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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SCOTT M. BOYETTE, JUDITH GAYLE PRUITT, JOHN KNOPE, ADRIAN DENVIR, CHARLES GREENWALD and ALEX ERDMAN[1]

Appeal 2019-005016
Application 14/524,858
Technology Center 1600

Before DONALD E. ADAMS, ERIC B. GRIMES, and DAVID COTTA, *Administrative Patent Judges.*

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

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

We REVERSE.

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[1] Appellant identifies the real party in interest as NCH Corporation. Appeal Br. 4. We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a).

STATEMENT OF THE CASE

"Probiotics have been used in farm and agricultural applications for many years. . . . Some forms of commercially available DFM [direct-fed microbial] products contain bacterial spores, particularly *Bacillus* species, which are considered more stable and may have long shelf lives." Spec. ¶ 3. The Specification discloses "stabilized probiotic compositions . . . and method[s] for delivering the compositions to animals and plants, including delivering the compositions with acidified water to provide additional benefits." *Id*. ¶ 15.

Claims 1, 3, 5–8, 11–15, 54, 57, 63, 64, 66, and 68–83 are on appeal. Claims 1 and 73, reproduced below, are the only independent claims:

1. An orally ingestible probiotic suspension composition for treating animals, the composition comprising:

water;

one or more of *Bacillus pumilus*, *Bacillus licheniformis*, *Bacillus amylophilus*, *Bacillus subtilis*, *Bacillus clausii*, *Bacillus firmus*, *Bacillus megaterium*, *Bacillus mesentericus*, *Bacillus subtilis var. natto*, or *Bacillus toyonensis* in spore form;

one or more of citric, benzoic, sorbic, fumaric, or propionic acids or salts of these acids; and

a thickener;

wherein the composition comprises less than 1% total of the one or more acids or salts of acids by weight of the composition;

wherein the composition has a pH between 4.5 and 5.5; and

wherein all ingredients in the composition meet U.S. federal GRAS standards and the composition is storage stable with the bacteria remaining in spore form during storage for at least one month.

73. An orally ingestible probiotic suspension composition for treating animals, the composition consisting of:

1% to 10% of a bacteria spore blend containing salt and one or more of *Bacillus pumilus*, *Bacillus licheniformis*, *Bacillus amylophilus*, *Bacillus subtilis*, *Bacillus clausii*, *Bacillus firmus*, *Bacillus megaterium*, *Bacillus mesentericus*, *Bacillus subtilis var. natto*, or *Bacillus toyonensis* in spore form;

0.3% to 1% total of one or more acids or salts of acids; and

0.2% to 0.5% of a thickener;

0.1–0.3% sodium chloride, potassium chloride, or a combination thereof;

0.00005% to 3.0% of a surfactant; and

86.2% to 98.4% water;

wherein the composition has a pH between 4.5 and 5.5;

wherein all ingredients in the composition meet federal GRAS standards; and

wherein all percentages are by weight of the composition.

The claims stand rejected as follows:

Claims 1, 3, 5, 6, 11, 13–15, 54, 57, 63, 70–73, 76, 77, and 79–83 under 35 U.S.C. § 103(a) as obvious based on Reuter[2] and Chen,[3] as evidenced by Yeo[4] (Ans. 3, 19);

Claims 7, 8, 64, 66, 68, 69, 74, and 78 under 35 U.S.C. § 103(a) as obvious based on Reuter, Chen, and Draaisma[5] (Ans. 13, 22);

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[2] Reuter et al., US 2012/0100094 A1, published Apr. 26, 2012.
[3] Chen et al., WO 2009/126473 A1, published Oct. 15, 2009.
[4] Siok-Koon Yeo et al., *Antihypertensive Properties of Plant-Based Prebiotics,* International Journal of Molecular Sciences 10:3517–3530 (2009).
[5] Draaisma et al., WO 2012/079973 A1, published June 21, 2012.

