

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.,  
Petitioner

v.

HORIZON THERAPEUTICS, LLC,  
Patent Owner

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Case IPR2018-00459  
Patent 9,561,197

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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:

<b>Exhibit No.</b>	<b>Description</b>
<b>2001</b>	Declaration of Vernon Reid Sutton, M.D.
<b>2002</b>	Curriculum vitae of Vernon Reid Sutton, M.D. (“Sutton CV”)
<b>2003</b>	Marshall Summar et al., “The Incidence of Urea Cycle Disorders,” <i>Mol. Gen. Metab.</i> 110, 179-180, 180 (2013) (“Summar 2013”)
<b>2004</b>	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”)
<b>2005</b>	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”)
<b>2006</b>	Ari Auron et al., “Hyperammonemia in Review: Pathophysiology, Diagnosis, and Treatment,” <i>Pediatr. Nephrol.</i> , Feb. 27(2), 207-222, 207 (2012) (“Auron”)
<b>2007</b>	Johannes Haberle, “Clinical Practice: The Management of Hyperammonemia,” <i>Eur. J. Pediatr.</i> 170:21-34, 21 (2011) (“Haberle 2011”)
<b>2008</b>	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”)
<b>2009</b>	Gregory Enns, “Nitrogen Sparing Therapy Revisited 2009,” <i>Mol. Gen. Metab.</i> 100:S65-S71, S65 (2010) (“Enns 2009”)
<b>2010</b>	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”)
<b>2011</b>	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”)

<b>2012</b>	J.V. Leonard et al., "Urea Cycle Disorders," <i>Semin. Neonatol.</i> 7:27-35, 33-34 (2002) ("Leonard")
<b>2013</b>	F. Feillet et al., "Alternative Pathway Therapy for Urea Cycle Disorders," <i>J. Inher. Metab. Dis.</i> 21:101-111, 101, 109 (1998) ("Feillet")
<b>2014</b>	Gerard Berry et al., "Long-Term Management of Patients with Urea Cycle Disorders," <i>J. Pediatr.</i> 138(1):S56-S61, S56 (2001) ("Berry")
<b>2015</b>	Nicholas Mew et al., "Urea Cycle Disorders Overview," <i>GeneReviews</i> , 1-23 at 3/23-4/23 (2015) ("Mew")
<b>2016</b>	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")
<b>2017</b>	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")
<b>2018</b>	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")
<b>2019</b>	"Specialties in Medical Genetics and Genomics," <i>Am. Board of Medical Genetics and Genomics</i> (last accessed May 22, 2018), <a href="http://www.abmgg.org/pages/training_options.shtml">http://www.abmgg.org/pages/training_options.shtml</a> ("ABMGG")
<b>2020</b>	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")
<b>2021</b>	June 27, 2018 Settlement Agreement (Confidential).

/ M.C. Phillips /

Matthew C. Phillips, Reg. No. 43,403  
Backup Counsel for Patent Owner

## CERTIFICATE OF SERVICE

I hereby certify that on July 9, 2018, copies of the foregoing PATENT OWNER'S UPDATED EXHIBIT LIST and all documents filed with it were served via electronic mail, as agreed to by counsel, upon the following counsel for the Petitioner:

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