

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 38

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte JOHN M. LIPARI,
DAWN M. RAYMOND, and TOM REILAND

Appeal No. 2004-0482
Application No. 09/216,247

ON BRIEF¹

Before WINTERS, SCHEINER, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 3-5, 12, and 14-16, which are all the claims pending in the application.

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

1. A composition consisting of a fibrate dissolved in at least one medium chain glycerol ester of a fatty acid.

The examiner relies on the following reference:

¹ Appellants waived (Paper No. 37, received April 8, 2004) their request for oral hearing, therefore we considered this appeal on Brief.

Lacy et al. (Lacy)

5,645,856

Jul. 8, 1997

GROUND OF REJECTION

Claims 1, 3-5, 12, and 14-16 stand rejected under 35 U.S.C. § 103 as being unpatentable over Lacy.

We reverse.

DISCUSSION

Appellants' claims are drawn to a composition and method of using the composition. As set forth above, claim 1 is drawn to a composition consisting of (1) a fibrate, which can be fenofibrate (see e.g., appellants' claim 3 and appellants' specification page 3, lines 28-31), and (2) at least one medium chain glycerol ester of a fatty acid, which can be caprylate/caprinate triglyceride (see e.g., appellants' claim 5 and appellants' specification, bridging paragraph, pages 3-4).

According to the examiner (Answer, page 4), Lacy discloses compositions containing fenofibrate, "a monoglyceride or a triglyceride, polyglycerol esters of fatty acids (surfactant) and a cosolvent...." The examiner recognizes, however, "Lacy does not teach omission of the surfactant." Id. Nevertheless, the examiner concludes (id.), "it is deemed obvious to one of ordinary skill in the art [at the time the invention was made] not to include a surfactant if it is deemed to be not necessary." The examiner, however, offers no evidence to suggest that the components of Lacy's composition that are not present in appellants' claimed composition would be unnecessary in Lacy's composition. In this regard, appellants assert (Brief, page 6), "Lacy clearly and unambiguously teaches a

drug carrier system that necessitates the inclusion of a surfactant.” In this regard, appellants point out (Brief, bridging paragraph, pages 5-6),

Lacy discloses a carrier system for a hydrophobic drug including a digestible oil and a surfactant component. The surfactant component includes 1) a hydrophilic surfactant component that fails to substantially inhibit the lipolysis of the digestible oil, or 2) a hydrophilic surfactant component that substantially inhibits the in vivo lipolysis of the digestible oil and a lipophilic surfactant component capable of at least substantially reducing the inhibitory effect of the hydrophilic surfactant....

Accordingly, appellants assert (Brief, page 4), Lacy teaches away from the claimed invention. According to appellants (Brief, page 6), contrary to the disclosure of Lacy, their claimed composition “specifically excludes a surfactant.”

Appellants are correct (see e.g., Brief, page 6) in that Lacy discloses in the background of the specification (column 1, lines 21-23), “the administration of drug in oil alone is not advantageous because of the poor miscibility of the oil with the aqueous environment of the gastrointestinal tract.” Upon review of Lacy, we find that Lacy discloses (column 3, lines 39-45), the invention “in its broadest aspect provides a carrier system for a hydrophobic drug which comprises: (a) a digestible oil, and (b) a pharmaceutically acceptable surfactant for dispersing the oil in vivo upon administration of the carrier system, said surfactant comprising a hydrophilic surfactant component....” As we understand Lacy’s disclosure, Lacy overcomes the disadvantages of using drug in oil alone by including a hydrophilic surfactant to the drug in oil composition.

However, as Lacy points out (column 3, lines 50-52), the majority of hydrophilic surfactants “will inhibit the lipolysis of the digestible oil component.” Therefore, to overcome the inhibitory effect of the hydrophilic surfactant, Lacy’s

composition must also include a lipophilic co-surfactant. Lacy, column 3, lines 52-55. Accordingly, as we understand Lacy's disclosure, Lacy's composition includes four components, (1) a hydrophobic drug, (2) a digestible oil², (3) a hydrophilic surfactant, and (4) a lipophilic surfactant. See e.g., Lacy, column 3, lines 56-67. In contrast, appellants' claimed invention includes only (1) a hydrophobic drug (a fibrate), and (2) at least one medium chain glycerol ester of a fatty acid. Therefore, as we understand the issue on appeal, the question is whether Lacy suggests removing two of the four components of the disclosed composition and if so, are the two remaining components (1) a fibrate and (2) a at least one medium chain glycerol ester of a fatty acid?

