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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MOHAMED NABIL BOSCO, MANUEL OLIVEIRA, FREDERIC DESTAILLATS, VIRAL BRAHMBHATT, and JALIL BENYACOUB

Appeal 2019-000716
Application 14/127,606
Technology Center 1600

Before RAE LYNN P. GUEST, DEBORAH KATZ, and TAWEN CHANG, *Administrative Patent Judges*.

KATZ, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] seeks our review[2], under 35 U.S.C. § 134(a), of the Examiner's decision to reject claims 1, 4–6, 8, 9, 12, and 14–20. We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Nestec S.A. (Appeal Br. 2.)

[2] We consider the Final Office Action issued March 26, 2018 ("Final Act."), the Appeal Brief filed July 5, 2018 ("Appeal Br."), the Examiner's Answer

The Examiner rejects claims 1, 4–6, 8, 9, 12, and 14–20 under 35 U.S.C. § 103(a) as being unpatentable over Berge,[3] Chen,[4] Web MD,[5] Grootjans.[6] (Final Act. 4–9.)

Appellant's claim 1 recites:

> A method for the treatment of intestinal damages following ischemia-reperfusion in a splanchnic area of a human patient, the method comprising:
>
> administering a composition comprising DHA and EPA as active ingredients to a human patient needing treatment of intestinal damages following ischemia-reperfusion in a splanchnic area of the human patient, the EPA and DHA provided from a lipid source consisting essentially of marine oils and optionally one or more additional lipid sources selected from the group consisting of soybean oil, sunflower oil, and cocoa butter, in a combined daily dose of at least 400 mg and in a weight ratio of 2:1 to 1:1.

(Appeal Br. 15.) Appellant's claim 5 is also independent, reciting a composition with EPA and DHA provided from a lipid source consisting essentially of 15–25 weight-% fish oil, and optional lipid sources of about 5–

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issued on October 5, 2018 ("Ans."), the Reply Brief filed October 25, 2018 ("Reply Br.").

[3] Berge, International Patent Application Publication WO 2006/009464 A2, published January 26, 2006.

[4] Chen et al., "Oxidative Stress in Ischemic Brain Damage: Mechanisms of Cell Death and Potential Molecular Targets for Neuroprotection," *Antioxidants & Redox Signaling*, 14:1505–17 (2011).

[5] WebMD: Inflammatory Bowel Disease available at https://www.webmd.com/ibd-crohns-disease/inflammatory-bowel-syndrome.

[6] Grootjans, et al., "Human Intestinal Ischemia-Reperfusion-Induced Inflammation Characterized," *The American Journal of Pathology*, 176:2283–91 (2010).

10 weight-% cocoa butter, about 45–55 weight-% soybean oil, and about 20–25 weight-% sunflower oil. (*See id*. at 15.)

Berge teaches using combinations of β-oxidizable fatty acids and plant or fish oils to treat a number of ailments, including myocardial infarction, stroke (oxidative stress induced by ischemia reperfusion), and inflammatory disorders, including inflammatory bowel disease ("IBD"). (*See* Berge 1, 39 (claim 3); *see* Final Act. 5.) Table 2 of Berge teaches including EPA (called "20:5 n-3") at 5.9, 5.9, and 5.8 % of the total fatty acids and DHA (called "22:6 n-3") at 6.4, 6.2, and 6.2 % of the total fatty acids in a composition. (*See* Berge Tables 2 and 7, p. 22; *see* Final Act. 5.)

The Examiner finds that it is inherent to the method of Berge that intestinal damage following ischemia reperfusion would be limited by the composition taught because Berge teaches treating stroke and IBD with the composition. (*See* Final Act. 5, citing Berge claim 5.) The Examiner supports this finding by citing WebMD, which teaches that IBD involves inflammation of the intestine, and by citing Chen, which teaches that ischemia/reperfusion after stroke causes oxidative stress. (*See* Final Act. 6; *see* Chen Abstract.) The Examiner also cites Grootjans for its teaching that human intestinal, i.e. splanchnic or abdominal, ischemia reperfusion is known to cause inflammation. (*See* Final Act. 6.) According to the Examiner, because Berge teaches that fish oils are known to be used to treat stroke, myocardial infarctions, and IBD and because IBD is known to cause inflammation in the intestines, it would have been obvious that the fish oil could be used to treat intestinal damages following ischemia-reperfusion in a splanchnic area. (*See id*. at 6–7.)

Appellant argues that Berge teaches away from the claimed method because it teaches that non β-oxidizable fatty acid analogues such as the 3-thia fatty acid tetradecylthioacetic acid ("TTA") can lead to increased hepatic and muscle mitochondrial and peroxisomal fatty acid oxidation in mammals. (*See* Appeal Br. 7, citing Berge ¶¶ 1, 5; *see also* Reply Br. 2–3.) According to Appellant, this "oxidation is precisely the opposite of what is needed for the treatment of intestinal damages following ischemia-reperfusion in a splanchnic area of a human patient, as recited in present Claim 1, as ischemia reperfusion is a disorder related to oxidative stress." (Appeal Br. 7, citing Spec. 2:8–11.)

Although we agree that Berge teaches β-oxidation can lead to increased hepatic and muscle mitochondrial and peroxisomal fatty acid oxidation in farm animals when used "for muscle growth," we disagree that this teaches away from Appellant's claimed method, which recites "intestinal damages." First, Appellant's argument that the increase in oxidation caused by β-oxidizable fatty acid analogues is the opposite of the method of claim 1 is not supported by evidence. The portions of the Specification, page 2, lines 8–11, cited by Appellant states that "there is a need in the art for alternative compositions that – when administered – allow to treat, prevent or alleviate disorders related to oxidative stress, in particular following ischemia reperfusion (IR)." This statement does not indicate that the oxidation discussed in Berge would interfere or prevent treating "intestinal damages" resulting from ischemia reperfusion. Appellant's assertion that the oxidation from feeding animals as discussed in Berge and intestinal damage resulting from ischemia reperfusion are the same is

unsupported. "Attorney's argument in a brief cannot take the place of evidence." *In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974).

In addition, Appellant does not dispute the Examiner's finding that Berge's teachings of treating stroke, myocardial infarction, and IBD inherently teaches treating intestinal damages following ischemia reperfusion in a splanchnic area of a human patient. Thus, because Berge teaches treating these conditions with EPA and DHA, we are not persuaded that Berge would have discouraged one of ordinary skill from administering a composition comprising DHA and EPA for intestinal damages following ischemia-reperfusion as claimed. *See In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.).

Appellant also argues that the lipid source of claim 1 excludes non β-oxidizable fatty acid analogues such as the 3-thia fatty acid tetradecylthioacetic acid taught in Berge because it recites "the EPA and DHA provided from a lipid source consisting essentially of marine oils." (*See* Appeal Br. 8; *see* Reply Br. 3–4.) Similarly, Appellant argues that claim 5 excludes non-β-oxidizable fatty acid analogues taught in Berge because it recites "the EPA and DHA provided from a lipid source consisting essentially of 15-25 weight-% fish oil." (*See* Reply Br. 3–4.) According to Appellant, because Berge includes plant oil in the pharmaceutical or nutritional composition for synergistic beneficial biological effects, its teachings are excluded by the transitional phrase "consisting essentially of." (*See* Appeal Br. 8.)

We are not persuaded by this argument because the methods of claim 1 and claim 5 recite a "method comprising: administering a composition *comprising* DHA and EPA as active ingredients to a human patient . . ." (*See* Appeal Br. 15 (emphasis added).) Thus, although the source of the DHA and EPA consists essentially of marine oil (claim 1) or a lipid source of 15–25% weight fish oil (claim 5), the overall composition administered in Appellant's claims may include other ingredients. Appellant argues that the Specification discloses DHA and EPA as the only active ingredients provided from marine oils to treat oxidative stress, but we review the scope of what Appellant claims, not discloses, in our analysis of obviousness. Appellant's claims requires EPA and DHA be provided from a lipid source "consisting essentially" of marine or fish oils but does not limit the overall composition administered to the patient. (*See* Ans. 5–6.) Appellant does not dispute that Berge teaches a composition comprising DHA and EPA sourced from fish (marine) oil. (*See* Appeal Br. 8.)

Appellant argues further that Berge does not teach an EPA to DHA weight ratio of 2:1 to 1:1, as required in claim 1. (*See* Appeal Br. 9.) Appellant argues that neither Tables 2 or 7–9 teaches a weight ratio within the claimed range, and instead, Table 2 provides weight ratios of EPA to DHA of 5.9/6.4, 5.9/6.2, and 5.8/6.2, which are less than 1:1 and that none of the other examples provide weight ratios within range. (*See* Appeal Br. 9.)

We are not persuaded by Appellant's argument because we agree with the Examiner that the weight ratio provided in claim 1 does not indicate the order of components present "in a weight ratio of 2:1 to 1:1." (*See* Ans. 8–9.) Instead, claim 1 recites both "DHA and EPA" and to "EPA and DHA" at

different parts of the claim. Thus, the broadest reasonable interpretation of claim 1 encompasses a ratio of DHA to EPA of 2:1 to 1:1, as well as a ratio of EPA to DHA of 2:1 to 1:1. Accordingly, the ratios taught in Table 2 of Berge fall within the scope of Appellant's claims. Furthermore, we agree with the Examiner that even if claim 1 is limited to a weight ratio of DHA to EPA of 2:1 to 1:1, the ratios taught in Berge would be rounded to 1:1 if expressed in single digits. (*See* Ans. 9.) Accordingly, we are not persuaded that Appellant's claimed method is non-obvious because of the recited ratio.

Appellant argues that the Specification demonstrates unexpected results that render the claimed method non-obvious. (*See* Appeal Br. 9–12.) Appellant points to the examples in the Specification, wherein rats underwent either an I/R procedure of ischemia and reperfusion, or a sham procedure, followed by either a control diet or a diet supplemented with a lipid blend that included cocoa butter, soybean oil, fish oil, and sunflower oil. (*See* Appeal Br. 10; *see* Spec. 10–15.) Appellant reports that the specific EPA and DHA provided from a lipid source comprising marine oils, in a combined daily dose of at least 400 mg and in a weight ratio of 2:1 to 1:1, resulted in a statistically significant increase of CAT, SOD, 17, 18-EEP, and TXB3 expression. (*See* Appeal Br. 10–11; *see* Reply Br. 4–7.)

We are not persuaded by Appellant's argument for several reasons. First, Appellant does not point to evidence that these results would have been unexpected by those of ordinary skill in the art over the teachings of the prior art. For example, Appellant does not direct us to evidence of a comparison between the effects of the composition recited in claims 1 or 5 and the composition taught in Berge on the treatment of intestinal damage following ischemia-reperfusion. *See In re Baxter Travenol Labs*., 952 F.2d

388, 392 (Fed. Cir. 1991) ("when unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art."). The Specification states only that "[i]nterestingly, NRC lipid blend fed animals display a higher expression of enzymes of the oxidative stress machinery and lipidomic analyses of intestinal tissue clearly show global increase of antiinflammatory lipid metabolites" and that the results were shown for the first time (Spec. 15), but fails to state or show that these results were unexpected over the prior art.

We are also not persuaded by Appellant's argument of unexpected results because the results presented are not commensurate with the scope of the claims. The lipid blend used in the examples includes cocoa butter, soybean oil, and sunflower oil, as well as fish oil. (*See* Spec. 13, Table 1a.) Because these other oils are only optional in Appellant's claimed method, a persuasive showing of unexpected results would also include results without plant-based oils because they are not necessary to the invention. "It is well settled 'that objective evidence o[f] non-obviousness must be commensurate in scope with the claims which the evidence is offered to support.'" *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983) (quoting *In re Tiffin*, 448 F.2d 791 (CCPA 1971)).

Appellant's argument that the oils other than fish oil are simply a mixture to provide EPA and DHA in the context of a food matrix that corresponds to a normal diet does not persuade us otherwise. (*See* Reply Br. 6–7.) Claims 1 and 5 encompass administering compositions without these other oils. Therefore Appellant's burden is to show that compositions without these oils also produce the results asserted to be unexpected. We note further that the control composition in the examples of Appellant's

Specification has a different amount of corn oil, cocoa butter, and sunflower oil than the "NRC blend" experimental composition.[7] (*See* Spec. 13, Table 1a.) Thus, the example does not necessarily show the effects of only EPA and DHA administration following ischemia-reperfusion, as Appellant argues, because the effects could be due to the different plant-based oils components of the comparative compositions. (*See* Reply Br. 7.)

Appellant relies on the same arguments in regard to the rejection of independent claim 5. (*See* Appeal Br. 12–13.) For the reasons provided above, we do not find these arguments to be persuasive and are not persuaded that the Examiner erred in rejecting claim 1 or claim 5.

Appellant does not provide separate arguments for the rejection of the claims that depend on claim 1 or claim 5. Accordingly, we are not persuaded that the Examiner erred in rejecting them either.

Conclusion

Upon consideration of the record and for the reasons given, we affirm the Examiner's rejection.

In summary:

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
1, 4–6, 8, 9, 12, 14–20	103(a)	Berge, Chen, Web MD, Grootjans	1, 4–6, 8, 9, 12, 14–20	

[7] The control composition is reported to have 35% corn oil, 15% cocoa butter, and 50% soybean oil, whereas the "NRC blend" has 7% cocoa butter, 50% soybean oil, 20% fish oil, and 23% sunflower oil. (*See* Spec. 13, Table 1a.)

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

AFFIRMED