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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SHASHANK POTNIS, RAVI SUBRAMANYAM, and
RAJITHA NAIR¹

Appeal 2020-000335
Application 14/648,715
Technology Center 1600

Before ERIC B. GRIMES, FRANCISCO C. PRATS, and
LILAN REN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to a topical analgesic gel, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ Appellant identifies the real party in interest as Colgate-Palmolive Company. Appeal Br. 2. We use the word “Appellant” to refer to “applicant” as defined in 37 C.F.R. § 1.42(a).

STATEMENT OF THE CASE

The invention is directed to a “topical ‘leave on’ gel formulation that permits sustained delivery of pain-relieving herbal extracts to [an] affected tooth.” Spec. ¶ 3.

Claims 1–21, 24, and 25 are on appeal. Claims 1 and 24, reproduced below, are the only independent claims (emphasis added):

1. An orally acceptable topical analgesic gel comprising:
a mixture of analgesic oils comprising (a) *clove oil and/or eugenol*, (b) *a cooling agent*, and (c) *camphor*; and
an orally acceptable gel base comprising:
an anionic polymer and a basic amino acid;

wherein the gel base provides controlled release of the mixture of analgesic oils following application to a tooth, and wherein *the ratio of (a) to (b) to (c) is 70–100 : 5–15 : 5–15.*

24. A method of making an orally acceptable topical analgesic gel comprising a mixture of analgesic oils comprising (a) *clove oil and/or eugenol*, (b) *a cooling agent*, and (c) *camphor*; and an orally acceptable gel base comprising a cross-linked poly(acrylic acid) polymer, nonionic surfactants, a basic amino acid, and water, comprising:

- e. forming a water-in-oil emulsion wherein the oil phase comprises the mixture of analgesic oils, the water phase comprises the poly(acrylic acid) polymer and water, and the nonionic surfactants facilitate the emulsion formation,
- f. adding the basic amino acid to raise the pH of the emulsion thus formed to a level sufficient to ionize the carboxyl groups on the cross-linked poly(acrylic acid) polymer, thereby forming a stable gel,

wherein *the ratio of (a) to (b) to (c) is 70–100 : 5–15 : 5–15.*

OPINION

Claims 1–21, 24, and 25 stand rejected under 35 U.S.C. § 103(a) as obvious based on Hughes.² Ans. 3. The Examiner finds that “Hughes teaches an oral care composition comprising a gel network comprising at least one fatty amphiphile, at least one surfactant, and a solvent . . . , and further comprising a flavoring agent.” *Id.* The Examiner finds that “Hughes further teaches that the flavoring agent can be clove oil or eugenol, menthol, and camphor.” *Id.* The Examiner finds that Hughes also teaches that its composition can comprise a basic amino acid, as well as polyacrylic acid. *Id.*

The Examiner concludes that

[i]t would have been obvious to combine eugenol, clove oil, menthol, and camphor together and with the additionally claimed ingredients . . . because at the time the invention was made, it was known that a gel base could be combined with arginine, eugenol, clove oil, menthol, and camphor and the additionally claimed ingredients are effective ingredients that provide an orally administered gel formulation for application to teeth as clearly taught by Hughes.

Id. at 4. With regard to the ratio of (a) to (b) to (c) recited in the claims, the Examiner reasons that

it would have been well in the purview of one of ordinary skill in the art practicing the invention . . . to modify the amounts of the ingredients and of the formulation itself to provide a safer and more effective formulation for oral application. Thus, the claimed invention is no more than the routine optimization of a result effect variable.

Id.

² Hughes et al., US 2010/0135921 A1, published June 3, 2010.

Appellant argues that “Hughes generally discloses clove oil, eugenol, menthol and camphor in the list of essential oils that are disclosed to be other suitable flavoring agents (paragraph [0059] - [0064]), in lists disclosing nearly 100 separate alternatives” but “does not teach or suggest the specific combination of (a) clove oil and/or eugenol, (b) a cooling agent, and (c) camphor.” Appeal Br. 5–6.

Appellant argues that “there is no teaching or suggestion in Hughes that would guide one of skill in the art to the specific combination of (a) clove oil and/or eugenol, (b) a cooling agent, and (c) camphor,” and the two specific blends disclosed by Hughes do not contain clove oil, menthol, or camphor. *Id.* at 7. Appellant also argues that “Hughes does not disclose any value or range overlapping the claimed ratio ranges recited in [the] claims.” *Id.*

We agree with Appellant that the Examiner has not shown that the claimed composition would have been obvious based on Hughes, which discloses “an oral care composition comprising fused silica and a flavoring agent. In some embodiments, the flavoring agent comprises an oil, in some embodiments, an essential oil.” Hughes ¶ 9. Hughes states that

[s]uitable flavoring components include oil of wintergreen, clove bud oil, menthol, anethole, methyl salicylate, eucalyptol, *cassia*, 1-menthyl acetate, sage, eugenol, parsley oil, oxanone, alpha-irisone, marjoram, lemon, orange, propenyl guaethol, cinnamon, vanillin, ethyl vanillin, heliotropine, 4-cis-heptenal, diacetyl, methyl-para-tert-butyl phenyl acetate, cranberry, chocolate, green tea, and mixtures thereof.

Id. ¶ 59. Thus, Hughes lists clove bud oil, menthol, and eugenol as suitable flavoring agents for its composition, among a list of twenty-seven such agents. Hughes also includes menthol, camphor, eugenol, and clove oil as

essential oils that are suitable flavoring agents, among a list of sixty such essential oils. *Id.* ¶ 63.

Hughes states that “[a] flavor composition is generally used in the oral care compositions at levels of from about 0.001% to about 5%, by weight of the oral care composition. The flavor composition will preferably be present in an amount of from about 0.01% to about 4%, more preferably from about 0.1% to about 3%, and more preferably from about 0.5% to about 2% by weight.” *Id.* ¶ 61.

The Examiner points to Hughes’ disclosure that menthol can be used in its composition as a cooling agent in an amount of 0.015–1%. Ans. 6 (citing Hughes ¶ 121). The Examiner has not, however, pointed to a suggestion in Hughes of combining specific flavoring agents in specific proportions, as recited in Appellant’s claims. As Appellant points out (Appeal Br. 7), the specific blends of flavoring agents described by Hughes do not include a cooling agent or camphor, as required by Appellant’s claims. *See* Hughes ¶¶ 64, 65.

The Examiner reasons that it would have been obvious to combine the recited analgesic oils, in the recited proportions, because it would have been obvious “to modify the amounts of the ingredients and of the formulation itself to provide a safer and more effective formulation for oral application.” Ans. 4.

Hughes, however, does not state that the amount of clove oil, eugenol, menthol, or camphor affect either the safety or efficacy of its composition, which can be a “toothpaste, dentifrice, tooth gel, tooth powders, tablets, rinse, subgingival gel, foam, mouse, chewing gum, lipstick, sponge, floss,

prophy paste, petrolatum gel, or denture product.” Hughes ¶ 36. Rather, Hughes describes each of clove oil, eugenol, and camphor simply as being among the many “flavoring agents” that could be used in its composition, and describes menthol as both a flavoring agent and a cooling agent. *Id.* ¶¶ 63, 121.

In short, the Examiner has not provided evidence or sound technical reasoning to show that a person of ordinary skill in the art would have had a reason, based on Hughes’ list of possible flavoring agents and possible total amount of flavoring agent(s) in its composition, to combine 70–100 parts of clove oil and/or eugenol, with 5–15 parts of a cooling agent such as menthol, and with 5–15 parts of camphor, for use in Hughes’ oral care composition. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”); *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011) (“[O]bviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.”).

Because the Examiner has not shown, by a preponderance of the evidence, that a skilled artisan would have considered it obvious to combine the prior art elements in the manner claimed, we reverse the rejection of claims 1–21, 24, and 25 under 35 U.S.C. § 103(a) based on Hughes.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1-21, 24, 25	103(a)	Hughes		1-21, 24, 25

REVERSED