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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BARTHOLOMEW WELDON, EDWARD KOBUS, SANDRYNE DUMOULIN, AIMESTHER BETANCOURT, and PATRICK GOSSELIN

Appeal 2019-004731
Application 14/945,865
Technology Center 1600

Before FRANCISCO C. PRATS, 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 liquid composition supersaturated in calcium ions and phosphate ions and associated methods of treatment. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies Valeant Pharmaceuticals International, Inc. as the real party in interest. Appeal Br. 1.

STATEMENT OF THE CASE

The Specification explains that "human saliva is normally supersaturated with respect to calcium and phosphate." Spec. ¶ 12. According to the Specification, "[t]he present invention involves the formulation of powders which, when dissolved in water, form a liquid composition supersaturated with calcium and phosphate ions" that "can be used as an oral rinse for the prevention and treatment of inflammation of the soft tissues of the oral cavity . . . or for the prevention or treatment of xerostomia or chronic hyposalivation or complications therefrom." *Id.* ¶ 1.

The Specification describes known oral rinse products comprising calcium and phosphate salts used to treat "dryness of the mouth (hyposalivation, xerostomia)." *Id.* ¶¶ 3, 4. For example, the Specification explains that

> [t]he NeutraSal® product that has been provided commercially is a powder containing . . . calcium chloride dihydrate, sodium chloride, sodium phosphate salts, and sodium bicarbonate. The commercial product is provided in packets containing 538 mg of powder, and the directions state that the powder should be mixed in 30 ml of tap, distilled or purified water, thereby forming a liquid that is supersaturated with both calcium and phosphate ions.

Id. ¶ 3. The Specification describes a composition that differs from NeutraSal in that it "comprises calcium glycerophosphate, calcium lactate gluconate, or a mixture thereof." *Id.* ¶ 8.

Claims 12–18 and 33–44 are on appeal and can be found in the Claims Appendix of the Appeal Brief. Claim 14 is representative of the claims on appeal. It reads as follows:

> 14. A liquid composition supersaturated in calcium ions and phosphate ions, the liquid composition being the product of mixing a powder with water, in a weight ratio of powder to water from about 0.005:1 about 0.1:1, wherein the powder comprises: calcium glycerophosphate or calcium lactate gluconate, a sodium phosphate, and sodium chloride.

Appeal Br., Claims App. 2.

Appellant seeks review of Examiner's rejection of claims 12–18 and 33–44 under 35 U.S.C. § 103 as unpatentable over Boschetti,[2] Tancredi,[3] Phillips,[4] and Gerstner.[5] Appeal Br. 2. Appellant does not argue any claim separately from independent claim 14 so claims 12, 13, 15–18, and 33–44 stand or fall with claim 14. 37 C.F.R. § 41.37 (c)(1)(iv).

The issue is whether the preponderance of the evidence supports Examiner's conclusion that the composition in claim 14 is obvious over the cited prior art.

Findings of Fact

FF1. Boschetti describes "an effervescent tablet, which upon dissolution in water provides a solution useful as a mouth wash or oral rinse for the prevention or treatment of inflammatory processes of the soft tissues of the mouth, throat and oral cavity." Boschetti, Abstr. Boschetti teaches this tablet comprises "sodium phosphate" and a calcium salt such as "calcium chloride" or "calcium chloride dihydrate." *Id.* ¶¶ 28–29, 87. In addition, Boschetti teaches that the tablet "may also comprise flavours and/or

[2] US 2015/0272873 A1; published Oct. 1, 2015 ("Boschetti").
[3] US 2007/0237725 A1; published Oct. 11, 2007 ("Tancredi").
[4] US 2010/0130542 A1; published May 27, 2010 ("Phillips").
[5] Gerhard Gerstner, "*Calcium Lactate Gluconate – the innovative solution for extra calcium,*" Innovations in Food Technology, Vo1. 16, 2–3 (2002) ("Gerstner").

sweeteners providing a nice and/or sweet taste of the solution obtained when dissolving the present effervescent tablet in water." *Id.* ¶ 82.

