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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LYNDSAY SCHAEFFER-KORBYLO
and JORGE FRIAS-LOPEZ

Appeal 2019-006477
Application 14/777,461
Technology Center 1600

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and TAWEN CHANG, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from Examiner's decision to reject claims 1–16, 25–28, 30, and 31 (*see* Final Act.[2] 2).[3] 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. Appellant identifies the real party in interest as "Colgate-Palmolive Company" (Appellant's March 4, 2019 Appeal Brief (Appeal Br.) 2).

[2] Examiner's October 4, 2018 Final Office Action.

[3] Appellant's pending claims 1–15 and 26 stand withdrawn from consideration (*see* Final Act. 2).

STATEMENT OF THE CASE

Appellant's disclosure "relates to oral care compositions containing deoxy sugar antimetabolites and methods of inhibiting microbial biofilm formation and/or degrading a microbial biofilms" (Spec.[4] ¶ 12). Appellant's claims 16 and 31 are reproduced below:

> 16. An oral care composition for inhibiting microbial biofilm formation and/or degrading a microbial biofilm in the oral cavity of a subject comprising a deoxy sugar antimetabolite wherein the deoxy sugar antimetabolite is present in the composition at a concentration of from 0.005% to 0.7 % based on the total weight of the composition and wherein the deoxy sugar antimetabolite is selected from the group consisting of 6-deoxy-D-glucose, 2-fluoro-2-deoxy-D-glucose, 2-amino-2-deoxy-D-mannosamine and mixtures thereof; an orally acceptable carrier for a toothpaste, a dental cream, a mouthwash, a chewing gum or a denture adhesive;
>
> one or more of agents selected from the group consisting of an anti-plaque agent, a whitening agent, cleaning agent, a flavoring agent, a sweetening agent, adhesion agents, surfactants, foam modulators, abrasives, pH modifying agents, humectants, mouth feel agents, colorants, abrasive, tartar control (anticalculus) agent, fluoride ion source, saliva stimulating agents, an antisensitivity agent, an antioxidant agent, nutrients, viscosity modifiers, diluents, opacifiers, breath freshening agents and zinc salts and combinations thereof; and
>
> does not contain an additional antibacterial agent.

(Appeal Br. 16.)

> 31. The method of claim 16, wherein the deoxy sugar antimetabolite is selected form the group consisting of 6-deoxy-D-glucose, 2-amino-2-deoxy-D-mannosamine and mixtures thereof.

(*Id.* at 17.)

[4] Appellant's September 9, 2015 Specification.

Grounds of rejection before this Panel for review:

Claims 16, 25, 27, 28, and 30 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Dills[5] and Gaffar.[6]

Claim 31 stands rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Dills, Gaffar, Dashper,[7] and Toner.[8]

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 1. Dills "relates to an anticaries composition for inhibiting the carbohydrate induced production of acid by human dental plaque bacteria, thereby reducing the incidence or severity of human dental caries" (Dills 1: 2–5; *see id.* at ll. 22–26 (Dills' "composition for reducing the incidence or severity of human dental caries, the composition comprising fluoride ion and a nonmetabolizable analogue of a cariogenic carbohydrate, in association with a pharmaceutically acceptable carrier"); *see generally* Final Act. 3).

FF 2. Dills defines "[t]he term 'nonmetabolizable analogue of a cariogenic carbohydrate' (hereinafter, cariogen analogue) . . . [as] a structural analogue of a cariogen which does not support detectable growth within 24 hours of

[5] Dills, EP 0 055 109 A2, published June 30, 1982.
[6] Gaffar, US 4,143,126, issued Mar. 6, 1979.
[7] Dashper et al., *Characterization of Transmembrane Movement of Glucose and Glucose Analogs in Streptococcus mutans Ingbritt*, 172 (2) *J. Bacteriology* 556–63 (1990).
[8] Toner et al., US 2007/0042339 A1, published Feb. 22, 2007.

acidogenic human plaque bacteria when cultured under standard laboratory conditions" (Dills 2: 9–14).

