

PUBLIC VERSION

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C. 20436**

ORIGINAL

In the Matter of)
CERTAIN PRODUCTS ADVERTISED)
AS CONTAINING CREATINE ETHYL ESTER)
_____)

Investigation No. 337-TA-

**COMPLAINT OF UNeMed CORPORATION
UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED**

Complainant

UNEMED CORPORATION
986099 Nebraska Medical Center
Omaha Nebraska 68198-6099
(402) 559-2468

Proposed Respondents

BODYONICS, LTD.
140 Lauman Lane
Hicksville, New York 11801
(516) 822-1230

CONTROLLED LABS
133A North Avenue
New Rochelle, New York 10804
(800) 692-4558

ENGINEERED SPORTS
TECHNOLOGY, INC.
4250 Alafaya Trail
Oviedo, Florida 32765
(407) 273-5555

NRG-X LABS
10636 West Highway 72 #1001
Bentonville, Arkansas 72712

PROVIANT TECHNOLOGIES, INC.
309 West Hensley Road
Champaign, Illinois 61822-8401
(217) 398-0000

SAN CORPORATION
716 North Ventura Road #431
Oxnard, California 93030
(805) 988-0640

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LIST OF EXHIBITS

- A. U.S. Patent No. 6,897,334
- B. U.S. App. Pub. No. 2007/0203076
- C. U.S. App. Pub. No. 2003/0212130
- D. PCT App. Pub. No. WO 2002/22135
- E. Declaration of Michael J. Dixon, Ph.D.
- F. Declaration of Mark Faulkner
- G. www.hbees.com/es2120082.html?productid=es2120082&channelid=BCOME
- H. www.controlledlabs.com/product_desc.php?id=28
- I. www.estnutrition.com/supplementfacts/ester-sized-xp.jpg
- J. <http://nrgxlabs.com/NRGXITEMS/CEE3000.html>
- K. http://www.ahpnutrition.com/products/ergo_pharm_cell_fuel_180_caps.shtml
- L. http://www.sann.net/shop/index.php?main_page=product_info&cPath=18&products_id=11

Physical Exhibits

- 1. Bodyonics, Ltd., Pinnacle PermMax Creatine 4000
- 2. Controlled Labs, Green Bulge-Creatine Matrix Volumizer
- 3. Engineered Sports Technology, Inc., XP Ester Sized
- 4. NRG-X Labs, CEE 3000
- 5. Proviant Technologies, Inc., Cell Fuel Anabolic Creatine Matrix
- 6. San Corporation, Cm2 Alpha-Creatine Ethyl Ester-HCl

I. INTRODUCTION

1. This Complaint is brought pursuant to Section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337 by the complainant, UNeMed Corporation (“UNeMed”) against the respondents named herein by virtue of their importation into, and sale in, the United States of products falsely advertised as containing creatine ethyl ester, resulting in an injury to UNeMed’s domestic industry dedicated to the licensing of intellectual property rights in food supplements containing creatine ethyl ester.

II. THE COMPLAINANT

2. UNeMed Corporation, a for-profit corporation organized under the laws of the State of Nebraska, is the technology transfer entity of the University of Nebraska Medical Center (“UNMC”), and the exclusive licensee of patents filed and issued to the Board of Regents of the University of Nebraska on behalf of UNMC employees.
3. UNeMed’s portfolio includes U.S. Patent No. 6,897,334, entitled *Production of creatine esters using in situ acid production* (“the ‘334 patent”) (Ex. A), U.S. App. Pub. No. 2007/0203076, entitled *Creatine Ester Pronutrient Compounds and Formulations* (“the ‘076 application”) (Ex. B), U.S. App. Pub. No. 2003/0212130, entitled *Creatine Ester Anti-inflammatory Compounds and Formulations* (“the ‘130 application) (Ex. C), and PCT App. Pub. No. WO 2002/22135, entitled *Creatine Ester Pronutrient Compounds and Formulations* (the ‘135 application) (Ex. D) (collectively “the UNMC Intellectual Property”), which relate to creatine ethyl ester used as a nutritional supplement, an anti-inflammatory and a novel way of manufacturing that material. UNeMed is the owner, by valid assignment, of the entire right, title, and interest in and to the UNMC Intellectual Property.

