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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GUDRUN CLAUS-HERZ and GUENTHER BELLMANN

Appeal 2012-001260
Application 11/577,149
Technology Center 1600

Before ERIC GRIMES, MELANIE L. McCOLLUM, and
ULRIKE W. JENKS, *Administrative Patent Judges*.

JENKS, *Administrative Patent Judge*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims directed to a composition comprising omega-3 fatty acids, omega-6 fatty acids, and zinc. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The Specification is directed to compositions for the treatment of dry eye conditions.

There has been growing evidence that the dry eye condition can have an aetiology in inflammation. The addition of zinc in the form of a zinc compound in the inventive compositions containing omega-3 fatty acids and omega-6 fatty acids promotes the conversion of these fatty acids into PGE1 and PGE3, leading to improved results in the treatment of the dry eye syndrome.

(Spec. ¶ 0013.)

Claims 1-14 are on appeal, and can be found in the Claims Appendix of the Appeal Brief (App. Br. 12-14). Claims 1 and 8 are independent claims and are representative of the claims on appeal, and read as follows (emphasis added):

1. A composition comprising: at least an omega-3 fatty acid, at least an omega-6 fatty acid, and zinc, the composition being suitable for treatment or amelioration of a dry eye condition, in concentrations effective as dietary prophylaxis, treatment, or amelioration of dry eye syndrome; wherein a concentration of total omega-6 fatty acids is *in the range from about 0.1 to about 5 percent by weight* of the total composition.

8. A composition, based on a single dose of the composition, comprising:

- (a) at least an omega-3 fatty acid in an amount from about 10 to about 500 mg;
- (b) gamma-linolenic acid in an amount from about 1 to about 10 mg;
- (c) vitamin E in an amount from about 1 to about 5 mg;
- (d) vitamin C in an amount from about 1 to about 50 mg;
- (e) vitamin B₆ in an amount from about 0.1 to about 1 mg;
- (f) vitamin B₁₂ in an amount from about 0.01 µg to about 1 µg; and

(g) zinc in an amount from about 0.1 to about 10 mg; wherein the composition is effective as dietary phophylaxis [sic] or treatment of dry eye syndrome; and a concentration of total omega-6 fatty acids is *in the range from about 0.1 to about 5 percent by weight* of the total composition.

The Examiner has rejected the claims as follows:

- I. claims 1-7 and 10-14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Trejo;¹ and
- II. claims 8-11, 13, and 14 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Trejo in view of Hoffman.²

I.

The Issue

The Examiner takes the position that Trejo disclosed a composition comprising omega-3 fatty acids, omega-6 fatty acids, and zinc. The daily dose of the essential fatty acids is from about 0.1g to about 3g, while the daily dose of a micronutrient metal, such as zinc, is in an amount from 0.0005g to about 0.1g. (Trejo ¶¶ 0037, 0062-0063; Ans. 5.) The Examiner calculates that Trejo's exemplary composition contains less than 11.5% omega-6 fatty acids, and therefore the range of omega-6 fatty acids overlaps the range recited in claim 1 (Trejo, ¶¶ 0153-0155; Ans. 4-5).

Appellants contend that "Trejo does not teach or suggest limiting the concentration of total omega-6 fatty acids to about 0.1-0.5 [sic] percent by weight of the total composition, as recited in the claims." (App. Br. 5.)

¹ Trejo et al., US 2004/0258645 A1, published Dec. 23, 2004.

² Hoffman et al., US 2004/0048926 A1, published Mar. 11, 2004.

The issue is: Has the Examiner established by a preponderance of the evidence that Trejo renders obvious the composition of claim 1?

Findings of Fact

FF1. Trejo disclosed a product suitable for oral consumption comprising an essential fatty acid, sugar amino acid or salt thereof, and an anti-oxidant. (Trejo claim 1; Ans. 4.) “[T]he essential fatty acid is selected from the group consisting of omega-3 fatty acids, omega-6 fatty acids, and mixtures thereof.” (Trejo claim 2; Ans. 4.)

FF2. Trejo disclosed a composition comprising an omega-3 fatty acid where the omega-3 fatty acid is selected from “the group consisting of alpha-linolenic acid, stearidonic acid, eicosapentanoic acid [(EPA)], docosahexanoic acid [(DHA)], and mixtures thereof.” (Trejo claim 3; Ans. 4.)

FF3. Trejo disclosed a composition comprising an omega-6 fatty acid where the omega-6 fatty acid is selected from “the group consisting of linoleic acid, gamma-linolenic acid, arachidonic acid, and mixtures thereof.” (Trejo claim 4; Ans. 4.)

FF4. Trejo disclosed a composition comprising essential fatty acids with an anti-oxidant, where the anti-oxidant is selected from the group consisting of “grape seed extract, ester-C+, beta-carotene, lycopene, lutein, vitamin E, vitamin C; their derivatives; their salts; and mixtures thereof.” (Trejo claim 8; Ans. 4.)

FF5. Trejo disclosed a composition comprising essential fatty acids with a vitamin, where the vitamin is selected from “the group consisting of vitamin A, vitamin B, vitamin C, vitamin D, vitamin K; their derivatives;

and mixtures thereof.” (Trejo claim 10; Ans. 4.) Vitamin B is further selected from a group consisting of “vitamin B₁, vitamin B₂, vitamin B₃, vitamin B₅, vitamin B₆, vitamin B₁₂, vitamin B₁₅, their derivatives, and mixtures thereof.” (Trejo claim 11; Ans. 4.)

FF6. Trejo disclosed a composition comprising essential fatty acids as well as micronutrients selected from the group consisting of “copper, iron, zinc, selenium, manganese, and mixtures thereof.” (Trejo claim 12; Ans. 4.)

FF7. Trejo disclosed that the daily dose of essential fatty acids ranges from 0.1 to about 3 g (Trejo ¶ 0037), the daily dose of vitamins ranges from 0.00001g to about 1 g (Trejo ¶ 0048), the daily dose of micronutrients ranges from 0.00001g to about 1 g (Trejo ¶ 0062), and the daily dose of anti-oxidants ranges from 0.00001g to about 1 g (Trejo ¶ 0045).

FF8. Trejo disclosed an oral capsule formulated as follows:

Calories		10
Polyunsaturated Fat		359 mg
EPA	120 mg	
DHA	100 mg	
DPA	24 mg	
Other	115 mg	
Monounsaturated Fat		260 mg
Saturated Fat		311 mg
Cholesterol		2.8 mg
Sodium		0
Carbohydrate		0
Protein		0
Other		57.2 mg

(Trejo ¶ 0155.) The capsule is an oral supplement having a total weight of 1000mg (1g). (Trejo ¶¶ 0153-0154.)

Principle of Law

“The combination of familiar elements according to known methods

is likely to be obvious when it does no more than yield predictable results.”
KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 416 (2007).

Analysis

Appellants assert that “Trejo does not teach or suggest limiting the concentration of total omega-6 fatty acids to about 0.1-0.5 [sic] percent by weight of the total composition, as recited in the claims.” (App. Br. 5.) Appellants contend that the zinc concentration is “disclosed as the daily dosage range of micronutrient metals . . . [and] not even the amount in a composition.” (*Id.* at 7-8.) Appellants contend that “other” fatty acids in the exemplified capsule of Trejo does not necessarily mean omega-6 fatty acids (*id.* at 7).

We are not persuaded by Appellants’ arguments. We agree with the Examiner’s position that Trejo discloses a composition comprising a mixture of omega-3 and omega-6 fatty acids, and zinc (FFs 1-3, 6). The Examiner relies on Trejo’s exemplified capsule to arrive at a maximum weight ratio for omega-6 fatty acids (Ans. 9-10). The Examiner finds that the EPA, DHA, and DPA in Trejo’s exemplified capsule are all omega-3 fatty acids (Ans. 10³) and therefore any omega-6 fatty acids must be included in the “other” polyunsaturated fat component of the capsule (*id.*). The Examiner therefore concludes that the amount of omega-6 fatty acids in the exemplified capsule must be “equal to or less than 115 mg in a 1000 mg composition (11.5% by weight)” (*id.*; FF8).

³ Appellants agree with this finding (App. Br. 8).

