IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioner,

v.

HORIZON THERAPEUTICS, LLC,
Patent Owner.

Case IPR: Unassigned
U.S. Patent No. 9,561,197

DECLARATION OF NEAL SONDHEIMER, M.D., Ph.D.

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I, Neal Sondheimer, do hereby declare as follows:

I. Overview

1. I am over the age of 18 and otherwise competent to make this declaration. I am a medical doctor with specialties in Pediatrics, Clinical Genetics and Clinical Biochemical Genetics. I am also qualified to give testimony under oath. The facts and opinions listed below are within my personal knowledge.

2. I am being compensated for my time in this proceeding at my standard consulting rate of $650/hour. My compensation in no way depends on the outcome of this *Inter Partes* Review ("IPR") proceeding or the content of my opinions. I am not employed by, nor receiving grant support from Par Pharmaceutical, Inc. ("Par") or any related companies. I am receiving compensation from Par solely for my time spent working on this matter and based only on my standard hourly consulting fees.

3. I have been asked to review U.S. Patent No. 9,561,197 ("the '197 Patent") (EX1001) and other documents that are exhibits to Par's Petition, and to provide my opinions on what those documents disclose. I understand that the '197 patent issued on February 7, 2017 and resulted from U.S. Application No. 13/610,580, filed on September 11, 2012, which claims the benefit of U.S. Provisional Application No. 61/636,256, filed on April 20, 2012. I understand that, based on that April 20, 2012 date, the earliest possible date to which the '197

patent may claim priority is April 20, 2012. I have been asked to provide my analysis of the '197 patent based on prior art and the knowledge in the art before April 20, 2012. I also understand that the face page of the '197 patent states that the '197 patent is currently assigned to Horizon Therapeutics, LLC ("Horizon").

4. I have also relied upon my experience in the relevant art and considered the viewpoint of a person of ordinary skill in the art before April 20, 2012.

5. Independent claims 1 and 2 of the '197 patent generally recite a method of treating a subject with a urea cycle disorder ("UCD") comprising administering to the subject a dose of the nitrogen scavenging drug glyceryl tri-[4-phenylbutyrate] ("GPB") in an amount effective to achieve a specific plasma ratio of phenylacetic acid ("PAA")[1] and phenylacetylglutamine ("PAGN"), if the subject's PAA:PAGN plasma ratio is outside a specific range.

[1] The '197 patent defines PAA as "phenylacetic acid." (EX1001, 2:4-10, 2:38-55.) A person of ordinary skill in the art would have understood that "phenylacetic acid" includes phenylacetic acid or its conjugate base, phenylacetate. As used herein, PAA means either phenylacetic acid or phenylacetate. Similarly, a person of ordinary skill in the art would understand that "phenylbutyric acid"

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