FF 3. Dills discloses:

> the use of a combination of fluoride ion and a cariogen analogue, the fluoride constituent being present at a concentration which is noninjurious to a human hos[t], will effectively inhibit the cariogen induced acid production of human dental plaque bacteria thereby reducing the incidence of and severity of human dental caries. It has further been discovered that when utilized in combination, each constituent may be present at a concentration where neither would be a clinically efficacious anti-caries agent if utilized alone.

(Dills 3: 2–13; *see* Final Act. 6.)

FF 4. Dills discloses that "[m]any cariogen analogues are known and may be used in the practice of [its] invention" and specifically exemplifies, *inter alia*, 2-fluoro-2-deoxy-D-glucose, 2-deoxy-D-glucose, and glucosamine as cariogen analogues within the scope of its disclosure, wherein Dill prefers 2-deoxy-D-glucose and glucosamine (Dills 7: 13–34; *see* Final Act. 4–5).

FF 5. Dills discloses that its "combination [of fluoride ion and cariogen analogue] may be added to any standard preparation normally used in the mouth; such as mouth rinses, mouth washes, mouth deodorizers, gargles, toothpastes, tooth powders and the like" (Dills 8: 11–20; *see* Final Act. 4).

FF 6. Dills exemplifies the following dentifrice formulation:

Dicalcium phosphate	45 %
Glycerine	8 %
Detergent	10 %
Whitener	1 %
Flavor including sweetener	1 %
Thickener and emulsifiers	17 %
Sodium Fluoride	1.5%
2-deoxy-D-glucose	.8%
Water	q.s.
	100 %

(Dills 9: 24–34; *see* Final Act. 3–4 (Examiner finds that dicalcium phosphate is an abrasive and glycerine is a humectant); *see also id.* at 4 (Examiner finds that Dills discloses that detergent is "an optional component . . . and therefore, to the extent that a 'detergent,' as listed in Dills' exemplary embodiment encompasses[an] antibacterial agent[] . . . [it] may be excluded from Dills' exemplary embodiment as an optional ingredient"); *see id.* (citing Gaffar 1: 55–57) (Examiner finds that Gaffar supports a finding that glycerine is a dental humectant").)

FF 7. Dills discloses that the preferred concentration range for the fluoride ion component is "25 mmolar to 50 mmolar" and for the cariogen analogue component is "10 mmolar to 100 mmolar" (Dill 9: 9–12; *see* Final Act. 6 (Examiner finds that a 2-deoxy-D-glucose concentration of 10 mmolar to "corresponds to 0.16 wt.% to 1.64 wt.% (assuming a composition, i.e., 'comp.' density of 1 g/L" (emphasis omitted)))).

FF 8. Examiner finds that Dills does not provide "a specific exemplary embodiment containing 2-fluoro-2-deoxy-D-glucose . . . [or] a 'deoxy sugar antimetabolite'" (Final Act. 4; *see also id.* at 12).

FF 9. Examiner finds that Dashper and Toner both discloses that 6-deoxy-D-glucose and 2-deoxy-D-glucose are nonmetabolizable sugar analogs (Final Act. 13 (citing Dashper 556 and 559); *see also* Final Act. 13 (citing Toner ¶¶ 13 and 16)).

ANALYSIS

The rejection over the combination of Dills and Gaffar:

Based on the combination of Dills and Gaffar, Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious to substitute 2-fluoro-2-deoxy-D-glucose for the 2-deoxy-D-

glucose in Dills' exemplary dentifrice composition, because Dills discloses that 2-fluoro-2-deoxy-D-glucose and 2-deoxy-D-glucose are both nonmetabolizable sugar, or cariogen, analogues within the scope of its disclosure (Final Act. 4–5; *see* FF 1–6). Examiner further reasons that the claimed deoxy sugar antimetabolite range, of 0.005 to 0.7 %, is prima facie obvious in view of the overlapping range, of 0.16 to 1.64 wt.%, that Dills discloses for the nonmetabolizable sugar, or cariogen, analogue component of its composition (*see* FF 7; *cf.* Appeal Br. 16). *See In re Geisler*, 116 F.3d 1465, 1468 (Fed. Cir. 1997) (Overlapping ranges support a prima facie case of obviousness.). Examiner further reasons that because Dills' nonmetabolizable sugar analogue is an active agent in its composition it would have been prima facie obvious to determine the optimum or workable range of nonmetabolizable sugar analogue by routine experimentation (*see* Final Act. 6–7). *See In re Aller*, 220 F.2d 454, 456 (CCPA 1955) ("[W]here 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.").

