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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CARL MYERS and REHANA BEGUM-GAFUR[1]

Appeal 2020-000488
Application 15/366,327
Technology Center 1600

Before ERIC B. GRIMES, FRANCISCO C. PRATS, and
LILAN REN, *Administrative Patent Judges.*

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to an oral care composition, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

STATEMENT OF THE CASE

The Specification states that "[o]ne approach to reducing staining and erosion [of teeth] as well as reducing biofilm formation is the use of anionic

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[1] Appellant identifies the real party in interest as Colgate-Palmolive Company. Appeal Br. 2. We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42.

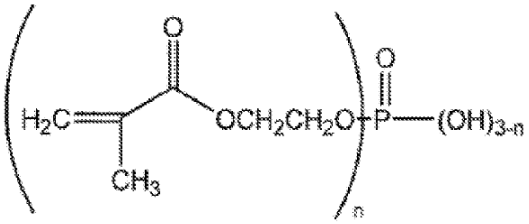
polymers that help coat and protect the enamel." Spec. ¶ 8. "These polymers, however, can interact with cationic antimicrobial agents, leading to formulation incompatibilities." *Id*.

The Specification discloses that "addition of a stabilizing amount of an orally acceptable polyamine compound, e.g., lysine, to formulations comprising an anionic polymer and a cationic antibacterial agent inhibits the association of these components and enhances delivery to the teeth." *Id*. ¶ 10.

Claims 1, 4–16, and 19 are on appeal. Claim 1, reproduced below, is illustrative:

1. An oral care composition comprising

a) an orally acceptable acidic polymer, wherein said acidic polymer comprises a copolymerized product of a mixture of acrylic acid, methacrylic acid, and 2-hydroxyethyl methacrylate phosphates of Formula 1:



wherein n is 0, 1 or 2;

b) an orally acceptable nonionic polymer;

c) an effective amount of orally acceptable cationic active agent, in free or orally acceptable salt form;

d) a polyamine compound, in free or orally acceptable salt form, present in an amount sufficient to stabilize the cationic active agent, wherein the polyamine is lysine or polylysine; and

e) water.

The claims stand rejected as follows:

Claims 1, 4–6, 8–12, 14–16, and 19 under 35 U.S.C. § 103 as obvious based on Prencipe[2] and Subramanyam[3] (Ans. 3);

Claim 7 under 35 U.S.C. § 103 as obvious based on Prencipe, Subramanyam, and Gaffar[4] (Ans. 5); and

Claim 13 under 35 U.S.C. § 103 as obvious based on Prencipe, Subramanyam, and Dolan[5] (Ans. 6).

OPINION

All of the claims stand rejected as obvious based on Prencipe and Subramanyam, by themselves, or combined with either Gaffar or Dolan with respect to claims 7 and 13, respectively. Appellant has waived arguments based on Gaffar or Dolan. *See* Appeal Br. 9–10. We therefore address the rejections together.

The Examiner finds that Prencipe "discloses oral care compositions comprising a phosphate/acrylate copolymer," and specifically "the instantly elected species of acidic polymer, and which reads upon instantly recited element a)." Ans. 3. The Examiner also finds that Prencipe's "composition also can comprise a humectant such as polyethylene glycol . . . , which reads upon instantly recited element b)." *Id*. Finally, the Examiner finds that Prencipe "suggests the inclusion of antibacterial agents, such as a bisguanide antiseptic such as chlorhexidine and zinc salts . . . , which reads upon

[2] WO 2015/094336 A1; June 25, 2015.
[3] US 2011/0052509 A1; Mar. 3, 2011.
[4] US 5,525,330; June 11, 1996.
[5] US 2004/0101492 A1; May 27, 2004.

instantly recited element c).” *Id*. “Thus, Prencipe et al. teaches all of the limitations recited by instant claim 1 except for the polyamine compound recited as element d),” although Prencipe “suggests anti-caries agents in from 0.1 to 10 wt%.” *Id*.

The Examiner finds that Subramanyam “discloses oral care compositions with a basic amino acid in free or salt form and a soluble carbonate or bicarbonate salt,” where “[t]he basic amino acid can be lysine” or its hydrochloride salt. *Id*. at 4. The Examiner finds that Subramanyam discloses that “basic amino acids are useful in inhibiting cavity formation . . . , and the combination taught provides for reducing the accumulation of plaque,” among other benefits. *Id*.

