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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte RONALD ALLEN FARIS, ANN MEEJIN FERRIE,
VASILIY NIKOLAEVICH GORAL,
GREGORY ROGER MARTIN, and JIN LIU

Appeal 2020-000576
Application 14/663,533
Technology Center 1600

Before RICHARD M. LEBOVITZ, DEBORAH KATZ, and
JOHN A. EVANS, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

The Examiner rejected claims 1–9 and 21–23 under 35 U.S.C. § 103 as obvious. Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject the claims. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM, but designate the affirmance a NEW GROUND OF REJECTION under 37 C.F.R. § 41.50(b).

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[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 Corning Incorporated. Appeal Br. 3.

STATEMENT OF THE CASE

Appellant appeals from the Examiner's Final Rejection of claims 1–9 and 21–23 under 35 U.S.C. § 103 as obvious in view of Fike et al. (WO 2013/096858 A1, published June 27, 2013) "as cited by"[2] US 9,410,118 B2, issued Aug. 9, 2016) ("Fike") and Jain et al. (US 2007/0128276 A1, published June 7, 2007) ("Jain"). Final Act. 3.

Claim 1, the only independent claim on appeal, is reproduced below:

> 1. An *ex vivo* cell culture sustained release composition, comprising:
>
> a solid form mixture comprising:
>
> a sustenant in an amount of from 60 to 96 wt%, wherein the sustenant comprises a compound that maintains or promotes the growth or proliferation of cells, or cellular production of biologically active substances; and
>
> a non-biodegradable binder in an amount of from 1 to 20 wt%; and
>
> a non-biodegradable and water insoluble encapsulant coat comprising at least one of cellulose ethers and cellulose esters and that encapsulates the mixture, in an amount of from 1 to 20 wt%, based on 100 wt% of the total composition, the coat having a weight as measured by relative weight increase of the solid form mixture of between about 5 wt. % and about 15 wt.%.

REJECTION

Claim 1 is directed to an *ex vivo* cell culture sustained release composition. The composition comprises: 1) a solid form mixture and 2) an encapsulant coat that encapsulates the mixture. The coat, which is the disputed element of the claim, comprises "at least one of cellulose ethers and cellulose esters" in an amount of 1–20% of the composition. The

[2] WO 2013/096858 A1 is the PCT publication on which the U.S. Patent is based. The Examiner only cited to the U.S. Patent in the Final Office Action, and not to the PCT.

encapsulant coat has "a weight as measured by relative weight increase of the solid form mixture of between about 5 wt. % and about 15 wt.%. As explained in the Specification, "[c]oating thickness was evaluated as a percentage of tablet mass increase after the coating procedure." Spec. ¶ 87.

The Examiner found that Fike describes a solid form mixture with a sustenant and binder as claimed. Final Act. 3. The Examiner also found that the mixture has an encapsulant coat, but not comprising "at least one of cellulose ethers and cellulose esters" as required by the claim. *Id.* at 3–4. However, the Examiner found that Jain describes ethylcellulose as an encapsulant for a controlled release composition. *Id.* at 4. Ethylcellulose is a cellulose ether. Spec. ¶ 82. The Examiner determined it would have been obvious to use ethylcellulose as an encapsulant in Fike's composition because it is a "known standard, equivalent of a slow release encapsulant, and with a reasonable expectation for successfully obtaining an effective sustained release composition." *Id.*

With respect to the amounts of the coating, the Examiner found that Fike teaches that the coating amounts can be optimized to achieve the best results to achieve the desired release profile. Final Act. 6.

Appellant contends that Fike is "silent with respect to the weight percent of the encapsulant coat (or 'percent amounts of coating'), and [does] not recognize weight percent of a coating as being a result-effective variable that achieves a particular result." Reply Br. 3 (emphasis omitted). Appellant argues that, instead, "Fike only discloses that the presence of the encapsulant coat or capsular material can extend release of components. In fact, regarding variables of the encapsulant itself, Fike focuses on the material or

formulation of the encapsulant, not the weight percent of the encapsulant." *Id.* (emphasis omitted).

DISCUSSION

The issue in this rejection is the obviousness of using ethylcellulose as the seed coating in Fike in the claimed amount of "a weight as measured by relative weight increase of the solid form mixture of between about 5 wt. % and about 15 wt.%."

Fike discloses a coating comprised of PLGA (poly-lactic-co-glycolic acid) which delays the release of the cell culture media it encapsulates. Fike 1:39–49; 12:55–59; 13:31–38. Example 4 of Fike, cited by the Examiner, describes coating a bead with PLGA. *Id.* at 22:18–38. The example discloses:

> Several parameters like coating component concentration, bead size, % alginate, protocols for coating, drying conditions and level of dryness, solvents for pre-coating, etc. had to be optimized in order to achieve the best results.

Fike 22:35–38.

This disclosure from Fike, as discussed by the Examiner, indicates that coating parameters can be optimized to achieve a desired result.

Fike does not disclose a coat comprising the recited "cellulose ethers and cellulose esters." The Examiner found that ethylcellulose is a cellulose ether derivative. Final Act. 4. Ethylcellulose, as found by the Examiner, is a well-known coating for pharmaceuticals. The Examiner cited Jain as evidence of this fact, which Appellant does not dispute. In addition to Jain,

Muschert[3] is newly cited as evidence that ethylcellulose was widely used at the time of the invention in pharmaceutical coatings for controlled release.[4]

Muschert discloses a coating comprising ethylcellulose to which "small amounts of poly(vinyl acetate)-poly(ethylene glycol)-graft-copolymer (PVA–PEG-graft-copolymer)" have been added. Muschert 138 (Abstract). The claimed coat comprises at least one of a cellulose ester or cellulose ether, but does not exclude other components, such as the added polymer in Muschert.

