UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC,
Petitioner

v.

CEPHALON, INC.,
Patent Owner

Case IPR2016_____
Patent No. 8,791,270

DECLARATION OF MICHAEL J. AKERS, Ph.D., UNDER 37 C.F.R. § 1.68 IN SUPPORT OF PETITION FOR *INTER PARTES* REVIEW OF U.S. PATENT NO. 8,791,270

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I, Michael J. Akers, Ph.D. hereby declare as follows:

I. INTRODUCTION

1. I have been retained as an expert witness on behalf of Fresenius Kabi USA, LLC ("Fresenius") for the above-captioned Petition for *Inter Partes* Review ("IPR") of U.S. Patent No. 8,791,270 ("the '270 patent"). I have been asked to provide my opinions regarding the motivation to combine certain prior art references from the perspective of a person having ordinary skill in the art at the time of the alleged invention.

2. I am being compensated at a rate of $300 per hour for my study and testimony in this matter. I am also being reimbursed for reasonable and customary expenses associated with my work and testimony in this investigation. My compensation is not contingent on the outcome of this matter or the specifics of my testimony.

II. BACKGROUND AND QUALIFICATIONS

3. I received a Bachelor of Arts degree in Biology from Wabash College in 1968. I received my Ph.D. in Pharmaceutics from the University of Iowa in 1972. I have over 40 years' experience in pharmaceutical formulation and development, with a special focus on formulation of lyophilized and parenteral products.

4. From 1974-1977, I was the Senior Scientist and Head of the

Preformulation Research Section of Alcon Laboratories. At Alcon, I personally participated in the formulation development of numerous sterile products, including Balanced Salt Solution (BSS) 500 ml; BSS PLUS Intraocular Irrigating Solution; Natcyn (Natamycin) Ophthalmic Suspension; ZOLYSE (alpha-chymotrypsin) Solution; DENDRID (idoxuridine) Ointment; EPINAL (epinephyrl borate) Ophthalmic Solution; and TOBREX (tobramycin) Ophthalmic Solution. I also contributed to numerous IND and NDA submissions.

5. For nearly 20 years, I held various positions at Eli Lilly and Company ("Lilly"), including Head of the Parenteral and Liquid Product Department. At Lilly, I personally participated in the formulation and development of at least 3 lyophilized products, and was the lead scientist on numerous Lilly parenteral compounds including both proteins and small molecules. I was also responsible for QC activities for all (>200) Lilly-marketed parenteral products, including insulin vials and freeze-dried and powder filled items. I personally participated in the preparation of NDAs for Glucagon Emergency Kit, Tazidime®, Keftab®, Keflet®, Humulin® Cartridges, Vancocin® Frozen Minibag, and Gemzar®.

6. From 2002 through my retirement in 2012, I became Senior Director of Pharmaceutical Research and Development at Baxter Biopharma Solutions ("Baxter"). At Baxter, I was the leader of the Baxter Lyophilization Center of Excellence, and personally participated in the formulation of approximately 10

lyophilized compounds. I also provided technical training and offered over 20 lectures on various sterile products.

7. I have taught extensively in the fields pharmaceutical formulation and development with a special focus on development of parenterals. From 1977-1981, I was Assistant Professor and then Associate Professor at the University of Tennessee College of Pharmacy. I taught courses on physical chemistry, parenterals, ophthalmics, and pharmaceutical technology. I have also served as an Adjunct Professor at Purdue University, the University of Illinois College of Pharmacy, the University of Cincinnati College of Pharmacy, and the Butler University College of Pharmacy, and have taught an estimated 3000+ professionals on the basics of sterile product development, manufacturing, and quality control.

8. I have published 47 peer-reviewed articles in various journals, with a number of those papers specifically focusing on parenteral and/or lyophilized formulations. *See, e.g.*, Kim, AI, Akers, MJ, and Nail, SL, The Physical State of Mannitol After Freeze-Drying: Effects of Mannitol Concentration, Freezing Rate, and a Non Crystallizing Cosolute, *J. Pharm. Sci.,* 87, 931-931, 1998; Akers, MJ, Nail, SL, and Groves, MJ, Top Ten Technical Issues in Parenteral Science--Revisited, 1997, *Pharm Tech,* 21, 126-136, 1997; Schwegman, JJ, Hardwick, LM, and Akers, MJ, Formulation and Process Development of Freeze-Dried Biopharmaceuticals, *Pharm. Dev. Tech.,* 10, 151-173, 2005; and Hardwick, LM,

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