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Table with 5 columns: APPLICATION NO., FILING DATE, FIRST NAMED INVENTOR, ATTORNEY DOCKET NO., CONFIRMATION NO.
11/256,861 10/24/2005 Harsh M. Trivedi 7443-00-OC 9991

23909 7590 11/21/2016
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Table with 1 column: EXAMINER
DAVIS, DEBORAH A

Table with 2 columns: ART UNIT, PAPER NUMBER
1655

Table with 2 columns: NOTIFICATION DATE, DELIVERY MODE
11/21/2016 ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte HARSH M. TRIVEDI, TAO XU,
CORTNEY L. WORRELL, and KIMBERLEE PANALIGAN

Appeal 2015-004326
Application 11/256,861
Technology Center 1600

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and
RYAN H. FLAX, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal¹ under 35 U.S.C. § 134 involving a method of treating an inflammatory condition of the oral cavity. The Examiner rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Statement of the Case

Background

“Dentifrices in the form of toothpaste, mouth rinses, chewing gums, edible strips, and the like have been formulated with a wide variety of active materials that provide a number of benefits to the user. Among these

¹ Appellants identify the Real Party in Interest as Colgate-Palmolive Company (*see* App. Br. 2).

benefits are antibacterial, anti-inflammatory, and antioxidant properties.”
(Spec. ¶ 2).

The Claims

Claims 45–60 are on appeal. Claim 45 is representative and reads as follows:

1. A method of treating an inflammatory condition of the oral cavity comprising administering to a subject in need thereof, an effective amount of a composition comprising:
 - a humectant;
 - an abrasive material;
 - 0.01% to 0.6% by weight, of a source of ursolic acid and carnosic acid wherein the source contains containing 10% to 40% by weight of the source of ursolic acid and 10% to 25% by weight of the source of carnosic acid; and
 - 0.1% to 2% by weight, of a halogenated diphenylether compound; andwherein said composition further comprises an anticaries agent and an anionic polycarboxylate polymer.

The Issue

The Examiner rejected claims 45–60 under 35 U.S.C. § 103(a) as obvious over Deasy,² Okuda,³ Vogel⁴ and Van Der Ouderaa⁵ (Final Act. 2–7).

² Deasy et al., *Effect of a Dentifrice Containing Triclosan and a Copolymer on Plaque Formation and Gingivitis*, 13 CLIN. PREVENTIVE DENTISTRY 12–19 (1991) (“Deasy”).

³ Okuda et al., JP 2003-261454 A, published Sept. 16, 2003, English Translation pages numbered 1–15 (“Okuda”).

⁴ Vogel et al., US 5,225,441, issued July 6, 1993 (“Vogel”).

⁵ Van Der Ouderaa et al., US 5,240,696, issued Aug. 31, 1993 (“Van Der Ouderaa”).

The Examiner finds Deasy teaches “a method of treating gingivitis (an inflammatory condition of the oral cavity) comprising administering to a subject in need thereof an effective amount of a composition comprising 0.3% triclosan, an abrasive material (silica) and an anticaries agent which is a fluoride releasing compound (sodium fluoride)” (Final Act. 2–3). The Examiner acknowledges that Deasy does not teach a composition further containing “0.01 % to 0.6% by weight of a source of ursolic acid and carnosic acid, containing 10-40-% [sic] by weight of the sources of ursolic acid and 10-25% by weight of the sources of carnosic acid, or a humectant or an anionic polycarboxylate polymer” (Final Act. 3).

The Examiner finds that Okuda teaches “rosemary extract decreased PGE2 (had a PGE2 depressor effect) at concentrations of 0.5% and 1.0%” and is “a source of ursolic acid and carnosic acid, the cited concentrations of 0.5% and 1.0% of rosemary extract overlap the claimed ranges” (*id.*). The Examiner finds Vogel teaches “prostaglandins are powerful mediators of inflammatory and immune response agents which inhibit PGE synthesis in the gingival tissue have therapeutic value in treating both gingivitis and periodontitis when administered either systemically or topically” (*id.*). The Examiner finds that Van Der Ouderaa teaches periodontitis treatment compositions may comprise “the usual dentifrice ingredients, such as silica, humectants including glycerol, sorbitol and propylene glycol (see e.g. col 2, lines 56-68), binders and thickeners such as copolymers of polyvinylmethylether with maleic anhydride” (Final Act. 4).

