

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 44

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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Ex parte CHRISTIAN MELIN

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Appeal No. 95-2633  
Application 08/121,663<sup>1</sup>

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ON BRIEF

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Before McKELVEY, Senior Administrative Patent Judge, and SCHAFER and LEE, Administrative Patent Judges.

SCHAFER, Administrative Patent Judge.

**Decision on Appeal Under 35 U.S.C. § 134**

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<sup>1</sup> Application for patent filed September 15, 1993. According to appellant, the application is a continuation of Application 07/562,413, filed August 2, 1990, now abandoned, which is a continuation of Application 07/222,810, filed July 22, 1988, now abandoned.

This appeal is from a decision of a primary examiner rejecting claims 1-5, 7-9, and 11-15. We reverse the rejection of claims 1-4 and affirm the rejection of claims 5, 7-9 and 11-15.

The invention relates to a process for refining olive oil (claims 1-4), a refined olive oil made by the process (claim 5) and parenteral and enteral formulations including the refined olive oil (claims 7-9 and 11-15). See the Appendix to Appellant's Appeal Brief (Appendix) found at pp 13-16 of applicant's brief.

In arguing the rejection, applicant does not argue the patentability of the dependent claims separate from the independent claims from which they depend. Brief, p. 6. So we could decide this appeal on the basis of independent claims 1, 14 and 15. However, claim 5 is a product-by-process and requires treatment separate from the other claims dependent on claim 1. Accordingly we decide this appeal on the basis of claims 1, 5, 14 and 15, which are reproduced below:

1. A process for making a purified olive oil for use in enteral and parenteral nutritional formulations, the method comprising:
  - providing an olive oil sample to be purified having a previously determined oleic acid content;
  - neutralizing the oleic acid present in the oil by contacting the oil sample with an amount of a saturated aqueous solution of alkaline carbonate equivalent to two to ten times the weight of oleic acid present in the oil sample, allowing an aqueous phase to separate and washing the oil with water until complete neutrality to provide a neutralized oil sample; and
  - drying and decolouring the neutralized oil sample by contacting the neutralized oil sample with bleaching earth under an inert atmosphere at a temperature of between about 20°C to about 80°C to provide a purified oil product having an acceptably low amount of peroxides, free acids and pigments for enteral and parenteral nutritional administration.
5. A[n] olive oil, suitable for use as an enteral or parenteral foodstuff, wherein the oil is obtained by the process defined in claim 1.

14. A parenteral formulation including a purified olive oil product obtained by a method comprising:

providing an olive oil sample to be purified having a previously determined oleic acid content;

neutralizing the oleic acid present in the oil by contacting the oil sample with an amount of a saturated aqueous solution of alkaline carbonate equivalent to two to ten times the weight of oleic acid present in the oil sample, allowing an aqueous phase to separate and washing the oil with water until complete neutrality to provide a neutralized oil sample; and

drying and decolouring the neutralized oil sample by contacting the neutralized oil sample with bleaching earth under an inert atmosphere at a temperature of between about 20°C to about 80°C to provide a purified oil product having an acceptably low amount of peroxides, free acids and pigments for parenteral and nutritional administration.

15. An enteral formulation including a purified olive oil product obtained by a method comprising:

providing an olive oil sample to be purified having a previously determined oleic acid content;

neutralizing the oleic acid present in the oil by contacting the oil sample with an amount of a saturated aqueous solution of alkaline carbonate equivalent to two to ten times the weight of oleic acid present in the oil sample, allowing an aqueous phase to separate and washing the oil with water until complete neutrality to provide a neutralized oil sample; and

drying and decolouring the neutralized oil sample by contacting the neutralized oil sample with bleaching earth under an inert atmosphere at a temperature of between about 20°C to about 80°C to provide a purified oil product having an acceptably low amount of peroxides, free acids and pigments for enteral and nutritional administration.

Appendix, pp. 13-16. Claims 5, 14 and 15 are product-by-process claims which incorporate or specifically recite the steps of claim 1.

The examiner rejects all claims under 35 U.S.C. § 103(a) over the combined teachings of U.S. Patents 4,816,189 (Rothbart)<sup>2</sup> and 4,497,800 (Larson)<sup>3</sup> Examiner's Answer, pp. 3-5. The examiner also separately rejected claims 7-9 and 11-15 over Larson alone. Examiner's Answer, p. 6

The Rothbart patent is directed to a process for refining "edible frying oils," particularly soybean oils. Rothbart, col. 1, lines 6-9. Rothbart describes the process at col. 3, lines 12-21:

In general, the process involves the steps of: treating unrefined, unbleached soybean oil with a caustic agent; heating and water washing the treated oil; . . . dispersing into the oil a minor amount of finely divided, activated metallic salts and oxides including bleaching earths, clays, etc., and heating the resulting dispersion in a carbon dioxide atmosphere to a temperature between about 212 degrees F. to about 260 degrees F. for a predetermined time.

About 212° to about 260°F is the same as about 100° C to about 125°C.

The examiner has identified three differences between the claimed process and the Rothbart patent: (1) the express recitation of olive oil, (2) the express recitation of the amount of carbonate used to neutralize the oleic acid, and (3) the temperature used to dry and decolor (bleach) the neutralized oil. Examiner's Answer, p. 4. The examiner concluded that none of these differences would have rendered the claimed invention unobvious and presented argument supporting his conclusion. Examiner's Answer, p. 4. Applicant's brief challenges the examiner's conclusion only with respect to the temperature difference. Brief, pp. 9-10.

In the examiner's view "to modify the time and temperature at which the oil of Rothbart is treated is seen to be an obvious matter of choice with regard to the particular oil treatment conditions which are desired." Examiner's Answer, pp. 4-5. Missing from the examiner's rationale is any explanation as to why one having ordinary skill in the art would be motivated to modify the process by using a lower temperature.

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<sup>2</sup> Issued March 28, 1989, based on an application filed August 7, 1986.

<sup>3</sup> Issued February 5, 1985, based on an application filed July 6, 1982.

“The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.” In re Fritch, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784-85 (Fed. Cir. 1992); In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Nothing in the prior art relied upon by the examiner in rejecting the process claims suggests the desirability of using a temperature of “about 20°C to about 80°C.”<sup>4</sup>

The rejection of claims 1-4 is reversed.

As we indicated above, claims 5, 14 and 15 are product-by-process claims. While product-by-process claims are limited by and defined by the process, determination of patentability is based solely on the product itself. In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985); In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972); In re Pilkington, 411 F.2d 1345, 1348, 162 USPQ 145, 147 (CCPA 1969). The patentability of a product does not depend on its method of production. Thorpe 777 F.2d at 697, 227 USPQ at 966; Pilkington, 411 F.2d at 1348, 162 USPQ at 147. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. Thorpe 777 F.2d at 697, 227 USPQ at 966; In re Marosi, 710 F.2d 799, 803, 218 USPQ 289, 292-93 (Fed. Cir. 1983). Thus, in evaluating the patentability of product-by-process claims we compare the claimed product with the product described in the prior art. The comparison includes the expressly claimed properties and characteristics as well as those implicitly resulting from the process.

Claim 5 is directed to an olive oil “suitable for use as an enteral or parenteral foodstuff.” Claims 14 and 15 are directed to parenteral and enteral formulations, respectively, “including a purified olive oil product . . . having an acceptably low amount of peroxides, free acids and pigments” for enteral, parenteral and nutritional administration. Thus the issue with respect to the product-by-process claims

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<sup>4</sup> In this regard, we note that bleaching of vegetable oils, such as olive oil, subsequent to deacidification is typically carried out at a temperature of 90-110°C under a vacuum. 23 Kirk-Othmer Encyclopedia of Chemical Technology, pp. 717, 724-26 (3rd Ed., 1983).

is whether the prior art teaches or suggests an olive oil having these characteristics. More specifically, does the prior art teach or suggest an olive oil “suitable for use as an enteral or parenteral foodstuff” or an olive oil containing formulation having an “acceptably low amount of peroxides, free acids and pigments” suitable for enteral, parenteral, and nutritional administration.

The examiner relies on the Larson patent as evidence that the product-by-process claims are not patentable. Larson relates to liquid diet formulations. Larson’s disclosed formulation includes “a lipid [(fat)] component of safflower oil or a suitable equivalent.” Larson, col. 4, lines 33-34 (emphasis and bracketed material added). Larson goes on to teach that the

fatty component in the diet may be provided in various forms. Natural fat components such as, for example, safflower oil, soybean oil, corn oil, cotton seed oil, coconut oil, olive oil, and the like, may be used.

Larson, col. 5, lines 29-32 (emphasis added). While the patent exemplifies the use of safflower oil, the above-quoted language expressly teaches that olive oil is a “suitable equivalent” to safflower oil. In view of this clear suggestion and direction, it would have been prima facie obvious for one having ordinary skill in the art to use olive oil in the Larson formulations.

Larson also teaches that it

is intended that this composition be used for enteral feeding, either orally or by intubation, for patients suffering from malnourishment and conditions associated therewith as well as for maintenance of patients with compromised digestive and/or absorptive function which can arise from a variety of causes.

Larson, col 4, lines 56-62. Thus, Larson expressly teaches a foodstuff suitable enteral feeding. The olive-oil containing formulations suggested by Larson meet the limitation of claim 5 that the formulation be “suitable for use as an enteral or parenteral foodstuff.”

The Larson formulations also appear to meet the limitations of claims 14 and 15, that the formulations have “an acceptably low amount of peroxides, free acids and pigments” for both enteral and parenteral and nutritional administration. Larson’s teaching that the diet formulation is suitable for

“maintenance of patients with compromised digestive and/or absorptive function” suggests that the formulations may also be used for parenteral administration. Since the Larson formulations are nutritionally complete and are useful for enteral and parenteral administration, the formulations implicitly have an “acceptably low amount of peroxides, free acids and pigments.”

Based on the record before us, a prima facie case of obviousness has been made out with respect to the subject matter of claims 5, 14 and 15. The burden, thus shifted to applicant to demonstrate that the olive oil-containing formulations suggested by Larson do not possess the characteristics set out in the claims. Thorpe, 777 F.2d at 697, 227 USPQ at 966. The PTO does not have the ability to manufacture products or to obtain and compare prior art products. In re Best, 562 F. 2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977). Applicant has not sustained this burden.

Applicant argues that Larson fails “to describe or suggest . . . that the olive oil used should be free from harmful lipid peroxides . . .” (Emphasis added.) Brief, p. 11. Applicant relies on inventor Melin’s declaration as evidence that refining olive oil at a temperature of about 100°C would produce harmful lipid peroxides. Melin testifies:

[I]f a neutralized and washed olive oil sample is contacted with the bleaching earth and the sample is heated in an inert atmosphere at a temperature of about 100°C. for a period of about 35 minutes and is filtered and analyzed, that thermal oxidation of that oil sample will occur so that the resulting product will contain undesirable amounts of peroxide contaminants and possibly other harmful lipid oxidation products.

Melin Declaration, p. 2, ¶ 4.

The problem with applicant’s argument is that claims 5, 14 and 15 do not require that the olive oil “be free from harmful lipid peroxides.” The claims only require that the olive oil be “suitable for use as an enteral or parenteral foodstuff” or have “acceptably low amount of peroxides, free acids and pigments for” enteral, parenteral and nutritional administration. In our view, Larson suggests olive oil-containing formulations which meet the claim requirements. The Melin declaration does not demonstrate that the olive

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oil-containing formulations suggested by Larson do not have the characteristics required by claims 5, 14, and 15.

The rejection of claims 5, 7-9 and 11-15 is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a). 37 CFR § 1.196(f).

**AFFIRMED-IN-PART**

	)
FRED E. McKELVEY, Senior	)
Administrative Patent Judge	)
	)
	)
	) BOARD OF PATENT
RICHARD E. SCHAFER	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
	)
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