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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte Tropicana Products, Inc.
(Inventors: Bryan Hitchcock, Jeff Schroen, Ted Rivera,
Nicholas Colin Shields, David Lam, and Sabrina Christiaens)

Appeal 2011-007424
Application 11/194,176
Technology Center 1700

Before RICHARD E. SCHAFFER, CHARLES F. WARREN, and
MICHAEL P. COLAIANNI, *Administrative Patent Judges*.

SCHAFFER, *Administrative Patent Judge*.

DECISION ON APPEAL

Tropicana Products, Inc. (Applicant) appeals from an Examiner's decisions rejecting claims 1, 3-7, and 11-18. 35 U.S.C. §§ 6(b) and 134(a). We affirm.

The Claimed Subject Matter

The invention relates to a method of making a beverage containing cholesterol-reducing plant sterols and stanols. Plant sterols and stanols are known to reduce cholesterol when ingested. These benefits are said to be hard to achieve because of the difficulties involved in incorporating the hydrophobic sterols and stanols into food products. Applicant's method

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addresses that problem. Rather than using free sterols and stanols, Applicant uses their esterified versions or their mixtures. The esters used are said to be a semi-solid. The esters are heated to a temperature above their melting point to provide a heated liquid, mixed with a preheated aqueous liquid to obtain a uniform dispersion of the esters in the liquid. This homogenized mixture is cooled to a temperature below the ester melting point. The concentration of the cholesterol-reducing ester is specified to be in the range of 0.8 grams/liter to 200 grams/liter.

Applicant also claims the ester-containing beverage made by the method. The claim is presented in product-by-process format. In the product-by-process claims, the aqueous liquid is limited to juices and the use of emulsifiers is specifically precluded.

The Rejections

In the Answer, the Examiner maintained two rejections, both under 35 U.S.C. § 103(a):

1. Claims 6-7, and 11-18 over the combined teachings of Lerchenfeld,¹ Schmitz,² and 21 C.F.R. 101.83 (2001);³ and
2. Claims 1 and 3-5 over the combined teachings of Schmitz, Lerchenfeld and Stern.⁴

Lerchenfeld

Lerchenfeld relates to a method of making aqueous beverages, such as juices, that contain a stable uniform dispersion of plant sterols and stanols.

¹ U.S. Patent 7,335,389 B2.

² U.S. Patent 6,610,320 B2.

³ “Health claims: plant sterol/stanol esters and risk of coronary heart disease (CHD),” 65 Fed. Reg. 54686, 54717 (Sept. 8, 2000) as amended 65 Fed. Reg. 70466 (Nov. 24, 2000).

⁴ U.S. Patent 3,004,043.

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Lerchenfeld, 1:13-15. Lerchenfeld notes that sterols and stanols are hydrophobic which makes their incorporation into aqueous beverages difficult. Lerchenfeld, 1:59-65. Lerchenfeld's process is said to overcome this problem. Lerchenfeld, 3:50-60. Lerchenfeld describes mixing the plant sterols with an aqueous liquid. Lerchenfeld, 4:13-18. This first dispersion is heated to a temperature between 43-100°C and homogenized to obtain a second dispersion. Lerchenfeld, 4:18-28. The homogenized beverage may be subject to subsequent heating and cooling. Lerchenfeld, 4:36-43. The process results in a

substantially stable dispersion comprising at least one hydrophobic plant sterol and an aqueous material such as an aqueous beverage concentrate wherein the at least one plant sterol is selected from plant sterols and plant stanols, and wherein the dispersion does not contain any added emulsifiers and thickening agents and other so-called "manufacturing aids," used in the food arts, e.g., encapsulation materials.

Lerchenfeld, 6:3-12.

Analysis

I. Claim 6, 7, and 11-18

Applicant does not argue the subject matter of Claims 7 and 11-18 separately from Claim 6. Our decision on Claim 6 will be dispositive of Claims 7 and 11-18 as well. 37 C.F.R. § 41.37(c)(1)(vii).

We reproduce independent Claim 6 below:

6. A method of preparing a beverage comprising:
heating a cholesterol reducing ester selected from the group consisting of sterol esters, stanol esters, and mixtures thereof, the cholesterol reducing ester being in a semi-solid form, to a temperature above its melting point to form a liquid and preheating an aqueous liquid beverage component;

blending the liquid cholesterol reducing ester and the preheated aqueous liquid beverage component to form a heated mixture;

a first homogenizing of said heated mixture to form a resulting beverage characterized by a uniform dispersion of the cholesterol reducing ester in the aqueous medium;

after said first homogenizing, optionally heating said resulting beverage to a pasteurization temperature;

cooling said resulting beverage to a temperature below the melting point of the cholesterol reducing ester present in the beverage; and

wherein the sterol or stanol portion of the molecule is present in the beverage in a concentration of from about 0.8 grams/liter to about 200 grams/liter of beverage.

Claims Appendix i-ii.

Applicant argues the following differences between Lerchenfeld's process and the claimed process:⁵

1. Lerchenfeld does not teach a uniform dispersion of a cholesterol reducing ester (Brief 17);
2. Lerchenfeld does not teach using a cholesterol reducing ester in a semi-solid form (brief 16); and
3. Lerchenfeld does not teach heating sterols and stanols above their melting points (Brief 17).

