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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JAMES EASSON, WALTER HAMM, and GUENTER MODDELMOG[1]

Appeal 2021-001129
Application 15/466,187
Technology Center 1600

Before DONALD E. ADAMS, ERIC B. GRIMES, and JEFFREY N. FREDMAN, *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 tabletting composition, which have been rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] Appellant identifies the real party in interest as Merck Patent GmbH. Appeal Br. 1. "Appellant" refers to "applicant" as defined in 37 C.F.R. § 1.42.

STATEMENT OF THE CASE

"Direct compression (DC) is a simple, rapid, inexpensive and flexible tablet production process which protects the active compound." Spec. 1:9–10. "Anhydrous calcium hydrogenphosphate as such is a suitable basic substance" for preparing some tablet formulations. *Id.* at 1:15–17. "Owing to poor flow properties and lack of compressibility, however, pulverulent, anhydrous calcium hydrogenphosphate usually cannot be employed as tablet vehicle in direct tabletting without special additives." *Id.* at 1:19–21.

"The present invention relates . . . to a directly compressible composition for the production of tablets, comprising anhydrous calcium hydrogenphosphate and a flexible Tabletting aid." *Id.* at 2:24–26. "Particularly good properties have been found . . . using a combination of 50 - 85% by weight of anhydrous calcium hydrogen phosphate, 10 - 40% by weight of mannitol and 5 - 20% by weight of sorbitol." *Id.* at 3:1–4.

The Specification states that the disclosed compositions can be metered well for tableting

> since they have a favourable flow angle in the range from 29 to 33.4°. Since these compositions have bulk densities in the range from 0.56 to 0.77 g/ml and tamped densities[2] in the range from 0.73 to 0.92 g/ml, they can be converted particularly well into tablets having comparatively high tablet hardnesses.

Id. at 3:25–30.

Claims 21–41 are on appeal. Claim 21, reproduced below, is illustrative:

> 21. A directly compressible tabletting composition, comprising 50 - 85% by weight of anhydrous calcium

[2] The Specification and claims also refer to this property as "tapped density." *See, e.g.*, Spec. 17:17; claim 21.

> hydrogenphosphate, 10 - 40% by weight of mannitol and 5 - 20% by weight of sorbitol, wherein said composition has a flow angle in the range of 29 to 33.4° and a bulk density in the range of 0.56 to 0.77 g/ml with a tapped density in the range of 0.73 to 0.92 g/ml.

The claims stand rejected as follows:

Claims 21–35 and 38–41 under 35 U.S.C. § 103(a) as obvious based on Yokoi,[3] Ranchhordas,[4] and Reiff[5] (Final Action[6] 6) and

Claims 36 and 37 under 35 U.S.C. § 103(a) as obvious based on Yokoi, Ranchhordas, Reiff, and Schwarz[7] (Final Action 8).

OPINION

Claims 21–35 and 38–41 stand rejected as obvious based on Yokoi, Ranchhordas, and Reiff, and claims 36 and 37 stand rejected as obvious based on Yokoi, Ranchhordas, Reiff, and Schwarz. The same issue is dispositive for both rejections.

The Examiner finds that "Yokoi teaches a powdered composition for using in tablets . . . consisting of anhydrous calcium hydrogen phosphate (see [0027]) and a sugar alcohol such as fructose, xylitol, **mannitol**, erythritol and **sorbitol** (see [0029])." Final Action 6. With regard to the proportions recited in claim 21, the Examiner finds that Yokoi's composition comprises "calcium hydrogen phosphate . . . in an amount of between 99.5–40% by weight and the sugar alcohol . . . in an amount of between 0.5–60%

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[3] Yokoi et al., EP 1008353 A1, published June 14, 2000.
[4] Sheth et al., US Patent 3,134,719, issued May 26, 1964. The Examiner and Appellant refer to this reference as "Ranchhordas," so we do as well.
[5] Reiff et al., 4,507,511, issued Mar. 26, 1985.
[6] Office Action mailed Jan. 28, 2020.
[7] Schwarz et al., US 6,165,511, issued Dec. 26, 2000.

by weight (see [0019]).” *Id.* The Examiner also finds that Yokoi teaches specific calcium hydrogen phosphate:erythritol weight ratios of 85:15, 75:25, and 65:35. *Id.*

With regard to the flow angle range recited in claim 21, the Examiner reasons that “the properties of flow angle, . . . etc., are properties of the composition claimed rather than a structural limitation, absent evidence to the contrary,” and “[a]s the claimed product and the obvious product of the art are essentially identical in that they possess the same components in the same amounts, the composition must have the same properties, unless shown otherwise.” *Id.* at 7.

The Examiner acknowledges that Yokoi does not teach that its composition has a bulk density and a tapped density within the ranges recited in claim 21. *Id.* However, the Examiner finds that “Ranchhordas teaches that dibasic calcium phosphate (anhydrous calcium hydrogen phosphate) has a bulk density of between 0.5–1.0 g/mL,” and “Reiff teaches that sorbitol (flexible tableting aid) has a bulk density of between 0.4–0.7 g/mL.” *Id.* at 7–8.

The Examiner reasons that, “[g]iven that the physical properties of anhydrous calcium hydrogen phosphate and sorbitol overlap with the properties of the composition being claimed, it would be the case that the mixture of the two would result in a formulation having the instantly claimed properties.” *Id.* at 8.

The Examiner also reasons that, “while neither reference specifically mentions tapped density, all other properties are overlapping and so the tapped density would be expected to overlap as well.” *Id.* The Examiner concludes that “[t]he invention as a whole is *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references." *Id.*

Appellant argues, among other things, that "[o]nly by preparing the claimed compositions with the specific combination of three components and by a co-spray-granulation process, either batchwise or continuously, in a fluidised-bed granulator, is the composition with the claimed properties obtained." Appeal Br. 7. With respect to the recited ranges of flow angle, bulk density, and tapped density, Appellant argues that the rejection relies on "a clear misapplication of the law of inherency." *Id.* at 11–12. Appellant argues that these

> properties are distinguishing because they recite an additional limiting requirement of the claimed invention, not merely a result. A composition which has all of the three components but does not have each of the three recited properties would be outside the literal claim scope. Thus, it is not correct that any composition with the three components would necessarily also have all three of the recited specific properties in claim 21.

Id. at 12.

We agree with Appellant that the Examiner has not shown that a composition having the components *and properties* recited in claim 21 would have been obvious to a person of ordinary skill in the art based on Yokoi, Ranchhordas, and Reiff. Yokoi discloses "[s]pray-dried powders containing calcium hydrogen phosphate and saccharides having excellent powder-fluidity and compression-moldability." Yokoi, abstract. Yokoi states that "the calcium hydrogen phosphate and anhydrous calcium hydrogen phosphate obtained by the known process may be employed" in its powders. *Id.* ¶ 27. "As the saccharide," Yokoi states that "sugar alcohols such as erythritol, mannitol, sorbitol, xylitol and the like," can be used. *Id.* ¶ 29.

Yokoi states that "[t]he amount used of sugar alcohols is not particularly limited." *Id.* ¶ 31. Yokoi also states that

> [t]he combining ratio of calcium hydrogen phosphate to saccharide such as erythritol in the composition of the present invention is not particularly limited. However, 0.5 ~ 99.5 % by weight of calcium hydrogen phosphate to 99.5 ~ 0.5 % by weight of erythritol as an example of saccharide, more preferably, 40 ~ 99.5 % by weight of calcium hydrogen phosphate to 60 ~ 0.5 % by weight of erythritol.

Id. ¶ 19.

Thus, Yokoi discloses (a) that its composition comprises calcium hydrogen phosphate and "saccharides" (*id.*, Abstract), including "sugar alcohols" (*id.* ¶ 29); (b) that anhydrous calcium hydrogen phosphate is suitable (*id.* ¶ 27); (c) that mannitol and sorbitol are among the sugar alcohols that are suitable (*id.* ¶ 29); and (d) exemplary ranges of 40–99.5 wt% calcium hydrogen phosphate and 60–0.5 wt% of erythritol (a sugar alcohol) (*id.* ¶ 19).

