UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/307,782	10/28/2016	Michael Prencipe	10305-00-US-01-OC	2255

23909 7590 03/02/2020

COLGATE-PALMOLIVE COMPANY
909 RIVER ROAD
PISCATAWAY, NJ 08855

EXAMINER
LIU, TRACY

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
03/02/2020	ELECTRONIC

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

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Patent_Mail@colpal.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL PRENCIPE and STEVEN WADE FISHER[1]

Appeal 2018-007986
Application 15/307,782
Technology Center 1600

Before JEFFREY N. FREDMAN, DEBORAH KATZ, and JOHN G. NEW, *Administrative Patent Judges*.

NEW, *Administrative Patent Judge*.

DECISION ON APPEAL

---

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Colgate-Palmolive Company as the real party-in-interest. App. Br. 2.

SUMMARY

Appellant files this appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of claims 1, 2, 5–12, and 14–16 as unpatentable under 35 U.S.C. § 103 over Patel et al. (US 2012/0264078 A1, October 18, 2012) ("Patel").

Claim 13 stands rejected as unpatentable under 35 U.S.C. § 103 over the combination of Patel and Robinson et al. (US 2006/0286044 A1, December 21, 2006) ("Robinson).[2]

We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

NATURE OF THE CLAIMED INVENTION

Appellant's invention is directed to an oral care composition including a silica abrasive having a particle size no greater than the diameter of a dentin tubule, zinc citrate, a bioadhesive agent, and an anticalculus agent. Spec. ¶ 8.

REPRESENTATIVE CLAIM

Claim 1 is representative of the claims on appeal and recites:

1. An oral care composition comprising

---

[2] The Examiner withdrew a rejection of claims 1, 2, and 5–16 on the ground of nonstatutory double patenting over claims 1, 4, and 9 of co-pending Application No. 15/337,226 in view of Patel. Ans. 3.

> (a) a silica abrasive having an average particle size of 1.5–6 microns in an amount of 2% to 10% by weight based on the total weight of the composition;
>
> (b) zinc citrate in an amount of 0.2% to 5% by weight based on the total weight of the composition,
>
> (c) a bioadhesive agent, and
>
> (d) an anticalculus agent,
>
> wherein the bioadhesive agent is a polyvinyl methyl ether/maleic anhydride copolymer in amount of 0.5 % to 4% by weight based on the total weight of the composition, and
>
> wherein the anticalculus agent is tetrapotassium pyrophosphate or tetrasodium pyrophosphate in an amount of from 0.5% to 5% by weight based on the total weight of the composition.

App. Br. 14.

ISSUES AND ANALYSIS

We agree with, and expressly adopt, the Examiner's findings, reasoning, and conclusion that the claims are obvious over the combined prior art. We address below the arguments raised by Appellant.

Issue 1

Appellant argues there is no sufficient motivation to modify Patel to obtain the specific combination of components recited by the claimed composition. Appeal. Br. 5.

Analysis

The Examiner finds that Patel teaches an oral care composition in the form of a dentifrice. Final Act. 3 (citing Patel Abstr., ¶ 31). The Examiner finds that the oral composition includes at least one abrasive in an amount of 5% to 70% by weight of the composition. *Id.* (citing Patel ¶ 79). The abrasive may include less than 6% by weight silica having a particle size of 0.1 to 30 μm. *Id.* The Examiner finds that the oral composition may include zinc citrate in an amount of 0.05% to 3% by weight. *Id.* (citing Patel ¶ 72). The Examiner finds that the composition may include one or more anticalculus agents in a total amount of 0.01% to 50% by weight. *Id.* (citing Patel ¶ 67). The anticalculus agents may include tetrasodium pyrophosphate and polyvinyl methyl ether/maleic anhydride (PVME/MA) copolymer. *Id.*

The Examiner determines that, although the components of the oral care composition "must be selected from various lists/locations in the reference," "[i]t would have been obvious to make the combination since each component is taught as being useful in making the compositions of the prior art." Final Act. 4. The Examiner determines that the modification represents "nothing more than the predictable use of prior art elements according to their established functions." *Id.* at 5. With respect to the specific amounts and particle size of components recited in the claims, the Examiner determines that Patel discloses amount and size ranges that overlap with the claimed ranges. Ans. 8. Accordingly, the Examiner concludes that the claims would have been *prima facie* obvious over the prior art. *Id.*

Appellant argues that "[a]lthough Patel mentions silica abrasive, zinc citrate, [PVME/MA copolymer], and tetrasodium pyrophosphate in several

different places, Patel does not disclose or suggest the specific combination of them, much less the amounts of them recited in claim 1." App. Br. 5. Appellant contends that the Examiner has failed to provide "any rationale as to why the invention as claimed would have been obvious to a person of ordinary skill in the art at the time of invention." *Id.* at 6.

Appellant contends the Examiner should apply a "lead-modification analysis" for obviousness of chemical formulation. App. Br. 5 (citing *Unigene Laboratories, Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361–1362 (Fed. Cir. 2011). Appellant argues that Patel at Table 3 discloses a dentifrice that should serve as the lead formulation. *Id.* Appellant argues that the disclosed dentifrice does not contain zinc citrate, PVME/MA copolymer, or silica adhesive having a particle size of 1.5–6 microns. *Id.*

Appellant argues further that Patel teaches photosensitive GRAS (Generally Regarded as Safe) dyes provide anti-bacterial activity to the disclosed compositions, and thus "are essential elements" in Patel's compositions. App. Br. 7. Appellant argues that the "Examiner has not provided any articulated reasoning why one of skill in the art would be motivated to add the specific combination of" silica, zinc citrate, PVME/MA copolymer, and anticalculus agent "into Patel's compositions containing photosensitizing dyes." *Id.*

Finally, Appellant argues that, although Patel teaches an abrasive with an average particle size of 0.1 to 30 microns, Patel does not teach or suggest "the use of a **silica** having an average particle size of 1.5–6 microns." App. Br. 7 (emphasis in original). Appellant argues "[t]here is no teaching or suggestion anywhere in Patel that would motivate one of skill in the art to

use a silica having an average particle size of 1.5–6 microns … much less the claimed amount of it." *Id.* at 8.

We are not persuaded by Appellant's arguments. Patel teaches oral compositions including conventional dentifrice components, e.g., abrasives, anticalculus agents, and antimicrobial agents. *See* Patel ¶¶ 60, 61, 77. These conventional dentifrice components more specifically include silica abrasive, zinc citrate antimicrobial agent, and tetrasodium pyrophosphate and PVME/MA copolymer anticalculus agents. *See* Patel ¶¶ 67, 72, 79. The Examiner has identified a reason to combine these components for their established functions in a dentifrice. *See* App. Br. 5. "In determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls. … [A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 420 (2007).

Furthermore, we do not agree with Appellant with respect to applying a "lead-modification analysis." *Unigene*, upon which Appellant relies, held that a reference composition analysis, which refers to new formulations of known compounds as Appellant claims, in contrast to new compounds, is appropriate only in certain infringement contexts, which are not applicable here. *See Unigene*, 655 F.3d at 1361–62; *see also Eisai Co. v. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353, 1357 (Fed. Cir. 2008) ("Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e., a lead compound) in a particular way to achieve

the claimed compound. *See Takeda Chem. Indus. v. Alphapharm Pty., Ltd.,* 492 F.3d 1350, 1356 (Fed.Cir.2007).”). Moreover, *Unigene* cannot run counter to the flexible analysis set out by the Supreme Court in *KSR* that recognizes the obviousness of pursuing known options within the technical grasp of the skilled artisan. *KSR*, 550 U.S. at 420–421. Accordingly, we do not agree with Appellant that Patel’s teachings are limited to the dentifrice formulation of Table 3. Rather, Patel’s teachings must be taken as a whole, including the suggestion to combine conventional dentifrice components for their established functions.

Likewise, we are not persuaded by Appellant’s argument that Patel’s teaching of “essential” GRAS dyes distinguishes the prior art from the claimed composition. First, the claim 1 recites “an oral care composition *comprising* ….” Use of the transitional term “comprising” “creates a presumption … that the claim does not exclude additional, unrecited elements.” *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1348 (Fed. Cir. 2001). Therefore, the claims do not exclude additional components taught by Patel, e.g., GRAS dyes. Second, as discussed *supra*, Patel teaches that the conventional dentifrice components may be combined in oral care compositions, including those containing GRAS dyes, for their known functions. “[A]ll disclosures of the prior art, including unpreferred embodiments, must be considered.” *In re Lamberti*, 545 F.2d 747, 750 192 USPQ 278, 280 (C.C.P.A. 1976).

Finally, we are not persuaded by Appellant’s argument that Patel does not teach the identical amounts of components and particle size of silica abrasive. Patel teaches the same components in ranges that overlap the claimed ranges. Likewise, Patel teaches abrasives, e.g., silica, having a

particle size range that overlaps the claimed range.[3] "A *prima facie* case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art." *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003). We consequently agree with the Examiner that claims 1, 2, 5–12, and 14–16 would have been *prima facie* obvious over Patel.

Appellant repeats the same arguments against the combination of Patel and Robinson with respect to claim 13. For the reasons set forth *supra*, we are not persuaded. We consequently agree with the Examiner that claim 13 would have been *prima facie* obvious over Patel and Robinson.

Issue 2

Appellant argues the Examiner is required to consider the data presented in the Examples demonstrating beneficial effects of the claimed composition. App. Br. 8.

Analysis

Appellant argues the data in Example 2 of the Specification shows that the claimed composition (Formula A), has greater efficacy in inhibiting biofilm growth than the comparative unclaimed compositions (Formula C, D, E, and Competitive dentifrice 1). App. Br. 8. Appellant argues the data

---

[3] Appellant's Specification acknowledges that the "[u]se of silica particles having an average particle size of no greater than the diameter of a dentin tubule for occluding dentinal tubules and treating dentinal hypersensitivity is disclosed in US patent application no. 2009/0092562." Spec. ¶ 6.

in Example 2 shows that Formula A has higher efficacy against plaque than Competitive dentifrice 2. *Id.* Appellant contends that the compositions of Formula C, D, E, and Competitive dentifrices 1 and 2, "are closer to the claimed composition than Patel's dentifrice formulation" taught in Table 3. *Id.* at 9. Although the amounts of anticalculus agent vary among the Examples, Appellant argues "each anticalculus or antiplaque agent has its own effective concentration range" and "a lower amount of amount of an anticalculus agent could exhibit greater efficacy in inhibiting biofilm growth than a higher amount of another anticalculus agent." *Id.*

Appellant further argues that the data in Example 4 shows Formula A "provides a strong tooth hypersensitivity benefit by comparing it with Formula B (Colgate cavity protection toothpaste)." App. Br. 10. Appellant contends "Patel does not discuss anything regarding tooth hypersensitivity." *Id.* Therefore, Appellant contends that the closer prior art is Formula B, which contains dicalcium phosphate dehydrate for treating hypersensitive dentine. *Id.* Appellant contends "[t]he beneficial effects of the claimed combination shown in Examples 2–4 … are not taught or suggested by Patel." *Id.*

The Examiner finds that Formula A contains 3.94% anticalculus agents (tetrapotassium pyrophosphate and PVME/MA copolymer) as compared to Formula B (0.25% tetrapotassium pyrophosphate), Formula C (3% tetrasodium and tetrapotassium pyrophosphates), Formula D (2% tetrasodium and tetrapotassium pyrophosphates), and Formula E (0% anticalculus agents). Final Act. 7–8. The Examiner finds "[o]ne of ordinary skill in the art would reasonably expect a composition with more

anticalculus agents to have a greater reduction in biofilm growth compared to compositions with lesser amounts of anticalculus agents." *Id.* at 8.

With respect to hypersensitivity, the Examiner finds that "[t]he instant claims do not recite treating tooth hypersensitivity." Ans. 12. The Examiner determines that Formula B is not the closest prior art for comparison to Formula A, as Formula B contains dicalcium phosphate dehydrate as a desensitizing agent, and not silica. *Id.*

We are not persuaded by Appellant's arguments and evidence with respect to the allegedly unexpected results. We agree that the Specification arguably shows a difference of efficacy between the described formulations.

However, Appellant has not shown that the difference would have been unexpected. Rather, we agree with the Examiner that the "greater efficacy in inhibiting biofilm growth" and "higher efficacy against plaque" would have been expected given the increase in anticalculus agent. *See* Spec. ¶¶ 79, 82. Appellant's argument that each anticalculus agent has its own effective range is unsupported by any evidence of probative value. "An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness." *In re Geisler*, 116 F.3d 1465, 1470, 43 USPQ2d 1362, 1365 (Fed. Cir. 1997).

Finally, we address the difference in tooth sensitivity effectiveness between Formula A and Formula B. Appellant contends that Formula A, containing a silica abrasive having an average particle size of 1.5–6 microns, shows improved tooth sensitivity as compared to Formula B, containing dicalcium phosphate dehydrate. App. Br. 10. Even if we agree that the results of the tooth sensitivity test are unexpected, unexpected results that

are probative of nonobviousness are those that are "different in kind and not merely in degree from the results of the prior art." *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004) (citation omitted). Appellant does not adduce any evidence of record to persuade us that the differences between the properties of the claimed oral composition and those of Formula B are differences in kind, rather than merely of degree.

We are consequently not persuaded that the Examiner erred in concluding that the claims would have been obvious over Patel (and Robinson for claim 13), and we affirm the Examiner's rejection of the claims.

CONCLUSION

The rejection of claims 1, 2, and 5–16 as unpatentable under 35 U.S.C. § 103, is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1).

AFFIRMED

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1, 2, 5–12, 14–16	103	Patel	1, 2, 5–12, 14–16	
13	103	Patel, Robinson	13	
Overall Outcome			1, 2, 5–16	