Appellant's claim 16 is not limited to the use of 6-deoxy-D-glucose or 2-amino-2-deoxy-D-mannosamine, therefore, we are not persuaded by Appellant's contentions regarding these two nonmetabolizable sugar analogues (*see* Appeal Br. 5).

With respect to the claimed 2-fluoro-2-deoxy-D-glucose, Dills expressly identifies this sugar as a nonmetabolizable sugar analogue and, as discussed above, discloses a concentration range for the nonmetabolizable sugar analogue, which may be optimized through routine experimentation (*see* FF 4). Therefore, we are not persuaded by Appellant's contention that

"Dills does not disclose any composition comprising 2-fluoro-2-deoxy-D-glucose and does not teach or suggest anything regarding the concentration of 2-fluoro-2-deoxy-D-glucose in a composition" (Appeal Br. 5). *See In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976) (A reference disclosure is not limited only to its preferred embodiments, but is available for all that it discloses and suggests to one of ordinary skill in the art.); *see also In re Susi*, 440 F.2d 442, 446 n.3 (CCPA 1971) (Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments.).

Dills discloses a "composition comprising fluoride ion and a nonmetabolizable analogue of a cariogenic carbohydrate" that is useful "for reducing the incidence or severity of human dental caries" (FF 1). In this regard, Dills discloses that when the fluoride ion and nonmetabolizable analogue of a cariogenic carbohydrate are "utilized in combination, each constituent may be present at a concentration where neither would be a clinically efficacious anti-caries agent if utilized alone" (FF 3). Therefore, we are not persuaded by Appellant's contention that because the data in its Specification shows that 0.01% 2-fluoro-2-deoxy-D-glucose is not an effective antibacterial agent, "one of skill in the art would not [have been] motivated to add a low amount (0.005%-0.7%) of 2-fluoro-2-deoxy-D-glucose into the [Dills'] anticaries composition with a reasonable expectation of success that such a low amount of 2-fluoro-2-deoxy-D-glucose would be effective in reducing dental caries" (Appeal Br. 5; *see also id.* at 7 (Appellant contends that "one of skill in the art would not be motivated to add a low amount (0.005%-0.7%) of 2-fluoro-2-deoxy-D-glucose, which has a high biofilm inhibition activity but has a low bacterial

reduction activity, into the [Dills'] anticaries composition"); Reply Br. 3–4). A person of ordinary skill in this art would have had reason to include the sugar with the fluoride ion because Dill expressly teaches that they are synergistic. Stated differently, although a specific amount of the sugar may not have been effective, Dill teaches that its combination with a fluoride ion yields a synergistic result.

For the same reason, we are not persuaded by Appellant's asserted unexpected result, wherein "0.01% 6-deoxy-D-glucose and 2-fluoro-2-deoxy-D-glucose display biofilm inhibition far greater than what would have been predicted from their bacterial reduction" (Appeal Br. 6; *see also* Reply Br.[9] 3). The results for the single, 0.01%, concentration tested by Appellant is not commensurate in scope with the range of: (a) from 0.005% to 0.7% set forth in Appellant's claim 16 or (b) from 0.16 wt.% to 1.64%, disclosed by Dills, the closest prior art, which overlaps Appellant's claimed range. *See In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011) (In order to be persuasive of non-obviousness, "[e]vidence of secondary considerations must be reasonably commensurate with the scope of the claims."); *see also In re Baxter-Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991) ("[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art.").

