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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEPHEN FARRALL MELLOR, GREGORY CHARLES
WEATHERHEAD, and JAMES RICHARD HUMPHREY

Appeal 2020-001092
Application¹ 14/401,668
Technology Center 1600

Before ULRIKE W. JENKS, AMEE A. SHAH, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to an emulsion comprising polyunsaturated fatty acids, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

Appellant’s Specification states: “long chain polyunsaturated fatty acids, including omega-3, omega-6 and omega-9 fatty acids, are vital to everyday life and function.” (Spec. 1.) “Since omega-3 fatty acids are not

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 Croda International PLC. (Appeal Br. 1.)

synthesised by the human body, they must be obtained through food or dietary supplement.” (*Id.*) “Many polyunsaturated fatty acids are sensitive to oxidation, can have an unpleasant taste and be difficult to formulate in a stable form.” (*Id.*) Appellant’s invention is directed at an oil-in-water emulsion comprising polyunsaturated fatty acids. (*Id.* at 2; *see also* claim 1.)

Claims 1–6, 9, 10, 12, and 14–23 are on appeal.² Claim 1 is representative and reads as follows:

1. An emulsion comprising:

- (i) 65 to 74 by weight of an aqueous phase;
- (ii) 26 to 35% by weight of an oil phase comprising
 - (a) 65 to 75% by weight of a capric/caprylic triglyceride, and
 - (b) 18 to 22% by weight of at least one polyunsaturated fatty acid and/or derivative thereof, expressed as free fatty acid concentration;
- (iii) an emulsifier selected from the group consisting of acacia gum and alkoxyated sorbitan esters, wherein the emulsifier is present in an amount less than 4% by weight; and
- (iv) one or both of a flavouring agent and a sweetening agent that is selected from the group consisting of sucrose, fructose, maltose, lactose, xylitol, and artificial sweeteners,
 - provided that the emulsion comprises a gum component,
 - wherein the gum component comprises guar gum and xanthan gum at a weight ratio in the range from 0.1 to 10:1.

(Appeal Br. 7.)

The prior art relied upon by the Examiner is:

² Claim 13 remains pending but has been withdrawn from consideration. (Final Action 2.)

Name	Reference	Date
Morgan	US 4,875,929	Oct. 24, 1989
Chen	US 6,720,001 B2	Apr. 13, 2004
Ferruzzi	US 2004/0096547 A1	May 20, 2004
Srivastava	US 2005/0196503 A1	Sept. 8, 2005
Newman	US 2006/0134300 A1	June 22, 2006
Harel	US 2008/0044481 A1	Feb. 21, 2008
Nuralam	US 2008/0124439 A1	May 29, 2008
Mehansho	US 2010/0104730 A1	Apr. 29, 2010
Driscoll	WO 2010/104575 A2	Sept. 16, 2010
Puder	US 2010/0256235 A1	Oct. 7, 2010
JA Casas, <i>Viscosity of guar gum and xanthan/guar gum mixture solutions</i> , 80 J. Sci Food Agric., 1722–27 (2000)		

The following grounds of rejection by the Examiner are before us on review:

Claims 1–6, 9, 10, 12, 14, 15, and 20 under 35 U.S.C. § 103(a) as unpatentable over Driscoll, Harel, Mehansho, Puder, Morgan, and Casas.

Claim 16 under 35 U.S.C. § 103(a) as unpatentable over Driscoll, Harel, Mehansho, Puder, Morgan, Casas, and Chen.

Claims 17 and 19 under 35 U.S.C. § 103(a) as unpatentable over Driscoll, Harel, Mehansho, Puder, Morgan, Casas, and Ferruzzi.

Claim 18 under 35 U.S.C. § 103(a) as unpatentable over Driscoll, Harel, Mehansho, Puder, Morgan, Casas, Ferruzzi, Srivastava, and Newman.

Claims 21–23 under 35 U.S.C. § 103(a) as unpatentable over Driscoll, Harel, Mehansho, Puder, Morgan, Casas, and Nuralam.

DISCUSSION

We address the Examiner’s rejection as it relates to claim 1 below because Appellant argues all of the rejections together and focuses only on

claim 1. All other pending claims fall with claim 1. 37 C.F.R.
§ 41.37(c)(1)(iv).

The Examiner finds, and Appellant does not dispute, that Driscoll teaches an oil-in-water emulsion that includes (a) an emulsifier such as a phospholipid, (b) fish oil triglycerides, including the polyunsaturated fats (PUFAs) EPA and DHA, and (c) at least one medium chain triglyceride, such as a mixture of caprylic and capric acid, and that these elements are within the ranges set forth in claim 1. (Final Action 4; *see* Appeal Brief 3–5 (arguing only that Driscoll is concerned with parenteral emulsions and “one of ordinary skill in the art would not have a reason to apply the teachings Mehansho, Morgan and Casas to the teachings of Driscoll” where those references are concerned with including stabilizers to increase the viscosity of an emulsion).) The Examiner finds that “the claims of Driscoll are directed generically to emulsions” of PUFAs and thus, while Driscoll states that the “emulsion can be used, for example, in parenteral administration” (pg. 1),” such parenteral administration “is simply one embodiment of administration” and Driscoll “does not teach away from other modes of administration.” (Ans. 13.)

