UNITED STATES PATENT AND TRADEMARK OFFICE

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IN THE UNITED STATES PATENT TRIAL AND APPEAL BOARD

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PAR PHARMACEUTICAL, INC.
Petitioner

v.

HYPERION THERAPEUTICS, INC.
Patent Owner

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CASE IPR: UNASSIGNED
U.S. PATENT NO. 8,642,012

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

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

1. I am a medical doctor with specialties in Medical and 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 $500/hour. My compensation in no way depends on the outcome of this 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. 8,642,012 (which I refer to as the '012 Patent) (Ex. 1001) and the other documents that are exhibits to the petition, and to provide my opinions on what those documents disclose. I was also asked to review and provide opinions regarding U.S. Patent No. 8,404,215, and have provided opinions specific to that patent in a separate declaration. I also reviewed additional scientific literature references discussed in this declaration that are not exhibits to the petition.

4. Of particular relevance to the '012 Patent, I have reviewed and am familiar with, among others, the following documents:

a. 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. 1005.

b. Fernandes, Saudubray Berghe (editors), *Inborn Metabolic Diseases Diagnosis and Treatment*, 219-222 (3d ed. 2000) ("*Fernandes*"), which is marked as Ex. 1011.

c. Brusilow, *Phenylacetylglutamine May Replace Urea as a Vehicle for Waste Nitrogen Excretion*, 29 Pediatric Research, 147-150 (1991) ("*Brusilow '91*"), which is marked as Ex. 1012.

d. Kasumov, *et al.*, *New Secondary Metabolites of Phenylbutyrate in Humans and Rats*, 32 Drug Metabolism and Disposition, 10-19 (2004) ("*Kasumov*"), which is marked as Ex. 1015.

e. Sherwin, *et al.*, *The Maximum Production of Glutamine by the Human Body as Measured by the Output of Phenylacetylglutamine*, 37 J. Biol. Chem., 113-119 (1919) ("*Sherwin*"), which is marked as Ex. 1016.

f. Shiple, *et al.*, *Synthesis of Amino Acids in Animal Organisms. I. Synthesis of Glycocoll and Glutamine in the Human Organism*, 44 J. American Chem. Society, 618-624 (1922) ("*Shiple*"), which is marked as Ex. 1017.

g. U.S. Patent No. 4,284,647 to Brusilow, *et al.*, filed January March 31, 1980, issued August 18, 1981 ("the '647 Patent"), which is marked as Ex. 1018.

h. Comte, *et al.*, Identification of phenylbutyrylglutamine, a new metabolite of phenylbutyrate metabolism in humans, J. Mass. Spectrom. 2002:37:581–90 ("*Comte*"), which is marked as Ex. 1025.

i. U.S. Patent No. 5,968,979 to Brusilow, filed Feb. 7, 1995, issued Oct. 19, 1999 ("the '979 patent"), which is marked as Ex. 1026.

j. Collins et al., Oral Sodium Phenylbutyrate Therapy in Homozygous β Thalassemia: A Clinical Trial, 85 Blood 43 (1995) ("*Collins*"), which is marked as Ex. 1027.

5. I provide my conclusions regarding the disclosures of the documents I reviewed as applied to the '012 Patent below.

6. I was also asked to provide my opinion on the technical feasibility of combining certain exhibits, and offer my opinion on the feasibility of these

combinations in this declaration. I have also offered my opinions about what a person of skill in the art would understand about the combinations of documents.

7. I am not offering any conclusions as to the ultimate determinations I understand the Patent Trial and Appeal Board will make in this proceeding. Specifically, I am not offering opinions on ultimate issues of validity. I am simply providing my opinion on the technical aspects of the documents and on the combinability of the concepts disclosed in those documents from a technical perspective (i.e., from the perspective of one of ordinary skill in the relevant art).

I. BACKGROUND

8. A copy of my curriculum vitae is attached to this declaration as Ex. 1003.

9. I received my A.B. in Biology from Harvard University in 1994, my Ph.D. in Molecular Genetics and Cell Biology from the University of Chicago in 2000, and my M.D. from the University of Chicago Pritzker School of Medicine in 2002. I also completed a postdoctoral fellowship at the University of Pennsylvania in Genetics in 2009.

10. I am currently an Attending Physician at The Children's Hospital of Philadelphia in the Division of Biochemical Genetics. I am also currently the Training Director for Clinical Biochemical Genetics at The University of Pennsylvania, as well as the Program Director for Medical Genetics at The

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