

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

HARVEST TRADING GROUP, INC.,
Petition

v.

VIREO SYSTEMS, INC. AND
UNEMED CORPORATION,

Patent Owners

U.S. PATENT NO. 8,354,450
IPR 2016-00945

U.S. PATENT NO. 8,962,685
IPR 2016-00947

DECLARATION OF ALEKHA K. DASH, R.Ph., Ph.D.

Ex. 2010

DECLARATION

I, Alekha K. Dash, hereby declare and say:

1. I am over the age of eighteen (18) and have personal knowledge of the matters set forth herein.

2. I have been retained by counsel for Patent Owner Vireo Systems, Inc. to provide an expert declaration in support of Owner's Preliminary Response to the Petition for *Inter Partes* Review filed by Harvest Trading Group, Inc (Paper 1).

PROFESSIONAL BACKGROUND

3. I hold a Bachelor of Pharmacy degree with first class honors from Jadavpur University in Calcutta, India in 1981, a Masters in Pharmacy in Pharmaceutics from Jadavpur University in 1983, and a Doctor of Philosophy in Pharmaceutics in 1990 from the University of Minnesota.

4. I am a professor and the Gilbert F. Taffe, Jr. Endowed Chair in the Department of Pharmacy Sciences at the School of Pharmacy & Health Professions of Creighton University. I am also the Interim Associate Dean for Research in the School of Pharmacy and Health Professions. I have been employed as a professor and researcher at Creighton University since 1990.

5. I have been a Fellow of the American Association of Pharmaceutical Scientists since 2012, and was an Academic Leadership Fellow in the American Association of Colleges of Pharmacy in 2008-2009. I have been a member of the on-

site evaluation team for the Accreditation Council for Pharmacy Education since 2007. I have served as a chair or member on numerous professional association committees. I have served as a peer reviewer for 23 medical and pharmaceutical journals.

6. Part of my academic and pharmaceutical research has included studying creatine and various creatine derivatives. In 1999 I received a grant for “Evaluation of the Solid-State Properties and Oral Bioavailability of Creatine Monohydrate.” I also served as Master’s thesis advisor for the graduate student involved in this research. In 2000 I received an additional fellowship grant for the study of “Solid-State Properties of Creatine Monohydrate.” In 2009-2010, I received a grant for the study of “Creatine Nitrate Solubility and Stability.” In 2015, I received a grant regarding the “Evaluation of Creatine Permeability Studies.”

7. I am a named co-author on 11 abstracts, 5 peer-reviewed published journal articles, and a book chapter concerning creatine and creatine derivatives. These include the following publications:

- Dash, A.K., Miler, D. W., Huai-Yan, H, Carnazzo, J. and Stout, J. R., Evaluation of the Creatine Monohydrate Permeability Using Caco-2 Monolayers as an *In Vitro* Model for Intestinal absorption, *J. Pharm. Sci.*, 90 (2001) 1593-1598;
- Dash, A. K., Mo, Y., and Pyne, A., Solid-State Properties of Creatine Monohydrate, *J. Pharm. Sci.*, 91 (2002) 708-718;

- Dash, A. K. and Sawhney A., A Simple LC Method with UV Detection for the Analysis of Creatine and Creatinine and its Application to Several Creatine Formulations, *J. Pharm. Biomed. Anal.*, 29 (2002) 939-945;
- Mo, Y., Dobberphul, D. and Dash, A. K., A Simple HPLC Method with Pulsed EC Detection for the Analysis of Creatine, *J. Pharm. Biomed. Anal.*, 32 (2003) 125-132;
- Ganguly, S., Jayappa, S. and Dash, A.K. Evaluation of the Stability of Creatine in Solutions Prepared from Effervescent Creatine Formulations, *AAPS PharmSciTech* 2003; 4 (2) Article 26;
- Dash, A. K., and Singh, S. “Creatine Monohydrate,” in *Analytical Profiles of Drug Substances and Excipients*: Edited by H. Brittain, ed., Academic Press, San Diego, CA, Volume 34 (2009) pp. 1-37.

8. A full copy of my curriculum vitae is submitted with this Declaration as Ex. 2011.

OVERVIEW AND MATERIALS REVIEWED

9. I understand that Vireo is one of the co-owners of U.S. Patent Nos. 8,354,450 (the “ ‘450 Patent”), 8,962,685 (the “ ‘685 Patent”), 8,026,385 (the “ ‘385 Patent”), and 7,608,641 (the “ ‘641 Patent”).

10. I understand that the ‘450 Patent is subject to a petition for *inter partes* review in Proceeding No. IPR2016-00945, and that the ‘685 Patent is subject to a petition for *inter partes* review in Proceeding No. IPR2016-00947. I further

understand that the '450 Patent is identified as a continuation in part of the '385 Patent, and the '385 Patent is a continuation of the '641. I further understand and that the '685 Patent is a divisional of the '450 Patent.

11. In connection with this matter, I have reviewed the '450 Patent, the '685 Patent, the '641 Patent, Exhibits 1001-1034 filed with the Petition in IPR2016-00945, Exhibits 1101-1134 filed with the Petition in IPR-00947, and the following additional documents:

Owner Exhibit	Document
2009	U.S. Pat. No. 7,608,641
2012	Declaration of Jason Wiggers
2013	Declaration of Samir A. Saleh
2014	The American Heritage Dictionary of the English Language (3d ed. 1992)
2015	Chambers Dictionary of Science & Technology (2007)
2016	The Merck Index (8 th ed. 1968)
2017	<i>Remington: The Science and Practice of Pharmacy, Vol. 1</i> (19th ed. 1995)
2018	Grant, D.J.W. and Brittain H.G., "Solubility of Pharmaceutical Solids," in <i>Physical Characterization of Pharmaceutical Solids</i> (1995) (ed. Brittain, H.G.)
2019	"Creatinine," MP Biomedicals, http://www.mpbio.com/detailed_info.php?family_key=02153916&country=223 (last accessed July 31, 2016)
2020	Krstulovic, A.M. & C.R. Lee, "Defining drug purity through chromatographic and related methods: current status and perspectives," <i>J. Chromatography B</i> 689 (1997), 137-153

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