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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(2) is not binding precedent of the Board.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. 43

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte GUY DUTOT

Appeal No. 94-0591
Application 07/755,610¹

ON BRIEF

Before WINTERS, JOHN D. SMITH, and GRON, Administrative Patent Judges.

GRON, Administrative Patent Judge.

DECISION ON APPEAL UNDER 35 U.S.C. § 134

¹ Application for patent filed September 5, 1991. According to applicant, this application is a continuation of Application 07/453,359, filed December 19, 1989, now abandoned; which is a continuation of Application 07/223,120, filed July 22, 1988, now abandoned. Applicant claims the benefit under 35 U.S.C. § 119 of French Application 87.10407, filed July 23, 1987.

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1. Introduction

This is an appeal from an examiner's rejection of Claims 1-9, 11, 12 and 16-20, all claims pending in this application. All claims stand rejected under 35 U.S.C. § 103 over the combined teachings of Bilton, WO 84/02271, published June 21, 1984; Wruble et al. (Wruble), U.S. 3,085,939, patented April 16, 1963; and Babayan et al. (Babayan), WO 86/01715, published March 27, 1986. All claims stand or fall together (Appellant's Brief (Br.), p. 3). Independent Claim 1 is representative of the claimed subject matter and reads:

1. A lipid emulsion suitable for use as a parenteral or enteral foodstuff, comprising from 5 to 50% by weight, relative to the total weight of the emulsion, of a lipid phase in water, said lipid phase consisting essentially of a mixture of long-chain fatty acids in which 15 to 45% by weight of the total fatty acids are essential fatty acids, the essential fatty acids being linoleic acid and α -linolenic acid.

2. Claim interpretation

The claimed lipid emulsion comprises a lipid phase in water (5-50% by weight lipids relative to the total weight of the emulsion), "said lipid phase consisting essentially of a mixture of long-chain fatty acids" (Claim 1). Of the total fatty acids present in the lipid phase, 15-45% are selected from the group of essential fatty acids consisting of linoleic acid and α -linolenic acid.

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We interpret the phrase "said lipid phase consisting essentially of a mixture of long-chain fatty acids" in Claim 1 to close the lipid phase to other fatty acids and/or lipids which "materially affect the basic and novel characteristics" of the lipid phase of the claimed lipid emulsion. Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1574, 224 USPQ 409, 412 (Fed. Cir. 1984); In re Herz, 537 F.2d 549, 551, 190 USPQ 461, 463 (CCPA 1976); and In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963). Appellant's specification describes the basic and novel characteristics of the lipid phase of the claimed lipid emulsion as follows (Specification (Spec.), pp. 2-3, bridging para.):

The present invention seeks to provide a more balanced lipid emulsion having a lower content of polyunsaturated fatty acids, which, while ensuring that the essential fatty acid requirements are covered, has the following advantages:

better utilization of the essential fatty acids to form their higher derivatives, avoiding the risk of inhibition of conversion of the fatty acids by excess substrate,

smaller intake of polyunsaturated fatty acids, enabling lipid peroxidation to be limited, in particular in subjects suffering from inflammatory syndromes, with the production of free radicals.

Based on the specification's description of the basic and novel characteristics of the lipid emulsion and the oils appellant employs to formulate the lipid phase of his lipid

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emulsion, we conclude that the "lipid phase" of the claimed lipid emulsion is open to fatty acids which are not long-chain fatty acids and other lipids, including triglycerides of medium-chain fatty acids, but only in those abnormal amounts that persons skilled in the art would not expect to find in "oils selected from apricot, almond, groundnut, avocado, wheat, safflower, rapeseed, coconut, cottonseed, lupin, maize, hazelnut, walnut, olive, oenothera, palm, palm-kernel, peach, grape, rice, rye, sesame, soybean, sunflower, tomato, linseed and citrus oils" (Spec., p. 3, l. 17-22). See dependent Claim 2. Moreover, we hold that the "long-chain fatty acids" of which the lipid phase of the claimed lipid emulsion essentially consists read on long-chain fatty acids in the form of their triglycerides found in polyunsaturated vegetable oils (Babayan, p. 3, last para.).²

² We note here Babayan's teaching at p. 3, last para., that "[t]he long chain triglycerides may be polyunsaturated vegetable oils such as, corn oil, peanut oil, safflower oil, soybean oil, sunflower seed oil, and fish oils. The preferred long chain triglyceride oils are safflower oil, soybean oil, and sunflower seed oil." Consistent with our holding that the "long-chain fatty acids" of Claim 1 encompass the triglycerides thereof, appellant stated at page 6, 1st full para., of their Appeal Brief (emphasis added):

