### 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

\_\_\_\_\_

Case IPR2018-00459 Patent 9,561,197

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DECLARATION OF VERNON REID SUTTON, M.D.

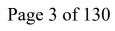


## **Table of Contents**

I.	INT	TRODUCTION4						
II.	EXI	PERT QUALIFICATIONS5						
III.	LEC	GAL PRINCIPLES8						
IV.	SUN	JMMARY OF OPINIONS10						
V.	PERSON OF ORDINARY SKILL IN THE ART							
VI.	TECHNOLOGY BACKGROUND							
	A.	UCDs and UCD Treatments						
		1.	Ammonia (or Nitrogen) Scavenging Drugs	20				
		2.	PAA Prodrugs	21				
		3.	PAA Toxicity	23				
		4.	Dosing	25				
	B.	Resp	onse to Dr. Vaux's Technology Overview	27				
		1.	Dr. Vaux Oversimplifies the Metabolism of PAA Prod	rugs27				
		2.	Dr. Vaux Ignores the Differences in PAA Prodrug Met Amongst Various Patient Populations					
		3.	Dr. Vaux Improperly Assumes a Ratio Can Be Derived Intravenous Studies on PAA or PBA					
	C.	The Cited Prior Art						
		1.	MacArthur	35				
		2.	Enns 2010	45				
		3.	Thibault	51				
		4.	Piscitelli	55				
		5.	Zeitlin	60				
		6.	Simell	65				
VII.	OVERVIEW OF THE '197 PATENT							
	A.	The '197 Patent Specification71						
	B.	The '	2197 Patent Claims	76				
		1.	"A method of treating a UCD in a subject"  Page 2 of 125	77				



		2.	"a subject having a plasma PAA to PAGN ratio outs target range of 1 to 2 [2.5]"				
		3.	"administering to [the] subject a dosage of glycer phenylbutyrate] (HPN-100) effective to achieve a pl to PAGN ratio within the target range"	asma PAA			
VIII.	CLAIM CONSTRUCTION						
	A. "PAA" and "PAGN"						
	В.	"A me	ethod of treating a urea cycle disorder in a subject"	82			
	C.	"a subject having a plasma PAA to PAGN ratio outside the target range of [claim 1:1 to 2] [claim 2: 1 to 2.5]"86					
	D.	100)	nistering a dosage of glyceryl tri-[4-phenylbutyrat effective to achieve a plasma PAA to PAGN ratio wit range of [claim 1: 1 to 2] [claim 2: 1 to 2.5]"	thin the			
IX.	DISC	JPIN'S PETITION FAILS TO IDENTIFY PRIOR ART THAT SCLOSES A CALCULATED PAA TO PAGN RATIO OR CLAIMED ARGET RANGES91					
X.	THE PRIOR ART, ALONE OR IN COMBINATION, FAILS TO TEACH OR SUGGEST THE SUBJECT MATTER OF CLAIMS 1-297						
	A.	The Prior Art Does Not Teach or Suggest the Use of a PAA to PAGN Ratio or a Specific Target Range of a PAA to PAGN Ratio in Treating UCDs					
		1.	The Prior Art Does Not Disclose a PAA to PAGN R Utility in a Method of Treating UCD Patients				
		2.	The Prior Art Does Not Teach or Suggest the Claim Range of Ratio Values	_			
	B.	B. A POSA Would Have Had No Reason to Combine the Prior Art					
	C.	Teaching Away in the Prior Art1					
XI.	CON	ICLUS	ION	130			





I, Vernon Reid. Sutton, M.D., hereby declare as follows:

### I. INTRODUCTION

- 1. I have been retained by Green, Griffith & Borg-Breen LLP on behalf of Horizon Therapeutics, LLC as an independent expert in the field of Molecular & Human Genetics, including the clinical care and treatment of patients with inborn errors of metabolism including patients with urea cycle disorders ("UCDs"). My curriculum vitae establishes my qualifications in this area. I am being compensated for the time I spend on this matter, but no part of my compensation depends on the outcome of this proceeding.
- 2. I understand that this proceeding involves U.S. Patent No. 9,561,197 ("the '197 patent"). I understand that the application for the '197 patent was filed on September 11, 2012, as U.S. Patent Application No. 13/610,580 ("the '580 application"), and that the patent issued on February 7, 2017. I understand that the '197 patent claims priority to Provisional Application No. 61/636,256 ("the '256 application"), filed on April 20, 2012. I have therefore considered the state of the art and the prior art available as of April 20, 2012. None of my opinions would

Page 4 of 130



<sup>&</sup>lt;sup>1</sup> Ex. 2002 (Sutton CV).

Case No. IPR2018-00459 U.S. Patent No. 9,561,197

change if I were to assume in the alternative that the date of invention was September 11, 2012, which is the date on which the application for the '197 patent was filed.

- 3. I understand that Petitioner has asserted that a combination of Enns 2010, MacArthur, and Piscitelli, in view of the knowledge of a person of ordinary skill in the art, renders obvious all claims (claims 1 and 2) of the '197 patent.
- 4. In preparing this declaration, I have considered the '197 patent and its prosecution history, the Petition for *Inter Partes* Review of U.S. Patent No. 9,561,197 (Paper No. 3, "Petition"), the Declaration of Keith Vaux, M.D.,<sup>2</sup> the prior art and references identified in the Petition and Dr. Vaux's Declaration, my knowledge and expertise in the art, and any additional references cited herein.

## II. EXPERT QUALIFICATIONS

5. I am currently a Professor in the Department of Molecular & Human Genetics at Baylor College of Medicine, the Medical Director of the Baylor Biochemical Genetics Laboratory, and the Director of the Inborn Errors of Metabolism service at Texas Children's Hospital.

Page 5 of 130



<sup>&</sup>lt;sup>2</sup> Ex. 1002 ("Vaux").

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