We agree with the Appellants' point that "other" polyunsaturated fat does not necessarily include only omega-6 fatty acids (App. Br. 7), however, Trejo does not exclude that possibility. We find that the "other" polyunsaturated fat is also not limited to only omega-3 fats as suggested by Appellants; the "other" component can mean any mixture of fatty acids as long as they are polyunsaturated (FFs 1, 8). Therefore, the "other" polyunsaturated fat component of the capsule could include other omega-3 fatty acids, omega-6 fatty acids as well as other non-disclosed polyunsaturated fatty acids. Because Trejo suggests the combination of omega-3 and omega-6 fatty acids (FF1), we find the Examiner has a reasonable position for concluding that the "other 115 mg polyunsaturated fat" component of the capsule could encompass omega-6 fatty acid, specifically, including up to 115 mg of omega-6 fatty acid (Ans. 5, 9-10). "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda* 401 F.2d 825, 826 (CCPA 1968).

As discussed above, we do not agree with Appellants' position that "other" polyunsaturated fat component of the capsule is limited to only omega-3 fatty acid (App. Br. 8). Trejo specifically suggests the combination of omega-3 and omega-6 fatty acids (FF1), therefore, it is reasonable to infer that the "other" polyunsaturated fatty acid in the example might include omega-6 fatty acids (FFs 1, 8). We agree with the Examiner's conclusion that the "other" polyunsaturated fat component in the capsule (Ans. 9-10; FF8) could reasonably encompass omega-6 fatty acids (FFs 1, 3).

Although a specific amount of omega-6 fatty acid is not disclosed by Trejo's exemplified capsule (FF8), we agree with the Examiner that it is also reasonable to infer that the maximum amount of omega-6 fatty acids that can be included in the total 115 mg "other polyunsaturated fat" would result in a maximum amount of 11.5 % by weight of the total composition (Ans. 5, 12). We find the better position is to view the 115 mg "other polyunsaturated fat" as an upper limit for omega 6 fatty acids because the "other" component could include omega-3 fatty acids (Ans. 5) or additional undisclosed polyunsaturated fatty acids. Thus, the exemplified capsule can comprise anywhere from 0-11.5% omega-6 fatty acid by weight of the total composition (Ans. 5). A prima facie case of obviousness exists where the claimed ranges "overlap or lie inside ranges disclosed in the prior art." *In re Wertheim*, 541 F.2d 257, 267 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575 (Fed. Cir. 1990).

We conclude that the preponderance of the evidence of record supports the Examiner's conclusion that Trejo renders obvious the composition comprising omega-3 fatty acid, omega-6 fatty acid, and zinc of claim 1. We thus affirm the rejection of claim 1 under 35 U.S.C. § 103(a) as being obvious, and as claims 2-7 and 12 stand or fall with that claim, we affirm the rejection as to those claims as well.

We vacate the rejection of dependent claims 10, 11, 13, and 14 under 35 U.S.C. § 103(a) as being unpatentable over Trejo, because the Examiner did not address independent claim 8 from which claims 10, 11, 13, and 14 depend solely with the Trejo reference.

II.

The Issue

The Examiner takes the position that Trejo disclosed a composition comprising omega-3 fatty acids, omega-6 fatty acids, and zinc, as discussed in the rejection over Trejo (Ans. 7). The Examiner combines Trejo with Hoffman to arrive at the specific concentrations of vitamins not disclosed in Trejo (*id.* at 9).

Appellants contend that “Trejo only discloses that the daily dose of essential fatty acid may be from 0.1 g to about 3 g, among other possible ranges.” (App. Br. 10.)

The issue is: Has the Examiner established by a preponderance of the evidence that the combination of Trejo and Hoffman renders obvious the composition of claim 8?

Findings of Fact

FF9. Hoffman disclosed an infant formula having a DHA content of about 17 mg/100 kcal and an ARA (arachidonic acid) content of about 34 mg/100 kcal, the formula further comprising:

<u>Term Infant Formula Nutrient Levels (per 100 Cal)</u>		
Nutrient	Unit	Term Formula
Protein	g	2.1
Fat	g	5.3
Linoleic Acid	mg	860
Carbohydrate	g	10.9
Vitamin A	IU	300
Vitamin D	IU	60
Vitamin E	IU	2
Vitamin K	µg	8
Thiamin (vitamin B1)	µg	80
Riboflavin (vitamin B2)	µg	140
Vitamin B6	µg	60
Vitamin B12	µg	0.3
Niacin	µg	1000
Folic acid (folacin)	µg	16
Pantothenic acid	µg	500
Biotin	µg	3
Vitamin C (ascorbic acid)	mg	12
Choline	mg	12
Inositol	mg	6
Calcium	mg	78
Phosphorus	mg	53
Magnesium	mg	8
Iron	mg	1.8
Zinc	mg	1
Manganese	µg	15
Copper	µg	75
Iodine	µg	10
Selenium	µg	2.8
Sodium	mg	27
Potassium	mg	108
Chloride	mg	63

(Hoffman ¶0147, Table 12.) Table 12 shows the composition of an infant formula for every 100 kcal dose (Hoffman ¶¶ 0146-0147), with a protein content of 2.1g, a fat content of 5.3g, and a carbohydrate content of 10.9g accounting for a combined weight of 18.6g.

Principle of Law

“[A] prior art reference that discloses a range encompassing a

somewhat narrower claimed range is sufficient to establish a *prima facie* case of obviousness.” *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003). *See also In re Harris*, 409 F.3d 1339, 1341 (Fed. Cir. 2005).

Analysis

Appellants contend that Trejo only discloses daily doses of essential fatty acids. “[T]his is an amount of essential fatty acids, which Trejo classifies [the fatty acids] ‘as either omega-3 fatty acids or omega-6 fatty acids.’ Thus, it is illogical to ascribe this amount exclusively only to omega-3 fatty acids or omega-6 fatty acids or to any specific amounts allocated to omega-3 or omega-6 fatty acids.” (App. Br. 10.) Appellants contend that “[o]ne of ordinary skill cannot take Hoffman's isolated amount of vitamin B₁₂ and combine with Trejo to arrive at claims 8 and 9. Thus, the combination of Trejo and Hoffman does not teach or suggest all of the limitations of each of claims 8 or 9.” (*Id.*)

We are not persuaded. As discussed above we have found no deficiency in the Examiner’s *prima facie* case based on Trejo with respect to claim 1. Trejo provides daily dosing limits for the various components recited in claim 8 (FF7). The Examiner points to table 12 in Hoffman for a teaching of a nutritional profile of a single dose of infant formula that is used to improve vision (Ans. 8). Hoffman’s disclosed composition in table 12 (FF9) comprises: 17 mg of DHA (docosahexanoic acid, an omega-3 fatty acid; FF2), 34 mg ARA (arachidonic acid, an omega-6 fatty acid; FF3), 860 mg of linoleic acid (an omega-6 fatty acid; FF3), 2 IU (=0.9 or 1.34 mg⁴)

⁴ “1 IU of alpha-tocopherol is equivalent to 0.67 mg of the natural form or

vitamin E, 12 mg of vitamin C, 60 µg of vitamin B₆, 0.3 µg of vitamin B₁₂ and 1 mg zinc. We note that the total omega 6 fatty acid component of 0.894g comprises 4.8 % by weight of the total 100 kcal dose (FF9). The test for obviousness is what the combined teachings of the references as a whole would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). Here, the combination of Trejo and Hoffman would suggest compositions comprising omega-3, omega-6, and zinc (FFs 1-7, 9). Additionally, Trejo disclosed fatty acid compositions comprising gamma-linolenic acid (FF3), specifically, including a mixture of linoleic acid, gamma-linolenic acid, and arachidonic acid. We agree with the Examiner's position that arriving at the specific limitations recited in claim 8 would only require routine experimentation because the general working parameters were already disclosed in the combination of Trejo and Hoffman. *In re Aller*, 220 F.2d 454, 456 (CCPA 1955).

We conclude that the preponderance of the evidence of record supports the Examiner's conclusion that Trejo in view of Hoffman renders obvious the composition of claim 8. We thus affirm the rejection of claim 8 under 35 U.S.C. § 103(a) as being obvious, and as claims 9-11 and 13-14 stand or fall with that claim, we affirm the rejection as to those claims as well.

SUMMARY

We affirm the rejection of claims 1-7 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Trejo.

We vacate the rejection of dependent claims 10, 11, 13, and 14 under 35 U.S.C. § 103(a) as being unpatentable over Trejo, because the Examiner did not address claim 8 from which claims 10, 11, 13, and 14 depend.

We affirm the rejection of claims 8-11, 13, and 14 under 35 U.S.C. § 103(a) as being unpatentable over Trejo in view of Hoffman.

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

cdc