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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte NICOLAAS EMILE DEUTZ,
NORMAN ALAN GREENBERG, KALA MARIE KASPAR,
CANDIS KVAMME, and YVETTE CHARLOTTE LUIKING

Appeal 2012-001546
Application 12/293,283
Technology Center 1600

Before ERIC GRIMES, MELANIE L. McCOLLUM, and JACQUELINE WRIGHT BONILLA, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for treating, reducing, or inhibiting satiety and/or dyspepsia. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 1, 2, 4-6, and 9-15 are on appeal (App. Br. 4).[1] The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(iv). Claim 1 is representative and reads as follows:

> 1. A method for treating, reducing, or inhibiting, at least one of satiety and dyspepsia in a mammal, the method comprising:
>
> increasing a concentration of nitric oxide (NO) in the mammal's cells by administering to the mammal an orally-administrable nutritional supplement having a quantity of L-citrulline and at least one of a protein, a soluble fiber, an insoluble fiber, a fatty acid, a vitamin, a mineral, a carbohydrate, a flavor agent, a medicament, and a therapeutic agent, wherein the increased concentration of NO results in a relaxation of smooth muscles of the stomach.

Claims 1, 2, 4-6, and 9-15 stand rejected under 35 U.S.C. § 103(a) as obvious over Bandarage[2] as evidenced by Yu[3] and in view of Cha[4] and Osowska-Vincent[5] (Ans. 4).

The Examiner relies on Bandarage for teaching "treating dyspepsia . . . by administering nitrosylated compounds such as citrulline" (*id.* at 5). The Examiner finds that "[i]ntrinsically Bandarage's administration of citrulline increases concentration of NO necessarily results in a relaxation of smooth muscles of the stomach and in the mammal's cells" (*id.*). The

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[1] Claims 16-45 are also pending but have been withdrawn from consideration (App. Br. 4).
[2] Bandarage et al., US 6,593,347 B2, Jul. 15, 2003.
[3] Yu et al., *Quantitative aspects of interorgan relationships among arginine and citrulline metabolism*, 271 Am. J. Physiol. Endocrinol. Metab. E1098-E1109 (1996) (Abstract only).
[4] Cha et al., WO 2006/002096 A2, Jan. 5, 2006.
[5] Osowska-Vincent et al., US 2005/0239891 A1, Oct. 27, 2005.

Examiner also finds that it "is reasonable that the citrulline will further necessarily be a L- citrulline because it's a precursor of L- arginine" (*id.*).

The Examiner relies on Yu as evidence that the "conversion of L-citrulline to arginine is an inherent property of the compound" (*id.*).

The Examiner relies on Cha for teaching "treating a number of disease[s] wherein L-citrulline is administered as dietary supplements comprising vitamins and at least one sugar . . . which thereby increases arginine levels in the treatment of diseases that benefit from an increase in NO" (*id.* at 6).

The Examiner relies on Osowska-Vincent for teaching features of dependent claims, specifically for teaching "treating intestinal insufficiency by administering L-citrulline in mammals suffering of malnutrition . . . that have had re-sectioning of the intestine (gastric bypass . . .)" (*id.*).

The Examiner concludes:

> One of ordinary skill in the art would have been motivated to expand the treatment method of Bandarage to include the methods of Cha et al. and Osowska-Vincent et al. to treat patients with satiety and dyspepsia with a nutritional supplement that is administered orally because both Cha et al. and Osowska-Vincent et al. teach that L-citrulline may be administered orally.

(*Id.*)

ISSUE

Does the evidence support the Examiner's conclusion that it would have been obvious to treat, reduce, or inhibit dyspepsia by administering L-citrulline in a nutritional supplement that also comprises at least one of a

protein, a soluble fiber, an insoluble fiber, a fatty acid, a vitamin, a mineral, a carbohydrate, a flavor agent, a medicament, and a therapeutic agent?

ANALYSIS

For at least the reasons stated in the Answer, we agree with the Examiner that it would have been obvious to treat, reduce, or inhibit dyspepsia by administering L-citrulline in a nutritional supplement that also comprises at least one of a protein, a soluble fiber, an insoluble fiber, a fatty acid, a vitamin, a mineral, a carbohydrate, a flavor agent, a medicament, and a therapeutic agent.

In particular, Bandarage specifically teaches

> methods for decreasing and/or preventing gastrointestinal disorders by administering to the patient in need thereof a therapeutically effective amount of . . . at least one nitrosated and/or nitrosylated NSAID, and, optionally, at least one compound that donates, transfers or releases nitric oxide, or elevates levels of endogenous [endothelium-derived relaxing factor] or nitric oxide, or is a substrate for nitric oxide synthase.

(Bandarage, col. 30, l. 60, to col. 31, l. 2.) Bandarage also discloses that the gastrointestinal disorders include dyspepsia (*id.* at col. 31, ll. 4-7) and that "compounds that stimulate endogenous NO or elevate levels of endogenous endothelium-derived relaxing factor (EDRF) in vivo or are substrates for nitric oxide synthase" include citrulline (*id.* at col. 30, ll. 11-23). Given the "comprising" language, claim 1 is clearly open to administering at least one nitrosated and/or nitrosylated NSAID and, in fact, specifically recites that a medicament and/or a therapeutic agent may be included.

The Examiner relies on Cha for teaching administering L-citrulline in a dietary supplement (Ans. 6 (citing Cha 7: 7-20)). We agree with the

Examiner that it would have been obvious to administer L-citrulline in the form of a dietary supplement, as described in Cha, in order to decrease and/or prevent dyspepsia, as described in Bandarage. For the reasons stated by the Examiner (Ans. 8-10), Appellants do not persuade us that "the skilled artisan would have no reason to combine the cited references to arrive at the present claims" (App. Br. 8, 10-12).

CONCLUSION

The evidence supports the Examiner's conclusion that it would have been obvious to treat, reduce, or inhibit dyspepsia by administering L-citrulline in a nutritional supplement that also comprises at least one of a protein, a soluble fiber, an insoluble fiber, a fatty acid, a vitamin, a mineral, a carbohydrate, a flavor agent, a medicament, and a therapeutic agent. We therefore affirm the obviousness rejection.

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

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