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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JAMES LOWDER, RAMON SEVA, and VASSILI KOTLOV

Appeal 2026-001025
Application 17/818,310
Technology Center 1600

Before DONALD E. ADAMS, DONNA M. PRAISS, and JOHN E. SCHNEIDER, *Administrative Patent Judges.*

SCHNEIDER, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 2–6, 14, 16, and 20. *See* Final Act. 1. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE and enter a new ground of rejection pursuant to 37 C.F.R. § 41.50(b).

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[1] "Appellant" refers to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Impact Naturals, Inc. Appeal Br. 2.

CLAIMED SUBJECT MATTER

Cannabidiol (CBD) is a naturally occurring cannabinoid which is believed to have potential as a treatment for a wide variety of medical conditions. Spec. ¶ 3. CBD has low oral bioavailability and is inconsistently absorbed into the bloodstream. *Id.* ¶ 4.

The invention relates to mirco- or anao-emulsion formulations of cannabinoids with enhanced bioavailablilty. *Id.* ¶ 6. Claim 20, reproduced below, illustrates the claimed subject matter:

> 20. A self-emulsifying composition, comprising: a) an active pharmaceutical ingredient (API) in an amount of 8-12% by weight of the composition, b) mono-, di- and triglycerides and polyethylene glycol (PEG-6) (MW 300) mono- and diesters of linoleic ($C_{18:2}$) acid in an amount of about 27% by weight of the composition; c) polysorbate 80 in an amount of 29-34% by weight of the composition; and d) polyoxyl 35 castor oil in an amount of 29-34% by weight of the composition.

Appeal Br. 13 (Claims App.).

REFERENCES

The Examiner relies on the following references to reject the claims:

Name	Reference	Date
Murty	WO 2016/022936 A1	Feb. 11, 2016
Benita	WO 2020/212976 A1	Oct. 22, 2020
Capano	Evaluation of the effects of CBD hemp extract on opioid used and quality of life indicators in chronic pain patients: a prospective Cohort study, *Postgraduate Medicine 132: 56*	2020

REJECTIONS

The Examiner maintains the following rejections:

Claims 2, 4–6, 14, 16, and 20 are rejected under 35 U.S.C. § 103 as unpatentable over Murty and Benita.

Claim 3 is rejected under35 U.S.C. § 103 as unpatentable over Murty, Benita, and Capano.

OPINION

We review appealed rejections for reversible error based on the arguments and evidence Appellant provides for each issue Appellant identifies. 37 C.F.R. § 41.37(c)(1)(iv)(2024); *Ex parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (precedential) (cited with approval in *In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011) ("it has long been the Board's practice to require an [A]pplicant to identify the alleged error in the [E]xaminer's rejections")). "After evidence or argument is submitted by the [A]pplicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992).

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The Examiner finds Murty teaches a self-emulsifying composition comprising a pharmacologically active cannabinoid, an oily medium comprising (i) one or more triglycerides formed from long chain fatty having from C_{13} to C_{24} carbon atoms; (ii) one or more mixed glycerides formed from long chain fatty having from C_{13} to C_{24} carbon atoms; and (iii) one or more free fatty acids formed from un-esterified long chain fatty acids having

from C_{13} to C_{24} carbon atoms; and, about 10 to 60 wt% of a surfactant which promotes self-emulsification. Final Act. 5–6. The Examiner finds Murty teaches the active cannabinoid can be present in amounts ranging from 1 to 90%, the oily medium comprises 20 to 80 wt% and the surfactant comprises 20 to 60 wt%. *Id.*

The Examiner finds Murty teaches

> the use of one or more nonpolar solvents that can be used in the formulation; this includes sesame oil and corn oil, among other triglycerides used (see, p. 9, II. 7-19; C8-C18 fatty acids, along with multiple equivalents for substitution (see, p. 14, ll. 26-31, and p. 15). To one of ordinary skill in the art, the substitution of one oil for another is considered routine optimizations, based on the desired outcome. See MPEP § 2144.05. Formulation #33, for example, on p. 46, Table 16, for example, consists of one or more long chain triglyceride: comprising soybean oil (28.125%), and Glyceryl Monolinoleate (28.125%).

Id. at 7.

The Examiner finds Benita teaches a self-emulsifying composition comprising one lipophilic compound, at least one oil in a content of at least 10 wt% of the formulation, at least one surfactant, and at least one structurant (p. 5) and teaches polyoxylglycerides (Labrafil® M 1944 CS and Labrafil® M 2125 CS), -- wherein "Labrafil M2125 CS oil" is an oil-in-water surfactant. *Id.* at 8.

The Examiner finds Benita teaches the oils can be present in an amount of from 15 to 30 wt%. *Id.*

The Examiner concludes

> It would have therefore been obvious to one of ordinary skill in the art, at the time of filing, to include the claimed oils from known oily medium comprising triglycerides, glycerol esters of saturated C8-C18 fatty acids, along with their equivalents for substitution in the art as taught by Murty in

> view of Benita in order to arrive at the claimed composition. One would have been motivated to do so, with reasonable expectation of success, because these oily medium comprising triglycerides, glycerol esters of saturated C8-C18 fatty acids, are routine in the art and function, not only as non-polar solubilizing agents, but also to as carriers that help to stabilize particles in a formulation. Moreover, regarding the claimed ranges a *prima facie* case of obviousness exists in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Furthermore, itt [sic] is therefore within the skill of an artisan to routinely optimize and formulate the claimed range in order to arrive at the claimed invention with reasonable expectation of success. See *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955) which states, "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP § 2144.05, "II. Optimization of Ranges".