Claim 12 under 35 U.S.C. § 103(a) as obvious based on Reuter, Chen, and Garbolino[6] (Ans. 18); and

Claim 75 under 35 U.S.C. § 103(a) as obvious based on Reuter, Chen, Draaisma, and Garbolino (Ans. 23).

OPINION

Obviousness: Reuter and Chen, as evidenced by Yeo

The Examiner finds that Reuter teaches a composition comprising stabilized *Bacillus* spores that is useful as a food or as a feed additive. Ans. 4. "Reuter teaches the organic acid (i.e., acetic acid) in the composition lowers the pH so the spores are inhibited from germination and growth." *Id*. The Examiner finds that Reuter teaches that other suitable acids include citric acid. *Id*.

The Examiner finds that "Reuter teaches a pH from about 3.8 to about 4.2," but also suggests "a low, yet spore-enabling pH of 5–6 allows spores 'to begin' their metabolic activity." *Id*. at 4–5. "Reuter teaches the acetic, or other organic acid, is used in an amount of 1%–5% or any amount suitable to obtain the desired pH." *Id*. at 5.

The Examiner finds that Reuter does not teach a concentration of acid of less than 1% but Chen discloses "a stable, aqueous formulation comprising a mixture of spores" and "teaches buffers can be added to regulate pH, said buffers including organic acids such as citric acid." *Id*. The Examiner also finds that Chen teaches that "[t]he amount of buffer added is dependent upon the preferred pH" and "may be present in the range of about

[6] Garbolino et al., US 2009/0041898 A1, published Feb. 12, 2009.

0.1% w/w to about 3% w/w." *Id*. The Examiner cites Yeo only with respect to dependent claim 54. *Id*. at 10.

The Examiner concludes that "[i]t would have been obvious to one of ordinary skill in the art to combine the teachings of Reuter and Chen to use less than 1% citric acid in the disclosed composition." *Id*. at 5. The Examiner reasons that "Reuter teaches citric acid is used to adjust the pH of the Bacillus composition. Reuter teaches a concentration of 1–5%, but teaches other concentrations may be use to achieve the desired pH." *Id*. The Examiner notes that Reuter "teaches the pH of the composition can be adjusted to a pH of 5–6," which overlaps the claimed pH range. *Id*. at 6. "Because citric acid would lower the pH of a composition, one would use less to raise the pH of the composition. One would do so since Reuter[] teaches the pH of the composition may be increased to stimulate the metabolic activity of the spores in the composition." *Id*.

Alternatively, the Examiner reasons that

> Reuter teaches a pH range between about 3.8 to about 4.2. While the art does not explicitly teach a pH between 4.5 and 5.5, a pH of 4.2 is interpreted to be sufficiently close enough to 4.5 that it would be expected to have the same properties. This is supported by Reuter, who teaches a pH of 4.2 maintains a sporastatic condition. The MPEP teaches a *prima facie* case of obviousness exists where the claimed range and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties.

Id.

Regarding claim 73, the Examiner acknowledges that "Reuter does not teach sodium chloride or potassium chloride in said composition. [Reuter] does not explicitly teach a surfactant." *Id*. at 21. The Examiner

finds that "Chen teaches preparation of a 'spore module' to produce a stable aqueous formulation." *Id*. at 19. "Chen teaches a spore module embodiment containing three ingredients: Bacillus firmus, Agnique (a surfactant) and potassium chloride. Therefore Chen discloses potassium chloride and a surfactant can be used with a composition containing Bacillus." *Id*. at 21. The Examiner finds that Chen teaches that both potassium chloride and surfactants are stabilizers. *Id*. "Therefore one would be motivated to add potassium chloride and a surfactant to the ingredients taught by Reuter to stabilize the probiotic composition." *Id*.