4. The inventors named on the '076 application, Dr. Jonathan Vennerstrom and Dr. Donald Miller, were the first to discover that creatine, a popular nutritional supplement, when in esterified form, absorbs more efficiently in the human body, thereby reducing the amount of nutritional supplement required to maximize the benefits thereof. '076 Application (Ex. B), ¶ 31.

III. THE PROPOSED RESPONDENTS

5. Upon information and belief, Bodyonics, Ltd. ("Bodyonics") is a corporation with a principal place of business at 140 Lauman Lane, Hicksville, New York 11801. Bodyonics sells Pinnacle PermMax Creatine 4000, advertised as containing creatine ethyl ester. (Ex. G).
6. Upon information and belief, Controlled Labs is a corporation with a principal place of business at 133A North Avenue, New Rochelle, New York 10804. Controlled Labs sells Green Bulge-Creatine Matrix Volumizer, advertised as containing creatine ethyl ester. (Ex. H).
7. Upon information and belief, Engineered Sports Technology, Inc. ("EST") is a corporation with a principal place of business at 4250 Alafaya Trail, Oviedo, Florida 32765. EST sells XP Ester Sized, advertised as containing creatine ethyl ester. (Ex. I).
8. Upon information and belief, NRG-X Labs ("NRG-X") is a corporation with a principal place of business at 10636 West Highway 72 #1001, Bentonville, Arkansas 72712. NRG-X sells CEE 3000, advertised as containing creatine ethyl ester. (Ex. J).
9. Upon information and belief, Proviant Technologies, Inc. ("Proviant") is a corporation with a principal place of business at 309 West Hensley Road, Champaign, Illinois 61822-8401.

Proviant sells Cell Fuel Anabolic Creatine Matrix, advertised as containing creatine ethyl ester. (Ex. K).

10. Upon information and belief, San Corporation ("San") is a corporation with a principal place of business at 716 North Ventura Road #431, Oxnard, California 93030. San sells Cm2 Alpha-Creatine Ethyl Ester-HCl, advertised as containing creatine ethyl ester. (Ex. L).

IV. HARMONIZED TARIFF SCHEDULE NUMBER

11. The raw creatine contained in the respondents' afore-described products is imported from under subheading 2925.20.9000 of the Harmonized Tariff Schedule of the United States (HTS).

V. UNFAIR ACTS COMMITTED BY RESPONDENTS – FALSE ADVERTISING

12. Vireo Systems, Inc., UNEMed's sublicensee to the UNMC Intellectual Property, is the sole manufacturer of raw creatine ethyl ester, *i.e.*, creatine that has been esterified, in the United States. The raw materials contained in all other products advertised as containing creatine ethyl ester are manufactured outside of the United States, primarily in the People's Republic of China. Dixon Decl. (Ex. E), ¶ 9; Faulkner Decl. (Ex. F), ¶ 3.
13. As none of the respondents purchase raw creatine ethyl ester from Vireo, they are purchasing products advertised as creatine ethyl ester from manufacturers overseas for formulation into finished nutritional supplements advertised as containing creatine ethyl ester. Faulkner Decl. (Ex. F), ¶ 4.

14. The respondents have advertised the above-identified products as containing creatine ethyl ester, when such products contain no creatine ethyl ester, and have thus falsely advertised the composition of such products.
15. UNeMed has tested the afore-identified respondents' products advertised as containing creatine ethyl ester using both nuclear magnetic resonance and high performance liquid chromatography. The results of those tests reveal that such products contain no creatine ethyl ester. Dixon Decl. (Ex. E), ¶ 9.
16. The sales of these falsely-advertised products is a violation of section 43(a) of the Lanham Act (15 U.S.C. §1125(a)), and the Nebraska Uniform Deceptive Trade Practices Act, R.R.S. Neb. §87-302 (2008).

VI. COMPLAINANTS' BUSINESS AND THE AFFECTED DOMESTIC INDUSTRY

17. UNeMed currently offers an extensive portfolio of over 100 technologies available for licensing, and negotiates approximately 250 technology transfer contracts per year. The '334 patent and the '076 application are a significant part of UNMC's overall intellectual property portfolio. Dixon Decl. (Ex. E), ¶ 2.¹
18. Drs. Vennerstrom and Miller, both of whom were professors at UNMC at the time, performed the research underlying the UNMC Intellectual Property at the facilities of UNMC in Omaha, Nebraska. UNMC invested financial resources to support the research in the form of Dr. Vennerstrom's and Dr. Miller's salaries. Dixon Decl. (Ex. E), ¶ 3.

19. UNeMed has invested \$199,121.56 in the UNMC Intellectual Property, including patent prosecution costs and maintenance fees. Dixon Decl. (Ex. E), ¶ 4.
20. UNeMed employs 12 full-time employees devoted to the licensing of technology on behalf of UNMC, including the UNMC Intellectual Property. These 12 employees include the President and Vice-President of UNeMed, three licensing specialists, an intellectual property specialist, a patent associate, a marketing specialist, three professional support personnel, and a post-doctoral fellow. Also affiliated with UNeMed are seven interns and one outside consultant. Organizationally, the President of UNeMed is also the Associate Vice Chancellor for Research and reports to the Vice Chancellor of Research for UNMC. Dixon Decl. (Ex. E), ¶ 5.
21. UNeMed has an annual operating budget in 2008-09 of _____, approximately _____ million of which is apportioned for salaries, and _____ of which is apportioned for operating expenses and services. Dixon Decl. (Ex. E), ¶ 6.
22. UNeMed is the exclusive licensee of the UNMC Intellectual Property. Dixon Decl. (Ex. E), ¶ 7.
23. UNeMed originally licensed the UNMC Intellectual Property to Pronutrient Technologies, Inc. (“Pronutrient”) of Omaha, Nebraska. Dixon Decl. (Ex. E), ¶ 8.
24. UNeMed terminated its sublicense with Pronutrient and subsequently sublicensed the UNMC Intellectual Property to Vireo Systems, Inc. of Madison, Tennessee (“Vireo”). Dixon Decl. (Ex. E), ¶ 9.

25. Pronutrient was, and Vireo is, in the business of, *inter alia*, manufacturing creatine ethyl ester according to the claims of the '334 patent, and offering for sale and selling creatine ethyl ester according to the claims of the '076 application. These manufacturing and selling activities have been under sublicense to the UNMC Intellectual Property from UNeMed. Faulkner Decl. (Ex. F), ¶ 2; Dixon Decl. (Ex E), ¶ 10.

26. Pronutrient was, and Vireo is, to pay UNeMed a royalty pursuant to the sublicense between the two companies for the creatine ethyl ester that Vireo sells. UNeMed has received _____ in royalties from its licensees; _____ from Vireo and _____ from Pronutrient. Dixon Decl. (Ex. E), ¶ 11.

27. UNeMed does not itself manufacture products embodying the UNMC Intellectual Property.

28. For the period 2005-06 Vireo's annual sales of raw creatine ethyl ester ranged from _____ a year, primarily to Medical Research Institute in San Francisco, California. Beginning in 2006, however, Vireo's annual sales of raw creatine ethyl ester were reduced to _____ per year. This reduction in sales was coincident with the widespread introduction of product advertised as containing creatine ethyl ester, wherein the raw material for such product was imported from overseas, principally the People's Republic of China. Faulkner Decl. (Ex. F), ¶ 8

