

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,

and

LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.
Petitioners,

v.

HORIZON THERAPEUTICS, INC.,
Patent Owner.

Case IPR2015-01117¹
Patent 8,642,012

PETITIONER'S UPDATED EXHIBIT LIST

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¹ Case IPR2015-00283, instituted on a petition filed by Lupin Ltd. and Lupin Pharmaceuticals, Inc., has been joined with this proceeding.

IPR2015-01117
Patent No. 8,642,012
Petitioner's Updated Exhibit List

Pursuant to 37 C.F.R. § 42.63(e), the Petitioner hereby provides an updated exhibit list:

Exhibit #	Description
1001	U.S. Patent No. 8,642,012 to Scharschmidt (“the ’012 patent), filed January 7, 2009, issued February 4, 2014.
1002	Declaration of Dr. Neal Sondheimer.
1003	Curriculum vitae of Dr. Neal Sondheimer.
1004	Reserved.
1005	Simell, et al., <i>Waste Nitrogen Excretion Via Amino Acid Acylation: Benzoate and Phenylacetate in Lysinuric Protein Intolerance</i> , 20 <i>Pediatric Research</i> , 1117–1121 (1986). (“Simell”).
1006	Reserved.
1007	Reserved.
1008	Reserved.
1009	Reserved.
1010	Reserved.
1011	Fernandes, Saudubray Berghe (editors), <i>Inborn Metabolic Diseases Diagnosis and Treatment</i> , 219–220 (3d ed. 2000). (“Fernandes”).
1012	Brusilow, <i>Phenylacetylglutamine May Replace Urea as a Vehicle for Waste Nitrogen Excretion</i> , 29 <i>Pediatric Research</i> , 147–150 (1991). (“Brusilow ’91”).
1013	Reserved.

IPR2015-01117
Patent No. 8,642,012
Petitioner's Updated Exhibit List

Exhibit #	Description
1014	Reserved.
1015	Kasumov, et al., <i>New Secondary Metabolites of Phenylbutyrate in Humans and Rats</i> , 32 Drug Metabolism and Disposition, 10–19 (2004). (“Kasumov”).
1016	Sherwin, et al., <i>The Maximum Production of Glutamine by the Human Body as Measured by the Output of Phenylacetylglutamine</i> , 37 J. Biol. Chem., 113–119 (1919). (“Sherwin”).
1017	Shiple, et al., <i>Synthesis of Amino Acids in Animal Organisms. I. Synthesis of Glycocoll and Glutamine in the Human Organism</i> , 44 J. American Chem. Society, 618–624 (1922). (“Shiple”).
1018	U.S. Patent No. 4,284,647 to Brusilow et al., filed March 31, 1980, issued August 18, 1981 (“the ’647 patent”).
1019	Reserved.
1020	Reserved.
1021	Prosecution History of the ’012 patent.
1022	Joint Claim Construction filed March 13, 2015 in Eastern District of Texas District Court, Case 2:14-cv-00384.
1023	Piscitelli, et al., <i>Disposition of Phenylbutyrate and its Metabolites, Phenylacetate and Phenylacetylglutamine</i> , 35 J. Clin. Pharmacol., 368–373 (1995). (“Piscitelli”).
1024	Reserved.
1025	Comte, et al., <i>Identification of phenylbutyrylglutamine, a new metabolite of phenylbutyrate metabolism in humans</i> , 37 J. Mass. Spectrom. 581–90 (2002). (“Comte”).

IPR2015-01117
Patent No. 8,642,012
Petitioner's Updated Exhibit List

Exhibit #	Description
1026	U.S. Patent No. 5,968,979 to Brusilow, filed Feb. 7, 1995, issued Oct. 19, 1999 (“the ’979 patent”).
1027	Collins et al., <i>Oral Sodium Phenylbutyrate Therapy in Homozygous β Thalassemia: A Clinical Trial</i> , 85 Blood 43 (1995). (“Collins”).
1028	Declaration of Barry Gilman.
1029	Declaration of Dr. Neal Sondheimer, Ex. 1002 previously filed in IPR2015-01117. (Deposition Exhibit, Not Filed)
1030	Declaration of Dr. Neal Sondheimer, Ex. 1002 previously filed in IPR2015-01127. (Deposition Exhibit, Not Filed)
1031	Current curriculum vitae of Dr. Neal Sondheimer, prepared January 23, 2016. (Deposition Exhibit, Not Filed)
1032	API website printout re sodium phenylbutyrate. (Deposition Exhibit, Not Filed)
1033	Deardorff, M. et al., <i>Complex Management of a Patient with a Contiguous Xp11.4 Gene Deletion Involving Ornithine Transcarbamylase: A Role for Detailed Molecular Analysis in Complex Presentations of Classical Diseases</i> , 94(4) Mol. Genet. Metab. 498-502 (2008). (Deposition Exhibit, Not Filed)
1034	Petitioner's Objections Under 37 C.F.R. § 42.62 to Evidence Submitted by Patent Owner, served in IPR2015-01117 on April 4, 2016.
1035	Reserved.
1036	Email from E. Simic to A. Burgy et al., re: IPR-2015-01117 and 01127

IPR2015-01117
Patent No. 8,642,012
Petitioner's Updated Exhibit List

Exhibit #	Description
1037	Dawson-Saunders, B. et al., Basic & Clinical Biostatistics, 46 (Appelton & Lange, 2d ed. 1994).
1038	Reserved.
1039	Mokhtarani, M. et al., <i>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> , 110(4) Mol. Genet. Metab. 446-453 (2013).
1040	Kingsbury, F. et al., <i>A Rapid Method for the Determination of Hippuric Acid in Urine</i> , 48 J. Biol. Chem. 13-20 (1921)

Date: June 14, 2016
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Respectfully Submitted,



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