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Paper 16
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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 IPR2013-00401[1]
Patent 5,527,533

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

SNEDDEN, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

[1] Consolidated with Case IPR2013-00404

I. INTRODUCTION

Cyanotech Corporation ("Cyanotech") filed corrected petitions in IPR2013-00401 (Paper 9, "Pet. '401") and IPR2013-00404 (IPR2013-00404, Paper 8, "Pet. '404") requesting *inter partes* review of claims 1–27 of U.S. Patent No. 5,527,533 ("the '533 patent"). The Board consolidated IPR2013-00401 and IPR2013-00404 and instituted trial for the challenged claims on the following grounds of unpatentability asserted by Cyanotech:

Reference(s)	Basis	Claims challenged
Grangaud[2]	§ 102	1, 3, 8–15, 21, 22, and 26
Grangaud and Dowling[3]	§ 103	1–15, 21, 22, and 26

Decision to Institute, 19 (Paper 17 ("Dec.")).

After institution and consolidation of both trials, the Board of Trustees of the University of Illinois ("the University"), filed its Patent Owner's Response ("Resp."). Paper 32.[4] Cyanotech filed a Reply (Paper 43, "Reply."). The University did not file a motion to amend claims.

Cyanotech relies upon declarations of Florian J. Schweigert (Ex. 1033) and C. Kathleen Dorey, Ph.D. (Ex. 1045) in support of its

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[2] RENÉ GRANGAUD, RESEARCH ON ASTAXANTHIN, A NEW VITAMIN A FACTOR (1951) (unpublished doctorate dissertation, University of Lyon) (Ex. 1003, the English translation of which is Ex. 1002).

[3] J.E. Dowling & I.R. Gibbons, *The Effect of Vitamin A Deficiency on the Fine Structure of the Retina*, in THE STRUCTURE OF THE EYE 85-99 (1961) (Ex. 1026).

[4] This reference to "Paper" and all other references to "Paper" from this point forward in this Final Written Decision of consolidated proceedings IPR2013-00401 and IPR2013-00404 refer to paper numbers on record in IPR2013-00401.

Petition. The University relies upon a declaration of Shalesh Kaushal M.D., Ph.D. (Ex. 2015) in support of its Response.

Cyanotech filed a Motion to Exclude certain of the University's evidence. Paper 47. The University filed an Opposition (Paper 51), and Cyanotech filed a Reply (Paper 54).

Oral argument was conducted on July 16, 2014. A transcript is entered as Paper 64 ("Tr.").

This Final Written Decision addresses challenges to the patentability of claims 1–15, 21, 22, and 26.

Cyanotech has proved by a preponderance of the evidence that claims 1–14 and 26 of the '533 patent are unpatentable. Cyanotech has failed to prove the unpatentability of claims 15, 21, and 22.

A. The '533 Patent (Ex. 1001)

The retina of the eye, a component of the central nervous system, is important for sight. Ex. 1001, 1:49–52; *see also*, Ex. 1045, 6–12. Retinal structures important to vision include: a ganglion cell layer, which connects the retina to the brain; an inner nuclear layer containing neurons, such as bipolar cells; and an outer nuclear or photoreceptor cell layer. Ex. 1045, 6–12. Photoreceptor cells convert light into signals that are transmitted to the other neurons. Ex. 1001 at 1:57–60. The loss of a significant number of photoreceptor cells adversely affects visual function. *Id.* at 3:6–13.

The '533 patent discloses that eye diseases or injuries that can cause damage to the retinal tissue and neurons include age-related macular degeneration, photic injury, photoreceptor cell damage, ganglion cell damage, traumatic injury, ischemic insult-related diseases, and inflammatory

diseases. *Id.* at 1:9–14. Regarding photic injury, the ’533 patent discloses that excessive light energy reaching the retina can overwhelm the metabolic systems of photoreceptor cells causing damage to these neurons, either directly or indirectly. *Id.* at 1:65–67. The ’533 patent further discloses that free radical species can be generated by enzymatic processes or from the combination or continuous or excessive exposure to light and the relatively high concentration of oxygen in the eye. *Id.* at 2:1–5. The ’533 patent discloses that the free radical species lead to functional impairment of cell membranes and may cause temporary or permanent damage to retinal tissue. Ex. 1001, 2:13–21. According to the ’533 patent, however, the presence of antioxidant compounds counteracts the free radical species generated by light to protect the retina from damage. *Id.* at 2:29–32.

The ’533 patent relates to methods of treating diseases and injuries to the central nervous system, especially the eyes, comprising administering a therapeutically-effective amount of astaxanthin. Ex. 1001, 1:9–19 and 6:54–62. The ’533 patent discloses that astaxanthin is a highly-effective antioxidant and ameliorates free radical-induced eye damage. *Id.* at 15:56–60. Astaxanthin is disclosed as particularly suited for treatment of the eye because, unlike other carotenoids such as β-carotene, astaxanthin can cross the blood-retinal brain barrier readily. *Id.* at 10:18–22. According to the ’533 patent, comparative studies with β-carotene demonstrate that astaxanthin is more effective than β-carotene at protecting rats from photic injury. *Id.* at 13:60 to 14:50.

B. Exemplary Claims

Independent claims 1, 13, 14, 21, and 26 are illustrative of the claims at issue in this *inter partes* review and recite as follows:

> 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.
>
> 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.

II. DISCUSSION

A. Claim Interpretation

In an *inter partes* review, claim terms in an unexpired patent are interpreted according to their broadest reasonable construction in light of the specification of the patent in which they appear. 37 C.F.R. § 42.100(b);

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