



US006660297B2

(12) **United States Patent**  
**Bartels et al.**

(10) **Patent No.: US 6,660,297 B2**  
(45) **Date of Patent: Dec. 9, 2003**

(54) **NUTRITIONAL SUPPLEMENT TO TREAT MACULAR DEGENERATION**

(75) Inventors: **Stephen Paul Bartels**, Wyckoff, NJ (US); **Cara Lorraine Baustian**, Palisades, NY (US); **George Edwin Bunce**, Blacksburg, VA (US); **Leon Ellenbogen**, New City, NY (US); **Frederick L. Ferris, III**, Columbia, MD (US); **Jin Kinoshita**, El Macero, CA (US); **James Cecil Smith, Jr.**, Glenn Dale, MD (US); **David A. Souerwine**, Pittsford, NY (US)

(73) Assignee: **Bausch & Lomb Incorporated**, Rochester, NY (US)

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/816,284**

(22) Filed: **Mar. 23, 2001**

(65) **Prior Publication Data**

US 2002/0182266 A1 Dec. 5, 2002

(51) **Int. Cl.**<sup>7</sup> ..... **A61K 9/20**  
(52) **U.S. Cl.** ..... **424/464**; 424/451; 424/489; 424/400; 424/427

(58) **Field of Search** ..... 424/439, 617, 424/489, 464, 400, 451, 484, 427

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

5,075,116	A	*	12/1991	LaHaye et al.	424/617
5,607,707	A		3/1997	Ford et al.	426/2
5,739,156	A		4/1998	Bissett	514/458
5,770,217	A		6/1998	Kutilek, III et al.	424/442
5,948,443	A		9/1999	Riley et al.	424/643
5,976,568	A		11/1999	Riley	424/451
6,020,351	A		2/2000	Pero	514/355
6,103,756	A	*	8/2000	Gorsek	514/458

**FOREIGN PATENT DOCUMENTS**

DE	200 12 510 U 1	11/2000	.....	A23L/1/29
EP	0 930 072	7/1999	.....	A61K/33/00
GB	2 301 775 A	12/1996	.....	A61K/31/07
WO	WO 01 19383	3/2001	.....	A61K/35/78
WO	WO 01 91765	12/2001	.....	A61K/35/00

**OTHER PUBLICATIONS**

Newsome, D. A., Oral Zinc in Macular Degeneration, Arch. Ophthalmol., vol. 106, Feb. 1988, pp. 192-198.\*  
Age-Related Eye Disease Study Research Group, The Age-Related Eye Disease Study: A Clinical Trial of Zinc and Antioxidants—Age-Related Eye Disease Study Report No. 2, Journal of Nutrition, 2000.  
R. E. Wyszynski, A Donor-Age-Dependent Change in the Activity of alpha-Mannosidase in Human Cultured RPE Cells, Investigative Ophthalmology & Visual Science, vol. 30, No. 11, Nov. 1989, pp. 2341-2347.

D. B. Milne, Effect of Ascorbic Acid on Copper and Cholesterol in Adult Cynomolgus Monkeys Fed a Diet Marginal in Copper, The American Journal of Clinical Nutrition, Nov. 1981, pp. 2389-2393.

D. B. Milne, Effects of Ascorbic Acid Supplements and a Diet Marginal in Copper on Indices of Copper Nutrition in Women, Nutrition Research, vol. 8, 1988, pp. 865-873.

D. A. Newsome, Oral Zinc in Macular Degeneration, Arch. Ophthalmol.—vol. 106, Feb. 1988, pp. 192-198.

Storz Ophthalmics, A Closer Look at the Consequences of Radical Behavior in the Eye, Jul. 1997.

Copper responsive anemia, induced by oral zinc therapy in a patient with acrodermatitis enteropathica Authors: Hoo-genraad, et al. Sci Total Environ, (1985) Mar. 15:42 (1-2):37-43.

Zinc-induced copper deficiency in an infant Authors: Botash, et al. Am J Dis Child, (1992) Jun., 146 (6):209-11.

Zinc-induced copper deficiency Authors: Hoffman, et al. Gastroenterology (1988) Feb., 94(2):508-12.

Hypocupremia induced by zinc therapy in adults Authors: Prasad, et al. JAMA, (1978) Nov. 10, 240(20); 2166-8.

Age-Related Eye Disease Study Research Group: "A Randomized, Placebo-Controlled, Clinical Trial of High-Dose Supplementation with Vitamins C and E, Beta Carotene and Zinc for Age-Related Macular Degeneration and Vision Loss: AREDS Report No. 8", Archives of Ophthalmology, vol. 119, No. 10 Oct. 2001, pp. 1417-1436.

Age-Related Eye Disease Study Research Group: "A Randomized, Placebo-Controlled, Clinical Trial of High-Dose Supplementation with Vitamins C and E and Beta Carotene for Age Related Cataract and Vision Loss: AREDS Report No. 9", Archives of Ophthalmology, vol. 119, No. 10, Oct. 2001, pp. 1439-1452.

Sardi B: "Nutrition and the eyes:clearing up misconception", Health Foods Business 1997, vol. 43, No. 8, pp. 29-30.

Olson R J: "Supplemental Dietary Antioxidant Vitamins and Minerals in Patients with Macular Degeneration", Journal of the American College of Nutrition, vol. 10, No. 5, 1991, p. 550.

Brown N A et al.: "Nutrition supplements and the eye", Eye (London, England) England 1998, vol. 12 (Pt 1), 1998, pp. 127-133.

\* cited by examiner

*Primary Examiner*—Thurman K. Page

*Assistant Examiner*—Robert M. Joynes

(74) *Attorney, Agent, or Firm*—Rita D. Vacca; Denis A. Polyn

(57) **ABSTRACT**

A nutritional or dietary supplement composition that strengthens and promotes retinal health through the prevention, stabilization, reversal and/or treatment of visual acuity loss by reducing the risk of developing late stage or advanced age-related macular degeneration in persons with early age-related macular degeneration. The nutritional or dietary supplement composition may likewise reduce the risk of vision loss associated with the development of cataracts. The essential ingredients of the nutritional or dietary supplement composition are vitamin C, vitamin E, beta-carotene, zinc and copper. The essential ingredients are preferably provided in a tablet form suitable for oral ingestion. Preferably the composition is taken in the form of one or two tablets taken twice daily.

**21 Claims, No Drawings**