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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* DAVID G. DAVIES<sup>1</sup>

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Appeal 2018-003106  
Application 13/945,207  
Technology Center 1600

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Before ERIC B. GRIMES, RACHEL H. TOWNSEND, and  
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

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

We REVERSE.

STATEMENT OF THE CASE

“[N]atural and artificial chemical agents are unable to adequately attack and destroy infectious biofilm populations.” Spec. ¶ 4. “The present

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<sup>1</sup> Appellant identifies the real party in interest as the Research Foundation for the State University of New York. Appeal Br. 1. We use the word Appellant to refer to “applicant” as defined in 37 C.F.R. § 1.42(a).

invention addresses the ‘biofilm problem’ by artificially inducing bacteria to undergo physiological process of biofilm dispersion.” *Id.* ¶ 28. “The examples of situations in which artificial dispersion would be of benefit include improved cleaning of . . . teeth.” *Id.* The Specification discloses that dispersion inducers include cis-2-decenoic acid. *Id.* ¶¶ 88–90.

Claims 21, 22, 24, and 26–28 are on appeal. Claim 21, reproduced below, is illustrative:

21. A dentifrice composition comprising:

cis-2-decenoic acid, wherein the concentration of cis-2-decenoic acid in the composition is 0.001  $\mu$ M to 30  $\mu$ M,

said dentifrice composition being selected from the group consisting of breath spray, tooth powder, whitening strips, prophylaxis strips, breath strips, lozenges, and breath mints.

All of the other claims on appeal also are directed to a type of oral care (dentifrice, mouthwash, or toothpaste) composition comprising 0.001  $\mu$ M to 30  $\mu$ M cis-2-decenoic acid.

The claims stand rejected as follows:

Claims 21, 22, 24, and 28 under 35 U.S.C. § 103(a) as obvious based on Thiele<sup>2</sup> as evidenced by McDonnell<sup>3</sup> (Ans. 2) and

Claims 26 and 27 under 35 U.S.C. § 103(a) as obvious based on Thiele and Burzynski<sup>4</sup> (Ans. 4).

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<sup>2</sup> US 4,442,125, iss. Apr. 10, 1984.

<sup>3</sup> Gerald McDonnell et al., *Antiseptics and Disinfectants: Activity, Action, and Resistance*, *Clinical Microbiology Reviews* 12(1): 147–179 (1999).

<sup>4</sup> US 2004/0241107 A1, pub. Dec. 2, 2004.

OPINION

All of the claims on appeal stand rejected under 35 U.S.C. § 103(a) as obvious based on Thiele, by itself (as evidenced by McDonnell), or combined with Burzynski. The same issue is dispositive for both rejections.

The Examiner finds that “Thiel[e] teaches a composition for preventing microorganisms . . . from attaching to a surface by causing a dispersion of the microorganisms in the body fluids.” Ans. 2. The composition can be a dentifrice. *Id.* at 3. The Examiner finds that Thiele’s composition comprises a fatty acid having one double bond (i.e., monoethenoid), “includ[ing], *inter alia*, 2-decenoic acid (col 6, line 41) and wherein a preferred isomeric form of the monoethenoid fatty acid is cis (‘trans isomers . . . do not give anywhere as good results’).” *Id.*

The Examiner finds that “Thiel[e] further teaches that the fatty acid ranges from 0.5 to about 10 percent by weight of the composition (col 10, lines 1–4) and can be modulated based on the threshold or dose-related effect.” *Id.* The Examiner cites McDonnell as evidence that the ethanol in Thiele’s composition is an antimicrobial agent. *Id.*

The Examiner concludes that it would have been obvious to select[] cis-2-decenoic acid as a monoethenoid fatty acid and optimiz[e] the concentration to 0.001  $\mu\text{M}$  to 30  $\mu\text{M}$  because Thiel[e] teaches that the concentration of the fatty acid component is a result-effective variable for determining optimum or workable ranges by routine experimentation based on the threshold or dose-related effect of the specific microorganism.

*Id.* at 4.

Appellant argues, among other things, that the Davies Declaration<sup>5</sup> presents evidence that “[t]he claimed concentrations of cis-2-decenoic acid are 0.001  $\mu$ M to 30  $\mu$ M, are between 3 and 7 *orders of magnitude* less than the concentrations of Thiele.” Appeal Br. 20–21. Appellant argues that “[a] person of ordinary skill would not, based on Thiele, have *expected* that any fatty acid, let alone cis-2-decenoic acid, would have had a significant effect on bacteria at a concentration below 30  $\mu$ M, three orders of magnitude below the minimum concentration suggested by Thiele as being effective.” *Id.* at 21.

We agree with Appellant that the Examiner has not shown that it would have been obvious to formulate Thiele’s composition to comprise 0.001–30  $\mu$ M cis-2-decenoic acid with a reasonable expectation of success. Thiele discloses “a process for preventing and/or retarding microbes from attaching or reattaching to surfaces.” Thiele 3:5–7. Thiele’s process uses a composition comprising a fatty acid salt “prepared from an unsaturated fatty acid having one double bond and from an alkali metal, alkaline earth metal,” etc. *Id.* at 3:23–25. Thiele discloses that one suitable fatty acid is 2-decenoic acid. *Id.* at 6:41. (Appellant disputes whether a skilled artisan would have considered 2-decenoic acid, or the cis isomer thereof, to be obvious choices based on Thiele’s disclosure, but for the reasons discussed below, we find it unnecessary to address those issues.)

