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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/262,015	09/29/2011	Lynette Zaidel	8408-00-US-01-OC	1031

23909 7590 11/15/2019

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ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
11/15/2019	ELECTRONIC

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte LYNETTE ZAIDEL, MICHAEL PRECIPE,
and SUMAN K. CHOPRA

_____

Appeal 2019-000941
Application 13/262,015
Technology Center 1600

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Before DONALD E. ADAMS, JEFFREY N. FREDMAN,
and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant[1] submits this appeal under 35 U.S.C. § 134 involving claims to an oral care composition including a bioactive glass and a bioadhesive polymer. The Examiner rejected the claims as obvious. 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(a). Appellant identifies Colgate-Palmolive Company as the real party in interest. Appeal Br. 2.

STATEMENT OF THE CASE

"The invention encompasses oral care compositions comprising one or more active components and one or more bioadhesive polymers, which cause the active component to adhere to a tooth surface." Spec. ¶ 1. "In certain embodiments, the active agent is an occlusion agent" that helps "prevent or alleviate tooth sensitivity." *Id.* "In certain embodiments, the occlusion agent is bioactive glass." *Id.* ¶ 7. According to the Specification, suitable bioadhesive polymers include, "for example, PEG/PPG copolymers (*e.g.*, BASF Pluracare[®] L1220), polyvinylmethylethermaleic acid copyolmer [sic] (*e.g.*, Gantrez[®], ISP), . . . and ester gum (e.g., Eastman Chemicals)." *Id.* ¶ 7.

Claims 31–41 are on appeal.[2] Claim 31, the only pending independent claim, is illustrative and reads:

> 1. An oral care composition comprising an occlusion agent, the occlusion agent comprising bioactive glass in an amount of 1 wt. % to 35 wt. %, based on total weight of the composition;
>
> and one or more bioadhesive polymer components in an amount of from 20% to 68.7% by weight of the composition comprising PEG/PPG copolymers, polyvinylmethylether/maleic acid, cross-linked PVP, shellac, ester gum, and combinations thereof;

[2] This application was subject to an earlier appeal to the Board, in which we affirmed the Examiner's rejections for obviousness and indefiniteness but reversed the rejection for anticipation. *Ex parte Zaidel*, Appeal No. 2014-007519 (PTAB Aug. 4, 2016). The claims at issue in the earlier appeal were later withdrawn, and the claims at issue in this appeal were added by amendment. *See, e.g.*, Request for Continued Examination and Amendment filed Oct. 4, 2016.

> wherein the composition comprises a PEG/PPG copolymer and a polyvinylmethylether/maleic acid;
>
> wherein the oral care composition provides a fluid flow rate of no greater than about 45% of the fluid flow rate of etched dentin.

Appeal Br. 13–14 (Claims App.).

The claims stand rejected as follows:

I. Claims 31–39 under 35 U.S.C. § 103(a) as obvious over Napolitano[3] and Ghosh.[4] Final Act. 3–5; *see also* Advisory Action (mailed Apr. 19, 2018, hereinafter "Adv. Act.") 2; and Ans. 3–5.

II. Claims 31–39 under 35 U.S.C. § 103(a) as obvious over Muscle.[5] Final Act. 5–6; *see also* Adv. Act. 2; and Ans. 5–6.

III. Claims 40 and 41 under 35 U.S.C. § 103(a) as obvious over (i) Napolitano and Ghosh, or (ii) Muscle, either (i) or (ii) in further view of Greenspan.[6] Final Act. 6–7; *see also* Ans. 6–8.

DISCUSSION

Obviousness of Claims 31–39 over Napolitano and Ghosh

The Examiner rejects each of claims 31–39 under 35 U.S.C. § 103 over the combined teachings of Napolitano and Ghosh. Final Act. 3–5.

The Examiner finds that Napolitano teaches compositions that adhere to dental surfaces and that act to create a physical barrier to dental pain and

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[3] Napolitano, WO 2004/045446 A1, published June 3, 2004.
[4] Ghosh et al., US 2007/0166244 A1, published July 19, 2007.
[5] Muscle et al., US 2009/0324516 A1, published Dec. 31, 2009.
[6] Greenspan et al., US 2007/0264291 A1, published Nov. 15, 2007.

hypersensitivity. *Id.* at 3 (citing Napolitano Abst.). According to the Examiner, one of the occlusive, pain-inhibiting agents disclosed for use in Napolitano's compositions is a bioactive glass. Final Act. 3; *see also* Napolitano 7:31–37 ("Agents capable of occluding the dentinal tubules [includes] but [is] not limited to . . . bioactive glass."), 8:14–17 ("The tubule blocking agent/occluder is incorporated in this composition in a desensitizing tubule occluding effective amount. . . . Suitably, the tubule blocking agent will be in an amount of about 0.1 to 15 wt.%.").

The Examiner further finds that Napolitano teaches the compositions may include one or more bioadhesive polymers. Final Act. 3–4. According to the Examiner, Napolitano discloses, for example, polyethylene oxide (Polyox®), alkylvinylether/maleic acid or anhydride copolymer (Gantrez®), as well as hydroxypropyl cellulose (HPC), and carboxymethyl cellulose (CMC) for such purposes. *See* Final Act. 3; *see also* Napolitano 6:14 ("The composition . . . is capable of adhering to natural teeth or surrounding soft tissue and comprises at least one water-swellable or water-soluble polymer. Suitable polymers include, but are not limited to, cellulose derivatives . . . polyethylene oxide ('Polyox®') . . . ('Gantrez®'), and mixtures thereof."). The Examiner further cites Napolitano's Example 7 as teaching film compositions including, *inter alia*, 15% Gantrez®, 5% HPC, 3% CMC, thus suggesting amounts of adhesive polymer within the scope of the range recited in claim 31 ("from 20% to 68.7%"). Final Act. 3–4, 5; *see also* Napolitano 12:20–32. The Examiner reasons that, because the general conditions of the claimed compositions were known in the art, it would have been obvious and routine to optimize the amounts of bioadhesive polymers,

such as Gantrez®, in Napolitano's compositions. Final Act. 4 (citing *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)).

The Examiner recognizes that Napolitano does not expressly disclose a PEG/PPG copolymer within its enumerated list of bioadhesive polymers. Final Act. 4. Nevertheless, the Examiner again notes Napolitano's disclosure of "Polyox®" as among the examples of suitable bioadhesive polymers that are listed, and then looks to Ghosh. Final Act. 4; *see also* Napolitano 6:19–20, 12:20–32 (Example 7 (listing Polyox® at 45 wt.%)).

For evidence of other known and suitable bioadhesives for use in oral care compositions, the Examiner cites Ghosh's teachings. Final Act. 4. The Examiner finds that Ghosh "teaches bioadhesive materials for adhering to teeth comprising Polyox and Pluronic (PEG/PPG copolymers)." Final Act. 4; *see also* Ghosh ¶ 36 ("Useful bioadhesive materials . . . include commercially available materials such as polyethylene oxide under the tradename Polyox from Dow Chemical Company; [and] block copolymers of ethylene oxide and propylene oxide designated under the tradenames Pluronic and Pluraflo from BASF," among others.). From this, the Examiner reasons that Polyox® and Pluronic® are known and suitable bioadhesive equivalents and that "it is obvious to replace one component for another equivalent component." Final Act. 4; Adv. Act. 2 ("Persons of ordinary skill in the art use known compounds based on their suitability for their intended use."); Ans. 4–5 ("[I]t is reasonable to conclude the sufficiency of the use of the PEG/PPG copolymer of Ghosh as adhesive polymer in Napolitano since the PEG/PPG copolymer of Ghosh is described therein as bioadhesive and equivalent in that regard to an adhesive polymer taught in Napolitano, i.e. Polyox.").

We agree with the Examiner on this record. We explain further below.

As an initial matter, we note that the pending claims do not specify the particular amounts of the PEG/PPG copolymer (e.g., Pluronic®) and polyvinylmethylether/maleic acid (e.g., Gantrez®) that must be included in bioadhesive polymer portion of the composition. To the contrary, the claims merely require that the total amount of any of the enumerated list of bioadhesive polymers in claim 31, alone or in combination, fall within the range of 20–68.7% by weight of the total composition—provided there is at least some PEG/PPG copolymer and polyvinylmethylether/maleic acid included. In other words, claim 31 would encompass, for example, a composition with 20% by weight Gantrez® and only a small amount of PEG/PPG copolymer. Similarly, claim 31 would encompass a composition with, for example, at least 20% by weight of another bioadhesive such as an ester gum, and only small amounts of Gantrez® and Pluronic®.

As the Examiner demonstrates, Napolitano teaches or suggests oral care compositions for essentially the same use as Appellant's invention—compositions that adhere to the teeth and include at least one occlusion agent that alleviates tooth sensitivity. Napolitano discloses that occlusion agents include bioactive glass, and suggests amounts of such agents (0.1–15 wt.%) that are largely encompassed by claim 31's broadly recited range (1 wt.% to 35 wt. %). Napolitano also identifies a *non-exhaustive* list of suitable bioadhesive polymers, one of which is Gantrez®, a known and commercially available polyvinylmethylether/maleic acid encompassed by claim 31. In examples, Napolitano includes Gantrez® in combination with

other bioadhesive, such as Polyox®, in amounts above the 20% lower bound recited in claim 31.

The only difference between Napolitano and the claimed invention is that Napolitano does not expressly identify PEG/PPG copolymers among its list of suitable bioadhesives. But, as explained by the Examiner, that deficiency is remedied by Ghosh. Ghosh evidences that PEG/PPG copolymers are known and commercially available bioadhesives (e.g., Pluronic®) for oral care compositions, and usable as an alternative or in addition to bioadhesives such as Polyox®. Ghosh ¶ 36. We are persuaded that the substitution or modification of the art proposed in this case involves little more than the predictable use of known prior art compounds for their known properties. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) ("[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious," the answer depends on "whether the improvement is more than the predictable use of prior art elements according to their established functions.").

Neither do the ranges of the bioactive glass and bioadhesive polymers recited in claim 31 patentably distinguish over the prior art. As explained, the claimed range of bioactive glass overlaps with the range suggested in Napolitano. Napolitano 7:28–8:21. And the range of bioadhesive polymers in Napolitano similarly overlaps the broad range of the claims, but for the inclusion of a known and substitutable PEG/PPG copolymer. *See, e.g.*, Napolitano 12:21–31; *see also In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) ("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 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."). Under these circumstances, and absent persuasive evidence to the contrary, the compositions of the prior art would possess the property related to a fluid flow rate in claim 31's final wherein clause. *See in re Spada*, 911 F.2d 705, 709 (Fed. Cir. 1990); *see also In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (requiring that the applicant demonstrate that obvious substantially identical products in the prior art do not possess such characteristics). Accordingly, we determine that the preponderance of the evidence here supports the Examiner's conclusion that claim 31 would have been obvious.

Appellant argues the prior art does not disclose all the claim elements. Appeal Br. 5. According to Appellant, because the cellulose compounds in Napolitano are not within the list of claimed bioadhesives, and because the highest concentration of Gantrez® is 15%, not at least 20% as claimed, the Examiner has not shown that the prior art range of bioadhesive polymers, in fact, overlaps with the claimed subject matter. *Id.*

This argument is unavailing. As explained, the range of bioadhesive polymer concentrations does overlap, but for the fact that Napolitano uses certain compounds that are known, alternative bioadhesive polymers for adhering compositions to the teeth compared to those recited in the claims. Upon the substitution of PEG/PPG copolymer, for example, with Napolitano's Polyox®, or with the cellulose bioadhesives, the ranges do overlap. Appellant provides no persuasive evidence to the contrary.[7]

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[7] Moreover, especially given that Napolitano and the claimed invention have essentially the same use, the amount of Gantrez®, as a bioadhesive for providing desired attachment to the tooth, is aptly characterized as a result-

Appellant argues "there is no evidence that the PEG/PPG copolymer of Ghosh would be suitable in Napolitano." Appeal Br. 6. According to Appellant, "the selection of polymers in Napolitano is crucial," and "Napolitano does not mention PEG/PPG copolymers." Appeal Br. 6; *see also* Reply Br. 2–3.

We find this argument unpersuasive. True, Napolitano does not expressly identify PEG/PPG copolymers; hence, the Examiner's reliance on Ghosh. But Appellant's contention that polymer selection is "crucial" in Napolitano is contradicted by Napolitano itself, which states that "[s]uitable [bioadhesive] polymers include, *but are not limited to*," polymers such as Gantrez® and Polyox®. Napolitano 6:14–22 (emphasis added). Thus, as pointed out by the Examiner, Napolitano's listing of bioadhesive polymers is not intended to be limiting or exhaustive. Ans. 4. On balance, we agree with the Examiner that the skilled artisan, considering Napolitano and Ghosh together, would consider Ghosh's PEG/PPG polymers, such as Pluronic®, as providing a similar bioadhesive function to Napolitano's Polyox® and consider those compounds to be substitutable alternatives within Napolitano's compositions.

Appellant argues that Ghosh uses its bioadhesives to enhance the adhesive property of its particular silicone pressure-sensitive compounds, yet Napolitano "does not contain any reference to silicone-containing materials." Appeal Br. 6–7. So, Appellant contends, there is no reason to

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effective variable, and its proportion in the compositions optimized accordingly.

use, or reasonable expectation of success in using, a PEG/PPG copolymer in Napolitano's composition.

We do not agree. There is nothing in Napolitano, nor any other evidence cited, to suggest any incompatibility or problem in using a PEG/PPG copolymer, such as the commercially available Pluronic® from BASF, as an alternative bioadhesive (e.g., to Polyox®) in Napolitano's composition. Although Ghosh may have discerned a particular advantage in using Pluronic® and/or Polyox® with its silicone-based dental compositions, that does not undermine the Examiner's finding that the skilled person would regard those compounds as alternative bioadhesive polymers that are more broadly suitable for the general function of adhering compositions to a subject's teeth.

Appellant also argues no reference here discloses the concurrent use of a PEG/PPG copolymer and a polyvinylmethylether/maleic acid. Appeal Br. 7. As this is a rejection for obviousness, it is not necessary that any one reference explicitly disclose both of those polymers in use together. The reasons for modifying or combining the bioadhesive polymer components is already discussed above. Appellant also cites no evidence to suggest a skilled person would have been concerned about their use alone or together—again, the evidence reflects both were known bioadhesives suitable for adhering compositions to the teeth. And, as discussed above concerning the interpretation of the claims, only very minor amounts of those particular polymers is necessary, with no evidence that this allegedly "unique combination" brings about any unique or unexpected benefits. *Id.*

In sum Appellant's argument do not demonstrate error in the Examiner's conclusion of obviousness on this record. We affirm the

rejection of claim 31 as obvious over Napolitano and Ghosh. Dependent claims 32–39 were not argued separately and we, therefore, affirm the rejection of those claims as well.

Obviousness of Claims 31–39 over Muscle

The Examiner rejects each of claims 31–39 under 35 U.S.C. § 103 over Muscle. Final Act. 5–6; *see also* Adv. Act. 2.

The Examiner finds that Muscle teaches dental compositions that include a bioactive glass (from 0.5–15 wt.%) to improve fluoride uptake, and that such compositions also include bioadhesive polymers. Final Act. 5. For example, the Examiner finds that Muscle's dental varnishes may include 0–75% of a colophony resin, which may be esterified to create an ester gum, one of the bioadhesive polymers encompassed by claim 31. *Id.* (citing Muscle ¶¶ 12, 72).

The Examiner further finds that Muscle discloses that its oral care compositions may include Gantrez® as a polymer enhancing agent, in a range of 0.001–5% and Pluronic® as a surfactant in a range of 0–20%. Final Act. 5. By combining Gantrez® (polyvinylmethylether/maleic acid) and Pluronic® (PEG/PPG copolymer) within the ranges suggested, the Examiner finds the composition would include biodhesive polymers within the claimed range of 20 to 68.7%. *Id.*

We generally agree with and adopt the Examiner's findings and conclusions as discussed below. Muscle discloses oral care compositions, such as dentifrice, for improved delivery of fluoride to the teeth. Muscle, Abstr., ¶ 2. Muscle discloses that the compositions may include a bioactive glass with concentrations (0.5–15% by weight) largely encompassed by the claimed range, and further suggests that additional polymer components,

such as Gantrez® and Pluronic® may be included in amounts that exceed 20% by weight (e.g., 18% Pluronic® as a surfactant, and 3% Gantrez® as a polymer enhancing agent). Muscle ¶¶ 45–47. Given the overlapping structural components (and concentrations) of the oral care composition suggested in the prior art compared to what is claimed, we agree with the Examiner that the claimed composition, including its recited properties, would have been obvious absent persuasive evidence to the contrary. *In re Best*, 562 F.2d at 1255.

Appellant argues Muscle describes *low* concentrations of PEG/PPG copolymers, in amounts under the 20% threshold of claim 31. Appeal Br. 7 ("Muscle exemplifies only sodium lauryl sulfate as a surfactant, at a concentration of 1.1%"); Reply 3–4. Appellant also argues Muscle's concentration of Gantrez® is "far below the range recited in the present claims," with no reasoning from the Examiner why higher amounts of Gantrez® would be used. Appeal Br. 7–8.

These arguments are unpersuasive. Muscle is not limited to what it exemplifies. To the contrary, it must be considered for all that it fairly teaches or suggests. *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012) ("[J]ust because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes."); *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989). And here, Muscle includes a disclosure that surfactants, such as Pluronic®, may be used in its oral care compositions in amounts up to 20%. Muscle ¶ 46. The Examiner does not rely on a rationale for increasing the amount of Gantrez® from 5% to 20%, but instead relies on Muscle's suggestion that Gantrez may be used in combination with other polymers (i.e., Pluronic®) such that the *total*

bioadhesive polymer component exceeds 20% as claimed. Appellant's argument about the Gantrez® concentration being below the claimed bioadhesive polymer range are, thus, inapposite. Appeal Br. 8.

Appellant also argues that Muscle does not teach the use of Gantrez® or surfactants with an esterified colophony resin. Appeal Br. 8; Reply Br. 3–4. As Appellant notes, Muscle describes use of an esterified colophony resin (e.g., to produce an ester gum) only with dental varnishes with no sufficient disclosure or technical reasoning from the Examiner to explain why, in the context of a varnish, the skilled artisan would also add a surfactant (e.g., Pluronic® as disclosed) as well as Gantrez® as a polymer-enhancing agent. Reply Br. 4 (citing Muscle ¶ 20, describing differences in the oral-care compositions and in particular varnishes, which are noted as not including surfactants).

On this point, we find Appellant's argument persuasive. The generalized chart in Muscle that the Examiner cites in response (Ans. 6) does not explain adequately why the particular combination of compounds would be used with Muscle's varnish example—the only one where there is any suggestion of esterifying the colophony resin. Nevertheless, as Muscle's teachings are not limited to the varnishes with esterified colophony resins, and because of Muscle otherwise suggests that Pluronic® and Gantrez® may be used with other oral care compositions in Muscle, the rejection is affirmed.

For the above reasons, we determine that the preponderance of the evidence supports the Examiner's conclusion that claim 31 would have been obvious over Muscle. Dependent claims 32–39 have not been argued separately and fall with claim 31.

Obviousness of Claims 40 and 41 over Napolitano, Ghosh, and Greenspan, or over Muscle and Greenspan

The Examiner's findings of fact and reasoning in support of the rejection of claims 40 and 41 are provided at pages 6–7 of the Final Rejection. *See* Ans. 6–8. We agree with and adopt the Examiner's findings and conclusion of obviousness on claims 40 and 41 for the reasons given. Appellant contends only that Greenspan does not cure the deficiencies with Napolitano/Ghosh, or Muscle, which it argued above. Appeal Br. 8. Having decided that Napolitano/Ghosh and Muscle are not deficient, we similarly reject Appellant's argument here.

CONCLUSION

For the reasons explained above, we find the preponderance of the evidence cited by the Examiner supports the Examiner's conclusion that claims 31–41 would have been obvious over the applied prior art.

DECISION SUMMARY

In summary:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
31–39	103(a)	Napolitano, Ghosh	31–39	
31–39	103(a)	Muscle	31–39	
40, 41	103(a)	Napolitano, Ghosh, Greenspan, or Muscle, Ghosh, Greenspan	40, 41	
Overall Outcome			31–41	

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