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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MORRIS ZELKHA, RACHEL LEVY, ESTHER PARAN,
YOAV SHARONI, and JOSEPH LEVY

Appeal 2018-001897
Application 13/137,061¹
Technology Center 1600

Before RICHARD M. LEBOVITZ, JEFFREY N. FREDMAN, and
ELIZABETH A. LAVIER, *Administrative Patent Judges*.

LAVIER, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellants seek review of the Examiner's rejection of claims 1, 15–17, 25, and 26. We have jurisdiction under 35 U.S.C. § 6(b). For the reasons set forth below, we AFFIRM.

BACKGROUND

The Specification describes compositions combining polyphenols and carotenoids, which may be useful in the inhibition of inflammatory mediators. *See* Spec. 1.

Claim 1 is illustrative, and recites:

¹ Appellants identify Lycored, Ltd., as the real party in interest. Br. 3.

1. A therapeutic composition comprising curcumin, and lutein and lycopene combined in the following weight ranges:

Lycopene:	Lutein:	Curcumin,
0.1-1.5:	0.1-1.5:	0.1-1.0.

Br. 11 (Claims Appendix) (some formatting added).

REJECTION MAINTAINED ON APPEAL

Claims 1, 15–17, 25, and 26 stand rejected under 35 U.S.C. § 103(a) (pre-AIA) as unpatentable over Nishino,² Stahl,³ and Sharoni.⁴ Ans. 2.

DISCUSSION

As relevant to illustrative claim 1, the Examiner relies on Nishino as teaching compositions including, *inter alia*, lycopene, lutein, and curcumin. See Final Action 4 (citing Nishino ¶¶ 104,⁵ 105 and Example 1). The Examiner notes that although Example 1 of Nishino provides for lycopene: lutein: curcumin in a 1: 0.6: 10 ratio (*id.*), Nishino also discloses that “the amount of curcumin can be employed approximately 5 to 250 parts by weight (particularly about 10-100 parts by weight) per 100 parts by weight

² Nishino et al., US 2004/0116514 A1, published June 17, 2004.

³ Stahl et al., *Carotenoid Mixtures Protect Multilamellar Liposomes against Oxidative Damage: Synergistic Effects of Lycopene and Lutein*, 427 FEBS LETTERS 305 (1998).

⁴ Sharoni et al, US 2004/0259959 A1, published Dec. 23, 2004.

⁵ The Examiner cites to paragraph “140” of Nishino rather than paragraph 104, as we have cited here. As Nishino does not include a paragraph 140, we presume the Examiner meant to cite paragraph 104, which, along with paragraph 105, constitutes Nishino’s Example 1.

of carotenoid compounds” (*id.* (citing Nishino ¶ 75)). Nishino lists lycopene and lutein among its examples of carotenoid compounds. *See* Nishino ¶ 48. Therefore, Nishino’s ratio ranges of carotenoids:curcumin overlap with the ratio ranges of lycopene:lutein:curcumin recited in claim 1. *See* Final Action 4. This alone constitutes a *prima facie* case of obviousness of claim 1. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (“In cases involving overlapping ranges, we and our predecessor court have consistently held that even a slight overlap in range establishes a *prima facie* case of obviousness.”); *see also In re Aller*, 220 F.2d 454, 456–58 (CCPA 1955) (“[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.”). However, the Examiner further supports the rejection through reference to Stahl, for the synergistic effect of lycopene and lutein. *See* Final Action 5 (citing Stahl 307, Title).⁶ The Examiner finds it would have been obvious to combine the references by optimizing the amount of curcumin in Nishino’s Example 1 to curcumin levels within the claimed range, because it would be a matter of discovering optimal or workable ranges, well within the abilities of the ordinarily skilled artisan. *See id.* at 5–6 (citing *Aller*).

Appellants do not dispute the Examiner’s specific findings regarding the individual elements of claim 1. *See generally* Br. 6–9. Instead,

⁶ The Examiner also cites to Sharoni, as teaching that lycopene, or lycopene and additional carotenoids, can enhance the inhibitory effects of phytoene and phytofluene on mammary cancer cell proliferation. *See* Final Action 5 (citing Sharoni Abstract, ¶¶ 8, 25). These teachings are relevant to certain dependent claims, which recite phytoene and/or phytofluene.

Appellants assert that their claims embody a previously-unappreciated insight, i.e., that “curcumin at certain levels (e.g. as defined by the ratio between the carotenoids and curcumin) results in a previously entirely unknown — and previously unexpected — synergistic interaction with certain carotenoids, leading to unexpectedly high levels of inhibition of the production of some key anti-inflammatory mediators.” *Id.* at 6. Therefore, according to Appellants, the teachings of synergism between carotenoids cited by the Examiner would not have motivated the ordinarily skilled artisan to optimize curcumin levels to achieve the claimed ranges. *See id.* at 8; *see also id.* at 9. In support, Appellants point to Figures 13A, 13B, and 14 of the drawings filed with the Specification, which Appellants assert show a “marked synergism” when lycopene, lutein, and curcumin are used in combination, as compared to the additive effect one would expect from summing the results for each component individually. *Id.* at 8 (discussing Figs. 13A, 13B); *see also id.* at 9 (discussing Fig. 14).