The Examiner recognizes that Driscoll does not teach including flavoring agents or the claimed emulsifier or including xanthan gum and guar gum, although it does teach that other pharmaceutical adjuvants, such as stabilizers, can be added. (Final Action 6 (“Driscoll does not teach the emulsifier to be an alkoxyated sorbitan ester.”), 7 (“Driscoll teaches that additional ingredients can be added to stabilize the emulsions (Pg. 14)”), 8 (flavoring agent not taught).)

The Examiner relies on Puder for teaching that it was known to provide dietary formulas for nutrition in the form of an oil emulsion both enterally and parenterally, and that for enteral bound formulations, flavorings can be added to make the formulation more palatable. (Final Action 8.) The Examiner concludes that inclusion of such an ingredient would have been obvious in an enteral formulation of Driscoll to make such a formulation more palatable. (*Id.* at 9.)

As to the claimed emulsifier, the Examiner finds, and Appellant does not dispute, that Harel teaches the functional equivalence of the emulsifiers taught in Driscoll and polysorbates, i.e., the claimed “alkoxylated sorbitan esters” and concludes that substitution of a polysorbate for use in the composition of Driscoll would have been obvious with a reasonable expectation of success. (Final Action at 6.)

As to inclusion of xanthan gum and guar gum, the Examiner concludes that these gums would have been obvious to add to the formulation of Driscoll in light of the teachings of Mehansho, Morgan, and Casas. (*Id.* at 7, 9.) The Examiner finds that Mehansho teaches stable aqueous PUFA formulations that include emulsifiers of the type disclosed in Driscoll in combination with stabilizers, such as whey protein, xanthan gum, and guar gum, among others, which stabilizers may assist in “preventing coalescence, flocculation, or creaming of the dispersed phase” and which may be used in combination. (*Id.* at 7, 8 (“Mehans[h]o teaches that xanthan gum/and or guar gum can be used”).) The Examiner relies on Morgan and Casas for concluding that the use of guar gum in combination with xanthan gum within the claimed ratio to have a stable and viscous emulsion over a

variety of conditions would have been obvious with a reasonable expectation of success, absent evidence to the contrary. (*Id.* at 9.)

Appellant does not dispute the Examiner’s findings regarding the teachings of Mehansho, Morgan, and Casas, just the Examiner’s conclusion that one of ordinary skill in the art would have combined viscosity enhancing agents in the emulsion formulations of Driscoll destined for parenteral use. (Appeal Br. 5–6; Reply Br. 2.) Appellant explains that increasing the viscosity of Driscoll’s formulation to that suggested by Morgan “would render the parenteral emulsion unsuitable for its intended purpose.” (Appeal Br. 6.)

We do not find Appellant’s argument persuasive of Examiner error. “The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference. . . . Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art.” *In re Keller*, 642 F.2d 413, 425 (CCPA 1981)(citations omitted).

Driscoll teaches a PUFA emulsion. (Driscoll abs.) It is true that Driscoll teaches the PUFA emulsion can be used for nutritional purposes in those having a dysfunctional gastrointestinal tract or in critically ill patients parenterally. (Driscoll 14–15.) However, Driscoll does not criticize or discredit using PUFA formulations as nutritional supplements generally. As the Examiner points out, Puder teaches dietary formulations in the form of an oil emulsion that includes PUFA’s as in Driscoll, noting that such formulations can be provided enterally or parenterally for nutrition. (Puder ¶¶ 9, 14, 23, 29.) In light of the foregoing, we conclude that one of ordinary skill in the art would have considered that the Driscoll formulation could be

used enterally, and as such could include stabilizers that increase the viscosity of the oil-in-water emulsion. (*See, e.g.*, Puder ¶ 84 (“The dietary formulation or supplement of the invention may also contain a stabilizer such as λ -carrageenan. λ -carrageenan increases the viscosity of the formula without forming a gel structure, . . . Xanthan gum or other standard stabilizers may also be used as a stabilizer in the same fashion as λ -carrageenan.”).)

Moreover, the reason one would want to include such stabilizers is provided by the teachings of Mehansho, another reference describing the formulation of an emulsion of PUFA’s for enteral use, as the Examiner points out, i.e., to assist in stabilizing the emulsion by preventing coalescence, flocculation, or creaming of the dispersed phase. (Mehansho ¶¶ 38, 40.)

Thus, for the foregoing reasons, we affirm the Examiner’s rejection of claim 1 as being obvious over Driscoll, Harel, Mehansho, Puder, Morgan, and Casas. And because Appellant does not argue the claims or rejections separately, we also affirm the Examiner’s rejection of the remaining claims as being obvious over the cited references.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–6, 9, 10, 12, 14, 15, 20	103(a)	Driscoll, Harel, Mehansho, Puder, Morgan, Casas	1–6, 9, 10, 12, 14, 15, 20	
16	103(a)	Driscoll, Harel, Mehansho, Puder, Morgan, Casas, Chen	16	

17, 19	103(a)	Driscoll, Harel, Mehansho, Puder, Morgan, Casas, Ferruzzi	17, 19	
18	103(a)	Driscoll, Harel, Mehansho, Puder, Morgan, Casas, Ferruzzi, Srivastava, Newman	18	
21–23	103(a)	Driscoll, Harel, Mehansho, Puder, Morgan, Casas, Nuralam	21–23	
Overall Outcome			1–6, 9, 10, 12, 14–23	

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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED