

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

PAR PHARMACEUTICAL, INC.,
Petitioner,

v.

HORIZON THERAPEUTICS, INC.,
Patent Owner.

Case IPR: Unassigned
Patent 9,095,559

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

*Inter Partes Review of USPN 9,095,559
Declaration of Neal Sondheimer, M.D., Ph.D. (Exhibit 1002)*

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Declaration of Neal Sondheimer, M.D., Ph.D. (Exhibit 1002)

I. INTRODUCTION

I, Dr. Neal Sondheimer, M.D., Ph.D., do hereby declare and say:

1. I am a medical doctor with specialties in Pediatrics, Clinical Genetics and Clinical Biochemical Genetics. I am over the age of twenty-one (21) and competent to make this declaration. 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 IPR proceeding or the content of my opinions. I am not employed by, nor receiving grant support from Par Pharmaceutical, Inc., which I refer to as “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. 9,095,559 (which I refer to as the ’559 Patent) (Ex. 1001) and the other documents that are exhibits to the petition, and to provide my opinions on what those documents disclose.

4. I have reviewed and am familiar with, among others, the following documents:

- a. U.S. Patent No. 9,095,559 to Scharschmidt *et al.* (“’559 Patent”), filed February 22, 2013, issued August 4, 2015 is marked as Ex. 1001.

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- b. U.S. Patent Publication No. 2010/0008859, filed January 7, 2009, published January 14, 2010 (“’859 Publication”), which is marked as Ex. 1004.
- c. Moser, *et al.*, *Argininosuccinic Aciduria Report of Two New Cases and Demonstration of Intermittent Elevation of Blood Ammonia*, 42 *American Journal of Medicine*, 9-26 (1967) (“Moser”), which is marked as Ex. 1005.
- d. Blau, Duran, Blaskovics, Gibson (editors), *Physician’s Guide to the Laboratory Diagnosis of Metabolic Diseases*, 261-276 (2d ed. 1996) (“Blau”), which is marked as Ex. 1006.
- e. Simell, *et al.*, *Waste Nitrogen Excretion Via Amino Acid Acylation: Benzoate and Phenylacetate in Lysinuric Protein Intolerance*, 20 *Pediatric Research*, 1117-1121 (1986) (“Simell”), which is marked as Ex. 1007.
- f. Feillet, *Alternative Pathway Therapy for Urea Cycle Disorders*, 21 *Journal of Inherited Metabolic Disease Suppl. 1*, 101-111 (1998) (“Feillet”), which is marked as Ex. 1008.
- g. Scientific Discussion for Ammonaps, EMEA 2005, available at http://www.ema.europa.eu/docs/en_GB/document_library/EPA

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