

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(2) is not binding precedent of the Board.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. 24

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ALAIN RIBIER and
JEAN-THIERRY SIMMONET

Appeal No. 1996-1783
Application 08/195,025¹

ON BRIEF

Before WARREN, WALTZ, and SPIEGEL, Administrative Patent
Judges.

WALTZ, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the
examiner's final rejection of claims 20 through 38.

Subsequent to the final rejection, appellants submitted two

¹ Application for patent filed February 14, 1994.

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amendments. The first amendment, dated May 19, 1995 (Paper No. 8), amended claim 26 and cancelled claim 38. The examiner stated that, upon the filing of an appeal, this amendment would be entered (see the Advisory Action dated May 26, 1995, Paper No. 9). The second amendment after the final rejection was submitted with appellants' Reply Brief dated Feb. 21, 1996 (Paper No. 14), proposing an amendment of claim 20. According to an Office communication from the examiner dated Mar. 13, 1996, the "amendment to claim 20 filed 02/21/96 has been entered." (Paper No. 17, page 1). However, upon review of this record, neither amendment has been physically entered into the file record. Accordingly, upon return of this application to the jurisdiction of the examiner, these amendments must be entered into the file record. For purposes of this appeal, we consider the claims as if these amendments were physically entered into the file record. Therefore claims 20 through 37 are on appeal before us and these are the only claims remaining in this application.

According to appellants, the invention is directed to a method and composition where vesicles of amphiphilic lipids encapsulating an aqueous phase are stabilized by addition of

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at least one of a glycerol alginate, a propylene glycol alginate, gellan gum or welan gum (Brief, page 3). Claim 20 is illustrative of the subject matter on appeal and is reproduced below:

20. A process for the stabilization of vesicles formed from a lipid-phase membrane containing at least one ionic or nonionic amphiphilic lipid or a mixture thereof, said process comprising encapsulating an aqueous phase, in the form of a dispersion in an aqueous phase, adding at least one stabilizing agent to said aqueous dispersion phase, said stabilizing agent being selected from the group consisting of a glycerol alginate, a propylene glycol alginate, gellan gum and welan gum and being present in an amount effective so as to stabilize said vesicles against surfactants and, when present, an additional phase comprising a fatty phase.

The examiner has relied upon the following references as evidence of obviousness:

Fujiwara et al. (Fujiwara)	4,670,185	Jun. 2, 1987
Popescu et al. (Popescu)	4,708,861	Nov. 24, 1987
Handjani et al. (Handjani)	4,830,857	May 16, 1989
Tin	5,008,109	Apr. 16, 1991
Meybeck et al. (Meybeck)	5,290,562	Mar. 1, 1994
Gaonkar	5,332,595	Jul. 26, 1994

(filed Nov. 5, 1992)

Claims 20 through 25 stand rejected under 35 U.S.C. §

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112, second paragraph, as being indefinite (Answer, page 4).² Claims 20 through 37 stand rejected under 35 U.S.C. § 103 as unpatentable over Meybeck or Fujiwara or Handjani in view of Tin and/or Popescu and Gaonkar (Answer, page 5). We reverse all of the rejections on appeal for reasons which follow.

OPINION

A. The Rejection under § 112, Second Paragraph

The examiner states that "[i]t is unclear as to what appellant intends to convey, by 'when present, a fatty phase' in claim 20." (Answer, page 4). The examiner rebutted appellants' argument that the specification discloses the

²The examiner has withdrawn the rejection of the "rest of the 112 rejections, both the first and second paragraph rejections based on other issues and as applied to claims 26-37," i.e., the only rejections under § 112, paragraph one and two, repeated by the examiner in the Answer were based on the phrase "when present, a fatty phase" as recited in claims 20-25 (Answer, page 2). Although not explicitly stated by the examiner, the withdrawal of these rejections was apparently in response to the amendment dated May 19, 1995, Paper No. 8, amending claim 26 and cancelling claim 38. Furthermore, in response to the amendment accompanying the Reply Brief (Paper No. 14, dated Feb. 21, 1996), the examiner has withdrawn the entire rejection under § 112, first paragraph (Letter dated Mar. 13, 1996, Paper No. 17). Accordingly, the only remaining rejection on appeal under 35 U.S.C. § 112 is the rejection of claims 20-25 under the second paragraph of § 112.

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presence of an additional fatty phase by noting that claim 20 does not clearly indicate that the fatty phase is in addition to the lipidic phase (Id.).

Appellants specifically addressed the examiner's argument by amending claim 20 on appeal by insertion of "an additional phase comprising" between "when present" and "a fatty phase" (see the amendment dated Feb. 21, 1996, Paper No. 14, and the Reply Brief, pages 3-4).

