

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

HARVEST TRADING GROUP, INC.

Petitioner

v.

VIREO SYSTEMS, INC. AND

UNEMED CORPORATION

Patent Owner

U.S. PATENT NO. 8,962,685

Case IPR: Unassigned

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. GROUNDS FOR STANDING.....	1
III. MANDATORY NOTICES (37 C.F.R. § 42.8)	2
A. Real Party in Interest (§ 42.8(b)(1))	2
B. Related Matters (§ 42.8(b)(2))	3
C. Lead and Backup Counsel (§ 42.8(b)(3)).....	3
D. Service Information (§ 42.8(b)(4)).....	3
IV. PAYMENT OF FEES (37 C.F.R. §§ 42.15(a) and 42.103).....	3
V. U.S. PATENT NO. 8,962,685	4
A. Overview	4
B. Prosecution History	4
C. Priority.....	6
VI. CLAIM CONSTRUCTION	8
VII. IDENTIFICATION OF CHALLENGED CLAIMS.....	13
A. 35 U.S.C. §102(b)/103(a).....	13
B. 35 U.S.C. §103(a).....	14
VIII. DETAILED EXPLANATION OF CHALLENGE	14
A. Overview	14
B. Grounds for Invalidity.....	22
IX. CONCLUSION.....	60

TABLE OF EXHIBITS

Exhibit	Description
1101	U.S. Patent No. 8,962,685
1102	U.S. Publication No. 2004/0242691
1103	U.S. Provisional No. 60/470,356
1104	Docket Sheet: ProMera Health, LLC v. Vireo Sys., Inc., et al., 1:15-cv-10595-NMG, D. Mass.
1105	Second Amended Complaint: ProMera Health, LLC v. Vireo Sys., Inc., et al., 1:15-cv-10595-NMG, D. Mass.
1106	Zumdahl, Steven S., Chemistry, Third Ed. , Heath and Company: Lexington MA, 1993. Section 15.6
1107	Declaration of Richard van Breemen
1108	Hilal SH et al, Quantitative Treatments of Solute/Solvent Interactions: Theoretical and Computational Chemistry Vol. 1 , Elsevier, pp. 291-353 (1994).
1109	Gufford et al., Physiochemical Characterization of Creatine N-Methylguanidinium Salts , Journal of Dietary Supplements, 7(3); 240-252 (2010).
1110	Abdon et al., On the appearance of phosphocreatine in blood at uraemia , Acta Medica Scandinavica, 95(S90); 444-454 (1938).
1111	Practising Law Institute, Faber on Mechanics of Patent Claim Drafting, 7 th Ed., Chapter 6: Composition of Matter Claims-Chemical Cases.
1112	Needham et al., Solubility of Amino Acids in Pure Solvent Systems. J. Pharm. Sci., 60(4); 565-567 (1971)
1113	Cannan et al., CXV. The Creatine-Creatinine Equilibrium. The Apparent Dissociation Constants of Creatine and Creatinine. Bioch. 59: 920-929 (1928).
1114	CN101407478
1115	How CON-CRET™ Works Website 2004 available at: https://web.archive.org/web/20041206041250/http://concret.com/howitworks.html .
1116	U.S. Pat. No. 5,627,172
1117	MSDS CON-CRET™ Rev. Date: August 18, 2004.
1118	Bastin et al., Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities , Org. Process Res. Dev., 4, 427-435 (2000).
1119	Heymsfield, et al., Assessing Skeletal Muscle Mass: Historical Overview and State of the Art , 5: 9-18 (2014).

Exhibit	Description
1120	Folin and Denis, Protein Metabolism from the Standpoint of Blood and Tissue Analysis: Third Paper. Further Absorption Experiments with Especial Reference to the Behavior of Creatine and Creatinine and to the Formation of Urea , Journal of Biological Chemistry (1912); 12: 141-162.
1121	Benedict and Osterberg, Studies in Creatine and Creatinine Metabolism V. The Metabolism of Creatine , Journal of Biological Chemistry (1923); 56: 229-252.
1122	Chanutin, The Fate of Creatine when Administered to Man , Journal of Biological Chemistry (1926); 67: 29-41.
1123	Pick, Hollinck and Zacharellis, Uber Hemmungs and Potenzierungs-Phanomene am quergestreiften Muskel , Arch. exper. Patn u. Phamakol, 220: 83-99 (1953).
1124	Buford, et al., International Society of Sports Nutrition position stand: creatine supplementation and exercise , Journal of International Society of Sports Nutrition, 4: 6 (2007).
1125	U.S. Patent No. 3,933,797
1126	Creatinine HCl Data Sheet- Sigma Aldrich
1127	Declaration of Brad Curran
1128	Hunter, A., Creatine and Creatine , Monographs on Biochemistry, Vol. 8, Longmans, Green and Co, Ltd., p. 36 (1928)
1129	Richard van Breemen CV
1130	Jager et al, Analysis of the efficacy, safety, and regulatory status of novel forms of creatine , Amino Acids 40:1369-1383 (2011)
1131	Response filed January 18, 2011 in U.S. App. No. 12/4,77,413
1132	CON-CRET® Label Proof Copyright 2008
1133	File Wrapper '685 Patent
1134	U.S. Patent No. 8,354,450

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Atlas Powder Co. v. Ireco Inc.</i> , 190 F.3d 1342 (Fed. Cir. 1999).....	20
<i>Augustine Med., Inc. v. Gaymar Indus., Inc.</i> , 181 F.3d 1291 (Fed. Cir. 1999)	7
<i>In re Best</i> , 562 F.2d 1252 (CCPA 1977).....	20, 23
<i>Bristol-Myers Squibb v. Ben Venue Labs</i> , 246 F.3d 1368 (Fed. Cir. 2001)	49
<i>In re Chu</i> , 66 F.3d 292 (Fed. Cir. 1995)	7
<i>Clio USA, Inc. v. The Procter and Gamble Co.</i> , IPR2013-00438 (Jan. 9, 2014, Paper 9 at 7)	1
<i>In re Cuozzo Speed Techs., LLC</i> , 778 F. 3d. 1271 (Fed. Cir. 2015), cert. granted, 136 S. Ct. 890 (January 15, 2016)	8
<i>In re Donohue</i> , 766 F.2d 531 (Fed. Cir. 1985).....	20
<i>Eli Lilly & Co. v. Barr Labs., Inc.</i> , 251 F.3d 955 (Fed.Cir.2001)	23, 49, 52
<i>Florida Dep't of State v. Treasure Salvors, Inc.</i> , 458 U.S. 670 (1982).....	2
<i>Ex parte Gelles</i> , 22 USPQ2d 1318 (Bd. Pat. App. & Inter. 1992)	20
<i>In re Huston</i> , 308 F.3d 1267 (Fed. Cir. 2002)	7
<i>Jet, Inc. v. Sewage Aeration Sys.</i> , 223 F.3d 1360 (Fed. Cir. 2000)	2
<i>In re Kratz</i> , 592 F.2d 1169 (CCPA 1979).....	23, 49, 52
<i>Kropa v. Robie</i> , 187 F.2d 150 (CCPA 1951).....	9
<i>Lockwood v. Am. Airlines, Inc.</i> , 107 F.3d 1565 (Fed. Cir. 1997).....	7
<i>Phillips v. AWH Corp.</i> , 415 F. 3d 1303 (Fed. Cir. 2005)	48, 52
<i>Pitney Bowes, Inc. v. Hewlett-Packard Co.</i> , 182 F.3d 1298 (Fed. Cir. 1999)	9

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.