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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte OLIVER PETERMANN, MATTHIAS SPREHE, and WARREN K. MILLER

Appeal 2019-003201
Application 14/420,911
Technology Center 1600

Before TAWEN CHANG, TIMOTHY G. MAJORS, and MICHAEL A. VALEK, *Administrative Patent Judges*.

VALEK, *Administrative Patent Judge.*

DECISION ON APPEAL

Appellant[1] submits this appeal under 35 U.S.C. § 134(a) involving claims to a process for preparing an esterified cellulose ether. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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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 Dow Global Technologies, LLC, a wholly-owned subsidiary of The Dow Chemical Company, as the real party in interest. Appeal Br. 3.

STATEMENT OF THE CASE

"The present invention relates to an improved process for preparing an esterified cellulose ether in the presence of an alkali metal carboxylate and an aliphatic carboxylic acid." Spec. 1:6–8. The Specification describes various prior art processes for preparing esterified cellulose ethers (*see id.* at 1:10–4:30), but asserts that such "processes . . . are expensive in terms of raw materials and purification procedures." *Id.* at 5:1–4. The Specification additionally explains "that controlling the weight average molecule weight of an esterified cellulose ether is an important factor for influencing drug release rate from solid dispersions of a drug in an esterified cellulose ether." *Id.* at 5:11–13. According to the Specification:

> Surprisingly, it has been found that the weight average molecular weight of an esterified cellulose ether can be varied by varying the molar ratio [aliphatic carboxylic acid / anhydroglucose units of cellulose ether] and/or varying the molar ratio [alkali metal carboxylate / anhydroglucose units of cellulose ether] in the process for producing the esterified cellulose either. Even more surprisingly, it has been found that esterified cellulose ethers having substantially the same or even a higher weight average molecular weight as in prior art processes can be produced even if the molar ratio [alkali metal carboxylate / anhydroglucose units of cellulose ether] and the molar ratio [aliphatic carboxylic acid / anhydroglucose units of cellulose ether] are both reduced in the process for producing the esterified cellulose ether, as compared to the specific processes taught in the prior art.

Id. at 5:19–28.

Claims 1–6 and 9–16 are on appeal and can be found in the Claims Appendix of the Appeal Brief. Claim 1 is representative of the claims on appeal. It reads as follows:

> 1. A process for preparing an esterified cellulose ether wherein a cellulose ether is esterified with (i) succinic anhydride or phthalic anhydride or with (ii) succinic anhydride in combination with an aliphatic monocarboxylic acid anhydride selected from the group consisting of acetic anhydride, butyric anhydride and propionic anhydride in the presence of an alkali metal carboxylate and an aliphatic carboxylic acid, wherein the molar ratio [alkali metal carboxylate / anhydroglucose units of cellulose ether] is from [0.30 / 1] to [1.00 / 1], the molar ratio [aliphatic carboxylic acid / anhydroglucose units of cellulose ether] is from [3.55 / 1] to [9.0 / 1][2] and the cellulose ether is a hydroxypropyl methylcellulose having a viscosity of from 2.4 to 200 mPa·s, measured as a 2 weight-% solution in water at 20°C according to ASTM D2363 – 79 (Reapproved 2006), and the prepared esterified cellulose ether has a weight average molecular weight M_w of from 70,000 to 700,000 Dalton.

App. Br. 15. Appellant's other independent claims, claims 12 and 13, recite an alkali metal carboxylate ratio and aliphatic carboxylic acid ratio within the same ranges as claim 1.

Appellant seeks review of Examiner's rejection of claims 1–6 and 9–16 under 35 U.S.C. § 103 as obvious over Onda[3] in view of Cade[4] and Odidi.[5] *See* Appeal Br. 6–18. The issue is whether the preponderance of the evidence supports Examiner's conclusion that the process in Appellant's claims is obvious over the cited prior art combination.

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[2] Herein, we refer to the molar ratio of alkali metal carboxylate to anhydroglucose units of cellulose ether as the "alkali metal carboxylate ratio" and the molar ratio of aliphatic carboxylic acid to anhydroglucose units of cellulose ether as the "aliphatic carboxylic acid ratio."
[3] US 4,226,981, issued Oct. 7, 1980 ("Onda").
[4] WO 2008/050209 A1, published May 2, 2008 ("Cade").
[5] US 6,296,876 B1, issued Oct. 2, 2001 ("Odidi").

Analysis

Examiner finds that Onda Example 1 discloses a process of preparing esterified cellulose either wherein hydroxypropyl methylcellulose ("HPMC") is reacted with acetic acid (corresponding to the recited "aliphatic carboxylic acid"), sodium acetate (corresponding to the recited "alkali metal carboxylate"), and succinic anhydride and acetic anhydride. Final Act. 4. Examiner acknowledges that Onda does not teach the alkali metal carboxylate ratio and aliphatic carboxylic acid ratio ranges recited in claim 1, but determines "[c]hanges in concentrations of the components of an old process [i.e., the process taught in Onda Example 1] do not impart patentability unless the recited ranges are critical." *Id*. at 4–5 (citing *In re Aller*, 220 F.2d 454 (C.C.P.A. 1955)); *see also* Ans. 8 ("According to MPEP 2144.05(II)(A), optimization of a concentration . . . within prior art conditions is obvious unless there is a showing that the concentration is critical."). Examiner further relies on Cade and Odidi as evidence that HPMC with viscosity values and hydroxypropyl methylcellulose acetate succinate with M_w values within the recited ranges were known in the art. *See id.* at 5–6.