Muschert further teaches:

> *Potentially too rapid drug release can effectively be slowed down by increasing the coating level*. Thus, adapting the polymer blend ratio and *coating thickness* desired and long term stable drug release profiles (even under stress conditions and open storage) can be provided for very different types of drugs and starter cores by the addition of small amounts of PVA–PEG-graft-copolymer to aqueous ethylcellulose dispersion.

Muschert 138 (Abstract) (emphasis added).

Thus, as indicated in the disclosure reproduced above, Muschert teaches that "coating level" or "coating thickness" is varied to achieve the desired drug release profile. A thicker coating would mean that more coating is present, adding more weight to the total composition. Muschert therefore

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[3] S. Muschert et al., "Improved long term stability of aqueous ethylcellulose film coatings: Importance of the type of drug and starter core," *Int'l J. Pharmaceutics*, 2009, 368:138–145.

[4] "Ethylcellulose is a highly suitable polymer for film coating (Wallace, 1990; Iyer et al., 1993; Ye et al., 2007). It is nontoxic, nonallergenic, nonirritant and a good film former (Wade and Weller, 1994; Naelpäa et al., 2007). For many years this polymer has been widely used in oral pharmaceutical formulations for various purposes, including moisture protection, taste masking (DeMerlis et al., 2005) and controlled release." Muschert 138.

provides evidence that the weight of the coating affects the drug release characteristics of the drug, making it a "result-effective variable." "[W]here 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." *In re Aller*, 220 F.2d 454, 456 (1955) (citations omitted). As explained *In re Applied Materials, Inc.*, 692 F.3d 1289, 1295 (Fed. Cir. 2012), "[t]his rule is limited to cases in which the optimized variable is a 'result-effective variable.' *In re Antonie*, 559 F.2d 618, 620 (CCPA 1977); *see* [*In re*] *Boesch*, 617 F.2d [272, 276 CCPA 1980)] ('[D]iscovery of an optimum value of a result effective variable . . . is ordinarily within the skill of the art.')." Thus, because coating weight percent is a "result-effective variable," it would be routine optimization, as found by the Examiner, to determine the weight percent of the encapsulant coating to achieve the desired drug release profile. Jain also describes varying the release controlling material in the coating from 0.1% to 99% w/w of the composition (Jain ¶ 9), which would necessarily change the weight percent of the coating in the sustained release composition.

Muschert also discloses:

> In addition to the variation of the PVA–PEG-graft-copolymer content[,] also the variation of the coating level is an efficient tool to adjust desired release patterns from the investigated systems (Fig. 3). *An increase in the coating level from 5% to 15% (w/w)* resulted in a significant decrease in the absolute and relative release rates, irrespective of the type of release medium.

Muschert 143 (paragraph spanning columns 1–2) (emphasis added).

Muschert teaches that the "w/w" is determined by the weight gain of the composition after coating,[5] which is the same way the coat weight increase is measured in the rejected claims and in the Specification (Spec. ¶ 87). Muschert describes a coat weight percent gain of 5–15% that is substantially the same and overlaps with the claimed "relative weight increase of the solid form mixture of between about 5 wt. % and about 15 wt.%." It is well established that, when there is a range disclosed in the prior art, and the range recited in the claim overlaps or falls within that range, there is a presumption of obviousness. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003); *Iron Grip Barbell Co. v. USA Sports, Inc*., 392 F.3d 1317, 1322 (Fed. Cir. 2004).

> [The] law is replete with cases in which the difference between the claimed invention and the prior art is some range or other variable within the claims . . . in such a situation, the applicant must show that the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.

In re Woodruff, 919 F.2d 1575, 1578 (Fed. Cir. 1990) (citation omitted).

Here, Appellant has not provided objective evidence that the recited range of "between about 5 wt. % and about 15 wt.%" is critical in view of the teachings of Fike, Jain, and Muschert.

Appellant did not provide separate arguments for dependent claims 2–9 and 21–23. These claims therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

[5] "The coating dispersions were sprayed onto the diltiazem HCl-layered sugar cores until a weight gain of 5–30% (w/w) was achieved (as indicated)." Muschert 140.

Although we affirm the rejection for the reasons set forth by the Examiner, Muschert is newly cited as evidence that ethylcellulose is a result-effective variable. For this reason, the affirmance is cited as a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). The new ground of rejection is as follows:

Claims 1–9 and 21–23 are rejected under 35 U.S.C. § 103 as obvious in view of Fike, Jain, and Muschert.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed	New Ground
1–9, 21–23	103	Fike, Jain, Muschert	1–9, 21–23		1–9, 21–23

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 appellant, 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 examiner, in which event the prosecution will be

> remanded to the examiner. The new ground of rejection is binding upon the examiner unless an amendment or new Evidence not previously of Record is made which, in the opinion of the examiner, overcomes the new ground of rejection designated in the decision. Should the examiner reject the claims, appellant 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 also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the MPEP § 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).

AFFIRMED; 37 C.F.R. § 41.50(b)