We note that Lacy carves out an exception to the use of digestible oils. Specifically, Lacy discloses (column 4, lines 1-5), "[i]f the lipophilic surfactant is itself a digestible oil, or can serve as the source of lipolytic products, then in a modification of the preferred carrier system a separate digestible oil component may be omitted...." In this regard, we note the examiner's reference (Answer, page 4) to "polyglycerol esters of fatty acids" which Lacy characterizes as an example of a lipophilic surfactant (see column 5, lines 19-26). As we understand

² We note that Lacy discloses (column 9, lines 20-28), the digestible oil may be capric and/or caprylic triglyceride oils" including: "Miglyol 810, Miglyol 812, Neobee M5, Neobee 0, Captex 300, Captex 355 and Captex 8000."

the Answer, it appears to be the examiner's position that these polyglycerol esters of fatty acids would meet the limitation in appellants' claim drawn to "at least one medium chain glycerol ester of a fatty acid." However, as appellants point out (Brief, page 5), "[e]ven if one was to accept this characterization of the teachings of Lacy, Lacy clearly does not disclose 'a composition consisting of a fibrate dissolved in at least one medium chain glycerol ester of a fatty acid' as required by claim 1. For the following reasons we agree with appellants.

According to Lacy (column 6, lines 14-16), these lipophilic surfactants "are capable of serving as the digestible oil component in this invention, or serving as the source of lipolytic products," therefore in a modification of Lacy's preferred carrier system a separate digestible oil component may be omitted. Accordingly, such a composition would include (1) a hydrophobic drug, (2) a hydrophilic surfactant, and (3) a lipophilic surfactant. Assuming, arguendo, Lacy's hydrophobic drug and lipophilic surfactant are within the scope of appellants' claimed invention; Lacy's composition includes an additional component, a hydrophilic surfactant, which is specifically excluded from appellants' claimed invention. Accordingly, this embodiment of Lacy's disclosure does not support the examiner's position.

Lacy also carves out an exception to the use of lipophilic surfactants, we note that Lacy discloses (column 8, lines 14-18), this applies to "one class of hydrophilic surfactants, namely the transesterification products of polyoxyethylene glycol with glycerol esters of capric and caprylic acids ... [which do] not substantially inhibit the in vivo lipolysis of digestible oils." According to

Lacy (column 8, lines 19-23), “with this class of hydrophilic surfactants there is no necessity to include any lipophilic surfactant component at all....”

Accordingly, Lacy discloses (column 8, lines 24-30):

[I]n a further aspect, the present invention provides a carrier system for a hydrophobic drug which comprises:

- (a) a digestible oil,
- (b) a transesterification product of polyoxy-ethylene glycol with glycerol esters of capric and/or caprylic acids as hydrophilic surfactant, and
- (c) optionally a lipophilic surfactant.

Lacy discloses that Labrasol (glyceryl caprylate/caprate and PEG-8 caprylate/caprate) and Softigen 767 (PEG-6 caprylic/capric glycerides) as examples of this type of hydrophilic surfactant. See Lacy, column 8, lines 31-37. Since this composition includes (1) a hydrophobic drug, (2) a digestible oil, and (3) a hydrophilic surfactant, this embodiment of Lacy’s disclosure also does not support the examiner’s position.

Therefore, while it may be true that Lacy suggests, under certain circumstances, that a digestible oil or a lipophilic surfactant are not necessary, and may be removed from Lacy’s composition, for the foregoing reasons we find nothing in Lacy to suggest that even if these components were removed they would lead to appellants’ claimed invention. In this regard, we remind the examiner that “[t]he Patent Office has the initial duty of supplying the factual basis for its rejection. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis.” In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967). For the foregoing reasons, it is

our opinion that the examiner has fallen “victim to the insidious effect of hindsight syndrome wherein that which only the inventor taught is used against its teacher.” W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983).

Accordingly, we reverse the rejection of claims 1, 3-5, 12, and 14-16 under 35 U.S.C. § 103 as being unpatentable over Lacy.

REVERSED

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Sherman D. Winters)	
Administrative Patent Judge)	
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)	BOARD OF PATENT
Toni R. Scheiner)	
Administrative Patent Judge)	APPEALS AND
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Donald E. Adams)	
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