The Examiner finds it obvious that because “both triclosan and rosemary extract (a source of ursolic acid and carnosic acid as instantly

claimed) are known to inhibit prostaglandins,” “it would have been obvious to one of ordinary skill in the art to combine rosemary extract and triclosan for use in a method of treating inflammatory conditions of the oral cavity, including gingivitis and periodontitis” (Final Act. 5).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that claim 45 is obvious over the cited prior art?

Findings of Fact

1. The Specification teaches that a “non-limiting example of halogenated diphenylether compound is triclosan” (Spec. ¶ 28).
2. The Specification teaches: “Rosemary extract contains carnosic acid, rosmarinic acid, ursolic acid . . . Typically, the extract contains about 10% to about 40% by weight of ursolic acid and about 10% to about 25% by weight carnosic acid” (Spec. ¶¶ 21–22).
3. Deasy teaches a “double-blind, parallel 6-month clinical study was conducted to determine the effect on supragingival plaque formation and gingivitis, after an oral prophylaxis, of a dentifrice containing 0.3% Triclosan and 2.0% of a copolymer in a 0.243% sodium fluoride/silica base, as compared to a 0.243% sodium fluoride/silica placebo dentifrice” (Deasy 18, col. 2).
4. Deasy teaches “[a]fter 6 months, the Triclosan/copolymer dentifrice provided statistically significant reductions of 32.32% in supragingival plaque formation and 25.64% in gingivitis, as compared to the placebo dentifrice. Both reductions were statistically significant at the 99% level of confidence” (Deasy 18, col. 2).

5. Okuda teaches “an anti-inflammatory agent, a PGE₂ production depressant” including rosemary extract (Okuda ¶¶ 1, 5).

6. Okuda teaches the “anti-inflammatory agent of this invention can be made into pharmaceutical forms, such as lotions, milky lotions, a cream kind, ointment, and packs, as skin external preparations, for example” (Okuda ¶ 9).

7. Okuda teaches:

The example 2 of preparation [Preparation of a rosemary extract] The fragment of the leave and stem of a rosemary was air-dried and carried out, and it was immersed in the ethanol solution 50% overnight, it filtered through the filter paper, and the extract was obtained. According to Embodiment 1, PGE₂ production depressor effect was examined using the embodiment 7 (PGE₂ production depressor effect of rosemary extract) rosemary 50% ethanol extract. A result is shown in drawing 7. So that clearly from drawing 7 a rosemary 50% ethanol extract, It decreased to about 6 ng(s)/ml medium with the 0.5% of rosemary extract concentration solution, and decreased that the PGE₂ production amount was about 7 ng(s)/ml medium when this rosemary extract was not included to about 5 ng(s)/ml medium with the solution 1.0%. Therefore, the rosemary 50% ethanol extract had PGE₂ production depressor effect.

(Okuda ¶¶ 27–29).

8. Vogel teaches “if the omega-3 PUFA inhibits PGE synthesis in the gingival tissue, they can very well have therapeutic value in the treatment of both gingivitis and periodontitis when administered either systemically or applied topically” (Vogel 3:11–15).

9. Van Der Ouderaa teaches “[t]riclosan has a considerable anti-cyclo-oxygenase activity, thus significantly inhibiting the formation of

prostaglandins. Inhibiting the biosynthesis of the prostaglandins locally would thereby significantly inhibit or prevent alveolar bone resorption. Triclosan has been shown to be retained by gingival tissue both in vitro and in vivo following topical application” (Van Der Ouderaa 1:47–54).

10. Van Der Ouderaa teaches:

The medicament furthermore may comprise further, conventional ingredients, such as pharmaceutically acceptable carriers like starch, sucrose, polyols, surfactants, water or water/alcohol systems etc. When formulated into a dentifrice, such formulation may contain all the usual dentifrice ingredients. Thus, they may comprise particulate abrasive materials such as silicas, aluminas, calcium carbonates, dicalciumphosphates, hydroxyapatites, trimetaphosphates, insoluble hexametaphosphates and so on, usually in amounts between 5 and 60% by weight.

(Van Der Ouderaa 2:56–66).

Principles of Law

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417.

Wrigley found a “strong case of obviousness based on the prior art references of record. [The claim] recites a combination of elements that were all known in the prior art, and all that was required to obtain that combination was to substitute one well-known . . . agent for another.” *Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC*, 683 F.3d 1356, 1364 (Fed. Cir. 2012).

Analysis

We adopt the Examiner's findings regarding the scope and content of the prior art (Final Act. 2–7; FF 1–10) and agree that the claimed device would have been obvious over the teachings of Deasy, Okuda, Vogel, and Van Der Ouderaa. We address Appellants' arguments below.

Appellants contend

the Examiner relies on Okuda's disclosure of rosemary extract having a PGE₂ depressor effect. (Final Office Action, p 3). However, when making the "as a whole determination," there is no reason why one of skill in the art (who, unlike the Examiner, would not have the Appellants' claims before them) would have modified Deasy's composition to include this missing limitation based on Okuda.

(App. Br. 5–6).

We do not find this argument persuasive because it fails to address the combined teachings of all of the prior art references. The Examiner's reasoning is that because Deasy teaches treatment of gingivitis (FF 34) and Vogel teaches that compounds which "inhibit[] PGE synthesis in the gingival tissue . . . can very well have therapeutic value in the treatment of both gingivitis and periodontitis" (FF 8), the ordinary artisan would have been motivated to incorporate PGE inhibiting compositions into Deasy's dentrifice (*see* Final Act. 5). Okuda teaches that rosemary extract is a composition that inhibits PGE and functions as an anti-inflammatory (FF 5, 7) and the Examiner reasonably explains that because the prior "art recognizes the link between inhibiting prostaglandins and treating both gingivitis and periodontitis, it would have been obvious to one of ordinary skill in the art to combine rosemary extract and triclosan for use in a method

of treating inflammatory conditions of the oral cavity, including gingivitis and periodontitis” (Final Act. 5).

Appellants contend that:

Okuda is directed toward topical applications for treating inflammations on the skin. On the other hand, Deasy is directed toward toothpastes for treating plaque and gingivitis inside the mouth. Thus, these two references are directed to entirely different fields, and one skilled in the art would not look to Okuda to modify Deasy’s composition.

(App. Br. 6).

We find this argument unpersuasive because dentrifices are topical applications of medications to the oral cavity and because Okuda is pertinent to the problems with which Deasy was concerned. The test for non-analogous art is first whether the art is within the field of the inventor's endeavor and, if not, whether it is “reasonably pertinent to the particular problem with which the inventor was involved.” *In re Wood*, 599 F.2d 1032, 1036 (CCPA 1979). “A reference is reasonably pertinent if, even though it may be in a different field” of endeavor, it logically would have commended itself to an inventor’s attention in considering his problem “because of the matter with which it deals.” *In re Clay*, 966 F.2d 656, 659 (Fed. Cir. 1992).

Here, Okuda’s teaching appears to satisfy both prongs of the analogous art test, as it relates to topical application of anti-inflammatory compounds (FF 6) and Deasy teaches topically applied dentrifices for treatment of the inflammatory condition, gingivitis (FF 3). Moreover, even if Okuda were in a different field of endeavor, Vogel establishes that PGE inhibitor compounds treat gingivitis (FF 8), the concern of Deasy (FF 3), and

Okuda teaches that rosemary extract is a PGE inhibitor (FF 7). Thus, the ordinary artisan would have found Okuda's teaching of topical application of rosemary extract to reduce PGE induced inflammation pertinent to Deasy's dentrifice to reduce inflammation in the PGE induced condition of gingivitis.

We recognize, but find unpersuasive, Appellants' contention that "just because a single ingredient such as an antiseptic (*i.e.*, triclosan) can be used in toothpaste and in hand cream/lotion does not mean that the hand cream/lotion can be used as a toothpaste and vice versa" (App. Br. 6). The Examiner's reasoning is not based on incorporation of an entire hand cream composition into the dentrifice of Deasy, but rather upon incorporation of the active, anti-inflammatory rosemary extract taught by Okuda as a PGE inhibitor that can be applied topically (*see* Ans. 9).

Appellants contend that "[n]othing would have lead one skilled in the art to specifically pick rosemary extract from among Okuda's laundry list of anti-inflammatory agent choices, especially where Okuda specifically teaches only three of those choices are outstanding or excellent" (App. Br. 7).