Since Appellant's invention consists essentially of only long-chain fatty acids, Babayan teaches away from the claimed invention. Babayan is specifically directed to a composition comprising a mixture of medium-chain triglycerides and long-chain triglycerides. Babayan requires the use of both medium-chain triglycerides and long-chain triglycerides to increase protein synthesis

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However, the claimed "lipid emulsion" comprises but 5 to 50% by weight lipid phase. Accordingly, while the lipid phase is closed to other components which materially affect its basic and novel characteristics, the non-lipid phase of the emulsion "does not exclude additional, unrecited elements." Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1271 n. 6, 229 USPQ 805, 812 n. 6 (Fed. Cir. 1986). The emulsion appellant claims is not only open to "plant, animal or synthetic phospholipids" (Spec., p. 4, l. 17-19), "tonicity-regulating agents such as glycerol, glucose, a polyol or an amino acid" (Spec., p. 5, l. 1-2), "amino acids, carbohydrates, vitamins, carnitine, trace elements or keto analogues of amino acids" (Spec., p. 5, l. 3-8), pharmaceuticals, solvents, and adjuvants (Spec., p. 5, l. 9-13), but also to unrecited components.

3. Findings

A. Bilton

The object of Bilton's invention is "to provide a composition which will enhance the lymphatic absorption of naturally-occurring essential fatty acids" (Bilton, p. 3, 3rd

in subjects undergoing severe metabolic stress. To the extent that Babayan purportedly discloses the use of long-chain fatty acids, it teaches away from the present invention in that it teaches the use of a high polyunsaturated acid content.

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full para.), more particularly "linolenic acid, di-homo-gamma-linoleic acid and arachidonic acid . . . [which] have been shown to be necessary for the tissue biosynthesis of the prostaglandins, which perform vital hormone-like activities in the transmission of genetic information in all cells," "cannot be manufactured by the body," and therefore "are essential dietary components" (Spec., p. 1, 2nd para.). To that end, Bilton formulates oil-in-water emulsions by (Spec., pp. 4-5, bridging para.):

. . . emulsifying a vegetable or animal oil rich in polyunsaturated, long-chain fatty acids with an emulsifying agent in the presence of one or more polyhydric alcohol stabilizers, and antibacterial or antifungal preservatives. Oil-soluble nutrients, such as the naturally-occurring amino acids, vitamins and their analogs may also be included in the emulsions, as well as minor amounts of coloring and flavoring. Buffers may also be included when necessary.

According to Bilton (Spec., p. 5, 2nd full para.):

The vegetable or animal oil or mixture of oils will make up the major proportion of the oil phase of the present emulsions, and preferably will comprise 5-45% by weight of the entire emulsion, most preferably about 10-30%.

Most pertinent to the invention appellant describes is Bilton's description of the animal or vegetable oils useful in his emulsions. Bilton employs those oils (Spec., p. 5, 1st full para.; emphasis added):

. . . which contain a high proportion of unsaturated C₁₂-C₁₈ fatty acids to C₁₄-C₁₈ saturated fatty acids, since it is the polyunsaturated fatty acids which

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have been implicated in the in vivo biosynthesis of biologically active prostaglandins. The preferred oils possess an unsaturated fatty acid to saturated fatty acid ratio of from 10:1 [to] about 5:1. Preferred vegetable oils include primrose oil, safflower oil, sunflower oil, sesame oil, cottonseed oil, etc.

B. Wruble

Wruble describes stable oil-in-water emulsions for oral administration comprising an edible unsaturated oil and sitosterol (Wruble, col. 1, lines 11-20). According to Wruble (Wruble, col. 1, l. 56-61):

In contradistinction to other preparations containing an edible unsaturated oil and sitosterol, it was found that the present preparation possesses unexpected stability and palatability. It was found that averting contact in the final product between the sitosterol and the oil provides a superior product. Averting said contact is accomplished by preparing separately an emulsion of the oil and an aqueous dispersion of the sitosterol, preferably utilizing protective colloidal materials and emulsifiers.

With respect to component proportions, Wruble teaches (Wruble, col. 2, l. 31-36):

The amount of the [edible unsaturated] oil can vary from about 1 to about 35 percent by volume of the preparation, with from 22 to about 33 percent preferred. The amount of sitosterol can vary from about 1 to about 17 percent weight/volume, with from about 10 to about 15 percent preferred.