Appellant does not dispute Examiner's finding that Onda teaches an esterification process using the same reactant and catalyst ingredients as claim 1, albeit at molar ratios that exceed the upper boundary of the two recited ranges. *See* Appeal Br. 7–11. Instead, Appellant contends that the use of those ingredients in amounts corresponding to the recited molar ratios produces "a new and unexpected result" as compared to the process in Onda. *Id.* at 12. Specifically, Appellant relies on evidence from WO 2014/031422 A1 ("the '422 Publication") showing that "when using i) only about ¼ of the

amount of acetic acid solvent and ii) only about ¼ the amount of sodium acetate catalyst (per mole of HPMC) taught by Onda in Example 1 . . . comparable degrees of succinoyl substitution DOS_s and acetyl substitution DOS_{Ac} are achieved." *Id*. at 12–13. According to Appellant, this result is surprising because a skilled artisan would expect these degrees of substitution to "be significantly reduced when the amount of catalyst is drastically reduced, as compared to the amounts of catalyst taught in all Examples of the Onda reference." *Id.* at 13. Appellant further argues that the higher aliphatic carboxylic acid ratio taught in Onda results in a M_w outside the claimed 70,000 to 700,000 Dalton range (*see id.* at 14–15), whereas the evidence in the '422 Publication demonstrates "a clear trend that the M_w increases as the [aliphatic carboxylic acid] ratio decreases" within the recited ranges. *See* Reply Br. 5–7.

Upon considering the record as a whole, we determine that Examiner's conclusion of obviousness is not supported by the preponderance of the evidence of record. As explained below, Appellant's evidence of unexpected results is sufficient to overcome Examiner's prima facie showing of unpatentability.

Appellant points out that all of Onda's examples use concentrations of reactants and catalyst that equate to substantially higher carboxylate and carboxylic acid ratios (*see* Appeal Br. 7–11), but does not specifically dispute Examiner's determination that it would be routine to optimize those concentrations. Moreover, Appellant does not dispute Examiner's finding that the recited ratio ranges "are encompassed by" and "substantially overlap" with the broader reactant and catalyst ranges that Onda teaches, but does not specifically exemplify. Ans. 8. Accordingly, we find no error in

Examiner's determination that Onda supports a prima facie case of obviousness.

What distinguishes the present claims, however, is Appellant's evidence of unexpected results. Examples 10 and D–H of the '422 Publication show the results of esterification reactions using the same ingredients as Onda Example 1, but in different amounts. *See* '422 Publication 29–30 (Tables 1 and 2). Example 10 corresponds to the process in Appellant's claim 1 where the "alkali metal carboxylate" catalyst (sodium acetate) is provided at a carboxylate ratio of 0.53 and the "aliphatic carboxylic acid" (acetic acid) is provided at a carboxylic acid ratio of 4.9. *Id.* Whereas, Examples D–H use sodium acetate and acetic acid in higher amounts corresponding to the carboxylate ratio (2.47) and carboxylic acid ratio (16.9) in Onda Example 1. *Id.* As Examiner acknowledges, the "total degree of ester substitution" for Example 10 is "similar" to that for Examples D–H, notwithstanding the use of substantially less catalyst and acetic acid. Ans. 9. However, based on various "observations" drawn from the examples in the '422 Publication, Examiner finds this result would be "expected and well understood" to a skilled artisan. *Id.* at 9–10. The problem with Examiner's finding is that it is premised entirely on data from the'422 Publication, which Examiner has not shown to be prior art to the present application.[6] Accordingly, Examiner has not demonstrated that

[6] Appellant asserts that the '422 Publication is not prior art because it and the present application are commonly-owned and share the same priority date. Appeal Br. 13. Examiner does not dispute that allegation, nor has Examiner identified evidence to support that the data in the '422 Publication would have otherwise been known to one of ordinary skill in the art as of the priority date of the present application.

Appellant's evidence showing that a similar degree of esterification can be achieved with "dramatically reduced raw material utilization" would have been expected from the prior art. *See* Appeal Br. 13–14.

In addition, the data from the '422 Publication supports Appellant's argument that the recited molar ratio ranges are critical because they result in an esterified cellulose ether with a higher M_w than those produced by the process taught in Onda Example 1. *See* Appeal Br. 14–15. The M_w of the esterified HPMC in Example 10 of the '422 Publication is 142 kDA. '429 Publication 30 (Table 2). In contrast, the M_w for Examples D–H (which correspond to the molar ratios in Onda Example 1) range from 36–41 kDa and are, therefore, outside the "70,000 to 700,000 Dalton" range recited in Appellant's claims. In addition, we agree with Appellant that the data in the '422 Publication evidences a "trend that the M_w increases as the [aliphatic carboxylic acid] ratio decreases," whereas "M_w decreases as the [alkali metal carboxylate] ratio decreases." Reply Br. 5–7. Examiner has not shown that these trends would have been obvious to one of skill in the art, or otherwise expected from the cited prior art. Thus, the record supports Appellant's argument the recited molar ratio ranges achieve an unexpected balance wherein an esterified cellulose ether with a higher M_w is obtained using a significantly lower amount of catalyst than that taught in the prior art.

For these reasons, and based on the record presently before us, we agree with Appellant that the recited molar ratio ranges are critical and probative of non-obviousness. Considering "the entire merits of the matter" in light of this evidence, we determine that the preponderance of the evidence does not support the rejection. *See In re Hedges*, 783 F.2d 1038, 1039 (Fed. Cir. 1986). Accordingly, we reverse.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–6, 9–16	103	Onda, Cade, Odidi		1–6, 9–16

REVERSED