

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*.

**PETITIONER'S REPLY TO PATENT OWNER'S OPPOSITION
TO PETITIONER'S MOTION TO EXCLUDE EVIDENCE
PURSUANT TO 37 C.F.R. § 42.64(c)**

Submitted: June 30, 2014

^[1] Consolidated with Case IPR2013-00404

In Paper No. 42, Patent Owner (“PO”) offered four licensing agreements (Ex. 2033-2036 and Ex. 2043) in support of its argument (Paper 32, at 49) that the challenged claims are not obvious because of the “strong licensing history” of the patent in issue. In Paper No. 47, Cyanotech Corporation (“Petitioner”) moved to exclude PO's Exhibits 2033-2036 because the agreements were not actually sublicenses of U.S. Patent No. 5,527,533 (the ‘533 patent), but licenses of trademarks, manufacturing rights, and formulation rights of PO’s licensee /sublicensor (“Valensa”), which do not purport to license any claims of that patent and are therefore not indicia of any third parties’ commercial valuation of any patent claims, let alone the challenged claims.

The proffered agreements also provide for either zero or token royalties (\$1,000 in one instance), which is hardly probative evidence of any significant industry valuation of the licensed IP, let alone the actual claims of the patent in suit. Moreover, PO never quantified the value of the only other consideration in the licenses, an exclusive supply agreement, by providing any evidence that any sales of any products were actually ever made under the proffered agreements.

In Paper No. 50, PO opposed Petitioner’s Motion to Exclude Evidence and submitted as Supplemental Evidence a license agreement between Valensa and Swanson Health Products, Inc. (Ex. 2043), an amendment to which had been previously submitted by PO (Ex. 2036, adding product use and trademark rights

for Valensa's Cran-Gyn DDSTM urinary tract healthcare product). Ex. 2043, like the previously submitted Ex. 2034, is identified as a "Product Use and Trademark License," not a patent license. It grants "trademark rights," "advertising rights," "Product-related trade secrets and know-how," and rights to manufacturing "Product I," which is defined as "Valensa's Zanthin® brand of Astaxanthin." (Ex. 2043 at 1, and Exhibit A)

In Paper No. 50, PO asserts that the following is a grant of rights in the challenged claims of the '533 patent:

"Licensee agrees ... that it will: Only use Product I provided solely by the Licensor and no other entity if the Licensee includes the use of at least Valensa's Zanthin brand of Product I and its associated trademark contained in licensee's eye healthcare products labeling for the management of **eye health issues related to** the claims of US 5527533," (Ex. 2043, Section I(1)(b)(1)) (emphasis added)

Exs. 2033-2036 and 2043 do not identify any such "eye health issues" or how they are "related" to the '533 patent; do not identify any method of use of a formulation; do not identify any claims of the '533 patent; do not identify any retinal diseases or conditions; and do not contain any of the words "damage", "injury", "disease", "degeneration", "suffering", "treating", "retina", or "retinal." Without any indicated nexus to the actual claims of the '533 patent and without any (or token) license fees or royalty payments to Valensa, Exs. 2033-2036 and 2043 are only

agreements for the exclusive supply of astaxanthin to licensee in exchange for use of Valensa's trademarks and know-how, none of which has any bearing on any issue in this proceeding.

If PO had actually licensed claims of the '533 patent, it would have created exposure to enforcement actions by the Federal Drug Administration ("FDA"). Valensa's "eye health" dietary supplement licensees sell products with FDA "structure/function" claims and Valensa's Zanthin® trademark on the label. The Dietary Supplement Health and Education Act of 1994 ("DSHEA," 21 U.S.C. ch. 9 § 301 et seq.) requires the following disclaimer on dietary supplements that bear labels with "structure/function" claims, e.g., labels with "eye healthcare" claims:

"This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, **treat**, cure, or prevent any disease." (21 C.F.R. §101.93(c)(1), (emphasis added).

All 27 claims of the '533 patent, including the 18 challenged claims, describe a "method of treating an individual" for specified diseases or conditions of the eye or central nervous system. Had Valensa actually licensed the '533 patent, or any claims thereunder to the identified dietary supplement licensees with only structure/function claiming authority, it would have exposed itself and PO to vicarious liability for DSHEA violations, including exposure to the criminal enforcement powers of the FDA. It didn't do that. On the contrary, Valensa

licensed certain trademark and know-how rights concerning “eye health” issues, which are completely untethered to any claim of the ‘533 patent. Accordingly, these agreements have no probative value.

The licensed uses granted by Valensa are not patent rights and, more specifically, are not ‘533 patent rights, because, *inter alia*, Valensa omitted or avoided any grant of rights to “a method of treating an individual,” as specifically required by each of the challenged claims.

Under FRE 402, made applicable to the current proceedings by 37 C.F.R. § 42.62, evidence must be relevant to be admissible. More particularly, “there must be a nexus between the merits of the claimed invention and the evidence of secondary considerations,” and “the burden of showing that there is a nexus lies with the patent owner.” (*Nichia Corp. v. Emcore Corp.*, IPR2012-00005, slip. op. 44, PTAB Feb. 11, 2014, Paper 68). The subject matter of the challenged claims, a method of treating individuals for degenerations, diseases, injuries, or neuronal conditions of the retina, is absent from all four licenses. Just as the words “treat,” “disease” and “retina” do not appear in Exs. 2033-2036 or 2043, the terms “eye healthcare” and “eye health” do not appear in the ‘533 patent. Patent Owner has failed to show that there is any nexus between the challenged patent claims and the “licensing history” it has proffered. Uses “related to a patent” are not licenses of “the patent” or “claims of the patent”.

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