

**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 IPR2017-01768

Patent 9,095,559

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

Horizon Exhibit 2006

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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. 9,095,559 (“the ’559 patent”). (Ex. 1001.) I understand that the application for the ’559 patent was filed February 22, 2013 as U.S. Patent Application No. 13/775,000. The ’559 patent is also the subject of IPR No. 2016-00829, 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 that IPR proceeding. 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 U.S. 9,326,966 (“the ’966 patent”), *Lupin Ltd. et al. v. Horizon Therapeutics, LLC*, IPR2017-01160, and related U.S. Patent U.S. No. 9,254,278 (“the ’278 patent”), *Lupin Ltd. et al. v. Horizon Therapeutics, LLC*, IPR2017-01159. 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. v. Horizon Therapeutics, LLC*, IPR2017-01769, and the ’278 patent, *Par Pharmaceutical, Inc. et al. v. Horizon Therapeutics, LLC*, IPR2017-01767.

3. I understand that the ’559 patent issued on August 4, 2015, and that the ’559 patent claims priority to 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. None of my opinions would change if I were to assume in the alternative that the date of invention was February 22, 2013, which is the date on which the application for the '559 patent was filed.

5. I understand that Petitioner has asserted that claims 1-15 of the '559 patent are unpatentable on the grounds listed in the table below:

| Ground | Basis | References   | Challenged '559 Patent Claims  |
|--------|-------|--|--|
| 1      | § 103 | Fernandes in view of the '859 Publication, optionally in view of Blau, Simell, and/or Lee                          | <u>Independent Claims:</u> 1-2<br><u>Dependent Claims:</u> 4, 7-10, 12, 13 |
| 2      | § 103 | Fernandes in view of the '859 Publication and Lee or Lichter-Konecki, optionally in further view of Blau or Simell | <u>Dependent Claim:</u> 5  |
| 3      | § 103 | The '859 Publication optionally in view of Pandya and/or Lee   | <u>Independent Claim:</u> 3<br><u>Dependent Claims:</u> 7-9, 11, 14        |
| 4      | § 103 | The '859 Publication in view of Fernandes, optionally in further view of Pandya, Blau, Simell and/or Lee           | <u>Dependent Claims:</u> 6, 15   |

6. In preparing this declaration, I have considered the '559 patent and its prosecution history, the Petition for *Inter Partes* Review of No. U.S. Patent 9,095,559, 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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