Thiele states that “[t]he liquefied composition should contain between about 0.5 to 1 and about 10 percent by weight of the fatty acid salt and usually contains between 4 and 6 percent by weight of the fatty acid salt.”

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<sup>5</sup> Declaration under 37 C.F.R. § 1.132 of David G. Davies, filed June 21, 2016.

*Id.* at 10:1–4. Thus, Thiele suggests using a minimum of 0.5% by weight of a fatty acid salt (e.g., a salt of 2-decenoic acid) in its composition, while the claims on appeal are limited to a maximum of 30  $\mu\text{M}$  cis-2-decenoic acid.

The Davies Declaration states that the “0.5 to 10 percent by weight of a fatty acid salt . . . concentrations of Thiele correspond to” between 29,388.6 and 587,371.6  $\mu\text{M}$  for cis-2-decenoic acid. Davies Decl. ¶ 15. Dr. Davies states that “[t]he claimed concentrations of cis-2-decenoic acid are . . . between 3 and 7 *orders of magnitude* less than the concentrations of Thiele.” *Id.*

In response, the Examiner states that

it is unclear how Appellant determined the specific micromolar concentrations of cis-2-decenoic acid of Thiel[e] based on the exemplary fatty acid weight percentages of Thiel[e] without considering the molecular weight of the other remaining components of the composition (e.g., thickeners and other excipients; see, e.g., col 11, lines 1–35) and the final density of the composition.

Ans. 14. The Examiner concludes that “the data proved in Table 1 in the Davies Declaration and the data in Appellant’s arguments is based on assumptions and unsubstantiated facts that are improper for rebutting the *prima facie* case of obviousness.” *Id.* at 15.

However, the Examiner has not pointed to evidence or provided persuasive technical reasoning showing that the sources of potential error he points to in Appellant’s calculation would result in the converted values being three orders of magnitude—a thousand times—higher than they should be. Nor has the Examiner provided an alternative calculation showing that Thiele’s 0.5% by weight minimum is close to the claims’ 30  $\mu\text{M}$  maximum.

In essence, the Examiner reasons that, because Thiele discloses that a range of fatty acid salt concentrations can be used, a skilled artisan would recognize that fatty acid salt concentration is a result-effective variable; thus, it would have been obvious to use *any* concentration, no matter how different from Thiele's expressly described range, as a matter of routine optimization. *See* Ans. 15–16. This position is not consistent with the Examiner's burden of showing *prima facie* obviousness.

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness.” *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). “[A] proper analysis under § 103 requires, *inter alia*, consideration of . . . [whether] those of ordinary skill would have had a reasonable expectation of success.” *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). “[T]he reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure.” *Id.*

A desire to optimize result-effective variables does not negate the requirement for a reasonable expectation of success. It is true that, “where *the general conditions of a claim* are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) (emphasis added). The “general conditions of a claim,” however, include the values of the parameters recited in a claim. *See In re Applied Materials*, 692 F.3d 1289, 1295 (Fed. Cir. 2012) (“In the present case, because the prior art disclosed values overlapping the claimed ranges, the ‘general conditions’ of the claim are disclosed.”).

The court has stated that a *prima facie* case of obviousness can exist even when the claimed and prior art values do not overlap, but even then

they must be “close enough such that one skilled in the art would have expected them to have the same properties.” *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003). Thus, the burden remains on the Examiner to show that the prior art would have suggested the claimed conditions to a skilled artisan.

Where, as here, the Examiner has not presented a basis for concluding that the amounts recited in the reference are comparable to the amounts required by the claims, and Appellant has presented calculations showing that the claimed and prior art amounts differ by at least a thousand-fold, “routine optimization” alone cannot be relied on to show that the claimed amount of cis-2-decenoic acid would have been obvious to a skilled artisan. We conclude that the Examiner has not shown that a skilled artisan would have had a reasonable expectation of success in modifying Thiele’s composition to comprise 0.001–30  $\mu$ M cis-2-decenoic acid, as claimed.

The Examiner has not pointed to any disclosure in McDonnell or Burzynski that remedies the deficiency in Thiele. We therefore reverse the rejection of claims 21, 22, 24, and 28 under 35 U.S.C. § 103(a) based on Thiele as evidenced by McDonnell, and the rejection of claims 26 and 27 under 35 U.S.C. § 103(a) as obvious based on Thiele and Burzynski.

DECISION SUMMARY

In summary:

<b>Claims Rejected</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>	<b>Affirmed</b>	<b>Reversed</b>
21, 22, 24, 28	103(a)	Thiele, McDonnell		21, 22, 24, 28
26, 27	103(a)	Thiele, Burzynski		26, 27
<b>Overall Outcome</b>				21, 22, 24, 26–28

REVERSED