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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/106,279	06/18/2016	Joe Vazquez	9927-00-US-01-OC	2355
23909	7590	06/19/2020	EXAMINER	
COLGATE-PALMOLIVE COMPANY			ROBERTS, LEZAH	
909 RIVER ROAD			ART UNIT	PAPER NUMBER
PISCATAWAY, NJ 08855			1612	
			NOTIFICATION DATE	DELIVERY MODE
			06/19/2020	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOE VAZQUEZ, HARSH M. TRIVEDI,
LATONYA KILPATRICK-LIVERMAN, and STACEY LAVENDER

Appeal 2019-006020
Application 15/106,279
Technology Center 1600

Before DONALD E. ADAMS, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal^{1,2} under 35 U.S.C. § 134(a) involving claims to an oral composition. The Examiner rejected the claims as obvious and on the grounds of obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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 (*see* Appeal Br. 2).

² We have considered and refer to the Specification of June 18, 2016 (“Spec.”); Final Action of June 25, 2018 (“Final Act.”); Appeal Brief of Dec. 26, 2018 (“Appeal Br.”); Examiner’s Answer of June 7, 2019 (“Ans.”); and Reply Brief of Aug. 7, 2019 (“Reply Br.”).

Background

“One of the major contributors to malodor in the oral cavity is the bacteria present on the soft and hard oral tissues. Manual brushing and rinsing help to remove the bacteria, but they eventually repopulate over a period of time” (Spec. ¶ 1). “Zinc ions act as a bacteriostatic agent by binding with bacteria and slowing down the growth phase, leading to slower cell division and repopulation. Zinc salts in oral care products are known to react with sulfur compounds found in bad breath” (*id.* ¶ 2). “[T]here is still a need in the art for oral care compositions which have even greater efficacy in reducing oral malodor than previous zinc ion-containing compositions” (*id.* ¶ 3).

The Claims

Claims 1, 4–14, and 17 are on appeal³. Claim 1 is representative and reads as follows:

1. An oral care composition comprising:
 - a) arginine in free or salt form; and
 - b) zinc ions,wherein the zinc ions are present in the composition at a concentration selected from the group consisting of from 0.0005 mols/100g to 0.001 mols/100 g, and from 0.00052 mols/100g to 0.00062 mols/100g, based on the total weight of the composition, wherein the composition is a mouthwash.

The Issues

- A. The Examiner rejected claims 1, 4–10, 13, 14, and 17 under 35 U.S.C. § 103(a) as obvious over Mello⁴ (Ans. 3–4).

³ Claims 2, 3, 15, 16, and 18 were cancelled (*see* Appeal Br. 11–12).

⁴ Mello et al, US 2013/0078197 A1, published Mar. 28, 2013.

- B. The Examiner rejected claims 10–12 under 35 U.S.C. § 103(a) as obvious over Mello and Robinson⁵ (Ans. 4–5).
- C. The Examiner rejected claims 1, 4–11, 13, 14, and 17 under 35 U.S.C. § 103(a) as obvious over Porter⁶ (Ans. 5–6).
- D. The Examiner rejected claims 10–12 under 35 U.S.C. § 103(a) as obvious over Porter and Robinson (Ans. 6–7).
- E. The Examiner rejected claims 1, 4–6, 8–14, and 17 on the ground of provisional nonstatutory obviousness-type double patenting as obvious over claims 1–13 and 15–24 of copending US application 15/106,457⁷ (Ans. 7).

A. 35 U.S.C. § 103(a) over Mello

The Examiner finds that Mello teaches therapeutic oral compositions that comprise “arginine in free or salt form” and zinc salts that “include zinc citrate and zinc oxide” (Ans. 3). The Examiner finds Mello teaches “the amount of zinc used ranges from 0.01 to 5%, whereas the instant claims recite 0.0005 mols/100g to 0.001 mols/100[g] and 0.00052 mols/100g to 0.00062 mols/100g” (*id.* 4).

The Examiner finds the claims obvious because “where the claimed ranges ‘overlap or lie inside ranges disclosed by the prior art’, a prima facie case of obviousness exists” (Ans. 4).

⁵ Robinson et al, US 2010/0330002 A1, published Dec. 30, 2010.

⁶ Porter et al., WO 2011/123123 A1, published Oct. 6, 2011.

⁷ We note that US application 15/106,457 issued as US 10,441,517 on Oct. 15, 2019.

The issues with respect to this rejection are:

(i) Does a preponderance of the evidence of record support the Examiner's conclusion that Mello teaches an overlapping range of zinc ions as required by claim 1?

(ii) If so, has Appellant provided evidence of unexpected results that outweighs the evidence supporting the prima facie case of obviousness?

Findings of Fact

1. Mello teaches "a therapeutic oral composition useful in the treatment of dentinal hypersensitivity, anticaries, bad breath" (Mello ¶ 10).

2. Mello teaches the "oral care composition of the preferred embodiments includes arginine in free or salt form . . . zinc salts" (Mello ¶ 22).

3. Mello teaches the "composition preferably is in the form of a mouthwash or mouthrinse" (Mello ¶ 22).

4. Mello teaches the "arginine in free or salt form may be present in the compositions described herein in an amount of 0.1 wt. % to 20 wt. % of the total composition weight" (Mello ¶ 28).

5. Mello teaches the "antibacterial agent . . . may be CPC, chlorhexidine, zinc citrate, zinc oxide, and mixtures thereof" (Mello ¶ 35).

6. Mello teaches "zinc salts may be present in amounts within the range of from 0.01-5% by weight, more preferably from 0.1-1 % of zinc salt weight, based on the total weight of the composition" (Mello ¶ 35).

7. The Examiner finds the "endpoint 0.1 % encompasses 0.00054 mol. of zinc, when using zinc citrate and zinc oxide" (Ans. 8). Appellant calculates that "1 % zinc citrate corresponds to 0.00522 mols/100g ($1 \div 574.338 \times 3$), while 1 % zinc oxide corresponds to 0.0122 mols/100g ($1 \div 81.38 \times 1$)" (Appeal Br. 6).

8. Table 1 of Mello exemplifies compositions II and VI that contain 0.28 wt. % zinc citrate, which equals 0.0015 mols/100g ($0.28 \div 574.338 \times 3$) (*see* Mello ¶ 71).

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).

Analysis

Prima facie obviousness

We adopt the Examiner’s findings of fact and reasoning regarding the scope and content of the prior art (Ans. 3–5; FF 1–7) and agree that Mello renders the claims obvious. We address Appellant’s arguments below.

Appellant contends

Although Mello discloses broad ranges of weight percent for zinc salts, Mello does not disclose or teach any molar concentration of zinc ions. The molar concentration of zinc ions in a composition depends not only on the weight percent of zinc salt but also on the molar mass of the zinc salt and the number of zinc ions present in the zinc salt.

(Appeal Br. 6). Appellant states “[t]hus, 1% zinc citrate corresponds to 0.00522 mols/100g . . . while 1% zinc oxide corresponds to 0.0122 mols/100g” (*id.*).

We find this argument unpersuasive because the ordinary artisan would recognize that weight percent and molar mass are two known alternative approaches for measuring amounts of components in compositions. In this case, Mello teaches that either zinc citrate or zinc oxide may be used (FF 5) in amounts “from 0.01-5% by weight, more preferably from 0.1-1 % of zinc salt weight” (FF 6). The calculations of Appellant demonstrate that at the upper endpoint of the Mello’s preferred

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0.1-1% range, 1 % zinc citrate corresponds to 0.00522 mols/100g and 1 % zinc oxide corresponds to 0.0122 mols/100g (FF 7). Using the same equation, at the 0.1% lower endpoint of Mello's preferred range, 0.1% zinc citrate would be 0.000522 mols/100g and 0.1% of zinc oxide would be 0.00122 mols/100 g. At the lowest range endpoint disclosed by Mello of 0.01%, zinc citrate would be 0.0000522 mols/100g and zinc oxide would be 0.000122 mols/100g.

Thus, the evidence of record demonstrates that the Mello ranges for either zinc citrate or zinc oxide overlap those recited by claim 1. *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.”). Appellant provides no evidence that persuasively rebuts the Examiner's finding that the range of Mello overlaps with that recited by claim 1.

Appellant contends that “one of skill in the art would not be motivated to lower the amount of zinc salts in Mello's mouthwash to arrive at the claimed composition with a reasonable expectation of success that the low amount of zinc salts would be sufficient to reduce VSC” (Appeal Br. 7).

We find this argument unpersuasive because Mello expressly teaches values as low as 0.01%, a value lower than the ranges recited in claim 1 as discussed above (*see* FF 6). The ordinary artisan would have had reason to use any value within the range disclosed by Mello. “The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.” *Peterson*, 315 F.3d at 1330.

Unexpected Results

Appellant contends that:

This application is based on the surprising and unexpected discovery that the combination of arginine and a zinc ion source can reduce volatile sulfur compounds (VSC) found in bad breath to an extent that is significantly greater - almost twice as great - than the combined individual effects of the arginine and zinc ion source.

(Appeal Br. 6). Appellant contends that Table 2 shows experiments where “zinc salts alone provided a reduction of VSCs from about 36% to 43%, and arginine alone removed about 8% of VSCs” (*id.*). Appellant contends that “[w]hile the additive effect would have been expected to be about 51 % or less, the combination of arginine and zinc salts removed 95% to 97% of the VSCs” (*id.*).

We find the asserted unexpected results unpersuasive for several reasons. First, no comparison is performed with the composition disclosed in Table 1 of Mello. Thus, Appellant fails to provide any comparison showing an unexpected result compared with the closest prior art. *See 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.”).

Second, unexpected results must be “commensurate in scope with the degree of protection sought by the claimed subject matter.” *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005). In this case, the results in Table 2 of the Specification are demonstrated for a single value of zinc oxide of 0.05 weight % and a single value of zinc citrate of 0.1 weight %, as well as single values of zinc lactate and zinc chloride (*see Spec.* ¶ 72). Claim 1, however, recites a range that extends from 0.0005 mols/100g to 0.001 mols/100g, and

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the single values tested do not demonstrate unexpected results through this entire range.

Third, we find the evidence of the Specification does not demonstrate a difference in kind because the change identified by Appellant ranges from 44 to 46% (either Appellant's 95% or 97% results minus the additive effect of 51% shown for the arginine and zinc separately). Appellant does not explain why a change of 46% is a difference in kind rather than degree. In *Harris*, the court found that a "32–43% increase in stress-rupture life, however, does not represent a 'difference in kind' that is required to show unexpected results." *In re Harris*, 409 F.3d 1339, 1344 (Fed. Cir. 2005).

Conclusions of Law

(i) The evidence of record supports the Examiner's conclusion that Mello renders the claims prima facie obvious.

(ii) Appellant has not provided evidence of unexpected results that outweighs the evidence supporting the prima facie case of obviousness.

B. 35 U.S.C. § 103(a) over Mello and Robinson

Appellant does not argue separately claims 10–12 in this obviousness rejection, instead relying upon overcoming Mello (*see* App. Br. 7). Having found no deficiency in Mello as it relates to Appellant's claim 1, we are not persuaded by Appellant's contention to the contrary regarding the obviousness of claims 10–12 over Mello and Robinson.

C. 35 U.S.C. § 103(a) over Porter

The Examiner finds Porter teaches "oral care compositions comprising a metal oxide particle such as zinc oxide. The metal oxide may comprise up to 5% by weight of the composition, preferably 0.5 to 2%"

(Ans. 5). The Examiner finds that “compositions comprise at least one amino acid such as L-arginine . . . [and] may be used in mixtures and comprise 0.5 to 5% by weight” (*id.*). The Examiner finds that “[i]n the case where the claimed ranges ‘overlap or lie inside ranges disclosed by the prior art’, a prima facie case of obviousness exists” (*id.* at 6).

The issues with respect to this rejection are:

(i) Does a preponderance of the evidence of record support the Examiner’s conclusion that Porter teaches an overlapping range of zinc ions as required by claim 1?

(ii) If so, has Appellant provided evidence of unexpected results that outweighs the evidence supporting the prima facie case of obviousness?

Findings of Fact

9. Porter teaches “an oral care composition, for example a dentifrice composition, for enhanced delivery of an antiplaque/ anticalculus agent to the oral surfaces in the oral cavity, and which may additionally treat or prevent hypersensitivity of the teeth” (Porter ¶ 1).

10. Porter teaches the composition includes “at least one amino acid comprises L-arginine. . . . and typically may be present in an amount of up to 5% by weight, further optionally from 0.5 to 5% by weight” (Porter ¶¶ 50–51).

11. Porter teaches the composition may include “one or more metal oxides selected from zinc oxide” and “may be present in an amount of up to 5 % by weight, preferably of up to 2% by weight, more preferably from 0.5 to 2% by weight” (Porter ¶¶ 52–53).

Principles of Law

A prima facie case for obviousness “requires a suggestion of all limitations in a claim,” *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333,

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1342 (Fed. Cir. 2003) and “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *KSR*, 550 U.S. at 418.

Analysis

Prima facie obviousness

Appellant contends “[z]inc oxide is the only metal oxide containing zinc ions. 0.5% zinc oxide provides 0.0061 mols of zinc ions/100g ($0.5 \div 81.38 \times 1$). Thus, the range (from 0.5% to 2%) disclosed in Porter does not overlap the claimed molar concentration range of zinc ions” (Appeal Br. 8). Appellant contends that “[s]ince Porter does not disclose or teach any range or value overlapping the claimed molar concentration range of zinc ions, the claimed range would not be prima facie obvious over Porter” (*id.*).

The Examiner responds

Porter discloses a composition comprising a combination of zinc oxide and arginine. Although the amounts are not close or the same as that of the instant claims or instant examples, Appellants have not shown these to be critical amounts by comparing the compositions of the examples with comparative examples varying the amounts.

(Ans. 14).

We find that Appellant has the better position. As Appellant correctly points out, the lowest disclosed range endpoint in Porter results in 0.0061 mols of zinc ion, which is six times higher than the upper endpoint disclosed in claim 1. Thus, Porter does not teach an overlapping range or even a range that is almost adjacent to the claimed range. Moreover, the Examiner provides no reason why Porter or the ordinary artisan would choose to select values of zinc oxide six-fold lower than those disclosed in Porter.

Therefore, the rejection neither provides a suggestion of all the limitations of

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claim 1 nor does the rejection provide a reason to modify Porter to obtain the claimed invention. We therefore need not reach the issue of secondary considerations.

D. 35 U.S.C. § 103(a) over Porter and Robinson

Having reversed the obviousness rejection of claim 1 over Porter for failing to disclose the zinc ion range required by claim 1 for the reasons given above, we also find that the further combination with Robinson does not address this issue and therefore does not render the rejected claims obvious for the same reasons.

E. Obviousness-type Double Patenting

The Examiner finds the instant claims are not patentably distinct from those in US application 15/106,457 (now Prencipe et al., US patent 10,441,517 B2, issued Oct. 15, 2019) because

the claims are coextensive insofar as both recite oral compositions comprising a zinc salt and an arginine. The claims differ insofar as the instant claims recite mols/g whereas the copending claims recite percentages. However the claims encompass the same amounts.

(Ans. 7).

Appellant contends “the molar concentration of zinc ions according to pending claims of 15/106,457 is greater than 0.00184 moles/100g. Since the ranges disclosed in the pending claims of 15/106,457 do not overlap the claimed molar concentration range of zinc ions, the claimed range would not be prima facie obvious” (Appeal Br. 9). Appellant also contends that “the specific combination of arginine and a zinc ion source can synergistically reduce volatile sulfur compounds (VSCs) as described in the present

specification, and this is unexpected reduction is ‘of a significant, practical advantage’” (*id.* at 10).

Claims 1 and 3 of the ’517 patent are reproduced below:

1. An oral care composition comprising:
 - a. arginine, in free or salt form; and
 - b. zinc oxide and zinc citrate,wherein a molar ratio of arginine to total zinc salts is 0.4:1 to 0.8:1 and wherein a weight ratio of zinc oxide to zinc citrate is 1.7:1 to 2.3:1 and wherein the arginine is present in an amount of 1.4 weight % to 1.6 weight % based on the total weight of the composition.

3. The oral care composition of claim 1, wherein the total concentration of zinc salts in the composition is 0.2 weight % to 5 weight %, based on the total weight of the composition.

As Appellant correctly points out, the lowest value of zinc salts is 0.2 weight % and because the claim requires both zinc citrate and zinc oxide in a particular molar ratio, Appellant calculates a final value of 0.00184 moles/100 g for zinc in total. Appellant posits that an examiner can only find a prima facie case of obviousness if there is an overlap between the claimed range and prior art range.

We note that *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 783 (Fed. Cir. 1985) found a case of obviousness when the “proportions are so close that prima facie one skilled in the art would have expected them to have the same properties. Appellee produced no evidence to rebut that prima facie case.” *Id.* Here, the instant Specification demonstrates that the ranges can be flexibly applied, for example “a weight ratio of zinc oxide to zinc citrate is 1.5: 1 to 4.5: 1, 1.5: 1 to 4: 1, 1.7 :1 to 23:1, 1.9:1 to 2.1:1, or about 2:1. Also, the corresponding molar ratios based on these weight ratios can be used” (Spec. ¶ 6). Therefore, we find that the range here lacks a

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showing of criticality and the presence of flexible endpoints supports a finding of obviousness.

Here, Appellant provides no evidence showing that the addition of 0.00084 mols/100g of zinc salts would have been expected to have different properties from those of the composition recited in claim 1. *See In re Peterson*, 315 F.3d at 1329 315 F.3d 1325, 1329 (Fed. Cir. 2003) (recognizing “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.”)

As to Appellant’s asserted unexpected results, we find them unpersuasive for the reasons given above, specifically that the evidence has not been compared to the closest prior, is not commensurate in scope with the claims, and fails to show a difference in kind relative to the prior art.

We therefore find the instant claims obvious over the claims in US patent 10,441,517.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
1, 4–10, 13, 14, 17	103	Mello	1, 4–10, 13, 14, 17	
10–12	103	Mello, Robinson	10–12	
1, 4–11, 13, 14, 17	103	Porter		1, 4–11, 13, 14, 17
10–12	103	Porter, Robinson		10–12
1, 4–6, 8–14, 17	Double Patenting	US 15/106,457	1, 4–6, 8–14, 17	
Overall			1, 4–14, 17	

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Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
Outcome				

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