Wruble defines the term edible unsaturated oils as (Wruble, col. 2, l. 5-19; emphasis added):

. . . those edible oils containing unsaturated fatty acids. The unsaturated fatty acids include, for example, oleic acid (1 double bond), linoleic acid (2 double bonds), linolenic acid (3 double bonds), moroctic acid (4 double

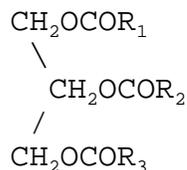
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bonds) and the like. The edible unsaturated oils include, for example, olive, palm, cottonseed, peanut, soybean, sesame, corn, sunflower seed, linseed, rapeseed, sardine, menhaden, tung, safflower, poppyseed, rice bran, almond, wheat germ oils, and the like. Oily dispersions of the unsaturated fatty acids can be used. In the present preparation it is preferred to use the edible unsaturated oils having substantial percentages of linoleic acid, for example, soybean oil, safflower oil, corn oil, sunflower seed oil, and mixtures thereof.

C. Babayan

Babayan describes "triglyceride preparations for enteral or parenteral administration to prevent catabolism and to increase protein synthesis in subjects undergoing severe metabolic stress" (Babayan, p. 1, 1st para.), i.e., the "invention provides medium chain and long chain fatty acids chemically synthesized into structured triglycerides (lipids) for enteral or parenteral administration as the lipid calorie source" (Babayan, p. 3, 1st para.; emphasis added). Babayan states (Babayan, p. 3, l. 6, to p. 4, l. 5):

The structural lipids of this invention are randomly rearranged mixtures of medium chain triglycerides (MCT) and long chain triglycerides (LCT). They may be represented by the following formula,



wherein R₁ and R₂ may be independently a C₆ to C₁₂ acid,

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or a C_{12} to C_{18}' acid, and R_3 may be a C_{18}'' or C_{18}''' acid. Preferably, R_1 may be a C_6 to C_{12} acid, and R_2 a C_{12} to C_{18}' acid.

C_{18}' , C_{18}'' and C_{18}''' represent the number of double bonds in the fatty acid moiety being one, two and three double bonds respectively.

The medium chain triglycerides may be lauric oils such as, balassee oil, coconut oil, cohune oil, palm kernel oil, tucum oil and fractions thereof. The preferred medium chain triglyceride oil is coconut oil.

The long chain triglycerides may be polyunsaturated vegetable oils such as, corn oil, peanut oil, safflower oil, soybean oil, sunflower seed oil, and fish oil. The preferred long chain triglyceride oils are safflower oil, soybean oil, and sunflower seed oil.

Preferably, the percent composition of mixtures of medium chain triglycerides to long chain triglycerides of this invention may be 70 to 30%, 80 to 20%, 85 to 15%, or 90 to 10%. The 80 to 20%, and the 85 to 15% mixtures are most preferred.

4. Discussion

Whether the long-chain fatty acids which form the lipid phase of the lipid emulsions described by Bilton are present in the lipid phase as long-chain fatty acids or as triglyceride derivatives of long-chain fatty acids, the vegetable and animal oils employed are "rich in polyunsaturated, long-chain fatty acids" (Bilton, p. 4, final para.). Bilton's disclosure would have led persons having ordinary skill in the art away from emulsions wherein essential fatty acids constitute no more than 15-45% of the total fatty acids in the lipid phase of the lipid emulsion. Bilton's "preferred oils possess an unsaturated fatty

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acid to saturated fatty acid ratio of from about 10:1 [to] about 5:1" (Bilton, p. 5, 1st full para.). On the other hand, while the calorie-rich lipid compositions Babayan describes are formulated with polyunsaturated vegetable or animal oils comprising the long-chain triglyceride content found in corn oil, peanut oil, safflower oil, soybean oil, sunflower seed oil, and fish oils (Babayan, p. 3) and have a final long-chain fatty acid triglyceride content 10 to 30% by weight of the total fatty acid triglyceride content (Babayan, p. 4, 1st para.), Babayan's compositions require a high percentage of medium-chain fatty acid triglycerides in the lipid phase, i.e., Babayan teaches away from compositions comprising a lipid phase "consisting essentially of a mixture of long-chain fatty acids" in accordance with appellant's claims. Moreover, we find no reasonable suggestion in the combined prior art teachings of Bilton and Babayan either to reduce the amount of essential fatty acids in Bilton's compositions or to increase the long-chain triglyceride content in Babayan's compositions. Accordingly, to sustain the examiner's rejection, the suggestion to reduce the amount of essential fatty acids in the lipid phase of Bilton's emulsions or to increase the long-chain triglyceride content and decrease the medium-chain triglyceride content in the lipid phase of Babayan's emulsions must come from the combined teachings of Bilton,

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Babayan and Wruble. However, the examiner has not explained where Wruble describes an oil-in-water emulsion encompassed by appellant's claims or would have reasonably suggested that persons having ordinary skill in the art make and use a lipid emulsion appellant claims. Accordingly, on this record, we find that the combined teachings of Bilton, Wruble and Babayan would not have led persons having ordinary skill in the art to the invention appellant claims and must reverse the rejection of all claims under 35 U.S.C. § 103.

