

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 SAMIR A. SALEH

Ex. 2013

DECLARATION

I, Samir A. Saleh, MS, 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 am a research scientist in drug discovery and pharmacology, and I worked as a research scientist at Vanderbilt University in Nashville, TN for 36 years. I have a bachelor's degree in Chemistry from Middle Tennessee State University in 1976, and a masters degree in Organic Chemistry from Middle Tennessee State University in 1979. As part of my research and work, I am familiar with protocols for measuring the purity of chemical substances, including drugs and nutritional or dietary supplements.
3. I was retained by Vireo Systems, Inc. to determine to purity of creatine hydrochloride in certain samples provided to me by Mr. Jason Wiggers on June 20, 2016.
4. I received the samples in sterile packaging. The packaging was unopened at the time of receipt. A copy of the samples' chain of custody documentation, which I received and executed on June 20, 2016, is attached hereto as **Exhibit A**.
5. The first sample was labeled as produced using a manufacturing method based on acetyl chloride.

6. The second sample was labeled as produced using hydrochloride gas infusion.

7. For each sample, I opened the sterile packaging and dissolved a weight of 20 mg of the sample in 600ul DMSO-d₆. This solution was transferred to a 5 mm glass nuclear magnetic resonance (NMR) tube and loaded to an Avance 400 MHz Bruker instrument probe. The full test procedure for each sample is described in the analysis prepared by me and attached hereto as **Exhibit B**. This resulted in two spectrographs, one for each sample. The spectrographs are attached hereto as **Exhibit C**.

8. To identify the amount of creatine hydrochloride, I compared the area under the peaks in each NMR spectra.

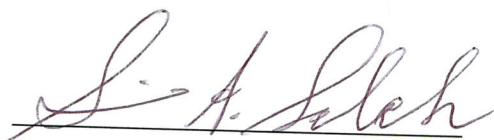
9. As seen in the results in Exhibit C, Sample 1, identified as manufactured using acetyl chloride, comprised creatine hydrochloride at a purity of greater than or equal to 98% compared to less than or equal to 2% of impurities. Sample 2, identified as manufactured using hydrochloride gas infusion, comprised creatine hydrochloride at a purity of greater than or equal to 95% compared to less than or equal to 5% impurities.

10. I personally conducted and am familiar with the testing protocols used in the purity testing described above and in the exhibits. The procedures and equipment

identified in Exhibit B are standard and well known for testing purity of a particular sample. I can testify to such protocols if called upon to do so.

11. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements were made with the knowledge that willful or false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the patents to which this proceeding pertains.

Respectfully submitted,



Samir A. Saleh

Date: 8-1-2016



Chain of Custody

Item #	Description of Item
Sample 1	Creatine HCl synthesized via method (1) in Patent #7,608,641
Sample 2	Creatine HCl synthesized via alternative method (2) in Patent #7,608,641

Source:	Vireo Systems, Inc. Lab: Batch #CHCL2016PT0620-1 and Batch #CHCL2016PT0620-2 Manufacturing supervised by Jason Wiggers, Chief of Operations
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Relinquished by: <i>Filter Paper</i>		Received by: <i>Sterile Packaging</i>	
Signature and Print Last Name <i>Chandler Patty</i> PATTY		Signature and Print Last Name <i>Chandler Patty</i> PATTY	
Company VIREO SYSTEMS	Time & Date 9:32 AM 6/20/2016	Company VIREO SYSTEMS	Time & Date 9:33 AM 6/20/2016
Method of Transfer Used plastic scraper to transfer the Creatine HCl from filter paper to sterile bags.			

Relinquished by: <i>Chandler Patty</i>		Received by: <i>Jason Wiggers</i>	
Signature and Print Last Name <i>Chandler Patty</i> PATTY		Signature and Print Last Name <i>J. Wiggers</i> Wiggers	
Company VIREO SYSTEMS	Time & Date 1:45 PM 6/20/2016	Company Vireo Systems	Time & Date 13:46 6/20/2016
Method of Transfer <i>Person to Person Transfer</i>			

Relinquished by: <i>Jason Wiggers</i>		Received by: <i>Samir Saleh</i>	
Signature and Print Last Name <i>J. Wiggers</i> Wiggers		Signature and Print Last Name <i>S. Saleh</i> Saleh	
Company Vireo Systems	Time & Date 15:30 6/20/2016	Company Contract Chemist	Time & Date 15:30 6/20/2016
Method of Transfer <i>Person to Person Transfer</i>			

Vireo Systems, Inc.

305 Williams Avenue

Madison, TN 37115

855-442-6466

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