

**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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PAR PHARMACEUTICAL, INC.,

Petitioner

v.

HORIZON THERAPEUTICS, LLC,

Patent Owner

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Case IPR2017-01767

Patent 9,254,278

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**DECLARATION OF DR. GREGORY M. ENNS**

**TABLE OF CONTENTS**

I.	INTRODUCTION .....	1
II.	QUALIFICATIONS .....	3
	A. Education .....	3
	B. Professional Experience.....	4
	C. Publications and Presentations.....	6
	D. Honors and Awards.....	6
	E. Professional Organizations and Service Activities .....	7
III.	LEGAL PRINCIPLES .....	7
IV.	SUMMARY OF OPINIONS .....	9
V.	PERSON OF ORDINARY SKILL IN THE ART .....	11
VI.	TECHNOLOGY BACKGROUND .....	15
VII.	OVERVIEW OF THE '278 PATENT .....	22
	A. The Claims of the '278 Patent .....	25
VIII.	CLAIM CONSTRUCTION.....	28
	A. “upper limit of normal” .....	28
IX.	THE PRIOR ART DOES NOT DISCLOSE OR SUGGEST THE SUBJECT MATTER OF CLAIMS 1-15 .....	29
	A. The Prior Art Does Not Disclose Increasing a Dosage of Glyceryl Tri-[4- phenyl-butyrate] in a Patient with a Fasting Plasma Ammonia Level Between Half the ULN and the ULN .....	29
	B. The Prior Art Provides No Reason to Adjust the Treatment Regimen of a Subject with a Fasting Plasma Ammonia Level in the Normal Range.....	42
	1. The Prior Art as a Whole Provided no Reason to Increase the Dosage When Plasma Ammonia Levels were Already in the Normal or Near-Normal Range .....	44
	2. The Reported Variability in Plasma Ammonia Levels Discouraged Reliance on Normal Plasma Ammonia Levels in Making Dosage Adjustment Decisions .....	49

- 3. The Prior Art Did Not Suggest Reliance on Fasting Plasma Ammonia Measurements for Dosage Adjustments ..... 55
- C. There Was No Reasonable Expectation that Administering an Increased Dosage to a Patient with a Plasma Ammonia Level Already in the Normal Range Would Confer a Treatment Benefit ..... 59
- D. The Prior Art Did Not Disclose or Suggest Targeting a Plasma Ammonia Level at or Below Half the ULN..... 61
- X. CONCLUSION..... 69

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 ’278 patent is also the subject of currently pending IPR No. 2017-01159, filed by Lupin Ltd. and Lupin Pharmaceuticals Inc. (collectively, “Lupin”). I have submitted an expert declaration on behalf of Patent Owner, Horizon Therapeutics, LLC in IPR2017-01159. I have also submitted expert declarations on behalf of Patent Owner Horizon Therapeutics, LLC in the currently pending IPR proceedings also filed by Lupin concerning related U.S. Patent No. 9,326,966 (“the ’966 patent”), *Lupin Ltd. et al. v. Horizon Therapeutics, LLC*, IPR2017-01160, and the ’559 patent, *Lupin Ltd. et al. v. Horizon Therapeutics, Inc.*, IPR2016-00829. Finally, I have also submitted expert declarations on behalf of Patent Owner Horizon Therapeutics, LLC in the currently pending IPR proceedings filed by instant Petitioner Par Pharmaceutical, Inc. (“Par”) concerning the ’966 patent, *Par Pharmaceutical, Inc. et al. v. Horizon Therapeutics, LLC*, IPR2017-01769, and the ’559 patent, *Par Pharmaceutical, Inc. et al. v. Horizon Therapeutics, LLC*, IPR2017-01768.

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 claims 1-15 of the '278 patent are unpatentable on the grounds listed in the table below:

Ground	Basis	References	Challenged '278 Patent Claims
1	§ 102	The '859 Publication	<u>Independent Claim:</u> 1 <u>Dependent Claim:</u> 2-3
2	§ 103	Fernandes in view of the '859 Publication and Lee or Lichter-Konecki, optionally in further view of Blau or Simell	<u>Independent Claim:</u> 1 <u>Dependent Claims:</u> 2-3
3	§ 103	Fernandes in view of the '859 Publication, optionally in further view of Blau, Simell and/or Lee	<u>Independent Claims:</u> 4, 8, 12 <u>Dependent Claims:</u> 6, 7, 10, 11, 14, 15
4	§ 103	Fernandes in view of the '859 Publication and Lee or Lichter-Konecki, optionally in further view of Blau or Simell	<u>Dependent Claims:</u> 5, 9, 13

5. 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. Sondheimer (Ex. 1002) ("Sondheimer"), the prior art and references identified in the Petition and the Sondheimer Declaration, my knowledge and expertise in the art, and any additional materials cited herein.

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