

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

DECLARATION OF VERNON REID SUTTON, M.D.

Table of Contents

I.	INTRODUCTION	4
II.	EXPERT QUALIFICATIONS.....	5
III.	LEGAL PRINCIPLES.....	8
IV.	SUMMARY OF OPINIONS.....	10
V.	PERSON OF ORDINARY SKILL IN THE ART	12
VI.	TECHNOLOGY BACKGROUND.....	14
A.	UCDs and UCD Treatments	14
1.	Ammonia (or Nitrogen) Scavenging Drugs.....	20
2.	PAA Prodrugs	21
3.	PAA Toxicity	23
4.	Dosing.....	25
B.	Response to Dr. Vaux’s Technology Overview	27
1.	Dr. Vaux Oversimplifies the Metabolism of PAA Prodrugs....	27
2.	Dr. Vaux Ignores the Differences in PAA Prodrug Metabolism Amongst Various Patient Populations	29
3.	Dr. Vaux Improperly Assumes a Ratio Can Be Derived from Intravenous Studies on PAA or PBA.....	32
C.	The Cited Prior Art	35
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	70
A.	The ’197 Patent Specification	71
B.	The ’197 Patent Claims	76
1.	“A method of treating a UCD in a subject”	77

- 2. “a subject having a plasma PAA to PAGN ratio outside of the target range of 1 to 2 [2.5]”78
- 3. “administering to [the] subject ... a dosage of glyceryl tri-[4-phenylbutyrate] (HPN-100) effective to achieve a plasma PAA to PAGN ratio within the target range”79
- VIII. CLAIM CONSTRUCTION80
 - A. “PAA” and “PAGN”81
 - B. “A method 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. “administering ... a dosage of glyceryl tri-[4-phenylbutyrate] (HPN-100) effective to achieve a plasma PAA to PAGN ratio within the target range of [claim 1: 1 to 2] [claim 2: 1 to 2.5]”89
- IX. LUPIN’S PETITION FAILS TO IDENTIFY PRIOR ART THAT DISCLOSES A CALCULATED PAA TO PAGN RATIO OR CLAIMED TARGET RANGES.....91
- X. THE PRIOR ART, ALONE OR IN COMBINATION, FAILS TO TEACH OR SUGGEST THE SUBJECT MATTER OF CLAIMS 1-2.....97
 - 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 UCDS97
 - 1. The Prior Art Does Not Disclose a PAA to PAGN Ratio or its Utility in a Method of Treating UCD Patients.....98
 - 2. The Prior Art Does Not Teach or Suggest the Claimed Target Range of Ratio Values111
 - B. A POSA Would Have Had No Reason to Combine the Prior Art122
 - C. Teaching Away in the Prior Art124
- XI. CONCLUSION.....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.¹ 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

¹ Ex. 2002 (Sutton CV).

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.,² 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.

² Ex. 1002 ("Vaux").

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