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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte WEI WANG, JAMES R. BROWN,
HARSH M. TRIVEDI, and JOE VAZQUEZ¹

Appeal 2014-009539
Application 13/701,227
Technology Center 1600

Before FRANCISCO C. PRATS, ULRIKE W. JENKS, and
TAWEN CHANG, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134(a) involves claims to a mouthwash composition. The Examiner rejected the claims for obviousness.

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

STATEMENT OF THE CASE

The sole rejection before us for review is the Examiner's rejection of claims 1–3, 8, 9, and 21 under 35 U.S.C. § 103(a) as being unpatentable over Weiss.² Final Action 2–4.³

¹ Appellants state that the “real party in interest for this appeal and for the above-referenced application is the assignee, Colgate-Palmolive Company.” Br. 2.

² U.S. Patent No. 5,840,322 (issued Nov. 24, 1998).

Claim 1, the sole independent claim on appeal, is representative and reads as follows (App. Br. 8, paragraphing added):

1. An oral care composition in the form of a mouthwash comprising cranberry extract nondialyzable material and an orally acceptable vehicle,
wherein the cranberry extract non-dialyzable material is present in the composition in a concentration of about 0.3% w/w and
wherein the composition does not contain a component that deactivates the cranberry extract non-dialyzable material.

OBVIOUSNESS

The Examiner found that Weiss describes mouthwash compositions having nearly all of the features of claim 1, but conceded that Weiss differs from claim 1 in that Weiss does not teach that the cranberry extract non-dialyzable material is present in Weiss's compositions at a concentration of about 0.3% w/w. Final Action 2–3. The Examiner concluded, however, that because Weiss “teaches that the effective amount [of the active ingredient] is determined by the person having ordinary skill in the art, it would have been obvious to adjust the concentration of the extract to about 0.3%.” *Id.* at 3.

The Examiner reasoned in particular that it would have been a matter of routine optimization to determine suitable concentrations of the active ingredient and thereby arrive at the concentration of cranberry extract non-dialyzable material required by claim 1. *Id.* at 3–4 (citing MPEP § 2144.05, II. A; *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)). The Examiner reasoned further that, because the claimed concentration of active ingredient falls within the prior art's suitable concentration range, the claimed concentration

³ Final Action entered October 21, 2013.

would have been *prima facie* obvious. *Id.* at 4 (citing *In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003)).

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

[T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . .

After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

We select claim 1 as representative of the rejected claims. 37 C.F.R. § 41.37(c)(1)(iv). Appellants' arguments do not persuade us that a preponderance of the evidence fails to support the Examiner's *prima facie* case of obviousness as to claim 1.

Appellants argue initially that Weiss does not teach or suggest claim 1's requirement for the mouthwash to contain 0.3 % w/w cranberry extract non-dialyzable material. App. Br. 5–6; Reply Br. 3.

We are not persuaded. Weiss discloses “a non-food oral hygiene composition comprising a suitable carrier and an effective amount of the isolated [antibacterial] adhesion inhibitory fraction from juice from berries of the plant genus *Vaccinium*. . . . The preferred embodiment is prepared from cranberry juice or juice concentrate.” Weiss 3:31–54.

As the Examiner found, and as required by claim 1, Weiss discloses a method of inhibiting oral bacteria in which “the inventive compositions may constitute an integral part of a toothpaste, dental cream or gel, tooth powder, *or mouthwash*” *Id.* at 4:41–43 (emphasis added).

As the Examiner found, Weiss discloses that its active ingredient is produced by dialyzing cranberry juice to produce “non-dialyzable material

(NDM),” which is then lyophilized and fractionated on a polyacrylamide resin column to produce ultimately an antibacterial active fraction designated “PF-1.” *Id.* at 4:52–65.

As the Examiner found, and as required by claim 1, Weiss discloses that the NDM can be used as the active ingredient in the disclosed compositions:

NDM as shown in the examples can be used in the present invention to inhibit or reverse intergeneric coaggregation/adhesion of oral bacteria, and a pharmaceutically acceptable carrier. The concentration of NDM however in the carrier is between 25 µg/ml and 100 mg/ml. For inhibition of coaggregation a range between 0.05 mg/ml and 0.4 mg/ml can be used. For reversal of coaggregation a range between 1 mg/ml and 4 mg/ml can be used.

Id. at 4:66–5:6; *see also id.* at 6:32–37 (“In a preferred embodiment an effective amount of the isolated adhesion inhibitory fraction PF-1 is used. However, in an alternative embodiment NDM can be used.”).

As the Examiner found, Weiss discloses that its active ingredient may be present in oral hygiene compositions at a “concentration of the isolated adhesion inhibitory fraction . . . between 1 µg and 10 mg per milliliter.” *Id.* at 22:53–54 (claim 1).

As the Examiner found, and Appellants do not dispute, the range recited in Weiss’s claim 1 converts to a range of 0.0001 % to 1 %. Ans. 3; *see also App. Br. 5* (“1 µg to 10 mg/ml is the approximate equivalent of 0.0001 % to 1 % concentration.”).

As the Examiner found, Weiss discloses that the effective amount of its active ingredients can be determined by a skilled artisan:

The pharmaceutically “effective amount” for purposes herein is determined by such considerations as are known in the art. The amount must be effective to achieve improvement including but not limited to inhibition and/or reversal of oral intra- and inter-bacterial species coaggregation as described in the Examples herein below and to improvement or elimination of symptoms and other indicators as are selected as appropriate measures by those skilled in the art.

Id. at 6:22–30.

In view of Weiss’s teaching (*id.*) that the effective amount of its active ingredient can be determined by skilled artisans, we agree with the Examiner that, absent evidence of some unexpected property inhering from the claimed concentration of 0.3 % w/w of the NDM, the concentration recited in claim 1 would have been *prima facie* obvious. *See In re Aller*, 220 F.2d at 456 (“[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.”); *see also In re Peterson*, 315 F.3d at 1330 (“[A]n applicant may overcome a *prima facie* case of obviousness by establishing that the claimed range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range.”) (internal quotations and bracketing omitted). In the instant case, Appellants do not advance persuasive evidence that the claimed concentration produces an unexpected result.

As the court also explained in *Peterson*, “even a slight overlap in range establishes a *prima facie* case of obviousness.” *In re Peterson*, 315 F.3d at 1329. Thus, that Weiss’s suitable concentration range for its active ingredient, including the range recited in Weiss’s claims 6, 8, and 10, may have been relatively broad (*see App. Br.* 5–6), or that the concentration in

Appellants' claim 1 might be outside Weiss's preferred range (Reply Br. 3), does not persuade us that an ordinary artisan would have failed to recognize that claim 1's concentration of NDM is within the broadest range of suitable concentrations taught in Weiss, and therefore would have been prima facie obvious.

To that end, Appellants contend that the concentration range recited in Weiss's claim 1 relates to Weiss's PF-1 fraction, which is distinct from Weiss's NDM fraction, the active agent required by Appellants' claim 1. Reply Br. 2–3.

We do not find this argument persuasive. We first note that, despite the opportunity, this new argument was not made in Appellants' Appeal Brief, and therefore constitutes improper new argument:

Any argument raised in the reply brief which was not raised in the appeal brief, or is not responsive to an argument raised in the examiner's answer, including any designated new ground of rejection, will not be considered by the Board for purposes of the present appeal, unless good cause is shown.

37 C.F.R. § 41.41(b)(2). In any event, as noted above, Weiss discloses that in its compositions, the “concentration of NDM . . . in the carrier is between 25 µg/ml and 100 mg/ml” (Weiss 5:2–3), a concentration range that, like the range recited in Weiss's claim 1, includes the concentration of NDM recited in Appellants' claim 1.

Accordingly, for the reasons discussed, Appellants do not persuade us that the Examiner erred in finding that Weiss suggests a mouthwash composition that includes the concentration of cranberry extract NDM recited in Appellants' claim 1.

Appellants also do not persuade us that Weiss fails to suggest a mouthwash composition that does not contain a component that deactivates the cranberry extract non-dialyzable material, as claim 1 also requires. In that regard, Appellants contend that Weiss discloses that its mouthwash compositions can contain up to 15% anionic and nonionic surfactants, which include well known poloxamer surfactants, and which inhibit the activity of cranberry extract NDM. App. Br. 6; Reply Br. 3–4. Appellants note in particular that poloxamers are specifically excluded from the claimed mouthwash by Appellants’ claim 21, which depends from claim 1. App. Br. 6. In addition, Appellants contend, the Examiner’s finding that it would be common sense to ensure the absence of components that deactivate Weiss’s active ingredient is based on improper hindsight, because no prior art suggests that poloxamers deactivate Weiss’s cranberry extract NDM. App. Br. 6–7; Reply Br. 4–6.

We are not persuaded. We acknowledge the disclosure in Appellants’ Specification that “the present inventors discovered that oral compositions comprising surfactants inhibit the ability of cranberry extract non-dialyzable material [NDM] to inhibit bacterial co-aggregation.” Spec. ¶ 20. The sole specific compounds identified in the Specification as deactivating cranberry extract NDM are the poloxamer surfactants Poloxamer 338 NF and Poloxamer 407 NF. *Id.* at ¶¶ 44–45 (Example 2).

Turning to the prior art, as to surfactants in its mouthwashes, Weiss discloses that “[m]outhwashes are typically comprised of a water/alcohol solution, flavor, humectant, sweetener, foaming agent, and colorant.” *Id.* at 6:48–50. Although Weiss does not mention poloxamers specifically, Weiss discloses that “[s]uitable foaming agents include soap, anionic, cationic,

nonionic, amphoteric and/or zwitterionic surfactants. These may be present at levels of 0 to 15%, preferably 0.1 to 15%, more preferably 0.25 to 10% by weight.” *Id.* at 7:12–15.

Thus, while Weiss might prefer including surfactants in its mouthwashes, Weiss nonetheless discloses expressly that its mouthwashes may contain 0%, that is, no surfactant. Because Weiss discloses that its mouthwashes may contain no surfactant, Appellants do not persuade us that Weiss fails to teach or suggest a mouthwash that does not include a component that deactivates the cranberry extract non-dialyzable material, as claim 1 requires, or that preparing a mouthwash lacking that component would be based on improper hindsight.

That a mouthwash lacking surfactant might not have been Weiss’s preference does not demonstrate that Weiss fails to suggest a surfactant-free composition, given its express disclosure that its mouthwashes may contain no surfactant. *See Merck & Co. Inc. v. Biocraft Labs. Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (“[I]n a section 103 inquiry, the fact that a specific [embodiment] is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered.”) (internal quotations omitted); *see also See DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1327 (Fed. Cir. 2009) (“A reference does not teach away . . . if it merely expresses a general preference for an alternative invention but does not criticize, discredit, or otherwise discourage investigation into the invention claimed.”) (internal quotations omitted).

Moreover, because Weiss discloses that its mouthwashes may contain no surfactant, and thus expressly suggests compositions that meet the

negative limitation in Appellants' claim 1, we do not find Appellants' arguments (Reply Br. 5–6) based on *Leo Pharmaceutical Products, Ltd. v. Rea*, 726 F.3d 1346 (Fed. Cir. 2013), persuasive.

We first note that, despite the opportunity, this new argument in the Reply Brief based on *Leo Pharmaceutical* was not made in Appellants' Appeal Brief, and therefore constitutes improper new argument. *See* 37 C.F.R. § 41.41(b)(2). That an ordinary artisan might not have recognized that poloxamers deactivate cranberry extract NDM does not negate Weiss's express disclosure of the suitability of including no surfactant in its mouthwashes. That is, even if it were true that poloxamers were not known to deactivate cranberry extract NDM, Weiss, nonetheless, suggests a mouthwash that lacks poloxamers, and thereby meets the limitation at issue.

In addition, Appellants do not persuade us that the Examiner erred in suggesting that it would have been common sense to exclude deactivating agents, or that an ordinary artisan would have considered it obvious that conventional excipients might interfere with the cranberry extract NDM's antibacterial activity. To the contrary, Weiss expressly teaches that active ingredient-inhibiting excipients should be avoided:

The present invention provides for a composition comprising an effect[ive] amount of an isolated adhesion inhibitory fraction from *Vaccinium*, in a preferred embodiment the isolated adhesion inhibitory fraction from cranberry juice, PF-1, and a *pharmaceutically acceptable carrier which does not react with the active ingredients of the invention and which does not decrease the biological activity of the present invention.*

Weiss 6:9–16 (emphasis added).

In sum, for the reasons discussed, Appellants' arguments do not persuade us that Weiss fails to teach or suggest a cranberry extract NDM-containing mouthwash that does not contain a component that deactivates the NDM, as required by Appellants' claim 1. Because Weiss teaches that its mouthwashes may contain no surfactant, Appellants also do not persuade us that Weiss fails to teach or suggest a mouthwash that does not contain a poloxamer, as recited in Appellants' claim 21.

Accordingly, because Appellants do not persuade us, for the reasons discussed, that a preponderance of the evidence fails to support the Examiner's conclusion that Weiss renders obvious a composition having all of the ingredients and features recited in claims 1 and 21, we affirm the Examiner's rejection of those claims over Weiss. The remaining claims fall with claims 1 and 21.

SUMMARY

For the reasons discussed, we affirm the Examiner's rejection of claims 1-3, 8, 9, and 21 under 35 U.S.C. § 103(a) as being unpatentable over Weiss.

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