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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte CHRISTOPHER N. JOBDEVAIRAKKAM and VIKRAM KATRAGADDA

Appeal 2017-002177
Application 12/423,552
Technology Center 1600

Before MICHAEL J. FITZPATRICK, ULRIKE W. JENKS, and TIMOTHY G. MAJORS, *Administrative Patent Judges*.

FITZPATRICK, *Administrative Patent Judge*.

DECISION ON APPEAL

Christopher N. Jobdevairakkam and Vikram Katragadda ("Appellants")[1] appeal under 35 U.S.C. § 134(a) from a final decision rejecting claims 1, 5, 8, 15, 17, 26, 27, 29, and 30. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

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[1] The real party in interest is identified as "Navinta, LLC." Appeal Br. 2.

STATEMENT OF THE CASE

The Specification

According to Appellants, the present invention "relates to a composition of a rapidly disintegrating buccal dosage form containing the medicament, such as a drug, at least one non-effervescent base such as an alkali metal oxide and/or alkaline earth metal oxide or hydroxide, and a disintegrant." Spec. ¶2. "The base used in the composition does not generate any gaseous products upon contact with saliva, and eventually it regulates the pH gradient useful to deliver the drug to the buccal or sublingual or oral mucosal membranes at a desired rate of absorption." *Id.*

Appellants' invention is focused specifically on such compositions in which the drug is fentanyl. Spec. ¶17 ("The present invention has disclosed the use of inorganic bases such as alkali metal and alkaline earth metal oxides and hydroxides which can convert ionic fentanyl to the unionized fentanyl."). Prior to their invention, Appellants states that "no prior art [was] known to compose a rapid disintegration buccal tablet suitable to deliver fentanyl without using effervescent agents." *Id.*

The Rejected Claims

Claims 1, 5, 8, 15, 17, 26, 27, 29, and 30 stand rejected. Final Act. 1.[2] Claims 1 and 29 are representative and reproduced below with emphasis added to limitations Appellants dispute as not taught or suggested by the asserted prior art.

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[2] Claims 2–4, 6, 7, 9–14, 16, 18–25, and 28 are cancelled. Appeal Br. 20–21.

1. An orally disintegrating tablet composition comprising:

fentanyl,

less than 10% (w/w) citric acid,

at least one disintegrant, and

at least one alkaline earth, bivalent metal oxide or hydroxide,

wherein said composition is *free of an effervescent base, no gaseous products are generated upon contact with saliva*, and the at least one alkaline earth, bivalent metal oxide or hydroxide promotes the conversion of the fentanyl from a substantially ionized form to a substantially unionized form upon contact with saliva.

29. An orally disintegrating tablet consisting essentially of:

less than 2% (w/w) fentanyl citrate;

more than 50% (w/w) filler material;

a disintegrant from about 0.1 % to about 12% (w/w);

magnesium oxide or hydroxide;

less than 10% (w/w) acid; and

less than 5% (w/w) lubricant,

wherein the pH of the tablet is from about 6 to about 11, said tablet is *free of an effervescent base, no gaseous products are generated upon contact with saliva*, said less than 2% (w/w) fentanyl citrate converts from a substantially ionized form to a substantially unionized form upon contact with saliva, and *said pH of the tablet changes by less than 1 pH unit when dissolved in 1 to 5 ml of solvent.*

Appeal Br. 20–22 (emphasis added).

The Appealed Rejection

Claims 1, 5, 8, 15, 17, 26, 27, 29, and 30 stand rejected under 35 U.S.C. § 103 as unpatentable over Moe[3] and Singh[4] (Final Act. 2);

Appellants requested oral argument in this appeal, which was heard October 11, 2018.

DISCUSSION

Moe and Singh both describe fentanyl-containing dosage forms for oral administration across the oral mucosa. Moe, at [57]; Singh, at [57], ¶12.

The Examiner found that "Moe teaches an effervescent formulation comprising fentanyl citrate, citric acid, sodium starch glycolate [a disintegrant], mannitol, and ferric oxide (e.g. Example 5, ¶237)." Final Act. 2. The Examiner further found that Moe teaches all of the subject matter of the claims except that "Moe does not teach magnesium oxide as the base." Final Act. 3; *see also* Appeal Br. 20 (claim 1 reciting "at least one alkaline earth, bivalent metal oxide or hydroxide"), 21 (claim 29 reciting "magnesium oxide or hydroxide").