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"The legal standard for definiteness is whether a claim reasonably apprises those of skill in the art of its scope."
In re Warmerdam, 33 F.3d 1354, 1361, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994). Claim 20 on appeal now clearly sets forth that the fatty phase is in addition to the lipidic phase. The examiner has not submitted, on this record, any evidence or argument that one of ordinary skill in the art would not be apprised of the scope of claim 20 on appeal. Accordingly, the examiner's rejection of claims 20-25 under the second paragraph of 35 U.S.C. § 112 is reversed.

B. The Rejection under § 103

The examiner and appellants agree that the primary references, Meybeck, Fujiwara, and Handjani, teach compositions containing vesicles but fail to teach stabilization of vesicles by use of the agents recited in claim 20 on appeal (Answer, page 5, and Brief, page 14). Similarly, the examiner and appellants agree that the alternative secondary references, Tin and/or Popescu, disclose the problem of stability in vesicle formation but add stabilizing agents which do not include those recited in claim 20 on appeal (Answer, pages 5 and 7, Brief, page 16).

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Accordingly, the examiner applies Gaonkar for the teaching of stabilizing emulsions by using various polysaccharide gums, including gellan gum or propylene glycol alginate (Answer, pages 5-6). Appellants argue that Gaonkar fails to teach the stabilization of vesicles and only relates to water/oil/water and oil/water/oil emulsions (Brief, page 18).

With regard to the proper combination of references, our reviewing court has stated:³

When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references. [Citation omitted]. Although the suggestion to combine references may flow from the nature of the problem, [citation omitted], the suggestion more often comes from the teachings of the pertinent references, [citation omitted], or from the ordinary knowledge of those skilled in the art that certain references are of special importance in a particular field, [citations omitted]. . . .

On this record, we determine that the examiner has not established any reason, suggestion, or motivation for combining the teachings of Gaonkar, directed to the stabilization of multiple emulsions, with the teachings of the remaining references which are directed to vesicle (liposome)

³In re Rouffet, 149 F.3d 1350, 1355-56, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998).

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formation and stabilization. The examiner has not established that the references may be combined due to the nature of the problem, i.e., the examiner has not shown that stabilization of vesicles as taught by Tin and Popescu is the same problem that Gaonkar is concerned with, namely, stabilization of water/oil/water or oil/water/oil emulsions. Tin discloses that liposomes (especially small sonicated vesicles) are thermodynamically unstable at low temperatures and tend to aggregate or fuse to form larger unilamellar vesicles on long-term storage (column 1, lines 31-36). Tin teaches that this aggregation or fusion is overcome by the storage of micellar particles in a polymeric gel matrix formed by polysaccharides or polypeptides (column 1, lines 53-60). Popescu teaches sequestering liposomes in a gel matrix to provide resistance to "clearance or degradation," where the gel matrix is formed from various carbohydrates (column 3, lines 45-50; column 7, lines 27-42). Gaonkar discloses the inherent instability of water/oil/water systems where the breakdown of the emulsion occurs when discontinuities in the lipid phase permit the separated aqueous phase to coalesce, especially upon standing at low temperatures (column 1, lines 40-56). Gaonkar teaches

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that these emulsions are stabilized by forming a continuous gelatinous layer in the interfacial region between the internal and intermediate phases by use of aqueous soluble/gellable polysaccharides (column 3, lines 64-68; column 4, lines 53-65).

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The examiner has failed to show that the artisan would have considered the teachings of Gaonkar to solve the stabilization problems disclosed by Tin or Popescu.⁴ The examiner rebutted appellants' argument regarding the applicability of Gaonkar by stating that "mixing of an amphiphilic compound with an aqueous phase can only result in either micellar or liposomal (vesicular) types of compositions." (Answer, paragraph bridging pages 7-8, noting Ex. 8 of Gaonkar). However, appellants have challenged this statement by the examiner and provided reasons why this statement is not necessarily correct (Reply Brief, pages 4-5). Accordingly, the burden has been shifted to the examiner and the examiner has not replied to this countervailing argument (see the Letter dated Mar. 13, 1996, Paper No. 17). See In re Ahlert, 424 F.2d 1088, 1091-92, 165 USPQ 418, 420-21 (CCPA 1970). For the foregoing reasons, the examiner has failed to establish a prima facie case of obviousness. Therefore we need not reach the issue of the

⁴On this record, the examiner does not allege that the primary references disclose or suggest any stabilization problem or solution involved with vesicle storage.

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sufficiency of appellants' rebuttal evidence (page 25 of the specification; see the Brief, page 19, and the Reply Brief, pages 5-6). In re Geiger, 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed. Cir. 1987). Accordingly, the examiner's rejection of claims 20 through 37 under 35 U.S.C. § 103 as unpatentable over Meybeck or Fujiwara or Handjani in view of Tin and/or Popescu and Gaonkar is reversed.

The decision of the examiner is reversed.

REVERSED

CHARLES F. WARREN)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
THOMAS A. WALTZ)	APPEALS AND
Administrative Patent Judge)	INTERFERENCES
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)	
CAROL A. SPIEGEL)	
Administrative Patent Judge)	

TAW:svt

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