The Examiner concludes that it would have been obvious “to have included lysine hydrochloride in the composition taught by Prencipe et al., and to do so in the amount taught therein [for an anti-caries agent]” because “it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use.” *Id*. The Examiner finds that “such an amount of the anti-caries agent would provide for the stability instantly recited by claim 1, as this amount is taught as such by the instant specification (paragraph [22]).” *Id*.

We agree with the Examiner that the claimed composition would have been obvious to a skilled artisan based on Prencipe and Subramanyam. Prencipe discloses “an oral care composition comprising a phosphate/ acrylate co-polymer, a synthetic anionic linear polycarboxylate, and an orally acceptable carrier,” as well as “a method of forming the composition as a mouth rinse that includes the phosphate/acrylate co-polymer and the

synthetic anionic linear polycarboxylate polymer as well as a zinc salt and a cationic antibacterial agent." Prencipe ¶¶ 9, 10. The resulting mouth rinse also comprises water. *Id*. ¶ 10. One phosphate/acrylate co-polymer disclosed by Prencipe is the same as the "acidic polymer" recited in claim 1. *Id*. ¶ 16.

Prencipe suggests including a humectant in its composition to "keep[] oral care compositions from hardening upon exposure to air," as well as to "impart desirable sweetness or flavor to oral care compositions." *Id*. ¶ 31. One of the humectants suggested by Prencipe is polyethylene glycol. *Id*. Appellant's Specification states that polyethylene glycol is an example of the "orally acceptable nonionic polymer" recited in claim 1. Spec. ¶ 29.

Thus, Prencipe suggests an oral care composition (e.g., a mouth rinse) comprising components a), b), c), and e) of claim 1. Prencipe does not suggest including lysine or polylysine in the composition. However, Subramanyam discloses an "oral care composition, e.g., a dentifrice, comprising a basic amino acid, e.g., arginine, . . . together with a soluble carbonate salt, e.g., sodium carbonate, sodium bicarbonate or mixtures thereof, wherein a bicarbonate of the basic amino acid is formed in situ." Subramanyam ¶ 6.

Subramanyam discloses that its compositions "are effective in inhibiting or reducing the accumulation of plaque, reducing levels of acid producing (cariogenic) bacteria, remineralizing teeth, and inhibiting or reducing gingivitis." *Id*. ¶ 5. Subramanyam discloses that the basic amino acid can be "arginine, lysine, citrullene [sic], ornithine," etc. *Id*. ¶ 9 (Composition 1.0.1). Subramanyam discloses that the basic amino acid can be present in an amount of "about 0.1—about 20%, e.g., about 1 wt. % to

about 10 wt. % of the total composition weight." *Id*. ¶ 9 (Composition 1.0.8). Subramanyam also discloses that its composition can be a mouthrinse. *Id*. ¶ 9 (Composition 1.0.62).

Based on these disclosures, it would have been obvious to modify Prencipe's composition to include a basic amino acid, such as lysine, and a soluble carbonate salt, because Subramanyam discloses that these components provide several beneficial effects: "inhibiting or reducing the accumulation of plaque, reducing levels of acid producing (cariogenic) bacteria, remineralizing teeth, and inhibiting or reducing gingivitis." *Id*. ¶ 5. It would have been obvious to provide the basic amino acid (e.g., lysine) in an amount of 1–10 wt% of the total composition, because Subramanyam expressly suggests using that amount in order to gain the benefits described by Subramanyam. Appellant's Specification discloses that 1–5% lysine or 2–4% lysine hydrochloride is an appropriate amount to provide the desired stabilizing effect. Spec. ¶ 22 (Compositions 1.35, 1.37). Thus, the composition of claim 1 would have been obvious to a skilled artisan based on the disclosures of Prencipe and Subramanyam.