Wruble teaches that the edible unsaturated oils which constitute the oil phase of his oil-in-water emulsions for oral administration (Wruble, col. 2, l. 10-14):

include, for example, olive, palm, cottonseed, peanut, soybean, sesame, corn, sunflower seed, linseed, rapeseed, sardine, menhaden, tung, safflower, poppyseed, rice bran, almond, wheat germ oils, and the like.

However, Wruble indicates that oily dispersions may be prepared from the unsaturated fatty acids apart from the oils (Wruble, col. 2, l. 14-15). We find that Wruble expresses a distinct preference for using "edible unsaturated oils having substantial percentages of linoleic acid, for example, soybean oil, safflower oil, corn oil, sunflower seed oil, and mixtures thereof" (Wruble, col. 2, l. 15-19). Combined with the teachings of Bilton and Babayan with regard to the fatty acid content of the same oils, we find no reasonable suggestion in Wruble to reduce the amount

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of essential fatty acids in the lipid phase of Bilton's emulsions or to increase the long-chain triglyceride content and decrease the medium-chain triglyceride content in the lipid phase of Babayan's emulsions.

We are at a loss to understand why the combined prior art teachings reasonably would have led persons having ordinary skill in the art to use a lipid emulsion as a parenteral or enteral foodstuff which comprises a lipid phase consisting essentially of long-chain fatty acids in which 15 to 45% by weight of the total fatty acids are essential fatty acids. It would appear that absent some reason, incentive, or motivation to reduce the quantity of high-calorie, essential fatty acids in an enterally or parenterally deliverable foodstuff composition, persons having ordinary skill in the art would have been led by the combined prior art teachings to make and use oil-in-water emulsions decidedly "rich in" essential fatty acids (Bilton, p. 4, final para.), i.e., oil-in-water emulsions including "substantial percentages of" essential fatty acids (Wruble, col. 2, l. 17). Thus, we reverse the examiner's rejection of Claims 1-9, 11, 12 and 16-20 under 35 U.S.C. § 103 in view of the combined teachings of Bilton, Wruble and Babayan.

5. Other issues

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We understand from the specification at p. 3, l. 17-22, and p. 4, the Table, and dependent Claim 2 on appeal that the lipid phase of the claimed lipid emulsion "consisting essentially of a mixture of long-chain fatty acids in which 15 to 45% by weight of the total fatty acids are essential fatty acids" (Claim 1) may be prepared simply by mixing together a mixture of "oils selected from apricot, almond, groundnut, avocado, wheat, safflower, rapeseed, coconut, cottonseed, lupin, maize, hazelnut, walnut, olive, oenothera, palm, palm-kernel, peach, grape, rice, rye, sesame, soybean, sunflower, tomato, linseed and citrus oils" (Spec., p. 3, l. 17-22; emphasis added). The lipid emulsion to which Claim 2 is drawn appears to be a lipid emulsion wherein the "lipid phase comprises a mixture of two or more oils selected from the groups consisting of apricot, almond, groundnut, avocado, wheat, safflower, rapeseed, coconut, cottonseed, lupin, maize, hazelnut, walnut, olive, oenothera, palm, palm-kernel, peach, grape, rice, rye, sesame, soybean, sunflower, tomato, linseed and citrus oils" (Claim 2; emphasis added). Considered in that light, we must remand the case to the examiner (1) to determine the metes and bounds of the subject matter claimed, and thereafter, (2) to evaluate the significance of Wruble's teaching under 35 U.S.C. § 102. Wruble teaches that the edible

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unsaturated oils useful in formulating his oil-in-water emulsions also may include (Wruble, col. 2, l. 10-19; emphasis added):

. . . olive, palm, cottonseed, peanut, soybean, sesame, corn, sunflower seed, linseed, rapeseed, sardine, menhaden, tung, safflower, poppyseed, rice bran, almond, wheat germ oils, and the like. Oily dispersions of the unsaturated fatty acids can be used. In the present preparation it is preferred to use the edible unsaturated oils having substantial percentages of linoleic acid, for example, soybean oil, safflower oil, corn oil, sunflower seed oil, and mixtures thereof.