Appellant argues, among other things, that "both claims 1 and 73 require using less than 1% total of acids or salts of acids to achieve a pH of 4.5 to 5.5." Appeal Br. 13. Appellant argues that, "as shown by examples in the present Application, the results of varying the amounts of acids in the composition are not predictable." *Id*. at 14. Appellant points out that "Examples 1 and 2 of the Application used 1% total of potassium sorbate, citric acid, and sodium benzoate, but had pH values around 2.2," even though the total amount of acids in those examples was at the low end of the range taught by Reuter. *Id*.

Appellant also points out that "Examples 3 and 8 of the Application used 0.3% total of potassium sorbate, citric acid, and sodium benzoate, resulting in pH values of 6.6 and 4.5+/- 0.2, respectively." *Id*. Appellant argues that "[t]he differing pH levels using the same amounts of the same acids further indicates th[at] there is no reasonable expectation of success in simply modifying the amount of acid used or that the results of such modification would be predictable." *Id*. Thus, Appellant argues, "the

requisite expectation of success or predictability in combining Reuter and Chen is missing." *Id*.

We agree with Appellant that the evidence of record does not support a prima facie case of obviousness for a composition as defined by claim 1; specifically, a composition having a pH between 4.5 and 5.5 *and* less than 1% total of citric, benzoic, sorbic, fumaric, or propionic acid(s) or salts thereof.

Reuter discloses a method comprising suspending "*Bacillus* spores in a liquid consisting essentially of water and acetic acid, wherein the acetic acid lowers the pH so that the spores are inhibited from germination and growth." Reuter ¶ 9. Reuter states that "[o]ther acids suitable for the purposes of the methods and compositions of the invention include . . . lactic-, citric-, succinic-, malic-, and formic acid, and the like." *Id*. ¶ 42.

"[T]he one or more organic acids lower the pH of the liquid (e.g., to about 3.8 to about 4.2) so that the *Bacillus* spores are inhibited from germination and growth." *Id*. ¶ 18. Reuter states:

> In any aspect of the invention comprising a suspending step, in a particular embodiment of the present invention the pH in the suspending step is lowered to a pH from about 3.8 to about 4.2. In another, the acetic acid (or other acids) in said liquid in the suspending step is at a concentration of 1 to 5% or any amount suitable to obtain a desired pH.

Id. ¶ 23.

Reuter discloses that, in addition to preventing growth of *Bacillus* spores, the acid in its composition provides an ammonia-reducing effect, because ammonia generated by animal waste neutralizes the acetic acid in the composition. *Id*. ¶ 35. The *Bacillus* spores become active when "the

organic acid is completely or substantially neutralized," after which the enabled *Bacillus* provide additional ammonia-reducing effect. *Id*.

Reuter discloses that,

> when the initial amount of present ammonia is low and/or the expected generation rate of ammonia is low, it may be desirable to partially neutralize the *Bacillus* suspension (e.g., to a low, yet spore-enabling pH of about 5–6 or 5–7) so that the spores can begin their metabolic activity while the composition retains some acidity capable of neutralizing further ammonia.

Id. Reuter states that

> [s]uch partial neutralization can be performed by adding a neutralizing base to the suspension prior to application or by buffering the suspension (e.g., to a pH of about 5–6 or 5–7, for example including sodium, alkali metal, or other salts of the organic acid(s) or common buffer systems such as bicarbonate, phosphate, etc.) prior to application.

Id.

Thus, Reuter suggests lowering the pH of its composition to between 3.8 and 4.2 using a concentration of an organic acid (such as citric acid) in the range of 1–5%, "or any amount suitable to obtain a desired pH." *Id*. at 23. Reuter also suggests, for certain uses, partially neutralizing the composition to raise its pH to 5–6 or 5–7 by adding a neutralizing base or a salt of the organic acid as a buffer. *Id*. at 35. Reuter does not expressly suggest adjusting the pH of its composition to between 4.5 and 5.5 by using a concentration of, for example, citric acid of less than 1%.

