

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,

Petitioner

v.

HORIZON THERAPEUTICS, LLC,

Patent Owner

Case IPR2017-01769

Patent 9,326,966

DECLARATION OF DR. GREGORY M. ENNS

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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. 9,326,966 (“the ’966 patent”). (Ex. 1001.) I understand that the application for the ’966 patent was filed on December 3, 2015, as a continuation of U.S. Patent Application No. 14/816,674, filed August 3, 2015, now U.S. Patent No. 9,254,278 (“the ’278 Patent”), which is a continuation of U.S. Application No. 13/775,000, filed February 22, 2013, now U.S. Patent No. 9,095,559 (“the ’559 Patent”). The ’966 patent is also the subject of currently pending IPR No. 2017-01160, 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 IPR2017-01160. 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 the ’278 patent, *Lupin Ltd. et al. v. Horizon Therapeutics, LLC*, IPR2017-01159, 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 ’278 patent, *Par Pharmaceutical, Inc. et al. v. Horizon Therapeutics, LLC*, IPR2017-01767, and the ’559 patent, *Par Pharmaceutical, Inc. et al. v. Horizon Therapeutics, LLC*, IPR2017-01768.

3. I understand that the '966 patent issued on May 3, 2016, and that the '966 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 '966 patent are unpatentable on the grounds listed in the table below:

Ground	Basis	References	Challenged '966 Patent Claims
1	§ 103	Fernandes in view of the '859 Publication, optionally in view of Blau, Simell and/or Lee	<u>Independent Claims:</u> 1, 6, 9 <u>Dependent Claims:</u> 2, 3, 5, 8, 11
2	§ 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> 4, 7, 10
3	§ 103	The '859 Publication in view of Lee or Lichter-Konecki, optionally in further view of Blau	<u>Dependent Claim:</u> 13

5. In preparing this declaration, I have considered the '966 patent and its prosecution history, the Petition for *Inter Partes* Review of No. U.S. Patent 9,326,966, 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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