FF2. Boschetti teaches that the total weight of its effervescent tablet "ranges from about 500 mg to about 5000 mg" and is suitable for dissolution in "50 ml of water." Boschetti ¶¶ 97, 99. Assuming a water density of 1 g/ml, this equates to a weight ratio of tablet to water of about 0.01:1 to 0.1:1.

FF3. Boschetti describes "NeutraSal®" as a "solid powder . . . dissolved in water prior to administration . . . to form a supersaturated calcium phosphate rinse." Boschetti ¶ 16. According to Boschetti, its tablet and NeutraSal "contain about the same quantity of therapeutic moiety, but in different form, i.e. an effervescent tablet vs. a dissolving powder." *Id.* ¶ 122. Boschetti describes the results of a "comparative study" of the two wherein "[u]pon dissolution in 30 ml water," NeutraSal "resulted in an opalescent solution comprising insoluble particles, whereas the composition according to the present invention resulted in a clear solution without any insoluble particles." *Id.*

FF4. Tancredi describes

> oral delivery systems, such as confectionery and chewing gum compositions, and methods for remineralizing tooth enamel in mammals. In particular, the oral delivery systems include a phosphopeptide or phosphoprotein stabilized calcium phosphate or calcium fluoride phosphate complex and a salt selected from calcium salts, phosphate salts and combinations thereof.

Tancredi, Abstr. Tancredi teaches that "[s]uitable calcium salts" for these oral delivery systems include calcium glycerophosphate, calcium lactate, calcium gluconate and combinations thereof. *Id.* ¶ 49. Tancredi teaches that "[s]uitable phosphate salts" include "sodium phosphate." *Id.* ¶ 50. Tancredi

teaches that these compositions may also comprise salts, such as sodium chloride, as a "flavor potentiator." *Id.* ¶ 199.

FF5. Tancredi teaches that its compositions may be in the form of "gels" as well as "mouthwashes, rinses and sprays." Tancredi ¶¶ 160–166. According to Tancredi, "[g]els may be provided as a dry powder" and "reconstituted by adding water." *Id.* ¶ 162; *see also* ¶ 161 ("Each gel also may include sufficient water or other aqueous solution to produce the desired consistency.").

FF6. Phillips describes "pharmaceutical compositions comprising omeprazole, lansoprazole and sodium bicarbonate." Phillips, Abstr. Phillips teaches these compositions may also comprise buffering agents such as "calcium glycerophosphate" and "sodium phosphate" as well as lubricants such as "sodium chloride." *Id.* ¶¶ 53, 103. According to Phillips, such compositions may be packaged in a variety of liquid dosage forms including as "a powder for suspension that can be suspended in a liquid vehicle prior to administration to a subject." *Id.* ¶¶ 133–135.

FF7. Gerstner teaches that calcium lactate gluconate "is a mixture of the commonly used calcium sources calcium lactate and calcium gluconate and so far it has served mainly as a pharmaceutical calcium source such as in the well-known effervescent tablets Calcium-Sandoz®." Gerstner 2. According to Gerstner, calcium lactate gluconate "has the highest solubility of all commonly used calcium salts" and "a neutral taste, even at high concentrations." *Id.* Gerstner teaches that calcium lactate gluconate "is primarily used in applications where solubility and clarity is important" such as in "concentrated preparations and pre-blends" and "instant preparations." *Id.* at 3. In addition, Gerstner explains that the advantage of using calcium

lactate gluconate is that "clear" liquid solutions may "be fortified without the addition of chelating agents" and that "[h]igher calcium concentrations can be reached." *Id.*