Appellant argues that "[o]ne problem with the Examiner's logic is that if Subramanyam is intended to provide an antibacterial agent, why would one of skill in the art pick lysine rather than arginine, which Subramanyam expressly prefers and identifies?" Appeal Br. 5. This argument is unpersuasive, because Subramanyam expressly suggests using basic amino acids other than arginine. *See* Subramanyam ¶¶ 9, 21. "[I]n a section 103 inquiry, 'the fact that a specific [embodiment] is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred

embodiments, must be considered.'" *Merck & Co. Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (quoting *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976).)

Appellant also argues that "the Examiner takes the view that the lysine is the antibacterial agent, thus presumably no cationic antibacterial agent would be required." Appeal Br. 6. This argument is also unpersuasive, because Prencipe expressly suggests specific anti-bacterial agents, including cationic agents, and suggests that "mixtures thereof" are suitable for use in its composition. Prencipe ¶ 48. Based on this teaching, it would have been obvious to use a mixture of anti-bacterial agents in Prencipe's composition. In addition, Subramanyam discloses that a basic amino acid, such as lysine, provides other benefits besides reducing the level of cariogenic bacteria. *See* Subramanyam ¶ 5.

Appellant argues that "[n]either Prencipe nor Subramanyam disclose, recognize, or solve the problem of incompatibilities between the claimed acidic polymer and cationic active agent." Appeal Br. 6. This argument is also unpersuasive, because Prencipe discloses a method of making a composition comprising a phosphate/acrylate copolymer, which can be the same polymer as recited in part a) of Appellant's claim 1, and a cationic antibacterial agent. *See* Prencipe ¶ 78. Prencipe states that "[t]he method can form a stable composition that is stable and transparent." *Id*.

Appellant argues that "[t]he Examiner has not suggested that the amount of lysine or polylysine should be 'in an amount sufficient to stabilize the cationic active agent' as claimed." Appeal Br. 6. This argument is unpersuasive, because the Examiner pointed out that the amount of lysine

suggested by Subramanyam encompasses the amounts of lysine or lysine hydrochloride disclosed in Appellant's Specification as effective to stabilize the claimed composition. *See* Ans. 4, Spec. ¶ 22 (Compositions 1.35, 1.37). Thus, the amount suggested by the prior art is "an amount sufficient to stabilize the cationic active agent," as recited in claim 1.

Appellant also argues that "[t]he skilled artisan, upon studying the cited prior art, would have no motivation to use lysine as a stabilizer." Appeal Br. 6. That is, "lysine, while known in the art as an anti-caries agent, was not known for its ability to stabilize a composition characterized by the presence of a negatively charged polymer and a cationic active agent." *Id*. Thus, Appellant argues,

> the Examiner still has not shown that the combination of Prencipe and Subramanyam would have rendered **lysine's stabilizing effect** on the claimed composition to be obvious. At best, the Examiner has only shown that lysine could be used if a composition called for an anti-caries agent. As argued exhaustively already, that is not the purpose of the claimed lysine.

Id. at 8.

These arguments are also unpersuasive. "In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007). "[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *Id*. at 420. Here, the cited references provide a reason to include lysine in Prencipe's composition: as an anti-caries agent. Whether the prior art suggests including lysine as a stabilizer is immaterial to the issue of whether the

claimed composition would have been obvious to a skilled artisan. *See KSR*, 550 U.S. at 419 ("What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.").

Appellant also argues that its position is supported by *Leo Pharmaceutical Products, Ltd. v. Rea*, 726 F.3d 1346 (Fed. Cir. 2013). Appeal Br. 7. Appellant argues that

> [i]n *Leo*, the USPTO found prior art accounting for more than eight different classes of additives (e.g., diluents, buffers, thickeners, lubricants), and more than ten different categories of composition forms (e.g., liniments, lotions, Appellants [sic, applicants], oil-in-water or water-in-oil emulsions such as creams, ointments, pastes, or gels). *Leo* at 1356. The Board concluded that a person of ordinary skill in the art would have been capable of selecting the correct formulation from available alternatives. Id. The Federal Circuit rejected such analysis, holding "[t]o the contrary, the breadth of these choices and the numerous combinations indicate that these disclosures would not have rendered the claimed invention obvious to try." Id.

Id.