Id. (emphases added).

Appellant contends that one skilled in the art would not have been motivated to modify the composition of Murty to make the claimed composition with a reasonable expectation of success. Appeal Br. 5.

Appellant contends that while Murty teaches a composition that comprises 30 to 89 wt% of an oily medium, Murty does not teach that the oily medium can comprise mono-, di-, and triglycerides and polyethylene glycol (PEG-6) (MW 300) mono- and diesters of linoleic (C18:2) acid, commercially known as Labrafil M2125 CS. *Id.* at 6.

Appellant contends that while Benita teaches the use of Labrafil 2125 CS, Benita teaches its use as a surfactant, not as an oily medium. *Id.* Appellant contends neither of the references teach the use of Labrafil 2125

CS as an oily medium, which is required by the claims. *Id.* Appellant contends that one skilled in the art would not have had a reasonable expectation of success in substituting Labrafil 2125 CS for a portion of the oily medium of Murty. *Id.*

Appellant contends that even if one skilled in the art were motivated to use Labrafil 2125 CS, Benita only teaches its use in an amount of up to 27 wt%, well below the range recited in the claims. *Id.* at 7. Appellant contends the Examiner has misconstrued the term as used in the claim as the Examiner is attempting to expand the oily medium range by 10%. Appellant contends one skilled in the art would not interpret the term "about" in connection with the oily medium to extend down to 27%. *Id.*

Appellant contends that while Benita teaches an oil content range of from 15 to 30%, Benita does not teach that Labrafil 2125 CS is an oil but rather teaches it is a surfactant. *Id.*

Appellant contends that when the amounts of all of the surfactants recited in the claim are totaled (86%), it exceeds the range of surfactants taught by Murty (10 to 60%). *Id.* at 8. Appellant contends this not motivation to increase the level of surfactants to the range required by the claims. *Id.*

Appellant contends there is evidence of unexpected results sufficient to support a finding of nonobviousness. *Id.* at 9. Appellant contends the data reported in Example 1, which compares a formulation of the invention (Formulation 2) with that of the prior art (Formulation 3), exhibits a preferable dispersion pattern. *Id.* Appellant contends the data supports the formulation would self-emulsify in the GI tract. *Id.* Appellant contends the results achieved are unexpected given the teaching of the prior art. *Id.*

New Ground of Rejection - Indefiniteness

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2124 (2014).

"[A]mbiguity in claim scope is at the heart of the definiteness requirement of 35 U.S.C. § 112, ¶ 2." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003).

As seen from the discussion above one of the issues before us is the question of whether Labrifil 2125 CS should be considered a surfactant or an oily substance. The problem we face in deciding this issue is that both the present Specification and the prior art teach that Labrafil 2125 CS can be used either as a surfactant or as a non-polar solvent, i.e. an oily substance. Spec. ¶¶ 28–29; Murty 14–16. This makes it difficult to determine whether the amounts of Labrafil 2125 used in the prior art or as permitted by Appellant's Specification should be considered to meet the claim limitation calling for mono-, di-, and triglycerides and polyethylene glycol (PEG-6) (MW 300) mono- and diesters of linoleic (C18:2) acid in an amount of about 27% by weight of the composition, or as part of the total amount of surfactants argued by the Appellant. This ambiguity renders the pending claims indefinite.

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The Remaining Rejections

Because we have entered a new rejection of claims 2–6, 14, 16, and 20 as indefinite, we reverse, *pro forma*, the Examiner's enablement and prior art rejections because the claims are not sufficiently definite to allow determination of whether the claims are enabled or whether Murty and Benita or Murty, Benita, and Capano render the claims unpatentable as obvious. Therefore, we reverse these rejections consistent with *Steele* because

> "substantial confusion exists in the record at all levels of the prosecution as to the proper interpretation to be given to the appealed claims. We believe that this confusion arose and has continued because the claims do not particularly point out and distinctly claim the invention as required by 35 U.S.C. § 112."

In re Steele, 305 F.2d 859, 863 (CCPA 1962).

"Our decision is not to be construed as meaning that we consider the claims on appeal to be patentable as presently drawn." *In re Steele*, 305 F.2d at 863. Instead, it should be understood that the reversal is not based on the merits of these rejections. If the indefiniteness issues are resolved, the cited references are available for prior art or enablement rejections if the Examiner decides later in prosecution that they support a rejection of the claims.

CONCLUSION

The Examiner's rejections are REVERSED and a new ground of rejection is entered.

DECISION SUMMARY

The following table summarizes our decision:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed	New Ground
2, 4–6, 14, 16, 20	103	Murty, Benita		2, 4–6, 14, 16, 20	
3	103	Murty, Benita, Capano		3	
2–6, 14, 16, 20	112	Indefiniteness			2–6, 14, 16, 20
Overall Outcome				2–6, 14, 16, 20	2–6, 14, 16, 20

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). Section 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." Section 41.50(b) also provides:

When the Board enters such a non-final decision, the [A]ppellants, within two months from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the [E]xaminer, in which event the prosecution will be remanded to the [E]xaminer. The new ground of

rejection is binding upon the [E]xaminer unless an amendment or new Evidence not previously of Record is made which, in the opinion of the [E]xaminer, overcomes the new ground of rejection designated in the decision. Should the [E]xaminer reject the claims, [A]ppellant may again appeal to the Board pursuant to this subpart.

(2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a) (1). *See* 37 C.F.R. §§ 41.50(f), 41.52(b).

REVERSED; 37 C.F.R. § 41.50(b)