The examiner should consider whether Wruble would have "described" an invention encompassed by Claim 2 on appeal to a person having ordinary skill in the art within the meaning of the term in 35 U.S.C. § 102(a) and (b). The examiner should ascertain in the first instance whether or not Wruble's disclosure of mixtures of edible unsaturated oils "having substantial percentages of linoleic acid" (Wruble, col. 2, l. 17), preferably "soybean oil, safflower oil, corn oil, sunflower seed oil, and mixtures thereof" (Wruble, col. 2, l. 18-19), inherently describes "a mixture of long-chain fatty acids in which 15 to 45% by weight of the total fatty acids are essential fatty acids" (Claim 1) and accordingly placed an invention within the scope of appellant's claims in the possession of the public. The record is unclear on this issue.

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In reevaluating the claimed subject matter in light of Wruble's disclosure, the examiner may wish to consider the following:

(1) Claims are to be given their broadest reasonable interpretation consistent with the description of the invention in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

(2) An examiner should refrain from inquiring whether claimed subject matter is novel until after having ascertained what subject matter is being claimed. In re Wilder, 429 F.2d 447, 450, 166 USPQ 545, 548 (CCPA 1970).

(3) Where the claimed subject matter and the prior art subject matter reasonably appear to be identical or substantially the same, it is proper to find a prima facie case of inherency. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434; In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

(4) All disclosures of the prior art must be considered, including nonpreferred embodiments. In re Lamberti, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976).

(5) Specific preferences in the prior art are material to an analysis under 35 U.S.C. § 102. Merck & Co., Inc. V. Biocraft Laboratories Inc., 874 F.2d 804, 807, 10 USPQ2d 1843, 1846 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

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Furthermore, in reversing the examiner's rejection of all claims under 35 U.S.C. § 103 in view of the combined teachings of Bilton, Wruble, and Babayan, we indicated that the cited prior art would not have provided persons having ordinary skill in the art with reason, incentive, or motivation to reduce the amount of essential fatty acids relative to the amount of total fatty acids in the lipid phase of the prior art oil-in-water emulsions so to make and use the lipid emulsions appellant claims. Put simply, persons having ordinary skill in the art would not have been led by Bilton, Wruble, and Babayan to solve unknown problems. However, in a Supplemental Information Disclosure Statement filed April 26, 1995 (Paper No. 39), appellant submitted of record a copy of UK Patent Application GB 2067587, published July 30, 1981. The new reference teaches at p. 2, l. 10-17 (emphasis added):

An additional consideration for a humanized fat composition made of vegetable oils is to provide a physiological level of linoleic acid. Inadequate amounts of dietary essential fatty acids produce a nutritional deficiency disease. Excessive levels of linoleic acid can be harmful. The foregoing literature survey has revealed that milk fat from lactating mothers contains from about 6% to 16% linoleic acid.

On consideration of this additional prior art teaching that "[e]xcessive amounts of linoleic acid can be harmful" and that 6% to 16% linoleic acid is optimum for simulated human mother's milk

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formulations, the examiner should determine in the first instance the patentability of the subject matter appellant claims under 35 U.S.C. § 103 in view of the combined teachings of the prior art herein applied and UK Patent Application GB 2067587.

6. Conclusion

We reverse the examiner's rejection of Claims 1-9, 11, 12 and 16-20 under 35 U.S.C. § 103 in view of the combined teachings of Bilton, Wruble, and Babayan.

We remand this case to the examiner to determine the metes and bounds of the subject matter claimed, and thereafter, to consider its patentability under 35 U.S.C. § 102 over Wruble's disclosure and under 35 U.S.C. § 103 in view of the Bilton, Wruble, Babayan, and GB 2067587.

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This application, by virtue of its "special" status, requires an immediate action, M.P.E.P. § 708.01(d). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REVERSED and REMANDED

SHERMAN D. WINTERS)	
Administrative Patent Judge))	
)	
)	
JOHN D. SMITH)	BOARD OF PATENT
Administrative Patent Judge))	APPEALS AND
)	INTERFERENCES
)	
)	
TEDDY S. GRON)	
Administrative Patent Judge))	

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Fleit, Jacobson, Cohn, Price,
Holman & Stern
400 Seventh Street, N.W.
Washington, DC 20004