We do not agree that *Leo* supports Appellant's position. As Appellant correctly notes, the rejection in *Leo* depended on choosing the claimed elements from prior art disclosures of eight different classes of additives and more than ten different composition forms, on the basis that a skilled artisan "would have been capable of selecting the correct formulation from available alternatives." *Leo*, 726 F.3d at 1356. Here, by contrast, a skilled artisan need only choose lysine from among the basic amino acids disclosed by Subramanyam, and include it in Prencipe's composition for the reason disclosed by Subramanyam, in order to achieve the claimed composition. The facts of this case are therefore readily distinguishable from those of *Leo*.

Finally, Appellant argues that the Specification's

> data show [that] combining the anionic polymer with the cationic active agent interferes with both the anti-staining properties of the former and the antibacterial activity of the latter, but the addition of lysine, in accordance with the claims, is able to restore these activities – an unexpected effect which could not have been predicted from the art cited.

Appeal Br. 8.

We have considered the data presented in the Specification, but do not agree that it demonstrates unexpected results that support a conclusion of nonobviousness. Appellant argues that the "stabilizing effect of the lysine turns out to be absolutely critical in preserving . . . both the anti-stain efficacy of the anionic polymer (DV8801; see, Table 3, para. [0060] – [0061]) and the antibacterial effect of the cationic active agent (CHX; see, Table 5, para. [0064] – [0065])." Appeal Br. 8.

However, Table 3 does not include samples containing an acidic polymer (e.g., DV8801) and a cationic active agent (e.g., CHX), with and without lysine, that would demonstrate the criticality of lysine in preserving the activity of DV8801 and CHX. Rather, the only compositions in Table 3 that contain both DV8801 and CHX also contain lysine, another polymer (Gantrez S-97), and a surfactant (SLS), or all of those components plus PEG 10K. Spec. ¶ 61, Table 3 (*see also id*. ¶ 59, Table 2).

Similarly, while the Specification's Table 5 shows that the combination of CHX and DV8801 has much less antibacterial activity than CHX alone, the table does not include a sample containing only CHX, DV8801, and lysine, which would demonstrate the criticality of lysine in restoring CHX's antibacterial activity in the presence of DV8801. Rather,

the composition that adds lysine to CHX and DV8801 also adds Gantrez S-97, SLS, and PEG 10K. Spec. ¶ 64, Table 5. The data therefore do not demonstrate that *lysine* provides an unexpected effect on a composition comprising a cationic active agent and an acidic polymer.

Consistent with the results shown in Tables 3 and 5, the Specification states that "CHX and DV can be formulated in such a way to prevent precipitation (or to re-dissolve the precipitate) through the inclusion of lysine (Lys), polyethylene glycol (PEG), *and* low levels of sodium lauryl sulfate." Spec. ¶ 59 (emphasis added). The Specification also states that "[w]hen chlorhexidine digluconate is combined with the acidic polymers (DV and Gantrez S-97), and Lys alone (solution 4), no CHX is deposited on to the HAP [hydroxyapatite] surface, likely because [it] existed as a precipitate. . . . The addition of SLS . . . brings CHX back into solution, and re-enables its ability to deposit to HAP." *Id*. ¶ 63.

The evidence relied on by Appellant therefore does not show that lysine provides an unexpectedly beneficial effect when combined with a cationic active agent and an acidic polymer, as recited in claim 1.

In summary, a preponderance of the evidence of record supports the Examiner's rejection of claim 1 under 35 U.S.C. § 103 based on Prencipe and Subramanyam. We affirm the rejection of claim 1. Claims 4–6, 8–12, 14–16, and 19 fall with claim 1 because they were not argued separately. 37 C.F.R. § 41.37(c)(1)(iv). For the reasons discussed above, we also affirm the rejection of claim 7 under 35 U.S.C. § 103 based on Prencipe, Subramanyam, and Gaffar, and the rejection of claim 13 under 35 U.S.C. § 103 based on

Prencipe, Subramanyam, and Dolan, because Appellant has waived arguments directed to Gaffar or Dolan.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 4–6, 8–12, 14–16, 19	103	Prencipe, Subramanyam	1, 4–6, 8–12, 14–16, 19	
7	103	Prencipe, Subramanyam, Gaffar	7	
13	103	Prencipe, Subramanyam, Dolan	13	
Overall Outcome			1, 4–16, 19	

TIME PERIOD FOR RESPONSE

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

AFFIRMED