UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

FRESENIUS KABI USA, LLC,
Petitioner

v.

CEPHALON, INC.,
Patent Owner

Case IPR2016-00111
Patent No. 8,895,756

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. 8,895,756

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P.O. Box 1450
Alexandria, VA 22313-1450

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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. 8,895,756 ("the '756 patent"). I have been asked to provide my opinions regarding the motivation to combine certain prior art references from the perspective of one of 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 of 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

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