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Paper 15

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CYANOTECH CORPORATION
Petitioner

V.

THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS
Patent Owner

Case IPR2013-00404¹ Patent 5,527,533

Before SCOTT E. KAMHOLZ, SHERIDAN K. SNEDDEN, and GEORGIANNA W. BRADEN, *Administrative Patent Judges*.

SNEDDEN, Administrative Patent Judge.

DECISION

Institution of *Inter Partes* Review and Consolidation with Case IPR2013-00404 *37 C.F.R.* §§ 42.108, 42.122

Case IPR2013-00401 has been consolidated with this proceeding.



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I. INTRODUCTION

In Case IPR2013-00401, Cyanotech Corporation ("Cyanotech") filed a corrected petition (Paper 9, "Pet. '401") to institute an *inter partes* review of claims 1-27 of U.S. Patent No. 5,527,533 ("the '533 patent"). Patent Owner, the Board of Trustees of the University of Illinois ("the University"), filed a preliminary response (Paper 15, "Prelim. Resp. '401").

In Case IPR2013-00404, Cyanotech filed a corrected petition (Paper 8, "Pet. '404") to institute an *inter partes* review of claims 1-27 of the '533 patent. The University filed a preliminary response (Paper 13, "Prelim. Resp. '404").

Case IPR2013-00401 and Case IPR2013-00404 involve the same patent and parties, and there is overlap in the asserted prior art and additional evidence submitted by Cyanotech. As discussed in detail below, we conclude that, under the present circumstances, securing the just, speedy, and inexpensive resolution of the instant proceeding would best be served by consolidating these proceedings.

The Board has jurisdiction under 35 U.S.C. § 314. The standard for instituting an *inter partes* review is set forth in 35 U.S.C. § 314(a), which states:

THRESHOLD.—The Director may not authorize an inter partes review to be instituted unless the Director determines that the information presented in the petition filed under section 311 and any response filed under section 313 shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.

Upon consideration of the above-mentioned petitions and preliminary responses, we conclude that Cyanotech has established that there is a reasonable likelihood that it will prevail with respect to at least one of the challenged claims.



Therefore, we grant the petition to institute an *inter partes* review as to claims 1-15, 21, 22, and 26, but deny the petition as to claims 16-20, 23-25, and 27.

A. Related Proceedings

The parties represent that the '533 patent was involved in a declaratory-judgment civil action, *Cyanotech Corporation v. U.S. Nutraceuticals, LLC d/b/a Valensa International and The University of Illinois* (Civ. No. 1:12-cv-00352) (D. Hawaii) (hereinafter "Hawaii Action"). Pet. '401, 2; Prelim. Resp. '401, 2. Cyanotech filed the action on June 20, 2012, and challenged the validity of claims of the '533 patent (Ex. 1037 and Ex. 2001).

The University moved for dismissal from the Hawaii Action on the basis of sovereign immunity. Prelim. Resp. '401, 2. The court in the Hawaii Action granted the motion and dismissed the action under FRCP 41(b) for failure to join an indispensable party. *Id.* The dismissal was without prejudice to Cyanotech bringing its claims in a co-pending parallel proceeding styled *U.S. Nutraceuticals LLC d/b/a Valensa International; and The Board of Trustees of the University of Illinois v. Cyanotech Corporation, and Nutrex Hawaii, Inc. Civ. 5:12-cv-366-OC-10TBS (M.D. Fla), filed June 29, 2012. Ex. 1038, 2.*

B. The '533 Patent (Ex. 1001)

The '533 patent relates "to methods of treating central nervous system and eye insult resulting from disease or injury" comprising the administration of astaxanthin. Ex. 1001, col. 1, ll. 9-11. Astaxanthin "ameliorates neuronal damage to the retina, wherein the neuronal damage is a result of photic injury, or ischemic, inflammatory or degenerative insult." *Id.* at col. 6, ll. 67 to col. 7, ll. 2. "With



respect to damage from photic injury, astaxanthin decreases the loss of photoreceptor cells. With respect to damage from ischemic insult, astaxanthin ameliorates the loss of ganglion cells and the inner layers of the retinal neuronal network." *Id.* at col. 8, 11. 54-56.

Additionally, "[b]ecause astaxanthin is a highly-effective antioxidant and ameliorates free radical-induced eye damage, the administration of astaxanthin also provides a method of treating free radical-induced disease or injury to the central nervous system in general." *Id.* at col. 15, ll. 56-60. Thus, "astaxanthin can be administered to stroke victims to ameliorate the ischemic insult-related injury attributed to the stroke" and "can be administered to individuals suffering from a traumatic injury to the spinal cord which leads to free radical-induced damage." *Id.* at col. 15, ll. 60-65.

Astaxanthin, unlike other carotenoids studied, can cross the blood-retinal brain barrier readily (unlike β -carotene) without accumulating pathologically in the eye. *Id.* at col. 10, ll. 18-22. Comparative studies with β -carotene demonstrate that astaxanthin is more effective than β -carotene at protecting rats from photic injury. *Id.* at col. 13, l. 60 to col. 14, l. 50.

C. Independent Claims

The challenged claims encompass nine independent claims, reproduced below, with emphasis added:

- 1. A method of treating an individual suffering from *retinal* damage or retinal disease, said method comprising administering a therapeutically effective amount of astaxanthin to the individual to improve the vision of the individual.
- 13. A method of treating an individual comprising



- administering a therapeutically effective amount of astaxanthin to the individual *to protect neurons in a retina* of the individual from free-radical induced retinal injury.
- 14. A method of treating an individual suffering from *neuronal* damage to a retina comprising administering a therapeutically-effective amount of astaxanthin to the individual to improve the condition of the retina.
- 16. A method of treating an individual suffering from *age-related macular degeneration* comprising administering a therapeutically-effective amount of astaxanthin to the individual to retard the progress of age-related macular degeneration.
- 17. A method of treating an individual suffering from an ischemic or intraocular pressure-related disease of a retina comprising administering a therapeutically-effective amount of astaxanthin to the individual to improve the condition of the retina and to prevent further damage to the retina.
- 19. A method of treating an individual suffering from an *inflammatory disease of a retina* comprising administering a therapeutically effective amount of astaxanthin to the individual to improve the condition of the retina and to prevent further damage to the retina.
- 21. A method of treating an individual suffering from a *free* radical-induced injury to a central nervous system, said method comprising administering a therapeutically-effective amount of astaxanthin to the individual to improve the condition of the central nervous system.
- 26. A method of treating an individual suffering from a degenerative retinal disease, said method comprising administering a therapeutically effective amount of astaxanthin to the individual to retard the progress of the disease.
- 27. A method of treating an individual suffering from a degenerative central nervous system disease of a *brain or spinal cord*, said method comprising administering a therapeutically effective amount of astaxanthin to the individual to retard the



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