Analysis

Examiner finds Boschetti discloses the elements of claim 14, but "does not specifically teach . . . compositions comprising calcium glycerophosphate or calcium lactate gluconate and sodium chloride." Final Act. 5 (emphasis omitted). Examiner finds that Tancredi and Phillips each teach compositions suitable for oral administration comprising the recited calcium salts, sodium phosphate, and sodium chloride. *Id.* at 6. According to Examiner, it would be obvious "to modify the compositions taught by Boschetti to include such calcium salts as calcium glycerophosphate or calcium lactate gluconate in combination with sodium chloride" because "Tancredi, Phillips and Gerstner teach that the use of . . . said compounds allow[s] . . . remineralization of the tooth enamel, provid[es] increas[ed] concentration of calcium, and/or control[s] the taste of the compositions." *Id.* at 7 (emphasis omitted). Moreover, Examiner finds one of skill in the art would expect this combination to be beneficial because Gerstner teaches that calcium lactate gluconate has "high solubility in water" and would allow "(1) . . . high/increasing concentration of calcium in water, and/or (2) controlling the taste of the compositions." *Id.* at 11 (emphasis omitted).[6]

Appellant disputes Examiner's rejection for several reasons. First, Appellant contends Tancredi, Phillips, and Gerstner are each "directed

[6] Contrary to Appellant's assertion, this rationale for combining the cited prior art was presented in the Examiner's office action and, therefore, was not "newly presented" in Examiner's Answer. *See* Reply Br. 1.

towards a distinct field of endeavor from that of Boschetti" and, therefore, "there is no teaching or suggestion in such further cited references to use such further cited salts as components in the effervescent tablets of Boschetti." Appeal Br. 3. Second, Appellant argues Boschetti "teaches away from the use of powder compositions (see, e.g., paragraph [0016], [0019], [0020], and comparative Example 7), stating that solutions prepared from powder compositions are prone to precipitation in comparison to use of the described effervescent tablet compositions." *Id.* at 4. Finally, Appellant urges that

> the selection of the specific claimed calcium salts in combination with sodium phosphates as claimed overcomes a problem of precipitate formation in production of liquid compositions supersaturated with calcium and phosphate from powder compositions of such salts as demonstrated in the Examples 4c-4f, in comparison to use of other calcium salts (e.g., calcium chloride dihydride as used in Examples 4a-4b). Such demonstrated performance difference is not taught or suggested by any of Boschetti, Tancredi, Phillips or Gerstner, and the present claimed invention thus clearly would not have been obvious from the combination of such references.

Id. at 5.

We adopt the Examiner's findings of fact and reasoning regarding the scope and content of the prior art (Final Act. 4–11; FF1–FF7) and agree that the claims are obvious over Boschetti in combination with Tancredi, Phillips, and Gerstner. We address Appellant's arguments below.

We are not persuaded by Appellant's argument that Tancredi, Phillips, and Gerstner are directed to a different "field of endeavor" than Boschetti. *See* Appeal Br. 3. Like Boschetti, both Tancredi and Phillips describe orally-administered liquid compositions comprising calcium and phosphate

salts. FF4–FF6. Gerstner likewise describes calcium lactate gluconate as a source of calcium ions both in pharmaceutical compositions as well as fortified food products such as "instant preparations" where "solubility and clarity is important." FF7. Accordingly, the record supports that all the cited references are either "in the field of the applicant's endeavor" or "reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992).

We also determine that Examiner has articulated a sufficient rationale for modifying Boschetti's composition to include calcium lactate gluconate and sodium chloride. Boschetti teaches that both flavor and solubility are concerns for oral mouth rinse compositions. *See* FF1, FF3. As such, Gerstner evidences an express and compelling motivation to use calcium lactate gluconate as a calcium ion source because it "has the highest solubility of all commonly used calcium salts" as well as a "neutral taste." FF7. Tancredi similarly teaches the use of sodium chloride as a "flavor potentiator." FF4. Accordingly, the record supports that a skilled artisan would be motivated to combine the cited references for the reasons Examiner has articulated.

Appellant's argument that Boschetti teaches away from the use of a powder to form the recited liquid composition is likewise unpersuasive. As our reviewing court has observed, "[a] reference does not teach away . . . if it merely expresses a general preference for an alternative invention but does not criticize, discredit, or otherwise discourage investigation into the invention claimed." *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013) (quoting *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009)). Here, Boschetti

discloses compositions packaged as both an effervescent tablet and dissolvable powder (NeutraSal). FF1–FF3. Boschetti expresses a preference for its effervescent tablet formulation because "comparative studies performed by the present inventors" showed that "the dissolution of NeutraSal® yields an opalescent solution comprising insoluble particles." Boschetti ¶ 16; *see also id.* ¶¶ 119–122 (Ex. 7). Boschetti does not, however, discourage investigation into dissolvable powders generally. To the contrary, it discloses that NeutraSal is commercially-available as a dissolvable powder and teaches that such powders are "convenient in respect of packaging and storage costs."[7] *Id.* ¶ 16. In addition, the concern Boschetti identifies concerning insoluble particles is directly addressed by the articulated modification of Boschetti to employ a more soluble calcium salt, i.e., calcium lactate gluconate, as taught in Gerstner. Nothing in Boschetti teaches away from that combination. Indeed, a skilled artisan would reasonably expect that replacing the calcium salt used in a prior art powder like NeutraSal with a more soluble calcium salt would reduce the particulate observed in Boschetti's comparative dissolution study. For these reasons, and based on the record before us, we determine that Examiner's burden to establish a prima facie case of obviousness has been met. *See Oetiker*, 977 F.2d at 1445.

We are not persuaded by Appellant's argument that Examiner's prima facie case is overcome because Example 4 in the Specification demonstrates

[7] Appellant's Specification also describes NeutraSal as "commercially available" in the form of "a powder" that is dissolved in water to form a "liquid that is supersaturated with both calcium and phosphate ions." Spec. ¶ 3.

that use of the recited calcium salts "overcomes a problem of precipitate formation." *See* Appeal Br. 5–8. Example 4 purports to compare a "reference blend" comprising the ingredients in NeutraSal (Ex. 4a–b) to one with the same ingredients with the exception that calcium glycerophosphate is substituted for calcium chloride dihydrate (Ex. 4c–f). Spec. ¶¶ 39–50. According to the Specification, the results in Example 4 demonstrate that "the use of calcium glycerophosphate showed improved solubility in combination with dibasic sodium phosphate and led to a reconstituted turbid dispersion, but no . . . visible precipitates were observed." *Id.* ¶ 47. These results, however, are not commensurate with the scope of claim 14 because Examples 4c–f are limited to compositions containing calcium glycerophosphate. Thus, contrary to Appellant's argument, Example 4 does not evidence that the use of calcium lactate gluconate, as recited in claim 14, provides a "demonstrated performance difference" with respect to the prior art. *See* Appeal Br. 5; *see also In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005) (Evidence of alleged unexpected results must be "commensurate in scope with the degree of protection sought by the claims" to demonstrate non-obviousness.).

Moreover, even if we were to assume that the results in the Specification demonstrate that use of both of the recited calcium salts reduces precipitation as compared to prior art powders, such results would not be unexpected to one of ordinary skill in the art in light of Gerstner. As explained above, Gerstner specifically teaches the use of calcium lactate gluconate, in lieu of less soluble calcium salts, to achieve clear liquid compositions with higher calcium concentrations and improved taste. FF7. In this sense, the alleged improvement of the combination of ingredients

recited in claim 14 is nothing "more than the predictable use of prior art elements according to their established functions." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007). Such "[e]xpected beneficial results are evidence of obviousness" that do not overcome Examiner's prima facie showing. *See In re Gershon*, 372 F.2d 534, 537 (CCPA 1967) ("Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected beneficial results are evidence of unobviousness thereof.").

For these reasons, we determine the preponderance of the evidence supports Examiner's rejection of claim 14. Appellant does not argue any of the other claims separately from claim 14. Thus, we affirm Examiner's rejection of claims 12, 13, 15–18, and 33–44 for the same reasons. 37 C.F.R. § 41.37 (c)(1)(iv).

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
12–18, 33–44	103	Boschetti, Tancredi, Phillips, Gerstner	12–18, 33–44	

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