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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BRUNO PROVSTGAARD NIELSEN, JAN DALHOFF, and
GITTE LORENZEN¹

Appeal 2015-000932
Application 12/954,516
Technology Center 1600

Before ERIC B. GRIMES, FRANCISCO C. PRATS, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

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

We affirm.

STATEMENT OF THE CASE

The Specification states that

[w]hen manufacturing a compressed chewing gum tablet . . . an initial conventional mixing of the gum base [is] . . . followed by

¹ Appellants identify the Real Party in Interest as Fertin Pharma A/S. (Appeal Br. 3.)

a granulation of the obtained gum base mix. The obtained chewing gum granules may then be mixed with further chewing gum ingredients, such as sweeteners and flavor. This final granule mix may then be compressed into a chewing gum tablet.

(Spec. ¶ 115.)

The Specification states that “[c]ompressed chewing gum tablets are characterized in that a considerable amount of water soluble chewing gum ingredients is released immediately upon the first few bites into the chewing gum tablet.” (*Id.* ¶ 3.) The Specification discloses that “adding liquid flavor to a compressed chewing gum tablet in a film coating surrounding the tablet can moderate the taste sensation in a way as to make the chewing gum satisfactorily usable for a prolonged period of time.” (*Id.* ¶ 12.)

Claims 1–11, 13, and 15–19 are on appeal. Claim 1 is illustrative and reads as follows (emphasis added):

1. A compressed chewing gum tablet comprising at least one compressed chewing gum module, the at least one compressed chewing gum module including a compressed particulate chewing gum composition, said compressed particulate chewing gum composition comprising compressed chewing gum particles containing gum base, wherein the content of gum base is at least 5 % by weight of the tablet, and wherein the chewing gum tablet is provided with an outer film coating,

wherein *the outer film coating comprises liquid flavoring in an amount of more than 1% by weight* of the dry outer film coating, and

wherein an amount of liquid flavor in the chewing gum tablet, including the outer film coating, is above 0.05 % by weight of the chewing gum tablet.

The claims stand rejected as follows:

Claims 1–7, 10, 11, 13, 15–17, and 19 under 35 U.S.C. § 103(a) as obvious based on Nissen² and Song³ (Ans. 2);

Claims 1–10, 13, 15–17, and 19 under 35 U.S.C. § 103(a) as obvious based on Nissen and Levi⁴ (Ans. 6);

Claim 18 under 35 U.S.C. § 103(a) as obvious based on Nissen, Song, and Andersen⁵ (Ans. 8); and

Claim 18 under 35 U.S.C. § 103(a) as obvious based on Nissen, Levi, and Andersen (Ans. 9).

I

The Examiner has rejected claims 1–7, 10, 11, 13, 15–17, and 19 as obvious based on Nissen and Song. The Examiner finds that Nissen discloses a compressed chewing gum tablet containing liquid and/or powdered flavorings. (Ans. 2–3.) The Examiner finds that Nissen’s chewing gum comprises an outer coating, which can be a film coating and can contain flavors, but Nissen does not disclose a liquid flavoring in an amount of more than 1%. (*Id.* at 4.)

The Examiner finds that Song teaches a coating for chewing gum that contains flavoring agents such as essential oils in an amount of 0.2% to 3% of the coating. (*Id.* at 5.) The Examiner concludes that it would have been obvious “to utilize the amount of flavor in the coating of Song et al for use

² Nissen, WO 2006/002622 A1, published Jan. 12, 2006.

³ Song et al., US 6,586,023 B1, issued July 1, 2003.

⁴ Levi et al., US 2007/0231387 A1, published Oct. 4, 2007.

⁵ Andersen et al., US 2006/0240143 A1, published Oct. 26, 2006.

in the chewing gum of Nissen since Song et al teach that the presence of flavors in the coating in the disclosed amounts yields a medicated chewing gum with improved characteristics.” (*Id.* at 6.)