Having reviewed Appellants’ Figures 13A, 13B, and 14, we conclude that Appellants’ proffered evidence of unexpected results are not entitled to substantial weight. Figure 14 is reproduced below:

Fig. 14

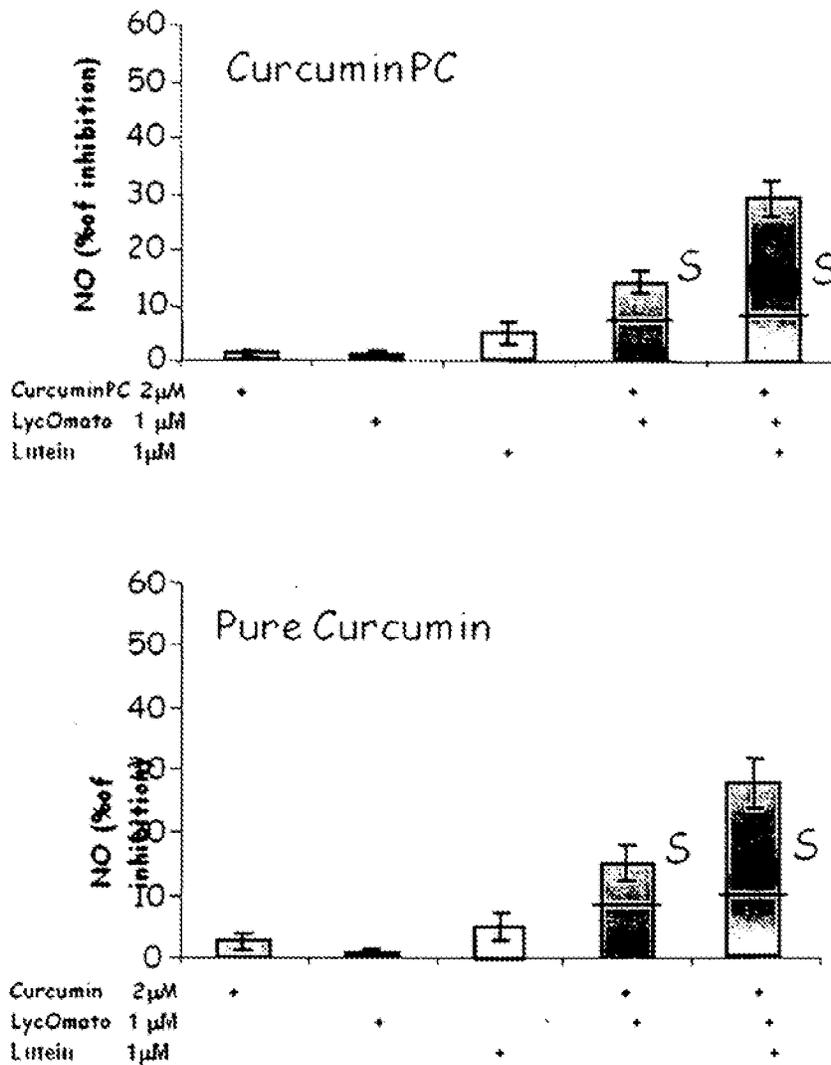


Figure 14 is a pair of bar graphs demonstrating the percentage of nitrous oxide (NO) inhibition observed in the presence of curcumin, lycopene, or lutein alone (first three bars, both graphs), curcumin and lycopene together (fourth bar, both graphs), and curcumin, lycopene, and lutein together (last

bar, both graphs).⁷ The “S” indicates what Appellants calculate to constitute synergistic inhibition. *See* Spec. 50.

As illustrated by (but not limited to) Figure 14 of the Specification, Appellants’ data do not include a comparison with the combination already known in the prior art as having synergistic effects, i.e., lycopene and lutein together. *See, e.g.*, Stahl Abstract; Sharoni ¶ 8. Nor did Appellants compare their combination(s) to the composition of Example 1 of Nishino, to show that claimed ratio had unexpected advantages while the composition of Nishino having all three components did not. *See* Ans. 4. Without such a comparison, a determination cannot be made as to whether the synergistic effects reported in the Specification and Figures 13A, 13B, and 14 are due to the combination of lycopene and lutein, to the addition of curcumin to the already-known-to-be-synergistic lycopene/lutein combination, or, as Appellants maintain, to the specifically claimed ratios of lycopene: lutein: curcumin. Thus, we agree with the Examiner’s general finding that Appellants have failed to compare their invention to the closest prior art. *See* Ans. 4.

Having considered Appellants’ arguments, we are not persuaded of any reversible error by the Examiner in rejecting claim 1. Appellants do not separately argue claims 15–17, 25, or 26; these fall with claim 1. *See* 37 C.F.R. § 41.37(c)(1)(iv).

⁷ “Curcumin-PC” is a commercially available curcumin preparation with improved miscibility. *See* Spec. 8. “Curcumin” refers to pure curcumin. *See id.* at 50. “Lycomato” is a commercially available tomato extract, used as a source of lutein. *See id.* at 8, 16.

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CONCLUSION

We sustain the Examiner's rejection of claims 1, 15–17, 25, and 26. No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED