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Williams Mullen 8300 Greensboro Drive Suite 1100 Tysons, VA 22102			NGUYEN, COLETTE B	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte ANISUL QUADIR and SAKAE OBARA

Appeal 2019-004353
Application 15/132,627
Technology Center 1700

Before JEFFREY T. SMITH, LILAN REN, and
MERRELL C. CASHION, JR., *Administrative Patent Judges*.

CASHION, *Administrative Patent Judge*.

DECISION ON APPEAL
STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), the Appellant¹ appeals from a Final Office Action, dated April 7, 2017, rejecting claims 8–11. We have jurisdiction under 35 U.S.C. § 6.

We AFFIRM.

¹We 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 SE Tylose USA, Inc. and Shin-Etsu Chemical Co., Ltd. Appeal Br. 1.

Claim 8 is illustrative of the subject matter on appeal and is reproduced below:

8. An aqueous enteric coating composition comprising:
- a) 5 to 20 percent hydroxypropylmethylcellulose acetate succinate;
 - b) 0.05 to 1.0 percent L-alanine, L-histidine, or L-lysine;
 - c) 0.5 to 10 percent plasticizer;
 - d) 0.1 to 10 percent anti-tacking agent;
 - e) 0.05 to 0.5 percent surfactant; and
 - f) 65 to 95 percent water.

Appellant requests review of the Examiner's rejection of claims 8–11 under 35 U.S.C. § 103 as unpatentable over Hardee (US 2012/0322851 A1, published December 20, 2012). Appeal Br. 2; Final Act. 2.

Appellant does not argue any claim separate from the other. *See generally* Appeal Br. Accordingly, we select claim 8 as representative of the subject matter on appeal and decide the appealed ground of rejection based on the arguments Appellant makes in support of the patentability of claim 8.

OPINION

After review of the respective positions the Appellant and the Examiner present, we AFFIRM the Examiner's rejection of claims 8–11 under 35 U.S.C. § 103 for the reasons the Examiner provides in the Final Action and the Answer. We add the following for emphasis.

Claim 8 recites an aqueous enteric coating composition comprising hydroxypropylmethylcellulose acetate succinate (HPMCAS).

The Examiner determines that Hardee teaches an aqueous enteric coating composition satisfying all of the limitations of claim 8, including the use of HPMCAS in the composition, and concludes Hardee would have rendered the claim obvious. Final Act. 2–3.

Appellant argues that, even though Hardee teaches the use of HPMCAS and the claimed amino acids, there is no reason to modify Hardee’s composition by replacing or modifying hydroxypropylmethylcellulose (HPMC) with HPMCAS, and then adding the claimed amino acid to arrive at the claimed invention. Appeal Br. 4–6. According to Appellant, there is no recognition that either HPMC or HPMC-AS contributes to anti-agglomeration properties of the composition and, therefore, one skilled in the art would not have an expectation of success in achieving the anti-agglomeration properties of the claimed invention. Appeal Br. 5–6.

Appellant’s arguments are not persuasive of reversible error.

Appellant’s arguments do not dispute that Hardee discloses HPMCAS and the claimed amino acids as components of the disclosed composition. *See generally* Appeal Br. Instead, the premise of Appellant’s arguments is that Hardee does not teach the specifically claimed composition. *Id.* at 5–6. Such arguments are appropriate for addressing an anticipation rejection under 35 U.S.C. § 102. But, this is not the rejection before us for review on appeal. The rejection presented for review on appeal is under 35 U.S.C. § 103.

We note that the Examples in the Specification attribute the anti-agglomeration/anti-coagulation properties to the addition of the claimed

amino acids. Spec. ¶¶ 28–31 (discussing a comparison between a conventional formulation having no amino acid with an inventive Example 1 having L-histidine). Given that Hardee discloses compositions that encompass compositions comprising the claimed HPMCAS and amino acids, Appellant fails to explain adequately why one skilled in the art would not have been capable of arriving at the claimed invention from Hardee’s teachings and reasonably expect Hardee’s composition to also possess anti-agglomeration properties. *In re O’Farrell*, 853 F.2d 894, 904 (Fed. Cir. 1988) (“For obviousness under § 103, all that is required is a reasonable expectation of success.”). Thus, Appellant does not explain adequately why one skilled in the art, using no more than ordinary creativity, would not have been able to arrive at the claimed invention from Hardee’s teachings. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”); *see also In re Sovish*, 769 F.2d 738, 743 (Fed. Cir. 1985) (presuming skill on the part of one of ordinary skill in the art).

Appellant contends that the Examples in the Specification shows unexpected results for the claimed invention because they demonstrate that the inventive Examples reduce agglomeration and act as a processing aid to avoid nozzle clogging during a coating application when compared against a composition having no amino acids. Appeal Br. 6.

When evidence of secondary considerations is submitted, we begin anew and evaluate the rebuttal evidence along with the evidence upon which the conclusion of obviousness was based. *In re Rinehart*, 531 F.2d 1048, 1052 (CCPA 1976). The burden of establishing unexpected results rests on the Appellant. Appellant may meet this burden by establishing that the

difference between the claimed invention and the closest prior art was an unexpected difference. *See In re Klosak*, 455 F.2d 1077, 1080 (CCPA 1972). The unexpected results must be established by factual evidence; attorney statements are insufficient to establish unexpected results. *See In re Geisler*, 116 F.3d 1465, 1470–71 (Fed. Cir. 1997). Further, a showing of unexpected results supported by factual evidence must be reasonably commensurate in scope with the degree of protection sought by the claims on appeal. *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983); *In re Clemens*, 622 F.2d 1029, 1035 (CCPA 1980).

We have considered Appellant’s evidence of unexpected results and find it insufficient to overcome a prima facie case of obviousness. First, it is not clear that Appellant has compared the claimed invention against the closest prior art (Hardee). Further, the evidence presented in the Specification compares a limited number of inventive compositions having a either 10% or 13% HPMCAS and either 0.03% or 0.33% amino acid. Appellant does not explain why the limited number of inventive compositions tested is representative of the broad scope of compositions claimed.

Thus, on this record, Appellant has not explained adequately why the evidence relied upon would have been unexpected by one of ordinary skill in the art or is reasonably commensurate in the scope with the claims.

Accordingly, we affirm the Examiner’s prior art rejection of claims 8–11 under 35 U.S.C. § 103 for the reasons the Examiner presents and we give above.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
8-11	103	Hardee	8-11	

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)(iv).

AFFIRMED