The Examiner relies on Singh as teaching the use of magnesium oxide as a suitable base for making a buffer system for providing fentanyl in unionized form. Final Act. 3; Singh ¶15 ("The buffering agents of the buffer system may be independently selected from the group consisting of sodium carbonate, sodium bicarbonate, potassium carbonate, potassium bicarbonate, potassium citrate, potassium phosphate monobasic, magnesium oxide,

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[3] US 2005/0142198 A1, published June 30, 2005 ("Moe")
[4] US 2005/0042281 A1, published Feb. 24, 2005 ("Singh").

magnesium carbonate, magnesium bicarbonate, alkaline starch, ascorbic acid, and mixtures thereof.").

The Examiner concludes that "one of ordinary skill in the art formulating the ODT [i.e., orally disintegrating tablet] of Moe would find it obvious to use the magnesium oxide of Singh as the pH adjusting substance given for the phosphate of Moe given both are recognized as basic buffering agents. *See* MPEP 2144.06(II)" (substituting equivalents known for the purpose). Final Act. 4.

Appellants assert that the Examiner's rejection fails to meet the following limitations: (1) "free of an effervescent base [such that] no gaseous products are generated upon contact with saliva" (claims 1, 5, 8, 15, 17, 26, 27, 29, and 30); (2) "less than 10% (w/w) citric acid" (claims 1, 5, 8, 15, 17, 26, and 27); and (3) "said pH of the tablet changes by less than 1 pH unit when dissolved in 1 to 5 ml of solvent" (claims 29 and 30). Appeal Br. 4–5. However, Appellants include detailed arguments for only the first two of these three limitations. *See* Appeal Br. 7–17 (§ iv.B.), 17–19 (§ iv.C.); *see also* 37 C.F.R. § 41.37(c)(iv) ("[A]ny arguments or authorities not included in the appeal brief will be refused consideration by the Board").

"free of an effervescent base [such that] no gaseous products are generated upon contact with saliva"

Appellants argue that Moe does not teach or suggest a tablet that is "free of an effervescent base [such that] no gaseous products are generated upon contact with saliva." Appeal Br. 7. We disagree.

As pointed out by the Examiner, Moe teaches the following:

> It has been discovered that the use of effervescence and/or a pH adjusting substance, and most preferably both, can provide significant advantages particularly in terms of the amount of

> fentanyl that is required for dosing. It has also been found that certain disintegrants and fillers in combination with at least one effervescent couple and at least one pH adjusting substance can provide even better, and very unexpected, results.

Moe ¶36; Final Act. 2–3 (citing the same)). This passage teaches: (1) the use of effervescence together with a pH adjusting substance, (2) the use of effervescence alone, and (3) the use of a pH adjusting substance alone. Moe ¶36 ("effervescence and/or a pH adjusting substance").

Appellants label paragraph 36 a "passing reference" and argue that a person of ordinary skill in the art "reading Moe as a whole would understand Moe to teach *only* effervescent compositions." Appeal Br. 7–8 (emphasis added). To support this argument, Appellants point to Moe's extensive description of compositions that employ effervescence. *Id.* at 8–11. But such description, no matter how extensive, cannot undo the teaching of paragraph 36.

A person of ordinary skill in the art, reading Moe as a whole, would not understand it to teach only effervescent compositions. Rather, he or she would understand Moe to teach both effervescent and effervescent-free compositions, with the former being preferred. The Examiner's reliance on Moe's teaching of the latter was appropriate. *See Application of Lamberti*, 545 F.2d 747, 750 (CCPA 1976) ("all disclosures of the prior art, including unpreferred embodiments, must be considered").

"less than 10% (w/w) citric acid"

Appellants argue that Moe does not teach or suggest a tablet comprising "less than 10% (w/w) citric acid." Appeal Br. 17. We disagree.

In various examples, Moe teaches tablets that are 15% (w/w) citric acid. *See*, *e.g.*, Moe ¶233 (200 mg tablet having 30 mg of citric acid); *see also* Appeal Br. 17 ("[T]he examples of Moe disclose 15% w/w citric acid.").

The Examiner points to a teaching in Moe that multiple acids may be used in the same tablet (*see* Moe ¶205) and, thus, concludes that a person "of ordinary skill in the art would find it obvious to use smaller amounts of multiple acid sources from the group taught by Moe rather than citric acid as the entire acid component as demonstrated in the examples." Final Act. 4; Moe ¶205 (referring to "at least one acid source"), ¶206 (listing various acids, including citric acid).