VII. RESPONDENTS' ACTIONS HAVE CAUSED AND THREATEN TO CAUSE SUBSTANTIAL INJURY TO THE DOMESTIC INDUSTRY

29. Because purchasers of products falsely advertised as containing creatine ethyl ester do not receive the benefits of the esterified form of creatine, such purchasers have developed a negative commercial impression of the relatively higher-priced creatine ethyl ester products generally. This has resulted in an overall decrease in demand for formulated creatine ethyl

ester products, which, in turn, reduces the demand for Vireo's raw creatine ethyl ester used in the manufacture of those products. The sales of such falsely-advertised products have substantially injured UNeMed insofar as such sales have taken market share away from UNeMed's licensee, Vireo, thereby reducing the royalties paid by Vireo to UNeMed for sales of raw creatine ethyl ester. Faulkner Decl. (Ex. F), ¶ 5.

30. The esterification of creatine is a process step that substantially adds to the cost of production of raw materials used in products advertised as containing creatine ethyl ester. To the extent that companies falsely advertise raw materials that have not undergone the esterification process step, such companies are able to lower the manufacturing costs for their raw material. This results in lost sales to Vireo, which does perform the esterification process step, thus incurring the costs associated with such step. For example, raw creatine HCL (a form of creatine that does not undergo esterification) sells for between \$4.00 and \$6.00 per kilogram. In contrast, Vireo sells raw creatine ethyl ester (creatine that has undergone esterification) for between \$18.00 and \$22.00 per kilogram. Vireo is unable to compete on a cost basis with companies that sell such relatively cheaper, falsely-advertised product. Faulkner Decl. (Ex. F), ¶ 6.

31. Although there are foreign manufacturers of creatine ethyl ester, the unfair acts of the respondents described herein are uniquely injurious to Vireo. With other economic factors being relatively equal, domestic formulators of products containing creatine ethyl ester will tend to favor domestic supplier of such raw material in light of the proximity and reliability of such suppliers. Faulkner Decl. (Ex. F), ¶ 7.

VIII. OTHER LITIGATION

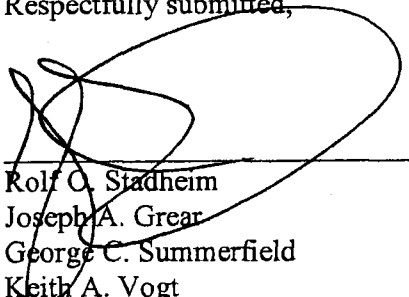
32. The subject matter of this Complaint has not been the subject of any court proceeding.

IX. RELIEF REQUESTED

WHEREFORE, the complainant, UNeMed Corp., respectfully requests that the Commission:

- 1) institute an investigation into the afore-described unfair acts;
- 2) upon the completion of such investigation, issue orders: a) excluding from entry into the customs territory of the United States raw material purporting to be creatine ethyl ester, but which contains no creatine ethyl ester; and b) mandating the cessation of sales and distribution by the respondents of products formulated with imported raw materials falsely advertised as containing creatine ethyl ester; and
- 3) Grant such further relief as the Commission deems just.

Respectfully submitted,



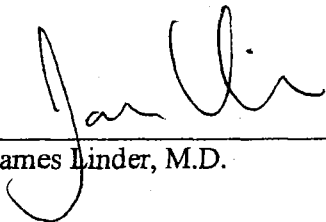
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Date: May 19, 2009

CERTIFICATION PURSUANT TO 19 C.F.R. § 212(a)(1)

I, Dr. James Linder, the Chief Executive Officer of UNeMed Corporation ("UNeMed"), located at Annex 14, 4460 Farnam Street, Suite 3000, Omaha Nebraska 68198, Telephone (402) 559-2468, hereby declare under penalty of perjury that I have read this Complaint, and that: 1) It is not being presented for any improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of the investigation or related proceeding; 2) The claims, defenses, and other legal contentions therein are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law; and 3) the allegations and other factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.



James Linder, M.D.

Date: 5/12/09