al., “Long-Term Management of Patients with Urea Cycle Disorders,” <i>J. Pediatr.</i> 138(1):S56-S61, S56 (2001) (“Berry”)
2015	Nicholas Mew et al., “Urea Cycle Disorders Overview,” <i>GeneReviews</i> , 1-23 at 3/23-4/23 (2015) (“Mew”)
2016	Marwan Ghabril et al., “Glycerol Phenylbutyrate in Patients With Cirrhosis and Episodic Hepatic Encephalopathy: A Pilot Study of Safety and Effect on Venous Ammonia Concentration,” <i>Clin. Pharm. Drug Dev.</i> 2(3):278-284 (2013) (“Ghabril”)
2017	Alain Thibault et al., “Phase I Study of Phenylacetate Administered Twice Daily to Patients with Cancer,” <i>Cancer</i> Vol. 75, No. 12, 2932, 2937 (1995) (“Thibault 1995”)
2018	M. Mokhtarani et al., “Elevated Phenylacetic Acid Levels Do Not Correlate with Adverse Events in Patients with Urea Cycle Disorders or Hepatic Encephalopathy and Can Be Predicted Based on the Plasma PAA to PAGN Ratio,” <i>Mol. Gen. Metab.</i> 110:446-453, 447 (2013) (“Mokhtarani 2013”)
2019	“Specialties in Medical Genetics and Genomics,” <i>Am. Board of Medical Genetics and Genomics</i> (last accessed May 22, 2018), http://www.abmgg.org/pages/training_options.shtml (“ABMGG”)

Exhibit No.	Description
2020	Declaration of Inventor Bruce F. Scharschmidt, M.D., in Support of Plaintiff Horizon's Opposition To Par's Motion For Summary Judgment Of Invalidity Under 35 U.S.C. § 101, <i>Horizon Therapeutics LLC v. Par Pharmaceutical, Inc.</i> , Case No. 2:17-cv-5901-KM-MAH (D.N.J.) (Docket Item 62-3) ("Scharschmidt")

Respectfully submitted,

Dated: May 23, 2018

By: / M.C. Phillips /

CERTIFICATE OF SERVICE

I hereby certify that on May 23, 2018, copies of the foregoing PATENT OWNER'S INITIAL EXHIBIT LIST and all documents filed with it were served via electronic mail, as agreed to by counsel, upon the following counsel for the Petitioners:

Elizabeth J. Holland: eholland@goodwinlaw.com

Cynthia Lambert Hardman: chardman@goodwinlaw.com

Andrew E. Riley: ariley@goodwinlaw.com

Dated: May 23, 2018

By: / M.C. Phillips /