> Moe paragraph 205 states, in relevant part, the following:
>
> Effervescent couples generally are water- or saliva-activated materials usually kept in a anhydrous state with little or no absorbed moisture or in a stable hydrated form. Typically these involve at least one acid source and at least one source of a reactive base, usually a carbonate or bicarbonate.

Moe ¶205. Appellants argue (correctly) that the relied-upon teaching of Moe is in reference to an effervescent tablet. Appeal Br. 17. However, the claims were rejected for obviousness, not anticipation. We are not persuaded that a person of ordinary skill in the art would consider Moe's teaching that multiple acids could be used for the acid component of only an effervescent tablet, where Moe also teaches non-effervescent tablets that also include an acid component. *See In re Baird*, 16 F.3d 380, 383 (Fed. Cir. 1994) ("[A] reference must be considered not only for what it expressly teaches, but also for what it fairly suggests.") (quoting *In re Burckel*, 592 F.2d 1175, 1179 (CCPA 1979).

Additionally, on the record presented, we do not consider the claimed range of "less than 10% (w/w) citric acid" to be inventive, given that it was known in the art to use citric acid for fentanyl tablets and that citric acid's use in that regard is a result effective variable. For example, the Federal Circuit has held:

> "it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Only if the "results of optimizing a variable" are "unexpectedly good" can a patent be obtained for the claimed critical range. *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977).

In re Geisler, 116 F.3d 1465, 1469 (Fed. Cir. 1997).

As pointed out by the Examiner, the person of ordinary skill in the art would know that raising or lowering the acid concentration would cause a predictable decrease or increase in the pH. As additionally pointed out by the Examiner, the person of ordinary skill in the art would have a reason, when making fentanyl tablets, to use less acid.

> While the specific examples of Moe tend to use 15% citric acid, the broad disclosure of Moe teaches that "[i]f the ideal conditions for transmission of a particular drug are basic, the addition of a sufficient excess of suitably strong acid as part of the manufacture of an effervescent couple or as a pH adjusting substance may not be indicated" [¶208]. Moe also teaches that "a basic substance is preferred for the delivery of fentanyl" [¶209]. Thus, one of ordinary skill in the art would find it obvious to reduce the amount of acid when delivering fentanyl in order to provide a more basic environment for the fentanyl, as taught to be preferred by Moe.

Ans. 4.

Claim 29

Claim 29 recites "said pH of the tablet changes by less than 1 pH unit when dissolved in 1 to 5 ml of solvent." Appellants argue, in their Reply, that "[t]he Examiner has never cited to where in the cited art [this] is taught." Reply 2. However, in their Appeal Brief, Appellants did not argue claim 29 separately from claim 1. *See, e.g.*, Appeal Br. 3 ("**Claims 1, 5, 8, 15, 17, 26–27, and 29–30 are Patentable Over Moe In View of Singh**"); 37 C.F.R. § 41.37(c)(iv) ("Under each heading identifying the ground of rejection being contested, any claim(s) argued separately or as a subgroup shall be argued under a separate subheading that identifies the claim(s) by number."). As such, we need not consider the patentability of claim 29 separately. *See id.* ("[T]he failure of appellant to separately argue claims which appellant has grouped together shall constitute a waiver of any argument that the Board must consider the patentability of any grouped claim separately.").

In any event, we are not persuaded that this claim language distinguishes over the combination of the art proposed by the Examiner. The claim language is "said pH of the tablet changes by less than 1 pH unit when dissolved in 1 to 5 ml of solvent." Appellants argue this is an inherent result of a tablet comprised of the specific components that are recited in claim 29. *See* Appeal Br. 4 ("The use of magnesium oxide or hydroxide specifically is important because it allows the pH of the tablets of claims 29 and 30 to change by less than 1 pH when dissolve[d] in 1 to 5 mL of solvent."); Reply 3 ("[I]t is advantageous that the pH of the claimed tablets only changes by 1 unit when in 1 to 5 mL solvent . . . . Use of the specifically claimed water insoluble metal oxide and hydroxides enables this

control."); Transcript 10:10–11 ("It is a result of the formulation that is claimed in claim 29").

SUMMARY

For the reasons discussed, we affirm the Examiner's rejection of claims 1, 5, 8, 15, 17, 26, 27, 29, and 30.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED