



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.
13/932,088	07/01/2013	Gertrud KAWA	OASP-0036	3270
16375	7590	11/23/2018	EXAMINER	
Medley, Behrens & Lewis, LLC 6100 Rockside Woods Blvd. Suite 440 Independence, OH 44131			MILLIGAN, ADAM C	
			ART UNIT	PAPER NUMBER
			1612	
			NOTIFICATION DATE	DELIVERY MODE
			11/23/2018	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):

tbehrens@medleybehrens.com
nlewis@medleybehrens.com
admin-docketing@medleybehrens.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GERTRUD KAWA, SHIREEN UPPAL,
and DAVID URQUHART

Appeal 2017-007464
Application 13/932,088¹
Technology Center 1600

Before JEFFREY N. FREDMAN, RYAN H. FLAX and DAVID COTTA,
Administrative Patent Judges.

COTTA, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of treating xerostomia or mouth dryness. The Examiner rejected the claims on appeal under 35 U.S.C. § 103(a) as obvious.

We reverse.

¹ According to Appellants, the real parties in interest are GlaxoSmithKline Consumer Healthcare GmbH & Co KG, Glaxo Group Limited, and Oasis Consumer Healthcare, LLC. App. Br. 2.

STATEMENT OF THE CASE

The Specification discloses that “[x]erostomia, or dry mouth, is a condition in which an excessive dryness within the oral cavity occurs.”

Spec. 1. “Xerostomia is not itself a disease, but a symptom of various medical conditions, a side effect of radiation to the head and neck, or a side effect of a variety of medications.” *Id.* “Xerostomia is often a contributing factor for both minor and serious health problems; it can affect nutrition and dental, as well as psychological health.” *Id.* “[I]t would be advantageous to provide compositions for oral use as a lubricant to alleviate the discomfort associated with xerostomia.” *Id.* The Specification teaches that “the symptoms of dry mouth may be reduced by the use of an oral care composition comprising a combination of polyvinyl pyrrolidone (PVP) or a derivative thereof with an anionic mucoadhesive polymer.” *Id.* at 2.

Claims 9–12 and 21–36 are on appeal. Claims 9, 29, and 35, the only independent claims on appeal, are illustrative and read as follows:

9. A method of treating xerostomia or mouth dryness by administering to a person in need thereof a liquid composition comprising:

(A) ingredients in effective amounts for treating xerostomia or mouth dryness consisting of:

(i) polyvinyl pyrrolidone or a derivative thereof

and

(ii) an anionic mucoadhesive polymer; and

(B) one or more orally acceptable carriers or excipients selected from the group consisting of: flavoring agents, humectants, binders, sweetening agents, surfactants, preservatives, buffering agents, coloring agents and water.

29. A method of treating xerostomia or mouth dryness by administering to a person in need thereof a liquid composition comprising:

0.1 to 20% by weight polyvinyl pyrrolidone or a derivative thereof; and
an anionic mucoadhesive polymer;
wherein the weight ratio of the polyvinyl pyrrolidone or derivative thereof to the anionic mucoadhesive polymer is from 4:1 to 2:1;
wherein the liquid composition is exclusive of abrasive polishing materials.

35. A method of treating xerostomia or mouth dryness by administering to a person in need thereof a liquid composition consisting of:

0.1 to 20% by weight polyvinyl pyrrolidone or a derivative thereof;
an anionic mucoadhesive polymer;
one or more orally acceptable carriers or excipients selected from the group consisting of: flavoring agents, humectants, binders, sweetening agents, surfactants, preservatives, buffering agents, coloring agents and water;
optionally, additional ingredients selected from the group consisting of: antimicrobial agents, moisturizing agents, breath freshening agents, and desensitising agents;
wherein the weight ratio of the polyvinyl pyrrolidone or derivative thereof to the anionic mucoadhesive polymer is from 4:1 to 2:1.

Claim App'x.

The claims stand rejected as follows.²

Claims 9–12, 22–32, and 35 were rejected under 35 U.S.C. § 103(a) as obvious over Bannister.³

² In the Examiner's Answer, the Examiner withdrew the pending rejection of claims 9–12 and 21–36 under 35 U.S.C. § 112 for failing to comply with the written description requirement. Ans. 4. This rejection is thus no longer part of this appeal.

³ Bannister, WO 2004/000252 A1, published Dec. 31, 2003 (“Bannister”).

Claims 9–12 and 21–36 were rejected under 35 U.S.C. § 103(a) as obvious over the combination of Bannister and Majeti.⁴

OBVIOUSNESS OVER BANNISTER

Claims 9–12 and 21–28

The Examiner finds that Bannister discloses “a method for treating xerostomia comprising administering an oral lubricant composition to the oral cavity.” Final Act. 4. The Examiner concludes that the method disclosed in Bannister renders the method of claim 9 obvious. *Id.* Appellants argue that claim 9 is not obvious because the compositions Bannister uses to treat dry mouth include phosphoprotein and it would not have been obvious to remove phosphoprotein from Bannister’s compositions. App. Br. 5. We find that Appellants have the better position.

We begin by construing the claims. Claim 9 requires “ingredients in effective amounts for treating xerostomia or mouth dryness consisting of . . . polyvinyl pyrrolidone . . . [and] an anionic mucoadhesive polymer.” It is well settled that the transitional phrase “consisting of” is closed to elements not recited. *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1358 (Fed. Cir. 2016). Here, the transitional phrase “consisting of” appears in the body of the claim in a clause identifying ingredients effective for treating xerostomia or mouth dryness. It is preceded by the transitional phrase “comprising” in the preamble. Accordingly, we construe the transitional phrase “consisting of” in the clause at issue to limit the ingredients that are effective for treating xerostomia or mouth dryness to those recited in the claim, but not to limit

⁴ Majeti et al., US Patent Publication No. 2003/0124065 A1, published July 3, 2003 (“Majeti”).

other method steps. *Mannesmann Demag Corp. v. Engineered Metal Products Co.*, 793 F.2d 1279, (Fed. Cir. 1986) (finding that “[t]he district court correctly observed that the phrase ‘consisting of’ appears in clause (a), not the preamble of the claim, and thus limits only the element set forth in clause (a)”).

The compositions disclosed in Bannister include phosphoproteins as an active ingredient for treating xerostomia. *See, e.g.*, Bannister 2 (“The present invention provides formulations for use as an oral lubricant and for use as saliva substitutes in humans or animals, wherein said formulations comprise phosphoproteins. Further, the present invention provides formulations that are particularly useful for treating humans or animals with xerostomia.”). As discussed above, claim 9 limits the ingredients that are effective for treating xerostomia or mouth dryness to those recited in the claim. Because phosphoproteins are effective for treating xerostomia, and because they are not among the ingredients listed in claim 9, they are excluded from the claim.

The Examiner argues that phosphoproteins are not excluded because “a phosphoprotein may be anionic and mucoadhesive.” Ans. 5. We are not persuaded because, as Appellants point out (Reply Br. 3), the Examiner does not provide evidence to support this assertion.

The Examiner also argues that it would have been obvious to remove phosphoprotein and replace it with CMC (carboxymethyl cellulose) or PVP (polyvinylpyrrolidone) because phosphoprotein, CMC, and PVP are all taught to be viscosity modifiers. Ans. 5. The Examiner contends that “phosphoprotein is merely a preferred embodiment rather than a critical ingredient” and thus “substituting the phosphoprotein for PVP and CMC

would not change the performance of the composition given that phosphoprotein, PVP and CMC are all taught by Bannister as equivalents for the same purpose.” *Id.* at 6. We are not persuaded.

Even if we were to credit the Examiner’s assertion that CMC, and PVP are all taught to be viscosity modifiers,⁵ the Examiner still failed to carry the burden to demonstrate that it would have been obvious to substitute CMC and PVP for Bannister’s phosphoproteins because the Examiner does not identify any teaching that CMC and PVP are equivalent to phosphoproteins as oral lubricants. Bannister repeatedly describes phosphoprotein as the critical lubricating component. *See e.g.*, Bannister, 1 (“This invention relates to formulations containing phosphoprotein, designed for use as oral lubricant or as artificial saliva, and methods of using the formulations.”); *id.* (“Phosphoproteins have been described for use in formulations for the treatment or prevention of diseases resulting from the action of bacteria in the oral cavity, for example, caries and gingivitis. However, such formulations have not been described for use as an oral lubricant or as a saliva substitute.”); *id.* at 2 (“The present invention provides formulations for use as an oral lubricant and for use as saliva substitutes in humans or animals, wherein said formulations comprise phosphoproteins.”); *id.* at 4 (“Typically, the formulation may comprise any two or more of the phosphoproteins disclosed herein. Inclusion of casein phosphoprotein in a

⁵ Bannister discloses “proteins” among a list of suitable viscosity modifiers (Bannister 7), but the Examiner does not identify anything in Bannister specifically identifying phosphoproteins as viscosity modifiers. We do not reach the issue of whether Bannister discloses CMC, PVP, and phosphoproteins as equivalent viscosity modifiers because it is not necessary to our decision.

formulation for lubrication of the oral cavity provides improved lubrication, for example by providing a more effective lining of the surfaces of the oral cavity compared to formulations in which casein phosphoprotein is absent.”). The Examiner does not identify, and we do not find, anything in Bannister to suggest that CMC or PVP can be substituted for phosphoprotein as an oral lubricant.

Accordingly, we reverse the Examiner’s rejection of claim 9 as obvious over Bannister. Claims 10–12, and 22–28 depend from claim 9 and we reverse the Examiner’s rejection of these claims for the reasons discussed in connection with claim 9.

Claims 29–36

Independent claims 29 and 35 both require that “the weight ratio of the polyvinyl pyrrolidone . . . to the anionic mucoadhesive polymer is from 4:1 to 2:1.” In finding that Bannister renders the claimed weight ratio obvious, the Examiner relied principally on Bannister’s disclosure that PVP and CMC were both viscosity modifiers. The Examiner explained:

Bannister teaches using PVP and CMC as viscosity modifiers. Thus, the prior art recognizes that a combination of PVP and CMC will provide viscosity modification to a composition. Specifically, Bannister teaches the use of these viscosity modifiers . . . to replicate the viscosity of natural saliva. Applicants have provided no evidence of unexpected results or criticality of the claimed range. One of ordinary skill in the art would find it prima facie obvious to follow the teachings of Bannister and combine known viscosity modifiers in amounts sufficient to replicate natural saliva.

Final Act. 6–7. We are not persuaded.

We acknowledge that Bannister discloses both PVP and CMC as two among a long list of viscosity modifiers that may be present in Bannister’s

compositions in a concentration between 0.001% and 20%. Bannister 7. However, the Examiner does not identify, and we do not find in Bannister, any reason to include PVP and CMC in the specific ratio recited in the claims. The Examiner asserts that it would be obvious to combine viscosity modifiers in amounts sufficient to replicate natural saliva, but does not explain why replicating saliva would lead one to use PCP and CMC in the claimed ratio. Because the Examiner has not persuasively explained why the skilled artisan would combine PVP and CMC in the claimed ratio, we reverse the Examiner's rejection of claims 29 and 35 as obvious over Bannister. Claims 30–34 depend from claim 29 and claim 36 depends from claim 35. We reverse the Examiner's rejection of these claims for the reasons discussed in connection with claims 29 and 35.

OBVIOUSNESS OVER BANNISTER AND MAJETI

Claims 9–12 and 21–28

In rejecting claims 9–12 and 21–28 as obvious over the combination of Bannister and Majeti, the Examiner applied Bannister in the same manner discussed above with respect to the rejection over Bannister alone.

Accordingly we reverse the Examiner's rejection of claim 9–12 and 21–28 for the reasons discussed above with respect to the rejection over Bannister.

Claims 29–36

As discussed above, independent claims 29 and 35 both require that “the weight ratio of the polyvinyl pyrrolidone . . . to the anionic mucoadhesive polymer is from 4:1 to 2:1.” In finding these claims obvious, the Examiner relies on Bannister's disclosure that both PVP and CMC are viscosity modifiers. Final Act. 9. This is not persuasive for the reasons discussed above. In addition, the Examiner relies on Majeti's disclosure of

“an oral dentifrice composition comprising 3% PVP/VA, 0.8% sodium carboxymethylcellulose (NaCMC) and 0.5% xanthan gum (Example IVB)” which the Examiner concludes is a ratio of PVP to CMC of 3.75:1. Final Act. 9. Appellants argue that Majeti discloses compositions for cleaning teeth and that a skilled artisan would not have reason to combine such a composition with Bannister’s composition for treating dry mouth. App. Br. 8. We find that Appellants have the better position.

Majeti discloses “oral care compositions and methods for overall cleaning, whitening and preventing, reducing or removing surface deposited stains on natural teeth and dental prosthesis.” Majeti Abstract. The Examiner asserts that it would have been obvious to combine Bannister and Majeti because they are both oral compositions and oral compositions “clearly treat dry mouth.” Final Act. 8 (“given that oral compositions clearly treat dry mouth, it would have been *prima facie* obvious to combine two compositions that would treat dry mouth to form a third composition for the same purpose”). The Examiner, however, does not identify any evidence to support the general proposition that oral compositions treat dry mouth. Nor does the Examiner offer evidence to support the more specific proposition that the compositions disclosed in Majeti treat dry mouth. Accordingly, the Examiner has not carried the burden to establish that it would have been obvious to combine the compositions of Majeti and Bannister because they are both useful for treating dry mouth.

The Examiner also asserts that it would have been obvious to combine the teachings of Majeti and Bannister because Majeti teaches that using a derivative form of PVP provides greater retention on oral surfaces. *Id.* From this, the Examiner concludes that “[t]he ability to form a coating on

oral surfaces would be expected to treat xerostomia as one symptom of xerostomia is damaged teeth. Thus, protection of teeth is, in the broad sense, ‘treating’ xerostomia.” *Id.* (internal citations omitted). We agree with Appellants that this connection is too attenuated and that a skilled artisan “would not reasonably consider treating tooth and dental prosthesis stains as a treatment for xerostomia or dry mouth.” App. Br. 9. Accordingly, we reverse the Examiner’s rejection of claims 29–36.

SUMMARY

In summary, we reverse the Examiner’s rejection of claims 9–12, 22–32, and 35 under 35 U.S.C. § 103(a) as obvious over Bannister

We reverse the Examiner’s rejection of claims 9–12 and 21–36 under 35 U.S.C. § 103(a) as obvious over the combination of Bannister and Majeti.

REVERSED