We agree with the Examiner that Nissen and Song support a prima facie case of obviousness. Nissen discloses a multi-module compressed chewing gum tablet. (Nissen 3:22.) The tablets comprise at least 5% by weight gum base granulates (i.e., particles). (*Id.* at 16:4–10.) The tablets can contain pharmaceutically active agents. (*Id.* at 17:3–6.) Nissen states that “the chewing gum element comprises about 0 to about 75% by weight of an outer coating applied onto the chewing gum center.” (*Id.* at 28:14–15.) “[S]uitable coating types include hard coatings, film coatings and soft coatings of any composition including those currently used in coating of chewing gum, pharmaceutical products and confectioneries.” (*Id.* at 28:18–21.)

Nissen discloses that its gum tablet can contain aroma and flavoring agents, including essential oils. (*Id.* at 20:4–9.) “The essential oils include peppermint, spearmint, menthol,” etc. (*Id.* at 20:15–17.) “Additionally, film coatings may contain one or several auxiliary substances such as flavors.” (*Id.* at 31:18–19.)

Song discloses “chewing gum with physically modified active agents such as caffeine to control their release. Such active agents are added to a gum coating to deliver the active agents systemically without unpleasant tastes.” (Song 2:36–40.) Song discloses that its chewing gum is made by mixing the ingredients of the gum base, shaping it, and then coating it. (*Id.* at 12:53–59.) “[T]he coating may contain ingredients such as flavoring

agents . . . includ[ing] those commonly known in the art such as essential oils.” (*Id.* at 13:6–11.) “The flavoring agents may be used in an amount such that the coating will contain from about 0.2% to about 3% flavoring agent, and preferably from about 0.7% to about 2.0% flavoring agent.” (*Id.* at 13:15–18.)

We agree with the Examiner that the product of claim 1 would have been obvious based on Nissen and Song. Nissen suggests a chewing gum tablet that meets all of the limitations of claim 1 except that it does not expressly disclose a *liquid* flavoring in the coating, in an amount of more than 1% by weight. However, Nissen describes flavorings useful in its chewing gum as including essential oils, and Song describes a chewing gum tablet having up to 3% flavoring, such as essential oils, in a coating. Thus, it would have been obvious to include an essential oil in an amount greater than 1% in the film coating of Nissen’s chewing gum tablet.

Appellants argue that it would not have been obvious to include more than 1% of a liquid flavoring in the coating of Nissen’s chewing gum tablet because Nissen’s only disclosure of liquid flavorings is in relation to its gum tablet itself, not the outer film coating. (Appeal Br. 12.) Appellants argue that “the presence of liquid flavoring in the film coating based on the disclosure of Nissen would inherently give rise to problems with moisture penetrating the porous compressed chewing gum.” (*Id.* at 14.)

Similarly, Appellants argue that Nissen teaches that the coating of its chewing gum “avoids dissolution and diffusion of moisture and gases across the film” and therefore “those skilled in the art would have no expectation that a liquid flavoring in the film coating would be possible to use because

this would inherently imply that moisture would penetrate the structure of the porous compressed chewing gum.” (*Id.* at 14–15.) Appellants cite the Andersen Declaration⁶ in support of their argument. (*Id.* at 12–15.)

Appellants’ argument on this point is not persuasive. The Andersen Declaration acknowledges that Nissen describes liquid flavorings, but notes that its disclosure in this regard “refers back to a method of producing compressed gum at a low temperature” and thus would be understood to mean that the liquid flavorings “are incorporated into a compressed chewing gum at a low temperature and would therefore inherently not be present in an outer film coating.” (Andersen Decl. ¶ 8.)

The Andersen Declaration also states that “compressed chewing gum is made of discrete chewing gum granules which are adhered together by compression force” and, therefore, “the structure of a compressed chewing gum is porous in nature, and . . . liquid would potentially penetrate the structure of compressed chewing gum.” (*Id.* ¶¶ 12–13.) The Andersen Declaration concludes that Nissen teaches away from using a liquid flavoring in the outer film coating “since the presence of liquid flavoring in the film coating based on the disclosure of Nissen would inherently give rise to problems with moisture penetrating the porous compressed chewing gum.” (*Id.* ¶ 14.)

The Andersen Declaration, however, does not explain *why* a liquid flavoring in the coating of Nissen’s chewing gum would be expected to cause problems, when the compressed chewing gum itself can contain liquid

⁶ Declaration under 37 C.F.R. § 1.132 of Carsten Andersen, signed Jan. 12, 2013.

flavorings. The presence of a liquid flavoring in the chewing gum, which is expressly suggested by Nissen, suggests that having a liquid flavoring in the chewing gum would not cause problems. Appellants cite no additional evidence to support their position that those skilled in the art would not have used a liquid flavoring in the film coating of a compressed chewing gum.

Appellants also argue that Song's disclosure relates to the process of pan coating, or hard coating, which is different from film coating. (Appeal Br. 16.) Appellants have not, however, explained why the amount of liquid flavoring (e.g., essential oils) suggested by Song would not be considered appropriate for the film coating of Nissen's compressed chewing gum.

Claims 2–7, 10, 11, 13, 15–17, and 19 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

II

The Examiner has rejected claims 1–10, 13, 15–17, and 19 under 35 U.S.C. § 103(a) as obvious based on Nissen and Levi. As with the rejection based on Nissen and Song, the Examiner finds that Nissen teaches the claimed product, but does not teach a liquid flavoring in an amount of more than 5% or 10%, as recited in claims 8 and 9, respectively. (Ans. 6–7.)

The Examiner finds that Levi discloses a dissolvable film coating for solid dosage forms that comprises a “sensory cue agent,” such as an essential oil, in an amount of 0.01% to 25%. (*Id.* at 7.) The Examiner concludes that it would have been obvious to include up to 25% liquid flavorant in Nissen's coating “since Levi et al teaches that the use of liquid flavorants in coatings in the range of greater than 5% or greater than 10% can convey the sensation that a drug is having a therapeutic effect before the

drug has achieved systemic exposure.” (*Id.* at 8.) We agree with the Examiner’s fact-finding and conclusion.

Appellants argue that the Examiner cites Levi’s paragraph 19 as disclosing liquid flavorings but “[t]he only flavoring agents mentioned in this section and pointed to by the Examiner are eucalyptol, thymol, camphor, methyl salicylate, benzaldehyde, ginger or the like. However, these are not mentioned to be in liquid form.” (Appeal Br. 18.)

This argument is unpersuasive. The Examiner finds that Levi’s preferred sensory cue agents include “essential oils such as peppermint, wintergreen, eucalyptus, spearmint, cinnamon, clove, bay, thyme, bitter almond, sage, nutmeg, citrus (e.g., lemon, orange, lime) and liquid flavoring agents such as eucalyptol, thymol, and benzaldehyde.” (Ans. 7.) This finding is supported by the evidence. (*See* Levi ¶ 19.) Appellants’ Specification states that liquid flavorings that can be used in the disclosed film coating include essential oils such as “peppermint, spearmint, menthol, eucalyptus, clove oil, bay oil, anise, thyme, cedar leaf oil, nutmeg,” etc. (Spec. ¶¶ 108–109.) Thus, Levi discloses liquid flavorings.

Appellants also argue that “a core as defined for the invention of Levi et al. is mentioned to be ‘...distinguished from soft dosage forms such as gelatin capsules, hard gums and the like.’ Hence, Levi et al. seems to disclaim chewing gum.” (Appeal Br. 18–19.)

This argument is also unpersuasive. The Examiner cites Levi only for its teaching of using at least 5–10% liquid flavoring in Nissen’s film coating. Levi discloses that its invention could be used in chewable tablets, and although Levi does not disclose its coating for use in “hard gums,”

Appellants have not pointed to evidence showing that it could not be used with Nissen's compressed chewing gum.

Claims 2–10, 13, 15–17, and 19 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

III

The Examiner has rejected claim 18 under 35 U.S.C. § 103(a) as obvious based on either Nissen, Song, and Andersen (Ans. 8) or Nissen, Levi, and Andersen (*id.* at 9). The Examiner cites Nissen, Song, and Levi for the disclosures discussed previously, and cites Andersen as disclosing a chewing gum containing biodegradable polymers, as recited in claim 18. We agree with the Examiner's fact-finding and conclusion that claim 18 would have been obvious in view of the cited references.

Appellants argue that Andersen does not remedy the deficiencies of the previously discussed references with regard to claim 1. (Appeal Br. 19–21.) However, for the reasons discussed above, we conclude that Nissen combined with either Song or Levi support a *prima facie* case of obviousness with respect to claim 1. The rejections of claim 18 are therefore affirmed.

SUMMARY

We affirm all of the rejections on appeal.

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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