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EXAMINER

CONSTANTINE, CHARLES Z

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ALEXANDER B. RABOVSKY and JEREMY IVIE¹

Appeal 2015-006014
Application 12/854,944
Technology Center 1600

Before DONALD E. ADAMS, JOHN E. SCHNEIDER, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

SCHNEIDER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a dietary supplement which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

The present invention is directed to a dietary supplement which is “useful in reducing cholesterol and improving overall cardiovascular health.” Spec. 1.

¹ Appellants identify the Real Party in Interest as Melaleuca, Inc. Br. 1.

Claims 1–5, and 7–11 are on appeal. Claim 1 is illustrative and reads as follows:

1. A dietary supplement, comprising, per daily dosage:
 - a) from about 1400 mg to about 2800 mg phytosterols;
 - b) from about 300 mg to about 800 mg omega-3 fatty acids;
 - c) from about 20 mg to about 40 mg coenzyme Q-10;
 - d) from about 20 mg to about 36 mg alpha lipoic acid; and
 - e) bromelain.

The claims stand rejected as follows:

Claims 1–5, and 7–11 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Cho² in view of Sabharwal.³

DISCUSSION

Issue

In rejecting the pending claims, the Examiner finds that Cho teaches a nutritional supplement which contains “phytosterols, omega-3 fatty acids, bromelain and antioxidants such as Coenzyme-Q-10.” Final Act. 3. The Examiner finds that while Cho does not teach the use of alpha lipoic acid, it is known in the art that alpha lipoic acid is an antioxidant, radical scavenger and reducing agent known to prevent LDL oxidation as taught by Sabharwal. Final Act. 4. The Examiner concludes that

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose and for the following reasons: Both

² Cho, US 2005/0032757 A1, published Feb. 10, 2005 (“Cho”).

³ Anup K. Sabharwal and James M. May, *α-Lipoic acid and ascorbate prevent LDL oxidation and oxidant stress in endothelial cells*, 309 Mol. Cell. Biochem. 125 (2008) (“Sabharwal”).

are known to reduce/protect against LDL oxidation. In *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), the Supreme Court reaffirmed “the conclusion that when a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *Id.* at 417 (quoting *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273,282 (1976)). The Supreme Court also emphasized a flexible approach to the obviousness question, stating that the analysis under 35 U.S.C. § 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* at 418; see also *id.* at 421 (“A person of ordinary skill is ... a person of ordinary creativity, not an automaton.”). The Supreme Court thus implicitly endorsed the principle, stated in *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980) (citations omitted), that: It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Final Act. 5.

Appellants contend that, insofar as the skilled in the art would consider the teachings of Sabharwal with respect to the addition of alpha lipoic acid, the skilled person would only use the amounts of alpha lipoic acid recited in Sabharwal, which is above the amounts in the claimed range. Appeal Br. 3–4. Appellants also contend that there is no reason to combine the claimed ingredients in the claimed amounts. Appeal Br. 4–5. Appellants next argue that the Examiner has not given a reason why Cho was used to select a “lead compound.” Appeal Br. 6–8.

The issue with respect to this rejection is whether the Examiner has established by a preponderance of the evidence that claims 1–3 would have been obvious over Cho combined with Sabharwal as defined by 35 U.S.C. § 103(a).

Findings of Fact

We adopt as our own the Examiner’s findings and analysis. The following findings are included for emphasis and reference convenience.

FF1. Cho teaches a nutritional supplement comprising a phytosterol, a fatty acid compound such as an omega-3 fatty acid, a carboxylic acid ester, a surfactant, and an enzyme or enzyme blend such as bromelain. Cho ¶ 6.

FF2. The supplement of Cho can also contain antioxidants such as Coenzyme-Q-10. Cho ¶ 6 and 96.

FF3. The phytosterol compounds in Cho are present in the supplement in amounts ranging from 10 to 900 mg. Cho ¶ 64.

FF4. The omega-3 fatty acids in Cho are present in amounts ranging from about 10 to 55% by weight of the supplement. Cho ¶ 78.

FF5. The enzyme or enzyme blend used in the compositions of Cho is present in amounts ranging from 0.1 to 5% by weight of the supplement. Cho ¶ 88.

FF6. The antioxidants used in the supplement of Cho can be present in amounts ranging from 0.01 to 2% by weight of the supplement. Cho ¶ 96.

FF7. Sabharwal teaches the use of alpha lipoic acid as an antioxidant. Sabharwal 129–30.