For its part, Chen discloses a "stable aqueous formulation" comprising Bacillus spores and having "a pH of 2.5 to 9.5." Chen ¶ 28. Chen states that "[b]uffers can be added to regulate pH and include organic acids, such as citric acid and ascorbic acid, as well as inorganic acids such as hydrochloric

acid or sulfuric acid." *Id*. ¶ 70. "When utilized, buffers may be present in the range of about 0.1% w/w to about 3% w/w." *Id*. ¶ 71. "The amount of buffer added is dependent upon the preferred pH which, in turn, depends on the stability and dormancy of the bacterial spore utilized." *Id*. ¶ 70.

Thus, Chen discloses that organic acids, including citric acid, can be used as buffers in concentrations that include the claimed range, but discloses only a broad pH range of 2.5–9.5, without describing specific buffer concentrations to achieve specific pH values. In particular, it does not state that a concentration of less than 1% citric acid produces a composition having a pH of 4.5 to 5.5, as required by claim 1.

As Appellant points out, the Specification's examples provide evidence that the amount of organic acids in the claimed composition has an unpredictable effect on its pH. The Specification presents eight "examples of probiotic compositions according preferred embodiments of the invention [that] were made and tested for different parameters." Spec. ¶ 29.

"Each formula was targeted to have a pH between about 4.0 and 5.5, but some formulas were found to have actual pH values far less than expected." *Id*. at 31. Specifically, formulas 1 and 2 both contained 0.33% potassium sorbate, 0.34% citric acid, and 0.33% sodium benzoate, for a total of 1% of the acids or salts thereof recited in claim 1. *Id*. ¶ 30.[7] The Specification states that "Formula No. 1 was targeted to have a pH between 5.0 and 5.5, but its actual pH was around 2.1–2.3, which is too low. . . . Formula No. 2 had an actual pH of around 2.2–2.3." *Id*. ¶ 31.

[7] "Formula No. 2 is the same as No. 1, except the source of water is different." *Id*. ¶ 31.

The Specification states that "[t]he amount of acids and salts of acids in Formula No. 3 was decreased to raise the pH." *Id*. Formula 3 contained 0.1% each of potassium sorbate, citric acid, and sodium benzoate. *Id*. ¶ 30. "[I]ts actual pH was 6.6, over the target value range." *Id*. ¶ 31. "The amount of acid in Formula No. 5 was substantially increased" as compared to formula 3, by increasing the citric acid to 5.0% and adding 10% sodium propionate. *Id*. ¶¶ 30, 31. This "resulted in an actual pH of around 1.0." *Id*. ¶ 31. The Specification states that formula 8, with 0.1% each of potassium sorbate, citric acid, and sodium benzoate "is the most preferred as it . . . had an actual pH of around 4.5 +/- 0.2." *Id*.

Thus, the Specification's examples demonstrate that formulas 1 and 2, which contained 1% total of the acids or salts thereof recited in claim 1, and which were targeted to have a pH of 4.0–5.5, actually had a pH of 2.1–2.3, much lower than expected. These examples thus demonstrate that a composition cannot be presumed to have a pH within the range recited in claim 1 simply because it has 1% or less of the recited acids or salts thereof.

The Specification's formulas 3 and 8 further demonstrate that the effect on pH of a given amount of acids or salts thereof is unpredictable. These formulas both contain 0.1% each of potassium sorbate, citric acid, and sodium benzoate, and differ only in the following components: formula 3 contains 0.2% xanthan gum, and no sodium chloride or potassium chloride; while formula 8 contains 0.5% xanthan gum, 0.2% sodium chloride, and 0.1% potassium chloride. Spec. ¶ 30.

The Examiner has not pointed to evidence or provided any technical explanation of why the amount of xanthan gum, sodium chloride, or

potassium chloride would be expected to affect the pH of a spore-containing composition, but the Specification discloses that formula 3 had a pH of 6.6, while formula 8 had a pH of 4.5. These examples thus provide evidence that two spore-containing compositions cannot be presumed to have the same pH simply because they comprise the same amounts of the same acids or salts thereof, if those compositions differ in other constituents.

In summary, Reuter provides a reason to make compositions containing Bacillus spores and having a pH of 5–6, and suggests achieving a desired pH using citric acid (among other organic acids) or salts thereof. Reuter ¶¶ 35, 42. However, neither Reuter nor Chen provide a basis for reasonably expecting that the resulting composition would contain less than 1% of the acids or salts thereof that are recited in claim 1, in view of the evidence of unpredictability provided by Appellant's Specification.

A prima facie case of obviousness requires evidence that a skilled artisan would have had a reason to combine prior art teachings in a way that results in the *claimed* invention; i.e., a product meeting *all* of the claim limitations. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) ("[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does."). For the reasons discussed above we conclude that the evidence does not support a reasonable expectation that combining Reuter and Chen, as posited by the Examiner, would result in a composition having *both* a pH of 4.5 to 5.5 and less than 1% total of the acids or salts of acids recited in claim 1.

With regard to the Examiner's alternative reasoning—that "a pH of 4.2 is interpreted to be sufficiently close enough to 4.5 that it would be expected to have the same properties" (Ans. 6)—we agree with Appellant's position that the Examiner has not provided sufficient evidence to support a conclusion of obviousness. *See* Appeal Br. 19–20. As Appellant points out, and the Examiner does not dispute, pH is measured using a logarithmic scale, so one pH unit corresponds to a ten-fold change in acidity. The Examiner has provided no evidence or technical reasoning to support the position that a change of pH from 4.2 to 4.5 would not change the properties of a composition.

The Examiner relies on the same reasoning for claim 73 as for claim 1 with regard to the amount of acid and pH range of the composition. Ans. 19–22. For the reasons discussed above, we reverse the rejection of independent claims 1 and 73, as well as dependent claims 3, 5, 6, 11, 13–15, 54, 57, 63, 70–72, 76, 77, and 79–83, under 35 U.S.C. § 103(a) based on Reuter and Chen, with evidence provided by Yeo.

Obviousness: Reuter, Chen, and Draaisma and/or Garbolino

The Examiner rejected claims 7, 8, 64, 66, 68, 69, 74, and 78 as obvious based on Reuter, Chen, and Draaisma; claim 12 as obvious based on Reuter, Chen, and Garbolino; and claim 75 as obvious based on Reuter, Chen, Draaisma, and Garbolino. Ans. 13, 18, 22, 23.

For each of these rejections, the Examiner relies on the conclusion, discussed above, that Reuter and Chen would have made obvious the composition of independent claims 1 and 73. The Examiner relies on

Draaisma and Garbolino only with respect to the additional limitations of the dependent claims. *Id*. at 13–19, 22–24.

Therefore, the rejections based on Reuter and Chen combined with Draaisma and/or Garbolino suffer from the same deficiency discussed above with respect to the rejection based on Reuter and Chen (with evidence provided by Yeo), and are reversed for the same reason.

DECISION SUMMARY

In summary:

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
1, 3, 5, 6, 11, 13–15, 54, 57, 63, 70–73, 76, 77, 79–83	103(a)	Reuter, Chen, Yeo		1, 3, 5, 6, 11, 13–15, 54, 57, 63, 70–73, 76, 77, 79–83
7, 8, 64, 66, 68, 69, 74, 78	103(a)	Reuter, Chen, Draaisma		7, 8, 64, 66, 68, 69, 74, 78
12	103(a)	Reuter, Chen, Garbolino		12
75	103(a)	Reuter, Chen, Draaisma, Garbolino		75
Overall Outcome				1, 3, 5–8, 11–15, 54, 57, 63, 64, 66, 68–83

REVERSED