However, Yokoi does not disclose the flow angle, bulk density, or tapped density of its compositions. The Examiner points to Ranchhordas and Reiff for disclosing the bulk densities of anhydrous calcium hydrogen phosphate and sorbitol, respectively. The Examiner reasons that, because "the physical properties [i.e., bulk densities] of anhydrous calcium hydrogen phosphate and sorbitol overlap with the properties of the composition being claimed, it would be the case that the *mixture of the two* would result in a formulation having the instantly claimed [bulk density]." Final Action 8 (emphasis added).

The claimed composition, however, is a mixture of *three* components: anhydrous calcium hydrogen phosphate, sorbitol, and 10–40 wt% mannitol.

The Examiner has not pointed to evidence in the record disclosing the bulk density of mannitol, or otherwise showing that a composition comprising 10–40 wt% mannitol, along with 50–85 wt% anhydrous calcium hydrogen phosphate and 5–20 wt% sorbitol, would necessarily have a bulk density in the range of 0.56–0.77 g/ml.

In addition, claim 21 encompasses compositions comprising as little as 50 wt% anhydrous calcium hydrogen phosphate, 10 wt% mannitol, and 5 wt% sorbitol. In other words, the claimed composition can include as much as 35 wt% of unspecified ingredients, having unknown bulk densities. Thus, it is not necessarily true that any composition encompassed by claim 21 will have a bulk density between those of calcium hydrogen phosphate and sorbitol.

Finally, the evidence of record contradicts the Examiner's reasoning that,

> [a]s the claimed product and the obvious product of the art are essentially identical in that they possess the same components in the same amounts, the composition must have the same properties, unless shown otherwise. . . . Thus, the properties of flow angle, . . . etc., are properties of the composition claimed rather than a structural limitation.

Final Action 7. *See also id.* at 8 ("With respect to the tapped density, . . . all other properties are overlapping and so the tapped density would be expected to overlap as well.")

The evidence of record does not support this conclusion. Appellant's Specification exemplifies five compositions (C–G) having proportions of calcium hydrogen phosphate anhydride, mannitol, and sorbitol within the ranges recited in claim 21. Spec. 30, Table 1. Compositions F and G, however, have bulk densities of 0.92 and 0.93 g/ml, respectively, and tapped

densities of 1.11 and 1.13 g/ml, respectively. *Id.* at 31, Table 2. Thus, these compositions are not encompassed by claim 21, because their bulk densities and tapped densities are too high, even though they comprise proportions of anhydrous calcium hydrogen phosphate, mannitol, and sorbitol within the ranges recited in the claim.

In summary, the Examiner has not pointed to sufficient evidence in the record to support a prima facie case of obviousness based on Yokoi, Ranchhordas, and Reiff. We reverse the rejection of claim 21, and dependent claims 22–35 and 38–41, under 35 U.S.C. § 103(a).

Regarding the rejection based on Yokoi, Ranchhordas, Reiff, and Schwarz, the Examiner acknowledges that Yokoi does not teach fluidized-bed granulation, but concludes that "it would have been obvious to modify Yokoi's centrifugal atomization process to further include fluidized-bed granulation to further dry the granules capable of readily producing smooth tablets," as taught by Schwarz. Final Action 8–9.

The Examiner does not, however, point to any teachings in Schwarz that make up for the previously discussed deficiencies of Yokoi. We therefore reverse the rejection of claims 36 and 37 under 35 U.S.C. § 103(a) for the reasons discussed above.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
21–35, 38–41	103(a)	Yokoi, Ranchhordas, Reiff		21–35, 38–41
36, 37	103(a)	Yokoi, Ranchhordas, Reiff, Schwarz		36, 37
Overall Outcome				21–41

REVERSED