Principles of Law

“It is *prima facie* obvious to combine two composition each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

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. . . . We have also held that a *prima facie* case of obviousness exists when the claimed range and the prior art range do not overlap but are close enough such that one skilled in the art would have expected them to have the same properties.

In re Peterson, 315 F.3d 1325, 1329 (Fed. Cir. 2003).

To show criticality of a claimed range, “‘it is not inventive to discover the optimum or workable ranges by routine experimentation.’” *In re Aller*, 220 F.2d 454, 456 (CCPA 1955). Only if the ‘results of optimizing a variable’ are ‘unexpectedly good’ can a patent be obtained for the claimed critical range. *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977).” *In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997).

Analysis

Claim 1 is representative of the rejected claims and is directed to a nutritional supplement containing phytosterols, omega-3 fatty acids, Coenzyme Q-10, alpha lipoic acid and bromelain.

We agree with the Examiner that the subject matter of claim 1 would have been obvious to one skilled in the art at the time the invention was made. Cho teaches a nutritional supplement containing all of the claimed components with the exception of alpha lipoic acid. FF1. The amounts of the components recited in Cho either overlap or are close to the amounts recited in the claims. FF2–6. Sabharwal teaches the use of alpha lipoic acid as an antioxidant. FF7. We agree with the Examiner that it would have been obvious to one skilled in the art to use alpha lipoic acid as an additional antioxidant in the supplement of Cho.

Appellants contend that one skilled in the art would have used alpha lipoic acid in the amounts taught by Sabharwal rather than according to the amounts of antioxidants recited in Cho. Appeal Br. 3; Reply Br. 2. Appellants argue that this would result in an amount of alpha lipoic acid well in excess of the amount recited in the instant claims. We are unpersuaded. As the Examiner points out, Cho specifically related to a dietary supplement whereas Sabharwal is directed to the effect of alpha lipoic acid on individual cells exposed to oxidative stress. Ans. 7. We agree with the Examiner that one skilled in the art would predictably follow the teachings of Cho in developing a supplement with appropriate concentrations of antioxidants.

Appellants next argue that there is no reason why one skilled in the art would use alpha lipoic acid instead of the antioxidants recited in Cho. Reply Br. 2. Again, we are unpersuaded. “It is *prima facie* obvious to combine two composition each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.” *In re Kerkhoven*, 626 F.2d at. 850. Here

Appellants combined two known antioxidants, coenzyme Q-10 and alpha lipoic acid to form a mixture used as an antioxidant.

Appellants go on to argue that Cho offers no guidance as to the specific components to use or the amounts of the ingredients. Appeal Br. 4. We remain unpersuaded. As the Examiner points out, Cho teaches almost all of the components in the first paragraph of the summary of the invention. Ans. 9–10. Cho provides specific examples which contain phytosterol, bromelain, Coenzyme Q-10 and omega-3 fatty acids. Ans. 9; Cho ¶¶ 115 and 123. The amounts of the components recited in Cho overlap with or are close to those recited in the claims. FF2–6; Ans. 3–4.

Appellants conclude by arguing that the Examiner failed to properly explain why Cho was selected to determine the lead composition as required by *Daiichi Sankyo Co., Ltd v. Matrix Labs., Ltd*, 619 F.3d 1346, 1354 (Fed. Cir. 2010). We agree with the Examiner that Appellants' reliance on *Daiichi* is misplaced. *Daiichi* addressed the development of a new compound from a lead compound. *Id* at 1348. As the Examiner points out,

[t]he rationale and case law to determine the obviousness of a structure of a compound is entirely different than that of compositions, and this rationale and case law has not been used in the instant rejection[.] A single chemical change on a compound can render a drug much improved or useless for its purpose. The addition or subtraction of a component does not alter the ability of the composition to serve as a dietary supplement. Rationale, case law and guidance based on determining whether or not a composition containing certain components and claimed ranges is obvious have been used. The use of all but one component is explicitly taught by Cho, and a specific reason to add the single component not taught by Cho has been given through the combination with Sabharwal.

Further the combination teaches the use of the instantly claimed ranges.

Ans. 11.

With respect to claims 2 and 3, we agree with the Examiner that the specific ranges recited in those claims fall within the ranges taught by Cho. Discovery of the optimum amounts is a matter of routine experimentation. *In re Aller*, 220 F.2d at 456.

Conclusion of Law

We conclude that the Examiner has established by a preponderance of the evidence that claims 1–3 would have been obvious over Cho combined with Sabharwal under 35 U.S.C. § 103(a).

Claims 4, 5, and 7–11 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

SUMMARY

We affirm the rejection of claims 1–3 under 35 U.S.C. § 103(a).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED