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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte KAMAL KHAWALED and TANYA MUSHYAKOV

Appeal 2019-003330
Application 15/102,572¹
Technology Center 1600

Before ERIC B. GRIMES, TAWEN CHANG, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

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

We affirm and designate our affirmance as to one claim a NEW GROUND OF REJECTION pursuant to our authority under 37 C.F.R. § 41.50(b).

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 Co. (Appeal Br. 2.)

STATEMENT OF THE CASE

“A variety of dental bleaching compositions . . . exist on the market.”

(Spec. 1.) Appellant’s Specification states that:

Most common bleaching agents are peroxides, including but not limited to hydrogen peroxide, carbamide peroxide, sodium perborate, and sodium percarbonate. The simplest way to shorten the treatment time is to increase the concentration of the peroxide. This can however, result in irritation and even some damage of gums or lips or other soft tissue.

(*Id.*) “It was the object of the present invention to provide a bleaching gel composition that is less irritating than prior art gels, is highly efficient, can bleach within shorter time and results in whitened teeth when applied.” (*Id.* at 2.)

Claims 1, 3–5, 9–11, 13, 14, 18, and 20 are on appeal.² Claim 1 is representative and reads as follows:

1. A dental bleaching gel composition comprising:
 - aqueous hydrogen peroxide in an amount of 6 to 9% w/w of peroxide, by weight of the composition,
 - a cross-linked polyacrylate polymer in an amount of 1 to 5% w/w;
 - an aqueous vehicle comprising glycerin in an amount of 20 to 30% w/w, and water in an amount of 25 to 50% w/w;
 - electrical conductivity enhancing ingredients comprising at least one alkali hydroxide in an amount of 1 to 5% w/w; and
 - wherein the electrical conductivity of the gel is higher than 250 microsiemens/cm;

² Claims 15 and 16 remain pending but are withdrawn from consideration. (Advisory Action 1.)

wherein the dental bleaching gel is a stable, single-component gel;

wherein the gel does not comprise an alkali nitrate.

(Appeal Br. 10.)

The following grounds of rejection by the Examiner are before us on review:

Claims 1, 4, 9–11, 13, 14, 18, and 20 under 35 U.S.C. § 103 as unpatentable over Allred.³

Claims 3 and 5 under 35 U.S.C. § 103 as unpatentable over Allred and Montgomery.⁴

DISCUSSION

Claim 1

The Examiner finds that Allred teaches a composition at Example 5 that includes water, hydrogen peroxide, glycerin, sodium hydroxide, polyvinyl pyrrolidone, and Carbopol 974. (Final Action 2.) The Examiner also finds that this composition does not include an alkali nitrate. (*Id.* at 3.)

The Examiner finds that Allred Example 4, which like Example 5 is a dental bleaching composition, includes glycerin in an amount of 29.85%, which is in the range required by claim 1.

The Examiner recognizes that the composition of Example 5 does not have the claimed amount of cross-linked polyacrylate polymer (Carbopol 974) and the hydrogen peroxide recited in claim 1. (*Id.*) However, the Examiner finds that the amounts of these two ingredients are just “slightly

³ Allred et al., US2006/0029908 A1, published Feb. 9, 2006.

⁴ Montgomery, US 7,189,385 B2, issued Mar. 13, 2007.

outside the claimed ranges for each component” and that a *prima facie* case of obviousness exists including with respect to the composition of Allred having the claimed electrical conductivity property (*id.*; *see also* Advisory Action 2 (noting further that “the prior art teaches a range of 1–90% for the bleaching agents . . . para. [0093]”)), particularly because Allred teaches the inclusion of the electrolyte sodium hydroxide, which is an alkali hydroxide as claimed (Ans. 3 (citing *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977))).

We agree with the Examiner’s factual findings and conclusion of obviousness. Claim 1 recites a dental bleaching gel “comprising” a number of ingredients, all of which are present in Example 5 of Allred. “In the patent claim context, the term ‘comprising’ is well understood to mean ‘including but not limited to’.” *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007). Thus, that Allred includes “many other components” (Appeal Br. 6) does not preclude a conclusion that the invention claimed is *prima facie* obvious in light of the amount of each of the required ingredients that Example 5 of Allred does include. We agree with the Examiner that the 10.5% hydrogen peroxide of Allred’s composition is close enough to being within the 6–9% peroxide range claimed and similarly that the 5.3% Carbopol 974 of Allred’s composition is close enough to being within the 1–5% crosslinked polyacrylate required by the claims that one of ordinary skill in the art would have expected the composition of Example 5 to have the electrical conductivity claimed. *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (“We have also held that a *prima facie* case of obviousness exists when the claimed range and the prior art range do not overlap but are close enough such that one skilled in the art would have expected them to have the same properties.”).

Appellant's Specification does not establish that 9% is a critical limit for the peroxide range or that 5% is a critical limit for the cross-linked polyacrylate. Indeed, the Specification teaches that "[a] useful amount" of the thickening agent that is the cross-linked polyacrylate "is in the range of 1 to 5 % w/w" but that "the skilled artisan can find a suitable amount in known manner." (Spec. 5.) And with respect to the hydrogen peroxide bleaching agent, the Specification states:

The bleaching agent is used in an amount that provides at least some whitening of teeth but less than an amount that irritates or hurts the tissue or mucous membrane. The amount of bleaching agent can be in a range of 1 to 35 % w/w, in particular 3 to 10 % w/w or 6 to 9 % w/w peroxide, based on the weight of the final bleaching gel composition.

(*Id.*)

Furthermore, in light of Allred's teaching of a dental bleaching composition in Example 4 that contains 29.85% glycerin, we conclude that it would have been obvious to adjust the amount of glycerin in Example 5 to within the claimed range as well. "[I]t is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456 (CCPA 1955).

We also agree with the Examiner, that it is well-established that "[w]here . . . the claimed and prior art products are identical or substantially identical . . . the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . [The] fairness [of the burden-shifting] is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). In light of the

foregoing discussion regarding Allred's Example 5, it was entirely appropriate for the Examiner to conclude without "any specific technical basis" (Appeal Br. 6) that a prima facie case of obviousness was made out with respect to the claimed electrical conductivity property and shift the burden to Appellant to establish that Example 5 of Allred does not possess the claimed electrical conductivity. Rather than provide testing evidence to establish that Allred Example 5 does not have the claimed conductivity, Appellant argues that "[c]urrently available on the market dental bleaching compositions are either electrically non-conductive or have very low conductivity typically below 200 microsiemens/cm." (*Id.* (citing Spec. 4–5).)

Appellant's argument does not establish that Example 5 of Allred is a composition available on the market, nor does it provide evidence that the specific composition of Example 5 does not meet the claimed electrical conductivity. "Attorney argument is not evidence." *Icon Health & Fitness, Inc. v. Strava, Inc.*, 849 F.3d 1034, 1043 (Fed. Cir. 2017). Moreover, Appellant's Specification also does not provide test data to establish that Example 5 of Allred or some substantially similar composition does not have the claimed electrical conductivity.

Appellant's additional argument that

Allred does not recognize the same problem to be solved as disclosed in the instant invention, much less the use of an electrical conductivity enhancing ingredient, *e.g.*, sodium hydroxide, in the presence of other components as recited in amended claim 1 by applying a microcurrent to achieve teeth whitening within a short time and lasting longer

(*id.* at 7), fails to persuade us that the Examiner's rejection is in error. First, Appellant's claim is a composition claim that does not require applying the

composition to teeth and “applying a microcurrent to achieve teeth whitening within a short time and lasting longer” than through use of a composition that does not have electrical conductivity of higher than 250 microsiemens/cm. Second, the prior art need not address the motivation that prompted Appellant to arrive at the claimed invention. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 419–20 (2007) (“In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls.”). “What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.” *Id.* For the reasons discussed, we find that the Examiner has established a prima facie case of obviousness as to the composition recited by claim 1 with the composition of Example 5 of Allred, including regarding having the claimed electrical conductivity. Thus, we also do not find persuasive Appellant’s argument that Allred does not disclose all the recited limitations of claim 1 sufficiently to establish prima facie obviousness (Appeal Br. 7).

Appellant’s argument in the Reply Brief that the present rejection is similar to the conclusion of obviousness by the Board in *Leo Pharmaceuticals Products, Ltd. v. Rea*, 726 F.3d 1346 (Fed. Cir. 2013), which was reversed by the Federal Circuit (Reply Br. 2–3), is not persuasive. The facts in *Leo* were fundamentally different from the present situation in many respects. First, in *Leo* one of the prior art references was missing an element that a second prior art reference was said to make obvious. *Leo*, 726 F.3d 1350–51. Here, Allred teaches in Example 5 the presence of every compositional element recited in claim 1. Additionally, in *Leo* “the prior art either discouraged combining vitamin D analogs and corticosteroids in a

single formulation, or attempted the combination without recognizing or solving the storage stability problems associated with the combination.” *Id.* at 1353. There is no such discouragement or failure here. In addition, comparative experimental evidence was presented to demonstrate unexpected superiority of the claimed invention in *Leo*. *Id.* at 1354. No comparative evidence at all, much less against the prior art Allred, is present on this record. Finally, the Federal Circuit in *Leo* also noted “in the face of such divergent compositions with express disclaimers of the other’s contents, the record showing that Turi, Serup, and Dikstein describe compositions for the same therapeutic purpose does not rise to the level of a motivation to combine.” *Id.* at 1356. There is no such disclaimer of contents in this record.

Accordingly, for the reasons discussed, we affirm the Examiner’s rejection of claim 1 as being obvious over Allred.

Claims 4, 9–11, 13, 14, 18, and 20 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

Claims 3 and 5

The Examiner finds that while Allred does not teach using potassium hydroxide (KOH) as the alkali hydroxide (claim 5) or a pH range of 5–7 (claim 3) for the dental bleaching composition of Example 5, these would have been obvious from the teachings of Montgomery. (Final Action 4.) The Examiner finds that Montgomery teaches a dental bleaching composition that includes buffers to achieve a pH for optimal penetration of the composition into the tooth enamel, in excess of about pH 5.2, and that potassium hydroxide is a suitable buffer for that purpose. (*Id.*) The Examiner determines that it would have been obvious to one having ordinary

skill in the art to use potassium hydroxide in the composition of Allred as a buffering agent to achieve a pH in excess of about 5.2 so as to provide optimal penetration of the Allred composition into the tooth enamel. (*Id.*)

We agree with the Examiner's findings and conclusion of obviousness. Montgomery teaches several alkaline buffers including sodium hydroxide (NaOH) and potassium hydroxide may be used in a dental bleaching composition in an amount of from 0.5 to about 3 % by weight of the composition. (Montgomery 8:8–16.) Montgomery further teaches that these alkaline buffers “may also serve the purpose of neutralizing carboxylic acid side chains in thickening polymers.” (*Id.*) Thus, claim 5 recites the use of elements that were all well-known in the prior art, and all that was required to obtain the claimed composition was to substitute one well-known buffer for another.

We agree with the Examiner that it would have been obvious to substitute KOH as an alternative to NaOH in Allred with a reasonable expectation of success. It is well understood that it is obvious to those skilled in the art to substitute one known equivalent for another. *See In re Omeprazole Patent Litigation*, 483 F.3d 1364, 1374 (Fed. Cir. 2007) (“[T]his court finds no . . . error in [the] conclusion that it would have been obvious to one skilled in the art to substitute one ARC [alkaline reactive compound] for another.”). Here, Montgomery teaches a finite number of suitable alkaline buffers for use in dental bleaching compositions to provide a specific pH for optimal penetration of the composition into the tooth enamel. Thus, we conclude that the claimed composition employing KOH was “the product not of innovation but of ordinary skill and common sense.” *KSR*, 550 U.S. at 421.

Appellant's argument that Allred describes "other potassium salts" as "one of the active agents, whereas sodium hydroxide is listed as one of the non-active agents" (Appeal Br. 8) is not persuasive to establish non-obviousness. Just because potassium nitrate and other potassium salts are described as desensitizing agents that may be used in the dental treatment composition in Allred (Allred ¶¶ 96–97) does not establish that using KOH as an alternative buffer to NaOH would not work in the dental treatment compositions described. As the Examiner explains, Montgomery teaches the equivalence of NaOH and KOH as buffers in dental bleaching compositions, and Appellant has not established a scientific reason why one of ordinary skill in the art would not find these known buffers to be substitutable in Example 5 of Allred nor provided evidence that such substitution would not have been made by one of ordinary skill in the art in the composition of Example 5 of Allred.

Appellant's argument that KOH is not used as a buffer in Appellant's claimed bleaching composition (Appeal Br. 8) is not persuasive of non-obviousness. First, KOH will necessarily act as a buffer in the claimed aqueous composition. Second, "the law does not require that the references be combined for the reasons contemplated by the inventor." *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992). "What matters is the objective reach of the claim." *KSR*, 550 U.S. at 419. Here, as explained, Montgomery establishes the equivalence of NaOH and KOH as buffering agents in a bleaching composition, and Allred teaches the use of an alkaline hydroxide agent in the amount required by Appellant's claim 1. Thus we agree with the Examiner that claim 5 "extends to what is obvious" and is thus unpatentable under § 103. *Id.*

Regarding the pH range claimed, as the Examiner notes, Montgomery teaches that a pH level in excess of about 5.2 is desirable because peroxyacetic acid forms quickly at this pH. (*Id.* at 8: 30–39.) However, we agree with Appellant that Montgomery does teach a pH above 5.2 because of a desire to produce peroxyacetic acid from hydrogen peroxide and glyceryl triacetate quickly. (Appeal Br. 8.)

Nevertheless, we also note that Montgomery teaches that prolonged exposure of teeth to bleaching compositions with a pH less than 5.5 is known to have the negative effect of solubilization of calcium from the enamel layer with associated demineralization. (Montgomery 2:35–39.) And, as the Examiner noted, Montgomery teaches that keeping the pH at a particular level will provide optimal penetration of the composition into the tooth enamel. (*Id.* 8:8–10.) We understand from these two teachings that the optimum pH of Montgomery’s composition is at least 5.5, to avoid solubilizing calcium. Thus, we conclude that Montgomery does provide motivation to keep the pH of the Example 5 Allred composition, which does not include glyceryl triacetate, at or above pH 5.5, and pH 5.5 is within the range recited in claim 3.

Thus, for the foregoing reasons we find that claim 3 is obvious over Allred and Montgomery. Because our conclusion is based on additional facts not relied upon by the Examiner and reasoning that differs somewhat from the Examiner’s, we designate our affirmance as to claim 3 a new ground of rejection pursuant to our authority under 37 C.F.R. § 41.50(b) to provide Appellant with a full and fair opportunity to respond to the rejection. *See In re Biedermann*, 733 F.3d 329, 336–337 (Fed. Cir. 2013) (Appellants are entitled to a fair opportunity to react to the thrust of the rejection).

CONCLUSION

In summary:

| Claims Rejected | 35 U.S.C. § | Reference(s)/ Basis | Affirmed | Reversed | New Ground |
|----------------------------|-------------|---------------------|------------------------------|----------|------------|
| 1, 4, 9–11, 13, 14, 18, 20 | 103 | Allred | 1, 4, 9–11, 13, 14, 18, 20 | | |
| 3, 5 | 103 | Allred, Montgomery | 3, 5 | | 3 |
| Overall Outcome | | | 1, 3–5, 9–11, 13, 14, 18, 20 | | 3 |

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.”

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. . . .

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Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

AFFIRMED, 37 C.F.R. § 41.50(b)