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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CLAUDIA R. MORRIS¹

Appeal 2015-005962
Application 13/439,192
Technology Center 1600

Before MELANIE L. McCOLLUM, RICHARD J. SMITH, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to method of treating apraxia and/or autism spectrum disorder. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 18, 19, 22, 27, 29, and 30 are on appeal (Br. 1).² Claim 18 is representative and reads as follows:

¹ Appellant identifies the real party in interest as Children's Hospital & Research Center at Oakland (Br. 3).

² Claims 20, 21, 26, 28, and 31 are also pending but have been withdrawn from consideration (Final Act. 1).

18. A method of treating apraxia and/or autism spectrum disorder, the method comprising orally administering to an individual in need thereof an effective amount of a formulation comprising:

- a) eicosapentaenoic acid (EPA);
- b) docosohexaenoic acid (DHA);
- c) α -tocopherol;
- d) γ -tocopherol;

wherein the ratio of EPA to DHA is in a range of from about 1.5:1 to about 5:1,

wherein the α -tocopherol is present in an amount of from about 500 mg to about 3000 mg per unit dose,

wherein the γ -tocopherol is present in an amount of from about 200 mg to about 1000 mg per unit dose,

wherein the EPA is present in an amount of from about 500 mg to about 3000 mg per unit dose,

wherein the DHA is present in an amount of from about 100 mg to about 400 mg per unit dose.

(Br. 16 (Claims Appendix).) Claim 27 depends from claim 18 and recites that “the formulation further comprises vitamin K in an amount of from about 100 μ g to about 2 mg per unit dose” (*id.* at 16–17).

Claims 18, 19, 22, 29, and 30 stand rejected under 35 U.S.C. § 103(a) as obvious over Murphy et al. (US 2005/0249823 A1, Nov. 10, 2005) in view of Miller et al. (US 6,426,362 B1, July 30, 2002) (Final Act. 3).

Claims 18, 19, 22, 27, 29, and 30 stand rejected under 35 U.S.C. § 103(a) as obvious over Murphy in view of Miller and Manning et al. (US 2006/0088574 A1, Apr. 27, 2006) (Final Act. 5).

PRINCIPLES OF LAW

A claim “composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). The

relevant question is “whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *Id.*

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citation omitted).

I

The Examiner relies on Murphy for teaching “methods for the treatment of an individual with a neurological condition such as autism comprising orally administering to the individual an effective amount of a composition comprising EPA, DHA and tocopherols (vitamin E . . .)” (Final Act. 3). The Examiner finds: Murphy “teaches that the composition may comprise, for example, 1200-2000 mg EPA and 300-500 mg DHA Thus, the reference teaches that the ratio of EPA to DHA may be, for example, 4:1 (e.g., 1200 mg EPA to 300 mg EPA).” (*Id.*) However, the Examiner finds that “Murphy does not teach that the composition comprises the specific tocopherols recited in the claims in the concentrations recited in the claims” (*id.* at 4).

The Examiner relies on Miller for teaching “tocopherol compositions comprising alpha- and gamma-tocopherols” (*id.*). The Examiner finds that Miller “teaches that the compositions may comprise up to 1000 mg of tocopherols as a mixture of alpha- and gamma-tocopherols” and “that the compositions may be useful for treating an individual, such as one with a vitamin E deficiency” (*id.*). The Examiner concludes:

One of ordinary skill in the art would have been motivated to combine the teachings of Murphy and Miller to arrive at the claimed invention because Murphy teaches that the compositions contain tocopherols (vitamin E) because some neurological conditions may be caused by a vitamin E deficiency, and Miller teaches improved compositions comprising tocopherols that are useful for the treatment of vitamin E deficiency. . . . Since [Miller] teaches the use of 1000 mg of a mixture of alpha- and gamma-tocopherols, one of ordinary skill in the art would have been motivated to use, for example, 500 mg of alpha-tocopherol and 500 mg of gamma-tocopherol, and would therefore have arrived at a composition comprising the claimed amounts of tocopherols based on the teachings of the prior art.

(*Id.* at 4–5.)

Analysis

Appellant argues that “Murphy does not disclose or suggest the amounts of α -tocopherol and γ -tocopherol recited in instant claim 18” (Br. 5). Appellant also argues that, “[b]ecause an individual with [autism spectrum disorder] would not necessarily have been considered to have a ‘vitamin E deficiency,’ it could not have been obvious to treat such individuals with a formulation as recited in claim 18” (*id.* at 10–11). We conclude that the Examiner has not set forth a prima facie case of obviousness.