None of these differences render the claimed subject matter unobvious. Schmitz relates to beverages including cholesterol reducing ingredients. Schmitz, 2:20-24. The cholesterol reducing ingredients may be sterol and stanol based agents. Schmitz, 2:35-39. The sterol and stanol based agents include the free sterols and stanols as well as their esterified versions. Schmitz, 6:59-7: 9; 7:66-67. Thus, sterol and stanol esters are

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known alternatives to free sterols and stanols as cholesterol reducing agents. One having ordinary skill in the art would have recognized that the esters are hydrophobic, and like sterols and stanols, would benefit from Lerchenfeld's method for obtaining a stable dispersion of the cholesterol reducing agents. The substitution of the esterified sterols and stanols into Lerchenfeld's process would have been obvious.

The choice of semi-solid form of the esters also does not present an unobvious distinction. As noted by Applicant, the sterol and stanol esters are known and commercially available as a solid, a semi-solid or liquid. Specification, ¶ 26-27. Schmitz does not specify using any particular form of the esters. It would have been obvious to use, or at least to try, any of these ester forms in Lerchenfeld's process. In this regard we note that Applicant's specification does not indicate that any form of ester is preferred over the others. Thus, Applicant teaches that the esters may be provided as a solid, a semi-solid or a liquid and still obtains the desired goal. Specification, ¶¶ 35-37.

With respect to heating the esters above the melting point, the Examiner found that the esters typically melt in the range of 35 to 80°C. Answer 9. Applicant has not challenged the Examiner's finding. *See also* Specification, ¶ 12. Lerchenfeld's process heats the first dispersion to 43-100°C. Lerchenfeld, 4:13-18. Thus, the substitution of the esters in Lerchenfeld's process would result in heating the esters above their melting points.

In summary, Applicant's invention employs a known process using known materials, for their known purposes, and achieves only the results

that would have reasonably been predicted. The subject matter of Claim 6 would have been obvious.⁶

The Examiner decision rejecting Claims 6, 7 and 11-18 is affirmed.

II. Claims 1 and 3-5

Applicant does not argue the subject matter of Claims 1 and 3-5 separately from Claim 1. We therefore decide the appeal of these claims with reference to Claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

Claims 1 and 3-5 are directed to a beverage that includes a uniform dispersion that is made essentially by the process of Claim 6. The process steps recited in Claim 1 are essentially the same as the steps required by Claim 1. Claim 1 limits the beverages to juices, does not require any particular concentration of the esters, and precludes the presence of an emulsifier.

Claim 1 is reproduced below:

1. A beverage comprising a uniform dispersion prepared by the process comprising:
 - heating a cholesterol reducing ester selected from the group consisting of sterol esters, stanol esters, and mixtures thereof, the cholesterol reducing ester being in a semi-solid form, to a temperature above its melting point to form a liquid and preheating an aqueous liquid beverage component, wherein the aqueous liquid beverage is selected from the group consisting of juices;
 - blending the liquid cholesterol reducing ester and the preheated aqueous liquid beverage component to form a heated mixture;
 - homogenizing the heated mixture to reduce the particle size of the cholesterol reducing ester and to form

⁶ The Examiner also relied on the technical disclosure in 21 C.F.R. § 21. 101.83 to support the rejection. However, since Applicant has not directed any argument relating to the regulation, it is not necessary for us to address it.

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a resulting homogenized mixture characterized by a uniform dispersion of the cholesterol reducing ester in the aqueous liquid beverage component; and
cooling the homogenized mixture to a temperature below the melting point of the cholesterol reducing ester to provide the uniform dispersion;
wherein the uniform dispersion does not contain added emulsifier.

Claims Appendix i.

The Examiner rejected Claim 1 over the combined teachings of Schmitz, Lerchenfeld and Stern.

Applicant contends that

[n]one of Schmitz, Lerchenfeld or Stern, either alone or in combination, teaches or suggests at least a uniform dispersion of cholesterol reducing esters, initially provided in semi-solid form, in an aqueous juice composition, in the absence of emulsifiers, as required by claim 1.

Brief 11. Applicant further argues that

there simply would have been no reason for one of skill in the art to develop the invention of claim 1 from the proposed combination of Schmitz and Lerchenfeld at least because Schmitz teaches the use of emulsifiers to provide water soluble sterol/stanol powders, Lerchenfeld teaches the use of plant sterols or stanols that are not esterified, and Stern teaches the use of water-soluble polyethylene glycol esters of plant sterols or stanols.

Brief 15-16.

We disagree. The claimed beverage would have been obvious because the method of making the claimed beverage would have been obvious for the reasons we stated above with respect to Claim 6. The additional requirements of Claim 1 that the beverage is selected from the group consisting of juices and that no emulsifiers be included in the

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beverage do not patentably distinguish the claimed process. Lerchenfeld teaches forming a stable dispersion of cholesterol reducing agents in juices without the need for emulsifiers. Lerchenfeld, 4:29-35. The substitution of semi-solid esterified sterols and stanols in Lerchenfeld's process would have been obvious for the reasons stated above with respect to Claim 6.

Applicant presents a number of arguments related to the Stern reference. Brief 13-16. The Examiner relied on Stern as evidence that it is desirable to incorporate sterol and stanol esters into fruit juice. Answer 7. Applicant has not challenged the Examiner's finding on this point. Accordingly, it is unnecessary to address Applicant's arguments related to the purported deficiencies in that reference.

The Examiner's decision rejecting Claims 1 and 3-5 is affirmed.

We have considered Applicant's other arguments and find none that warrant reversal. *Cf., Loughlin v. Ling*, 684 F.3d 1289, 1295 (Fed. Cir. 2012).

DECISIONS

The Examiner's decisions rejecting 1, 3-7, and 11-18 under 35 U.S.C. § 103(a) are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1).

AFFIRMED

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