We are not persuaded. The Examiner's rejection is consistent with *Wrigley*, where the Federal Circuit found a "strong case of obviousness based on the prior art references of record. [The claim] recites a combination of elements that were all known in the prior art, and all that was required to obtain that combination was to substitute one well-known . . . agent for another." *Wrigley*, 683 F.3d at 1364. Okuda establishes that each of the extracts, including rosemary extract, were known prior art

compositions that inhibit PGE and act as anti-inflammatories (FF 5, 7). The flexible analysis set out by the Supreme Court in *KSR* recognizes the obviousness of pursuing known options within the technical grasp of the skilled artisan, e.g., known equivalents. *See KSR*, 550 U.S. at 421. Here, it is fair to say that there were a finite number of identified, predictable solutions to the problem of finding PGE inhibiting compounds for use in treatment of gingivitis and that selection of one of the known alternative compositions, rosemary extract, taught by Okuda (FF 7), was the “product not of innovation but of ordinary skill and common sense.” *See Wrigley*, 683 F.3d at 1364–65 (citing *KSR*, 550 U.S. at 421).

Appellants “submit that the Examiner’s proposed modification was impermissibly made using hindsight gleaned from Appellants’ specification and claims. MPEP 2142. Therefore, withdrawal of this rejection is respectfully requested” (App. Br. 8).

We are not persuaded. While we are fully aware that hindsight bias may plague determinations of obviousness, *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966), we are also mindful that the Supreme Court has clearly stated that the “combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR*, 550 U.S. at 416. In the instant case, incorporation of Okuda’s rosemary extract, a known PGE inhibitor and anti-inflammatory, into Deasy’s dentrifice for treatment of the inflammatory condition gingivitis, would have been reasonably expected to result in a therapeutic treatment of gingivitis because Vogel teaches that PGE synthesis inhibitors

“have therapeutic value in the treatment of both gingivitis and periodontitis when administered . . . topically” (FF 8).

Appellants contend that “one skilled in the art would use a rosemary concentration greater than the 0.6% upper limit claimed in Appellants’ claim 45 since Okuda teaches that 0.5% rosemary extract concentration only decreased PGE₂ production by 1 ng/ml, while a 1.0% rosemary extract concentration decreased PGE₂ production by 2 ng/ml” (App. Br. 8).

We do not find this argument persuasive because Okuda teaches that both 0.5 % and 1 % functioned to reduce PGE₂ production (FF 7), a range that overlaps the requirement of claim 45. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (“In cases involving overlapping ranges, we and our predecessor court have consistently held that even a slight overlap in range establishes a prima facie case of obviousness.”) Appellants have provided no persuasive evidence demonstrating any secondary consideration that overcomes this prima facie case of obviousness.

Appellants contend that “Vogel teaches away from Appellants’ claimed invention because Vogel’s primary teaching is his surprising discovery that omega-3 PUFA can inhibit PGE synthesis (and thus teaching away from using rosemary extract)” (App. Br. 8).

We find the teaching away argument unpersuasive. A teaching away requires a reference to actually criticize, discredit, or otherwise discourage the claimed solution. *See In re Fulton*, 391 F.3d 1195, 1201 (Fed. Cir. 2004) (“The prior art’s mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution

claimed.”) Appellants do not identify, and we do not find, any teaching in Okuda or the other cited prior art that teaches that incorporation of rosemary extract into a dentrifice would have been undesirable in any way. 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 442, 446 n.3(CCPA 1971).

Appellants contend that “since Deasy’s composition already contains triclosan (which Ouderaa teaches inhibits prostaglandin formation), Ouderaa’s discovery would lead one skilled in the art **not** to modify Deasy’s composition at all” (App. Br. 9).

We do not find this argument persuasive because the person of ordinary skill would have reasonably combined two known PGE inhibitors, triclosan and rosemary extract, for treatment of gingivitis because the combination of these two compositions is merely a “predictable use of prior art elements according to their established functions.” *KSR*, 550 U.S. at 417; *see also In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980) (“It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.”).

Conclusion of Law

The evidence of record supports the Examiner’s conclusion that claim 45 is obvious over the cited prior art.

SUMMARY

In summary, we affirm the rejection of claim 45 under 35 U.S.C. § 103(a) as obvious over Deasy, Okuda, Vogel and Van Der Ouderaa. Claims 46–60 fall with claim 45.

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