Further, as Examiner explains, Appellant's evidence of unexpected results relates to the use of a single ingredient of its claimed composition, i.e. 2-deoxy-D-glucose, 6-deoxy-D-glucose, or 2-fluoro-2-deoxy-D-glucose,

[9] Appellant's August 28, 2019 Reply Brief.

which is neither commensurate in scope with its claimed invention or a comparison against the closest prior art, Dills (*see* Ans.[10] 10; *cf.* Spec. ¶ 105). In this regard, Examiner explains, both Appellant's claimed invention and Dills encompass compositions comprising a nonmetabolizable sugar analogue in combination with a fluoride ion source (*see* Ans. 10; Spec. ¶¶ 121–122; FF 1–8).

Thus, for the foregoing reasons, we are not persuaded by Appellant's contention that "the composition containing 0.01% 2-deoxy-D-glucose in Example 1 of [Appellant's Specification] . . . is more closely related to the claimed composition than Dills' composition" (Appeal Br. 6) or that a comparison against a composition comprising a fluoride ion is not required because Appellant's "[c]laim 16 does not require sodium fluoride as an essential component" (Reply Br. 5).

Appellant also fails to provide an evidentiary basis on this record to support a finding that a composition, within the scope of Dills, comprising 0.8% 2-deoxy-D-glucose is *not* capable of maintaining a healthy microflora. Therefore, we are not persuaded by the assertions of Appellant's counsel that Appellant's

> data shows that 0.01% 2-deoxy-D-glucose causes 9.81% bacterial reduction, which is significantly higher than % bacterial reduction caused by 0.01% 6-deoxy-D-glucose (1.54%) and 0.01% 2-fluoro-2-deoxy-D-glucose (0%). If a higher (0.8%) amount of 2-deoxy-D-glucose as in Dills' composition is used, the reduction of bacteria would be increased even more. In contrast, Table 1 shows that 6-deoxy-D-glucose and 2-fluoro-2-deoxy-D-glucose show significantly less % bacterial reduction compared to 2-deoxy-D-glucose (1.54%, 0% vs 9.81%) but show a high biofilm inhibition. The

[10] Examiner's June 28, 2019 Answer.

> data demonstrates that the claimed amount of 6-deoxy-D-glucose and 2-fluoro-2-deoxy-D-glucose are effective and efficient inhibitors of biofilm formation and can also maintain healthy microflora, i.e., have a high biofilm inhibition efficacy (1644.81 and[]>>> 1000). These beneficial effects are unexpected.

(Appeal Br. 7.) Appellant did not provide evidence or a statement that the results are unexpected as asserted by counsel. *See In re Pearson*, 494 F.2d 1399, 1405 (CCPA 1974) ("Attorney's argument in a brief cannot take the place of evidence.").

"Where all structural elements of a claim exist in a prior art product, and that prior art product is capable of satisfying all functional or intended use limitations, the claimed invention is nothing more than an unpatentable new use for an old product." *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 654 (Fed. Cir. 2011). Therefore, we are not persuaded by Appellant's contention that "Dills does not disclose anything regarding the maintenance of healthy microflora or inhibition of biofilm" (Appeal Br. 7; *see also* Reply Br. 3) or that Appellant's "data demonstrates beneficial effects of 6-deoxy-D-glucose and 2-fluoro-2-deoxy-D-glucose over 2-deoxy-D-glucose at a low concentration (0.01%)" (Appeal Br. 8).

We decline to address Appellant's contentions regarding a species election, which were presented for the first time in Appellant's Reply Brief (*see* Reply Br. 2–3). *See Ex parte Borden*, 93 USPQ2d 1473, 1474 (BPAI 2010) (informative) ("[T]he reply brief [is not] an opportunity to make arguments that could have been made in the principal brief on appeal to rebut the Examiner's rejections, but were not.").

The rejection over the combination of Dills, Gaffar, Dashper, and Toner:

Based on the combination of Dills, Gaffar, Dashper, and Toner Examiner concludes that, at the time Appellant's invention was made, it would have been prima facie obvious to substitute the 2-deoxyglucose, nonmetabolizable sugar, component of Dills' dentifrice composition with the nonmetabolizable sugar, 6-deoxyglucose, suggested by Dashper and Toner (*see* Final Act. 13–14; *see also* FF 1–9).

Appellant recognizes that "Dashper and Toner disclose that 6-deoxyglucose is a nonmetabolizable glucose analogue" (Appeal Br. 8). Nonetheless, Appellant contends that the evidence of record fails to support a conclusion that 6-deoxyglucose is a "nonmetabolizable analogue of a cariogenic carbohydrate," as defined by Dills, because "[t]here is no teaching or suggestion anywhere in Dashper and Toner that a low amount (0.005%-0.7%) of 6-deoxy-D-glucose does not support detectable growth within 24 hours of acidogenic human plaque bacteria when cultured under standard laboratory conditions" (Appeal Br. 8–9; *cf.* FF 2). We are not persuaded. Appellant failed to establish an evidentiary basis on this record to support a conclusion that those of ordinary skill in this art would have reasonably expected that any amount of a glucose analogue that is *not capable of being metabolized* would support detectable growth within 24 hours of acidogenic human plaque bacterial when cultured under standard laboratory conditions.

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments. *In re Susi*, 440 F.2d at 446 n.3. On this record, Dills discloses compositions comprising fluoride ion and a nonmetabolizable glucose analogue (*see*, *e.g.*,

FF 1). Although Dills does not exemplify 6-deoxyglucose, the evidence of record teaches that 6-deoxyglucose is a nonmetabolizable glucose analogue (*see* FF 9; *see also* Appeal Br. 8 ("Dashper and Toner disclose that 6-deoxyglucose is a nonmetabolizable glucose analogue")). Therefore, we are not persuaded by Appellant's contention that because "Dills does not disclose or suggest 6-deoxyglucose as a cariogen analogue . . ., the ranges disclosed in Dills are not applied to 6-deoxy-D-glucose" (Appeal Br. 9; *see* Reply Br. 6).

Dills discloses a "composition comprising fluoride ion and a nonmetabolizable analogue of a cariogenic carbohydrate" that is useful "for reducing the incidence or severity of human dental caries" (FF 1). In this regard, Dills discloses that when the fluoride ion and nonmetabolizable analogue of a cariogenic carbohydrate are "utilized in combination, each constituent may be present at a concentration where neither would be a clinically efficacious anti-caries agent if utilized alone" (FF 3). Therefore, we are not persuaded by Appellant's contention that because the data in its Specification

> shows that 0.01% 6-deoxy-D-glucose [is] not [an] effective antibacterial agent[,] [o]ne of skill in the art would not [have been] motivated to add a low amount (0.005%-0.7%) of 6-deoxy-D-glucose into the [Dills'] anticaries composition with a reasonable expectation of success that such a low amount of 6-deoxy-D-glucose would be effective in reducing dental caries.

(Appeal Br. 9.)

For the reasons set forth above, we are not persuaded by Appellant's asserted unexpected results (Appeal Br. 9–10).

Appellant's claim 31 is not limited to a composition comprising 2-amino-2-deoxy-D-mannosamine, therefore, we are not persuaded by

Appellant's contention that because "[n]one of the cited references disclose or teach 2-amino-2-deoxy-D-mannosamine . . . [an] oral care composition comprising 2-amino-2-deoxy-D-mannosamine would not be *prima facie* obvious over the cited references" (*id.* at 10; *see also* Reply Br. 6).

CONCLUSION

The preponderance of evidence relied upon by Examiner supports a conclusion of obviousness.

The rejection of claims 16, 25, 27, 28, and 30 under 35 U.S.C. § 103(a) as unpatentable over the combination of Dills and Gaffar is affirmed. Claims 25, 27, 28, and 30 are not separately argued and fall with claim 16.

The rejection of claim 31 under 35 U.S.C. § 103(a) as unpatentable over the combination of Dills, Gaffar, Dashper, and Toner is affirmed.

DECISION SUMMARY

In summary:

Claims Rejected	**35 U.S.C. §**	**Reference(s)/Basis**	**Affirmed**	**Reversed**
16, 25, 27, 28, 30	103	Dills, Gaffar	16, 25, 27, 28, 30	
31	103	Dills, Gaffar, Dashper, Toner	31	
Overall Outcome			**16, 25, 27, 28, 30, 31**	

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).

AFFIRMED