

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 IPR 2017-01159

Patent 9,254,278

DECLARATION OF DR. GREGORY M. ENNS

Horizon Exhibit 2006

| | | |
|-------|---|----|
| I. | Introduction..... | 1 |
| II. | Qualifications | 2 |
| | A. Education | 2 |
| | B. Professional Experience..... | 3 |
| | C. Publications and Presentations..... | 5 |
| | D. Honors and Awards..... | 6 |
| | E. Professional Organizations and Service Activities..... | 6 |
| III. | Legal Principles | 7 |
| IV. | Summary of Opinions..... | 9 |
| V. | Person of Ordinary Skill in the Art..... | 11 |
| VI. | Technology Background..... | 14 |
| VII. | Overview of the '278 Patent | 21 |
| | A. The Claims of the '278 Patent | 24 |
| | B. Prosecution History of the '278 Patent | 26 |
| VIII. | Claim Construction | 28 |
| | A. “upper limit of normal” | 28 |
| | B. “the subject” | 29 |
| IX. | The Prior Art Does Not Disclose or Suggest Subject Matter of Claims 1-15 | 30 |
| | A. The Prior Art Does Not Disclose Increasing a Dosage of Glyceryl Tri-[4-phenyl-butyrate] in a Patient with a Plasma Ammonia Level Between Half the ULN and the ULN..... | 30 |
| | B. No Motivation to Adjust the Dosage of Nitrogen Scavenging Drug for a Subject with Plasma Ammonia Levels in the Normal Range..... | 39 |
| | 1. A POSA Did Not Account for a Fasting v. Fed Ammonia Level When Making Dosing Determinations | 40 |

- 2. The Prior Art Disclosed Normal Plasma Ammonia Levels Were Acceptable and Only Increased Dosage When Levels Were Well Above Normal..... 44
- 3. A POSA Would Not Have Been Motivated to Combine the '859 Publication with Simell or Blau..... 50
- C. No Reasonable Expectation that an Increased Dosage Would Lower a Patient's Baseline Ammonia and Ensure a Normal Plasma Ammonia over the Course of a Day..... 56
- D. The Prior Art Did Not Disclose or Suggest Targeting a Plasma Ammonia Level Below Half the ULN..... 58
- X. Conclusion 63

I, Dr. Gregory M. Enns, hereby declare as follows:

I. Introduction

1. I, Dr. Gregory M. Enns, have been retained by Green, Griffith & Borg-Breen LLP on behalf of Horizon Therapeutics, LLC, as an independent expert in the field of clinical biochemical genetics. My curriculum vitae establishes my qualifications in this area. (Ex. 2007.) I am being compensated for the time I spend on this matter, but no part of my compensation depends directly or indirectly on the outcome of this proceeding or any related proceeding.

2. I understand that this proceeding involves U.S. Patent No. 9,254,278 (“the ’278 patent”). (Ex. 1001.) I understand that the application for the ’278 patent was filed on August 3, 2015, as a continuation of U.S. Patent Application No. 13/775,000, filed February 22, 2013, now U.S. Patent No. 9,095,559 (“the ’559 Patent”). The ’559 patent is the subject of IPR No. 2016-00829. As discussed further below, I have submitted an expert declaration on behalf of Patent Owner, Horizon Therapeutics, LLC in the IPR proceeding concerning the ’559 patent claims. (See Ex. 2001, Declaration of Dr. Gregory M. Enns, M.D., *Lupin Ltd. et al. v. Horizon Therapeutics, Inc.*, IPR2016-00829 (“Enns ’559 Declaration.”).) I have also submitted an expert declaration on behalf of Patent Owner Horizon Therapeutics, LLC in the IPR proceeding concerning related U.S. Patent U.S. 9,326,966 (“the ’966 patent”), *Lupin Ltd. et al. v. Horizon Therapeutics, Inc.*, IPR2017-01160. I note that Lupin’s expert in this proceeding, Dr. Keith Vaux, has also submitted declarations in support of Lupin’s Petitions in the IPR proceedings concerning the ’559 and ’966 patents, which rely on the same primary prior art references and largely the same arguments as those included in the instant matter.

3. I understand that the '278 patent issued on February 9, 2016, and that the '278 patent claims priority to Provisional Application No. 61/564,668 ("the '668 application"), filed on November 29, 2011, and Provisional Application No. 61/542,100, filed on September 30, 2011. (Ex. 1001.) I have therefore considered the state of the art and the prior art available as of September 30, 2011.

4. I understand that Petitioner has asserted that the '859 Publication (Ex. 1007) renders obvious claims 1-3 of the '278 patent; that a combination of Blau (Ex. 1006), Simell (Ex. 1005), and the '859 Publication renders obvious claims 4-7, and 12-15; and that a combination of Blau, Simell, the '859 Publication, and the Brusilow '979 Patent (Ex. 1024) renders obvious claims 8-11. (Petition at 13.) In preparing this declaration, I have considered the '278 patent and its prosecution history, the Petition for *Inter Partes* Review of No. U.S. Patent 9,254,278, the Declaration of Dr. Vaux (Ex. 1002) ("Vaux"), the prior art and references identified in the Petition and the Vaux Declaration, my knowledge and expertise in the art, and any additional materials cited herein.

II. Qualifications

A. Education

5. I received a Bachelor of Arts degree in Biology from Pomona College in 1984. In 1987, I obtained a Diploma in Medical Science from the University of St. Andrews, Scotland. In 1990, I received my U.K. Medical Degree from the University of Glasgow, Scotland.

6. From 1990 to 1991, I was a Junior House Officer at the Royal Hospital for Sick Children and the Glasgow Royal Infirmary, working in both Pediatric Surgery and General Medicine. I then completed my U.S. residency training in Pediatrics at the Children's Hospital of Los Angeles ("CHLA"), beginning as Intern and Resident from 1991 to 1994, and serving as

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