In particular, Murphy is directed to “nutritional supplements that are specifically tailored to treat and/or prevent neurological, neurogenetic, or psychiatric diseases, disorders, conditions, or distress in both adult and pediatric patients” (Murphy, ¶ 15). Murphy discloses that “the present invention provides compositions containing vitamins B₆ and E, magnesium oxide, Essential Fatty Acids . . . , and folate” and that “[c]ontemplated

dosage ranges for compositions of the invention include the following: in pediatric use, . . . vitamin E at a range of 150-250 Iu, . . . Essential Fatty Acids at ranges of 600-1000 mg EPA and 150-250 mg DHA” (*id.* ¶ 16). Murphy also discloses that “[s]pecific pediatric conditions that can be prevented and/or treated by administering the formulations of the present invention include . . . autism” (*id.* ¶ 38). However, it is undisputed that Murphy does not teach the claimed amounts of tocopherols (Ans. 4).

Miller is directed to “compositions or formulations for amelioration of disruption of energy metabolism secondary to stress comprising a tocopherol selected from the group consisting of alpha-, delta- and gamma-tocopherol and combinations or derivatives thereof” (Miller, col. 4, ll. 31–37). In particular, Miller discloses “a mixture of alpha and gamma tocopherol ranging from about 10–1000 mg, preferably about 50–600 mg” (*id.* at col. 15, ll. 2–3). In addition, Miller discloses that “[c]ertain concentrations of (+/–) alpha tocopherol and gamma-tocopherol exhibited synergistic effects” and that “[o]ther concentration combinations provided optimized concentrations, where the effects were additive or slightly better than additive” (*id.* at col. 47, ll. 32–41). However, we agree with Appellant that the Examiner does not adequately explain why it would have been obvious to include the claimed amounts of alpha- and gamma-tocopherols in a composition for the treatment of autism.

The Examiner concludes:

One of ordinary skill in the art would have been motivated to combine the teachings of Murphy and Miller to arrive at the claimed invention because Murphy teaches that the compositions contain tocopherols (vitamin E) because some neurological conditions may be caused by a vitamin E deficiency, and Miller

teaches improved compositions comprising tocopherols that are useful for the treatment of vitamin E deficiency.

(Final Act. 4.) Miller, however, describes alpha- and gamma-tocopherols use to counteract disruptions of normal energy metabolism secondary to stress, meaning “injury(ies) to cells, organs or organisms associated with, resulting in or caused by alterations in oxidative metabolism or respiration” (Miller, col. 4, ll. 32–35, & col. 12, ll. 9–13), wherein reactive oxygen species, e.g., free radicals, are produced (*see, e.g.*, col. 1, l. 66, to col. 3, l. 38). The stresses described do not refer to a vitamin deficiency, but rather, things like hypothermia, drug toxicity, physical exertion, and aging (*id.* at col. 12, l. 28, to col. 13, l. 23).

Moreover, even if one were to conclude that Miller describes the use of alpha- and gamma-tocopherols to ameliorate neurological conditions, the question in this appeal is not whether it would have been obvious to include the claimed amounts of tocopherols for *any* neurological condition. Instead, given that claim 18 is directed to a method for treating specific disorders, the question is whether it would have been obvious to include the claimed amounts of tocopherols in a formulation for use in the treatment of apraxia and/or autism spectrum disorder. The Examiner does not adequately explain why this would have been obvious.

Conclusion

The Examiner has not set forth a prima facie case that Murphy and Miller suggest the method of claim 18. We therefore reverse the obviousness rejection over Murphy and Miller of claim 18 and of claims 19, 22, 29, and 30, which depend from claim 18.

II

In the second rejection, the Examiner relies on Murphy and Miller as discussed above (Final Act. 5). However, the Examiner finds that “neither of the references specifically teaches the administration of a formulation comprising the specific amount of vitamin K” (*id.* at 6).

The Examiner relies on Manning for teaching “recommended daily values for vitamins” (*id.*). In particular, the Examiner finds that Manning “teaches that the recommended daily value for vitamin K for individuals 4 years or older is 80 micrograms” (*id.*). The Examiner concludes:

One of ordinary skill in the art would have been motivated to use the amount of vitamin K disclosed by Manning in the method of Murphy and Miller because Murphy discloses that the composition should comprise vitamin K, but does not disclose a specific amount. One would therefore have been motivated to consult the dietary recommendations for this nutrient and would have arrived at a recommended dosage, such as that taught by Manning, in the course of routine experimentation.

(*Id.*)

Analysis

For the reasons discussed above, we conclude that the Examiner has not set forth a prima facie case that Murphy and Miller suggest the method of claim 18. In addition, we agree with Appellant that the Examiner has not adequately shown that Manning cures the deficiencies of Murphy and Miller (Br. 14).

Conclusion

The Examiner has not set forth a prima facie case that Murphy, Miller, and Manning suggest the method of claim 18. We therefore reverse the

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obviousness rejection over Murphy, Miller, and Manning of claim 18 and of claims 19, 22, 27, 29, and 30, which depend from claim 18.

REVERSED